The FDA's Attempt to Scare the Smoke Out of You: Has the FDA Gone Too Far with the Nine New Cigarette Warning Labels?

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I. INTRODUCTION

> But I would have thee remember that if thou shoulds't become a non-smoker, it will be because thou hadst decided for thyself . . . for every man has a free will to accept or reject *tobacco* unless it has, by its very nature, taken such a hold on him as to compel him to make a choice in its favour.[1]

The Family Smoking Prevention and Tobacco Control Act ("The Act")[2] of June 2009 marked the first change to cigarette warning labels in the United States in over 25 years.[3] The Act, for the first time, gave the Food and Drug Administration (FDA) authority to regulate tobacco products.[4] In June 2011, under The Act, the FDA introduced the Required Warnings for Cigarette Packages and Advertisements ("The Rule"),[5] which imposed new regulations on cigarettes.[6]

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1. ESTHER WANNING, MEDITATIONS FOR SURVIVING WITHOUT CIGARETTES 7 (1994) (citing A.A. WILLIAMS, A SMOKER'S PILGRIM'S PROGRESS (1922) (emphasis added).

2. Family Smoking Prevention and Tobacco Act ("The Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended at 15 U.S.C. § 1333 (2006 & Supp. 2009)).

3. In 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act, which gave the FDA exclusive jurisdiction to regulate tobacco, while specifically prohibiting the FDA from banning tobacco sales. *Id.* The Act marked the first change in cigarette labels since 1984 when the Comprehensive Smoking Education Act established four warning labels, which were to be rotated on cigarette packages and advertisements. Comprehensive Smoking Education Act, 15 U.S.C. §§ 1331-40 (1994).

4. *See* Pub. L. No. 111-31, § 201(a) (amending 15 U.S.C. § 1333(d)).

5. FDA, Required Warnings for Cigarette Packages and Advertisements ("The Rule"), 76 Fed. Reg. 36,628-36,629 (June 22, 2011).

6. *See id.*

Under The Rule, one of nine new graphic warning labels is required to appear on all cigarette packages and advertisements by September 2012.[7] The Rule requires the warning labels to include colored images such as a plume of cigarette smoke enveloping an infant who is receiving a kiss from her mother; a healthy lung adjacent to a diseased lung; an image of the inside of a mouth afflicted with cancerous lesions; a bare-chested male cadaver lying in the morgue; and a woman weeping uncontrollably.[8] In addition to the graphic warnings, The Rule mandates that all cigarette packages display both a direct exhortation to smokers to quit[9] and one of the nine specified textual warnings required by The Act.[10] The warnings include "Cigarettes cause cancer," "Smoking during pregnancy can harm your baby," and "Smoking can kill you."[11] Under The Act, the warning labels must be prominently displayed on the top 50 percent of the front and back panels of all cigarette packages and advertisements.[12] Unlike previous warning labels, which conveyed purely factual information, the new warning labels cross over the line of informative warnings into anti-smoking advocacy.[13] While The Act dictates many of the requirements for The Rule and provides the FDA with the power to regulate cigarettes, The Rule proposed by the FDA goes beyond its regulatory authority and imposes additional restrictions on the speech of tobacco companies.[14]

In August 2011, five of the largest cigarette companies sued the FDA in the United States District Court for the District of Columbia in response to The Rule's graphic label requirements.[15] The tobacco companies alleged that The Rule violated their free speech protected under the First Amendment of the United States Constitution.[16] The

7. *See* 76 Fed. Reg. at 36,628-29.

8. *Id.* at 36,696 (stating that graphics were selected to show depictions of the effects of sickness and disease caused by smoking).

9. *See id.* (requiring each package to prominently display "1-800-QUIT-NOW," a telephone number the FDA dedicated to provide cessation assistance).

10. *See* Pub. L. No. 111-31, § 201 (amending 15 U.S.C. § 1333).

11. *See id.*

12. Pub. L. No. 111-31, § 201 (amending 15 U.S.C. § 1333(a)(2)) ("Each label statement required by paragraph (1) shall be located in the upper portion of the front and rear panels of the package, directly on the package underneath the cellophane or other clear wrapping. Each label statement shall comprise the top 50 percent of the front and rear panels of the package. The word 'WARNING' shall appear in capital letters and all text shall be in conspicuous and legible 17-point type.").

13. *See* discussion *infra* Section IV.

14. Pub. L. No. 111-31, § 201 (amending 15 U.S.C. § 1333(d)) (providing requirements for the warning labels in order to "promote a greater public understanding of the risk associated with the use of tobacco products").

15. *See* Complaint, R.J. Reynolds Tobacco Company Co. v. FDA, No. 1:11CV01482 (D.D.C. 2011), *available at* http://bit.ly/qpvly5.

16. *See id.* at *2.

FDA insisted that its alleged substantial government interest—to inform the public about the risk of smoking—outweighed the infringement on the tobacco companies' constitutional free speech rights.[17] The FDA commissioner reasoned that the government "want[s] to make a difference and help people who are smoking stop smoking and discourage people who haven't taken up the habit yet."[18] On November 7, 2011, the district court granted a temporary injunction enjoining the FDA from enforcing any of the new requirements contained in The Rule until 15 months after a final ruling of the district court.[19] Following the temporary injunction, on February 29, 2012, the district court granted the tobacco companies' summary judgment motion effectively halting The Rule from enactment.[20] The district court found The Rule unconstitutional because it violated the tobacco companies' First Amendment rights by compelling speech.[21]

The government has since appealed the district court's ruling to the United States Court of Appeals for the District of Columbia.[22] The circuit court heard oral argument on April 10, 2012.[23] A ruling is expected in late 2012; however, any decision is expected to be appealed.[24] The United States Court of Appeals for the Sixth Circuit has also recently ruled on this topic, but the Sixth Circuit's ruling is at odds with the DC district court ruling.[25] However, the Sixth Circuit addressed The Rule's requirements about the size and placement of the new warning labels and not the nine new graphic warnings.[26] With the

17. *See* Press Briefing, Kathleen Sebelius, Sec'y of Health & Human Servs., and Margaret Hamburg, FDA Comm'r (June 21, 2011), *available at* http://bit.ly/FDA-press-briefing [hereinafter Press Briefing].

18. *Id.*

19. Order Granting Preliminary Injunction, R.J. Reynolds Tobacco Co. v. FDA, No. 1:11CV01482 (D.D.C. 2011).

20. Order Granting Summary Judgment, R.J. Reynolds Tobacco Co. v. FDA, 2012 WL 653828 (D.D.C. Feb. 29, 2012).

21. *Id.*

22. R.J. Reynolds Tobacco Co. v. FDA, No. 11-5332 (D.C. Cir. 2012).

23. *Id.*

24. *See* discussion *infra* note 26.

25. In March 2012, the United States Court of Appeals for the Sixth Circuit largely upheld the government's authority to regulate tobacco products, including requirements calling for stronger graphic warnings on cigarettes. *See* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509 (6th Cir. 2012). The Sixth Circuit ruling involved the overall tobacco law, including the labels, whereas the D.C. Circuit case focuses on the labels as the FDA currently proposes them. *Id.* One of the three judges in the Sixth Circuit case issued a dissenting opinion on the graphic portion of the labels, writing that requiring a product manufacturer to place a large-scale color graphic on a product-warning label is simply unprecedented. *Id.*

26. *See id.*

divergent rulings in the lower courts, it is highly likely that the United States Supreme Court will make the ultimate decision.[27]

When granting the tobacco companies' summary judgment motion, the district court applied a strict scrutiny evaluation.[28] Under strict scrutiny analysis, the government carries the burden of demonstrating that The Rule is narrowly tailored to achieve a compelling government interest.[29] Commercial speech, however, is not always afforded a strict scrutiny analysis under the First Amendment.[30] In evaluating commercial speech, intermediate scrutiny is often applied.[31] The Supreme Court held that, when the speech being compelled does not consist of purely factual and uncontroversial information, strict scrutiny applies.[32] A court must therefore first decide whether the compelled speech is purely factual in order to determine the level of scrutiny to be applied.[33]

To further explore whether The Rule is constitutional or whether the courts should permanently enjoin the FDA from enforcing The Rule, this Comment will first outline the history of the FDA and relevant tobacco regulations in Section II.[34] Specifically, Subsection II.A will discuss the history of the FDA's regulatory authority on tobacco products, and, in addition, will provide an overview of relevant legislative acts that have been enacted to regulate tobacco products.[35] Subsection II.B will analyze The Act,[36] the federal government's most recent and controversial legislative act designed to impose new regulations on tobacco products.[37] In addition, Subsection II.C will examine The Rule[38]

27. *Id.*

28. Order Granting Summary Judgment, R.J. Reynolds Tobacco Co. v. FDA, 2012 WL 653828, *6 (D.D.C. Feb. 29, 2012).

29. *Id.*

30. *See* Tamara R. Piety, *Against Freedom of Commercial Expression*, 29 CARDOZO L. REV. 2583, 2592 (2008).

31. *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980).

32. *See* Zauderer v. Office of Disciplinary Counsel for Sup. Ct. of Ohio, 471 U.S. 626, 651 (1985) (quoting *In re* R.M.J., 455 U.S. 191, 201 (2002)).

33. *See* Wooley v. Marnard, 430 U.S. 705, 715 (1997) (explaining that the First Amendment prohibits the government from compelling corporations to "use their private property as a 'mobile billboard' for State's ideological message").

34. *See* discussion *infra* Section II.

35. *See* discussion *infra* Section II.A.

36. Family Smoking Prevention and Tobacco Act ("The Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009).

37. *See* discussion *infra* Section II.B.

38. FDA, Required Warnings for Cigarette Packages and Advertisements ("The Rule"), 76 Fed. Reg. 36,628 (June 22, 2011).

enacted by the FDA requiring tobacco companies to adhere nine new graphic warning labels to all cigarette packaging and advertisements.[39]

Section III of this Comment will examine the development of the commercial freedom of speech doctrine[40] under the First Amendment.[41] Specifically, Subsection III.A will discuss the landmark case on commercial freedom of speech, *Central Hudson Gas and Electric Corporation v. Public Service Commission of New York*.[42] This Supreme Court case provided a four-part test for determining the constitutionality of free speech, which will also be analyzed further.[43] This analysis is followed by Subsection III.B, which examines *Lorillard Tobacco Corporation v. Reilly*,[44] one of the Supreme Court's most recent commercial free speech cases.[45]

Section IV will analyze whether The Rule is constitutional.[46] First, the analysis will assess The Rule under the *Central Hudson* four-part test[47] to determine if it violates the tobacco companies' First Amendment rights.[48] Next, the analysis will focus on whether the FDA is overstepping its regulatory authority with the new restrictions[49] it imposes on tobacco companies under The Rule.[50]

Section V of this Comment will address alternatives that the FDA can use to inform consumers about the adverse health effects of cigarettes without violating tobacco companies' First Amendment rights.[51] This Comment will conclude with Part VI, which summarizes why The Rule will likely be found unconstitutional, the direction the government should take to benefit public health and safety, and why it is in the best interest of the public for the Supreme Court to grant a permanent injunction on the FDA's Rule.[52]

39. *See* discussion *infra* Section II.C.
40. *See* U.S. CONST. amend. I.
41. *See* discussion *infra* Section III.
42. Cent. Hudson Gas & Elec. Corp. v. Public Serv. Comm'n, 447 U.S. 557 (1980); *see* discussion *infra* Section III.A.
43. *See id.*
44. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001).
45. *See* discussion *infra* Section III.B.
46. *See* discussion *infra* Section IV.
47. *See* U.S. CONST. amend. I.
48. *See* discussion *infra* Section IV.A.
49. *See* FDA, Required Warnings for Cigarette Packages and Advertisements ("The Rule"), 76 Fed. Reg. 36,628 (June 22, 2011).
50. *See* discussion *infra* Section IV.B.
51. *See* discussion *infra* Section V.
52. *See* discussion *infra* Section IV.

II. BACKGROUND

While recent attempts to regulate tobacco products have been highly publicized, these recent attempts are not the federal government's first regulations or first attempts to tighten regulations imposed on tobacco products.[53] However, the recent attempt marks the first time that the FDA has successfully gained regulatory authority over tobacco products, marking a significant benchmark in how aggressive a role the United States government wants to take in cigarette regulation.[54] To understand the scope of The Rule, this section will include a brief legislative history of tobacco products.[55] This history will be followed by an examination of The Act's requirements, the regulatory authority The Act granted the FDA, and the nine new warning labels The Rule established under The Act.[56] This section will conclude with the current status of The Rule.[57]

A. The History of Tobacco Regulations and the FDA's Expanding Regulatory Authority

In 1938, the FDA made its first attempt to gain regulatory authority over cigarettes when Congress enacted the Federal Food, Drug, and Cosmetic Act (FDCA),[58] which defined the scope of the FDA's jurisdiction over food, drugs, cosmetics, and devices.[59] The FDA lobbied, albeit unsuccessfully, for Congress to include tobacco in the FDCA's definition of "drugs."[60] Ultimately, the FDCA rejected the

53. *Compare* Family Smoking Prevention and Tobacco Act ("The Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009) (providing the FDA with the authority to regulate tobacco products), *and* The Rule, 76 Fed. Reg. 36,628 (establishing nine new cigarette warning labels), *with* Comprehensive Smoking Education Act, 15 U.S.C. §§ 1331-40 (1994) (establishing four warning labels, which were to be rotated on cigarette packages and advertisements). *See also* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 137-39 (2000) (stating that Congress has directly addressed the problem through legislation on six occasions since 1965).

54. *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201, 123 Stat. 1776 (2009) (codified as amended in scattered sections of 5 U.S.C., 15 U.S.C., and 21 U.S.C.); *see also* Press Briefing, *supra* note 17.

55. *See* discussion *infra* Section II.A.

56. *See* discussion *infra* Section II. B.

57. *See* discussion *infra* Section II.C; *see also* 15 U.S.C. § 1333 (2006).

58. Federal Food, Drug, & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-99 (2006)).

59. 21 U.S.C. § 321 (2006) (establishing regulative authority boundaries for the FDA by clearly identifying the FDA's control to include only food, drugs, cosmetics, and devices, not tobacco products).

60. *See* 21 U.S.C. § 321 (2006); *see also* Jennifer Costello, Comment, *The FDA's Struggle to Regulate Tobacco*, 49 ADMIN. L. REV. 671, 673-79 (1997) (describing Congress's exclusion of the FDA in the development of tobacco regulation).

FDA's claim that tobacco products were "drugs," explicitly denying the FDA's attempt to expand its authority to include tobacco products.[61]

After the FDA's failed attempt to gain regulatory authority over tobacco products, the federal government refrained from taking on the tobacco industry again until 1965.[62] In 1965, the federal government began its campaign to educate the public about cigarettes with the enactment of the Federal Cigarette Labeling and Advertising Act (FCLAA).[63] With the enactment of the FCLAA, Congress bestowed upon the Federal Trade Commission (FTC) the authority to regulate cigarette labels while simultaneously giving the Federal Communications Commission (FCC) the authority to regulate tobacco advertising on radio and television.[64] In addition to the FTC and FCC, Congress provided regulatory authority over tobacco products to other government agencies such as the Internal Revenue Services (IRS), the Department of Agriculture (USDA), and the Bureau of Alcohol, Tobacco, Firearms, and Explosives (ATF).[65]

The FCLAA required tobacco companies to display warning labels with the following textual warning, "Caution: Cigarette Smoking May Be Hazardous to Your Health," on all cigarette advertisements, packs, and cartons.[66] The black and white textual warning was enclosed in a black outlined box displayed on the side panel of every cigarette package.[67] According to the Senate report, Congress passed the bill with the belief "that the individual must be safeguarded in his *freedom of choice*—that he has the *right to choose* to smoke or not to smoke—[but also] that the individual has the right to know that smoking may be hazardous to his health."[68]

Congress tightened the regulation in 1970, with the Public Health Cigarette Smoking Act (PHCSA),[69] which amended the FCLAA to

61. *Id.*

62. *See* Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-40 (1970)).

63. *See id.*

64. *See* Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331-40 (1970)); *see also* Costello, *supra* note 60, at 677 n.32 (describing the FCC's initial regulatory role, which required smoking cessation advertising in conjunction with smoking advertising).

65. *See* Costello, *supra* note 60, at 678 n.42 (explaining the IRS's role in taxing tobacco sales, the Department of Agriculture's regulation of tobacco farming, and the ATF's task of fighting illegal tobacco sales and distribution).

66. Pub. L. No. 89-92 (codified as amended at 15 U.S.C. § 1333 (1970)).

67. *See id.*

68. *See* S. REP. NO. 195, at 4 (1965).

69. Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331-40 (2006)).

include additional requirements on cigarette warning labels.[70] The PHCSA required the warning labels to include the amended text, "WARNING: The Surgeon General Has Determined that Cigarette Smoking is Dangerous to Your Health."[71] In addition, the PHCSA placed an electronic ban on cigarette advertisements prohibiting cigarette advertisements from broadcast on the radio or on television.[72] Despite the increased regulation over cigarette packaging and advertising, as well as the Surgeon General's official declaration that cigarette smoking was harmful, Congress still refused to grant the FDA regulatory authority over cigarettes.[73]

The next significant change in tobacco regulations occurred in 1984 when Congress again rejected the option to grant the FDA the authority to regulate tobacco products.[74] Instead, Congress created further advertising regulation by enacting the Comprehensive Smoking Education Act (CSEA).[75] The CSEA was intended to address concern over the need to educate the public about potential health risks caused by smoking.[76] To accomplish its intent, the CSEA made additional amendments to the cigarette warning labels requiring one of four new textual warnings to be placed on all cigarette packages.[77] The CSEA required the warning labels to include one the following four textual warnings: (1) "Smoking Causes Lung Cancer, Heart Disease and May Complicate Pregnancy"; (2) "Quitting Smoking Now Greatly Reduces Serious Risk to Your Health"; (3) "Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, and Low Birth Weight"; and (4) "Cigarette Smoke Contains Carbon Monoxide."[78] The CSEA's four warning labels have been fixtures on all tobacco products since the CSEA was enacted nearly 30 years ago.[79]

While the government seemed content with the required warning labels, the FDA continued its attempts to gain regulatory authority over

70. *See id*.
71. *See id*. § 1333.
72. *See id*.
73. *See, e.g.*, H.R. 11280, 84th Cong. (1956), *and* S. 2554, 85th Cong. (1957), *and* H.R. 592, 85th Cong. (1957) (showing Congress' refusal to grant the FDA the regulative authority over tobacco products by failing to pass bills with provisions that would allow for the FDA to expand its authority).
74. Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984) (codified as amended at 15 U.S.C. §§ 1331-40 (1994)).
75. *See id*.
76. *Id*.
77. *Id*. § 1333(a)(1).
78. *Id*.
79. *See generally* Ronald M. Davis et al., Note, *The Rotation of Health Warnings in Cigarette Advertisements: Compliance with the Comprehensive Smoking Education Act of 1984*, 9 J. PUB. HEALTH POL'Y 403 (1988).

tobacco products. Specifically, in 1996, the FDA unsuccessfully made another attempt to gain regulatory authority over cigarettes through the FDCA.[80] As previously stated, the FDCA prohibits any misbranded food, drugs, or devices from entering into interstate commerce.[81] Pursuant to this broad regulatory power, the FDA attempted to claim that cigarettes were a "misbranded drug," and therefore, should be within the FDA's regulatory authority.[82] The issue reached the U.S. Supreme Court in *FDA v. Brown & Williamson Tobacco Corporation*,[83] where the Court ruled in favor of the tobacco companies and denied the expansion of the FDA's authority.[84] The Court cited Congress' repeated actions to ensure the legality of cigarettes as justification for rejecting the FDA's argument that it possessed the jurisdictional power to regulate, or even ban, cigarettes.[85]

Indicative in the history of the regulation of tobacco products is both Congress's, and the Court's, desire to prevent the FDA from regulating tobacco.[86] The legislative history also indicates that the government's main goal at the time of enactment was to inform consumers about the potential health related risks linked to smoking so that they may make informed decisions, but to do so in a manner that neither infringes on the consumers freedom of choice nor on the tobacco companies freedom of speech.[87]

80. *See* FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

81. *See* Regulations Restricting the Sale & Distribution of Cigarettes & Smokeless Tobacco to Protect Children & Adolescents, 61 Fed. Reg. 44,396, 44,615-18 (Aug. 28, 1996).

82. *See* 21 U.S.C. § 321(h)(2)-(3) (2006) (defining a "device" as having an "intended" effect on the structure or function of the body or an "intended" use in the cure or prevention of disease); *see also* Costello, *supra* note 60, at 681-83 (discussing the FDA's struggle to establish jurisdiction through indirect evidence of intent); United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes, 178 F. Supp. 847, 851 (D.N.J. 1959) (holding that cigarette labels showed the manufacturer's intent to affect the structure or function of a user's body).

83. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120 (2000).

84. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 132-33 (applying the two-prong statutory interpretation test set forth by the Supreme Court in Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984)); *see also* Costello, *supra* note 60, at 677 & n.32 (describing Congress's exclusion of the FDA in the development of tobacco regulation).

85. *See Brown & Williamson Tobacco Corp.*, 529 U.S. at 137 ("Congress has directly addressed the problem of tobacco and health through legislation on six occasions since 1965.").

86. *See* Medtronic v. Lohr, 518 U.S. 479, 491 (1996) ("[I]f Congress intended such a result, its failure even to hint at is spectacularly odd.").

87. *See* S. REP. NO. 195, at 4 (1965).

B. Family Smoking Prevention and Tobacco Control Act

In 2009, President Barack Obama signed into law the Family Smoking Prevention and Tobacco Control Act ("The Act"),[88] marking the first change to United States cigarette regulation in over 25 years.[89] The stated purpose of The Act was to discourage young people from starting to smoke, as well as to encourage adult smokers to quit by informing them of the possible harmful effects of smoking.[90] In contrast to all prior legislation, The Act extends the FDA's regulatory authority to include tobacco products.[91] The Act provides:

> Not later than 24 months after June 22, 2009, the Secretary shall issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the label statements specified in subsection (a)(1). The Secretary may adjust the type size, text and format of the label statements specified in subsections (a)(2) and (b)(2) as the Secretary determines appropriate so that both the graphics and the accompanying label statements are clear, conspicuous, legible and appear within the specified area. . . .[92]

One of the only provisions in The Act that is consistent with prior legislation is the provision limiting the FDA's power by disallowing a complete ban on tobacco sales and the elimination of nicotine from cigarettes.[93]

The most significant changes made by The Act were in the provisions dictating the new cigarette warning label requirements.[94] First, The Act requires all cigarette packages to include one of the following new textual warnings: (1) "Cigarettes are addictive"; (2) "Tobacco smoke can harm your children"; (3) "Cigarettes cause fatal lung disease"; (4) "Cigarettes cause cancer;" (5) "Cigarettes cause strokes and heart disease"; (6) "Smoking during pregnancy can harm your baby"; (7) "Smoking can kill you"; (8) "Tobacco smoke causes fatal lung disease in nonsmokers"; or (9) "Quitting smoking now greatly

88. Family Smoking Prevention and Tobacco Act ("The Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009).

89. *See* Press Release, U.S. Dep't Health & Human Servs., FDA Unveils Final Cigarette Warning Labels (June 21, 2011), *available at* http://bit.ly/FDA-unveils-final-labels.

90. *See Regulating Tobacco: Q&A with Lawrence Deyton*, FOOD & DRUG ADMIN., 2 (Sep. 28, 2009), http://bit.ly/FDA-QA-Deyton (discussing with the Director of the Center for Tobacco Products the FDA's plan to regulate tobacco products in a way that protects the vulnerable youth population from undue influence by tobacco advertising).

91. *See* Pub. L. No. 111-31, § 201 (amending 15 U.S.C. § 1333).

92. *See id.*

93. *Id.*

94. *Id.*

reduces serious risks in your health."[95] In addition, The Act specified that the labels "shall comprise the top 50 percent of the front and rear panels of the package" and that the word "WARNING" should appear in capital letters in 17-point font.[96] The most significant deviation from previous cigarette regulations is The Act's requirement that "color graphics depicting the negative health consequences of smoking" must accompany the textual warnings.[97] The expansion of the FDA's regulatory authority to include tobacco products under The Act paved the way for the FDA to attempt the most monumental change in the history of cigarette regulations.

C. The FDA's Nine New Cigarette Warning Labels

In response to The Act, in June 2011, the FDA announced the Required Warning for Cigarettes Packages and Advertisements ("The Rule").[98] The Rule includes nine new cigarette-warning labels, which include both new graphic and textual warnings. Prior to the injunction discussed above, these warnings were required to appear on all cigarette packages and advertising by September 2012.[99] The FDA claims that The Rule will increase awareness of specific health risks associated with smoking, encourage smokers to quit, and empower young people to say "no" to tobacco.[100] The Rule marks a monumental change in the regulation of the sale of goods; never before in the United States have producers of lawful products been required to use their own packaging to convey an emotionally-charged government message urging adult consumers to shun their products.[101]

The emotional-charge of the government's new regulations seems to stem from the graphics that are now required to be placed on all tobacco products. The graphics required under The Rule include: color images of close-ups of cancerous mouth sores; a man smoking through a tracheotomy; a mother blowing smoke at her baby; a man on life support; and a corpse lying on an autopsy table.[102] In addition to the graphics and textual warnings, the labels are also required to contain a direct

95. *Id.*
96. *See* Pub. L. No. 111-31, § 201 (amending 15 U.S.C. § 1333).
97. *Id.*
98. FDA, Required Warnings for Cigarette Packages and Advertisements ("The Rule"), 76 Fed. Reg. 36,628 (June 22, 2011).
99. *See id.*
100. *See id.* at 36,638; *see also* Press Release, U.S. Dep't Health & Human Servs., FDA Unveils Final Cigarette Warning Labels (June 21, 2010), *available at* http://bit.ly/FDA-unveils-final-labels.
101. *See* 76 Fed. Reg. at 36,639.
102. *See id.*

exhortation to smokers to quit smoking, with the placement of "1-800-Quit-Now" prominently displayed on all packages.[103]

In response to these new labels, five large cigarette manufacturers have sued the FDA, challenging the constitutionality of the new warning labels.[104] The tobacco companies' state in their complaint that, for more than 45 years, the government has required various Surgeon General Warnings to be affixed to all cigarette packages sold in the United States, yet never before have the tobacco companies challenged the legality of any of the previous warning labels.[105] However, these companies claim that the FDA has gone too far with its new graphic images requirement by seeking to make consumers "depressed, discouraged, and afraid" to buy cigarettes.[106] The tobacco companies allege that the vulgar graphic images and direct exhortation to smokers to "Quit-Now"[107] go beyond what any other warnings previously required. No longer is the government requiring tobacco manufacturers to include uncontroversial factual information on their products to allow consumers to make educated decisions as to whether to buy their product; instead, the tobacco companies argue that the government is now unlawfully compelling manufacturers to affix government anti-smoking advocacy messages on their cigarette packages.

In support of their position, the tobacco companies quote FDA Commissioner Margaret Hamburg;[108] Hamburg stated that the purpose of the warnings is to ensure that "every single pack of cigarettes in our country will in effect become a mini-billboard" for the Government's anti-smoking message.[109] The tobacco manufacturers further argue that such compelled messages requiring the companies to advocate against the purchase of their own lawful product is precisely the type of thing that the First Amendment is designed to prevent.[110] Furthermore, the

103. *See id*. at 36,753-55.

104. *See* Complaint, *supra* note 15, at *38 (stating that the warnings required no later than September 22, 2012, would force cigarette makers to "engage in anti-smoking advocacy" on the government's behalf).

105. *See* Complaint, *supra* note 15, at *2.

106. *Id.*

107. *Id.*

108. *See* Complaint, *supra* note 15, at *2.

109. FDA, *Tobacco Control Announcement* (Nov. 10, 2010), http://1.usa.gov/div W2O; *see also* Press Briefing, *supra* note 17.

110. *See* Complaint, *supra* note 15, at *35; *see also* Wooley v. Maynard, 430 U.S. 705, 715 (1997) (ruling that the First Amendment prohibits the Government from compelling corporations to "use their private property as a 'mobile billboard' for the State's ideological message"); Sorrell v. IMS Health Inc., 2011 WL 247296 at *17 (June 23, 2011) (holding that "[t]he State can express [its] view through its own speech. But a State's failure to persuade does not allow it to hamstring the opposition. The state may not burden the speech of others in order to tilt public debate in a preferred direction").

complaint states that the new warnings do not provide the consumers with any new information, nor will they have any material impact on smoking prevalence.[111]

III. COMMERCIAL FREEDOM OF SPEECH AND CONSTITUTIONAL RIGHTS IMPLEMENTED THROUGH THE FIRST AMENDMENT

To better understand the constitutional analysis that The Rule must withstand, this Section will first discuss the commercial freedom of speech doctrine. Specifically, Subsection III.A of this Comment will discuss *Central Hudson Gas and Electric Company v. Public Service Commission*,[112] the landmark case establishing both the doctrine of commercial free speech and the four-part test to determine if government regulation violates commercial free speech.[113] Next, subsection III.B will discuss the Court's most recent freedom of commercial speech case, *Lorillard Tobacco Company v. Reilly*,[114] discussing the Court's use of *Central Hudson*'s four-part test to determine if the government's tobacco regulation was constitutional.[115]

As illustrated in the R.J. Reynolds Tobacco Company Complaint, one argument against The Rule is that it is an infringement on the tobacco companies' constitutional rights.[116] Free speech is a fundamental right embodied in the First Amendment,[117] and many consider it as the cornerstone of our democratic society.[118] The First Amendment protects "both the right to speak freely and *the right to refrain from speaking at all*."[119] The tobacco companies' right to refrain from speaking is what is in jeopardy with the enactment of The Rule. For corporations and individuals, the choice to speak includes "within it the choice of what not to say."[120] It is for this reason that, when a statute compels speech from one who would not otherwise make such speech, the Court holds this type of compelled speech as "presumptively unconstitutional."[121] However, within the constructs of compelled commercial speech, narrow exceptions apply.

111. *See* Complaint, *supra* note 15, at *35.
112. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980).
113. *See id.* at 566; *see also* discussion *infra* Section III.A.
114. *See* discussion *infra* Section III.B; *see also* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525 (2001).
115. *See id.* at 575.
116. *See* Complaint, *supra* note 15, at *2.
117. *See* U.S. CONST. amend. I.
118. *See generally* 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 500 (1996).
119. Wooley v. Maynar, 430 U.S. 705, 714 (1997) (emphasis added).
120. Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n of Cal. 475 U.S. 1, 16 (1986).
121. Rosenberger v. Rector & Visitors of Univ. of Va., 515 U.S. 819, 839 (1995); Entertainment Software Ass'n v. Blagojevich, 469 F.3d 641, 651 (7th Cir. 2006).

For instance, the government may be allowed to compel certain commercial speech in order to protect consumers from "confusion or deception."[122] When challenged, courts may apply a lesser, intermediate level of scrutiny to this narrow category of compelled speech if the required disclosure is "purely factual and uncontroversial information."[123] Even under an intermediate scrutiny analysis, purely factual and uncontroversial information may violate the First Amendment if the compelled speech is "unjustified or unduly burdensome."[124]

The evidence of anti-smoking advocacy, emotional assault on consumers, and lack of efficacy suggest that The Rule's graphic image requirements will not be considered the type of purely factual and uncontroversial information that would allow for intermediate scrutiny analysis. While it is likely that the court will apply a strict scrutiny analysis, there is controversy as to which level of scrutiny should apply. Therefore, this Comment will analyze whether an application of the lesser intermediate scrutiny test would invalidate The Rule. If The Rule fails intermediate scrutiny analysis, then it also fails under strict scrutiny analysis. In sum, this section will provide a detailed framework for determining when a government-imposed regulation violates commercial free speech under the First Amendment.

A. The Development of the Commercial Free SpeechDoctrine and Central Hudson*'s Four Part Test*

In *Central Hudson*, the Supreme Court applied intermediate scrutiny analysis to commercial free speech for the first time.[125] It was one of the most significant cases in the history of the commercial free speech doctrine.[126] After years of uncertainty regarding commercial speech jurisprudence,[127] the Court in *Central Hudson* implemented a

122. Zauderer v. Office of Disciplinary Counsel for Sup. Ct. of Ohio, 471 U.S. 626, 651 (1985) (quoting *In re* R.M.J., 455 U.S. 191, 201 (2002)).

123. *See id.*

124. *Id.*

125. *Id.*

126. *See id.*

127. *Compare* Valentine v. Chrestensen, 316 U.S. 52, 54 (1942) (holding that the First Amendment protects informational and political speech, not commercial advertising), *overruled* by Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc. 425 U.S. 748 (1976), *and* Breard v. Alexandria 341 U.S. 622, 642 (1951) (finding a regulation prohibiting door-to-door solicitation constitutional despite the "fact that periodicals are sold does not put them beyond the protection of the First Amendment"), *abrogated* by Village of Schaumburg v. Citizens for a Better Env't, 444 U.S. 620 (1980), *with* Bigelow v. Va., 421 U.S. 809, 825-26 (1975) (deeming Virginia's statue unconstitutional where it restricted pharmacists' advertisements of prescription drug prices because a state may not "completely suppress the dissemination of concededly

four-part test to determine if a government regulation infringed on a company's constitutional freedom of speech rights.[128] The first part of the *Central Hudson* four-part test is to determine whether the First Amendment protects the expression; second, it must be determined whether the asserted governmental interest is substantial. If the first two prongs are answered in the affirmative, the third determination to be addressed is whether the regulation directly advances the governmental interest asserted. Fourth, a court must determine whether the regulation is more extensive than necessary to advance the government's interest.[129] The *Central Hudson* Court stated that, if a regulation fails any one of the four prongs, the regulation is unconstitutional.

In *Central Hudson*, the Court applied its newly articulated four-part test and found New York's regulation, which banned all promotional advertising by electric utility companies, unconstitutional.[130] The New York Public Service Commission implemented the ban in the wake of a winter energy shortage; however, the ban remained in effect after the shortage had ended.[131] The Court applied the four-part test to the facts of the case and concluded that the first two prongs of the test were satisfied.[132] The Court found that the promotional advertising was lawful and not misleading[133] and that regulations promoting energy conservation represented a substantial government interest in conserving energy and maintaining equitable rates.[134]

Because the first two prongs were met, the Court turned to the test's third prong.[135] The Court agreed with the government's argument that the advertisements were directly related to the increase in demand.[136] Therefore, the ban on such advertisements from utility companies directly advanced the government's interest in energy conservation.[137]

truthful information about entirely lawful activity, fearful of that information's effect upon its disseminators and its recipients").

128. *See Central Hudson*, 447 U.S. at 566.

129. *See id.* at 566.

130. *See id.* at 557.

131. *Id.* at 558-59.

132. *Id.*

133. *See id.* at 559 (rejecting the reasoning of the New York Court of Appeals that advertising by a monopoly cannot improve decision making by consumers and, thus, is not worthy of First Amendment protection).

134. *See id.* at 559 (upholding a complex economic argument advanced by the Commission, which argued that promotional advertising would more likely lead to inequitable energy rates and distribution among consumers).

135. *Id.*

136. *Id.*

137. *See id.* at 569 ("There is an immediate connection between advertising and demand for electricity. Central Hudson would not contest the advertising ban unless it believed that promotion would increase its sales. Thus, we find a direct link between the state interest in conservation and the Commission's order.").

Finally, the Court addressed the fourth prong of the test, analyzing whether the means used to further the Commission's substantial interest in energy conservation were more extensive than necessary.[138] It was here that the Court found that the Commission failed to satisfy its burden.[139] The Court held that use of the ban on all advertisements was both unjustifiable and overly broad.[140] Specifically, the Commission was unable to show that a more limited restriction would not serve its interest in energy conservation.[141] The holding in *Central Hudson* established the intermediate scrutiny standard that is applied today when determining if commercial freedom of speech has been violated.[142] In Section IV, this Comment will apply the test set forth in *Central Hudson* to the FDA's Rule.[143]

B. Recent Commercial Free Speech Jurisprudence

One of the Court's most recent decisions on commercial speech is *Lorillard.*[144] In *Lorillard*, the Massachusetts Attorney General implemented regulations that attempted to restrict "outdoor advertising, point-of-sale advertising, retail sales transactions, transactions by mail, promotions, sampling of products, and labels for cigars."[145] The Court found that that the regulations were preempted because "Congress prohibited state cigarette advertising regulations that were motivated by concerns about smoking and health."[146] Despite finding that the regulations were preempted, the Court applied the *Central Hudson* four-part test to decide whether the regulations violated the tobacco companies' First Amendments rights.[147]

Again, the Court found that the first and second prongs were easily met and, thus, the issue remained as to whether the third and fourth prongs were satisfied.[148] The Court looked at whether the outdoor advertising and point-of-sale restrictions imposed by the regulations on all smokeless tobacco and cigar advertisements directly advanced the

138. *See id.* at 570.
139. *Id.*
140. *Id.*
141. *See id.* at 569-70.
142. *Id.*
143. *See* discussion *infra* Section IV.
144. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, (2001).
145. *Id.* at 534.
146. *Id.* at 548.
147. *See id.* at 554-55 ("We see no need to break new ground . . . *Central Hudson*, as applied in our more recent cases, provides an adequate basis for decision.").
148. *See id.* at 555 (noting that, in regards to the first two prongs, the parties agreed that the speech was entitled to First Amendment protection and that the government had a substantial interest in preventing minors from using tobacco).

government interest and whether these restrictions were narrowly tailored.[149] After considering these questions, the Court found that the regulations directly advanced the Government's interest satisfying the third prong of the *Central Hudson* test.[150] The Court in *Lorillard* reasoned that the evidence provided, which cited studies that supported the correlation between advertising and tobacco use, was enough to satisfy the test's third prong.[151] However, the Court then found that the regulations were not a "reasonable fit between the means and ends of the regulatory scheme."[152] Like in *Central Hudson*, even when the first, second, and third prongs are satisfied, in *Lorillard* the Court held that the regulations failed to satisfy the fourth prong.[153] The Court explained that the regulations were in fact more extensive than necessary to accomplish the government's stated goals.[154]

When deciding if commercial freedom of speech rights are being violated, the Court continuously acknowledges the importance of balancing one of our most cherished constitutional rights—the First Amendment—with the public's right to be informed.[155]

IV. HAS THE FDA CREATED AN UNCONSTITUTIONAL RULE?

This section will analyze whether the FDA's Rule is an unconstitutional infringement on the tobacco companies' First Amendment rights. In order to determine if The Rule violates commercial free speech, this section will apply the four-part *Central*

149. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, (2001).

150. *Id.*

151. *See id.* ("[I]n previous cases we have acknowledged the theory that product advertising stimulates the demand for products, while suppressed advertising may have the opposite effect.").

152. *Id.* ("[T]he breadth and scope of the regulations, and the process by which the Attorney General adopted the [Massachusetts] regulations, do not demonstrate a careful calculation of the speech interest involved."). At the center of the Court's finding was the fact that the 1000-foot restriction was inappropriate for every area. *See id.* at 562-63. For that reason, the Court found that the effect of such regulation would vary depending on the location and therefore should be tailored. *See id.* at 563. In addition, the Court found that it was unclear why a ban on oral communication was necessary and that the restrictions on the size of signs was overbroad. *Id.* The Court emphasized the rights of the tobacco manufacturers in conveying information about their products to adults and the mutual right of adults to receive such information. *Id.* at 564.

153. *Id.*

154. *See* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 566 (2001) (citing *Central Hudson* and concluding that a regulation must fail if it only offers "ineffective or remote support" for the government's stated purpose).

155. Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 500 n.10 (1996) (Stevens, J.) (quoting Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 574 (1980) (Blackmun, J., concurring in the judgment) (agreeing that even "though 'commercial' speech is involved, such a regulation strikes at the heart of the First Amendment").

Hudson test to The Rule.[156] In addition, this section will discuss whether The Rule enacted by the FDA was within the FDA's regulatory authority.

In order to determine whether The Rule meets *Central Hudson*'s first prong, a court must decide whether it implicates speech that is entitled to First Amendment protection.[157] If the information is "neither misleading nor related to unlawful activity," the Government's ability to restrict the communication is limited due to the protection afforded to speech under the First Amendment.[158] The Supreme Court has continuously adopted a broad stance as to what speech is protected as non-misleading under the First Amendment.[159] This broad stance was exemplified by the holding in *Lorillard*.[160]

In *Lorillard*, the Court promptly found the government satisfied *Central Hudson*'s first prong without providing any substantive analysis.[161] The Court made it clear that, like forms of commercial speech that express a company's product in a positive light, compelled speech that forces companies to distribute negative information is subject to the same First Amendment protections afforded to all other commercial speech.[162] Therefore, The Rule likely satisfies the first prong by implicating speech that is entitled to First Amendment protection.

After a determination that the speech in question implicates the First Amendment, the second prong of the *Central Hudson* test requires a showing that the regulation furthers a substantial government interest.[163] As described in The Act, the purpose for granting the FDA the power to regulate tobacco was to reduce youth tobacco use and "to effectively convey the negative health consequences of smoking on cigarette packages and in advertisements."[164] In *Lorillard*, the Court found that there was little merit in contesting whether the State possessed a

156. *Central Hudson*, 447 U.S. at 566.

157. *See id.*

158. *See id.* at 566 (finding that "[f]or commercial speech to come within that provision, it at least must concern lawful activity and not be misleading"); *see also Lorillard*, 533 U.S. at 554-55 (majority opinion).

159. *Central Hudson*, 447 U.S. at 566.

160. *See id.* at 554-55.

161. *See id*.

162. *See id.* at 554.

163. *See Central Hudson*, 447 U.S. at 566.

164. *See* Family Smoking Prevention and Tobacco Act ("The Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended at 15 U.S.C. § 1333) (describing congressional findings and the purposes of The Act); *see also* U.S. DEP'T OF HEALTH & HUMAN SERVS., PREVENTING TOBACCO USE AMONG YOUNG PEOPLE: A REPORT OF THE SURGEON GENERAL 5, 135 (1994) (describing the effects of youth smoking on adult smoking and noting that "well over 80 percent of adolescents who smoked half a pack a day or more as seniors in high school . . . were smoking five to six years later as young adults").

substantial interest in "preventing the use of tobacco products by minors."[165] The Court believed that that State's interest was clear and substantial.[166] Consequently, in the wake of *Lorillard*, it would seem clear that the government's interest in preventing minors from beginning to smoke would pass the substantial interest prong. The government's other stated interest of educating the public about the health risks of smoking is not as straightforward as its interest in discouraging smoking in the youth population; yet, as presented, it would still make a strong *prima facie* case that The Rule promotes a substantial government interest.

However, closer inspection reveals that the governments primary purpose is not, as it claims, to simply inform.[167] Instead, the government, through its own words and data, concedes that its actual purpose is to advocate for a change in consumer behavior, *i.e.*, to quit smoking.[168] For that reason, what would seem like a clear cut case in the wake of *Lorillard* may turn out to be a point of substantial debate. The government acknowledges that the images chosen for the labels were not the images that would best inform the viewer; instead, the images chosen were those that had the highest shock value.[169] In addition, the FDA Commission announced that the purpose of The Rule was to encourage smokers to quit and to deter others from starting to smoke.[170] For those reasons, although the government stated that the statutory purpose of The Rule was to inform the public, a court may find that The Rule's actual purpose was to launch an anti-smoking campaign using the tobacco companies as the platform and financial backing. It has even been alleged that The Rule's stated purpose may have been put forth simply as a means of easily satisfying a challenge to the substantial government interest prong.[171] The purposed motivation for The Rule, compelling anti-smoking advocacy, has never been found to satisfy the substantial interest prong. In fact, the Court has repeatedly struck down such paternalistic attempts by the government.[172] In light of the strong direct evidence indicating the FDA has an ulterior motive, a court would likely hold that the government's interest in pushing an anti-smoking campaign at the expense of tobacco companies' is not a compelling interest;

165. *Lorillard*, 533 U.S. at 555.
166. *See id.* at 36,638-639.
167. *Id.*
168. *Id.*
169. *See id.*
170. *See* Press Briefing, *supra* note 17.
171. *See* Pearson v. Shalala, 130 F. Supp. 2d 105, 113 (D.D.C. 2001).
172. *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 563 (1980).

therefore, The Rule will not satisfy the second prong of *Central Hudson*.[173]

Although the above analysis discredits the government's stated interest in The Rule, for the purposes of further examination, the following analysis will show deference to the government and proceed as if their stated interest was genuine. If a court were to determine that the government's primary purpose behind The Rule is to inform the public, it will still be difficult for The Rule to satisfy the third prong by showing that the warning labels imposed by The Rule "directly and materially advance" the government's interest.[174] Rather, as discussed below, it is more likely that a court would find that the warning labels have little, if any, impact on consumers understanding of the potential health related consequences caused by smoking.

The FDA claims that the graphic warning images imposed by The Rule will alleviate harm caused by cigarettes to a material degree.[175] However, yet again the government's own data and statements contradict its claim. The government acknowledged that the study conducted for the purpose of selecting graphic images to be used for the warning labels did not test whether the graphic images would have an impact on consumer awareness of smoking-related risks.[176] Rather, the study assessed "the *relative* impact of different warnings based on participants' exposure to one graphic warning on one occasion."[177] This admission is a strong indication that the government was more concerned with the cognitive responses the images produced.[178] The FDA further concedes that the images selected were the ones that had the strongest tendency to make viewers "depressed, discouraged, and afraid" and were not images that were particularly informative to the viewer.[179] As a result, it will be difficult for the government to show that the graphic images required by The Rule further, or correlate to, the statutorily stated interest of informing the public.

173. *See Central Hudson*, 447 U.S. at 566.

174. *See id.* at 566 (holding that "[i]f both inquiries yield positive answers, we must determine whether the regulation directly advances the governmental interest asserted"); *see also* Edenfiled v. Fane, 507 U.S. 761, 770-73 (1993) (requiring evidence that commercial speech prohibitions "serve [the government's] purposes in a direct and material manner" under the third prong of the *Central Hudson* test).

175. *See* 76 Fed. Reg. at 36,638-39.

176. *See id.*

177. *Id.*

178. *See id.*

179. *See id.* (measuring "salience," which is defined as an image's tendency to make viewers "depressed, discouraged, and afraid," and stating that the FDA chose warnings that scored high on such a measure and that "arouse[d] fear," triggered "greater negative emotional reactions," or "confer[red] negative feelings about smoking").

In support of the FDA's claim, the FDA also cites the successful use of similar graphic warning labels on cigarette packages in Canada.[180] The FDA relies on a Canadian study in support of the position that the warning labels imposed by The Rule would directly reduce the smoking rates in the United States by 0.212 percent.[181] However, the research used to calculate this estimate relied on two flawed assumptions and failed to account for possible confounding factors.[182] The FDA concedes that "[i]mplicit in this method [was] the assumption that these otherwise unexplained differences may be attributed solely to the presence in Canada of graphic warning labels."[183] The FDA further acknowledges that, because of their inability to account for "confounding factors," it renders the data from the study highly uncertain.[184] Even without the flaws, the FDA has conceded that the alleged estimated reduction percentage of 0.212 percent was, in fact, "not statistically distinguishable from zero."[185] Despite the apparent statistical errors, the FDA still uses the data as justification for the warning labels.[186] The major flaws in the FDA's benefit analysis, combined with the questionable testing preformed on the graphic images, leaves the government lacking any empirical data supporting the claim that The Rule furthers its stated interest. Therefore, The Rule will likely fail to satisfy *Central Hudson*'s third prong.[187]

Finally, *Central Hudson*'s fourth prong requires a case-by-case inquiry into whether there is "a reasonable fit between the means and ends of the regulatory scheme" imposed by the new regulation.[188] The Court has held that the fit need not be perfect; however, the scope of the

180. *See id.* at 69,453.

181. *Id.*

182. *See* Complaint, *supra* note 15, at *15 (citing two flawed assumptions made by the FDA: (1) after Canada introduced similar cigarette warning labels in 2000, any decrease in Canadian smoking rate trends beyond those that occurred in the United States during the same period of time were caused by the new cigarette warning labels as opposed to other factors; and (2) the cigarette warning labels would cause the same change in U.S. smoking rates).

183. 75 Fed. Reg. at 69,453.

184. *Id.* at 69,456 ("[T]he U.S. social policy climate may have been so different from Canada's during the years 1999-2008 that this proxy is inappropriate.").

185. *See id.*

186. *Compare* 75 Fed. Reg. 69,543, *with* 76 Fed. Reg. 36,721 (indicating that the FDA's estimated reduction for smoking in the United States decreased from 0.212% in the Proposed Rule to 0.088% in the Final Rule), *and* 76 Fed. Reg. 36,724 (explaining further that the "FDA's estimate of a 0.088 percentage point reduction in the U.S. smoking rate").

187. *Central Hudson*, 447 U.S. at 566.

188. *See id*. at 566 (stating that you must determine whether the regulation is "not more extensive than is necessary to serve that interest"); *see also* Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 561-66 (2001) (conducting a rigorous application of the fourth prong of the *Central Hudson* test).

regulation must be "in proportion to the interest served; that employs not necessarily the least restrictive means but . . . [is] narrowly tailored to achieve the desired objective."[189] In addition, The Rule must have been imposed through careful calculations of "the cost and benefits associated with the burden on speech imposed by the regulations."[190] Applying this standard to The Rule, it is obvious that it will be difficult for the government to support the claim that The Rule is narrowly tailored and was imposed through careful calculations to ensure that the least burdensome means available was used.

To begin, the sheer size and placement requirements for the graphic images suggest they are not narrowly tailored.[191] Simply because The Act promulgated the FDA to impose a rule consistent with the regulations given in The Act does not mean The Rule will automatically pass constitutional muster.[192] Commandeering 50 percent of the fronts and backs of all cigarette packages is likely not a directive that will be capable of being seen as narrowly tailored.[193] The overtly large size indicates not only that The Rule is not narrowly tailored but also that the labels are not being used for the stated purpose of informing the public of the hazards of smoking. In fact, the Secretary of Health and Human Services indicated that the purpose of the large labels was "to rebrand . . . our cigarette packs" to make every cigarette package in the country a "mini-billboard."[194] In the wake of *Entertainment Software Association v. Blagojevich*,[195] it will be difficult for the government to make a credible argument that the size of these "mini-billboards" was narrowly tailored.[196] In *Blagojevich*, the Seventh Circuit Court of Appeals held that a four-square-inch sticker on a video game box failed to be narrowly tailored because "it covered a substantial portion of the box."[197] The video game boxes were much larger than the cigarette packages,[198] and

189. *Central Hudson*, 447 U.S. at 566.

190. *Id.*

191. *See* Act, 15 U.S.C. § 1333(a)(2) (providing the size and placement requirements for the warning labels).

192. *See id.*

193. *Id.*

194. *See* Press Briefing, *supra* note 17 (quoting HHS Secretary Sebelius that the warnings effectively "rebrand . . . our cigarettes").

195. Entertainment Software Ass'n v. Blagojevich, 469 F.3d 641 (7th Cir. 2006).

196. *See id.* at 652.

197. *See id.* ("[C]ertainly we would not condone a health department's requirement that half of the space on a restaurant menu be consumed by the raw shellfish warning. Nor will we condone the State's justified requirement of the four square-inch '18' sticker.").

198. *See* FDA, Required Warnings for Cigarette Packages and Advertisements ("The Rule"), 76 Fed. Reg. 36,628 (June 22, 2011).

the four-inch-square that failed the tailoring test covered far less than 50 percent of the package.

In addition to the size requirements under The Rule, the actual graphic images are not narrowly tailored. The FDA claims that the chosen images are "warnings," but it seems inaccurate to describe them as such when the images were designed to elicit disgust, fear, and shock from consumers.[199] While The Act requires color image warnings, the chosen images do not necessarily fall under the category of "warning" images at all; some are cartoons and others are photographs that have been notably modified by computer programs.[200] The FDA has even admitted that "some of the photographs were technologically modified to depict the negative health consequences of smoking."[201]

There are several ways that the FDA could have more narrowly tailored the warning images. Alternatives might include a graph that shows a correlation between the number of people who try to quit versus those who actually do or a graph that indicates the increase in medical complications that may occur for expecting mothers who smoke in comparison to those who do not smoke. These are just a few examples of alternative graphic-images for warning labels that would be better tailored to educate the public about the risk of smoking.

Beyond the graphic images themselves, The Rule's requirement that each warning prominently display "1-800-QUIT-NOW," the smoking cessation hotline, furthers the argument that The Rule is not narrowly tailored.[202] The cessation provision supports the argument that The Rule compels tobacco companies to advocate the government's anti-smoking campaign.

When considering the totality of The Rule's label requirements—the ineffectiveness of the content, the content itself, the size of the labels, and the placement of the labels—the Rule is unlikely to satisfy *Central Hudson*'s fourth prong.[203] A court would likely find that The Rule is unconstitutional because the warning labels are more extensive than necessary and because they are not the least restrictive means available to accomplish the government's goal. Instead, the government should use one of the numerous alternatives available to them. Such alternatives would be no less, if not more, effective than the warnings in question

199. *See* 76 Fed. Reg. at 36,696.
200. *See id*.
201. *See id*.
202. *See* 76 Fed. Reg. at 36,686-87.
203. *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980).

while imposing a lower burden on the First Amendment rights of tobacco companies.[204]

After analyzing The Rule under *Central Hudson*'s four-part test, it seems clear that The Rule is an unconstitutional infringement on the tobacco companies' freedom of speech.[205] The Rule is a bold attempt by the government to further its efforts in minimizing or eliminating tobacco use in the United States, however, it is likely that courts will seek to protect fundamental First Amendment rights and strike down The Rule. If the government wishes to ban tobacco use in the United States, it may do so. However, as long as cigarettes remain a legal product, the government may not push its anti-smoking agenda by violating tobacco companies' rights, packaging, and bank accounts to promote and fund an agenda that directly harms the interest of those same companies.

Another strong argument for striking down The Rule in favor of First Amendment protection manifests when one examines the logical expansion of the government's reasoning for the compelled graphic images. There are many products that are potentially harmful yet are legal to sell and purchase within the United States.[206] If the FDA is allowed to infringe upon the tobacco companies' free speech rights in the name of public health, next the American public may see alcoholic beverage containers that display color images of people with yellowed skin suffering from jaundice or images of fatal car accidents. In theory, such images would be accompanied by large text with such statements as "Alcohol Can Kill" and "Quit-Now."[207] Moreover, with obesity related deaths and health complications on the rise, informing young people about avoiding obesity and encouraging adults to choose a healthy life style could be the government's next substantial interest.[208] If the FDA is allowed to compel graphic images to prevent and inform the public of these dangers, Americans may next see images of diseased gallbladders, livers, and hearts before biting into a Big Mac hamburger at McDonald's. By comparison, if alcohol and unhealthy foods prove to be beyond the FDA's regulatory authority, arguably, so should cigarettes.

204. *See* discussion *infra* section IV (discussing alternatives the government could use to achieve their stated purpose without infringing on the tobacco companies First Amendment rights).

205. *See Central Hudson*, 447 U.S. at 566.

206. *See, e.g.*, *Alcohol Related Disease Impact*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://1.usa.gov/IfMIn5 (last visited Aug. 18, 2012).

207. *See id.*

208. Lauren Kaplin, *A National Strategy to Combat the Childhood Obesity Epidemic*, 15 U.C. DAVIS J. JUV. L. & POL'Y 347, 351 (2011) (discussing how obesity has become "the most expensive preventable healthcare cost, with over a quarter of Americans and seventeen percent of children and adolescents weighing in as obese").

In sum, the FDA cannot promulgate a Rule that violates the Constitution, even if such a rule complies with legislative requirements. Therefore, regardless of the fact that The Act granted the FDA the power to regulate cigarettes, The Rule created in response to The Act likely violates the First Amendment. Simply put, it is likely that the labels at issue go too far, calling for emotionally charged images instead of factual, uncontroversial information to ensure that the public is well informed. In attempting to ensure that tobacco marketing does not deceive the public, the government has effectively crossed the line into anti-smoking advocacy.

V. ALTERNATIVES MEASURES

This Section will discuss possible alternatives the government could employ that would enable them to inform the public about the potential health related risks of smoking[209] without infringing on the tobacco companies constitutional rights. Alternatives include school-based smoking prevention programs, increased legal penalties for the sale of tobacco products to minors, and criminalization of the possession of tobacco products by minors. There are other possible alternatives the government could use that would be less restrictive means of informing the public as well, including similar current regulations the FDA finds adequate to regulate food and drug products in the United States. Many of these alternatives, further described below, have been statistically proven to decrease smoking.

First, consistent with First Amendment principles, if the government wants to decrease smoking in the United States, it should employ a policy of "counter speech" instead of compelled speech.[210] If the government is concerned about health risks related to smoking, it is "free to propagandize against [it]" by engaging in speech counter to the tobacco industry.[211] The counter speech alternative to the government's current proposed policy would be more consistent with First Amendment ideology and would encourage the free flow of information.[212] The use of counter speech would balance out the distortions and biases that the government believes have been created by the tobacco industry, giving significant voice to the opposing party. Studies have shown that counter speech against tobacco companies is a more effective method than

209. *See* 76 Fed. Reg. at 36,697.

210. *See* Whitney v. California, 274 U.S. 357, 377 (1927) (Brandeis, J. concurring) ("If there be time to expose through discussion the falsehood and fallacies, to aver the evil by the processes of education, the remedy to be applied is more speech.").

211. *See* Kathleen M. Sullivan, *Cheap Spirits, Cigarettes, and Free Speech: The Implications of 44* Liquormart, 1996 SUP. CT. REV. 123, 141 (1996).

212. *See Whitney*, 274 U.S. at 377.

compelled speech.[213] As Kathleen Sullivan, a Stanford University law professor, writes, "[T]he best answer to speech is not regulation but more speech."[214] Sullivan supports the theory of counter speech with statistical proof: a decrease in smoking directly correlated to the anti-smoking campaigns run by the American Cancer Society and other groups in the 1960s.[215] Studies from this period indicate that the anti-smoking campaigns were so effective that they contributed to a reduction in cigarette smoking.[216]

Creating more school-based smoking prevention programs is another possible alternative that would specifically target and discourage smoking among adolescents. Studies have shown that school-based programs centered on the social-influence-resistance model ("The Model") are most effective in long-term smoking prevention among youths.[217] The Model recognizes and emphasizes the social environment in the decision-making process and helps build the skills necessary to resist peer pressure.[218] School-based programs would directly influence the youth population by providing them with information about the potential harms of smoking. More importantly, instead of simply trying to scare the youth from smoking, the Model helps youth build the necessary skills needed to resist pressure among their peers to start smoking.[219] Similar to the counter speech alternative, school-based programs are statistically proven to be effective; moreover, the school-based programs would not infringe on tobacco companies' First Amendment rights.

In addition to school-based prevention programs, there are numerous other non-speech restrictive alternatives available to the federal government that could effectively assist the government in reaching their stated goal of preventing youth smoking.[220] Alternatives include increasing the enforcement of state laws which prohibit the sale of tobacco products to minors; criminalizing possession, not just use, of tobacco products for minors; increasing anti-smoking education campaigns; prohibiting smoking in all workplaces that employ workers

213. *See* Costello, *supra* note 60, at 687.

214. Kathleen M. Sullivan, *Muzzle Joe Camel? It May Be Illegal*, NEWSDAY, May 30, 1996, at A51.

215. *See id.*

216. *See id.*

217. PETER D. JACOBSON ET AL., COMBATING TEEN SMOKING: RESEARCH AND POLICY STRATEGIES 117-18 (2001).

218. *See id*.

219. *Id*. at 118.

220. *See* Press Release, U.S. Dep't of Health and Human Servs., FDA Unveils Final Cigarette Warning Labels (June 21, 2010), *available at* http://bit.ly/FDA-unveils-final-labels.

below the legal smoking age; further increasing the cost of tobacco products; and imposing federal restrictions on possessing or selling cigarettes to minors.[221] All of these listed alternatives would be less burdensome than the restriction on free speech imposed by The Rule. In addition, the government is required to show that they are using the most tailored means available to regulate. Therefore, by failing to first implement such non-speech restrictive alternatives, The Rule will likely be rendered unconstitutional because it is overly broad.[222]

The government could also employ similar regulations that have been used on other legal products sold in the United States. For example, the government requires information leaflets to be included within contraceptive packaging. The government believes that these information leaflets are an efficient way to provide the public with information and warnings about the potential health consequences that could occur from using contraceptives.[223] Similarly, the government could require information leaflets to be included within each cigarette package. These informational leaflets would allow for a less obtrusive way of providing the public with factual information regarding cigarettes, the potential health effects of smoking, and information on how to quit. Another example of a regulation previously employed by the government is the use of uniform nutrition labels on food.[224] The Nutrition Labeling and Education Act was implemented to inform and protect the public from misbranded food. The Nutrition Labeling and Education Act required that nutrition information and ingredients be listed on a label on the outside of the food package.[225] The government could require similar labels to be affixed to cigarette packages, which would identify all the ingredients and chemicals in the cigarettes. While both of these alternatives require information to be either included in the cigarette packages or affixed on the outside of the package, these alternatives would likely pass constitutional muster because the

221. *See* Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512, 536-38 (W.D. Ky. 2010).

222. *See id.*

223. *See* Dunkin v. Syntex Laboratories, Inc., 443 F. Supp. 121 (1977) (W.D. Tenn. 1977). The case held that, as a matter of law, a leaflet contained in each birth control pill dispenser was an adequate warning given by the drug manufacturer. *Id.* at 123. The leaflet labeled "patient information" warned that safe use of birth control pills required a careful discussion with a doctor and that the most serious known side effect of birth control pills was abnormal blood clotting; the court found that, in terms of precision, "the warning was adequate because it pointed out the risk. *Id.*

224. Nutrition Labeling & Education Act, 21 U.S.C. § 343 (2006).

225. *See* United States v. Kocmond, 200 F.2d 370 (Ill. 1952), *certiorari denied*, 345 U.S. 924 (1953) (concluding that the purpose of the labeling requirement was to prohibit commerce in misbranded articles and to inform and protect the ultimate consumer); *see also* 21 U.S.C. § 343 (2006).

information would be purely factual and uncontroversial.[226] In sum, these alternatives have been found to be effective in informing and protecting the public from potential health risks without infringing on First Amendment rights.

Because there are numerous alternatives the government could use that would likely not infringe on tobacco companies' First Amendment rights, it is likely that The Rule's warning labels are not the most tailored alternative the government could use to achieve its stated purpose. Therefore, a court would likely hold that The Rule is unconstitutional due to a lack of tailoring.[227] Moreover, many of the available alternatives have statistical data proving efficacy,[228] whereas The Rule is arguably overbroad and utterly devoid of any empirical evidence indicating its effectiveness.[229] The government should thus reconsider The Rule and use an alternative method that would not infringe on the tobacco companies' First Amendment rights.

VI. CONCLUSION

The First Amendment protects not only consumers and public information but also unpopular speech directed at influencing consumer vices.[230] If the government wants to publicize its anti-smoking message, as well as provide information on how to quit smoking, it may do so; however, it must do so by constitutional means which employ narrowly tailored methods that do not infringe on the tobacco companies' First Amendment rights. The government cannot require tobacco manufacturers to make their legal products into mini billboards to broadcast the government's anti-smoking campaign, and it cannot force tobacco companies to bear the cost in doing so. The Supreme Court has repeatedly used *Central Hudson*'s four-part test to deny paternalistic attempts at government interference that would thwart consumer choice.

The FDA rule requiring graphic visual images to be displayed on cigarette packages is overly broad and poorly aligned with the government's overall purpose. By ignoring less restrictive and more

226. *See* Zauderer v. Office of Disciplinary Counsel of Sup. Ct. of Ohio, 471 U.S. 626, 651 (1985) (stating that warnings imposed by The Rule are not "purely factual and uncontroversial" and are subject to strict scrutiny).

227. *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980) (holding that the government must satisfy the four-part test for the regulation to be constitutional, and, under the fourth prong, the regulation must be the most tailored means available).

228. *See* discussion *supra* Section III.

229. *See id.*

230. Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 590 (2001) (Thomas, J., concurring in part, concurring in judgment).

tailored means, the nine new cigarette-warning labels are likely an unconstitutional affront to the commercial speech doctrine.

In the future, some adults will choose to avoid smoking altogether, some will choose to quit smoking to protect their health, and others will choose to smoke and accept the risk. Whatever their choices may be, what matters is that it remains just that: a choice that is free from government interference that threatens to diminish the constitutional rights of all American citizens. If The Rule is not struck down as unconstitutional, it will encourage a slippery slope where the government can continue to exceed its legislative authority by imposing unjust regulations on legal products as it sees fit, and one of our most cherished constitutional rights will be further eroded and diminished.