COMMENT

LIGHTING A FIRE UNDER FREE SPEECH: THE FDA'S GRAPHIC ATTEMPTS TO REDUCE SMOKING RATES

I. INTRODUCTION

More than forty-three million adult Americans are cigarette smokers.[1] Cigarette smoking accounts for 400,000 deaths annually—more than AIDS, alcohol, cocaine, heroin, homicide, suicide, motor vehicle crashes, and fires combined—making cigarettes the leading preventable cause of death in the United States.[2] Tomorrow, approximately 4,000 children under the age of eighteen will experiment with cigarettes for the first time and another 1,500 will become regular smokers.[3] Of those that smoke regularly, about half will eventually die from tobacco use.[4] Tobacco-related illnesses in the United States alone cost approximately $193 billion each year in lost productivity and health care expenditures.[5] These sobering statistics have encouraged public health officials and lawmakers to take drastic action designed to encourage smokers to quit and to prevent young adults from ever lighting up.[6] The Family Smoking Prevention and Tobacco Control Act ("FSPTCA" or "the Act") and its implementing regulations pro-

1. Ctrs. for Disease Control & Prevention, *Current Cigarette Smoking Among Adults—United States 2011*, 61 MORBIDITY & MORTALITY WKLY. REP. 889, 891 (Nov. 2011), http://www.cdc.gov/mmwr/pdf/wk/mm6144.pdf.

2. SUZANNE H. REUBEN, U.S. DEP'T OF HEALTH & HUM. SERVS., PRESIDENT'S CANCER PANEL, PROMOTING HEALTHY LIFESTYLES: POLICY, PROGRESS, AND PERSONAL RECOMMENDATIONS FOR REDUCING CANCER RISK 61 (2007), *available at* http://deainfo.nci.nih.gov/advisory/pcp/annualReports/pcp07rpt/pcp07rpt.pdf.pdf.

3. *Id.* at 64.

4. *Id.*

5. *See* Matt Shechtman, Comment, *Smoking Out Big Tobacco: Can the Family Smoking Prevention and Tobacco Control Act Equip the FDA to Regulate Tobacco Without Infringing on the First Amendment?*, 60 EMORY L.J. 705, 707 (2011).

6. *See* discussion *infra* Part III.

mote the government's anti-smoking agenda—at the expense of tobacco companies' constitutionally protected free speech.[7]

Signed into law by President Obama in June 2009, the FSPTCA gave the Food and Drug Administration ("FDA") exclusive authority to regulate tobacco products for the first time.[8] Under the Act, the FDA promulgated its Required Warnings for Cigarette Packages and Advertisements ("the Rule") in 2011.[9] For the first time in twenty-five years, the Rule modified the requirements for cigarette warning labels to require graphic images to accompany textual warnings displayed on the top fifty percent of all cigarette packaging and advertising.[10]

Tobacco companies immediately challenged the Act and the Rule in federal courts, arguing that the new graphic warnings violated their free speech rights.[11] At first, these new warnings appeared to have solid constitutional footing. In March 2012, the Sixth Circuit affirmed a district court decision finding that the Act's graphic warning requirements were a constitutional application of the government's authority to protect consumers from misleading or deceptive advertising.[12] However, this victory was short lived. Only five months later, the D.C. Circuit struck down the specific warning labels created by the Rule for violating tobacco companies' First Amendment rights.[13]

Many believed the Supreme Court would make the final decision on this issue after tobacco companies petitioned the Court for certiorari of the Sixth Circuit's decision in October 2012.[14] However, the FDA quickly withdrew the Rule and declined to appeal the D.C. Circuit's decision against it, arguing that its actions ren-

7. *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) [hereinafter FSPTCA] (codified as amended in scattered sections of 5, 15, and 21 U.S.C.).

8. *See id.* § 3, 123 Stat. at 1781 (codified at 21 U.S.C. § 387a (Supp. V 2012)).

9. Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,629 (June 22, 2011) [hereinafter Required Warnings].

10. *Id.*; *see also* discussion *infra* Section III.

11. Notably absent from these challenges was Altria, the largest tobacco manufacturer in the United States. *See* Duff Wilson, *Tobacco Firms Sue to Block Marketing Law,* N.Y. TIMES, Sept. 1, 2009, at B1.

12. *See* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 527, 531 (6th Cir. 2012).

13. R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1208 (D.C. Cir. 2012).

14. Petition for Writ of Certiorari, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013) (No. 12-521), 2012 WL 5353900.

dered the issue moot by temporarily resolving the circuit split.[15] By retreating, the government deftly avoided the finality of a Supreme Court decision on the issue, instead sending the FDA back to the drawing board to design a graphic warning "consistent with the Act and the First Amendment."[16]

This article explores whether such a graphic warning is possible or preferable in the government's fight against tobacco. Part II outlines a brief history of tobacco regulation in the United States. Part III turns to the FSPTCA and the FDA's initial rulemaking process. Part IV outlines the doctrine of commercial free speech, and Part V discusses why the Rule faced insurmountable challenges under this jurisprudence. Part VI explores how the FDA may overcome these hurdles in its future rulemaking, while Part VII discusses alternative methods through which the government can pursue its anti-tobacco agenda without encroaching on tobacco companies' constitutional rights.

II. HISTORY OF TOBACCO REGULATION IN AMERICA

Despite its longstanding and controversial place in American society,[17] tobacco has been federally regulated for less than fifty years. In 1965, the federal government passed the Federal Cigarette Labeling and Advertising Act ("FCLAA"), the nation's first legislation aimed at regulating tobacco products.[18] The FCLAA was designed to protect the rights of individual consumers while ensuring the public was informed about the health risks associated with smoking.[19] This legislation required tobacco companies to include warning labels on all cigarette advertising and packaging for the first time[20] and provided several government agencies with

15. Brief for the Respondents in Opposition at 16–17, *Am. Snuff Co.*, 133 S. Ct. at 1996 (No. 12-521), 2013 WL 1209163. The Supreme Court subsequently denied certiorari in *American Snuff* on April 22, 2013. *See Am. Snuff Co.*, 133 S. Ct. at 1996.

16. Brief for the Respondents in Opposition, *supra* note 15, at 16.

17. *See generally* Nathan Cortez, *Do Graphic Tobacco Warnings Violate the First Amendment?*, 64 HASTINGS L.J. 1467, 1473–76 (2013) (describing the history of tobacco in American culture).

18. 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 (2012)).

19. *See* S. REP. NO. 80-195, at 4 (1965) ("[T]he individual must be safeguarded in his freedom of choice—that he has the right to choose to smoke or not to smoke—[but] . . . the individual has the right to know that smoking may be hazardous to his health.").

20. Federal Cigarette Labeling and Advertising Act § 4, 79 Stat. at 283. The warning "Caution: Cigarette Smoking May Be Hazardous to Your Health" was required to be dis-

concurrent authority to regulate various aspects of the tobacco industry.[21] Five years later, Congress took tobacco regulation one step further by enacting the Public Health Cigarette Smoking Act,[22] which increased restrictions on tobacco packaging[23] and prohibited tobacco advertising on television and radio.[24] Congress shifted gears in tobacco regulation in the early 1980s, focusing on public education regarding the health risks associated with smoking through the Comprehensive Smoking Education Act ("CSEA").[25] The CSEA required one of four specific textual warnings on all cigarette packaging;[26] these are the same warnings printed on cigarette packaging and advertising today.[27]

Although Congress has increasingly focused on the health risks associated with tobacco use, the FDA has been notably absent from tobacco regulation for most of its history.[28] In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act ("FDCA"), which defined the scope of the FDA's jurisdiction over food, drugs, cosmetics, and medical devices.[29] At this time, the FDA lobbied Congress to include tobacco in the FDCA's definition of "drug,"

played in black and white enclosed in a black outlined box on the side panel of all cigarette packages. *Id.*

21. *Id.* §§ 5, 10, 79 Stat. at 283–84. The Federal Trade Commission, Federal Communications Commission, Internal Revenue Service, Department of Agriculture, and Bureau of Alcohol, Tobacco, Firearms, and Explosives all played a role in tobacco regulation under the FCLAA. *See* Jennifer Costello, Comment, *The FDA's Struggle to Regulate Tobacco*, 49 ADMIN. L. REV. 671, 676–78 & n.42 (1997) (explaining the role of various government agencies in tobacco regulation under the FCLAA).

22. 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 (2012)).

23. *See id.* § 2, 84 Stat. at 88. The required warning was changed to "Warning: The Surgeon General Has Determined that Cigarette Smoking is Dangerous to Your Health." *Id.*

24. *See id.* § 2, 84 Stat. at 89.

25. Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200 (1984) (codified as amended at 15 U.S.C. §§ 1331–40 (2012)).

26. *See id.* § 4, 98 Stat. at 2201–02. These four warnings are: "Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy;" "Quitting Smoking Now Greatly Reduces Serious Risks to Your Health;" "Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight;" and "Cigarette Smoke Contains Carbon Monoxide." *Id.*

27. Tobacco companies have never challenged these textual warnings on First Amendment grounds. *See* R.J. Reynolds Tobacco Co. v. FDA, 823 F. Supp. 2d 36, 40 n.4 (D.D.C. 2011).

28. *See* Costello, *supra* note 21, at 674–78 (describing the FDA's absence from tobacco regulation).

29. Federal Food, Drug, & Cosmetics Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301–99 (2006 & Supp. V 2012)).

but Congress declined to do so.[30] Nearly sixty years later, the FDA once again lobbied for a place in tobacco regulation, proposing a rule and undertaking a jurisdictional analysis asserting its authority to regulate tobacco products pursuant to the FDCA.[31]

A group of tobacco manufacturers, retailers, and advertisers challenged the FDA's 1996 final rule in *FDA v. Brown & Williamson Tobacco Corp.*, arguing that the FDA lacked jurisdiction to regulate tobacco products and that the regulations exceeded the FDA's statutory authority and violated the First Amendment.[32] The Supreme Court applied the *Chevron* doctrine[33] to determine whether the FDA had authority to regulate tobacco products.[34] The Court first examined the "essential purpose" of the FDCA, which is "to ensure that any product regulated by the FDA is 'safe' and 'effective' for its intended use."[35] With this "mission" in mind, the Court found that the FDA's "exhaustive" documentation of the dangers of tobacco products "logically [implied] that, if tobacco products were 'devices' under the FDCA, the FDA would be required to remove them from the market."[36] The Court then noted that Congress's refusal to ban tobacco despite its known health risks and Congress's repeated legislation addressing to-

30. *See* Kristin M. Sempeles, Comment, *The FDA's Attempt to Scare the Smoke Out of You: Has the FDA Gone Too Far with the Nine New Cigarette Warning Labels?*, 117 PENN. ST. L. REV. 223, 228–29 (2012) (discussing the FDA's early attempts to regulate tobacco under the FDCA).

31. *See* Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,418 (1996). This rule sought to regulate tobacco advertising in order to prevent future tobacco addiction by (1) limiting sale and distribution of tobacco products to minors; (2) regulating labeling and advertising to prevent tobacco products from being attractive to minors; and (3) requiring tobacco manufacturers to establish and maintain educational programs directed at minors. *Id.* at 44,499; *see also* Laura M. Farley, Comment, *With the Passage of the Family Smoking Prevention and Tobacco Control Act, Will Commercial Speech Rights Be Up in Smoke?*, 7 J.L. ECON. & POL'Y 513, 521–23 (2011) (explaining the FDA's attempted regulation of tobacco products under the 1995 proposed rule).

32. 529 U.S. 120, 129–30 (2000).

33. *See* Chevron U.S.A., Inc. v. Nat. Res. Def. Council, Inc., 467 U.S. 837, 842–43 (1984). In *Chevron,* the Supreme Court outlined a test for determining whether a regulatory agency has legislative authorization to act on a certain issue. Under *Chevron*, the court must first decide whether Congress has directly spoken on the issue at hand. *Id.* at 842. If it has, the court must defer to Congress's unambiguously expressed intent. *Id.* at 842–43. If the court determines that Congress has not spoken directly on the issue, the court must defer to the agency's own construction of its legislative authority so long as its construction is permissible. *Id.* at 843.

34. *Brown & Williamson Tobacco Corp.*, 529 U.S. at 132.

35. *Id.* at 133 (citation omitted).

36. *Id.* at 134–35 (internal quotation marks omitted).

bacco issues demonstrated clear Congressional intent to *not* ban tobacco.[37] Therefore, the Court held that Congress did not intend for the FDA to regulate tobacco products, invalidating the 1996 rule and thwarting the FDA's attempts to control the tobacco industry.[38]

III. THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT AND THE FDA'S RULE

In 2009, Congress reversed course in tobacco regulation for the first time in twenty-five years by enacting the FSPTCA.[39] The Act gave the FDA exclusive jurisdiction to regulate tobacco while specifically prohibiting the FDA from banning tobacco sales.[40] Congress sought to "ensure that consumers are better informed" and "to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases,"[41] after finding that current government warnings and regulations inadequately conveyed the important health consequences of smoking.[42] The Act contains myriad regulations and restrictions on tobacco production, manufacture, and advertisement, most of which fall beyond the scope of this article.[43] The most drastic changes created by the Act concern warning labels on cigarette packaging and advertising.

The FSPTCA's warning label requirements represent an enormous departure from prior warning requirements—both literally and figuratively. Section 201 of the Act includes specific requirements for tobacco warning labels.[44] All cigarette packages must include one of nine new textual warnings[45] and "color graphics depicting the negative health consequences of smoking."[46] These

37. *Id.* at 137–39.

38. *Id.* at 142–43.

39. *See supra* text accompanying notes 8–10.

40. FSPTCA, Pub. L. No. 111-31, § 3, 123 Stat. 1776, 1781–82 (2009).

41. *Id.* § 3, 123 Stat. at 1782.

42. *Id.* § 2, 123 Stat. at 1777.

43. *See generally id.* § 1, 123 Stat. at 1776.

44. *Id.* § 201, 15 U.S.C. § 1333 (2012).

45. *Id.* § 201(a)(1), 15 U.S.C. § 1333(a)(1). These textual warnings include: (1) "Cigarettes are addictive;" (2) "Smoking can kill you;" (3) "Cigarettes cause cancer;" (4) "Smoking during pregnancy can harm your baby;" (5) "Tobacco smoke causes fatal lung disease in nonsmokers;" and (6) "Tobacco smoke can harm your children." *Id.*

46. *Id.* § 201(d), 15 U.S.C. § 1333(d).

warning labels must occupy the top fifty percent of the front and rear panels of the package, with the word "WARNING" appearing in 17-point font.[47] The Act required the FDA to issue regulations regarding the color graphic warnings within twenty-four months of the FSPTCA's enactment.[48]

In June 2011, the FDA introduced the Required Warnings for Cigarette Packages and Advertisements in response to the FSPTCA.[49] Under the Rule, each warning label would include one of the nine textual warnings mandated by the Act,[50] the telephone number 1-800-QUIT-NOW,[51] and one of nine color images.[52] The required images included pictures of cigarette smoke surrounding a mother kissing her child, a diseased lung beside a healthy lung, a mouth covered in cancerous lesions, a male cadaver lying in a morgue, a woman sobbing, and a man smoking a cigarette through a tracheotomy hole.[53] The FDA selected these graphics to demonstrate the effects of sickness and disease caused by smoking,[54] stating that these particular images evoked a visceral response designed to encourage current smokers to quit and to prevent young people from smoking for the first time.[55]

The FDA selected these images based in part on an 18,000 person consumer study in which a control group was shown the current text-only warnings and a treatment group was shown the proposed warnings containing the graphic images, smoking cessation hotline number, and new textual warnings.[56] Each group responded to questions designed to assess whether the graphic warnings increased viewers' knowledge of the health risks associated with smoking, whether the graphic warnings increased their intention to quit or refrain from smoking, and the images' "sali-

47. *Id.* § 201(a)(2), 15 U.S.C. § 1333(a)(2).

48. *Id.* § 201(d), 15 U.S.C. § 1333(d).

49. Required Warnings, 76 Fed. Reg. 36,628, 36,628 (June 22, 2011). The FDA withdrew the Rule subsequent to the constitutional challenges. *See supra* text accompanying notes 13–15.

50. *See* Required Warnings, 76 Fed. Reg. at 36,674.

51. *Id*. This telephone number connects callers to a hotline created by the FDA to provide smoking cessation assistance. *Id*. at 36,686.

52. *Id.* at 36,674.

53. *See* Cortez, *supra* note 17, at 1469.

54. Required Warnings, 76 Fed. Reg. at 36,633.

55. *See id*.; *see also* Press Release, U.S. Dep't of Health & Hum. Servs., FDA Unveils Final Cigarette Warning Labels (June 21, 2011), *available at* http://www.hhs.gov/news/press/2011pres/06/20110621a.html.

56. Required Warnings, 76 Fed. Reg. at 36,637–38.

ence"—meaning whether the graphic warnings caused viewers to feel "depressed" or "discouraged."[57] The FDA received numerous criticisms during the rulemaking process that this study failed to assess the actual effects of the proposed warnings and failed to demonstrate that the graphic warnings actually decreased smoking rates.[58] The FDA admitted the study did not provide evidence of the "long-term, real-world effects" of the proposed warnings, but nonetheless argued that the results of the study, coupled with existing scientific literature, "provide[d] a substantial basis for [its] conclusion that the required warnings will effectively communicate the health risks of smoking, thereby encouraging smoking cessation and discouraging smoking initiation."[59] FDA Commissioner Margaret Hamburg proudly stated that the overall purpose of the graphic warnings was to ensure that "every pack of cigarettes in our country [would] in effect become a mini-billboard" for the government's anti-smoking message.[60] As Commissioner Hamburg freely admits, the FDA designed these graphic warnings to commandeer tobacco companies' own product for an advertising campaign explicitly designed to put them out of business.[61] Tobacco companies challenged this campaign in federal courts, arguing it violated their right to free speech.

IV. COMMERCIAL FREE SPEECH

Free speech is a fundamental constitutional right protected by the First Amendment,[62] which protects "both the right to speak freely and the right to refrain from speaking."[63] The right to free

57. *See id.* at 36,638 (internal quotation marks omitted).

58. *See id.* at 36,639.

59. *Id.* The FDA relied heavily on social science from other countries that require graphic warning labels on tobacco products, including a Canadian study that found graphic warning labels encouraged smokers to think about quitting. *See id.* at 36,633–34. However, none of these studies conclusively demonstrated that graphic warnings actually result in increased cessation rates. *See* Disc. Tobacco City & Lottery, Inc. v. United States, 624 F.3d 509, 530 (6th Cir. 2012).

60. *See Graphic Health Warning Announcement*, FDA (Nov. 10, 2010), http://www.fda.gov/TobaccoProducts/NewsEvents/ucm232556.htm; *see also* Margaret Hamburg, Comm'r, Food & Drug Admin., Comments at the White House Press Briefing (June 21, 2011), http://www.whitehouse.gov/the-press-office/2011/06/21/press-briefing-press-secretary-jay-carney-secretary-health-and-human-ser (describing the new graphic warning labels to be displayed on cigarette packs and the reasoning behind them).

61. *See Graphic Health Warning Announcement*, *supra* note 60.

62. U.S. CONST. amend. I.

63. *See* Wooley v. Maynard, 430 U.S. 705, 714 (1977); *see also* Pac. Gas & Elec. Co. v.

speech applies to both individuals and commercial entities; so-called "commercial speech" serves the speaker's economic interests and also educates consumers by promoting dissemination of information.[64] However, commercial speech is afforded only a limited measure of constitutional protection proportionate to its inferior rank among First Amendment values.[65] Tobacco advertising has consistently been recognized as qualifying for commercial free speech protection.[66]

The Supreme Court first established that the First Amendment protects commercial speech from unjustified government regulation in *Virginia Board of Pharmacy v. Virginia Citizens Consumer Council*.[67] The *Virginia Board* Court struck down a Virginia statute banning pharmacists from advertising the prices of prescription drugs, noting that an economic motivation does not eliminate a speaker's First Amendment protections and that a "consumer's interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day's most urgent political debate."[68] The Court emphasized that readily available commercial information serves the First Amendment's goal of "englighten[ed] public decisionmaking in a democracy," thus warranting free speech protection.[69] However, the Court also recognized legitimate government interests in regulating and limiting commercial speech when it is misleading or advertising an illegal product or transaction.[70] One way that the government may permissibly regulate commercial speech is through compelled disclosures designed to warn consumers about potentially deceptive commercial products.[71]

Four years after recognizing commercial speech in *Virginia Board*, the Supreme Court further defined the doctrine in *Central*

Pub. Utils. Comm'n, 475 U.S. 1, 16 (1986) (stating that "[f]or corporations as for individuals, the choice to speak includes within it the choice of what not to say").

64. *See* Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 561–62 (1980).

65. Jennifer M. Keighley, *Can You Handle the Truth? Compelled Commercial Speech and the First Amendment*, 15 U. PA. J. CONST. L. 539, 547 (2012).

66. *See, e.g.*, Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 553–55 (2001).

67. 425 U.S. 748, 761 (1976).

68. *Id.* at 763, 770.

69. *Id.* at 765.

70. *Id.* at 771; *see also* C. Edwin Baker, *The First Amendment and Commercial Speech*, 84 IND. L.J. 981, 982 (2009) (discussing the *Virginia Board* Court's limitations on commercial free speech).

71. *See, e.g.*, Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985).

Hudson Gas & Electric Corp. v. Public Service Commission of New York, stating that "[t]he protection available for particular commercial expression turns on the nature both of the expression and of the governmental interests served by its regulation."[72] In *Central Hudson*, the Court articulated a four-part intermediate scrutiny test to determine whether a regulation infringes on the free speech of a commercial entity.[73] Under the *Central Hudson* analysis, the court must first determine whether the commercial expression is protected by the First Amendment.[74] Then the court must decide whether the government has a substantial interest in regulating the commercial speech.[75] If both of these questions are answered affirmatively, the court must next examine whether the regulation at issue directly advances the government's interest.[76] If it does, the court must determine whether the regulation is narrowly tailored so that it is only as extensive as needed to advance this interest.[77] If a regulation fails to satisfy any of these requirements, it is unconstitutional.[78]

In *Central Hudson*, the Court applied this test to a New York regulation banning all promotional advertising by electric utility companies.[79] The Court found that the first three prongs of the test were satisfied because the advertising was for a legitimate product and banning utility advertisements advanced the government's substantial interest in energy conservation.[80] However, the Court found that the regulation failed to satisfy *Central Hudson*'s fourth requirement because a complete ban of electric utility advertising was unjustifiably broad and the government could not prove that a more limited restriction would not also serve its interests.[81]

Although *Central Hudson* provides the standard under which commercial speech issues are generally reviewed, courts have articulated exceptions for governmentally compelled commercial

72. 447 U.S. 557, 563 (1980).
73. *Id.* at 566.
74. *Id.*
75. *Id.*
76. *Id.*
77. *Id.*
78. *See id.*
79. *Id.* at 558.
80. *Id.* at 566–69.
81. *Id.* at 569–71.

speech.[82] For example, the government can require commercial disclosures of "purely factual and uncontroversial information" to protect consumers from potentially misleading commercial speech.[83] These disclosures are examined under a less exacting rational basis standard and are deemed constitutional so long as they are "reasonably related to the State's interest in preventing deception of consumers."[84]

For example, in *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, an attorney challenged a state regulation requiring contingency-fee advertisements to include a disclosure alerting potential clients that they would be required to pay costs if their lawsuit was unsuccessful, arguing that this disclosure requirement violated his commercial free speech rights.[85] The Supreme Court declined to apply the four-part *Central Hudson* test in this case, holding that a compelled disclosure is permissible when it is purely factual and noncontroversial and is related to the state's interest in protecting consumers from misleading advertisements.[86] The Court reasoned that compelled factual disclosures differ from complete proscriptions on speech like those at issue in *Central Hudson* "[b]ecause the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides . . . [therefore,] disclosure requirements trench much more narrowly on an advertiser's interests than do flat prohibitions on speech."[87] Thus, the government is not required to use only the "least restrictive means" available when requiring purely factual commercial disclosures.[88] However, the *Zauderer* court articulated some limits on compelled disclosures, stating that "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech."[89]

82. *See* Stephanie Jordan Bennett, Comment, *Paternalistic Manipulation Through Pictorial Warnings: The First Amendment, Commercial Speech, and the Family Smoking Prevention and Tobacco Control Act,* 81 MISS. L.J. 1909, 1918 (2012) (outlining exceptions to the *Central Hudson* test for commercial free speech).

83. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985).

84. *Id.*

85. *Id.* at 630–32, 636.

86. *Id.* at 651.

87. *Id.*

88. *Id.* at 651 n.14.

89. *Id.* at 651.

On the other hand, when a compelled disclosure is "subjective and highly controversial," some courts have required the regulation to survive a strict scrutiny standard of review, under which the government must demonstrate that the regulation is "narrowly tailored to serve a compelling government interest."[90] For example, in *Entertainment Software Association v. Blagojevich*, the Seventh Circuit used strict scrutiny to evaluate the constitutionality of an Illinois statute requiring video game sellers to display a large "18" sticker on any video game deemed "sexually explicit."[91] The court reasoned that this compelled disclosure went beyond "purely factual" information because the definition of "sexually explicit" was controversial and "opinion-based."[92] The *Blagojevich* court also found that the compelled disclosure was not narrowly tailored to achieve the state's objective of informing parents about the explicit content of video games because the state had not "demonstrated that it could not accomplish [its] goal with a broader educational campaign about the [video game rating] system."[93] The court further noted that "at four square inches, the '18' sticker *literally* fails to be narrowly tailored—the sticker covers a substantial portion of the box."[94]

The graphic warnings crafted by the FDA during its initial rulemaking contained both uncontroversial factual information[95] and highly controversial subjective information.[96] Because these hybrid compelled disclosures did not fit neatly into any commercial speech analytical framework, federal courts struggled to determine what level of scrutiny they deserved. And because the FDA prevented the Supreme Court from providing definitive guidance on this subject, the uncertainty created by the courts' decisions in *R.J. Reynolds Tobacco Co. v. FDA* and *Discount To-*

90. Entm't Software Ass'n v. Blagojevich, 469 F.3d 641, 647, 652 (7th Cir. 2006).

91. *See id.* at 643 (internal quotation marks omitted).

92. *Id.* at 652 (internal quotation marks omitted).

93. *Id.*

94. *Id.*

95. *See* Required Warnings, 76 Fed. Reg. 36,628, 36,695 (June 22, 2011) ("The nine new health warning statements and the accompanying graphic images selected by FDA convey information that is factual and uncontroversial . . . . The comments do not dispute that the warning statements are true.").

96. The graphic images required by the Rule are intended to elicit a subjective emotional response from viewers. Some of the required textual warnings are also arguably subjective in application through the use of personal pronouns: for example, "Warning: Tobacco smoke can harm *your* children." *Id.* at 36,696 (emphasis added); *see* Bennett, *supra* note 82, at 1920–21.

bacco City & Lottery, Inc. v. United States will loom large during the FDA's second attempt to create constitutional graphic warnings.

V. FEDERAL COURTS' REVIEW OF THE FSPTCA AND THE RULE

The compelled commercial disclosures required by the FSPTCA have faced multiple challenges in federal court since the FDA's initial rulemaking in 2011. Both the Sixth Circuit and the D.C. Circuit grappled with what standard of review should be applied to these graphic warning labels, producing divergent outcomes that illustrate how thorny this issue has become.

A. *The Sixth Circuit Upholds the Act's Graphic Warning Requirement Under* Zauderer

Almost immediately following the FSPTCA's enactment and prior to the FDA's promulgation of the Rule, a group of manufacturers and sellers of tobacco products mounted a facial challenge against the Act on free speech, due process, and takings grounds in *Commonwealth Brands, Inc. v. United States*.[97] The district court upheld the constitutionality of the graphic warning label requirement under *Central Hudson*'s intermediate scrutiny test.[98] The court stated that "the government's goal [was] not to stigmatize the use of tobacco products on the industry's dime; it [was] to ensure that the health risk message is actually *seen* by consumers in the first instance," and found that the warning requirement was narrowly tailored to achieve this legitimate government interest.[99] Plaintiffs promptly appealed.[100]

97. 678 F. Supp. 2d 512, 519 (W.D. Ky. 2010), *aff'd in part, rev'd in part sub nom.* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509 (6th Cir. 2012). This case considered the Act as a whole, including provisions restricting commercial marketing of "Modified Risk Tobacco Products," a ban on statements that convey the impression that tobacco products are safer due to being regulated by the FDA, restrictions on the advertising of tobacco products to black text on a white background in most media, a ban on the distribution of free samples of tobacco products, and tobacco sponsorship of athletic or social events. *Id.* at 519–20. These provisions, as well as the plaintiffs' due process and takings arguments, fall beyond the scope of this article.

98. *Id.* at 532.

99. *Id.* at 530.

100. *Disc. Tobacco*, 674 F.3d at 518. Although the Rule was released prior to the Sixth Circuit's decision in this case, the court reviewed the district court's decision regarding the facial challenge to the Act's graphic warning requirements and did not examine the Rule

On appeal, a Sixth Circuit majority affirmed the district court's decision in *Commonwealth Brands* (now known as *Discount Tobacco City & Lottery, Inc. v. United States*) with regard to the graphic warning labels, but did so under the deferential rational basis review set forth in *Zauderer*.[101] Writing for the majority on this issue, Judge Stranch specifically rejected *Central Hudson*'s intermediate scrutiny analysis as applying only to "[l]aws that restrict speech."[102] The court also distinguished the strict scrutiny analysis applied in *Blagojevich*, stating that

> [t]he health risks of smoking tobacco have been uncovered through scientific study. They are facts. Warnings about these risks—whether textual or graphic—can communicate these facts. In contrast, what constitutes a sexually explicit video game is a matter of personal taste and sexual morals that is necessarily based on opinion . . . . [Thus,] *Blagojevich* and the standards it articulates are inapplicable here.[103]

Judge Stranch emphasized that in order for a more stringent standard of review to apply to this facial challenge, plaintiffs "would have to establish that a graphic warning cannot convey the negative health consequences of smoking accurately, a position tantamount to concluding that pictures can never be factually accurate, only written statements can be," which would be "at odds with reason."[104]

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itself. *Id.* at 569 n.17. Therefore, the Sixth Circuit did not consider the specific images selected by the FDA for use on the graphic warning labels, which were unveiled just one month before *Discount Tobacco* was argued before the court. *See id.*; *supra* note 55, FDA Unveils Final Cigarette Warning Labels (noting that the FDA's Final Rule was released on June 21, 2011).

101. *Disc. Tobacco*, 674 F.3d at 551–52, 561 ("The Act's required textual and graphic warnings are constitutional if there is a rational connection between the warnings' purpose and the means used to achieve that purpose.").

102. *Id.* at 552.

103. *Id.* at 561. However, in his dissent, Judge Clay noted that plaintiffs' argument for strict scrutiny was "not wholly unpersuasive," acknowledging that the warnings may not be properly categorized as "mere health disclosure warnings" due to the inherently subjective nature of visual images. *Id.* at 526 (Clay, J., dissenting).

104. *Id.* at 558–59 (Stranch, J.). Judge Stranch hammered this point home by

> envision[ing] many graphic warnings that would constitute factual disclosures under *Zauderer*. . . . [including a] drawing of a nonsmoker's and smoker's lungs displayed side by side; a picture of a doctor looking at an x-ray of either a smoker's cancerous lungs or some other part of the body presenting a smoking-related condition; a picture or drawing of the internal anatomy of a person suffering from a smoking-related medical condition; . . . and any number of pictures consisting of text and simple graphic images.

Id. at 559.

Under *Zauderer*, the Sixth Circuit found that the Act's graphic warning requirements were constitutional because of the "rational connection between the warnings' purpose and the means used to achieve that purpose."[105] The court stated that the purpose of the warnings was "to 'promote greater public understanding of [the] risks'" associated with tobacco use, particularly among youth.[106] Given the deceptive history of tobacco advertising and the ineffectiveness of the current warnings,[107] the court found that "[t]he new warnings rationally address these problems by being larger and including graphics."[108] The court specifically noted that under *Zauderer*'s unexacting standard of review, the government was not required to put forth compelling evidence demonstrating that the Act's warning requirements would successfully change consumers' behavior.[109] Instead, the court could "assume, based on common sense, that larger warnings incorporating graphics will better convey the risks of using tobacco to consumers."[110]

Judge Clay specifically dissented from the portion of the majority opinion concerning the graphic warning labels, stating that he "would find the portion of the provision requiring color graphic images to accompany the textual warnings on tobacco product packaging unconstitutional."[111] Judge Clay agreed with the majority that *Zauderer* provided the appropriate standard of review in this case, but he noted that although "the hurdle that *Zauderer* erects for the government is a relatively low one, it is still a hurdle that the government must surmount in order to uphold the form of the warning label requirement that it seeks to impose on the tobacco industry."[112] Simply put, Judge Clay believes that not "all forms of required warnings will . . . survive First Amendment scrutiny" under *Zauderer*.[113]

Judge Clay further agreed with the majority that consumers lack adequate awareness of the health risks associated with to-

105. *Id.* at 561.

106. *Id.* at 561, 564 (quoting FSPTCA, Pub. L. No. 111-31, § 202(b), 123 Stat. 1776, 1845–46 (2009) (codified as amended at 15 U.S.C. § 1333(d) (2012))).

107. *Id.* at 562–64.

108. *Id.* at 564.

109. *Id.* at 564–65.

110. *Id.*

111. *Id.* at 530 (Clay, J., dissenting).

112. *Id.*

113. *Id.* at 528.

bacco and that current tobacco warnings fail to convey health information effectively.[114] However, he found that the "large scale color graphic[s]" required by the FSPTCA were "simply unprecedented," and that the government "ha[d] not adequately shown that the inclusion of color graphic warning labels is a properly or reasonably tailored response to address" the harms associated with tobacco use, especially in light of the changeable impact of the warnings based on the viewer himself.[115] Further, Judge Clay distinguished between disclosures of factually accurate information that may be frightening and disclosures designed to "simply frighten consumers or . . . to flagrantly manipulate [their] emotions."[116] In this case, Judge Clay found the government attempted to do the latter.[117] Thus, he found the warnings were not "reasonably tailored" to the government's interest in consumer awareness and were therefore unconstitutional.[118]

The Sixth Circuit determined the Act's graphic warning requirement did not violate tobacco companies' freedom of speech on its face; however, the specific graphic warning labels promulgated by the FDA pursuant to the Act remained vulnerable to commercial free speech challenges after this decision.

B. *The D.C. Circuit Strikes Down the Rule's Graphic Warnings Under* Central Hudson

While *Discount Tobacco* was pending in the Sixth Circuit, five tobacco companies challenged the FSPTCA and the Rule in *R.J. Reynolds Tobacco Co. v. FDA*, arguing that the specific graphic warnings proposed by the FDA violated the First Amendment.[119] The D.C. District Court agreed, granting summary judgment in favor of the tobacco companies and issuing a permanent injunction banning implementation of the portion of the Rule related to these graphic warnings.[120] The district court rejected the FDA's argument that *Zauderer*'s rational basis standard of review should apply, finding that the highly subjective nature of the

114. *Id.*
115. *Id.* at 528, 530.
116. *Id.* at 529.
117. *Id.*
118. *Id.*
119. 845 F. Supp. 2d 266, 268 (D.D.C. 2012).
120. *Id.* at 277.

graphic labels suggested they "were neither designed to protect the consumer from confusion or deception, nor to increase consumer awareness of smoking risks; rather, they were crafted to evoke a strong emotional response calculated to provoke the viewer to quit or never start smoking."[121] Due to the subjective, emotional nature of the images selected by the FDA, the court applied a strict scrutiny analysis similar to that applied by the *Blagojevich* court,[122] requiring the government to demonstrate that the warning labels were narrowly tailored to achieve a compelling government interest.[123] The district court stated that "'the sheer size and display requirements for the graphic images [were] anything but narrowly tailored,'" and held that the Rule was unconstitutional.[124] The FDA appealed.[125]

A divided D.C. Circuit affirmed the district court's decision, applying a different standard of review to reach the same conclusion.[126] The majority again rejected the FDA's argument that the warnings should be analyzed using *Zauderer*'s rational basis review,[127] finding that cigarette packaging was not misleading or deceptive without the new graphic warnings and that the warnings were designed to evoke an emotional response instead of conveying purely factual information.[128] However, the majority also declined to apply the strict scrutiny analysis articulated by the district court.[129] The court acknowledged that "'the standard for assessing burdens on commercial speech has varied,'" but found that "'the Supreme Court's bottom line is clear: the government must affirmatively demonstrate its means are narrowly tailored

121. *Id.* at 272.

122. *See supra* notes 91–92 and accompanying text.

123. *R.J. Reynolds Tobacco Co.*, 845 F. Supp. 2d at 274 (citing A.N.S.W.E.R. Coal. v. Kempthorne, 537 F. Supp. 2d 183, 195 (D.D.C. 2008)); *see supra* text accompanying notes 90–94.

124. *R.J. Reynolds Tobacco Co.*, 845 F. Supp. 2d. at 275 (quoting R.J. Reynolds Tobacco Co. v. FDA, 823 F. Supp. 2d 36, 48 (D.D.C. 2011)). The district court also noted that the government may have failed to assert a compelling state interest, reasoning that the government's asserted interest may be "not to inform or educate, but rather to advocate a change in behavior." *Id.*

125. *See* R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1211 (D.C. Cir. 2012).

126. *Id.* at 1208, 1217.

127. *Id.* at 1217.

128. *Id.* at 1216. The court noted that "[t]hese inflammatory images and the provocatively-named hotline cannot rationally be viewed as pure attempts to convey information to consumers." *Id.* at 1216–17.

129. *Id.* at 1217.

to achieve a substantial government goal.'"[130] With this goal in mind, the D.C. Circuit analyzed the required graphic warnings using *Central Hudson*'s four-part intermediate scrutiny standard of review.[131]

The court found the first prong of *Central Hudson* was satisfied because the First Amendment applies to advertisements of lawful goods, including tobacco products.[132] The court then "[a]ssume[d]" that the asserted government interest in reducing smoking rates was legitimate and substantial.[133] The government was thus required to demonstrate that the graphic warning labels directly advanced this interest.[134] The court found that the FDA "ha[d] not provided a shred of evidence" demonstrating that the graphic warnings required by the Rule would directly advance the government's interest by reducing the number of Americans who smoke.[135] The court pointed to the FDA's "questionable" data, including social science from other countries[136] and its own Regulatory Impact Analysis, which estimated that the new warnings would reduce smoking rates by only 0.088%.[137] The majority reasoned that the FDA was required to present sufficient data demonstrating that its regulations would substantially advance its interest before imposing a burden on the tobacco companies' freedom of speech, and that in this case the FDA failed to do so.[138] Because the court found that the Rule failed to satisfy the third prong of the *Central Hudson* analysis, it did not reach the ques-

130. *Id.* (quoting United States v. Phillip Morris USA Inc., 566 F.3d 1095, 1143 (D.C. Cir. 2009)).

131. *Id.* at 1217 (citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 566 (1980)).

132. *Id.* at 1217 n.11.

133. *Id.* at 1218. Despite this assumption, the court noted its skepticism that the government could articulate a substantial interest in discouraging citizens from purchasing a lawful product, even when the product has been linked to health consequences. *Id.* at 1218 n.13. The FDA also argued an alternative government interest in "'effective' communication" regarding the negative health effects of smoking; however, the court dismissed this interest as "too vague to stand on its own." *Id.* at 1221.

134. *Id.* at 1218 (quoting *Cent. Hudson*, 447 U.S. at 566).

135. *Id.* at 1219.

136. *Id.* The FDA relied on Canadian and Australian studies of the impact of similar graphic warning labels. However, the FDA offered "no evidence showing that such warnings have *directly caused* a material decrease in smoking rates in any of the countries that now require them." *Id.*

137. *Id.* at 1220. The majority characterized the Regulatory Impact Analysis as "essentially conced[ing] the agency lack[ed] any evidence showing that the graphic warnings are likely to reduce smoking rates." *Id.* at 1219–20.

138. *Id.* at 1221.

tion of whether the graphic warnings were sufficiently narrowly tailored to achieve the government's objective.[139] The D.C. Circuit vacated the graphic warning requirement as well as the permanent injunction issued by the district court and remanded to the agency.[140]

Judge Rogers dissented, describing the graphic warning labels as a constitutionally permissible required disclosure designed to prevent consumer deception.[141] Judge Rogers applied *Zauderer* rational basis review to the labels, requiring the government to demonstrate only that they were "reasonably related to its stated and substantial interest in effectively conveying . . . information to consumers."[142] Judge Rogers found this lower level of scrutiny was appropriate in part due to "tobacco companies' history of deceptive advertising."[143] She further noted that when a product negatively impacts public health, the government's interest in preventing consumer deception "takes on added importance."[144]

Judge Rogers also disputed the majority's assertion that the required images demand a higher level of scrutiny due to their subjective, non-factual nature.[145] She noted that pictorial warning labels have long been used to convey information,[146] because "'the use of illustrations or pictures in advertisements serves important communicative functions: it attracts the attention of the audience . . . and it may also serve to impart information directly.'"[147] Judge Rogers also stated that the disturbing nature of the images "does not necessarily make them inaccurate . . . [or] undermine the [textual] warnings' factual accuracy."[148] In light of the government's significant interest and the factual nature of the disclosures as a whole, she found the graphic warning labels

139. *See id.* at 1222.
140. *Id.*
141. *Id.* at 1222–23 (Rogers, J., dissenting).
142. *Id.*
143. *Id.* at 1222.
144. *Id.* at 1223 (quoting Pearson v. Shalala, 164 F.3d 650, 656 (1999)) (internal quotation marks omitted).
145. *Id.* at 1222–23.
146. *Id.* at 1230 (citations omitted).
147. *Id.* (quoting Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 647 (1985)).
148. *Id.*

to be constitutional under *Zauderer* despite their emotional charge.[149]

In two years of leapfrog litigation, federal courts have articulated wildly different opinions as to the appropriate constitutional standard of review for the FDA's graphic tobacco warnings. Although the FDA has withdrawn the Rule and the Department of Justice has refused further appellate review of *R.J. Reynolds Tobacco Co.*, the government has been clear that the "FDA . . . remains free to conduct [a] new rulemaking" and "will undertake research to support a new rulemaking consistent with" the FSPTCA, whose graphic warning requirements still stand after the Sixth Circuit's decision in *Discount Tobacco*.[150] Any forthcoming FDA rule will certainly face similar challenges from tobacco companies in the federal courts; thus, the FDA's next round of rulemaking must occur in the shadow of these decisions.

VI. FDA RULEMAKING AFTER *DISCOUNT TOBACCO* AND *R.J. REYNOLDS TOBACCO CO.*

If the FDA hopes to successfully craft a graphic warning label that satisfies the FSPTCA's requirements without violating the tenets of commercial free speech, it must consider the applicable constitutional standard of review during its next round of rulemaking. Whether the federal courts will apply *Central Hudson*'s intermediate scrutiny standard or *Zauderer*'s rational basis review in any future litigation will likely depend on the contours of the FDA's forthcoming rule.[151]

149. *Id.* at 1233. Judge Rogers stated that she would also find the warning labels constitutional under the more rigorous *Central Hudson* analysis used by the majority, because these disclosures are not more extensive than needed to directly advance the government's substantial interest in conveying health information to consumers, particularly given the government's finding that prior warning labels were ineffective. *Id.* at 1234–37.

150. Letter from Eric Holder, U.S. Att'y Gen., to John Boehner, Speaker of the House of Representatives (Mar. 15, 2013), *available at* http://www.mainjustice.com/files/2013/03/Ltr-to-Speaker-re-Reynolds-v-FDA.pdf.

151. Arguably, a federal court could also examine the graphic warnings under the stringent strict scrutiny standard applied by the district court in *R.J. Reynolds Tobacco Co*. *See* 845 F. Supp. 2d 266, 274 (D.D.C. 2012). Strict scrutiny may not be a "wholly unpersuasive" standard of review due to the subjective and emotional nature of the graphic images. *See* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 526 (6th Cir. 2012). However, it is ultimately unlikely that the FDA's graphic warning labels, which contain both objective factual information and arguably subjective graphic images, will be required to withstand such an exacting review. Although some federal circuits have applied strict scrutiny to compelled commercial speech, see Entm't Software Ass'n v. Blago-

A. *A More Limited Review Under* Zauderer

At first glance, the *Zauderer* rational basis standard of review applied by the Sixth Circuit in *Discount Tobacco* and the dissent in *R.J. Reynolds Tobacco Co.* appears to be the natural choice for reviewing the graphic warnings, because it explicitly applies to government compelled commercial disclosures like the graphic warning labels required by the FSPTCA.[152] Under this deferential standard, the FDA would only be required to demonstrate a rational relationship between the government's objectives and the means used to achieve them.[153] Upon closer inspection, however, unresolved tensions prevent *Zauderer* from being as readily applicable as it may appear.

First, the *Zauderer* court applied rational basis review in that case specifically because of the government's compelling interest in "preventing [the] deception of consumers."[154] In *R.J. Reynolds Tobacco Co.*, the D.C. Circuit declined to apply *Zauderer* because the court found it applied *only* when the government intends to prevent consumer deception through a compelled disclosure.[155] However, other courts have expanded on *Zauderer*'s narrow holding, applying its rational basis standard of review to compelled

jevich, 469 F.3d 641, 652 (7th Cir. 2006), the Supreme Court has thus far reserved strict scrutiny analysis for compelled *noncommercial* speech, which is afforded a greater level of protection than commercial speech. *See* Wooley v. Maynard, 430 U.S. 705, 715–17 (1977) (applying strict scrutiny in the compelled noncommercial speech context to strike down a New Hampshire statute prohibiting individuals from covering up the state motto, "Live Free or Die," on state license plates); *see also* Cortez, *supra* note 17, at 1479–80.

152. *See* Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985).

153. *Id.* However, the Sixth Circuit opinions illustrate the ambiguity that exists with regard to just how tenuous this "rational relationship" can be. According to the *Discount Tobacco* majority, courts can use "common sense" to connect the dots between the government's goals and the means it selects to achieve them. *See* 674 F.3d 509, 564 (6th Cir. 2012). But the dissent demands more, requiring some empirical evidence demonstrating that the government's compelled disclosure will actually further its articulated objective. *See id.* at 530 (Clay, J., dissenting). Considering that *Zauderer* explicitly states that unduly burdensome disclosure requirements may violate the First Amendment, the government will likely be required to provide *some* objective evidence beyond "common sense" to justify its use of compelled graphic warning labels, even under a lenient rational basis review. *Zauderer*, 471 U.S. at 651.

154. *Zauderer*, 471 U.S. at 651.

155. *See* R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1214 (D.C. Cir. 2012) ("*Zauderer* [and its progeny] thus establish that a disclosure requirement is only appropriate if the government shows that, absent a warning, there is a self-evident—or at least 'potentially real'—danger that an advertisement will mislead consumers."). The *R.J. Reynolds Tobacco Co.* court found that the government failed to demonstrate that "absent disclosure, consumers would likely be deceived" by cigarette packaging. *Id.* at 1216.

disclosures meant to further other important state interests.[156] The FSPTCA outlines several critical state interests served by the graphic warnings, including increasing consumer awareness regarding the health risks associated with smoking and encouraging smoking cessation; however, the Act does not explicitly articulate a goal of preventing consumer deception as required by a more narrow reading of this precedent.[157] Moreover, tobacco packaging *already* includes a government mandated disclaimer designed to prevent consumer deception by alerting consumers to the health risks associated with tobacco use.[158] Nevertheless, the FDA may argue that consumers continue to be misled by the "decades-long deception by Tobacco Companies . . . who represent[ed] the alleged pleasures or satisfactions of cigarette smoking," bringing the graphic images under the gamut of even the most narrow interpretation of *Zauderer*.[159]

More importantly, *Zauderer*'s rational basis review applies only to "purely factual and uncontroversial" disclosures of information,[160] not to subjective opinions or emotional appeals. The *Discount Tobacco* majority imagined many graphics that might satisfy the Act's requirements while remaining factual and noncontroversial.[161] However, the final images selected by the FDA in its initial rulemaking were far from purely factual. Instead, they were explicitly designed to evoke emotional responses of fear, disgust, and shame rather than impassively conveying neutral health information.[162] These subjective, "inflammatory" graphics led the D.C. Circuit to reject *Zauderer*'s rational basis review.[163]

156. *See* Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 310 (1st Cir. 2005) (applying rational basis review to compelled disclosure designed to promote access to high quality health care); Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001) (applying rational basis review to a compelled disclosure intended to protect health and the environment).

157. *See* FSPTCA, Pub. L. No. 111-31, § 3, 123 Stat. 1776, 1781 (2009).

158. *See supra* note 26 and accompanying text; *see also R.J. Reynolds Tobacco Co.*, 696 F.3d at 1215 (stating that the "argument that cigarette packages . . . that fail to prominently display the negative health consequences of smoking are misleading seems to blame the [tobacco] industry for playing by the government's rules").

159. Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 562 (6th Cir. 2012).

160. Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985).

161. *See Disc. Tobacco*, 674 F.3d at 559.

162. *See supra* text accompanying notes 56–61.

163. *See R.J. Reynolds Tobacco Co.*, 696 F.3d at 1216.

If the FDA wants its next iteration of graphic warnings to be reviewed under *Zauderer*'s more lenient rational basis review, it must ensure that it selects graphics that convey factual information in an uncontroversial way. For example, the warnings could include graphs, charts, or tables to visually depict the negative effects of tobacco use in a purely factual manner. Even simple drawings might illustrate the risks of smoking without subjectively appealing to consumer emotion.[164] However, such milquetoast graphics may not effectively capture consumers' attention, failing to further the government's anti-smoking agenda.[165]

B. *A More Exacting Review Under* Central Hudson

The FDA's new graphic warnings may also face *Central Hudson*'s intermediate scrutiny standard of review. *Central Hudson* has generally been applied to government restrictions on speech rather than government compelled disclosures, arguably making it an "ill-fitting precedent" under which to analyze the FDA's compelled graphic warnings.[166] However, the Act's graphic warning requirements have created an unanticipated commercial speech conundrum by requiring both noncontroversial factual information and highly subjective graphic images. To solve this problem, the federal courts should focus on the Supreme Court's bottom line: that "the government must affirmatively demonstrate its means are narrowly tailored to achieve a substantial government goal," as set forth in *Central Hudson*.[167]

In applying *Central Hudson* to the FDA's second round of graphic warning labels, the federal courts will likely find the first two elements of its analysis are easily satisfied, because tobacco companies are advertising and selling a legal product, and the government has a substantial interest in protecting consumers, especially with regard to public health.[168] However, it will be more challenging for the FDA to demonstrate that its new graphic

164. *See Disc. Tobacco*, 674 F.3d at 559 (discussing the use of graphic images in other compelled disclosures).

165. *See supra* text accompanying note 60.

166. See Cortez, *supra* note 17, at 1489, 1492.

167. *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1217.

168. In fact, the Supreme Court suggested in *FDA v. Brown & Williamson Tobacco Corp.* that the government may have a substantial interest in reducing smoking rates in particular, because smoking poses "perhaps the single most significant threat to public health in the United States." 529 U.S. 120, 161 (2000).

warnings satisfy the third and fourth prongs of the *Central Hudson* analysis, which require proof that the graphic warnings directly advance the government's interest and are only as extensive as necessary.[169]

The scientific evidence produced by the FDA during its first rulemaking proved to be woefully inadequate to demonstrate that its graphic warnings advanced the government's interest in reducing smoking rates; in fact, much of the FDA's research demonstrated that the graphic labels had little impact on consumers' actual choices regarding tobacco use.[170] As the *R.J. Reynolds Tobacco Co.* court flatly stated, the FDA "cannot satisfy its First Amendment burden with 'mere speculation and conjecture.'"[171] Thus, in order for the FDA's second round of graphic warnings to pass muster under *Central Hudson*, it must undertake more extensive, long-term studies to produce clear evidence that graphic warning labels directly affect Americans' decisions regarding tobacco use.

Under *Central Hudson*, the FDA must also be prepared to demonstrate that the large-scale graphic warnings are narrowly tailored to achieve its goal. The *R.J. Reynolds Tobacco Co.* court declined to address this issue, providing the FDA with little guidance as to what a "narrowly tailored" compelled disclosure might look like. In her dissent, Judge Rogers stated that the graphic warnings should be considered narrowly tailored because "[e]xisting warnings . . . are ineffective" and tobacco companies have not demonstrated that the new graphic warnings hinder their "ability to get their own message to consumers."[172] However, courts have found that large-scale warning labels are *not* narrowly tailored in other circumstances, particularly when the government is unable to demonstrate that a less intrusive method would not achieve the same result.[173]

The disparate opinions in *Discount Tobacco* and *R.J. Reynolds Tobacco Co.* do little to clarify what constitutional standard of review will ultimately apply to the government's graphic warning labels. In its second round of rulemaking, the FDA should ensure

169. 447 U.S. 557, 566 (1980).

170. *See supra* text accompanying notes 56–60 and notes 135–38.

171. 696 F.3d at 1219.

172. *Id.* at 1228, 1233 (Rogers, J., dissenting).

173. *See, e.g.*, Entm't Software Ass'n v. Blagojevich, 469 F.3d 641, 652 (7th Cir. 2006).

its new graphic warning labels satisfy *Central Hudson*'s more rigorous intermediate scrutiny review, because any graphics found constitutional under *Central Hudson* will almost certainly meet *Zauderer*'s less exacting standards. To do so, the FDA must undertake substantial additional research in order to definitively demonstrate that its graphic warnings actually further the Act's articulated objectives and are narrowly tailored to this end. This research will require time and money, and could ultimately prove fruitless. Thus, the government should explore additional, constitutional means of promoting its anti-tobacco message.

VII. OTHER CONSTITUTIONALLY SOUND MEASURES TO REDUCE SMOKING RATES

Even if the FDA's second set of graphic warnings fails to withstand constitutional scrutiny, all hope is not lost for the government's anti-smoking initiatives. Other constitutionally permissible methods could, and *should*, be implemented to encourage current smokers to quit and to prevent new smokers from beginning. First, the graphic warnings comprise only a small portion of the FSPTCA's requirements, many of which will likely pass constitutional muster. The nine new textual warnings have not yet been challenged by tobacco companies; these warnings alone do more to emphasize the dangers of smoking than past warnings.[174] The Act's size requirements[175] may also survive constitutional scrutiny, because tobacco companies have not yet conclusively demonstrated that the remaining packaging area is insufficient for their "brand names, logos, or other information."[176] Even textual warnings alone will likely cause consumers to sit up and take notice if they comprise fifty percent of the front and back of all tobacco packaging.[177]

Most importantly, the government should use other means to promote nonsmoking without relying on tobacco packaging at all. First, the government can use its own "counter speech" to contra-

174. *Compare supra* note 26 and accompanying text, *with supra* note 45 and accompanying text.

175. *See supra* text accompanying note 47.

176. *See* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 531 (6th Cir. 2012) (Clay, J., dissenting).

177. *Id.* at 530 ("The government has illustrated, as Congress found, that larger warnings materially affect consumers' awareness of the health consequences of smoking and decisions regarding tobacco use.").

dict the tobacco companies' messages.[178] In fact, some suggest "'the best answer to speech is not regulation but more speech.'"[179] Advertisements illustrating the health consequences of tobacco use can effectively encourage smokers to quit by relying on the same emotional charge underlying the FDA's graphic warnings.[180] For example, in 2012, the Centers for Disease Control ("CDC") launched a twelve-week advertising campaign on television, radio, billboards, Facebook, and Twitter featuring "personal, emotionally fraught stories" of Americans affected by tobacco use.[181] The number of calls received by the CDC's smoking cessation hotline doubled during the campaign and visits to its website tripled, suggesting these advertisements encouraged smokers to at least consider quitting.[182] The National Cancer Institute has noted similar results, finding that anti-tobacco "media campaigns [are] effective in reducing smoking in the youth and adult target populations."[183]

The government has many options available to target adolescents in particular, a goal explicitly articulated by the FSPTCA. First, school-based anti-smoking initiatives that "emphasize[] the [role of the] social environment in the decision-making process and help[] build skills necessary to resist peer pressure" have been shown to effectively discourage youth smoking.[184] These programs experience success in part because "instead of simply trying to scare the youth from smoking, [they] help[] youth build the necessary skills needed to resist pressure among their peers to start smoking" in the first place.[185] The government can also rely on the enforcement and extension of current tobacco legislation in order to decrease youth smoking;[186] for example, the government

178. *See* Sempeles, *supra* note 30, at 247–48.

179. *Id.* at 248 (quoting Kathleen M. Sullivan, *Muzzle Joe Camel? It May Be Illegal*, NEWSDAY, May 30, 1996, at A51).

180. For example, anti-smoking campaigns run by the American Cancer Society in the 1960s contributed to a reduction in cigarette smoking during this time period. *Id.*

181. Rosie Mestel, *Anti-Smoking Campaign by the CDC—Did It Help?*, L.A. TIMES (Sept. 25, 2012), http://articles.latimes.com/2012/sep/25/news/la-heb-anti-smoking-campaign-by-cdc-20120924.

182. *Id.*

183. Nat'l Cancer Inst., *The Role of the Media in Promoting and Reducing Tobacco Use*, TOBACCO CONTROL MONOGRAPH 21 (June 2008), *available at* http://cancercontrol.cancer.gov/brp/tcrb/monographs/19/m19_complete.pdf.

184. *See* Sempeles, *supra* note 30, at 248.

185. *Id.*

186. The Campaign for Tobacco-Free Kids has reported that "strong enforcement of

can encourage enforcement of laws prohibiting the sale of tobacco to minors, increase penalties for adults who provide tobacco to minors, foster smoke-free environments in locations where youths are likely to be present, or criminalize tobacco possession by minors.[187]

The government can also promote nonsmoking through its power to "lay and collect [t]axes."[188] Tobacco has long been taxed, and the CDC estimates that an increase in taxes could reduce adolescent cigarette consumption by nearly four percent.[189] For example, President Obama signed the Children's Health Insurance Program Authorization Act in 2009, which in part, increased the federal cigarette tax from thirty-nine cents to $1.01 per pack beginning in April 2009.[190] By 2011, tobacco use had declined significantly, particularly among teens and the poor.[191] The CDC predicts this tax increase and the subsequent lowered smoking rates may significantly reduce future health care costs.[192] This tax increase also garnered $30 billion in new revenue[193]—money that could be used to fund future anti-smoking initiatives. California's Proposition 99 similarly increased taxes on cigarettes, resulting in increased state revenues for health care and anti-smoking initiatives, as well as state smoking rates that declined at double the national rate.[194] These results suggest that additional state or federal tobacco taxes would further reduce smoking rates. These alternative government actions may not be practical or popular; however, they have proven effective at raising awareness about

youth access laws substantially reduce[s] illegal sales to minors." Jessica Guilfoyle, *Enforcing Laws Prohibiting Cigarette Sales to Kids Reduces Youth Smoking*, CAMPAIGN FOR TOBACCO-FREE KIDS (Nov. 11, 2010), http://www.tobaccofreekids.org/research/factsheets/pdf/0049.pdf.

187. *See* Commonwealth Brands v. United States, 678 F. Supp. 512, 536–38 (W.D. Ky. 2010).

188. U.S. CONST. art. I, § 8.

189. *Tobacco Use: Targeting the Nation's Leading Killer*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 16, 2012), http://www.cdc.gov/chronicdisease/resources/publications/aag/osh.htm.

190. Children's Health Insurance Program Reauthorization Act of 2009, Pub. L. No. 111-3, § 701, 123 Stat. 8 (codified as amended at I.R.C. § 5701(b)(1) (Supp. V 2012)).

191. *See* Dennis Cauchon, *Tax Hike Cuts Tobacco Consumption*, USA TODAY (Sept. 13, 2012), http://usatoday30.usatoday.com/news/nation/story/2012-09-10/cigarette-tax-smoking/57737774/1 ("Teen smoking immediately fell 10% to 13% when the tax hike took effect . . . .").

192. *Id.*

193. *Id.*

194. *See* Costello, *supra* note 21, at 688.

the dangers of tobacco use and reducing smoking rates. Moreover, they do not require the government to unconstitutionally curb the First Amendment rights of tobacco companies in the process.

VIII. CONCLUSION

There is no doubt that tobacco use poses a considerable threat to Americans' health; reducing smoking rates will save lives.[195] However, the FSPTCA's graphic warning requirement and the FDA's initial rulemaking tread on the ideals underlying commercial free speech protection by limiting the free flow of commercial information that is necessary for educated public decision-making. The Supreme Court has been particularly wary of government restrictions that "seek to keep people in the dark for what the government perceives to be their own good."[196] The graphic warning requirement does the opposite, but with the same paternalistic intent. These warnings seek to elicit a visceral response, encouraging consumers to shun tobacco products out of fear and disgust, rather than educating the public to help individuals make informed, rational decisions regarding the health risks of tobacco use.

The Supreme Court has emphasized that although the government may constitutionally ban products deemed dangerous to public health or morals, the government does not have the power to eliminate the First Amendment protections of the manufacturers of an unpopular, but legal, product.[197] The subjective, emotional nature of these graphic warnings goes beyond merely "warning" Americans; they serve to suppress the free speech of tobacco manufacturers and border on propaganda. Images of the morbidly obese on McDonald's bags or diseased livers and mangled cars on beer bottles would similarly fail to satisfy the requirements of commercial free speech doctrine despite legitimate and possibly compelling government concerns regarding Americans' health and safety.

195. *See supra* text accompanying notes 1–4.

196. 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503 (1996) (finding a state statute banning advertisement of alcohol prices unconstitutional because the advertisements were not misleading and the ban hindered consumer choice and impeded truthful debate over public policy).

197. *Id.* at 513–14.

Although the government is well within its bounds to enact legislation designed to ensure that American consumers are fully informed about the dangers of smoking, the First Amendment draws the line at regulations that unduly burden tobacco companies' right to free speech. The FDA's first graphic warnings crossed this line, confiscating the tobacco companies' product and turning them into "billboards" designed to manipulate consumer emotion and promote conformity with government-approved behavior.[198] The FDA must consider the contours of commercial free speech in order to craft new graphic warnings that comply with the requirements of the First Amendment. In the meantime, the government must find another way to light a fire under American smokers.

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198. *See supra* text accompanying note 60.

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