Clearing the Air: The Constitutionality of the FDA's Discarded Tobacco Warning Labels and the Resulting Implications on the FDA's Future Warning Labels

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I. INTRODUCTION

> "The individual must be safeguarded in his [or her] freedom of choice – that he [or she] has the right to choose to smoke or not to smoke . . . equally . . . the individual has the right to know that smoking may be hazardous to his [or her] health."[1]

Regardless of one's views on smoking,[2] it is indisputable that tobacco products have significantly impacted American society from the time John Rolfe successfully experimented with tobacco cultivation to the present day.[3] The business of tobacco marketing had formally emerged by 1789 when the first American cigarette advertisements appeared in a local New York newspaper.[4] Despite its prominence, the tobacco industry remained generally unregulated until Congress began enacting legislation in the 1960s to educate the public on the hazards of smoking.[5] While the government has gradually increased its regulatory authority over tobacco companies during the past fifty years, the passage of the Family Smoking

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[1] H.R. Rep. No. 89-449 (1965), *reprinted in* 1965 U.S.C.C.A.N. 2350, 2352 (1965).

[2] Mark Twain once commented that he adopted a rule "never to smoke when asleep, and never to refrain when awake." MILTON MELTZER, MARK TWAIN HIMSELF: A PICTORIAL BIOGRAPHY 266 (1960). He continued by noting that "[i]t is a good rule. I mean, for me; but some of you know quite well that it wouldn't be the answer for everybody that's trying to get to be seventy." *Id.* In contrast, Horace Greeley expressed his disdain for smoking when he stated that "the chewing, smoking, or snuffing of tobacco has seemed to me, if not the most pernicious, certainly the vilest and most detestable abuse of his [or her] corrupted sensual appetites whereof depraved man [or woman] is capable." FRANCIS NICOLL ZABRISKIE, HORACE GREELEY: THE EDITOR 357 (2009).

[3] SAMUEL ELIOT MORISON, THE OXFORD HISTORY OF AMERICAN PEOPLE 52 (1965).

[4] Jeremy R. Singer, *Taking on Tobacco: The Family Smoking Prevention and Tobacco Control Act*, 34 NOVA L. REV. 539, 541 (2010).

[5] Federal Cigarette Labeling and Advertising Act, Pub L. No. 89-92, 79 Stat. 282 (1965) ("FCLAA"); Kristin M. Sempeles, *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, 229 (2012).

Prevention and Tobacco Control Act [hereinafter "FSPTCA"] in 2009 led to a vocal outcry from the tobacco industry and its advocates who claimed that the government grossly overstepped its powers under the Constitution.[6] A primary source of contention was a 2011 regulation promulgated by the Food and Drug Administration (hereinafter "FDA"), entitled "Required Warnings for Cigarette Packages and Advertisements" [hereinafter "FDA Warning Label Regulation"], which imposed newer and more stringent warning labels on tobacco advertisements and packaged tobacco products.[7]

The FDA Warning Label Regulation required tobacco companies to display one of nine textual statements as provided by the FSPTCA.[8] Accompanying each of these statements was one of nine respective graphic images that illustrated the linked statement.[9] For instance, "WARNING: Smoking can kill you" was supplemented by an image of a cadaver lying in a morgue, while "WARNING: Smoking during pregnancy can harm your baby" was juxtaposed with an image of a baby observing an ominous cloud of smoke.[10] The warning labels would have covered the top 50% of the front and rear panels of tobacco packages and 20% of tobacco advertisements.[11]

Predictably, tobacco companies challenged the FSPTCA and the FDA Warning Label Regulation in the federal courts. In 2009, shortly after the enactment of the FSPTCA, but before the promulgation of the FDA Warning Label Regulation, tobacco companies filed suit in a Kentucky district court challenging the FSPTCA on its face as a violation of the First Amendment right to commercial speech, the Fifth Amendment right to Due Process, and the Fifth Amendment's Takings Clause.[12] The tobacco companies argued that the FSPTCA's mandate to publish one of the nine listed textual statements and to include any associated graphic warning label on their advertisements and packaging was unconstitutional as a

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[6] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified in scattered sections of 5, 15, and 21 U.S.C.) ("FSPTCA"); *see* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012) (*en banc* rehearing denied); *see also* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509 (6th Cir. 2012), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013); *see* Attorney General Eric H. Holder, Jr.'s Letter to Speaker of the House of Representatives John Boehner, at 2−3 (Mar. 15, 2013), http://perma.cc/9QYL-DNE9 ("Holder's Letter").

[7] *See* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2012)), *declared unconstitutional by* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012) (*en banc* rehearing denied) ("FDA Warning Label Regulation").

[8] *Id.* at 36,628.

[9] *Id.*

[10] *Id.* at 36,649, 36,654.

[11] FSPTCA, 123 Stat. at 1843.

[12] Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512, 519 (W.D. Ky. 2010).

commercial speech violation.[13] The district court ruled for the FDA on that issue, holding that the use of one of the nine textual statements joined by a graphic image did not violate the tobacco companies' commercial speech rights.[14] On appeal, the Sixth Circuit affirmed the district court's holding on that issue.[15] The tobacco companies filed a Petition for a Writ of Certiorari asking the Supreme Court to review the Sixth Circuit's decision,[16] but the Supreme Court denied the petition.[17]

In a subsequent case, tobacco companies filed suit in the D.C. district court, claiming the FDA Warning Label Regulation was unconstitutional under the First Amendment right to commercial speech.[18] Unlike the issue before the Sixth Circuit, the tobacco companies here objected to the nine specific images that the FDA had chosen to accompany the textual statements.[19] The district court held for the tobacco companies on that issue,[20] and the D.C. Circuit Court affirmed the district court's decision.[21] The FDA filed a petition for a rehearing *en banc*,[22] but the D.C. Circuit Court denied the petition.[23]

Although the constitutionality of the proposed warning labels seemed primed for Supreme Court review, the FDA decided to forego petitioning the Supreme Court to examine the D.C. Circuit's holding and withdrew its proposed labels.[24] Instead, the FDA announced its intent to conduct further research and undergo new rulemaking procedures to produce another set of upgraded warning labels.[25]

Despite the FDA's decision, whether the now-discarded warning labels were constitutionally sound remains a legitimate issue to address not only

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[13] *Id.* Because this suit was filed before the promulgation of the FDA Warning Label Regulation, the Plaintiffs could not challenge the specific nine images the FDA mandated that tobacco companies use in the now-discarded warning labels. Instead, the Plaintiffs facially challenged the use of graphic images on their products. *Id.* at 528−29.

[14] *Id.* at 532.

[15] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 531 (6th Cir. 2012), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

[16] Petition for Writ of Certiorari, Am. Snuff Co. v. United States, 2012 WL 3535900 (U.S. Oct. 26, 2012).

[17] Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

[18] R.J. Reynolds Tobacco Co. v. F.D.A., 845 F. Supp. 2d 266 (D.D.C. 2012).

[19] *Id.* at 268.

[20] *Id.* at 277.

[21] R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205, 1222 (D.C. Cir. 2012) (*en banc* rehearing denied).

[22] Appellant's Pet. for Reh'g and Reh'g En Banc, R.J. Reynolds Tobacco Co. v. F.D.A., 2012 WL 4844135 (D.C. Cir. Oct. 9, 2012).

[23] Holder's Letter, *supra* note 6, at 2−3.

[24] *Cigarette Health Warnings*, FDA, http://perma.cc/0whYGbDC1sC (last updated June 3, 2013); Nathan Cortez, *Do Graphic Warning Labels Violate the First Amendment?*, 64 HASTINGS L.J. 1467, 1486 (2013).

[25] Cortez, *supra* note 24, at 1486.

for its own sake, but also for its implications on the legality of future warning labels, considering the same questions and issues surrounding the discarded labels will likely need to be addressed when the FDA eventually unveils a new labels proposal. Numerous authors have commented on the commercial speech issues surrounding the FSPTCA and FDA Warning Label Regulation. The majority of commentators argued that the FDA's discarded warning labels were unconstitutional under the intermediate standard of review created in *Central Hudson Gas & Electric Corporation v. Public Service Commission* [hereinafter "*Central Hudson* standard"].[26] Without conducting a thorough analysis, two commentators suggested that the FDA Warning Label Regulation would have potentially passed constitutional muster under the *Central Hudson* standard,[27] while another author left the question open.[28] A smaller number of commentators considered the constitutionality of the discarded warning labels in light of the rational basis test created in *Zauderer v. Office of Disciplinary Counsel* [hereinafter "*Zauderer* standard"]. Some authors concluded that the *Zauderer* standard was inapplicable;[29] two argued against its applicability

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[26] *See* Stephanie Jordan Bennett, *Paternalistic Manipulation Through Pictorial Warnings: The First Amendment, Commercial Speech, and the Family Smoking Prevention and Tobacco Control Act*, 81 MISS. L.J. 1909, 1930−34 (2012); *see also* Clay Calvert, Wendy Allen-Brunner & Christina M. Locke, *Playing Politics or Protecting Children? Congressional Action & a First Amendment Analysis of the Family Smoking Prevention and Tobacco Control Act*, 36 J. LEGIS. 201, 233 (2010); *see also* Laura M. Farley, *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, 535 (2011); *see also* Sempeles, *supra* note 5, at 244−47; *see also* Elaine Stoll, *The Family Smoking Prevention and Tobacco Control Act and the First Amendment: Why a Substantial Interest in Protecting Public Health Won't Save Some New Restrictions on Tobacco Advertising*, 65 FOOD & DRUG L.J. 873, 894−96 (2010); *see also* Jennifer Thacker, *Enough Smoke and Mirrors! — Why the Graphic-Warning Mandate Under the Family Smoking Prevention and Tobacco Control Act is Speech Consumers Don't Want to Hear*, 44 U. TOL. L. REV. 659, 679−84 (2013).

[27] *See* Kristin Faucette, *First Amendment Challenges to the Family Smoking Prevention and Tobacco Control Act: Balancing Congress' Interest in Preserving Public Health With the Tobacco Industry's Right to Freely Communicate With Adult Smokers*, 6 J. HEALTH & BIOMEDICAL L. 301, 333−34 (2010) (arguing that nearly all of the FSPTCA's provisions that tobacco companies challenged in *Commonwealth Brands, Inc.*, including the FDA Warning Label Regulation, satisfied the "least restrictive means" prong of *Central Hudson* and were constitutional, but not discussing the constitutionality of the nine specific, now-discarded warning labels); *see also* Jennifer M. Keighley, *Can You Handle the Truth? Compelled Commercial Speech and the First Amendment*, 15 U. PA. J. CONST. L. 539, 586−88 (2012) (noting that a thorough *Central Hudson* analysis exceeded the scope of the article, but suggesting that the discarded warning labels could satisfy review under that standard).

[28] Associate Professor Nathan Cortez argued that courts could apply *Zauderer* when analyzing tobacco warning labels and that *Central Hudson* was an "ill-fitting" standard, but he did not explicitly state that *Central Hudson* is inapplicable and suggested that courts might utilize it when reviewing future warning labels. *See* Cortez*, supra* note 24, at 1471, 1488, 1492.

[29] *See* B. Ashby Hardesty, Jr., *Joe Camel v. Uncle Sam: The Constitutionality of Graphic Cigarette Warning Labels*, 81 FORDHAM L. REV. 2811, 2849−51 (2013); *see also* Nat Stern & Mark Joseph Stern, *Advancing an Adaptive Standard of Strict Scrutiny for Content-Based Commercial Speech Regulation*, 47 U. RICH. L. REV. 1171, 1194, 1196 (2013).

but also contended that the discarded warning labels failed the standard even if it was applicable;[30] one argued for its applicability but did not conduct a thorough analysis of the discarded labels under the standard,[31] and two suggested *Zauderer* could be applicable but failed to provide any detailed analysis of the discarded labels under the standard.[32] Other authors cited First Amendment concerns with the remaining provisions of the FSPTCA, but did not address the discarded warning labels in depth.[33]

In contrast to prior academic literature on the subject, this Note resolutely argues that the discarded warning labels did not violate the tobacco industry's First Amendment commercial speech rights under either the *Zauderer* standard or the *Central Hudson* standard. In finding the FDA Warning Label Regulation constitutional, this Note first provides a brief history of the government's regulation of tobacco products, including a synopsis of the FSPTCA and the FDA Warning Label Regulation. Second, this Note provides an overview of commercial speech jurisprudence, which will provide the proper framework when examining the constitutionality of the FDA's discarded warning labels. This discussion involves the general First Amendment free speech doctrine, the commercial speech doctrine, and the compelled commercial speech doctrine. This section also details the standards of review that the Supreme Court has created under each doctrine, namely the strict scrutiny standard, the intermediate *Central Hudson* standard, and the rational basis *Zauderer* standard. Third, this Note argues that the appropriate standard to review the FDA Warning Label Regulation and future regulations establishing warning labels is the *Zauderer* standard. Fourth, this Note applies the *Zauderer* standard and concludes that the discarded warning labels were constitutional under its rational basis review. In addition, because some courts have used the *Central Hudson* standard to review the FDA Warning Label Regulation, this Note analyzes the discarded warning labels under *Central Hudson* and ultimately determines that the discarded warning labels would have been constitutional under that standard as well. Finally, this Note concludes by

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[30] *See* Bennett, *supra* note 26, at 1921−25; *see also* Thacker, *supra* note 26, at 684−88.

[31] *See* CASE COMMENT, *D.C. Circuit Holds That FDA Rule Mandating Graphic Warning Images on Cigarette Packaging and Advertisements Violates First Amendment.*—R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012), 126 HARV. L. REV. 818, 818−25 (2013).

[32] *See* Cortez, *supra* note 24, at 1499−1500; *see also* Keighley, *supra* note 27, at 585.

[33] *See* Laura M. Dowgin, *Unlucky Strike: Big Tobacco's First Amendment Challenge to the Family Smoking Prevention and Tobacco Control Act*, 35 SETON HALL LEGIS. J. 410, 436−41 (2011); *see also* Matt Shechtman, *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, 723−44 (2011); *see also* Kate E. Wigginton, *Will the Supreme Court Knock Tobacco Advertising Out of the Park for Good?: The Commercial Speech Implications of the Family Smoking Prevention and Tobacco Control Act*, 21 SETON HALL J. SPORTS & ENT. L. 553, 555−60 (2011).

arguing that the FDA's future warning labels will be constitutionally sufficient and emphasizing the need for consistency in reviewing commercial speech claims and the need to better educate the public on the dangers of smoking.

II. BACKGROUND

Although the FSPTCA is a highly publicized and polarizing statute, it is not Congress' first attempt to regulate the tobacco industry.[34] It is, however, the first time that the FDA has received explicit regulatory authority over tobacco products from Congress, indicating the federal government's intent to increase its supervision over the tobacco industry.[35]

A. History of Prior Tobacco Legislation

The FDA first attempted to regulate tobacco products in 1938, pursuant to the Federal Food, Drug, and Cosmetic Act [hereinafter "FDCA"].[36] The FDCA enabled the FDA to regulate food, drugs, cosmetics, and devices for the purpose of protecting the public health.[37] The FDA did not succeed in lobbying Congress to include tobacco in the statute's definition of "drugs," however, leaving the FDA powerless in its early efforts to regulate the tobacco industry.[38]

Nearly thirty years passed before the government made another attempt to tackle the tobacco industry. In 1964, Surgeon General Luther Terry published an Advisory Committee Report on Smoking and Health, which relied on over 7,000 articles to highlight the serious health consequences of tobacco.[39] Subsequently, Congress passed the Federal Cigarette Labeling and Advertising Act ("FCLAA") in 1965, which authorized the Federal Trade Commission to regulate cigarette labels.[40] The FCLAA required tobacco companies to print a textual warning label

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[34] *See* Federal Food, Drug, & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938).

[35] Sempeles, *supra* note 5, at 228.

[36] Federal Food, Drug, & Cosmetic Act, Pub. L. No. 75-717, 52 Stat. 1040 (1938); Sempeles, *supra* note 5, at 228; Shechtman, *supra* note 33, at 708. The United States Department of Agriculture's Bureau of Chemistry, the predecessor to the FDA, also made some efforts to regulate tobacco products. *See* Farley, *supra* note 26, at 520.

[37] Federal Food, Drug, & Cosmetic Act, 52 Stat. at 1042; Sempeles, *supra* note 5, at 228; Shechtman, *supra* note 33, at 708.

[38] Sempeles, *supra* note 5, at 228.

[39] *The Reports of the Surgeon General: The 1964 Report on Smoking and Health*, U.S. NATIONAL LIBRARY OF MEDICINE, *available at* http://perma.cc/09LgukhmZ66 (last visited Nov. 15, 2013); Wigginton, *supra* note 33, at 540−41.

[40] FCLAA, Pub L. No. 89-92, 79 Stat. 282, 283 (1965); Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 518 (6th Cir. 2012), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013); Faucette, *supra* note 27, at 305; Sempeles, *supra* note 5, at 229.

on all cigarette packages.[41] The mandatory text of the label read: "Caution: Cigarette Smoking May Be Hazardous to Your Health."[42]

Congress increased the stringency of the FCLAA by passing the Public Health Cigarette Smoking Act of 1969.[43] The bill required tobacco companies to include the following amended text on their products: "WARNING: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health."[44] In spite of these increased measures, Congress continued to deny the FDA any regulatory power over tobacco products.[45]

Nearly fifteen years later, Congress enacted the Alcohol and Drug Abuse Amendments of 1983.[46] While the Amendments did not create any new regulations for the tobacco industry, they were significant in requiring the Department of Health and Human Services to perform research and submit reports on the health impacts of tobacco products.[47]

Shortly thereafter, Congress passed the Comprehensive Smoking Education Act ("CSEA").[48] The CSEA originated out of Congress' concern that, in spite of the previous regulations, the public was not adequately aware of the negative health effects of smoking.[49] The Act created additional amendments to the existing warning labels, mandating that one of four new warnings be placed on all cigarette packages. The four possible warnings were: (1) "Smoking Causes Lung Cancer, Heart Disease, Emphysema, 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."[50] These warning labels have remained on tobacco packaging to this day.[51]

Congress extended restrictions on normal tobacco products to smokeless tobacco by enacting the Comprehensive Smokeless Tobacco

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[41] FCLAA, 79 Stat. at 283; Sempeles, *supra* note 5, at 229.

[42] FCLAA, 79 Stat. at 283; Faucette, *supra* note 27, at 305; Sempeles, *supra* note 5, at 229.

[43] Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970); *Disc. Tobacco City & Lottery*, 674 F.3d at 518; Sempeles, *supra* note 5, at 229−30.

[44] Public Health Cigarette Smoking Act of 1969, 84 Stat. at 88; Sempeles, *supra* note 5, at 229−30.

[45] Sempeles, *supra* note 5, at 229−30.

[46] Alcohol & Drug Abuse Amendments, Pub. L. No. 98-24, 97 Stat. 175 (1983).

[47] *Id.* at 176, 178, 182−83; Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 518 (6th Cir. 2012), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

[48] Comprehensive Smoking Educ. Act, Pub L. No. 98-474, 98 Stat. 2200 (1984).

[49] Sempeles, *supra* note 5, at 230.

[50] Comprehensive Smoking Educ. Act, 98 Stat. at 2201−02.

[51] Sempeles, *supra* note 5, at 230.

Health Education Act of 1986.[52] This legislation included a mandate for smokeless tobacco packaging to include one of three warning labels: (1) "WARNING: THIS PRODUCT MAY CAUSE MOUTH CANCER"; (2) "WARNING: THIS PRODUCT MAY CAUSE GUM DISEASE AND TOOTH LOSS"; (3) "WARNING: THIS PRODUCT IS NOT A SAFE ALTERNATIVE TO CIGARETTES."[53]

The FDA made another unsuccessful effort to regulate tobacco products under the FDCA in 1996. Relying on its findings that tobacco use was the leading cause of premature death in America and evidence that tobacco companies were manipulating the addictiveness of cigarettes, the FDA promulgated regulations pursuant to the FDCA aimed to govern the promotion, labeling, and accessibility of tobacco products to youths.[54] Although Congress previously denied the FDA's categorization of tobacco as a "drug" under the FDCA, the FDA repeated its argument that tobacco constituted a "drug" and cigarettes constituted delivery "devices" that subjected tobacco to the FDA's regulatory authority.[55] Tobacco companies challenged the FDA's asserted jurisdiction and the Supreme Court ruled in their favor in *F.D.A. v. Brown & Williamson Tobacco Corporation*, noting that prior tobacco legislation and congressional intent irrefutably illustrated that the FDA did not have the power to police the tobacco industry under the FDCA.[56]

B. The Family Smoking Prevention and Tobacco Control Act

The FDA repeatedly attempted to regulate the tobacco industry without success until 2009, when Congress enacted the FSPTCA.[57] The statute explicitly granted the FDA the power, under the FDCA, to regulate the "manufacture, marketing, and distribution of tobacco products."[58]

According to the FSPTCA, the "use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and adults," which is "significantly" driven by "[t]obacco advertising and marketing."[59] These advertisements "often misleadingly portray[] the use of tobacco as

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[52] Comprehensive Smokeless Tobacco Health Educ. Act, Pub. L. No. 99-252, 100 Stat. 30 (1984); Wigginton, *supra* note 33, at 542.

[53] Comprehensive Smokeless Tobacco Health Educ. Act, 100 Stat. at 31.

[54] F.D.A. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 120 (2000); Cortez, *supra* note 24, at 1475.

[55] *Brown & Williamson Tobacco Corp.*, 529 U.S. at 120; Cortez, *supra* note 24, at 1475.

[56] *Brown & Williamson Tobacco Corp.*, 529 U.S. at 161; Sempeles, *supra* note 5, at 231.

[57] FSPTCA, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified in scattered sections of 5, 15, and 21 U.S.C.).

[58] *Id.* at 1781.

[59] *Id.* at 1777.

socially acceptable and healthful to minors."[60] The FSPTCA noted that a "consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects."[61] More specifically, the FSPTCA cited statistics indicating that tobacco use contributes to over 400,000 deaths per year in the United States and has led to chronic illnesses suffered by nearly 8,600,000 Americans.[62] Furthermore, reducing tobacco use by minors by 50% would prevent nearly 10,000,000 children from becoming daily smokers, saving over 3,000,000 of those children from premature death due to some tobacco-related disease, and would reduce healthcare costs by an estimated $75,000,000,000.[63] Based on this data, Congress determined that "it is in the public interest . . . to adopt legislation to address the public health crisis created by actions of the tobacco industry."[64]

The primary tool Congress intended to use to address this public health crisis was an upgraded warning label on tobacco products and advertising. The current warning labels comprise 4% of the side panels of cigarette packages and are solely textual.[65] To improve these outdated labels, the FSPTCA amended the FCLAA to mandate that all tobacco packaging had to include new warning labels encompassing 50% of the front and rear of the packages and contain color graphics.[66] The text of the warning had to be printed in 17-point type and either be typed in white or black to contrast the background.[67] Tobacco advertisements likewise had to include the updated warning labels, which would have comprised 20% of the space on the advertisements.[68]

In addition to the mandate that the FDA promulgate regulations that establish updated warning labels, the FSPTCA contains a number of other major provisions.[69] For instance, the FSPTCA prohibits the distribution of free samples of smokeless tobacco at sporting or entertainment events.[70]

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[60] *Id.* at 1778.

[61] *Id.* at 1777.

[62] *Id.* at 1777.

[63] FSPTCA, Pub. L. No. 111-31, 123 Stat. 1776, 1777 (2009).

[64] *Id.* at 1778.

[65] FDA Warning Label Regulation, 76 Fed. Reg. 36,281, 36,678 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2012)), *declared unconstitutional by* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012) (*en banc* rehearing denied).

[66] *Id.* at 36674.

[67] FSPTCA, 123 Stat. at 1843. The text could be printed in black if set against a white background, or in black if set against a black background, in a manner that contrasts, by typography, layout, or color, with all other printed material on the package. *Id.*

[68] *Id.*

[69] *See generally* FSPTCA, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified in scattered sections of 5, 15, and 21 U.S.C.).

[70] *Id.* at 1832.

The law also contains a "Modified Risk Tobacco Products" provision that prohibits tobacco companies from advertising certain products as being less dangerous than regular cigarettes.[71] Further, the Act prevents tobacco companies from flavoring their cigarettes with certain additives, though the Act explicitly excludes menthol from that prohibition.[72]

C. The FDA Warning Label Regulation

On June 22, 2011, the FDA promulgated a regulation outlining the requirements for the discarded warning labels that tobacco manufacturers had to include on their packaging and advertisements.[73] The FDA Warning Label Regulation mandated that one of the nine new textual statements would be included on all cigarette packages and advertisements and be accompanied by a respective color graphic that illustrated the message of the warning.[74] The nine respective textual warnings and graphics required were as follows:

1. "WARNING: Cigarettes Are Addictive," accompanied by an image of a man smoking through a hole in his throat;
2. "WARNING: Tobacco Smoke Can Harm Your Children," accompanied by an image of a child looking at approaching tobacco smoke;
3. "WARNING: Cigarettes Cause Fatal Lung Disease," accompanied by an image of a set of healthy lungs juxtaposed to a set of diseased lungs;
4. "WARNING: Cigarettes Cause Cancer," accompanied by an image of an individual with cancerous lesions on the individual's lips;
5. "WARNING: Cigarettes Cause Stroke and Heart Disease," accompanied by an image of a man wearing an oxygen mask;
6. "WARNING: Smoking During pregnancy can harm your baby," accompanied by a drawn picture of a baby crying in an incubator;
7. "WARNING: Smoking Can Kill You," accompanied by a cadaver lying on a bed with stitches down its chest;

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[71] *Id.* at 1814.

[72] *Id.* at 1799.

[73] FDA Warning Label Regulation, 76 Fed. Reg. 36,628 (June 22, 2011) (codified at 21 C.F.R. 1141 (2012)), *declared unconstitutional by* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012) (*en banc* rehearing denied).

[74] *Id.* at 36,628.

8. "WARNING: Tobacco Smoke Causes Fatal Lung Disease in Nonsmokers," accompanied by an image of a woman crying uncontrollably; and
9. "WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health," accompanied by an image of a man wearing an "I Quit" shirt.[75]

Each label also contained the hotline number "1-800-QUIT-NOW."[76]

The FDA initially developed thirty-six proposed warning labels after analyzing graphic warning labels used in other countries and consulting with experts in health communications, marketing research, graphic design, and advertising.[77] The FDA then conducted research,[78] examined relevant scientific information, and accepted public comments to narrow down the list of proposed labels to nine.[79]

In justifying the use of the discarded warning labels, the FDA relied on a substantial volume of evidence suggesting that the current warning labels are inefficient in effectively relaying the negative health effects of smoking to consumers, particularly to minors.[80] Although pack-a-day smokers are exposed to the current warning labels an estimated 7,000 times per year,[81] one report branded the existing textual warning labels as "invisible"[82] and another considered them to be "stale and unnoticed."[83] The current labels have not changed in over twenty-five years.[84] According to the FDA, updating, enlarging, and creating more visually noticeable warning labels would "offer significant health benefits over the existing warnings"[85] and "effectively communicate the health risks of smoking."[86] Further, Congress examined data from over thirty other countries that use graphic warning labels on tobacco products and concluded that large graphic labels would get consumers' attention, increase their awareness of the health risks

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[75] *Id.* at 36,649–57.

[76] *Id.* at 36,674.

[77] *Id.* at 36,636.

[78] This research included measuring the effectiveness of the proposed labels by conducting an online study with over 18,000 participants. *Id.* at 36,637.

[79] FDA Warning Label Regulation, 76 Fed. Reg. 36,628, 36,637 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2012)), *declared unconstitutional by* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012) (*en banc* rehearing denied).

[80] *Id.* at 36,629.

[81] *Id.* at 36,631.

[82] *Id.* at 36,629.

[83] Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,530 (Nov. 12, 2010) (proposed rule).

[84] FDA Warning Label Regulation, 76 Fed. Reg. at 36,631.

[85] *Id.* at 36,629.

[86] *Id.* at 36,639.

of smoking, and affect their smoking behavior.[87] These findings laid the groundwork for the FDA's now-discarded warning labels.

III. FREE SPEECH, COMMERCIAL SPEECH, AND COMPELLED COMMERCIAL SPEECH DOCTRINES UNDER THE FIRST AMENDMENT

At the center of the tobacco companies' challenges to the FDA's Warning Label Regulation, and their prospective contentions with future warning labels, are the First Amendment commercial speech rights of the tobacco industry in marketing its tobacco products.

A. Free Speech Doctrine

The First Amendment demands that Congress "shall make no law . . . abridging the freedom of speech."[88] It is a well-established principle that the First Amendment protects "the right to speak freely and the right to refrain from speaking at all."[89] These dual rights are "complementary components of the broader concept of individual freedom of mind" that are protected under the First Amendment.[90] Freedom of speech "embodies the Constitution's 'commitment to the free exchange of ideas'"[91] and "reflects the national commitment to open debate of 'public issues' and 'governmental affairs.'"[92] Normally, speakers have the freedom to "choose the content of [their] own message."[93] A general rule is that a speaker's right to tailor his or her speech "applies not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid."[94] This applies to both individuals and corporations.[95] The Supreme Court has found that "ideologically driven attempts to suppress a point of view are presumptively unconstitutional."[96]

Whenever a government attempts to compel individuals or corporations to express certain views, the government's action, if challenged, must typically pass strict scrutiny review.[97] This requires the

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[87] *Id.* at 36,633.

[88] U.S. CONST. amend. I.

[89] Wooley v. Maynard, 430 U.S. 705, 714 (1977).

[90] R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205, 1211 (D.C. Cir. 2012) (*en banc* rehearing denied).

[91] Jennifer L. Pomeranz, *No Need to Break New Ground: A Response to the Supreme Court's Threat to Overhaul the Commercial Speech Doctrine*, 45 LOY. L.A. L. REV. 389, 395 (2012) (internal citations omitted).

[92] *Id.* (internal citations omitted).

[93] Hurley v. Irish-American Gay, Lesbian and Bisexual Grp. of Bos., 515 U.S. 557, 573 (1995).

[94] *Id.*

[95] Pac. Gas & Electric Co. v. Public Util. Comm'n, 475 U.S. 1, 16 (1986).

[96] Rosenberger v. Rector, 515 U.S. 819, 830 (1995).

[97] United States v. Playboy Entm't Grp., 529 U.S. 803, 813 (2000).

government to show that it is promoting a substantial governmental interest in its regulation and that the regulation is the least restrictive means available to promote that interest.[98]

"Free speech," however, is a complex phrase that encompasses a variety of forms of speech. Certain subsets of free speech are subjected to a lower standard of review than strict scrutiny. For instance, the Supreme Court did not use strict scrutiny in deciding that the Federal Communications Commission could regulate offensive phrases in radio broadcasts,[99] that states could ban the sale of "indecent" material to minors,[100] that schools could regulate student expressions in school publications,[101] that school districts could regulate union communications in teachers' school mailboxes,[102] or that cities could limit political speech on vehicles used as part of their transit systems.[103] This indicates that the Supreme Court affords varying degrees of First Amendment protection based on the type of free speech involved in the specific case. Justice Breyer confirmed this when he once commented, "[b]ecause virtually all human interaction takes place through speech, the First Amendment cannot offer all speech the same degree of protection. Rather, judges must apply different protective presumptions in different contexts, scrutinizing government's speech-related restrictions differently depending on the general category of activity."[104]

B. Commercial Speech Doctrine

In light of the disparities existing between the various forms of free speech, courts apply different reviewing standards depending on the specific speech at issue in each case. Commercial speech, which "serves the speaker's economic interests and assists in the education of consumers by promoting the greatest possible dissemination of information," is a subset of free speech that is entitled to a lower level of scrutiny under the First Amendment.[105] This results from the concern that, because commercial speech is "the offspring of economic self-interest," it is imperative for the government to have the authority to force commercial

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[98] *Id.*

[99] F.C.C. v. Pacifica Found., 438 U.S. 726, 748–50 (1978); Pomeranz, *supra* note 94, at 396.

[100] Ginsberg v. New York, 390 U.S. 629, 641–43 (1968); Pomeranz, *supra* note 94, at 396.

[101] Hazelwood Sch. Dist. v. Kuhlmeier, 484 U.S. 260, 276 (1988); Pomeranz, *supra* note 94, at 396.

[102] Perry Educ. Ass'n v. Perry Local Educators' Ass'n, 460 U.S. 37, 54 (1983); Pomeranz, *supra* note 94, at 396.

[103] Lehman v. City of Shaker Heights, 418 U.S. 298, 301–02 (1974); Pomeranz, *supra* note 94, at 396.

[104] Garcetti v. Ceballos, 547 U.S. 410, 444 (2006) (Breyer, J., dissenting).

[105] Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 456 (1978); Calvert et al., *supra* note 26, at 211.

speakers to disclose factual information, effectively handle misleading and deceitful commercial speech, and protect consumers from dishonest commercial speakers.[106] While the level of scrutiny is lower, commercial speakers are still protected as the government's intrusion must pass some level of review.[107] Together, these aspects of the commercial speech doctrine enable the "free flow of commercial information" to build markets based on "intelligent and well informed" consumers.[108]

The Supreme Court did not always extend First Amendment protections to commercial speech. In 1942, the Supreme Court noted that the Constitution imposed "no restraints" on states from restricting "purely commercial advertising."[109] This understanding remained the prevailing precedent for over thirty years thereafter.[110]

In 1975, the Supreme Court first explicitly applied the First Amendment to commercial speech in *Bigelow v. Virginia*.[111] In that case, a newspaper editor was convicted under a Virginia statute that prohibited the encouragement or procurement of an abortion after he published an ad publicizing the availability of legal abortions in New York.[112] The Court held that speech, in the form of paid commercial ads, is "not stripped of First Amendment protection merely because [it appears] in that form."[113] The Court stressed that the ad "conveyed information of potential interest and value to a diverse audience," and that such speech is afforded protection under the First Amendment.[114]

A year later, in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc*., the Supreme Court held that speech proposing a commercial transaction deserves First Amendment protection.[115] According to the Court, regulators could not ban the advertisement of drug prices by pharmacists since the State's interest in maintaining the "professionalism of pharmacists" did not justify banning information that would help consumers make "intelligent" decisions.[116] Although the Court noted that commercial speech that is either false or proposes an illegal transaction is not afforded First Amendment protection, commercial speech is generally protected.[117] The Court further cited four general

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[106] Pomeranz, *supra* note 94, at 402.
[107] *Id.*
[108] *Id.*
[109] Valentine v. Chrestensen, 316 U.S. 52, 54 (1942).
[110] Stoll, *supra* note 26, at 875.
[111] Bigelow v. Virginia, 421 U.S. 809, 818 (1975); Stoll, *supra* note 26, at 875.
[112] *Bigelow*, 421 U.S. at 809.
[113] *Id.* at 818.
[114] *Id.* at 825.
[115] Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 748 (1976).
[116] *Id.* at 748, 765.
[117] *Id.* at 771.

principles to justify its reasoning that commercial speech is constitutionally protected: (1) profit motivation does not dispel First Amendment protection; (2) there is a public need for companies communicating commercial information to consumers; (3) the free dissemination and accessibility of commercial information is necessary to "sustain a free economy and democracy;" and (4) the government may not restrict the "free flow of commercial information for the purpose of affecting public decisions."[118]

1. Central Hudson *Intermediate Scrutiny Standard*

Four years later, the Supreme Court decided the seminal case *Central Hudson Gas & Electric Corporation v. Public Service Commission*, which explicitly reaffirmed the two notions that commercial speech is (1) protected under the First Amendment and (2) reviewed under a lower level of scrutiny than general free speech claims.[119] In that case, the Public Service Commission of New York ordered electric utilities in New York to stop advertisements that promoted the sale of electricity, which the companies complained violated their First Amendment rights.[120]

The Supreme Court held for the utility companies, noting that the First Amendment protected their commercial speech from unwarranted state regulation.[121] The Court reasoned that people "will perceive their own best interests if only they are well enough informed, and . . . the best means to that end is to open the channels of communication rather than to close them."[122] Even if advertising disclosed only some of the relevant facts, the Court noted that "the First Amendment presumes that some accurate information is better than no information at all."[123]

The Court explained that there is a "commonsense distinction" between commercial speech and other forms of free speech, which necessitates that commercial speech be afforded a lower level of protection under the Constitution.[124] The Court proceeded to define a four-step standard to use in reviewing commercial speech cases.[125] The first step

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[118] Farley, *supra* note 26, at 530 (internal citation omitted).

[119] Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 562−63 (1980).

[120] *Id.* at 558.

[121] *Id.* at 571−72.

[122] *Id.* at 562.

[123] *Id.*

[124] *Id.*

[125] *Cent. Hudson Gas & Electric Corp.*, 447 U.S. at 562−64. At this juncture the Court did not make a distinction between restrictions on free speech or forced disclosures; rather, it merely stated that the four-step test applies to cases involving commercial speech violations. As this Note later explains, subsequent Supreme Court cases have applied the *Central Hudson* standard only to affirmative limitations on commercial speech and reserved the *Zauderer* standard for compelled disclosure claims. *See* discussion *infra* Part III.C.

involves a threshold question to decide whether the commercial speech is afforded any First Amendment protection. A reviewing court must determine whether the content of the speech is (a) a lawful activity and (b) not misleading.[126] The Court emphasized that deceitful speech is not awarded any First Amendment safeguards, so the government may restrict or ban such speech freely.[127] If the speech pertains to lawful activity that is non-misleading, the review proceeds to the second step, which requires the government to possess a substantial interest underlying its regulation of the speech.[128] If a substantial interest is present, the third step requires that the regulation must directly advance the government's interest.[129] Lastly, the Court must decide whether the regulation is more extensive than necessary to promote the interest.[130]

C. Compelled Commercial Speech Doctrine

The Supreme Court noted that the *Central Hudson* standard applies generally to commercial speech cases.[131] Since then, the Court has clarified its position on First Amendment protections. A subset of commercial speech regulations—disclosure requirements—enjoy a lower level of scrutiny than outright prohibitions of commercial speech under the First Amendment.[132]

1. Zauderer *Rational Basis Scrutiny Standard*

In *Zauderer v. Office of Disciplinary Counsel*, the Supreme Court further refined commercial speech jurisprudence by creating a separate, less restrictive test to apply to compelled commercial disclosures.[133] In *Zauderer*, an attorney from Ohio ran advertisements in local and statewide newspapers that ran afoul of state disciplinary rules.[134] One of those ads informed the public of defects found in a popular contraceptive device; that the attorney represented clients suing as a result of those defects; that his fee was contingency based; and that that no legal fees would be owed if he did not succeed in the lawsuit.[135] The Ohio Office of Disciplinary Counsel filed a complaint against the attorney, alleging that the ad was deceptive because it failed to inform clients that they would still be liable for

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[126] *Id.* at 563.
[127] *Id.*
[128] *Id.* at 564.
[129] *Id.*
[130] *Id.*
[131] *Cent. Hudson Gas & Electric Corp.*, 447 U.S. 557, 562 (1980).
[132] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 650−51 (1985).
[133] *Id.*
[134] *Id.* at 629−30.
[135] *Id.*

litigation costs, as opposed to legal fees, even if they lost the case.[136]

In its opinion, the Supreme Court rejected the attorney's contention that either strict scrutiny or the *Central Hudson* test was the appropriate standard to review the claim.[137] The Court noted that the attorney had overlooked "material differences between disclosure requirements and outright prohibitions on speech."[138] The Court emphasized that, because extending First Amendment protection to commercial speech is primarily motivated by the "value to consumers of the information such speech provides," an individual or entity that is forced to provide factual and uncontroverted information is only suffering minimal harm to the constitutionally-protected right of commercial speech.[139] So long as disclosure requirements are "reasonably related to the State's interests in preventing deception to customers," they are not "unjustified or unduly burdensome" to the point that they may "chill[] protected commercial speech," and they thereby pass constitutional muster.[140]

In light of this newly created standard, the Court ruled that the disclosure requirement at issue in *Zauderer* was appropriate.[141] There was a clear potential for deception to customers, since the Court found that it was "commonplace that members of the public are often unaware of the technical meanings of such terms as 'fees' and 'costs.'"[142] The State had a clear general interest in preventing consumer deception and could reasonably require a disclosure requirement without imposing any great burden on the attorney.[143]

IV. ANALYSIS OF THE FDA WARNING LABEL REGULATIONS' CONSTITUTIONALITY

Courts have been conspicuously inconsistent in their application of a specific standard of review when deciding whether the FDA's discarded warning labels were constitutional under the First Amendment. The D.C. district court in *R.J. Reynolds Tobacco Company v. F.D.A.* used strict

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[136] *Id.* at 631.

[137] *Id.* at 638.

[138] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 650 (1985).

[139] *Id.* at 651.

[140] *Id.* Some commentators have suggested a broader reading of *Zauderer* wherein curbing deception is only one possible interest motivating a disclosure requirement, although no Supreme Court cases have yet extended *Zauderer* that far. Because this Note contends that the discarded warning labels were intended to remediate deceptive practices conducted by the tobacco industry, it will not address the potential reach of *Zauderer* beyond curbing consumer deception. For a more in-depth discussion of that argument, *see* Case Comment, *supra* note 31, at 818; *see also* Cortez, *supra* note 24, at 1488−89; *see also* Keighley, *supra* note 27, at 543.

[141] *Zauderer*, 471 U.S. at 656.

[142] *Id.* at 652.

[143] *Id.* at 653.

scrutiny review after ruling that the discarded warning labels did not fit the *Zauderer* paradigm.[144] The district court correctly stated that "[i]n the arena of compelled commercial speech . . . narrow exceptions exist and allow the Government to require certain disclosures to protect consumers from 'confusion or deception.'"[145] In testing the discarded warning labels under the standard, however, the district court found that the FDA Warning Label Regulation's graphic warnings did not convey "purely factual and uncontroversial" information because, according to the district court, the images were "crafted to evoke a strong emotional response calculated to provoke the viewer to quit or never start smoking."[146] Further, the district court found that the images were neither "factual nor accurate," and instead simply promoted the government's anti-smoking agenda.[147] As a result, the district court decided to apply strict scrutiny.[148]

On appeal, a majority of the D.C. Circuit concurred with the district court's conclusion that the discarded warning labels failed to convey "purely factual and uncontroversial" information because consumers could misconstrue the FDA's selected graphic images and, moreover, the graphic labels elicited visceral emotions from consumers that could not be considered "purely factual."[149] Furthermore, the Court found that *Zauderer* only applies in cases where a regulating agency implements a disclosure requirement to correct deceptive practices and, thereby, *Zauderer* was inapplicable because the Court determined that the government was solely attempting to disclose the health risks of smoking through the warning labels.[150] Lastly, even if the government's intent was to remediate deception, the D.C. Circuit argued that there was no evidence that tobacco packaging and advertisements were deceiving consumers.[151] As a result, the D.C. Circuit ruled *Zauderer* inapplicable.[152] Unlike the district court, however, the D.C. Circuit held that *Central Hudson* was the appropriate reviewing standard rather than strict scrutiny, having found that its own precedent mandated that compelled commercial disclosures be analyzed under the *Central Hudson* standard.[153]

Judge Rogers filed a dissenting opinion in *R. J. Reynolds*.[154] Noting

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[144] R.J. Reynolds Tobacco Co. v. F.D.A., 845 F. Supp. 2d 266, 274 (D.D.C. 2012).

[145] *Id.* at 272 (quoting Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985)).

[146] *Id.* at 272.

[147] *Id.* at 273−74.

[148] *Id.* at 277.

[149] R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205, 1216 (D.C. Cir. 2012) (*en banc* rehearing denied).

[150] *Id.* at 1213.

[151] *Id.* at 1214−15.

[152] *Id.* at 1217.

[153] *Id.*

[154] *Id.* at 1222 (Rogers, J., dissenting).

that the discarded warning labels were disclosure requirements targeting commercial speech that was misleading based on the tobacco industry's "decades-long campaign to deceive consumers" about the health consequences of smoking, she argued that *Zauderer* scrutiny applied.[155]

The Kentucky district court deciding *Commonwealth Brands, Inc. v. United States* rejected strict scrutiny as the appropriate test in evaluating the warning labels and chose to apply *Central Hudson*, although it failed to discuss why *Zauderer* was inapplicable.[156] On appeal, the Sixth Circuit agreed with the district court that strict scrutiny review was the wrong standard to apply to the forthcoming warning labels.[157] Instead, the Court concluded that the *Zauderer* standard governed, contending that the forthcoming warning labels, including the textual and graphic components, were disclosure requirements that could convey factual information.[158]

A. Applicability of the Zauderer *Standard*

For *Zauderer* to govern a commercial speech case, a regulating entity must be imposing (1) a disclosure requirement (2) containing purely factual and uncontroversial information that is (3) directed at misleading commercial speech.[159]

1. The Discarded Warning Labels Were Disclosure Requirements

The first element requires that the government impose a disclosure requirement rather than restrict speech. As the Supreme Court has noted, "the less exacting scrutiny described in Zauderer" applies when "challenged provisions impose a disclosure requirement rather than an affirmative limitation on speech."[160] Here, the FDA Warning Label Regulation required tobacco manufacturers to disclose certain information about the severe health effects of smoking.[161] This was, in the most basic

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[155] R.J. Reynolds Tobacco Co. v. F.D.A. 696 F.3d 1205, 1216 (D.C. Cir. 2012) (Rogers, J., dissenting) (*en banc* rehearing denied).

[156] Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512, 532 (W.D. Ky. 2010). The opinion cited *Zauderer* a few times, but did not discuss its applicability. *Id.* at 522, 525, 530.

[157] Disc. Tobacco City & Lottery, Inc., v. United States, 674 F.3d 509, 527 (6th Cir. 2012), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

[158] *Id.* at 528, 530, 551, 569.

[159] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 650−51 (1985); Milavetz, Gallop & Milavetz, P.A. v. United States, 559 U.S. 229, 255 (2010).

[160] *Milavetz*, 559 U.S. at 249; *see also* Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001) ("Zauderer*,* not [*Central Hudson*]*,* describes the relationship between means and ends demanded by the First Amendment in compelled commercial disclosure cases. The *Central Hudson* test should be applied to statutes that *restrict* commercial speech.").

[161] *See generally* FDA Warning Label Regulation, 76 Fed. Reg. 36,628 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2012)), *declared unconstitutional by* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012) (*en banc* rehearing denied).

sense, a disclosure requirement analogous to the compelled speech in *Zauderer* and its progeny, as the FDA required the tobacco industry to participate in speech rather than prohibiting tobacco companies from speaking. Even the D.C. Circuit labeled the FDA Warning Label Regulation a "compelled commercial disclosure."[162]

2. *The Discarded Warning Labels Contained Purely Factual and Uncontroversial Information*

Under the second element, the disclosure must contain "purely factual and uncontroversial information."[163] The disclosure may not contain opinions or unsettled viewpoints that the government is forcing a commercial speaker to make.

Here, the discarded warning labels communicated information that was purely factual and uncontroversial. The messages conveyed by each warning label were supported by copious amounts of scientific data and sheer common sense.[164] Congress found that a "consensus exists within the scientific and medical communities that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects."[165] As the Sixth Circuit noted, "[i]t is beyond cavil that smoking presents the serious health risks described in the warnings . . . . The 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."[166]

The D.C. district court, the D.C. Circuit Court, and some commentators argued that the graphic illustrations comprising part of the warning labels did not convey purely factual and uncontroversial material and thereby failed this step.[167] Both D.C. courts claimed that the images accompanying the textual warnings did not attempt to communicate information, but were rather meant to "shock" and "disgust" the public and evoke an emotional response to prevent individuals from smoking.[168] The government itself has noted that the images would likely have such an

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[162] R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205, 1217 (D.C. Cir. 2012) (*en banc* rehearing denied).

[163] *Id.* at 1216.

[164] *See* FSPTCA, Pub. L. No. 111-31, 123 Stat. 1776, 1777−81 (2009) (codified in scattered sections of 5, 15, and 21 U.S.C.); *see also* FDA Warning Label Regulation, 76 Fed. Reg. at 36,629−36.

[165] FSPTCA, 123 Stat. 1777 (2009).

[166] Disc. Tobacco City & Lottery, Inc., v. United States, 674 F.3d 509, 558, 561 (6th Cir. 2012) (Stranch, J., concurring in part, dissenting in part), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

[167] R.J. Reynolds Tobacco Co. v. F.D.A., 845 F. Supp. 2d 266, 272 (D.D.C. 2012); Bennett, *supra* note 26, at 1924; Hardesty, Jr., *supra* note 29, at 2850−51; Stern & Stern, *supra* note 29, at 1196.

[168] R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205, 1216 (D.C. Cir. 2012) (*en banc* rehearing denied); *R.J. Reynolds Tobacco Co.*, 845 F. Supp. 2d at 276.

effect on consumers.[169]

The courts' and commentators' logic that the discarded warning labels, particularly the graphic components, failed to convey factual and uncontroversial information is flawed. In addition to analyzing a disclosure requirement, the Supreme Court in *Zauderer* also reviewed whether a professional conduct rule prohibiting the use of graphics in attorney advertisements was constitutional.[170] In support of the rule, the state argued that the use of illustrations would create "unacceptable risks that the public [would] be misled, manipulated, or confused."[171] According to the state, illustrations could "play on the emotions of [the] audience and convey false impressions."[172] The Court in *Zauderer* explicitly rejected that contention, noting that "[t]he use of illustrations or pictures in advertisements serves important communicative functions: it attracts the attention of the audience to the advertiser's message, and it may also serve to impart communication directly."[173] This is particularly important in light of the fact that American warning labels require a college reading level that may be difficult for poorer, uneducated Americans and youths to fully comprehend.[174] According to one study, a quarter of American smokers have not graduated high school and 45% have only a GED.[175] In addition, there are 32,000,000 Americans who are considered illiterate.[176] It is also important to consider those individuals for whom English is a second language[177] and people with disabilities such as dyslexia.[178] The graphic components of the warning labels thereby played a critical role, along with the textual statements, in effectively communicating the health effects of smoking to consumers. As Judge Stranch of the Sixth Circuit correctly explained, "there is no reason why a picture could not . . . accurately represent a negative health consequence of smoking."[179]

The graphics accompanying the textual warnings were thereby critical

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[169] *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1216.

[170] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 647−49 (1985).

[171] *Id.* at 648.

[172] *Id.*

[173] *Id.* at 647; *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1230 (Rogers, J., dissenting).

[174] ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION 437 (Richard J. Bonnie et al. eds., 2007).

[175] *Adult Smoking in the US*, CENTERS FOR DISEASE CONTROL AND PREVENTION 3 (Sept. 2011), http://perma.cc/0WMJjTAF9mG.

[176] *Illiteracy Statistics*, STATISTIC BRAIN (Feb. 2, 2012), http://perma.cc/0DUtqmUYUZe.

[177] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 563 (6th Cir. 2012), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013) (internal citation omitted).

[178] *Id.*; *see also Dyslexia Statistics*, DYSLEXIA HEALTH, http://perma.cc/0vzhwPvbSyo (last visited Nov. 16, 2013) (noting that fifteen to twenty percent of the population has a language based learning disability, with dyslexia being the most common form).

[179] *Disc. Tobacco City & Lottery*, 674 F.3d at 560.

to providing a better medium for conveying the factual messages contained in the warning labels. As the FDA found, "considerable scientific evidence shows that health warnings that elicit strong emotional and cognitive reactions . . . are better processed and more effectively communicate information about the negative health consequences of smoking."[180] Further, simply because the illustrations in the warning labels evoked emotional responses did not make them inaccurate or nonfactual.[181] As Judge Stranch aptly stated, "[f]acts can disconcert, displease, provoke an emotional response, spark controversy, and even overwhelm reason, but that does not magically turn such facts into opinions."[182] Likewise, Judge Rogers stressed in her dissenting opinion to *R.J. Reynolds* that "factually accurate, emotive, and persuasive are not mutually exclusive descriptions."[183]

Even if it was plausible that the graphic images alone failed to convey factual and uncontroversial information, the FDA Warning Label Regulation should have been examined as a whole rather than separated into distinct portions, as Judge Rogers emphasized in her dissent.[184] That is, the discarded warning labels were comprised of both the textual and the graphic elements together. The D.C. Circuit examined the graphic images separately from their respective accompanying textual statements when determining whether the warning labels violated the First Amendment.[185] That tactic, however, unfairly undermined the FDA's purpose of utilizing the graphics, which were intended to complement the textual warnings.[186] The selected graphics were all linked directly to a specific textual statement and were not randomly selected images that provided no effect but shock and disgust. Those elements worked in tandem to attract the viewer's attention and deliver an accurate and ubiquitous message pertaining to the risks of smoking. Under this framework, the discarded warning labels were purely factual and uncontroversial.

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[180] FDA Warning Label Regulation, 76 Fed. Reg. 36,628, 36,642 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2012)), *declared unconstitutional by* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012) (*en banc* rehearing denied).

[181] R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205, 1230 (D.C. Cir. 2012) (Rogers, J., dissenting) (*en banc* rehearing denied).

[182] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 569 (6th Cir. 2012), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

[183] *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1230 (Rogers, J., dissenting).

[184] *Id.*

[185] *Id.* at 1217.

[186] FSPTCA, Pub. L. No. 111-31, 123 Stat. 1776, 1845 (2009) (codified in scattered sections of 5, 15, and 21 U.S.C.).

3. The Government Created the Discarded Warning Labels to Address Consumer Deception

To meet the final element, the government must have created the disclosure requirement to address product advertisements that had the "possibility of deception" or "tendency to mislead."[187] This step does not require direct, unequivocal evidence that the particular commercial speech is misleading. As the Supreme Court has elucidated, the government does not need to "conduct a survey of the . . . public before it [may] determine that the [advertisement] has a tendency to mislead" if the threat of deception is "self-evident."[188] In *Zauderer*, the Court did not require any evidence that the attorney's ads were actually misleading.[189] In *Milavetz, Gallop & Milavetz, P.A. v. United States*, a case concerning a disclosure requirement, the Supreme Court rejected the petitioner's argument that a lack of direct evidence indicating that the ads at issue were actually misleading failed to meet the threshold requirements laid out in *Zauderer*.[190] In contrast, the Supreme Court struck down a disclosure requirement in *Ibanez v. Florida Department of Business and Professional Regulation* because it could not identify any potential harm or find any evidence in the record indicating that an attorney's advertisement misled consumers.[191]

One of the D.C. Circuit's arguments against the applicability of *Zauderer* was the government's failure to "affirmatively" prove that consumers were deceived by tobacco product advertisements.[192] As the Supreme Court established, however, concrete evidence of deception is unnecessary when the risk of deception is "self-evident."[193] History has revealed that tobacco companies have traditionally portrayed tobacco deceptively in their advertisements. Congress itself found that "[t]obacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors,"[194] and the D.C. Circuit has acknowledged that tobacco companies tended to misinform consumers based on the companies' decades of deception regarding each of the risks identified in the warning labels.[195] Major tobacco companies have

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[187] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 652−53 (1985).

[188] *Id.*

[189] *Id.*

[190] Milavetz, Gallop & Milavetz, P.A. v. United States, 559 U.S. 229, 251 (2010).

[191] Ibanez v. Fla. Dept. of Bus. & Prof'l Reg., Bd. Of Accountancy 512 U.S. 136, 146 (1994); *see also* CASE COMMENT, *supra* note 31, at 824.

[192] R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205, 1214–15 (D.C. Cir. 2012) (*en banc* rehearing denied).

[193] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 652–53 (1985).

[194] FSPTCA, Pub. L. No. 111-31, 123 Stat. 1776, 1778 (2009) (codified in scattered sections of 5, 15, and 21 U.S.C.).

[195] United States v. Philip Morris USA Inc., 566 F.3d 1095, 1108 (D.C. Cir. 2009) (per curiam).

routinely, among other things, falsely denied the adverse effects of smoking, falsely denied marketing to youths, and suppressed documents, research, and information to prevent the public from learning the truths about the dangers of smoking.[196] One way the tobacco industry disseminated these falsehoods was through advertising.[197] That track record illustrates that the likelihood of continued deception in tobacco product advertisements is self-evident and "hardly . . . speculative."[198]

In justifying the FSPTCA and the FDA Warning Label Regulation, the government did not explicitly state that its motive was to overcome deceitful marketing tactics of the tobacco industry. Instead, the government maintained that the primary purpose was to convey critical information about the health effects of tobacco use.[199] As a result, the D.C. Circuit and some commentators also contended that the governmental interest in informing the public about the health risks of smoking was unrelated to the governmental interest in curing consumer deception. They alleged that, therefore, *Zauderer* could not govern the review of the discarded warning labels.[200]

That argument is unavailing because it focuses on the government's explicit goal of conveying information about the health effects of smoking without addressing an important inquiry: why did the government believe conveying that information was necessary? The government decided to act because the tobacco industry has "knowingly and actively conspired to deceive the public about the health risks and addictiveness of smoking for decades."[201] The government was combating deceit in the tobacco industry's marketing ploys by implementing the disclosure requirements in an attempt to undo years of misleading information that the tobacco industry has injected into society. The majority in *R. J. Reynolds* erroneously viewed a disclosure requirement illustrating the negative health consequences of smoking as mutually exclusive from an interest in protecting consumers from misleading information and curing them of their misconceptions about tobacco products.[202] In fact, requiring a health disclosure and protecting the public from misleading information "are

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[196] *Id.*

[197] *Id.*

[198] Milavetz, Gallop & Milavetz, P.A. v. United States, 559 U.S. 229, 251 (2010); CASE COMMENT, *supra* note 31, at 825 n.80 (internal citations omitted).

[199] FDA Warning Label Regulation, 76 Fed. Reg. 36,628, 36,633 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2012)), *declared unconstitutional by* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012) (*en banc* rehearing denied)

[200] *See* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205, 1213 (D.C. Cir. 2012) (*en banc* rehearing denied); Bennett, *supra* note 26, at 1922; Hardesty, Jr., *supra* note 29, at 2849.

[201] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 562 (6th Cir. 2012), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

[202] CASE COMMENT, *supra* note 31, at 822−23.

compatible (or even identical) [interests]."[203]

B. Application of the Zauderer *Standard*

Based on the considerations detailed above, *Zauderer* should have been the reviewing standard utilized by the courts when examining the discarded warning labels and should, for similar reasons, be used when reviewing the constitutionality of future warning labels. Under *Zauderer*, a disclosure requirement is constitutional if it is "reasonably related to the [government's] interest in preventing deception to consumers."[204] Despite the insistence of some lower courts and commentators, there is no mandatory separate requirement that a court must find that a disclosure requirement is not "unjustified or unduly burdensome" before ruling it constitutional if the first prong above is met.[205]

1. The Discarded Warning Labels Were Reasonably Related to the FDA's Interest in Preventing Consumer Deception

Zauderer and its progeny set a relatively low standard in determining that a disclosure requirement is "reasonably related" to a governmental interest in preventing consumer deception. In *Milavetz*, and similarly in *Zauderer,* the disclosure requirements at issue were reasonably related to an interest in preventing consumer deception as they only required commercial speakers to provide factual statements without preventing them from conveying additional information.[206]

As a result of the tobacco industry's history of deception in its advertisements,[207] the FDA promulgated the rule requiring upgraded warning labels. The current warning labels cover less than 5% of cigarette advertisement and packaging, and only appear on one side of cigarette packaging and advertising.[208] As the Surgeon General found, the existing warnings were given little attention or consideration by viewers.[209] One study showed that more than 40% of adolescents did not view the warnings, and 20% viewed but ignored them.[210] Realizing this infirmity,

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[203] *Id.* at 822.

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

[205] *Id.*

[206] Milavetz, Gallop & Milavetz, P.A. v. United States, 559 U.S. 229, 250 (2010); *see also* Spirit Airlines, Inc. v. U.S. Dept. of Transp., 687 F.3d 403, 414–15 (D.C. Cir. 2012) (finding disclosure requirement reasonably related to preventing consumer confusion); *see also* Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001).

[207] *See* discussion *supra* Part IV.A.3.

[208] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 563 (6th Cir. 2012), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

[209] *Id.* (internal citations omitted).

[210] *Family Smoking Prevention and Tobacco Control Act: Hearing Before the House Subcommittee on Health of the Committee on Energy and Commerce,* 110th Cong. 42 (2007).

the government acted to create newer, more noticeable labels.[211] As the scientific data illustrates, the discarded warning labels were reasonable measures used to attract consumers' attentions and improve their understanding of the health consequences of smoking. These measures would help undo the damage done by the tobacco industry's history of misleading advertising tactics.

2. Zauderer *Does Not Require an Undue Burden Analysis*

The D.C. Circuit and some commentators have erroneously argued that *Zauderer* requires a reviewing court to further find that a disclosure requirement is not unduly burdensome or unjustified in order to pass *Zauderer* scrutiny.[212] This is based on an incorrect reading of *Zauderer*, considering the Supreme Court itself recognized "that unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech. *But we hold that an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers.*"[213] Therefore, if the disclosure requirements are reasonably related to the government's interest in preventing consumer deception, they are inherently not unduly burdensome or unjustified.

Even if this second prong did exist, however, the warning labels were not unduly burdensome or unjustified. Although the labels cover the top 50% of the front and rear panels of cigarette packages and 20% of cigarette advertisements, cigarette manufacturers keep 50% of the front and rear panels of cigarette packages and 80% of cigarette advertisements to use as they please, which provides more than enough space for other voluntary speech.[214] Further, the FDA found that similarly sized warning labels have effectively been used in other countries.[215]

C. Application of the Central Hudson *Standard*

It is evident that the *Zauderer* standard was the appropriate test to

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[211] FDA Warning Label Regulation, 76 Fed. Reg. 36,628, 36,631−32 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2012)), *declared unconstitutional by* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012) (*en banc* rehearing denied).

[212] R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205, 1212 (D.C. Cir. 2012) (*en banc* rehearing denied); John P. Strouss, *Medical Pornography or Fair Warning: Should the United States Adopt Canada's Gruesome New Tobacco Labels?*, 27 J. CORP. L. 315, 329–30 (2002); Stern & Stern, *supra* note 29, at 1196.

[213] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985) (emphasis added).

[214] FSPTCA, Pub. L. No. 111-31, 123 Stat. 1776, 1843 (2009) (codified in scattered sections of 5, 15, and 21 U.S.C.).

[215] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 565−66 (6th Cir. 2012), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

analyze the constitutionality of the FDA's discarded warning labels and should be used for any challenges against the FDA's future warning labels. Some lower courts and commentators, however, applied the *Central Hudson* standard when analyzing the constitutionality of the FDA Warning Label Regulation.[216] Even assuming *arguendo* that *Central Hudson* was the appropriate standard, the discarded warning labels would still have passed the *Central Hudson* test.

The *Central Hudson* standard requires that (1) the regulated commercial speech discuss lawful activity and not be misleading; (2) the restriction on the commercial speech must serve a substantial governmental interest; (3) the restriction must directly advance the asserted governmental interest; and (4) the restriction is not more extensive than necessary.[217]

1. The Regulated Speech Must Address Lawful Activity and May Not Be Misleading

It is indisputable that the sale of tobacco products, with some restrictions regarding sales to minors, is legal.[218] The second part of this prong is not easily met, however, considering the inherent deception present in cigarette advertisements.[219] In fact, the Supreme Court has established that misleading commercial speech is not afforded any First Amendment protection at all.[220] Arguably, therefore, the government should be free to regulate tobacco advertising without any First Amendment concerns. For the sake of argument, however, this Note will temporarily assume that tobacco advertisements are non-misleading and satisfy this prong.[221]

2. The Regulation Must Serve a Substantial Governmental Interest

The government has a substantial interest in protecting the public, particularly minors, by informing individuals about the dangers of

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[216] *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1217; Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512, 532 (W.D. Ky. 2010); *see also* Bennett, *supra* note 26, at 1932–34; *see also* Farley, *supra* note 26, at 535; *see also* Sempeles, *supra* note 5, at 246; *see also* Stoll, *supra* note 26, at 893–96.

[217] Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 563–64 (1980).

[218] Singer, *supra* note 4, at 547–48.

[219] *See supra* Part IV.A.3.

[220] *Cent. Hudson Gas and Electric Co.*, 447 U.S. at 563.

[221] Bennett, *supra* note 26, at 1931; Calvert et al., *supra* note 26, at 231; Farley, *supra* note 26, at 535; Keighley, *supra* note 27, at 587–88; Sempeles, *supra* note 5, at 240; Thacker, *supra* note 26, at 679; Wigginton, *supra* note 33, at 554.

smoking.[222] In creating the FSPTCA and its subsequent regulations, the government relied on a substantial volume of data indicating that smoking has become a serious nationwide problem, particularly among adolescents.[223] It has also been found that tobacco use is the leading cause of preventable death in America.[224] In a previous case dealing with tobacco regulation, the Supreme Court confirmed that the government has a substantial interest in "preventing the use of tobacco products by minors."[225] Like the first prong, this step is also satisfied.[226]

3. The Regulation Must Directly Advance the Government's Asserted Interest

According to the Supreme Court, the third prong requires the government to show more than "mere speculation or conjecture" that the restriction will succeed in advancing its interest by "a material degree."[227]

The D.C. Circuit and some commentators argued that the FDA's discarded warning labels failed to directly advance any significant state interests.[228] However, there is a clear, strong causal link between cigarette advertising and youth smoking.[229] As a result of that clear link, the government's actions did aim to directly promote the awareness of the health hazards of smoking and a reduction in youth consumption. As the government noted, the current labels are insufficient to warn the public, including minors, of the dangers of smoking.[230] Upgrading the warning labels would have attracted viewers' attentions and helped spread knowledge about the significant dangers of smoking, thereby providing the necessary link between the regulation and the advancement of the

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[222] *See generally*, FDA Warning Label Regulation, 76 Fed. Reg. 36,628, 36,628−29 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2012)), *declared unconstitutional by* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012) (*en banc* rehearing denied).

[223] FSPTCA, Pub. L. No. 111-31, 123 Stat. 1776, 1777−81. (2009) (codified in scattered sections of 5, 15, and 21 U.S.C.).

[224] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 555 (2001).

[225] *Id.*

[226] Calvert et al., *supra* note 26, at 231; Farley, *supra* note 26, at 535; Keighley, *supra* note 27, at 587−88; Thacker, *supra* note 26, at 680; *cf.* Bennett, *supra* note 26, at 1931 (arguing the government's interest is to force people to quit or never begin smoking, which is not substantial); *cf.* Sempeles, *supra* note 5, at 240−41 (arguing that, although conveying the health consequences in smoking and reducing youth consumption are substantial interests, the government's true interest is to force people to quit smoking).

[227] Rubin v. Coors Brewing Co., 514 U.S. 476, 487 (1995).

[228] R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205, 1219 (D.C. Cir. 2012) (*en banc* rehearing denied); Bennett, *supra* note 26, at 1932−33; Calvert et. al, *supra* note 26, at 232−33; Farley, *supra* note 26, at 533; Sempeles, *supra* note 5, at 242−43; Thacker, *supra* note 26, at 680.

[229] Dowgin, *supra* note 33, at 420; Faucette, *supra* note 27, at 333 n.193.

[230] FSPTCA, 123 Stat. at 1777−81.

government's asserted interests.[231]

4. The Regulation Must Not Be More Extensive Than Necessary

Finally, the government must show the warning labels are not more extensive than necessary. This is not a requirement demanding that the government show it used the least restrictive means necessary, as in strict scrutiny.[232] This prong requires a "fit between the legislature's ends and the means chosen to accomplish those ends." [233] The means must be "narrowly tailored to achieve the desired objective."[234]

Critics contended that the warning labels were not narrowly tailored due to their size, content, and the purported availability of less restrictive alternatives.[235] In this case, however, the government succeeded in choosing a means narrowly tailored to help spread awareness of the dangers of smoking and decrease the prevalence of tobacco use, especially among minors. It is true that the discarded warning labels required more space in advertisements and tobacco packaging than the previous labels. However, tobacco manufacturers were not stripped of their entire palette, as they still retained 50% of space on tobacco packaging products and 80% of space on advertisements to use for their own messages.[236] Furthermore, the discarded warning labels were similar in design to those effectively used in other countries.[237]

Moreover, there were no narrower means for the government to utilize to advance its interest. Other methods to spread knowledge and reduce tobacco use, like using excise taxes or improving anti-smoking programs, have proven to be inadequate.[238] The smaller warning labels currently in place are also plainly ineffective.[239] The use of upgraded warning labels did not extend beyond what is necessary to accomplish the government's asserted interest in increasing the public's knowledge about tobacco products and reducing tobacco consumptions, particularly amongst minors.

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[231] *Id.*; *see* Faucette, *supra* note 27, at 333 n.193.

[232] Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 556 (2001).

[233] *Id.*

[234] *Id.*

[235] Bennett, *supra* note 26, at 1933−34; Calvert et al, *supra* note 26, at 233; Farley*, supra* note 26, at 533; Sempeles, *supra* note 5, at 243−45; Stoll, *supra* note 26, at 895−96; Thacker, *supra* note 26, at 681−84.

[236] FSPTCA, Pub. L. No. 111-31, 123 Stat. 1776, 1843 (2009).

[237] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 565−66 (6th Cir. 2012), *cert. denied*, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

[238] FDA Warning Label Regulation, 76 Fed. Reg. 36,628, 36,700 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2012)), *declared unconstitutional by* R.J. Reynolds Tobacco Co. v. F.D.A., 696 F.3d 1205 (D.C. Cir. 2012) (*en banc* rehearing denied); Farley, *supra* note 26, at 531; Faucette, *supra* note 27, at 334−35.

[239] FDA Warning Label Regulation, 76 Fed. Reg. at 36,677.

V. CONCLUSION

The FDA Warning Label Regulation was a valid directive created to inform the public of the severe dangers associated with smoking and to remedy the decades of misleading information that the tobacco industry disseminated to the public through advertisements. Although commercial speech jurisprudence is muddled regarding the appropriate reviewing standard for alleged First Amendment violations, the FDA Warning Label Regulation passed constitutional muster under both the *Zauderer* and *Central Hudson* standards.

The FDA will eventually promulgate a new rule imposing another set of upgraded warning labels. Considering the challenges that the discarded warning labels encountered, the FDA will likely make a concerted effort to create labels that are "less offensive" than those in the first group. The new labels, however, need not be significantly downsized. The scientific data that supported the discarded labels will still exist. Furthermore, neither the Supreme Court nor the majority of circuit courts had an opportunity to review the discarded labels. Although the D.C. Circuit found the discarded labels unconstitutional, the majority erroneously used *Central Hudson* over *Zauderer* and, moreover, reached the wrong conclusion under *Central Hudson*. Additionally, the D.C. Circuit's opinion in *R.J. Reynolds* was not unanimous. The FDA should contest any challenges to the future warning labels in multiple courts, and in light of the constitutionality of the discarded warning labels, the future labels should be upheld regardless of the reviewing standard that the courts utilize.

It is imperative to emphasize that consistency is needed in the application of the proper standards of review in all free speech cases. Disclosure requirements, as opposed to affirmative limitations on commercial speech, are afforded a less demanding reviewing standard due to the inherent differences between compelled speech and restricted speech as recognized by the Supreme Court. Applying a stricter standard to disclosure requirements, such as the discarded and future warning labels, increases the danger of courts striking down appropriate commercial speech regulations when their adoption is crucial to combat deceptive speech and ensure the public is accessing viable, reliable information. Inconsistent applications of reviewing standards also force regulating entities to second-guess whether their regulations are constitutional rather than enabling them to maintain a clear understanding of the scope of their authority.

Policy implications must be considered in addition to the constitutional questions underlying the discarded and future warning labels. In deciding to upgrade the warning labels currently in place, the government realized that most Americans, particularly adolescents, begin or continue to smoke

while remaining largely ignorant to the health risks associated with smoking. Smoking kills over 400,000 Americans per year[240] and results in 5,100,000 years of potential life lost annually.[241] Over 46,600,000 American adults smoke.[242] On a daily basis, over 4,000 youths under the age of eighteen try their first cigarette and 1,000 youths under the age of eighteen become daily smokers.[243] The government and courts have found that the majority of Americans are shockingly unaware of the severe health consequences of smoking.[244] While the government cannot be given free reign in addressing these infirmities, the lack of knowledge concerning the health effects of tobacco is a dangerous problem. The government should be encouraged to address this issue within constitutional limits.

The discarded warning labels were appropriate tools that, by all indication, would have assisted in the gradual enlightenment of the American public concerning the legitimate health risks of smoking. The FDA should promulgate a regulation establishing similar warning labels in the future, and courts should acknowledge the validity and necessity of those warning labels when tobacco companies once again come knocking on the courthouses' doors.

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[240] Smoking & Tobacco Use, *Adult Cigarette Smoking in the United States: Current Estimate*, CDC, http://perma.cc/0xmQCv29kRK (last visited Nov. 15, 2013).

[241] Smoking & Tobacco Use, *Economic Facts About U.S. Tobacco Production and Use*, CDC, http://perma.cc/0axE2NKqvG7 (last visited Nov. 15, 2013).

[242] FDA Warning Label Regulation, 76 Fed. Reg. at 36,629.

[243] Smoking & Tobacco Use, *Fast Facts*, CDC, http://perma.cc/0iSyNDodGJW (last visited Nov. 15, 2013).

[244] United States v. Philip Morris USA Inc., 449 F. Supp. 2d 1, 578 (D.D.C. 2006), *aff'd, in relevant part,* 566 F.3d 1095 (D.C. Cir. 2009) (noting that "most people have only a superficial awareness that smoking is dangerous."); FDA Warning Label Regulation, 76 Fed. Reg. at 36,632.