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FDA Puffery: Smoking Out the Constitutionality of Graphic Cigarette Warning Labels

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Cover Page Footnote

J.D., Fordham University School of Law, 2013; B.A., summa cum laude, Political Science, Psychology, Touro College, 2009. Thank you to Prof. Erik Bierbauer and Prof. Cheryl Bader for their guidance and insightful comments, and to Ryan Fox, Tiffany Miao, Sasha Segall, Tiffany Mahmood, Laura Lagone, Matthew Marcucci, and the rest of the IPLJ staff for their hard work and careful review. For their assistance throughout my academic and professional pursuits, thank you to Judge Martin Cronin, Prof. Miriam Petrowsky, Prof. Thomas Rozinski, Prof. Norman Bertram, Dr. Mark Press, Dr. Morris Bronstein, Christopher Morvillo, Rachel Weisman, Elizabeth Crotty, Jeremy Saland, Fischel Bensinger, and David Kupfer. Most importantly, thank you to my friends, family, and parents, Nathan and Frieda Klein, for their constant encouragement and unwavering support

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Israel Klein*

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INTRODUCTION

The story of Joe Camel is a tragic one.¹ Born and orphaned in Europe in 1974,² Joe worked his way up the economic ladder to financial success. Joe's big break came in 1988 when the R.J. Reynolds Tobacco Company selected Joe to become the brand's mascot, the "face" of Camel Cigarettes.³ Featured on the front panel of Camel Cigarette packages⁴—as well as various billboards, advertisements, catalogues, and promotional merchandise like

¹ The following story is a dramatization. The R.J. Reynolds Tobacco Company began using Joe Camel, a whimsical caricatured camel, as a marketing campaign in 1988. See Stuart Elliot, *The Media Business: Advertising; Camel's Success and Controversy*, N.Y. TIMES, Dec. 12, 1991, available at <http://www.nytimes.com/1991/12/12/business/the-media-business-advertising-camel-s-success-and-controversy.html> [hereinafter Elliot, *Camel's Success and Controversy*]. However, despite its widespread success, the Joe Camel campaign was retired in 1997 amid great controversy—a large consensus believed Joe Camel was intended to, and did, target and encourage children to smoke. See Stuart Elliot, *Joe Camel, a Giant in Tobacco Marketing, Is Dead at 23*, N.Y. TIMES, July 11, 1997, available at <http://www.nytimes.com/1997/07/11/business/joe-camel-a-giant-in-tobacco-marketing-is-dead-at-23.html?pagewanted=all&src=pm> [hereinafter Elliot, *Dead at 23*]; Elliot, *Camel's Success and Controversy*, *supra*.

² See Elliot, *Camel's Success and Controversy*, *supra* note 1.

³ See *id.*

⁴ See *Joe Camel Ignites Fury by Appearing on Cigarette Pack*, ASSOCIATED PRESS, May 7, 1994, available at <http://www.deseretnews.com/article/351820/JOE-CAMEL-IGNITES-FURY-BY-APPEARING-ON-CIGARETTE-PACK.html?pg=all>.

caps, t-shirts, and lighters⁵—Joe was catapulted into the public spotlight and instant stardom. In fact, according to the American Medical Association, at the height of his career, Joe Camel rivaled the iconic Mickey Mouse in recognition among six-year-old children.⁶ However, in 1997, just nine years after beginning at Camel Cigarettes, Joe died of lung cancer at the young age of twenty-three.⁷ Joe was not a smoker, but all of the executives at R.J. Reynolds were.⁸

Unfortunately, Joe's story is not uncommon among Americans. "Cigarette smoking kills an estimated 443,000 Americans," including children, each year.⁹ In fact, in the United States, cigarette smoking is the foremost cause of preventable death and disease,¹⁰ resulting in more annual deaths than "AIDS, alcohol, illegal drug use, homicide, suicide, and motor vehicle crashes combined."¹¹ For instance, "[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."¹² Furthermore, the negative health

⁵ See Elliot, *Dead at 23*, *supra* note 1; Elliot, *Camel's Success and Controversy*, *supra* note 1.

⁶ See Paul M. Fischer et al, *Brand Logo Recognition by Children Aged 3 to 6 Years*, 266(22) JAMA 3145, 3147–48 (1991), available at <http://legacy.library.ucsf.edu/documentStore/m/z/w/mzw84f00/Smzw84f00.pdf>.

⁷ See Elliot, *Dead at 23*, *supra* note 1.

⁸ This is a dramatization. There is neither evidence nor intended truth surrounding this statement.

⁹ See Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,525 (Nov. 12, 2010) (to be codified at 21 C.F.R. § 1141 (2011)) [hereinafter Proposed Rule] (FDA proposing thirty-six graphic labels and eight textual warnings for public comment) (citing Centers for Disease Control and Prevention, *Smoking-Attributable Mortality, Years of Potential Life Lost, and Productivity Losses—United States, 2000–2004*, 57(45) MMWR 1226–1228 (Nov. 14, 2008), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5745a3.htm>).

¹⁰ See *id.* at 69,526 (citing U.S. DEP'T OF HEALTH AND HUMAN SERVS., THE HEALTH CONSEQUENCES OF SMOKING, A REPORT OF THE SURGEON GENERAL (2004), available at <http://www.surgeongeneral.gov/library/smokingconsequences/index.html>).

¹¹ See *id.* (citing Centers for Disease Control and Prevention, *Surveillance for Cancers Associated with Tobacco Use—United States, 1999–2004*, 57(SS08) MMWR 1–33 (Sept. 5, 2008), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5708a1.htm>).

¹² R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1224 (D.C. Cir. 2012) (Rogers, J., dissenting) (quoting Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2(2), 123 Stat. 1776, 1777 (2009) (codified at 21

effects of smoking are not limited to smokers, but also plague nonsmokers who inhale secondhand smoke.¹³ However, despite the fact that smoking cessation has been shown to prevent and even reverse these adverse health effects to a certain extent,¹⁴ approximately one-fifth of Americans are cigarette smokers¹⁵—perhaps partly due to the consensus within the scientific and medical communities that “[n]icotine is an addictive drug.”¹⁶

Accordingly, in 2009, Congress passed the Family Smoking Prevention and Tobacco Control Act (“Smoking Act”), granting the Federal Drug Administration (“FDA”), for the first time, the authority to regulate cigarettes.¹⁷ The Smoking Act was in response to scientific research indicating that current cigarette warning labels are ineffective.¹⁸ Specifically, after observing the adoption of pictorial cigarette warnings worldwide,¹⁹ the FDA concluded that larger prominent warnings, with pictures, “are more likely to be noticed, communicate information about health risks to consumers, and reinforce intentions among tobacco users who want to quit.”²⁰

U.S.C § 387 Note (2011) [hereinafter Smoking Act]) (alteration in original) (internal quotation marks omitted); *see also* Proposed Rule, 75 Fed. Reg. at 69,527–29 (collecting scientific evidence).

¹³ *See* Proposed Rule, 75 Fed. Reg. at 69,527 (citing Centers for Disease Control and Prevention, *supra* note 9).

¹⁴ *See id.* at 69,529.

¹⁵ *See id.* at 69,526 (collecting scientific evidence).

¹⁶ *Reynolds*, 696 F.3d at 1224 (Rogers, J., dissenting) (quoting the Smoking Act § 2(3), 123 Stat. at 1777 (codified at 21 U.S.C § 387 Note (2011))) (internal quotation marks omitted); *see also* Proposed Rule, 75 Fed. Reg. at 69,528–29 (collecting scientific evidence).

¹⁷ Smoking Act § 3(1), § 201(a) (codified at 15 U.S.C. § 1333 (2006 & Supp. 2009)).

¹⁸ *See* Proposed Rule, 75 Fed. Reg. at 69,529–31.

¹⁹ *See id.* at 69,525, 69,531–33. “Countries/jurisdictions that have implemented pictorial warning requirements for tobacco packaging include: Australia; Belgium; Brazil; Brunei; Canada; Chile; Colombia; Cook Islands; Djibouti; Egypt; Hong Kong; India; Iran; Jordan; Latvia; Malaysia; Mauritius; Mexico; Mongolia; New Zealand; Pakistan; Panama; Paraguay; Peru; Romania; Singapore; Switzerland; Taiwan; Thailand; Turkey; United Kingdom; Uruguay; and Venezuela.” *Id.* at 69,525 n.4. “Countries/jurisdictions with pending requirements include: France; Guernsey, Honduras; Malta; Norway; Philippines; and Spain.” *Id.*

²⁰ *Id.* at 69,529 (citing Centers for Disease Control and Prevention, *Health Warnings on Tobacco Products—Worldwide*, 2007, 58(19) MMWR 528–29 (May 22, 2009))

Pursuant to the Smoking Act, the FDA promulgated the Required Warnings for Cigarette Packages and Advertisements (“Final Rule”) in June 2011.²¹ The Final Rule marked the first change to cigarette warnings in the United States in over twenty-five years.²² Unlike previous warnings, the Final Rule requires that one of nine graphic images, in conjunction with nine new textual warnings and a “1-800-QUIT-NOW” telephone number, appear on all cigarette packages.²³ The Final Rule’s nine new warnings include graphic images such as “a man exhaling cigarette smoke through a tracheotomy hole in his throat” and “a plume of cigarette smoke enveloping an infant.”²⁴ Furthermore, unlike previous warnings, the Final Rule’s warnings are not to appear on the sides of tobacco packages, but instead purport to cover the top fifty percent of the front and back panels of all cigarette packs.²⁵ Although the Final Rule was supposed to take effect in September 2012,²⁶ challenges to its constitutionality have halted its applicability.

As of this Note’s publication, four courts (“Four Decisions”) have addressed whether the government’s requiring graphic warning labels on cigarette packaging violates the tobacco companies’ freedom of speech protected under the First

available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5819a3.htm>); see also *id.* at 69,531–35 (collecting scientific evidence).

²¹ Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,628–29 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2011)) [hereinafter Final Rule].

²² See *id.*; Proposed Rule, 75 Fed. Reg. at 69,529; Kristin M. Sempeles, Comment, *The FDA’s Attempt to Scare the Smoke out of You: Has the FDA gone too far with the Nine Cigarette Warning Labels?*, 117 PENN ST. L. REV. 223, 223 (2012).

²³ Compare Final Rule, 76 Fed. Reg. at 36,648–57, and 36,681, with Comprehensive Smoking Education Act, Pub. L. No. 98-474, § 4(a), 98 Stat. 2200, 2201–03 (1984) (codified as amended at 15 U.S.C. § 1331 (1994)) [hereinafter CSEA].

²⁴ *R.J. Reynolds Tobacco Co. v. United States Food and Drug Admin.*, 823 F. Supp. 2d 41 (D.D.C. 2011) (citing Plaintiff’s Complaint ¶¶ 57, 59); see also *infra* Part I.A.3.

²⁵ Compare Final Rule, 76 Fed. Reg. at 36,674, with CSEA § 4(a), and Proposed Rule 75 Fed. Reg. at 69,529; see also Stephanie J. 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, 1912 (2012).

²⁶ See Final Rule, 76 Fed. Reg. at 36,628–29.

Amendment.²⁷ In *Discount Tobacco City & Lottery v. United States*, the Sixth Circuit affirmed the district court's ruling, holding that the new size and placement requirements and the inclusion of graphic images on cigarette warning labels are constitutional.²⁸ Furthermore, though the tobacco industry appealed the Sixth Circuit's ruling following a denied request for rehearing and rehearing en banc,²⁹ the Supreme Court subsequently denied the appellants' petition for certiorari.³⁰ However, in *R.J. Reynolds Tobacco Co. v. Food & Drug Administration*, the D.C. Circuit affirmed the district court's ruling, holding that the FDA's nine selected images render the Final Rule's cigarette warning labels unconstitutional.³¹ Thus, the D.C. Circuit vacated the FDA's Final Rule and remanded it to the agency.³²

Following the D.C. Circuit's ruling, and a subsequent denied request for rehearing and rehearing en banc,³³ the FDA declined to

²⁷ See *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012); *Disc. Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012); *R.J. Reynolds Tobacco Co. v. United States Food and Drug Admin.*, 845 F. Supp. 2d 266 (D.D.C. 2011); *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010).

²⁸ Compare *Disc. Tobacco*, 674 F.3d at 561–565, with *Commonwealth Brands*, 678 F. Supp. 2d at 512.

²⁹ See Petition for Writ of Certiorari, *Am. Snuff Co. v. United States*, 133 S. Ct. 1996 (2013) (No. 12–521), available at <http://www.natocentral.org/wp-content/uploads/2012/11/Petition-for-Writ-of-Certiorari-to-U.S.-Supreme-Court.pdf>; Brent Kendall & Jennifer Corbett Dooren, *Tobacco Industry's Challenge to Law Requiring Graphic Labels is Rejected*, WALL ST. J. (Apr. 22, 2013, 3:14 PM), <http://online.wsj.com/article/SB10001424127887323735604578438594078101904.html>.

³⁰ See Petition for Writ of Certiorari Denied, *Am. Snuff Co. v. United States*, 133 S. Ct. 1996 (2013) (No. 12–521); Kendall & Dooren, *Tobacco Industry's Challenge to Law Requiring Graphic Labels is Rejected*, *supra* note 29.

³¹ Compare *Reynolds*, 696 F.3d at 1208, with *Reynolds*, 845 F. Supp. 2d at 268.

³² *Reynolds*, 696 F.3d at 1222.

³³ See Appellants' Petition for Rehearing and Rehearing En Banc Denied, *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, Nos. 11–5332, 12–5063 (D.C. Cir. 2012), available at http://www.library.ucsf.edu/sites/all/files/ucsf_assets/order%20denying%20en%20banc.pdf; Gavin Broady, *DC Circ. Won't Rehear Tobacco Warning Label Case*, LAW360 (Dec. 5, 2012, 1:36 PM), <http://www.law360.com/articles/399045/dc-circ-won-t-rehear-tobacco-warning-label-case>; see also Appellants' Petition for Rehearing and Rehearing En Banc, *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, Nos. 11–5332, 12–5063 (D.C. Cir. 2012), 2012 WL 4844135.

appeal to the Supreme Court.³⁴ Instead, the FDA intends to conduct additional research and create new graphic images for inclusion on cigarette warnings labels.³⁵ In creating these new labels, the FDA may look to the Four Decisions for guidance in determining the constitutional parameters for selecting new graphic images. Additionally, future courts will look to the Four Decisions in resolving any prospective challenges to the constitutionality of the FDA's redesigned warnings. However, these cases provide little guidance on the issue as both districts and both circuits are respectively split and employ differing constitutional standards of review.³⁶ Furthermore, each respective circuit is internally split 2–1 in both its ruling and adopted constitutional standard of review.³⁷

³⁴ See Letter from Attorney General Holder to Speaker Boehner (Mar. 15, 2013), available at <http://www.regulationonline.net/chapters/reg-ch7/fda-warnings> (outlining the FDA's intended course of action); Steve Almasy, *FDA Changes Course on Graphic Warning Labels for Cigarettes*, CNN (Mar. 20, 2013, 9:04 AM), <http://www.cnn.com/2013/03/19/health/fda-graphic-tobacco-warnings>.

³⁵ See Letter from Attorney General Holder to Speaker Boehner, *supra* note 34 (outlining the FDA's intended course of action); Almasy, *FDA Changes Course on Graphic Warning Labels for Cigarettes*, *supra* note 34.

³⁶ See *Reynolds*, 696 F.3d at 1217 (applying “intermediate scrutiny” to hold the graphic warning labels unconstitutional); *Disc. Tobacco City & Lottery v. United States*, 674 F.3d 509, 561–65 (6th Cir. 2012) (applying “rational-basis” review to hold the graphic warning labels constitutional); *Reynolds*, 845 F. Supp. 2d 266, 276–277 (applying “strict scrutiny” to hold the graphic warning labels unconstitutional); *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 520–21, 541 (W.D. Ky. 2010) (applying “intermediate scrutiny” to hold the graphic warning labels constitutional). See generally *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985); *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980); *Wooley v. Maynard*, 430 U.S. 705 (1977).

³⁷ Compare *Reynolds*, 696 F.3d at 1217 (majority applying “intermediate scrutiny” to hold the graphic warning labels unconstitutional), *with id.* at 1222–23, 1237–38 (Rogers, J., dissenting) (dissent applying “rational-basis” review to hold the graphic warning labels constitutional), *id.* at 1237–38 (Rogers, J., dissenting) (dissent holding the graphic warning labels also withstand “intermediate scrutiny”), *and id.* at 1234, 1236–38 (Rogers, J., dissenting) (dissent applying “intermediate scrutiny” to hold the “1–800–QUIT–NOW” telephone number unconstitutional); compare *Disc. Tobacco*, 674 F.3d at 561–65 (majority applying “rational-basis” review to hold the graphic warning labels constitutional), *with id.* at 522–31 (Clay, J., dissenting), 568 (dissent merging “intermediate scrutiny” and “rational-basis” reviews to hold the graphic warning labels, excluding the size and position requirements, unconstitutional). See generally *Zauderer*, 471 U.S. at 626; *Cent. Hudson*, 447 U.S. at 557; *Wooley*, 430 U.S. at 705.

Accordingly, in an attempt to clarify the constitutionality of the FDA's previous and impending graphic cigarette warning labels, this Note will analyze and attempt to resolve the Four Decisions' divergent holdings regarding the Smoking Act and the FDA's Final Rule. Specifically, Part I of this Note will discuss the legislative background surrounding the Smoking Act and the Final Rule, as well as provide an overview of the legal background concerning the free Speech and commercial speech doctrines. Next, Part II will outline the current circuit split between the Sixth and D.C. Circuits, and identify the differing constitutional standards of review the Four Decisions employ.

Contrary to the Four Decisions,³⁸ Part III will then propose that a "rational-basis" and "intermediate scrutiny" hybrid is the applicable standard of review, and, in an abundance of caution, include an analysis of the Final Rule's constitutionality under "strict scrutiny," "intermediate scrutiny," and "rational-basis" reviews. Finally, this Note will conclude that, except for its nine textual warnings, the Final Rule fails to pass constitutional muster under all three constitutional standards of review, and will suggest how new graphic warning labels can circumvent the Final Rule's constitutional pitfalls.

Thus, this Note will conclude that if a picture is worth a thousand words, then the Final Rule's graphic warning labels are worth a thousand words that violate free speech.

³⁸ See *Reynolds*, 696 F.3d at 1217 (applying "intermediate scrutiny" to hold the graphic warning labels unconstitutional); *Disc. Tobacco*, 674 F.3d 509, 561–65 (applying "rational-basis" review to hold the graphic warning labels constitutional); *Reynolds*, 845 F. Supp. 2d 266, 276–277 (applying "strict scrutiny" to hold the graphic warning labels unconstitutional); *Commonwealth Brands*, 678 F. Supp. 2d 512, 520–21, 541 (applying "intermediate scrutiny" to hold the graphic warning labels constitutional). See generally *Zauderer*, 471 U.S. at 626; *Cent. Hudson*, 447 U.S. at 557; *Wooley*, 430 U.S. at 705.

I. BACKGROUND

A. *Legislative Background—The FDA’s Attempt to Foster Smoking Abstinence*

1. Current Cigarette Warning Labels

In response to the Surgeon General’s landmark report on smoking and health in 1964,³⁹ Congress passed the Federal Cigarette Labeling and Advertising Act of 1965.⁴⁰ This legislation required, for the first time, that a printed warning appear on all cigarette packages to warn consumers of the potential hazards of cigarette smoking.⁴¹ The warning, which was required to be conspicuous and legible, was displayed in small print on one of the side panels of cigarette packages.⁴² The warning read, “CAUTION: Cigarette Smoking May Be Hazardous to Your Health.”⁴³ This language appeared on all cigarette packages sold from January 1, 1966, through October 31, 1970.⁴⁴

Subsequently, in 1969, Congress passed the Public Health Cigarette Smoking Act,⁴⁵ which slightly modified the warning statements on cigarette packs.⁴⁶ The new warning language read, “Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health.”⁴⁷ This label appeared on

³⁹ See Proposed Rule, 75 Fed. Reg. 69,254, 69,525 (Nov. 12, 2010) (to be codified at 21 C.F.R. § 1141 (2011)) (“In 1964, the Surgeon General of the Public Health Service issued the landmark report titled ‘Smoking and Health,’ which comprehensively assessed the available scientific evidence relating to the health effects of cigarette smoking”); see also *id.* at 69,529. The report concluded that cigarette smoking is a health hazard of sufficient importance in the United States, and that appropriate remedial action was warranted. See *id.* at 69,525.

⁴⁰ Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965) (codified as amended at 15 U.S.C. §§ 1331–41 (1970)) [hereinafter FCLAA]; see also Proposed Rule, 75 Fed. Reg. at 69,529.

⁴¹ FCLAA § 4; see also Proposed Rule, 75 Fed. Reg. at 69,525.

⁴² See FCLAA § 4; see also Proposed Rule, 75 Fed. Reg. at 69,529.

⁴³ FCLAA § 4; see also Proposed Rule, 75 Fed. Reg. at 69,529–30.

⁴⁴ See Proposed Rule, 75 Fed. Reg. at 69,530.

⁴⁵ Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (1970) (codified as amended at 15 U.S.C. §§ 1331–41 (2006)) [hereinafter PHCSA].

⁴⁶ *Id.* § 4; see also Proposed Rule, 75 Fed. Reg. at 69,530.

⁴⁷ PHCSA § 4; see also Proposed Rule, 75 Fed. Reg. at 69,530.

all cigarette packages sold in the United States from November 1, 1970, through October 11, 1985.⁴⁸

Finally, in 1984, Congress passed the Comprehensive Smoking Education Act of 1984,⁴⁹ again modifying the cigarette warnings to their present state.⁵⁰ This legislation required that four new rotational⁵¹ health warnings be placed on all cigarette packages and cigarette advertisements.⁵² The four warnings read: (1) “SURGEON GENERAL’S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, and May Complicate Pregnancy;” (2) “SURGEON GENERAL’S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health;” (3) “SURGEON GENERAL’S WARNING: Smoking by Pregnant Women May Result in Fetal Injury, Premature Birth and Low Birth Weight;” and (4) “SURGEON GENERAL’S WARNING: Cigarette Smoke Contains Carbon Monoxide.”⁵³ These are the warning labels currently required on cigarette packages.⁵⁴

2. The Family Prevention and Tobacco Control Act

In light of the superiority of international pictorial warning labels over America’s textual warning labels,⁵⁵ Congress passed the Family Prevention and Tobacco Control Act (“Smoking Act”) in 2009.⁵⁶ The Smoking Act, for the first time, granted the FDA the authority to regulate the manufacture and sale of tobacco products in order “to promote cessation [of tobacco use] to reduce

⁴⁸ See Proposed Rule, 75 Fed. Reg. at 69,530.

⁴⁹ 15 U.S.C. §§ 1331–41 (1994).

⁵⁰ 15 U.S.C. § 1333; see also Proposed Rule, 75 Fed. Reg. at 69,530.

⁵¹ The Comprehensive Smoking Education Act mandated that the four warnings be rotated quarterly in alternating sequence to prevent the warnings from becoming stale. 15 U.S.C. § 1333(c)(2); see also Proposed Rule, 75 Fed. Reg. at 69,530.

⁵² See 15 U.S.C. § 1333(a)(1), § 1333(b)(1); see also Proposed Rule, 75 Fed. Reg. at 69,530.

⁵³ See 15 U.S.C. § 1333(a)(1); see also Proposed Rule, 75 Fed. Reg. at 69,530.

⁵⁴ See Proposed Rule, 75 Fed. Reg. at 69,530.

⁵⁵ See *id.* at 69,531–35 (collecting scientific evidence).

⁵⁶ Smoking Act, Pub. L. No. 111-31, 123 Stat. 1776 (codified in part at 21 U.S.C. § 301 Note, § 331 Note, § 333 Note, § 387, §§ 387(a)–(u), § 387(a)–(I), § 387(c) Note, § 391, §§ 392 and Note, §§ 393–399(a) (2011), and codified in part at 15 U.S.C. §§ 1333 and Note, § 4402 Note (2006 & Supp. 2009)).

disease risk and the social costs associated with tobacco-related diseases.”⁵⁷

Under the Smoking Act, all cigarette packages must include one of the following nine new textual warnings: (1) “Cigarettes are addictive;” (2) “Tobacco smoke can harm your children;” (3) “Cigarettes cause fatal lung disease;” (4) “Cigarettes cause cancer;” (5) “Cigarettes cause strokes and heart disease;” (6) “Smoking during pregnancy can harm your baby;” (7) “Smoking can kill you;” (8) “Tobacco smoke causes fatal lung disease in nonsmokers;” or (9) “Quitting smoking now greatly reduces serious risks in your health.”⁵⁸ Additionally, the Smoking Act specifies that the labels “shall comprise the top 50 percent of the front and rear panels of the package” and that the word “WARNING” should appear in capital letters in seventeen-point font.⁵⁹ Finally, the Smoking Act requires that “color graphics depicting the negative health consequences of smoking” must accompany the textual warnings.⁶⁰

3. The Required Warnings for Cigarette Packages and Advertisements Rule

Pursuant to the Smoking Act, the FDA submitted a proposed rule for public comment on November 12, 2010,⁶¹ and subsequently published a Final Rule on June 22 2011.⁶² Under the Final Rule, one of nine graphic images is required to appear on all cigarette packages, along with one of the Smoking Act’s nine

⁵⁷ Disc. *Tobacco City & Lottery v. United States*, 674 F.3d 509, 520 (6th Cir. 2012) (quoting the Smoking Act § 3(9) (codified at 21 U.S.C § 387 Note (2011))) (alteration in original) (internal quotation marks omitted); Smoking Act § 3(1) (codified at 21 U.S.C § 387 Note (2011)); *see also* *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1208 (D.C. Cir. 2012).

⁵⁸ Smoking Act § 201(a) (codified at 15 U.S.C. § 1333(a)(1) (2006 & Supp. 2009)).

⁵⁹ *Id.* at § 201(a), 123 Stat. 1843 (codified at 15 U.S.C. § 1333(a)(2) (2006 & Supp. 2009)).

⁶⁰ *Id.* at § 201(a), 123 Stat. 1845 (codified at 15 U.S.C. § 1333(d) (2006 & Supp. 2009)).

⁶¹ Proposed Rule, 75 Fed. Reg. 69,525 (Nov. 12, 2010) (to be codified at 21 C.F.R. § 1141 (2011)).

⁶² Final Rule, 76 Fed. Reg. 36,628 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2011)).

new specified textual warnings⁶³ and a “1-800-QUIT-NOW” telephone number.⁶⁴ The nine different warning labels are to rotate in publication according to an agency-approved plan.⁶⁵

The Final Rule’s nine graphic warnings include color images of: (1) “a man exhaling cigarette smoke through a tracheotomy hole in his throat,” paired with the text “Warning: Cigarettes are addictive;”⁶⁶



(2) “a plume of cigarette smoke enveloping an infant receiving a kiss from his or her mother,” paired with the text “Warning: Tobacco Smoke Can Harm Your Children;”⁶⁷

⁶³ *Id.* at 36,648–57.

⁶⁴ *Id.* at 36,681.

⁶⁵ See Smoking Act, Pub. L. No. 111-31, § 201(a), 123 Stat. 1776, 1844 (codified at 15 U.S.C. § 1333(c)(2) (2006 & Supp. 2009)); see also *R.J. Reynolds Tobacco Co. v. United States Food and Drug Admin.*, 845 F. Supp. 2d 266, 270 (D.D.C. 2011).

⁶⁶ *R.J. Reynolds Tobacco Co. v. United States Food and Drug Admin.*, 823 F. Supp. 2d 41 (D.D.C. 2011) (citing Plaintiffs’ Complaint ¶¶ 57, 59); Final Rule, 76 Fed. Reg. at 36,657; *Overview: Cigarette Health Warnings*, U.S. FOOD AND DRUG ADMIN. (May 15, 2013) (last visited July 29, 2013) (displaying the nine graphic images), <http://www.fda.gov/TobaccoProducts/Labeling/ucm259214.htm>.

⁶⁷ *Reynolds*, 823 F. Supp. 2d at 41 (citing Plaintiffs’ Complaint ¶¶ 57, 59); Final Rule, 76 Fed. Reg. at 36,659; *Overview: Cigarette Health Warnings*, *supra* note 66 (displaying the nine graphic images).



(3) “a pair of diseased lungs next to a pair of healthy lungs,” paired with the text “Warning: Cigarettes cause fatal lung disease;”⁶⁸



(4) “a diseased mouth afflicted with what appears to be cancerous lesions,” paired with the text “Warning: Cigarettes cause cancer;”⁶⁹

⁶⁸ *Reynolds*, 823 F. Supp. 2d at 41 (citing Plaintiffs’ Complaint ¶¶ 57, 59); Final Rule, 76 Fed. Reg. at 36,660; *Overview: Cigarette Health Warnings*, *supra* note 66 (displaying the nine graphic images).

⁶⁹ *Reynolds*, 823 F. Supp. 2d at 41 (citing Plaintiffs’ Complaint ¶¶ 57, 59); Final Rule, 76 Fed. Reg. at 36,662; *Overview: Cigarette Health Warnings*, *supra* note 66 (displaying the nine graphic images).



(5) “a man breathing into an oxygen mask,” paired with the text “Warning: Cigarettes cause strokes and heart disease;”⁷⁰



(6) “a stylized cartoon (as opposed to a staged photograph) of a premature baby in an incubator,” paired with the text “Warning: Smoking During Pregnancy Can Harm Your Baby;”⁷¹

⁷⁰ *Reynolds*, 823 F. Supp. 2d at 41 (citing Plaintiffs’ Complaint ¶¶ 57, 59); Final Rule, 76 Fed. Reg. at 36,664; *Overview: Cigarette Health Warnings*, *supra* note 66 (displaying the nine graphic images).

⁷¹ *Reynolds*, 823 F. Supp. 2d at 41 (citing Plaintiffs’ Complaint ¶¶ 57, 59); Final Rule, 76 Fed. Reg. at 36,665; *Overview: Cigarette Health Warnings*, *supra* note 66 (displaying the nine graphic images).



(7) “a bare-chested male cadaver lying on a table, and featuring what appears to be post-autopsy chest staples down the middle of his torso,” paired with the text “Warning: Smoking can kill you;”⁷²



(8) “a woman weeping uncontrollably,” paired with the text “Warning: Tobacco smoke causes fatal lung disease in nonsmokers;”⁷³

⁷² *Reynolds*, 823 F. Supp. 2d at 41–42 (citing Plaintiffs’ Complaint ¶¶ 57, 59); Final Rule, 76 Fed. Reg. at 36,665; *Overview: Cigarette Health Warnings*, *supra* note 66 (displaying the nine graphic images).

⁷³ *Reynolds*, 823 F. Supp. 2d at 42 (citing Plaintiffs’ Complaint ¶¶ 57, 59); Final Rule, 76 Fed. Reg. at 36,667; *Overview: Cigarette Health Warnings*, *supra* note 66 (displaying the nine graphic images).



and (9) “a man wearing a t-shirt that features a ‘no smoking’ symbol and the words ‘I Quit,’” paired with the text “Warning: Quitting smoking now greatly reduces serious risk to your health.”⁷⁴



The FDA selected these nine graphic images due to their superior salience (i.e., noticeability and readability) and ability to depict the negative health consequences of smoking.⁷⁵ Furthermore, the FDA believes that these images are consistent

⁷⁴ *Reynolds*, 823 F. Supp. 2d at 42 (citing Plaintiffs’ Complaint ¶¶ 57, 59); Final Rule, 76 Fed. Reg. at 36,669; *Overview: Cigarette Health Warnings*, *supra* note 66 (displaying the nine graphic images).

⁷⁵ *See* Final Rule, 76 Fed. Reg. at 36,648–57, 36,637–38, 36,696; Proposed Rule, 75 Fed. Reg. 69,524, 69,531 (Nov. 12, 2010) (to be codified at 21 C.F.R. § 1141 (2011)).

with the types of pictorial warnings required or developed by other international governments, such as Canada, the European Union, and Australia, whose “sets of warnings include a balance of images, some more visually disturbing than others.”⁷⁶ The FDA also believes that “including a varied set of warnings is consistent with the existing scientific literature concerning the effectiveness of graphic health warnings.”⁷⁷

The Final Rule’s new graphic warnings were scheduled to take effect for all cigarette packages manufactured on or after September 2012,⁷⁸ but challenges to its constitutionality have halted its applicability.⁷⁹ Though the FDA intends to conduct additional research and redesign the Final Rule’s graphic warnings,⁸⁰ this Note will, nevertheless, proceed with an evaluation of the Rule’s present constitutionality; such will aid the FDA and future courts in determining the constitutionality of prospective graphic cigarette warning labels.

B. Legal Background—The Free Speech and Commercial Speech Doctrines

Both the right to speak freely and the right to refrain from speaking are “complementary components of the broader concept of individual freedom of mind” protected under the First Amendment.⁸¹ This protection includes any governmental attempt “to compel individuals to express certain views”⁸² or “to subsidize speech to which they object.”⁸³ Additionally, this protection “applies not only to expressions of value, opinion, or endorsement,

⁷⁶ Proposed Rule, 75 Fed. Reg. at 69,534.

⁷⁷ *Id.*

⁷⁸ See Final Rule, 76 Fed. Reg. at 36,628.

⁷⁹ See discussion, *infra* Part II.

⁸⁰ See Letter from Attorney General Holder to Speaker Boehner, *supra* note 34 (outlining the FDA’s intended course of action); Almsy, *FDA Changes Course on Graphic Warning Labels for Cigarettes*, *supra* note 34.

⁸¹ *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1211 (D.C. Cir. 2012) (quoting *Wooley v. Maynard*, 430 U.S. 705, 714 (1977)) (internal quotation marks omitted).

⁸² *Id.* (quoting *Wooley v. Maynard*, 430 U.S. 705, 714–15 (1977)).

⁸³ *Id.* (quoting *United States v. United Foods, Inc.*, 533 U.S. 405, 410–11 (2001)).

but equally to statements of fact the speaker would rather avoid.”⁸⁴ “This holds true whether individuals”⁸⁵ or “corporations are being compelled to speak.”⁸⁶ Furthermore, this First Amendment protection also applies to commercial speech, including tobacco advertising,⁸⁷ with “commercial illustrations [being] entitled to the [same] First Amendment protections afforded to verbal commercial speech.”⁸⁸

However, there are instances when the government is permitted to infringe on one’s First Amendment rights.⁸⁹ This is true particularly for commercial speech, which the Supreme Court held is subject to less robust protection than other forms of speech—such as religious or political speech.⁹⁰ In determining whether the government is permitted to infringe on one’s freedom of speech, the Supreme Court continuously acknowledges the importance of balancing the First Amendment with the public’s right to be

⁸⁴ *Id.* (quoting *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Bos.*, 515 U.S. 557, 573–74 (1995)) (internal quotation mark omitted).

⁸⁵ *Id.* (quoting *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 642 (1943)).

⁸⁶ *Id.* (quoting *Pac. Gas & Elec. Co. v. Pub. Utils. Comm’n*, 475 U.S. 1, 16 (1986) (plurality opinion)).

⁸⁷ *See Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 527–28 (2001) (“the First Amendment protects the [tobacco advertisements] [] of petitioners”); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 761–762 (1976) (“[S]peech does not lose its First Amendment protection because money is spent to project it, as in a paid advertisement of one form or another.”) (citations omitted); *Sempeles*, *supra* note 22, at 239 n.155 (citing *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 500 n.10 (1996) (“[E]ven though ‘commercial’ speech is involved, such a regulation strikes at the heart of the First Amendment.”) (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 574 (1980)) (internal quotation marks omitted)).

⁸⁸ *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 638 (1985).

⁸⁹ *See id.*

⁹⁰ *See id.* at 651 (“Ohio has not attempted to ‘prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion’”); *Cent. Hudson*, 447 U.S. at 562–63 (1980) (citation omitted) (“The Constitution therefore accords a lesser protection to commercial speech than to other constitutionally guaranteed expression.”); *Reynolds*, 696 F.3d at 1212 (quoting *Turner Broad. Sys., Inc. v. FCC*, 512 U.S. 622, 641 (1994) (listing a “handful of ‘narrow and well-understood exceptions’ to the general rule that content-based speech regulations—including compelled speech—are subject to strict scrutiny”)).

informed.⁹¹ Commercial speech can help educate consumers by facilitating the greatest possible dissemination of crucial information.⁹² Compelled commercial disclosures, in particular, enable the government to warn unsuspecting consumers about the potential dangers of various products.⁹³

Accordingly, in addressing these countervailing interests, courts utilize one of three constitutional standards of review to determine whether the government's infringement on free speech violates the First Amendment.⁹⁴ Under the most-exacting *Wooley* "strict scrutiny" standard, the government must demonstrate that "the regulation is narrowly tailored to achieve a compelling governmental interest."⁹⁵ Under *Central Hudson's* "intermediate scrutiny" standard, courts must determine whether: (1) the regulation counteracts speech that is not misleading and concerns a lawful activity; (2) the "governmental interest is substantial;" (3) "the regulation directly advances" the government's interest; and (4) "the regulation is no more than necessary to serve" the government's interest.⁹⁶ Finally, under the least-exacting *Zauderer* "rational-basis" standard, the government's regulation is constitutional if it is "reasonably related to the State's interest in preventing deception of consumers,"⁹⁷ and is not "unjustified or unduly burdensome."⁹⁸

⁹¹ See *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 500 (1996) (weighing the possibility that "a ban on speech could screen from public view the underlying governmental policy") (quoting *Cent. Hudson*, 447 U.S. at 566 n.9); *Sempeles, supra* note 22, at 239 (citation omitted).

⁹² See *Bennett, supra* note 25, at 1915 (citing *Cent. Hudson*, 447 U.S. at 561–62).

⁹³ See *id.* (citing *Zauderer*, 471 U.S. at 641).

⁹⁴ See *Zauderer*, 471 U.S. at 626; *Cent. Hudson*, 447 U.S. at 557; *Wooley v. Maynard*, 430 U.S. 705, 705 (1977).

⁹⁵ *Bennett, supra* note 25, at 1917 (quoting *Wooley*, 430 U.S. at 706) (internal quotation marks omitted).

⁹⁶ *Id.* (quoting *Cent. Hudson*, 447 U.S. at 566) (internal quotation marks omitted).

⁹⁷ *Id.* at 1916–17 (quoting *Zauderer*, 471 U.S. at 651) (internal quotation marks omitted).

⁹⁸ *Zauderer*, 471 U.S. at 651, 653 n.15 (holding the disclosure requirements not unduly burdensome under "rational-basis" review). *But see* *Disc. Tobacco City & Lottery v. United States*, 674 F.3d 509, 525, 566–67 (6th Cir. 2012) (Clay, J., dissenting) (majority opinion differing from the dissent in holding that compelled disclosures may be unjustified or unduly burdensome under "rational-basis" review).

Though these three constitutional standards of review appear to provide straightforward guidance in evaluating the constitutionality of governmental regulations compelling commercial speech disclosures, there has been much confusion and disagreement among courts in determining when a given standard applies.⁹⁹

II. CONFLICT: THE SIXTH AND D.C. CIRCUIT SPLIT

A. *The Sixth Circuit Employs Zauderer’s “Rational-Basis” Standard to Hold the Smoking Act’s Graphic Cigarette Warning Labels Constitutional*

In *Commonwealth Brands, Inc. v. United States*, six tobacco companies¹⁰⁰ brought suit in the Western District of Kentucky against the United States of America and others.¹⁰¹ The suit alleged that provisions of the Smoking Act¹⁰² violate the tobacco companies’ freedom of speech protected under the First

⁹⁹ See, e.g., *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205 (D.C. Cir. 2012) (dividing 2–1 over what commercial speech standard to apply); *Disc. Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012) (dividing 2–1 over what commercial speech standard to apply); *R.J. Reynolds Tobacco Co. v. United States Food and Drug Admin.*, 823 F. Supp. 2d 36, 47–49 (D.D.C. 2011) (applying strict scrutiny to analyze the constitutionality of the Final Rule’s graphic cigarette warning labels); *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 520–21, 541 (W.D. Ky. 2010) (applying *Central Hudson* to analyze the constitutionality of the Smoking Act’s graphic cigarette warning labels). See generally *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985); *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980); *Wooley v. Maynard*, 430 U.S. 705, 706 (1977).

¹⁰⁰ The six tobacco companies included Discount Tobacco City & Lottery, Inc., Lorillard Tobacco Company, National Tobacco Company, L.P., R.J. Reynolds Tobacco Company, Commonwealth Brands, Inc., and Conwood Company, LLC (currently known as American Snuff Company, LLC). See *Disc. Tobacco*, 674 F.3d at 509, 521 n.2; *Commonwealth Brands*, 678 F. Supp. 2d at 512.

¹⁰¹ 678 F. Supp. 2d 512 (W.D. Ky. 2010). The tobacco companies also brought suit against the FDA, Margaret Hamburg (Commissioner of the FDA), and Kathleen Sebelius (Secretary of the United States Department of Health and Human Services). See *id.*

¹⁰² The tobacco companies’ suit was brought over ten months before the FDA proposed any specific graphic images, and over seventeen months before the FDA published its Final Rule identifying the final nine graphic images. See *Disc. Tobacco*, 674 F.3d at 553. Accordingly, the tobacco companies’ suit challenged provisions of the Smoking Act, not the Final Rule. *Commonwealth Brands*, 678 F. Supp. 2d 512, 521.

Amendment.¹⁰³ Specifically, the tobacco companies challenged the Smoking Act's requirement that tobacco manufacturers reserve a significant portion of cigarette packaging for the display of health warnings, including graphic images, intended to illustrate the dangers of smoking.¹⁰⁴

Following the district court's summary judgment ruling in favor of the government,¹⁰⁵ the tobacco companies appealed to the Sixth Circuit.¹⁰⁶ Upon review, the circuit held that the district court erred in applying "intermediate scrutiny."¹⁰⁷ Nevertheless, the circuit employed "rational-basis" review to affirm the district court's ruling.¹⁰⁸ The circuit's dissent found the graphic warning labels, excluding the size and position requirements, unconstitutional under a merged "intermediate scrutiny" and "rational-basis" standard.¹⁰⁹ However, the circuit held that "rational-basis" review, alone, applied because the Smoking Act: (1) compels commercial speech disclosures of factual information, as opposed to compelled commercial speech disclosures of personal or political opinion;¹¹⁰ and (2) seeks to remedy the tobacco companies' "potentially misleading" commercial speech.¹¹¹

¹⁰³ *Commonwealth Brands*, 678 F. Supp. 2d at 521.

¹⁰⁴ *Id.* at 528–32; *see also Disc. Tobacco*, 674 F.3d at 520.

¹⁰⁵ *Commonwealth Brands*, 678 F. Supp. 2d at 541.

¹⁰⁶ *Disc. Tobacco*, 674 F.3d at 518.

¹⁰⁷ *Compare Disc. Tobacco*, 674 F.3d at 558, *with Commonwealth Brands*, 678 F. Supp. 2d at 520–21.

¹⁰⁸ *Compare Disc. Tobacco*, 674 F.3d at 558, *with Commonwealth Brands*, 678 F. Supp. 2d at 512. The circuit's holding was not unanimous, but was split between Judge Stranch, Judge Barrett, and Judge Clay. *Disc. Tobacco*, 674 F.3d at 518, 551–52.

¹⁰⁹ *Disc. Tobacco*, 674 F.3d at 522–31 (Clay, J., dissenting), 568 (dissent merging "intermediate scrutiny" and "rational-basis" reviews to hold the graphic warning labels, minus the size and position requirements, unconstitutional).

¹¹⁰ *Id.* at 555–59 (citing *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1340–41 (2010); *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 650 (1985); *National Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 114 (2d Cir. 2001)) (other internal citations omitted).

¹¹¹ *Id.* at 558 (quoting *Int'l Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 641 (6th Cir. 2010) (holding that "*Zauderer* applies not only when the required disclosure 'targets speech that is *inherently* misleading,' but also 'where, as here, the speech is *potentially* misleading.'")).

In employing “rational-basis” review, the circuit held it undisputed that the textual warnings constitute factual disclosures uncovered through scientific study.¹¹² Additionally, the circuit held that graphic images depicting factual information can¹¹³ constitute factual disclosures¹¹⁴ even if they are intended to “evoke a visceral response that subsumes rationale decision-making.”¹¹⁵ Furthermore, the circuit held that the tobacco companies “knowingly and actively conspired to deceive the public about the health risks and addictiveness of smoking for

¹¹² *Id.* at 568 n.16 (citing the World Health Organization, Report on the Global Tobacco Epidemic 44 (2011)).

¹¹³ Because the tobacco companies’ suit was brought over ten months before the FDA proposed any specific graphic images, and over seventeen months before the FDA published its Final Rule identifying the final nine graphic images, the tobacco companies could not argue that any specific graphic image violated the First Amendment. *See Disc. Tobacco*, 674 F.3d at 553. Rather, the circuit court held that “[w]ithout any specific graphic images to challenge, Plaintiffs’ argument is and must necessarily be that the graphic-warning requirement on its face violates the First Amendment.” *Id.* Accordingly, the circuit ruled that “[b]ecause Plaintiffs bring a facial challenge to the warning requirements, our concern is not the specific images the FDA chose . . . but rather whether Plaintiffs can show that ‘no set of circumstances exists under which [the statute] would be valid, or that the statute lacks any plainly legitimate sweep.’” *United States v. Stevens*, 130 S. Ct. 1577, 1587 (2010) (citations omitted) (internal quotation marks omitted). “To satisfy this burden, Plaintiffs would have to establish that a graphic warning [can never] 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.” *Disc. Tobacco*, 674 F.3d at 559.

¹¹⁴ The circuit court stated that a non-exhaustive list of graphic images that constitute factual disclosures include “a picture or 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; a picture or drawing of a person suffering from a smoking-related medical condition; and any number of pictures consisting of text and simple graphic images.” *Disc. Tobacco*, 674 F.3d at 559. Furthermore, the circuit held that “[t]here is nothing in the graphics-warning provision that forbids the graphics from merely being words. For example, a graphic could consist of one of the required textual warnings— ‘WARNING: Tobacco smoke can harm your children.’—written in what appears to be a child’s handwriting. Such a graphic would clearly be a factual and accurate disclosure that therefore would be scrutinized for a rational basis.” *Id.*

¹¹⁵ *Disc. Tobacco*, 674 F.3d at 560 n.9 (quoting dissent at 529).

decades,”¹¹⁶ and, thus, current cigarette warning labels are “potentially misleading.”¹¹⁷

Finally, the circuit held that there is a “rational connection” between the required textual and graphic warnings’ purpose and the means used to achieve that purpose.¹¹⁸ The circuit ruled that current cigarette warning labels are outdated and fail to effectively convey the risks of smoking.¹¹⁹ Additionally, the circuit held that the Smoking Act’s textual and graphic warnings are better able to promote public understanding of the full dangers of tobacco use.¹²⁰ Moreover, the circuit held that the size and position of these warnings, which cover the top fifty percent of the front and back panels of all cigarette packages, are not unduly burdensome because they help further such understanding.¹²¹ Accordingly, the circuit ruled that the graphic images are “reasonably related” to the warnings’ purpose of preventing consumers from being misled about the health risks of using tobacco, and, thus, are constitutional.¹²²

B. The D.C. Circuit Employs Central Hudson’s “Intermediate Scrutiny” Standard to Hold the Final Rule’s Graphic Cigarette Warning Labels Unconstitutional

In *R.J. Reynolds Tobacco Company v. United States Food and Drug Administration*, five tobacco companies¹²³ brought action in

¹¹⁶ *Id.* at 562 (citing *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1105–08, 1119–20, 1122–24 (D.C. Cir. 2009) (per curiam) (“affirming the district court’s finding of deception for nine tobacco manufacturers—two of whom are plaintiffs in [*Disc. Tobacco*]”).

¹¹⁷ *Id.* at 562–63.

¹¹⁸ *Id.* at 561–62 (citing *National Elec. Mfrs. Ass’n v. Sorrell*, 272 F.3d 104, 115 (2d Cir. 2001)).

¹¹⁹ *Id.* at 563 (collecting scientific evidence).

¹²⁰ *Id.* at 564–66 (collecting scientific evidence).

¹²¹ Smoking Act § 201(a), 123 Stat. 1843 (codified at 15 U.S.C. § 1333(a)(2) (2006 & Supp. 2009)); *Disc. Tobacco*, 674 F.3d at 561, 561 n.10.

¹²² *Disc. Tobacco*, 674 F.3d at 561–62, 565.

¹²³ The five tobacco companies included R.J. Reynolds Tobacco Company, Lorillard Tobacco Company, Commonwealth Brands, Inc., Liggett Group LLC, and Santa Fe Natural Tobacco Company. See *R.J. Reynolds Tobacco Co. v. United States Food and Drug Admin.*, 823 F. Supp. 2d 36 (D.D.C. 2011).

the D.C. District against the FDA and other officials.¹²⁴ The suit challenged the agency's Final Rule¹²⁵ requiring tobacco companies to reserve a significant portion of cigarette packaging for the display of graphic health warnings.¹²⁶ Specifically, the tobacco companies alleged that the Final Rule's graphic warnings unconstitutionally compel speech,¹²⁷ and, thus, violate the First Amendment.¹²⁸

Following the district court's preliminary injunction¹²⁹ and subsequent summary judgment¹³⁰ orders in favor of the tobacco companies, the FDA appealed to the D.C. Circuit.¹³¹ Upon review, the D.C. Circuit held that the district court erred in applying strict

¹²⁴ *Id.* The tobacco companies also brought action against Margaret Hamburg (Commissioner of the FDA) and Kathleen Sebelius (Secretary of the United States Department of Health and Human Services). *See id.*

¹²⁵ This case is distinguishable from *Commonwealth Brands* and *Disc. Tobacco* in that it challenged the FDA's Final Rule. *Compare id.* at 43–44, with *Disc. Tobacco*, 674 F.3d at 521, and *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 519 (W.D. Ky. 2010). *See also* discussion, *supra* note 102. As opposed to *Reynolds*, both *Commonwealth Brands* and *Disc. Tobacco* were briefed and decided after the Smoking Act was passed, but before the FDA's Final Rule was promulgated. *See Reynolds*, 823 F. Supp. 2d at 44 n.17 (citing Plaintiffs' Complaint ¶ 24 n.3; Defendants' Opposition ¶ 14 n.7); *see also Disc. Tobacco*, 674 F.3d at 553; discussion, *supra* note 102. Thus, the plaintiffs in *Disc. Tobacco* and *Commonwealth Brands* were incapable of challenging any of the nine graphic images the FDA ultimately selected. *See Reynolds*, 823 F. Supp. 2d at 44 n.17; *see also Disc. Tobacco*, 674 F.3d at 553; discussion, *supra* note 113. Those plaintiffs, unlike the plaintiffs in this case, were only able to mount a facial challenge to the constitutionality of graphic warnings in general. *See Reynolds*, 823 F. Supp. 2d at 44 n.17; *see also Disc. Tobacco*, 674 F.3d at 553; discussion, *supra* note 113. Accordingly, because this case turned on facts that were not available in *Commonwealth Brands* and *Disc. Tobacco*, it is distinguishable in that "it presents new questions of law and fact—and new applications of law to facts." *Reynolds*, 823 F. Supp. 2d at 44 n.17.

¹²⁶ *Reynolds*, 823 F. Supp. 2d at 43–44 (citing Trial Record at 9:1-3; 10:20-23).

¹²⁷ *Id.* at 44 (citing *Hurley v. Irish-Am. Gay, Lesbian & Bisexual Grp. of Boston, Inc.*, 515 U.S. 557, 573–74 (1995); *Wooley v. Maynard*, 430 U.S. 705, 714 (1977)).

¹²⁸ *Id.* at 44 (citing Trial Record at 10:20-23).

¹²⁹ *Id.* at 39.

¹³⁰ *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 519 (W.D. Ky. 2010).

¹³¹ *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1208 (D.C. Cir. 2012).

scrutiny.¹³² Nevertheless, the circuit employed “intermediate scrutiny” to affirm the district court’s ruling.¹³³

The circuit’s dissent found the graphic warning labels, excluding the “1-800-QUIT-NOW” telephone number, constitutional under “rational-basis” review.¹³⁴ However, the circuit held that “intermediate scrutiny” review applied¹³⁵ because the circuit held that the FDA’s Final Rule: (1) compels commercial speech disclosures of personal opinion, as opposed to commercial speech disclosures of factual information;¹³⁶ and (2) does not seek to remedy any “potentially misleading” commercial speech.¹³⁷ The circuit held that the Final Rule’s graphic images do not depict factual information because they are misleading and subject to misinterpretation.¹³⁸ Additionally, the circuit held that even if cigarette warning labels are considered “potentially misleading” speech, “none of the proposed warnings [remedied such speech because they do not] purport to address the [consumer] information gaps identified by the government.”¹³⁹

In employing “intermediate scrutiny” review, the circuit agreed with the district court that “the Government’s *actual* purpose [in requiring the graphic warning labels] is not to inform or educate, but rather to advocate a change in behavior—specifically to encourage smoking cessation and to discourage potential new

¹³² Compare *id.* at 1217, with *Reynolds*, 845 F. Supp. 2d at 271.

¹³³ *Reynolds*, 696 F.3d at 1221–1222. The circuit’s holding was not unanimous, but was split between Judge Randolph and Judge Brown, and Judge Rogers. *Id.* at 1208, 1222.

¹³⁴ *Id.* at 1222–23, 1237–38 (Rogers, J., dissenting) (dissent applying “rational-basis” review to hold the graphic warning labels constitutional); *id.* at 1234, 1236–38 (Rogers, J., dissenting) (dissent applying “intermediate scrutiny” to hold the “1-800-QUIT-NOW” telephone number unconstitutional); see also *id.* at 1237–38 (Rogers, J., dissenting) (dissent holding the graphic warning labels also withstand “intermediate scrutiny”).

¹³⁵ *Id.* at 1217.

¹³⁶ *Id.* at 1216–17.

¹³⁷ *Id.* at 1213–16.

¹³⁸ *Id.* at 1216–17.

¹³⁹ *Id.* at 1215 n.8.

smokers from starting.”¹⁴⁰ However, unlike the district court, the circuit was uncertain whether the government’s interest in advocating for smoking cessation could constitute a “substantial interest.”¹⁴¹ Accordingly, the circuit proceeded with its analysis under the assumption that promoting smoking cessation is a “substantial interest.”¹⁴²

Even assuming that the government has a “substantial interest” in altering smoking behavior, the circuit held that the FDA provided no evidence that the Final Rule’s graphic warning labels will “directly advance[] the governmental interest” in reducing the number of Americans who smoke, “to a ‘material degree.’”¹⁴³ Thus, the D.C. Circuit held that the Final Rule’s graphic warning labels are unconstitutional.¹⁴⁴

III. ARGUMENT: THE FINAL RULE’S GRAPHIC WARNING LABELS ARE UNCONSTITUTIONAL

A. “Rational-Basis” and “Intermediate Scrutiny” Hybrid is the Applicable Standard of Review

1. “Strict Scrutiny” Review Does Not Apply

In contesting the constitutionality of the Final Rule’s graphic warning labels, the tobacco companies contend that the labels “attempt[] to regulate ‘what shall be orthodox in . . . matters of opinion’—i.e., whether individuals should buy and use a lawful product—[and, thus,] must be subject to strict scrutiny.”¹⁴⁵

¹⁴⁰ R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1208 (D.C. Cir. 2012) (citation omitted); see also *Reynolds*, 696 F.3d at 1218; *Reynolds*, 823 F. Supp. 2d at 47–48.

¹⁴¹ *Reynolds*, 696 F.3d at 1218 n.13.

¹⁴² *Id.* at 1218.

¹⁴³ *Id.* at 1218 (alteration in original) (quoting *Fl. Bar v. Went For It, Inc.*, 515 U.S. 618, 626 (1995); *Cent. Hudson*, 447 U.S. at 566); see also *Reynolds*, 696 F.3d at 1219–21.

¹⁴⁴ *Reynolds*, 696 F.3d at 1222.

¹⁴⁵ *Id.* at 1226 n.5 (Rogers, J., dissenting) (quoting Appellees’ Brief at 31 (quoting *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985))) (internal quotation marks omitted).

However, the Supreme Court has held that “our decisions have recognized ‘the ‘commonsense’ distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech.’”¹⁴⁶ The Constitution therefore affords a lesser protection to commercial speech than to other constitutionally guaranteed expression,¹⁴⁷ such as religious or political speech,¹⁴⁸ except under limited circumstances not here present.¹⁴⁹ Furthermore, the Court held that this distinction—affording lesser constitutional protection to commercial speech than noncommercial speech—applies to both speech restrictions and compelled disclosures.¹⁵⁰

¹⁴⁶ *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 562–63 (1980) (quoting *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 455–456 (1978)) (internal quotation marks omitted).

¹⁴⁷ *Id.*; see also *Cent. Hudson*, 447 U.S. at 566; *Zauderer*, 471 U.S. at 651.

¹⁴⁸ See *Zauderer*, 471 U.S. at 651 (quotation omitted) (“Ohio has not attempted to ‘prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion.’”).

¹⁴⁹ See, e.g., *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 2665 (2011) (applying “strict scrutiny” to a commercial speech regulation imposing “a burden based on the content of speech and the identity of the speaker”); *Brown v. Entm’t Merchs. Ass’n*, 131 S. Ct. 2729, 2733 (2011) (citation omitted) (applying “strict scrutiny” to a commercial speech regulation affixing the number “18” to video games deemed “violent,” holding that “video games communicate ideas—and even social messages—through many familiar literary devices (such as characters, dialogue, plot, and music),” and “‘esthetic and moral judgments about art and literature . . . are for the individual to make, not for the Government to decree, even with the mandate or approval of a majority’”); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 501 (1996) (“[W]hen a State entirely prohibits the dissemination of truthful, nonmisleading commercial messages for reasons unrelated to the preservation of a fair bargaining process, there is far less reason to depart from the rigorous [‘strict scrutiny’] review that the First Amendment generally demands.”); *Pac. Gas & Elec. Co. v. Pub. Utils. Comm’n*, 475 U.S. 1, 9, 10 (1986) (internal citations omitted) (applying “strict scrutiny” to a regulation that “discriminates on the basis of the viewpoints of the selected speakers,” and “extends well beyond speech that proposes a business transaction and includes the kind of discussion of matters of public concern that the First Amendment both fully protects and implicitly encourages”).

¹⁵⁰ See *44 Liquormart*, 517 U.S. at 501 (“When a State regulates commercial messages to protect consumers from misleading, deceptive, or aggressive sales practices, or requires the disclosure of beneficial consumer information, the purpose of its regulation is consistent with the reasons for according constitutional protection to commercial speech and therefore justifies less than strict review.”). Despite the Court’s ruling, the Four Decisions are divided on whether “strict scrutiny,” absent an exception specified,

supra, note 149, applies to commercial speech disclosures. See *Reynolds*, 696 F.3d at 1212 n.5, 1217; *id.* at 1222 (Rogers, J., dissenting); *Disc. Tobacco*, 674 F.3d at 554 (citing *Entm't Software Ass'n v. Blagojevich*, 469 F.3d 641, 651–52 (7th Cir. 2006)); *id.* at 527 (Clay, J., dissenting); *Reynolds*, 845 F. Supp. 2d at 274; *Commonwealth Brands*, 678 F. Supp. 2d at 520, 531. Specifically, the argument posed is that the lesser protection espoused in the Court's distinction—affording lesser constitutional protection to commercial speech than noncommercial speech—refers to “intermediate scrutiny,” which it is argued only applies to the commercial speech restrictions *Central Hudson* addressed. See *Cent. Hudson*, 447 U.S. at 557, 562–63; B. Ashby Hardesty, Jr., Note, *Joe Camel Versus Uncle Sam: The Constitutionality of Graphic Cigarette Warning Labels*, 81 FORDHAM L. REV. 2811, 2848. Thus, according to this view, commercial speech disclosures must be examined under “strict scrutiny,” unless *Zauderer* carves out an exception for utilizing “rational-basis” review. See Hardesty, *supra* note 150, at 2846–2849. However, aside from ignoring *Liquormart's* ruling, this argument must fail on its own face. See *44 Liquormart*, 517 U.S. at 501 and accompanying parenthetical explanation, *supra* note 149. It is true that the Court has never applied “intermediate scrutiny” to compelled disclosures. See Hardesty, *supra* note 150, at 2848. However, the Court never specified *Central Hudson's* contours, nor affirmatively limited its scope to commercial speech restrictions. See *id.* Additionally, the *Zauderer* Court reiterated the commercial versus non-commercial distinction in two separate instances when applying “rational-basis” review to commercial speech disclosures. Compare *Zauderer*, 471 U.S. at 637 (citing *Cent. Hudson*, 447 U.S. at 557) (“There is no longer any room to doubt that what has come to be known as ‘commercial speech’ is entitled to the protection of the First Amendment, albeit to protection somewhat less extensive than that afforded ‘noncommercial speech.’”) (other citations omitted), with *id.* at 638 (citing *Cent. Hudson*, 447 U.S. at 566) (“Our general approach to restrictions on commercial speech is also by now well settled . . . Commercial speech that is not false or deceptive and does not concern unlawful activities, however, may be restricted only in the service of a substantial governmental interest, and only through means that directly advance that interest.”); see also *Fl. Bar v. Went For It, Inc.*, 515 U.S. 618, 623 (1995). Accordingly, it cannot be said that the distinction's first articulation in *Zauderer*, though referencing *Central Hudson*, only referred to commercial speech restrictions for such would render the second articulation, which clearly referred to commercial speech restrictions, superfluous. Rather, in repeating this distinction, the Court must have intended for the first articulation to refer to a general rule that all commercial speech, including disclosures, is subject to lesser constitutional protection than non-commercial speech, and then utilized the second articulation to apply this general rule specifically to commercial speech restrictions. It is further true that the *Milavetz* Court held that “[b]ecause the challenged provisions impose a disclosure requirement rather than an affirmative limitation on speech, . . . the less exacting scrutiny described in *Zauderer* [and not *Central Hudson*] governs our review.” Hardesty, *supra* note 150, at 2848 (quoting *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339 (2010)). However, the Supreme Court has held that “the difference [between compelled speech and compelled silence] is without constitutional significance,” except that “in the context of commercial speech, compulsion to speak may be less violative of the First Amendment than prohibitions on speech and thus trigger a lower level of scrutiny.” *Riley v. Nat'l Fed'n of the Blind of N.C., Inc.*, 487 U.S. 781, 796 (1988); *Reynolds*, 696 F.3d at

None of the Four Decisions' majority opinions, nor any of their dissenting opinions, deny that "[t]he speech at issue—proposing the sale of cigarettes—is indisputably commercial speech."¹⁵¹ In fact, "[t]he tobacco companies [themselves] advance no argument that their cigarette packaging and advertisements propose anything other than a commercial transaction."¹⁵² Accordingly, as the D.C. Circuit's dissent in *Reynolds* stated, "because matters of opinion over whether individuals should buy and use a lawful product fall squarely within the domain of commercial advertising recognized by the Supreme Court, [the Final Rule's graphic warning labels] thereof [are] not, as the [*Reynolds*] district court ruled, subject to strict scrutiny."¹⁵³ Thus, "the question is whether, under the traditional standards adopted by the Supreme Court, the government's [graphic] warning label requirement is subject to the

1227 (Rogers, J., dissenting) (citing *Zauderer*, 471 U.S. at 650–51) (alteration in original). Therefore, *Zauderer* must be viewed as a permissive exception to *Central Hudson*, not a restriction, whereas *Central Hudson* must be viewed as a restriction on *Zauderer*—though one's First Amendment rights are not adequately protected in applying the most lenient "rational-basis" standard to the more violative commercial speech restrictions, applying the more stringent "intermediate scrutiny" standard to the less violative commercial speech disclosures further safeguards those rights (not to mention the government's interests as the alternative argument requires "strict scrutiny" when *Zauderer* is inapplicable). See Hardesty, *supra* note 150, at 2849–2852 (applying "strict scrutiny" to commercial disclosures when *Zauderer* is inapplicable). Thus, *Milavetz* did not hold nor imply that "intermediate scrutiny" cannot apply to commercial speech disclosures where "rational-basis" review is inapplicable (such as where the regulation does not address potentially misleading speech); rather, the Court held that where a regulation does not concern a commercial speech restriction, but a disclosure that falls under *Zauderer*'s ambit, "rational-basis" review takes precedence over "intermediate scrutiny." *Milavetz*, 130 S. Ct. at 1339. Nevertheless, even assuming, *arguendo*, that "strict scrutiny" applies in "intermediate scrutiny's" place, the Final Rule's graphic warning labels do not even withstand the much lower "intermediate scrutiny" and "rational-basis" standards of review. See *infra* Part III.B. Accordingly, this Note will proceed with its analysis under the lower burdens of *Central Hudson* and *Zauderer*. *Cent. Hudson*, 447 U.S. at 566; *Zauderer*, 471 U.S. at 651.

¹⁵¹ *Reynolds*, 696 F.3d at 1217, 1222, 1226 n.5 (Rogers, J., dissenting); *Reynolds*, 845 F. Supp. 2d at 272–74; *Disc. Tobacco*, 674 F.3d at 518, 522, 551–52 (Clay, J., dissenting); *Commonwealth Brands*, 678 F. Supp. 2d at 520–21.

¹⁵² *Reynolds*, 696 F.3d at 1226 n.5 (Rogers, J., dissenting).

¹⁵³ *Id.* (citing *Zauderer*, 471 U.S. at 651; *Cent. Hudson*, 447 U.S. at 562; *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1142–44 (D.C. Cir. 2009)). *But see* discussion, *supra* note 150.

‘less exacting scrutiny’ of *Zauderer* [], or to intermediate scrutiny under *Central Hudson*.”¹⁵⁴

Even assuming, *arguendo*, that the *Reynolds* district court and the comparable Seventh Circuit *Blagojevich* court were correct in applying “strict scrutiny” to the present issue,¹⁵⁵ the Final Rule’s graphic warning labels do not even withstand the much lower “intermediate scrutiny” and “rational-basis” standards of review.¹⁵⁶ Accordingly, this Note will proceed with its analysis under the lower burdens of *Central Hudson* and *Zauderer*.¹⁵⁷

2. “Rational-Basis” Review Only Applies to Four of the Final Rule’s Graphic Images

At first glance, it appears that “rational-basis” review applies to all nine of the Final Rule’s graphic images and textual warnings, and the “1-800-QUIT-NOW” telephone number. For instance, the Supreme Court held that “because the challenged provisions impose a disclosure requirement rather than an affirmative limitation on speech, . . . the less exacting scrutiny described in *Zauderer* governs our review.”¹⁵⁸ According to the Supreme

¹⁵⁴ *Reynolds*, 696 F.3d at 1222 (internal citations omitted) (Rogers, J., dissenting). *But see* discussion, *supra* note 150.

¹⁵⁵ *Entm’t Software Ass’n v. Blagojevich*, 469 F.3d 641, 652 (7th Cir. 2006); *Reynolds*, 823 F. Supp. 2d at 46; *Reynolds*, 845 F. Supp. 2d at 274. *Blagojevich* is comparable to the present issue in that it addressed mandated warning labels affixing the number “18” to video games deemed “sexually explicit.” *Blagojevich*, 469 F.3d at 641. However, *Blagojevich* can be distinguished from the present issue as it “involved labels that were necessarily subjective and exclusively nonfactual.” *Reynolds*, 696 F.3d at 1231 n.9 (Rogers, J., dissenting); *see also Blagojevich*, 469 F.3d at 652 (“The sticker ultimately communicates a subjective and highly controversial message—that the game’s content is sexually explicit.”). Unlike the Final Rule’s warning labels, the very definition of “sexually explicit” is necessarily opinion based, and, thus, *Blagojevich*’s “labels [are] nonfactual because there [are] no facts to convey.” *Reynolds*, 696 F.3d at 1231 n.9 (Rogers, J., dissenting); *infra* text accompanying notes 192–95. Additionally, unlike the present issue, “strict scrutiny” may be applied in *Blagojevich* under the rationale espoused in *Brown*. *See Brown*, 131 S. Ct. at 2733 and accompanying parenthetical explanation, *supra* note 149.

¹⁵⁶ *See infra* Part III.B.

¹⁵⁷ *Cent. Hudson*, 447 U.S. at 566; *Zauderer*, 471 U.S. at 651.

¹⁵⁸ *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339 (2010). The Court’s ruling, however, does not foreclose the application of “intermediate scrutiny” to compelled disclosures. *See supra* note 150.

Court, this is because “disclosure requirements trench much more narrowly on an advertiser’s interests than do flat prohibitions on speech.”¹⁵⁹

It is true that an argument can be made that the size of the warnings—which cover the top fifty percent of the front and back panels of all cigarette packages¹⁶⁰—inhibits the tobacco companies’ ability to add more information or advertisements to the cigarette packages, and, thus, affirmatively limit their speech. However, the tobacco companies have not provided “any evidence that similar restrictions elsewhere have hindered the tobacco companies ability to get their own message to consumers,”¹⁶¹ nor that the tobacco companies would have utilized the confiscated portions to provide additional information or advertisements.¹⁶² Accordingly, it seems clear that the Final Rule’s graphic warning labels do not affirmatively limit free speech, and, thus, should be subject to “rational-basis” review.

However, though the Final Rule’s graphic warning labels appear to only impose disclosure requirements, such, alone, does not meet the Supreme Court’s threshold for applying “rational-basis” review.¹⁶³ In addition to not affirmatively limiting speech,

¹⁵⁹ *Zauderer*, 471 U.S. at 651.

¹⁶⁰ *See* Final Rule, 76 Fed. Reg. 36,628, 36,674 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2011)).

¹⁶¹ *Reynolds*, 696 F.3d at 1233 (Rogers, J., dissenting).

¹⁶² *See Reynolds*, 696 F.3d at 1205; *Disc. Tobacco*, 674 F.3d at 509; *Reynolds*, 845 F. Supp. 2d at 266; *Commonwealth Brands*, 678 F. Supp. 2d at 512. Perhaps an argument can also be made that the Final Rule’s warning labels—which cover the top fifty percent of the front and back panels of all cigarette packages—prevent the tobacco companies from advertising or providing information on the portion of cigarette packages most likely to be seen and read by consumers, and, thus, affirmatively limit and hinder their ability to disseminate information (at least in regard to some consumers who will not read the bottom portions or side panels of cigarette packages). *See* Final Rule, 76 Fed. Reg. at 36,674. However, as stated above, the tobacco companies have not provided “any evidence that similar restrictions elsewhere have hindered the tobacco companies’ ability to get their own message to consumers.” *Reynolds*, 696 F.3d at 1233 (Rogers, J., dissenting). Additionally, because it appears that the Final Rule’s graphic warning labels do not even withstand the less-exacting “rational-basis” standard of review, this Note will proceed with its analysis under the assumption that the warning labels do not affirmatively limit the tobacco companies’ free speech. *See infra* Part III.B.

¹⁶³ *See Zauderer*, 471 U.S. at 651.

the Supreme Court has held that, for *Zauderer* to apply, the regulation must impose compelled disclosures of “purely factual and uncontroversial information.”¹⁶⁴ This requirement is buttressed by the policy consideration behind applying lower scrutiny to commercial speech disclosures.¹⁶⁵ As the Supreme Court stated, “[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, appellants’ constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal.”¹⁶⁶

Furthermore, before “rational-basis” review may be applied, the commercial speech disclosure must involve “potentially misleading” speech.¹⁶⁷ As the Supreme Court held, *Zauderer* applies to regulations “directed at misleading commercial speech,” but “[i]f the communication is neither misleading nor related to unlawful activity, the government’s power is more circumscribed[—][t]he State must assert a substantial interest . . . [and] the restriction must directly advance the state interest involved.”¹⁶⁸ Moreover, the Supreme Court has held that the speech need not actually be misleading for “rational-basis” review to apply.¹⁶⁹ According to the Court, the government need only show that the targeted commercial speech presents the “possibility of deception” or a “tendency to mislead.”¹⁷⁰ In fact, if the speech is actually misleading, the Supreme Court has held that it enjoys no First Amendment protection.¹⁷¹

¹⁶⁴ *Id.*

¹⁶⁵ *See id.*

¹⁶⁶ *Id.* (citing *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976)).

¹⁶⁷ *See Milavetz*, 130 S. Ct. at 1339; *Cent. Hudson*, 447 U.S. at 564.

¹⁶⁸ *Milavetz*, 130 S. Ct. at 1339; *Cent. Hudson*, 447 U.S. at 564; *see also* 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 508 (1996) (applying *Central Hudson* to non-misleading commercial speech); *Edenfield v. Fane*, 507 U.S. 761, 768–69 (1993) (applying *Central Hudson* to non-misleading commercial speech).

¹⁶⁹ *See Milavetz*, 130 S. Ct. at 1340.

¹⁷⁰ *See R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1227 (D.C. Cir. 2012) (Rogers, J., dissenting) (citing *Milavetz*, 130 S. Ct. at 1340) (citation and internal quotation marks omitted).

¹⁷¹ *See id.* (citing *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 367 (2002); *Cent. Hudson*, 447 U.S. at 566).

This requirement that the speech be “potentially misleading” for *Zauderer* to apply also accords with the policy consideration behind applying lower scrutiny to commercial speech disclosures.¹⁷² As the Supreme Court held, “warning[s] or disclaimer[s] [enjoy lower constitutional protection] . . . in order to dissipate the possibility of consumer confusion and deception.”¹⁷³

Among the Four Decisions, there seems to be unanimity that the labels must consist of factual information and address “potentially misleading” speech for “rational-basis” review to apply.¹⁷⁴ However, the Four Decisions disagree on whether the warning labels must consist of *purely* factual and *uncontroversial* information.¹⁷⁵ Additionally, there is disagreement across these decisions regarding whether the warning labels must seek to, and actually, remedy “potentially misleading” speech.¹⁷⁶ Accordingly, in an abundance of caution, this Note will proceed with its analysis under the assumption that the warning labels need not contain *purely* factual and *uncontroversial* information, and need not seek to, nor actually, remedy “potentially misleading” speech for *Zauderer* review to apply.

Nevertheless, even assuming, *arguendo*, that the Final Rule’s graphic warning labels need not provide *purely* factual and

¹⁷² See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985).

¹⁷³ *Id.* (first and second alterations in original) (quoting *In re R.M.J.*, 455 U.S. 191, 201 (1982) (citations omitted)).

¹⁷⁴ See *Reynolds*, 696 F.3d at 1213–17, 1227–32 (Rogers, J., dissenting); *R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 845 F.Supp.2d 266, 272–274 (D.D.C. 2012); *Disc. Tobacco & Lottery, Inc. v. U.S.*, 674 F.3d 509, 522–31, 555–59 (6th Cir. 2012) (Clay, J., dissenting); *Commonwealth Brands, Inc. v. U.S.*, 678 F. Supp. 2d 512, 512 (W.D. Ky. 2010).

¹⁷⁵ Compare *Reynolds*, 696 F.3d at 1215 (holding information must be *purely* factual and *uncontroversial* for *Zauderer* to apply), and *R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 823 F.Supp. 2d 36, 45 (D.D.C. 2011) (holding information must be *purely* factual and *uncontroversial* for *Zauderer* to apply), with *Disc. Tobacco*, 674 F.3d at 558–559 n.8 (holding information need not be *purely* factual and *uncontroversial* for *Zauderer* to apply).

¹⁷⁶ See *Reynolds*, 696 F.3d at 1215–16 n.8 (holding information must seek to, and actually, remedy “potentially misleading” speech for *Zauderer* to apply); *Disc. Tobacco*, 674 F.3d at 558 (holding information need not seek to, nor actually, remedy “potentially misleading” speech for *Zauderer* to apply) (citation omitted) (internal quotation marks omitted).

uncontroversial information, and need not seek to, nor actually, remedy “potentially misleading” speech, “rational-basis” review only applies to the Final Rule’s nine textual warnings and four of its graphic images. None of the Four Decisions, nor the tobacco companies themselves, assert that the nine textual warnings contain non-factual information.¹⁷⁷ Additionally, it seems that cigarette packages do constitute “potentially misleading” speech.¹⁷⁸ However, only four of the Final Rule’s nine graphic images depict factual information.¹⁷⁹ Accordingly, because five of the Final Rule’s graphic images and the “1-800-QUIT-NOW” telephone number fail to convey any factual information,¹⁸⁰ these five images and the quit-line number must be reviewed under “intermediate scrutiny.”¹⁸¹

a) Only Four of the Final Rule’s Graphic Images Depict Factual Information

The FDA concedes that the Final Rule’s nine graphic images evoke an emotional response intended to shock the viewer to retain the information in the textual warnings.¹⁸² However, the fact that “the graphic warning labels are intended to create a visceral reaction in the consumer, in order to make a consumer less emotionally likely to use or purchase a tobacco product;’ and that ‘colorful graphic images can evoke a visceral response that subsumes rationale [sic] decision-making,’” does not render these images non-factual.¹⁸³

¹⁷⁷ See *Reynolds*, 696 F.3d at 1217–23, 1229–30 (Rogers, J., dissenting); *Reynolds*, 845 F. Supp. 2d 266; *Disc. Tobacco*, 674 F.3d 509; *Commonwealth Brands*, 678 F. Supp. 2d 512.

¹⁷⁸ See *infra* Part III.A.2.b.

¹⁷⁹ See *infra* Part III.A.2.a.

¹⁸⁰ See *id.*

¹⁸¹ But see discussion, *supra* note 150.

¹⁸² See *Reynolds*, 696 F.3d at 1216 (citing Appellants’ Brief at 33 (“citing research showing that ‘pictures are easier to remember than words’”), 38 (“citing FDA’s finding that a substantial body of scientific literature shows that emotional responses, such as worry and disgust, ‘reliably predict the likelihood that consumers will understand and appreciate the substance of the warnings’”)).

¹⁸³ *Disc. Tobacco*, 674 F.3d at 560 n.9 (quoting dissent at 529).

As the D.C. Circuit in *Reynolds* held, “factually accurate, emotive, and persuasive are not mutually exclusive descriptions; the emotive quality of the selected images does not necessarily undermine the warnings’ factual accuracy.”¹⁸⁴ Furthermore, the use of graphic images, even if digitally enhanced or illustrated, does not necessarily render the warnings nonfactual.¹⁸⁵ For instance, the Supreme Court held 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 information directly.”¹⁸⁶

Accordingly, it seems clear that four of the Final Rule’s graphic images depict factual information regarding the negative health consequences of smoking. The images of: (1) “a pair of diseased lungs next to a pair of healthy lungs;” (2) “a diseased mouth afflicted with what appears to be cancerous lesions;” (3) “a man breathing into an oxygen mask;” and (4) “a stylized cartoon (as opposed to a staged photograph) of a premature baby in an incubator”¹⁸⁷ “are, in fact, accurate depictions of the negative effects of sickness and disease caused by smoking,”¹⁸⁸ and “the tobacco companies do not suggest otherwise.”¹⁸⁹ “That such images are not [] comforting to look at does not necessarily make them inaccurate.”¹⁹⁰ The fact is, “the severe, life-threatening and sometimes disfiguring health effects of smoking conveyed in the

¹⁸⁴ *Reynolds*, 696 F.3d at 1230 (Rogers, J., dissenting).

¹⁸⁵ *See id.*

¹⁸⁶ *Id.* (quoting *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 647 (1985)) (citing *N.Y. Times Co. v. NASA*, 920 F.2d 1002, 1005 (D.C. Cir. 1990); 16 C.F.R. § 1500.14 (2011) (“requiring skull-and-crossbones warnings on poisonous products”).

¹⁸⁷ *R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 823 F.Supp.2d 36, 41–42 (D.D.C. 2011) (citing Plaintiff’s Complaint ¶¶ 57, 59); *see also supra* Part I.A.3 (displaying the nine graphic images).

¹⁸⁸ *Reynolds*, 696 F.3d at 1230 (Rogers, J., dissenting) (quoting Final Rule, 76 Fed. Reg. 36,628, 36,696 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2011)) (internal quotation marks omitted); *see also* Proposed Rule, 75 Fed. Reg. 69,524, 69,527–29 (Nov. 12, 2010) (to be codified at 21 C.F.R. § 1141 (2011)) (collecting scientific evidence).

¹⁸⁹ *Reynolds*, 696 F.3d at 1230 (Rogers, J., dissenting).

¹⁹⁰ *Id.*

required warnings are disturbing and the images [] . . . selected appropriately reflect this fact.”¹⁹¹

Though the Seventh Circuit in *Blagojevich* held that a four-square-inch sticker with the number “18” (representing a restricted age requirement) amounted to non-factual information,¹⁹² *Blagojevich* is distinguishable from the present issue. As the Sixth Circuit stated in *Discount Tobacco*, “what constitutes a sexually explicit video game is a matter of personal taste and sexual morals that is necessarily based on opinion, as enshrined in the very definition of ‘sexually explicit’ that *Blagojevich* examined.”¹⁹³ “In other words, a game could be deemed sexually explicit solely on the basis of widely divergent local standards.”¹⁹⁴ Thus, the Sixth Circuit concluded, “[a] required disclosure announcing that the game is sexually explicit communicates the government’s *opinion* that the game is sexually explicit.”¹⁹⁵ In contrast, “[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.”¹⁹⁶

However, five of the Final Rule’s graphic images “fail[] to convey any factual information supported by evidence about the actual health consequences of smoking.”¹⁹⁷ In fact, the FDA admits that the images of: (1) “a man exhaling cigarette smoke through a tracheotomy hole in his throat;” (2) “a plume of cigarette smoke enveloping an infant receiving a kiss from his or her mother;” (3) “a bare-chested male cadaver lying on a table, and featuring what appears to be post-autopsy chest staples down the middle of his torso;” (4) “a woman weeping uncontrollably;” and (5) “a man wearing a t-shirt that features a ‘no smoking’ symbol

¹⁹¹ *Id.* (quoting Final Rule, 76 Fed. Reg. at 36,696) (emphasis omitted).

¹⁹² *Entm’t Software Ass’n v. Blagojevich*, 469 F.3d 641, 643, 651–52 (7th Cir. 2006).

¹⁹³ *Disc. Tobacco & Lottery, Inc. v. U.S.*, 674 F.3d 509, 561 (6th Cir. 2012) (referencing *Blagojevich*, 469 F.3d at 648–50).

¹⁹⁴ *Id.* (internal citation and quotation marks omitted).

¹⁹⁵ *Id.*

¹⁹⁶ *Id.*

¹⁹⁷ *R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 845 F. Supp. 2d 266, 273 (D.D.C. 2012).

and the words ‘I Quit,’”¹⁹⁸ are not meant to be interpreted literally, but rather symbolize their accompanying textual warning statements—“which provide ‘additional context for what is shown.’”¹⁹⁹

Furthermore, in addition to not depicting any factual information regarding the negative health consequences of smoking, two of these images actually depict misleading information. Specifically, the image of “a man exhaling cigarette smoke through a tracheotomy hole in his throat”²⁰⁰ suggests that such a procedure is a common consequence of smoking.²⁰¹ However, the FDA concedes that such information is inaccurate.²⁰² Instead, the FDA claims the image is used to symbolize “‘the addictive nature of smoking,’” a fact the image does not accurately depict.²⁰³ Additionally, the image of “a bare-chested male cadaver lying on a table, and featuring what appears to be post-autopsy chest staples down the middle of his torso,”²⁰⁴ suggests that smoking leads to autopsies.²⁰⁵ However, the FDA provides no evidence that autopsies are a common consequence of smoking.²⁰⁶ Instead, the FDA contends that “the image symbolizes that ‘smoking kills 443,000 Americans each year,’”²⁰⁷ a fact that image does not accurately depict.

It is true that the D.C. Circuit’s dissent in *Reynolds* held that “[a]ll of these objections pertain to the images divorced from their accompanying text and thus fail to address the relevant question—

¹⁹⁸ R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 823 F. Supp. 2d 36, 41–42 (D.D.C. 2011) (citing Plaintiff’s Complaint ¶¶ 57, 59); *see also supra* Part I.A.3 (displaying the nine graphic images).

¹⁹⁹ *Reynolds*, 696 F.3d at 1216 (quoting Final Rule, 76 Fed. Reg. 36,628, 36,655 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2011))).

²⁰⁰ *Reynolds*, 823 F. Supp. 2d at 41 (citing Plaintiff’s Complaint ¶¶ 57, 59); *see also supra* Part I.A.3 (displaying the nine graphic images).

²⁰¹ *See Reynolds*, 696 F.3d at 1216.

²⁰² *See Reynolds*, 845 F. Supp. 2d at 273 (citing Defendants’ Opposition at 43).

²⁰³ *Id.* (quoting Defendants’ Opposition at 43).

²⁰⁴ *Reynolds*, 823 F. Supp. 2d at 41–42 (citing Plaintiff’s Complaint at ¶¶ 57, 59); *see also supra* Part I.A.3 (displaying the nine graphic images).

²⁰⁵ *See Reynolds*, 845 F. Supp. 2d at 273.

²⁰⁶ *See Reynolds*, 845 F. Supp. 2d at 273 (citing Defendants’ Opposition at 42).

²⁰⁷ *Id.* (quoting Defendants’ Opposition at 42).

whether the images render the *overall* message conveyed by the warning labels nonfactual. Viewed with the text they accompany, none of these images has that effect.”²⁰⁸ For instance, the *Reynolds* dissent held that:

The image accompanying the textual warning “Cigarettes are addictive” depicts a man smoking through a tracheotomy opening in his throat. Viewed with the accompanying text, this image conveys the tenacity of nicotine addiction: even after undergoing surgery for cancer, one might be unable to abstain from smoking This image thus serves to underline the factual, and now uncontroversial, statement that cigarettes are highly addictive. Similarly, the image of a man with staples in his chest lying on an autopsy table works with, not against, the textual warning “Smoking can kill you.” . . . [Additionally,] [t]he images of a baby enveloped in smoke and a woman crying both depict the significant harms of secondhand smoke. These images accompany the textual warnings “Tobacco smoke can harm your children” and “Tobacco smoke causes fatal lung disease in nonsmokers,” respectively Addressing potential purchasers of cigarettes, these two warning labels convey the message that smoking poses risks not only to them, but also to their family members and others [Furthermore,] the image of a man wearing a t-shirt that reads “I QUIT” . . . in connection with the textual warning “Quitting smoking now greatly reduces serious risks to your health,” [] conveys the message “I quit, and I am alive and healthy.”²⁰⁹

²⁰⁸ R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1231 (D.C. Cir. 2012) (Rogers, J., dissenting).

²⁰⁹ *Id.* at 1231–32 (Rogers, J., dissenting).

However, the *Reynolds* dissent failed to provide any legal support for its assertion that the whole is greater than its parts.²¹⁰ Furthermore, such a notion fails to properly weigh the tobacco companies' First Amendment right, to refrain from speaking, against the public's right to be informed.²¹¹ Each compelled speech disclosure—that is, every compelled statement and every compelled graphic image—potentially violates the tobacco companies' freedom of speech anew,²¹² and, thus, the constitutionality of each disclosure must be assessed individually. Accordingly, in determining whether *Zauderer* review applies, a court cannot merely look to whether a compelled disclosure in conjunction with another compelled disclosure constitutes a factual disclosure as a whole; rather, courts must assess the factual nature of each individual compelled speech disclosure.

Nevertheless, even assuming, *arguendo*, that the *Reynolds* dissent was correct in asserting that the graphic images need only be factually accurate as a whole (in conjunction with its corresponding textual warning) and thus *Zauderer* review applies to all nine graphic images, such would not alter the constitutionality of the five graphic images in question.²¹³ As this Note will demonstrate below, all nine graphic images fail to pass constitutional muster even under *Zauderer*'s "rational-basis" review.²¹⁴

Finally, the "1-800-QUIT-NOW" telephone number, displayed in conjunction with the Final Rule's nine textual and graphic warnings, also fails to depict any factual information regarding the health consequences of smoking; rather, the quit-line number merely provides a medium through which factual

²¹⁰ *See id.*

²¹¹ *See* 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 500 (1996) (weighing the possibility that "a ban on speech could screen from public view the underlying governmental policy") (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 n.9 (1980); *Wooley v. Maynard*, 430 U.S. 705, 714 (1977) (the right to refrain from speaking is protected under the First Amendment).

²¹² *See Wooley*, 430 U.S. at 714 (the right to refrain from speaking is protected under the First Amendment).

²¹³ *See infra* Part III.B.

²¹⁴ *See id.*

information can be obtained. Specifically, the FDA imposed this requirement in order “to provide a place where smokers and other members of the public can obtain smoking cessation information from staff trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support.”²¹⁵

b) Cigarette Packages Are “Potentially Misleading”

It appears that cigarette packages do constitute “potentially misleading” information. It is true that there are no “congressional findings on the misleading nature of cigarette packaging itself.”²¹⁶ However, the Supreme Court has held that where “‘the likelihood of deception’ is ‘hardly a speculative one,’ the Government need not produce ‘evidence that [the] advertisements are misleading.’”²¹⁷ Furthermore, the FDA claims that consumers are uninformed about “the nature and extent of the health risks associated with smoking cigarettes,”²¹⁸ such as “the severity and magnitude” of those risks, their personal risks, the effects of secondhand smoke, and the highly addictive nature of cigarettes.²¹⁹ Accordingly, in light of the tobacco companies’ history of deceiving consumers about the negative health effects of smoking,²²⁰ it seems clear that cigarette packages remain likely to mislead consumers notwithstanding the existing warnings.

As the D.C. Circuit’s dissent in *Reynolds* noted:

[I]t is [] beyond dispute that the tobacco companies have engaged in a decades-long campaign to deceive consumers about [the negative health effects of smoking] []. [For instance,] [d]espite

²¹⁵ Proposed Rule, 75 Fed. Reg. 69,524, 69,540 (Nov. 12, 2010) (to be codified at 21 C.F.R. § 1141 (2011)).

²¹⁶ *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1214–15 (D.C. Cir. 2012).

²¹⁷ *Id.* at 1227 (Rogers, J., dissenting) (citing *Spirit Airlines, Inc. v. U.S. Dep’t of Transp.*, 687 F.3d 403, 413 (D.C. Cir. 2012) (alteration in original) (quoting *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1340 (2010) (internal quotation marks omitted)).

²¹⁸ Final Rule, 76 Fed. Reg. 36,628, 36,632 (June 22, 2011) (codified in 21 C.F.R. § 1141 (2011)).

²¹⁹ *Id.* at 36,632–33.

²²⁰ *See Reynolds*, 696 F.3d at 1224 (Rogers, J., dissenting).

knowledge of “the negative health consequences of smoking, the addictiveness and manipulation of nicotine, [and] the harmfulness of secondhand smoke,” tobacco company executives “made, caused to be made, and approved public statements contrary to this knowledge.” Specifically, they “publicly denied and distorted the truth about the addictive nature of their products, suppressed research revealing the addictiveness of nicotine, and denied their efforts to control nicotine levels and delivery,” all while “engineer[ing] their products around creating and sustaining [nicotine] addiction.” The tobacco company executives “knew of the[] falsity” of their statements “at the time” and “made the statements with the intent to deceive.” . . . [Additionally,] Congress found that in 2005 the tobacco companies “spent more than \$13 [billion] to attract new users, retain current users, increase current consumption, and generate favorable long-term attitudes toward smoking and tobacco use,” “often misleadingly portray[ing] the use of tobacco as socially acceptable and healthful to minors.”²²¹

Moreover, in addition to the tobacco companies’ decades-long deception, it seems that cigarette packages, in their own right, actually deceive consumers if they do not properly warn consumers about tobacco’s serious health risks.²²² The Supreme Court has expressly acknowledged this fact when it approvingly referenced the Federal Trade Commission’s conclusion that “[t]o avoid giving a false impression that smoking [is] innocuous, the cigarette manufacturer who represents the alleged pleasures or satisfactions of cigarette smoking in his advertising must also

²²¹ *Id.* (quoting *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1107, 1121, 1124 (D.C. Cir. 2009); Smoking Act, Pub. L. No. 111-31, §§ 2(16)–(17), 123 Stat. 1776, 1778 (2009) (codified at 21 U.S.C § 387 Note (2011))).

²²² *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 527 (1992); *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc.*, 425 U.S. 748, 772 n.24 (1976).

disclose the serious risks to life that smoking involves.”²²³ The Court also held that these disclosures may “appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive.”²²⁴

Additionally, the D.C. Circuit’s dissent in *Reynolds* noted that a previous D.C. Circuit case is instructive on the current issue.²²⁵ Specifically:

[In] *Spirit Airlines*, [the D.C. Circuit] addressed a Department of Transportation (“DOT”) rule requiring that the most prominent number displayed in airfare advertisements be the total price, inclusive of taxes. Notwithstanding the airlines’ compliance with preexisting regulations requiring advertisements to display the entire ticket cost as well as the amount of any tax, the court accepted [the] DOT’s determination, based on common sense and experience, “that it was deceitful and misleading when the most prominent price listed by an airline is anything other than the total, final price of air travel.” Accordingly, the court proceeded to review the rule under *Zauderer*. [Thus, the *Reynolds* dissent held that] [e]ven absent any affirmatively misleading statements, cigarette packages and other advertisements that fail to display the final costs of smoking in a prominent manner are at least as misleading as the airline advertisements in *Spirit Airlines*.²²⁶

Despite this evidence, among the Four Decisions, the D.C. Circuit alone holds that cigarette packages do not constitute

²²³ *Disc. Tobacco*, 674 F.3d at 562–63 (quoting *Cipollone*, 505 U.S. at 527 (quoting Statement of Basis and Purpose, Unfair or Deceptive Advertising and Labeling of Cigarettes in Relation to the Health Hazards of Smoking, 29 Fed. Reg. 8,356 (1964))) (alteration in original) (internal quotation marks omitted).

²²⁴ *Id.* (quoting *Va. State*, 425 U.S. at 772 n.24) (internal quotation marks omitted).

²²⁵ *See Reynolds*, 696 F.3d at 1228 (Rogers, J., dissenting).

²²⁶ *Id.* (quoting *Spirit Airlines, Inc. v. U.S. Dep’t of Transp.*, 687 F.3d 403, 413 (D.C. Cir. 2012)) (citing *Spirit Airlines*, 687 F.3d at 408–09, 413–14).

“potentially misleading” speech.²²⁷ Nevertheless, even assuming, *arguendo*, that the D.C. Circuit was correct that cigarette packages do not constitute “potentially misleading” speech, such would not alter the constitutionality of the four graphic images in question.²²⁸ As this Note will demonstrate below, all nine graphic images and the “1-800-QUIT-NOW” telephone number fail to pass constitutional muster even under *Zauderer*’s “rational-basis” review, much less “intermediate scrutiny” review.²²⁹

B. The Final Rule’s Graphic Images and “1-800-QUIT-NOW” Telephone Number Do Not Withstand “Intermediate Scrutiny” or “Rational-Basis” Review

1. The FDA Cannot Demonstrate That the Graphic Images Advance the Government’s Interest

None of the Four Decisions question the seemingly obvious purpose behind the Final Rule’s nine textual warnings, nor their ability to advance their intended outcome.²³⁰ Accordingly, this Note will proceed under the assumption that the nine textual warnings are intended to, and actually do, educate consumers on the negative health consequences of smoking. Additionally, it seems clear that the “1-800-QUIT-NOW” telephone number’s purpose is to effect smoking cessation, and that the quit-line number actually advances that intended outcome.²³¹

²²⁷ See *id.* at 1213–16 (majority holding cigarette packages do not constitute “potentially misleading” speech); see also Hardesty, *supra* note 150, at 2850. But see *Reynolds*, 696 F.3d at 1223 (Rogers, J., dissenting) (dissenting opinion holding cigarette packages do constitute “potentially misleading speech”); *Disc. Tobacco*, 674 F.3d at 562–63 (majority holding cigarette packages do constitute “potentially misleading speech”); *id.* at 523–24 (Clay, J., dissenting) (dissenting opinion holding cigarette packages do constitute “potentially misleading” speech); *Reynolds*, 845 F. Supp. 2d at 266 (failing to address the issue); *Commonwealth Brands*, 678 F. Supp. 2d at 512 (failing to address the issue).

²²⁸ See *infra* Part III.B.

²²⁹ See *id.*

²³⁰ See *Reynolds*, 696 F.3d at 1205; *Disc. Tobacco*, 674 F.3d at 509; *Reynolds*, 845 F. Supp. 2d at 266; *Commonwealth Brands*, 678 F. Supp. 2d at 512.

²³¹ See *Reynolds*, 696 F.3d at 1234, 1236 (Rogers, J., dissenting).

As the D.C. Circuit's dissent in *Reynolds* stated, the quit-line telephone number is "not designed directly to inform consumers of the health consequences of smoking, but to assist smokers in their cessation efforts."²³² Furthermore, the dissent noted that "[t]he FDA imposed this requirement, pursuant to separate statutory authority, 21 U.S.C. § 387f(d), in order 'to provide a place where smokers and other members of the public can obtain smoking cessation information from staff trained specifically to help smokers quit by delivering unbiased and evidence-based information, advice, and support.'"²³³

Additionally, the dissent held that:

There [] is substantial evidence to support the FDA's determination that the display of the "1-800-QUIT-NOW" number will directly advance this interest [in reducing smoking rates]. The biological and psychological effects of nicotine "can make smoking cessation extremely difficult," "about 40 percent of smokers try to quit" each year, but "95 percent of those who try to quit on their own relapse." In comparison to minimal or no counseling interventions, quitlines have been found to "significantly increase abstinence rates." International experience referenced in the rulemaking, further supports the common sense proposition that informing smokers of cessation resources is likely to increase rates of successful quit attempts.²³⁴

²³² *Id.* (citing Final Rule, 76 Fed. Reg. 36,628, 36,681 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2011))).

²³³ *Id.* at 1234 (Rogers, J., dissenting) (quoting Proposed Rule, 75 Fed. Reg. 69,524, 69,540 (Nov. 12, 2010) (to be codified at 21 C.F.R. § 1141 (2011))) (citing Final Rule, 76 Fed. Reg. at 36,681).

²³⁴ *Id.* at 1236 (Rogers, J., dissenting) (quoting President's Cancer Panel, *Promoting Healthy Lifestyles* 62 (2007); Final Rule, 76 Fed. Reg. at 36,681, 36,687 (citing U.S. Dep't Health & Human Servs., Public Health Serv., *Treating Tobacco Use and Dependence: 2008 Update* 91 (May 2008)) (citing Final Rule, 76 Fed. Reg. at 36,682) (other internal citations omitted).

However, regarding the Final Rule's nine graphic images, it is unclear whether the FDA articulated one or two complementary interests—to effect smoking cessation and/or to educate consumers on the negative health consequences of smoking.²³⁵ Furthermore, there is disagreement among the Four Decisions on whether either interest constitutes a “substantial interest” under *Central Hudson*.²³⁶ Nevertheless, it appears that the nine graphic images fail to advance the intended outcome of either interest, and, thus, cannot withstand *Central Hudson* or *Zauderer* review.²³⁷

a) The FDA's Interest in Utilizing Graphic Images

A review of the Smoking Act and the administrative record makes clear that the FDA's primary interest in requiring the Final Rule's graphic warnings is to encourage current smokers to quit and dissuade other consumers from ever buying cigarettes.²³⁸ For instance, one of the Smoking Act's many stated purposes is “promot[ing] cessation to reduce disease risk and the social costs associated with tobacco-related diseases.”²³⁹ Additionally, in its Final Rule, the FDA explained that “this effective communication can help both to discourage nonsmokers, including minor children, from initiating cigarette use and to encourage current smokers to consider cessation to greatly reduce the serious risks that smoking poses to their health.”²⁴⁰ Furthermore, in the preamble to its Proposed Rule, the FDA also stated that it has a “substantial

²³⁵ See *infra* Part III.B.1.a.

²³⁶ See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980); *infra* Part III.B.1.a.

²³⁷ See *infra* Part III.B.1.b.

²³⁸ See Smoking Act, Pub. L. No. 111-31, § 3(9), 123 Stat. 1776, 1782 (2009) (codified at 21 U.S.C § 387 Note (2011)); *Reynolds*, 696 F.3d at 1218; Final Rule, 76 Fed. Reg. 36,628, 36,628, 36,633, 36,640 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2011)); Proposed Rule, 75 Fed. Reg. 69,524, 69,525 (Nov. 12, 2010) (codified at 21 C.F.R. § 1141 (2011)).

²³⁹ *Reynolds*, 696 F.3d at 1218 (alteration in original) (quoting the Smoking Act § 3(9) (codified at 21 U.S.C § 387 Note (2011))) (internal quotation marks omitted).

²⁴⁰ *Id.* at 1225 (Rogers, J., dissenting) (quoting Final Rule, 76 Fed. Reg. at 36,633) (internal quotation marks omitted).

interest in reducing the number of Americans, particularly children and adolescents, who use cigarettes and other tobacco products.”²⁴¹

Moreover, the Institute of Medicine Report, on which the FDA relied for some of its evidence supporting its Final Rule,²⁴² states unequivocally that “the primary objective of tobacco regulation is not to promote informed choice but rather to discourage consumption of tobacco products . . . as a means of reducing tobacco-related death and disease.”²⁴³ The report further states that “[e]ven though tobacco products are legally available to adults, the paramount public health aim is to reduce the number of people who use and become addicted to these products, through a focus on children and youths,” and recommend that the “warnings must be designed to promote this objective.”²⁴⁴ Finally, David Hammond, one of the principal researchers on whom the FDA relies,²⁴⁵ recommended that “the graphic warnings should ‘elicit negative emotional reactions’ to convince smokers to quit.”²⁴⁶

It is true that, both in its Proposed Rule and Final Rule, the FDA stated that its “primary goal” in selecting the nine graphic images is to “effectively convey the negative health consequences of smoking on cigarette packages.”²⁴⁷ However, it seems that this

²⁴¹ *Id.* at 1218 (quoting Proposed Rule, 75 Fed. Reg. at 69,525) (internal quotation marks omitted).

²⁴² *See id.* at 1218 n.12.

²⁴³ *Id.* (quoting INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION 291 (Richard J. Bonnie, Kathleen Stratton, and Robert B. Wallace eds., 2007), available at <http://www.iom.edu/Reports/2007/Ending-the-Tobacco-Problem-A-Blueprint-for-the-Nation.aspx>) (internal quotation marks omitted).

²⁴⁴ *Id.* (quoting INSTITUTE OF MEDICINE OF THE NATIONAL ACADEMIES, ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION, *supra* note 243 (alteration in original) (internal quotation marks omitted).

²⁴⁵ *See Reynolds*, 696 F.3d at 1220; *R.J. Reynolds Tobacco Co. v. United States Food and Drug Admin.*, 845 F. Supp. 2d 266, 273 (D.D.C. 2011).

²⁴⁶ *Reynolds*, 845 F. Supp. 2d at 273 (quoting David Hammond, *Health Warnings Messages on Tobacco Products: A Review*, 20 TOBACCO CONTROL 327, 331–32 (2011), available at <http://tobaccocontrol.bmj.com/content/20/5/327.full.pdf>).

²⁴⁷ Final Rule, 76 Fed. Reg. 36,628, 36,633 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2011)); *see also Reynolds*, 696 F.3d at 1235 (Rogers, J., dissenting) (quoting Final Rule, 76 Fed. Reg. at 36,641) (citing Final Rule, 76 Fed. Reg. at 36,630, 36,633–42, 36,646–47, 36,696–97, 36,699); Proposed Rule, 75 Fed. Reg. 69,524, 69,526, 69,531–35 (Nov. 12, 2010) (to be codified at 21 C.F.R. § 1141 (2011)) (“the purpose of these

purported interest merely describes the means by which the FDA is attempting to fulfill its true interest in reducing smoking rates. As the FDA stated, “[t]he goal of effectively communicating the risks of cigarette smoking is, of course, related to the viewer’s decision to quit, or never to start, smoking.”²⁴⁸ In fact, the *Reynolds* district court went so far as to suggest that “the Government appears to have chosen this ‘informational’ goal as its official purpose because it most closely mirrors the *Zauderer* exception and would thus be subject to a lesser standard of scrutiny.”²⁴⁹

Furthermore, the notion that the FDA’s true goal in requiring the graphic images is to educate consumers does not seem to comport with the evidence the FDA used to support its Final Rule.²⁵⁰ As the *Reynolds* district court held:

[T]he Government—through its own data and, in fact, its own words—evinces a purpose wholly separate from education. In particular, the Government spends much of its brief discussing the 18,000-consumer study that the FDA commissioned to help determine which of the 36 proposed graphic images it would ultimately select. In so doing, the Government acknowledges that the study was *not* designed to assess whether the proposed graphic images would have a statistically significant impact on consumer awareness of smoking risks, but rather to “assess[] the *relative* impact of different warnings based on participants’ exposure to one graphic warning on one occasion.” Thus, instead of focusing on its own alleged primary goal—providing information to consumers—the Government effectively admits that it looked only to *relative* impact, thus side-stepping the basic

required warnings is to communicate effectively and graphically the very real, scientifically established adverse health consequences of smoking.”).

²⁴⁸ *Reynolds*, 696 F.3d at 1221 (alteration in original) (quoting Appellants’ Brief at 47) (internal quotation marks omitted).

²⁴⁹ *Reynolds*, 823 F. Supp. 2d at 47.

²⁵⁰ *See id.* at 47–48.

question of whether any singular graphic warning was effective on its own terms. This fundamental failure, coupled with the Government's emphasis on the images' ability to provoke emotion, strongly suggests that the Government's *actual* purpose is not to inform, but rather to advocate a change in consumer behavior.²⁵¹

Moreover, the FDA's reliance on the graphic images—which “were chosen based on their ability to provoke emotion, a criterion that does not address whether the graphic images affect consumers' knowledge of smoking risks”—coupled with the toll free number buttresses the conclusion that “the Government's actual purpose is to convince consumers that they should ‘QUIT NOW.’”²⁵²

Despite this evidence, there is disagreement among the Four Decisions regarding whether the FDA actually articulated two complementary, but distinct, interests in requiring the graphic warning labels: (1) an interest in effectively conveying information about the negative health consequences of smoking to consumers; and (2) an interest in decreasing smoking rates.²⁵³ Accordingly, in an abundance of caution, this Note will proceed with its analysis under the assumption that the FDA articulated both an interest to educate consumers and to encourage smoking cessation.

It seems clear that the FDA's interest in educating consumers on the negative health effects of smoking constitutes a “substantial interest.” For instance, the Supreme Court held that “there is no

²⁵¹ *Id.* (quoting Defendants' Opposition at 29) (citing Defendants' Opposition at 27–30); *see also Reynolds*, 845 F. Supp. 2d at 275.

²⁵² *Reynolds*, 845 F. Supp. 2d at 275.

²⁵³ *See Reynolds*, 696 F.3d at 1218 n.12 (holding the FDA's primary interest is to encourage smoking cessation); *id.* at 1223 (Rogers, J., dissenting) (dissenting opinion holding that the FDA articulated complementary interests in educating the public and encouraging smoking cessation); *Disc. Tobacco City & Lottery v. United States*, 674 F.3d 509, 561–67 (6th Cir. 2012) (holding the FDA's interest is to educate consumers); *id.* at 528–29 (Clay, J., dissenting) (dissenting opinion holding the FDA's interest is to educate consumers); *Reynolds*, 845 F. Supp. 2d at 275 (holding the FDA's sole interest is to encourage smoking cessation); *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 530 (W.D. Ky. 2010) (holding the FDA's interest is to educate consumers).

question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial."²⁵⁴ However, it seems that the FDA's interest in encouraging smoking cessation does not constitute a "substantial interest." It is true that the Supreme Court held that "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States,"²⁵⁵ and that "the government has a substantial interest in promoting the health, safety, and welfare of its citizens."²⁵⁶ However, the Supreme Court has also held that "where the State's interest is to disseminate an ideology, no matter how acceptable to some, such interest cannot outweigh an individual's First Amendment right to avoid becoming the courier for such message."²⁵⁷

Despite the Supreme Court's ruling, there is disagreement across the Four Decisions regarding whether the FDA's interests in educating consumers and encouraging smoking cessation constitutes a "substantial interests."²⁵⁸ In fact, the D.C. Circuit in *Reynolds* held that the FDA could not even articulate an interest in educating consumers as "an interest in 'effective' communication is too vague to stand on its own."²⁵⁹ Though this determination is

²⁵⁴ *Reynolds*, 696 F.3d at 1235 (Rogers, J., dissenting) (quoting *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir.1999)) (alteration in original) (internal quotation marks omitted).

²⁵⁵ *Id.* (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000)).

²⁵⁶ *Id.* (quoting *Pearson*, 164 F.3d at 656) (internal quotation marks omitted).

²⁵⁷ *Wooley*, 430 U.S. at 717.

²⁵⁸ *See Reynolds*, 696 F.3d at 1218 n.13 (uncertain as to whether encouraging smoking cessation is a substantial interest); *id.* at 1221 (holding FDA cannot articulate a substantial interest in educating consumers); *id.* at 1235 (Rogers, J., dissenting) (dissenting opinion holding the FDA's interest in educating consumers is substantial); *id.* at 1236 (Rogers, J., dissenting) (dissenting opinion holding the FDA's interest in encouraging smoking cessation is substantial); *R.J. Reynolds Tobacco Co. v. United States Food and Drug Admin.*, 845 F. Supp. 2d 266, 275 (D.D.C. 2011) (holding the FDA's interests in encouraging smoking cessation is not substantial).

²⁵⁹ *Reynolds*, 696 F.3d at 1221. As the circuit stated, "[i]ndeed, the government's chosen buzzwords, which it reiterates through the rulemaking, prompt an obvious question: 'effective' in what sense? Allowing [the] FDA to define 'effectiveness' however it sees fit would not only render *Central Hudson*'s 'substantial interest' requirement a complete nullity, but it would also eviscerate the requirement that any restriction 'directly advance' that interest." *Id.* (citing *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557, 566 (1980)).

irrelevant regarding the Final Rule’s four factual images and nine textual warnings, as the government need not demonstrate a “substantial interest” under “rational-basis” review,²⁶⁰ it is necessary regarding the Final Rule’s five non-factual images and the “1-800-QUIT-NOW” telephone number—which are reviewed under “intermediate scrutiny.”²⁶¹ Accordingly, in an abundance of caution, this Note will proceed with its analysis under the assumption that the FDA has a “substantial interest” in both educating consumers and encouraging smoking cessation.

b) Lack of Statistical Evidence Regarding the Final Rule’s Graphic Images

Even assuming, *arguendo*, that the FDA articulated a “substantial interest” in both educating consumers and encouraging smoking cessation, the Final Rule’s nine graphic images do not even withstand “rational-basis” review.²⁶² The FDA has failed to demonstrate a “rational connection” between the government’s interests and the means used to achieve those interests,²⁶³ much less a regulation that directly advances the government’s interest, as required under “intermediate scrutiny.”²⁶⁴

As the *Reynolds* district court stated regarding the FDA’s interest in educating consumers:

[T]he Government argues that “[t]he most relevant metric in evaluating the warnings is . . . the extent to which they more effectively convey information about health risks to consumers and potential customers.” Yet it offers no evidence pointing to the FDA’s attempt to *measure* improvement in this area, much less whether the warnings *actually* achieved the purported goal of increasing consumer awareness. Needless to say, generalized scientific

²⁶⁰ See *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985).

²⁶¹ See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of N.Y.*, 447 U.S. 557, 566 (1980).

²⁶² See *Zauderer*, 471 U.S. at 651.

²⁶³ See *id.*

²⁶⁴ See *Cent. Hudson*, 447 U.S. at 566.

literature and the “experiences of countries such as Canada, Australia, and the United Kingdom” (none of which afford First Amendment protections like those found in our Constitution), say nothing about the nine graphic images at issue in this case.²⁶⁵

Furthermore, regarding the FDA’s interest in effecting smoking cessation, the D.C. Circuit in *Reynolds* held that:

The FDA makes much of the “international consensus” surrounding the effectiveness of large graphic warnings, but offers no evidence showing that such warnings have [] *caused* a material decrease in smoking rates in any of the countries that now require them. While studies of Canadian and Australian youth smokers showed that the warnings on cigarette packs caused a substantial number of survey participants to think—or think more—about quitting smoking, and [the] FDA might be correct that intentions are a “necessary precursor” to behavior change, it is mere speculation to suggest that respondents who report increased *thoughts* about quitting smoking will actually follow through on their intentions. And at no point did these studies attempt to evaluate whether the increased thoughts about smoking cessation led participants to actually quit. Another Australian study reported increased quit *attempts* by survey participants after that country enacted large graphic warnings, but found “no association with short-term quit success.” Some Canadian and Australian studies indicated that large graphic warnings *might* induce individual smokers to reduce consumption, or to help persons who have already quit smoking remain abstinent. But again, the study did not purport to show that the implementation of

²⁶⁵ R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 823 F. Supp. 2d 36, 48 n.21 (D.D.C. 2011) (quoting Defendants’ Opposition at 23, 24).

large graphic warnings has *actually* led to a reduction in smoking rates.²⁶⁶

Finally, the D.C. Circuit noted that:

The FDA's Regulatory Impact Analysis ("RIA") essentially concedes the agency lacks any evidence showing that the graphic warnings are likely to reduce smoking rates. One way in which the RIA analyzed the expected benefits of the Rule was by comparing the impact of similar warnings introduced in Canada in 2000. It (1) analyzed the change in smoking trends in Canada before and after 2000; (2) assumed any difference in the post-2000 change between Canada and the United States was solely attributable to the introduction of graphic warnings; and (3) assumed similar warnings would have an identical impact on U.S. smoking rates. Describing its approach as "rudimentary," [the] FDA acknowledged that apart from differences in cigarette taxes, the RIA "d[id] not account for potential confounding variables," such as the introduction of more stringent smoking bans and advertising restrictions in Canada during the relevant time period, or the fact that Canadian cigarette prices are generally higher than U.S. prices . . . [In fact,] [t]he RIA estimated the new warnings would reduce U.S. smoking rates by a mere 0.088%, a number the FDA concedes is "in general not statistically distinguishable from zero." Indeed, because it had access to "very small data sets," [the] FDA could not even reject the statistical

²⁶⁶ *Reynolds*, 696 F.3d at 1219 (citing Final Rule, 76 Fed. Reg. 36,628, 36,642 (June 22, 2011) (codified at 21 C.F.R. § 1141 (2011)); Proposed Rule, 75 Fed. Reg. 69,524, 69,532 (Nov. 12, 2010) (to be codified at 21 C.F.R. § 1141 (2011))).

possibility that the Rule would have *no* impact on U.S. smoking rates.²⁶⁷

2. The Final Rule’s Graphic Images and “1–800–QUIT–NOW” Telephone Number are Unduly Burdensome

None of the Four Decisions assert that requiring textual warnings on cigarette packages is unduly burdensome.²⁶⁸ In fact, requiring textual messages on cigarette packages has been an acceptable practice since the 1960s.²⁶⁹ Additionally, the tobacco companies themselves do not contest replacing the Surgeon General’s warnings, currently displayed on the sides of cigarette packages, with any of Congress’s nine new textual warnings.²⁷⁰

Furthermore, because the textual warnings merely inform consumers of the negative health consequences of smoking, and do not seem to actively encourage smokers to quit,²⁷¹ the nine textual warnings do not appear to directly contradict the tobacco companies’ interest in selling cigarettes. Moreover, the Supreme Court has held that “the least restrictive means is not the standard; instead, the case law requires a reasonable fit between the legislature’s ends and the means chosen to accomplish those ends.”²⁷² Thus, it appears that the textual warnings’ position and size, and the FDA’s failure to utilize other alternatives, are not unduly burdensome.²⁷³ Accordingly, it seems that the Final Rule’s nine textual warnings are constitutional.

²⁶⁷ *Reynolds*, 696 F.3d at 1219–20 (citing Final Rule, 76 Fed Reg. at 36,719–20, 36,720–21, 36,755, 36,776; Plaintiffs’ Comment Letter on Proposed Rule (Jan. 11, 2010) and Statement of Robert S. Maness).

²⁶⁸ *See Reynolds*, 696 F.3d at 1205; *Disc. Tobacco City & Lottery v. United States*, 674 F.3d 509 (6th Cir. 2012); *R.J. Reynolds Tobacco Co. v. United States Food and Drug Admin.*, 845 F. Supp. 2d 266 (D.D.C. 2011); *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512 (W.D. Ky. 2010).

²⁶⁹ *See supra* Part I.A.

²⁷⁰ *See R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 823 F. Supp. 2d 36, 43 (D.D.C. 2011) (citing the Trial Record at 9:24–25–10:1–3; 15:11–12).

²⁷¹ *See supra* Part III.B.i.

²⁷² *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 556 (2001) (citations and internal quotation marks omitted).

²⁷³ *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985).

However, it is clear that the “1-800-QUIT-NOW” telephone number is intended to effect smoking cessation.²⁷⁴ Additionally, the Final Rule’s nine graphic images seem to “go beyond the textual warnings to shame and repulse smokers and denigrate smoking as an antisocial act . . . ‘[B]y effectively shouting . . . that the risks from smoking outweigh the pleasure that smokers derive from it, and that smokers make bad personal decisions, and should stop smoking.’ . . . In effect, the graphic images are not warnings, but admonitions: ‘[D]on’t buy or use this product.’”²⁷⁵ This emotive attack goes beyond merely informing individuals of the negative health effects of smoking, and takes an active role in encouraging smoking cessation.

Furthermore, combined, these factors significantly increase the likelihood that the graphic warnings cross the line from information to advocacy, where the FDA “has ‘conscript[ed] [tobacco manufacturers] into an anti-smoking brigade.’”²⁷⁶ Accordingly, it appears that the nine graphic images and the quit-line number directly contradict the tobacco companies’ desired message at the point of sale—that consumers should purchase cigarettes—thereby imposing a significant burden on their protected commercial speech.²⁷⁷

It is true that the least restrictive means is not necessary for finding a “reasonable fit” between the FDA’s utilized means and purported ends to uphold the challenged rule.²⁷⁸ However, the Supreme Court held that “if there are numerous and obvious less-burdensome alternatives to the restriction on commercial speech, that is certainly a relevant consideration in determining whether the ‘fit’ between ends and means is reasonable.”²⁷⁹ Thus, it seems

²⁷⁴ See *supra* Part III.B.i.

²⁷⁵ See *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1211–12 (D.C. Cir. 2012) (alterations in original).

²⁷⁶ See *R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 823 F. Supp. 2d 36, 49 n.28 (D.D.C. 2011) (quoting Trial Record at 33:19–20).

²⁷⁷ See *Reynolds*, 696 F.3d at 1236 (Rogers, J., dissenting).

²⁷⁸ See *Lorillard Tobacco Co.*, 533 U.S. at 556; see also *Zauderer*, 471 U.S. at 651 n.14 (“We reject appellant’s contention that we should subject disclosure requirements to a strict ‘least restrictive means’ analysis.”).

²⁷⁹ *Disc. Tobacco City & Lottery v. United States*, 674 F.3d 509, 523 (6th Cir. 2012) (Clay, J., dissenting) (quoting *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S.

that: (1) the images' and the quit-line number's position and size; (2) the images' graphic nature; and (3) the FDA's failure to utilize other alternatives to both the images and the quit-line number are unduly burdensome. Accordingly, it appears that the Final Rule's nine graphic images and the "1-800-QUIT-NOW" telephone number are unconstitutional even under "rational-basis" review.

a) The Graphic Images' and the "1-800-QUIT-NOW"
Telephone Number's Position and Size

The graphic images' and the "1-800-QUIT-NOW" telephone number's sheer size and placement requirements alone suggest that they are unduly burdensome.²⁸⁰ By requiring that the top fifty percent of the front and back panels of cigarette packages display the Final Rule's warning labels, the tobacco companies are forced to act as the government's mouthpiece and disseminate the government's anti-smoking message: *Do not purchase this product.*²⁸¹ These dimensions "alone clearly demonstrate 'that the Rule was designed to achieve the very objective articulated by the Secretary of Health and Human Services: to 'rebrand[] our cigarette packs,' treating (as the FDA Commissioner announced last year) 'every single pack of cigarettes in our country' as a 'mini-billboard.' A 'mini-billboard,' indeed, for its obvious anti-smoking agenda!'"²⁸²

Instead of requiring that the graphic warnings be displayed on the top fifty percent of the front and back panels of cigarette packages, the government could reduce the space appropriated for

410, 417 n.13 (1993)) (internal quotation marks omitted) (citing *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 491 (1995) (finding that "the availability of alternatives that would prove less intrusive to the First Amendment's protections for commercial speech" further highlighted the statute's defects)); see also *Zauderer*, 471 U.S. at 651, 653 n.15 (analyzing whether the compelled disclosure was unduly burdensome before holding the regulation reasonably related to the state's interest under "rational-basis" review).

²⁸⁰ See Smoking Act, Pub. L. No. 111-31, § 201(a), 123 Stat. 1776, 1843 (2009) (codified at 15 U.S.C. § 1333(a)(2) (2006 & Supp. 2009)) (providing the size and placement requirements for the warning labels).

²⁸¹ See *R.J. Reynolds Tobacco Co. v. United States Food and Drug Admin.*, 845 F. Supp. 2d 266, 275-76 (D.D.C. 2011).

²⁸² *Id.* (quoting *R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin.*, 823 F. Supp. 2d 36, 48 n.28 (D.D.C. 2011)) (emphasis in original).

the warnings to twenty percent of the packaging; alternatively, the government could require graphic warnings on only the front *or* the back of cigarette packaging, not both.²⁸³ Additionally, if the FDA's concern is that consumers will not see the warnings if they are displayed on a smaller scale, the government could instead enlarge the textual warnings.²⁸⁴

Furthermore, simply because the Smoking Act directed the FDA to impose a rule consistent with its provisions regarding size and position does not mean that the Final Rule will automatically pass constitutional muster.²⁸⁵ In fact, as the *Reynolds* district court stated, "the parties have conceded, there is no evidence that Congress even considered the First Amendment implications when drafting the Smoking Act."²⁸⁶ Moreover, as the district court held:

The FDA's contention that neither it nor this Court has the authority to second-guess Congress, even if the congressional mandate violates the First Amendment, is an oh-too-convenient dodge To say the least, implementing a Final Rule consistent with a congressional mandate does not require a Court to hold that the Rule automatically passes constitutional muster. Congress must pass laws, and the FDA must implement final rules, that are consistent with the requirements of the Constitution.²⁸⁷

b) The Images' Graphic Nature

It seems clear that utilizing pictorial warnings on cigarette warning labels serves an important purpose. For instance, pictorial warnings can stimulate individuals into contemplating the negative

²⁸³ See *id.* at 276 (citing Plaintiffs' Motion at 29–30).

²⁸⁴ See Bennett, *supra* note 25, at 1925.

²⁸⁵ See Smoking Act § 201(a) (codified at 15 U.S.C. § 1333(a)(2) (2006 & Supp. 2009)) (providing the size and placement requirements for the warning labels); Sempeles, *supra* note 22, at 244.

²⁸⁶ *Reynolds*, 845 F. Supp. 2d at 275–76 (citing Summary Judgment Trial Record 30:10–13 (defendants); 42:3–13 (plaintiffs)).

²⁸⁷ *Id.* (citing Summary Judgment Trial Record 36:22–25; 37:13–17; *Reynolds*, 823 F. Supp. 2d at 48 n.25).

health consequences of smoking to an extent unlike textual warnings.²⁸⁸ Additionally, pictorial warnings can caution an illiterate or non-English speaking audience on the dangers of cigarettes, information they would be unable to receive through the mandated English textual warnings.²⁸⁹

However, there are other less burdensome alternatives to using pictorial warnings with a graphic component that would still allow the government to utilize the advantages inherent in pictorial warnings. Specifically, the government could employ images that convey only *purely* factual and *uncontroversial* information, rather than those of a graphic nature designed to disgust the consumer.²⁹⁰ In fact, the *Reynolds* district court noted that:

[The tobacco companies do not object to publishing] a graph demonstrating the difficulty of quitting smoking by showing the correlation between the number of people who try to quit and the percentage who actually do . . . [or to publishing] . . . a “graphic that depicts the types of harms that befall children if they are exposed to secondhand smoke or the types of birth defects that arise, and their likelihood, if mothers smoke during the course of pregnancy.”²⁹¹

Furthermore, the government could utilize bilingual warnings for non-English speaking citizens, or a picture of the world-renowned symbol for danger, a skull and crossbones, for illiterate citizens.²⁹²

²⁸⁸ See Proposed Rule, 75 Fed. Reg. 69,524, 69,531–35 (Nov. 12, 2010) (to be codified at 21 C.F.R. § 1141 (2011)) (collecting scientific evidence).

²⁸⁹ See *Disc. Tobacco City & Lottery v. United States*, 674 F.3d 509, 563 (6th Cir. 2012) (citation omitted); Proposed Rule, 75 Fed. Reg. at 69,531; Bennett, *supra* note 25, at 1924.

²⁹⁰ See *Reynolds*, 845 F. Supp. 2d at 276 (citing Plaintiffs’ Motion at 30).

²⁹¹ *Reynolds*, 823 F. Supp. 2d at 48–49 (quoting Trial Record at 20:18–21) (citing Defendants’ Opposition at 22; Trial Record at 20:5–8).

²⁹² See Bennett, *supra* note 25, at 1924 n.62 (“The symbol of a skull and crossbones is used by both the United States and the United Nations to symbolize dangerous, toxic, or hazardous material.”) (citing EPA, PESTICIDES: INTERNATIONAL ACTIVITIES, SKULL AND CROSSBONES, <http://www.epa.gov/oppfead1/international/ghs/skull-crossbones.htm> (last visited July 9, 2013)).

c) Alternatives to Utilizing Graphic Images and the “1-800-QUIT-NOW” Telephone Number

Even if the FDA eliminated the pictorial warnings’ graphic nature and altered the images’ and the “1-800-QUIT-NOW” telephone number’s position and size, there are still other possible alternatives the government could utilize as a less restrictive means of conveying the negative health consequences of smoking.

i. Counter-Speech Informational Campaigns

First, as the *Reynolds* district court stated, “the Government could disseminate its anti-smoking message itself, for example, by increasing its anti-smoking advertisements or issuing additional statements in the press urging consumers to quit smoking or both.”²⁹³ Such methods have proven effective in encouraging smoking cessation. For instance, a decrease in smoking directly correlated the American Cancer Society’s and other groups’ anti-smoking campaigns in the 1960s.²⁹⁴

ii. School-Based Prevention Programs

Second, the government could create more school-based smoking prevention programs to specifically target and discourage smoking among adolescents.²⁹⁵ These programs could directly influence the youth population by providing them with information about the potential harms of smoking.²⁹⁶ In fact, studies have shown that school-based programs centered on the Social-Influence-Resistance Model are effective in long-term smoking prevention among youths.²⁹⁷

iii. Informational Inserts

Third, the government could utilize informational inserts as used with other legal products sold in the United States.²⁹⁸ For

²⁹³ *Reynolds*, 845 F. Supp. 2d at 276 (citing Plaintiffs’ Motion at 28).

²⁹⁴ See Semples, *supra* note 22, at 248 (citing Kathleen M. Sullivan, *Muzzle Joe Camel? It May Be Illegal*, *NEWSDAY*, May 30, 1996, at A51).

²⁹⁵ *See id.*

²⁹⁶ *See id.*

²⁹⁷ *See id.* (citing PETER D. JACOBSON ET AL., *COMBATING TEEN SMOKING: RESEARCH AND POLICY STRATEGIES* 117–18 (2001)).

²⁹⁸ *See id.* at 249.

instance, “the government requires information leaflets to be included within contraceptive packaging.”²⁹⁹ The government believes that these informational inserts are an efficient way to warn the public about the potential health consequences that could occur from using contraceptives.³⁰⁰ Similarly, the government could require that information leaflets describing the dangers of smoking be included within every cigarette package.³⁰¹

iv. Banning Public Smoking

Fourth, the government could encourage municipalities and states to follow cities in Maine, Texas, Oregon, New York, and Michigan, and ban tobacco use in public places.³⁰² Banning smoking in public places has proven effective overseas in encouraging smoking cessation.³⁰³ For instance, a London ban on public smoking encouraged over 400,000 London smokers to quit.³⁰⁴

v. Increasing Cigarette Taxes

Fifth, the FDA could lobby for increased federal taxes on tobacco products and encourage states to tax tobacco products at a

²⁹⁹ *Id.* (citing *Dunkin v. Syntex Laboratories, Inc.*, 443 F. Supp. 121 (W.D. Tenn. 1977)).

³⁰⁰ *See id.* at 249 n.223 (“The case held that, as a matter of law, a leaflet contained in each birth control pill dispenser was an adequate warning given by the drug manufacturer.”) (citing *Dunkin v. Syntex Laboratories, Inc.*, 443 F. Supp. 121, 123 (W.D. Tenn. 1977)).

³⁰¹ *See id.*

³⁰² *See Bennett, supra* note 25, at 1936 (citing Katharine Q. Seelye, *Increasingly, Smoking Indoors Is Forbidden at Public Housing*, N.Y. TIMES, Dec. 18, 2011, at A25, available at http://www.nytimes.com/2011/12/18/us/public-housing-authorities-increasingly-ban-indoor-smoking.html?pagewanted=all&_r=0; *Report: Ban Smoking in Public Places, Surgeon General says 126 Million Nonsmokers Exposed to Tobacco Hazards*, ASSOCIATED PRESS (June 27, 2006, 4:11 PM), available at <http://www.nbcnews.com/id/13569976/ns/health-addictions/t/report-ban-smokingpublic-places>).

³⁰³ *See id.*

³⁰⁴ *See id.* (citing *Smoking Bans Spurs 400,000 People to Quit the Habit*, DAILY MAIL REP. (July 4, 2008, 4:23 PM), <http://www.dailymail.co.uk/health/article-1030575/Smoking-ban-spurs-400-000-people-quit-habit.html>).

higher rate.³⁰⁵ According to the Centers for Disease Control and Prevention, “a 10% increase in price [alone] . . . [would] reduce overall cigarette consumption among adolescents and young adults by about 4%.”³⁰⁶ Although, as the *Liquormart* Court discussed, severe addicts may not be affected by a “‘marginal price increase’ on tobacco products and instead choose to forego necessities to feed their habit,”³⁰⁷ this method may deter less-addicted individuals from smoking.

vi. Increased Penalties Surrounding Underage Tobacco Use

Finally, the FDA could encourage stricter federal and state statutory penalties for the sale of tobacco products to underage individuals.³⁰⁸ Additionally, increasing the enforcement of current state laws that prohibit the sale of tobacco products to minors and criminalizing the possession, not just use, of tobacco products for minors may also prove effective.³⁰⁹ As the Campaign for Tobacco-Free Kids states, “‘strong enforcement of youth access laws [has] substantially reduced illegal sales to minors’ in many states already, including California and Massachusetts.”³¹⁰

CONCLUSION

Assuming the role of surrogate parent, the FDA wishes to teach us that the antitheses to the old adage “an apple a day keeps the

³⁰⁵ See *R.J. Reynolds Tobacco Co. v. United States Food and Drug Admin.*, 845 F. Supp. 2d 266, 276 (D.D.C. 2011) (citing Plaintiffs’ Motion at 29); Bennett, *supra* note 25, at 1934.

³⁰⁶ Bennett, *supra* note 25, at 1935 (quoting *Smoking & Tobacco Use: Economic Facts About U.S. Tobacco Production and Use*, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 15, 2012), http://www.cdc.gov/tobacco/data_statistics/fact_sheets/economics/econ_facts).

³⁰⁷ *Id.* (quoting 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 506 (1996)).

³⁰⁸ See *Reynolds*, 845 F. Supp. 2d at 276 (citing Plaintiffs’ Motion at 29); Bennett, *supra* note 25, at 1938.

³⁰⁹ See *Reynolds*, 845 F. Supp. 2d at 276 (citing Plaintiffs’ Motion at 29); Sempeles, *supra* note 22, at 248.

³¹⁰ See Bennett, *supra* note 25, at 1939 (quoting 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>).

doctor away” is “a pack a day and the doctor will stay to treat your lung cancer, emphysema, stroke, and heart disease.”³¹¹ As children, our parents force us to eat our vegetables so we can grow up strong and healthy. As youths and adults, the FDA is employing graphic images to “shock” us into quitting smoking so we can remain healthy. However, in the spirit of challenging authority, courts must join the rebellious teenager within us in sarcastically retorting OMG, FDA, TMI.³¹²

The Final Rule’s requirements regarding its images’ graphic nature, position, and size, as well as the “1-800-QUIT-NOW” telephone number’s position and size, provide “too much information” and are unduly burdensome. Furthermore, the Final Rule’s graphic images also fail to advance the FDA’s interest in encouraging smoking cessation. Thus, except for its textual warnings, the Final Rule’s nine graphic warning labels fail to withstand all three constitutional standards of review.

However, like all parents, the FDA refuses to “just leave us alone.” Instead, the FDA intends to modify its graphic cigarette warning labels, perhaps presaging its regulating alcohol and McDonald’s “Big Mac” hamburgers. Accordingly, prospective courts must ensure that the FDA’s redesigned warning labels accord with the principles set forth, above, in Part III.B.2 of this Note. Otherwise, unless courts curtail the FDA’s “parental rights” to make our personal choices for us, the FDA, drunk with power, is likely to continue ordering “graphic warning labels all around.”

³¹¹ See Proposed Rule, 75 Fed. Reg. 69,524, 69,527–29 (Nov. 12, 2010) (to be codified at 21 C.F.R. § 1141 (2011) (collecting scientific evidence).

³¹² See *Definition of TMI in English*, OXFORD DICTIONARIES (2013), http://oxforddictionaries.com/us/definition/american_english/TMI (“TMI” is the abbreviation for “Too Much Information.”); *Definition of OMG in English*, OXFORD DICTIONARIES (2013), http://oxforddictionaries.com/us/definition/american_english/OMG?q=omg (“OMG” is the abbreviation for “Oh My G-d”); *supra* text accompanying note 17 (“FDA” has been defined above as the “Federal Drug Administration”).