Do Graphic Tobacco Warnings Violate the First Amendment?

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When Congress passed the nation's first comprehensive tobacco bill in 2009, it replaced the familiar Surgeon General's warnings, last updated in 1984, with nine blunter warnings. The law also directed the U.S. Food and Drug Administration ("FDA") to require color graphics to accompany the textual warnings. By law, the warnings would cover the top fifty percent of the front and back of tobacco packaging and the top twenty percent of print advertisements, bringing the United States closer to many peer countries that now require graphic warnings. Tobacco companies challenged the requirement on First Amendment grounds, arguing that the compelled disclosures violated their free speech rights. In 2012, the Sixth Circuit Court of Appeals treated the challenge as a facial attack and upheld the law in Discount Tobacco City & Lottery v. United States; five months later, the D.C. Circuit vacated the graphic warnings selected in the FDA's final rule in R.J. Reynolds v. FDA. Although many expected the Supreme Court to resolve the apparent circuit split, the government withdrew the rule and opposed Supreme Court review. As such, the FDA will reinitiate the lumbering rulemaking process and propose new graphic warnings. And when it does, the tobacco industry most likely will challenge the graphic warnings again on First Amendment grounds. This Article considers several ambiguities that these cases have left unresolved and suggests how the FDA and courts should confront these questions during the next round of rulemaking and litigation. The Supreme Court will probably have another chance to resolve these ambiguities and its decision could have significant consequences for future government efforts to catch our attention at the point of sale.

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INTRODUCTION

After two centuries of non-regulation and another four decades of piecemeal oversight, Congress in 2009 passed the first comprehensive tobacco legislation, the Family Smoking Prevention and Tobacco Control Act.¹ The Act requires tobacco companies to rotate nine written warnings on their packaging and advertisements and directs the U.S. Food and Drug Administration ("FDA") to issue regulations that "require color graphics depicting the negative health consequences of smoking."²

The stakes are familiar but striking. Tobacco use kills "more than 400,000 Americans every year—more deaths than from AIDS, alcohol, car accidents, murders, suicides, drugs, and fires combined."³ Adult smokers overwhelmingly adopt the habit as adolescents.⁴ Every day, 1500 children under eighteen years of age become regular smokers, of whom "about half eventually will die from a disease caused by tobacco use."⁵

In response, Congress mandated nine new written warnings and directed the FDA to select images to accompany them.⁶ By law, the

I. Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified as amended at 21 U.S.C. §§ 387–87u (2009)).

^{2.} *Id.* § 201(d).

^{3.} SUZANNE H. REUBEN, U.S. DEP'T OF HEALTH & HUMAN SERVS., PRESIDENT'S CANCER PANEL, PROMOTING HEALTHY LIFESTYLES: POLICY, PROGRAM, AND PERSONAL RECOMMENDATIONS FOR REDUCING CANCER RISK 61 (2007).

^{4.} Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (Aug. 28, 1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897).

^{5.} REUBEN, *supra* note 3, at 64.

^{6.} Family Smoking Prevention and Tobacco Control Act § 201(d), 123 Stat. 1842, 1845 (2009)

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warnings must occupy the top fifty percent of the front and back of tobacco packaging and twenty percent of print ads.⁷ The FDA selected the following nine warnings:⁸

FIGURE 1: FDA-SELECTED GRAPHIC TOBACCO WARNINGS



Tobacco companies promptly challenged these warnings on First Amendment grounds, arguing that the compelled disclosures violate their free speech rights. The companies first filed suit in the Western District of Kentucky⁹ and then in the District of Columbia.¹⁰ Appeals from these cases generated disparate rulings on graphic warnings. In March 2012, the Sixth Circuit Court of Appeals upheld graphic warnings in *Discount Tobacco City & Lottery v. United States*.¹¹ Five months later, the D.C. Circuit invalidated the graphic warnings selected by the FDA in *R.J. Reynolds Tobacco Co. v. FDA*.¹²

⁽codified as amended at 15 U.S.C. § 1333 (2009)).

^{7.} *Id.* § 201(a)(2).

^{8.} Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,629 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).

^{9.} Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512 (W.D. Ky. 2010).

^{10.} R.J. Reynolds Tobacco Co. v. FDA, 823 F. Supp. 2d 36 (D.D.C. 2011).

^{11. 674} F.3d 509 (6th Cir. 2012).

^{12. 696} F.3d 1205 (D.C. Cir. 2012) (denying rehearing en banc).

Tobacco companies petitioned the Supreme Court to overturn the Sixth Circuit ruling¹³ and most expected the Court to grant certiorari.¹⁴ But before it could do so, the FDA both withdrew its proposed rule and decided against appealing the D.C. Circuit's decision. As a result, the Department of Justice urged the Court to deny certiorari in the Sixth Circuit case in March 2013, arguing that the FDA's action rendered the case moot and that it no longer presented an inter-circuit conflict.¹⁵ The FDA informed the Department of Justice that it would "undertake research necessary to support a new rulemaking consistent with the Act and the First Amendment."¹⁶

The FDA's removal was a strategic step to avoid a Supreme Court that has aggressively protected corporate speech.¹⁷ The decision not to appeal *R.J. Reynolds* marks the second major recent case in which the FDA has decided not to appeal a circuit court decision limiting its authority on First Amendment grounds.¹⁸ But the cost of letting *R.J. Reynolds* stand will be years of research to support more years of rulemaking—followed most likely by even more years of litigation.

In the meantime, several unresolved legal questions on graphic warnings linger. This Article examines them as the parties prepare for another round of rulemaking and, most likely, another round of litigation. Given the unresolved ambiguities, the Supreme Court may yet have another chance to resolve these issues.

Graphic warnings are governed by the First Amendment's commercial speech doctrine,¹⁹ which itself is not yet four decades old.²⁰ As the law on commercial speech has developed, courts have focused largely

18. United States v. Caronia, 703 F.3d 149 (2d Cir. 2012), is the other case. Caronia overturned a sales representative's conviction for misbranding under the Federal Food, Drug, and Cosmetic Act under *Central Hudson* because it punished his speech. *Id.* at 168.

19. See generally Jennifer M. Keighley, Can You Handle the Truth? Compelled Commercial Speech and the First Amendment, 15 U. PA. J. CONST. L. 539 (2012) (discussing the government compelling speech including graphic warnings).

20. Nathan Cortez, *Can Speech by FDA-Regulated Firms Ever Be Noncommercial*?, 37 AM. J.L. & MED. 388, 388 (2011) ("[T]he Supreme Court reversed its longstanding position that the First Amendment does not protect commercial speech [in Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, 425 U.S. 748, 762 (1976)].").

^{13.} Petition for Writ of Certiorari, Am. Snuff Co. v. United States, 2013 WL 1704718 (Apr. 22, 2013) (No. 12-521), 2012 WL 5353900.

^{14.} See, e.g., Ronald Bayer et al., Repackaging Cigarettes-Will the Courts Thwart the FDA?, 367 NEW ENG. J. MED. 2065 (2012).

^{15.} Brief for the Respondents in Opposition, *Am. Snuff Co.*, 2013 WL 1704718 (No. 12-521), 2013 WL 1209163, at *17.

^{16.} *Id*. at *16.

^{17.} See, e.g., Ronald K.L. Collins, Exceptional Freedom: The Roberts Court, the First Amendment, and the New Absolutism, 76 ALB. L. REV. 409 (2012); Richard L. Hasen, Citizens United and the Illusion of Coherence, 109 MICH. L. REV. 581 (2011) (addressing First Amendment limits on campaign finance law).

on *restrictions* on speech. Despite the prevalence of compelled commercial disclosures, courts have said very little about them.²¹ In 1985, the Supreme Court first established a test for mandatory commercial disclosures in *Zauderer v. Office of Disciplinary Counsel*, which upheld disclosures required for certain types of attorney advertising.²² But the Court has not updated *Zauderer* in nearly thirty years.²³ It has applied *Zauderer* only twice since 1985²⁴ and addressed it briefly in only three other cases.²⁵ The dearth of cases (and thus doctrine) provides ample room for the Supreme Court to elaborate on the law governing mandated commercial disclosures.

During the next round of rulemaking and litigation, the FDA and courts must confront five fascinating but difficult questions: First, what standard of review applies to graphic warnings? Must the Court apply rational basis review under *Zauderer*²⁶ because this problem involves mandatory commercial disclosures? Or is it more appropriate to apply intermediate scrutiny under *Central Hudson Gas & Electric Corp. v. Public Services Commission*,²⁷ which traditionally applies to *restrictions* on commercial speech? Or should the Court craft a unique standard for graphic warnings? Both the Sixth²⁸ and the D.C.²⁹ Circuits have concentrated on locating the appropriate standard of review, which itself required determining whether *Zauderer*'s friendlier standard could accommodate different state interests (for example, protecting public health rather than preventing consumer deception).

Second, to answer the first question, both the FDA and the courts will have to confront another subsidiary question: Were the graphic warnings that the FDA selected factual? *Zauderer* addresses itself to disclosures of

25. United States v. United Foods, Inc., 533 U.S. 405, 416 (2001) (declining to apply Zauderer in striking down a law that required mushroom growers to fund generic advertisements for mushrooms); Glickman v. Wileman Bros. & Elliot, Inc., 521 U.S. 457, 490–91 (1997) (Souter, J., dissenting) (arguing that Zauderer should be limited to mandated disclosures that are intended to prevent consumer deception); Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n, 475 U.S. 1, 8 (1986) (declining to apply Zauderer to a requirement by a state agency that utility companies include a third party's newsletter in its billing envelopes).

^{21.} Keighley, supra note 19, at 541.

^{22. 471} U.S. 626, 651–52 (1985).

^{23.} Keighley, supra note 19, at 541.

^{24.} Milavetz, Gallop & Milavetz, P.A. v. United States, 130 S. Ct. 1324, *1339–41 (2010) (applying *Zauderer* to uphold a requirement under the Bankruptcy Code that advertisements for debt relief services must also disclose that the services essentially help clients file for bankruptcy); Ibanez v. Fl. Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 142–43 (1994) (applying principles from *Zauderer*, but finding that the Board of Accountancy violated the commercial speech rights of an attorney when it censured her for truthfully advertising her accounting and financial planning credentials).

^{26. 471} U.S. at 638-42.

^{27.} Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980).

^{28.} Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509 (6th Cir. 2012).

^{29.} R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205 (D.C. Cir. 2012).

"purely factual and uncontroversial information."³⁰ Do emotionally salient graphic warnings fit this criterion? Or are they nonfactual, or at least factually controversial?

Third, the FDA and the courts will need to consider whether graphic warnings necessarily appeal to our emotions, rather than to our minds, and whether this matters for First Amendment purposes. Are images categorically distinct from text under the commercial speech doctrine? And can the government use consumer product packaging to appeal to our hearts and not just our minds? When speaking on private packaging, is the government limited to statements of fact? And what if facts are emotionally salient (or even troubling)?

Fourth, will the First Amendment rights of marketers give way to the core value that animates commercial speech doctrine—ensuring "the free flow of commercial information"?³¹ The Supreme Court in *Zauderer* stressed that the marketer's "interest in *not* providing any particular factual information in his advertising is minimal."³² Will the Court prefer—as it has in other commercial speech cases—"more disclosure, rather than less"?³³ Which priority gives way, given the immense public health dimension here?

Finally, will the courts anticipate the next generation of disclosure laws? If the Supreme Court were to invalidate the FDA's graphic tobacco warnings, it would implicate few, if any, existing disclosure laws. Such a decision would not, most likely, overturn decades or even years of congressional enactments.³⁴ Rather, a decision striking down the first serious attempt to catch our attention with mandatory graphic warnings would freeze such disclosure laws in time. As society grows more numb to bland, black-and-white textual warnings, the government's hands would become tied. If the government cannot use graphics to warn about the risks of tobacco use—which for decades has been one of our most pressing public health problems—then what would justify graphic warnings for less urgent problems?

This Article proceeds in three parts. Part I maps the long trajectory of tobacco regulation, placing both the 2009 Act and the recent First Amendment litigation in context. Part II identifies several fault lines that both the FDA and the courts must confront during the next round of

^{30. 471} U.S. at 626.

^{31.} Id. at 646.

^{32.} Id. at 651.

^{33.} Bates v. State Bar of Ariz., 433 U.S. 350, 375 (1977).

^{34.} See, e.g., Citizens United v. FEC, 130 S. Ct. 876, 930 (2010) (Stevens, J., dissenting) (arguing that the "Court today rejects a century of history" in striking down federal campaign finance laws); INS v. Chadha, 462 U.S. 919, 959–60 (1982) (Powell, J., concurring) (noting that striking down the legislative veto might invalidate "literally hundreds of statutes, dating back to the 1930s").

rulemaking and litigation. Part III evaluates the five questions posed above and suggests how courts should answer them if given the chance.

I. THE LONG TRAJECTORY OF TOBACCO REGULATION

After two decades of intense litigation, legislation, and regulation, one could believe that the tobacco industry finally has had its comeuppance. For example, one might recall the multi-state tobacco litigation of the 1990s.³⁵ Or one might remember the moment when chief executives from the seven major tobacco companies testified under oath before Congress that nicotine was not addictive.³⁶ Others might think of the 1996 interview on *60 Minutes* with the Brown & Williamson whistleblower Jeffrey Wigand,³⁷ or perhaps remember the movie based on that interview, *The Insider.*³⁸ Still others might recall one of the most important Supreme Court decisions of that era, *FDA v. Brown & Williamson Corp.*, a weighty opinion on the relative authority of the legislative and executive branches.³⁹ By the time the satiric film *Thank You for Smoking* was released in 2006, the industry was depicted as beleaguered by the media, by Congress, and by the courts.⁴⁰

Despite the recent media attention and tobacco litigation, the tobacco industry went largely unregulated in the United States for almost two full centuries, until Congress passed the first federal anti-smoking law in 1965.⁴¹

Looking back, the nation's earliest experiences with tobacco portended today's public health battles. For example, Christopher Columbus triggered controversy over the health risks of tobacco when he brought the crop back to Europe from the new world in 1492.⁴² In 1604, King James I of England declared smoking to be "a custom loathsome to the eye, hateful to the nose, harmful to the brain, [and] dangerous to the lung.⁴³ New Haven (in what was then the colony of Connecticut) adopted

- 37. See Jeffrey Wigand, Ph.D., 60 Minutes (CBS television broadcast Feb. 4, 1996).
- 38. See The Insider (Touchstone Pictures 1999).

^{35.} See Graham E. Kelder, Jr. & Richard A. Daynard, *The Role of Litigation in the Effective Control of the Sale and Use of Tobacco*, 8 STAN. L. & POL'Y REV. 63, 71–75 (1997).

^{36.} Regulation of Tobacco Products: Hearing Before the Subcomm. on Health and Environment of the H. Comm. on Energy and Commerce, 103rd Cong. 1–149 (1994).

^{39.} See 529 U.S. 120 (2000).

^{40.} See THANK YOU FOR SMOKING (Fox Searchlight Pictures 2006). The novel upon which the movie was based was written in 1994. See CHRISTOPHER BUCKLEY, THANK YOU FOR SMOKING (1994) (depicting a fictional tobacco industry lobbyist Nick Naylor).

^{41.} Theodore W. Ruger, *The Story of* FDA v. Brown & Williamson: *The Norm of Agency Continuity, in* STATUTORY INTERPRETATION STORIES 334, 337–39 (William N. Eskridge, Jr., et al. eds., 2011).

^{42.} ERIC BURNS, THE SMOKE OF THE GODS: A SOCIAL HISTORY OF TOBACCO 14-19 (2007); Ruger, supra note 41, at 338.

^{43.} Ruger, *supra* note 41, at 338 (alteration in original) (quoting Allan M. Brandt, The Cigarette Century: The Rise, Fall and Deadly Persistence of the Product That Defined America 21 (2007)).

the first anti-smoking law in America in 1646, which imposed a six-pence penalty for each instance of smoking in public.⁴⁴

Our founding fathers even debated smoking: In 1794, Benjamin Franklin and Alexander Hamilton opposed smoking and "supported a hefty tobacco tax as an early federal revenue-raising and behavior-altering measure," but James Madison (of tobacco-producing Virginia) vigorously opposed the measure.⁴⁵ Of course, tobacco grew gradually in economic importance over the next several decades, particularly in the southern states.⁴⁶

A century and a half later, tobacco use peaked at nearly sixty percent of American men in 1955.⁴⁷ By 1965, the percentage of American women who smoked peaked at thirty-four percent.⁴⁸ That same year, Congress passed the first federal law regulating tobacco products, the Federal Cigarette Labeling and Advertising Act of 1965.⁴⁹ The law introduced the now-familiar, weakly worded warning: "Caution: Cigarette Smoking May Be Hazardous to Your Health."⁵⁰

The 1965 Act was the first of six major laws passed by Congress addressing tobacco products.⁵¹ Just four years later, Congress passed the Public Health Cigarette Smoking Act of 1969, which banned television and radio ads of tobacco products and strengthened the standard warning to read: "Warning: The Surgeon General Has Determined That Smoking Is Dangerous to Your Health."⁵²

In 1983, Congress passed the Alcohol and Drug Abuse Amendments, which required the U.S. Department of Health and Human Services to research the health effects of smoking.⁵³ In 1984, Congress again modified tobacco warning labels pursuant to the Comprehensive Smoking Education Act⁵⁴—the last such modification until 2009. The 1984 Act required cigarette packages and advertising to rotate four different warnings, which also became familiar:

49. Pub. L. No. 89-92, 79 Stat. 282 (1965).

^{44.} BURNS, supra note 42, at 101; Ruger, supra note 41, at 338.

^{45.} Ruger, supra note 41, at 339.

^{46.} *Id.* at 339–40.

^{47.} *Id.* at 340.

^{48.} Id. (citing Steven A. Schroeder, We Can Do Better—Improving the Health of the American People, 357 New Eng. J. MED 1221, 1222 (2007)).

^{50.} Id. at 283.

^{51.} See Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 518 (6th Cir. 2012) (recounting a brief history of tobacco legislation). Congress has passed several other, minor laws touching on tobacco. See Selected Actions of the U.S. Government Regarding the Regulation of Tobacco Sales, Marketing, and Use, CTRS. FOR DISEASE CONTROL & PREVENTION (Nov. 15, 2012), http://www.cdc.gov/tobacco/data_statistics/by_topic/policy/legislation/index.htm.

^{52.} Pub. L. No. 91-222, 84 Stat. 87, 88 (1970).

^{53.} Pub. L. No. 98-24, 97 Stat. 175 (1983).

^{54.} Pub. L. No. 98-474, 98 Stat. 2200 (1984).

SURGEON GENERAL'S WARNING: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy. SURGEON GENERAL'S WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health.

SURGEON GENERAL'S WARNING: Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight.

SURGEON GENERAL'S WARNING: Cigarette Smoke Contains Carbon Monoxide.⁵⁵

The tobacco industry never challenged these mandated warnings on First Amendment grounds.⁵⁶

In 1986, Congress extended warnings to smokeless tobacco packages and ads and vested the Federal Trade Commission with enforcement authority.⁵⁷ In 1992, Congress passed another federal statute to encourage states to better enforce the age restrictions on tobacco sales.⁵⁸

Thus between 1965 and 1986, Congress passed six major bills regulating tobacco. Due to successful lobbying by the industry, however, these bills were neither comprehensive nor very burdensome.⁵⁹ During this period, tobacco companies enjoyed unprecedented success in court, as "more than three hundred lawsuits filed in the thirty years before 1980 resulted in not a single plaintiff's verdict."⁶⁰ That record stood until 1997.⁶¹

Yet by the early 1990s, evidence had accumulated that tobacco use was our nation's most significant public health concern. Between 1992 and 1995, the FDA investigated tobacco industry practices and built a case toward asserting jurisdiction over nicotine as a "drug" and cigarettes as drug-delivery "devices."⁶² Emboldened by media exposés and waves of lawsuits, the FDA began to gather previously confidential internal corporate documents showing that tobacco companies were manipulating the nicotine content of cigarettes to amplify their addictiveness.⁶³

^{55.} Id. at 2201–02, § 4(a) (codified as amended at 15 U.S.C. § 1333(a) (2009)).

^{56.} R.J. Reynolds Tobacco Co. v. FDA, 823 F. Supp. 2d 36, 40 n.4 (D.D.C. 2011).

^{57.} Comprehensive Smokeless Tobacco Health Education Act, Pub. L. No. 99-252, 100 Stat. 30 (1986).

^{58.} Alcohol, Drug Abuse, and Mental Health Administration Reorganization Act, Pub. L. No. 102–321, 106 Stat. 323, 394 (1992).

^{59.} Ruger, *supra* note 41, at 340–41.

^{59.} Ruger, supra note 41, at 340–41.

^{60.} *Id.* at 341. Indeed, Donald Garner's 1980 article observed that the "automobile, drug, and machine tool industries, as well as various consumer product industries, have all been held liable for injuries associated with their dangerous products; only the tobacco industry can boast of defeating every attempt to hold it accountable for injuries caused by its product." Donald W. Garner, *Cigarette Dependency and Civil Liability: A Modest Proposal*, 53 S. CAL. L. REV. 1423, 1423–24 (1980).

^{61.} George J. Annas, *Tobacco Litigation as Cancer Prevention: Dealing with the Devil*, 336 NEW ENG. J. MED. 304, 304–09 (1997); Peter D. Jacobson & Kenneth E. Warner, *Litigation and Public Health Policy Making: The Case of Tobacco Control*, 24 J. HEALTH POL. POL'Y & L. 769, 770 (1999).

^{62.} Ruger, supra note 41, at 345-48.

^{63.} Id. at 348-49.

Buoyed by this evidence, the FDA proposed a rule in August 1995 that would have regulated the sale, distribution, and marketing of tobacco products.⁶⁴ During the public comment period, the agency received over 710,000 comments,⁶⁵ more than "at any other time in its history on any other subject."⁶⁶ A year later, the agency published its final rule.⁶⁷

The FDA's efforts were quickly challenged in federal court and were ultimately struck down in *FDA v. Brown & Williamson Tobacco Corp.*⁶⁸ In a narrow 5–4 decision, the majority held that even the broad language of the Federal Food, Drug, and Cosmetic Act could not justify FDA jurisdiction over tobacco without specific congressional authority.⁶⁹

That authority finally came in 2009, when the 111th Congress passed the Family Smoking Prevention and Tobacco Control Act (the "Act"),⁷⁰ the first comprehensive legislation regulating tobacco.⁷¹ Similar bills had failed in previous congresses, including the 110th Congress in 2008, when the House passed legislation but it was not taken up by the Senate.⁷² The bill only became law after President Barack Obama won the 2008 presidential election and Democrats won majorities in both the House and the Senate.⁷³

71. The 2009 Act directed the FDA to reissue the regulations that were invalidated by the Supreme Court in *FDA v. Brown & Williamson*. Pub. L. No. 111-31, \$ 102(a)(2) (codified at 21 U.S.C. \$ 387a-1 (2009)).

72. Family Smoking Prevention and Tobacco Control Act, H.R. 1108, 110th Cong. (2008). Late in the summer of 2008, the House passed H.R. 1108 by a vote of 326–102. 154 Cong. Rec. H7577 (July 30, 2008). The Senate became preoccupied with the emerging worldwide financial crisis and never took up the bill. S. 625, 110th Cong., 1st Sess. (2008); 154 CONG. Rec. S8033 (Aug. 1, 2008). Yet, even without the financial crisis, passage of H.R. 1108 was not guaranteed because President George W. Bush had threatened a veto. Jacob Goldstein, *Bush Administration Opposes FDA Regulation of Tobacco*, WALL ST. J. HEALTH BLOG (July 23, 2008, 12:35 PM), http://blogs.wsj.com/health/2008/07/23/ bush-administration-opposes-fda-regulation-of-tobacco. The tobacco industry was surprisingly divided on the bill, with market share leader Philip Morris favoring the bill and all of its smaller competitors opposing it. *Id.*

73. The final votes in the House and Senate were conclusive: H.R. 1256 passed the House 298– 112, and the Senate 79–17. 155 CONG. REC. H4414–15 (Apr. 2, 2009); 155 CONG. REC. S6501 (June 11, 2009). The House then agreed to the Senate's amendments 307–97. 155 CONG. REC. H6660 (June 12, 2009).

^{64.} Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 60 Fed. Reg. 41,314 (proposed Aug. 11, 1995).

^{65.} Ruger, supra note 41, at 352.

^{66.} Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco Products to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,418 (Aug. 28, 1996) (to be codified at 21 C.F.R. pts. 801, 803, 804, 807, 820, 897).

^{67.} See id. at 44,396.

^{68. 529} U.S. 120, 130 (2000).

^{69.} Id. at 159-60.

^{70.} Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. §§ 387–87u (2009)) (adding a new Chapter 9 to the Federal Food, Drug, and Cosmetic Act, and creating a new Center for Tobacco Products within the FDA).

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The 2009 Act authorized the FDA to regulate how tobacco products are manufactured, marketed, and sold.⁷⁴ Although tobacco companies challenged other requirements imposed by the Act,⁷⁵ the First Amendment controversy centered largely on the new graphic warnings.

Section 201 of the Act requires tobacco packaging and advertising to rotate nine newer, more graphic, and less verbose written warnings.⁷⁶ It requires these warnings to occupy the top fifty percent of the front and back of tobacco product packaging and twenty percent of the area on print advertisements.⁷⁷ Section 201 also requires the FDA to "issue regulations that require color graphics depicting the negative health consequences of smoking to accompany" these nine textual warnings.⁷⁸ The FDA proposed thirty-six graphic images in its proposed rule,⁷⁹ settling on nine in its June 2011 final rule.⁸⁰ The nine warnings are as follows:

WARNING: Cigarettes are addictive. [Showing a man holding a cigarette and exhaling smoke from a tracheostomy hole in his throat.]

WARNING: Tobacco smoke can harm your children. [Showing a mother holding a baby surrounded by smoke.]

WARNING: Cigarettes cause fatal lung disease. [Showing healthy, pink lungs next to diseased, yellowish lungs.]

WARNING: Cigarettes cause cancer. [Showing a diseased mouth with browning teeth and an open wound on the lower lip.]

WARNING: Cigarettes cause strokes and heart disease. [Showing a man laying back, breathing through an oxygen mask with a resuscitator bag.]

WARNING: Smoking during pregnancy can harm your baby. [Showing a cartoon illustration of an infant crying in an incubator, hooked up to a breathing tube and monitors.]

WARNING: Smoking can kill you. [Showing the head and chest of a dead male, apparently lying on an autopsy table, with surgical staples holding together a long, closed incision running down the middle of his chest.]

WARNING: Tobacco smoke causes fatal lung disease in nonsmokers. [Showing an adult woman sobbing.]

^{74. 21} U.S.C. §§ 387-87u (2009); see 15 U.S.C. §§ 1331-41 (2009) (scattered sections).

^{75.} See, e.g., Lorillard, Inc. v. FDA, No. 11-440 (RJL), 2012 WL 3542228 (D.D.C. Aug. 1, 2012) (challenging the composition of the FDA's Tobacco Product Scientific Advisory Committee); Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509 (6th Cir. 2012) (challenging several aspects of the law).

^{76.} Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201, 123 Stat. 1842 (2009) (codified as amended at 15 U.S.C. § 1333 (2009)).

^{77.} *Id.* § 201(a).

^{78.} *Id.* § 201(d).

^{79.} Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,534 (proposed Nov. 12, 2010) (to be codified at 21 C.F.R. pt. 1141).

^{80.} Cigarette Package and Advertising Warnings, 21 C.F.R. § 1141 (2012).

WARNING: Quitting smoking now greatly reduces serious risks to your health. [Showing an adult man wearing a t-shirt with a "No Smoking" symbol and the words "I QUIT."]St

Each of these graphics also includes the phone number 1-800-QUIT-NOW, the number for the National Cancer Institute's smoking cessation hotline.^{8_2}

President Obama signed the Act on June 22, 2009. As with the FDA's doomed rulemaking effort in 1996, tobacco companies immediately sued to challenge the new law.⁸³ On August 31, 2009, five tobacco manufacturers and sellers filed suit in the U.S. District Court for the Western District of Kentucky.⁸⁴ In January 2010, the court held that the graphic images did not violate the plaintiffs' First Amendment rights.⁸⁵ The plaintiffs then appealed to the Sixth Circuit.

Five tobacco companies—including three of the five plaintiffs in the earlier case—filed a similar challenge in the federal district court for the District of Columbia in August 2011, one month after oral argument in the Sixth Circuit case⁸⁶ and two months after the FDA's final rule.⁸⁷ In November 2011, the D.C. district court enjoined the FDA's regulations from taking effect⁸⁸ and later ruled for the tobacco companies on summary judgment.⁸⁹ The government appealed.

II. A CIRCUIT SPLIT?

In 2012, the Sixth Circuit and D.C. Circuit published seemingly disparate opinions on whether graphic warnings violate the First Amendment. In March of that year, the Sixth Circuit upheld the FDA's authority in *Discount Tobacco City & Lottery*; in August, the D.C. Circuit struck down the graphic warnings rule in *R.J. Reynolds.*⁹⁰ Both decisions were divided. And both turned on the appropriate standard of review.

^{81.} Cigarette Health Warnings, FOOD & DRUG ADMIN., http://www.fda.gov/downloads/TobaccoProducts/Labeling/UCM259401.pdf (last visited Mar. 31, 2013).

^{82.} Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg 36628, 36,681 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).

^{83.} Note that Altria, the parent company of Philip Morris, was not party to these suits.

^{84.} See generally Complaint, Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512 (W.D. Ky. 2010) (No. 1:09-CV-00117). The five companies that joined this suit were Discount Tobacco City & Lottery, Inc., Lorillard Tobacco Co., National Tobacco Co., R.J. Reynolds Tobacco Co., Commonwealth Brands, Inc., and American Snuff Co. (formerly Conwood Co.).

^{85.} Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512 (W.D. Ky. 2010).

^{86.} See generally Complaint, R.J. Reynolds Tobacco Co. v. FDA, 823 F. Supp. 2d 36, 39 (D.D.C. 2011) (No. 1:11-CV-01482). The five companies joining this suit were R.J. Reynolds Tobacco Co., Lorillard Tobacco Co., Commonwealth Brands, Inc., Liggett Group L.L.C., and Santa Fe Natural Tobacco Co.

^{87.} Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. at 36,628.

^{88.} R.J. Reynolds Tobacco Co. v. FDA, 823 F. Supp. 2d 36, 39 (D.D.C. 2011).

^{89.} R.J. Reynolds Tobacco Co. v. FDA, 845 F. Supp. 2d 266, 268 (D.D.C. 2012).

^{90.} Id. The D.C. Circuit denied a request to rehear the case en banc on December 5, 2012.

A. THE SIXTH CIRCUIT UPHOLDS GRAPHIC WARNINGS

The Sixth Circuit Court of Appeals issued the first appellate court ruling on graphic tobacco warnings, upholding them in a 2–1 divided opinion. Judge Stranch wrote for the majority, joined by Judge Barrett;⁹¹ Judge Clay wrote in dissent.⁹² Both opinions consider the appropriate standard of review at length.⁹³ The three judges agreed that commercial speech doctrine applies rather than the stricter scrutiny afforded to noncommercial speech, as the industry argued.⁹⁴

The majority chose between Zauderer's rational basis test and the strict scrutiny standard for compelled noncommercial speech in Wooley v. Maynard and discarded Central Hudson as an option.⁹⁵ Judge Clay's dissent contemplated Zauderer and Central Hudson, without addressing Wooley.⁹⁶

It is worth nothing that for more than thirty years, the Supreme Court's 1980 *Central Hudson* decision⁹⁷ provided the default standard in commercial speech cases. Central Hudson Gas and Electric, an electric utility, challenged an order by the New York Public Service Commission that banned all advertising by utilities that "promot[e] the use of electricity."⁹⁸ The Court struck down the rule as violating the utility's First Amendment rights, establishing the famous three-step test that has been used in hundreds of federal cases.⁹⁹

The Supreme Court has said very little about compelled speech and even less about compelled commercial speech. Perhaps for this reason, the Sixth Circuit majority cites *Wooley v. Maynard*, a 1977 Supreme Court opinion.¹⁰⁰ Disregarding *Wooley* seems apt, however, as the case involved core religious speech, not commercial speech. In *Wooley*, the

^{91.} Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 551–69 (6th Cir. 2012) (Stranch, J., concurring in part, dissenting in part). On the graphic warnings issue, Judge Stranch wrote the majority opinion, joined by Judge Barrett; Judge Clay's opinion constitutes the dissent on that issue. *Id.* at 517-18.

^{92.} Id. at 524–31 (Clay, J., concurring in part, dissenting in part).

^{93.} Id. at 521-27; id. at 554-61 (Stranch, J., concurring in part, dissenting in part).

^{94.} Judge Clay's dissent rejected the industry's argument that strict scrutiny should apply because the graphic warnings attempt "to convert commercial speakers into [the government's] mouthpiece for a subjective and highly controversial marketing campaign expressing its disapproval of their lawful products." *Id.* at 525 (Clay, J., concurring in part, dissenting in part) (internal quotation marks omitted) (quoting Entm't Software Ass'n v. Blagojevich, 469 F.3d 641, 652 (7th Cir. 2006)).

^{95.} *Id.* at 554–61 (Stranch, J., concurring in part, dissenting in part).

^{96.} Id. at 524–31 (Clay, J., concurring in part, dissenting in part).

^{97.} Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980).

^{98.} Id. at 558-59.

^{99.} The first step asks whether the speech is false or misleading. *Id.* at 564. If it is not, the second step asks whether the restriction on speech advances a substantial government interest. *Id.* Third, the restriction "must be designed carefully to achieve the State's goal," meaning it "directly advances" the state interest, and is not more restrictive than necessary. *Id.*

^{100.} *Disc. Tobacco*, 674 F.3d at 554 (Stranch, J., concurring in part, dissenting in part) (citing Wooley v. Maynard, 430 U.S. 705 (1977)).

plaintiff was a Jehovah's Witness who objected to a New Hampshire requirement that license plates bear the state motto "Live Free or Die," which the plaintiff found "morally, ethically, religiously and politically abhorrent."¹⁰¹ The Court prohibited the government from punishing citizens like George Maynard who covered up the state motto.¹⁰²

It was not until 1985 that the Supreme Court set a standard for compelled commercial disclosures. In Zauderer v. Office of Disciplinary Counsel, the Supreme Court upheld a state rule of professional conduct that required attorneys who advertised contingency fee arrangements to disclose that even unsuccessful litigants would have to pay certain court fees and litigation expenses.¹⁰³ The Court declared that "an advertiser's rights are adequately protected as long as disclosure requirements are reasonably related to the State's interest in preventing deception of consumers."104 The Zauderer opinion emphasizes three considerations that are important for the graphic tobacco warnings litigation. First, it readily distinguishes Wooley and other cases involving noncommercial speech.¹⁰⁵ Second, it observes that the purpose of extending First Amendment protection to commercial speech is to inform consumers-a marketer's "interest in not providing any particular factual information in his advertising is minimal."¹⁰⁶ Finally, Zauderer rejects the "least restrictive means" analysis from Central Hudson.¹⁰⁷

In *Discount Tobacco City & Lottery*, the Sixth Circuit majority applied *Zauderer* because it found that the warnings represented fact, not opinion.¹⁰⁸ Judge Stranch's decision emphasized first that the *textual* warnings are factual beyond dispute: "It is beyond cavil that smoking presents the serious health risks described in the warnings...."¹⁰⁹ Second, she argued that because the Act requires the FDA to select color graphics to depict the textual warnings, and because the challenge is necessarily a facial one (predating the FDA's proposed graphic warnings), the industry "would have to establish that a graphic warning cannot convey the negative health consequences of smoking accurately, a position tantamount to concluding that pictures can never be factually accurate,

109. *Id.* at 558.

^{101.} Wooley, 430 U.S. at 713.

^{102.} Id.

^{103. 471} U.S. 626, 636 (1985).

^{104.} Id. at 651.

^{105.} *Id.* ("Ohio has not attempted to prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion.... The State has attempted only to prescribe what shall be orthodox in commercial advertising...." (internal quotation marks omitted)).

^{106.} *Id*.

^{107.} Id. at 651 n.14.

^{108.} Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 555–58 (6th Cir. 2012) (Stranch, J., concurring in part, dissenting in part).

only written statements can be."¹¹⁰ She stressed that this argument is "at odds with reason."¹¹¹ Judge Stranch then described several graphic images that would constitute factual disclosures of the risks of smoking under *Zauderer*, some of which seem to be taken from the FDA's proposed rule.¹¹²

Judge Stranch also carefully distinguished graphic tobacco warnings from the Illinois law in *Entertainment Software Ass'n v. Blagojevich*, which required "sexually explicit" video games to be labeled with a large sticker ("18") reflecting the minimum age required to purchase them.¹¹³ The Seventh Circuit in *Blagojevich* applied strict scrutiny.¹¹⁴ To Judge Stranch, the case is distinguishable because opinions might reasonably differ as to what video games qualify as "sexually explicit," depending on "personal taste and sexual morals," but the health risks of smoking are fact, not opinion: "The health risks of smoking tobacco have been uncovered through scientific study. They are facts. Warnings about these risks—whether textual or graphic—can communicate these facts."¹¹⁵

Thus, the Sixth Circuit majority applied *Zauderer*. Although *Zauderer* is almost thirty years old, the Supreme Court reaffirmed its basic principles in 2010 in *Milavetz, Gallop & Milavetz, P.A. v. United States*, which considered a law that required a disclaimer in debt relief ads.¹¹⁶ The Court in *Milavetz* applied *Zauderer* rather than *Central Hudson* for reasons that parallel the tobacco case: The disclosure counters misleading claims, the disclosure is factually accurate, and the disclosure does not prevent the marketer from communicating its own additional information.¹¹⁷

In his dissent, Judge Clay lingered on the distinction between *Central Hudson*, which governs restrictions on truthful, non-misleading commercial speech,¹¹⁸ and *Zauderer*, which governs mandated disclosures intended to prevent consumer deception.¹¹⁹ *Zauderer* applies, he argued, because tobacco companies have long marketed "the alleged pleasures or satisfactions of cigarette smoking" and so "must also disclose the serious risks to life that smoking involves."¹²⁰

116. See generally Milavetz, Gallop & Milavetz, P.A. v. United States, 130 S. Ct. 1324 (2010).

^{110.} Id. at 558–59. Indeed, a contrary conclusion would read like a particularly bad analogy on the SAT college entrance exam (Text : Graphics :: Fact : Opinion).

^{111.} Id. at 559.

^{112.} Id.

^{113. 469} F.3d 641, 651–52 (7th Cir. 2006).

^{114.} Id.

^{115.} Disc. Tobacco, 674 F.3d at 561 (Stranch, J., concurring in part, dissenting in part).

^{117.} Disc. Tobacco, 674 F.3d at 556 (Stranch, J., concurring in part, dissenting in part).

^{118.} See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980).

^{119.} See Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626 (1985).

^{120.} Disc. Tobacco, 674 F.3d at 526–27 (Clay, J., concurring in part, dissenting in part) (quoting Cipollone v. Liggett Grp., 505 U.S. 504, 527 (1992)).

Judge Clay's dissent also distinguished *Blagojevich* and a similar Supreme Court case, *Brown v. Entertainment Merchants Ass'n*,¹²¹ because the laws in those cases (both concerning video games) affirmatively limited speech and concerned core speech (art and literature) rather than commercial speech.¹²² In contrast, Judge Clay observed, the FDA's graphic warnings "serve as disclaimers to the public regarding the incontestable health consequences of using tobacco."¹²³

Judge Clay's dissent thus did not quibble with the standard of review. The point of departure was whether the graphic warnings satisfy even the rational basis test of *Zauderer*, which again allows disclosures that are "reasonably related to the State's interest."¹²⁴ Judge Clay found that they do not.

Judge Clay's unease with graphic warnings is that they are both unprecedented and subjective—which he contrasted with the textual warnings, which are both precedented and objective.¹²⁵ On the first measure, he is correct: Graphic warnings are new. On the second, Judge Clay's reasoning underwhelms. For example, he objected to the "visceral reaction" that graphic warnings are intended to evoke, arguing that the government cannot "frighten consumers" or try to "flagrantly manipulate" their emotions.¹²⁶ This, he argued, can undermine rational decisionmaking,¹²⁷ as if the decision to smoke is entirely rational. As Judge Stranch wrote in retort: "Facts can disconcert, displease, provoke an emotional response, spark controversy, and even overwhelm reason, but that does not magically turn such facts into opinions."¹²⁸

Judge Clay also noted that "color graphics cannot accurately convey *all* of the health risks associated with tobacco use,"¹²⁹ as if that were required to satisfy *Zauderer*.¹³⁰ The Court in *Zauderer*, in fact, explicitly rejected the idea that disclosures must "get at all facets of the problem."¹³¹ Judge Clay then objected that persons seeing the graphic

^{121. 131} S. Ct. 2729, 2738 (2011).

^{122.} Disc. Tobacco, 674 F.3d at 526–27 (Clay, J., concurring in part, dissenting in part).

^{123.} Id. at 527.

^{124.} Zauderer, 471 U.S. at 651.

^{125.} Disc. Tobacco, 674 F.3d at 528 (Clay, J., concurring in part, dissenting in part).

^{126.} Id. at 529.

^{127.} Id.

^{128.} Id. at 569 (Stranch, J., concurring in part, dissenting in part).

^{129.} Id. at 530 (Clay, J., concurring in part, dissenting in part) (emphasis added).

^{130.} For example, prescription drug labels also cannot convey all possible risks of a drug, even though labels are somewhat comprehensive. *See, e.g.*, Jon Duke et al., *A Quantitative Analysis of Adverse Events and "Overwarning" in Drug Labeling*, 171 ARCHIVES INTERNAL MED. 941 (2011) (finding an average of almost seventy discrete adverse drug event warnings in each FDA-approved prescription drug label).

^{131.} Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 n.14 (1985) ("[W]e are unpersuaded by [the] argument that a disclosure requirement is subject to attack if it is 'under-

warnings might interpret them differently,¹³² as if textual warnings are not similarly subject to interpretation. Finally, Judge Clay suggested that the graphic warnings requirement "may rest on different individual viewpoints and ideologies,"¹³³ as if the health effects of smoking are ideological and not proven.

Though Judge Clay acknowledged the low hurdle presented by *Zauderer*, he found that the graphic warnings do not clear it.¹³⁴ Thus, the split opinion in the Sixth Circuit boils down not to the standard of review (on which the majority and dissent agree), but to whether the government has a rational basis for requiring graphic warnings under *Zauderer*.

B. THE D.C. CIRCUIT STRIKES DOWN GRAPHIC WARNINGS

Five months after the Sixth Circuit upheld graphic warnings, the D.C. Circuit struck them down.¹³⁵ It is worth noting two differences in scope. First, the Sixth Circuit confronted many more questions on appeal than did the D.C. Circuit. For example, does the requirement that the FDA preapprove marketing for "modified risk" tobacco products (those claiming to be "light," "mild," and the like) violate the First Amendment? (No.)¹³⁶ Does the prohibition against tobacco companies sponsoring certain events, producing certain branded merchandise, and giving away free samples violate their free speech rights? (No.)¹³⁷ Does the Act violate the speech rights of tobacco marketers by limiting their advertising to black and white text? (Yes.)¹³⁸ And does the Act's restriction against claims that tobacco products are safer or less harmful by virtue of FDA regulation violate marketers' First Amendment rights? (No.)¹³⁹ The D.C. Circuit was not presented with these issues on appeal.

Second, the Sixth Circuit treated this as a facial challenge, as the FDA had not yet proposed its graphic warnings when the Western District of Kentucky entered summary judgment for the government.¹⁴⁰ In contrast, the D.C. Circuit was able to address the actual graphic warnings selected by the FDA, as the final rule was published two months before the companies filed their complaint.¹⁴¹ This favored the government in the

inclusive'-that is, if it does not get at all facets of the problem it is designed to ameliorate.").

^{132.} Disc. Tobacco, 674 F.3d at 530 (Clay, J., concurring in part, dissenting in part) ("The color graphics can be seen one way by some smokers, yet another by other smokers—one way by some non-smokers and yet an entirely different interpretation by other non-smokers.").

^{133.} Id.

^{134.} Id.

^{135.} R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1222 (D.C. Cir. 2012).

^{136.} Disc. Tobacco, 674 F.3d at 531-37 (Clay, J., concurring in part, dissenting in part).

^{137.} Id. at 537-44.

^{138.} *Id.* at 544–48.

^{139.} Id. at 548-51.

^{140.} Id. at 522; id. at 552-53 (Stranch, J., concurring in part, dissenting in part).

^{141.} Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628 (June 22,

Sixth Circuit but favored the tobacco companies in the D.C. Circuit. This difference allowed the government to argue that there is no circuit split.¹⁴²

Scope aside, there are parallels between the two decisions. Like the Sixth Circuit, the D.C. Circuit divided 2–1, but against graphic warnings.¹⁴³ Judge Brown wrote for the majority, joined by Judge Randolph.¹⁴⁴ Judge Rogers wrote in dissent.¹⁴⁵ Also, like the Sixth Circuit, the opinions spent considerable time contemplating the proper standard of review.

Judge Brown's majority opinion considered *Zauderer* at length but found it inapt for several reasons. First, *Zauderer* governs disclosures designed to address consumer deception, not those designed to communicate health risks¹⁴⁶ for which there seems to be no directly controlling precedent. To Judge Brown, the FDA did not demonstrate that consumers risk being deceived without graphic warnings.¹⁴⁷ She discounted arguments that the government designed the graphic warnings to counter decades of deceptive tobacco marketing.¹⁴⁸ On this point, the dissent cited the D.C. Circuit's own language in *Pearson v. Shalala*, which states that "the government's interest in preventing consumer fraud/confusion may well take on added importance in the context of a product... that can affect the public's health."¹⁴⁹ Thus, both the Sixth and D.C. Circuits struggled with whether *Zauderer* applies only when the state's interest is countering consumer deception, or if it also applies to other state interests.

Second, the D.C. Circuit majority held that *Zauderer* applies only to "purely factual and uncontroversial" disclosures.¹⁵⁰ Judge Brown found the FDA's graphic warnings to be neither. This part of the opinion is the most strident because it aggressively second-guesses the policy judgments of Congress and the FDA. For example, the image of a man exhaling smoke through the tracheostomy hole in his throat must, to Judge Brown, portray a "common consequence of smoking";¹⁵¹ it may not symbolize "the addictive nature"¹⁵² of it. The majority maintained that graphic warnings

142. Brief for the Respondents in Opposition, supra note 15, at 13.

^{2011) (}to be codified at 21 C.F.R. pt. 1141).

^{143.} R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1208 (D.C. Cir. 2012).

^{144.} Id. at 1208.

^{145.} Id. at 1222 (Rogers, J., dissenting).

^{146.} *Id.* at 1213 (majority).

^{147.} Id.

^{148.} *Id.* at 1214–15.

^{149.} Id. at 1235 (Rogers, J., dissenting) (alteration in original) (quoting Pearson v. Shalala, 164 F.3d 650, 656 (D.C. Cir. 1999)).

^{150.} Id. at 1216 (majority).

^{151.} Id.

^{152.} *Id.* (quoting Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,649 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141)). The government argues that this phenomenon (smoking through one's tracheostomy hole, even after cancer surgery) is not unusual. *Id.* at 1231 (Rogers, J., dissenting).

cannot be purely factual if they are designed to evoke emotion or "shock the viewer."¹⁵³ The majority also seemed to require that the images themselves convey some information apart from the textual warnings.¹⁵⁴ But Congress directed the FDA to "require color graphics depicting the negative health consequences of smoking to *accompany* the label statements."¹⁵⁵ As the dissent noted, the graphics and text should be viewed together as a single presentation, not separately.¹⁵⁶ Finally, the majority concluded that the images are "inflammatory" and represent "unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting."¹⁵⁷

Thus instead of *Zauderer*'s rational basis review, the majority applied intermediate scrutiny under *Central Hudson*, following two earlier D.C. Circuit opinions addressing whether corrective advertising violates the First Amendment.¹⁵⁸

In dissent, Judge Rogers argued that *Zauderer* should apply.¹⁵⁹ In *Zauderer*, she noted, the Supreme Court found that preventing consumer deception is a sufficient government interest to justify mandatory disclosures, but not the *only* government interest that could do so.¹⁶⁰ She also argued that although consumer deception is not necessary to invoke *Zauderer*, it is present here because the tobacco industry has a history of deceptive advertising that parallels the risk of deception in *Zauderer* itself.¹⁶¹ Actual deception is not required—just the risk of it.¹⁶² Moreover, the mandatory warning does not affirmatively limit the companies' own speech, as they claimed.¹⁶³

The Rogers dissent then considered whether the warnings were factually accurate and non-controversial.¹⁶⁴ She found the textual warnings were factual.¹⁶⁵ The question became whether the color images rendered the warnings as a whole to be "nonfactual or controversial."¹⁶⁶ On this

^{153.} Id. at 1216 (majority).

^{154.} Id.

^{155.} Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 201(d), 123 Stat. 1776 (2009) (emphasis added).

^{156.} R.J. Reynolds, 696 F.3d at 1230 (Rogers, J., dissenting).

^{157.} *Id.* at 1216–17 (majority).

^{158.} *Id.* at 1217 (discussing both *United States v. Philip Morris*, 566 F.3d 1095 (D.C. Cir. 2009), and *Novartis Corp. v. FTC*, 223 F.3d 783 (D.C. Cir. 2000)).

^{159.} Id. at 1223 (Rogers, J., dissenting).

^{160.} Id. at 1227 n.6 (citing both the Supreme Court's opinion in Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 650–51 (1985), and the Sixth Circuit's opinion in Discount Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 556 (6th Cir. 2012)).

^{161.} Id. at 1222, 1227 n.6.

^{162.} *Id.* at 1227.

^{163.} *Id.* at 1229 (citing Milavetz, Gallop & Milavetz, P.A. v. United States, 130 S. Ct. 1324, 1339 (2010)).

^{164.} Id. at 1229.

^{165.} Id.

^{166.} *Id.* at 1230.

point, the dissent invoked the common sense observation in *Zauderer* that illustrations or pictures draw attention to and amplify the textual message being communicated.¹⁶⁷ Like the Sixth Circuit majority, the Rogers dissent rebutted the logical fallacy that images cannot by their nature be factually accurate.

The Rogers dissent also considered whether the specific images selected by the FDA in its final rule were factual. The images, she observed, "are, in fact, accurate depictions of the effects of sickness and disease caused by smoking."¹⁶⁸ Just because the images may be discomforting or even disturbing to look at does not make them factually inaccurate.¹⁶⁹ As Rogers emphasized, "factually accurate, emotive, and persuasive are not mutually exclusive descriptions."¹⁷⁰

Still, this logic did not persuade a majority on the D.C. Circuit. As such, the decision vacated the graphic warnings rule and remanded back to the FDA.

C. The Government Withdraws

To many, the disparate court of appeals rulings presented a circuit split that the Supreme Court would have to resolve. But in March 2013, the FDA withdrew its graphic warnings rule and the Department of Justice decided to forego Supreme Court review.

The FDA made no formal announcement of its decision. But a March 15 letter from Attorney General Eric Holder to Speaker of the House John Boehner explained that the Department of Justice would not petition the Supreme Court to review *R.J. Reynolds.*¹⁷¹ The government had petitioned the D.C. Circuit to rehear *R.J. Reynolds* en banc, which the court denied.¹⁷²

But that is as far as the government would press. The Holder letter emphasized that *R.J. Reynolds* invalidated only "the particular graphic warnings adopted in FDA's regulation" and that "FDA therefore remains free to conduct new rulemaking."¹⁷³ The letter also explained "that FDA

^{167.} Id. (quoting Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 647 (1985)).

^{168.} Id. (quoting Cigarette Package & Adver. Warnings, 21 C.F.R. § 1141 (2012)).

^{169.} *Id.* The one exception, according to the dissent, is the required disclosure of the National Cancer Institute's hotline, 1-800-QUIT-NOW, which "does not directly disclose factual information about the health consequences of smoking." *Id.* at 1234, 1236. Thus, the dissent analyzes this provision under *Central Hudson* rather than *Zauderer*. *Id.* at 1236.

^{170.} Id. at 1230.

^{171.} Letter from Eric Holder, U.S. Attorney General, to John Boehner, Speaker of the House of Representatives (Mar. 15, 2013) (on file with author).

^{172.} Appellants' Petition for Rehearing and Rehearing En Banc, *R.J. Reynolds*, 696 F.3d 1205 (Nos. 11-5332, 12-5063), 2012 WL 4844135, *rehearing en banc denied*, Nos. 11-5332, 12-5063 (Dec. 5, 2012) (per curiam).

^{173.} Letter from Eric Holder, *supra* note 171, at 3.

will undertake research to support a new rulemaking consistent with the Tobacco Control Act."¹⁷⁴ Thus, the letter continued, "the Solicitor General has determined, after consultation with HHS and FDA, not to seek Supreme Court review of the First Amendment issues at the present time."¹⁷⁵ The paragraph concluded by noting that Supreme Court review would be possible if "a court of appeals were to set aside new regulations issued by FDA at a later date."¹⁷⁶

Around the same time, the Solicitor General filed a brief in opposition to the industry's petition for certiorari, which is notable for a few reasons. First, it emphasized that the Sixth Circuit's decision upholding the FDA's authority under the Act to issue graphic warnings is correct.¹⁷⁷ Second, it argued that the case was moot because the D.C. Circuit vacated the only remaining legal source that imposed graphic warnings (the FDA's rule) and because "the government has decided not to petition for certiorari in *Reynolds.*"¹⁷⁸ The Solicitor General's brief also emphasized that "the Act does not directly impose graphic warnings," but instead authorizes the FDA to promulgate regulations that require them.¹⁷⁹ This caveat appeared several times in the brief and was likely intended to inoculate the statute from the First Amendment vulnerabilities of the FDA's rule.

Thus, the Attorney General's letter and the Solicitor General's brief close the latest chapter in the long struggle to regulate tobacco. As it now stands, the FDA will conduct research to support new rulemaking to require graphic warnings that accompany the nine written warnings imposed under the Tobacco Control Act. As we start a new chapter in this saga, both the FDA and the industry (and eventually the courts) will have to confront five lingering doctrinal ambiguities, which are discussed in Part III.

III. CAN THE GOVERNMENT FIGHT FOR OUR HEARTS (AND MINDS)?

At stake in the next round of graphic warnings rulemaking and litigation is the government's ability to catch our attention at the point of sale. Black-and-white textual warnings are frequently overlooked and ignored, because consumers are inundated with such warnings¹⁸⁰ and have become numb to disclaimers and words of caution. How can the government grab our attention? In the cacophony of advertisements,

^{174.} Id.

^{175.} Id.

^{176.} Id.

^{177.} Brief for the Respondents in Opposition, *supra* note 15, at 13.

^{178.} Id. at 13–14.

^{179.} *Id.* at 16.

^{180.} Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know" from the "Need to Know" About Consumer Product Hazards*, 11 YALE J. ON REG. 293, 374–78 (1994).

messages, and marketing, how far can the government go to be heard? And what can it do when it shares the same space (here, tobacco packaging) with private companies?

First Amendment doctrine is largely silent on these questions. Indeed, First Amendment doctrine says very little on the broader issue of compelled commercial disclosures, despite their prevalence.¹⁸¹

Yet as the FDA begins to consider new graphic warnings, and as it contemplates inevitable judicial review, the agency will have to confront these questions. This Article looks at five questions in particular that may determine the fate of not just graphic tobacco warnings, but future graphic warnings that the government could deem necessary: (i) What standard of review applies to graphic warnings? (ii) Were the FDA's graphic warnings factual or factually controversial? (iii) Did the graphic warnings appeal to rationality or emotion, and does this matter for First Amendment purposes? (iv) Will the rights of marketers give way to the core value animating commercial speech doctrine, which is to encourage more speech, not less? Finally, (v) will a negative Supreme Court opinion hamstring future government efforts to be heard?

A. THE STANDARD OF REVIEW BATTLE

As noted above, whether graphic warnings are permissible under the First Amendment depends largely on the standard of review applied. One lingering question after *Discount Tobacco* and *R.J. Reynolds* is whether *Zauderer* only applies when the state interest is preventing consumer deception or if other state interests could also qualify. A careful examination of *Zauderer* suggests that the core principal animating commercial speech doctrine is encouraging information to circulate, not simply preventing deception.¹⁸² The government has many reasons for circulating information: to minimize product safety hazards, health hazards, or environmental hazards, to name a few. Preventing consumer deception is just one reason why the government might need to circulate information.

Applying *Central Hudson* rather than *Zauderer* based on the specific state interest has little grounding. The D.C. Circuit is somewhat of an outlier in applying *Zauderer* so narrowly. The First, Second, and now the Sixth Circuits have applied *Zauderer* when the state interest is something other than preventing consumer deception.¹⁸³ Thus, although

^{181.} Keighley, *supra* note 19, at 541.

^{182.} Id. at 557–58; Robert Post, Transparent and Efficient Markets: Compelled Commercial Speech and Coerced Commercial Association in United Foods, Zauderer, and Abood, 40 VAL. U. L. REV. 555, 577 (2006).

^{183.} For example, in addition to the Sixth Circuit, the First and Second Circuits both have applied *Zauderer* to laws pursuing other state interests. *See* Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294,

appellate courts are divided, they lean heavily in one direction. Commercial speech *restrictions* governed by *Central Hudson* are routinely justified by state interests other than preventing consumer deception,¹⁸⁴ even though the law in *Central Hudson* itself was predicated on different grounds.

Another threshold question that was not given much attention by either appellate court is whether the speech at issue is commercial or noncommercial. Tobacco companies argued before the Sixth Circuit that strict scrutiny should apply rather than the less demanding tests for commercial speech.¹⁸⁵ The D.C. Circuit considered the question, but only briefly.¹⁸⁶ Because the battleground here is tobacco packaging and advertising rather than the pages of scientific journals or news wires, the speech is most likely commercial.

When confronted with different kinds of speech by FDA-regulated firms, courts have been quite uniform.¹⁸⁷ Even with compelled disclosures, there is a wide gap between attempts to "prescribe what shall be orthodox in politics, nationalism, [or] religion"¹⁸⁸ and attempts "to prescribe what shall be orthodox in commercial advertising."¹⁸⁹ Although the Supreme Court would have little reason in this case to probe the fine lines between commercial and noncommercial speech, many are waiting for the Court to do so eventually.

B. FACT OR CONTROVERSY?

Another lingering ambiguity that the FDA and reviewing courts will have to resolve is whether the FDA's graphic tobacco warnings were factual. Both *Zauderer* and *Central Hudson* address factual speech. *Zauderer* speaks of mandatory disclosures that convey "purely factual and uncontroversial information."¹⁹⁰ *Central Hudson* reaffirms that the First Amendment protects commercial speech that is not false or "misleading."¹⁹¹ The two are mirror images: *Zauderer* addresses disclosures authored by

^{310 (1}st Cir. 2005) (involving a state interest in ensuring access to high quality, cost-effective health care); Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001) (involving a state interest in "protecting human health and the environment").

^{184.} Keighley, supra note 19, at 558-61.

^{185.} Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 522 (6th Cir. 2012) (citing Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557 (1980)).

^{186.} R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1217 (D.C. Cir. 2012); see id. at 1226 (Rogers, J., dissenting).

^{187.} See generally Cortez, supra note 20 (reviewing twenty-four cases in which FDA-regulated firms claimed First Amendment protection since commercial speech was formally recognized in 1976, and finding that all but two cases concluded that the speech was commercial rather than noncommercial, with the other two cases not involving FDA rules or enforcement).

^{188.} Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985).

^{189.} Id. at 651; see R.J. Reynolds, 696 F.3d at 1226 n.5 (Rogers, J., dissenting).

^{190. 471} U.S. at 651.

^{191.} Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 564, 566 (1980).

the government, while *Central Hudson* addresses speech authored by commercial interests. As such, both the Sixth and D.C. Circuits evaluated not only how "factual" the graphic warnings are (or, in the Sixth Circuit, can be), but also whether they respond to years of false or misleading marketing by tobacco companies.

The veracity of the nine new textual warnings is entirely noncontroversial; the tobacco companies do not seriously dispute them.¹⁹² The question thus turns on whether the graphic images selected by the FDA to "accompany" these textual warnings rendered them nonfactual or at least factually controversial.

The D.C. Circuit majority tipped its hand when it framed the question: "[H]ow much leeway should this Court grant the government when it seeks to compel a product's manufacturer to convey the state's subjective—and perhaps even ideological—view that consumers should reject this otherwise legal, but disfavored, product?"¹⁹³

Richard Epstein echoed similar sentiments, calling the graphic warnings "falsehoods" and even suggesting that the images themselves were misleading unless they (somehow) communicated all of the other factors that contribute to the health risks pictured actually materializing—such as "the number of cigarettes smoked, their tar and nicotine content, the level of inhalation, and the age at which smoking takes place."¹⁹⁴ It is unrealistic to expect any single image to convey such a catalog of clarifications without also turning it into a long, pharmaceutical-like package insert (and perhaps inducing sleep). Moreover, as I note above, the Supreme Court in *Zauderer* rejected the idea that a mandated disclosure has to "get at all facets of the problem it is designed to ameliorate."¹⁹⁵

There is some sense, as Jennifer Keighley recommends, in distinguishing "factual" speech that discloses facts about the world from "normative" speech that urges the audience to do or not to do something.¹⁹⁶ For example, the text, "WARNING: Smoking can kill you" seems much less problematic than the text, "WARNING: You should not smoke because it can kill you." The implication is clear in the first message, but the second plods toward the "unduly burdensome" disclosures contemplated by *Zauderer*.¹⁹⁷

^{192.} Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 525-26 (6th Cir. 2012).

^{193.} *R.J. Reynolds*, 696 F.3d at 1212.

^{194.} Richard A. Epstein, *When Government Distorts the Truth*, DEFINING IDEAS (Sept. 4, 2012), http://www.hoover.org/publications/defining-ideas/article/127086.

^{195. 471} U.S. at 651 n.14.

^{196.} Keighley, *supra* note 19, at 569–70.

^{197. 471} U.S. at 651.

Facially, both warnings convey similar messages. But the subtext differs. "WARNING: Smoking can kill you" implies, "Smoke if you wish, but know that it can kill you." The government's interest is to inform the would-be smoker, though it leaves the ultimate decision to the individual. The second statement implies nothing. "WARNING: You should not smoke because it can kill you" means what it says. The government could not claim that its interest merely is to inform. While the government undoubtedly could urge people not to smoke in its own publications, it might become "unduly burdensome" when the warnings are required on tobacco packaging and advertisements. Carrying the government's billboard.¹⁹⁸

But these examples involve text. Would adding graphics render the warnings nonfactual or factually controversial? Take the statement, "WARNING: Smoking can kill you," accompanied by the picture of a dead body with an autopsy scar along the chest. This warning is less problematic (though much more disturbing and gripping) than the statement, "WARNING: Quitting smoking now greatly reduces serious risks to your health," accompanied by a picture of a man wearing a t-shirt with a "no smoking" symbol and the words "I QUIT." The first image is factual, if disturbing; the second image is normative, if mundane. Similarly, the hotline number I-800-QUIT-NOW is normative, not factual.¹⁹⁹

An image does not necessarily turn a factual message into a normative one, as long as the image itself is factual and not misleading. Thus the burden for compelled graphic warnings should be whether they are false or misleading. The government can speak normatively in its own publications, but compelled disclosures should be factual and not misleading. This would be symmetrical with the commercial speech doctrine governing speech restrictions, which recognizes that the First Amendment does not protect false or misleading messages.

Consider the statement, "WARNING: Smoking can kill you," accompanied by the image of a dead body with an autopsy scar. Given that smoking can, in fact, cause death, a body deceased from the consequences of smoking is not misleading. It happens. As the dissent in the D.C. Circuit observed:

^{198.} Keighley, *supra* note 19, at 570 (citing Wooley v. Maynard, 430 U.S. 705, 715 (1977)). Years ago, the Administrative Conference of the United States considered whether agencies should communicate risk information simply to inform and educate, or to change behavior. *See* Risk Communication as a Regulatory Alternative for Protecting Health, Safety, and the Environment, 55 Fed. Reg. 13,538, 13,539 (proposed Apr. 11, 1990).

^{199.} The hotline number is the one feature of the graphic warnings that the dissent in the D.C. Circuit would have invalidated. R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1234, 1236 (D.C. Cir. 2012) (Rogers, J., dissenting).

The FDA might have opted for an image of a decaying cadaver or of a pile of ashes to portray the likely physical consequences of smoking, but it was not limited to such images in its representation of those consequences. An autopsy scar is merely one way of communicating that the man in the image is dead; viewed in connection with the textual warning, the image conveys the message that smoking can result in death.²⁰⁰

The tobacco companies also objected to the image of a man exhaling smoke through the tracheostomy hole in his throat, accompanied by the text, "WARNING: Cigarettes are addictive."²⁰¹ By amplifying the textual warning, the image undoubtedly does as it intends. But smoking through a tracheostomy hole after cancer surgery is "not so extreme or unusual" as to be nonfactual.²⁰² As the government showed, "fifty percent of neck and head cancer patients continue to smoke."²⁰³ The image thus drives home a fact: "Cigarettes are addictive." That the image is particularly effective should not render it unconstitutional.

Thus, if the next reviewing court decides that the graphic warnings chosen by the FDA are factual rather than nonfactual or factually controversial, then it should apply the rational basis test in *Zauderer*. Otherwise, the graphic warnings must surmount a more searching review, perhaps under *Central Hudson* or other similarly ill-fitting precedents.

A factual dispute also revolves around whether the graphic warnings selected by the FDA were necessary to convey the true health risks of smoking, which itself turns on whether consumers (particularly adolescents) fully appreciate these risks. Both sides agreed that adolescents generally overestimate the risk of developing cancer.²⁰⁴ Yet, research also suggests that adolescents generally underestimate or misunderstand the other health risks of tobacco use, including the long-term risks and the specific risks to themselves.²⁰⁵

Given the persistent number of smoking-related deaths each year (around 400,000),²⁰⁶ we are faced with one of two possibilities: Either new smokers generally are well aware of the health risks and make rational decisions to smoke anyway, or new smokers discount the risks, perhaps due to cognitive biases or a lack of adequate information (or a lack of adequately memorable information). If the former is true, then graphic warnings probably will not work. If the latter is true, they should.²⁰⁷ If the

^{200.} *Id.* at 1232.

^{201.} Id. at 1209 (majority).

^{202.} Id. at 1231 (Rogers, J., dissenting).

^{203.} Id.

^{204.} Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 525 (6th Cir. 2012).

^{205.} Id.

^{206.} REUBEN, *supra* note 3, at 61.

^{207.} Aside from the FDA's consumer study, the other empirical evidence is largely comparative.

As noted by the D.C. Circuit, thirty-three countries (Australia, Belgium, Brazil, Brunei, Canada,

answer is a mix of both, why should courts second-guess the judgment of both Congress and the FDA, as long as the graphic warnings are neither false nor misleading?

Either way, this represents another factual dispute between the tobacco industry and two branches of government—the legislative and executive. How much evidence should the third branch of the government (the judicial) require from the other two? Should Congress have to prove empirically that graphic warnings will indeed reduce smoking levels, or even smoking deaths?

The D.C. Circuit engaged in a searching review of the evidence used by the FDA to justify its final selection of images, even scrutinizing the design of the FDA's consumer study that attempted to measure the effectiveness of the proposed warnings.²⁰⁸ The Sixth Circuit found support in the Second Circuit's *National Electrical Manufacturers Ass'n v. Sorrell* decision that the government could rely on common sense intuitions that larger, color graphics would have more force than black-and-white text.²⁰⁹

Will courts expect hard empirical evidence that graphic warnings will actually reduce smoking levels or smoking deaths? Will it require empirical data showing that color images are more effective than blackand-white text? Or will it rely on common sense intuitions per *Sorrell*? The FDA will have to consider this question as it conducts new research to support another round of rulemaking.

C. MIND OR EMOTION?

Another fascinating (and perhaps irresolvable) issue hovering after *Discount Tobacco* and *R.J. Reynolds* is whether graphic warnings necessarily appeal to our emotions rather than to our minds—and whether this matters for First Amendment purposes. Both appellate courts divided on this question.

In his Sixth Circuit dissent, Judge Clay objected that graphic warnings trigger a "visceral reaction" aimed to "frighten consumers" and "flagrantly manipulate [their] emotions," which can undermine rational decisionmaking.²¹⁰ Likewise, in her D.C. Circuit majority opinion, Judge

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) currently require graphic warnings on tobacco packaging. *R.J. Reynolds*, 696 F.3d at 1209 n.3. Similar requirements are pending in seven other countries: France, Guernsey, Honduras, Malta, Norway, the Philippines, and Spain. *Id.* The D.C. Circuit majority in *R.J. Reynolds* was underwhelmed by the effects of graphic warnings in other countries, although it admitted that confounding variables complicated the data. *Id.* 208. *Id.* at 1200–10.

^{209.} Disc. Tobacco, 674 F.3d at 555–58, 564 (citing Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001), which upheld a Vermont statute requiring manufacturers of light bulbs containing mercury to label them as such and to tell consumers to recycle or dispose of them as hazardous waste).

^{210.} Id. at 528-29 (Clay, J., concurring in part, dissenting in part).

Brown argued that graphic warnings cannot be "purely factual" if they are designed to "evoke emotion" or "shock the viewer."²¹¹

In contrast, Judge Stranch's majority opinion for the Sixth Circuit retorted: "Facts can disconcert, displease, provoke an emotional response, spark controversy, and even overwhelm reason, but that does not magically turn such facts into opinions."²¹² Likewise, Judge Rogers' dissent in the D.C. Circuit stressed that even though the FDA's graphic images may be discomforting or disturbing, they were accurate depictions of the effects of smoking.²¹³ She observed that "factually accurate, emotive, and persuasive are not mutually exclusive descriptions."²¹⁴

Are visuals so persuasive that they "stop us from thinking," as the director Errol Morris once said?²¹⁵ Research in the field of psychology supports the commonsense observation that images grip people more quickly and trigger their emotions more easily than text.²¹⁶ Indeed, that is why Congress chose to use images, following the example of forty other countries that require graphic tobacco warnings or have such requirements pending.²¹⁷

Critics argue that quicker, more intuitive reactions to images subvert rational decisionmaking.²¹⁸ Judge Richard Posner, after reviewing such research, observed that emotion "short-circuits reason conceived of as a conscious, articulate process of deliberation, calculation, analysis, or reflection."²¹⁹

Is this true, and does it matter for First Amendment purposes? As the Sixth Circuit's majority and the D.C. Circuit's dissent observed, graphic images do not magically transform facts into opinions. The demonstrated health effects of smoking *are* disconcerting and disturbing. Should the government be required to communicate these facts in the dullest possible manner? As the D.C. Circuit's dissent noted, this "argument leads to the counterintuitive conclusion that the more concerning the negative health effects of a particular product, the more constrained the government is in mandating disclosures of those facts."²²⁰ This cannot be the case.

^{211.} R.J. Reynolds, 696 F.3d at 1216–17.

^{212.} Disc. Tobacco, 674 F.3d at 569.

^{213.} R.J. Reynolds, 696 F.3d at 1230 (Rogers, J., dissenting).

^{214.} Id.

^{215.} Nadia N. Sawicki, *Tobacco Labeling and the Ethics of Persuasion*, BILL OF HEALTH BLOG (Sept. 11, 2012), http://blogs.law.harvard.edu/billofhealth/2012/09/11/tobacco-labeling-and-the-ethics-of-persuasion (describing the "fear appeal" of some public health campaigns); *see* Michael Meyer, *Errol Morris on Abu Ghraib: An Interview with the Filmmaker*, COLUM. JOURNALISM REV. (Mar. 5, 2008, 2:40 PM), http://www.cjr.org/q_and_a/errol_morris_on_abu_ghraib.php.

^{216.} Sawicki, supra note 215.

^{217.} *R.J. Reynolds*, 696 F.3d at 1209 n.3.

^{218.} Sawicki, supra note 215.

^{219.} RICHARD A. POSNER, FRONTIERS OF LEGAL THEORY 228 (2001).

^{220.} R.J. Reynolds, 696 F.3d at 1231.

Moreover, is the decision to smoke a rational, calculated process? Is it, as Judge Posner describes (with his characteristic law and economics

sensibilities), "a conscious, articulate process of deliberation, calculation, analysis, or reflection"?²²¹ If not—or if the process is a more complicated mix of reasoning and emotion—then why should the First Amendment not allow factual warnings that touch both nerves? Again, the FDA will have to consider these questions very carefully as it crafts new graphic warnings.

D. "More Disclosure, Rather than Less"?

In 1919, Justice Oliver Wendell Holmes first articulated the thought that the First Amendment enables a marketplace of ideas, in which speech competes for attention based on its merits.²²² But it was not until 1976 that the Supreme Court formally recognized ideas in the marketplace.²²³ In the now-famous case *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, the Court emphasized that the core concern in protecting commercial speech under the First Amendment is to ensure "the free flow of commercial information" so that consumers can make decisions that are "intelligent and well informed."²²⁴

Since then, commercial speech doctrine has always been predicated on the value of information to consumers.²²⁵ When evaluating government restrictions on commercial speech, the Supreme Court has long reminded us that "the preferred remedy [for false or misleading speech] is more disclosure, rather than less."²²⁶ In a 2012 concurring opinion, Justice Kennedy reiterated that the "remedy for speech that is false is speech that is true."²²⁷ The Court has recognized that consumers have a significant interest in "receiving truthful information about tobacco products."²²⁸ First Amendment doctrine clearly prefers disclosure to suppression.²²⁹ That

^{221.} POSNER, *supra* note 219, at 228.

^{222.} Abrams v. United States, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting) ("But when men have realized that time has upset many fighting faiths, they may come to believe even more than they believe the very foundations of their own conduct that the ultimate good desired is better reached by free trade in ideas—that the best test of truth is the power of the thought to get itself accepted in the competition of the market, and that truth is the only ground upon which their wishes safely can be carried out. That at any rate is the theory of our Constitution.").

^{223.} See Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748 (1976).

^{224.} Id. at 748. The Supreme Court invoked Alexander Meiklejohn, who was one of the most notable proponents of free speech in the twentieth century. See generally ALEXANDER MEIKLEJOHN, FREE SPEECH AND ITS RELATION TO SELF-GOVERNMENT (1948).

^{225.} Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985); 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 503 (1996).

^{226.} Bates v. State Bar of Ariz., 433 U.S. 350, 375 (1977) (striking down a state bar rule prohibiting price advertising by attorneys).

^{227.} United States v. Alvarez, 132 S. Ct. 2537, 2550 (2012) (Kennedy, J., concurring).

^{228.} Lorillard Tobacco Co. v. Reilly, 533 U.S. 525, 564 (2001).

^{229.} Pearson v. Shalala, 164 F.3d 650, 657 (D.C. Cir. 1999).

basic value—more information, not less—likely animates most mandatory disclosure requirements.²³⁰

Compelling factual disclosures in commerce is justified both on economic grounds (correcting information asymmetries as a market failure) and on democratic ones (enabling robust deliberation by an informed citizenry).²³¹ As the Court in *Zauderer* observed, the marketer's interest "in *not* providing any particular factual information in his advertising is minimal."²³² Commercial speech doctrine has always preferred more speech to less. Graphic warnings support rather than undermine this core tenet.

E. IMPLICATIONS FOR OTHER DISCLOSURE REGIMES

Engaging in commerce has long meant making certain disclosures and bearing other informational costs of compliance.²³³ For example, corporations have to disclose mountains of financial information.²³⁴ Publicly traded firms must disclose any information "material" to investors.²³⁵ New vehicles must disclose their gas mileage and safety ratings.²³⁶ Products containing certain poisonous chemicals must be labeled as poisonous.²³⁷ Food labels must include the food's ingredients and nutritional content, including unflattering things like total fat, cholesterol, and sodium.²³⁸ Drug labels must include the most salient health risks,²³⁹ which also tend to be unflattering (e.g., "Antidepressants may increase suicidal thoughts or behaviors in some children, teenagers, and young adults").²⁴⁰ Hazardous materials must be labeled as such

^{230.} Robert Post, *The Constitutional Status of Commercial Speech*, 48 UCLA. L. REV. I, 14 (2000) ("The Court has been quite explicit that commercial speech should be constitutionally protected so as to safeguard the circulation of information.").

^{231.} Keighley, *supra* note 19, at 550–55 (summarizing the theoretical justifications for mandatory disclosures).

^{232.} Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985).

^{233.} Milavetz, Gallop & Milavetz, P.A. v. United States, 130 S. Ct. at *1340–41. For a contemporary treatment of these disclosure regimes, see Archon Fung et al., Full Disclosure: The Politics, Perils and Promise of Targeted Transparency (2007).

^{234.} See, e.g., Geoffrey A. Manne, *The Hydraulic Theory of Disclosure Regulation and Other Costs of Disclosure*, 58 ALA. L. REV. 473 (2007) (describing the phalanx of mandatory financial disclosure laws and how they can sometimes be counterproductive).

^{235.} This requirement dates back to the Securities and Exchange Act of 1934, 15 U.S.C. § 78 (2013).

^{236. 16} C.F.R. § 259.1 (2012); Transportation Recall Enhancement, Accountability and Documentation (TREAD) Act, Pub. L. No. 106-414, § 12, 114 Stat. 1800 (2000) (codified as amended in scattered sections of 49 U.S.C.).

^{237.} See, e.g., 15 U.S.C. § 1261(p)(1).

^{238. 21} U.S.C. § 343(q) (2012).

^{239. 21} C.F.R. §§ 201.57(a)(10) (requiring a concise summary of clinically significant warnings and precautions for prescription drugs); *id.* § 201.66(c)(5) (requiring certain salient warnings for over-the-counter drug labels).

^{240.} Bristol-Myers Squibb, Abilify: Important Safety Information, ABILIFY, http://www.abilify.com

and specify their risks.²⁴¹ Home appliances must disclose how much energy they consume.²⁴² Toy packaging must recommend an appropriate age for use.²⁴³ Pesticides must list their ingredients and include instructions on how to use them properly.²⁴⁴ Restaurant chains will soon have to disclose the calories in their menu offerings,²⁴⁵ which could be a frightening prospect to some. Health warnings have been required for decades on alcohol products²⁴⁶ and, of course, tobacco products.

Many of these required disclosures are predicated on state interests other than preventing consumer deception, like protecting the public health, reducing environmental hazards, and ensuring product safety.²⁴⁷ If these disclosures were thus not subject to rational basis review under *Zauderer*, but instead to *Central Hudson*'s intermediate scrutiny, would they survive? These disclosure regimes enjoy widespread acceptance.²⁴⁸ As Keighley observes, the common theme among these disclosure requirements is that they seem to be "motivated by the state's interest in a more informed public."²⁴⁹ And again, the government might have a substantial interest in informing the public for several predicate reasons. Subjecting disclosures aimed at public health and safety to more scrutiny than disclosures aimed to address consumer deception would, perversely, flip these priorities.²⁵⁰

But, one might counter, graphic warnings are different: Textual warnings are old and accepted and some are even hoary by now. Graphic warnings are novel and differ from textual warnings in type, not just degree. They need not. As long as graphic warnings are factual—rather than non-factual, factually controversial, or normative—then they should be subject to rational basis review under *Zauderer*, which governs compelled commercial disclosures.

Still, a later Supreme Court decision on the FDA's graphic warnings would implicate potential future disclosure regimes rather than the ones just described. A decision striking down the first serious attempt to catch our attention at the point of sale with graphics, rather than words, would

⁽last visited Mar. 31, 2013).

^{241. 15} U.S.C. § 1261(p).

^{242. 16} C.F.R. § 305.11 (2012).

^{243.} Id. § 1501.2.

^{244. 40} C.F.R. § 156.10 (2012).

^{245.} Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 4205, 124 Stat. 119 (2010).

^{246. 27} U.S.C. § 215 (2012).

^{247.} Keighley, *supra* note 19, at 563-65.

^{248.} Id. at 564-65.

^{249.} Id. at 564 (citing Entm't Software Ass'n v. Blagojevich, 469 F.3d 641, 651 (7th Cir. 2006)).

^{250.} Id. at 566. State laws requiring women seeking abortions to view ultrasounds of the fetus before finalizing their decision are often compared to the FDA's graphic warnings. See, e.g., Sawicki, supra note 215. Although both represent novel efforts to persuade, the state ultrasound laws obviously concern noncommercial speech.

suspend mandatory disclosure laws in time and thereby hamstring future efforts. This is troubling for several reasons.

Textual consumer product warnings are becoming more and more stale and ineffective. First, they are probably overused.²⁵¹ As Lars Noah observed almost twenty years ago, the "proliferation of warnings may dilute the impact of truly important cautionary information."²⁵² The FDA, in fact, has long recognized the need to resist diluting its warnings and overloading consumers with information.²⁵³ Other agencies have recognized the problem too.²⁵⁴ Media often mock our propensity to overwarn.²⁵⁵ Second, many widely accepted disclosure requirements are demonstrated to be ineffective. For example, many physicians disregard the warnings in pharmaceutical labels, even so-called "black box" warnings required for the most severe risks.²⁵⁶ In fact, the FDA has "openly chastised physicians for disregarding instructions in the labeling for newly approved drugs," and has turned to more aggressive mechanisms like requiring risk management plans.²⁵⁷ Likewise, in 2007, the Institute of Medicine concluded that cigarette warnings, last updated in 1984, had become stale and ineffective.²⁵⁸ Most smokers know that smoking presents risks, but they see these risks as remote and hypothetical and fail to appreciate their own personal risks.²⁵⁹

What happens when the government determines that a bland, blackand-white textual warning is being ignored? Should the government not

^{251.} To the government, warnings are frequently seen as low-cost interventions. The incentives created by product liability litigation contributes to over-warning. Noah, *supra* note 180, at 374–78.

^{252.} Id. at 374.

^{253.} Id. at 381.

^{254.} *See, e.g.*, Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 58 Fed. Reg. 46,551, 46,554 (Sept. 2, 1993) (to be codified at 49 C.F.R. pts. 571, 585); Choking Hazards Associated with Toys and Articles Intended for Children Three Years of Age and Older; Withdrawal of Advance Notice of Proposed Rulemaking, 58 Fed. Reg. 8013, 8015 (proposed Feb. 11, 1993); Noah, *supra* note 180, at 374–85.

^{255.} See, e.g., Peter Carlson, Hey, Don't Say They Didn't Warn You..., WASH. POST, Sept. 1, 2006, at CI.

^{256.} See, e.g., Karen E. Lasser, Timing of New Black Box Warnings and Withdrawals for Prescription Medications, 287 JAMA 2215 (2002) (finding that during 2002, 33,778 patients were prescribed drugs with special "black box" warnings, but 2354 prescriptions were written for uses that directly contravened those warnings); Thomas J. Moore et al., *Time to Act on Drug Safety*, 279 JAMA 1571, 1572 (1998) (finding similarly ineffective an effort to warn patients about the addictive properties of the drug propoxyphene); Walter Smalley et al., *Contraindicated Use of Cisapride: Impact of Food and Drug Administration Regulatory Action*, 284 JAMA 3036 (2000) (finding warnings about a life-threatening condition caused by a particular drug "had no material effect on" the product's use).

^{257.} LARS NOAH, LAW, MEDICINE, AND MEDICAL TECHNOLOGY: CASES AND MATERIALS 312–13 (3d ed. 2012).

^{258.} Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,530 (proposed Nov. 12, 2010) (to be codified at 21 C.F.R. pt. 1141).

^{259.} Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,632 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).

be able to respond with more effective messaging techniques, including the use of colors and images? Are warnings to remain forever impotent? If the government cannot use graphics to warn about the risks of tobacco use—for decades perhaps our biggest public health problem—then what would ever justify graphic warnings for less urgent problems? For example, could the government use graphics to convey the health risks of eating fast food? Or texting while driving? Or using handguns? And would these messages be viewed at all if not at the point of purchase?

Of course, even if courts again invalidated the FDA's graphic tobacco warnings, this would not automatically preclude other graphic warnings. As *Zauderer* and *Central Hudson* anticipate, commercial speech regulation is a matter of degree. Courts have always had trouble policing the line between permissible and impermissible restrictions on commercial speech. For example, how large can a graphic warning be? If occupying fifty percent of the front and back labels goes too far, what about forty-five percent? Or forty percent? If color images overwhelm our senses, what about monochromatic ones? If the image of a dead body violates tobacco companies' First Amendment rights, how else might the government communicate that "smoking can cause death," without relying solely on text? Surely there must be a way.

These are judgment calls that should draw deference from courts. Indeed, in *Zauderer* itself, the Supreme Court specifically rejected the argument that mandatory disclosures must be subject to a "least restrictive means" analysis.²⁶⁰ We should encourage our democratically elected representatives to experiment with disclosure methods that actually work—meaning they are actually seen and digested rather than ignored. As long as the required disclosures are not themselves false, misleading, or normative, then marketers should have little First Amendment protection from making factual disclosures about their products or services.

CONCLUSION

In 2009, Congress made a policy judgment that after two-hundred years of non-regulation and another four decades of partial oversight, tobacco products should have to disclose their true health risks in a meaningful way at the point of sale. This policy judgment was challenged on First Amendment grounds, and the challenge was sustained by the D.C. Circuit. But a law that generates more effective information does not run counter to the First Amendment—particularly the commercial speech variant—it supports it.

Tobacco companies spend billions of dollars each year persuading consumers to buy their products—in both subtle and not-so-subtle ways, and by appealing both to our minds and our emotions. Our two elected

^{260.} Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 n.14 (1985).

branches, in full view of the public, chose to empower the FDA to join this fight. Will courts relegate the FDA (and future regulators of unforeseen problems) to the sidelines? Will courts force the government to bring "a butter knife to a gun fight"?²⁶¹ It is not difficult to envision countless government disclosure requirements that are relatively impotent and would thus benefit from graphic makeovers. The judicial branch should let the legislative and executive branches experiment with disclosure requirements that actually work.

In the meantime, the FDA might be forced to choose between graphic disclosures that actually work and blander, more ineffectual ones that do not offend *R.J. Reynolds*. But as this Article argues, First Amendment doctrine provides ample room for the FDA to use effective graphic warnings.

^{261.} R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1221 (D.C. Cir. 2012).