THE GRAPHIC WARNING REQUIREMENT ON TOBACCO PACKAGES AND ADVERTISEMENTS: A CONSTITUTIONAL RESPONSE TO DECADES OF DECEPTION

by
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When the FDA issued a graphic warning requirement for cigarette packages and advertisements, tobacco companies challenged the rule on First Amendment grounds, and the Sixth and District of Columbia Circuits came to conflicting decisions on the merits of the challenge. The Sixth Circuit, considering a facial challenge prior to promulgation of the final rule, found that the graphic warning directive required the tobacco companies to disclose factual, if graphic, information in order to counter deceptive claims about the health risks of tobacco use. The District of Columbia Circuit, on the other hand, concluded that the graphic warnings neither correct a deception nor convey factual, uncontroversial information, and ultimately affirmed the United States District Court for the District of Columbia's grant of the tobacco companies' motion for summary judgment.

This Comment argues that because the tobacco industry deceived the American public about the health risks of smoking for the last half century, [and that this overarching deception is a valid reason to apply] applying a looser First Amendment standard to the graphic warning requirement is constitutionally appropriate. Furthermore, the Comment posits that the images convey factual information, which are reasonably related to the tobacco companies' deceptive claims, and may indeed be essential for the average consumer to learn and understand the health risks of tobacco use. Finally, although the rule was withdrawn, the Comment warns against diluting the government's ability to compel factual information from commercial speakers because of its minimal intrusion on the First Amendment rights of the compelled speakers and its vital role in protecting consumers.

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Introduction

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), for the first time delegating to the United States Food and Drug Administration (FDA) the jurisdiction to regulate the manufacture, marketing, and distribution of tobacco. In response to this grant of authority, the FDA proposed a rule requiring graphic warning labels on cigarette packaging and advertising. After the standard process, the FDA promulgated a rule requiring nine graphic warning labels to accompany textual warnings that cigarette companies would cycle through on cigarette packaging and advertising.

Before the final rule was promulgated, six tobacco manufacturers and retailers filed suit in the United States District Court for the Western District of Kentucky, challenging the provisions of the Tobacco Control Act directing the FDA to require graphic warning labels, among other provisions.[1] In addition, after the final rule was promulgated, five tobacco manufacturers challenged the actual graphic warning requirement in the

[1] Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512 (W.D. Ky. 2010), *aff'd in part, rev'd in part sub nom.* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509 (6th Cir. 2012).

United States District Court for the District of Columbia.[2] Both cases went to their respective circuits, which came to conflicting decisions on the constitutionality of the graphic warning requirement. The Sixth Circuit classified the requirement as compelled speech, and analyzed it under the standard set forth in *Zauderer v. Office of Disciplinary Counsel*,[3] ultimately concluding that the FDA could compel visual depictions of factual information in furtherance of the important state purposes of preventing consumer deception on the health risks of tobacco and promoting greater understanding of the risks inherent in smoking.[4] The court also emphasized the tobacco industry's long history of deception and the ineffectiveness of the current warning system.[5] The D.C. Circuit, however, used the stricter *Central Hudson Gas & Electric v. Public Service Commission of NY*[6] standard in striking down the requirement as a violation of the tobacco companies' First Amendment rights.[7] The court classified the FDA's interest as discouraging smoking, and determined that it did not demonstrate that the graphic labels actually influenced smokers, either potential or existing.[8] Neither panel was unanimous, with strong dissents arguing for opposite results.

In this Comment, I compare the decisions of the Sixth and D.C. Circuits. I argue that the *Zauderer* standard is appropriate because of the vast deception the tobacco companies perpetrated against the American public for over 50 years. Next, I apply the *Zauderer* standard to the graphic warning requirement to demonstrate that all but one of the warnings permissibly correct the industry's historical and indeed ongoing deception of the consumers. In addition, I briefly analyze the warnings under a reframed *Central Hudson* standard, arguing that communicating health risks to potential customers is a legitimate and substantial state interest that the graphic warnings directly advance. I then propose a less extensive alternative that fully complies with the First Amendment. Finally, I examine the devastating effects of the opposite result on the govern-

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[2] R.J. Reynolds Tobacco Co. v. FDA, 823 F. Supp. 2d 36, 39 (D.D.C. 2011) [hereinafter *R.J. Reynolds I*], *vacated*, 696 F.3d 1205 (D.C. Cir. 2012).

[3] 471 U.S. 626 (1985). The *Zauderer* standard says that when commercial speech is misleading or deceptive, the state has an automatic interest in correcting that deception by compelling the speaker to provide factual information. *Id.* at 651.

[4] *Disc. Tobacco City & Lottery*, 674 F.3d at 561–62.

[5] *Id.* at 562–63.

[6] 447 U.S. 557 (1980). Central Hudson developed a four-part test for government regulation of commercial speech. First, in order for commercial speech to be protected, it must concern lawful activity and may not be misleading. Second, the government must assert a substantial governmental interest in regulating the protected commercial speech. Third, the regulation must directly advance that substantial governmental interest. And finally, the regulation must not be more extensive than necessary. *Id.* at 566.

[7] R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1222 (D.C. Cir 2012) [hereinafter *R.J. Reynolds II*].

[8] *Id.* at 1219.

ment's ability to compel factual information and thereby protect consumers from dangerous—even deadly—products.

I. Background

In 1964, the United States Department of Health, Education, and Welfare[9] released the first-ever Surgeon General's report on smoking and its effects on health, concluding that "[c]igarette smoking is a health hazard of sufficient importance in the United States."[10] In response to the newly published concerns about the risks of tobacco use, Congress passed the Federal Cigarette Labeling and Advertising Act of 1965 (FCLA).[11] The purpose of the FCLA was to regulate cigarette labels and advertising to ensure that "the public may be adequately informed that cigarette smoking may be hazardous to health."[12] In order to accomplish that purpose, the FCLA, overseen by the Federal Trade Commission, required all cigarette packages sold in the United States to bear the warning "Caution: Cigarette Smoking May Be Hazardous to Your Health." Furthermore, the FCLA required the warning to be in a conspicuous location and in conspicuous, legible text, contrasted with the package's other typography, layout, and color.[13]

In 1984, Congress recognized that the existing warnings were no longer "making Americans . . . aware of any adverse health effects of smoking,"[14] so it implemented a quarterly rotating "SURGEON GENERAL'S WARNING" system with four mandatory warnings: Smoking Causes Lung Cancer, Heart Disease, Emphysema, And May Complicate Pregnancy; Quitting Smoking Now Greatly Reduces Serious Risks to Your Health; Smoking By Pregnant Women May Result in Fetal Injury, Premature Birth, And Low Birth Weight; and Cigarette Smoke Contains Carbon Monoxide.[15] The Comprehensive Smoking Education Act of 1984 (CSEA) further mandated such warnings on cigarette advertising and billboards, with specific requirements regarding the warning's format, size, typography, placement, and border.[16] Tobacco companies complied

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[9] Now the Department of Health and Human Services. 20 U.S.C. § 3508 (2012).

[10] U.S. Dep't of Health, Educ., & Welfare, Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service 33 (1964).

[11] Federal Cigarette Labeling and Advertising Act, Pub. L. No. 89-92, 79 Stat. 282 (1965).

[12] *Id.* § 2, 79 Stat. at 282.

[13] *Id.* § 4, 79 Stat. at 283.

[14] Comprehensive Smoking Education Act, Pub. L. No. 98-474, § 2, 98 Stat. 2200, 2200 (1984).

[15] *Id.* § 4, 98 Stat. at 2201–03.

[16] *Id.* § 4, 98 Stat. at 2202.

with—and in fact never challenged—these mandatory and particular warning requirements.[17]

In 1996, the FDA attempted to assert jurisdiction to regulate tobacco products under the Food, Drug, and Cosmetic Act (FDCA), claiming that nicotine is a "drug" and cigarettes are "devices" that deliver that drug to the body.[18] The Supreme Court struck down this effort in *FDA v. Brown and Williamson Tobacco Corporation*, however, concluding that "the FDA's claim to jurisdiction contravenes the clear intent of Congress."[19] The Court reasoned that, because one of the objectives of FDCA is to ensure that drugs and devices are "safe" and "effective" for their intended uses and because cigarettes are inherently dangerous when used as intended, granting the FDA the authority to regulate cigarettes under the FDCA would require the FDA to remove cigarettes from the market entirely.[20] Based on the country's long love affair with tobacco, the Court determined that such a broad grant of authority would need to be explicit, and, under the FDCA, it was not.[21]

Apparently ready to explicitly grant such authority in 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act).[22] Section 3 of the Tobacco Control Act unequivocally states:

> [t]he purposes of this division are [] to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act, by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products as provided for in this division.[23]

The Tobacco Control Act once again updated the warning requirements.[24] Section 201 of the Tobacco Control Act lists nine new textual warnings,[25] but also specifically directs the Secretary of the Department of Health and Human Services to issue mandatory color graphic warnings

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[17] *R.J. Reynolds I*, 823 F. Supp. 2d 36, 40 n.4 (D.D.C. 2011), *vacated*, 696 F.3d 1205 (D.C. Cir. 2012).

[18] FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 127 (2000); Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco 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, and 897).

[19] *Brown & Williamson Tobacco Corp.*, 529 U.S. at 132.

[20] *Id.* at 133–35.

[21] *Id.* at 159–60.

[22] Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat. 1776 (2009).

[23] *Id.* at 1781 (internal citation omitted).

[24] *Id.* at 1842–45.

[25] "Cigarettes are addictive"; "Tobacco smoke can harm your children"; "Cigarettes cause fatal lung cancer"; "Cigarettes cause cancer"; "Cigarettes cause strokes and heart disease"; "Smoking during pregnancy can harm your baby"; "Smoking can kill you"; "Tobacco smoke causes fatal lung disease in nonsmokers." *Id.*

"depicting the negative health consequence of smoking," designed to accompany the textual warnings on cigarette packages and advertisements.[26] The Tobacco Control Act further mandates that the graphic warnings cover "the top 50 percent of the front and rear panels of the package" and "at least 20 percent of the area of the advertisement."[27] Before the final rule was promulgated, however, the Tobacco Control Act itself faced a challenge in federal court.

II. *Discount Tobacco City & Lottery, Inc. v. United States*

In late August 2009, a group of six tobacco manufacturers and retailers filed suit in the United States District Court for the Western District of Kentucky, challenging certain provisions of the Tobacco Control Act, including the graphic warning requirement directive.[28] Because the final rule had not yet been promulgated, the suit was a facial challenge, alleging that the FDA could not possibly devise graphic warnings that complied with the First Amendment.[29] The tobacco companies argued that the graphic warning requirement should fail under a strict scrutiny analysis because the warnings constitute a government anti-tobacco marketing campaign, and not factual information.[30] Yet, even if the court classified the as-yet-identified graphic warnings as "factual information," the tobacco companies maintained they should nonetheless fail under the less exacting scrutiny of *Zauderer v. Office of Disciplinary Counsel* [31] because they are unjustified and unduly burdensome.[32]

The district court granted summary judgment to the government on the issue of the graphic warning label requirement, and the United States Court of Appeals for the Sixth Circuit affirmed that decision with one judge dissenting.[33]

A. Zauderer *Standard*

Even though the Supreme Court has recognized commercial speech as protected under the First Amendment,[34] the government may none-

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[26] *Id.*

[27] *Id.*

[28] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 518, 521 & n.2 (6th Cir. 2012) (providing date of filing); Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512 (W.D. Ky. 2010), *aff'd in part, rev'd in part sub nom. Disc. Tobacco City & Lottery*, 674 F.3d 509.

[29] *Disc. Tobacco City & Lottery*, 674 F.3d at 552–53.

[30] Principal Brief of Plaintiffs-Appellants/Cross-Appellees at 26–27, *Disc. Tobacco City & Lottery*, 674 F.3d 509 (No. 10-5234) (citing Entm't Software Ass'n v. Blagojevich, 469 F.3d 641, 652 (7th Cir. 2006)).

[31] 471 U.S. 626 (1985).

[32] Principal Brief of Plaintiffs-Appellants/Cross-Appellees at 16, *Disc. Tobacco City & Lottery*, 674 F.3d 509 (No. 10-5234).

[33] *Disc. Tobacco City & Lottery*, 674 F.3d at 527 (Clay, J., dissenting).

[34] Bigelow v. Virginia, 421 U.S. 809, 825–26 (1975).

theless compel certain speech in commercial contexts under certain circumstances. In *Zauderer*, the Supreme Court held that the government may compel disclosure of factual information in order to counter actually or potentially deceptive claims, and any such compelled disclosure would be subjected to low-level scrutiny.[35] The Court reasoned that the First Amendment concern of a vibrant marketplace of ideas is not threatened when the government compels disclosure of factual information to correct deception of consumers, in which the state has an automatic interest.[36]

B. Applying Zauderer

1. Asserted State Interest

The tobacco companies asserted that, because *Zauderer* only applies to remedy consumer deception and because the public is already aware of the harms of tobacco use, the state has no interest in compelling graphic warnings.[37] The court, however, classified the state's interest as ensuring "that the health risk message is actually *seen* by consumers in the first instance."[38] Although the government has mandated warnings on cigarette packages and advertising since 1965, the court agreed with the FDA's experts that the existing warnings "do not effectively convey the risks of smoking."[39] According to the court, the government therefore has an interest in effectively conveying those risks, thus supplying the constitutional backdrop for the new graphic warning requirement.

2. Deception

The tobacco companies again focused on the existing warnings and the public's awareness of the risks of tobacco use, claiming that since the public is already aware of the risks, disclosures are unnecessary to correct any misinformation or deception.[40] The companies posited that, not only is the public aware of the risks, but the public often *over*-estimates the detrimental effects of tobacco use.[41] Their expert, Dr. Viscusi, explained "the average perceived risk that a smoker will develop lung cancer is over 40%, whereas the actual risk is about 10%."[42] The court, however, viewed the warning requirement's purpose as "prevent[ing] consumers from be-

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[35] *Zauderer*, 471 U.S. at 651.

[36] *Id.*

[37] Principal Brief of Plaintiffs-Appellants/Cross-Appellees at 21, *Disc. Tobacco City & Lottery*, 674 F.3d 509 (No. 10-5234).

[38] Commonwealth Brands, Inc. v. United States, 678 F. Supp. 2d 512, 530 (W.D. Ky. 2010), *aff'd in part, rev'd in part sub nom. Disc. Tobacco City & Lottery*, 674 F.3d 509.

[39] *Disc. Tobacco City & Lottery*, 674 F.3d at 563.

[40] Principal Brief of Plaintiffs-Appellants/Cross-Appellees at 21, *Disc. Tobacco City & Lottery*, 674 F.3d 509 (No. 10-5234).

[41] *Id.* at 5–6.

[42] *Id.* (internal quotation marks omitted).

ing misled about the health risks of using tobacco."[43] Furthermore, relying on the landmark tobacco case, *United States v. Philip Morris*,[44] the court rejected Dr. Viscusi's findings, noting that his research was "commissioned by tobacco-industry law firms specifically for use in litigation."[45] The court also placed the graphic warnings in historical context and concluded that, based on the tobacco industry's decades-long knowing and intentional deception of the public about the consequences and addictiveness of smoking, the public does not adequately understand the dangers of tobacco use.[46] The graphic warning requirement corrects this deception.

3. Factual Information

In addition, the tobacco companies asserted that the graphic labels display subjective and controversial information, rather than the factual information permitted under *Zauderer*.[47] Since the companies classified the warnings as not purely factual, they argued that the court should apply a strict scrutiny analysis and strike down the graphic label requirement.[48] The court was unconvinced.

First, as noted above, because there was no final rule or actual graphics to examine at the time of the litigation, the suit was a facial attack. As a result, the plaintiffs would need to demonstrate that it was impossible to create graphic warnings that convey factual information.[49] This was too high a burden for the tobacco companies to meet, as the court conceived of half a dozen images that convey factual information about the risks of tobacco use, such as a picture depicting the lungs of a smoker next to those of a nonsmoker or a doctor examining an x-ray of a smoker's cancerous lungs.[50]

Second, *Zauderer* itself recognized that factual information may be conveyed through graphics. One of the issues in *Zauderer* involved a ban on the use of illustrations in attorney ads.[51] The *Zauderer* Court struck down the ban, protecting the attorney's right to use illustrations in ads, because "[t]he use of illustrations or pictures in advertisements serves important communicative functions: it attracts the attention of the audience to the advertiser's message, and it may also serve to *impart information directly*."[52] Although in *Zauderer* the attorney voluntarily used

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[43] *Disc. Tobacco City & Lottery*, 674 F.3d at 561.

[44] 566 F.3d 1095 (D.C. Cir. 2009) (per curiam).

[45] *Disc. Tobacco City & Lottery*, 674 F.3d at 567.

[46] *Id.* at 562–63.

[47] Principal Brief of Plaintiffs-Appellants/Cross-Appellees at 27, *Disc. Tobacco City & Lottery*, 674 F.3d 509 (No. 10-5234).

[48] *Id.*

[49] *Disc. Tobacco City & Lottery*, 674 F.3d at 558–59.

[50] *Id.* at 559.

[51] *See id.* at 560 (citing Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 647 (1985)).

[52] *Zauderer*, 471 U.S. at 647 (emphasis added).

graphics (specifically an intrauterine device illustration) in violation of a rule, and here the government is compelling the tobacco companies to include graphics through a rule, the court's reasoning on the issue of graphics is pertinent: "[i]f a picture can accurately represent an [intrauterine device], then there is no reason why a picture could not also accurately represent a negative health consequence of smoking."[53] That the tobacco companies were trying to invalidate the graphic warnings by saying they were necessarily subjective using the very case that recognized the importance of graphics in imparting factual information did not escape the court's notice.

4. Unjustified and Unduly Burdensome

Relying again on *Zauderer*, the tobacco companies insisted that the court evaluate whether the compelled disclosures, even if found to be correcting a deception and portraying factual information, were unjustified or unduly burdensome.[54] In fact, the tobacco companies dedicated considerable attention to this argument: their brief devotes 1,362 out of 2,062 words within the section "The New Warnings Violate The First Amendment" to contending that the requirement is unjustified and unduly burdensome.[55] The Sixth Circuit noted that, while *Zauderer* recognized that "unjustified or unduly burdensome disclosure requirements *might* offend the First Amendment by chilling protected commercial speech,"[56] the actual test of constitutionality is only "whether a disclosure requirement is reasonably related to the purpose."[57] Accordingly, the court addressed, and dismissed, the tobacco companies' unjustified and unduly burdensome arguments. First, because the court already found that the warnings remedy a deception, the court easily rejected the argument that they are an unjustified attempt to market the government's anti-tobacco message.[58] Second, the tobacco companies' own assertion that the warnings were ineffective undercut their unduly burdensome argument; if the warnings will not sway the potential or current buyer of cigarettes, then they are necessarily not unduly burdensome.[59] The tobacco companies essentially conceded that they would be able to effectively market tobacco products even with the graphic labels taking up a portion of their packages and advertisements.

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

[54] Principal Brief of Plaintiffs-Appellants/Cross-Appellees at 20–21, *Disc. Tobacco City & Lottery*, 674 F.3d 509 (No. 10-5234).

[55] *Id.* at 18–27.

[56] *Disc. Tobacco City & Lottery*, 674 F.3d at 566 (quoting *Zauderer*, 471 U.S. at 651).

[57] *Id.* at 566–67.

[58] *See id.* at 567.

[59] *Id.*

C. *Dissent*

Judge Eric L. Clay dissented from the portion of the opinion on the graphic warning requirement.[60] Proclaiming that visual images are necessarily subjective, Judge Clay nonetheless applied a modified *Zauderer* standard, concluding that the color graphics requirement "cannot accurately convey all of the health risks associated with tobacco use," and that the "message that they convey will vary with the interpretation and context of its viewer."[61] He, therefore, would reverse the district court and find the graphic warning requirement unconstitutional.[62]

III. Final Rule and Graphic Warnings

While *Discount Tobacco* was making its way through its appeal, the FDA proposed and ultimately promulgated a final rule, selecting nine images to accompany the textual warnings on cigarette packages and advertisements.[63] The final rule discussed the inadequacy of the existing warnings, and the need to better communicate the health risks of smoking.[64] The rule also explained the FDA's process in selecting the graphic images and the textual warnings to accompany them.[65] In addition, the rule addressed comments on the constitutionality of the warnings under the First Amendment, and in fact cited to *Commonwealth Brands* with approval.[66]

IV. *R.J. Reynolds Tobacco Co. v. FDA*

Following promulgation, a group of five tobacco companies, three of which were plaintiffs in the *Discount Tobacco* suit,[67] challenged the final rule in United States District Court for the District of Columbia in August 2011.[68] The *R.J. Reynolds* plaintiffs claimed that the warnings violated not only the *Zauderer* standard for compelled speech but that they also constituted an unlawful restriction on commercial speech under *Central Hudson*

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[60] *Id.* at 527 (Clay, J., dissenting).

[61] *Id.* at 528–31 (Clay, J., dissenting).

[62] *Id.* at 530 (Clay, J., dissenting).

[63] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,628 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141). For graphic warnings, see FDA, Cigarette Required Warnings, FDA-2010-N-0568-0691 (June 22, 2011) [hereinafter Cigarette Required Warnings], *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2010-N-0568-0691 (incorporated by reference at 76 Fed. Reg. at 36,693).

[64] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. at 36,629–36.

[65] *Id.* at 36,636–37.

[66] *Id.* at 36,695.

[67] R.J. Reynolds Tobacco Company, Lorillard Tobacco Company, and Commonwealth Brands, Inc. all participated in both suits.

[68] *R.J. Reynolds I*, 823 F. Supp. 2d 36, 36, 39 (D.D.C. 2011).

Gas & Electric Corp. v. Public Service Commission of NY.[69] The plaintiffs identified the chosen warnings as "anti-smoking advocacy" in violation of *Zauderer*.[70] They further stressed that the government's only possible interest in the warnings is to reduce smoking, and not only do the warnings not achieve that goal, even if they did, they are not the least restrictive means to do so.[71] Because they identified the rule as unconstitutional, the *R.J. Reynolds* plaintiffs sought to temporarily enjoin enforcement of the rule until a decision was reached on the merits.[72]

The United States District Court for the District of Columbia granted the preliminary injunction on November 7, 2011, finding "a substantial likelihood that [the tobacco companies] will prevail on the merits of their position that these mandatory graphic images unconstitutionally compel speech . . . ."[73] The district court then granted the plaintiff tobacco companies' motion for summary judgment on February 29, 2012.[74] The FDA appealed, and the United States Court of Appeals for the District of Columbia Circuit affirmed.[75]

A. Central Hudson *Standard*

As noted earlier, the First Amendment affords protection to commercial speech. However, unlike other forms of speech that are protected by strict scrutiny, when the government regulates commercial speech it is subject to an intermediate level of scrutiny under *Central Hudson*.[76] In order for *Central Hudson* to apply, the speech at issue must concern a lawful activity and may not be deceptive.[77] In order to regulate commercial speech that is neither misleading nor concerning illegal activity, the government "must assert a substantial interest to be achieved by [the] restrictions on commercial speech."[78] In addition, "the restriction must directly advance" that substantial state interest, and may not be more extensive than necessary.[79]

The D.C. Circuit, agreeing with the district court, declined to apply the *Zauderer* standard.[80] The court first noted that the "FDA does not frame *this* rule as a remedial measure designed to counteract specific deceptive claims made by the Companies . . . . [nor has it] shown that the

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[69] 447 U.S. 557, 566 (1980).

[70] Brief for Appellees at 20, 38, *R.J. Reynolds II*, 696 F.3d 1205 (D.C. Cir. 2012) (No. 11-5332).

[71] *See id.* at 38–39.

[72] *R.J. Reynolds I*, 823 F. Supp. 2d at 39.

[73] *Id.*

[74] *R.J. Reynolds II*, 696 F.3d at 1208.

[75] *Id.*

[76] 447 U.S. 557, 563–64 (1980).

[77] *Id.*

[78] *Id.* at 564.

[79] *Id.*

[80] *R.J. Reynolds II*, 696 F.3d at 1212–17.

graphic warnings were designed to correct any false or misleading claims made by cigarette manufacturers in the past."[81] Second, it found that the warnings do not convey factual and uncontroversial information.[82] In fact, the court noted, the FDA specifically designed the warnings to provoke an emotional response in the viewer, not to provide information.[83] As a result of these findings, the D.C. Circuit determined *Zauderer* was inappropriate and instead applied the *Central Hudson* standard.

B. Applying Central Hudson

1. State Interest

The FDA asserted in the rule and in its brief that the state's interest in requiring the graphic warning label was to effectively communicate the health consequences of smoking.[84] However, the D.C. Circuit agreed with the tobacco companies' argument that the government's interest is actually "to encourage current smokers to quit and dissuade other consumers from ever buying cigarettes."[85] In fact, the D.C. Circuit identified the interest in discouraging smoking as "[t]he *only* explicitly asserted interest in either the Proposed or Final Rule."[86] Characterizing the state's interest in this way set an extremely high burden for the government to meet: in order to require the graphic warnings, the warnings must essentially stop consumers from buying cigarettes, which itself might be unconstitutional.[87]

The D.C. Circuit did, however, address the FDA's proposed interest in effectively communicating health information, if only to dismiss it as "the *means* by which FDA is attempting to reduce smoking rates . . . ."[88] Labeling the interest as "effective communication," according to the court, would provide no means to assess whether the restriction advances that interest because the agency would be free to define "effective" however it chooses.[89] As a result, "effective communication" of information could not itself support the graphic warning requirement as a substantial state interest.

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[81] *Id.* at 1215–16.

[82] *Id.* at 1216.

[83] *Id.*

[84] 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); Brief for Appellants at 28, *R.J. Reynolds II*, 696 F.3d 1205 (No. 11-5332).

[85] *R.J. Reynolds II*, 696 F.3d at 1218 (citing Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat. 1776, 1782 (2009)).

[86] *Id.* (emphasis in original).

[87] *See id.* at 1218 n.13 ("Like the district court, we are skeptical that the government can assert a substantial interest in discouraging consumers from purchasing a lawful product, even one that has been conclusively linked to adverse health consequences.").

[88] *Id.* at 1221 (emphasis in original).

[89] *See id.* at 1221 n.16.

2. Restriction Directly Advances State's Substantial Interest

Assuming a legitimate and substantial state interest for purposes of continuing the *Central Hudson* analysis, the D.C. Circuit then evaluated the graphic warning requirement under the second prong of *Central Hudson*, inquiring "whether FDA has offered substantial evidence showing that the graphic warning requirements directly advance the governmental interest asserted to a material degree."[90] The court concluded that the "FDA has not provided a shred of evidence . . . showing that the graphic warnings will directly advance its interest in reducing the number of Americans who smoke."[91] In its rule, the FDA relied on data from other countries that have already implemented graphic warning requirements on cigarette packages and advertising, focusing especially on Canada, which has required graphic warnings since 2001.[92] However, the D.C. Circuit rejected most of the data as "questionable social science," noting that, even if the data were to be believed, the most the FDA could argue was "the data are suggestive that large graphic warnings may reduce smoking consumption," which was too speculative to support the graphic warning requirement.[93]

3. Not More Extensive Than Necessary

The D.C. Circuit did not reach this prong of *Central Hudson* because the regulation failed under the previous two.[94]

C. Dissent

Judge Judith W. Rogers dissented from the opinion, arguing that the majority erred in applying *Central Hudson* because *Zauderer* was appropriate. First, she explained that the government should be permitted to compel factual information to correct the tobacco industry's long history of misleading the public about the health consequences of tobacco use, as expressed in *United States v. Philip Morris*.[95] Furthermore, Judge Rogers cited the Tobacco Control Act's congressional findings that, as late as 2005, the tobacco companies "misleadingly portray[ed] the use of tobacco as socially acceptable and healthful to minors."[96] Second, Judge Rogers would classify the government's interest as effectively conveying the

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[90] *Id.* at 1218 (citations and internal quotation marks omitted).

[91] *Id.* at 1219 (internal quotation marks omitted).

[92] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,633–34 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141); Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,531–32 (proposed Nov. 12, 2010) (to be codified at 21 C.F.R. pt. 1141).

[93] *R.J. Reynolds II*, 696 F.3d at 1219 (citations and internal quotation marks omitted).

[94] *See id.* at 1222.

[95] *Id.* at 1222–24 (Rogers, J., dissenting) (citing United States v. Philip Morris USA Inc., 566 F.3d 1095, 1121 (D.C. Cir. 2009) (per curiam)).

[96] *Id.* at 1224–25 (internal quotation marks omitted) (citing Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat. 1776, 1778 (2009)).

health consequences of tobacco use on packages and advertising *in order to* encourage cessation in smokers and discourage non-smokers from starting.[97] Third, she recognized that the graphic warnings combined with the textual warnings convey factual, uncontroversial information.[98] Finally, Judge Rogers found sufficient evidence to support the size and placement of the labels, and would reject the tobacco companies' arguments that the requirement is undue or unjustified.[99]

In spite of finding *Zauderer* applicable, Judge Rogers nonetheless analyzed the warning requirement under *Central Hudson*, and found it constitutional because of the state's interest in conveying the health risks of tobacco use.[100] The only portion Judge Rogers would strike down is the addition of "1 800 QUIT NOW" on the labels because "it is not designed directly to inform consumers of the health consequences of smoking, but to assist smokers in their cessation efforts."[101]

In *R.J. Reynolds*, the D.C. Circuit vacated the graphic warning requirement and remanded back to the FDA, which withdrew the rule and announced it did not intend to petition for certiorari to the Supreme Court.[102] The plaintiffs in *Discount Tobacco*, on the other hand, filed a petition for certiorari, asking the Supreme Court to reverse the Sixth Circuit's opinion that the graphic warning requirement is constitutional. This petition has since been denied.[103] Although the FDA is unlikely to require these specific graphic warnings in the future, the question of the constitutionality of the requirement still has important regulatory implications regarding the government's ability to compel information in general, as well as in the narrower context of cigarette packaging and advertising. While the cases challenged different procedural components of the graphic warning requirement, and the FDA withdrew the rule, the conflict between the circuits on its constitutionality practically demands attention by the Supreme Court. Which standard is appropriate, *Zauderer*, *Central Hudson*, or something else entirely? Is the graphic warning requirement constitutional? And finally, what are the broader implications if the Supreme Court strikes down the requirement?

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[97] *Id.* at 1225.

[98] *Id.* at 1231.

[99] *Id.* at 1233.

[100] *Id.* at 1234–35.

[101] *Id.* at 1236 (citing Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,681 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141)).

[102] Letter from Eric H. Holder, Jr., Attorney General, to John Boehner, Speaker of the House of Representatives (Mar. 15, 2013).

[103] Petition for Writ of Certiorari, Disc. Tobacco City & Lottery, Inc. v. United States (No. 12-521), *denied*, 133 S. Ct. 1996 (2013).

V. Standard: Deception?

As noted above, the First Amendment affords less protection to commercial speech that is actually or potentially deceptive.[104] Typically, a factual disclosure under *Zauderer* is triggered by a particular assertion made by the commercial speaker that deceives or tends to deceive consumers.[105] Here, the particular cigarette advertising and packaging affected by the requirement may or may not be deceptive, however the Court should still find deception and apply *Zauderer* based on the extensive, enduring, and collusive scheme the tobacco industry engaged in to defraud the American public.

A. The Tobacco Industry Continually Deceives Consumers by Minimizing or Denying the Health Risks of Using Tobacco Products

In the landmark tobacco industry case, *United States v. Philip Morris*[106] (*Philip Morris*), the United States District Court for the District of Columbia found, and the United States Court of Appeals for the District of Columbia Circuit affirmed, that a large and powerful portion of the tobacco industry "join[ed] together in a decades-long conspiracy to deceive the American public about the health effects and addictiveness of smoking cigarettes."[107] The D.C. Circuit identified four general lies the industry has perpetuated for more than half a century: (1) cigarette smoking does not cause disease; (2) nicotine is not addictive; (3) light cigarettes present lower health risks than regular cigarettes; and (4) secondhand smoke has no known negative health effects.[108] The companies were not only aware of independent research that contradicted their fraudulent assertions, but they actually employed their own scientists who established the truth conclusively.[109] Those risks were "well known, acknowledged, and accepted throughout the corporations."[110]

In spite of this knowledge, high level officials at the tobacco companies "made or approved statements they knew to be false or misleading."[111] The *Philip Morris* trial and appellate opinions together span more than 1,000 pages, largely detailing this knowledge and deceit; the trial lasted nine months, included oral testimony from 84 witnesses, written

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[104] *See supra* Part II.A.

[105] *See, e.g.*, Milavetz, Gallop & Milavetz, P.A. v. United States, 130 S. Ct. 1324, 1340 (2010); Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation, 512 U.S. 136, 143–44 (1994); Peel v. Attorney Registration & Disciplinary Comm'n, 496 U.S. 91, 101–02 (1990).

[106] 566 F.3d 1095 (D.C. Cir. 2009) (per curiam). The government brought the case as a Racketeer Influenced and Corrupt Organizations Act case under 18 U.S.C. §§ 1961–1968. *Id.* at 1105.

[107] *Id.* at 1105–06.

[108] *Id.* at 1119.

[109] *Id.*

[110] *Id.*

[111] *Id.* at 1118.

testimony from 162 witnesses, and contained roughly 14,000 exhibits in evidence.[112] There are far too many examples chronicled in those opinions to cite here,[113] but a few are instructive. For instance, in a 1971 televised interview then President of Philip Morris, Joseph Cullmann III, denied that cigarettes posed any health risk to pregnant women or their infants, wholly contradicting research that the Vice President for Corporate Research and Development had given Cullmann directly.[114] In addition, after their own scientists declared not only that cigarettes contained carcinogens, but that this fact was "well established," R.J. Reynolds published an advertisement pronouncing that the "connection between smoking and disease [is] an open controversy."[115] The tobacco companies knew the truth about the health risks of their products, yet spread lies denying those risks for years.

Moreover, this deception persists to very recent times, and may be ongoing today. In a 1997 deposition for a class action suit brought by flight attendants for health problems caused by secondhand smoke,[116] the President and CEO of Philip Morris compared the addictiveness of cigarettes to the addictiveness of gummy bears.[117] Even at the 2004 *Philip Morris* trial, Lorillard general counsel testified that "the company's public position has always been and *continues to be* that secondhand smoke is not a proven health hazard."[118] The district court issued the injunction in part because Philip Morris, R.J. Reynolds, Brown & Williamson, Lorillard, America, Altria, and BATCo "continued to make false and misleading statements *at the time of trial*."[119] And, in drafting the Family Smoking Prevention and Tobacco Control Act, Congress found that as late as 2005, tobacco companies "misleadingly portray[ed] the use of tobacco as socially acceptable and healthful to minors."[120] Even bound by the Master Settlement Agreement (MSA), signed in 1998 by Attorneys General in 46 states,[121] the tobacco companies perpetuated their lies: "The district court . . . found Defendants began to evade and at times even violate the

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[112] *See id.* at 1106; United States v. Philip Morris USA, Inc., 449 F. Supp.2d 1 (D.D.C. 2006) (987-page opinion).

[113] The D.C. Circuit said on appeal that "[a] few examples cannot adequately present the volumes of evidence underlying the district court's findings of fact" on the scheme. *Philip Morris*, 566 F.3d at 1120.

[114] *Id.* at 1118–19.

[115] *Id.* at 1121 (internal quotation marks omitted).

[116] After the District Court of Appeal of Florida, Third District, certified the flight attendants as a class in *Broin v. Philip Morris Cos.*, 641 So. 2d 888, 892 (Fla. Dist. Ct. App. 1994), the suit was eventually settled. *See* Myron Levin, *Tobacco Firms to Settle Flight Attendants' Suit*, L.A. TIMES, Oct. 11, 1997, at A1.

[117] Myron Levin, *Jury Views CEO's 'Gummy Bear' Deposition*, L.A. TIMES, July 18, 1997, at D3.

[118] *Philip Morris*, 566 F.3d at 1121 (emphasis added).

[119] *Id.* at 1109 (emphasis added).

[120] Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat. 1776, 1778 (2009).

[121] *Tobacco*, NAT'L ASS'N OF ATTORNEYS GEN., http://www.naag.org/tobacco.php.

MSA's prohibitions almost immediately after signing the agreement . . . ."[122] The tobacco industry as a whole has spent decades and billions deceiving the American public about the health risks of tobacco use. Thus, the graphic warnings are an appropriate response to that deceit.

B. Historical Deceit Is a Valid Reason to Apply Zauderer

Based on the industry-wide deception executed on tobacco consumers and potential consumers for more than half a century, the Court should apply the *Zauderer* standard to find the graphic warning requirement constitutional. There are many instances where courts look to the history of a particular actor in choosing which standard or rule to apply and in ultimately making decisions. Two particularly apt examples come to mind: school desegregation in equal protection jurisprudence and rules of evidence regarding use of prior criminal convictions for impeachment purposes.

After *Brown v. Board of Education*,[123] which held that segregating public schools violated the Equal Protection Clause of the Fourteenth Amendment, the Court faced the difficult task of ensuring that school districts that vehemently disagreed with the decision, and with desegregation generally, actually desegregated their schools. In *Green v. County School Board of New Kent County, Virginia*, for instance, the Supreme Court considered the county's "freedom-of-choice" plan which allowed both black and white students within the county to select between two schools, a historically black one and a historically white one.[124] The plan itself was not discriminatory; black and white children were each afforded the choice of which school to attend.[125] If enacted on a blank slate, the law very well may have survived challenge, even if the schools ended up mostly segregated.[126] However, because the county had compulsory segregation laws previously,[127] the freedom-of-choice plan was an inadequate response: "We do not hold that a 'freedom-of-choice' plan might of itself be unconstitutional, although that argument has been urged upon us. Rather, all we decide today is that in desegregating a dual system a plan

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[122] *Philip Morris*, 566 F.3d at 1133. While the MSA only binds four companies (Philip Morris, R.J. Reynolds, Brown & Williamson, and Lorillard), and the *Philip Morris* defendants included nine tobacco companies and two trade organizations and did not comprise all of the plaintiffs from *R.J. Reynolds* and *Discount Tobacco*, the D.C. Circuit in *Philip Morris* determined that the RICO enterprise included not only the defendant companies but also "other organizations and individuals." *Id.* at 1111. Therefore the deception, and its enduring effects on the public, span industry wide.

[123] 347 U.S. 483 (1954).

[124] Green v. Cnty. Sch. Bd., 391 U.S. 430, 431–32 (1968).

[125] *Id.* at 433–34, 441.

[126] *Id.* at 439–41.

[127] These were struck down in *Brown*. *See id.* at 432; *Brown*, 347 U.S. at 486 n.1.

utilizing 'freedom of choice' is not an end in itself."[128] Based on the county's history of de jure segregation, the Court examined the challenged plan using a higher standard than it otherwise would have applied.[129]

Another illustration is admission of criminal convictions for purposes of impeachment per the Federal Rules of Evidence. The general rule for impeachment is to exclude evidence of a witness's prior criminal conviction.[130] Yet under Rule 609(a)(2), when the prior conviction "required proving—or the witness's admitting—a dishonest act or false statement" then not only is the evidence allowed to be admitted, it "*must be* admitted."[131] During the drafting of the Federal Rules of Evidence, the Supreme Court originally proposed a rule that would allow the use of prior convictions for all felonies and for misdemeanors that involved dishonesty or false statement.[132] However, as the proposed rule made its way through Congress, the convictions allowed for impeachment under the rule became more limited. Admission of prior convictions was especially limited against criminal defendants who testify because "the jury may be prejudiced not merely on the question of credibility but also on the ultimate question of guilt or innocence."[133] In the end, Congress concluded that crimes involving "dishonesty or false statement" are relevant, and therefore admissible, because they implicate the reliability of the actual testimony the witness gives on the crime with which he is being charged.[134] When a witness—even the defendant—testifies, the jurors have a right to know that he has been proven dishonest in the past because they may conclude that he is also being dishonest in the present matter and may thus afford less weight to his testimony.

In all these instances, courts adjust the test based on the actor's past conduct. In school desegregation, whereas some school districts' desegregation plans would otherwise have been constitutional, because they followed years of de jure segregation, courts judged those plans more strictly. In an area that did not engage in de jure segregation, even if the schools were as racially segregated as an area that practiced de jure segregation, the test was less strict because it depended on the past actions of the school district. And, in perhaps the most applicable example, the jury may take into account a witness's proven history of dishonesty in deciding how credible his testimony is. The Court here should apply the

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[128] *Green*, 391 U.S. 430 at 439–40.

[129] *See, e.g.*, Keyes v. Sch. Dist. No. 1, Denver, Colo., 413 U.S. 189 (1973); Swann v. Charlotte-Mecklenburg Bd. of Educ., 402 U.S. 1 (1971).

[130] Rule 609(a)(1)(A) provides an exception for felonies against civil defendants and non-defendant witnesses in criminal cases. FED. R. EVID. 609(a)(1)(A). Rule 609(a)(1)(B) allows evidence of a prior criminal conviction against defendant witnesses when "the probative value of the evidence outweighs its prejudicial effect to that defendant." FED. R. EVID. 609(a)(1)(B).

[131] FED. R. EVID. 609 (emphasis added).

[132] S. Rep. No. 93-1277 (1974), *reprinted in* 1974 U.S.C.C.A.N. 7051, 7060–61.

[133] *Id.* at 7061.

[134] Conf. Rep. 93-1597 (1974), *reprinted in* 1974 U.S.C.C.A.N. 7098, 7102–03.

same general concept to the graphic warning requirement and apply the *Zauderer* standard.

The tobacco industry has deceived consumers about the health risks of tobacco for over 50 years. There is no way to know how deeply this deception has permeated into the American public's psyche. The current warnings, however, have been ineffective for 20 years.[135] The history of the industry wide deception, and the ineffective public response to it, is a valid reason for the Court to apply the *Zauderer* standard.

Moreover, applying *Zauderer* to the graphic warning requirement would not impermissibly or even perceptively loosen First Amendment protection of commercial speech. The deception here is incomparable. It traversed an entire industry and endured for over five decades. Furthermore, it greatly influenced the health of our country. Smoking is currently the foremost cause of preventable death in the United States, killing approximately 443,000 people per year.[136] In addition, "8.6 million people live with a serious illness caused by smoking."[137] It is unlikely that the Court will face another instance of such wide-spread, longstanding deception. Applying *Zauderer* here would have little effect on First Amendment jurisprudence, but could begin to repair the damage done by the vast deception executed by the tobacco companies.

VI. Applying *Zauderer*

Once the Court determines that the *Zauderer* standard is appropriate in light of the tobacco industry's deceit, the Court must apply the standard to decide whether the graphic warning requirement is constitutional. *Zauderer* states that, once the Court finds the commercial speech misleading, the government may compel factual and uncontroversial information that is reasonably related to correcting that deception.[138] The graphics in the warnings, combined with the text that accompanies them, convey factual, uncontroversial information that is reasonably related to the deception the tobacco companies carried out. The graphic warning requirement therefore survives *Zauderer* scrutiny.

A. Images May Convey Factual Information

In *Discount Tobacco*, the tobacco companies argued, and the Sixth Circuit rejected, that the graphic warnings would unavoidably display

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[135] 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) (In its response to a comment that the current warnings were adequate, the FDA stated that "in its 1994 report the Surgeon General noted that the warnings had become ineffective due to their size, shape, and familiarity.").

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

[137] *Tobacco Facts and Figures*, Be Tobacco Free, http://betobaccofree.hhs.gov/about-tobacco/facts-figures/index.html.

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

subjective and controversial rather than factual information.[139] In *R.J. Reynolds*, the D.C. Circuit found that the warnings do not convey factual or uncontroversial information, noting that the FDA specifically designed the warnings to provoke an emotional response in the viewer rather than to provide information.[140] All but one of the graphic warnings, when combined with their textual counterparts, convey factual information about the health risks of smoking.

First, images may convey factual information.[141] Photographs of actual events are the most obvious model; however, even staged portrayals and illustrations may communicate facts. For example, illustrations of pivotal Civil War battles in elementary school history books convey factual information about the parties fighting, the conditions of battle, the weapons available at the time, and the casualties. In addition, a reproduction of an event that uses actors may also represent actual events factually. Civil War reenactments may convey the same information as the elementary schoolbook illustrations. The use of imagery may not be classified as necessarily factual or fictional; like text, it may convey facts or fiction, depending on its content. Imagery is the vehicle of the information, and its truth depends entirely on its content.

Second, conveying health and risk information particularly demands a graphic element. Medical textbooks are filled with illustrations of conditions, diseases, injuries, and treatments. For instance, the seminal human anatomy textbook, *Gray's Anatomy*,[142] comprises 1,576 pages and contains about 2,000 images.[143] A medical student cannot be expected to learn about health information without visual aids. Likewise, a layperson cannot be expected to fully understand the health risks of smoking without seeing them. Furthermore, studies have shown that disadvantaged groups in particular struggle to access, process, and act on health information, a phenomenon known as "communication inequality."[144] The images on the warnings, combined with the accompanying text, serve to impart factual information about the health risks of smoking to all viewers, and therefore satisfy the first part of the *Zauderer* standard.

Finally, the government already mandates *graphic* warnings for other dangerous products. One example is the transportation of hazardous materials. The Code of Federal Regulations lays out labeling requirements

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[139] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 525 (6th Cir. 2012); Principal Brief of Plaintiffs-Appellants/Cross-Appellees at 27, *Disc. Tobacco City & Lottery, Inc.*, 674 F.3d 509 (No. 10-5234).

[140] *R.J. Reynolds II*, 696 F.3d 1205, 1216 (D.C. Cir. 2012).

[141] *See Zauderer*, 471 U.S. at 647.

[142] HENRY GRAY, GRAY'S ANATOMY: THE ANATOMICAL BASIS OF CLINICAL PRACTICE (Susan Standring ed., 40th ed. Elsevier 2008) (1858).

[143] *See id.*

[144] Kasisomayajula Viswanath, *Public Communications and its Role in Reducing and Eliminating Health Disparities*, *in* NAT'L ACAD. OF SCIS., EXAMINING THE HEALTH DISPARITIES RESEARCH PLAN OF THE NATIONAL INSTITUTES OF HEALTH: UNFINISHED BUSINESS 215, 222 (Thomson et al. eds., 2006).

for transporting certain classifications of hazardous materials.[145] The regulations specify the placement,[146] durability, design, size, and color of the labels.[147] The image required depends on the hazard classification. For instance, explosive materials require a depiction of an explosion, accompanied by the text "EXPLOSIVE."[148] Flammable gas requires an image of a fire over a thick black line, accompanied by "FLAMMABLE GAS."[149] Materials that are corrosive require display of two beakers of liquid, one being poured on and corroding a black bar, one being poured on and corroding a human hand, both with squiggly lines emanating from the poured liquid, representing the substance corroding.[150] The purpose of regulating transportation of hazardous materials, including the label requirements, is to "protect against the risks to life, property, and the environment that are inherent in the transportation of hazardous material in intrastate, interstate, and foreign commerce."[151] The graphic labels immediately convey the dangerousness of the product and the risks of handling it.[152] Here, the graphic warnings on cigarette packaging and advertisements would also serve to convey the risks of using the product.

B. The Graphic Warnings Are Both Factual and Reasonably Related to Correcting the Tobacco Industry's Longstanding Deception

Eight of the nine warnings the FDA devised and promulgated in the final rule convey factual information that is reasonably related to correcting the tobacco industry's deception.[153] As noted above, the four main lies the tobacco industry has propagated for over 50 years are: (1) cigarette smoking does not cause disease; (2) nicotine is not addictive; (3) light cigarettes present lower health risks than regular cigarettes; and (4) secondhand smoke has no known negative health effects.[154] The Tobacco Control Act separately addresses claims about light cigarettes by prohibiting "modified risk tobacco products" entirely.[155] The text and graphics on these eight labels directly address the three remaining lies, providing information on the diseases caused by smoking, the addictive nature of nicotine, and the negative health effects of secondhand smoke.

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[145] 49 C.F.R. § 172.400 (2012).

[146] *Id.* § 172.406.

[147] *Id.* § 172.407.

[148] *Id.* § 172.411.

[149] *Id.* § 172.417.

[150] *Id.* § 172.442.

[151] 49 U.S.C. § 5101 (2006).

[152] While the graphic labels here are used during transportation rather than purchase, the buyer likely sees them, thereby impacting the seller's commercial speech.

[153] *See* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,649–56 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).

[154] *See supra* note 109 and accompanying text.

[155] Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat. 1776, 1783, 1812, 1814 (2009).

The labels "Cigarettes cause fatal lung disease," "Cigarettes cause cancer," "Cigarettes cause strokes and heart disease," "Smoking during pregnancy can harm your baby," and "Smoking can kill you" all directly address the first deception, clarifying that smoking cigarettes does indeed cause disease. In addition, the graphics all display those diseases caused by or exacerbated by smoking.

The "Cigarettes cause fatal lung disease" label displays healthy lungs compared with diseased lungs.[156] Lung disease, including chronic obstructive pulmonary disease, emphysema, chronic bronchitis, pneumonia, and lung cancer, are all common effects of long term smoking.[157] Male smokers are estimated to be 25 times more likely than male nonsmokers to develop lung cancer; female smokers develop lung cancer 25.7 times more than their nonsmoking counterparts.[158]

The "Cigarettes cause cancer" warning shows a mouth with rotting teeth and a cancerous lip lesion.[159] Lung cancer is the most widely understood risk of smoking,[160] but smoking also increases the risk of many other types of cancer, including cancer of the throat, mouth, nasal cavity, esophagus, stomach, pancreas, kidney, bladder, and cervix.[161] The image of a cancerous lip lesion, combined with the warning that "Cigarettes cause cancer" broadly, not just lung cancer, help inform the public about the risks of smoking and correct the tobacco industry's lie that "the connection between smoking and disease [is] an open controversy."[162]

Similarly, the labels "Cigarettes cause strokes and heart disease," "Smoking during pregnancy can harm your baby," and "Smoking can kill you" exhibit other health consequences caused by smoking. The fact that the "Smoking during pregnancy" label displays an illustration, rather than a photograph, of a baby in an incubator does not diminish its relationship to correcting the deception. The illustration still displays the health risk conveyed in the text, that smoking can harm the baby, implying specifically that it leads to increased rates of preterm delivery.[163] The

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[156] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. at 36,651; *see also* Cigarette Required Warnings, *supra* note 63, at 89.

[157] *Cigarette Smoke Affects Your Body*, BE TOBACCO FREE, http://betobaccofree.hhs.gov/gallery/health-effects.html.

[158] *Health Effects of Cigarette Smoking*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/index.htm. (last updated Feb. 6, 2014).

[159] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. at 36,651; *see also* Cigarette Required Warnings, *supra* note 63, at 126.

[160] *See* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. at 36,632.

[161] *Cigarette Smoking: Health Risks and How To Quit*, NAT'L CANCER INST., http://www.cancer.gov/cancertopics/pdq/prevention/control-of-tobacco-use/Patient/page2.

[162] *See supra* note 115 and accompanying text.

[163] *Health Effects of Cigarette Smoking*, *supra* note 158; *see also* Cigarette Required Warnings, *supra* note 63, at 200. In *R.J. Reynolds*, the tobacco companies argued, and the D.C. Circuit agreed, that the graphics were designed to provoke an emotional response rather than convey factual information. *R.J. Reynolds II*, 696 F.3d 1205, 1216 (D.C. Cir.

use of actors rather than actual sufferers likewise has no effect on the communication of factual information because, as noted above, the use of actors is the vehicle rather than the information itself. These five labels are therefore all reasonably related to correcting the tobacco industry's deception that cigarette smoking does not cause disease.

The label "Cigarettes are addictive" directly repudiates the tobacco companies' longstanding denial that cigarettes and nicotine are addictive. The graphic shows a man smoking out of a tracheotomy hole in his throat, conveying that, even when a smoker experiences extremely negative consequences from smoking, he is so addicted that he may nonetheless be unable to quit.[164] The label is therefore reasonably related to correcting that misleading and lasting claim.

The labels "Tobacco smoke can harm your children" and "Tobacco smoke causes fatal lung disease in nonsmokers" both unambiguously address the lie that secondhand smoke does not have negative health effects. The "Tobacco smoke can harm your children" label shows a puff of smoke approaching a baby, while "Tobacco smoke causes fatal lung disease in nonsmokers" shows a woman crying.[165] While these images do not directly convey particular health risks caused by smoking—like those displayed in the other images—they show that one's own smoking negatively impacts nonsmokers, including children and other loved ones.[166] Because the tobacco companies have denied for decades that secondhand smoke has negative health effects, these warnings are necessary to demonstrate that smoking affects not only the smoker, but also those nonsmokers who are regularly exposed to secondhand smoke.

The only warning that is not reasonably related to correcting the tobacco companies' deception is "Quitting smoking now greatly reduces serious risks to your health." The graphic shows a man parting a buttoned shirt to show a t-shirt that says "I QUIT." Unlike the other warnings, this one displays the "positive health benefits of *quitting* smoking."[167] The purpose of the graphic warning requirement is to convey the health consequences of smoking in order to counteract the industry's decep-

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2012). However, the use of a photograph here would be undoubtedly more "provocative" than the illustration. In selecting the images, the FDA specifically considered using a photograph, but determined the photograph rated too high on the "difficult to look at measure" and was thus less effective at conveying health information. *See* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. at 36,647 (internal quotation marks omitted).

[164] *See* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. at 36,649; *see also* Cigarette Required Warnings, *supra* note 63, at 15.

[165] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. at 36, 649, 36,655; *see also* Cigarette Required Warnings, *supra* note 63, at 57, 275.

[166] COMM. ON SECONDHAND SMOKE EXPOSURE & ACUTE CORONARY EVENTS, INST. OF MED., NAT'L ACAD. OF SCI., SECONDHAND SMOKE EXPOSURE AND CARDIOVASCULAR EFFECTS: MAKING SENSE OF THE EVIDENCE 1–5 (2010).

[167] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. at 36,656 (emphasis added); *see also* Cigarette Required Warnings, *supra* note 63, at 316.

tion.[168] While the health benefits of quitting smoking are related to the harms of smoking, the message is one step removed. One must understand the harms of smoking in order to understand that quitting smoking can improve them. This image is therefore not reasonably related to correcting the deception and does not survive *Zauderer* scrutiny.

VII. Reframed *Central Hudson* Analysis

Even if the Court refuses to apply the *Zauderer* standard, some form of graphic warning requirement would survive under a reframed *Central Hudson* analysis. Rather than a government interest in "encourage[ing] current smokers to quit and dissuad[ing] other consumers from ever buying cigarettes,"[169] the interest should be classified as communicating the negative health consequences of smoking. Studies show that the graphic warnings convey the risks of smoking, and convey the risks more effectively than purely textual warnings.[170] The warnings therefore directly advance the state interest in communicating the harms of smoking. However, restrictions on the remaining portion of the advertisement, and the requirement that the graphic labels cover a minimum percentage of the advertisements and packages,[171] are probably more extensive than necessary. If the FDA removed the restrictions on the remaining portion of the advertisements, and shrank the graphic warnings to fit within the portion covered by the existing, textual warnings, the regulation would no longer be more extensive than necessary and would therefore survive under the *Central Hudson* standard as well.

Implications and Conclusion

Compulsion of factual information is a powerful and generally accepted regulatory tool, both in public health specifically and in administrative law generally.[172] Its effect on First Amendment rights has traditionally been viewed as minimal. While the First Amendment protects the right to speak as well as the right to choose *not* to speak,[173] compelling factual information from commercial speakers does not implicate the same concerns as it would for non-commercial speakers. As the Court

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[168] *See supra* note 138 and accompanying text.

[169] *R.J. Reynolds II*, 696 F.3d 1205, 1218 (D.C. Cir. 2012) (citing Family Smoking Prevention and Tobacco Control and Federal Retirement Reform, Pub. L. No. 111-31, 123 Stat. 1776, 1782 (2009)).

[170] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. at 36, 633.

[171] 123 Stat. at 1843–44.

[172] *See, e.g.*, 21 U.S.C. § 352 (2012) (prescription and over the counter drug labeling requirements); 21 C.F.R. § 101.9 (2013) (nutrition facts); 49 C.F.R. pt. 172 (2012) (dangerous products in interstate travel).

[173] *E.g.*, Wooley v. Maynard, 430 U.S. 705 (1977); Miami Herald Publ'g Co. v. Tornillo, 418 U.S. 241 (1974); W. Va. State Bd. of Educ. v. Barnette, 319 U.S. 624 (1943).

stated in *Zauderer*, "extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides . . . [so a] constitutionally protected interest in *not* providing any particular factual information . . . is minimal."[174] The factual information is seen as contributing to the vibrant marketplace of ideas,[175] rather than inhibiting it.

In *Sorrell v. IMS Health Inc.*, the Supreme Court applied heightened scrutiny to strike down a Vermont statute that "restrict[ed] the sale, disclosure, and use of pharmacy records that reveal the prescribing practices of individual doctors" because of its incidental effect on pharmaceutical manufacturers' First Amendment rights.[176] Justice Breyer vehemently dissented, arguing that:

> Since ordinary regulatory programs can affect speech, particularly commercial speech, in myriad ways, to apply a heightened First Amendment standard of review whenever such a program burdens speech would transfer from legislatures to judges the primary power to weigh ends and to choose means, threatening to distort or undermine legitimate legislative objectives.[177]

The majority of the Court, however, was unconvinced.

Sorrell's influence on our government's ability to regulate the market and protect its citizens is potentially catastrophic. Striking down the graphic warning requirement would constrain the government even further. Over the last 50 years, the tobacco industry perpetrated one of the most egregious and damaging deceptions in the history of our country. Ideally, no such scheme will be tolerated in the future. But preventing the government from correcting that deception with factual information, in the form of the graphic warnings, betrays the American public, and does nothing to discourage other industries from attempting such a conspiracy again.

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

[175] *See* Abrams v. United States, 250 U.S. 616, 630 (1919) (Holmes, J., dissenting).

[176] Sorrell v. IMS Health Inc., 131 S. Ct. 2653, 2659 (2011).

[177] *Id.* at 2673, 2675 (Breyer, J., dissent) (internal quotation marks omitted).