SMOKE AND MIRRORS: PREVENTING DECEPTION OF CONSUMERS IN THE TOBACCO MARKET THROUGH GRAPHIC WARNING LABELS

Kelly O'Donovan[*]

INTRODUCTION 292
I. THE DEVELOPMENT OF COMMERCIAL FREE SPEECH CASE LAW 295
II. THE CIRCUIT SPLIT CONCERNING THE GRAPHIC WARNING LABEL PROVISION OF THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT 303
III. *ZAUDERER*'S LOWER LEVEL OF SCRUTINY SHOULD BE APPLIED EVEN WHERE THERE IS NO DECEPTIVE ADVERTISEMENT, ONLY A GENERAL CONFUSION IN THE MARKET 307
IV. *ZAUDERER* SHOULD HAVE BEEN USED TO ANALYZE THE FDA'S GRAPHIC IMAGES UNDER REVIEW IN *R.J. REYNOLDS*; AND, A LOWER LEVEL OF SCRUTINY SHOULD BE APPLIED TO FUTURE IMAGES PROPOSED BY THE FDA.. 309
CONCLUSION 318

[*] J.D. candidate, Albany Law School, 2014; Managing Editor for Business & Production, *Albany Government Law Review*, 2013–2014; B.A. English, B.A. Philosophy, State University of New York at Geneseo.

INTRODUCTION

The Family Smoking Prevention and Tobacco Control Act, signed by President Obama on June 22, 2009, grants the FDA the authority to regulate tobacco products, and further requires color graphics depicting the negative health consequences of smoking to be printed on tobacco products.[1] No later than two years after the date of enactment, graphic warning labels were supposed to cover fifty percent of the front and rear of cigarette packaging, and thirty percent of the display panels of smokeless tobacco products.[2] The images eventually developed by the FDA, including a man smoking with a stoma in his neck, a cancerous lesion on a lip, and an image of healthy lungs adjacent to diseased lungs, have yet to appear on tobacco products, as a result of litigation between the federal government and tobacco companies.[3]

Two federal circuit courts have made rulings on the constitutionality of the graphic warning labels required by the Act.[4] In March of 2012, the Sixth Circuit, in *Discount Tobacco City & Lottery, Inc. v. United States*, rejected a facial challenge to the Act, which alleged that the graphic warning labels burdened the free speech rights of tobacco companies and forced them to disseminate the government's anti-smoking message.[5] The Sixth Circuit held that, not only did the provision requiring graphic warnings serve to counteract a "decades-long deception by Tobacco Companies," but it also conveyed the dangers of smoking to consumers more effectively.[6]

In August of 2012, the District of Columbia Circuit analyzed the specific images chosen by the FDA to be included on tobacco products in *R.J. Reynolds Tobacco Co. v. Food and Drug Administration*.[7] Applying a stricter scrutiny than the Sixth

---

[1] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, §§ 3, 201(a), 123 Stat. 1776, 1781, 1845 (2009).

[2] *Id.* at §§ 201, 204.

[3] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628, 36649, 36651 (June 22, 2011) (to be codified at 21 C.F.R. pt. 1141). *See generally* Nanci Bompey, *Groups Push for FDA Cigarette Warnings After SCOTUS Declines Case*, FDA WEEK, Apr. 26, 2013.

[4] R.J. Reynolds Tobacco Co. v. FDA, 696 F.3d 1205, 1221–22 (D.C. Cir. 2012); Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 569 (6th Cir. 2012).

[5] *Disc. Tobacco City & Lottery Inc.*, 674 F.3d at 569.

[6] *Id.* at 562–69.

[7] *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1211.

Circuit in *Discount Tobacco City & Lottery*, the District of Columbia Circuit found the graphic warnings to be unconstitutional, as the government did not present evidence adequate to show the graphic warnings would advance their goal of reducing smoking rates.[8] Under this Court's interpretation, the lower level of scrutiny used by the Sixth Circuit in *Discount Tobacco City & Lottery* was inapplicable because the government was not mandating these warning labels in response to a particular misleading tobacco advertisement.[9]

As these graphic images concern commercial speech, they should be analyzed under the standards set forth in *Central Hudson Gas & Electric Corporation v. Public Service Commission of New York* and *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*.[10] Dispute about the standard under which the graphic image provision should be analyzed has fueled the debate about the constitutionality of the graphic warning label provision.[11] Under *Central Hudson*, a government restriction on commercial speech is valid only if it directly advances a substantial government interest, which cannot be accomplished by a less restrictive means of regulation.[12] *Zauderer* sets the standard for evaluating compelled commercial speech, requiring that compelled speech or disclosures must be reasonably related to a government's interest in preventing the deception or confusion of consumers.[13] It was this lower level of scrutiny which was used to uphold the provision in *Discount Tobacco City & Lottery*, and which the D.C. Circuit rejected in *R.J. Reynolds*.[14]

These new graphic warning labels have been likened to putting similar warnings on packages of fast food or candy bars.[15] But,

[8] *Id.* at 1219.

[9] *Id.* at 1214–15, 1219. *See generally Disc. Tobacco City & Lottery Inc.*, 674 F.3d at 526–27, 562, 569.

[10] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985); Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 564 (1980).

[11] *Compare Disc. Tobacco City & Lottery Inc.*, 674 F.3d at 569 (applying the *Zauderer* standard), *with R.J. Reynolds Tobacco Co.*, 696 F.3d at 1212–14 (rejecting the *Zauderer* standard as too lenient, absent a showing that an advertisement was likely to mislead consumers).

[12] *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 564.

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

[14] *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1213; *Disc. Tobacco City & Lottery, Inc.*, 674 F.3d at 526–27, 568.

[15] *See* Brief for Appellees at 32–33, *R.J. Reynolds Tobacco Co.*, 696 F.3d 1205 (No. 11-5532).

instead of picturing the government developing the most grotesque images possible to steer consumers away from any potentially unhealthy indulgence, this provision should be examined in relation to the product at which it is aimed. The tobacco industry is entirely unique in that it is authorized to sell a highly addictive product that kills approximately one half of its users when it is used in the manner the manufacturers intended.[16]

In March of 2013, the federal government chose not to seek a review of the District of Columbia Circuit's decision in *R.J. Reynolds*, abandoning the images that were under review in *R.J. Reynolds* to have the FDA develop new warning labels.[17] On April 22, 2013, the U.S. Supreme Court denied *certiorari* in an appeal taken by tobacco companies from the Sixth Circuit's ruling in *Discount Tobacco City & Lottery*.[18] The determination of the Sixth Circuit in *Discount Tobacco City & Lottery*, that the FDA's authority to require graphic warning labels on tobacco products is constitutional, will stand.[19] But, considering the D.C. Circuit's outright rejection of the constitutionality of every one of the nine images developed by the FDA, it is hard to imagine any other proposed image will pass constitutional muster. This paper will argue that the D.C. Circuit should have applied the lower scrutiny *Zauderer* standard in *R.J. Reynolds* and that these graphic warnings should have been held to be constitutional.

Part I will look at the development of commercial free speech case law, highlighting that several federal circuit courts have applied the lower level scrutiny of *Zauderer* to cases where there is no deceptive advertisement, only a misconception in the market surrounding a product or service. Part II will examine the rulings by the Sixth Circuit and the D.C. Circuit concerning the graphic warning label provision of the Family Smoking Prevention and Tobacco Control Act.

When the U.S. Supreme Court developed the lower level of scrutiny applied to compelled disclosures in commercial speech in *Zauderer*, the case at hand involved a deceptive advertisement.[20]

[16] World Health Org., *Tobacco: Deadly in any Form or Disguise*, at 18 (2006), http://www.who.int/tobacco/communications/events/wntd/2006/Tfi_Rapport.pdf.

[17] Michael Felberbaum, *U.S. to Revise Cigarette Warning Labels*, THE ASSOCIATED PRESS, March 19, 2013.

[18] Brief for Respondent at 1, Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013) (No. 12-521).

[19] *See id.* at 13.

[20] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 633–34 (1985).

This lower level of scrutiny was justified by the need to correct the confusion or deception of consumers.[21] In Part III, this paper will argue that whether an advertisement is misleading or not, the purpose of compelling speech by the manufacturer is to prevent deception or confusion of the consumer, so this lower level of scrutiny can be applied even in situations where there is only a general confusion in the market.[22] Part IV will examine why *Zauderer* should have been used to analyze the FDA's graphic images under review in *R.J. Reynolds* and why a lower level of scrutiny should be applied to future images proposed by the FDA. These proposed graphic images, when paired with the warning statements that accompany the images, serve to better convey the health risks associated with smoking to consumers and are not unjustified or unduly burdensome on tobacco companies. Therefore, when analyzed under the correct lower scrutiny, the original graphic images proposed by the FDA will pass constitutional muster.

I. THE DEVELOPMENT OF COMMERCIAL FREE SPEECH CASE LAW

In 1975, the United States Supreme Court definitively stated that commercial speech is protected by the First Amendment,[23] but this protection is subject to "reasonable regulation."[24] Commercial speech is accorded less protection by the First Amendment than other types of protected expression because it is fundamentally different.[25] This difference has been recognized as a "common-sense" distinction, as commercial speech "occurs in an area [which is] traditionally subject to government regulation" and is "commensurate with [a] subordinate position in the scale of First Amendment values."[26] To impose the same regulations on commercial speech and other forms of First Amendment protected speech would be to dilute all forms of protected expression other

[21] *Id.* at 651.
[22] *Id.*
[23] Bigelow v. Virginia, 421 U.S. 809, 818 (1975).
[24] *Id.* at 826.
[25] Ohralik v. Ohio State Bar Ass'n, 436 U.S. 447, 455–56 (1978); Bates v. State Bar of Ariz., 433 U.S. 350, 380–381 (1977) (quoting Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 771 n.24 (1976)).
[26] *Ohralik*, 436 U.S. at 455–56; *Bates*, 433 U.S. at 381; *Va. State Bd. of Pharmacy*, 425 U.S. at 771 n.24.

than commercial speech.[27] Because some commercial speech is, by nature, deceptive or misleading, the Supreme Court has recognized that the government must have the ability to "insur[e] that the stream of commercial information flow[s] cleanly as well as freely."[28]

First Amendment protection was extended to commercial speech to guarantee that such speech would be truthful and accurate, thus ensuring, also, that consumers would be protected from "commercial harms."[29] Such First Amendment protection is applied "not so much because it pertains to the seller's business as because it furthers the societal interest in the 'free flow of commercial information.'"[30]

Central Hudson laid out the test that would determine the government's power to suppress commercial speech.[31] The nature of an expression, and the interest the government has in regulating the expression, will determine the protection that will be accorded by the First Amendment.[32] The government certainly has the power to regulate commercial speech that is false, deceptive, or misleading, and commercial speech that is related to illegal activity.[33] If the speech is neither deceptive, nor related to illegal activities, the government must take on the burden of showing the regulation to be in furtherance of a substantial interest.[34] The Court used two criteria to evaluate the government's proffered relation between the regulation and the substantial interest:

> First, the restriction must directly advance the state interest involved; the regulation may not be sustained if it provides only ineffective or remote support for the government's purpose. Second, if the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.[35]

It has been recognized that, where suppression of commercial speech is too drastic a violation of the First Amendment, "limited

[27] *Ohralik*, 436 U.S. at 456.
[28] *Va. State Bd. of Pharmacy*, 425 U.S. at 771–72.
[29] 44 Liquormart, Inc. v. R.I., 517 U.S. 484, 502 (1996).
[30] First Nat'l Bank of Bos. v. Bellotti, 435 U.S. 765, 783 (1978) (quoting *Va. State Bd. of Pharmacy*, 425 U.S. at 764).
[31] Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 564 (1980).
[32] *Id.* at 563.
[33] *Id.* at 563–64.
[34] *Id.* at 564.
[35] *Id.*

supplementation, by way of warning or disclaimer or the like, might be required."[36] These supplementations are one of the "more limited restriction[s] on commercial speech" that would undermine a government's attempts at suppression.[37] Warning labels or disclaimers, therefore, are a scaled back version of government regulation of commercial speech.[38]

Requirements for disclosure are different from outright prohibitions on commercial speech, as the government is no longer preventing information from being conveyed, but requiring more information than an advertiser originally wanted to convey.[39] The Supreme Court has held that, in some instances, compelled speech can violate First Amendment protections as much as restrictions on, or suppression of, speech.[40] But, the Court has developed a standard pertaining specifically to cases involving commercial speech, which is used to determine when compelled speech violates the First Amendment.[41]

In *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, the Court outlined the test to determine whether compelled speech in the commercial arena violates First Amendment protections.[42] The purpose of required disclosures is to prevent "consumer confusion or deception."[43] Though an advertiser's interests are disturbed less through disclosure requirements than through suppression of speech, "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech."[44]

---

[36] *Id.* at 565 (quoting Bates v. State Bar of Ariz., 433 U.S. at 384).

[37] *Cent. Hudson Gas & Elec. Corp.*, 447 U.S. at 564.

[38] *Id.* at 565.

[39] *See* Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 650 (1985) (The Court recognizes "material differences between disclosure requirements and outright prohibitions on speech.").

[40] *See, e.g.*, *id.*; Wooley v. Maynard, 430 U.S. 705, 717 (1977) (holding that New Hampshire could not require appellees to display the state motto on their vehicle license plates); Miami Herald Publ'g Co. v. Tornillo, 418 U.S. 241, 258 (1974) (holding that a Florida statute, which required a newspaper to print, free of cost, the reply of a candidate for election to a statement made in the newspaper against his personal character or official record, does not comply with the First Amendment); W. Va. State Bd. of Educ. v. Barnette, 319 U.S. 624, 642 (1943) (holding that students could not be compelled to salute the flag and say the pledge of allegiance in school, as such compulsion violated the First Amendment).

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

[42] *Id.*

[43] *Id.*

[44] *Id.*

Therefore, disclosure requirements must be reasonably related to a government's interest in preventing deception or confusion of consumers to avoid violating First Amendment protections.[45]

Zauderer involved an advertisement by an attorney that conveyed the message "if there is no recovery, no legal fees are owed by our clients," referring to a contingent-fee arrangement, where clients would be liable for costs, but not legal fees.[46] The Court ruled that the government can require an attorney to disclose that "clients will have to pay costs even if their lawsuit [is] unsuccessful . . . [and still] easily pass[] muster under this standard."[47] Laymen are not aware of the differences between "legal fees" and "costs" as terms of art, especially as they are virtually interchangeable in ordinary usage.[48] The government also has no burden to present evidence on the deceptive character of an advertisement, where the court can deduce the likelihood of deception "is hardly a speculative one."[49] In *Zauderer*, the Court thought it "commonplace" that members of the public would often be unaware of the differences between "fees" and "costs" in an attorney's advertisement.[50] The risk for deception in this case was "self-evident" and the government's disclosure requirement was reasonable.[51]

When cases arise that concern government regulation, either through compelled disclosure or restriction of speech, courts often struggle most with whether *Central Hudson* or *Zauderer* would provide the appropriate standard of review.[52] Courts have come to differing conclusions on whether *Zauderer* should be applied to all cases concerning compelled disclosures or just those that are deemed to be deceptive or misleading.[53]

The Supreme Court has revisited *Zauderer* and its application in *Milavetz, Gallop & Milavetz, P.A. v. United States*.[54] *Milavetz*

[45] *Id.*
[46] *Id.* at 652.
[47] *Id.* (alteration in original).
[48] *Id.*
[49] *Id.* at 652–53.
[50] *Id.* at 652–53.
[51] *Id.* at 652.
[52] United States v. Philip Morris USA, Inc., 907 F. Supp. 2d 1, 11 (D.D.C. 2012).
[53] *Compare* N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 133 (2d Cir. 2009), *and* Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 310 (1st Cir. 2005), *with* R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1214–15 (D.C. Cir. Aug. 24, 2012).
[54] Milavetz, Gallop & Milavetz, P.A. v. United States, 130 S. Ct. 1324, 1331

involved the validity of a provision of the Bankruptcy Abuse Prevention and Consumer Protection Act, requiring that any advertisement of bankruptcy services contain a disclosure that the services advertised are with respect to bankruptcy, and a disclosure that an agency is a debt relief agency which helps people to file for bankruptcy.[55] The provisions under review in *Milavetz* and *Zauderer* were similar, in that the required disclosures were meant "to combat the problem of inherently misleading commercial advertisements."[56] The disclosures required accurate statements to be made, and the entities involved were not prevented from conveying any additional information.[57] The Court noted that in *Zauderer* "First Amendment protection for commercial speech [wa]s justified in large part by the information's value to consumers."[58] The Court concluded that, because the provisions were directed at misleading speech, and because they "impose[d] a disclosure requirement rather than an affirmative limitation on speech . . . the less exacting scrutiny described in *Zauderer* govern[ed] our review."[59]

Though *Milavetz* affirmed the difference between the situations where *Zauderer* and *Central Hudson* standards should apply—disclosures and suppressions—some courts still differ on whether *Zauderer* or *Central Hudson* should apply when compelled disclosures are not directed at inherently misleading speech.[60] The United States Court of Appeals for the First and Second Circuits (hereinafter First or Second Circuit) have both embraced a broader reading of *Zauderer*, choosing to apply it in cases where the commercial speech itself is not deceptive.[61] These Courts highlight that there are no cases limiting *Zauderer*'s application only to deceptive advertising[62] and that the furtherance of

(2010).

[55] *Id.* at 1330.

[56] *Id.* at 1340.

[57] *Id.*

[58] *Id.* at 1339.

[59] *Id.* (alteration in original).

[60] *Compare* N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 133 (2d Cir. 2009), *and* Pharm. Care Mgmt. Ass'n, v. Rowe, 429 F.3d 294, 309–10 (1st Cir. 2005), *with* R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1214–15 (D.C. Cir. 2012).

[61] *See N.Y. State Rest. Ass'n*, 556 F.3d at 133; *Pharm. Care Mgmt. Ass'n*, 429 F.3d at 310; Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 114–15 (2d Cir. 2001).

[62] *N.Y. State Rest. Ass'n*, 556 F.3d at 133.

Zauderer's goals, preventing consumer deception, is achieved through better informing consumers.[63]

Though the facts in *Zauderer* and its progeny highlight that the government-required disclosures, which were upheld by the U.S. Supreme Court, were in response to advertisements that were deemed to be deceptive, it is important to remember the primary purpose on which *Zauderer*'s test is based—preventing consumer deception.[64] Though *Zauderer* and *Milavetz*, the only two U.S. Supreme Court cases that have addressed the constitutionality of commercial speech disclosures, may have focused on advertisements that were in themselves deceptive, it may be necessary to require disclosures not only to counteract deceiving information in an advertisement, but to correct a consumer's confusion or deception about a particular product.[65]

Several federal courts have upheld statutes that compel disclosure on the theory that the compelled speech is correcting a misguided belief or a deception of the consumer.[66] The First Circuit confronted this issue with Maine's 2003 enactment of the Unfair Prescription Drug Practices Act.[67] The Act imposed requirements on pharmacy benefit managers to disclose conflicts of interest and financial arrangements with third parties, and disgorge profits from self-dealing to health benefit providers, such as insurance companies, the State Medicaid program, and employer health plans.[68] Applying *Zauderer*, the Court found the provisions of the Unfair Prescription Drug Practices Act did not violate the First Amendment.[69] While the pharmacy benefit managers had a minimal interest in withholding the information that was required to be disclosed by the statute, Maine had a great interest in ensuring its citizens received the best and most cost-effective health care possible through banning unfair practices.[70] The Court also found the disclosure requirements to be reasonably

---

[63] *Id.*

[64] *Milavetz, Gallop & Milavetz, P.A.*, 130 S. Ct. at 1331; Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985).

[65] *Milavetz, Gallop & Milavetz, P.A.*, 130 S. Ct. at 1340; *Zauderer*, 471 U.S. at 651.

[66] *See N.Y. State Rest. Ass'n*, 556 F.3d at 136; *Pharm. Care Mgmt. Ass'n*, 429 F.3d at 310; *Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 115.

[67] *Pharm. Care Mgmt. Ass'n*, 429 F.3d at 299.

[68] *Id.*

[69] *Id.* at 310.

[70] *Id.*

related to Maine's interest in preventing consumer deception and increasing public access to prescription drugs.[71]

The Second Circuit has also made several rulings that interpret *Zauderer* to allow compelled disclosures for the purpose of better informing consumers.[72] The Court upheld a statute requiring manufacturers of products containing mercury to label their products and packaging to inform consumers that the products contained mercury, and should be recycled or disposed of as hazardous waste.[73] Although the overall goal of the statute was to reduce the amount of mercury released into the environment, increasing consumer awareness of the presence of mercury in a product was essential to achieving that goal.[74] "[T]he reasonable-relationship rule outlined in *Zauderer*" was found to exist in this case, as the suggested labeling would likely contribute to a reduction of mercury pollution, regardless of the possibility that the statute may fail to eliminate all, or even most, of the mercury pollution in Vermont.[75] The possibility that some citizens of Vermont would properly dispose of mercury-containing products as a result of the labeling, and thereby reduce the amount of mercury pollution, meant the statute was rationally related to the State's goal and did not violate the First Amendment.[76]

The Second Circuit also upheld a regulation compelling disclosure of caloric information from certain chain restaurants in New York City, on the basis that it not only corrected consumer confusion, but also that it informed consumers.[77] Using the *Zauderer* rational basis test, the Court found that New York City had demonstrated a reasonable relationship between the goal of reducing confusion and informing consumers about caloric values to reduce obesity and related diseases and the compelled disclosure of caloric information.[78] Having access to nutrition information is essential to a consumer being able to properly assess the caloric value of food.[79] Compelling disclosure of caloric

---

[71] *Id.*

[72] *See* N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 133 (2d Cir. 2009); Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001).

[73] *Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 107, 115.

[74] *Id.* at 115.

[75] *Id.*

[76] *Id.*

[77] *N.Y. State Rest. Ass'n*, 556 F.3d at 133.

[78] *Id.* at 134.

[79] *Id.* at 136 ("[A] statement which we do not doubt upon being informed,

information provided the tools for New York City consumers to combat obesity, making it possible for obesity to be reduced, and establishing for the Court that informing consumers of caloric information was a valid means to reach the goal under rational basis review.[80]

There are also federal courts which have declined to follow the theory that *Zauderer* can be applied to cases where compelled speech is not aimed at correcting deceiving information in an advertisement, but instead, a strict scrutiny analysis is justified for advertisements containing information which is not "purely factual and uncontroversial."[81] The Seventh Circuit further developed the standards needed for compelled speech to pass constitutional muster, stating that such warnings or disclosures, though permitted for the purpose of improving consumer awareness, should be factual and uncontroversial.[82] Illinois' Sexually Explicit Video Game Law, which required a four square inch label with the numerals "18" to be placed on any videogame judged to be sexually explicit, failed to pass this test.[83] The State's judgment of what was sexually explicit was too subjective for the Court to consider review under any standard less than strict scrutiny.[84] The label communicated a message that was subjective and controversial, particularly unlike the factual nature of a surgeon general's health warning on a pack of cigarettes.[85] The statute was held unconstitutional under strict scrutiny because it was not narrowly tailored to the State's goal.[86] Illinois could not demonstrate that other methods would not be effective to achieve its goal of informing parents of the sexually explicit content in a video game.[87]

---

counter-intuitively, that a smoked turkey sandwich at Chili's contains 930 calories, more than a sirloin steak, which contains 540, or that 2 jelly-filled doughnuts at Dunkin' Donuts have fewer calories than a sesame bagel with cream cheese.").

[80] *Id.*

[81] *See* Entm't Software Ass'n v. Blagojevich, 469 F.3d 641, 652 (7th Cir. 2006) (quoting Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985) (second alteration in original)).

[82] *Id.* at 652.

[83] *Id.* at 643, 652.

[84] *Id.* at 652.

[85] *Id.*

[86] *Id.*

[87] *Id.*

II. THE CIRCUIT SPLIT CONCERNING THE GRAPHIC WARNING LABEL PROVISION OF THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

The graphic warning label provision of the Family Smoking Prevention and Tobacco Control Act is meant to benefit the American people in both "human and economic terms."[88] Reducing the use of tobacco would not only save millions from an early death, due to health risks that arise from smoking tobacco, but would save approximately $75 billion in healthcare costs.[89] The Act recognized the power of tobacco product advertisements to foster favorable beliefs about using tobacco and thereby contribute to new users of tobacco products.[90] It also took notice of the failure of past efforts by the government to curb tobacco use, prompting some of the more controversial provisions of the Act.[91] The graphic warning labels mandated by the Act were to replace the four rotating textual warnings, placed in small print on the side of cigarette packages, which have remained unchanged since 1984.[92]

The Act grants the FDA the authority to regulate tobacco products for the purpose of better informing consumers of the health effects and safety of tobacco products.[93] In accordance with this purpose, the Act requires all cigarette packages sold in the United States to carry a label covering fifty percent of the front and rear panels of a cigarette package, comprised of a textual warning statement and a color graphic "depicting the negative health consequences of smoking."[94] The nine textual statements and graphic images chosen by the FDA are as follows: "WARNING: Cigarettes are Addictive," depicting a man who is still smoking despite prior evidence (a stoma in his neck) of surgery for cancer; "WARNING: Tobacco Smoke Can Harm Your Children," depicting smoke approaching a baby; "WARNING:

---

[88] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2(12), 123 Stat. 1176, 1777 (2009).

[89] *Id.* at § 2(14).

[90] *Id.* at § 2(15).

[91] *Id.*

[92] *See* Comprehensive Smoking Education Act, Pub. L. No. 98-474, 98 Stat. 2200, 2201–03 (1984); Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69524, 69530 (Nov. 12, 2010) (to be codified at 41 C.F.R. pt. 1141).

[93] § 3(6), 123 Stat. at 1782.

[94] *Id.* at § 210.

Cigarettes Cause Fatal Lung Disease," depicting a set of healthy lungs next to a set of diseased lungs; "WARNING: Cigarettes Cause Cancer," depicting a cancerous lesion on a lip; "WARNING: Cigarettes Cause Strokes and Heart Disease," depicting an oxygen mask on a man's face; "WARNING: Smoking During Pregnancy Can Harm Your Baby," paired with a graphic illustration of a baby in an incubator; "WARNING: Smoking Can Kill You," depicting a man with chest staples from an autopsy; "WARNING: Tobacco Smoke Causes Fatal Lung Disease in Nonsmokers," depicting a woman crying; "WARNING: Quitting Smoking Now Greatly Reduces Serious Risks to Your Health," depicting a man wearing a t-shirt on which the words 'I Quit' are printed.[95]

On August 31, 2009, a group of manufacturers and sellers of tobacco, including Discount Tobacco City & Lottery, Inc., Lorillard Tobacco Company, National Tobacco Company, R.J. Reynolds Tobacco Company, Commonwealth Brands, Inc., and the American Snuff Company, brought suit against the United States in the District Court of the Western District of Kentucky.[96] These plaintiffs brought a facial challenge against the Family Smoking Prevention and Tobacco Control Act's graphic warning requirement, alleging it was unconstitutional as it "unjustifiably and unduly burden[ed] Plaintiffs' commercial speech . . .[and] unconstitutionally compel[led] Plaintiffs to disseminate the Government's anti-tobacco message."[97] The District Court did not buy into the plaintiffs' suggestion that "the government's goal must be to browbeat potential tobacco consumers . . . over the head with its anti-tobacco message at the manufacturers' expense."[98] Faced with evidence that current warning labels on tobacco products were simply not being viewed, or even read, by a significant portion of consumers, the Court found the new graphic warnings to be justified.[99] In addition, the size and content of these warnings were not arbitrary, as they were based on

[95] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628, 36649, 36651–56 (proposed June 22, 2011) (to be codified at 21 C.F.R. 1141).

[96] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 521 (6th Cir. 2012).

[97] Commonwealth Brands v. United States, 678 F. Supp.2d 512, 528 (W.D. Ky. 2010) (first and second alteration and ellipsis in original) (third alteration added).

[98] *Id.* at 530 (ellipsis added).

[99] *Id.* at 530–31.

suggestions from the World Health Organization's Framework Convention on Tobacco Control.[100] The District Court did not feel strict scrutiny was needed as a standard of review because the textual warnings conveyed factual information that has not been controversial for decades.[101] The addition of the graphic images did not alter the message conveyed by the textual warnings.[102]

On appeal, the Sixth Circuit affirmed the District Court's ruling on the graphic label requirements.[103] Although the Sixth Circuit agreed a strict scrutiny analysis should not be applied, they recognized a difference between the purely objective, uncontroversial textual warnings, similar to, or the same as, those which have been on cigarette packages since 1965, and the subjective visual images, which "cannot be categorized as mere health disclosure warnings."[104] This was not a case of an affirmative limitation on speech, as the plaintiffs asserted. This instead involved disclaimers, governed by *Zauderer*, which may "appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive."[105] Essentially, the character of the images themselves as being subjective was irrelevant, as they served the purpose of preventing consumer deception.[106] The Court saw itself as upholding a fifty-year-old proposition from the Supreme Court: "[t]o avoid giving a false impression that smoking [is] innocuous, the cigarette manufacturer who represents the alleged pleasures or satisfactions of cigarette smoking in his advertising must also disclose the serious risks to life that smoking involves."[107] Finally, the Court agreed with the District Court's determination of the reasonableness of the size and placement of the warning labels, and the plaintiff's inability to demonstrate the remaining portions of their packages were insufficient for them to place their brand name, logo, or other information.[108]

On August 16, 2011, R.J. Reynolds Tobacco, Lorillard Tobacco,

[100] *Id.* at 531.
[101] *Id.*
[102] *Id.* at 532.
[103] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 531 (6th Cir. 2012).
[104] *Id.* at 525–26.
[105] *Id.* at 527 (quoting Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 771 n.24 (1976)).
[106] *Id.*
[107] *Id.*
[108] *Id.* at 530–31.

Commonwealth Brands, Liggett Group, and Santa Fe Natural Tobacco brought a similar suit against the FDA in the District Court for the District of Columbia, this time arguing that the specific graphic images selected by the FDA under the provisions of the Act violated their First Amendment rights.[109] The Court determined that the message the FDA aimed to convey through its warnings was not factual and uncontroversial, as they were designed to create a negative emotional response.[110] Because of the Court's interpretation of the images as subjective and controversial, they were subjected to a strict scrutiny analysis.[111] The rule failed strict scrutiny analysis because the Court believed the government's real reason behind the rule, to stop people from smoking, was not a compelling interest, the size of the images was too large to be narrowly tailored to the government's purpose, and there were less restrictive alternatives that would accomplish the government's goal.[112] The alternatives highlighted by the Court were: increased anti-smoking advertisements, requiring the graphic images to cover a smaller portion of tobacco packaging, selecting images that are purely factual and not gruesome, and increasing cigarette taxes.[113]

The FDA appealed to the District of Columbia Circuit Court, which affirmed.[114] The Court called the images "unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting."[115] Analysis under *Zauderer* was not warranted, as the Court found the images were not purely factual.[116] The Court proceeded to analyze the graphic image provision through a *Central Hudson* framework, assuming the FDA's interest was in discouraging non-smokers from starting and encouraging smokers to quit, rather than in informing consumers about the health consequences of smoking.[117] The lack of any substantial evidence that similar uses of graphic images on tobacco products in other countries had

[109] R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 845 F. Supp. 2d 266, 268 (D.D.C. 2012).
[110] *Id.* at 273.
[111] *Id.* at 274.
[112] *Id.* at 275–76.
[113] *Id.* at 276.
[114] R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 696 F.3d 1205, 1222 (D.C. Cir. 2012).
[115] *Id.* at 1217 (parenthesis in original).
[116] *Id.* at 1216.
[117] *Id.* at 1217–18.

actually led to a reduction in smoking prompted the Court to find the FDA had not shouldered its burden of showing the warnings would directly advance its interest.[118] The FDA could not satisfy its burden with what the Court called "mere speculation and conjecture."[119] The Court rejected the FDA's claim that the interest the rule was meant to advance was an interest in "effectively communicating health information."[120] This interest was merely a means by which the FDA would reduce smoking, and was too vague, in the sense that the government could define "effective" in any way it pleased, skirting the *Central Hudson* requirement that a restriction directly advance a substantial interest.[121]

III. *ZAUDERER*'S LOWER LEVEL OF SCRUTINY SHOULD BE APPLIED EVEN WHERE THERE IS NO DECEPTIVE ADVERTISEMENT, ONLY A GENERAL CONFUSION IN THE MARKET

In *Zauderer*, the U.S. Supreme Court established a lower level of scrutiny for determining the constitutionality of a compelled disclosure from that which is used to determine the constitutionality of a suppression of speech.[122] The reason for applying this lower level of scrutiny arises from the very reason for according First Amendment protection to commercial speech—"insuring that the stream of commercial information flow[s] cleanly as well as freely" for the benefit of the consumer and society.[123] Though the *Zauderer* case dealt specifically with a deceptive advertisement, its holding—that disclosures were to be analyzed under a low level of scrutiny to promote the flow of truthful, accurate information in the marketplace—should be applied broadly to any situation where a disclosure is needed to address consumer deception or confusion, regardless of whether a particular advertisement contains deceiving or confusing information.[124]

Commercial speech is subject to greater regulation than other

[118] *Id.* at 1219.
[119] *Id.* (quoting Rubin v. Coors Brewing Co., 514 U.S. 476, 487 (1995)).
[120] *Id.* at 1221.
[121] *Id.*
[122] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 650–51 (1985).
[123] Va. State Bd. of Pharm. v. Va. Citizens Consumer Council, Inc., 425 U.S. 748, 763–65, 771–72 (1976).
[124] Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 113–14 (2d Cir. 2001).

types of speech because of the government's interest in protecting consumers from "commercial harms."[125] Indeed, the U.S. Supreme Court has stated that First Amendment protection applies to commercial speech "not so much because it pertains to the seller's business as because it furthers the societal interest in the 'free flow of commercial information.'"[126] The unique function of First Amendment protection in the realm of commercial speech arises because "the autonomy of speakers is not at stake" as it is in public discourse.[127]

The government's suppression of truthful, non-misleading commercial speech must be analyzed more carefully than disclosures, as there is a danger that speech will be suppressed based on content, and any alternative means of communicating that message will be precluded.[128] The same is not true of factual disclosures compelled by the government—"[r]equired disclosure of accurate, factual commercial information presents little risk that the state is forcing speakers to adopt disagreeable state-sanctioned positions, suppressing dissent, confounding the speaker's attempts to participate in self-governance, or interfering with an individual's right to define and express his or her own personality."[129] Thus, not only do factual, government-mandated disclosures not implicate the speaker's rights to any extent near that of suppression, they also further First Amendment goals of providing accurate, truthful information to consumers.[130]

Recognizing that factual, objective disclosures serve the First Amendment goal of protecting consumers through promoting the flow of clear, truthful speech in the marketplace, whether a particular advertisement is deceptive or misleading is then irrelevant to the question of the level of scrutiny which should be applied to a regulation of commercial speech.[131] The ultimate factor in determining whether a lower level of scrutiny should be applied is simply whether there is a need to protect consumers

---

[125] 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 502 (1996).

[126] First Nat'l Bank of Bos. v. Bellotti, 435 U.S. 765, 783 (1978) (quoting *Va. State Bd. of Pharmacy* 425 U.S. at 764).

[127] Robert Post, *The Constitutional Status of Commercial Speech*, 48 UCLA L. REV. 1, 27 (2000).

[128] *44 Liquormart, Inc.*, 517 U.S. at 501–02.

[129] *Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 114.

[130] *Id.*

[131] *See id.*

and address confusion or deception in the market.[132] Numerous federal regulatory programs, including nutritional labeling, tobacco labeling, and certain disclosures in prescription drug advertisements, require commercial disclosures, clearly aimed at providing beneficial information to consumers.[133] Some commercial speech in the marketplace simply must have an accompanying disclosure, regardless of whether there is any deceptive or misleading advertisement, as the nature of the product or service being advertised is too likely to cause harm to a consumer, or to society, when certain information about the product or service is not disclosed.[134] This was true of mercury-containing lamps in *Sorrell*, unfair practices which affected prescription drug costs in *Pharmaceutical Care Management Ass'n*, and caloric information in *New York State Restaurant Ass'n*.[135] Preventing harm to consumers was the primary purpose for providing First Amendment protection to commercial speech.[136] To maintain this purpose, the *Zauderer* level of scrutiny must be applied, not only in situations where an advertisement itself is deceptive or misleading, but where there is a general deception or confusion existing in the marketplace.[137]

IV. *ZAUDERER* SHOULD HAVE BEEN USED TO ANALYZE THE FDA'S GRAPHIC IMAGES UNDER REVIEW IN *R.J. REYNOLDS*; AND, A LOWER LEVEL OF SCRUTINY SHOULD BE APPLIED TO FUTURE IMAGES PROPOSED BY THE FDA

In *R.J. Reynolds*, the D.C. Circuit held that the subjective nature of the warning label images, and the absence of any deceptive advertisement that would give rise to a need for a

[132] *See id.*

[133] *Id.* at 116 (citing 2 U.S.C. § 434 (reporting of federal election campaign contributions); 15 U.S.C. § 78*l* (securities disclosures); 15 U.S.C. § 1333 (tobacco labeling); 21 U.S.C. § 343(q)(1) (nutritional labeling); 33 U.S.C. § 1318 (reporting of pollutant concentrations in discharges to water); 42 U.S.C. § 11023 (reporting of releases of toxic substances); 21 C.F.R. § 202.1 (disclosures in prescription drug advertisements); 29 C.F.R. § 1910.1200 (posting notification of workplace hazards); Cal. Health & Safety Code § 25249.6 ("Proposition 65") (warning of potential exposure to certain hazardous substances); N.Y. Envtl. Conserv. Law § 33-0707 (disclosure of pesticide formulas)).

[134] *See id.* at 115.

[135] N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health, 556 F.3d 114, 136 (2d Cir. 2009); Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 310 (1st Cir. 2005); *Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 114–15.

[136] 44 Liquormart, Inc. v. Rhode Island, 517 U.S. 484, 502 (1996).

[137] Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 114 (2d Cir. 2001).

corrective disclosure, mandated a stricter scrutiny review.[138] But, as *Zauderer* states, a lower level of scrutiny is justified by a need to inform consumers.[139] Considering both the importance of informing consumers of the health risks of tobacco use and the inability of prior health warnings to be seen or read by consumers, application of the lower scrutiny level is justified. In addition, the pairing of images and text in a warning label reduces any subjectivity.[140] The D.C. Circuit's convenient sidestepping of the FDA's stated interest in informing consumers, and its decision to analyze the graphic labels under the assumption that the FDA's goal was to reduce tobacco use, eliminated the need to address the substantial evidence supporting the warnings, and their ability to communicate information effectively.[141] Pairing this with the D.C. Circuit's belief that the warning labels were not factual, and that there was no misconception surrounding tobacco products which needed correction, this holding amounted to an outright rejection of the FDA's authority to require graphic image warning labels, rather than a careful analysis of each warning.[142]

The graphic warning labels developed by the FDA, under the authority of the Family Smoking Prevention and Tobacco Control Act, easily pass constitutional muster under the *Zauderer* test, as the warning labels are reasonably related to the government's interest in preventing the deception of consumers concerning the health hazards of tobacco products.[143] The reduced scrutiny required for disclosures cannot be easily discarded simply because these images are seen as shocking.[144] These warning labels are meant to convey information to consumers about the health risks of tobacco use, thereby promoting a better understanding of the risks, reducing their use, and preventing tobacco-related death and disease.[145] Consequently, these warnings should be analyzed under the *Zauderer* rational basis

[138] R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1211–12 (D.C. Cir. 2012).

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

[140] *See R.J. Reynolds Tobacco Co.*, 696 F.3d at 1231–32 (Rogers, J., dissenting).

[141] *Id.* at 1223 (Rogers, J., dissenting).

[142] *Id.* at 1212–15.

[143] *See Zauderer*, 471 U.S. at 651.

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

[145] *See generally* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628, 36630 (proposed June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).

standard, as they are not only disclosures, but they comport with the reasoning underlying the lower level of scrutiny applied to disclosures—they are meant to protect consumers by ensuring truthful information is provided.[146]

There is no question that the government has an interest in communicating the health risks of tobacco products. Smoking causes 443,000 premature deaths each year in the U.S., approximately 8.6 million suffer from at least one serious smoking-related illness, and each year 49,400 deaths from lung cancer and heart disease are attributed to secondhand smoke exposure.[147] Smoking results in health care costs and productivity losses, due to premature death, of $193 billion each year.[148] The government has an interest in reducing the economic costs of tobacco-related death and disease, as well as protecting the health of its citizens. Cigarette manufacturers collectively spend billions of dollars each year on advertisements, many of which aim at "generat[ing] favorable long-term attitudes toward smoking and tobacco use."[149] These advertisements glamorize tobacco and lead minors to overestimate the prevalence of its use.[150] Many smokers continue to believe low tar and light cigarettes are healthier, and as a result, these smokers are less likely to quit.[151] "Despite increasing public awareness that smoking is dangerous to one's health, most people still lack 'a complete understanding of the many serious diseases caused by smoking, the true nature of addiction, or what it would be like to experience either those diseases or addiction itself.'"[152] Given this large amount of misapprehension among consumers as to the actual health consequences of tobacco products, disclosures depicting these health consequences would increase consumer awareness and understanding, and thereby promote cessation.

The Court in *R.J. Reynolds* stated that the government's interest was in reducing the amount of smokers and not actually

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

[147] Required Warnings for Cigarette Packages and Advertisements, 75 FR 69524, 69527 (proposed November 12, 2010) (to be codified at 21 C.F.R. pt. 1141).

[148] *Id.*

[149] Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2(16), 123 Stat 1776, 1778 (2009).

[150] *Id.* at § 2(20).

[151] *Id.* at § 2(38).

[152] R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1224 (D.C. Cir. 2012) (Rogers, J., dissenting) (citing U.S. v. Philip Morris USA, Inc., 449 F. Supp. 2d 1, 578 (D.D.C. 2006)).

in communicating information about health consequences; therefore, the warning labels were not really disclosures at all, but promotion of the government's anti-smoking message.[153] In *Sorrell*, the Second Circuit found the goal of increasing awareness about the presence of mercury through disclosures was inextricably intertwined with the goal of reducing mercury in the environment.[154] According to the Second Circuit, the underlying goal did not invalidate the State's objective to inform consumers, nor did it offend the First Amendment goals of compelled disclosures to ensure truthful information is communicated to consumers.[155] The present situation is similar. The goals of reducing consumer deception and confusion regarding the health consequences of tobacco use is inextricably intertwined with the goal to reduce tobacco use, as the only way to avoid the risks of death or serious illness is to quit.

Whether or not the commercial speech these disclosures address is misleading, it is irrelevant to the level of scrutiny which should be applied to these warning labels, as the goal of disclosures is to correct consumer deception.[156] Consequently, when consumers are misled or deceived—regardless of whether that deception arises from the commercial speech which is actually being regulated—the government is authorized to compel a disclosure.[157] There is no argument that a carton of cigarettes or a package of chewing tobacco actually contains misleading speech. Despite this, consumers misunderstand the health consequences of using tobacco products.[158] This results from decades of pervasive and misleading advertisements on the part of tobacco companies, and from the inability of the current surgeon general's warnings on tobacco products to properly convey this message.[159]

The Court in *R.J. Reynolds* rejected the argument that years of deception in tobacco advertisements could justify the graphic warning labels.[160] Though cases like *Warner-Lambert Co. v. FTC*

[153] *Id.* at 1212.
[154] Nat'l Elec. Mfrs. Ass'n v. Sorrell, 272 F.3d 104, 115 (2d Cir. 2001).
[155] *Id.*
[156] Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985).
[157] *See Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 114.
[158] *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, §§ 2(25)–2(28), 123 Stat 1776, 1778 (2009).
[159] INST. OF MED. OF THE NAT'L ACAD., ENDING THE TOBACCO PROBLEM: A BLUEPRINT FOR THE NATION 291 (Richard J. Bonnie et al. eds., 2007).
[160] R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 696 F.3d 1205,

and *United States v. Phillip Morris USA Inc.* allowed disclosures as remedial measures in response to deceptive statements made in advertisements by companies, the graphic warning labels at issue here were not correcting any specific deceptive claims.[161] The graphic warning labels at issue here do not need to address any specific deception for the years of deception by tobacco companies to be necessarily relevant.[162] Tobacco companies denied the negative health effects of tobacco products for years, produced advertisements claiming their products had health advantages, and went far to establish an atmosphere of acceptance through placing products in popular media and advertising at sporting events.[163] These actions created deception and confusion in consumers, the very element that a compelled disclosure is meant to correct.[164]

The warnings are reasonably related to the goal of correcting deception or confusion among consumers, as they aim to communicate a message about the negative health consequences of smoking to consumers, through increasing the impact tobacco warning labels have on consumers.[165] The text-only warnings currently displayed on cigarettes occupy a small amount of space on the side of the carton and have remained unchanged for more than twenty-five years.[166] The current warnings are "unnoticed and stale, and they fail to convey relevant information in an effective way."[167] Consumers fail to notice, read, and remember the current warnings.[168] The ability of a warning label to attract the attention of a consumer is affected by its size and placement, and warnings that grab a consumer's attention are more likely to affect the consumer's awareness of risks.[169]

In determining what graphic images should accompany warnings on tobacco products, the FDA conducted an internet-based consumer research study with over eighteen thousand participants, which examined the efficacy of thirty-six proposed

1214–15 (D.C. Cir. 2012).

[161] *Id.*

[162] *See Nat'l Elec. Mfrs. Ass'n*, 272 F.3d at 114.

[163] § 2(19), 123 Stat. at 1778.

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

[165] § 3(6), 123 Stat. at 1782 (2009).

[166] Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69524, 69530 (proposed Nov. 12, 2010) (to be codified at 21 C.F.R. pt. 1141).

[167] INST. OF MED., *supra* note 159, at 291.

[168] 75 Fed. Reg. at 69530.

[169] INST. OF MED., *supra* note 159, at 294.

color graphic images.[170] The study measured the salience of the images, the recall by the participants, the influence on the participants' beliefs about the health risks of smoking, and whether the warning affected the behavioral intentions of participants in terms of how likely it would be that a participant would try to quit smoking or whether the warning would affect a participant's choice to start smoking.[171] Salience was measured based on an emotional scale, which evaluated whether the warnings made the participant feel "depressed," "discouraged," or "afraid," and on a cognitive scale which measured whether the participant felt the warning was "believable," "meaningful," or "convincing."[172] Such measures were chosen because research suggested that smokers who reported greater negative emotional reactions to cigarette warning labels were more likely to have quit, made an attempt to quit, or to have reduced their smoking.[173]

This legislation marks a turning point in the regulation of warning labels on tobacco products, not just as a change in law, but as a change of policy regarding how these warnings should be developed and maintained. Not only has the FDA conducted considerable research into which images would most effectively convey information to consumers, but they also intend to "conduct research and keep abreast of scientific developments regarding the efficacy of various required warnings and the types and elements of various warnings that improve efficacy."[174] The FDA declined to use more than nine images, as it desired to obtain data regarding the real-world efficacy of these nine warnings as soon as possible, so that the images could be changed as needed to increase their efficacy.[175]

The FDA's use of shock value to catch a consumer's attention and communicate its message does not make these disclosures unconstitutional.[176] Indeed, the problem with the warnings already on cigarette packages was that consumers were not

[170] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628, 36637 (proposed June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).

[171] *Id.* at 36637–38.

[172] *Id.* at 36638.

[173] *Id.* at 36639.

[174] *Id.* at 36637.

[175] *Id.*

[176] R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1230 (D.C. Cir. 2012) (Rogers, J., dissenting).

seeing the warnings.[177] The past text-only warnings were not effective in conveying the health risks of tobacco use to consumers.[178] Even those who read the text-only warning labels may not fully comprehend the health risks and addictive nature of tobacco products, but seeing an image of a man smoking a cigarette through a tracheostomy opening in his neck really makes the message hit home.[179]

The images are gruesome because the truth of tobacco-related diseases is that they are gruesome. Opposition to these images because they are shocking or upsetting is not a legitimate constitutional objection, as it does not detract from their objective, factual nature.[180] It is a fact that the health effects depicted in these images are consequences of smoking.[181] Indeed, a failure "to elicit emotional reactions . . . would also fail to communicate the described negative health consequences of smoking in a truthful, forthright manner."[182]

Though images are obviously more open to interpretation than text, the warning labels at issue here combine both text and images, which together serve to grab the reader's attention and communicate the intended message.[183] Despite contentions by tobacco companies that these images serve solely to repel consumers through the use of gruesome images and communicate the government's anti-smoking message, the images do depict actual consequences of using tobacco products.[184] The images depicting a man smoking through a tracheostomy opening, healthy lungs next to lungs damaged by smoking, a cancerous lesion on a lip, and a man with an autopsy incision that has been stapled closed, all show truthful and uncontroversial health consequences of smoking—lung cancer, oral cancer, nicotine addiction, and death.[185]

In addition, the image of a man smoking through a tracheostomy opening is factual because it represents the fifty

[177] INST. OF MED., *supra* note 159, at 291.

[178] *Id.*

[179] *See R.J. Reynolds Tobacco Co.*, 696 F.3d at 1230–31 (Rogers, J., dissenting).

[180] *Id.* at 1230.

[181] *See* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628, 36639 (proposed June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).

[182] *Id.* at 36696.

[183] *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1231–32 (Rogers, J., dissenting).

[184] *See* 76 Fed. Reg. at 36697.

[185] INST. OF MED., *supra* note 159, at 1, 30, 79, 108.

percent of neck and head cancer patients that continue to smoke after being diagnosed.[186] It is unlikely that these images will ever be misinterpreted as they are accompanied, respectively, by the phrases "Cigarettes are addictive," "Cigarettes cause fatal lung disease," "Cigarettes cause cancer," and "Smoking can kill you."[187] The picture of smoke approaching a child is paired with the text: "Tobacco smoke can harm your children."[188] It is clear that this image is meant to inform consumers that their children may also fall victim to negative health consequences if they are exposed to cigarette smoke. The image of a crying woman also depicts the effects of secondhand smoke. Paired with the text, "Tobacco smoke causes fatal lung disease in nonsmokers,"[189] it is clear that the woman is experiencing an emotional reaction to negative health consequences related to secondhand smoke.[190] The image of a man wearing an oxygen mask is accompanied by the text "Cigarettes cause strokes and heart disease."[191] Though on its own, it would be hard to discern the message this image conveyed— as a viewer could deduce only that the man is wearing an oxygen mask and so must have suffered from some disease, illness, or trauma—when paired with the text, it is clear this image represents a man suffering a negative consequence, such as a stroke or heart attack, from using cigarettes. The illustrated graphic depicting a baby in an incubator also does not make the information conveyed—that smoking during pregnancy can cause such negative consequences as increasing chances of preterm delivery, shortening gestation, and increasing the likelihood of low birth weight—any less factual.[192] Finally, the image of a relatively average man wearing a shirt with the words "I Quit" on the chest imparts knowledge to consumers through the text accompanying the picture, "Quitting smoking now greatly reduces serious risks to your health."[193]

These graphic warning labels cannot be analogized to the "18"

[186] *R.J. Reynolds Tobacco*, 696 F.3d at 1231 (Rogers, J., dissenting).

[187] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628, 36670 (proposed June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).

[188] *Id.* at 36696.

[189] *Id.*

[190] *Id.*

[191] *Id.*

[192] *Id.*

[193] Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628, 36696 (proposed June 22, 2011) (to be codified at 21 C.F.R. pt. 1141).

stickers in *Blagojevich*. The Court in *Blagojevich* did not find that the sticker itself was subjective and highly controversial, but that the message conveyed by the sticker was.[194] The sticker was communicating that the game's content was sexually explicit, a subjective judgment made by the government.[195] The D.C. Circuit confused what may be a reaction to the images with the message the government intended to convey through the images.[196] The health risks of tobacco are factual and uncontroverted, unlike what is deemed to be sexually explicit, as in *Blagojevich*.

No valid argument can be made that the graphic images are unduly burdensome. Tobacco companies are still left with fifty percent of the front and rear panels of cigarette cartons to display logos and brands.[197] The size and content of these warnings are not arbitrary, as they are based on suggestions from the World Health Organization's Framework Convention on Tobacco Control.[198]

Even if the graphic warning labels were subjected to the intermediate scrutiny of *Central Hudson*, they would still pass constitutional muster, as they are narrowly tailored to achieve the substantial government goal of effectively communicating the negative health consequences of tobacco use to consumers. The government's interest in communicating the negative health effects of tobacco use to consumers is certainly substantial, as "the government has a substantial interest in 'promoting the health, safety, and welfare of its citizens.'"[199] According to the Supreme Court, "[the government's] interest in ensuring the accuracy of commercial information in the market-place is substantial."[200]

The graphic warning labels directly advance the government's goal of better informing consumers. The FDA introduced a wealth of information demonstrating that the images were chosen based on their salience and ability to be recalled, both of which

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

[195] *See id.*

[196] R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 845 F. Supp. 2d 266, 272–73 (D.D.C. 2012).

[197] *See* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 524 (6th Cir. 2012).

[198] *Id.* at 530–31.

[199] R.J. Reynolds Tobacco Co. v. U.S. Food & Drug Admin., 696 F.3d 1205, 1235 (D.C. Cir. 2012) (quoting Rubin v. Coors Brewing Co., 514 U.S. 476, 485 (1995)).

[200] Edenfield v. Fane, 507 U.S. 761, 769 (1993).

were shown to be effective measures of how well a consumer understands a warning label.[201] There is no more direct a way to inform the consumer about the health risks associated with a product than to print a disclosure on the product itself. Nor are these disclosures more extensive than they need to be to serve the government's interest. The FDA had shown that the small, text-only warnings on the sides of cigarette cartons were so rarely read or recalled by consumers that they basically went unnoticed.[202] To effectively communicate the health risks of tobacco use, larger, more prominent, eye-catching warning labels need to be used.[203]

Conclusion

The graphic warning labels provided for in the Family Smoking Prevention and Tobacco Control Act aim to better inform consumers about the health consequences of tobacco use in the wake of years of deception in tobacco marketing and health warnings, which go unnoticed by consumers, having been unchanged since 1984.[204] The Supreme Court's denial of *certiorari* in the appeal of the Sixth Circuit's ruling in *Discount Tobacco City & Lottery* lends credence to that Court's application of *Zauderer* to the graphic warning labels.[205]

The lower level of scrutiny provided for in *Zauderer* should have been applied to the nine images under review in *R.J. Reynolds*. Instead, the D.C. Circuit mistakenly held all the warning labels to be violations of the First Amendment rights of tobacco companies.[206] The D.C. Circuit erred in holding that all

---

[201] *See generally* Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36628, 36636–39 (proposed June 22, 2011) (discussing the FDA's methodology of graphic image selection and response to submitted comments) (to be codified at 21 C.F.R. pt. 1141).

[202] Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69524, 69530 (proposed Nov. 12, 2010) (to be codified at 21 C.F.R. pt. 1141).

[203] *See id.*

[204] *See* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, §§ 2(25), 2(28), 123 Stat 1776, 1778 (2009); Comprehensive Smoking Education Act of 1984, Pub. L. No. 98–474, § 2, 98 Stat. 2200 (1984); 75 Fed. Reg. at 69530.

[205] Commonwealth Brands v. United States, 678 F. Supp. 2d 512 (W.D. Ky.2010), *aff'd in part*, Discount Tobacco City & Lottery v. United States, 674 F. 3d 509 (6th Cir. 2012), *cert. denied*, American Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

[206] R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1221–22 (D.C. Cir. 2012).

the warning labels were not factual and objective, as it failed to analyze these warnings in their entirety, leaving out the textual message, which substantially contributed to the intended message of the image.[207] It is hard to imagine a more objective image than that of smoke-damaged lungs next to healthy lungs. In fact, this is one of the very images imagined by the Sixth Circuit as constituting a factual disclosure under *Zauderer*.[208] In addition to the D.C. Circuit's quick dismissal of the objective nature of the graphic warnings, the Court erroneously held that *Zauderer* scrutiny could only be applied where there was a potentially deceptive advertisement that a disclosure could remedy.[209] The Court overlooked the primary purpose for affording lower scrutiny to disclosures—to protect and inform consumers, and to promote the First Amendment's goal of truthful, accurate language in the commercial market.[210] There is a need for disclosures to correct the misconceptions held by consumers concerning the health consequences of tobacco use, especially considering the seriousness of the illnesses and disease related to the use of tobacco products.[211]

The D.C. Circuit's holding that the nine proposed images would violate the First Amendment rights of tobacco companies was, seemingly, an objection to the FDA's very authority to promulgate graphic warnings. The Court seemed to hold that images, by their very nature, were subjective and, consequently, no image could possibly be generated under this Act which would pass constitutional muster.[212] Considering the U.S. Supreme Court's denial of *certiorari* in *Discount Tobacco City & Lottery*, this is arguably not the case.[213]

Considering the factual, objective nature of these disclosures and their goal of correcting consumer misconceptions about the dangers of tobacco use, the lower scrutiny of *Zauderer* should be applied.[214] Tobacco companies will likely challenge any future

---

[207] *Id.* at 1231–32 (Rogers, J., dissenting).

[208] Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 559 (6th Cir. 2012).

[209] *R.J. Reynolds Tobacco Co.*, 696 F.3d. at 1213–14.

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

[211] *See generally* Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, §§ 2(17), 2(20), 123 Stat 1776, 1778 (2009) (demonstrating factually misleading advertising regarding the health detriments of smoking).

[212] *R.J. Reynolds Tobacco Co.*, 696 F.3d at 1221–22 (D.C. Cir. 2012).

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

[214] §§ 2(16), 2(17), 2(20), 123 Stat. at 1778 (listing factual findings regarding the tobacco industry's advertising campaign); Disc. Tobacco City & Lottery, Inc.

images from the FDA again, and such images will likely only pass constitutional muster if the *Zauderer* standard of scrutiny is correctly applied. Without *Zauderer*, warning labels on tobacco products would likely remain in the same stale, overlooked state.

v. United States, 674 F.3d 509, 527 (6th Cir. 2012); *R.J. Reynolds Tobacco Co.*, 696 F.3d. at 1233 (Rogers, J., dissenting).