A Warning Worth a Thousand Words: First Amendment Challenges to the FDA’s Graphic Warning Label Requirements

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A WARNING WORTH A THOUSAND WORDS: FIRST AMENDMENT CHALLENGES TO THE FDA’S GRAPHIC WARNING LABEL REQUIREMENTS

INTRODUCTION

Every day, 3800 young Americans under the age of eighteen smoke their first cigarette.¹ One-fourth of high school seniors are regular smokers.² Cigarette smoking continues to be the leading cause of preventable death in the United States, accounting for approximately one out of every five deaths each year.³ More than eighty percent of regular smokers have their first cigarette before turning eighteen.⁴

These disturbing statistics, published in the most recent Surgeon General’s report,⁵ demonstrate the imminent need for government action. In 2009, Congress introduced the Family Smoking Prevention and Tobacco Control Act (the Act) to give the Food and Drug Administration (FDA) authority to regulate tobacco products.⁶ One of the most aggressive anti-smoking provisions of the Act requires new warning labels consisting of graphic images to take up fifty percent of cigarette packages.⁷

Like all past tobacco warning label requirements, this latest legislation has encountered much opposition from tobacco companies. Immediately after the Act was signed into law, six tobacco companies filed suit against the government challenging the constitutionality of several provisions, including the graphic images.⁸ Two years later, after the FDA released the nine specific required images,⁹ five tobacco companies again filed suit challenging the

2. Id. at 135.
3. Id. at i.
4. Id.
5. Id.
7. Id. § 201(a), 123 Stat. at 1843.
specific images under the First Amendment.\(^{10}\) The suits have resulted in a circuit split, with the Sixth Circuit upholding the graphic warnings as constitutional\(^{11}\) and the D.C. Circuit striking them down as violating the First Amendment.\(^{12}\)

Part I of this Note discusses the historical background of tobacco warning regulation in the United States. Part II explains the key provisions of the Family Smoking Prevention and Tobacco Control Act. Part III analyzes the differences between the Sixth and D.C. Circuits’ contradicting rulings on First Amendment challenges to the Act. Part IV suggests how the circuit split might be resolved using the intermediate scrutiny standard applied by the D.C. Circuit to reach the same conclusion as the Sixth Circuit in upholding the new warning requirements as constitutional.

I.  HISTORICAL BACKGROUND

A. Historical Overview of Tobacco Warning Regulations

Congress first required warnings on tobacco products in 1965 in response to the landmark 1964 Surgeon General report *Smoking and Health: Report of the Advisory Committee to the Surgeon General of the Public Health Service.*\(^{13}\) This was the Surgeon General’s first report highlighting the deleterious health consequences of smoking and declaring a causal relationship between smoking and lung cancer.\(^{14}\) The report also found smokers to have a seventy percent higher mortality rate and established a high correlation between smoking, emphysema, and heart disease.\(^{15}\) The report resulted in a wave of public concern; however, it did not set forth any specific policy recommendations.\(^{16}\) Within a week of its publication, the Federal Trade Commission (FTC) proposed a rule requiring health warnings to be printed on cigarette packages.\(^{17}\) In the face of inevitable regulation, tobacco companies turned to the tobacco-friendly members of Congress to encourage legislative action.\(^{18}\)

\(^{10}\)  R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1208 (D.C. Cir. 2012).

\(^{11}\)  *Disc. Tobacco*, 674 F.3d at 569.

\(^{12}\)  *R.J. Reynolds*, 696 F.3d at 1222.


\(^{15}\)  *Id.* at 32–38.

\(^{16}\)  Parascandola, *supra* note 13.

\(^{17}\)  *Id.*

\(^{18}\)  *Id.*
Congress responded quickly by enacting the Federal Cigarette Labeling and Advertising Act of 1965 (the 1965 Act) requiring cigarette packages to bear the warning, “Caution: Cigarette Smoking May Be Hazardous to Your Health.”\textsuperscript{19} Although the 1965 Act first introduced the warning label requirement, it was also heavily protective of the tobacco industry by prohibiting both the FTC and state and local governments from requiring any stronger warning labels on packages or in advertisements until at least 1969.\textsuperscript{20} The \textit{New York Times} categorized the 1965 Act as “a shocking piece of special interest legislation . . . a bill to protect the economic health of the tobacco industry by freeing it of proper regulation.”\textsuperscript{21}

The weak warning was eventually strengthened by the Public Health Cigarette Smoking Act of 1969 (the 1969 Act), which changed the required label to, “Warning: The Surgeon General Has Determined That Cigarette Smoking Is Dangerous to Your Health.”\textsuperscript{22} The legislation also prohibited television and radio cigarette advertisements.\textsuperscript{23} Although the 1969 Act strengthened the previous warning, it was still heavily influenced by the interests of the tobacco industry.\textsuperscript{24} Before the passage of the 1969 Act, tobacco companies successfully defeated an effort to add references to lung cancer and other diseases in favor of the extremely vague warning.\textsuperscript{25}

It was not until the passage of the Comprehensive Smoking Education Act of 1984 (the 1984 Act) that warnings became more specific and informative.\textsuperscript{26} The 1984 Act created a rotational warning system still in use today that requires both cigarette packages and advertisements to rotate four different warnings every three months.\textsuperscript{27} The warnings link cigarette smoking to specific adverse health effects such as lung cancer, emphysema, heart disease, and pregnancy complications.\textsuperscript{28} While the 1984 Act made huge improvements to the previous vague warnings, these outdated warnings are still in use today.\textsuperscript{29}

Although the United States was the first country to require warning labels on cigarette packages, it now requires one of the smallest, least prominent

\begin{flushleft}
\textsuperscript{20} \textit{Id.} at 282–83.
\textsuperscript{23} \textit{Id.} § 6, 84 Stat. at 89.
\textsuperscript{24} Parascandola, \textit{supra} note 13, at 675–76.
\textsuperscript{25} \textit{Id.} at 676.
\textsuperscript{27} \textit{Id.} § 4(a), 98 Stat. at 2203.
\textsuperscript{28} \textit{Id.} § 4(a), 98 Stat. at 2202.
\end{flushleft}
warnings compared to other countries. It is also one of the few countries left in the developed world that has not updated its warnings in nearly thirty years. Textual warnings are currently placed along one of the sides of cigarette packages, using small typeface and similar colors to the rest of the packaging. Canada, in contrast, requires one of sixteen different graphic warnings to take up at least fifty percent of the visible surface of cigarette packages. Each of the sixteen different warnings is accompanied by a brief explanation, such as statistical support for that warning, along with a picture illustrating that particular warning. In 2001, Canada became the first country to require graphic warnings on cigarette packages, and since then at least sixty-two other countries have followed suit including Australia, the United Kingdom, Brazil, and Switzerland.

B. Decades of Deceit Uncovered

The facts in United States v. Philip Morris USA Inc. highlight the magnitude of deceit by tobacco companies. In 1999, the United States filed a lawsuit against nine cigarette manufacturers and two tobacco-related trade organizations created by the tobacco companies. The complaint alleged that the defendants violated the Racketeer Influenced and Corrupt Organizations Act (RICO) by participating in a “decades-long conspiracy” to deceive the American public about the health risks and addictiveness of smoking cigarettes. Specifically, the conspiracy involved (1) denying the serious health risks associated with smoking and second-hand smoke, (2) denying the addictiveness of cigarettes, and, in fact, manipulating cigarettes to be even more addicting, (3) intentionally marketing to youth, and (4) concealing evidence to cover up the dangers of smoking.

After five years of discovery, nine months of trial, and around 14,000 exhibits, the district court issued a 987-page opinion that chronicled decades of deceit by tobacco companies and ultimately found the defendants liable for their conspiracy to defraud the American public about the dangers of smoking.

30. Id. app. C at 2–3.
31. Id. app. C at 2.
32. Final Rule, supra note 9, at 69,529.
34. Id.
36. 566 F.3d 1095 (D.C. Cir. 1999) (per curiam).
37. Id. at 1105.
38. Id. at 1105–06.
39. Id. at 1106.
40. Id.
smoking.\textsuperscript{41} The court noted that for approximately fifty years, each of the defendants “repeatedly, consistently, vigorously—and falsely—denied the existence of any adverse health effects from smoking” despite their “massive” internal documentation confirming these health effects.\textsuperscript{42} The court further found that in response to the scientific consensus that cigarette smoking causes lung cancer, the defendants launched “a campaign . . . designed to mislead the public about the health consequences of smoking” in order to maximize corporate profits.\textsuperscript{43}

The defendants appealed the decision to the D.C. Circuit, and the three-judge panel unanimously upheld the district court’s decision that found the defendants liable.\textsuperscript{44} The court also upheld a majority of the district court’s ordered remedies, including an injunctive order requiring the defendants to issue corrective statements concerning the topics about which they had previously deceived consumers.\textsuperscript{45} The defendants were required to publish the statements in cigarette package inserts, retail displays, newspapers, on television, and on their company websites.\textsuperscript{46} The court rejected the defendants’ arguments that the corrective statement requirements violated the First Amendment and the Federal Cigarette Labeling and Advertising Act.\textsuperscript{47}

II. THE FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

President Barack Obama signed the Family Smoking Prevention and Tobacco Control Act into law on June 22, 2009.\textsuperscript{48} The Act was introduced in part to give the FDA the authority to regulate tobacco products in response to the U.S. Supreme Court’s decision in \textit{FDA v. Brown \& Williamson Tobacco Corp.}, which held that Congress had not given the FDA such authority.\textsuperscript{49} The stated purpose of the Act is to provide the FDA with regulating authority in order to “address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco.”\textsuperscript{50}

One of the most notable and controversial provisions includes a requirement for new health warnings consisting of color graphics to illustrate the dangers of smoking.\textsuperscript{51} The warnings are required to cover fifty percent of

\textsuperscript{42} \textit{Id.} at 208.
\textsuperscript{43} \textit{Id.} at 187–88.
\textsuperscript{44} \textit{Philip Morris}, 566 F.3d at 1105.
\textsuperscript{45} \textit{Id.} at 1138–45.
\textsuperscript{46} \textit{Id.} at 1138.
\textsuperscript{47} \textit{Id.} at 1140–45.
\textsuperscript{50} Family Smoking Prevention and Tobacco Control Act § 3(2), 123 Stat. at 1781.
\textsuperscript{51} \textit{Id.} § 201(d), 123 Stat. at 1845.
the front and back of cigarette packages.\footnote{52} In addition, the Act limits the advertising of tobacco products to minors,\footnote{53} prohibits the sale of flavored cigarettes,\footnote{54} and requires tobacco companies to reveal all product ingredients and seek FDA approval for any new tobacco products.\footnote{55}

In promulgating the Act, Congress included several legislative findings to support its conclusion that tobacco use by adolescents is an issue “of particular concern to public health officials.”\footnote{56} Such findings include that almost all new users of tobacco products are under the legal age to purchase such products,\footnote{57} past efforts to restrict marketing have failed to adequately curb tobacco use among children,\footnote{58} and that children are more influenced by tobacco than adults.\footnote{59}

In June 2011, the FDA released nine color graphics to illustrate accompanying textual warnings that would be required to appear on every cigarette package.\footnote{60} The FDA chose the nine images from thirty-six proposed images after considering approximately 1700 public comments and results from its 18,000-person study of the effectiveness of the warnings.\footnote{61} The study was an internet-based consumer study examining the relative effectiveness of the warnings at communicating the dangers of smoking to three target groups: adults aged twenty-five and over, young adults aged eighteen to twenty-five, and youth aged thirteen to seventeen who currently smoke or are susceptible to smoking.\footnote{62} Each group viewed a hypothetical cigarette package containing one of the thirty-six graphic images, while the control group viewed a package with no graphic images.\footnote{63} The study then examined the emotional and cognitive responses of each participant and measured each participant’s ability to recall the content of the warning.\footnote{64} The FDA stated that in selecting the nine images, it considered all outcomes, but gave most weight to the “salience measures”—

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\footnote{52} Id. § 205(d), 123 Stat. at 1848–49.
\footnote{53} Id. § 102(a), 123 Stat. 1831.
\footnote{55} Id. § 387j.
\footnote{56} Family Smoking Prevention and Tobacco Control Act § 2, 123 Stat. at 1776–81; Id. § 3(2), 123 Stat. at 1781.
\footnote{57} Id. § 2(4), 123 Stat. at 1777.
\footnote{58} Id. § 2(6), 123 Stat. at 1777.
\footnote{59} Id. § 2(23), 123 Stat. at 1778.
\footnote{60} Final Rule, supra note 9, at 36,628. The implementation date of the new warnings was originally scheduled for September 2012, but is now uncertain due to the current litigation. Cigarette Health Warnings, U.S. FOOD AND DRUG ADMINISTRATION, http://www.fda.gov/TobaccoProducts/Labeling/Labeling/CigaretteWarningLabels/default.htm (last visited May, 22, 2013).
\footnote{61} Final Rule, supra note 9, at 36,629, 36,637–38.
\footnote{62} Id. at 36,367.
\footnote{63} Id. at 36,638.
\footnote{64} Id.
that is, the participants’ cognitive and emotional responses. In support of this methodology, the FDA cited research suggesting that “risk information is most readily communicated by messages that arouse emotional reactions.”

The selected images and textual warnings include: a body on an autopsy table to illustrate the warning, “Smoking can kill you,” a man blowing smoke out of the tracheotomy hole in his throat to accompany the warning, “Cigarettes are addictive,” a man smoking while holding a baby to accompany the warning, “Tobacco smoke can harm your children,” a cartoon image of a baby in an incubator to depict the warning, “Smoking during pregnancy can harm your baby,” side-by-side images of a diseased and healthy lung to accompany the warning, “Smoking can cause fatal lung disease,” a patient wearing an oxygen mask to accompany the warning, “Cigarettes cause strokes and heart disease,” a man wearing an “I Quit” t-shirt to illustrate the warning, “Quitting smoking now greatly reduces serious risks to your health,” a woman crying to accompany the warning, “Tobacco smoke causes fatal lung disease in nonsmokers,” and a close-up image of mouth cancer lesions to illustrate, “Cigarettes cause cancer.” Each graphic warning also includes the tobacco quit line number, “1-800-QUIT-NOW.”

III. THE CIRCUIT SPLIT

A. Sixth Circuit Upholds Warnings in Discount Tobacco

On August 31, 2009, in Discount Tobacco City & Lottery, Inc. v. United States, a group of tobacco manufacturers and retailers brought suit against the United States, challenging the constitutionality of the Act. Specifically, the companies challenged five provisions, including (1) the new requirements for graphic warning labels, (2) restrictions on the commercial marketing of modified risk tobacco products, (3) the prohibition on statements implicitly or explicitly conveying an impression that tobacco products are approved by the FDA, (4) the prohibition of color and graphics in tobacco advertisements, and (5) the prohibition on the distribution of free samples or on sponsorship at events. In particular, the plaintiffs contended that the mandated graphic warnings violated the First Amendment right to free speech. Because the

65. Id. at 36,638–39.
66. Final Rule, supra note 9, at 36,639.
67. Id. at 36,649–57, 36,696; see also Cigarette Health Warnings, supra note 60.
68. Final Rule, supra note 9, at 36,674; see also Cigarette Health Warnings, supra note 60.
70. Id. at 520.
71. Id. at 524.
specific required images had not yet been released at the time the complaint was filed, the plaintiffs made a facial challenge to the overall requirement.\textsuperscript{72}

The district court granted summary judgment to the United States on the challenges to the graphic warnings, along with the challenges to the restrictions on the marketing of modified risk tobacco products and the prohibition on sponsorship and distribution of free samples.\textsuperscript{73} In contrast, the district court granted summary judgment to the plaintiffs on the other two challenges.\textsuperscript{74} Both parties appealed.\textsuperscript{75}

On appeal, the United States Court of Appeals for the Sixth Circuit affirmed the district court’s decision to uphold the constitutionality of the Act’s warning label requirements, with Judge Clay dissenting on the constitutionality of the graphic images.\textsuperscript{76} The court also affirmed the district court’s grant of summary judgment to the plaintiffs on the Act’s restriction of tobacco advertising to black and white text and its upholding of the Act’s restriction on marketing of modified-risk tobacco products and ban on sponsorship and free sampling at events.\textsuperscript{77} The court reversed the district court’s holding regarding the other two provisions.\textsuperscript{78}

1. Application of the \textit{Zauderer} Rational-Basis Standard

In affirming the constitutionality of the Act’s new graphic warning requirements, all three judges agreed that the proper level of scrutiny was the rational-basis standard set forth in \textit{Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio.}\textsuperscript{79}

In \textit{Zauderer}, the U.S. Supreme Court upheld the constitutionality of an Ohio rule requiring attorneys who advertised contingency-fee services to disclose in their advertisements that a losing client might still be responsible for certain litigation fees.\textsuperscript{80} The Court reasoned that because the extension of the First Amendment protection to commercial speech is justified primarily by protecting the flow of accurate information to the consumer, the commercial speaker’s interest in not providing particular factual information is minimal.\textsuperscript{81} Thus, the standard for upholding required disclosures of factual information is

\textsuperscript{72.} \textit{Id.} at 553.
\textsuperscript{73.} \textit{Id.} at 521.
\textsuperscript{74.} \textit{Disc. Tobacco}, 674 F.3d at 521.
\textsuperscript{75.} \textit{Id.} at 518.
\textsuperscript{76.} \textit{Id.} at 551.
\textsuperscript{77.} \textit{Id.} at 518.
\textsuperscript{78.} \textit{Id.}
\textsuperscript{79.} \textit{Disc. Tobacco}, 674 F.3d at 554, 558 (citing \textit{Zauderer} v. Office of Disciplinary Counsel of the Sup. Ct. of Ohio, 471 U.S. 626 (1985) (majority opinion)).
\textsuperscript{80.} \textit{Zauderer}, 471 U.S. at 653 n.15.
\textsuperscript{81.} \textit{Id.} at 651.
lower than the standard for upholding outright prohibitions on commercial speech. In order for Zauderer to apply, the required disclosure must involve purely factual information and must be aimed at preventing consumer deception.

The court in Discount Tobacco rejected the plaintiffs’ argument that the government must survive strict scrutiny. The plaintiffs relied on Entertainment Software Association v. Blagojevich, in which the United States Court of Appeals for the Seventh Circuit invalidated an Illinois law requiring video game retailers to place the label “18” on any game deemed to be “sexually explicit,” thereby prohibiting the sale of that game to minors. There, the court applied strict scrutiny, reasoning that the labeling of a game as “sexually explicit” constituted a “subjective and highly controversial message.” The plaintiffs asserted that here, the government is similarly attempting to convert tobacco companies into “its mouthpiece for a subjective and highly controversial marketing campaign expressing its disapproval of their lawful products.”

Although all three judges agreed that the warnings in this case are distinguishable from the label in Blagojevich, they based this distinction on different grounds. Judge Stranch, writing for the majority, distinguished this case from Blagojevich on the ground that the required disclosures in this case involve factual information. The majority noted that whether a particular video is “sexually explicit” is necessarily based on opinion stemming from one’s own personal taste and morals. Thus, the required warning in Blagojevich would force video game manufacturers to communicate the government’s opinion that a game is sexually explicit. The graphic warnings at issue in this case, however, provide undisputed factual information regarding the health risks of smoking.

82. Id.
83. Id.
84. Id.
86. Entm’t Software Ass’n v. Blagojevich, 469 F.3d 641, 652 (7th Cir. 2006).
87. Id.
88. Disc. Tobacco, 674 F.3d at 525 (internal quotation marks omitted).
89. Id. at 561.
90. Id.
91. Id.
92. Id.
Judge Clay, writing for the dissent, agreed that the textual warnings contained purely factual warnings not subject to the strict scrutiny standard. But unlike the majority, he asserted that there could be “no doubt” that the graphic images are subjective based on their inherently persuasive nature. He further noted that the visual images could not be categorized as “mere health disclosure warnings” and thus the plaintiffs’ argument for strict scrutiny was “not wholly unpersuasive.” In contrast to the majority’s distinction between factual and subjective information, Judge Clay based his distinction on the extent of the restrictions imposed by each required disclosure. In Blagojevich, the warning required on video games deemed to be “sexually explicit” was not simply a warning, but also carried an affirmative limitation on speech in the form of a sales restriction. Conversely, the graphic warnings in this case serve only as disclaimers and carry no affirmative limitation on speech.

2. Analysis Under the Zauderer Standard

Under Zauderer’s rational-basis standard, the only question left for the court was whether there existed a rational connection between the purpose of the new warnings and the means used to achieve that purpose. The stated purpose of the Act overall is to “address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco.” The purpose of the new warning requirements in particular is to promote a greater understanding of the health risks associated with smoking.

In finding that the new warning requirements are in fact reasonably related to preventing consumer deception, the majority first pointed to the historical deception of tobacco companies about the health risks associated with smoking. The court cited to United States v. Philip Morris USA Inc. to highlight the “decades-long” conspiracy by tobacco companies to mislead

93. Disc. Tobacco, 674 F.3d at 527 (Clay, J., dissenting).
94. Id. at 526.
95. Id.
96. Id. at 526–27.
97. Id.
98. Disc. Tobacco, 674 F.3d at 527 (Clay, J., dissenting).
99. Id. at 561 (majority opinion).
101. See id. § 202(b), 123 Stat. 1845–46 (authorizing the FDA to adjust the formatting of the label requirements if necessary to “promote greater public understanding of the risks associated with the use of tobacco products.”).
102. Disc. Tobacco, 674 F.3d at 562.
103. Id. (citing United States v. Philip Morris USA Inc., 566 F.3d 1095 (D.C. Cir. 1999) (per curiam)).
consumers about the health risks of smoking.\textsuperscript{104} Thus, the court essentially equated “preventing deception” to “balancing past deception.”

The majority next asserted that the existing warnings do not effectively combat this deception for two primary reasons. First, the warnings are not prominent enough, and are thus easily overlooked.\textsuperscript{105} The existing warnings are printed along the side of cigarette packages and take up less than five percent of the package surface.\textsuperscript{106} The court pointed to both the 1994 Report of the Surgeon General and a 2007 Institute of Medicine report concluding that the warnings go largely unnoticed by viewers and fail to convey relevant information in an effective way.\textsuperscript{107} A second major problem with the current warnings, as the court pointed out, is the fact that in order for viewers to understand the warning, they must have a relatively high reading level.\textsuperscript{108} This is especially problematic considering that the Act intends to prevent smoking among youth.\textsuperscript{109} In the absence of more effective and attention-capturing warnings, youths especially fail to fully understand the dangers of smoking.\textsuperscript{110}

The court found that given these ineffective warnings, people do not fully understand the dangers of tobacco use.\textsuperscript{111} The court cited the district court’s opinion in Philip Morris, in which the court found that “[m]ost people do not have 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. Rather, most people have only a superficial awareness that smoking is dangerous.”\textsuperscript{112}

As the court noted, the problems with the current warnings alone were not enough to satisfy the rational-basis standard.\textsuperscript{113} The government must show a rational connection between the warnings’ purpose and the means used to achieve that purpose.\textsuperscript{114} The court applies the relatively low standard set forth in Sorrell, in which the United States Court of Appeals for the Second Circuit upheld a law requiring certain products to bear a warning label disclosing the mercury content.\textsuperscript{115} The court in Sorrell found that the required disclosure satisfied the rational-basis standard simply upon concluding that “[i]t is

\begin{flushleft}
104. Id.
105. Id. at 563.
106. Id.
107. Disc. Tobacco, 674 F.3d at 563.
108. Id.
109. Id. at 539.
110. Id. at 563.
111. Id.
113. Id. at 564.
114. Id. at 561.
\end{flushleft}
probable that some mercury lamp purchasers, newly informed by the Vermont label, will properly dispose of [the lamps] and thereby reduce mercury pollution.”116 The Sixth Circuit noted that the decision in Sorrell did not point to any evidence that the required disclosure would, in fact, change the behavior of any consumers, but simply relied on “common sense.”117 Thus, the court similarly assumed that it is probable, based on common sense, that the graphic warning requirements would influence some consumers not to purchase tobacco products.118

Ironically, the court actually used the plaintiffs’ own argument to support its “common sense” assumption.119 In arguing against the Act’s ban on color and graphics in tobacco advertisements, the plaintiffs asserted that such a prohibition would inhibit their ability to “effectively communicate with adult tobacco consumers using advertising that captures their attention.”120 The plaintiffs further admitted at oral argument that “color and imagery are the most effective way to get your ad noticed and communicate a message.”121

Therefore, the court held that the warnings were reasonably related to promoting greater public understanding of the health risks associated with tobacco use.122

B. D.C. Circuit Strikes Down Warnings in R.J. Reynolds

After the FDA published its final rule releasing the nine required graphic images in June, 2011,123 the “Big Five” tobacco companies, most of whom were plaintiffs in Discount Tobacco, again filed suit against the FDA.124 This time, rather than facially challenging the constitutionality of the warnings requirement, they challenged the FDA’s promulgation of the specific graphic warning labels incorporating textual warnings and the corresponding “1-800-QUIT-NOW” hotline number.125

In striking down the Act, the court first held that a more stringent intermediate scrutiny standard rather than the Zauderer rational-basis standard applied.126 Second, the court found that the government did not produce a

116. Id. at 115.
117. Disc. Tobacco, 674 F.3d at 564.
118. Id.
119. Id.
120. Id. (emphasis omitted).
121. Id. at 565 (emphasis omitted).
122. Disc. Tobacco, 674 F.3d at 564.
123. Final Rule, supra note 9, at 36,628.
125. Id. at 1211.
126. Id. at 1217.
“shred of evidence” to show that the graphic warnings would directly advance its interest in reducing smoking rates.  

1. Application of the Central Hudson Intermediate Scrutiny Standard

The court applied the same two-part test as in Discount Tobacco to determine whether the Zauderer rational-basis standard applied, but came to opposite conclusions on both prongs. The court concluded that, contrary to the decision in Discount Tobacco, there was no evidence that the current cigarette packages were deceiving. Thus, the graphic warnings could not be shown to meet the first requirement established in Zauderer—that is, that the disclosure requirements are aimed at “preventing deception of consumers.”

The court also ruled contrary to Discount Tobacco in finding that the graphic warnings were not “purely factual and uncontroversial.” These opposing conclusions, however, may be reconcilable based on the fact that in Discount Tobacco, the court dealt with a facial challenge to the statute, and did not consider the specific graphic images later released by the FDA. Thus, in Discount Tobacco, the court held only that there could be graphic images that were purely factual in nature. Here, however, the court found that the actual graphic images released by the FDA were not purely factual. Rather, the court considered the images to be “unabashed attempts to evoke emotion . . . and browbeat consumers into quitting.” The D.C. Circuit offered examples of the images that do not convey any factual information, including images of a woman crying, a small child, and a man wearing a t-shirt declaring “I QUIT.”

Because the court found the required warnings to be neither factual nor necessary to prevent deception, it determined that the Zauderer standard did not apply. However, it disagreed with the district court’s application of a strict scrutiny standard because “commercial speech receives a lower level of

127. Id. at 1219.
129. R.J. Reynolds, 696 F.3d at 1216.
130. Id.
132. R.J. Reynolds, 696 F.3d at 1216.
134. R.J. Reynolds, 696 F.3d at 1216.
135. Id. at 1217.
136. Id. at 1216.
137. Id. at 1217.
The court therefore applied the intermediate standard set forth in *Central Hudson.*

2. Warnings do not Survive Intermediate Scrutiny

Under the intermediate standard set forth in *Central Hudson*, the government must first show that its asserted interest is substantial. If so, then a court must next determine whether the regulation directly advances that interest, and whether it is not more extensive than necessary to do so. The government bears the burden of proving each element, and as the *R.J. Reynolds* court noted, this burden “is not light.”

The court considered the government’s asserted interest to be reducing smoking rates. Unlike the court in *Discount Tobacco*, which considered the more general purpose of promoting greater understanding of health risks associated with smoking, the court here found that this “describes only the means by which FDA is attempting to reduce smoking rates.” Thus, the government faced the much heavier burden of producing evidence that the warnings would directly lower smoking rates.

The court concluded, however, that the government did not produce a “shred” of such evidence. The FDA produced substantial evidence regarding the adoption of similar graphic warnings in Canada and Australia, along with studies suggesting that such warnings contributed to a reduction in smoking rates. However, the court found that such studies were too speculative and failed to take into account other factors affecting the smoking rates.

Judge Rogers, writing for the dissent, concluded not only that the less stringent *Zauderer* standard applied, but also that the new warnings would survive under either level of scrutiny. In concluding that the *Zauderer* standard applied, Judge Rogers first found that the warnings were aimed at preventing the deception of consumers. The dissent compared this case to *Spirit Airlines, Inc. v. U.S. Department of Transportation*, in which the court upheld, under the *Zauderer* standard, a rule requiring airlines to list the total

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138. *Id.*
139. *R.J. Reynolds*, 696 F.3d at 1217.
141. *Id.*
142. *R.J. Reynolds*, 696 F.3d at 1218.
143. *Id. at* 1221.
144. *Id.*
145. *Id. at* 1219.
146. *Id. at* 1219–20.
147. *R.J. Reynolds*, 696 F.3d at 1219.
148. *Id. at* 1237–38 (Rogers, J., dissenting).
149. *Id. at* 1228.
price as the most prominent number displayed.\textsuperscript{150} The Spirit Airlines court held that it was “deceitful and misleading when the most prominent price listed by an airline is anything other than the total, final price of air travel.”\textsuperscript{151} The dissent here applied the same logic to conclude that cigarette packages that “fail to display the final costs of smoking in a prominent manner are at least as misleading as the airline advertisements in Spirit Airlines.”\textsuperscript{152}

The dissent also disagreed with the majority in finding that the warnings were factual in nature.\textsuperscript{153} Unlike the majority, which seemed to define “purely factual” information as information that carries no emotional response,\textsuperscript{154} the dissent based this distinction simply on whether the information is accurate, noting that the “emotive quality of the selected images does not necessarily undermine the warnings’ factual accuracy.”\textsuperscript{155}

In addition to applying the less stringent Zauderer standard, the dissent also considered the FDA’s broader interest in promoting greater public understanding of the health risk associated with smoking.\textsuperscript{156} While the majority dismissed this stated interest as “too vague to stand on its own,”\textsuperscript{157} the dissent reasoned that in light of the serious public health consequences of smoking, the government’s interest in effective communication about such consequences “take[s] on added importance.”\textsuperscript{158} Unlike the majority, which pointed to the government’s failure to produce a “shred of evidence,”\textsuperscript{159} the dissent found that the government produced “substantial evidence” that the warnings would survive under not only the Zauderer rational-basis standard, but also under the Central Hudson intermediate scrutiny standard.\textsuperscript{160}

\ \ \ \ \ \ \ \ IV. RESOLVING THE CIRCUIT SPLIT

Should the U.S. Supreme Court decide to resolve the circuit split, it must first decide which of the three standards discussed—Zauderer’s rational-basis standard, Central Hudson’s intermediate scrutiny standard, or strict scrutiny—correctly applies to the warnings. Part A explains why the Court should apply Central Hudson’s intermediate scrutiny to the warnings requirements. Part B then analyzes the warnings under both Central Hudson and Zauderer.

\textsuperscript{150} Id.
\textsuperscript{151} Spirit Airlines, Inc. v. U.S. Dep’t of Transp., 687 F.3d 403, 413 (D.C. Cir. 2012).
\textsuperscript{152} R.J. Reynolds, 696 F.3d at 1228 (Rogers, J., dissenting).
\textsuperscript{153} Id. at 1232.
\textsuperscript{154} Id. at 1216 (majority opinion).
\textsuperscript{155} Id. at 1230 (Rogers, J., dissenting).
\textsuperscript{156} Id. at 1236.
\textsuperscript{157} R.J. Reynolds, 696 F.3d at 1221 (majority opinion).
\textsuperscript{158} Id. at 1223 (Rogers, J., dissenting) (quoting Pearson v. Shalala, 164 F.3d 650, 656 (D.C. Cir. 1999)).
\textsuperscript{159} Id. at 1219 (majority opinion).
\textsuperscript{160} Id. at 1236–38 (Rogers, J., dissenting).
A. Intermediate Scrutiny Should Apply

In order to evaluate the warnings as a whole, including the textual statements, graphic images, and reference to “1-800-QUIT-NOW,” the U.S. Supreme Court should apply Central Hudson’s intermediate scrutiny standard.161

The Zauderer standard is not applicable for two reasons. First, the standard only applies to disclosures that convey “purely factual and uncontroversial” information.162 While the textual warnings certainly meet this requirement, some of the accompanying graphic images do not. In support of the images, the FDA itself cited research suggesting that “risk information is most readily communicated by messages that arouse emotional reactions” and that “warnings that generate an immediate emotional response from viewers can confer negative feelings about smoking and undermine the appeal and attractiveness of smoking.”163 As the Sixth Circuit noted, “[f]acts can disconcert, displease, provoke an emotional response, spark controversy, and even overwhelm reason, but that does not magically turn such facts into opinions.”164 Although the fact that the images are intended to provoke an emotional response does not necessarily defeat their factual nature, some of the images do not convey factual information at all. For example, the photographs of a healthy lung next to a smoker’s lung and a man with a tracheotomy are purely factual in nature. Both photographs accurately convey common health consequences of smoking. However, the images of a woman crying, a cartoon drawing of a hospitalized baby, and a man wearing an “I Quit” t-shirt do not convey “factual and uncontroversial” information about the adverse health effects of smoking. Therefore, these specific images do not meet the first prong of Zauderer.

Second, none of the graphic images meet the second requirement of Zauderer because they are not aimed specifically at preventing consumer deception. The FDA stated that the purpose of the warnings was to reduce smoking among youth by promoting a greater understanding of the health risks associated with smoking.165 In finding that the warnings were aimed at preventing deception, the Sixth Circuit pointed to the “decades-long

163. Final Rule, supra note 9, at 36,635.
165. See Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 202(d), 123 Stat. 1776, 1777-78, 1845-466 (2009) (authorizing the FDA to adjust the formatting of the label requirements if necessary to “promote greater public understanding of the risks associated with the use of tobacco products.”).
deception” by tobacco companies.\textsuperscript{166} Citing \textit{United States v. Philip Morris USA Inc.}\textsuperscript{167} the court noted that tobacco companies “knowingly and actively conspired to deceive the public about the health risks and addictiveness of smoking for decades.”\textsuperscript{168} While this historical deception by tobacco companies provides strong policy support for the graphic warnings, it is not relevant in determining whether \textit{Zauderer} applies. \textit{Zauderer} explicitly applies to disclosures that are reasonably related to “preventing consumer deception,”\textsuperscript{169} not balancing the effects of past deception. The FDA presented no evidence suggesting that the current textual warnings are deceiving, just that they are not effective.\textsuperscript{170} Thus, \textit{Zauderer} does not apply.

Strict scrutiny also does not apply. As the U.S. Supreme Court noted in \textit{Central Hudson}, “[t]he Constitution... accords a lesser protection to commercial speech than to other constitutionally guaranteed expression.”\textsuperscript{171} Therefore, as noted in \textit{R.J. Reynolds}, “burdens imposed on [commercial speech] receive a lower level of scrutiny from the courts.”\textsuperscript{172} Both circuits were therefore correct in rejecting the application of strict scrutiny. Because the warnings involve compelled commercial speech, \textit{Central Hudson}’s intermediate scrutiny standard for regulations on commercial speech applies.

\textbf{B. Analysis Under Central Hudson and Zauderer}

\textbf{1. Central Hudson’s Intermediate Scrutiny Standard}

Under \textit{Central Hudson}, a court must first determine whether the asserted government interest is substantial.\textsuperscript{173} A key distinction between the Sixth and D.C. Circuits’ analyses was the “government interest” under which the warnings were analyzed. The Sixth Circuit analyzed the warnings under the government’s stated interest in “promoting greater public understanding of the risks” associated with smoking,\textsuperscript{174} while the D.C. Circuit analyzed the warnings under the government’s interest in directly reducing smoking rates.\textsuperscript{175}

\begin{footnotesize}
\begin{enumerate}
\item\textsuperscript{166} Disc. Tobacco, 674 F.3d at 562.
\item\textsuperscript{167} United States v. Philip Morris USA Inc., 566 F.3d 1095 (D.C. Cir. 2009) (per curiam).
\item\textsuperscript{168} Disc. Tobacco, 674 F.3d at 562.
\item\textsuperscript{170} Final Rule, \textit{supra} note 9, at 69,529.
\item\textsuperscript{172} R.J. Reynolds Tobacco Co. v. Food & Drug Admin., 696 F.3d 1205, 1217 (D.C. Cir. 2012) (quoting United States v. Philip Morris USA Inc., 566 F.3d 1095, 1142-43 (D.C. Cir. 2009) (per curiam)).
\item\textsuperscript{173} Cent. Hudson, 447 U.S. at 566.
\item\textsuperscript{174} Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 564 (6th Cir. 2012).
\item\textsuperscript{175} R.J. Reynolds, 696 F.3d at 1221.
\end{enumerate}
\end{footnotesize}
The latter interest imposes a significantly high burden on the government to prove that the warnings will directly advance that interest. Under the first interest, the government would satisfy its burden by providing evidence showing that more people will notice, read, and understand the warnings. Under the second interest, however, the government would only satisfy the burden by providing direct evidence that the warnings will in fact cause people to quit smoking, which, as explained below, is impossible to prove. Thus, the government interest considered by the Court would likely determine the outcome of the case.

The warnings should be analyzed under the government’s stated interest in “promoting greater public understanding of the risks” associated with smoking.176 The D.C. Circuit viewed this interest as describing “only the means by which FDA is attempting to reduce smoking rates,” which it considered to be “too vague to stand on its own.”177 However, the fact that effectively conveying information describes a means of lowering smoking rates does not necessarily make it too vague. Under this same logic, reducing smoking rates could be characterized as simply describing a means of improving the health of American citizens. Given the substantial interest of the government in reducing smoking among youth, effective communication of the dangers of smoking is simply a more narrowly defined interest that should not be dismissed as “too vague.”178 Additionally, the D.C. Circuit failed to take into account the impossibility of providing direct evidence to prove that these warnings would directly reduce smoking rates. Because the warnings have not yet been put into effect, any statistical predictions would necessarily be speculative. As the court itself noted, many factors determine a person’s decision to smoke,179 and it would be impossible to isolate the effect of new warnings on a person’s decision to quit or decline to start smoking. Therefore, the Court should analyze the more narrowly focused interest in promoting greater public understanding of the negative health consequences of smoking.

The government’s interest in reducing smoking rates, particularly among youth, by more effectively communicating the health risks associated with smoking is clearly a substantial interest. Smoking remains the nation’s largest public health problem.180 Tobacco use claims the lives of 440,000 Americans every year.181 Smoking accounts for more deaths than AIDS, alcohol use, cocaine use, heroin use, homicides, suicides, car accidents, and fires

176. Disc. Tobacco, 674 F.3d at 564.
177. R.J. Reynolds, 696 F.3d at 1221.
178. Id.
179. Id. at 1219.
181. Id. at 1.
combined.182 Smoking is the leading cause of preventable death in the United States, and more than eighty percent of smokers have their first cigarette before turning eighteen.183 Almost half (46.3%) of young Americans in grades nine through twelve have tried smoking, and 19.5% are current smokers.184 Smoking also involves a high risk of lung cancer, heart disease, emphysema, and pregnancy complications.185 The current warnings have been proven to go largely unnoticed and fail to effectively convey the dangers of smoking, especially to youth.186

In addition to the many serious health consequences of smoking, it is also important to note that tobacco use has taken an economic toll on America.187 Health care expenditures for smoking-related conditions are estimated to be around eighty-nine billion dollars each year.188 Lost work productivity as a result of death from tobacco use totals more than ninety-two billion dollars annually.189 The government has a substantial interest in promoting public understanding of these risks in order to (1) protect the health of Americans and (2) lower the nation’s health care costs associated with smoking.

Second, to survive intermediate scrutiny, the warning requirements must directly advance the government’s interest in promoting greater public understanding of the health risks of smoking.190 The FDA presented extensive evidence that the current textual warnings are ineffective and go largely unnoticed, especially by adolescents.191 One study of adolescents viewing tobacco advertisements showed that 63.3% of the adolescents did not even view the warning long enough to read any of its words, and most of the adolescents were unable to recall the warning or even recognize it from a list.192 Another study found that 85% of Canadian smokers cited cigarette packages (which, in Canada, require prominent pictorial warnings) as a source of health information, while only 47% of American smokers cited packages as a source of health information.193 Furthermore, another study showed that participants voluntarily viewed the graphic warnings on Canadian packages for

182. Id. at 2.
183. PREVENTING TOBACCO USE, supra note 1, at i.
184. Final Rule, supra note 9, at 36,629.
185. Id. at 36,631–32.
188. Id.
189. Id.
191. Disc. Tobacco, 673 F.3d at 563.
192. Final Rule, supra note 9, at 69,530.
193. ENDING THE TOBACCO PROBLEM, supra note 29, at 294.
longer periods of time than the textual warnings in the United States.194 Finally, the FDA cited research suggesting that graphic warning labels are (1) more likely to be noticed than text-only warnings, (2) more effective at conveying the health risks associated with smoking, and (3) associated with increased motivation to quit smoking.195

Another key problem with the current textual warnings is that viewers must have a relatively high reading level in order to understand the warnings.196 The warnings “require a college reading level”197 and are therefore ineffective at conveying information to many young Americans, adults with low education levels or reading disabilities, and those for whom English is not their first language. Smoking rates are higher among adults with low education levels.198 For example, 49.1% of adults with a General Education Development certificate and 28.5% of adults with less than a high school diploma were current smokers in 2009, compared with 5.6% of adults with a graduate degree.199 As the FDA noted, graphic warnings would provide a “particularly important communication tool” for these individuals, as evidence suggests that countries with graphic health warnings show fewer disparities in health knowledge across educational levels.200

Finally, Central Hudson requires that the warnings must not be more extensive than necessary to serve the government’s interest.201 Some would argue that the government could pursue other options to promote understanding of the health risks associated with tobacco, such as an advertising campaign. However, unlike the warning labels, no advertising campaign is guaranteed to reach every teenager at the moment they are considering whether to purchase their first package of cigarettes. As the FDA has shown, the only way to more effectively capture the attention of this critical viewer at the most critical time is to include graphic, color images on every cigarette package.202 Therefore, the graphic warning labels should be upheld under Central Hudson’s intermediate scrutiny standard.

2. Zauderer’s Rational Basis Standard

Although unlikely, the U.S. Supreme Court could agree with the Sixth Circuit in finding that Zauderer applies. This would require the Court to find

194. Final Rule, supra note 9, at 69,531.
195. Id.
196. ENDING THE TOBACCO PROBLEM, supra note 29, app. at C-3.
197. Id.
198. Final Rule, supra note 9, at 36,630.
199. Id.
200. Id.
202. See supra notes 191–194 and accompanying text.
the graphic images to be both factual in nature and intended to prevent deception by balancing the effects of the “decades-long deception” by the tobacco industry.\textsuperscript{203} Since the Court would already have equated “preventing deception” with balancing past deception in order for \textit{Zauderer} to apply, the government would bear the much lower burden of proving that the graphic images are “reasonably related” to balancing the past deception of tobacco companies.\textsuperscript{204} The use of color images to more effectively capture consumers’ attention would certainly help to balance out the “decades-long” deception by tobacco companies.\textsuperscript{205}

It is also possible that the Court could analyze the images individually under \textit{Zauderer}, upholding only those images that it determines to be “purely factual and uncontroversial.”\textsuperscript{206} Many of the images factually portray the effects of smoking, including the photograph of a man blowing smoke out of the tracheotomy hole in his throat, the photograph of decaying teeth and lesions caused by mouth cancer, and the photographs of a healthy lung next to a smoker’s lung. These images, paired together with the accompanying textual warnings, essentially convey the factual message that “this is a common consequence of smoking.” However, it is hard to imagine that some of the other images could be found to convey “purely factual” information. For example, the cartoon image of a baby in a hospital, the photograph of a woman crying, and the picture of man wearing an “I Quit” t-shirt do not convey factual information about the dangers of smoking. Thus, it is possible that the Court could uphold only some of the FDA’s images under the \textit{Zauderer} standard.

\textbf{CONCLUSION}

The United States was the first country to introduce tobacco warning labels, and now, ironically, it requires one of the least prominent warnings compared to other countries. Extensive research shows that the current textual warnings go largely ignored and unnoticed, and that prominent, colorful images are necessary to more effectively communicate the health risks associated with smoking. Given that smoking remains the leading cause of preventable death in the United States and that most smokers have their first cigarette before the legal age of eighteen, the government certainly has a substantial interest in promoting public awareness of the serious health risks associated with smoking. As substantial evidence shows, graphic color images are the only way to more effectively capture the attention of American

\textsuperscript{203} Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 562 (6th Cir. 2012).
\textsuperscript{205} United States v. Philip Morris USA Inc., 566 F.3d 1095, 1105-06 (D.C. Cir. 2009) (per curiam).
\textsuperscript{206} \textit{Id.} at 1144.
adolescents at the time they pick up their first package of cigarettes. Therefore, the U.S. Supreme Court should break away from the historical influence and deception of tobacco companies and uphold the new graphic warning labels as constitutional under the *Central Hudson* intermediate scrutiny standard.

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