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## CASE NOTE

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### THE FUTURE OF GOVERNMENT-MANDATED HEALTH WARNINGS AFTER *R.J. REYNOLDS* AND *AMERICAN MEAT INSTITUTE*

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#### INTRODUCTION

Government-mandated disclosures and warnings aimed at promoting public health are ubiquitous. Alcoholic beverage labels bear government warnings against alcohol consumption during pregnancy.<sup>1</sup> Both prescription and over-the-counter drugs must comply with extensive Food and Drug Administration (FDA) labeling requirements.<sup>2</sup> Automobiles carry mandatory safety rating labels.<sup>3</sup> Cigarette packages have included warnings about the dangers of smoking since 1965.<sup>4</sup> Even chain restaurants must now follow the federal nutrition labeling requirements that have applied to food packaging for two decades.<sup>5</sup> Warnings and disclosure requirements are likely to become even more widespread given President Obama's 2011 executive

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<sup>1</sup> See generally 27 U.S.C. §§ 213–219a (2012) (setting forth alcoholic beverage labeling requirements).

<sup>2</sup> See generally 21 C.F.R. pt. 201 (2014) (outlining labeling requirements for prescription and over-the-counter drugs).

<sup>3</sup> See 15 U.S.C. § 1232(g) (2012) (“Every manufacturer of new automobiles . . . shall . . . securely affix . . . one or more safety ratings . . . .”); 49 C.F.R. §§ 575.301–302 (2013) (providing detailed labeling guidance).

<sup>4</sup> See Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. No. 89-92, § 4, 79 Stat. 282, 283 (codified as amended at 15 U.S.C. § 1333 (2012)) (requiring cigarette packages to include the statement “Caution: Cigarette Smoking May Be Hazardous to Your Health”).

<sup>5</sup> See *infra* note 99 and accompanying text.

order encouraging administrative agencies to use these “[f]lexible [a]pproaches” wherever “relevant, feasible, . . . consistent with regulatory objectives, and . . . permitted by law.”<sup>6</sup>

Despite their widespread use as a regulatory tool, government-mandated warnings and disclosures are not immune from legal challenge. In the 2012 case of *R.J. Reynolds Tobacco Co. v. FDA*, the U.S. Court of Appeals for the D.C. Circuit invalidated FDA’s graphic cigarette warnings on First Amendment grounds.<sup>7</sup> The tobacco manufacturers’ challenge forced the D.C. Circuit to wade into uncharted waters. Although there is a long line of Supreme Court cases addressing First Amendment challenges to commercial speech restrictions (e.g., advertising bans), the Court has heard only two challenges to commercial speech disclosure requirements, neither involving government-mandated warnings.<sup>8</sup> Further, while the Court has been clear that it reviews commercial speech restrictions under the *Central Hudson* intermediate scrutiny test,<sup>9</sup> it has applied a standard akin to rational basis review when examining purely factual disclosure requirements targeting consumer deception, without explaining in what other circumstances rational basis review would apply.<sup>10</sup> Thus, faced with a novel question of law, the *R.J. Reynolds* court concluded that the graphic cigarette warning requirements did not merit rational basis review protection, because (1) they did not seek to cure consumer deception and (2) they were not purely factual and uncontroversial warnings, but rather “admonitions: ‘[D]on’t buy or use this product.’”<sup>11</sup> After deciding that *Central Hudson* intermediate scrutiny

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<sup>6</sup> Exec. Order No. 13,563, 76 Fed. Reg. 3821, 3822 (Jan. 21, 2011).

<sup>7</sup> 696 F.3d 1205, 1222 (D.C. Cir. 2012), *overruled in part by* Am. Meat Inst. v. USDA, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

<sup>8</sup> See generally *infra* Part I (discussing the Supreme Court’s First Amendment jurisprudence in the commercial speech context, and citing *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), and *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), as the sole Supreme Court cases addressing First Amendment challenges to commercial speech disclosure requirements).

<sup>9</sup> See *Central Hudson*, 447 U.S. at 564 (“If the communication is neither misleading nor related to unlawful activity, . . . [t]he State must assert a substantial interest to be achieved by restrictions on commercial speech . . . , the regulatory technique must be in proportion to that interest[, and t]he limitation on expression must be designed carefully to achieve the State’s goal.”).

<sup>10</sup> See, e.g., *infra* note 47 and accompanying text.

<sup>11</sup> *R.J. Reynolds*, 696 F.3d at 1211-17. While disclosures and warnings are two different types of government-mandated commercial speech, *R.J. Reynolds* did not indicate that warnings and disclosures inherently deserve different levels of judicial scrutiny. This Note takes the position that warnings and disclosures should not be treated differently: both may fulfill the First Amendment’s goal of promoting the dissemination of information without burdening individual liberty. Although there is a greater potential for a warning to cross the line into promoting an ideological message (thus burdening the commercial speaker’s First Amendment rights), the type

was the correct standard of review, the court held the warnings unconstitutional because FDA failed to produce sufficient evidence—indeed, “failed to present any data”—that the warnings would directly and materially advance its goal of reducing smoking rates.<sup>12</sup> Although most commentators expected the case to go to the Supreme Court,<sup>13</sup> FDA instead withdrew the proposed images and said it would issue revised graphic warnings.<sup>14</sup>

To the extent that *R.J. Reynolds* could be read as holding that only commercial speech mandates that are both purely factual and designed to correct consumer deception receive rational basis review, it was overruled by the 2014 en banc decision of the D.C. Circuit, *American Meat Institute v. USDA*.<sup>15</sup> Aligning the court’s position with that of other circuits, the D.C. Circuit held in *American Meat Institute* that *Zauderer v. Office of Disciplinary Counsel*,<sup>16</sup> the first Supreme Court case to apply rational basis review to a government-mandated disclosure requirement, extended “beyond problems of deception”—and thus applied to the U.S. Department of Agriculture (USDA) country-of-origin disclosures at issue in the case.<sup>17</sup>

Given that the D.C. Circuit is responsible for reviewing many federal agency regulations, *American Meat Institute* marks a significant victory for regulators. A contrary holding—one limiting the protection of *Zauderer* rational basis review to compelled speech aimed at curing deception—would have threatened to unsettle the current regulatory regime, and would have

of warning at issue (e.g., one that simply provides information about potential harms, as compared to one that goes further by admonishing consumers against buying a product) should be considered when determining whether the warning is purely factual and thus deserves rational basis review.

<sup>12</sup> *Id.* at 1217, 1220-22.

<sup>13</sup> See, e.g., Richard Craver, *Successful Appeal of Graphic Cigarette Labels Likely Headed for U.S. Supreme Court*, WINSTON-SALEM J. (Dec. 5, 2012, 5:52 PM), [http://www.journalnow.com/news/local/article\\_751e2000-3f2e-11e2-b08c-001a4bcf6878.html](http://www.journalnow.com/news/local/article_751e2000-3f2e-11e2-b08c-001a4bcf6878.html), archived at <http://perma.cc/VX28-X5SH> (noting that the case appeared “destined” for Supreme Court review). Tobacco manufacturers’ facial challenge to the Tobacco Control Act’s graphic warning requirement failed in the Sixth Circuit, and the Supreme Court denied the manufacturers’ petition for a grant of certiorari. *See* Disc. Tobacco City & Lottery, Inc. v. United States, 674 F.3d 509, 569 (6th Cir. 2012) (“[T]he Act’s warnings are reasonably related to the government’s interest in preventing consumer deception and are therefore constitutional.”), *cert. denied sub nom.* Am. Snuff Co. v. United States, 133 S. Ct. 1996 (2013).

<sup>14</sup> See Michael Felberbaum, *U.S. to Revise Cigarette Warning Labels*, NBC NEWS (Mar. 19, 2013, 2:27 PM), [http://vitals.nbcnews.com/\\_news/2013/03/19/17375279-us-to-revise-cigarette-warning-labels](http://vitals.nbcnews.com/_news/2013/03/19/17375279-us-to-revise-cigarette-warning-labels), archived at <http://perma.cc/ER7A-5U3Z> (noting how FDA planned to “undertake research to support a new rulemaking consistent with the Tobacco Control Act” (internal quotation marks omitted)).

<sup>15</sup> 760 F.3d 18, 22-23 (D.C. Cir. 2014) (en banc).

<sup>16</sup> 471 U.S. 626 (1985).

<sup>17</sup> *Am. Meat Inst.*, 760 F.3d at 20.

particularly threatened mandates aimed at promoting public health. These disclosure requirements often do not target potentially deceptive commercial speech, and they rarely are supported by the level of evidence *R.J. Reynolds* deemed necessary to satisfy *Central Hudson* intermediate scrutiny.<sup>18</sup> (These evidentiary difficulties arise in part because many public health problems are complex and cannot be eradicated by a disclosure requirement alone.) While *R.J. Reynolds* raised important questions about the effectiveness of disclosure requirements, the First Amendment should not be an insurmountable obstacle when the commercial speaker's constitutionally protected interest is, as the Court has said, "minimal"<sup>19</sup> and the government interest is substantial.<sup>20</sup>

Although *American Meat Institute* lessened the blow *R.J. Reynolds* dealt to regulators, both decisions left open important questions about the First Amendment treatment of government-mandated warnings that are neither "purely factual and uncontroversial"<sup>21</sup> disclosures nor overt government-sanctioned opinions, and about whether graphic cigarette warnings belong in this middle ground. *R.J. Reynolds* only addressed the constitutionality of the nine warnings before it,<sup>22</sup> and left unanswered whether another graphic warning depicting the negative health consequences of smoking could be constitutional. But, in characterizing FDA's graphic warnings as "a much different animal" than the mandated statements to which the Supreme Court has previously applied rational basis review,<sup>23</sup> and in viewing them as "intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning,"<sup>24</sup> *R.J. Reynolds* strongly implied that no graphic cigarette warning could ever receive rational basis review protection. Not only did the court seem to demand *Central Hudson* intermediate scrutiny review for all government-mandated graphic warnings, it created an overly burdensome intermediate scrutiny test by misapplying the Administrative Procedure Act's (APA)

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<sup>18</sup> See *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1219 (D.C. Cir. 2012) (chastising FDA for failing to produce "substantial evidence" supporting the effectiveness of its graphic cigarette warnings), *overruled in part by* *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

<sup>19</sup> See *Zauderer*, 471 U.S. at 651 (noting that a commercial speaker's "constitutionally protected interest in not providing any particular factual information in his advertising is minimal").

<sup>20</sup> See *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995) (recognizing the government's substantial interest in "promoting the health, safety, and welfare of its citizens").

<sup>21</sup> *R.J. Reynolds*, 696 F.3d at 1212 (quoting *Zauderer*, 471 U.S. at 651).

<sup>22</sup> See *id.* at 1209 (discussing FDA's nine selected images).

<sup>23</sup> *Id.* at 1216.

<sup>24</sup> *Id.*

“substantial evidence” standard to its First Amendment analysis, and by failing to look beyond the Court’s abstract statements about *Central Hudson* to its application of the test.<sup>25</sup>

Part I of this Note outlines the Supreme Court’s commercial speech jurisprudence. It explains the Court’s differential treatment of commercial speech restrictions and compelled commercial speech, and it outlines the open question of whether *Zauderer*, and its accompanying rational basis review protection, is limited to mandates aimed at correcting deception. Part II discusses the various interpretations of *Zauderer* advanced by circuit courts. It defends the broader interpretation of *Zauderer* adopted by the First Circuit, Second Circuit, and, most recently, the D.C. Circuit in *American Meat Institute*, and it criticizes the narrow interpretation articulated in *R.J. Reynolds*. Part II likewise outlines the doctrinal support and policy justifications for a broader interpretation of *Zauderer*, with particular focus on the importance of recognizing the government’s interest in promoting public health as worthy of rational basis review. Part III then looks at how FDA could issue revised graphic cigarette warnings that would pass constitutional muster. It examines the type of graphic cigarette warnings that could potentially merit review under the *Zauderer* standard, argues that *R.J. Reynolds* misapplied the *Central Hudson* intermediate scrutiny standard, suggests a better view of *Central Hudson* as applied to graphic cigarette warnings, and describes post-*Reynolds* scientific research supporting the effectiveness of graphic warnings.

## I. COMMERCIAL SPEECH AND THE FIRST AMENDMENT

Commercial speech received little First Amendment protection until 1976, when the Supreme Court first recognized pharmacists’ constitutional right to advertise prescription drug prices in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*<sup>26</sup> The Court declared that an advertiser’s purely economic motive does not disqualify the advertiser from First Amendment protection,<sup>27</sup> and the Court emphasized the informative value of commercial speech: a “consumer’s interest in the free flow of commercial information . . . may be as keen, if not keener by far, than his interest in the day’s most urgent political debate”;<sup>28</sup> “society also may have a strong interest in the free flow of commercial information”;<sup>29</sup> and “the

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<sup>25</sup> See *infra* subsection III.C.2.

<sup>26</sup> 425 U.S. 748, 762 (1976).

<sup>27</sup> *Id.*

<sup>28</sup> *Id.* at 763.

<sup>29</sup> *Id.* at 764.

free flow of commercial information is indispensable” to making intelligent and well-informed economic decisions.<sup>30</sup> The First Amendment, the Court held, did not permit the state to accomplish its goals “by keeping the public in ignorance.”<sup>31</sup> Yet the Court’s extension of First Amendment protection to commercial speech<sup>32</sup> was not without limits. The Court was careful to emphasize that “[u]ntruthful speech, commercial or otherwise, has never been protected,” and that the First Amendment “does not prohibit the State from insuring that the stream of commercial information flow cleanly as well as freely.”<sup>33</sup> It did not hold that commercial speech was “wholly undifferentiable from other forms,” but instead suggested that the differences between commercial and noncommercial speech justify a “different degree of protection.”<sup>34</sup> Since deciding that landmark case, the Court has clarified that commercial speech receives a lesser degree of protection than noncommercial speech.<sup>35</sup>

Although the First Amendment protects both the right to speak freely and the right not to speak,<sup>36</sup> the Supreme Court has applied a more lenient standard of review to commercial disclosure requirements than to commercial speech restrictions. The Court first articulated its test for commercial speech restrictions when it invalidated New York City’s prohibition on electric utility advertisements in *Central Hudson Gas & Electric Corp. v. Public Service Commission*.<sup>37</sup> Under *Central Hudson* intermediate scrutiny, a law restricting nonmisleading commercial speech regarding a lawful activity is constitutional only if it (1) is in furtherance of a substantial government interest; (2) directly and materially advances that interest; and (3) is not excessive.<sup>38</sup>

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<sup>30</sup> *Id.* at 765.

<sup>31</sup> *Id.* at 770.

<sup>32</sup> Commercial speech is defined as speech that “does ‘no more than propose a commercial transaction.’” *Id.* at 762 (quoting *Pittsburgh Press Co. v. Pittsburgh Comm’n on Human Relations*, 413 U.S. 376, 385 (1973)).

<sup>33</sup> *Id.* at 771-72.

<sup>34</sup> *Id.* at 771-72 n.24.

<sup>35</sup> *See, e.g., Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 563 (1980) (noting that the Constitution “accords a lesser protection to commercial speech than to other constitutionally guaranteed expression”). *But see Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2664-68 (2011) (blurring the distinction between commercial and core First Amendment speech, but ultimately applying *Central Hudson* intermediate scrutiny to invalidate Vermont’s restriction on the sale, disclosure, and use of pharmacy records for purposes of prescription drug promotion).

<sup>36</sup> *Wooley v. Maynard*, 430 U.S. 705, 714 (1977) (citing *W. Va. State Bd. of Educ. v. Barnette*, 319 U.S. 624, 633-34 (1943)).

<sup>37</sup> 447 U.S. at 564, 571.

<sup>38</sup> *Id.* at 564.

Five years later, in *Zauderer v. Office of Disciplinary Counsel*,<sup>39</sup> the Court declined to extend *Central Hudson*. In *Zauderer*, the Court reviewed an Ohio rule of professional conduct that required attorneys who advertised contingency-fee services to disclose whether fees were calculated before or after deduction of court expenses.<sup>40</sup> Instead of applying *Central Hudson* intermediate scrutiny, the Court applied rational basis review to uphold the disclosure requirement.<sup>41</sup> The Court began its analysis by noting the “material differences between disclosure requirements and outright prohibitions on speech”: Ohio had not prevented attorneys from conveying information to the public, but instead had merely “required them to provide somewhat more information than they might otherwise be inclined to present.”<sup>42</sup> Next, the Court contrasted the required disclosure with an attempt to “prescribe what shall be orthodox in politics, nationalism, religion, or other matters of opinion,” and pointed to the First Amendment interest in preserving the informational value commercial speech provides to consumers to conclude that a commercial speaker’s “constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal.”<sup>43</sup> Finally, the Court noted its consistent position that “disclosure requirements trench much more narrowly on an advertiser’s interests than do flat prohibitions on speech,” and held that “an advertiser’s rights are adequately protected as long as disclosure requirements are reasonably related to the State’s interest in preventing deception of consumers.”<sup>44</sup>

Despite the widespread use of commercial speech disclosure requirements as a regulatory tool, the Supreme Court has had few opportunities to address when these requirements violate the First Amendment.<sup>45</sup> *Zauderer* made clear that a “purely factual” disclosure requirement aimed at dispelling consumer deception should receive rational basis review protection but did not say whether government-mandated disclaimers supporting other state interests could as well.<sup>46</sup> Although the Court addressed the constitutionality of another disclosure requirement in 2010, the challenged law “share[d] the

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<sup>39</sup> 471 U.S. 626 (1985).

<sup>40</sup> *Id.* at 633.

<sup>41</sup> *See id.* at 650-51 (requiring only that the disclosure requirement be “reasonably related” to the relevant government interest).

<sup>42</sup> *Id.* at 650.

<sup>43</sup> *Id.* at 651 (internal quotation marks omitted).

<sup>44</sup> *Id.*

<sup>45</sup> *See generally* *Borgner v. Fla. Bd. of Dentistry*, 537 U.S. 1080, 1082 (2002) (Thomas, J., dissenting from denial of certiorari) (“Our decisions have not presumptively endorsed government-scripted disclaimers or sufficiently clarified the nature and the quality of the evidence a State must present to show that the challenged legislation directly advances the government interest asserted.”).

<sup>46</sup> *Zauderer*, 471 U.S. at 651.

essential features” of the ethics rule at issue in *Zauderer* (they were both purely factual disclosure requirements aimed at preventing consumer deception), and thus the Court upheld the law without expounding on the limits of *Zauderer* rational basis review.<sup>47</sup> The Court’s silence left a circuit split on the issue of whether *Zauderer* extends to government interests other than the interest in preventing consumer deception,<sup>48</sup> although that split was arguably resolved by the 2014 D.C. Circuit decision in *American Meat Institute*.<sup>49</sup>

## II. *AMERICAN MEAT INSTITUTE* CORRECTLY OVERRULED *R.J. REYNOLDS* BY ADOPTING A BROAD READING OF *ZAUDERER*

Commercial speech receives First Amendment protection for the informational value it provides to consumers, but this protection exists in the context of the Supreme Court’s statements that a commercial speaker’s protected interest in not providing factual information is “minimal.”<sup>50</sup> Given this backdrop, *American Meat Institute* correctly extended *Zauderer* beyond mandates correcting deception.<sup>51</sup> Not only would limiting *Zauderer* to mandates curing consumer deception have cemented a circuit split, it also would have created administrative complexity in situations where government

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<sup>47</sup> *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324, 1339–40 (2010).

<sup>48</sup> Compare *N.Y. State Rest. Ass’n v. N.Y.C. Bd. of Health*, 556 F.3d 114, 133 (2d Cir. 2009) (accepting a broader reading of *Zauderer* wherein it applies beyond consumer deception), and *Pharm. Case Mgmt. Ass’n v. Rowe*, 429 F.3d 294, 310 n.8 (1st Cir. 2005) (“[W]e have found no cases limiting *Zauderer* [to potentially deceptive advertising].”), with *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1213 (D.C. Cir. 2012) (“[B]y its own terms, *Zauderer*’s holding is limited to cases in which disclosure requirements are ‘reasonably related to the State’s interest in preventing deception of consumers.’” (quoting *Zauderer*, 471 U.S. at 651)), *overruled in part* by *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

<sup>49</sup> A petition for Supreme Court certiorari was recently denied in an unrelated case that raises the same issue as *American Meat Institute* (whether *Zauderer* is limited to government mandates requiring commercial speakers to disclose purely factual and uncontroversial information to prevent deception). See *Petition for a Writ of Certiorari* in *i, Anthem Prescription Mgmt., LLC v. Jerry Beeman & Pharmacy Servs., Inc.*, No. 14-0062 (U.S. July 17, 2014); Docket, No. 14-0062, *Anthem Prescription Mgmt., LLC v. Jerry Beeman & Pharmacy Servs., Inc.*, available at <http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/14-62.htm> (last updated Nov. 10, 2014), archived at <http://perma.cc/7ZTE-BYST> (denying certiorari on November 10, 2014). The petitioner argued that “[t]he Fourth Circuit has also applied heightened scrutiny to laws compelling speech by companies for purposes other than preventing consumer deception,” and that the Ninth Circuit has held that “the First Amendment is inapplicable to laws requiring companies to engage in factual speech.” *Id.* at 15, 19.

<sup>50</sup> *Zauderer*, 471 U.S. at 651.

<sup>51</sup> See *Am. Meat Inst.*, 760 F.3d at 20 (extending *Zauderer*’s applicability “beyond problems of deception”).



mandates reach both manufacturers who employ potentially deceptive marketing practices and those who do not. Furthermore, limiting *Zauderer*'s reach would have unsettled the current regulatory regime, in which government-mandated disclosures and warnings serve other important government interests but often do not target potential deception.

A. *Doctrinal Support for Expanding Zauderer to Government Interests Other than the Interest in Preventing Consumer Deception*

The Supreme Court's First Amendment commercial speech jurisprudence supports the *American Meat Institute* decision to extend *Zauderer* beyond mandates correcting deception.

As an initial matter, *R.J. Reynolds* and *American Meat Institute* disagreed about the extent to which the Supreme Court had ever addressed "whether the principles articulated in *Zauderer* apply more broadly to factual and uncontroversial disclosures required to serve . . . government interests [other than preventing consumer deception]." <sup>52</sup> Whereas *American Meat Institute* read *Zauderer* as "not giv[ing] a clear answer," <sup>53</sup> *R.J. Reynolds* asserted that "by its own terms, *Zauderer*'s holding is limited to cases in which disclosure requirements are 'reasonably related to the State's interest in preventing deception of consumers.'" <sup>54</sup> Likewise, while *American Meat Institute* recognized ambiguity in the Court's later application of *Zauderer*, <sup>55</sup> *R.J. Reynolds* cited Supreme Court precedent it believed "establish[ed] that a disclosure requirement is only appropriate if the government shows that, absent a warning, there is a self-evident—or at least 'potentially real'—danger that an advertisement will mislead consumers." <sup>56</sup>

*R.J. Reynolds* was correct when it stated that the Supreme Court has never extended *Zauderer* to disclosure requirements other than those correcting misleading commercial speech, <sup>57</sup> but the opinion mischaracterized the cases it cited as actually addressing the issue. <sup>58</sup> The only clear statement *R.J.*

<sup>52</sup> *Id.* at 21.

<sup>53</sup> *Id.*

<sup>54</sup> *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1213 (D.C. Cir. 2012) (quoting *Zauderer*, 471 U.S. at 651), *overruled in part by* *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

<sup>55</sup> See *Am. Meat Inst.*, 760 F.3d at 22 (noting that *Milavetz, Gallop & Milavetz, P.A. v. United States*, 130 S. Ct. 1324 (2010), could be interpreted as "simply descriptive of the circumstances to which the Court applied" *Zauderer*, or, alternatively, as "preclud[ing] any application beyond those circumstances").

<sup>56</sup> *R.J. Reynolds*, 696 F.3d at 1214 (quoting *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 146 (1994)).

<sup>57</sup> *Id.* at 1213.

<sup>58</sup> See *id.* at 1213-14 (citing *Milavetz*, 130 S. Ct. at 1340; *Ibanez*, 512 U.S. at 136, 146; and *Zauderer*, 471 U.S. at 651-52).

*Reynolds* provided for limiting the scope of *Zauderer* came from a dissenting opinion, not binding precedent.<sup>59</sup> No Justice speaking for the Court has ever made such a declaration. Indeed, the Court has never had an opportunity to do so. It has never faced a purely factual speech mandate that serves a government interest other than preventing consumer deception.

*United States v. United Foods*,<sup>60</sup> which *R.J. Reynolds* cited as an example of the Court's unwillingness to extend *Zauderer* beyond curing consumer deception,<sup>61</sup> hardly makes a statement on the issue.<sup>62</sup> The compelled speech at issue in that case (an assessment charged on each mushroom produced or imported to support advertisements promoting generic mushrooms) was indisputably nonfactual.<sup>63</sup> And, unlike *R.J. Reynolds*, *United Foods* contained no assertions about *Zauderer*'s limits. The brief paragraph addressing *Zauderer* merely distinguished *United Foods* in response to the argument that the Court's conclusions were inconsistent with its precedent.<sup>64</sup> At best, *United Foods* can be read as supporting the Court's unwillingness to extend *Zauderer* to mandates that share none of the characteristics of the mandated disclosure upheld in *Zauderer* (i.e., mandates involving compelled speech that is neither "purely factual" nor necessary to "prevent[] deception of consumers").<sup>65</sup>

*R.J. Reynolds*'s next citation, to *Pacific Gas & Electric Co. v. Public Utilities Commission*,<sup>66</sup> when viewed in context, actually provides support for expanding *Zauderer* beyond curing consumer deception. The passage the court cited ("[n]othing in *Zauderer* . . . suggests that the State is equally free to require [entities] to carry the messages of third parties, where the messages themselves are biased against or are expressly contrary to the [entity's] views")<sup>67</sup> merely stands for the proposition that nonfactual, opinion-based compelled messages

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<sup>59</sup> See *id.* at 1213 ("*Zauderer* 'carries no authority for a mandate unrelated to the interest in avoiding misleading or incomplete commercial messages.'" (quoting *Glickman v. Wileman Bros. & Elliott, Inc.*, 521 U.S. 457, 491 (1997) (Souter, J., dissenting))).

<sup>60</sup> 533 U.S. 405 (2001).

<sup>61</sup> *R.J. Reynolds*, 696 F.3d at 1213.

<sup>62</sup> See *N.Y. State Rest. Ass'n v. N.Y.C. Bd. of Health*, 556 F.3d 114, 133 (2d Cir. 2009) ("We think [the appellant] reads too much into *United Foods*. The paragraph on which [the appellant] relies simply distinguishes *Zauderer* . . . ; it does not provide that all other disclosure requirements are subject to heightened scrutiny.").

<sup>63</sup> See *United Foods*, 533 U.S. at 411 ("The message [of the mandatory subsidies for mushroom advertisements] is that mushrooms are worth consuming whether or not they are branded.").

<sup>64</sup> *Id.* at 416; see also *N.Y. State Rest. Ass'n*, 556 F.3d at 133 (asserting that *United Foods* "does not provide that all other disclosure requirements [that are not necessary to prevent consumer deception] are subject to heightened scrutiny").

<sup>65</sup> *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985).

<sup>66</sup> 475 U.S. 1 (1986) (plurality opinion).

<sup>67</sup> *R.J. Reynolds*, 696 F.3d at 1213-14 (quoting *Pacific Gas*, 475 U.S. at 16 n.12).

do not receive rational basis review. The preceding sentence of *Pacific Gas*, which *R.J. Reynolds* omitted, had suggested a broad government power to require factual disclosures from commercial speakers: “The State, of course, has substantial leeway in determining appropriate information disclosure requirements for business corporations.”<sup>68</sup>

*R.J. Reynolds* also overstated the significance of the final two Supreme Court cases it cited. *Ibanez v. Florida Department of Business & Professional Regulation*<sup>69</sup> does not so much “suggest[] that *Zauderer* should be construed to apply *only* when the government affirmatively demonstrates that an advertisement threatens to deceive consumers”;<sup>70</sup> rather, it simply affirms that the government cannot rely exclusively on bare allegations of consumer deception to justify a speech restriction. The action by the Florida Board of Accountancy at issue in *Ibanez* (punishing an attorney for advertising her Certified Financial Planner (CFP) designation)<sup>71</sup> is a speech restriction, not a disclosure requirement, thus rational basis review was never an option.<sup>72</sup> Moreover, the Florida Board’s only justification for its actions was that the attorney’s speech was “inherently mislead[ing]” or “potentially misleading.”<sup>73</sup> *Ibanez* certainly makes a statement about the level of evidence required to show actual or potential deception sufficient to justify a commercial speech restriction,<sup>74</sup> but it says nothing about other government interests.

The final case cited by *R.J. Reynolds*, *Milavetz, Gallop & Milavetz, P.A. v. United States*, addressed a disclosure requirement that “share[d] the essential features of the rule at issue in *Zauderer*,”<sup>75</sup> and thus took no position on expanding *Zauderer*,<sup>76</sup> as noted in Part I.<sup>77</sup>

*R.J. Reynolds* and *American Meat Institute* also differed in the degree to which *Zauderer*’s rationale influenced their interpretations of *Zauderer*. *R.J. Reynolds* failed to reconcile its analysis with *Zauderer*’s declaration that a

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<sup>68</sup> *Pacific Gas*, 475 U.S. at 15-16 n.12 (citing *Zauderer*, 471 U.S. at 651).

<sup>69</sup> 512 U.S. 136 (1994).

<sup>70</sup> *R.J. Reynolds*, 696 F.3d at 1214.

<sup>71</sup> *Ibanez*, 512 U.S. at 138-39.

<sup>72</sup> See *supra* notes 36-38 and accompanying text.

<sup>73</sup> *Ibanez*, 512 U.S. at 144, 146.

<sup>74</sup> See *id.* at 145.

<sup>75</sup> 130 S. Ct. 1324, 1339-40 (2010).

<sup>76</sup> *But see id.* at 1343-44 (Thomas, J., concurring in part and concurring in the judgment) (questioning the different treatment of commercial speech restrictions and mandates, expressing a willingness to “reexamine *Zauderer* and its progeny in an appropriate case,” and arguing that compelled speech is constitutional only where the targeted advertisement is “*inherently likely to deceive*” (quoting *In re R. M. J.*, 455 U.S. 191, 202 (1982) (emphasis added))).

<sup>77</sup> See *supra* note 47 and accompanying text; cf. *Am. Meat Inst. v. USDA*, 760 F.3d 18, 22 (D.C. Cir. 2014) (en banc) (noting *Milavetz*’s susceptibility to multiple interpretations regarding the scope of *Zauderer*).

commercial speaker's "protected interest in *not* providing any particular factual information in his advertising is minimal."<sup>78</sup> *American Meat Institute*, on the other hand, pointed to *Zauderer*'s core reasoning to support a broader application of rational basis review. First, the court noted that *Zauderer* rejected the *Central Hudson* test because of the "material differences between disclosure requirements and outright prohibitions on speech."<sup>79</sup> Next, the court pointed to *Zauderer*'s description of "the First Amendment interests implicated by disclosure requirements" as "substantially weaker than those at stake when speech is actually suppressed."<sup>80</sup> The court quoted from *Zauderer* once more<sup>81</sup> before concluding that "*Zauderer*'s characterization of the speaker's interest in opposing forced disclosure of [purely factual and uncontroversial] information as 'minimal' seems inherently applicable beyond the problem of deception, as other circuits have found."<sup>82</sup>

While Judge Brown's dissent in *American Meat Institute* accused the majority of "hing[ing] its claims on just three scraps from *Zauderer*,"<sup>83</sup> a complete examination of *Zauderer* and its historical context does not support Judge Brown's conclusion that "the state's option to require a curative disclosure cannot be disconnected from its right to entirely prohibit deceptive, fraudulent, or misleading commercial speech."<sup>84</sup> When the Supreme Court extended formal constitutional protection to commercial speech, the Court did note that untruthful speech remained unprotected, but the bulk of the Court's analysis (and its primary justification) was the informational value of commercial speech to consumers<sup>85</sup>—a justification in line with the language *American Meat Institute* cited from *Zauderer*. Further, the *Zauderer* language the majority cited is hardly "three scraps." On the contrary, it is a fair representation of the Court's analysis of Ohio's disclosure requirement.<sup>86</sup>

<sup>78</sup> *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985); cf. *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1213-15 (D.C. Cir. 2012) (discussing *Zauderer* without mentioning this statement), *overruled in part by* *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

<sup>79</sup> *Am. Meat Inst.*, 760 F.3d at 22 (quoting *Zauderer*, 471 U.S. at 650).

<sup>80</sup> *Id.* (quoting *Zauderer*, 471 U.S. at 652 n.14).

<sup>81</sup> *See id.* ("Because the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides, appellant's constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." (quoting *Zauderer*, 471 U.S. at 651 (citation omitted))).

<sup>82</sup> *Id.*

<sup>83</sup> *Id.* at 38 (Brown, J., dissenting).

<sup>84</sup> *Id.* at 39-40.

<sup>85</sup> *See supra* notes 28-31 and accompanying text.

<sup>86</sup> *See generally Zauderer*, 471 U.S. at 650-53; *see also supra* notes 39-44 and accompanying text.

Although neither *American Meat Institute* nor *R.J. Reynolds* showed how their respective readings of *Zauderer* would promote First Amendment goals, the Second Circuit did in the 2001 case of *National Electrical Manufacturers Ass'n v. Sorrell*.<sup>87</sup> To support its expanded reading of *Zauderer*, the Second Circuit pointed to “the core First Amendment values of promoting efficient exchange of information [and] protecting individual liberty,” reasoning that “mandated disclosure of accurate, factual, commercial information . . . furthers, rather than hinders,” these values.<sup>88</sup> Requiring disclosure of truthful information adds to the “marketplace of ideas” without infringing on individual liberty, the court explained.<sup>89</sup> Whereas state-mandated personal or political speech impairs individual liberty, requiring commercial speakers to disclose accurate factual 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.”<sup>90</sup> The court recognized that compelled disclosures could invoke privacy and property concerns but reasoned that rational basis review was still appropriate: courts afford less weight to privacy concerns in the commercial setting, and the common law of property and other constitutional rights adequately protect commercial speakers’ “legally cognizable interest in withholding accurate, factual information.”<sup>91</sup>

Expanding *Zauderer*’s reach to cases involving government interests besides curing consumer deception is consistent with recent Supreme Court precedent, notwithstanding the success of recent First Amendment challenges to commercial speech restrictions. Some may find it troubling that, in an era when the Supreme Court has given increasing deference to commercial speech, both the D.C. Circuit (in *American Meat Institute*) and the Second Circuit (in *National Electrical Manufacturers Ass'n*) failed to identify a Supreme Court decision other than *Zauderer*—which is now nearly 30 years old—to support extending the protection of rational basis review beyond preventing

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<sup>87</sup> 272 F.3d 104 (2d Cir. 2001). In *National Electrical Manufacturers Ass'n*, the Second Circuit extended *Zauderer* to a commercial speech mandate designed to “protect[] human health and the environment from mercury poisoning.” *Id.* at 115. The Vermont statute at issue required manufacturers of mercury-containing light bulbs to use packaging labels to inform buyers about the light bulbs’ mercury content and about the need to recycle or dispose of the light bulbs as hazardous waste. *Id.* at 107 & n.1.

<sup>88</sup> *Id.* at 114.

<sup>89</sup> *Id.*

<sup>90</sup> *Id.*

<sup>91</sup> *Id.*

deception.<sup>92</sup> While the Court has been more protective of commercial speech in recent years, this trend has merely responded to *speech restrictions*—without handicapping regulators’ ability to require disclosures. In *Milavetz*—the only purely factual disclosure requirement to come before the Court in the three decades since *Zauderer*—the Court applied *Zauderer’s* lenient standard of review, implying that *Zauderer’s* core reasoning still holds strong.<sup>93</sup> Moreover, the Court has justified its heightened skepticism of commercial speech *restrictions* with reference to the informational value that commercial speech provides to consumers: “The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good.”<sup>94</sup> This reasoning is consistent with *Zauderer* and supports a more lenient review of all factual disclosure requirements, which seek to apprise people of important information—not keep them in the dark.

Neither the D.C. Circuit’s nor the Second Circuit’s opinion seems, however, to fully appreciate how crucial a broad reading of *Zauderer* is to the current regulatory regime, particularly for protecting government-mandated speech aimed at promoting public health.<sup>95</sup> The following Section explores the impact that *R.J. Reynolds’s* narrow reading of *Zauderer* would have had on public health disclosure requirements, including those for which there is widespread public support.

### B. *The Undesirable Policy Implications of Limiting Zauderer Rational Basis Review to Mandates Curing Deception*

The current regulatory regime was predicated on the logic of *Zauderer*: that a commercial speaker’s right not to disclose factual information is “minimal,” not fundamental,<sup>96</sup> and that regulatory bodies can therefore chip away at serious public health problems through purely factual disclosures and warnings. These regulatory tools are meant to be a less burdensome

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<sup>92</sup> See generally *Am. Meat Inst. v. USDA*, 760 F.3d 18, 20-27 (D.C. Cir. 2014) (en banc); *Nat’l Elec. Mfrs. Ass’n*, 272 F.3d at 113-16.

<sup>93</sup> See *supra* notes 47, 75-77 and accompanying text.

<sup>94</sup> *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2671 (2011) (quoting 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 503 (1996) (plurality opinion)).

<sup>95</sup> Cf. Jennifer M. Keighley, *Can You Handle the Truth? Compelled Commercial Speech and the First Amendment*, 15 U. PA. J. CONST. L. 539, 565 (2012) (asserting that failing to extend *Zauderer* rational basis review could have drastic policy implications for the use of disclosure requirements as a regulatory strategy).

<sup>96</sup> *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985).

alternative to legislation that would *intrude more* on individual liberty.<sup>97</sup> (Note that these regulatory tools typically still receive the protection of rational basis review, unless they implicate a fundamental right.)<sup>98</sup> If the Supreme Court ever adopts the *R.J. Reynolds* approach, however, legislators and regulators might have to abandon disclosures and warnings in favor of more onerous, intrusive, and paternalistic measures to promote public health.

Because many government speech mandates target both commercial speakers employing deceptive practices and commercial speakers who do not,<sup>99</sup> under *R.J. Reynolds's* restrictive reading of *Zauderer*, the same commercial speech regulation could be reviewed using different levels of scrutiny depending on the challenger or the context.<sup>100</sup> Not only would *R.J. Reynolds's* regime create increased complexity for courts and regulators, but it could

<sup>97</sup> See Exec. Order No. 13,563, 76 Fed. Reg. 3821, 3821 (Jan. 21, 2011) (noting that the regulatory system should use the “least burdensome tools for achieving regulatory ends”).

<sup>98</sup> See, e.g., *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695, 712–13 (D.C. Cir. 2007) (en banc) (applying rational basis review to FDA’s policy limiting access to investigational drugs, a policy intended to protect patients from potentially unsafe drugs, because there is no fundamental right to experimental drugs).

<sup>99</sup> Nutrition labeling laws are one example of mandates that sometimes target deceptive practices, but more often serve other important purposes. For over two decades the Federal Food, Drug, and Cosmetic Act (FDCA) has required food packaging for “food intended for human consumption . . . and offered for sale” to contain a label listing the product’s caloric content and other key nutritional information. See Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 2(a), 104 Stat. 2353, 2353 (codified as amended at 21 U.S.C. § 343(q)(1) (2012)) (amending the FDCA and requiring nutrition labeling requirements). In 2010, the FDCA labeling requirements were extended to cover chain retail food establishments, which must now display calorie information for standard menu items. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 4205(b), 124 Stat. 119, 573-76 (2010) (codified at 21 U.S.C. § 343(q)(5)(H) (2012)) (amending the FDCA by requiring restaurants and similar retail food establishments that are “part of a chain with 20 or more locations” to “disclose in a clear and conspicuous manner . . . the number of calories contained in [a] standard menu item”).

To be sure, certain food industry practices arguably create the potential for consumer deception. See generally *BD. OF HEALTH, N.Y.C. DEP’T OF HEALTH & MENTAL HYGIENE, NOTICE OF ADOPTION OF A RESOLUTION TO REPEAL AND REENACT § 81.50 OF THE NEW YORK CITY HEALTH CODE 5-7* (2008) (“The systematic underestimation of calories suggests that consumers have distorted perceptions of calorie content and *de facto* have been misled to view oversized, high-calorie portions as ‘normal’ portions, containing acceptable numbers of calories.”). The 2010 federal menu labeling law, however, stretches beyond curing potential deception. It applies to chain restaurants regardless of whether their advertisements might mislead consumers and regardless of whether their food is considered “unhealthy.” It covers any “restaurant or similar retail food establishment” that is “part of a chain with 20 or more locations,” 21 U.S.C. § 343(q)(5)(H)(i)—a class of food establishments that includes the salad chain Sweetgreen, as well as traditional “fast food” restaurants.

<sup>100</sup> See *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1212 (D.C. Cir. 2012) (describing the *Central Hudson* test, which is used to review government-mandated restrictions on noncommercial speech, as “significantly more stringent than *Zauderer's* standard”), *overruled in part by Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

also (partially) invalidate many government-mandated disclosures and warnings, especially those with the ambitious goal of promoting public health.

*R.J. Reynolds's* limited application of *Zauderer* would be particularly troubling for public health regulators seeking to use disclosures or warnings for purposes other than preventing deception, because it declares that the regulators must first gather mountains of evidence.<sup>101</sup> Given the severity of many public health problems and health's paramount importance in our daily lives, public health law is an area where regulatory bodies cannot afford to wait for airtight evidence before they act. A regulatory agency tasked with disease prevention and health promotion does not serve its purpose by delaying action until it can accumulate the level of evidence that *R.J. Reynolds* interprets *Central Hudson* to require.<sup>102</sup> Moreover, the complexity of public health problems makes confounding factors nearly inevitable in any proposed intervention and makes it difficult if not impossible to provide the evidence that *R.J. Reynolds* requires.

As the Supreme Court noted in *Zauderer*, “[a]s a general matter, governments are entitled to attack problems piecemeal, save where their policies implicate rights so fundamental that strict scrutiny must be applied. The right of a commercial speaker not to divulge accurate information regarding his services is not such a fundamental right.”<sup>103</sup> Given the myriad factors that influence health and wellness, public health is an area where it is especially necessary to have the flexibility to take a piecemeal approach. Indeed, legislatures frequently choose to attack complex public health problems through multiple channels.<sup>104</sup>

While a simple disclosure requirement may not directly and materially advance an ambitious public health goal such as reducing obesity, evidence that it might directly improve the health of some individuals<sup>105</sup> should be enough to justify a mandate that poses a “minimal” burden to a commercial

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<sup>101</sup> See *id.* at 1221 (“*Central Hudson* requires FDA to find and present data supporting its claims prior to imposing a burden on commercial speech.”).

<sup>102</sup> *R.J. Reynolds's* misapplication of *Central Hudson* is discussed at length later in this Note. See *infra* subsection III.C.2.

<sup>103</sup> *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 652 n.14 (1985) (citation omitted).

<sup>104</sup> See generally, e.g., ROBERT WOOD JOHNSON FOUND., IMPACT OF MENU LABELING ON CONSUMER BEHAVIOR: A 2008–2012 UPDATE 8 (2013), available at <http://www.rwjf.org/content/dam/farm/reports/reports/2013/rwjf406357>, archived at <http://perma.cc/HKB9-2HYN> (“Menu labeling is only one of many interventions to reduce energy intake and should be viewed in the context of a broader set of strategies.”).

<sup>105</sup> See, e.g., *id.* at 3, 5 (explaining that menu labeling “may have a greater effect on women than men, on higher-calorie items, and among certain types of restaurant chains”).



speaker's First Amendment rights<sup>106</sup> and empowers consumers to make healthier choices without dictating how they should live their lives.<sup>107</sup> This approach should be further supported because many alternatives (e.g., directly limiting the types of foods or portion sizes restaurants can serve) would greatly intrude on individual liberty yet still receive rational basis review—because the freedom to consume whatever food one wants is not a fundamental right. Yet *R.J. Reynolds's* approach would have the interest balancing come out the other way, favoring the commercial speaker over public health whenever the government's interest is something other than preventing deception.

Granted, intuition alone should not be enough to support a disclosure requirement, but the proper guarantor of good regulation is the Administrative Procedure Act, not the First Amendment. *American Meat Institute* recognized the limited role that First Amendment rights should play in challenges to required disclosures of purely factual and uncontroversial information about commercial speakers' products.<sup>108</sup> But despite how *American Meat Institute* extends *Zauderer* beyond disclosure requirements that seek to prevent consumer deception, *R.J. Reynolds* still looms as a formidable obstacle to the viability of graphic cigarette warnings as a successful anti-tobacco regulatory tool. The next Part explores *R.J. Reynolds's* reasoning used to invalidate FDA's nine graphic cigarette warnings, and it provides recommendations for how FDA could propose graphic warnings that would overcome a future First Amendment challenge while still reducing tobacco consumption.

### III. A GRAPHIC CIGARETTE WARNING THAT COULD SURVIVE A FIRST AMENDMENT CHALLENGE

Although the D.C. Circuit has now partially overruled *R.J. Reynolds* and extended *Zauderer* beyond mandates curbing consumer deception, *R.J. Reynolds* still poses a difficult—if arguably surmountable—obstacle to graphic cigarette warnings as an anti-smoking regulatory tool. While challenging, it is possible to create a future graphic warning that would receive rational basis review protection. Moreover, a future court's conclusion that *Central Hudson*, not *Zauderer*, provides the correct level of scrutiny would not be fatal to the graphic warnings: *R.J. Reynolds* arguably misapplied *Central Hudson*, and scientific research conducted post-*R.J.*

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<sup>106</sup> *Zauderer*, 471 U.S. at 651.

<sup>107</sup> See *supra* note 97 and accompanying text.

<sup>108</sup> See *Am. Meat Inst. v. USDA*, 760 F.3d 18, 22 (D.C. Cir. 2014) (en banc) (discussing the “minimal” First Amendment rights at issue).

*Reynolds* provides additional support for graphic warnings' effectiveness in reducing tobacco consumption.

A. *Background: The Family Smoking Prevention and Tobacco Control Act, R.J. Reynolds, and American Meat Institute*

The Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) grants FDA the authority to regulate the manufacture and sale of tobacco products.<sup>109</sup> The Tobacco Control Act makes it illegal to “manufacture, package, sell, offer to sell, distribute, or import” cigarettes without one of nine graphic warnings on the cigarette labels.<sup>110</sup> The required graphic warnings contain two components: a textual warning and an associated graphic image. The Act lists the nine potential textual warnings<sup>111</sup> and directs FDA to “issue regulations that require color graphics depicting the negative health consequences of smoking to accompany the [textual warning] statements.”<sup>112</sup> The graphic warnings are meant to be noticed: they must “comprise the top 50 percent of the front and rear panels” of cigarette packages<sup>113</sup> and must “comprise at least 20 percent of the area” of each cigarette advertisement.<sup>114</sup> In its final rulemaking (the one at issue in *R.J. Reynolds*), FDA selected nine graphic images, as required by the Tobacco Control Act.<sup>115</sup> But FDA then went one step further and required each graphic warning to list the “1-800-QUIT-NOW” tobacco cessation hotline, a measure which it believed was “appropriate for the protection of the public health” in accordance with its authority under § 906(d) of the Federal Food, Drug, and Cosmetic Act (FDCA).<sup>116</sup>

<sup>109</sup> Pub. L. No. 111-31, sec. 101(b), § 901, 123 Stat. 1776, 1786-87 (2009) (codified at 21 U.S.C. § 387a (2012)).

<sup>110</sup> *Id.* sec. 201, § 4(a)(1), (d), 123 Stat. at 1842-43, 1845 (codified at 15 U.S.C. § 1333(a)(1), (d) (2012)).

<sup>111</sup> *Id.* sec. 201, § 4(a)(1), 123 Stat. at 1842-43 (codified at 15 U.S.C. § 1333(a)(1)).

<sup>112</sup> *Id.* sec. 201, § 4(a)(d), 123 Stat. at 1845 (codified at 15 U.S.C. § 1333(d)).

<sup>113</sup> *Id.* sec. 201, § 4(a)(2), 123 Stat. at 1843 (codified at 15 U.S.C. § 1333(a)(2)).

<sup>114</sup> *Id.* sec. 201, § 4(b)(2), 123 Stat. at 1843 (codified at 15 U.S.C. § 1333(b)(2)).

<sup>115</sup> Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,674, 36,753-54 (June 22, 2011) (codified at 12 C.F.R. §§ 1141.10, 1141.12).

<sup>116</sup> *Id.* at 36,680-81, 36,754-55 (codified at 12 C.F.R. § 1141.16); *see also* Family Smoking Prevention and Tobacco Control Act, sec. 101(b), § 906(d), 123 Stat. at 1796-97 (codified at 21 U.S.C. § 387f(d) (2012)) (adding section 906(d) to the FDCA so that “[t]he Secretary [of Health & Human Services] may by regulation require restrictions on the sale and distribution of a tobacco product . . . if the Secretary determines that such regulation would be appropriate for the protection of the public health”).

Although FDA's rulemaking cited research findings from other countries that had implemented similar graphic warning requirements,<sup>117</sup> when tobacco manufacturers brought a First Amendment suit against the rulemaking in the D.C. Circuit, the *R.J. Reynolds* court concluded that FDA had presented insufficient evidence of the warnings' effectiveness to pass *Central Hudson* intermediate scrutiny review.<sup>118</sup> The court thus held that the nine graphic warnings violated tobacco manufacturers' First Amendment rights.<sup>119</sup>

The *R.J. Reynolds* court gave two reasons for applying *Central Hudson* instead of *Zauderer*. First, the court pointed to the Tobacco Control Act's ban on certain advertisement practices and to "the absence of any congressional findings on the misleading nature of cigarette packaging itself" to conclude that cigarette advertisements are not potentially misleading.<sup>120</sup> Second, according to the court, the graphic warnings were not purely factual: "many of the images chosen by FDA could be misinterpreted by consumers" who might think they suggest typical outcomes of smoking, and the images were "primarily intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning."<sup>121</sup> After its defeat in the D.C. Circuit, FDA withdrew its nine graphic warnings and announced its intent to submit revised graphic cigarette warnings.<sup>122</sup>

Two years later in *American Meat Institute*, the D.C. Circuit readdressed *Zauderer*'s scope after a meat industry trade association brought a First Amendment challenge to a USDA regulation requiring meat products to carry labels indicating the country where the animal was born, raised, and slaughtered.<sup>123</sup> The court, sitting en banc, held "that *Zauderer* in fact does reach beyond problems of deception," and overruled *R.J. Reynolds* to the extent that it could be read as limiting *Zauderer* to disclosure requirements aimed at correcting deception.<sup>124</sup> Next, the court applied *Zauderer*, starting with an assessment of the adequacy of the interest motivating the country-of-origin disclosure requirement.<sup>125</sup> The court acknowledged that *Zauderer* "gives little indication of what type of interest might suffice" and noted that the Supreme Court has not clarified whether *Zauderer* would

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<sup>117</sup> *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1209-10 & 1209 n.3 (D.C. Cir. 2012), *overruled in part by* *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

<sup>118</sup> *Id.* at 1217-21; *see also infra* subsection III.C.1 (discussing how the evidence from other countries was weakened by confounding factors).

<sup>119</sup> *R.J. Reynolds*, 696 F.3d at 1222.

<sup>120</sup> *Id.* at 1214-15.

<sup>121</sup> *Id.* at 1216.

<sup>122</sup> *See supra* note 14 and accompanying text.

<sup>123</sup> *Am. Meat Inst. v. USDA*, 760 F.3d 18, 20-21 (D.C. Cir. 2014) (en banc).

<sup>124</sup> *Id.* at 20-23.

<sup>125</sup> *Id.* at 23.

allow government reliance on interests that do not qualify as “substantial” under *Central Hudson*.<sup>126</sup> Ultimately, the court did not decide whether a lesser interest would suffice, because it determined that the interest supporting the country-of-origin labeling requirement was indeed “substantial.”<sup>127</sup>

After its analysis of the relationship between the government’s disclosure requirement and stated interest, the D.C. Circuit went on to explain that the factors triggering *Zauderer* were “either unchallenged or substantially unchallenged.”<sup>128</sup> The required disclosures were clearly factual, and as such they were “directly informative of intrinsic characteristics of the product [the American Meat Institute members are] selling.”<sup>129</sup> Further, the disclosure was not “controversial”: (1) although the word “slaughter” “might convey a certain innuendo,” the regulation allowed retailers to use the unobjectionable term “harvested” instead; and (2) the labeling did not communicate “a message that is controversial for some reason other than dispute about simple factual accuracy”—such as a message “so one-sided or incomplete” that it is not “factual and uncontroversial.”<sup>130</sup> Nor did the requirement force “corporations to carry the messages of third parties, where the messages themselves are biased against or are expressly contrary to the corporation’s views.”<sup>131</sup> Finally, the disclosure was not “so burdensome that it essentially operates as a restriction on constitutionally protected speech.”<sup>132</sup> Accordingly, the D.C. Circuit upheld the USDA country-of-origin disclosure requirements.<sup>133</sup>

### B. *Could a Future Graphic Cigarette Warning Receive Rational Basis Review Protection?*

Now that the D.C. Circuit has extended *Zauderer* beyond mandates curing deception, FDA’s asserted interest in the graphic cigarette warnings (reducing smoking rates) will undoubtedly qualify as an interest adequate to trigger application of the *Zauderer* standard. Although *American Meat Institute* did not decide whether a less-than-“substantial” government

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<sup>126</sup> *Id.*

<sup>127</sup> *Id.* at 23-26.

<sup>128</sup> *Id.* at 27.

<sup>129</sup> *Id.*

<sup>130</sup> *Id.* (internal quotation marks omitted).

<sup>131</sup> *Id.* (quoting *Pac. Gas & Elec. Co. v. Pub. Utils. Comm’n*, 475 U.S. 1, 16 n.12 (1986) (plurality opinion)).

<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

interest would suffice, even *R.J. Reynolds* conceded that reducing smoking rates was a substantial government interest.<sup>134</sup>

*R.J. Reynolds*, however, appeared to make a strong statement against finding any graphic cigarette warning “purely factual and uncontroversial,” and there is little in *American Meat Institute* to temper this analysis.<sup>135</sup> The *R.J. Reynolds* court concluded that FDA’s original nine graphic warnings were not purely factual: “many of the images chosen by FDA could be misinterpreted by consumers” who might think they suggest typical outcomes of smoking, and the images were primarily “intended to evoke an emotional response, or, at most, shock the viewer into retaining the information in the text warning.”<sup>136</sup>

FDA might overcome this significant obstacle (the nonfactual nature of its required warnings) with a two-step strategy: select unenhanced images that clearly and directly depict the associated textual warnings without the need for consumer extrapolation, and then persuade the reviewing court to view *R.J. Reynolds*’s logic as heavily influenced by the particular graphic images before the *R.J. Reynolds* court at the time.

To rebut the D.C. Circuit’s worry about potential misinterpretation, FDA could presumably present evidence that consumers do not actually interpret images like “a man smoking through a tracheotomy hole”<sup>137</sup> as typical outcomes of smoking. In this manner, FDA could overcome the argument that its selected images are easily misinterpreted and thus nonfactual.<sup>138</sup> Better yet, FDA could select images that do not “require[] significant extrapolation on the part of the consumers”<sup>139</sup>—i.e., images that directly

<sup>134</sup> *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1218 (D.C. Cir. 2012), *overruled in part* by *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc); *see also* *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995) (recognizing the government’s substantial interest in “promoting the health, safety, and welfare of its citizens”).

<sup>135</sup> *See supra* notes 128-130 and accompanying text. The D.C. Circuit soon will have the opportunity to clarify the meaning of “purely factual and uncontroversial information.” In the recent case of *National Ass’n of Manufacturers v. SEC*, the court granted SEC’s petition for panel rehearing and ordered the parties to file supplemental briefs addressing multiple questions left unresolved by *Zauderer* and *American Meat Institute*. Order Granting Petition for Panel Rehearing, *Nat’l Ass’n of Mfrs. v. SEC*, No. 13-0635 (D.C. Cir. Nov. 18, 2014). One such question is the meaning of “purely factual and uncontroversial information” as used in *Zauderer* and *American Meat Institute*. *Id.*

<sup>136</sup> *R.J. Reynolds*, 696 F.3d at 1216.

<sup>137</sup> *Id.*

<sup>138</sup> While FDA could add disclaimers (e.g., “smoking through a tracheotomy hole is not a common consequence of smoking”), these disclaimers would defeat the entire purpose of the warnings: the warnings are meant to correct people’s *underestimation* of the risk smoking poses to them personally. *See id.* at 1228 (Rogers, J., dissenting) (noting that “many smokers underestimate their personal risks” (internal quotation marks omitted)).

<sup>139</sup> *Id.* at 1216 (majority opinion).

depict the accompanying textual warnings. Because such images are less prone to misinterpretation, a court will more likely accept them as “purely factual” and therefore worthy of *Zauderer* rational basis review.<sup>140</sup> Further, consumers with lower levels of education are more likely to remember health messages that include graphics directly correlating with accompanying text.<sup>141</sup>

The larger obstacle, however, will be rebutting *R.J. Reynolds*’s concern about FDA’s “tacit admission” that the graphic warnings are “primarily intended to evoke an emotional response” or “shock the viewer into retaining the information in the text warning.”<sup>142</sup> *R.J. Reynolds* drew this “tacit admission” from two assertions in FDA’s brief: (1) research shows “pictures are easier to remember than words” and (2) “emotional responses, such as worry and disgust, reliably predict the likelihood that consumers will understand and appreciate the substance of the warnings.”<sup>143</sup>

A court should not, however, interpret the D.C. Circuit’s language as holding that all images are inherently beyond *Zauderer*’s scope. FDA’s graphic images may be “a much different animal” than the mandates at issue in *Zauderer* and *Milavetz*,<sup>144</sup> but “*Zauderer* itself eviscerates the argument that a picture or drawing cannot be accurate and factual.”<sup>145</sup> As the Sixth Circuit explained in its analysis upholding the constitutionality of the Tobacco Control Act in *Discount Tobacco City & Lottery, Inc. v. United States*, the *Zauderer* Court rejected the argument that illustrations by attorneys create “unacceptable risks that the public will be misled, manipulated, or confused,” and noted the important communicative functions of pictures: they attract the attention of the audience and impart information directly.<sup>146</sup> If the Supreme Court in *Zauderer* pointed to pictures’ informative function as a reason to grant First Amendment protection to images in commercial

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<sup>140</sup> See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985) (endorsing rational basis review of government-mandated disclosures involving “purely factual and uncontroversial information”).

<sup>141</sup> See generally Julie C. LaVille, Note, *A Warning Worth a Thousand Words: First Amendment Challenges to the FDA’s Graphic Warning Label Requirements*, 58 ST. LOUIS U. L.J. 243, 262 (2013) (explaining how textual warnings “require a college reading level” and graphic warnings would facilitate comprehension by individuals across educational levels (internal quotation marks omitted)).

<sup>142</sup> *R.J. Reynolds*, 696 F.3d at 1216.

<sup>143</sup> *Id.* (citations and internal quotation marks omitted).

<sup>144</sup> *Id.*

<sup>145</sup> *Disc. Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 560 (6th Cir. 2012), cert. denied sub nom *Am. Snuff Co. v. United States*, 133 S. Ct. 1996 (2013).

<sup>146</sup> *Id.* (quoting *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 648 (1985)).

speech, then the use of graphics in cigarette warnings to impart health risk information effectively should not bar rational basis review protection.

As for the *R.J. Reynolds* court's contention that images evoking negative emotional responses are nonfactual, FDA can make a good case that a future court should abandon this reasoning. As the *R.J. Reynolds* dissent astutely noted, the *R.J. Reynolds* argument "leads to the counterintuitive conclusion that the more concerning the negative health effects of a particular product, the more constrained the government is in mandating disclosures of those facts."<sup>147</sup> The reasoning of *Discount Tobacco* is equally persuasive:

Facts can disconcert, displease, provoke an emotional response, spark controversy, and even overwhelm reason, but that does not magically turn such facts into opinions. . . . [W]hether a disclosure is scrutinized under *Zauderer* turns on whether the disclosure conveys factual information or an opinion, not on whether the disclosure emotionally affects its audience or incites controversy.<sup>148</sup>

Further, this reasoning is consistent with *American Meat Institute's* inquiry into whether the required country-of-origin labels were "biased against or . . . expressly contrary to the corporation's views" (because only an affirmative answer would merit heightened scrutiny) and with its characterization of "slaughter" as "a plain, blunt word for a plain, blunt action" (providing an accurate statement of fact, and thus meriting rational basis review).<sup>149</sup>

If a future court is unwilling to abandon *R.J. Reynolds's* reasoning altogether, FDA can still argue that the court's strong statements were specific to the particular images before it, and it may be able to escape *R.J. Reynolds* by selecting images that convey health warning information without reference to their associated textual warnings.

The *R.J. Reynolds* court was particularly bothered by three of FDA's selected images: the crying woman, the small child surrounded by a cloud of smoke, and the man wearing a t-shirt bearing the words "I QUIT."<sup>150</sup>

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<sup>147</sup> *R.J. Reynolds*, 696 F.3d at 1231 (Rogers, J., dissenting).

<sup>148</sup> *Disc. Tobacco*, 674 F.3d at 569.

<sup>149</sup> *Am. Meat Inst. v. USDA*, 760 F.3d 18, 27 (D.C. Cir. 2014) (en banc) (quoting *Pac. Gas & Elec. Co. v. Pub. Utils. Comm'n*, 475 U.S. 1, 16 n.12 (1986) (plurality opinion)). The court, however, did acknowledge that "slaughter" "might convey a certain innuendo," but because the rule allowed retailers to use the term "harvested" instead, the court found "no claim" that the disclosure requirement was "controversial in that sense." *Id.*

<sup>150</sup> *R.J. Reynolds*, 696 F.3d at 1216-17 (majority opinion). These images accompanied the following textual statements: (1) "WARNING: Tobacco smoke causes fatal lung disease in nonsmokers" (crying woman); (2) "WARNING: TOBACCO SMOKE CAN HARM YOUR CHILDREN" (small child); and (3) "WARNING: Quitting smoking now greatly reduces serious risks to your health" (man with "I QUIT" t-shirt). See John D. Kraemer & Sabeeh A. Baig, *Analysis of Legal and*

According to the court, these “inflammatory images” do not convey any warning information, “cannot rationally be viewed as pure attempts to convey information to consumers,” and are “unabashed attempts to evoke emotion (and perhaps embarrassment) and browbeat consumers into quitting.”<sup>151</sup>

Figure 1: FDA’s Proposed Graphic Warnings<sup>152</sup>



FDA certainly should abandon the image of the man with the “I QUIT” t-shirt because it does not “depict[] the negative health consequences of smoking” as required by the Tobacco Control Act.<sup>153</sup> And although the images of the crying woman and small child arguably communicate the negative consequences of smoking when the graphic warnings are considered together with their associated textual statements, the link between the images and the textual statements is attenuated. It takes an inferential leap to understand that the woman is crying because either she or a loved one has fatal lung disease, and it takes a similar inferential leap to understand

*Scientific Issues in Court Challenges to Graphic Tobacco Warnings*, 45 AM. J. PREVENTIVE MED. 334, 335 fig.1 (2013); see also *infra* Figure 1 (reproducing the complete set of nine graphic warnings proposed by FDA before *R.J. Reynolds*).

<sup>151</sup> *R.J. Reynolds*, 696 F.3d at 1216-17.

<sup>152</sup> Kraemer & Baig, *supra* note 150, at 335 fig.1.

<sup>153</sup> Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, sec. 201, § 4(d), 123 Stat. 1776, 1845 (2009) (codified at 15 U.S.C. § 1333(d) (2012)).



that the small child might be harmed by the smoke in the image. When viewed in isolation, these images do not convey warning information and therefore suffer from a substantial flaw, given that FDA's rulemaking noted the importance of using images to effectively communicate information to people with poor English or literacy skills.<sup>154</sup>

FDA should choose unenhanced images that clearly, directly, and independently depict the health warning information conveyed in the warning's textual statement. These warnings should, in the words of *American Meat Institute*, be "directly informative of intrinsic characteristics of the product."<sup>155</sup> In this manner, FDA may be able to rebut both reasons the *R.J. Reynolds* court provided for concluding that the graphic cigarette warnings were nonfactual and did not merit *Zauderer* rational basis review (potential consumer misinterpretation, and undue focus on an emotional response).<sup>156</sup>

### C. Satisfying Central Hudson

Even if FDA selects images that clearly, directly, and independently depict the negative health consequences of smoking, a court following *R.J. Reynolds* might still conclude that the warnings are *beyond Zauderer's* scope. This conclusion need not be a fatal blow to the revised graphic warnings, however, because *R.J. Reynolds* misapplied *Central Hudson's* intermediate scrutiny test. Also, there are good arguments for applying a more relaxed version of *Central Hudson* to graphic warnings aimed at reducing the number one cause of preventable death in the United States. Finally, recent

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<sup>154</sup> Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,709 (June 22, 2011).

<sup>155</sup> *Am. Meat Inst. v. USDA*, 760 F.3d 18, 27 (D.C. Cir. 2014) (en banc).

<sup>156</sup> The *R.J. Reynolds* majority dedicated surprisingly little space to assessing the requirement that cigarette labels include the "1-800-QUIT-NOW" number. It simply said that the number "hardly sounds like an unbiased source of information," given the lack of accompanying explanation about the services provided on the hotline. *R.J. Reynolds*, 696 F.3d at 1216.

The dissent, however, dedicated considerably more space to the constitutionality of the hotline number but nonetheless concluded that it could not pass *Central Hudson* intermediate scrutiny. *Id.* at 1236-37 (Rogers, J., dissenting). Judge Rogers reasoned that, although the hotline number's inclusion on the package directly served the substantial government interest in "assist[ing] smokers in their cessation efforts," less speech-restrictive means of achieving this goal existed and were inadequately addressed by FDA. *Id.*

Given that the Tobacco Control Act does not actually require inclusion of the hotline number, *see supra* note 116 and accompanying text, FDA should seriously consider how this additional requirement might influence a court's overall inquiry into the factual, unbiased, nonideological nature of the entire graphic warning. Similarly, FDA should consider whether equally effective but less speech-restrictive means exist to increase consumer awareness of cessation resources. *See, e.g., id.* at 1236 (suggesting a package insert as an alternative).

research efforts provide promising scientific evidence of graphic warnings' ability to reduce tobacco consumption.

### 1. The Lack of Evidence Presented in *R.J. Reynolds*

*R.J. Reynolds* found FDA's evidence supporting its claim that there was an "international consensus' surrounding the effectiveness of large graphic warnings" to be woefully inadequate.<sup>157</sup> The D.C. Circuit noted that the Australian and Canadian studies FDA cited showed only that graphic warnings caused people to think about quitting smoking or to attempt to quit; the studies did not "show that the implementation of large graphic warnings has *actually* led to a reduction in smoking rates."<sup>158</sup>

When FDA did present evidence from countries that introduced graphic cigarette warnings and saw an actual reduction in smoking rates, *R.J. Reynolds* discounted FDA's evidence by pointing to confounding factors. The D.C. Circuit characterized the causal link between Canada's graphic warning requirement and decreased smoking rates in the years following their implementation as "mere speculation and conjecture" because the Canadian government also implemented other smoking control initiatives (e.g., increased cigarette taxes and further restrictions on public smoking) during this period.<sup>159</sup> FDA did not help matters by conceding in its proposed rulemaking that it could not directly attribute any decrease in the Canadian smoking rate to graphic warnings.<sup>160</sup>

Finally, the *R.J. Reynolds* court pointed to the Regulatory Impact Analysis accompanying FDA's final regulation, which estimated that graphic warnings would reduce U.S. smoking rates by a mere 0.088%.<sup>161</sup> To the court, this paltry statistic was yet another factor showing FDA's failure "to present any data" proving the regulation would directly advance its goal.<sup>162</sup> But the court failed to mention FDA's reference to a Canadian study of young smokers, where 22.6% of males and 26.6% of females reported that graphic cigarette warnings caused them not to have a cigarette in the past month.<sup>163</sup> While restricting is not the same as quitting, evidence that an individual

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<sup>157</sup> *Id.* at 1219 (majority opinion).

<sup>158</sup> *Id.*

<sup>159</sup> *Id.* (quoting *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995)).

<sup>160</sup> *Id.*

<sup>161</sup> *Id.* at 1220 (citing Required Warnings for Cigarette Packages and Advertisements, 76 Fed. Reg. 36,628, 36,721 (June 22, 2011)).

<sup>162</sup> *Id.* at 1220-22.

<sup>163</sup> Required Warnings for Cigarette Packages and Advertisements, 75 Fed. Reg. 69,524, 69,532 (proposed Nov. 12, 2010).

reduced his cigarette consumption would certainly seem relevant to FDA's goal to reduce tobacco consumption.<sup>164</sup> Nonetheless, the *R.J. Reynolds* court concluded that FDA failed to present requisite evidence to show the graphic warnings directly advanced FDA's government interest.<sup>165</sup> The court thus did not reach the third prong of *Central Hudson*, which asks whether the speech regulation is narrowly tailored to achieve the governmental interest.<sup>166</sup>

## 2. *R.J. Reynolds* Demanded Too Much

Although *R.J. Reynolds* correctly questioned the sufficiency of FDA's evidence, the court applied a stricter standard than necessary under the "directly advance" prong of *Central Hudson*.<sup>167</sup> The court quoted several Supreme Court cases to establish that FDA had to do more than provide "only ineffective or remote support" for its methods and that FDA could not "satisfy its burden by mere speculation or conjecture."<sup>168</sup>

The D.C. Circuit did not, however, use any case law to clarify exactly what level of evidence was actually necessary to satisfy *Central Hudson*.<sup>169</sup> Instead, the court misapplied the APA's "substantial evidence" standard to its First Amendment analysis.<sup>170</sup> In doing so, the court failed to appreciate the considerable distance between "mere speculation or conjecture" and the unattainable standard it set: the requirement of airtight evidence that a

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<sup>164</sup> See generally Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, sec. 101(b), § 906(d), 123 Stat. 1776, 1796-97 (2009) (codified at 21 U.S.C. § 387f(d) (2012)) (granting FDA discretion to promulgate regulations to protect the public health, with special consideration given to whether the regulations will result in "increased . . . likelihood that existing users of tobacco will stop using such products").

<sup>165</sup> *R.J. Reynolds*, 696 F.3d at 1222.

<sup>166</sup> *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564-65 (1980) (requiring speech restrictions to be "narrowly drawn" (internal quotation marks omitted)).

<sup>167</sup> See *id.* at 566 ("[W]e must determine whether the regulation directly advances the governmental interest asserted.")

<sup>168</sup> See *R.J. Reynolds*, 696 F.3d at 1218-19 (quoting *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995), and *Edenfield v. Fane*, 507 U.S. 761, 770 (1993)).

<sup>169</sup> *Id.* at 1217-21.

<sup>170</sup> The court noted that the APA requires it to "hold unlawful and set aside agency action, findings, and conclusions found to be . . . unsupported by substantial evidence," and it then grafted the APA's "substantial evidence" requirement on to *Central Hudson*'s "directly advance" prong. *Id.* at 1218 (quoting 5 U.S.C. § 706(2)(E) (2012)); *id.* at 1219-22.

As an initial matter, 5 U.S.C. § 706(2)(E), the APA's "substantial evidence" test, is a separate challenge to an agency's formal rulemaking or adjudication. RICHARD J. PIERCE, JR., ET AL., *ADMINISTRATIVE LAW AND PROCESS* 321 (6th ed. 2014). It has nothing to do with a First Amendment challenge. Moreover, the APA's "substantial evidence test accords considerable deference to agency findings of fact." *Id.* at 322.

graphic warning by itself will “directly cause[] a material decrease in smoking rates.”<sup>171</sup>

*Central Hudson* has been criticized for being “difficult to apply in a consistent and predictable manner,” and courts disagree about the level of protection that it affords commercial speech.<sup>172</sup> Compounding the uncertainty, the Court has used *Central Hudson* almost exclusively for commercial speech restrictions, but its recent *Central Hudson* analysis in *Sorrell v. IMS Health* (a 2011 case involving a commercial speech restriction for pharmaceutical companies that was intended to promote public health) muddied the water by blurring the line between commercial and core First Amendment speech.<sup>173</sup> The Supreme Court cases most directly on point exemplify the Court’s inconsistent application of *Central Hudson*: *Lorillard Tobacco Co. v. Reilly* struck down Massachusetts regulations prohibiting any smokeless tobacco or cigar advertising within one thousand feet of schools or playgrounds, despite the Massachusetts Attorney General’s “ample documentation of the problem with underage use of smokeless tobacco and cigars.”<sup>174</sup> In contrast, the plurality opinion of *44 Liquormart, Inc. v. Rhode Island* invalidated Rhode Island’s ban on advertising the price of alcoholic beverages but was far less accepting of evidence produced by the state.<sup>175</sup>

Although *Lorillard* ultimately held that Massachusetts’s tobacco advertising ban violated tobacco manufacturers’ First Amendment rights, the Supreme Court concluded that the state had produced sufficient evidence showing the restriction directly advanced its goal of preventing underage tobacco use.<sup>176</sup> Massachusetts supported its position with evidence linking tobacco advertising practices to underage tobacco use.<sup>177</sup> It pointed to studies and

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<sup>171</sup> *R.J. Reynolds*, 696 F.3d at 1219 (emphasis omitted).

<sup>172</sup> Keighley, *supra* note 95, at 565 & n.129 (citing Alex Kozinski & Stuart Banner, *Who’s Afraid of Commercial Speech?*, 76 VA. L. REV. 627, 630-31 (1990), and Robert Post, *The Constitutional Status of Commercial Speech*, 48 UCLA L. REV. 1, 42 (2000)).

<sup>173</sup> See *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2664-68 (2011). The Court’s analysis in *Thompson v. Western States Medical Center* (another case about a commercial speech restriction for pharmaceutical companies intended to promote public health) was far more faithful to *Central Hudson*, but it was no more instructive on the “directly advance” prong of *Central Hudson*. See 535 U.S. 357, 370-77 (2002). The Court struck down the law’s prohibition on advertising compounded drugs because the speech restriction was more extensive than necessary, even while assuming it might indeed directly advance the government’s interests. *Id.* at 371.

<sup>174</sup> 533 U.S. 525, 561 (2001).

<sup>175</sup> 517 U.S. 484, 505-08 (1996) (plurality opinion).

<sup>176</sup> *Lorillard*, 533 U.S. at 556-561. The advertising restriction failed the final prong of *Central Hudson* because Massachusetts did not show its restriction was no more extensive than necessary. *Id.* at 561-66.

<sup>177</sup> *Id.* at 557-60.

Supreme Court precedent supporting the theory that advertising stimulates demand, while suppressing advertisements may have the opposite effect.<sup>178</sup> Massachusetts also pointed to FDA findings that an overwhelming majority of Americans start using tobacco products prior to adulthood and that advertising plays a crucial role in these decisions.<sup>179</sup> In addition, Massachusetts's evidence included reports by the Surgeon General and Institute of Medicine finding "sufficient evidence to conclude that advertising and labeling play a significant and important contributory role in a young person's decision to use cigarettes or smokeless tobacco products."<sup>180</sup> The state also cited evidence documenting smokeless tobacco sales, advertising techniques targeting youth, an attendant increase in younger smokeless tobacco users, and the link between advertising and demand for cigars.<sup>181</sup> Notably, *Lorillard* did not require Massachusetts to provide any evidence showing that restrictions on tobacco advertisements actually prevented underage tobacco use.<sup>182</sup> Rather, all the state had to show was that tobacco advertisements were partially responsible for the youth tobacco use problem.<sup>183</sup>

The 44 *Liquormart* plurality opinion, on the other hand, demanded considerably more from Rhode Island to support its ban on advertising the price of alcoholic beverages. In a portion of the opinion joined only by Justices Kennedy, Souter, and Ginsburg, Justice Stevens concluded that the price advertising ban failed *Central Hudson* because the state provided no evidentiary support whatsoever to show its ban would significantly advance its interest in reducing alcohol consumption.<sup>184</sup> Although Rhode Island presented evidence that the price advertising ban might have "some impact on the purchasing patterns of temperate drinkers of modest means," Justice Stevens found this evidence insufficient.<sup>185</sup> The state, he noted, had "presented no evidence to suggest that its speech prohibition w[ould] significantly

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<sup>178</sup> *Id.* at 557.

<sup>179</sup> *Id.* at 557-58.

<sup>180</sup> *Id.* at 558 (internal quotation marks omitted). The data showed that (1) children smoke fewer cigarette brands than adults, and tend to choose more heavily advertised brands; (2) the majority of children recognize Joe Camel, and after his introduction, Camel's share of the youth market rose from 4% to 13%; and (3) trends in tobacco consumption in a certain population correlate with the introduction and marketing of products to that population. *Id.* at 558-59.

<sup>181</sup> *Id.* at 559-61.

<sup>182</sup> *See id.* at 556-61.

<sup>183</sup> *See id.* at 561 (finding that Massachusetts's evidence was sufficient because the Court was "unable to conclude that the Attorney General's decision to regulate advertising of smokeless tobacco and cigars . . . was based on mere speculation and conjecture" (internal quotation marks omitted)).

<sup>184</sup> 44 *Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 505 (1996) (plurality opinion).

<sup>185</sup> *Id.* at 506.

reduce marketwide consumption.”<sup>186</sup> Justice Stevens seemed to require evidence showing that the ban would reduce alcohol consumption among all groups; he emphasized “the evidence suggest[ed] that the abusive drinker will probably not be deterred by a marginal price increase, and that the true alcoholic may simply reduce his purchases of other necessities.”<sup>187</sup>

A court evaluating the inevitable First Amendment challenge to FDA’s revised graphic cigarette warnings should look to the Court’s analysis in *Lorillard* for guidance rather than to the comparable analysis in *44 Liquormart*. In *44 Liquormart*, the link between Rhode Island’s speech restriction and its goal of reducing alcohol consumption was attenuated. The success of Rhode Island’s speech ban hinged on assumptions about the economic decisionmaking process and behavior of two distinct groups: alcohol manufacturers and consumers. Rhode Island’s price advertising ban was intended to prevent alcohol manufacturers from competing on the basis of price—which in theory would keep alcohol prices higher, thereby reducing demand (and consumption) across all alcohol consumer groups.<sup>188</sup> The logic behind FDA’s graphic cigarette warnings is more direct: as in *Lorillard*, the regulations involve presumptions about how information (about the health risks or pleasures of tobacco products) influences consumers’ decision to smoke. According to FDA, given the ample evidence that smokers (especially adolescents) smoke in part because they underestimate the personal health risks of smoking, closing the information gap with graphic warnings will motivate and empower smokers to quit, thereby decreasing tobacco consumption.<sup>189</sup> The link between the regulation and the intended effect involves just one intermediary (consumers), instead of two (manufacturers and consumers). *44 Liquormart*’s analysis should not apply to graphic cigarette warnings.

Further, even if FDA’s graphic cigarette warnings failed to materially decrease tobacco consumption, the means through which FDA hoped to achieve this goal (informing consumers of the health risks of smoking) served an independently important government interest;<sup>190</sup> the speech

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<sup>186</sup> *Id.*

<sup>187</sup> *Id.*

<sup>188</sup> *Id.* at 505.

<sup>189</sup> *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1209 (D.C. Cir. 2012), *overruled in part* by *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

<sup>190</sup> This statement does not mean to contend that promoting consumer knowledge of smoking risks alone is enough to satisfy *Central Hudson*, a position adopted (and overstated) by the *R.J. Reynolds* dissent. See *id.* at 1235-36 (Rogers, J., dissenting) (“The government’s informational interest in effectively conveying the negative health consequences of smoking clearly qualifies as ‘substantial’ under the second prong of *Central Hudson*.”). Judge Rogers cited *Edenfield v. Fane* for

restriction in *44 Liquormart* did not. While FDA's graphic cigarette warnings are designed to curb smoking by giving consumers more information, Rhode Island's alcohol price advertising ban sought to achieve its goal by keeping consumers in the dark. The Court in *44 Liquormart* emphasized several times that it was important to apply a demanding review because Rhode Island was *restricting* accurate commercial information.<sup>191</sup> Even if a court applies *Central Hudson* because it determines that the graphic cigarette warnings are not the "purely factual and uncontroversial" disclosures to which *Zauderer* applies, the warnings still promote—rather than block—the flow of factual information.<sup>192</sup> A commercial speaker—whose speech is protected in the first place because of the information it provides to consumers<sup>193</sup>—is more burdened by a speech restriction than by a mandate to disclose accurate (albeit emotionally evocative) information about its product.<sup>194</sup>

Most importantly, smoking, the public health problem both *Lorillard* and FDA's graphic cigarette warnings seek to attack, is the number one

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the proposition that "there is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial." *Id.* at 1235 (quoting *Edenfield v. Fane*, 507 U.S. 761, 769 (1993)). But *Edenfield* recognized a substantial state interest in ensuring the accuracy of commercial information *already* in the marketplace, not in injecting additional accurate information into the marketplace—especially where there is insufficient evidence that the existing information is inaccurate. *Edenfield*, 507 U.S. at 768-69. Moreover, if a court applying *Central Hudson* has already determined that the mandate is not "purely factual and accurate," using an "information interest" to satisfy *Central Hudson*—a considerably easier task than showing the mandate reduces smoking rates—appears to be an end-run around First Amendment requirements.

<sup>191</sup> See *44 Liquormart*, 517 U.S. at 499, 501 (explaining that "the State retains less regulatory authority when its commercial speech restrictions strike at the substance of the information communicated" and "complete speech bans . . . are particularly dangerous because they foreclose alternative means of disseminating certain information" (internal quotation marks omitted)).

<sup>192</sup> See *R.J. Reynolds*, 696 F.3d at 1229 (Rogers, J., dissenting) ("The tobacco companies do not challenge the factual accuracy of the textual statements included in the warning labels.").

<sup>193</sup> See *supra* notes 28-31 and accompanying text.

<sup>194</sup> Tobacco manufacturers argued that the message of the graphic warnings was "ideological and not informational" because the images "shame and repulse smokers and denigrate smoking as an antisocial act." *R.J. Reynolds*, 696 F.3d at 1211 (majority opinion). While FDA's warnings do contain disturbing images that accurately depict the gruesome consequences of smoking, see *supra* Figure 1, the images do not make the warnings any more "ideological" than the textual warnings tobacco manufacturers accepted as accurate; the images simply make the warnings more likely to be noticed and remembered. Although it can be argued that FDA's graphic warnings use cigarette packages to promote "the government's anti-smoking message," *R.J. Reynolds*, 696 F.3d at 1212, the same can be said of the textual warnings that have been on cigarettes for the past five decades. See *supra* note 4 and accompanying text. And it is beside the point that the graphic images undermine the manufacturers' "own economic interest," *R.J. Reynolds*, 696 F.3d at 1212: the disclosure requirement approved in *Zauderer*, which lessened the appeal of attorneys' contingency-fee rates, did as well. See *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626, 633, 650-63 (1985) (upholding a state rule requiring the attorneys' contingent-fee advertisements to disclose "whether percentages are computed before or after deduction of court costs and expenses" (internal quotation marks omitted)).

preventable cause of death in the United States.<sup>195</sup> It kills approximately 443,000 Americans each year.<sup>196</sup> The Supreme Court has stated that smoking poses “perhaps the single most significant threat to public health in the United States.”<sup>197</sup> Smoking is a serious public health problem because nicotine is highly addictive<sup>198</sup> and because, for decades, cigarette manufacturers lured smokers in at a young age before they could fully appreciate the health consequences of this highly addictive habit.<sup>199</sup> Substantial evidence exists showing a persistent information gap, particularly among adolescents.<sup>200</sup> People underestimate the personal health risks of smoking, fail to appreciate the highly addictive nature of cigarettes, and remain ignorant about the harmful effects of secondhand smoke on others.<sup>201</sup>

Because smoking is a public health problem of such great magnitude and importance, involves a highly addictive product, and carries with it great harms that consumers still fail to fully appreciate, courts should apply a relaxed version of *Central Hudson* when evaluating a graphic warning that accurately depicts smoking’s health consequences. The government should not have to prove that a disclosure requirement *alone* would significantly reduce marketwide tobacco consumption. It certainly should not be required to provide evidence that the graphic warning will significantly reduce tobacco consumption among those with greatest dependency on this highly addictive product, as *44 Liquormart* suggests.<sup>202</sup> To demand proof before implementation that a graphic cigarette warning significantly reduces

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<sup>195</sup> See Kraemer & Baig, *supra* note 150, at 334 (warning that smoking causes more U.S. deaths per year “than any other modifiable risk factor”).

<sup>196</sup> *Id.*

<sup>197</sup> FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 161 (2000).

<sup>198</sup> See OFFICE OF SMOKING & HEALTH, U.S. DEP’T OF HEALTH & HUMAN SERVS., DHHS PUB. NO. (CDC) 88-8406, THE HEALTH CONSEQUENCES OF SMOKING: NICOTINE ADDICTION 149 (1988) (“Basic observations and experimental research indicate that cigarette smoking is not a random or capricious behavior that simply occurs at the will of those who smoke. Rather, smoking is the result of behavioral and pharmacologic factors that lead to highly controlled or compulsive use of cigarettes.”).

<sup>199</sup> See Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44,396, 44,398 (Aug. 28, 1996) (“Most people who suffer the adverse health consequences of using cigarettes and smokeless tobacco begin their use before they reach the age of 18, an age when they are not prepared for, or equipped to, make a decision that, for many, will have lifelong consequences.”).

<sup>200</sup> See R.J. Reynolds Tobacco Corp. v. FDA, 696 F.3d 1205, 1228 (D.C. Cir. 2012) (Rogers, J., dissenting) (“[A]dolescents in particular fail to appreciate the highly addictive nature of cigarettes.”), *overruled in part by* Am. Meat Inst. v. USDA, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

<sup>201</sup> *Id.*

<sup>202</sup> See *supra* note 187 and accompanying text.



smoking rates<sup>203</sup> is not only unfeasible but also contrary to the government's interest in promoting public health.<sup>204</sup>

Instead, it should be sufficient for FDA to provide evidence that the graphic warnings are *likely* to encourage a significant number of smokers to reduce their cigarette consumption. If FDA can provide evidence that smokers who are better informed of smoking's health risks and have an increased desire to quit<sup>205</sup> are more likely to successfully quit (or reduce their cigarette consumption), then FDA's graphic warnings should be able to pass judicial scrutiny. FDA should thus be able to satisfy any First Amendment burdens with rigorous scientific studies showing that the graphic warnings increase consumers' knowledge of the health consequences of smoking and strengthen their desire to quit. This information could be supplemented with data from other countries showing a decrease in smoking rates after the implementation of similar graphic warning labels (even if other anti-smoking initiatives were advanced at the same time).<sup>206</sup>

Even if graphic cigarette warnings might be effective only in conjunction with other regulatory efforts to reduce smoking rates, that fact should not be an obstacle to satisfying *Central Hudson*. Given the severity of the smoking problem, legislative and regulatory bodies certainly should be using additional smoking control initiatives (e.g., increased cigarette taxes and further restrictions on public smoking) to reduce tobacco consumption. If the courts interpret *Central Hudson* to demand an evidentiary standard that is *harder* to satisfy when a legislature attacks a problem through multiple channels, the resulting regime disadvantages regulators seeking to alleviate complex problems. Such a regime poses a particular problem for public health law and especially for tobacco control, where a multifaceted approach involving multiple public health strategies and regulatory initiatives is often necessary.<sup>207</sup>

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<sup>203</sup> See *R.J. Reynolds*, 696 F.3d at 1221 (majority opinion) ("*Central Hudson* requires FDA to find and present data supporting its claims *prior to* imposing a burden on commercial speech.>").

<sup>204</sup> See generally 21 U.S.C. § 387f(d) (2012) (emphasizing FDA's discretion to promulgate regulations as "appropriate for the protection of the public health").

<sup>205</sup> See *R.J. Reynolds*, 696 F.3d at 1219 (discussing FDA's existing evidence showing that graphic warnings increase smokers' thoughts of quitting and attempts to quit).

<sup>206</sup> *Contra id.* (dismissing FDA's argument that the Canadian smoking rate decreased after graphic warnings were introduced in Canada, "because the Canadian government implemented other smoking control initiatives" concurrently).

<sup>207</sup> See generally Corinne G. Husten & Lawrence R. Deyton, *Understanding the Tobacco Control Act: Efforts by the U.S. Food and Drug Administration to Make Tobacco Morbidity and Mortality Part of the USA's Past, Not Its Future*, 381 LANCET 1570, 1578 (2013) ("It is only with the full implementation of both traditional public health strategies and new regulatory authorities that we will ensure that tobacco-related morbidity and mortality is part of the USA's past, not its future.>").

More specifically, as long as FDA can provide evidence that graphic warnings close the information gap and that consumers equipped with better information are more likely to reduce or eliminate their tobacco consumption, FDA should be able to rely on the evidence of the association between Canada's implementation of a graphic warning requirement and decreased Canadian smoking rates in the following years.<sup>208</sup> Given the Supreme Court's analysis in *Lorillard*, this level of evidence surely satisfies the government's burden of providing more than "mere speculation or conjecture."<sup>209</sup>

Further, the Supreme Court has appeared to be principally concerned about speech restrictions at odds with other regulations (i.e., an inconsistent and irrational regulatory regime that cuts against the state's asserted interest), rather than about informative disclosure requirements that work in conjunction with other regulations to achieve the state's important and ambitious goal (e.g., future FDA-mandated graphic cigarette warnings). This rationale undergirds *Rubin v. Coors Brewing Co.*, where the Supreme Court sustained an alcohol manufacturer's First Amendment challenge to the Federal Alcohol Administration Act (FAAA).<sup>210</sup> The Court took issue with the FAAA regulations because the statute prohibited disclosure of alcohol content on product labels *unless* disclosure was required by state law—but FAAA regulations prohibited these disclosures *only if* affirmatively prohibited by state law.<sup>211</sup> This "overall irrationality"—*not* the government's claim that the FAAA reduced pressure to market beer on the basis of alcohol content, thereby lowering beer alcohol levels—was FAAA's fatal flaw.<sup>212</sup>

When it comes to factual disclosure requirements, courts should move away from the standard set by *R.J. Reynolds*, where more complex problems and more ambitious government goals make it harder for a government-mandated disclosure requirement to pass constitutional muster. As shown in this subsection, a court may stray from *R.J. Reynolds*'s overly strict application of *Central Hudson* without breaking from Supreme Court precedent. Although the evidence before *R.J. Reynolds* would not have been

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<sup>208</sup> See *R.J. Reynolds*, 696 F.3d at 1219 ("In 2001, the year the warnings were introduced, the [Canadian] smoking rate dropped [from 24 percent] to 22 percent, and it further dropped to 21 percent in 2002.").

<sup>209</sup> *R.J. Reynolds*, 696 F.3d at 1219 (quoting *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995)); see also *supra* notes 174, 176-183 and accompanying text (discussing the Supreme Court's more lenient evidentiary standard in *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001)).

<sup>210</sup> *Rubin*, 514 U.S. at 478.

<sup>211</sup> *Id.* at 488.

<sup>212</sup> *Id.*

enough to satisfy the standard advocated here, researchers continue to build a strong scientific body of evidence showing that graphic cigarette warnings are likely to reduce tobacco consumption.

### 3. New Evidence

In the wake of the *R.J. Reynolds* decision, FDA and the National Institutes of Health (NIH) created fourteen Tobacco Centers of Regulatory Science.<sup>213</sup> Billed as “first-of-kind,” these regulatory centers are designed to “generate research to inform the regulation of tobacco products to protect public health”<sup>214</sup> and to “ensure that U.S. tobacco regulatory actions and activities are based on sound and relevant scientific evidence”<sup>215</sup>—a mission that heeds *R.J. Reynolds*’s warning. NIH’s Tobacco Centers Research Portfolio page reveals promising studies that could provide the necessary proof of graphic warnings’ effectiveness.<sup>216</sup> One study will expose participating smokers to different warning labels (graphic versus standard text) and monitor their smoking behavior and cigarette risk beliefs over fifty days.<sup>217</sup> Another looks at whether ingredient labels on cigarette packages “alter cessation behavior,” and at which labels “most effectively increase adult smokers’ cessation behaviors (quitting, attempting to quit, or smoking fewer cigarettes),” especially among minority populations.<sup>218</sup> Still another will focus on adolescents and young adults, identifying how pro- and anti-tobacco media and warning labels “influence perceptions of risks, benefits, acceptability, and subsequent tobacco use.”<sup>219</sup> *R.J. Reynolds* criticized FDA for its heavy reliance on evidence that graphic warnings increased smokers’ desire to

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<sup>213</sup> *FDA and NIH Create First-of-Kind Tobacco Centers of Regulatory Science*, NAT’L INSTS. OF HEALTH (Sept. 19, 2013, 12:30 PM), <http://www.nih.gov/news/health/sep2013/od-19.htm>, archived at <http://perma.cc/SVC4-ZN3M>.

<sup>214</sup> *Id.*

<sup>215</sup> *Centers Research Portfolio*, NAT’L INSTS. OF HEALTH, <https://prevention.nih.gov/tobacco-regulatory-science-program/research-portfolio/centers> (last updated Mar. 26, 2014), archived at <http://perma.cc/QH4Q-ZJLS>.

<sup>216</sup> *See id.* (listing studies investigating topics such as “Informing and Correcting Perceptions Regarding Tobacco Products in Young Adults” and “Communicating the Risks of Harmful Cigarette Smoke Constituents”).

<sup>217</sup> Andrew A. Strasser, *Abstract: Tobacco Product Messaging in a Complex Communication Environment*, NAT’L INSTS. OF HEALTH, <https://prevention.nih.gov/docs/trsp/rfa-da-13-003/webinar/strasser.pdf> (last visited Dec. 16, 2014), archived at <http://perma.cc/Y5PY-XGHM>.

<sup>218</sup> Noel T. Brewer, *Abstract: Effective Communication on Tobacco Product Risk and FDA Authority*, NAT’L INSTS. OF HEALTH, <https://prevention.nih.gov/docs/trsp/rfa-da-13-003/webinar/brewer.pdf> (last visited Dec. 16, 2014), archived at <http://perma.cc/4LJJ-KQAF>.

<sup>219</sup> Pamela Ling, *Abstract: Improved Models to Inform Tobacco Product Regulation*, NAT’L INSTS. OF HEALTH, <https://prevention.nih.gov/docs/trsp/rfa-da-13-003/webinar/ling.pdf> (last visited Dec. 16, 2014), archived at <http://perma.cc/LD4K-F5RQ>.

quit,<sup>220</sup> but a future court may find this evidence persuasive if supplemented with evidence showing a strong link between behavioral intent and action.

Additionally, in the two years since the D.C. Circuit invalidated FDA's graphic warnings, new scientific evidence has already emerged showing that graphic cigarette warnings "prevent smoking initiation and promote cessation."<sup>221</sup> According to a recent Canadian study, graphic warnings reduced smoking odds by approximately twelve percent and quit attempts by a third.<sup>222</sup> Another Canadian study found that "people for whom warning labels were more noticeable and salient were more likely to have quit or reduced smoking."<sup>223</sup> These research trends are promising and instill confidence that, by the time FDA issues its revised graphic cigarette warnings, the government will have amassed the scientific evidence necessary to overcome another First Amendment challenge.<sup>224</sup>

### CONCLUSION

*R.J. Reynolds* narrowed the scope of *Zauderer* rational basis review protection, while ratcheting up *Central Hudson* intermediate scrutiny to closely resemble strict scrutiny, thereby threatening the viability of public health disclosures and warnings by demanding an unattainable level of certainty and precision. In *American Meat Institute*, the D.C. Circuit seized the opportunity to preserve the current regulatory state and avoid administrative complexity by overruling *R.J. Reynolds* and extending *Zauderer* rational basis review to mandates beyond those curing deception. Despite this victory for regulators, FDA still faces a formidable challenge in selecting revised graphic cigarette warnings. FDA can overcome the obstacle *R.J. Reynolds* presents by selecting unenhanced images that clearly, directly, and independently convey the health risk information described in the accompanying textual warning, by arguing that *R.J. Reynolds* misapplied *Central*

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<sup>220</sup> *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205, 1219 (D.C. Cir. 2012), *overruled in part* by *Am. Meat Inst. v. USDA*, 760 F.3d 18 (D.C. Cir. 2014) (en banc).

<sup>221</sup> *Kraemer & Baig*, *supra* note 150, at 338.

<sup>222</sup> *Id.*

<sup>223</sup> *Id.*

<sup>224</sup> The final prong of *Central Hudson*—whether the speech regulation is “excessive”—was not addressed by *R.J. Reynolds*, but it should not pose a barrier for graphic cigarette warnings. See *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 564 (1980) (“[I]f the governmental interest could be served as well by a more limited restriction on commercial speech, the excessive restrictions cannot survive.”). As the *R.J. Reynolds* dissent noted, “[t]he failures of previous government efforts to convey the relevant information through small, textual warnings on the side of cigarette packages” shows that graphic images are no more extensive than necessary. *R.J. Reynolds*, 696 F.3d at 1236 (Rogers, J., dissenting).

*Hudson*, and by bolstering its evidence of graphic cigarette warnings' effectiveness.

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