
ORAL ARGUMENT NOT YET SCHEDULED

No. 17-5196

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NICOPURE LABS, LLC, *et al.*,

Plaintiffs-Appellants,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants-Appellees.

On Appeal from the United States District Court
for the District of Columbia, No. 1:16-cv-00878-ABJ
Hon. Amy Berman Jackson, U.S.D.J.

**BRIEF FOR AMICUS CURIAE PUBLIC CITIZEN, INC.,
IN SUPPORT OF APPELLEES AND AFFIRMANCE**

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**CERTIFICATE AS TO PARTIES, RULINGS, RELATED CASES,
FILING OF SEPARATE BRIEF, AND RULE 26.1 DISCLOSURE**

As required by Circuit Rules 26.1, 28(a)(1), and 29(d), and Federal Rule of Appellate Procedure 26.1, counsel for amicus curiae Public Citizen, Inc., hereby certify as follows:

A. Parties and Amici

Except as indicated below, all parties, intervenors, and amici appearing in the lower court and this court are listed in the certificates to the Opening Brief of Appellants Nicopure Labs LLC, *et al.*, and the Brief for Appellees Food & Drug Administration, *et al.* Those briefs do not list the following, who have filed or are expected to file briefs as amici curiae:

1. Amicus curiae Public Citizen, Inc., the filer of this brief, is appearing with consent of both parties in support of the defendants-appellees and affirmance. Public Citizen is a nonprofit organization that has not issued shares or debt securities to the public. It has no parent companies, and no publicly held company has any form of ownership interest in it. The general purpose of the organization is to advocate for the interests of consumers and the general public on a range of issues, including regulations to protect the health and safety of consumers.

2. In addition to Public Citizen and the amici listed in the briefs of the parties, the Public Health Law Center has filed a notice of intent to participate with consent of the parties as amicus curiae in support of defendants-appellees.

3. Counsel for Public Citizen also understand that a group of First Amendment scholars, Professors Robert C. Post, Jack Balkin, and Amy Kapczynski of Yale Law School, intend to file a brief as amici curiae in support of defendants-appellees.

B. Rulings Under Review

References to the district court decision under review appear in the certificates to the Opening Brief of Appellants Nicopure Labs LLC, *et al.*, and the Brief of Appellees Food & Drug Administration, *et al.*

C. Related Cases

An accurate description of related cases appears in the certificate to the Brief of Appellees Food & Drug Administration, *et al.*

D. Separate Brief

Public Citizen has filed a separate brief from the other amici supporting defendants-appellees because a single amicus curiae brief is not practicable in this case. Public Citizen and the other amici address distinct

aspects of the issues posed by the appeal in this case. Specifically, Public Citizen's brief focuses on and refutes appellants' argument that recent decisions of the United States Supreme Court require a level of First Amendment scrutiny more demanding than intermediate scrutiny for commercial-speech regulations that are "content-based," an argument discussed only briefly in appellees' brief but featured at length in an amicus brief supporting appellants filed by the Washington Legal Foundation. Public Citizen has considerable familiarity with this issue and has addressed it in other briefs in the Supreme Court and other courts of appeals. The other amici's arguments focus on different issues and reflect distinctive viewpoints of the amici, and combining these different approaches and viewpoints into a single brief would not be practicable. *See* D.C. Cir. R. 29(d).

Respectfully submitted,

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TABLE OF CONTENTS

CERTIFICATE AS TO PARTIES, RULINGS, RELATED CASES, FILING OF SEPARATE BRIEF, AND RULE 26.1 DISCLOSURE.....	i
TABLE OF AUTHORITIES	vi
GLOSSARY.....	xi
STATUTES AND REGULATIONS	1
INTEREST OF AMICUS CURIAE	1
SUMMARY OF ARGUMENT.....	3
ARGUMENT	7
I. Content-based commercial-speech restrictions are subject to intermediate scrutiny.	7
A. Decades of Supreme Court precedents support the intermediate scrutiny standard.	7
B. <i>Sorrell</i> and <i>Reed</i> do not displace intermediate scrutiny of content-based commercial-speech restrictions.....	11
C. The Supreme Court’s more recent decisions support continued application of intermediate scrutiny to content- based commercial-speech restrictions.	17
D. The bulk of federal appellate authority weighs against reading <i>Sorrell</i> and <i>Reed</i> to require stricter review of content- based commercial-speech restrictions.	19
E. Stricter scrutiny of content-based commercial-speech restrictions would impair efforts to regulate the marketplace in the interest of consumers.	27
II. The Tobacco Control Act’s requirements readily survive intermediate scrutiny.	31

CONCLUSION 34

CERTIFICATE OF COMPLIANCE

CERTIFICATE OF SERVICE

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>1-800-411-Pain Referral Service, LLC v. Otto</i> , 744 F.3d 1045 (8th Cir. 2014).....	23
<i>ACLU of Illinois v. Alvarez</i> , 679 F.3d 583 (7th Cir. 2012).....	24
<i>American Meat Institute v. Department of Agriculture</i> , 760 F.3d 18 (D.C. Cir. 2014).....	25, 26
<i>Board of Trustees of State University of New York v. Fox</i> , 492 U.S. 469 (1989).....	10, 33
<i>Bolger v. Youngs Drug Products Corp.</i> , 463 U.S. 60 (1983).....	9, 10, 19
<i>In re Brunetti</i> , 877 F.3d 1330 (Fed. Cir. 2017).....	25
* <i>Central Hudson Gas & Electric Corp. v. Public Service Commission</i> , 447 U.S. 557 (1980).....	7, 8, 11, 12, 13, 14, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 29, 30, 32, 34
<i>Centro de la Comunidad Hispana de Locust Valley v. Town of Oyster Bay</i> , 868 F.3d 104 (2d Cir. 2017).....	25
<i>Clark v. Jeter</i> , 486 U.S. 456 (1988).....	13
<i>Contest Promotions, LLC v. City and County of San Francisco</i> , 874 F.3d 597 (9th Cir. 2017).....	21
<i>Dana’s R.R. Supply v. Attorney General, Florida</i> , 807 F.3d 1235 (11th Cir. 2015).....	23

<i>Discount Tobacco City & Lottery, Inc. v. United States</i> , 674 F.3d 509 (6th Cir. 2012).....	25
<i>Edenfield v. Fane</i> , 507 U.S. 761 (1993).....	8, 9
<i>Educational Media Co. at Virginia Tech., Inc. v. Insley</i> , 731 F.3d 291 (4th Cir. 2013).....	25
<i>Expressions Hair Design v. Schneiderman</i> , 137 S. Ct. 1144 (2017).....	7, 17, 18
<i>Florida Bar v. Went For It, Inc.</i> , 515 U.S. 618 (1995).....	10
<i>Flying Dog Brewery, LLLP v. Michigan Liquor Control Commission</i> , 597 F. App'x 342 (6th Cir. 2015).....	25
<i>Friedman v. Rogers</i> , 440 U.S. 1 (1979).....	9
<i>Greater New Orleans Broadcasting Ass'n, Inc. v. United States</i> , 527 U.S. 173 (1999).....	9
<i>Hodge v. Talkin</i> , 799 F.3d 1145 (D.C Cir. 2015).....	33
<i>King v. Governor of State of New Jersey</i> , 767 F.3d 216 (3d Cir. 2014).....	24
<i>Lone Star Security & Video, Inc. v. City of Los Angeles</i> , 827 F.3d 1192 (9th Cir. 2016).....	22
<i>Matal v. Tam</i> , 137 S. Ct. 1744 (2017).....	7, 9, 17, 18

<i>Milavetz, Gallop & Milavetz, P.A. v. United States</i> , 559 U.S. 229 (2010).....	34
<i>Missouri Broadcasters Ass’n v. Lacy</i> , 846 F.3d 295 (8th Cir. 2017).....	22, 23
<i>Nationwide Biweekly Administration, Inc. v. Owen</i> , 873 F.3d 716 (9th Cir. 2017).....	22
<i>Nixon v. Shrink Missouri Government PAC</i> , 528 U.S. 377 (2000).....	13
<i>Oklahoma Corrections Professional Ass’n v. Doerflinger</i> , 521 F. App’x 674 (10th Cir. 2013).....	23, 24
<i>Ohralik v. Ohio State Bar Ass’n</i> , 436 U.S. 447 (1978).....	8, 29, 33
<i>R.A.V. v. City of St. Paul</i> , 505 U.S. 377 (1992).....	28
<i>In re R.M.J.</i> , 455 U.S. 191 (1982).....	10
<i>Reed v. Town of Gilbert</i> , 135 S. Ct. 2218 (2015).....	11, 15, 16, 17, 18, 19, 21, 22, 25, 27
<i>Retail Digital Network, LLC v. Prieto</i> , 861 F.3d 839 (9th Cir. 2017).....	19, 20, 21
<i>Rubin v. Coors Brewing Co.</i> , 514 U.S. 476 (1995).....	10
<i>San Francisco Arts & Athletics, Inc. v. U.S. Olympic Committee</i> , 483 U.S. 522 (1987).....	10

* <i>Sorrell v. IMS Health Inc.</i> , 564 U.S. 552 (2011).....	11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 31
<i>United States v. Caronia</i> , 703 F.3d 149 (2d Cir. 2012)	21, 24
<i>United States v. Virginia</i> , 518 U.S. 515 (1996).....	13
<i>Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.</i> , 455 U.S. 489 (1982).....	33
<i>Whitaker v. Thompson</i> , 353 F.3d 947 (D.C. Cir. 2004)	4
<i>Whitman v. America Trucking Ass'ns</i> , 531 U.S. 457 (2001).....	16
<i>Williams-Yulee v. Florida Bar</i> , 135 S. Ct. 1656 (2015).....	28
<i>Wollschlaeger v. Governor of Florida</i> , 848 F.3d 1293 (11th Cir. 2017).....	23
<i>Zauderer v. Office of Disciplinary Counsel</i> , 471 U.S. 626 (1985).....	7, 17, 26

Statutes & Regulations

15 U.S.C. § 1692d(3)–(4)	27
21 U.S.C. § 387j	3
21 U.S.C. § 387k(g)(1)	3
21 U.S.C. § 387k(g)(2)	4

49 U.S.C. § 32908(b)..... 28

21 C.F.R. § 101.9 28

21 C.F.R. § 101.14 27

21 C.F.R. § 107.10(b)..... 27

21 C.F.R. § 201.57 28

Miscellaneous

John C. Coates IV, *Corporate Speech & The First Amendment: History, Data, and Implications*, 30 Const. Comment. 223 (2015)..... 30

Tamara Piety, *The First Amendment and the Corporate Civil Rights Movement*, J. Bus. & Tech. L. 1 (2016) 30

Richard Samp, *Sorrell v. IMS Health: Protecting Free Speech or Resurrecting Lochner?*, 2011 Cato S. Ct. Rev. 129 (2010–2011)..... 31

GLOSSARY

FDA

Food and Drug Administration

STATUTES AND REGULATIONS

Applicable statutes and regulations are contained in the addendum to the Brief of Appellees Food and Drug Administration (FDA), *et al.*

INTEREST OF AMICUS CURIAE¹

Amicus curiae Public Citizen is a nonprofit consumer advocacy organization that appears on behalf of its members and supporters before Congress, administrative agencies, and courts on a wide range of issues. Public Citizen has long been involved in the development of commercial-speech doctrine. It has represented parties seeking to invalidate overbroad restraints on commercial speech when those restraints harmed competition and injured consumers, including in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). It has also defended commercial-speech regulations as amicus curiae in cases where those regulations were important to protecting public health or served other important public interests, for example in *POM Wonderful, LLC v. FTC*, 777 F.3d 478 (D.C. Cir. 2015), *American*

¹ All parties have consented to the filing of this brief. The brief was not authored in whole or part by counsel for a party. No party or counsel for a party, and no person other than the amicus curiae or its counsel, contributed money intended to fund the brief's preparation or submission.

Meat Institute v. Department of Agriculture, 760 F.3d 18 (D.C. Cir. 2014), and *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509 (6th Cir. 2010).

Public Citizen has become increasingly concerned that corporate and commercial interests are promoting stringent applications of commercial-speech doctrine that harm consumers by stifling legitimate economic regulatory measures. The advocacy of a more stringent standard of review for “content-based” commercial-speech regulations—a standard approaching or equivalent to strict scrutiny—has become a standard part of industry challenges to regulations that affect particular products or markets. Thus here, plaintiffs-appellants and their amici insist that the laws at issue in this case are subject to strict or near-strict scrutiny because those laws are content-based in the sense that they apply to commercial speech because of its subject-matter—the marketing of tobacco products. Adoption of this view would both threaten to thwart the important public-health benefits served by the Tobacco Control Act and, more broadly, unnecessarily tilt the First Amendment balance against a range of laws and regulations that serve important public interests by effectively subjecting all commercial-speech restrictions to strict scrutiny.

SUMMARY OF ARGUMENT

Appellants' brief abandons the argument that the FDA improperly determined e-cigarettes to be tobacco products subject to regulation under the Family Smoking Prevention and Tobacco Control Act. A necessary consequence of the FDA's determination is that the marketing of e-cigarettes requires premarket review and FDA approval under 21 U.S.C. § 387j. Moreover, the marketing of a "modified risk tobacco product"—one sold to reduce risks of harm associated with other tobacco products—requires additional premarket review, including substantiation that, as actually used, the product will reduce risks faced by current tobacco users and benefit the health of the population as a whole, considering both the interests of current tobacco users and those who do not currently use tobacco. *See id.* § 387k(g)(1). Manufacturers of new tobacco products that do not meet those requirements may obtain approval to sell the products if the manufacturer does not make health- or disease-related claims, but claims only that the product does not contain, or contains reduced amounts of, substances found in other tobacco products, on a showing that (among other things) the statements are truthful, that any benefits of reduced exposures to those substances are not overcome by higher

amounts of other harmful substances, that the product is expected to benefit the health of users and the public, and that users will not be misled into believing the product has been demonstrated to be less harmful than other products. *See id.* § 387k(g)(2).

Appellants' claim that imposing these requirements on e-cigarettes is facially unconstitutional under the First Amendment is unsustainable under this Court's holding in *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004). As *Whitaker* holds, requiring premarket approval of the marketing of a product for a particular intended use (such as to reduce health risks to users) does not pose a First Amendment issue because it is not properly viewed as a regulation of speech. *See, e.g.*, FDA Br. 27–30. The briefs of the FDA and other amici discuss this point, which will not be elaborated on here. This brief similarly will not elaborate on the points that, in any event, e-cigarette manufacturers have no claim to First Amendment protection unless they demonstrate the truth of any statements they propose to make, and that the First Amendment's prior restraint doctrine does not apply to commercial speech—points that, together, demonstrate that a preclearance regime requiring tobacco product manufacturers to substantiate that their health claims are

truthful and non-misleading before making them cannot be deemed a First Amendment violation. *See, e.g.,* Br. of First Amendment Scholars.

This brief focuses on a different flaw in the arguments advanced by appellants and their supporting amici. Even assuming that appellants' challenge, properly viewed, presents a viable First Amendment issue, the constitutionality of the statute's limitations on the marketing of modified-risk tobacco products must be determined under the constitutional standard applicable to restrictions on commercial speech. That intermediate scrutiny standard has, since First Amendment protection was first extended to commercial speech in the 1970s, permitted the government to impose content-based restrictions on commercial speakers where the restrictions directly advance substantial government interests—in contrast to the strict scrutiny standard applicable to fully protected speech, which requires that speech regulations be the least restrictive means of achieving a compelling government interest. Critical to the claim of appellants and their amici that the Tobacco Control Act fails to pass muster under the First Amendment is the assertion that recent decisions of the Supreme Court supplant intermediate scrutiny for content-based commercial-speech restrictions, and require either strict

scrutiny or some other stringent level of scrutiny approaching strict scrutiny.

That argument is fundamentally wrong. The Supreme Court has not overruled its long line of decisions establishing intermediate scrutiny as the appropriate standard for assessing the constitutionality of content-based commercial-speech restrictions. The decisions cited by appellants and their amici to establish some higher standard merely confirm that intermediate scrutiny is the form of “heightened” scrutiny (that is, scrutiny beyond the rational-basis review generally applicable to regulations that do not affect protected speech) appropriate for content-based restrictions of commercial speech. This Court should therefore confirm the growing ranks of appellate-court decisions rejecting the argument that intermediate scrutiny no longer applies to content-based commercial-speech restrictions. Thus, if the Court determines that the Tobacco Control Act provisions challenged here restrict protected commercial speech, it should apply intermediate scrutiny to uphold the statute.

ARGUMENT

I. Content-based commercial-speech restrictions are subject to intermediate scrutiny.

A. Decades of Supreme Court precedents support the intermediate scrutiny standard.

The United States Supreme Court has long recognized that restrictions of commercial speech, even if content-based, are subject to intermediate scrutiny, not to the strict scrutiny ordinarily applied to content-based restrictions on fully protected speech. *See Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980). The Court's most recent decisions bearing on the subject reinforce these longstanding principles. *See Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1151 (2017) (citing *Central Hudson* and *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985)); *Matal v. Tam*, 137 S. Ct. 1744, 1767 (2017) (Kennedy, J., concurring in part and concurring in the judgment) (recognizing that “content based discrimination” is not of “serious concern in the commercial context”).

Thus, for nearly four decades, the First Amendment standard that applies to content-based restrictions on commercial speech has been clear: Commercial speech is not protected at all if it is false or misleading, and

even where commercial speech qualifies for protection, the government may regulate it if the government has “substantial” interests in the regulation, the regulation “advances these interests in a direct and material way,” and “the extent of the restriction on protected speech is in reasonable proportion to the interests served.” *Edenfield v. Fane*, 507 U.S. 761, 767 (1993) (citing *Cent. Hudson*, 447 U.S. at 564). This standard—termed intermediate scrutiny or *Central Hudson* review—affords less protection for commercial speech than the strict scrutiny ordinarily applicable to fully protected speech, such as political, literary, artistic, or religious expression.

The “common-sense distinction” between commercial and noncommercial speech stems from commercial speech’s “subordinate position in the scale of First Amendment values.” *Ohralik v. Ohio State Bar Ass’n*, 436 U.S. 447, 455–56 (1978) (internal quotation marks omitted). Commercial speech primarily serves not the expressive interests that are at the heart of the First Amendment, but the economic interests of market participants, *see Cent. Hudson*, 447 U.S. at 561–62—interests that are “traditionally subject to government regulation,” *id.* (quoting *Ohralik*, 436 U.S. at 45–56). Because “[c]ommercial speech ... is ‘linked

inextricably' with the commercial arrangement that it proposes, ... the State's interest in regulating the underlying transaction may give it a concomitant interest in the expression itself." *Edenfield*, 507 U.S. at 767. Moreover, the powerful economic interests served by commercial speech make it "less likely than other forms of speech to be inhibited by proper regulation." *Friedman v. Rogers*, 440 U.S. 1, 10 (1979). For these reasons, the Supreme Court's decisions have long recognized that "regulation of commercial speech based on content is less problematic" than regulation of content-based noncommercial speech. *Bolger v. Youngs Drug Prods. Corp.*, 463 U.S. 60, 65 (1983); *accord Matal*, 137 S. Ct. at 1767 (Kennedy, J., concurring in part and concurring in the judgment) (citing *Bolger*).

The argument for strict scrutiny of content-based commercial-speech regulations runs counter to a long line of cases in which the Supreme Court has applied intermediate scrutiny to content-based restrictions on non-misleading commercial speech concerning otherwise lawful transactions. *See, e.g., Greater New Orleans Broad. Ass'n, Inc. v. United States*, 527 U.S. 173, 176, 183–84 (1999) (applying intermediate scrutiny to a statute that forbade broadcast advertising of casino gambling as applied to advertisements in jurisdictions where such gambling was

legal); *Fla. Bar v. Went For It, Inc.*, 515 U.S. 618, 620, 635 (1995) (applying intermediate scrutiny to uphold rule prohibiting attorneys from sending certain written solicitations to prospective clients that “relate[d] to an accident or disaster involving the person to whom the communication [was] addressed or a relative of that person”); *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 478, 482, 488 (1995) (applying intermediate scrutiny to a federal law that prohibited labels for beer, but not wine or distilled spirits, from displaying alcohol content); *Bd. of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 476–77 (1989) (concluding that intermediate scrutiny was the proper standard for evaluating a university rule as applied to prohibit commercial speech promoting the sale of housewares on campus); *San Francisco Arts & Athletics, Inc. v. U.S. Olympic Comm.*, 483 U.S. 522, 537 & n.16 (1987) (applying intermediate scrutiny to statute prohibiting commercial uses of the word “Olympic”); *Bolger*, 463 U.S. at 61, 68–69 (applying intermediate scrutiny in as-applied challenge to a statute that prohibited unsolicited advertisements for contraceptives); *In re R.M.J.*, 455 U.S. 191, 194, 205–07 (1982) (applying intermediate scrutiny to a rule that barred attorney advertisements from identifying jurisdictions in which attorneys were licensed).

In each case, the restrictions turned on the “subject matter” of the speech and the identity of the speaker. And in each case, the Court held that the restrictions were subject to intermediate scrutiny. Indeed, *Central Hudson* itself addressed a regulation that banned all “advertising intended to stimulate the purchase of utility services”—an explicitly content-based restriction. *Cent. Hudson*, 447 U.S. at 559 (internal quotation marks omitted). Thus, the argument for strict scrutiny of content-based commercial-speech restrictions posits that the Supreme Court applied the wrong standard in the very case that gave First Amendment intermediate scrutiny its name.

B. *Sorrell* and *Reed* do not displace intermediate scrutiny of content-based commercial-speech restrictions.

The argument for strict (or near-strict) scrutiny of all content-based restrictions hinges on the assertion that the Supreme Court, without expressly saying so, upset this longstanding body of law in its opinions in *Sorrell v. IMS Health Inc.*, 564 U.S. 552 (2011), and *Reed v. Town of Gilbert*, 135 S. Ct. 2218 (2015). Those decisions, however, do not step back from the Court’s well-established acceptance of lesser scrutiny for content-based commercial-speech regulations.

1. *Sorrell v. IMS Health*

In *Sorrell*, the Court struck down on First Amendment grounds a Vermont law that, with limited exceptions, prohibited “pharmacies, health insurers, and similar entities from disclosing or otherwise allowing prescriber-identifying information to be used for marketing” and “pharmaceutical manufacturers and detailers from using the information for marketing.” 564 U.S. at 563. The Court held that the law imposed a “speaker- and content-based burden on protected expression,” *id.* at 571, by allowing the use of information by other entities, such as “private or academic researchers,” *id.* at 563, and for non-marketing purposes, such as “educational communications,” *id.* at 564. The Court therefore concluded that “heightened judicial scrutiny [was] warranted.” *Id.* at 565.

The Court went on, however, to explain that two types of “heightened” scrutiny could potentially apply to the speech at issue: “a special commercial speech inquiry or a stricter form of judicial scrutiny.” *Id.* at 571. The Court concluded that it was unnecessary to decide whether the speech at issue was commercial because, even under the less stringent “commercial speech inquiry,” the law was unconstitutional. *See id.* at 571–72 (citing *Cent. Hudson*, 447 U.S. at 566). Far from announcing a new rule,

Sorrell's repeated distinction between these two forms of “heightened” scrutiny—*Central Hudson* intermediate scrutiny and the “stricter” standard the Court did not apply—supports the continued application of intermediate scrutiny to commercial speech.

Thus, as *Sorrell*'s own application of intermediate scrutiny makes clear, the phrase “heightened scrutiny” is not equivalent to strict scrutiny. In addition to *Sorrell*, many other Supreme Court opinions demonstrate that “heightened scrutiny” is a *generic* term indicating a level of scrutiny higher than rational-basis scrutiny, including both intermediate scrutiny and strict scrutiny. For example, the Court's equal protection precedents frequently use the term “heightened scrutiny” to describe the intermediate scrutiny applicable to gender classifications. *See, e.g., United States v. Virginia*, 518 U.S. 515, 533, 555 (1996); *Clark v. Jeter*, 486 U.S. 456, 463, 465 (1988). In the First Amendment area, the Court has similarly referred to the intermediate scrutiny applied to limits on political contributions as a form of “heightened judicial scrutiny.” *See Nixon v. Shrink Mo. Gov't PAC*, 528 U.S. 377, 391 (2000).

The Court's opinion in *Sorrell* uses the term “heightened scrutiny” in the same way as these precedents—as a general description of scrutiny

above a rational-basis test, not as a synonym for strict scrutiny. *Sorrell* is thus fully consistent with the continued application of intermediate scrutiny to content-based restrictions of commercial speech. Indeed, when it used the term, the Court in *Sorrell* was addressing the state's argument that the law at issue was not a speech regulation at all and was thus subject only to the rational-basis review applicable to economic regulations that implicate no fundamental rights. The Court held that the statute imposed a burden on protected speech (by operating through content- and speaker-based restrictions) and thus was subject to First Amendment review, necessitating heightened scrutiny as opposed to the rational-basis review advocated by the state. *See* 564 U.S. at 557, 565–70.

The *Sorrell* Court went on to acknowledge that the *form* of heightened scrutiny applicable to a content-based restriction of commercial speech is the intermediate scrutiny defined in *Central Hudson*, *id.* at 571–72, under which “commercial speech can be subject to greater governmental regulation than noncommercial speech,” *id.* at 579 (citation omitted). The Court, however, found that the law at issue failed that level of heightened scrutiny—a finding it reached by applying each element of the *Central Hudson* intermediate scrutiny standard without

imposing an increased burden on the state under any of them. *Id.* at 572–80. It was therefore unnecessary to address in *Sorrell* the challengers’ argument that the law restricted fully protected speech subject to strict scrutiny, rather than commercial speech. *See id.* at 571.

2. *Reed v. Town of Gilbert*

Likewise, *Reed* offers no support for universal application of strict scrutiny to content-based regulations. *Reed* struck down a local law that prohibited outdoor signs without a permit but exempted twenty-three categories of signs, including political and ideological signs and temporary directional signs of short duration. *See* 135 S. Ct. at 2224–25. The law did not, however, exempt signs that the plaintiffs—a church and its pastor—sought to display for extended periods to publicize the time and location of upcoming church services. *Id.* at 2225. The Court cited noncommercial-speech cases for the proposition that “[c]ontent-based laws—those that target speech based on its communicative content—are presumptively unconstitutional and may be justified only if the government proves that they are narrowly tailored to serve compelling state interests.” *Id.* at 2226.

The Court cited *Sorrell*, a commercial-speech case, only in defining the “commonsense meaning of the phrase ‘content based,’” *id.* at 2227—

not to address the level of scrutiny applicable to content-based restrictions applicable outside the realm of fully protect speech. The Court explained that “[g]overnment regulation of speech is content based if a law applies to particular speech because of the topic discussed or the idea or message expressed.” *Id.* (citing *Sorrell*, 564 U.S. at 565). The Court thus found that the town ordinance in *Reed* was content-based because it “single[d] out specific subject matter for differential treatment.” *Id.* at 2230. The Court then applied strict scrutiny to the ordinance as a content-based regulation of fully protected, noncommercial speech. *Id.* at 2231.

Critically, *Reed* did not hold—or even discuss the possibility—that strict scrutiny would apply to content-based commercial-speech restrictions. Had the Court intended to overrule its many decisions applying intermediate scrutiny to content-based commercial-speech restrictions, its opinion would undoubtedly have acknowledged such an important aspect of the decision. The Supreme Court, like Congress, “does not ... hide elephants in mouseholes.” *Whitman v. Am. Trucking Ass’ns*, 531 U.S. 457, 468 (2001). *Reed* provides no hint that it is concealing such an elephant. Indeed, the Court’s opinion does not use the term “commercial speech” even once.

C. The Supreme Court’s more recent decisions support continued application of intermediate scrutiny to content-based commercial-speech restrictions.

That *Reed* and *Sorrell* do not sweep so broadly as to require strict scrutiny of any content-based speech restriction is confirmed by the Supreme Court’s subsequent decisions in *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, and *Matal v. Tam*, 137 S. Ct. 1744. *Expressions* concerned a challenge to a New York statute prohibiting merchants from imposing surcharges on consumers who paid with credit cards. The Court determined that the law regulated speech rather than conduct, but did not determine whether it was properly viewed as a speech *prohibition* or a requirement that prices be *disclosed* in a particular way. *See* 137 S. Ct. at 1151 & n.3. Under either view, however, the law was “content-based” in the sense that its application either prohibited or required speech addressing a particular subject matter or with particular content. Nonetheless, the Court’s opinion does not suggest that the law might be subject to strict scrutiny. Rather, the Court remanded the case for consideration of the law either under *Central Hudson* intermediate scrutiny (if it were ultimately determined to be a speech restriction) or *Zauderer* (if it were determined to be a disclosure requirement). *See id.* at

1151. If the Court had determined in *Sorrell* and *Reed* that content-based commercial-speech regulations are properly subject to some more stringent level of scrutiny, its failure even to mention that possibility in *Expressions*, while remanding for application of one of two lesser standards, would be puzzling to say the least.

Matal concerned a federal statute prohibiting registration of offensive trademarks. Viewed as a speech restriction (as the Court determined it to be), it, too, was undoubtedly content-based, as it turned entirely on the content of the (commercial) speech at issue. But neither the Court's lead opinion, joined in relevant part by four Justices, nor the opinion of Justice Kennedy (also representing the views of four Justices) suggested that the law was subject to strict scrutiny solely because it was content-based. The lead opinion applied the *Central Hudson* standard to the law and held it unconstitutional because the interest in suppressing socially offensive speech is not legitimate, let alone substantial for the purpose of intermediate scrutiny. 137 S. Ct. at 1764. The opinion of Justice Kennedy (*Sorrell*'s author) applied strict scrutiny because the law was *viewpoint-based*—that is, because it regulated speech because of disagreement with its social or political message, not its commercial

message. At the same time, the Kennedy opinion reiterated the point, long-established in the Court's commercial-speech jurisprudence, that, in contrast to regulation aimed at suppressing social, political, or religious viewpoints, "content based discrimination" in itself is not "of serious concern in the commercial context." *Id.* at 1767 (citing *Bolger*, 463 U.S. at 65, 71–72).

D. The bulk of federal appellate authority weighs against reading *Sorrell* and *Reed* to require stricter review of content-based commercial-speech restrictions.

In light of the Supreme Court's jurisprudence, other courts of appeals that have addressed the question have rejected the claim that *Sorrell* and *Reed* supplanted intermediate scrutiny for content-based commercial-speech regulations.

The issue has received most attention in the Ninth Circuit, which, in a near-unanimous en banc decision, recently held that intermediate scrutiny remains the First Amendment standard applicable to content-based regulation of commercial speech. *See Retail Digital Network, LLC v. Prieto*, 861 F.3d 839 (9th Cir. 2017) (en banc). The court emphasized that "the Supreme Court repeatedly has declined ... to fundamentally alter *Central Hudson's* intermediate scrutiny standard." *Id.* at 846. Specifically

addressing the claim that *Sorrell* requires a stricter standard, the court determined that “*Sorrell* did not mark a fundamental departure from *Central Hudson*’s four-factor test, and *Central Hudson* continues to apply.” *Id.*

Retail Digital Network explains that *Sorrell* employed the term “heightened scrutiny” generically to refer to both strict scrutiny and *Central Hudson*’s intermediate scrutiny and to distinguish them from the rational-basis scrutiny applicable to non-speech restrictions—not to identify a new form of scrutiny more demanding than intermediate scrutiny. *See id.* at 847. Moreover, the en banc opinion emphasizes that the standard applied in *Sorrell* was *Central Hudson*’s intermediate scrutiny. *See id.* at 848–49.

Further, *Retail Digital Network* points out that applying strict scrutiny to content-based commercial-speech restrictions would be inconsistent with *Sorrell*’s continued recognition of “one of the core principles that animates the Court’s approach to commercial speech—that commercial speech may be subject to greater regulation than non-commercial speech.” *Id.* at 849 (citing *Sorrell*, 564 U.S. at 579 (“[T]he government’s legitimate interest in protecting consumers from

‘commercial harms’ explains ‘why commercial speech can be subject to greater governmental regulation than noncommercial speech.’”)). In part because “*every* commercial speech case, by its very nature, involves both content- and speaker-based speech restrictions,” *id.* at 847–48 (quoting *United States v. Caronia*, 703 F.3d 149, 180 (2d Cir. 2012) (Livingston, J., dissenting)), reading *Sorrell* to require stricter-than-intermediate scrutiny for content-based commercial-speech regulations would nullify *Sorrell*’s own recognition that such speech is subject to greater restrictions than fully protected speech and would “impose an inscrutable standard,” *id.* at 849. *Retail Digital Network* thus holds unambiguously that content-based (and speaker-based) commercial-speech regulations remain subject to intermediate scrutiny. *Id.*; see also *Contest Promotions, LLC v. City and County of San Francisco*, 874 F.3d 597, 601 (9th Cir. 2017) (“[T]he proper level of scrutiny” for content- and speaker-based commercial speech restrictions remains “the longstanding commercial speech doctrine, which calls for intermediate review.”).

The Ninth Circuit has “likewise rejected the notion that *Reed* altered *Central Hudson*’s longstanding intermediate scrutiny framework” for content-based commercial-speech restrictions. *Contest Promotions*, 874

F.3d at 601. In *Lone Star Security & Video, Inc. v. City of Los Angeles*, 827 F.3d 1192 (9th Cir. 2016), the court, citing both *Reed* and *Central Hudson*, noted that “although laws that restrict only commercial speech are content based, such restrictions need only withstand intermediate scrutiny.” *Id.* at 1198 n.3. More recently, in *Nationwide Biweekly Administration, Inc. v. Owen*, 873 F.3d 716 (9th Cir. 2017), the court explained its refusal to read into the Supreme Court’s decision in *Reed* some unstated disapproval of intermediate scrutiny for content-based commercial-speech restrictions. The court pointed out that “*Reed* did not relate to commercial speech ... and therefore did not have occasion to consider” the standard applicable to commercial-speech restrictions. *Id.* at 732. Rejecting the invitation to “find a new First Amendment principle between the lines of *Reed*,” the court concluded that “there is simply nothing there to find.” *Id.*

Other federal courts of appeals have similarly held that content-based commercial-speech restrictions remain subject to scrutiny under the *Central Hudson* standard. The Eighth Circuit has twice “rejected” the argument that “the Supreme Court defined a new standard for commercial speech in *Sorrell*.” *Mo. Broad. Ass’n v. Lacy*, 846 F.3d 295, 300 n.5 (8th

Cir. 2017). Rather, as that court held in *1-800-411-Pain Referral Serv., LLC v. Otto*, 744 F.3d 1045 (8th Cir. 2014), and reiterated in *Lacy*, the form of “heightened scrutiny” applicable to “content-based” commercial-speech regulations remains *Central Hudson*’s intermediate scrutiny: “The upshot is that when a court determines commercial speech restrictions are content- or speaker-based, it should then assess their constitutionality under *Central Hudson*.” *Otto*, 744 F.3d at 1055.

The Eleventh Circuit has likewise held that “intermediate scrutiny” remains applicable to content-based commercial-speech restrictions after *Sorrell*. Consistent with the decisions of the Eighth and Ninth Circuits, it characterized that standard as the “level of heightened scrutiny” applicable to commercial speech. See *Dana’s R.R. Supply v. Atty. Gen., Fla.*, 807 F.3d 1235, 1246 (11th Cir. 2015).² A panel of the Tenth Circuit also recognized that “intermediate scrutiny” is the form of “heightened scrutiny” applied by the Court in *Sorrell*. See *Okla. Corrections Prof. Ass’n*

² In *Wollschlaeger v. Governor of Florida*, 848 F.3d 1293, 1311–12 (11th Cir. 2017), the Eleventh Circuit again indicated that intermediate scrutiny was a form of “heightened scrutiny” under *Sorrell*.

v. Doerflinger, 521 F. App'x 674, 677 n.3 (10th Cir. 2013) (nonprecedential opinion).

Similarly, in *ACLU of Illinois v. Alvarez*, 679 F.3d 583 (7th Cir. 2012), the Seventh Circuit cited *Sorrell* for the boilerplate proposition that, “[i]n commercial-speech cases, the government must establish that the challenged statute ‘directly advances a substantial governmental interest and that the measure is drawn to achieve that interest,’” or, “[s]tated differently,” that “*intermediate scrutiny*” applies. *Id.* at 604 (emphasis added). And in *King v. Governor of State of New Jersey*, 767 F.3d 216 (3d Cir. 2014), the Third Circuit applied *Central Hudson* “intermediate scrutiny” to a professional-speech restriction, *id.* at 234, and rejected the argument that *Sorrell* required a more stringent standard of review because the restriction was content-based, *id.* at 236–37.

Finally, the Second Circuit in *United States v. Caronia*, 703 F.3d 149, acknowledged that *Sorrell* “did not decide the level of heightened scrutiny to be applied, that is, strict, intermediate, or some other form of heightened scrutiny.” *Id.* at 164. That observation, which recognizes that intermediate scrutiny is a form of heightened scrutiny, is at odds with the view that *Sorrell*’s use of the words “heightened scrutiny” is irreconcilable

with application of intermediate scrutiny. Subsequently, the Second Circuit has continued to apply intermediate scrutiny to content-based commercial-speech restrictions, without indicating that a stricter standard should apply. See *Centro de la Comunidad Hispana de Locust Valley v. Town of Oyster Bay*, 868 F.3d 104, 112–13 (2d Cir. 2017).³

Nothing in this Court’s precedents suggests a reason for the Court to create an inter-circuit conflict by adopting the view that *Sorrell* and *Reed* supplanted intermediate scrutiny of content-based commercial-speech restrictions with some stricter level of review. To the contrary, this Court’s most recent en banc consideration of commercial-speech issues in *American Meat Institute v. Department of Agriculture*, 760 F.3d 18 (D.C.

³ See also *In re Brunetti*, 877 F.3d 1330, 1350 (Fed. Cir. 2017) (stating that, under *Sorrell*, *Central Hudson* intermediate scrutiny remains applicable to content-based restrictions of purely commercial speech); *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 522 (6th Cir. 2012) (holding, after *Sorrell*, that *Central Hudson* intermediate scrutiny, not strict scrutiny, applies to content-based commercial-speech restrictions); *Flying Dog Brewery, LLLP v. Mich. Liquor Control Comm’n*, 597 F. App’x 342, 365 (6th Cir. 2015) (Moore, J., dissenting in part and concurring in judgment in part) (stating that “although *Sorrell* stated that ‘heightened judicial scrutiny’ applied, it reaffirmed the use of the *Central Hudson* test”). The Fourth Circuit has noted uncertainty concerning the meaning of “heightened scrutiny” as used in *Sorrell* but continued to apply intermediate scrutiny. See *Educ. Media Co. at Va. Tech., Inc. v. Insley*, 731 F.3d 291, 298 n.4 (4th Cir. 2013).

Cir. 2014)—decided after *Sorrell*—reinforces the view that *Central Hudson* provides the basic framework for analysis of commercial-speech restrictions. To be sure, the issue in *American Meat Institute* was not whether content-based commercial-speech restrictions are subject to more stringent review, but whether a commercial-speech disclosure requirement applicable to particular commercial speakers and addressing a specific subject-matter (country-of-origin meat labeling) was subject to a less stringent standard of review under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626. The shared premise of all the members of the Court, however, was that, if *Zauderer* did not apply (as the majority held it did), *Central Hudson* would—although the regulation at issue was undoubtedly both speaker-based (it applied only to sellers of meat) and content-based (it prescribed the contents of meat labels). See *Am. Meat Inst.*, 760 F.3d at 25–27 (majority); *id.* at 28 (Rogers, J., concurring in part); *id.* at 30 (Kavanaugh, J., concurring in the judgment); *id.* at 44–45 (Brown, J., dissenting).

E. Stricter scrutiny of content-based commercial-speech restrictions would impair efforts to regulate the marketplace in the interest of consumers.

Applying strict scrutiny to content-based commercial-speech restrictions would risk devastating consequences for the government's ability to adopt commonsense marketplace regulations. Regulations of commercial speech typically apply to specific market participants, such as food manufacturers, debt collectors, and drug companies, and they deal with problems unique to industries in which those participants operate. For example, federal law limits the circumstances in which food manufacturers can make claims about health benefits of their products, 21 C.F.R. § 101.14, or advertise the addition of vitamins to infant formula, *id.* § 107.10(b). It forbids debt collectors from advertising the sale of a debt to coerce a debtor to pay it, and from publishing lists of consumers who refuse to pay debts. 15 U.S.C. § 1692d(3)–(4). If content-based commercial-speech restrictions are subject to strict scrutiny, all these restrictions and numerous other useful, longstanding provisions might have to satisfy such scrutiny, on the theory that they apply “to particular speech because of the topic discussed or the idea or message expressed.” *Reed*, 135 S. Ct. at 2227.

In the disclosure context, too, the government frequently mandates speech on a particular subject and requires that commercial actors use specific language. For example, vehicle manufacturers must label, in accordance with Environmental Protection Agency rules, each vehicle with its average miles per gallon of fuel. 49 U.S.C. § 32908(b). Drug manufacturers must include “black box” warnings on labels of certain drugs to emphasize particular hazards. 21 C.F.R. § 201.57. And food manufacturers must disclose nutritional information about their products. *Id.* § 101.9.

The government would have a much higher burden to justify basic rules like these if they were subjected to strict scrutiny. It “is the rare case” in which the government “demonstrates that a speech restriction is narrowly tailored to serve a compelling interest,” as required to satisfy strict scrutiny. *Williams-Yulee v. Fla. Bar*, 135 S. Ct. 1656, 1665–66 (2015) (citation omitted). Indeed, the very point of strict scrutiny is to render laws subject to it “presumptively invalid.” *R.A.V. v. City of St. Paul*, 505 U.S. 377, 382 (1992). Applying strict scrutiny to content-based commercial-speech restrictions could obliterate many longstanding laws and

regulations that are critical to the protection of consumers and the marketplace.

In addition, applying strict scrutiny to content-based commercial-speech restrictions could have an unintended, harmful consequence for the protection of noncommercial speech. “To require a parity of constitutional protection for commercial and noncommercial speech alike could invite dilution, simply by a leveling process, of the force of the [First] Amendment’s guarantee with respect to the latter kind of speech.” *Ohralik*, 436 U.S. at 456. Adopting strict or near-strict scrutiny for all content-based commercial-speech regulations would call into question a slew of regulations on which the public has depended for decades. If those regulations are to stand, strict scrutiny as we know it might have to change, to the detriment of speakers engaged in fully protected expression.

Furthermore, application of strict scrutiny is not necessary to curb government excesses in the realm of commercial speech. If anything, the First Amendment pendulum in the commercial-speech context has already swung too far in favor of corporate interests, at the expense of important public goals. One recent quantitative analysis of Supreme Court and court of appeals decisions found that, even under *Central Hudson*, “First

Amendment cases in which businesses are the primary beneficiary have increasingly displaced cases in which individuals are the primary beneficiary.” John C. Coates IV, *Corporate Speech & The First Amendment: History, Data, and Implications*, 30 *Const. Comment.* 223, 262 (2015). And companies “are increasingly able to persuade courts ... to exploit the ‘fit’ requirement of the *Central Hudson* test to achieve de- or re-regulatory goals not obtainable through the political process”—a trend contributing to what the author referred to as a “corporate takeover of the First Amendment.” *Id.* at 269.

Moreover, commercial-speech restrictions are always, or virtually always, content- or speaker-based in that they apply to particular types of messages of specified market participants. Indeed, commercial speech, as a category, is defined by the contents of the speech involved and the nature of the speaker. Thus, as one commentator has observed, “this argument, that a statute which treats marketing differently than other speech, is constitutionally infirm *on that ground*, makes a hash of the commercial speech doctrine because, by definition, the commercial speech doctrine is applicable only to a specific type of content—commercial content.”

Tamara Piety, *The First Amendment and the Corporate Civil Rights Movement*, 11 J. Bus. & Tech. L. 1, 20 (2016).⁴

II. The Tobacco Control Act's requirements readily survive intermediate scrutiny.

The effect on this case of intermediate scrutiny's continued applicability to content-based commercial speech is apparent: Assuming that the challenged Tobacco Control Act provisions are properly viewed as restrictions of protected commercial speech, *but see* FDA Br. II.A., III.A., they are subject to intermediate scrutiny, without an additional level of stringency attributed to their "content-based" nature. As the briefs of the FDA and other amici demonstrate at length, the requirements that any statements that a product reduces risks of harm associated with other tobacco products receive premarket review, and that such statements be substantiated by evidence that e-cigarettes are less harmful not only to

⁴ Another commentator, and counsel for appellants' amicus Washington Legal Foundation, who advocates a very broad reading of *Sorrell* and "heightened scrutiny," likewise acknowledges the sweeping effect of such a reading: "If heightened scrutiny is to be applied to any commercial speech regulation that is based on the content of the speech being regulated, one could reasonably conclude that *all* such regulations will be subject to heightened scrutiny." Richard Samp, *Sorrell v. IMS Health: Protecting Free Speech or Resurrecting Lochner?*, 2011 Cato S. Ct. Rev. 129, 135 (2010–2011).

existing tobacco users but also to the public at large, readily survive intermediate scrutiny.

There can be no question that the government's interest in protecting members of the public from the harms associated with the marketing of highly addictive and dangerous substances is substantial, and would be implicated by the marketing of such substances in ways that falsely or misleadingly minimize their potential hazards. The Tobacco Control Act, moreover, directly advances those substantial interests by prohibiting authorization of the marketing of tobacco products to reduce health risks if they cannot be demonstrated to do so. And the statute's restrictions are reasonably proportionate in their application: They not only permit the marketing of modified risk tobacco products if their overall health benefits can be demonstrated, but also allow narrower claims—that a product is free from or has reduced levels of harmful substances present in other tobacco products—on a significantly reduced showing. These provisions reflect a nuanced judgment that such information is useful to and less likely to mislead potential consumers. Under *Central Hudson* and the many cases applying its test, the challenged provisions easily pass muster.

That this case is a *facial* challenge to the decision to subject e-cigarettes to the Tobacco Control Act's limits on the marketing of modified risk tobacco products underscores this conclusion. The Supreme Court's decisions have long established that commercial speech does not receive the added protection that the facial overbreadth doctrine provides for fully protected speech: The Court has flatly held that "the overbreadth doctrine does not apply to commercial speech." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.*, 455 U.S. 489, 497 (1982); *see also, e.g., Fox*, 492 U.S. at 481 ("[O]verbreadth analysis does not normally apply to commercial speech"); *Ohralik*, 436 U.S. at 463 n.20 ("Commercial speech is not as likely to be deterred as noncommercial speech, and therefore does not require the added protection afforded by the overbreadth approach."). Thus, "a statute whose overbreadth consists of unlawful restriction on commercial speech will not be facially invalidated on that ground." *Fox*, 492 U.S. at 481. Rather, a commercial-speech restriction, like most laws that do not affect fully protected speech, is facially unconstitutional only if it cannot be constitutionally applied in any of its applications. *See Village of Hoffman Estates*, 455 U.S. at 495; *Hodge v. Talkin*, 799 F.3d 1145, 1156 (D.C Cir. 2015).

Here, appellants make no pretense of having identified some application of the law to specific speech in which they propose to engage that cannot be sustained under the *Central Hudson* standard. In such circumstances, the Court must sustain the law “if there is any ‘conceivabl[e]’ manner in which it can be enforced consistent with the First Amendment.” *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 258 (2010) (Thomas, J., concurring). Appellants have not attempted to establish, let alone succeeded in establishing, that there is no set of assertions concerning the alleged health benefits of e-cigarettes to which the Tobacco Control Act’s provisions can be applied consistent with the standards of *Central Hudson*.

CONCLUSION

This Court should affirm the district court’s decision.

Respectfully submitted,

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May 9, 2018

CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Brief for Amicus Curiae Public Citizen, Inc., in Support of Appellees and Affirmance complies with the type-volume limitations of FRAP 32(a)(7)(B) and 29(d). The brief is composed in a 14-point proportional typeface, Century Schoolbook BT. As calculated by my word processing software (Microsoft Word 2016), the brief (excluding those parts permitted to be excluded under the Federal Rules of Appellate Procedure and this Court's rules) contains 6,497 words.

/s/ Scott L. Nelson

Scott L. Nelson

CERTIFICATE OF SERVICE

I hereby certify that, on May 9, 2018, this Brief for Amicus Curiae Public Citizen, Inc., in Support of Appellees and Affirmance was served through the Court's ECF system on counsel for all parties.

/s/ Scott L. Nelson

Scott L. Nelson