ORAL ARGUMENT NOT YET SCHEDULED
No. 17-5196

IN THE
United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

NICOPURE LABS, LLC and RIGHT TO BE SMOKE FREE COALITION,

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

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PLAINTIFFS-APPELLANTS, URGING REVERSAL

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CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Under D.C. Cir. R. 26.1(a), Washington Legal Foundation (WLF) states that it is a nonprofit corporation organized under § 501(c)(3) of the Internal Revenue Code; it has no parent company, issues no stock, and no publicly held company holds a 10% or greater ownership interest.

Under D.C. Cir. R. 26.1(b), WLF states that its "general nature and purpose" is a public-interest law firm and policy center that often appears in this Court in cases raising important First Amendment issues. WLF has no financial ties with any party to this appeal.

/s/ Cory L. Andrews
Cory L. Andrews

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GLOSSARY

FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
TCA	Tobacco Control Act
WLF	Washington Legal Foundation

IDENTITY AND INTEREST OF *AMICUS CURIAE*[1]

Washington Legal Foundation (WLF) is a nonprofit, public-interest law firm and policy center with supporters in all 50 states. WLF devotes much of its resources to defending and promoting free enterprise, individual rights, limited government, and the rule of law. In particular, WLF has devoted substantial resources over the years to promoting the free-speech rights of consumers and merchants in the marketplace, frequently appearing before federal courts in cases raising First Amendment issues. *See, e.g.*, *Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011); *Am. Beverage Ass'n v. City & Cty. of San Francisco*, 871 F.3d 884 (9th Cir. 2017); *United States v. Phillip Morris USA Inc.*, 801 F.3d 250 (D.C. Cir. 2015).

For several decades, WLF has actively litigated First Amendment limits on the Food and Drug Administration's (FDA) authority to restrict manufacturer speech. WLF has successfully challenged the constitutionality of FDA restrictions on pharmaceutical manufacturers' truthful speech. *See Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51 (D.D.C. 1998), *appeal dism'd*, 202 F.3d 331 (D.C. Cir 2000). As a result of that litigation, FDA is subject to a permanent injunction

[1] Under Fed. R. App. P. 29(a)(4)(E), WLF states that no counsel for any party authored this brief in whole or in part and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. All parties and proposed intervenors have consented to the filing of WLF's brief.

limiting FDA authority to suppress manufacturer dissemination of peer-reviewed journal articles and medical texts discussing off-label uses of their FDA-approved products. More recently, WLF played a key role in overturning—on First Amendment grounds—a pharmaceutical representative's criminal conviction for conspiring to violate the Food, Drug, and Cosmetic Act (FDCA); the defendant's "crime" consisted of speaking truthfully about off-label uses of a drug manufactured by his company. *See United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012).

WLF is concerned that FDA's regulation of the vapor industry unjustifiably restricts truthful, non-misleading speech in violation of the First Amendment. By requiring all manufacturers and retailers of vapor products to obtain FDA's preapproval before informing prospective consumers of their products' uncontested health advantages over traditional tobacco products, the Deeming Rule imposes a prior restraint on legally protected speech. The Rule also harms those members of the public trying to quit smoking, who are being deprived of truthful information about safer alternatives to combustible tobacco.

STATEMENT OF THE CASE

The relevant facts are set out in greater detail in the Appellants' opening brief. WLF wishes to highlight several facts of relevance to the issues on which this brief focuses.

An electronic cigarette or "e-cigarette" is a nicotine delivery device that is a popular alternative to combustible tobacco. In May 2016, FDA deemed e-cigarettes to be "tobacco products" subject to the federal laws that govern the promotion and marketing of conventional cigarettes. *See* "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," 81 Fed. Reg. 28,974 (May 10, 2016) (the Deeming Rule).

As a result of the Deeming Rule, e-cigarette manufacturers are now subject to a host of onerous regulatory requirements, including the Tobacco Control Act, 21 U.S.C. §§ 387-387u (the TCA). Under the TCA's regulation of "modified-risk tobacco products," 21 U.S.C. § 387k, manufacturers and retailers must obtain FDA's permission before marketing or labeling their products as "present[ing] a lower risk of tobacco-related disease or [being] less harmful than one or more other commercially marketed tobacco products." 21 U.S.C. § 387k(b)(2)(A)(i). The same restriction applies to any claim, whether explicit or implicit, that the product contains a reduced level of, or is free from, any substance, or that exposure to any substance is reduced or eliminated. *Id.* This restriction on speech applies not only to product labeling and advertising but also to "any action directed to consumers through the media *or otherwise*." *Id.* § 387k(b)(2)(A)(iii) (emphasis added). In

other words, the speech restriction covers virtually any communication to consumers.

The Deeming Rule's restrictions on manufacturer and retailer speech apply despite the veracity of that speech. If anything, FDA readily concedes that using e-cigarettes and other vapor products likely present less risk to individuals than smoking traditional cigarettes. In particular, FDA cites "emerging data that some individual smokers may potentially use [e-cigarettes] to transition away from combustible tobacco products" and admits that smokers have a "higher quit rate [20%] than those who used [nicotine replacement therapies] like patches or gum [10%] or those that did not use a cessation aid [15%.]" 81 Fed. Reg. at 29,037.

Even so, to obtain FDA's approval to utter truthful speech, a manufacturer or retailer must show to FDA's satisfaction not only that e-cigarettes will "significantly reduce harm and the risk of tobacco-related disease to individual tobacco users," but also that they will "benefit the health of the population as a whole taking into account both users of tobacco products and persons who do not currently use tobacco products." 21 U.S.C. § 387k(g)(1). To date, FDA has *never* approved an application for a modified risk tobacco product. *See* Slip Op. at 56.

Appellants include manufacturers and retailers of e-cigarette devices and liquids as well as a coalition of national and state-wide trade associations that advocate for the interests of manufacturers, distributors, and retailers of e-

cigarettes and other electronic nicotine delivery systems. Seeking to invalidate the Deeming Rule, Appellants sued FDA for, among other reasons, violating Appellants' right to free speech under the First Amendment. Most relevant here, Appellants alleged that FDA's restriction on modified-risk statements unconstitutionally prohibits manufacturers and retailers from making truthful and non-misleading statements about their products.

On cross-motions for summary judgment, the district court rejected Appellants' First Amendment claim, explaining that the First Amendment "accords a lesser protection to commercial speech than to other constitutionally guaranteed expression." Slip Op. 75. Contending that *Central Hudson Gas & Electric Corp. v. Public Service Commission*, 447 U.S. 557 (1980), provides the *only* relevant test for reviewing restrictions on commercial speech, the court held that FDA's imposing the TCA's restrictions on modified risk statements in a "commercial setting" easily satisfied *Central Hudson*'s intermediate scrutiny.[2] Slip Op 74-93.

In considering the "substantial interest" prong of *Central Hudson*, the court merely repeated FDA's asserted governmental goals and concluded: "FDA has articulated a substantial interest in regulating modified-risk claims." Slip Op. 91. In evaluating whether the TCA's restrictions on modified risk statements directly

[2] In reaching that conclusion, the district court declined to apply the heightened scrutiny the Supreme Court expressly required for all speaker-and content-based regulations of commercial speech in *Sorrell v. IMS Health*, 564 U.S. 552 (2011). Slip Op. 76-78.

advance FDA's interests, the court relied solely on an earlier Sixth Circuit decision upholding the TCA against a challenge by *tobacco* manufacturers and retailers. *Id*. at 92 (citing *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 537 (6th Cir. 2010)). Although that case did not consider application of the TCA to the e-cigarette industry, the district court nonetheless held that the Sixth Circuit's reasoning "in the context of a deadly and highly addictive product" nonetheless "applies with equal force to the regulation of e-cigarettes." *Id*.

Finally, in addressing *Central Hudson*'s requirement that the challenged regulation must be no more extensive than necessary, the district court rejected Appellants' contention that FDA could have simply required clarifying disclaimers on Appellants' modified-risk statements. In doing so, the court merely quoted—without further scrutiny or analysis—the TCA's prefatory finding that "consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification." Slip Op. 92-93. The court entered final judgment in favor of FDA; this appeal followed.

SUMMARY OF ARGUMENT

In recent years, federal courts have repeatedly held that FDA's restrictions on commercial speech are subject to significant First Amendment constraints and that those speech restrictions are constitutionally impermissible. *See, e.g.*,

Thompson v. W. States Med. Ctr., 535 U.S. 357 (2002); *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012); *Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir. 1999); *Amarin Pharma, Inc. v. FDA*, 119 F. Supp. 3d 196 (S.D.N.Y. 2015). Given this checkered history, it is disappointing that FDA would deem e-cigarettes to be "tobacco products" subject to the TCA, but fail to write the Deeming Rule in a manner demonstrating that FDA recognizes and respects the First Amendment's robust protection of truthful commercial speech.

Instead, the Deeming Rule imposes a prior restraint on manufacturers and retailers, requiring them to obtain FDA's permission before they may inform the public of the relative health risks of e-cigarettes compared to those of combustible tobacco products. Although the district court explicitly found that the Deeming Rule constitutes a "clear restriction on truthful and non-misleading speech," Slip Op. 90, it nonetheless upheld the Rule under an unusually relaxed application of *Central Hudson*. But the Supreme Court's decision in *Sorrell* unequivocally holds that all speaker- and content-based restrictions on commercial speech must withstand heightened judicial scrutiny to survive. Although *Sorrell* does not articulate a precise test for the mandated "heightened scrutiny," it makes clear that such review entails a First Amendment scrutiny at least more exacting than the *Central Hudson* intermediate review the district court applied here.

Regardless whether this Court undertakes an appropriately stringent

application of the *Central Hudson* test or something even stricter, the Constitution does not authorize the government to "pre-approve" truthful, non-misleading speech before commercial speakers may utter it. Indeed, this Court has already rejected the notion "that the health of consumers is advanced directly by barring *any* health claims not approved by the FDA." *Pearson*, 164 F.3d at 656 (emphasis added). If allowed to stand, the decision below will afford inappropriately broad deference to FDA's decision to restrict manufacturers' and retailers' truthful, non-misleading speech—in violation of the First Amendment.

The First Amendment injury inflicted by the Deeming Rule reaches far beyond the commercial interests of Appellants. It is undisputed that e-cigarettes and other vapor products are mainly used by adult smokers seeking to avoid the well-known health hazards associated with smoking cigarettes. Thus, for the millions of Americans seeking safer alternatives to combustible tobacco products, the Deeming Rule deprives them of valuable, truthful information. But "[t]he 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." *Sorrell*, 564 U.S. at 577. As the record conclusively shows, the district court was anything but "especially skeptical" about the speech restrictions at issue in this case.

ARGUMENT

I. THE CLEAR TRAJECTORY OF SUPREME COURT JURISPRUDENCE HAS BEEN TO INCREASE, NOT DECREASE, THE PROTECTION ACCORDED TO COMMERCIAL SPEECH

The district court began its constitutional analysis by emphasizing *Central Hudson*'s observation that the Supreme Court has historically accorded "a lesser protection to commercial speech than to other constitutionally guaranteed expression." Slip Op. 75 (quoting *Cent. Hudson*, 447 U.S. at 562-63). But that was hardly the Supreme Court's final word on commercial speech. To the contrary, the modern trend in Supreme Court jurisprudence has been to increase, rather than decrease, the level of protection accorded to commercial speech.

Even before *Central Hudson*—following decades of dormant First Amendment protection for commercial speech—the Supreme Court had already begun raising the bar for government restrictions on commercial speech. In 1975, the Court rejected the notion that laws regulating commercial speech are immune from First Amendment protection. In *Bigelow v. Virginia*, 421 U.S. 809 (1975), the Court considered a challenge to a Virginia law that made it a misdemeanor to advertise abortion services. In overturning the petitioner's conviction, the Court emphasized that the advertisement at issue "did more than simply propose a commercial transaction"—it also contained factual information of keen interest to the public. 421 U.S. at 822. Although *Bigelow* clarified that speech which both

proposes a commercial transaction and provides truthful information is deserving of First Amendment protection, it left unanswered whether purely commercial speech is also protected.

That question was soon answered in *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976), in which the Court struck down a state law prohibiting pharmacists from advertising prescription drug prices. Although Virginia claimed the law was necessary to maintain the professional image of pharmacists, the Court determined that any such interest was outweighed by the consumer's need for information on prescription-drug pricing. 425 U.S. at 763. The Court explicitly recognized that because 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," unhindered access to that information "is indispensable to the proper allocation of resources in a free enterprise system." *Id*. at 763, 765.

Central Hudson itself can also be understood as a case reiterating that commercial speech, like other forms of speech, deserves robust First Amendment protection. The *Central Hudson* Court considered a challenge to an energy-conservation regulation that prohibited utility companies from promoting electricity use. In a now-familiar test, the Court examined the regulation to decide whether it directly and materially advanced a substantial state interest and was

sufficiently tailored to further that interest. 447 U.S. at 568-71. Eight justices agreed that the challenged regulation failed that test. Writing for the majority, Justice Powell invoked *Virginia Board of Pharmacy*'s recognition of protections for "commercial speech from unwarranted governmental regulation" and reiterated that commercial speech "not only serves the economic interest of the speaker, but also assists consumers and furthers the societal interest in the fullest possible dissemination of information." *Id.* 561-62.

In the decades following *Central Hudson*, the Court went on to invalidate a litany of commercial-speech regulations. *See, e.g., W. States Med. Ctr.*, 535 U.S. at 357 (restriction on drug-compounding advertisements); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001) (regulation of tobacco advertising); *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173 (1999) (ban on casino and gambling advertisements); *44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484 (1996) (plurality opinion) (restriction on alcohol-price advertising); *Rubin v. Coors Brewing Co.*, 514 U.S. 476 (1995) (prohibition on disclosing alcohol content in beer labeling); *Edenfield v. Fane*, 507 U.S. 418 (1993) (regulation of attorney solicitations); *City of Cincinnati v. Discovery Network, Inc.*, 507 U.S. 410 (1993) (ban on commercial publication news racks); *Bd. of Trustees of the State Univ. of N.Y. v. Fox*, 492 U.S. 469 (1989) (prohibition on Tuppereware® parties in dorms); *Bolger v. Young Drug Prods. Corp.*, 463 U.S. 60 (1983) (ban on advertising

contraceptives); *Metromedia, Inc. v. City of San Diego*, 453 U.S. 490 (1981) (plurality opinion) (restriction on billboards).[3]

In the span of these opinions, the Court appears to have undertaken an increasingly vigorous review of commercial-speech restrictions while still casting *Central Hudson* as a test requiring "intermediate scrutiny." In fact, commentators postulate that the *Central Hudson* test applied by the Court today is "a standard so rigorous that it results in the virtually automatic invalidation of laws restraining truthful commercial speech." David C. Vladeck, *Lessons from a Story Untold:* Nike v. Kasky *Reconsidered*, 54 Case W. Res. L. Rev 1049, 1059 (2004) (arguing that the Court began to "recalibrate" the *Central Hudson* test almost immediately after it decided *Central Hudson*).

Unlike the Supreme Court, the lower federal courts have shown that the *Central Hudson* test can just as easily be manipulated to uphold excessive regulations as to invalidate them. As this case well reflects, the "substantial-interest" and "reasonable-tailoring" prongs of *Central Hudson*'s intermediate scrutiny test are particularly susceptible to self-serving constructions (including those urged by FDA below) that are unduly solicitous of regulatory judgments. As

[3] The notable outlier among this trend was *Posadas de Puerto Rico Assoc. v. Tourism Co.*, 478 U.S. 328, 342 (1986), whose overly deferential approach to government regulation of commercial speech the Court has since expressly disavowed. *44 Liquormart*, 517 U.S. at 509 (plurality opinion) ("[O]n reflection, we are now persuaded that *Posadas* erroneously performed the First Amendment analysis.").

a result, the Court in recent years has suggested that commercial speech should merit something close the same level of protection as non-commercial speech.

For example, when the commercial-speech regulation in question is content-based or speaker-based, the Court now holds that the intermediate scrutiny of *Central Hudson* must give way to "heightened" scrutiny. *See Sorrell*, 564 U.S. at 552 (discussed in depth in Section II, below). "Commercial speech is no exception," *Sorrell* explains, to the principle that the First Amendment "requires heightened scrutiny whenever the government creates a regulation of speech because of disagreement with the message it conveys." *Id.* at 566 (internal quotation marks omitted).

Although it could hardly be clearer, *Sorrell* has not fully succeeded in deterring local, state, and federal regulators from targeting truthful commercial speech in order to curb consumer demand for perfectly legal products and services the regulators disfavor. Indeed, lower courts have continued to use *Central Hudson* to undermine the First Amendment by upholding commercial-speech regulations that advance insubstantial, explicitly paternalistic regulatory goals. *See, e.g., Retail Digital Network, LLC v. Prieto*, 861 F.3d 839 (9th Cir. 2017) (en banc) (upholding ban on funding alcohol advertising); *Discount Tobacco City*, 674 F.3d at 534-537 (upholding TCA speech restrictions in traditional tobacco context).

Even so, "[t]he clear trajectory of the Supreme Court's jurisprudence is

toward greater protection for commercial speech, not less." *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 43 (D.C. Cir. 2014) (Brown, J., dissenting). After all, the text of the First Amendment explicitly guarantees the "freedom of speech" and on its face draws no distinction between commercial and non-commercial speech. Although the Court continues to apply the *Central Hudson* test, several justices have signaled their dissatisfaction with it. *See, e.g.*, *Nike, Inc. v. Kasky*, 539 U.S. 654, 676 (2003) (Breyer, J., dissenting) (arguing for applying "heightened scrutiny" to commercial speech restrictions when the speech involves a matter of public concern); *United States v. United Foods, Inc.*, 533 U.S. 405, 409-10 (2001) (noting "criticism" of *Central Hudson* test by several justices); *44 Liquormart*, 517 U.S. at 501, 510-14 (plurality opinion of Stevens, J., joined by Kennedy and Ginsburg, JJ.) ("The mere fact that messages propose commercial transactions does not in and of itself dictate the constitutional analysis that should apply to decisions to suppress them.").

And Justice Thomas has consistently stated that he "continue[s] to believe that when the government seeks to restrict truthful speech in order to suppress the ideas it conveys, strict scrutiny is appropriate, whether or not the speech in question may be characterized as 'commercial.'" *Matal v. Tam*, 137 S. Ct. 1744, 1769 (2017) (Thomas, J., concurring in part and concurring in the judgment) (quoting *Lorillard Tobacco Co.*, 533 U.S. at 572 (Thomas, J., concurring in part

and concurring in the judgment)).

The Supreme Court has freely acknowledged the widely perceived need for "a more straightforward and stringent test for assessing the validity of governmental restrictions on commercial speech." *Greater New Orleans*, 527 U.S. at 184. Many constitutional scholars agree. *See, e.g.*, Jonathan H. Adler, *Compelled Commercials Speech and the Consumer "Right to Know,"* 58 Ariz. L. Rev. 421, 431 (2016) (arguing that "*Central Hudson* provides a floor, not a ceiling, for commercial speech protection"); Martin H. Redish, *Commercial Speech, First Amendment Intuitionism and the Twilight Zone of Viewpoint Discrimination*, 41 Loy. L.A. L. Rev. 67, 108 (2007) (arguing that failure to extend *full* First Amendment protection to commercial speech is "a form of impermissible viewpoint discrimination undermining of the very core of what the First Amendment is all about"); Alex Kozinski & Stuart Banner, *Who's Afraid of Commercial Speech?*, 76 Va. L. Rev. 627, 628 (1990) (arguing that "the commercial/noncommercial distinction makes no sense").

The First Amendment jurisprudential landscape has changed much since the Supreme Court decided *Central Hudson* nearly four decades ago. By subjecting commercial speech regulations to stricter scrutiny, recent Supreme Court rulings have restored doctrinal clarity to First Amendment jurisprudence without compromising the government's legitimate, compelling interest in issuing narrowly

tailored directives to protect the commercial marketplace from fraud, deception, and serious threats to safety. The district court's analysis, by contrast, which is expressly premised on "lesser protection to commercial speech," turns back the clock on robust commercial-speech protections.

II. THE DISTRICT COURT'S LAX FIRST AMENDMENT SCRUTINY CANNOT BE SQUARED WITH THE SUPREME COURT'S DECISION IN *SORRELL*

Manifesting its growing discomfort with *Central Hudson*, the Supreme Court's landmark 2011 decision in *Sorrell v. IMS Health* reveals that the Court has revised its approach to commercial speech regulation in a way that is far less deferential to government regulators. To be sure, where a manufacturer's speech is "likely to deceive the public," or uttered to foment "illegal activity," the "government may ban [such] forms of communication." *Cent. Hudson*, 447 U.S. at 563-64. But when, as here, a manufacturer speaks truthfully and in a non-misleading way about its products and their lawful use, "heightened" judicial scrutiny applies. *Sorrell*, 564 U.S. at 571.

Sorrell can only be understood as holding that content- and speaker-based burdens on truthful commercial speech that seek to manipulate consumer choice are subject to higher scrutiny than the intermediate scrutiny prescribed by *Central Hudson*. That said, relying in part on the Ninth Circuit's controversial decision in *Retail Digital Network*, 861 F.3d at 839, the district court held that "the *Sorrell* opinion did not alter or replace the *Central Hudson* [intermediate] scrutiny

standard" for reviewing "content-based restrictions on speech." Slip.Op.76. "Indeed," the district court explained, *Sorrell* "struck down the state statute involved by invoking the elements of the *Central Hudson* test." *Id.* That reading not only contravenes a plain reading of *Sorrell*, but it renders that landmark decision incoherent.

Because the district court completely side stepped *Sorrell*'s explicit heightened-scrutiny requirement, the judgment below should be reversed.

A. *Sorrell* Mandates "Heightened" Judicial Scrutiny of Speaker- and Content-Based Restrictions on Commercial Speech

In *Sorrell*, the Court invalidated a speaker- and content-specific Vermont law that prohibited pharmaceutical manufacturers from taking advantage of prescriber-specific prescription information to target their marketing efforts and persuade physicians to prescribe their name-brand drugs instead of lower-cost generic alternatives. 564 U.S. at 564. Under the law, anyone else could use the same data to engage in target marketing efforts calculated to persuade physicians to *decrease* their reliance on name-brand drugs. *Id.*

Sorrell recognized that "[i]n the ordinary case it is *all but dispositive* to conclude that a law is content-based and, in practice, viewpoint-discriminatory." *Id.* at 571 (emphasis added). Reasoning that the Vermont law was invalid regardless "whether a special commercial speech inquiry [*i.e.*, intermediate scrutiny] or a stricter form of judicial scrutiny is applied," *Sorrell* held that the law

unconstitutionally discriminated against specific speakers and content. *Id.* at 571, 579-80.

Sorrell echoed the Court's earlier skepticism about the government's use of commercial speech regulations to modify perfectly lawful choices. *Id*. at 583-84. For example, the Court rejected the notion that the government may regulate commercial speech consistent with the First Amendment simply because that speech is highly persuasive and induces listeners to make what government regulators consider bad, although lawful, economic choices. *Id.* at 576.

Instead, the Court analogized limitations on truthful, non-misleading commercial speech to the suppression of political speech, explaining that such restrictions receive commensurably "heightened" First Amendment scrutiny:

> In an attempt to reverse a disfavored trend in public opinion, a State could not ban campaigning with slogans, picketing with signs, or marching during the daytime. Likewise, the State may not seek to remove a popular but disfavored product from the marketplace by prohibiting truthful, nonmisleading advertisements that contain impressive endorsements or catchy jingles. That the State finds expression too persuasive does not permit it to quiet the speech or to burden its messengers.

Id. at 577-78. The Court also rejected the notion that the government has a cognizable First Amendment interest in using speech regulation as a vehicle to direct or manipulate consumer choice:

> Those who seek to censor or burden free expression often assert that disfavored speech has adverse effects. But the "fear that people would make bad decisions if given truthful information" cannot justify

> content-based burdens on speech. … "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."

Id. at 577 (citations omitted).

Sorrell clarifies that so long as commercial speech is truthful and non-misleading, no principled basis exists for relegating it to second-class status for purposes of First Amendment analysis. The district court failed to take seriously that doctrinal principle here. Because FDA's modified-risk speech restrictions apply only to manufacturers and retailers—but to no one else—they are obviously speaker-based. Likewise, because those restrictions are triggered only by speech that suggests that e-cigarettes "present a lower risk of tobacco-related disease or [are] less harmful than one or more other commercially marketed tobacco products," 21 U.S.C. § 387k(b)(2)(A)(i), they are unquestionably content-based. For these reasons, under *Sorrell*, the Deeming Rule's speech restrictions are subject to *heightened*, not intermediate scrutiny. Yet the district court never even attempted to apply that heightened level of review in the first instance.

B. *Sorrell*'s Requisite "Heightened Scrutiny" Is *Not* the Intermediate Scrutiny of *Central Hudson*

Contrary to the district court (and the Ninth Circuit), *Sorrell*'s requisite "heightened scrutiny" for speaker- and content-based restrictions on truthful and non-misleading commercial speech is ***not*** the intermediate scrutiny of *Central Hudson*. While the Supreme Court declined in *Sorrell* to articulate precisely what

"heightened scrutiny" entails, its statement that speaker- and content-based commercial-speech restrictions are "presumptively invalid," 564 U.S. at 571, belies any suggestion that the Court equates "heightened scrutiny" with the intermediate scrutiny of *Central Hudson*.[4]

Although the Supreme Court ultimately determined that the Vermont speech restrictions at issue in *Sorrell* were unconstitutional even when analyzed under *Central Hudson* (and thus that the Court had no need to undertake a separate "heightened scrutiny" analysis of those restrictions), that determination cannot plausibly justify concluding that the Court equates the two standards of review. To the contrary, by stating that "the outcome is the same whether a special commercial speech inquiry or a stricter form of judicial scrutiny is applied," *Sorrell* leaves no doubt that the Court views "heightened scrutiny" as a "stricter form of scrutiny" than the *Central Hudson* standard traditionally applied to commercial-speech restrictions. 564 U.S. at 571.

[4] At least three other circuits have recognized that *Sorrell*'s heightened scrutiny is more stringent than *Central Hudson*'s intermediate scrutiny. *See, e.g.*, *Caronia*, 703 F.3d at 164 (explaining that *Central Hudson* imposed a "less rigorous intermediate test" than the "heightened scrutiny" required under *Sorrell*); *King v. Governor of the State of New Jersey*, 767 F.3d 216, 236 (3d Cir. 2014) (citing *Sorrell* and explaining that "content-based regulations are highly disfavored and subjected to strict scrutiny … even when the law in question regulates unprotected or lesser protected speech"); *Educ. Media Co. at Va. Tech. v. Insley*, 731 F.3d 291, 298 & n.4 (4th Cir. 2013) (leaving the question of heightened scrutiny "unanswered" because the challenged regulation "could not even withstand *intermediate scrutiny* under *Central Hudson*") (emphasis added).

A contrary reading would render superfluous *Sorrell*'s careful analysis of whether Vermont's law was content and speaker based. If intermediate scrutiny applies just as equally to content- and speaker-based regulations as to those that are not, then no need exists for a court to first determine whether a law is content-neutral on its face. Even the dissent in *Sorrell* recognized that the Court's decision points to "a standard yet stricter than *Central Hudson*." *Id.* at 588 (Breyer, J., dissenting).[5]

As the district court noted, "[t]he D.C. Circuit has not yet addressed the question of whether *Sorrell* calls for a new approach to regulations of commercial speech." Slip Op. at 77. WLF respectfully urges the Court to use this appeal as the appropriate vehicle for providing at least some minimal guidance on what constitutes "heightened" judicial scrutiny under *Sorrell*. One plausible approach is to apply the same strict scrutiny to speaker- and content-based restrictions on commercial speech that courts routinely apply in any other speech setting.

That approach would be fully consistent with *Sorrell*'s recognition that "[i]n the ordinary case it is *all but dispositive* to conclude that a law is content-based and, in practice, viewpoint-discriminatory." 564 U.S. at 571. WLF submits that this

[5] In his dissent in *Sorrell*, Justice Breyer also noted that the majority opinion implicates the FDA's regulatory framework because it, like the challenged Vermont law, imposes "speaker-based" restrictions on speech. 564 U.S. at 586-588. The Deeming Rule is no different.

is "the ordinary case." Applying strict scrutiny is also consistent with the larger rationale underlying *Sorrell*: that the "choice 'between the dangers of suppressing information, and the dangers of its misuse if it is freely available' is one that 'the First Amendment makes for us.'" *Id.* at 578 (quoting *Va. Bd. of Pharmacy*, 425 U.S. at 770).

Strict scrutiny would also be consistent with *Reed v. Town of Gilbert, Ariz.*, 135 S. Ct. 2218, 2227 (2015), which holds that *any* effort to classify speech by reference to its content, or to burden speech that falls into a disfavored category, constitutes a content-based restriction subject to strict scrutiny. *Reed* expressly relied on *Sorrell* to conclude that a speech regulation is content-based "if a law applies to particular speech because of the topic discussed or message expressed." 135 S. Ct. at 2227, 2230 (citing *Sorrell*, 131 S. Ct. at 2663-64). Although the case involved a challenge to a sign ordinance restricting the number and size of "Temporary Directional" signs a church could display on its property, *Reed* appears to draw no distinction between commercial and non-commercial speech.

Reed rejects the now-familiar contention of government regulators, repeated by FDA here, that a "regulation is content neutral—even if it expressly draws distinctions based on … communicative content—if those distinctions can be justified without reference to the content of the regulated speech." *Id.* at 2228 (internal quotation marks omitted). Instead, *Reed* holds that a content-based

regulation of speech is subject to strict scrutiny "regardless of the government's benign motive, content neutral justification, or lack of animus toward the ideas contained in the regulated speech." *Id.* Here, the way in which vapor manufacturers and retailers "communicate" with their customers is quintessentially expressive and, under *Reed*, always subject to strict First Amendment scrutiny.

Alternatively, at the very least, the Court should not only require FDA to make the three factual showings mandated by *Central Hudson*—that (1) the interest asserted by the government is substantial; (2) the challenged speech restriction directly advances the asserted interest; and (3) the restriction serves that interest in a narrowly tailored manner—but it should also require that FDA satisfy its evidentiary burden on those points by a *clear and convincing* standard of proof. This is the same quantum and quality of proof necessary to overcome free speech concerns in other First Amendment settings. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986); *New York Times v. Sullivan*, 376 U.S. 254 (1964).

So, for example, the "narrow tailoring" prong should, at a bare minimum, require FDA to complete one or more empirical studies establishing with a high degree of certainty that the government could not possibly achieve its asserted interests without restricting speech. The evidence in the administrative record and submitted by FDA during the summary judgment proceedings below comes nowhere near meeting that heightened evidentiary standard.

In *Sorrell* the Supreme Court had no need to apply the requisite heightened scrutiny because its application of *Central Hudson* sufficed as an independent basis for overturning the challenged law. In stark contrast, the district court below concluded that the Deeming Rule survived *Central Hudson* but then abandoned any further constitutional inquiry, entering judgment for FDA without applying heightened scrutiny. Because that approach to speaker- and content-based suppression of truthful speech cannot possibly be squared with *Sorrell*, the judgment below must be reversed.

III. IN UPHOLDING THE DEEMING RULE AGAINST APPELLANTS' FIRST AMENDMENT CHALLENGE, THE DISTRICT COURT FAILED TO TAKE INTO ACCOUNT LISTENERS' INTERESTS

The First Amendment's protections are not limited to speakers. A necessary corollary of the First Amendment right to free speech is the right to hear and receive information. "[M]anufacturers have an interest in conveying truthful information about their products to adults, and adults have a corresponding interest in receiving truthful information." *Lorillard Tobacco Co.*, 533 U.S. at 564; *see also Va. State Bd. of Pharmacy*, 425 U.S. at 756-57 (holding that the First Amendment "equally" protects the right of willing listeners to hear what a commercial speaker has to say); *Red Lion Broad. Co v. FCC*, 395 U.S. 367, 390 (1969) (confirming that the Constitution requires protection of "the right of the public to receive" speech).

As one commentator has explained, "[s]ince advertising performs a significant function for its recipients, its values are better viewed with the consumer, rather than the seller, as the frame of reference." Martin H. Redish, *The First Amendment in the Marketplace: Commercial Speech and the Values of Free Expression*, 39 Geo. Wash. L. Rev. 429, 434 (1971). Above all, the listener's interest is substantial because "the consumer's concern for the free flow of commercial speech often may be far keener than his concern for urgent political dialogue." *Bates v. State Bar of Arizona*, 433 U.S. 350, 364 (1977). Yet, in evaluating the Deeming Rule, the district court never considered the important listeners' interests so clearly at stake.

The First Amendment burden on the listener's First Amendment rights here results in a complete loss of the desired information to those who need it the most. That is no small matter. It is undisputed that e-cigarettes and other vapor products are mainly used by adult smokers seeking to avoid the significant health hazards associated with smoking cigarettes. If, as a result of the Deeming Rule, they are denied access to truthful information that would help them transition away from cigarettes, that would not only defeat the stated purpose of the TCA, but it would flout the Constitution.

To justify inflicting such a substantial First Amendment injury, the government must prove that is has a powerfully compelling interest that can be

accomplished only by completely eradicating listeners' rights to receive the desired, truthful speech. As Appellants' opening brief convincingly establishes, FDA has not come close to meeting that burden; nor can it. Given the importance of truthful, non-misleading information to individual consumers and to the public at large, any regulation of Appellants' speech must maximize, not eliminate, the delivery of such useful information. *See, e.g., Edenfield*, 507 U.S. at 767 ("The general rule is that the speaker *and the audience*, not the government, assess the value of the information presented.") (emphasis added).

These constitutional concerns are particularly acute when the information in question concerns matters affecting personal health and well-being. *See Sorrell*, 564 U.S. at 566 (emphasizing that the listener's interest "has great relevance in the fields of medicine and public health, where information can save lives"). Truthful health information, including accurate product comparisons, empowers consumers by helping them to make better-informed decisions, including the decision whether to continue smoking cigarettes or whether to try safer alternatives such as e-cigarettes.

In sum, not only has FDA failed to justify the Deeming Rule's extraordinary injury to listeners' First Amendment interests, but the district court failed even to take those interests into consideration. Of course, an alternative exists to FDA's highly paternalistic approach. "That alternative is to assume that this information is

not in itself harmful, that people will perceive their own best interests if only they are well enough informed, and that the best means to that end is to open the channels of communication rather than to close them." *Va. Bd. of Pharmacy*, 425 U.S. at 770. WLF respectfully urges the Court to follow that salutary (and constitutionally mandated) approach in this case.

CONCLUSION

The Court should reverse the district court's decision.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 29(a)(5) because it contains 5,711 words, excluding those portions of the brief exempted by Fed. R. App. P. 32(f). This brief complies with the typeface and typestyle requirements of Fed. R. App. P. 32(a)(5) and 32(a)(6) because it has been prepared in proportionately spaced typeface using Microsoft Word 2010 in Times New Roman 12-point font.

/s/ Cory L. Andrews
Cory L. Andrews

CERTIFICATE OF SERVICE

I certify that on this 20th day of February, 2018, I caused a true and correct the foregoing document to be served via electronic mail upon all counsel of record by operation of the Court's CM/ECF system.

/s/ Cory L. Andrews
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