ORAL ARGUMENT NOT YET SCHEDULED

No. 18-5195

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

CIGAR ASSOCIATION OF AMERICA, *et al.*

Plaintiffs-Appellants,

v.

UNITED STATES 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-1460-APM

BRIEF FOR AMICUS CURIAE PUBLIC CITIZEN SUPPORTING APPELLEES AND AFFIRMANCE

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CERTIFICATE AS TO PARTIES, RULINGS, RELATED CASES, FILING OF A 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 hereby certify as follows:

1. 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 Cigar Association of America, *et al.*, and the Brief for Appellees United States Food and Drug Administration, *et al.*

Amicus curiae Public Citizen, the filer of this brief, is appearing with the consent of the parties in support of 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.

In addition to Public Citizen, the following amici have appeared in this Court: Professor of Marketing J. Scott Armstrong, who has filed a brief in

support of neither party; and the State of Arizona, which has filed a brief in support of plaintiffs-appellants.

A notice of intent to file a brief in support of defendants-appellees has been filed by American Academy of Pediatrics, the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the American Thoracic Society, the Campaign for Tobacco-Free Kids, and Truth Initiative. Public Citizen understands the Public Health Law Center also intends to appear as amici in support of defendants-appellees.

2. Rulings Under Review

References to the district court decision under review appear in the certificates to the Opening Brief of Appellants Cigar Association of America, *et al.*, and the Brief of Appellees United States Food and Drug Administration, *et al.*

3. Related Cases

A description of related cases appears in the certificate to the Opening Brief of Appellants Cigar Association of America, *et al.*, and the Brief of Appellees United States Food and Drug Administration, *et al.*

4. Separate Brief

Public Citizen has filed a separate brief from the other amici that intend to file briefs supporting defendants-appellees. A single amicus curiae brief is

not practicable in this case because Public Citizen's brief addresses aspects of the issues posed by this appeal that the other amici do not intend to address. Specifically, Public Citizen's brief addresses the cigar industry's argument that the health warnings at issue in this case should be assessed under a level of First Amendment scrutiny more demanding than that required by precedent for government-mandated disclosure regulations. Public Citizen has considerable familiarity with this issue and has addressed it in other briefs in the Supreme Court, this Court, and other courts of appeals. Public Citizen understands that other amici's arguments will not focus on the appropriate First Amendment standard and will reflect distinctive viewpoints of those amici. *See* D.C. Cir. R. 29(d).

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INTEREST OF AMICUS CURIAE*

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, including issues relating to public health in general and regulation of foods, drugs, and tobacco products by the Food and Drug Administration (FDA) in particular. In addition, 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 Board of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748 (1976). It has also defended the constitutionality of commercial-speech regulations as amicus curiae in cases where the regulations were important to protecting public health or served other important public interests. *See, e.g.*, *Nicopure Labs, LLC v. FDA*, No. 17-5196 (D.C. Cir.) (pending); *POM Wonderful, LLC v. FTC*, 777 F.3d 478 (D.C. Cir. 2015); *Am. Meat Inst. v.*

* 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.

Department of Agric., 760 F.3d 18 (D.C. Cir. 2014); *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 pursuing aggressive applications of commercial-speech doctrine to stifle regulatory measures designed to protect consumers. It has become commonplace for regulated entities to raise First Amendment challenges to disclosure regulations that provide consumers with important information about the quality or nature of, or the risks associated with, products and services that consumers seek to purchase from commercial establishments. Commercial-speech doctrine developed from the recognition that complete prohibitions on truthful commercial speech, which historically fell outside of the protection of the First Amendment, rarely served legitimate government interests and often resulted in consumer harm. *See Virginia Bd. of Pharmacy*, 425 U.S. at 770. At the same time, legitimate government interests and consumer harm are threatened by industry attempts to blur or erase the distinctions that commercial-speech doctrine draws between disclosure requirements and restrictions on commercial speech, and between commercial speech and fully protected speech.

Here, for example, the appellant cigar-industry associations seek to impose on the disclosure regulation at issue a higher level of First Amendment scrutiny than is called for by applicable precedent. Adoption of this view would undermine the important public-health benefits served by the federal government's regulation of tobacco marketing and, more broadly, unnecessarily tilt the First Amendment balance against a range of laws and regulations that serve important public interests.

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in the Opening Brief of Appellants Cigar Association of America, *et al.*, and the Brief of Appellees United States Food and Drug Administration, *et al.*

SUMMARY OF ARGUMENT

I. Cigar Association of America and other appellants (collectively, Cigar Association), representing the interests of various cigar manufacturers and sellers, bring a First Amendment challenge to FDA regulation that requires the packaging and advertising of cigar products to disclose factual and noncontroversial information about the health risks of smoking tobacco. Under governing precedent, the cigar industry's challenge should be analyzed under *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985), to determine whether the regulation is

"unjustified or unduly burdensome" and "reasonably related" to the government's interest. *Id.* at 651.

The Cigar Association relies on dicta in various cases to suggest that a sufficiently burdensome regulation may be treated as a restriction on speech under *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980), and subjected to its intermediate-scrutiny standard rather than *Zauderer*'s reasonable-relationship test. It points to no case, however, that actually has treated a regulation this way. The absence of such authority makes sense because *Zauderer* already prohibits disclosure requirements that are unduly burdensome, making the Cigar Association's attempt to invoke *Central Hudson*'s higher standard of review little more than an end run around *Zauderer*.

The FDA's cigar regulation does not impose disclosure burdens that justify application of *Central Hudson* in any event. The health warnings required by the regulation take up only a fraction of cigar advertising and packaging space, leaving the bulk of those spaces available for whatever truthful messages the cigar industry wishes to convey to its customers. To be sure, the warnings occupy space that the cigar industry cannot use and contain design elements that make them noticeable to consumers. This Court, however, has rejected the argument that those features, in themselves,

take a disclosure requirement out of the realm of *Zauderer* and into that of *Central Hudson*. The possibility that cigar companies may alter their advertising choices in response to the disclosure requirement does not change the analysis, especially where, as here, the Cigar Association does not assert that the government required the disclosures for the purpose of restricting protected speech.

II. The Court should firmly reject the Cigar Association's argument that the FDA's disclosure requirement should be analyzed under strict scrutiny. This Court has already held that, where commercial speech is at issue, the applicable standards are the *Zauderer* standard (for disclosure requirements) or the *Central Hudson* standard (for commercial-speech restrictions falling outside *Zauderer*'s ambit). Contrary to the Cigar Association's suggestion, *National Institute of Family and Life Advocates v. Becerra*, 138 S. Ct. 2361 (2018) (*NIFLA*), did not involve the application of strict scrutiny to commercial disclosure requirements and, therefore, does not call for reconsideration of this Court's precedents or application of strict scrutiny here.

III. Insofar as it claims, in the alternative, that the health warnings for cigars fail the *Zauderer* test, the Cigar Association misapplies the *Zauderer* standard in two ways. First, the Cigar Association errs in denigrating the

importance of the government's interest in this case. Even assuming that *Zauderer* incorporates *Central Hudson*'s requirement that regulation of commercial speech must involve a "substantial" government interest, the government's interest here is substantial. The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009), which authorized the FDA's disclosure regulation, reflects Congress's intent to reduce consumer use of tobacco, and the Cigar Association concedes that the government has a substantial interest in that objective. Moreover, the government's interest in ensuring that consumers are informed of the health risks associated with products they purchase is substantial. This Court has repeatedly upheld disclosure rules that serve that salutary purpose.

Second, the Cigar Association errs in contending that *Zauderer* requires the government to adopt less restrictive alternatives to its disclosure requirement. *Zauderer* makes clear that the least-restrictive-means test has no place in review of commercial-speech disclosures, because disclosures are typically considered less restrictive than other means for achieving the government's legitimate interests. Contrary to the Cigar Association's contention, *NIFLA* did not upend this principle. *NIFLA*'s application of *Zauderer* makes no mention of a least-restrictive-means analysis. Although *Zauderer* does not permit an unduly burdensome disclosure requirement, it

does permit a disclosure requirement that is not unduly burdensome, even where a less burdensome alternative might exist.

ARGUMENT

The Supreme Court first recognized commercial speech as constitutionally protected expression in 1976, in *Virginia Board of Pharmacy*, 425 U.S. at 761, 770. In the ensuing four decades, courts have consistently applied two basic principles in assessing the constitutionality of laws that regulate commercial speech. First, courts have accorded commercial speech "less protection" than "other constitutionally safeguarded forms of expression" in light of "the 'common-sense' distinction between speech proposing a commercial transaction, which occurs in an area traditionally subject to government regulation, and other varieties of speech." *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 64–65 (1983) (quoting *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447, 455–56 (1978)).

Second, courts have recognized "material differences between disclosure requirements and outright prohibitions on speech." *Zauderer*, 471 U.S. at 650. Prohibitions on protected commercial speech are assessed under the test articulated in *Central Hudson*, 447 U.S. at 563–66. *Central Hudson* directs courts to apply "intermediate scrutiny" to the prohibition and to uphold it if the prohibition "directly advanc[es] a substantial governmental

interest and [is] no more extensive than is necessary to serve that interest." *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 249 (2010) (internal quotation marks and original brackets removed). In contrast, laws that compel the disclosure of information rather than prohibit speech are subject to "a lower level of scrutiny … in certain contexts." *NIFLA*, 138 S. Ct. at 2372. Specifically, when the law "require[s] the disclosure of 'purely factual and uncontroversial information about the terms under which … services will be available,'" it "should be upheld unless [it is] 'unjustified or unduly burdensome.'" *Id.* (quoting *Zauderer*, 471 U.S. at 651). Under *Zauderer*, a commercial disclosure standard is justified if it is "reasonably related" to the governmental interest that the law is designed to address. *Zauderer*, 471 U.S. at 651.

The Cigar Association seeks to disrupt this well-established framework with three alternative arguments. First, it asks this Court to review the requirement that the cigar industry disclose the health risks of its products under *Central Hudson* rather than *Zauderer*. Second, it asks this Court to employ "strict scrutiny," which applies to regulation of fully protected speech, but which has never applied to commercial-speech restrictions. Finally, it misapplies *Zauderer* in an attempt to require the government to satisfy a more stringent burden than *Zauderer* in fact imposes. As explained

below, the Cigar Association's arguments regarding the applicable First Amendment standard are inconsistent with precedent.

I. *Zauderer* states the proper standard for assessing the required cigar disclosures.

In *Zauderer*, the Supreme Court held that commercial-disclosure requirements are subject to a less stringent standard of review than laws that prohibit commercial speech based on content. *Zauderer* explains that the difference in the standards of review rests on "material differences between disclosure requirements and outright prohibitions on speech." 471 U.S. at 650. When commercial speakers are required to disclose information about their products or businesses, "the interests at stake … are not of the same order." *Id.* at 651. "Because the extension of First Amendment protection to commercial speech is justified principally by the value to consumers of the information such speech provides," a commercial speaker's "constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal." *Id.* Disclosure requirements are a preferred form of regulating commercial speech precisely because they "trench much more narrowly on an advertiser's interests than do flat prohibitions on speech." *Id.* These considerations led the Supreme Court in *Zauderer* to hold heightened scrutiny in any form (including *Central Hudson*'s intermediate scrutiny) inapplicable to requirements of factual disclosures in commercial

advertising, and to limit review of such requirements to a substantially more deferential level of constitutional scrutiny. *Id.*

The Cigar Association does not dispute that the FDA's regulation requiring health warnings on the packaging and advertising of cigar products governs only commercial speech. The Cigar Association does not contend that the regulation bars the cigar industry from truthfully speaking about its tobacco products. And it does not dispute that the disclosures the industry must provide contain only "factual and uncontroversial information" about its products. *NIFLA*, 138 S. Ct. at 2372 (quoting *Zauderer*, 471 U.S. at 651). Accordingly, the Cigar Association does not dispute that all of the elements required for application of the *Zauderer* standard are present in this case. *See id.*

Nonetheless, the Cigar Association argues (at 38–39) that this Court should apply *Central Hudson* rather than *Zauderer* because the burdens imposed by the FDA's disclosure regulation operate as restrictions on speech. The Court should reject that view.

Using *Central Hudson* to assess a disclosure requirement that falls squarely within *Zauderer* would be unprecedented, a point confirmed by the Cigar Association's failure to cite any precedent for it. It relies on dicta from a footnote from one decision of this Court that stated that the Court was not

deciding "when the compulsion to speak becomes more like a speech restriction than a disclosure." *See* Cigar Br. 38 (citing *Pursuing America's Greatness v. FEC*, 831 F.3d 500, 507 n.3 (D.C. Cir. 2016) (*PAG*)). *PAG*, however, did not involve commercial speech. It addressed a campaign-finance rule that prohibited certain political committees from "using candidates' names in the titles of their websites and social media pages." *Id.* at 503. To determine whether the rule imposed a disclosure requirement or a restriction on speech, the Court looked to *Zauderer* as "instructive." *Id.* at 507. Although the rule regulated noncommercial speech, the Court explained that it would "view disclosure rules far less skeptically than … bans on speech." *Id.* The Court concluded that the rule was a restriction rather than a disclosure requirement because it did "not obligate PAG to say anything" but instead "prevent[ed] PAG from conveying information to the public." *Id.* (quoting *Zauderer*, 471 U.S. at 650 (internal quotation marks omitted)).

Nothing in *PAG* suggests that the Court should look to the *burden* imposed by a disclosure requirement to determine whether it restricts commercial speech. Rather, *PAG* instructs that, "[t]o decide whether a law is a disclosure requirement or a ban on speech, [the Court] ask[s] a simple question: does the law require the speaker to provide more information to the audience than he otherwise would?" 831 F.3d at 507. That test does not

help the Cigar Association here, because the FDA's disclosure regulation obligates the cigar industry to provide more information to the public (about the health risks associated with tobacco products) and, unlike the regulation in *PAG*, does not prevent cigar companies from making any truthful statement they like.

The Cigar Association's reliance on two out-of-circuit decisions fares no better. In *Dwyer v. Cappell*, the Third Circuit considered a state-bar rule that "ban[ned] advertising with quotations from judicial opinions unless the opinions appear in full." 762 F.3d 275, 276 (3d Cir. 2014). The court found that the rule "necessarily prevent[ed] any form of advertisement with simply a judicial excerpt" and was "so cumbersome that it effectively nullifie[d] the advertisement" even assuming "theoretically endless capacity." *Id.* at 284. Importantly, the Third Circuit reached that conclusion without abandoning *Zauderer*. *Id.* at 282 ("Yet we need not decide whether [the regulation] is a restriction on speech or a disclosure requirement" because "it is unconstitutional under even the less-stringent *Zauderer* standard of scrutiny").

In *Tillman v. Miller*, 133 F.3d 1402, 1403 (11th Cir. 1998), also cited by the Cigar Association, the Eleventh Circuit invalidated a state law that required attorneys who ran television advertisements about their workers'

compensation practice to inform viewers that filing fraudulent workers' compensation claims was a crime. Applying *Zauderer*, the court found the requirement "too burdensome" because the disclosure was "not tied to an inherent quality of … legal services," and the state failed to show that "television advertising of legal services causes fraudulent workers' compensation claims to be filed or that including the pertinent compelled disclosure would likely significantly reduce fraudulent claims in Georgia." *Id*. Far from jettisoning *Zauderer* in favor of *Central Hudson*, the court's decision held the requirement to be unjustified and unduly burdensome under the *Zauderer* standard.

Although both *Dwyer* and *Tillman* suggest the possibility that a burdensome disclosure requirement may be viewed as a restriction on speech, both cases were resolved under *Zauderer*. That result is understandable, because a disclosure burden so onerous that it could justify application of *Central Hudson* would likely fail *Zauderer*'s undue-burden standard. *See Zauderer*, 471 U.S. at 651 (observing that "unjustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech"). Indeed, the test that the Cigar Association proposes for evaluating when a disclosure requirement crosses the hypothetical line into a restriction on speech appears

indistinguishable from *Zauderer*'s undue-burden standard. *Compare* Cigar Br. 33, *with id.* at 38.

The Cigar Association's position would sow doctrinal confusion by blurring the boundaries of *Central Hudson* and *Zauderer*. Absent some more compelling precedential support for taking such a step, the Court can and should assess the Cigar Association's claim that the FDA's disclosure regulation imposes an undue burden on the cigar industry under the *Zauderer* framework.

Even if dicta in *Dwyer* and *Tillman* were correct that disclosure requirements may be evaluated as speech restrictions in certain circumstances, the FDA's disclosure regulation does not come close to that line. The disclosure obligation in *Dwyer*, for example, required an attorney to reproduce the full text of a judicial opinion whenever the attorney quoted from it in an advertisement. The cigar industry's obligation, by contrast, is simply to devote a fraction of cigar packaging and advertising space to warnings about the health risks associated with their products. And unlike in *Tillman*, where the warnings about filing fraudulent workers' compensation claims were not directed at the legal services that the attorney was offering for sale, the health warnings required here are directly "tied to an inherent quality" of tobacco. *Tillman*, 762 F.2d at 1403. The FDA's cigar disclosure

requirement is thus of a piece with the various other types of disclosures that governments require of companies that market or sell products and services to consumers. *See*, *e.g.*, FDA Br. 41–42. Although the Cigar Association may prefer that the warnings be smaller and less noticeable to consumers, there is nothing unique about them that would remove them from *Zauderer*'s domain.

The Cigar Association asserts, however, that *Central Hudson* should apply because the cigar industry's speech is restricted to only 70 percent of packaging space (on the two principal panels) and 80 percent of advertising space and because the disclosure's required design elements "draw the eye." Cigar Br. 38. Every disclosure requires space, however, and efficacious disclosures will typically require more space—and perhaps more striking design elements—than ineffective ones. As this Court has held, those features of disclosures do not transform them into "affirmative limitation[s] on speech." *Spirit Airlines, Inc. v. United States Dep't of Transp.*, 687 F.3d 403, 413–14 (D.C. Cir. 2012) (applying *Zauderer* in upholding requirement that airlines "post the total, final price [of a ticket] in the most prominent manner" even though it "prohibit[ed] them from posting other numbers as prominently or more prominently than the total, final price").

Finally, the Cigar Association contends that the disclosure obligation should be analyzed as a speech restriction because two companies submitted declarations alleging that they would "likely" curtail certain media advertisements rather than provide the required warnings. Cigar Br. 38–39 (citing Anderson Decl. ¶ 13 (ECF No. 62-18); Koebel Decl. ¶ 7 (ECF No. 61-22)). But nothing in *Zauderer* suggests that the chilling effects over which the Court's opinion briefly expresses concern include those resulting from commercial speakers' preference not to provide factual disclosures that are reasonably related to legitimate interests in providing information to consumers. Rather, *Zauderer* says only that "*unjustified or unduly burdensome* disclosure requirements might offend the First Amendment by chilling protected commercial speech," 471 U.S. at 651 (emphasis added), and that inquiry cannot turn on whether a company makes a self-serving assertion about how it intends to respond to a disclosure requirement. The Cigar Association's contrary argument rests on a cite to *Dwyer*'s dictum stating that *Central Hudson* would be the proper standard to use if "the intention behind" a disclosure requirement were to restrict speech. Cigar Br. 38 (citing *Dwyer*, 762 F.3d at 284). It does not contend, however, that the FDA required the cigar industry to warn consumers about the health risks associated with tobacco products for the purpose of curtailing the industry's

speech, and it cites no record evidence to suggest that the disclosure requirement has any purpose other than ensuring that consumers understand the health risks associated with tobacco products.

II. Strict scrutiny does not apply to regulation of commercial speech.

Even more radical than the Cigar Association's request for *Central Hudson* review of a disclosure requirement is its alternative argument that strict scrutiny should apply here. That argument is foreclosed by precedent. In the decades since the Supreme Court first extended First Amendment protection to commercial speech, no Supreme Court or federal appellate precedent has applied strict scrutiny to a commercial-speech disclosure requirement. The FDA's cigar regulation undisputedly governs only commercial speech. Regulation of commercial speech is subject either to *Zauderer* or to intermediate scrutiny under *Central Hudson*. *See Milavetz*, 559 U.S. at 249 (describing *Central Hudson* and *Zauderer* as the two possible standards for scrutinizing laws that "regulate only commercial speech"); *Expressions Hair Design v. Schneiderman*, 137 S. Ct. 1144, 1151 (2017) (same).

In *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), this Court confirmed that *Central Hudson*'s intermediate-scrutiny standard—not strict scrutiny—applies to commercial-speech regulations that

do not fall within *Zauderer*. In that case, the Court considered an FDA rule requiring graphic warnings on cigarette packages. *Id.* at 1208. The Court first concluded that the graphic warnings at issue did not fall within *Zauderer, id.* at 1213–17, and then considered "which level of scrutiny—strict or intermediate—is appropriate," *id.* at 1217. Applying "governing precedent," the Court concluded that "*Central Hudson* is the appropriate standard." *Id.* Although *R.J. Reynolds*' basis for holding *Zauderer* inapplicable was later overruled by the Court sitting *en banc*, *see Am. Meat Inst. v. Dep't of Agric.*, 760 F.3d 18, 23 (D.C. Cir. 2014) (overruling *R.J. Reynolds* only "[t]o the extent" it "limit[s] *Zauderer* to cases in which the government points to an interest in correcting deception"), *R.J. Reynolds*' rejection of strict scrutiny for commercial speech remains binding precedent.

The Cigar Association rests its argument for applying strict scrutiny to a commercial-speech regulation on a single cite to *NIFLA*. *See* Cigar Br. 21. In that case, California had required licensed clinics that serve pregnant women to notify them that the state provided free or low-cost services, and had required unlicensed clinics to notify women that the clinics were not licensed to provide medical services. 138 S. Ct. at 2368. The Supreme Court invalidated both notices—without applying strict scrutiny to either one. The Court assessed the notice for unlicensed clinics under *Zauderer* and

invalidated it because the government had failed to demonstrate that it was reasonably related to a real governmental interest or that it was not unduly burdensome. *Id.* at 2377. The Court declined to apply *Zauderer* to the notice for licensed clinics because the Court found that the required disclosure did not involve factual information "relate[d] to the services that licensed clinics provide." *Id.* at 2372. The Court, however, did not apply strict scrutiny, despite uncertainty over whether the speech at issue was commercial. Rather, it declined to decide whether strict scrutiny should apply because it concluded that "the licensed notice cannot survive even intermediate scrutiny." *Id.* at 2375.

In evaluating the notice for licensed clinics, the Supreme Court generally rejected "professional speech" as "a unique category that is exempt from ordinary First Amendment principles" (although it did not "foreclose the possibility"). 138 S. Ct. at 2375. In so doing, the Court suggested that regulation of *noncommercial* professional speech is subject to strict scrutiny. *Id.* at 2371–72, 2374 (discussing "the noncommercial speech of lawyers," "professional fundraisers," "organizations that provide specialized advice about international law," and a "lawyer's statements … made in a context other than advertising"). Nothing in that discussion suggests any uncertainty about the Court's longstanding recognition that strict scrutiny is inapplicable

to commercial-speech regulations in general, and commercial disclosure requirements in particular.

Thus, the Court in *NIFLA* could state with confidence that its decision did not "question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." *Id.* at 2376. Health and safety warnings long considered permissible include consumer warnings about the health risks of tobacco, which cannot plausibly be described as noncommercial professional speech. *NIFLA* does not support the application of strict scrutiny in this case.

III. *Zauderer* permits the FDA to require the cigar industry to devote packaging and advertising space to warning consumers about the health risks of their tobacco products.

The Cigar Association's alternative argument that the FDA's disclosure requirement fails even under *Zauderer* rests principally on two grounds. First, it contends that the required warnings do not "serve a substantial governmental interest." Cigar Br. 21. Second, it argues that the warnings are overly broad or otherwise unduly burdensome. *Id.* 26–37. The government's brief explains why the district court correctly rejected these arguments based on the record evidence in this case. FDA Br. 32–45. We do not repeat those arguments here. We instead focus on two specific aspects of the *Zauderer* test that the Cigar Association misapplies.

A. The government's interest in ensuring that consumers are informed of the health risks of tobacco products satisfies *Zauderer*.

Under the *Zauderer* standard, a disclosure requirement is permissible where it is "reasonably related to the Government's interest." *Am. Meat Inst.*, 760 F.3d at 33. The Cigar Association argues that the FDA's disclosure requirement fails that test because the government's interest in "[i]mproving consumer understanding about the risks of tobacco products is not, standing alone, a 'substantial government interest.' " Cigar Br. 22. It is mistaken.

As the district court noted, whether *Zauderer* requires the government's interest to be "substantial"—a criterion nowhere stated in the *Zauderer* opinion—is an "open question" in this circuit. *Cigar Ass'n of Am. v. FDA*, 315 F. Supp. 3d 143, 167–68 (D.D.C. 2018) (citing *Am. Meat Ass'n*, 760 F.3d at 23); *see also* FDA Br. 32–33. This case does not require the Court to decide that question, however, because the government's interest in ensuring that consumers are informed of the health risks associated with products they purchase is manifestly a substantial one.

The government has a substantial interest in "the health, safety, and welfare of its citizens." *Posadas de Puerto Rico Assocs. v. Tourism Co. of Puerto Rico*, 478 U.S. 328, 341 (1986); *see also Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995); *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir.

1999). In *Posadas de Puerto Rico*, for example, the Supreme Court upheld restrictions on "advertising of casino gambling aimed at the residents of Puerto Rico," which "concern[ed] a lawful activity and [which was] not misleading or fraudulent." 478 U.S. at 340–41. The restriction was intended to reduce "demand for casino gambling by the residents of Puerto Rico" because the commonwealth believed gambling "would produce serious harmful effects on the health, safety and welfare of the Puerto Rican citizens." *Id.* at 341 (internal quotation marks omitted). The Court had "no difficulty" concluding that Puerto Rico's stated interests were substantial. *Id.*

The Cigar Association incorrectly argues that this case is different because cigar disclosures are not intended to "change consumer behavior." Cigar Br. 24; *see also id.* at 22. The Family Smoking Prevention and Tobacco Control Act, which authorized the FDA's regulation of cigars, reveals Congress's intent to reduce tobacco usage, including but not limited to use by minors. *See* Pub. L. No. 111-31, 123 Stat. 1776. Congress found, for example, that "tobacco products are inherently dangerous and cause cancer, heart disease, and other serious health effects" and that authorizing the FDA "to regulate tobacco products and the advertising and promotion of such products" would result in "benefits to the American people" that are "significant in human and economic terms." 21 U.S.C. § 387 note. Congress

also specified that one purpose of the statute was "to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases." *Id.* Congress thus authorized the FDA to restrict "access to, and the advertising and promotion of, [a] tobacco product" if the agency determines that such regulation would be appropriate for the protection of the public health." *Id.* § 387f(d)(1); *see also id.* § 387a(e). Therefore, even if the government were required to demonstrate under *Zauderer* that its required disclosures aim to change consumer behavior, the cigar disclosure regulation would satisfy that standard.

The government, however, is not required to make that showing. The government has a substantial interest in requiring disclosures even where its purpose is solely to provide consumers with relevant information about the products and services they are purchasing, especially when that information relates to health and safety. In *American Meat Institute*, for example, this Court held that the government had a substantial interest in mandating disclosure of country-of-origin information on meat products, citing "the context and long history of country-of-origin disclosures to enable consumers to choose American-made products; the demonstrated consumer interest in extending country-of-origin labeling to food products; and the individual health concerns and market impacts that can arise in the event of

a food-borne illness outbreak." 760 F.3d at 23; *see also id.* at 24 (discussing congressional intent to "enabl[e] customers to make informed choices based on characteristics of the products they wished to purchase"). The Court upheld the requirement even absent any claim that the disclosure was intended to or would in fact change the behavior of consumers who purchase meat. *See also New York State Rest. Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 134 (2d Cir. 2009) (upholding mandatory disclosure of calorie content as a valid means of "promot[ing] informed consumer decision-making so as to reduce obesity and the diseases associated with it"); *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1986) (rejecting mandatory disclosure about the use of bovine growth hormone where the court concluded that the information did not "bear[] on a reasonable concern for human health or safety").

Recognizing that the government has a substantial interest in ensuring that consumers understand the health risks of the products they purchase does not end "any meaningful scrutiny of the format" of disclosure requirements. Cigar Br. 22–23. The content of the disclosure still must "relate[] to" the products and services being provided. *NIFLA*, 138 S. Ct. at 2372; *see also Am. Meat Inst.*, 760 F.3d at 26 ("the disclosure mandated must relate to the good or service offered by the regulated party"); *Tillman*,

133 F.3d at 1403 (disclosure was unjustified and unduly burdensome under *Zauderer* because it was "not tied to an inherent quality of the thing [the attorney] is trying to sell"). And even a disclosure requirement that is related to the government's interest may nonetheless violate the First Amendment if it is otherwise "unduly burdensome." *Zauderer*, 471 U.S. at 651.

The Cigar Association relies heavily on *R.J. Reynolds*, *see* Cigar Br. 23–25, but there, this Court recognized the government's substantial interest in health warnings. *R.J. Reynolds* invalidated "graphic warnings" on cigarette packages designed to "shame and repulse smokers and denigrate smoking as an antisocial act." 696 F.3d at 1211. In the Court's view, the graphic warnings went "beyond making purely factual and accurate commercial disclosures" about cigarettes. *Id.* But the Court understood that "the government can *certainly* require that consumers be fully informed about the dangers of hazardous products." *Id.* at 1212 (emphasis added). That is what the FDA has done here.

In *R.J. Reynolds*, moreover, "[t]he *only* explicitly asserted interest [was] an interest in reducing smoking rates." 696 F.3d at 1218. To the extent the government asserted an informational interest in "effective" warnings, the Court did not address that interest as "an independent interest capable of sustaining" the graphic warnings, but merely as "the *means* by which FDA

is attempting to reduce smoking rates." *Id.* at 1221. If *R.J. Reynolds* had considered the government's informational interest as an independent interest, it would have held that interest to be sufficient to justify a purely factual disclosure because, as noted above, the Court expressly stated that "the government can certainly require that consumers be fully informed about the dangers of hazardous products." *Id.* at 1212. The Cigar Association offers no explanation for that statement if, as it contends, the Court had intended to foreclose the government from invoking informational interests in support of its disclosure regulations.

B. *Zauderer* does not require the government to demonstrate that a disclosure requirement is the least restrictive means of achieving its legitimate interests.

The Cigar Association faults the district court and the FDA for not considering "less restrictive alternative[s]" to the disclosure requirement under review, such as "smaller and less repetitive warnings" or a "public information campaign." Cigar Br. 28–29. *Zauderer* explains, however, that disclosure requirements are not subject to a "'least restrictive means' analysis under which they must be struck down if there are other means by which the State's purposes may be served." 471 U.S. at 651–52 n.14. That is because disclosure requirements are themselves considered "one of the acceptable less restrictive alternatives to actual suppression of speech." *Id.*

Indeed, the Supreme Court has consistently rejected least-restrictive-means analysis of *any* regulation of commercial speech. *See, e.g.*, *Board of Trustees of State Univ. of N.Y. v. Fox*, 492 U.S. 469, 480 (1989) (holding that *Central Hudson* permits restrictions on commercial speech that are "narrowly tailored to achieve the desired objective" even if they are not "the least restrictive means"); *see also Am. Meat Inst.*, 760 F.3d at 25–26.

The Cigar Association suggests, however, that *NIFLA* altered the settled law that disclosure regulation is not subject to a least-restrictive-means analysis. *See* Cigar Br. 26–28 & n.7. Not so. In *NIFLA*, the Supreme Court applied *Zauderer* to invalidate California's notice requirements for unlicensed clinics. In doing so, the Court emphasized the "[s]peaker-based" burdens imposed by the law and the chilling effect that the disclosure would have on the unlicensed facilities' speech. 138 S. Ct. at 2378. But the Court "expressed no view on the legality of a similar disclosure requirement that is better supported and less burdensome." *Id.* It did not suggest that the state was required to prove that such a disclosure was the least restrictive means that would advance the state's interests.

For similar reasons, the Cigar Association is wrong to suggest that *NIFLA* required the state to prove that a public information campaign would be ineffective before it could impose disclosure requirements properly

subject to *Zauderer*. *See* Cigar Br. 29 (citing *NIFLA*, 138 S. Ct. at 2376). *NIFLA* mentioned the possibility of a public information campaign in applying intermediate scrutiny (not *Zauderer*) to the notice required of licensed facilities, 138 S. Ct. at 2376, and even then only after concluding that the notice requirement was "not sufficiently drawn" to achieve the state's stated goals of "providing low-income women with information about state-sponsored services," *id.* at 2375–76.

Although *NIFLA* suggests that the possibility of a public-information campaign is a relevant consideration when the state has gone beyond the type of disclosure contemplated by *Zauderer* and enlisted private speakers to promote the state's own services, that decision does not suggest that the government may never require disclosures about a commercial speaker's own goods and services if the government could arguably convey the information itself. That view would require blanket condemnation of commercial disclosure requirements. As this Court has recognized, however, disclosure requirements that fall properly within *Zauderer*'s sphere—that is, requirements that require commercial speakers to convey factual information about their own products and services to serve legitimate interests in providing consumers with that information—necessarily satisfy any constitutional requirement of fit between ends and means: "To the extent

that the government's interest is in assuring that consumers receive particular information …, the means-end fit is self-evidently satisfied when the government acts only through a reasonably crafted mandate to disclose 'purely factual and uncontroversial information' about attributes of the product or service being offered." *Am. Meat Inst.*, 760 F.3d at 26.

Further, the Cigar Association is wrong in asserting that the "FDA warnings are far more intrusive than those struck down" in *NIFLA*. Cigar Br. 34. As the Supreme Court explained, the *NIFLA* disclosure would have required a "billboard for an unlicensed facility that says 'Choose Life'" to be surrounded by "a 29-word statement from the government, in as many as 13 different languages," with apparently no limit on the space that the statement would occupy. 138 S. Ct. at 2378. The FDA warnings, by contrast, take up only a fraction of the cigar industry's advertising and packaging space, leaving them free to use 80 and 70 percent (on two panels), respectively, of those spaces for messages it wishes to convey to consumers.

The Cigar Association's reliance (at 28, 37) on the Ninth Circuit's *en banc* decision in *American Beverage Association v. San Francisco*, 916 F.3d 749 (9th Cir. 2019), is also misplaced. That case does not hold that the government must demonstrate that its disclosure requirement is the least restrictive that can achieve its purposes. Rather, *American Beverage* holds

that San Francisco had failed to carry its "burden of proving that the warning is neither unjustified nor unduly burdensome" in the "preliminary [injunction] record" that was before the court. *Id.* at 756. The disclosure required in that case warned consumers of the health risks associated with sugar-sweetened drinks, and the law required product labels and advertisements for such beverages to devote 20 percent of their space to the disclosure. *Id.* at 753–54. In holding that San Francisco failed to carry its burden, the court weighed the evidence in the record, including a study cited by San Francisco's expert that indicated that devoting 10 percent of space to the disclosure would be effective. *Id.* at 757. But the court also made clear that it was not deciding that "a warning occupying 10% of product labels or advertisements necessarily is valid, [or] that a warning occupying more than 10% of product labels or advertisements necessarily is invalid," *id.*, and it specifically declined to suggest that its view would condemn tobacco warnings similar to those at issue here, *id.* In this case, the government's brief explains why the record before this Court supports the content and design of the FDA's cigar disclosure requirement. FDA Br. 36–40 (applying *Zauderer*), 46–48 (applying *Central Hudson*). *American Beverage* cannot inform this Court's analysis of that record.

CONCLUSION

This Court should affirm the judgment of the district court.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Brief for Amicus Curiae Public Citizen 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, Georgia. 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 6368 words.

/s/ Nandan M. Joshi
Nandan M. Joshi

CERTIFICATE OF SERVICE

I hereby certify that, on May 3, 2019, this Brief for Amicus Curiae Public Citizen in Support of Appellees and Affirmance was served through the Court's ECF system on counsel for all parties.

/s/ Nandan M. Joshi
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