ORAL ARGUMENT NOT YET SCHEDULED

No. 18-5195

United States Court of Appeals
for the District of Columbia Circuit

CIGAR ASSOCIATION OF AMERICA, *et al.*,

Appellants,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Appellees.

On Appeal from the United States District Court for the District of Columbia,
Docket No. 1:16-CV-01460-APM
Hon. Amit P. Mehta, U.S. District Judge

BRIEF OF *AMICI CURIAE* PUBLIC HEALTH GROUPS IN SUPPORT OF APPELLEES

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CORPORATE AND FINANCIAL DISCLOSURE STATEMENT

Amici curiae are all non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

STATEMENT OF COUNSEL PURSUANT TO FEDERAL RULE OF APPELLATE PROCEDURE 29(a)(4)(E)

Counsel for *amici curiae* hereby states that no counsel for any party to this litigation authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund, or did fund, the preparation or submission of this brief; and no person, other than *amici curiae*, contributed money that was intended to fund, or did fund, the preparation or submission of this brief.

CERTIFICATE OF COUNSEL PURSUANT TO CIRCUIT RULE 29(d)

The seven *amici curiae* submitting this brief are filing separately from other *amici*, because theirs is a distinct perspective with distinct concerns. This brief is necessary to aid the Court's understanding of the growth and evolution of the cigar market toward flavored products that appeal to young people, and how that shift underscores the importance to the public health of the cigar warnings as promulgated by FDA.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Regulations

Statutes

Administrative Record

Other Authorities

CERTIFICATE OF PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

The parties and *amici* in this case, the ruling under review, and any related cases are described in the brief of the Appellees.

STATUTES AND REGULATIONS

All applicable statutes and regulations are set forth in the brief of Appellees.

STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*

Amici are the 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. *Amici* are non-profit organizations that have worked for decades to protect the public from the devastating harms caused by tobacco products, which are the leading cause of preventable death in America, claiming over 480,000 lives every year. The organizations are described in Appendix A to this brief.

Amici have a strong interest in ensuring that cigars sold in the United States are accompanied by prominent, informative warning labels. *Amici* seek to protect the public from the serious, adverse health effects of cigars, given the severe risk of disease from smoking cigars; their addictiveness; cigar manufacturers' growing use of marketing strategies that appeal to young people; and persistently high rates of cigar smoking by young people. Prominent warning labels like those prescribed by the Food and Drug Administration ("FDA") in the Deeming Rule have been shown to be far more effective than the small, easily ignored warning labels that currently accompany most cigar packaging and advertisements. Accordingly, *amici* oppose Appellants' efforts to invalidate the warning labels required by FDA. All parties have consented to the filing of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

As the U.S. government has strengthened its regulation of cigarettes, the tobacco industry has redesigned cigars to be cheap, small, and kid-friendly. Today, most cigars are mass-produced, cigarette-like products, with sugary flavors designed to appeal to youth and carrying names like "Sweet Dreams" and "Da Bomb Blueberry." As a result, cigar smoking is now roughly as prevalent among youth as cigarettes, with more than 2,500 children under 18 smoking their first cigar every day. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28974, 28985 (May 10, 2016) (the "Deeming Rule" or the "Rule"). The current cigar market differs markedly from the image that Appellants attempt to present.

To address the substantial public health concern posed by cigars, FDA required warning labels disclosing factual information about the dangers of cigar use. The prescribed warnings are identical in size to those required of smokeless tobacco and smaller and *less* obtrusive than the graphic warnings that Congress prescribed for cigarettes. The district court's well-reasoned opinion held that the disclosures are permissible under the First Amendment and the Administrative Procedure Act.

Amici focus here on the public health risks presented by cigars and the Government's interest in providing consumers with accurate information about

those risks. The robust record compiled by FDA shows that youth cigar use is a substantial public health risk exposing more than a million children to Appellants' addictive, carcinogenic products. Moreover, cigar manufacturers have engaged in and benefited from deceptive tobacco marketing for decades, as both FDA and the Federal Trade Commission ("FTC") have found. Appellants deny even that the Government has a substantial interest in disseminating accurate information about health risks. Their arguments are contrary to well-settled law and an evidence-based consensus endorsed by courts, Congress, and numerous scientific organizations. Moreover, Appellants' suggestion that a recent Supreme Court decision, *Nat'l Inst. of Family & Life Advocates v. Becerra*, 138 S.Ct. 2361 (2018) ("*NIFLA*"), compels reversal of the district court is wrong.

The disclosure requirements of the Deeming Rule are a rational, well-justified response to the public health dangers associated with cigars. The Court should uphold the district court's decision.

ARGUMENT

I. CIGAR SMOKING PRESENTS A SIGNIFICANT PUBLIC HEALTH CONCERN

As FDA established in the Deeming Rule, cigar smoking presents substantial health risks—risks that are particularly concerning given the prevalence of cigar use among children and the tobacco industry's efforts to market cigars to youth.

A. Cigar Smoking Has Serious Adverse Health Impacts Among Both Adults and Youth.

As the Supreme Court has explained, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). This is as applicable to cigars as to other tobacco products. The evidence for the Deeming Rule amassed and considered by FDA establishes unequivocally that cigar smoking presents a significant public health risk, both to minors and adults. As FDA found, "All cigars pose serious negative health risks." 81 Fed. Reg. at 29020. In 2010 alone, regular cigar smoking was responsible for "approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older." *Id.*

"All cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco users," as well as "other adverse health effects, such as "increased risk of heart and pulmonary disease," "a marked increase in risk for chronic obstructive pulmonary disease (COPD)," a higher risk of death from COPD, and "a higher risk of fatal and nonfatal stroke than nonsmokers." *Id.*

Use of cigars by young persons raises particular public health concerns. As FDA explained, while it "remains concerned about the use of all tobacco products, particularly combusted tobacco products like cigars and cigarettes, . . . [it] remains

most concerned about use by youth and young adults given their *unique* susceptibility to the addictiveness of nicotine." *Id.* at 29023 (emphasis in original); *see also id.* at 29029 ("The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system".); *id.* at 29033 ("[N]icotine exposure during adolescence may have lasting adverse consequences for brain development.").

These adverse health effects are exacerbated because cigars' effective delivery of nicotine makes them powerfully addictive. *Id.* at 29022. "[A] cigar can contain as much tobacco as a whole pack of cigarettes, and nicotine yields from smoking a cigar can be up to eight times higher than yields from smoking a cigarette." *Id.* As FDA pointed out, "a leading review of the science of cigar smoking concluded that '[c]igars are capable of providing high levels of nicotine at a sufficiently rapid rate to produce clear physiological and psychological effects that lead to dependence, *even if the smoke is not inhaled*.'" *Id*. (emphasis added).

In addition to having more nicotine than cigarette smoke, cigar smoke contains many of the same harmful constituents and may have higher levels of several harmful compounds. *Id*. Cigars also produce significantly more secondhand smoke than cigarettes; cigar smoke causes negative health effects such as heart disease and lung cancer in nonsmokers. *Id*.; *see also* AR 145556 (citing studies showing that, a large cigar emits 20 times the carbon monoxide as a

similarly smoked cigarette, five times the respirable particles, and twice the amount of polycyclic aromatic hydrocarbons).

B. The Long History of Misleading Tobacco Product Marketing and Marketing To Children

As Congress, FDA, and federal courts have all found, the tobacco industry has for decades targeted young potential smokers in its marketing and misled consumers about the health risks of tobacco use. In 2006, the U.S. District Court for the District of Columbia found that the "central purpose of the tobacco companies' image advertising is motivating adolescents to smoke." *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 572 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009). Three years later, in enacting the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. §§ 387–387u) ("TCA"), Congress found that "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." *Id.* at § 2(15). Cigars, like cigarettes and other tobacco products, have been the subject and beneficiary of decades of misinformation, both by affirmative deception and misleading omission. As FDA noted in the proposed Deeming Rule, the FTC has found numerous cigar manufacturers to have engaged in deceptive and unfair marketing practices. *See* Deeming Tobacco Products To Be Subject to the Federal Food,

Drug, and Cosmetic Act, 79 Fed. Reg. 23143, 23164 (Apr. 25, 2014) (the "Proposed Rule") (citing seven "consent orders resolving allegations that failure to disclose the adverse health consequences of cigar use was deceptive and unfair"). The FTC summed up some of those practices:

> In its advertising, labeling, and sale of cigars, respondent has failed to disclose that regular cigar smoking can cause several serious adverse health conditions including, but not limited to, cancers of the mouth (oral cavity), throat (esophagus and larynx), and lungs. These facts would be material to consumers in their purchase and use of the product. Respondent's failure to disclose these facts has caused or is likely to cause substantial injury to consumers that is not outweighed by countervailing benefits to consumers or competition and is not reasonably avoidable by consumers. Therefore, the failure to disclose these facts was, and is, an unfair or deceptive practice.

In re Swisher Int'l, Inc., No. C-3964, 2000 WL 1207447, at *1 (F.T.C. Aug. 25, 2000) (complaint).[1]

As a result of this long history of consumer deception, "many people inaccurately think cigars . . . are safe alternatives to cigarettes." 79 Fed. Reg. at 23158. As FDA explained:

> [R]esearch suggests that youth perceive cigars in a more positive light than cigarettes and believe cigars are more natural and less harmful; and some do not realize that cigars contain nicotine. In addition, in a focus group of African-American youth aged 14 to 18, researchers found that the participants were not well versed in the harms caused by smoking cigars. In fact, the study found that youth had received

[1] The FTC made identical findings regarding seven cigar manufacturers that accounted for 95% of the domestic cigar market. *See* 79 Fed. Reg. at 23164 (collecting cases).

> very little cigar-specific health education, reinforcing the importance of alerting consumers about the dangers of smoking cigars.
>
> Use of cigar products by youth and young adults is no longer an "alternative" to cigarette use, but rather is now the primary tobacco product of choice in certain urban and suburban areas. One study also showed that adult cigar smokers (including cigarillo smokers) were three times as likely as non-cigar smokers to believe, mistakenly, that switching from cigarettes to cigars reduces a smoker's chance of illness (32.3 percent versus 11.2 percent), with former cigarette smokers the most likely among cigar smokers to believe that cigars are a safer alternative (47.9 percent).

Id. (citations omitted).[2]

C. The Tobacco Industry's Recent Focus on Kid-Friendly Cigars and Cigar Marketing

In the TCA, Congress authorized FDA to regulate the tobacco industry and its marketing practices. Among other things, the TCA required cigarette packages to carry textual and graphic warnings on "the top 50 percent of the front and rear

[2] *Amicus* J. Scott Armstrong argues that compelled warnings are unnecessary because market competition compels companies to make "effective" and "easy to understand" disclosures. Br. for Prof. J. Scott Armstrong as Amicus Curiae at 10. But Professor Armstrong instead bolsters the case for government-mandated factual warnings. He cites a text for the proposition that "when the FTC's prohibition on comparative health claims in cigarette advertisements was lifted, cigarette companies reduced levels of tar and nicotine in order to distinguish themselves from their competitors." *Id.* But that is 100% wrong. In fact, the tobacco companies purposefully redesigned cigarettes to lower tar and nicotine numbers when measured *by a machine*, but to deliver more nicotine to a human smoker. The companies knew that smokers would puff more frequently and deeply to satisfy their nicotine addiction, and thereby ingested levels of tar comparable to "full flavor" brands. They also knew that the truth was bad for business. The tobacco industry's massive "low tar" fraud had disastrous consequences for the public health. *See United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1107, 1120, 1124-26 (D.C. Cir. 2009).

panels of the package" and required similar warnings on "at least 20 percent of the area" of all cigarette advertisements. 15 U.S.C. §§ 1333(a)(2), (b)(2). It similarly required textual warnings on "the 2 principal display panels" of all smokeless tobacco packages, with each comprising "at least 30 percent" of each panel, and warnings comprising "at least 20 percent of the area" on all smokeless tobacco advertisements. 15 U.S.C. § 4402(a)(2) (A), (b)(2)(B). And it prohibited all characterizing flavors other than tobacco and menthol, including the various candy- and fruit-flavored cigarettes most popular with children. 21 U.S.C. § 387g(a)(1)(A).

In response, tobacco companies reformulated and promoted cigars to fill the niche. *See generally* AR 30022 ("Industry documents indicate that tobacco firms have been aware of disparities in the legal treatment of cigarettes and cigars and have made efforts to develop cigars that cigarette smokers would smoke.").

As the possibility of a flavored cigarette ban neared, Appellants' members dramatically increased the production of flavored cigars. Today, Appellants' members produce machine-made, flavored cigars by the billions, lacing them with sugary flavors from candy to chocolate to lemonade and giving them names like "Sweet Dreams" or "Da Bomb Blueberry." AR 3515, 154662. As FDA observed, young people are far more likely than older smokers to prefer flavored cigars. *See* 79 Fed. Reg. at 23146 ("sugar preference is strongest among youth and young

adults and declines with age."). As one of the Cigar Association's members acknowledged, "It is mainly new recruits to cigar smoking who take to the new flavors," AR 145585—and as has long been the case, "new recruits" are disproportionately minors. *See, e.g.*, 79 Fed. Reg. at 23155 ("Virtually all new users of most tobacco products are youth . . .."); *see also, e.g.*, AR 154660 (quoting a tobacco industry publication acknowledging: "While different cigars target a variety of markets, all flavored tobacco products tend to appeal primarily to younger consumers."). The modern cigar industry's focus on youth was accurately described by one study cited by FDA: according to a focus group of 14- to 18-year-olds, "cigars were easy to obtain," "new brands were targeting youth," and "the products were prominent in rap videos." 79 Fed. Reg. at 23158.

As the cigar industry shifted toward the youth market, its sales skyrocketed. From 2000 to 2013, cigar consumption increased by 114%. AR 145584. By contrast, cigarette smoking has declined significantly in recent years, dropping 37% from 2000 to 2012. *Id.* Today, the cigar market overwhelmingly and increasingly consists of mass-produced, machine-made products appealing primarily to youth.

D. Cigar Smoking Is Prevalent Among Youth

The result of this reorientation of cigars toward the youth market has been predictable and troubling: "youth cigar use has not declined when compared to use of other tobacco products" since the passage of the TCA. 81 Fed. Reg. at 29023. While cigarette smoking among young persons has declined in recent years (*e.g.*, from 18.1% in 2011 to 15.7% in 2013), AR 145553, cigar smoking among young persons has declined much less dramatically, if at all. *See* 81 Fed. Reg. at 29023 (noting 2000-2011 National Youth Tobacco Survey ("NYTS") data showing no change in the prevalence of cigar smoking among high school students and concluding that "[t]his lack of decline of cigar smoking is a concern considering cigarette smoking among high school students did significantly decline over these periods."). According to the 2014 National Survey on Drug Use and Health, more than 2,500 persons under the age of 18 smoke their first cigar each day. *Id*. at 28985; *see also* 79 Fed. Reg. at 23156 (reporting that more than 1 million people between the ages of 12 and 18 initiated cigar use in 2010, and that that number increased in 2011). Data from the 2014 NYTS showed that 8.2% of high school students (1.2 million young people) and 1.9% of *middle* school students (220,000) had smoked cigars in the past 30 days. 81 Fed. Reg. at 28985.

As a result of Appellants' reorientation, cigar smoking is now roughly as prevalent among youth as cigarette smoking:

- In 2013, current (past 30-day) use of cigars among U.S. high school males was slightly greater than current use of cigarettes (16.5% compared to 16.4%). *Id.* at 29023.

- According to the NYTS, in 2014, the number of high-school non-Hispanic black students that reported smoking cigars in the past 30 days was nearly *double* the number of students that reported smoking cigarettes in that period (8.8% to 4.5%). *Id.*

Moreover, FDA noted that "[m]easures of youth use of cigars may *underestimate* prevalence due to incorrect self-identification as a non-cigar smoker and confusion between the various cigar products." *Id.* (emphasis added).

Cigars by young people can also lead to cigarette smoking. One study shows that among high school students who tried cigars before trying cigarettes, almost 44% used both cigars *and* cigarettes. AR 145567.

II. THE DISCLOSURE REQUIREMENTS ARE JUSTIFIED AND ARE NOT UNDULY BURDENSOME

As Appellees have shown, disclosure requirements are "not unjustified" if they address a "potentially real not purely hypothetical" harm. Appellees Br. 32-34.[3] The cigar warnings readily meet this standard.

[3] Appellants' argument that the Supreme Court's *NIFLA* decision significantly alters the legal framework that governs this case is wrong. The Supreme Court stated explicitly in *NIFLA*: "[W]e do not question the legality of health and safety warnings long considered permissible, or purely factual and uncontroversial disclosures about commercial products." *NIFLA*, 138 S.Ct. at 2376. It is undisputed that this case involves exactly such a disclosure. Appellants do not dispute that health and safety warnings about tobacco products have "long [been] considered permissible." *Id.* The Supreme Court gave no basis to conclude that

A. The Government Has Substantial Interests in Requiring the Disclosure of Information Regarding the Health Risks and Addictiveness of Cigar Use.

Given the indisputable connection between cigar smoking, addiction, and disease, the Government has a correspondingly strong interest in requiring cigar manufacturers and retailers to disclose factual, uncontroversial information about the health risks of cigar smoking. These disclosures serve several substantial governmental interests: "prevent[ing] youths from initiating use" of cigars; "help[ing] current cigar smokers better understand and appreciate the health risks of using cigars"; combatting "confusion and misinformation about the harmfulness and addictiveness of cigars" among cigar consumers; and correcting for cigar manufacturers' "[f]ailure to disclose material facts about tobacco products." 79

Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio, 471 U.S. 626 (1985), does not continue to apply with full force to the category of disclosures at issue here. *See also Am. Beverage Ass'n v. City & Cty. of San Fran.*, 916 F.3d 749, 756 (9th Cir. 2019) ("*NIFLA* preserved the exception to heightened scrutiny for health and safety warnings" and reaffirming that *Zauderer* provides the appropriate framework to analyze a First Amendment claim involving compelled health and safety warnings).

Moreover, here FDA satisfied the evidentiary burden that the Court found lacking in *NIFLA*. *See NIFLA*, 138 S.Ct. at 2377. As the district court in this case correctly found, FDA demonstrated in the Deeming Rule that consumers, including youth, misperceive the health effects and addictiveness of cigars. *Cigar Ass'n of Am. v. FDA*, 315 F. Supp. 3d 143, 168 (D.D.C. 2018). Thus, even if this Court were to find that *NIFLA* did alter the *Zauderer* standard, FDA's decision to apply to cigars the warning label requirements for smokeless products established by Congress in the TCA meets that standard.

Fed. Reg. at 23158, 23167, 23164. As shown above, FDA demonstrated that these harms are real—not just potential or hypothetical.

Appellants—ignoring (i) the fact that cigars, when used as intended, cause serious adverse health effects and are addictive, and (ii) evidence of consumer confusion about the health effects and addictiveness of cigar smoking—contend that FDA's interests are insufficient. Appellants Br. 22. But the governmental interest here is not simply the communication of general information about cigars; it is an interest in communicating information about the serious health risks of cigars to consumers who misperceive the risks. Courts have consistently recognized such interests as substantial.[4] As this Court has stated, "government has a substantial interest in 'promoting the health, safety, and welfare of its citizens.'" *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999) (quoting *Edenfield v. Fane*, 507 U.S. 761, 769 (1993), and *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 485 (1995)); *accord, e.g.*, *CTIA-The Wireless Ass'n v. City of Berkeley, Cal.*, 854 F.3d 1105, 1118 (9th Cir. 2017), *cert. granted, judgment vacated sub nom.* (in *Zauderer* analysis, "[t]here is no question that protecting the health and safety of consumers is a substantial governmental interest"). Indeed, Appellants'

[4] As FDA argues, neither this Court nor the Supreme Court has held *Zauderer* to require that the interest supporting disclosure be substantial. Appellees Br. 32. However, the interests advanced here would plainly be found "substantial" even under *Central Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980).

largest members have themselves conceded "the substantiality of the state's interest in informing consumers of the health risks associated with cigar smoking" and that disclosure requirements indistinguishable from those at issue in this case are "reasonably related to that interest." *Consol. Cigar Corp. v. Reilly*, 218 F.3d 30, 55 (1st Cir. 2000), *aff'd in part and rev'd in part on other grounds sub nom.*, *Lorillard Tobacco Co. v. Reilly*, 553 U.S. 525 (2001).[5]

Appellants suggest that *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), which vacated an FDA rule implementing the TCA's graphic warning requirement for cigarettes described above, controls this case. Appellants Br. 23. It does not. Critically, *R.J. Reynolds* concerned specific pictorial images that the Court concluded "d[id] not convey *any* warning information at all," and were not "purely factual and uncontroversial" informational disclosures. 696 F.3d at 1216 (emphasis in original). That case did not consider the government's interest in disseminating textual information, which is at issue here. In *Reynolds*, the Court, applying *Central Hudson*, held that FDA had not sufficiently proven that the proposed graphic health warnings would directly advance the agency's

[5] Appellants wrongly suggest that the *NIFLA* Court's "reluctan[ce] to mark off new categories of speech for diminished constitutional protection," 138 S. Ct. at 2372, applies here. Appellants Br. 26. As the *NIFLA* Court itself recognized, health and safety warnings like the cigar communications are far from a "new category"—they are long-established.

professed purpose: reducing smoking incidence. *Id.* at 1219-20.[6] In contrast, as the discussion *infra* at 19-27 demonstrates, the governmental purpose here is to communicate accurate information and the administrative record demonstrates that FDA's larger cigar warnings are more effective than smaller, less prominent warnings in communicating health information by any number of measures, including salience, risk perception, desire to quit, consumption, and cessation.

The Supreme Court has found a wide variety of "pedestrian" governmental interests to be "substantial" for First Amendment purposes, from "preserving residential tranquility" to "promoting an educational rather than commercial atmosphere on [college] campuses." *Kansas v. United States*, 16 F.3d 436, 443 (D.C. Cir. 1994) (quoting *Bd. of Trustees v. Fox*, 492 U.S. 469, 475 (1989)). Appellants' denial to dispute that the government has a substantial interest in ensuring the communication of accurate information about an addictive and harmful product has no force.

B. The Warnings Are Reasonably Related to the Government's Interests.

The disclosure requirements FDA adopted are reasonably related to these substantial governmental interests. *See Zauderer*, 471 U.S. at 651 (compelled

[6] In *R.J. Reynolds*, the Court applied the *Central Hudson* test after concluding that the *Zauderer* standard applied only when disclosures are imposed to prevent consumer deception. 696 F.3d at 1213-15. However, the Court *en banc* has since overruled that aspect of *R.J. Reynolds*. *See Am. Meat Inst. v. USDA*, 760 F.3d 18, 22-23 (D.C. Cir. 2014).

disclosures are constitutional as long as they are "reasonably related" to the asserted governmental interest); *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229 (2010) (same). As FDA explained in the Proposed Rule, warnings "help consumers better understand and appreciate tobacco-related health risks" and "addictiveness risks." 79 Fed. Reg. at 23164. This is particularly true of "package warnings," which "are delivered both at the time of tobacco product use and at the point of purchase" and are thus "delivered to tobacco users at the most important times—when they are considering using or purchasing the tobacco product." *Id.*

For communication of a health risk "to be effectively understood and appreciated, consumers must notice and pay attention to the warning." *Id.* To achieve this goal, "the size, placement, and other design features of the warning" must be sufficient to get consumers' attention. *Id.* Over the past 20 years, scientists, researchers, judges, and policymakers around the world have concluded that bold warnings of *at least* 30% of the principal sides of packaging are necessary and appropriate to achieve this goal. This broad scientific consensus, referenced by FDA in the Proposed Rule (*id.* at 23164-65) includes, among others:

Institute of Medicine ("IOM"). The IOM (now the National Academy of Medicine) concluded that "current warnings are inadequate . . . when measured against an informed choice standard, [and] woefully deficient when evaluated in

terms of proper public health criteria." AR 5146. IOM found that pre-TCA warnings "communicat[e] ineffectively with smokers and potential smokers," "fail to convey relevant information in an informative way," and "have little effect on decision making or behavior" and concluded that "salient warnings"—*i.e.*, larger, more noticeable warnings—have "a beneficial effect on consumption and cessation." AR 5149.

Framework Convention on Tobacco Control. The World Health Organization's ("WHO") Framework Convention on Tobacco Control ("FCTC")—an evidence-based treaty signed by the United States and ratified by 167 countries—requires that package warnings "*should be* 50% or more of the principal display areas but *shall be* no less than 30% of the principal display areas." WHO FCTC, art. 11.1(b)(iv), June 16, 2003. As the WHO explained, "Evidence demonstrates that the effectiveness of health warnings and messages increases with their prominence" and "increases with their size." WHO, *Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control* ¶¶ 7, 12 (Nov. 2008) http://www.who.int/fctc/guidelines/article_11.pdf (cited in Deeming Rule, 81 Fed. Reg. at 28988-89).

U.S. Surgeon General. The Surgeon General has endorsed research "demonstrate[ing] that the new labels [introduced in other countries] attract the

attention of smokers and lead them to report that the labels have motivated them to consider quitting." AR 15439.

Congress. In the TCA, Congress found that "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth. Past efforts to oversee these activities have not been successful in adequately preventing such increased use." Congress concluded that identical disclosure requirements were immediately appropriate for smokeless tobacco, and that *more* obtrusive warnings (larger and with graphic components) were appropriate for cigarettes. 15 U.S.C. §§ 1333(a)(2), 4402(a)(2)(A). Because FDA has "the scientific expertise to identify harmful substances in products to which consumers are exposed, to design standards to limit exposure to those substances, to evaluate scientific studies supporting claims about the safety of products, and to evaluate the impact of labels, labeling, and advertising on consumer behavior in order to reduce the risk of harm and promote understanding of the impact of the product on health," Congress gave FDA discretion to determine the appropriate warning labels for other tobacco products, such as cigars. TCA § 2(44); 21 U.S.C. §§ 387a(b), 387f(d).

Federal Courts. Courts have found warnings of similar or larger size to be justified based on indistinguishable facts. *See, e.g.*, *Discount Tobacco City &*

Lottery, Inc. v. United States, 674 F.3d 509, 564 (6th Cir. 2012) ("A warning that is not noticed, read, or understood by consumers does not serve its function. The new warnings rationally address these problems by being larger. . ..").

In the Proposed Rule, FDA explained why the evidence and consensus recommendations about warning statements for cigarettes and smokeless tobacco apply to other tobacco products, including cigars. *See* 79 Fed. Reg. at 23165. "An agency may rely on evidence generated by analogous situations 'so long as whatever evidence the [agency] relies upon is reasonably believed to be relevant to the problem the [regulation] addresses.'" *Nicopure Labs, LLC v. FDA,* No. 16-cv-878, 2017 WL 3130312, at *45 (D.D.C. July 21, 2017) (quoting *Hutchins v. District of Columbia*, 188 F.3d 531, 544 (D.C. Cir. 1999)); *see also Lorillard*, 533 U.S. at 555 ("We do not require that empirical data come accompanied by a surfeit of background information. We have permitted litigants to justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny, to justify restrictions based solely on history, consensus, and simple common sense.") (internal quotation marks and alterations omitted).

Indeed, courts have recognized and accepted the relevance and logic of applying findings about smokeless and cigarette advertising to cigars. *See Consol. Cigar*, 218 F.3d at 47 (finding that "anecdotal evidence" of successful advertising

campaigns by smokeless tobacco and cigarette manufacturers sufficed to "establish a link between youth cigar smoking and advertising"); *Lorillard Tobacco Co. v. Reilly*, 84 F. Supp. 2d 180, 195 (D. Mass. 2000), *aff'd in rel. part sub nom.*, *Consol. Cigar*, 218 F.3d 30, *aff'd in part and rev'd in part on other grounds*, 553 U.S. 525 ("It is logical for the Attorney General to accept the proposition that cigar advertising has similar effects on underage smoking as cigarette advertising, even though there have been fewer studies so to demonstrate."). Appellants offer no legal support (or logic) for their contrary view. Their attempt to draw a distinction between cigars and cigarettes in this respect is even less tenable given the fact that Appellants' members have designed modern cigars to be effectively indistinguishable from pre-TCA cigarettes. *See supra* at 7-9.

As they did before the district court, Appellants ignore FDA's citations and discussion of the scientific literature and international consensus, instead cherry-picking part of a single sentence from FDA's explanation in its Regulatory Impact Analysis ("RIA") for why FDA could not *quantitatively* estimate the effects of various features of the Deeming Rule on the deemed products, including cigars and pipe tobacco. *See* Appellants Br. 3, 10, 32, 39-40, 46, 48 n.11 (selectively quoting the RIA that the agency was unaware of "reliable evidence" on the "impacts of warning labels, premarket review, and marketing restrictions on users of cigars, pipe tobacco, waterpipe tobacco, and ENDS.").

The selectively quoted sentence merely acknowledged that the undisputed benefits did not lend themselves to formal quantification. Indeed, the sentence preceding the one quoted by Appellants says, "FDA's detailed review of the *non-quantified* benefits concludes they would justify the costs." AR 23973 (emphasis added).

Appellants claim that FDA and the district court relied upon outdated evidence about consumer perception of the adverse health effects of cigars. Appellants Br. 32 & 33 n.10. But Appellants ignore FDA's citation in the Deeming Rule to much more recent evidence that cigar smokers believe cigars are a safe alternative to smoking. *E.g.*, 79 Fed. Reg. at 23159 (citing 2008 study); 81 Fed. Reg. at 29070 (citing 2013 study). Nor do Appellants cite any evidence that consumers do in fact correctly perceive the harms and addictiveness of cigar smoking.

In short, the extensive scientific evidence considered by FDA showed that the size and format of the text warning for cigars is "reasonably necessary" to accomplish the agency's stated goals. The warnings satisfy *Zauderer* and *NIFLA*.

C. The Disclosure Requirements Are Not Unduly Burdensome

Finally, the warning requirements are not unduly burdensome. Numerous courts have rejected claims that proportionally similar or even larger disclosure requirements are unduly burdensome, including courts considering cigars

warnings. *See, e.g.*, *Discount Tobacco*, 674 F.3d at 530-31; *Consol. Cigar*, 218 F.3d at 55 (upholding state requirement that warning cover 25% of the main panel of cigar packaging and 20% of advertisements). Appellants' arguments are indistinguishable from those that cigar companies made in *Consolidated Cigar*: that the warnings "will so burden cigar manufacturers that they will cease advertising altogether." *Consol. Cigar*, 218 F.3d at 55. The First Circuit's analysis responds directly to the argument recycled by Appellants here:

> The companies offer precious little to support this difficult-to-believe proposition, and we find it unpersuasive. Other industries, including the manufacturers of cigarettes and smokeless tobacco products, have successfully incorporated warning schemes into their advertising practices, and cigars present no special considerations that lead us to believe a different result will ensue here. Similar to the restrictions upheld in *Zauderer,* Massachusetts "has not attempted to prevent [cigar makers] from conveying information to the public; it has only required them to provide somewhat more information than they might otherwise be inclined to present." As such, the advertising restrictions do not violate the First Amendment.

Id. (quoting *Zauderer*, 471 U.S. at 650). Tobacco companies made the same claims in *Discount Tobacco* and again in comments on the Proposed Rule. But as FDA stated in the Deeming Rule, "the comments failed to substantiate that claim with evidence. Nor did the comments provide evidence that the same size requirements for smokeless tobacco—which have been in force since 2010—have unduly burdened the speech of smokeless tobacco manufacturers." 81 Fed. Reg. at 29988.

Appellants' reliance on *NIFLA* and *American Beverage Ass'n* for their contention that the cigar warnings are unduly burdensome is misplaced. Appellants Br. 34-37. First, *almost ten years* after Congress imposed on smokeless tobacco products the same warning label parameters that, in the Deeming Rule, FDA set for cigars, the Supreme Court in *NIFLA* did "not question the legality of health and safety warnings long considered permissible." 138 S.Ct. at 2376. Thus, warning labels exactly like those at issue here have existed for a decade before *NIFLA*. Moreover, in *NIFLA* the Court found, among other things, that the disclosure at issue—a 29-word statement in up to 13 different languages—could "drown out" the unlicensed clinic's speech and "effectively rule out" its ability to advertise via billboard. *Id.* at 2378.

Unlike the multi-language warnings in *NIFLA*, there is no possibility that the space taken up by the cigar warnings may expand. Appellants do not explain how or why warnings that take up at most 30% of a packaging panel would "drown out," "permanently suppress," or "effectively rule out" cigar companies' commercial message. Appellants Br. 36.

American Beverage Ass'n also differs from this case in important respects. In that case, the Defendant's own expert testified that a smaller warning would adequately communicate Defendant's message. 916 F.3d at 757. By contrast, smaller warnings have failed to communicate important health information about

cigars adequately, and there is significant record evidence that warnings of the size and format FDA has required are necessary. *See* 79 Fed. Reg. at 23164-65 (citing IOM, Congress, Article 11 of the FCTC, and EU Directive 2001/37/EC, and literature supporting the warning label formats supported by those bodies). Moreover, the absence of evidence that the warnings have unduly burdened or chilled the commercial speech of smokeless manufacturers act justifies FDA's conclusion that the same-format warnings will not chill cigar makers' speech, either. 81 Fed. Reg. 28988-89.

III. THERE IS NO SUBSTANTIVE OR FIRST AMENDMENT BASIS TO EXCLUDE PREMIUM CIGARS FROM THE CIGAR WARNINGS REQUIREMENT.

Appellants dispute the validity of FDA's decision to apply the cigar warnings to premium cigars. In the Proposed Rule, FDA specifically sought comments on the regulation of "premium cigars,"[7] including the warnings that were proposed for cigars. After carefully considering these comments, FDA determined to regulate all cigars, including premium cigars, and to apply the cigar warnings to them as well. The reasons for FDA's determination were extensively documented in both the Proposed and Final Rules and, contrary to Appellants'

[7] As Appellees note, "premium cigars" are not a distinct category of products and the criteria for determining what is a "premium cigar" are not fixed. Appellees Br. 6. For purposes of the comments FDA posited a set of criteria but commenters disagreed about the criteria.

contentions (Appellants Br. 31), FDA did "assemble evidence identifying [the] problem" with premium cigars. 81 Fed. Reg. at 29020-27, 29060-73; 79 Fed. Reg. at 23165-71.

FDA determined—and Appellants do not challenge—that premium cigars contain and deliver the same toxins and carcinogens as other cigars. As FDA found, no cigar use is safe, all cigars are addictive, and all cigars can cause the harms cited in the warnings. The warnings are as accurate when applied to premium cigars as they are when applied to all other cigars.[8]

Appellants argue that the warnings should not be applied because premium cigars are used less frequently than other cigars, but FDA found that "(1) all cigars pose serious negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults." 81 Fed. Reg. at 29020. Appellants rely on a study outside the administrative record to argue that most premium cigar smokers use premium cigars infrequently but even that study demonstrates that 6.7% of users smoke premium cigars every day.[9] Moreover, the fact that substantial percentages of

[8] Indeed, under an FTC consent order, the major manufacturers have for the past 16 years affixed warnings with substantially the same text as the warnings at issue here on all their cigars, including premium cigars.

[9] Catherine G. Corey, *et al.*, US Adult Cigar Smoking Patterns, Purchasing Behaviors, and Reasons for Use According to Cigar Type: Findings From the

premium cigar users also smoke other cigars (16.8%), cigarettes (29.9%), or other tobacco products (33.7%) demonstrates both that users of premium cigars are at substantial risk of tobacco-related disease and that many of them may, like other cigar smokers, underestimate the dangers of smoking cigars. *Id.*

FDA's issuance of an Advance Notice of Proposed Rulemaking in 2018 to gather additional information about premium cigars does not invalidate its decision to apply the warnings to premium cigars. In that Notice, FDA stated that comments opposing regulation in the Deeming Rule administrative record "provided little information to support the opinions expressed," and reiterated that after "carefully considering the public comments," FDA concluded in the Deeming Rule that "there was no appropriate public health justification to exclude premium cigars from regulation." 83 Fed. Reg. 12901, 12902 (Mar. 26, 2018). The fact that an agency continues to seek additional information does not invalidate regulations adopted on the basis of its prior consideration of an administrative record.

CONCLUSION

For the foregoing reasons, and the reasons stated in Appellees' responsive brief, the Court should reject Appellants' First Amendment claims.

Population Assessment of Tobacco and Health (PATH) Study, 2013-2014, Nicotine & Tobacco Research 5 (Sept. 15, 2017).

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 27(d)(2), because it contains 6,451 words, according to the count of Microsoft Word. I further certify that this brief complies with typeface requirements of Rule 27(d)(1)(E) because it has been prepared in 14-point Times New Roman Font.

/s/ Andrew N. Goldfarb
Andrew N. Goldfarb

APPENDIX A

Description of *Amici Curiae*

1. The American Academy of Pediatrics

The American Academy of Pediatrics (AAP), founded in 1930, is a national, not-for-profit organization dedicated to furthering the interests of children's health and the pediatric specialty. Since its inception, the membership of the AAP has grown from the original group of 60 physicians specializing in children's health to 67,000 pediatricians. Over the past 89 years, the AAP has become a powerful voice for children's health through education, research, advocacy, and expert advice and has demonstrated a continuing commitment to protect the well-being of America's children. The AAP has engaged in broad and continuous efforts to prevent harm to the health of children and adolescents caused by the use of tobacco products and exposure to secondhand tobacco smoke.

2. The American Cancer Society Cancer Action Network

The American Cancer Society Cancer Action Network (ACS CAN) is the nation's leading cancer advocacy organization dedicated to making cancer issues a priority. Created in 2001 as the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, ACS CAN educates the public, government officials, and candidates about cancer's devastating impact on public health and encourages them to make fighting cancer a top priority. ACS CAN has volunteers nationwide, many of whom advocate for effective tobacco control at the federal, state, and local levels. In 2019, an estimated 228,150 people in the US will be diagnosed with lung and bronchus cancer, the vast majority of which is attributable to tobacco use. This devastating impact makes regulation of tobacco products critical to our mission.

3. The American Heart Association

The American Heart Association ("AHA") is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. Founded in 1924, AHA now includes more than 33 million volunteers and supporters, with local chapters in all 50 states, as well as in Washington D.C., and Puerto Rico. The association invests in research, professional and public education, and advocacy so people across American can live stronger, longer lives. AHA

has long been active before Congress and regulatory agencies on tobacco and other health-related matters and has petitioned the Food and Drug Administration on several occasions seeking regulation of cigarette and other tobacco products under the Federal Food, Drug, and Cosmetic Act.

4. The American Lung Association

The American Lung Association is the nation's oldest voluntary health organization. Because smoking is a major cause of lung cancer and chronic obstructive pulmonary disease (COPD), the American Lung Association has long been active in research, education and public policy advocacy regarding the adverse health effects caused by tobacco use, as well as efforts to regulate the marketing, manufacture and sale of tobacco products.

5. The American Thoracic Society

The American Thoracic Society ("ATS") is an international educational and scientific organization founded in 1905 that represents more than 15,000 health care professionals. ATS works to prevent and fight respiratory disease around the globe through research, education, patient care, and advocacy. ATS publishes three peer-reviewed scientific journals that disseminate groundbreaking research, including studies on the adverse pulmonary health effects of tobacco use.

6. The Campaign for Tobacco-Free Kids

The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco, and it works to save lives by advocating for public policies that prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke.

7. Truth Initiative

The Truth Initiative envisions an America where tobacco is a thing of the past and where all youth and young adults reject tobacco use. Truth Initiative's proven -effective and nationally recognized public education programs include truth®, the national youth smoking prevention campaign that has been cited as contributing to significant declines in youth smoking; EX®, an innovative smoking cessation program; and research initiatives exploring the causes, consequences, and approaches to reducing tobacco use. Truth

Initiative also develops programs to address the health effects of tobacco use–with a focus on priority populations disproportionately affected by the toll of tobacco–through alliances, youth activism, training, and technical assistance. Located in Washington, D.C., Truth Initiative was created as a result of the November 1998 Master Settlement Agreement between attorneys general from 46 states, five U.S. territories, and the tobacco industry.

CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of May, 2019, I electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF system, which will send a notice of filing to all counsel of record.

/s/ Andrew N. Goldfarb
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