IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, *et al.*, *Plaintiffs*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Civil Action No. 16-1460 (APM)

BRIEF OF *AMICI CURIAE* PUBLIC HEALTH ORGANIZATIONS IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFFS' MOTIONS FOR PARTIAL SUMMARY JUDGMENT AND A PRELIMINARY INJUNCTION

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) AND LOCAL CIVIL RULE 7(o)(5)

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.

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STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*

Amici include 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, the Tobacco Control Legal Consortium, and Truth Initiative. These *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. *See* App'x A.

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 seriously adverse short- and long-term public 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. Warning labels of the type prescribed by the Food and Drug Administration ("FDA") have been shown to be far more effective than warning labels like the small, easily ignored disclaimers that currently accompany cigar packaging and advertisements. Accordingly, *amici* oppose Plaintiffs' efforts to invalidate the warning labels required by the FDA. The Court granted *amici* leave to file on April 3, 2017. Doc. No. 30.

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. 28,974, 28,985 (May 10, 2016) (the "Deeming Rule" or the "Rule").

To address this substantial public health concern, the Food and Drug Administration ("FDA") required warning labels disclosing factual information about the dangers of cigar use—warnings that were identical in size to those required of smokeless tobacco and *less* obtrusive than the warnings that Congress prescribed for cigarettes. The tobacco industry, appearing here through the trade groups Cigar Association of America, International Premium Cigar and Pipe Retailers Association, and Cigar Rights of America ("Plaintiffs"), seek to vacate and enjoin the disclosure requirements, which they claim to be a "breathtaking confiscation of communication," Pls.' Mot. for Partial Summ. J. ("Pls.' Br.") at 2—an argument that Plaintiffs' members and other tobacco purveyors have repeatedly made and repeatedly lost.

While all of Plaintiffs' arguments are meritless, *amici* focus here only on the public health concerns presented by cigars and the Government's interest in regulating them. According to Plaintiffs, there is no evidence of "a regulatory problem with respect to underaged use of cigars or pipe tobacco." Pls.' Br. at 20. This contention is belied by an ample record compiled by the FDA, which shows undeniably that youth cigar use is a substantial public health risk exposing more than a million children to Plaintiffs' addictive, carcinogenic products. Plaintiffs similarly claim that there has been no "consumer 'deception' by cigar or pipe tobacco manufacturers." *Id.* at 28. This argument too is false; cigar manufacturers have engaged in and benefited from deceptive tobacco marketing for decades, as both the FDA and the Federal Trade Commission ("FTC") have found. Plaintiffs also dispute whether larger warnings communicate health information more effectively and increase the warnings' efficacy, and deny even that the

Government has a substantial interest in disseminating accurate information about public health risks. These arguments are contrary to well-settled law and a universal, evidence-based consensus endorsed by courts, Congress, and numerous scientific organizations.

Stripped of Plaintiffs' misrepresentations, the disclosure requirements of the Deeming Rule are a rational, well-justified response to the public health issues associated with cigars. Accordingly, for the reasons stated herein and in Defendants' brief, the Court should grant summary judgment to Defendants and dismiss Plaintiffs' claims, and deny Plaintiffs' request for a preliminary injunction or dismiss it as moot.

ARGUMENT

I. Cigar Smoking Presents a Significant Public Health Concern

As the FDA laid out 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, Both Among 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 no less true of cigars than other tobacco products. The evidence amassed and considered by the FDA establishes unequivocally that cigar smoking presents a significant public health risk, both to minors and adults. As the FDA found, "[a]ll cigars pose serious negative health risks." 81 Fed. Reg. at 29,020. 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.*; *see also id.* at 28,984 n.7 (quoting 2014 Surgeon Generals' Report conclusion that "the

burden of death and disease from tobacco use in the United States is *overwhelmingly* caused by cigarettes *and other combusted tobacco products*" (emphasis added)).

Furthermore, as FDA also found, "[a]ll 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," a higher risk of death from COPD, and "a higher risk of fatal and nonfatal stroke compared to non-smokers." *Id.* at 29,020.

Use of cigars by young persons raises particular public health concerns. As the FDA explained, while it "remains concerned about the use of all tobacco products, particularly combusted 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 29,023 (emphasis in original). *See also id.* at 29,029 ("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 29,033 ("[N]icotine exposure during adolescence may have lasting adverse consequences for brain development.").

These adverse health effects are exacerbated by the fact that cigars are powerfully addictive due to their delivery of nicotine, the highly addictive substance also found in cigarettes. *Id.* at 29,022. "[A] cigar can contain as much tobacco as an entire pack of cigarettes, and nicotine yields from smoking a cigar can be up to eight times higher than yields from smoking a cigarette." *Id.* Nicotine dependence from smoking cigars can occur even if the cigar smoke is not inhaled. As FDA pointed out, "a leading review of the science of cigar making 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 surpassing cigarettes in nicotine content, cigar smoke contains many of the same harmful constituents as cigarette smoke and may have higher levels of several harmful compounds. *Id*. Cigars also produce significantly more secondhand smoke than cigarettes, which causes negative health effects such as heart disease and lung cancer in nonsmokers. *Id*. *See* AR 145556 (citing studies showing that compared to a similarly smoked cigarette, a large cigar emits 20 times the carbon monoxide, five times the respirable particles, and twice the amount of polycyclic aromatic hydrocarbons).

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

As Congress, the FDA, and federal courts have all determined, the tobacco industry has for decades targeted young potential smokers in its marketing and misled consumers about the health risks of tobacco use. 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). The "central purpose of the tobacco companies' image advertising," a district court later found, 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).

As part of this campaign, the tobacco industry misled consumers of all ages about the health risks and addictiveness of its products for decades. Since at least 1964, when the Surgeon General first began warning Americans about the health risks of tobacco use, tobacco

manufacturers engaged in a relentless multi-pronged campaign to minimize the risks of smoking, despite knowing the severity of those risks. This campaign involved "decades of press releases, reports, booklets, newsletters, television and radio appearances, and scientific symposia and publications," as well as "concerted . . . efforts to attack and undermine the studies in mainstream scientific publications such as the Reports of the Surgeon General." *Id.* at 855.

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 the FDA noted when seeking comments on the proposed Deeming Rule, the FTC has found numerous cigar manufacturers to have engaged in deceptive and unfair marketing practices. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, 79 Fed. Reg. 23,143, 23,164 (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 has 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.

Complaint, *In re Swisher Int'l, Inc.*, No. C-3964 (F.T.C. Aug. 18, 2000).[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 23,158. As the 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

[1] The FTC made identical findings regarding seven cigar manufacturers in total, who at the time accounted for 95% of the domestic cigar market. *See* 79 Fed. Reg. at 23,164 (collecting cases).

> 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 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).

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

In the TCA, Congress authorized the Food and Drug Administration ("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 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. *Id.* § 4402(a)(1)-(2), (b)(2)(B). And it banned all characterizing flavors other than tobacco and menthol, prohibiting the various candy- and fruit-flavored cigarettes most popular with children. 21 U.S.C. § 387g(a)(1)(A).

Under the law, the essential difference between a cigar and a cigarette is that a cigar contains tobacco in the wrapper, while a cigarette typically does not. *See* 15 U.S.C. § 1332(1)(a) (defining "cigarette"); 21 C.F.R. § 1143.1 (defining "cigar"). The tobacco industry has a long history of reformulating cigars or changing their marketing to allow sale of cigarette-like

products in the wake of regulation. *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.").

This pattern repeated itself as it became clear that Congress would ban flavored cigarettes and other practices for marketing cigarettes to youth. As the possibility of a flavored cigarette ban neared, Plaintiffs' members dramatically increased the production of flavored cigars. Today, Plaintiffs' members produce flavored cigars by the millions, 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 23,146 ("Research has shown that . . . sugar preference is strongest among youth and young adults and declines with age."). As one of Plaintiff Cigar Association of America's members has acknowledged, "[i]t is mainly new recruits to cigar smoking who take to the new flavors," AR 145585[2]—and as has long been the case, "new recruits" are disproportionately minors. *See, e.g.*, 79 Fed. Reg. at 23,155 ("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 well summed up by one study cited by the 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 23,158.

[2] The quote is from a vice president of Swedish Match, which subsequently merged with Scandinavian Tobacco Group, a current Cigar Association of America member. *See* Cigar Association of America, *Our Members*, http://cigarassociation.org/about/our-members.

As the cigar industry shifted toward the youth market, cigar 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.*

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 29,023. 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 29,023 (noting 2000-2011 National Youth Tobacco Survey ("NYTS") data showing no change in the prevalence of cigar smoking and concluding that "[t]his lack of decline of cigar smoking [among high school students overall from 2000-2011 according to the NYTS] 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 28,985; *see also* 79 Fed. Reg. at 23,156 (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. *Id*.

As a result of Plaintiffs' 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 29,023.

- 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, the FDA found 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).

Also troubling is that the use of cigars by young people can also lead to use of cigarettes. 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 Reasonably Related to Legitimate Government Interests and Are Not Unduly Burdensome

As Defendants have shown, disclosure requirements need only be reasonably related to a governmental interest. Defs.' Br. at 17-18.[3] The Deeming Rule readily passes this test.

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

Given the substantial public health concerns posed by cigars, 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;

[3] Plaintiffs' argument that *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), does not govern this case is frivolous. Plaintiffs assert that *Zauderer* does not apply because the government's message "dominates" or "crowds out" commercial speech. Pls.' Br. at 18. This theory is impossible to square with Supreme Court and D.C. Circuit precedent. *See Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 136, 146-47 (1994) (applying *Zauderer* to strike down a disclosure requirement that "effectively rules out" a type of speech altogether); *Spirit Airlines, Inc. v. U.S. Dep't of Transp.*, 687 F.3d 403, 413-14 (D.C. Cir. 2012) (applying *Zauderer* to affirm an explicit requirement that the government's message be the "most prominent" on an advertisement). As long as a disclosure requirement mandates "purely factual and uncontroversial information"—which plaintiffs do not deny is the case here—*Zauderer* is the correct standard. 471 U.S. at 651.

"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 Fed. Reg. at 23,158, 23,167, 23,164.

Courts have consistently recognized such interests as substantial.[4] *See, e.g.*, *Posadas de Puerto Rico Assoc. v. Tourism Co. of P.R.*, 478 U.S. 328, 341 (1986) ("[T]he health, safety, and welfare of [a government's] citizens constitute a 'substantial' governmental interest."); *Zauderer*, 471 U.S. at 651 (holding that government can require disclosures "to dissipate the possibility of consumer confusion or deception" (quoting *In re R.M.J.*, 455 U.S. 191, 201 (1982))); *Am. Meat Inst. v. U.S. Dep't of Agric.*, 760 F.3d 18, 24 (D.C. Cir. 2014) (upholding country-of-origin labeling requirements because they are reasonably related to government's interest in "enabling customers to make informed choices based on characteristics of the products they wished to purchase"). Indeed, Plaintiffs' 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 indistinguishable disclosure requirements 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). There can thus be no legitimate dispute that the government has a substantial interest in informing the public of the

[4] Although it is unclear "whether *Zauderer* would permit government reliance on interests that do not qualify as substantial under *Central Hudson*'s standard," *Am. Meat Inst.*, 760 F.3d at 23, the Court need not resolve the question because the interests advanced here are plainly substantial even under *Central Hudson*. That said, Plaintiffs are wrong to describe the D.C. Circuit's note as "question[ing]" whether an interest that does not satisfy *Central Hudson* would suffice. Pls.' Br. at 28. Quite to the contrary, the *en banc* court cited cases asking "whether *any* governmental interest—except those already found trivial by the Court—could fail to be substantial" *even under Central Hudson*. *Am. Meat Inst.*, 760 F.3d at 23 (quoting *Kansas v. United States*, 16 F.3d 436, 443 (D.C. Cir. 1994)). Whatever the answer to the doctrinal uncertainty the court noted, it plainly was not suggesting a high bar for *Zauderer* interests.

dangers of smoking, mitigating the effect of decades of deceptive tobacco marketing, and reducing youth tobacco use.

Plaintiffs dispute the substantiality of the FDA's interest in cigar warnings by misstating both the record and the law. Plaintiffs misstate the record by claiming that FDA was not attempting to address "a regulatory problem with respect to underaged use of cigars or pipe tobacco" or "consumer 'deception' by cigar or pipe tobacco manufacturers," Pls.' Br. at 20, 28; *see also id.* at 29. As outlined at length above, these assertions are simply wrong. Both the Proposed Rule and the Final Rule amply demonstrate the serious, troubling trend in youth cigar use as well as a history of deceptive messaging and widespread consumer misinformation about the health risks of cigars. *See supra* pp. 5-7. The *legislative* findings regarding these problems, *see infra* pp. 16-7, also establish the requisite governmental interest. *Cf. Am. Meat Inst.*, 760 F.3d at 25 (refusing to "allow the executive to torpedo otherwise valid legislation simply by failing to cite to the court the interests on which Congress relied").[5]

Plaintiffs next misstate the law by claiming that "[t]he FDA's stated interest in increasing understanding of the health risks of cigar and pipe tobacco products is not a constitutionally recognized substantial interest." Pls.' Br. at 28. But "[t]he Supreme Court has said 'there is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial,' and that "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.

[5] Even if Plaintiffs could wave away the legislative and regulatory findings on the tobacco industry's deception, *Zauderer* held that there was a sufficient government interest in "dissipat[ing] the possibility of consumer *confusion or* deception." 471 U.S. at 651 (quoting *In re R.M.J.*, 455 U.S. at 201) (emphasis added). As outlined above, FDA found ample evidence of consumer confusion and misinformation surrounding the risks of cigar smoking. *See supra* pp. 5-7. *See also, e.g.*, *Spirit Airlines*, 687 F.3d at 414 (allowing government to require a particular fact to be "the most prominent" piece on an advertisement to reduce "consumer confusion").

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) (in *Zauderer* analysis, "[t]here is no question that protecting the health and safety of consumers is a substantial government interest").

Indeed, the *en banc* D.C. Circuit recently concluded that the government had a substantial interest in country-of-origin disclosures on food products based on the long history of such disclosures, "demonstrated consumer interest," and "the individual health concerns and market impacts that can arise in the event of a food-borne illness outbreak." *Am. Meat Inst.*, 760 F.3d at 23. Like the trade group in *American Meat Institute*, Plaintiffs "disparage[] the government's interest as simply being that of satisfying consumers' 'idle curiosity.'" *Id.*; *see* Pls.' Br. at 28-29 ("[C]onsumer curiosity alone is not a strong enough state interest. . . ." (quoting *Int'l Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 74 (2d Cir. 1996)). But if the government's interest in providing information to aid health-related decisions in the rare case of food-borne bacterial outbreak suffices to justify labeling *all meat sold in America*, whether tainted or not, it certainly justifies providing information about the risks of inherently carcinogenic, addictive products.

Plaintiffs suggest the contrary, citing two inapposite cases. They point to *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 described above. But the D.C. Circuit has overruled *R.J. Reynolds*' core premise that *Zauderer* applies only to disclosures intended to directly rebut deception. *See Am. Meat Inst.*, 760 F.3d at 322-23. Moreover, *R.J. Reynolds* dealt with images that it concluded "d[id] not convey any warning information at all," and were not "purely factual and uncontroversial" informational disclosures. 696 F.3d at 1216. It thus did not consider the government's interest in disseminating *information*, which is at issue here. Furthermore, the *R.J.*

Reynolds majority assumed that the *non*-informational goal the government could advance—reducing smoking rates—was a substantial interest, noting that "the Supreme Court has at least implied that the government could have a substantial interest in reducing smoking rates because smoking poses 'perhaps the single most significant threat to public health in the United States.'" 696 F.3d at 451 & n.13 (quoting *Brown & Williamson*, 529 U.S. at 161)).

Plaintiffs' reliance on *Lorillard* is even further afield. *Lorillard* did not suggest that "an effort to reduce adult use of a tobacco product cannot justify restrictions of speech," as Plaintiffs claim. Pls.' Br. at 19. Indeed, *Lorillard* said nothing at all about whether the government's interest in reducing adult tobacco use or disclosing information about the health risks of tobacco is substantial; it was solely concerned (in the passage quoted by Plaintiffs) with a ban on *tobacco companies* "conveying truthful information about their products to adults." 533 U.S. at 564.

At bottom, as the D.C. Circuit has noted, 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*, 16 F.3d at 443 (quoting *Bd. of Trustees v. Fox*, 492 U.S. 469, 475 (1989)). Plaintiffs cannot seriously dispute that the government possesses a comparable interest in providing information about "the single most significant threat to public health in the United States." *Brown & Williamson*, 529 U.S. at 161.

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

The disclosure requirements the FDA adopted are reasonably related to these substantial governmental interests.[6] As the FDA explained, warnings "help consumers better understand

[6] Instead of addressing the applicable "reasonably related" test, Plaintiffs invoke (and misrepresent) the "directly advance" test of *Central Hudson*. This argument fails for the reasons stated by Defendants. *See* Defs.' Br. at 27-29.

and appreciate tobacco-related health risks" and "addictiveness risks." 79 Fed. Reg. at 23,164. 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.*

But for the 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 bring the warning to 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 includes, among others:

Institute of Medicine ("IOM"). The IOM 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 reached this conclusion because 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." *Id.* Citing studies of "the effectiveness of tobacco package warnings in getting the attention of consumers and potential consumers (salience), influencing their awareness of tobacco-related health risks (risk perception), and affecting their self-reported smoking intentions and behaviors," the IOM explained 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 Framework Convention on Tobacco Control, Art. 11.1(b), 2003.[7] As the WHO explained, "[e]vidence 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* (Nov. 2008), ¶¶ 7, 12, http://www.who.int/fctc/guidelines/article_11.pdf.

U.S. Surgeon General. The Surgeon General has endorsed research "demonstrat[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"; "[i]nternational experience shows that advertising regulations that are stringent and comprehensive have a greater impact on overall tobacco use and young people's use than weaker or less comprehensive ones"; and "[b]ecause past efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products are needed." 21 U.S.C. § 387 note.[8] Congress concluded that identical disclosure requirements were immediately

[7] Although the parties omitted the FCTC or its Guidelines from the Administrative Record, the FDA explicitly relied on the FCTC and its reasoning in the Deeming Rule, and it thus may be considered here. *See* 81 Fed. Reg. at 29032.

[8] Notably, Congress made these findings as to *all tobacco products*, not just cigarettes and smokeless tobacco. By contrast, when Congress wanted to refer *only* to cigarettes and/or smokeless tobacco, it did so. *See, e.g.*, TCA § 2(31)-(32), (38)-(39); 21 U.S.C. § 387 note.

appropriate for smokeless tobacco and *more* obtrusive warnings—larger and with graphic components—were appropriate for cigarettes. 15 U.S.C. §§ 1333(a)(2), 4402(a)(2)(A). Because the 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 it discretion to determine the appropriate warning labels for other tobacco products, such as cigars, in light of the noted failures of prior regulatory efforts. 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 face of this overwhelming consensus, Plaintiffs can only obfuscate. Continuing the tobacco industry's long-running "'open question' strategy of sowing doubt," *United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1106 (D.C. Cir. 2009), Plaintiffs ignore all of the FDA's citations to and discussion of the scientific literature and international consensus, instead relying on a single sentence from the FDA's Regulatory Impact Analysis ("RIA"), repeated seven times throughout Plaintiffs' Brief: "Reliable evidence on the impacts of warning labels . . . on users of cigars . . . [and] pipe tobacco . . . does not, to our knowledge, exist." AR 23973. *See* Pls.' Br. at 2, 11, 20, 25, 26, 34, 38.

Unsurprisingly, this sentence does not carry anything like the meaning Plaintiffs ascribe to it. It is part of the RIA's discussion of *quantifiable* benefits that could be used in a full-scale cost-benefit analysis. Far from "conced[ing] that it did not have the scientific research to determine the effect of larger warnings on cigar and pipe tobacco use," Pls.' Br. at 11, the FDA was merely acknowledging that the undisputed benefits did not lend themselves to formal quantification. As the preceding sentence says, "FDA's detailed review of the *non-quantified* benefits concludes they would justify the costs." AR 23973 (emphasis added). Plaintiffs do not dispute that the FDA could take non-quantified benefits into account, nor could they. *See, e.g.*, *FCC v. Fox Television Stations, Inc.*, 556 U.S. 509, 519 (2009) ("The [Federal Communications Commission] had adduced no quantifiable measure of the harm caused by the [profane] language, and we nonetheless held the government's interest in the well-being of its youth justified the regulation of otherwise protected expression.") (internal quotation marks and ellipsis omitted).

Plaintiffs further attempt to muddy the waters by asserting that "reliance on studies of *cigarette* use is . . . not enough to justify broad speech restrictions on cigars and pipe tobacco, which have dramatically different usage patterns." Pls.' Br. at 21. This is simple *ipse dixit*. Even Plaintiffs' professional declarant does not identify any reason to believe that studies of cigarette use are irrelevant to the efficacy of cigar warnings; he merely insists that he has not seen any proof of "the generalizability of warnings-related research on cigarette use to cigar use, especially as it may apply to underage cigar use." Decl. of Cecil R. Reynolds, Doc. No. 62-27 ("Reynolds Decl."), ¶ 13.[9]

[9] As Defendants note, Dr. Reynolds' declaration is outside the Administrative Record and should not be considered. In addition, if the Court were to entertain Dr. Reynolds' declaration, it should allow *Daubert* hearings to assess the reliability of Dr. Reynolds' methodology and conclusions. Dr. Reynolds is a repeat tobacco witness whose declarations in support of the tobacco industry

Lacking evidence or reasoning, Plaintiffs' claim cannot overcome the principle that "[a]n 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)).

Plaintiffs provide absolutely no reason to believe that studies regarding the efficacy of cigarette warnings shed no light on the efficacy of cigar warnings, particularly given the fact that Plaintiffs' members have designed modern cigars to be effectively indistinguishable from pre-TCA cigarettes. *See supra* pp. 7-9. Courts have previously rejected this conclusory assertion. *See, e.g.*, *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

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are often speculative and inconsistent with previous sworn declarations. *Compare, e.g.*, Reynolds Decl. ¶ VIII & 81(n) (opining that "increas[ing] the effective price" of tobacco products is "more likely to reduce underage tobacco use" (capitalization altered)) *with* Decl. of Cecil B. Reynolds, Ph.D., *Nat'l Ass'n of Tobacco Outlets, Inc. v. City of Providence*, No. 12-cv-96, Doc. No. 33 (D.R.I. Mar. 30, 2012), ¶¶ 65-66 (opining that studies of "the effect of price promotions on underage tobacco use [are] deeply flawed").

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.").

The Deeming Rule's disclosure requirements are modest by modern standards. They are smaller than the cigarette warnings that are required by the TCA and used in dozens of countries, and they lack a graphic component. Cigar companies have previously conceded that effectively indistinguishable disclosure requirements are "reasonably related to" the state's "substantial[] . . . interest in informing consumers of the health risks associated with cigar smoking." *Consol. Cigar Corp.*, 218 F.3d at 55. Plaintiffs ask the Court to ignore the extensive scientific and international consensus, and the conclusions of years of study by the FDA. It should not, and Plaintiffs' challenge should be rejected.

C. The Disclosure Requirements Are Not Unduly Burdensome

Finally, the warning requirements are not unduly burdensome.[10] Numerous courts have rejected claims that proportionally similar or even larger disclosure requirements are unduly burdensome, including courts considering tobacco products and even Plaintiffs' members' cigars. *See, e.g.*, *Discount Tobacco*, 674 F.3d at 530-31; *Consol. Cigar*, 218 F.3d at 55. Plaintiffs' arguments are indistinguishable from their members' arguments in *Consolidated Cigar* against a similar 20% advertising requirement: 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 is directly applicable to Plaintiffs' rewarmed argument:

> The companies offer precious little to support this difficult-to-believe proposition, and we find it unpersuasive. Other industries, including the manufacturers of

[10] Defendants err in asserting that "unduly burdensome" is an independent requirement under *Zauderer*. *See Discount Tobacco*, 674 F.3d at 567 ("[T]o the extent that Plaintiffs argue that we must separately analyze whether the warnings are unduly burdensome, they are mistaken. The test is simply that the warnings be reasonably related to the government's interest in preventing consumer deception."). For the sake of argument, however, *amici* will treat "undue burden" as an independent requirement rather than an explication of the "reasonably related" standard.

> 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 the FDA found, "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 29,988.

Plaintiffs rely most heavily on the Ninth Circuit's recent decision in *American Beverage Association v. City and County of San Francisco*, 871 F.3d 884 (9th Cir. 2017). According to Plaintiffs, "[t]here is not a glimmer of daylight between the San Francisco ordinance and the FDA rule." Pls.' Br. at 30. This assertion would come as a surprise to the Ninth Circuit, which expressly distinguished tobacco products from the non-addictive sugar-sweetened beverages at issue there. *Am. Beverage*, 871 F.3d at 897 n.11. More to the point, *American Beverage* found that the required disclosure failed the *first* requirement of *Zauderer*: that the disclosure be "purely factual and uncontroversial." *Id.* at 895-96. The court found that "the accuracy of the warning [was] in reasonable dispute" and was "misleading and, in that sense, untrue," in part because it was "contrary to statements by the FDA that added sugars are 'generally recognized as safe.'" *Id.* at 895 (quoting 21 C.F.R. § 184.1866).

While Plaintiffs present the *American Beverage* "undue burden" analysis in isolation, it was inextricable from the finding that the warning was misleading. According to the panel, the warning in that case was "ideological," "misleading and one-sided," which would force

advertisers of sugar-sweetened beverages to use their advertisements to "engage in counter-speech, to counter San Francisco's misleading message." *Id.* at 897. Nothing in the *American Beverage* decision indicates that true and factual warning labels on advertisements for products that are lethal, addictive, and attractive to children are "unduly burdensome" simply because they occupy 20% of the advertising space.

Here, by contrast, Plaintiffs *do not dispute* that the warning labels are entirely factual and uncontroversial: as the warning labels say, the products they market can cause cancer and heart disease, can harm nonsmokers and unborn children, contain the addictive chemical nicotine, and are not a safe alternative to cigarettes. 81 Fed. Reg. at 29,105. Including these labels would not require Plaintiffs' members to "engage in counter-speech, countering [the government's] misleading message," *Am. Beverage*, 871 F.3d at 897, because the message is not misleading and Plaintiffs could only counter it by *lying*. Thus, far from helping Plaintiffs, *American Beverage* shows just how appropriate these warning labels are.

Plaintiffs conveniently ignore the Sixth Circuit's decision upholding a requirement that 20% of the space on cigarette and smokeless tobacco advertisements be devoted to a warning label.[11] *Discount Tobacco,* 674 F.3d at 527-32. The Sixth Circuit found that a warning of the exact size applicable to advertising warnings in this case did not unduly interfere with the advertisers' ability to communicate their message, nor did significantly *larger* requirements for package labels. *Id.* This conclusion is plainly correct. None of Plaintiffs' cases, nor any case *amici* have found, has *ever* found a disclosure requirement to be "unduly burdensome" where it (a) required only factual, uncontroversial information, (b) was reasonably related to a potentially

[11] Plaintiffs' only acknowledgment of *Discount Tobacco* is a footnote pointing out that they challenge the Deeming Rule rather than the TCA itself, and that there have been no "findings of deception in the case of cigar manufacturers." Pls.' Br. at 30. The latter assertion is false, as discussed above, and Plaintiffs do not suggest any reason the former affects the Court's analysis.

real harm intrinsic to the labeled product, and (c) was not so large that it made it effectively impossible to speak in a particular medium altogether.

Even if Plaintiffs' arguments were legally colorable, they are frivolous on the evidence Plaintiffs present. They submit several images of cigar boxes and advertisements, shown with and without compliant warnings, presumably selected to maximize the supposed interference with Plaintiffs' commercial speech. But in nearly every example, the main thing obscured is blank space or easily relocated trade dress. *See, e.g.*, Decl. of George Koebel ("Koebel Decl.") Ex. B, Doc. No. 61-24; Decl. of Rob Norris Ex. A & B, Doc. No. 61-15 & -16; Decl. of Nadia Trowbridge Ex. A-C, Doc. No. 61-8 to -10. Even on products where Plaintiffs did position the labels to cover some original text, it is never more than several words that readily could be moved to a different location without undercutting Plaintiffs' message at all. *See, e.g.*, Decl. of Robert Brady Ex. A, Doc. No. 61-6; Koebel Decl. Ex. A & C, Doc. No. 61-23 to -25.[12] At best, Plaintiffs' concern is one of *aesthetics*, not any inability to speak. As courts have found every time Plaintiffs have made a similar argument about warning size, and as the FDA found in response to comments, Plaintiffs' arguments are simply unsupported by the evidence. *See* 81 Fed. Reg. at 28,988; *Discount Tobacco*, 674 F.3d at 531 ("Plaintiffs have not shown that the remaining portions of their packaging are insufficient for them to place their brand names, logos or other information."); *Consol. Cigar*, 218 F.3d at 55 ("The companies offer precious little to support this difficult-to-believe proposition, and we find it unpersuasive.")

[12] Unsurprisingly, Plaintiffs present the Court *only* with images of so-called "premium cigars," creating the false impression that that is what this case concerns. Plaintiffs voluntarily suspended their claims relating to premium cigars. Their current challenge is to the disclosure requirement for all cigars—most of which are mass-marketed cigarette-like products designed to appeal to children and impulse purchasers, lacking the "careful craftsmanship" that Plaintiffs claim is compromised. Pls.' Br. at 23; *see*, *e.g.*, AR 154663-64. In any event, premium cigars are no less hazardous to health than other cigars, as FDA concluded in issuing the deeming rule.

Plaintiffs' "evidence" on radio advertisements is even flimsier. Plaintiffs cite a tobacco retailer who claims that reading the one-sentence warnings will take as much as 7 seconds. Koebel Decl., Doc. No. 61-22, ¶ 7. This assertion is belied by any realistic recitation of the warnings. And even if it were correct, the required warnings are dwarfed by the prescription drug warnings required by the FDA, which regularly take 20 seconds or longer. *See* 21 C.F.R. § 202.1(e) (requiring a "[t]rue statement of information in brief summary relating to side effects, contraindications, and effectiveness"). Plaintiffs' argument has "wide-ranging implications" for these and other "long-established programs," *Nat'l Elec. Mfrs. Ass'n v. Sorrell*, 272 F.3d 104, 116 (2d Cir. 2001) and, even if it had theoretical legal merit, could not be accepted on such insubstantial speculation.[13]

Finally, Plaintiffs proffer affidavits from a few of their members surmising that they "might" cease advertising if forced to comply with the disclosure requirements. Of course, speculative assertions cannot support or defeat a motion for summary judgment. *See Martin v. Omni Hotels Mgt. Corp.*, 206 F. Supp. 3d 115, 123 (D.D.C. 2016) ("At the summary judgment stage, the Court must assess whether there is sufficient non-speculative evidence to support a verdict in favor of the non-movant."). Moreover, Plaintiffs' speculation is belied by the record. Tellingly, they do not identify *any* cigar companies that ceased advertising in Canada (or other countries) in the face of more obtrusive, graphic labeling requirements. Nor do they identify any smokeless tobacco companies that have ceased advertising or left the U.S. market since Congress subjected them to the same label-size requirements in 2010. To the contrary, government

[13] Moreover, any such claim is unripe. Plaintiffs' apparent concern that the advertisements must be read at a rate of two words per second will be confirmed or (far more likely) allayed once the FDA publishes its forthcoming "guidance on how to comply with the health warning requirements on unique types of media" such as radio. 81 Fed. Reg. at 29,064. Until that time, there is no basis for claiming the one-sentence requirement is unduly burdensome.

statistics show that spending to promote smokeless tobacco products has increased significantly since smokeless tobacco companies were subjected to identical disclosure requirements in 2010. *See* FTC Smokeless Tobacco Report for 2015, https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-cigarette-report-2015-federal-trade-commission-smokeless-tobacco-report/2015_smokeless_tobacco_report.pdf. Total advertising and promotional expenditures were 30% higher in the five calendar years *after* the disclosure requirements took effect than the five years before: $2.68 *billion* from 2011-2015, up from $2.06 billion from 2005-2009. *Id.* at Tables IA-IB. Notably, promotional spending on websites and the internet was more than 60% higher, belying Plaintiffs' claim that 20% disclosures somehow preclude advertisement of tobacco products. *Id.* at Tables 3H-3I. There is thus no reason to credit Plaintiffs' self-serving and conclusory assertions, nor to believe the tobacco industry will cease doing everything it can to promote its addictive, carcinogenic products.

CONCLUSION

For the foregoing reasons, and the reasons stated in Defendants' motion for summary judgment, summary judgment should be granted against Plaintiffs' First Amendment claims.

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Respectfully submitted,

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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 66,000 pediatricians. Over the past 85 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 more than one million volunteers nationwide, many of whom advocate for effective tobacco control at the federal, state, and local levels. In 2015, an estimated 221,000 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 30 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. The Tobacco Control Legal Consortium

The Tobacco Control Legal Consortium is a national network of nonprofit legal centers working to protect the public from the devastating health consequences of tobacco use. The Consortium's activities are coordinated by the Public Health Law Center, Inc., at Mitchell Hamline School of Law in St. Paul, Minnesota. Affiliated legal centers include: Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, at University of Maryland School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Center for Public Health and Tobacco Policy, at Northeastern University School of Law, Boston, Massachusetts; Smoke-Free Environments Law Project, at Center for Social Gerontology, Ann Arbor, Michigan; Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey.

8. 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.