IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, PREMIUM CIGAR ASSOCIATION, and CIGAR RIGHTS OF AMERICA Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, NORRIS COCHRAN, in his official capacity as Acting Secretary of Health and Human Services, Office of the Secretary, and JANET WOODCOCK, M.D., in her official capacity as Acting Commissioner of Food and Drugs, Defendants.	)	Civ. No. 1:16-cv-01460-APM

BRIEF OF *AMICI CURIAE* AMERICAN ACADEMY OF PEDIATRICS, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN HEART ASSOCIATION, AMERICAN LUNG ASSOCIATION, CAMPAIGN FOR TOBACCO-FREE KIDS AND TRUTH INITIATIVE IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND FOR A PERMANENT INJUNCTION AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

CORPORATE AND FINANCIAL DISCLOSURE STATEMENT

Amici curiae are 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 American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids and Truth Initiative are non-profit organizations that have worked for decades to protect the public from the devastating harms caused by tobacco products, the leading cause of preventable death in the United States, claiming over 480,000 lives every year. The organizations are described in the Appendix to this brief.

These organizations have a strong interest in ensuring that all cigars sold in the United States, including so-called "premium cigars," are regulated under the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 et. seq. (2009) (the "TCA"). Premium cigars, like all other cigars, are highly addictive products that increase the risk of death and disease both for smokers and for non-smokers exposed to tobacco smoke. *Amici* seek to ensure that all persons are sufficiently protected from the seriously adverse short- and long-term public health effects of these tobacco products and thus oppose Plaintiffs' efforts to exempt premium cigars from the statutory requirements established by Congress for tobacco products, including those deemed by the Food and Drug Administration ("FDA").

INTRODUCTION AND SUMMARY OF ARGUMENT

Regulation of premium cigars is essential to protect public health. All premium cigars deliver to their users the same toxins and carcinogens as other cigars and cigarettes. They cause multiple kinds of cancer and a myriad of other fatal diseases. All premium cigars deliver nicotine – a highly addictive substance – to their users. Secondhand tobacco smoke causes death and disease to non-users of tobacco products and smoke from premium cigars is no less likely to contribute to such serious health consequences than is smoke from any other combustible tobacco product.

Despite this known harmfulness of premium cigars, Plaintiffs ask this court to vacate the Deeming Rule's regulation of premium cigars, leaving these addictive and hazardous products entirely unregulated under federal law. Plaintiffs rely largely on two arguments: (1) that different patterns of use for premium cigars lead to lower health risks; and (2) that premium cigars are used infrequently by adults and are not used by youth in meaningful numbers. These arguments are fatally flawed.

The Final Deeming Rule, drawing on an extensive body of evidence, demonstrated the substantial adverse health effects and addictiveness of premium cigar use that justify FDA's regulatory oversight. Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule, 81 Fed. Reg. 28,974 (May 10, 2016) (the "Final Deeming Rule"). In the Final Deeming Rule, FDA determined that "deeming all cigars, rather than a subset, more completely protects public health." 81 Fed. Reg. at 29,020. FDA specifically considered Plaintiffs' arguments regarding varying patterns of use of premium cigars and explained that "[t]he fact that some premium cigar smokers might smoke such products infrequently or report that they do not inhale does not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others. Therefore, we find there is no appropriate public health justification to exclude premium cigars from the scope of the final deeming rule and that it is appropriate to deem them." *Id.* at 29,020. Based on a review of the evidence, FDA also concluded that youth use premium cigars. *Id.* at 29,022-24. FDA's decision to regulate premium cigars was not arbitrary and capricious but represented well-supported and reasoned decision-making.

Exempting premium cigars from the Deeming Rule would preclude the application of a wide range of provisions in the TCA that are essential to protecting the public from the harm of tobacco products – including regulations that protect youth from access to tobacco products, sales and advertising restrictions, product standards that reduce the toxicity and addictiveness of tobacco products, and provisions that authorize FDA to access tobacco product health information and ensure sound manufacturing practices. An exemption for premium cigars from the TCA would also lead to industry manipulation and consumer misunderstanding about premium cigars – this is especially likely in this instance because the term "premium cigars" does not have a precise definition that is understood and accepted by industry, government and consumers.

In summary, FDA's approach to premium cigars is a rational response to their health dangers; an exemption for premium cigars would be detrimental to public health.

ARGUMENT

I. There Is No Public Health Justification for Excluding Premium Cigars from FDA Regulation.

FDA documented with scientific evidence the reasons for asserting jurisdiction over premium cigars. In the Final Deeming Rule, FDA determined that "(1) all cigars pose negative health risks, (2) the available evidence does not provide a basis for FDA to conclude that the 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 29,020. Research since the issuance of the Deeming Rule further supports these conclusions.

A. All Cigars, Including Premium Cigars, Present a Significant Risk of Disease and Addiction to Users.

In the Final Deeming Rule, FDA established that all cigars, including premium cigars, pose serious negative health risks. *Id.* FDA found that, 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." *Id*. Cigar smokers also suffer from increased risk of heart and pulmonary disease, an increase in risk for chronic obstructive pulmonary disease (COPD), an increased risk of death from COPD, and a higher risk of fatal and nonfatal stroke. *Id*.

These adverse health effects are exacerbated because cigars' effective delivery of nicotine makes them powerfully addictive. *Id*. at 29,022. A single cigar can contain as much tobacco as a whole pack of cigarettes, and nicotine yields from smoking a premium cigar can be up to eight times higher than yields from smoking a cigarette. *Id*.; Proposed Deeming Rule, Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 79 Fed. Reg. 23,142, 23,154 (Apr. 25, 2014) ("Proposed Deeming Rule") (nicotine levels in premium cigar smoke were 13.3 mg, compared to 1.7 mg in nonfiltered cigarettes).

FDA also found that "cigar smoke contains many of the same harmful constituents as cigarettes and may have higher levels of several harmful compounds." 81 Fed. Reg.. at 29,020. FDA noted that tobacco smoke in general contains over 7,000 chemical compounds and there are more than 70 carcinogens in smoke generated from cigars, suggesting cigar smoke "tar" is at least as carcinogenic as cigarette smoke "tar" *Id.* at 29,070.

Plaintiffs, however, assert that premium cigars are different from other smoked tobacco products because they are crafted by artisans and made by using "the best, all-natural tobacco." Pls.' Br. at 1. Even if true, these assertions about how premium cigars are made do not affect

their toxicity, since the health harms from smoked tobacco products come primarily from combustion of the tobacco leaf itself. FDA found that because much of the established data on the health effects of cigar smoking is based on smokers of traditional, large cigars, these health effects are "applicable to the toxicity of premium cigars given that they share the same characteristics and are generally smoked in similar ways." 81 Fed. Reg. at 29,020. Furthermore, FDA specifically addressed studies cited by opponents of extending jurisdiction to premium cigars and cited overwhelming evidence, including "a recent systematic review of cigar smoking and mortality [that] summarized the results of 22 published studies from 16 different cohorts and found that primary cigar smoking was associated with increased risk of mortality from all causes, several types of cancers, coronary heart disease, and aortic aneurysm." *Id.* at 29,021. Thus, there is nothing arbitrary and capricious about FDA's determination that all cigars pose health risks.

B. Patterns of Use for Premium Cigars Do Not Justify Exemption from FDA Regulation.

Plaintiffs argue that different patterns of use for premium cigar smokers result in lower health risks because they smoke infrequently and do not inhale. Pls.' Br. at 25. Moreover, Plaintiffs argue that FDA's decision to regulate premium cigars because premium cigar use could lead to "any" adverse health effects, without regard to the frequency or severity of those problems, is arbitrary and capricious. Pls.' Br. at 2. But FDA did not ignore the issue of frequency of use. Rather, the agency examined all the evidence before it and concluded that patterns of use do not preclude premium cigar users from experiencing negative health effects. 81 Fed. Reg. at 29,024. Indeed, this court already has found that FDA gave due consideration to various commenters' arguments that premium cigar use patterns support exempting those

products from regulation. *Cigar Association of America v. FDA*, 436 F. Supp. 3d 70, 84 (D.D.C. 2020).

FDA found that there was no data to support the arguments that premium cigar smokers are not subject to disease risk and addiction. 81 Fed. Reg. at 29,024. FDA concluded that all cigars produce toxic cigar smoke. *Id.* FDA specifically concluded that while inhaling cigar smoke poses greater morbidity and mortality risks, a significant risk still exists for those who do not inhale. *Id.* Furthermore, regardless of whether cigar smokers inhale, they are still subject to the addictive and other adverse health effects of the product through absorption of nicotine and other harmful constituents. *Id.* at 29,024-25. FDA concluded even if prevalence of cigar smoking is lower than cigarette smoking, use of cigars still presents health risks. *Id.* at 29,025.

Thus, contrary to Plaintiffs' suggestion that FDA chose to regulate premium cigars without regard to the frequency or severity of adverse health effects among premium cigar consumers, FDA concluded it was important to regulate premium cigars specifically because the adverse health effects of all cigars, including premium cigars, is significant. Furthermore, FDA concluded that it was not appropriate to base an exemption on current use patterns of premium cigars because use patterns may change over time. *Id.* at 29,025. Thus, FDA reasonably concluded that regulating premium cigars with all other cigars was appropriate for the protection of public health.

C. All Cigars Create Significant Amounts of Harmful Secondhand Smoke.

The negative health effects of secondhand smoke, entirely ignored by Plaintiffs, were an important consideration in FDA's decision to regulate premium cigars. FDA concluded that, regardless of the type of cigar smoked, "[a]ll cigars produce secondhand smoke, which causes negative health effects such as heart disease and lung cancer in bystanders." *Id.* at 29,020. FDA noted that "[w]hile exposure to higher levels of cigar smoke for a longer period of time increases

the adverse health risks due to cigar smoking (just as it does for cigarettes), the Surgeon General has stated that no amount of smoking is safe." *Id*. Even if premium cigar smokers claim they do not inhale the smoke from the cigar, it is virtually impossible to avoid the secondhand smoke released from a lit cigar, which means they, and those around them, are being exposed to dangerous chemicals.

FDA examined the effect of secondhand smoke on lung and heart disease. In reviewing the known "causal relationship between lung cancer and secondhand smoke" with respect to various tobacco products, FDA stated, "[a]lthough data particular to cigars are not available, FDA believes it is reasonable to expect that cigar smoke would produce similar effects as cigarette smoke, given that data from the National Cancer Institute (NCI) cigar monograph shows that some carcinogens determined to cause lung cancer are present at higher levels in cigar smoke than in cigarette smoke and are present at levels comparable to other carcinogens linked to lung cancer." *Id.* at 29,070.

FDA also found a causal relationship between secondhand smoke and heart disease. *Id.* FDA found it reasonable to conclude that this relationship would also exist for secondhand cigar smoke, based on similar smoke profiles for cigars and cigarettes. *Id.* FDA also highlighted evidence that "[e]ven a relatively brief exposure to secondhand tobacco smoke can lead to heart disease, as some studies have demonstrated. The Institute of Medicine ("IOM") found there is compelling circumstantial evidence that a relatively brief exposure to secondhand smoke can bring about an acute coronary event." *Id.* at 29,071.

D. Premium Cigars Are Used by Youth and Young Adults.

Plaintiffs argue that FDA's decision to regulate premium cigars is arbitrary and capricious because youth do not use premium cigars in meaningful numbers. Pls.' Br. at 1. But FDA examined the relevant evidence and concluded that youth and young adults use premium

cigars, 81 Fed. Reg. at 29,022, a finding that deserves great deference. FDA explained that it is most concerned about use by youth and young adults due to the "unique susceptibility" of this population to nicotine addiction. *Id.* at 29,023. Specifically, FDA studied youth cigar usage trends in the National Youth Tobacco Survey ("NYTS"), National Survey on Drug Use and Health ("NSDUH") and National Youth Risk Behavior Surveillance ("YRBS") data sets over several years. *Id.* With respect to youth use of premium cigars specifically, FDA noted that "although youth and young adults tend to smoke mass market cigar brands, they are also using premium cigars." *Id.* One study from Delnevo et al., revealed that 3.8% of youth aged 12 to 17 and 12.1% of young adults aged 18 to 25 who were past-month cigar smokers identified certain premium cigars to be the brand they smoked most often.[1] *Id.* In another National Adults Tobacco Survey (NATS) study of participants 18 years and older, of those smokers whose type of cigar could be identified, 19.9% were premium cigar smokers. *Id.* Based on this and other evidence presented to FDA, FDA concluded that youth and young adults do use premium cigars.

Plaintiffs attack FDA's reliance on the Delnevo study and in particular cite to the small number of respondents in the study who reported premium cigar use. Pls.' Br. at 30. But extrapolating the data in the 2015 Delnevo study to the entire U.S. population would mean that, based on the latest U.S. Census Data, there are over 31,000 youth exposed to the harmfulness of premium cigars.[2] Moreover, this number does not include premium cigar smokers aged 18-20 who are underaged under the recently-enacted federal tobacco sales age of 21.

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[1] Cristine D. Delnevo, et al., *Preference for Flavoured Cigar Brands Among Youth, Young Adults and Adults in the USA*, 24 Tobacco Control, no. 4, 389, 392 (2015).

[2] 2019 U.S. Census data indicates that there are over 25 million 12-17 year old youth in the U.S. U.S. Census Bureau, *Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2010 to July 1, 2019* (NC-EST2019-AGESEX-RES), https://www.census.gov/data/tables/time-series/demo/popest/2010s-national-detail.html (accessed March 10, 2021).

Plaintiffs' arguments that youth cannot access premium cigars because they are expensive and generally sold in specialty shops are unsupported. Pls.' Br. 7. First, because there is no universally accepted definition of premium cigars, how can it be determined that youth will not access premium cigars because of their price? The definition of premium cigars adopted by this Court in previous orders, and by FDA, does not include a minimum price point. *Cigar Ass'n v. FDA*, 480 F. Supp. 3d 256, 281 (D.D.C. 2020); Defs.' Notice of Filing of Request for Clarification of Scope of Remedy Order in *AAP v. FDA* with Respect to FDA's Forthcoming Guidance on Premium Cigars, Dkt. No. 209, at 4 n.2 (Aug. 6, 2020). Thus, if premium cigars are exempted from the Deeming Rule based on the Court's definition of these products, price could not be a factor in limiting youth access.[3] Furthermore, in comments submitted to the Proposed Deeming Rule, public health groups, including *amici* here, urged FDA to set a minimum price of greater than $10, citing a study indicating that some youth are willing to pay more than $10 for a cigar.[4]

Moreover, Plaintiffs' assertion that premium cigars are only sold in specialty tobacco shops which do not permit youth access (Pls.' Br. at 28), is undercut by the premium cigar industry's current efforts to introduce premium cigars into convenience stores. For example, Scandinavian Tobacco Group, a member organization of Plaintiff Cigar Association of

[3] *See also* Comment of American Academy of Family Physicians et al., on Proposed Rule on Deeming Tobacco Products, Dkt. No. FDA-2014-N-0189, Aug. 8, 2014 at 17 ("Of all of FDA's proposed criteria for defining 'premium cigars,' a high price minimum likely is subject to the lowest risk of industry manipulation and evasion, and may be most important in ensuring that no 'premium cigars' are likely to be purchased by youth.").
[4] *Id.*

America,[5] which claims on its website to be "#1 in US" for handmade cigars,[6] sponsored an article in *CSP Daily News* (a convenience store trade publication), titled, *Putting the Convenience in Premium Cigar Sales*.[7] In this article, Bill Noah, Director of Sales and Operations at Scandinavian Tobacco Group, encouraged adding pre-packaged premium cigars to convenience store shelves and indicated that it is a "fast-growing, alternative tobacco profit stream potential….thanks to innovation in packaging."[8] He further observed that the novel packaging would "entice the occasional premium cigar smoker, typically younger generation consumers…." The author also noted that the novel premium cigar packaging "will continue to become part of the normal set of convenience products in the next couple of years…."[9]

These statements in *CSP Daily News* are hard to align with Plaintiffs' claim that youth are unlikely to have access to premium cigars because they are only sold in tobacco specialty shops. The industry strategy of introducing premium cigars into convenience stores is especially concerning because nearly half of adolescents in the U.S. visit a convenience store at least once a week,[10] and 58% of high schoolers who said they purchased tobacco products themselves in the past 30 days said they got them from gas stations or convenience stores.[11]

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[5] Cigar Association of America, *Our Member Companies*, https://www.cigarassociation.org/member-companies/ (last visited Apr. 8, 2021).
[6] Scandinavian Tobacco Group, *Our Company*, https://www.st-group.com/our-company/ (last visited April 8, 2021).
[7] CSP Daily News, *Putting the Convenience in Premium Cigar Sales* (May 30, 2018) https://www.cspdailynews.com/tobacco/putting-convenience-premium-cigar-sales (last visited Apr. 8, 2021).
[8] *Id.*
[9] *Id.*
[10] Ashley Sanders-Jackson, et al., *Convenience Store Visits by US adolescents: Rationale for Healthier Retail Environments*, 34 Health Place 63, 4 (2015).
[11] Sherry T. Liu, et al., *Youth Access to Tobacco Products in the United States, 2016-2018*, 5 Tob. Regul. Sci. 491, 494 (2019).

Plaintiffs also suggest that premium cigars do not pose a problem of youth use because they are marketed in publications that "cater exclusively to adults, like *Cigar Aficionado*…." Pls.' Br. at 28. However, the September/October 2019 issue of *Cigar Aficionado* featured 26-year-old musician and actor Nick Jonas on the cover, the youngest person ever to be featured holding a cigar on the cover of the magazine.[12] The feature article noted that Jonas is a "teen idol" and stated that Jonas began using premium cigars at 18 years old but was surrounded by cigar smokers prior to that, which piqued his interest.[13] Furthermore, Jonas stated in the article, "[o]ne of the things a lot of people say to me is: 'You're so young to like cigars.' … It is a narrative that I'm aware of, and actually something that I love being able to speak to… I think that cigars as a whole should be something that you share with friends, and there shouldn't be any barriers around who can enjoy them …. And no matter your age—you should be able to enjoy the process."[14] These examples of industry marketing and advertising demonstrate that FDA regulation of premium cigars is important not simply to address current youth usage and patterns of use, but also to monitor premium cigar industry marketing trends to ensure that youth are given the maximum protection. As FDA determined, "[b]asing an exemption for premium cigars on current use patterns would be inappropriate given that patterns may change over time and in response to regulation." 81 Fed. Reg. at 29,025.

[12] David Savona, *Nick Jonas Cover Score More Than 1 Million Like in the First 24 Hours*, Cigar Aficionado (Sept. 20, 2019), https://www.cigaraficionado.com/article/nick-jonas-cover-scores-more-than-1-million-likes-in-first-24-hours.
[13] David Savona, *The Jonas Effect*, Cigar Aficionado (Sept./Oct. 2019), https://www.cigaraficionado.com/article/the-jonas-effect.
[14] *Id.*

E. Research Since the Final Deeming Rule Does Not Support a Regulatory Exemption for Any Category of Cigars, Including Premium Cigars.

In arguing for a regulatory exemption for premium cigars, Plaintiffs rely largely on research published since FDA issued its Final Deeming Rule. But this more recent research only further supports FDA's decision to regulate premium cigars. This research further demonstrates that all cigars, including premium cigars, are harmful to health, dual use of premium cigars increases risk of disease, youth use premium cigars, and adults use premium cigars with sufficient frequency to support regulation.

i. New Research Continues to Demonstrate That All Cigars Expose Smokers to Hazardous Levels of Toxins and Addictive Levels of Nicotine.

New research continues to demonstrate that cigar smokers have an elevated risk of disease and mortality than never smokers, and all cigars, including large cigars (some of which are premium cigars), deliver significant amounts of toxins and nicotine.

One study identified variations in how the users puffed based on various cigar types. Large cigar users tended to take bigger (more volume) and faster (higher velocity) puffs compared to cigarillo or filtered cigar users and took about as many puffs as cigarillo users.[15] These results suggested that cigarillos and large cigar smokers may be exposed to more toxicants than other cigar smokers to achieve adequate levels of nicotine.[16] CDC researchers found that large cigars (including premium cigars) had the highest mean nicotine concentration compared to little cigars, cigarillos, mini-cigarillos, and pipe tobacco cigars, but there was wide variation in nicotine concentration within the cigar category.[17]

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[15] Wallace Pickworth, et al., *Dual Use of Cigarettes, Little Cigars, Cigarillos, and Large Cigars: Smoking Topography and Toxicant Exposure*, 3 Tob. Regu. Sci. S72 (2017).
[16] *Id.*
[17] Tameka S. Lawler, et al., *Surveillance of Nicotine and pH in Cigarette and Cigar Filler*, 3 Tob Regul Sci. S101, S112-113 (2017).

Additionally, one 2017 study concluded that exclusive cigar smokers have a higher risk of various smoking-related cancers than never smokers.[18] A 2018 study found that "exclusive current cigar smokers have higher all-cause mortality risks than never tobacco users" and specifically "had an elevated risk of dying from a tobacco-related cancer."[19] Plaintiffs cite to the same 2018 study as evidence that non-daily cigar use "does not lead to any statistically significant increase in mortality" Pls.' Br. at 24. However, this study only followed *exclusive* users of cigars, cigarettes, or pipes and thus underestimates the mortality risk by not accounting for increased risk among the substantial number of dual users of cigars and other tobacco products. Moreover, data from the study shows even non-daily exclusive cigar users are at an elevated risk of mortality, although the study sample was too small to support the conclusion that the risk elevation was statistically significant.[20] Lack of a statistically significant finding does not mean a lack of association and it is not arbitrary or capricious to rely on such a study as one component of the scientific case for regulation of premium cigars.

A recent study from FDA researchers concluded that "every day exclusive cigar smokers, irrespective of cigar type, are exposed to significant levels of several toxicants, comparable to those of every day exclusive cigarette smokers."[21] Specific to premium cigars, this study found "that urinary NNAL concentrations in every day exclusive traditional cigar smokers were similar to or higher than those compared with every day exclusive cigarette smokers."[22] NNAL (4-

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[18] Jyoti Malhotra, et al., *Association between Cigar or Pipe Smoking and Cancer risk in Men: A Pooled Analysis of Five Cohort Studies*, 10 Cancer Prev. Res. 704, 706 (2017).
[19] Carol H. Christensen, et al., *Association of Cigarette, Cigar, and Pipe Use With Mortality Risk in the US Population*, 178 JAMA Intern. Med. 469, 472 (2018).
[20] *Id.* at 472, 474.
[21] Cindy M. Chang, et al., *Biomarkers of Exposure among U.S. Adult Cigar Smokers: Population Assessment of Tobacco and Health (PATH) Study Wave 1 (2013-2014)*, 28 Cancer Epidemiology Biomarkers Prev. 943, 951 (2019).
[22] *Id.*

(methylnitrosamino)-1-(3-pyridyl)-1-butanol) is a known carcinogen to animals.[23] In addition, "[b]oth every day traditional and filtered cigar smokers had slightly higher CYMA concentrations compared with cigarette smokers."[24] CYMA is a metabolite of acrylonitrile, which is on FDA's list of harmful or potentially harmful constituents.[25] Studies also continue to demonstrate that all cigars increase the risk of disease. A study using 2000-2015 National Health Interview Survey (NHIS) data found "that nearly 200,000 cardiovascular conditions and cancer cases were attributable to exclusive cigar smoking among US adults aged ≥35 years in 2015. These results are consistent with previous findings that cigar smoking is associated with preventable diseases."[26] Another study also using 2000-2015 NHIS data determined that "[c]urrent and former sole cigar smoking was associated with excess annual utilization of 72,137 hospital nights, 32,748 ED [Emergency Department] visits, and 420,118 home-care visits."[27]

In sum, this data supports FDA's position that the health risks posed by the use of all cigars, including premium cigars, are substantial and justify regulation of these products.

ii. Adults Use Premium Cigars Frequently.

Plaintiffs argue that premium cigars are used infrequently by adults. Pls.' Br. at 6. This claim is contradicted by the premium cigar industry's own recent advertising. For example, an infographic sponsored by Swisher International, also a member of Plaintiff Cigar Association of

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[23] CDC, *Biomonitoring Summary: 4-(Methylnitrosamino)-1-(3-pyridyl)-1-butanol (NNAL)* (last reviewed Apr. 7, 2017), accessed Mar. 8, 2021 at https://www.cdc.gov/biomonitoring/NNAL_BiomonitoringSummary.html.
[24] *See Chang*, *supra* note 21.
[25] FDA, *Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke: Established List, April 2017*, accessed Mar. 8, 2021 at https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list.
[26] Brian L. Rostron, et al., *Cigar Smoking Prevalence and Morbidity among US adults, 2000–2015*, 14 Prevention Med. Rep. 100821, 2 (2019).
[27] Yingning Wang, et al., *Health Care Utilization and Expenditures Attributable to Cigar Smoking Among US Adults, 2000-2015*, 133 Public Health Rep. 329, 329 (2018).

America,[28] and its premium cigar subsidiary, Drew Estate, stated that "41% of adult tobacco consumers enjoy a premium cigar every day" and "93% enjoy one at least once a week."[29] Plaintiffs also cite a study from Corey, et al., using data from the Population Assessment of Tobacco and Health (PATH) study, to demonstrate that many smokers of premium cigars use them less frequently than users of other types of cigars, including other large, traditional cigars. Pls.' Br. at 22-23. But this study does not assess the relative health risks of smoking premium cigars vs. other cigars and thus furnishes no basis to question the FDA's Deeming Rule determination that, whatever the use patterns associated with premium cigars, they do not sufficiently reduce the health risks to users to justify a regulatory exemption. Furthermore, the same study demonstrates that 6.7% of established premium cigar smokers used premium cigars every day in the past 30 days.[30] According to this study, based on 2013-2014 data, .7% of the adult population were smokers of premium cigars, the equivalent of about 1.8 million people today.[31] If 6.7% of these people were daily users, then more than 118,000 people are daily users of premium cigars. Even if these 118,000 people were the only ones at risk of cigar-related disease, a number of this magnitude certainly justifies FDA regulation.

However, it is not only the 118,000 daily smokers of premium cigars who are at risk. The fact that the median number of usage days of premium cigar smokers was 1.7 days per month means that half of all premium cigar smokers – 900,000 people – used the product on

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[28] *Supra* note 5.
[29] Convenience Store News, *Premium Pays Off* (July 3, 2018), https://csnews.com/premium-pays *citing* Cigar Sense Survey 2014, https://www.cigarsense.com/premium-cigar-consumer-behavior/ (accessed April 7, 2021).
[30] Catherine G. Corey, et al., *U.S. Adult Smoking Patterns, Purchasing Behaviors and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014*, 20 Nicotine & Tobacco Research 1457, 1461 (2018).
[31] According to the U.S. Census Bureau, the adult population of the United States is approximately 253 million.

more than 1.7 days. Apart from showing that a disproportionately large percentage of this group smoked premium cigars every single day,[32] the data do not reveal the number of days on which any of these users were smoking premium cigars. Thus, it is likely that in addition to many premium cigar smokers who smoke daily, tens if not hundreds of thousands of other premium cigar smokers smoke these products on a frequent basis. Furthermore, as discussed in the next section, the same study also demonstrates significant prevalence of dual use among premium cigar smokers. With dual use, the risk posed by premium cigar use is cumulative of the risk posed by use of other tobacco products.

iii. Research Demonstrates That a Significant Portion of Premium Cigar Smokers Engage in Dual Use Behavior, Which Increases Their Risk of Disease.

The Corey, et al., study establishes that a significant portion of premium cigar smokers engage in dual use behavior, which increases risk of disease. Importantly, even if some premium cigar users smoke fewer cigars and less often, PATH data show that one in six (16.8%) premium cigar smokers also currently smoked other cigar products and nearly one in three (29.9%) premium cigar smokers also currently smoked cigarettes.[33]

The harms of dual use of cigarettes and cigars are well-documented and further support FDA's decision to regulate all types of cigars. One recent study of dual use of cigarettes and various categories of cigars found that "in efforts to achieve levels of nicotine, cigar smokers (especially cigarillo and large cigar users) expose themselves to toxicant levels of CO [carbon monoxide] and potentially other components of mainstream tobacco smoke."[34] Another recent study of dual users of cigarettes and large cigars found that "[b]y smoking large cigars, dual

[32] If the distribution of such users was spread proportionally over 30 days, the number of daily premium cigar smokers would only have been about 3.3% instead of the 6.7% that was observed.
[33] *See* Corey et al., *supra* note 30.
[34] Pickworth, *supra* note 15, at 7.

users expose themselves to toxic components that have been linked with the addiction risk, morbidity, and mortality of cigarette smoking."[35] The study concluded that "[t]he results of the present and previous studies indicate that all cigar products (little cigars, cigarillos, and large cigars), like cigarettes, rapidly deliver nicotine and CO to their consumers which represents a significant public health concern."[36] The authors concluded that "[t]hese findings support the rationale for regulation of cigar products as has recently been enacted by the FDA."[37]

A study using 2012-2013 NATS data found that dual users of cigarettes and cigars (type not specified) "report[ed] greater tobacco dependence symptoms than exclusive cigarette smokers based on higher cpd [cigarettes per day], shorter time to first tobacco use after waking, and greater likelihood of craving and withdrawal symptoms."[38] Dual use can also prolong tobacco use, which extends users' exposure to toxicants and increases their risk of tobacco-caused diseases. That same study showed that "dual cigarette and cigar users were less interested in quitting cigarettes than exclusive cigarette smokers, which may be indicative of greater dependence."[39] A 2020 study using 2013-2016 PATH data found "that the use of cigarettes along with cigars appears to hamper discontinuation of all tobacco products."[40]

Thus, evidence of dual use among premium cigar smokers and the increased risk of disease associated with dual use further justify FDA regulation of all cigars.

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[35] Zachary R. Rosenberry, et al., *Large Cigars: Smoking Topography and Toxicant Exposure*, 20 Nicotine & Tobacco Research 183, 183 (2018).
[36] *Id.* at 188.
[37] *Id.*
[38] Brian L. Rostron, et al., *Dependence Symptoms and Cessation Intentions among US adult Daily Cigarette, Cigar, and e-Cigarette Users, 2012-2013*, 16 BMC Public Health 814, 7 (2016).
[39] *Id.*
[40] Kathryn Edwards, et al., *Longitudinal Pathways of Exclusive and Polytobacco Cigar use among Youth, Young Adults and Adults in the USA: Findings from the PATH Study Waves 1–3 (2013–2016)*, 29 Tobacco Control S163, s168 (2020).

iv. Research Continues to Demonstrate That Youth and Young Adults Use Premium Cigars.

New research continues to bolster FDA's finding in the Final Deeming Rule that youth and young adults use premium cigars.

Data from the 2013-2014 PATH study found that 4.0% of 15–17-year-olds had ever used "traditional cigars" and 1.3% of 15-17 year-olds used them in the past 30 days.[41] Another recent study looking at PATH data from 2013 to 2017 determined that youth are susceptible to traditional cigar use as they get older. The study found that between ages 15 and 18, there was "a 26% increase (11.9% to 38%) in the proportion of youth who became susceptible to using cigarillos or filtered cigars and a 21% increase (10.1% to 31.3%) in those who became susceptible to use traditional cigars. By age 18, 18% of youth progressed to initiating ever use of cigarillos or filtered cigars, and 10% had progressed to initiating past 30-day use. Similar trends were found for traditional cigar use. Increases in the probability of initiation of ever and past 30-day cigarillo or filtered cigars and traditional cigar use continued to rise as these youth continued their transition into young adulthood."[42] The Corey study referenced by Plaintiffs (Pls.' Br. at 15-16) found that the median age at first regular use was 24.5 years old, with the 95% confidence interval ranging from 18.8 to 32.6 years old.[43] These findings point to the need for FDA regulation to minimize youth use of all cigars, including premium cigars.

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[41] Karin A. Kasza, et al., *Tobacco-Product Use by Adults and Youths in the United States in 2013 and 2014*, 376 New Eng. J. Med. 342, 348 (2017).
[42] Baojiang Chen, et al., *Age of Initiation of Cigarillos, Filtered Cigars and/or Traditional Cigars among Youth: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013–2017*, 15 PLoS One 1, 16 (2020).
[43] Catherine Corey, et al., *U.S. Adult Smoking Patterns, Purchasing Behaviors and Reasons for Use According to Cigar Type: Findings from the Population Assessment of Tobacco and Health (PATH) Study, 2013-2014*, 20 Nicotine Tobacco Research 1457, 1461 (2018).

II. It is Critical to Public Health for FDA to Apply to Premium Cigars All Provisions of the Tobacco Control Act Applicable to "Tobacco Products"

As discussed above, both research that FDA relied on in the Deeming Rule, and subsequent studies, establish that premium cigars pose health risks that are similar to other combustible tobacco products. If premium cigars are exempted from the Deeming Rule, FDA will be stripped of the ability to regulate a harmful tobacco product to protect public health. Furthermore, such an exemption will create the misimpression that premium cigars are safer tobacco products because they are unregulated. It also will invite product manipulation to qualify for the exemption. Thus, such an exemption would be detrimental to public health.

A. FDA Regulatory Authority over Premium Cigars Will Ensure That Premium Cigars Are Subject to the Provisions of the Tobacco Control Act That Protect Public Health.

Although this court previously vacated the FDA's Deeming Rule warnings and premarket review requirements as they apply to premium cigars, in no sense did it exempt premium cigars from those requirements.[44] Moreover, there are numerous additional provisions of the TCA that apply to deemed "tobacco products," and authorize FDA to regulate them to protect public health. If the court exempts premium cigars from the Deeming Rule entirely, *none* of the TCA provisions that protect public health, would apply to premium cigars.

[44] The court did not exempt premium cigars from the warning requirement but remanded this portion of the Deeming Rule to the agency for further proceedings to establish the appropriateness of particular health warnings for premium cigars. *Cigar Ass'n*, 436 F.Supp.3d 70, 89-90 (D.D.C. 2020). Similarly, the court did not exempt premium cigars from the premarket review requirements but remanded the Deeming Rule for the limited purpose of considering whether a streamlined substantial equivalence process is appropriate for premium cigars. *Cigar Ass'n*, 480 F.Supp.3d 256, 281 (D.D.C. 2020).

i. An Exemption for Premium Cigars Would Hinder FDA's Ability to Protect Youth from Gaining Access to Premium Cigars.

An essential purpose of the TCA is to address the use of tobacco by young people. TCA, §3(2). If premium cigars are exempted from the Deeming Rule, FDA would no longer have the authority to utilize these provisions to protect young people from the hazards of premium cigars.

In the Deeming Rule, FDA used its authority to impose restrictions on the sale and distribution of tobacco products under section 906(d) of the TCA to extend the minimum age of sale, and prohibition of vending machine sales, to all newly deemed products, including premium cigars. 81 Fed. Reg. 28,976. As a result of the Deeming Rule, the minimum age for the sale of all tobacco products was established at 18 years of age. *Id.*; TCA 906(d). In December 2019, Congress amended the TCA to raise the minimum legal sales age for tobacco products from 18 to 21.[45] However, if premium cigars are exempted from the Deeming Rule, there would be no minimum sale age whatsoever under federal law for premium cigars, 79 Fed. Reg. at 23,160, and retail sellers of tobacco products would be free to sell premium cigars to children of any age without fear of FDA enforcement.

Section 102 of the TCA, by prohibiting free samples of tobacco products, 21 U.S.C. § 387(a)-(1), also eliminates a pathway for youth access, reducing youth initiation. 79 Fed. Reg. at 23,149. As FDA noted in the Proposed Deeming Rule, the IOM report stated that free samples of cigarettes "encourage experimentation by minors with a risk free and cost-free way to satisfy their curiosity." *Id.* While the IOM report refers to cigarettes, the same rationale would apply to premium cigars, especially given Plaintiffs' assertion that cost is a reason youth are less likely to

[45] FDA, Press Release, *Newly Signed Legislation Raises Federal Minimum Age of Sale of Tobacco Products to 21* (Jan. 15, 2020), https://www.fda.gov/tobacco-products/ctp-newsroom/newly-signed-legislation-raises-federal-minimum-age-sale-tobacco-products-21 (FDA is in the process of updating regulations to reflect the change in law).

use premium cigars than lower-priced cigars. Pls.' Br. at 32. In the absence of FDA regulation, premium cigar sellers providing free samples would be free of the threat of federal enforcement action.

ii. Exempting Premium Cigars from Regulation Would Remove FDA's Authority to Prevent Misleading Claims from Premium Cigar Manufacturers.

A significant concern of Congress in the TCA was that "tobacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors." TCA, § 2(17). To address this concern, several provisions of the TCA grant FDA significant authority to regulate tobacco product labeling that is false or misleading. In particular, section 903 of the TCA protects consumers from "misbranded" tobacco products. 21 U.S.C. § 387c. Under section 903, a tobacco product is misbranded if its labeling is false or misleading. *Id.*. Exempting premium cigars from the Deeming Rule would deprive consumers of this basic protection against misleading claims.

Similarly, Section 911 of the TCA regarding modified risk products prevents a manufacturer from making claims that its product presents a lower risk of tobacco-related disease or contains a reduced level of a substance unless FDA has granted an application permitting such a claim. 21 U.S.C. § 387k. The modified risk provisions are directly linked to Congress's concern that "[t]hose who use products sold or distributed as modified risk products that do not in fact reduce risk, rather than quitting or reducing their use of tobacco products, have a substantially increased likelihood of suffering disability and premature death." TCA, Section 2(37). As FDA demonstrated in the Final Deeming Rule, all premium cigars are addictive and contain all or substantially all the same carcinogens and toxicants as cigarettes and other cigars. But many consumers – including premium cigar smokers – already inaccurately believe that cigars are less harmful than cigarettes. 81 Fed. Reg. at 29,024. Absent the application of this

provision to premium cigars, FDA would be deprived of important authority to prevent consumers from being misled into believing that premium cigars are safer and less addictive than other tobacco products.

iii. If Premium Cigars Are Exempted, FDA Would Lack the Authority to Issue Product Standards for Premium Cigars.

Section 907 of the TCA grants FDA authority to issue product standards that are appropriate for the protection of public health by making tobacco products less toxic and addictive. 21 U.S.C. § 387g. For example, FDA may use this authority to establish maximum levels for nicotine yield, reduction or elimination of other hazardous constituents, and appropriate testing and measurement. 21 U.S.C. § 387g(a)(4). FDA has the authority to enforce such product standards because tobacco products manufactured in violation of them would be "adulterated" products. 21 U.S.C. § 387b. For example, in July 2017, when FDA announced a new comprehensive plan for tobacco and nicotine regulation, the issuance of a product standard to reduce nicotine in combustible cigarettes to non-addictive or minimally addictive levels was a key component of the plan.[46] If premium cigars are exempted from the Deeming Rule, FDA would not have the authority to issue a product standard to similarly limit nicotine levels in premium cigars even if it found that doing so would be appropriate for the protection of public health. FDA would lack the ability to set parameters for nicotine and other toxins to reduce the addictiveness and toxicity of premium cigars, a result directly contrary to the public health mission of the agency.

[46] FDA, *FDA announces Comprehensive Regulatory Plan to shift Trajectory of Tobacco-related Disease, Death* (July 27, 2017), https://www.fda.gov/news-events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.

iv. Excluding Premium Cigars from the TCA Would Deprive FDA Access to Important Health Information for Tobacco Products.

Section 904 of the TCA provides FDA access to industry health and medical information for tobacco products. 21 U.S.C. § 387d. It requires manufacturers to submit a broad range of health information, including ingredient listing and a listing of harmful and potentially harmful constituents. Submission of this information provides a factual basis for FDA's formulation of regulatory policy. It also gives FDA the authority to obtain from manufacturers additional information concerning research findings on the health, toxicological, behavioral, or physiologic effects of tobacco products. Such information would facilitate the issuance of product standards pursuant to Section 907 of the statute. There is no public health justification for an exemption for premium cigars that would deprive FDA of critical information about these harmful and addictive products.

v. If Premium Cigars Are Not Subject to the TCA, FDA Would Lack Authority to Ensure That Premium Cigars Manufacturers Are Maintaining Proper Manufacturing Facilities.

Several provisions of the TCA also give FDA the authority to ensure that tobacco manufacturers meet appropriate manufacturing standards. Section 905 requires manufacturers to register manufacturing facilities with FDA and enables FDA to conduct inspections of these facilities. 21 U.S.C. § 387e. In addition, it requires registrants to provide FDA with a list of their products and labeling. Section 906(e) gives FDA authority to prescribe sound manufacturing practice requirements for tobacco products. 21 U.S.C. § 387f(e). Products manufactured in violation of such requirements could be taken off the market as "adulterated" products. 21 U.S.C. § 387b. Without this authority over premium cigars, FDA would be unable to require that premium cigar manufacturers demonstrate that they can produce products with rigorous ingredient quality controls, attain consistent levels of nicotine and other constituents and

ensure that products are being produced consistently in accordance with product specifications and minimum manufacturing standards.

B. Exempting Premium Cigars from Regulation Would Create the Misimpression That Some Cigars Do Not Present Health Risks.

Exempting premium cigars from the Deeming Rule would create the misimpression that premium cigars are less toxic, carcinogenic, or addictive than other cigars or other tobacco products and thus would undermine public health. In deciding not to exempt premium cigars from regulation, FDA explicitly agreed with the comment,

> "an exemption could mislead consumers to believe that premium cigars are safe, which contradicts the available evidence that all cigars are harmful and potentially addictive. In addition, the current population of premium cigar users would be left unprotected, potentially decreasing the likelihood that they would quit and leading more youth and young adults to initiate use of premium cigars or substitute products."

81 Fed. Reg. 29,021. If premium cigars are exempted from the Deeming Rule, their manufacturers would be free to advertise that their products are exempt from FDA regulation, creating the misimpression that premium cigars are safer and do not carry the same health risk as other cigars and tobacco products.

C. Creation of an Exemption from Regulation for Premium Cigars Would Invite Product Manipulation to Qualify for the Exemption.

Exempting premium cigars from the Deeming Rule would require FDA to establish a definition of "premium cigars." But there is no agreed-upon definition for "premium cigars" and different studies have defined them with reference to various characteristics. Even the Plaintiffs disagree among themselves as to the proper definition of premium cigars. Pls.' Br. at 7, n.2. Regardless of what definition is used, however, creation of an exemption would invite manufacturers to manipulate their products to qualify. There is a long history of tobacco product manipulation by manufacturers to circumvent regulation. For example, when a lower federal

excise tax rate was established for "large" cigars, manufacturers added weight to the cigar sticks to allow reclassification of their products.[47] Similarly, in a study looking at the physical properties of large cigars and cigarillos, researchers found that weights of large cigar and cigarillo products varied greatly and were not necessarily consistent with the labeled product type; indeed some products labeled as cigarillos weighed more than products called large cigars.[48] Given the wide variability among cigars and the absence of consistent features defining categories of cigars, any exemption of certain cigars from regulatory requirements would create public health risks by providing a strong incentive to manipulate products to qualify for the exemption.

CONCLUSION

For the foregoing reasons, and the reasons stated in Defendants' brief, the Court should deny Plaintiffs' request to vacate the Deeming Rule's application to premium cigars.

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Respectfully submitted,

/s/ Dennis A. Henigan
Dennis A. Henigan
D.C. Bar No. 951897
dhenigan@tobaccofreekids.org
Counsel for *Amici Curiae*
1400 Eye Street NW, Suite 1200
Washington, D.C. 20005
Tel. 202-481-9366

[47] U.S. Government Accountability Office, *Tobacco Taxes: Disparities in Rates for Similar Smoking Products Continue to Drive Market Shifts to Lower-Taxed Options*, GAO-14-811T, 13-14 (July 29, 2014), https://www.gao.gov/products/gao-14-811t.
[48] Bartosz Koslowski, et al., *Nicotine Content and Physical Properties of Large Cigars and Cigarillos in the United States*, 20 Nicotine & Tobacco Research 393, 395 & 397 (2018).

APPENDIX

Description of *Amici Curiae*

1. 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. Since its founding, 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. American Cancer Society Cancer Action Network

The American Cancer Society Cancer Action Network (ACS CAN) is the nation's leading voice advocating for public policies that are helping to defeat cancer. 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 2021, an estimated 235,760 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. 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 40 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 America can live longer, healthier 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 cigarettes, cigars, and other tobacco products under the Federal Food, Drug, and Cosmetic Act.

4. 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, including use of cigars, as well as efforts to regulate the marketing, manufacture and sale of tobacco products.

5. 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.

6. Truth Initiative

Truth Initiative Foundation, d/b/a Truth Initiative (Truth Initiative) is a 501(c)(3) Delaware corporation created in 1999 out of a 1998 master settlement agreement that resolved litigation brought by 46 states, five U.S. territories, and the District of Columbia against the major U.S. cigarette companies. Headquartered in Washington, D.C., Truth Initiative studies and supports programs in the United States to reduce youth smoking, vaping and nicotine use and to prevent diseases associated with tobacco products. Its nationally recognized truth® campaign has educated hundreds of millions of young people about the health effects and social costs of tobacco

CERTIFICATE OF SERVICE

I hereby certify that on this sixteenth day of April, 2021, I have 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/ Dennis A. Henigan
Dennis A. Henigan
Counsel for *Amici Curiae*