[NOT SCHEDULED FOR ORAL ARGUMENT]
No. 23-5220

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

CIGAR ASSOCIATION OF AMERICA, et al.,

Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants-Appellants.

On Appeal from the United States District Court for the District of Columbia, Docket No. 1:16-CV-1460-APM
Hon. Amit P. Mehta, U.S. District Judge

BRIEF OF *AMICI CURIAE* MEDICAL AND PUBLIC HEALTH GROUPS IN SUPPORT OF DEFENDANTS-APPELLANTS

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Cir. R. 28(a)(1), *amici curiae* Medical and Public Health Groups certify as follows:

A. Parties and *Amici*

All parties, intervenors and *amici* appearing before the District Court are listed in the Certificates as to Parties, Rulings, and Related Cases filed by Appellants (Oct. 31, 2023) and Appellees (Nov. 1, 2023).

Except for the following *amici* (collectively, "Medical and Public Health Groups"), all parties, intervenors and *amici* appearing in this Court are listed in the Certificates as to Parties, Rulings, and Related Cases filed by Appellants and Appellees:

American Academy of Pediatrics

American Cancer Society Cancer Action Network

American Heart Association

American Lung Association

Campaign for Tobacco-Free Kids

Truth Initiative

B. Rulings under Review

References to the rulings at issue appear in the Certificates as to Parties, Rulings, and Related Cases filed by Appellants and Appellees.

C. Related Cases

Related cases are listed in the Certificates as to Parties, Rulings, and Related Cases filed by Appellants and Appellees.

DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1(a) and D.C. Cir. R. 26.1, *amici curiae* are all non-profit organizations committed to advancing the public health. None of the *amici* has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the *amici*.

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GLOSSARY

COPD	Chronic obstructive pulmonary disease
FDA	U.S. Food and Drug Administration
NASEM	National Academies of Sciences, Engineering and Medicine
NCI	National Cancer Institute
PATH Study	Population Assessment of Tobacco and Health Study
JA	Joint Appendix
TCA	Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 et seq. (2009)

STATEMENT OF INTEREST OF AMICI CURIAE[1]

Amici are the following public health and medical non-profit organizations: American Academy of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative. These groups have worked for decades to protect the public from the devastating harms caused by tobacco products, which claim over 480,000 lives every year and are the leading cause of preventable death in the United States.

These organizations have a strong interest in ensuring that all cigars sold in the United States, including premium cigars, are regulated under the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 et seq. (2009) ("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 protected from the serious adverse public health effects of these products, and thus support reversal of the District Court's decisions creating a complete exemption for

[1] All parties have consented to the filing of this *amicus* brief. No counsel for any party authored this brief in whole or in part, neither the parties nor their counsel contributed money that was intended to fund preparing or submitting this brief, and no person—other than *amici*, their members, or their counsel—contributed money that was intended to fund preparing or submitting the brief. *See* Fed. R. App. P. 29(a)(4)(E).

premium cigars from the statutory requirements established by Congress for tobacco products, including products deemed to be tobacco products by the Food and Drug Administration ("FDA").

INTRODUCTION AND SUMMARY OF ARGUMENT

Regulation of premium cigars is necessary to advance the public health objectives of the TCA. All premium cigars deliver to their users the same toxins and carcinogens as other cigars and cigarettes. They cause multiple kinds of cancer and myriad other fatal diseases. Premium cigars also deliver nicotine, one of the "most addictive substances used by humans." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). Moreover, like other combustible tobacco products, premium cigars produce secondhand smoke, causing death and disease to non-users.

Despite the known harmfulness of premium cigars, the District Court vacated the Final Deeming Rule's regulation of premium cigars, leaving these addictive and hazardous products entirely unregulated under federal law. The District Court held that FDA failed to consider record evidence purportedly showing that different patterns of use for premium cigars lead to lower health risks. Appellees also argued that premium cigars are not used by youth in meaningful numbers. For the reasons below, the Court should reject these contentions.

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 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, 29,020-27 (May 10, 2016) ("Final Deeming Rule").

In the Final Deeming Rule, FDA reasonably determined that "deeming all cigars, rather than a subset, more completely protects public health." *Id.* at 29,020. FDA specifically considered whether varying patterns of use of premium cigars lead to fewer health risks and explained:

> [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. Based on a review of the evidence, FDA also concluded that youth use premium cigars, further justifying their regulation. *Id.* at 29,022-24. FDA's decision to regulate premium cigars was well-supported and reasoned, not arbitrary and capricious.

Vacating the Final Deeming Rule as applied to premium cigars would preclude the application of a wide range of provisions in the TCA that protect the

public from the harms of tobacco products—including regulations restricting youth access, sales and advertising restrictions, potential product standards that reduce the toxicity and addictiveness of tobacco products, and provisions that authorize FDA to access information about their health hazards 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, all to the detriment of public health. In sum, FDA's approach to premium cigars is a reasonable response to a dangerous and addictive product.

ARGUMENT

I. Exempting Premium Cigars from FDA Regulation Would Harm Public Health.

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." *Id.* at 29,020. As demonstrated below, each of these findings was supported by evidence in the administrative record. Research since the issuance of the Deeming Rule further supports these conclusions.

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

In the Final Deeming Rule, FDA established that all cigars, including premium cigars,[2] 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 an increased risk of heart and pulmonary disease, including 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 by cigars' effectiveness in delivering nicotine, making such products 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*.; *see also* 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

[2] The District Court adopted the definition of "premium cigar" put forth by FDA in an August 2020 notice, which omitted a minimum price point but otherwise matched the Proposed Deeming Rule's definition. *Cigar Ass'n of Am. v. FDA*, 480 F.Supp.3d 256, 281 (D.D.C. 2020); *see also* Appellants' Br. 17.

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 "[c]igar 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. As noted by FDA, 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.

FDA specifically determined 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." *Id.* at 29,020. FDA also addressed studies cited by opponents of extending jurisdiction to premium cigars and cited overwhelming evidence on the adverse health effects of cigar smoking, 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 premium cigars, like all other cigars, pose health risks.

B. Patterns of Use of Premium Cigars Do Not Justify an Exemption.

The District Court held that FDA failed to consider evidence suggesting that different usage patterns for premium cigars might lead to different health outcomes. JA 21-26. However, the administrative record shows that the agency examined all the evidence before it and concluded that premium cigar users' patterns of use do not obviate the negative health risk. 81 Fed. Reg. at 29,024-25. Thus, the agency reasonably concluded that those health risks justified FDA oversight of premium cigars under the TCA.

The District Court disputed FDA's statement in the Final Deeming Rule that there were "no data" to support the premise that different patterns of use of premium cigars leads to lower health risks. JA 23 (quoting 81 Fed. Reg.at 29,020). But, as Appellants argue, this statement should be considered in the broader context of FDA's evaluation of all the evidence before it. Appellants' Br. 33-34. FDA noted that while some comments "claimed that patterns of use preclude premium cigar smokers from experiencing the negative health effects of tobacco smoke because they smoke infrequently," others supported the opposite conclusion—that there is "increased disease risk and nicotine dependence [even] among infrequent cigar users." 81 Fed. Reg. at 29,024.

FDA specifically considered these comments, and the data cited therein, and explained that such data do not support the conclusion that "premium cigar smokers are not subject to disease risk and addiction." *Id.* "[A]ll cigars expose users to toxic and cancer-causing substances and increase the risk of harm," and "any cigar use exposes the throat and mouth to [harmful] tobacco smoke." *Id.* at 29,025. "Although studies indicate that some cigar smokers may absorb less tobacco smoke, they also show that all cigar smoking is harmful." *Id.* at 29,024. "The science is clear," FDA found, "cigar use of all types can lead to negative health effects." *Id.*

Thus, the record simply does not support the District Court's conclusion that FDA ignored industry comments suggesting that the patterns of premium cigar use may diminish their harmful effects. Rather, the agency considered and evaluated those comments and concluded that the adverse health effects of all cigars, including premium cigars, are sufficiently significant to support regulation. As this Circuit has made clear, such a determination, based on FDA's evaluation of "scientific data within its technical expertise," is entitled to an "extreme degree of deference." *NYC C.L.A.S.H., Inc. v. Fudge*, 47 F.4th 757, 763-64 (D.C. Cir. 2022) (quoting *Hüls Am., Inc. v. Browner*, 83 F.3d 445, 452 (D.C. Cir. 1996)).

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

In finding it arbitrary and capricious to apply the Final Deeming Rule to premium cigars, the District Court also ignored FDA's findings regarding the

negative health effects of secondhand smoke, which are alone sufficient to support regulation of 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." 81 Fed. Reg. 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 emitted by a lit cigar, which means they, and those around them, are being exposed to dangerous chemicals.

FDA also 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:

> Although 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 additionally found a causal relationship between secondhand smoke and heart disease. *Id.* And based on cigars' and cigarettes' similar smoke profiles, the

agency reasonably concluded that this relationship would exist for secondhand cigar smoke. *Id.* The agency further cited studies demonstrating that "[e]ven a relatively brief exposure to secondhand tobacco smoke can lead to heart disease." *Id.* at 29,071.

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

According to the District Court, the Final Deeming Rule "obscures the real math" quantifying youth usage of premium cigars when it implied that youth usage was "more than negligible." JA 31-32. But FDA examined the relevant evidence and concluded that youth and young adults use premium cigars to an extent sufficient to support regulation. 81 Fed. Reg. at 29,022. This finding deserves great deference. *See NYC C.L.A.S.H.*, 47 F.4th at 763-64.

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 examined youth cigar usage trends over several years in the National Youth Tobacco Survey, National Survey on Drug Use and Health, and National Youth Risk Behavior Surveillance data sets. *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.*

Appellees argued in the District Court that FDA misinterpreted a study from Delnevo et al. that 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. *See* JA 30 (citing 81 Fed. Reg. at 29,023). The District Court concluded that although all of the agency's statements about that study "are accurate . . . the reasonable reader would not be off base in understanding them to imply that a more-than-negligible number of youth smoke premium cigars." JA 32. However, 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 32,000 youth (ages 12-17) who smoke premium cigars.[3] Given that cigar smoke is both highly addictive and laden with dangerous toxicants, the District Court's assertion that this number is "negligible" is contrary to the record before FDA. It was certainly not arbitrary or capricious for FDA to conclude that it is reasonable to regulate an addictive, harmful product used by tens of thousands of children. Moreover, this number does not include premium cigar smokers aged 18-20, who are also below the federal legal sales age of 21 for tobacco products. 21 U.S.C. § 387f(d)(5). FDA reasonably concluded that youth and young adults use premium cigars to an extent justifying regulation.

Appellees also argued to the District Court that youth cannot access premium

[3] 2022 U.S. Census data reports an estimated 25,810,168 youth aged 12-17 years old living in this country. U.S. Census Bureau, *Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2020 to July 1, 2022* (NC-EST2022-SYASEXN), https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html (Dec. 8, 2023).

cigars because they are expensive and generally sold in specialty shops. Pls.' Mem. In Supp. of Pls. Mot for Summ. J. & for a Permanent Inj., *Cigar Ass'n of Am. v. FDA*, No. 1:16-cv-01460 (D.D.C. Feb. 19, 2021), ECF No. 247-1 ("Pls.' Mem."), at 7. This argument was entirely unsupported, and thus warrants no weight. First, the District Court's definition of premium cigars does not include a minimum price point. *See supra* note 2. Thus, price should not be regarded as a factor limiting youth access to premium cigars as defined by the District Court.

Moreover, Appellees' assertion that premium cigars are sold only in specialty tobacco shops which do not permit youth access (Pls.' Mem. 28) is contradicted by the premium cigar industry's recognition that selling premium cigars in *convenience stores* offers a "fast-growing, alternative tobacco profit stream." Scandinavian Tobacco Group, a member company of Appellee Cigar Association of America[4] and self-proclaimed "#1 in US" for handmade cigars,[5] sponsored an article in *CSP Daily News* (a convenience store trade publication), titled *Putting the Convenience in Premium Cigar Sales*.[6] In it, Bill Noah of Scandinavian Tobacco Group, encouraged adding pre-packaged premium cigars to convenience store shelves and indicated that

[4] Cigar Association of America, *Our Members*, https://cigarsusa.com/our-members/ (last visited Jan. 18, 2024).

[5] Scandinavian Tobacco Group, *About Us*, https://www.st-group.com/about-us/ (last visited Jan. 18, 2024).

[6] CSP Daily News, *Putting the Convenience in Premium Cigar Sales* (May 30, 2018) https://www.cspdailynews.com/tobacco/putting-convenience-premium-cigar-sales.

it is a "fast-growing, alternative tobacco profit stream potential . . . thanks to innovation in packaging."[7] He further observed that the novel packaging would "entice the occasional premium cigar smoker, typically younger generation consumers . . . ."[8]

Appellees also argued below that premium cigars are marketed in publications that "cater exclusively to adults, like *Cigar Aficionado*. . . ." Pls.' Mem. 28. However, the September/October 2019 issue of *Cigar Aficionado* featured then-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.[9] Mr. Jonas's posts promoting the cover received more than 1.23 million "likes" in less than 24 hours, the most "attention" any *Cigar Aficionado* cover has "ever drawn . . . on social media" in the publication's 27-year history.[10] The feature article noted that Jonas is a "teen idol" who began using premium cigars at 18 years old but was surrounded by cigar

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[7] *Id.*

[8] *Id.*

[9] David Savona, *Nick Jonas Cover Scores More Than 1 Million Likes in the First 24 Hours*, CIGAR AFICIONADO (Sept. 10, 2019), https://www.cigaraficionado.com/article/nick-jonas-cover-scores-more-than-1-million-likes-in-first-24-hours#:~:text=The%20posts%20were%20images%20of,times%20on%20Jonas'%20Instagram%20page.

[10] *Id.*

smokers prior to that, which piqued his interest.[11] In the article, Jonas also stated:

> "One 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," he says after taking another puff. "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**."[12]

Premium cigar makers also promote their products through social media, and a recent study concluded they use insufficient methods to prevent youth from accessing their promotional content, including a lack of age-gating and easy ways to bypass the age-gates that do exist.[13] Social media marketing themes also link premium cigars to celebrities, music, alcohol, and sex appeal.[14]

Finally, although Appellees attempted to distinguish the marketing of premium cigars from other types of cigars (Pls.' Mem. 28-29), a recent report on premium cigars from an FDA-commissioned National Academies of Sciences, Engineering and Medicine ("NASEM") committee found that premium cigar brands "are using similar marketing strategies as other cigar brands, such as e-mails to

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[11] David Savona, *The Jonas Effect*, CIGAR AFICIONADO (Sept./Oct. 2019), https://www.cigaraficionado.com/article/the-jonas-effect.

[12] *Id.* (emphasis added).

[13] Grace Kong, et al., *The Promotion of Premium Cigars on Social Media*, 25 (Supp. 1) NICOTINE & TOBACCO RES. S59, S61-62 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10380185/.

[14] *Id.* at S60.

promote non-cigar-specific themes that appeal to young people—music festivals, urban lifestyle, and hip-hop and rock music."[15]

These examples of industry marketing 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 protect youth. 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.

E. Research Since the Final Deeming Rule Continues to Demonstrate the Need for FDA Regulation of Premium Cigars.

Research published since the Final Deeming Rule reinforces the public health necessity of regulating premium cigars and the adverse consequences of the District Court's vacatur order. That recent evidence demonstrates that all cigars, including premium cigars, are harmful to health; many adults use premium cigars frequently; dual use of premium cigars with other tobacco products increases risk of disease; and youth use premium cigars in significant numbers.

1. Premium Cigars Expose Smokers to Hazardous Levels of Toxins, Increasing the Risk of Disease.

Research continues to demonstrate that all cigar smokers have an elevated risk

[15] NASEM, PREMIUM CIGARS: PATTERNS OF USE, MARKETING, AND HEALTH EFFECTS 144 (2022), https://nap.nationalacademies.org/catalog/26421/premium-cigars-patterns-of-use-marketing-and-health-effects.

of disease and mortality than never smokers, and that all cigars, including large cigars (many of which are premium cigars), deliver significant amounts of toxins and nicotine. After reviewing the 1998 NCI monograph on cigars, and subsequent research, the FDA-commissioned NASEM Committee determined that "there is conclusive evidence that the toxicants and carcinogens in cigar smoke . . . are qualitatively the same as those in cigarette smoke" and that there "is no reason to believe that toxicants and carcinogens in premium cigar smoke are any different from those in other types of cigars."[16]

Moreover, the generally larger size of cigars—particularly premium cigars—compared to cigarettes means users are burning more tobacco leaf, and releasing more associated toxicants and chemicals. The NASEM report found that "cigars could be as dangerous as or more dangerous than cigarettes, with respect to toxicant and carcinogen exposure per unit consumed."[17]

The NASEM committee recognized that patterns of use of premium cigars—including frequency and depth of inhalation—may affect health outcomes, yet still found that premium cigars "are not inherently less risky than other cigar products."[18] NASEM cited[19] one study that identified variations in how users puffed

[16] NASEM, *supra* note 15, at 10.

[17] *Id.* at 7.

[18] *Id.* at 2.

[19] *Id.* at 78.

based on various cigar types and found that 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.[20] These results suggested that large cigar (and cigarillo) smokers may be exposed to more toxicants than other cigar smokers to achieve adequate levels of nicotine.[21]

In sum, data published since the Final Deeming Rule continue to support the reasonableness of FDA's position that the health risks posed by all cigars, including premium cigars, justify regulation, and demonstrate the injury to public health from vacatur of the Rule as to premium cigars.

2. Adults Use Premium Cigars with Sufficient Frequency to Support Regulation.

The claim that premium cigars are used infrequently by adults is contradicted by the premium cigar industry's own advertising. For example, an infographic sponsored by Swisher International, a member of Appellee Cigar Association of America,[22] 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

[20] Wallace B. Pickworth et al., *Dual Use of Cigarettes, Little Cigars, Cigarillos, and Large Cigars: Smoking Topography and Toxicant Exposure,* 3 TOBACCO REG. SCI. S72, S77 & tbl.2 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5614467/.

[21] *Id.* at S80.

[22] Cigar Association of America, *supra* note 4.

once a week."[23] Appellees also cited a study from Corey, et al., using data from the governmental 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. Pls.' Mem. 22-23. But this study does not assess the relative health risks of smoking premium cigars versus other cigars and thus does not undermine the reasonableness of the Final Deeming Rule's determination that, whatever the use patterns associated with premium cigars, they do not sufficiently reduce the health risks to users to justify exempting them from any regulation.

While premium cigar use rates were generally stable at 0.7% of adults between 2014 to 2017, there was a recent increase, with PATH Study data showing that in 2021, 0.9% of adults smoked premium cigars and 6.9% of premium cigar users smoked them every day.[24] This translates to about 2.3 million current premium cigar users,[25] with nearly 163,000 people being daily users of premium

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[23] Convenience Store News, *Premium Pays Off* (July 3, 2018), https://csnews.com/premium-pays.

[24] Kathryn C. Edwards et al., *Patterns of Premium and Nonpremium Cigar Use in the United States: Findings from Wave 6 (2021) of the Population Assessment of Tobacco and Health Study*, 25 (Supp. 1) NICOTINE & TOBACCO RES. S5, S9 tbl.2 & S12 (2023), https://doi.org/10.1093/ntr/ntad010.

[25] According to 2023 U.S. Census data, approximately 262 million adults live in the U.S. U.S. Census Bureau, *Estimates of the Total Resident Population and Resident Population Age 18 Years and Older for the United States, States, District of Columbia, and Puerto Rico: July 1, 2023 (SCPRC-EST2023-18+POP)* (Dec. 8, 2023) https://www.census.gov/data/tables/time-series/demo/popest/2020s-national-detail.html.

cigars. Data from the 2021 PATH Study also shows that the *median* number of usage days of premium cigar smokers was 3 of the 30 day-period prior to the survey,[26] which means that *half* of all premium cigar smokers—nearly 1.2 million people—used the product on more than 3 days per month. Thus, in addition to the almost 163,000 premium cigar smokers who smoke daily, tens if not hundreds of thousands of other premium cigar smokers likely smoke these products on a frequent basis.

3. A Significant Portion of Premium Cigar Smokers Also Use Other Tobacco Products, Increasing Their Risk of Disease.

Data from the latest PATH Study establishes that a significant portion of premium cigar smokers engage in dual use behavior (i.e., using more than one type of tobacco product), which increases the risk of disease. Importantly, 18.1% of premium cigar smokers also currently used at least one other cigar product and 18.0% currently smoked cigarettes.[27]

The NASEM committee determined that "compared to those who only smoke cigars, dual users of cigars and cigarettes are more prone to smoking cigars with a greater intensity, and therefore, inhaling the smoke more deeply . . . Because of this tendency, dual use represents an especially harmful practice."[28] This led the

[26] Edwards, *supra* note 24, at S9 tbl.2.

[27] *Id.* at S9 tbl.2 & S11 tbl.4.

[28] NASEM, *supra* note 15, at 89-90.

committee to conclude that "concurrent users of premium cigars and other combustible tobacco products would experience greater health risks than those smoking only premium cigars."[29]

A study looking at transition patterns among premium cigar smokers from 2013 to 2019 found that 40% of dual users stayed dual users a year later.[30] However, about 34% of dual users of premium cigars and cigarettes switched to smoking cigarettes exclusively within a year.[31] This is particularly concerning given the higher consumption patterns—and therefore higher health risks—among cigarette smokers.

Evidence of dual use among premium cigar smokers and the increased risk of disease associated with dual use further justifies FDA regulation of all cigars.

4. Youth and Young Adults Use Premium Cigars.

New research also continues to bolster FDA's finding in the Final Deeming Rule that youth and young adults use premium cigars in sufficient numbers to support regulation. Data from the 2010-2019 National Survey on Drug Use and Health show that 0.1% of 12–17-year-olds smoked premium cigars in the past 30

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[29] *Id.* at 17.

[30] Jihyoun Jeon et al., *Cross-sectional Patterns and Longitudinal Transitions of Premium and Non-Premium Cigar Use in the United States*, 25 (Supp. 1) NICOTINE & TOBACCO RES. S16, S20 (2023), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10381102/.

[31] *Id.*

days.[32] As this group includes very young adolescents, who generally have much lower use rates, the prevalence rate for the youth at the older end of this range is much higher. Indeed, other studies show that youth initiation rates for traditional cigar use increase dramatically as they get older. Thus, cumulative initiation of past 30-day traditional cigars use increased 7-fold from ages 17 to 18 (0.8% to 5.9%), and reached 11.7% by age 20.[33] These findings point to the need for FDA regulation to minimize youth use of all cigars, including premium cigars.

II. Vacatur Would Leave Premium Cigars Federally Unregulated, Harming Public Health.

If premium cigars are exempted from the Final Deeming Rule, FDA will be stripped of the ability to regulate a harmful tobacco product, a result entirely at odds with the public health purposes of the TCA. Furthermore, such an exemption will create the misimpression that premium cigars are safer because they are unregulated and will invite product manipulation to qualify for the exemption. For these same reasons, if the Court finds that FDA failed to consider relevant evidence (it did not),

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[32] Julia Chen-Sankey et al., *Cross-sectional Use Patterns and Characteristics of Premium Versus Non-Premium Cigar Smokers in the United States, 2010–2019*, 25 (Supp. 1) NICOTINE & TOBACCO RES. S24, S27 tbl.1 (2023), https://pubmed.ncbi.nlm.nih.gov/37506241/.

[33] 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, 8 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7725294/pdf/pone.0243372.pdf.

remand without vacatur is the appropriate remedy.

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

If the Court exempts premium cigars from the Final Deeming Rule entirely, *none* of the TCA provisions that protect public health would apply to these addictive and hazardous products.

1. FDA Authority to Prevent Youth 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 Final Deeming Rule, critical statutory provisions intended to protect young people would no longer apply, including a minimum sales age, prohibition on free samples, and prohibition on vending machine sales (unless the machine is located in a facility that prohibits youth from entering at any time). *See* 81 Fed. Reg. at 28,976.

In the Final 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 restriction on vending machine sales to all newly deemed products, including premium cigars. *Id.* As a result of the Final 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.

Further Consolidated Appropriations Act, 2020, Pub. L. No. 116-94, § 603(a), 133 Stat. 3123 (2019) (amending 21 U.S.C. § 387f(d)(5)). However, if premium cigars are exempted from the Final Deeming Rule, retailers would be free to sell premium cigars to children of any age without fear of FDA enforcement. Although, as the District Court noted (JA12), state laws also limit youth access, the loss of federal enforcement authority unquestionably reduces the level of protection given young people.

Section 102 of the TCA (21 U.S.C. § 387(a)(1)) also closes a pathway for youth access by prohibiting free samples of tobacco products. 79 Fed. Reg. at 23,149. As FDA noted in the Proposed Deeming Rule, the Institute of Medicine has found that free samples of cigarettes "encourage experimentation by minors with a risk free and cost-free way to satisfy their curiosity." *Id.* While the statement refers to cigarettes, the same rationale applies to premium cigars. *See* Pls.' Mem. 32. In the absence of FDA regulation, premium cigar sellers providing free samples would be free of any threat of federal enforcement action.

2. FDA Authority to Prevent Misleading Claims from Premium Cigar Manufacturers.

In the TCA, Congress expressed concern that "[t]obacco product advertising often misleadingly portrays the use of tobacco as socially acceptable and healthful to minors." TCA § 2(17). Thus, several provisions of the TCA grant FDA significant authority to regulate tobacco product labeling that is false or misleading. *E.g.*, 21

U.S.C. § 387c(a) (tobacco product is misbranded if its labeling is false or misleading). Exempting premium cigars from the Final Deeming Rule would deprive consumers of this basic protection against misleading claims.

Similarly, Section 911 of the TCA, which concerns 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 § 2(37). As FDA demonstrated in the Final Deeming Rule, many consumers—including premium cigar smokers—already inaccurately believe that cigars are less harmful than cigarettes. 81 Fed. Reg. at 29,024. This conclusion is further bolstered by the recent NASEM Report, which found "conclusive evidence that premium cigars are advertised and promoted as less harmful than other tobacco products and as having benefits that outweigh their adverse health effects."[34]

Absent the application of this provision to premium cigars, FDA would be

[34] NASEM, *supra* note 15, at 14.

deprived of important authority to prevent tobacco companies from misleading consumers into believing that premium cigars are safer and less addictive than other tobacco products.

3. FDA 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, the reduction or elimination of other hazardous constituents, and appropriate testing and measurement. *Id.* § 387g(a)(4). If premium cigars are exempted from the Final Deeming Rule, FDA would not have the authority to issue any product standard applicable to premium cigars, no matter how strong the evidence demonstrating that such a standard would protect public health. Such a result would be directly contrary to the broad public health goals of the TCA.

4. 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 information bearing on the potential health effects of the product, 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, including the issuance of product standards. 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.

5. FDA Authority to Ensure Premium Cigar 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. It also requires registrants to provide FDA with a list of their products and labeling. *Id.* Section 906(e) gives FDA authority to prescribe sound manufacturing practice requirements for tobacco products. 21 U.S.C. § 387f(e).[35] Products manufactured in violation of such requirements could be taken off the market as "adulterated" products. *Id.* § 387b. Without this authority over premium cigars, FDA would be unable to require premium cigar manufacturers to demonstrate that they can produce products with rigorous ingredient quality controls and consistent levels of nicotine and other constituents.

[35] Using this authority, FDA has issued a Proposed Rule on Requirements for Tobacco Product Manufacturing Practice, 88 Fed. Reg. 15,174 (Mar. 10, 2023).

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

Exempting premium cigars from the Final Deeming Rule would create the misimpression that premium cigars are less toxic, carcinogenic, or addictive than other cigars or tobacco products and thus would undermine public health. As FDA concluded:

> [A]n 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. at 29,021.

These misperceptions can have adverse health consequences. The NASEM Report found that the "evidence indicates that lower perceived risks of cigars, which likely includes premium cigars, is associated with subsequent use,"[36] and that there is "strongly suggestive evidence . . . that lower perceived harm and addictiveness of cigars in general is associated with cigar use behavior, including current use in adults and initiation in youth."[37]

If premium cigars are exempted from the Deeming Rule, their manufacturers would be free to advertise that their products are exempt from FDA regulation,

[36] NASEM Report, *supra* note 15, at 188.

[37] *Id.* at 190.

creating the misimpression that premium cigars are safer and do not carry the same health risk as other cigars and tobacco products.

C. A Regulatory Exemption for Premium Cigars Would Invite Product Manipulation to Qualify for the Exemption.

Exempting premium cigars from the Deeming Rule would invite manufacturers to manipulate their products to qualify for the exemption, a concern noted by FDA in the Final Deeming Rule. 81 Fed. Reg. at 29,025. 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.[38] 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 a strong incentive to manipulate products to qualify for the exemption.

CONCLUSION

For these reasons, the Court should reverse the District Court and direct it to enter summary judgment for Defendants-Appellants.

[38] 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.

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CERTIFICATE OF SERVICE

I hereby certify that on February 7, 2024 the foregoing brief was filed via the CM/ECF system, which will send a Notification of Electronic Filing to all counsel of record.

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