ORAL ARGUMENT NOT YET SCHEDULED

No. 20-5266

United States Court of Appeals
for the District of Columbia Circuit

CIGAR ASSOCIATION OF AMERICA, *et al.*,

Appellants,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Appellees.

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

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

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CORPORATE AND FINANCIAL DISCLOSURE STATEMENT

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

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

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

CERTIFICATE OF COUNSEL PURSUANT TO CIRCUIT RULE 29(d)

The six *amici curiae* submitting this brief are filing separately from other *amici*, because this brief offers a distinct perspective with distinct concerns. In light of Appellants' effort to forestall meaningful review by the Food and Drug Administration of cigar products that entered the market after February 15, 2007, which products are therefore "new tobacco products" subject to "substantial equivalence" review under Chapter IX of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), this brief is necessary to aid the Court's understanding of the growth and evolution of the cigar market toward flavored products that appeal to young people, and how that shift underscores the importance to the public health of

application of the FDCA's premarket review and substantial equivalence provisions for all tobacco products, including cigars. We know of no other *amici* who intend to supply the Court with this perspective.

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CERTIFICATE OF PARTIES, RULINGS UNDER REVIEW, AND RELATED CASES

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

STATUTES AND REGULATIONS

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

STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*

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

Amici have a strong interest in ensuring that cigars introduced to the market since the enactment of the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 et. seq. (2009) (the "TCA") do not increase the risk of public health to all users and especially to children, which can only be assured by subjecting these products to the same premarket review requirements and standards that the FDCA applies to cigarettes and other tobacco products. *Amici* seek to protect the public from the serous, adverse health effects of cigars, given the severe risk of disease from smoking cigars; their addictiveness; and cigar manufacturers' deliberate strategy to target young people with cheap, flavored products, resulting in their use by hundreds of thousands of adolescents. The explosion in new cigar products created since enactment of the TCA, and in particular the flavored products that cigar makers developed to fill the vacuum after

the elimination by the TCA of flavored cigarette products, confirm the importance of the substantial equivalence and other premarket review requirements of the TCA. Accordingly, *amici* oppose Appellants' efforts to evade the statutory requirements established by Congress to apply to all new tobacco products, including those deemed by the Food and Drug Administration ("FDA").

Amici also are plaintiffs in *American Academy of Pediatrics v. FDA*, in which they obtained a federal court order vacating the FDA's 2017 Guidance suspending the operation of premarket review for several years for cigars and e-cigarettes and a remedial order establishing new deadlines for submission of premarket applications and for FDA review of those applications. 379 F. Supp. 3d 461 (D. Md.) and 399 F. Supp. 3d 479 (D. Md. 2019), *appeal dismissed sub nom. In re Cigar Ass'n of Am.*, 812 F. App'x 128 (4th Cir. 2020). *Amici* have a strong interest in opposing the relief sought by Appellants, which would effectively nullify the orders entered by the Maryland federal court.

All parties have consented to the filing of this brief.

INTRODUCTION AND SUMMARY OF ARGUMENT

Although cigarettes have been subject to FDA regulation since enactment of the TCA in 2009, cigar makers were entirely unregulated for seven years after the TCA was enacted, and have been subject to minimal regulation thereafter. Though aware of the TCA's premarket review provisions and FDA's intent, stated in 2010,

to subject cigars to its regulatory authority, the cigar industry took advantage of this period of governmental inactivity to fill the void created by the TCA's ban on flavored cigarettes. Appellants complain that FDA "never identified the problem in the last decade's worth of cigar . . . products that the substantial equivalence process was expected to detect and correct."[1] In fact, as the discussion below demonstrates, FDA repeatedly identified that problem: cigar makers redesigned cigars to be cheap, small, and kid-friendly. As FDA found, manufacturers introduced mass-produced, cigarette-like products with sugary flavors designed to appeal to youth, with names like "Sweet Dreams" and "Da Bomb Blueberry."

Amici focus here on describing the cigar market as it exists today and the related public health risks presented by cigars, especially to youth. These two factors underscore why the statutory requirements that FDA applied to cigars are essential to protect the public health and should be enforced. The robust record compiled by FDA shows that youth cigar use is a substantial public health risk, and that more than 900,000 children use Appellants' addictive, carcinogenic products. The premarket review requirements that the TCA imposed on cigarettes did not apply at all to the cigar industry until at least 2016, and the cigar industry benefited: youth cigar use has declined much less than youth cigarette use. When the TCA was enacted, high school students reported more current use of cigarettes (17.2%) than

[1] Appellants Br. at 14.

cigars (10.9%), but today the reverse is true: more high school students use cigars than cigarettes. The current cigar market differs markedly from the image that Appellants attempt to present, because the cigars that dominate the market bear little resemblance to "traditional" cigars. Indeed, many cigar products are almost indistinguishable from cigarettes.

Appellants' brief also studiously avoids any discussion of the health effects of cigar smoking. But the Deeming Rule,[2] drawing on an extensive body of evidence, demonstrated the substantial adverse health effects and addictiveness of cigar smoking that justify FDA's regulatory oversight. FDA's evidence-based decision was fully consistent with Congress's view that FDA, with "its mandate to promote health," was best positioned to regulate tobacco products because it has the scientific expertise to do. TCA § 2(44).

To address the substantial public health concern posed by tobacco products, Congress established a premarket review framework to ensure FDA evaluated new tobacco products before they entered the market. As a general matter, Congress allowed a manufacturer to market a "new" tobacco product (*i.e.*, to introduce a product into commerce after February 15, 2007, the "grandfather date") only if it can demonstrate that the product is "appropriate for the protection of the public

[2] 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, 81 Fed. Reg. 28,974 (May 10, 2016) (final rule) (the "Deeming Rule").

health." 21 U.S.C. § 387j(c)(2)(A). No cigar can possibly meet this "public health" standard since, as FDA has stated, "cigars are associated with significant risk and provide no public health benefit."

Thus, to bring a new cigar to market lawfully, a cigar manufacturer must submit a report demonstrating that the new product is "substantially equivalent" to a product on the market as of the grandfather date—i.e., that it has the "same characteristics" as a product on the market before that date or does not "raise different questions of public health." *Id.* § 387j(a)(2) & (a)(3). But kid-oriented, flavored cigars that were introduced after February 15, 2007 are unlikely to be found substantially equivalent to grandfathered products. The district court's well-reasoned opinion correctly held that the substantial equivalence requirements apply equally to cigars. Requiring manufacturers to file substantial equivalence reports will provide FDA, for the first time, with detailed information about new cigar products and enable it to deny market access to new products introduced after February 15, 2007 that threaten to increase the risk of addiction and disease. Invalidating the Deeming Rule as applied to cigars, the remedy sought by Appellants, would do serious damage to public health.

In summary, FDA's approach to cigars is a rational, well-justified response to cigars' public health dangers. *Amici* urge that the Court uphold the district court's decision.

ARGUMENT

I. CIGAR MAKERS HAVE RADICALLY TRANSFORMED THE CIGAR MARKET SINCE 2009, INCREASING THE APPEAL OF CIGARS TO CHILDREN.

Three significant provisions Congress included in the TCA to protect and promote the public health were: (i) the ban on all flavors except tobacco or menthol, a rule that Congress applied *only to cigarettes*, 21 U.S.C. § 387g(a)(1)(A); (ii) the section authorizing FDA by regulation to subject other products to the TCA's requirements, *id.* § 387a(b), providing the authority to extend the flavor ban to other tobacco products; and (iii) provisions directing FDA to conduct premarket review of all new tobacco products, defined as products commercially marketed after February 15, 2007, *id.* §§ 387e(j) and 387j.

In the Deeming Rule, FDA exercised its authority to deem cigars subject to the TCA. 81 Fed. Reg. 28,974. This case challenges the district court's decision that FDA properly enforced the substantial equivalence process against cigars by applying the TCA's premarket review provisions to cigars that qualify as new tobacco products.

A. Flavored, Cheap, Mass-Produced Cigars Now Predominate the Cigar Market.

In enacting the TCA, Congress noted that the "lack of government regulation has allowed the tobacco industry to design new products or modify existing ones in ways that increase their appeal to children and that contribute to the risk and

incidence of disease." H. Rep. 111-58 (Pt. 1), at 4 (2009). That statement also describes the conduct of the cigar industry in the period *after* the enactment of the TCA.

With the TCA's ban on flavors limited to *cigarettes*, 21 U.S.C. § 387g(a)(1)(A), cigar makers leapt into the breach. They have exploited the lack of active cigar product regulation by FDA to introduce cheap, flavored, machine-made products, including those that blur the distinctions between cigarettes and cigars. *See generally* 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, 79 Fed. Reg. 23,141, 23,147 (Apr. 25, 2014) (proposed rule) ("[I]ndustry documents indicate that tobacco firms have been aware of disparities in the legal treatment of cigarettes and cigars and have made efforts to develop small cigars that cigarette smokers would smoke.") (citations omitted); *see also id.* (FDA expressing "concern[] that manufacturers may be . . . representing tobacco products that are, in fact, cigarettes to be little cigars, cigarillos, or similar products in order to evade the prohibition against characterizing flavors in cigarettes.").

Under the TCA, the essential difference between a cigarette and a cigar is that a cigar contains tobacco in the wrapper, while a cigarette does not. *See* 15 U.S.C. § 1332(1)(a) (defining "cigarette"); 21 C.F.R. § 1143.1 (defining "cigar"). "To circumvent the FDA's ban on fruit- and candy-flavored cigarettes . . . , some

cigarette makers added tobacco to the wrapper and weight to their products so that they meet the definition of small or large cigars, even those sold in packs of 20 like cigarettes."[3] As demonstrated in the pictorial example below, some cigarettes were essentially remarketed after the TCA as cigars.[4]

[3] *See* Campaign for Tobacco-Free Kids, *Not Your Grandfather's Cigar: A New Generation of Cheap and Sweet Cigars Threatens a New Generation of Kids* at iii (Mar. 13, 2013), https://www.tobaccofreekids.org/assets/content/what_we_do/industry_watch/cigar_report/2013CigarReport_Full.pdf, AR 154646–154679; Doris G. Gammon et al., *Little filtered cigars: US sales, flavours, package sizes and prices*, 28-3 Tobacco Control 346–49 (2019).

[4] HHS, *Preventing Tobacco Use among Youth and Young Adults: A Report of the Surgeon General* 205 (2012), https://www.ncbi.nlm.nih.gov/books/NBK99237/pdf/Bookshelf_NBK99237.pdf. The Centers for Disease Control and Prevention defines a little cigar as "a small cigar that typically is about the same size as a cigarette and usually includes a filter," and a cigarillo is a "short (3–4 inches) and narrow cigar that typically contains about 3 grams of tobacco and usually does not include a filter." CDC, Smoking & Tobacco Use, Cigars Fact Sheet (2020), https://www.cdc.gov/tobacco/data_statistics/fact_sheets/tobacco_industry/cigars/index.htm.

Appellants' members have produced machine-made, flavored cigars by the billions, lacing them with sugary flavors from candy to chocolate to lemonade and giving them names like "Sweet Dreams" or "Da Bomb Blueberry." AR 3515, 154662.[5] In the years since the Deeming Rule, the proliferation of flavored cigars and cigarillos, with names like "Berry Fusion Burst," "Cherry Dynamite," "Swirl Chocolate & Vanilla," and "Swiss Roll," has continued, as shown by the labels reprinted below.

As FDA observed, young people are far more likely than older smokers to prefer flavored cigars. *See* 79 Fed. Reg. at 23,146 ("sugar preference is strongest among youth and young adults and declines with age."). And as one cigar maker acknowledged, "It is mainly new recruits to cigar smoking who take to the new

[5] *See also Not Your Grandfather's Cigar*, *supra* note 3, at 9 (noting flavored cigar product names, including "Purple Haze," "Hush Honey," and "Banana Split").

flavors," AR 145585—and as has long been the case, "new recruits" are disproportionately minors. *See, e.g.*, 79 Fed. Reg. at 23,155 ("Virtually all new users of most tobacco products are youth . . . ."); *see also e.g.*, AR 154660 (quoting a tobacco industry publication acknowledging: "While different cigars target a variety of markets, all flavored tobacco products tend to appeal primarily to younger consumers."). The modern cigar industry's focus on youth was accurately described by one study cited by FDA: according to a focus group of 14- to 18-year-olds, "cigars were easy to obtain," "new brands were targeting youth," and "the products were prominent in rap videos." 79 Fed. Reg. at 23,158.

B. Sales of Flavored, Mass-Produced Cigar Products Have Increased Significantly.

As the cigar industry shifted toward the youth market to fill the gap created by the ban on most flavored cigarettes, its sales skyrocketed. By 2019, cigar consumption was up 118% from 2000, while cigarette consumption declined by 49% from 2000 levels.[6]

The current cigar market overwhelmingly and increasingly consists of mass-produced, flavored products appealing primarily to youth. The 29% increase in cigar sales from 2012-2016, for instance, was largely driven by a 78% increase in sales of

[6] Derived from Alcohol and Tobacco Tax and Trade Bureau ("TTB"), Tobacco Statistics, https://www.ttb.gov/tobacco/tobacco-statistics.

cigarillos, which are often flavored and inexpensive.[7] From 2008 to 2015, there was explosive growth in kid-friendly flavored cigars with names like those mentioned above—the number of unique cigar flavor names more than doubled, from 108 to 250.[8] And sales reflected that growth: dollar sales of flavored cigar products increased by nearly 50% between 2008 and 2015, increasing flavored cigars' share of the overall cigar market to 52.1% in 2015.[9]

The result of this reorientation of cigars toward the youth market has been predictable and troubling: "youth cigar use has not declined when compared to use of other tobacco products" since the passage of the TCA. 81 Fed. Reg. at 29,023 (noting 2000–2011 National Youth Tobacco Survey ("NYTS") data showing no change in the prevalence of cigar smoking among high school students and concluding that "[t]his lack of decline in cigar smoking is a concern considering cigarette smoking among high school students did significantly decline over these

[7] Doris G. Gammon et al., *National and state patterns of concept-flavoured cigar sales, USA, 2012–2016*, 28 Tobacco Control 394–400 (2019) (published online August 1, 2018).

[8] *Id.* In addition, there has been a sharp growth, particularly among cigarillos, in "concept" products that do not explicitly identify a flavor. These products have names like "Pink Diva" and "Wild Rush." *See* Gammon et al., *supra* note 7.

[9] Cristine D. Delnevo et al., *Changes in the Mass Merchandise Cigar Market Since the Tobacco Control Act*, 3 Tobacco Reg. Sci. S8–S16 (2017).

periods"). Cigar usage among all high school students now exceeds cigarette usage.[10] Black high schoolers smoke cigars at more than three times the rate of cigarettes; and an estimated 190,000 high school students who smoked cigars in 2019 did so frequently (20 of preceding 30 days).[11] According to the 2019 National Survey on Drug Use and Health, more than 1,400 persons under the age of 18 smoke their first cigar each day.[12]

Use of flavored cigars by youth is high. In 2019, 43.2% of current high school cigar smokers used flavored cigars.[13] In a 2019 draft guidance, FDA reported its analysis of the federal government's Population Assessment of Tobacco and Health ("PATH") study, finding that 56.8% of 12 to 17 year-olds who had ever smoked

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[10] CDC, *Tobacco Product Use Among Middle and High School Students—United States, 2020*, 69 Morbidity & Mortality Weekly Report ("MMWR") 1881–88 (Dec. 17, 2020), https://www.cdc.gov/mmwrvolumes/69/wr/pdfs/mm6950a1-H.pdf.

[11] *See id.*; CDC, *Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019*, 68 MMWR, Surveillance Summaries (Dec. 6, 2019), https://www.cdc.gov/mmwr/volumes/68/ss/pdfs/ss6812a1-H.pdf.

[12] Substance Abuse and Mental Health Services Administration (SAMHSA), *Table 4.9A – Past Year Initiation of Substance Use among Persons Aged 12 or Older Who Initiated Use Prior to Age 18, Prior to Age 21, and at Age 21 or Older: Numbers in Thousands, 2018 and 2019* (2020), https://www.samhsa.gov/data/sites/default/files/reports/rpt29394/NSDUHDetailedTabs2019/NSDUHDetTabsSect4pe2019.htm. Cigars are defined as cigars, cigarillos, or little cigars.

[13] CDC, 69 MMWR, *supra* note 10.

cigarillos started with a flavored product.[14] Data from the 2013-2014 wave of the PATH study show that 73.8% of youth cigar smokers reported that they smoked cigars "because they come in flavors I like."[15]

Moreover, FDA noted that "[m]easures of youth use of cigars may *underestimate* prevalence due to incorrect self-identification as a non-cigar smoker and confusion between the various cigar products." 81 Fed. Reg. at 29,023 (emphasis added).

Finally, use of cigars by young people can also lead to cigarette smoking. One study shows that among high school students who tried cigars before trying cigarettes, almost 44% used both cigars *and* cigarettes. AR 145567. A recent study using PATH data showed that between 2013 and 2018, cigar use among 12- to 17-year-olds was significantly associated with increased odds of cigarette initiation one year later. In addition, "9.1% of cigarette initiation among non-Hispanic black youth was attributable to cigar products."[16]

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[14] FDA, Draft Guidance, *Modifications to Compliance Policy for Certain Deemed Products: Guidance for Industry*, at 16 (Mar. 13, 2019), https://beta.regulations.gov/document/FDA-2019-D-0661-0003.

[15] Bridget K. Ambrose et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014*, 314 J. of the Am. Med. Ass'n 1871–1873 (2015), https://jamanetwork.com/journals/jama/fullarticle/2464690.

[16] Andrew C. Stokes et al., *Racial/Ethnic Differences in Associations of Noncigarette Tobacco Product Use with Subsequent Initiation of Cigarettes in US Youths*, Nicotine & Tobacco Res., https://doi.org/10.1093/ntr/ntaa170.

In sum, the evidence cited by FDA in the Deeming Rule, confirmed by data and reports issued since then, is compelling: since enactment of the TCA, cigar makers have filed the void created by the TCA prohibition of flavors in cigarettes with new, inexpensive products with flavors known to appeal to youth. Today these mass-produced, flavored products dominate the market, and are the products of choice for the more than 900,000 youth cigar smokers in the US.[17]

II. CIGAR SMOKING PRESENTS A SIGNIFICANT PUBLIC HEALTH CONCERN

Appellants essentially ignore the important public health justification for FDA's decision to hold new cigars to the TCA's pre-market review requirements and the substantial equivalence pathway: cigar smoking presents substantial health risks to all users, risks that of particularly grave concern given the prevalence of cigar use among children and the tobacco industry's efforts to market cigars to youth.

A. Cigar Smoking Has Serious Adverse Health Impacts.

As the Supreme Court has explained, "tobacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). The evidence amassed and considered by FDA for the Deeming Rule establishes unequivocally that cigar smoking presents a significant public

[17] *See* CDC, 69 MMWR, *supra* note 10, at 1884.

health risk, both to minors and adults. As FDA found, "All cigars pose serious negative health risks." 81 Fed. Reg. at 29,020. In 2010 alone, regular cigar smoking was responsible for "approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older." *Id.*

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

Use of cigars by young people raises particular public health concerns. As FDA explained, while it "remains concerned about the use of all tobacco products, particularly combusted tobacco products like cigars and cigarettes, . . . [it] remains most concerned about use by youth and young adults given their *unique* susceptibility to the addictiveness of nicotine." *Id.* at 29,023 (emphasis in original); *see also id.* at 29,029 ("The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system".); *id.* at 29,033 ("[N]icotine exposure during adolescence may have lasting adverse consequences for brain development.").

These adverse health effects are exacerbated because cigars' effective delivery of nicotine makes them powerfully addictive. *Id.* at 29,022. "[A] cigar can

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

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

In short, as FDA stated in its 2019 draft guidance, "Cigars are associated with significant risk and provide no public health benefit."[18]

[18] FDA, Draft Guidance, *supra* note 14, at 16.

B. Contrary to Popular Perceptions, Cigars Are Not a Safe Alternative to Cigarettes.

In the wake of Congress's crackdown on flavored cigarettes, the development and marketing of mass-produced cigars that are flavored and packaged to appeal to young persons is no surprise. As Congress, FDA, and federal courts have all found, the tobacco industry has for decades targeted young potential smokers in its marketing and misled consumers about the health risks of tobacco use. In 2006, the U.S. District Court for the District of Columbia found that the "central purpose of the tobacco companies' image advertising is motivating adolescents to smoke." *United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 572 (D.D.C. 2006), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009). In the TCA, Congress found that "[a]dvertising, marketing, and promotion of tobacco products have been especially directed to attract young persons to use tobacco products, and these efforts have resulted in increased use of such products by youth." TCA § 2(15).

Cigars, like cigarettes and other tobacco products, have been the subject and beneficiary of decades of misinformation, both by affirmative deception and misleading omission. As FDA noted in the proposed Deeming Rule, the FTC has found numerous cigar manufacturers to have engaged in deceptive and unfair marketing practices. *See* 79 Fed. Reg. at 23,164 (citing seven "consent orders resolving allegations that failure to disclose the adverse health consequences of cigar use was deceptive and unfair"). The FTC described some of those practices:

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

In re Swisher Int'l, Inc., No. C-3964, 2000 WL 1207447, at *1 (F.T.C. Aug. 25, 2000) (complaint).[19]

As a result of this long history of consumer deception, "many people inaccurately think cigars . . . are safe alternatives to cigarettes." 79 Fed. Reg. at 23,158. As FDA explained in the proposed Deeming Rule:

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

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

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

Id. (citations omitted). *See also id.* at 23,146 ("young adults often mistakenly think non-cigarette tobacco products are safe alternatives to cigarettes").

III. LIKE CIGARETTES, CIGARS WITH NEW CHARACTERISTICS THAT WERE FIRST MARKETED AFTER FEBRUARY 15, 2007 SHOULD BE SUBJECT TO PREMARKET REVIEW.

The TCA's text and structure demonstrate Congress's intent to provide FDA with regulatory flexibility to account for the scope and changing nature of the tobacco industry and its products. Thus, in Section 3, Congress stated that the TCA's purposes included authorizing FDA "to regulate tobacco products under the [FDCA] by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products. . ." and "ensur[ing] that [FDA] has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people." TCA §§ 3(1) & (2). Consistent with its intent, Congress gave FDA authority to deem tobacco products subject to the Act. 21 U.S.C. § 387a(b).

Appellants have long been on notice of FDA's intent to subject cigars to the TCA's requirements, including the premarket review/substantial equivalence provisions. As early as Spring 2010, FDA announced its intent to use its deeming authority to bring cigars under the jurisdiction of the FDCA.[20]

And when FDA eventually proposed the Deeming Rule and again when it issued the final Deeming Rule, the Agency provided extensive documentation supporting its jurisdiction over cigars. 79 Fed. Reg. 23,150–59; 81 Fed. Reg. at 29,020–27.

The "substantial equivalence" pathway ensures that FDA has the information needed, and the opportunity, to evaluate proposed changes in tobacco products that increase the appeal, addictiveness, or toxicity of tobacco products, or that otherwise raise "different questions of public health." As FDA stated when it promulgated the Deeming Rule, "premarket review . . . will allow FDA to monitor product development and . . . to prevent more harmful or addictive products from reaching the market." 81 Fed. Reg. at 29,020; *cf. Nicopure Labs, LLC. v. FDA*, 944 F.3d 267,

[20] 2010 Office of Management and Budget, Unified Regulatory Calendar, https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201004&RIN=0910-AG38, showing FDA's intention to issue a proposed rule deeming cigars subject to the TCA. FDA reiterated this intention in 2011. Correspondence from Lawrence Deyton, Dir., FDA Ctr. for Tobacco Prods. & Janet Woodcock, Dir., FDA Ctr. for Drug Eval. & Res., Regulation of E-Cigarettes and Other Tobacco Products (Apr. 25, 2011), https://tinyurl.com/yx6xdsak.

271 (D.C. Cir. 2019) ("Congress . . . took the then-current tobacco product market as a baseline from which to ratchet down tobacco products' harms to public health.").

Many of the cheap, flavored cigars that are driving cigar smoking among youth were introduced after the February 15, 2007 grandfather date in the TCA. As demonstrated above, these products are unlikely to have the "same characteristics" as grandfathered cigars and are likely to raise new questions of public health. Accordingly, cigar makers' compliance with the TCA's premarket review provision is imperative for the protection of the public health. *See Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 493 (D. Md. 2019) (discussing how the long delay of the implementation of the substantial equivalence requirements gave tobacco companies a "holiday from meeting the obligations of the law").

Given that cigar makers have been on notice since 2010 at the latest that the TCA's substantial equivalence provisions would be applied to their products, and given that they took advantage of their decade-long regulatory "holiday" to introduce scores of youth-friendly flavored products that have come to dominate the cigar market with significantly adverse consequences for public health, the Court should reject Appellants' claim that their ability to comply with the TCA is prejudiced by the passage of time. It should similarly reject Appellants' efforts to further defer, if not avoid entirely, the regulatory scrutiny that Congress mandated.

CONCLUSION

For the foregoing reasons, and the reasons stated in Appellees' responsive brief, the Court should uphold the district court's decision.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 27(d)(2), because it contains 4,837 words, according to the count of Microsoft Word. I further certify that this brief complies with typeface requirements of Rule 27(d)(1)(E) because it has been prepared in 14-point Times New Roman Font.

/s/ Andrew N. Goldfarb
Andrew N. Goldfarb

APPENDIX A

Description of *Amici Curiae*

1. The American Academy of Pediatrics

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

2. The American Cancer Society Cancer Action Network

The American Cancer Society Cancer Action Network (ACS CAN) is the nation's leading cancer advocacy organization dedicated to making cancer issues a priority. Created in 2001 as the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, ACS CAN educates the public, government officials, and candidates about cancer's devastating impact on public health and encourages them to make fighting cancer a top priority. ACS CAN has volunteers nationwide, many of whom advocate for effective tobacco control at the federal, state, and local levels. In 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. The American Heart Association

The American Heart Association ("AHA") is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. Founded in 1924, AHA now includes more than 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 American 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 and other tobacco products under the Federal Food, Drug, and Cosmetic Act.

4. The American Lung Association

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

5. The 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 19th day of February, 2021, I electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF system, which will send a notice of filing to all counsel of record.

/s/ Andrew N. Goldfarb
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