IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA,

et al.,

Plaintiffs,

v. Civil Action 16-1460 (APM)

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants

EN FUEGO TOBACCO SHOP, LLC, d/b/a En Fuego Tobacco Shop, *et al.*,

Plaintiffs,

v. Civil Action 18-1797 (APM)

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants

BRIEF OF AMICI CURIAE PUBLIC HEALTH ORGANIZATIONS IN OPPOSITION TO THE MOTION OF EN FUEGO PLAINTIFFS FOR SUMMARY JUDGMENT AND A PERMANENT INJUNCTION AND IN SUPPORT OF THE CROSS-MOTION OF DEFENDANTS FOR SUMMARY JUDGMENT

CORPORATE AND FINANCIAL DISCLOSURE STATEMENT

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

STATEMENT OF COUNSEL PURSUANT TO FEDERAL RULE OF APPELLATE PROCEDURE 29(a)(4)(E) AND LOCAL CIVIL RULE 7(o)(5)

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

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STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*

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

Amici have a strong interest in ensuring that all cigars sold in the United States, including premium cigars, are accompanied by prominent, informative warning labels. *Amici* seek to ensure that consumers are provided with accurate information about the hazards of all cigars in order to protect them from the seriously adverse short- and long-term public health effects of all cigars, including premium cigars. All cigars, including premium cigars, increase the risk of death and disease both for smokers and for non-smokers exposed to tobacco smoke and all cigars, including premium cigars, are addictive. Prominent warning labels like those prescribed by the Food and Drug Administration ("FDA") have been shown to be far more effective than the small, easily ignored warning labels that currently accompany most cigar packaging and advertisements. Requiring warning labels on non-premium cigars but exempting premium cigars from this requirement would create the misimpression among consumers that use of premium cigars is safe and that the warnings required for other cigars are not valid as applied to premium cigars. Accordingly, *Amici* oppose Plaintiffs' efforts to invalidate the warnings required by the FDA, as applied to premium cigars. *Amici's* application for leave to file has been submitted concurrently with this brief.

For the reasons stated in this brief, Amici Curiae Public Health Organizations respectfully urge this Court to deny En Fuego Plaintiffs' Motion for Summary Judgment and a Permanent Injunction and to grant the Defendants' Cross-Motion for Summary Judgment.

INTRODUCTION

Plaintiffs seek a permanent injunction invalidating FDA's rule requiring specified warnings on cigar packaging and advertising, as applied to "premium cigars." *Amici* file this brief in opposition to Plaintiffs' Motion for Summary Judgment and in support of Defendants' Cross-Motion for Summary Judgment in order to demonstrate to the Court that exempting "premium cigars" from this requirement would have serious adverse consequences for the public health, that FDA's decision to require warning labels on all cigars, including premium cigars, was based on scientific evidence in the administrative record, and that none of the evidence in the administrative record, or cited in the Plaintiffs' Motion for Summary Judgment but not included in the administrative record, supports the conclusion that the Rule's requirement for warning labels on "premium cigars" would be invalid regardless of what legal standard is applied.[1]

In its Memorandum Opinion and Order in this case prior to the consolidation of the *En Fuego* case, this Court specifically found that FDA's findings with regard to the required warnings were sufficient to demonstrate that the agency had (1) made the required statutory findings and (2) properly exercised its discretion to find that the warnings required by the rule

[1] Plaintiffs argue that this Court should apply either strict scrutiny or the standard set forth in *Central Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980) in evaluating the constitutionality of the warnings. In its prior ruling reviewing warning labels in this case, this Court applied the standard set forth in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626 (1985), and *Amici* believe that it is the standard set forth in *Zauderer* that should be applied.

were appropriate for the protection of the public health, and (3) required warnings for cigars that were not inconsistent with the First Amendment. The Court concluded that "the warning statements are factual and uncontroversial disclosures aimed at informing the public about the risks of cigar and pipe tobacco use and at correcting the public's misperceptions about such products' use" and that "the rule does not impose these requirements in an unjustified or unduly burdensome manner."[2] The Cigar Association Plaintiffs appealed from this decision and their appeal is pending.[3]

In March, 2018, FDA initiated an advance notice of proposed rulemaking seeking further information developed after the close of the administrative record concerning the appropriateness of its assertion of jurisdiction over premium cigars.[4] However, although FDA announced that it was extending the deadline for imposition of some regulatory requirements applicable to cigars, it did not stay the requirement for warning labels. Subsequent to FDA's announcement, this Court enjoined FDA from implementing the requirement for warning labels pending resolution of Plaintiff Cigar Association's appeal.[5] After the Court issued this injunction, the complaint of Plaintiff En Fuego, originally filed in the United States District Court for the Eastern District of Texas, was consolidated with this action.

En Fuego's Motion for Summary Judgment and for a Permanent Injunction against the application of the warning requirement as to "premium cigars" does not merely seek an injunction pending resolution of the appeal or FDA's Advance Notice of Proposed Rulemaking

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[2] Cigar Ass'n of America v. FDA, 315 F. Supp. 3d 143 at 174 (D.D.C. 2018).

[3] Cigar Ass'n of America v. FDA, Docket No. 18-5195 (D.C. Cir). In their Initial Brief on appeal, Appellants argue that this Court's Order upholding requirement for warning labels has already determined that warning labels as applied to all cigars, including premium cigars, are valid. Initial Brief of Appellants, March 15, 2019, p. 32, n. 9.

[4] FDA, Advance Notice of Proposed Rulemaking on Regulation of Premium Cigars, 83 Fed. Reg. 12901 (Mar. 26, 2018)

[5] Cigar Ass'n of America v. FDA, 323 F.R.D. 354 (D.D.C. 2017).

(ANPRM), but rather seeks a permanent injunction against the application of the warning label requirements to premium cigars on the ground that, as applied to those cigars, the warning label requirement is arbitrary and capricious and therefore invalid under the Administrative Procedure Act, or, alternatively, that, as applied to premium cigars, it is in violation of the First Amendment.[6]

Despite the fact that this Court has already upheld the validity of the warnings required by FDA as to all cigars and rejected a challenge to those warnings brought by a trade association to which Plaintiffs belong,[7] Plaintiffs argue that the warnings should be permanently enjoined as applied to premium cigars. In so doing, Plaintiffs rely principally on (1) the fact that, subsequent to the promulgation of the rule in which FDA considered and rejected an exemption for premium cigars on the basis of an extensive administrative record, the agency initiated an Advance Notice of Proposed Rulemaking seeking additional information regarding the regulation of premium cigars; and (2) selected data points from a few studies published subsequent to the close of the administrative record that allegedly call into question whether premium cigars are used so infrequently that warning labels should not be required. In essence, Plaintiffs ask this Court to (1) reject the conclusion FDA reached on the basis of its careful examination of the administrative record already affirmed by this Court; (2) reject FDA's own characterization of its ANPRM and its reaffirmation of the conclusion it reached on the basis of the administrative record; and (3) assume, on the basis of Plaintiffs' characterization of a few data points in studies outside the administrative record, that a hypothetical administrative record completed following the ANPRM could not validly support the decision FDA had previously made.

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[6] Amici endorse the FDA's contention in its Cross-Motion for Summary Judgment that En Fuego's action is barred by res judicata or the rule against claim-splitting. FDA Br. at 11-15.

[7] *Id.*

Amici will not address the many legal infirmities in Plaintiffs' Motion but rather will address (1) the extensive evidence of the public health consequences FDA relied on in reaching its decision to require warning labels for all cigars; (2) the reasons why neither FDA's institution of the ANPRM nor the studies Plaintiffs cite that were not part of the administrative record support the issuance of a permanent injunction exempting premium cigars from the warning requirements; and (3) the reasons why exempting premium cigars from the warning requirement would be contrary to the protection of the public health.

SUMMARY OF ARGUMENT

In its discussion accompanying the proposed and final deeming rule, FDA has demonstrated by overwhelming scientific evidence that all cigars are toxic, carcinogenic, and addictive, whether or not cigar smokers inhale. FDA has adduced overwhelming scientific evidence to establish that every one of the warnings it has required for all cigars is factual. It has demonstrated that cigars can cause numerous types of cancer, including oral, throat, and lung cancer as well heart disease; that cigars contain nicotine and are addictive, whether or not a smoker inhales; that cigars are harmful to pregnant women and their babies; and that cigars are not a safe alternative to cigarettes.

Plaintiffs do not and cannot challenge the fact that premium cigars contain the same toxins and carcinogens as cigarettes and non-premium cigars or that premium cigars contain nicotine and are therefore as addictive as cigarettes and non-premium cigars. It is undisputed that premium cigars are intrinsically as toxic, carcinogenic, and addictive as non-premium cigars. Rather, Plaintiffs' argument rests solely on their contention that premium cigars are used so infrequently that the warnings applicable to other cigars cannot validly be required for premium cigars. However, FDA has expressly found that "all cigars pose serious negative health risks"

and rejected arguments that patterns of premium cigar use eliminated these health risks. Moreover, FDA found on the basis of extensive evidence that many cigar smokers underestimate the dangers posed by cigar smoking and do not understand that cigars are addictive, even to smokers who do not inhale. Based on these findings, it both asserted jurisdiction over premium cigars and required them to bear the same warnings as non-premium cigars.

Despite these express findings, Plaintiffs challenge the validity of the warnings as applied to premium cigars. In doing so they rely not on evidence in the administrative record, but rather on a few data points cherry-picked from studies completed subsequent to the close of the administrative record. Even assuming the Court could properly consider these studies, however, they do not support the Plaintiffs' arguments but rather show that premium cigars are in fact used on a daily basis by a substantial number of smokers as well as being used by youth. The studies do not call into question the validity of FDA's rule requiring warning labels for all cigars regardless of what legal standard is applied to test its validity.

ARGUMENT

I. FDA'S DECISION TO REQUIRE WARNINGS FOR ALL CIGARS AND THE SPECIFIC WARNINGS REQUIRED ARE THOROUGHLY SUPPORTED BY SCIENTIFIC EVIDENCE IN THE RECORD.

In 2014, when FDA initiated a proposed rulemaking regarding the regulation of cigars, the agency specifically requested comments on the appropriateness of its assertion of jurisdiction over premium cigars and on the need to require warnings for premium cigars.[8] In its discussion of the proposed rule and the alternatives, FDA extensively documented the evidence regarding the public health consequences of smoking all cigars, including premium cigars,[9] the widespread consumer misunderstanding among both youth and adult users of cigars, of the consequences of

[8] 79 Fed. Reg. 23,142 at 23,150-157 and 23,162-70, 23,178-84, April 25, 2014.

[9] *Id.*

smoking cigars,[10] including premium cigars, and the need for prominent warning labels to provide consumers with adequate information about the health consequences of cigar use.[11] After receiving and considering many thousands of comments, two years later FDA issued a final rule extending regulation to all cigars, including premium cigars, and, in addition, requiring warning labels on all cigars, including premium cigars.[12] In its discussion of the final rule, FDA extensively documented the reasons both for its decision to extend jurisdiction to premium cigars[13] and to require warning labels on all cigars.[14]

A. The Administrative Record Supports FDA's Findings that the Warnings as Applied to Premium Cigars are Factually Correct.

FDA documented with scientific evidence the reasons both for asserting jurisdiction over premium cigars and for not exempting premium cigars from the warning requirements. Both in the Proposed Rule and the Final Rule, FDA adduced extensive evidence demonstrating the specific factual validity of every one of the cigar warnings.[15]

FDA concluded on the basis of substantial scientific evidence that cigars contain a large number of virulent toxins and carcinogens, that those toxins and carcinogens are similar to those in cigarette tobacco, and that cigar smoking exposes smokers to such toxins and carcinogens, whether or not they inhale.[16] FDA also concluded that the data clearly establish cigar smoking as a cause of oral cancer, that cigar smoking can cause cancers of the mouth and throat even for smokers who do not inhale, and that a warning regarding these potential health consequences is necessary because of consumers' widely held, but erroneous, belief that cigars are safe if users

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10 *Id.* at 23,158-59.
11 *Id.* at 23,162-70.
12 81 Fed. Reg.28,974 at 28,976, 28,979, 28,988-89; 29,020-27; 29,060-73 (May 10, 2016)
13 *Id.* at 29,020-27.
14 *Id.* at 29,060-73.
15 *Id.* at 29,070-072; 79 Fed. Reg. at 23,167-70.
16 *Id.*

do not inhale the smoke.[17] FDA also concluded that cigar smoking is an established cause of lung, esophageal and laryngeal cancer,[18] as well as heart disease.[19] It further concluded that all cigar smoke produces carcinogens that increase the risk of cancer for non-smokers and that cigar smoke raises the risk of heart disease in non-smokers.[20] In support of these findings, FDA cited evidence from many sources, including the National Cancer Institute, the World Health Organization International Agency for Research on Cancer (IARC) and numerous scientific studies.[21] 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."[22]

Despite this evidence, Plaintiffs argue that the application of the warnings to premium cigars is arbitrary and capricious and in violation of the First Amendment because the evidence of the harmful effects of cigar smoke was not specifically tied to smoke from premium cigars. However, in its consideration of the Deeming Rule the FDA did examine the application of the warnings to premium cigars, both in the proposed rule and in the final rule. In choosing to apply the warning label requirements to premium cigars, FDA specifically found that "(1) all cigars pose serious 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

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17 81 Fed. Reg. at 29,071; 79 Fed. Reg. at 23,158.
18 81 Fed. Reg. at 29,070-71, 79 Fed. Reg. at 23,167-70.
19 81 Fed. Reg. at 29,070-71; 79 Fed. Reg. at 23,168-70.
20 81 Fed. Reg. at 29,070-71; 79 Fed. Reg. at 23,169-70.
21 81 Fed. Reg. at 29,020-27, 23,070-72; 79 Fed. Reg. at 23,167-70.
22 81 Fed. Reg. at 29,021.

exclusion, and (3) premium cigars are used by youth and young adults."[23] FDA concluded 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."[24] Moreover, FDA found that "the bulk of the established data on the health effects of cigar smoking is based on smokers of traditional, large cigars and, therefore, is applicable to the toxicity of premium cigars given that they share the same characteristics and are generally smoked in similar ways."[25] On the basis of the cited scientific evidence, FDA found that "no amount of smoking is safe" and that "there are no data indicating that premium cigar users are not susceptible to health risks."[26]

FDA noted that the studies in the administrative record cited in comments questioning the link between cigar smoking and disease did not support a conclusion that there is any class of cigars with no substantial health risk. The agency cited the statement in one such study that "cigars...are clearly associated with clinically significant health hazards," noted that another study found that "cigar smoking does result in morbidity, mortality, and dependence," and that a third study "found a significant association between primary cigar. . .smokers and lung cancer mortality risk."[27] Moreover, FDA found that all cigars are potentially addictive, that a single cigar can contain as much tobacco as a whole pack of cigarettes, that nicotine yields from smoking a cigar can be up to eight times higher than yields from smoking a cigarette and that even cigar smokers who do not inhale absorb nicotine that increases the risk of addiction.[28]

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23 81 Fed. Reg. at 29,020.
24 *Id.* at 29,020.
25 *Id.*
26 *Id.*
27 *Id.* at 29,021.
28 *Id.* at 29,022.

FDA also specifically addressed comments arguing that patterns of use preclude premium cigar smokers from experiencing negative health effects, noting that "all cigars produce toxic cigar smoke," "that cigar smoking can cause several different types of cancer even without inhalation," and that "one study found an increased risk in head and neck cancers in people who had previously smoked only cigars."[29] Furthermore, FDA analyzed the data on youth usage of cigars and found that, "although youth and young adults have a higher use of cigarillos and other mass market cigars, studies indicate that they are also using premium cigars."[30]

Following FDA's detailed discussion of the reasons for extending its jurisdiction to all cigars, including premium cigars, FDA also specifically addressed the need for warnings on all cigar packaging and advertising. For example, in response to a comment suggesting that the warning, "Cigar Smoking Can Cause Cancers of the Mouth and Throat, Even if You Do Not Inhale" should not apply to premium cigars, FDA responded that the National Cancer Institute Monograph, on which FDA had relied, applied to all types of cigars and supported the conclusion that "[a]ny cigar use exposes the mouth and throat to tobacco smoke and can cause several different types of cancer even without inhalation."[31]

In addition, with reference to the warning "Tobacco Smoke Increases the Risk of Lung Cancer and Heart Disease, Even in Nonsmokers," FDA found that "[t]here is a causal relationship between lung cancer and secondhand smoke" and that "[a]ll cigars produce higher levels [than cigarettes] of carcinogenic tobacco-specific nitrosamines" (among the most virulent carcinogens in tobacco smoke). FDA also found that there is a causal relationship between

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[29] *Id.* at 29,024.

[30] *Id.* at 29,022-23. Nevertheless, FDA also made it clear that its obligation to protect the public health was not limited to protection of youth, but rather that the Tobacco Control Act charges it with "protecting the public health generally, not only the health of minors." *Id.* at 29,024.

[31] *Id.* at 29,071.

secondhand smoke and heart disease, citing numerous sources.[32] With regard to the danger of secondhand smoke, there is clearly no basis for distinguishing between secondhand smoke from premium cigars and that from other cigars.[33]

Similarly, with regard to the reproductive health warning, FDA relied on NCI's Monograph on cigars, which concluded that "nicotine adversely affects maternal and fetal health."[34] As noted above, FDA concluded that the NCI Monograph applied to all types of cigars. FDA also specifically addressed the application of the addictiveness warning to premium cigars in response to comments suggesting that an addiction warning was unnecessary for premium cigars because users do not inhale the cigar smoke.[35] FDA responded that "regardless of whether cigar smokers inhale, they are still subject to the addictive effects through nicotine absorption. [C]onsumers using premium or other cigars can become addicted to cigars given the absorption of nicotine."[36]

Moreover, given the health effects of all cigars and the fact that many cigar smokers underestimate the health risks of cigars, FDA stated in the discussion of warnings in the proposed deeming rule, "Given the dangers associated with continued use of tobacco products, FDA believes it is critical to include a warning on *all* such products to help consumers better understand and appreciate the addictive nature of these products."[37] (emphasis added)

Plaintiffs cite two cases that allegedly stand for the proposition that warnings cannot be required where the evidence of cancer risk is uncertain. However, neither of these cases supports

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32 *Id.* at 29,070-71.
33 *Id.* at 29,070-71.
34 *Id.* at 29,071-72.
35 *Id.* at 29,069.
36 *Id.*
37 79 Fed. Reg. at 23,163.

their contentions. One case involved a warning concerning a chemical "where only one health organization had found that the substance in question causes cancer and virtually all government agencies and health organizations that have reviewed studies on the chemical had found that there was no evidence that it caused cancer."[38] The other involved a warning concerning cell phone use that the court characterized as "based on nothing more than the possibility that an agent may (or may not) turn out to be harmful."[39] The court in that case actually contrasted the speculative "risk" in that case to the actual risk presented by smoking. It stated, "[S]moking presents a risk in the sense that smoking is a known carcinogen but may or may not produce cancer in any given smoker, so there is a statistical risk that smoking will lead to cancer for any given individual."[40] In no sense do these cases support Plaintiffs' challenge to the warnings at issue here.

B. FDA Concluded on the Basis of Scientific Evidence that Consumers Substantially Underestimate the Dangers Posed by Cigar Smoking.

FDA also considered evidence regarding consumer understanding of the health risks of cigar smoking and found that many consumers substantially underestimate the dangers posed by cigar smoking.[41] Given the severity of the health consequences of cigar smoking and the lack of accurate consumer understanding of those consequences, FDA concluded that there was a governmental interest in "helping consumers better understand and appreciate the addictiveness of tobacco product use. . .and to help current and potential tobacco users understand and

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[38] Nat'l. Ass'n of Wheat Growers v. Zeise, 309 F. Supp. Ed 842 at 851 (E.D. Cal. 2018).

[39] CTIA—The Wireless Ass'n v. City and Cty. Of San Francisco, 827 F. Supp. 2d 1054 at 1061 (N.D. Cal. 2011).

[40] *Id.*

[41] 81 Fed. Reg. at 29,070; 79 Fed. Reg. 23,158.

appreciate the serious adverse consequences associated with tobacco product use."[42] In the Proposed Rule, FDA stated:

> [R]esearch reflects that many people inaccurately think cigars. . .are safe alternatives to cigarettes. Indeed, research 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."[43]

As this Court concluded in upholding the validity of the warning requirements in the Cigar Association of America case, "the agency relied on evidence establishing widespread misperceptions regarding the true health hazards of cigars and demonstrating that cigar smokers mistakenly believe that cigars are less addictive, more natural, and less harmful than cigarettes. That is true among both youth and adults."[44]

C. In Initiating its ANPRM, FDA Did Not Modify Its Conclusions Regarding the Need for the Warnings It Had Required in the Deeming Rule

In March, 2018, when FDA initiated an Advance Notice of Proposed Rulemaking regarding the regulation of premium cigars, it described the purpose of the ANPRM as "request[ing] new and different information, data, and analysis not submitted in response to FDA's proposed deeming rule that could inform FDA's regulation premium cigars."[45] In describing the conclusions it had reached in adopting the Deeming Rule and requiring warnings on all cigars, FDA reiterated that,

> After carefully considering the public comments on the rule, the Agency. . . conclude[ed] that there was no appropriate public health justification to exclude premium cigars from regulation. Specifically, FDA concluded that (1) all cigars pose serious 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. ...[A]lthough some premium cigar smokers might

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42 79 Fed. Reg. at 23,163.
43 79 Fed. Reg. at 23,158.
44 315 F. Supp. 3d 143 at 168.
45 83 Fed. Reg. 12,901 at 12,902.

> smoke these products infrequently or report that they do not inhale, these behaviors do not negate the adverse health effects of tobacco smoke or demonstrate that cigars do not cause secondhand smoke-related disease in others."[46]

FDA observed that although it had received numerous comments on the deeming proposal, "comments against regulation provided little data to support the opinions expressed, and where studies had been submitted, provided little information about the studies cited."[47] The ANPRM did nothing more than provide a vehicle for commenters to submit information developed subsequent to the closing of the record in order for the agency to take such evidence into consideration in the future. It did not modify FDA's conclusions or the regulations established in the Deeming Rule, but rather reiterated the absence of evidence in the administrative record for not regulating premium cigars.

II. PLAINTIFFS SEEK A PERMANENT INJUNCTION AGAINST THE WARNING LABELS ON PREMIUM CIGARS SOLELY ON THE BASIS OF INFORMATION OUTSIDE THE ADMINISTRATIVE RECORD.

Both FDA's decision requiring warning labels on all cigars, including premium cigars, and the ANPRM make it clear that the evidence submitted in the administrative record of the Deeming Rule was sufficient to support the requirement that warning labels cover all cigars, including premium cigars. Nor do Plaintiffs rely on such evidence now. Rather, Plaintiffs seek to overturn FDA's carefully documented conclusion on the basis of a few inaccurately characterized data points from selected studies that were not part of the administrative record.[48]

A. Plaintiffs' Motion Is Based Solely on the Contention that Premium Cigars are Used So Infrequently that the Warnings, as Applied to Premium Cigars, Cannot Legally be Justified.

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46 83 Fed. Reg. at 12,902, citing 81 Fed. Reg. at 29,020.

47 *Id.*

48 *Amici* endorse the argument made by FDA in its Cross-Motion that Plaintiffs cannot rely on evidence outside the administrative record to dispute the validity of the Rule. FDA Br. at 26, n.5.

Plaintiffs' Motion does not challenge FDA's decision to assert jurisdiction over all cigars, including premium cigars, nor does it challenge the validity of the warning labels FDA has required for non-premium cigars. Plaintiffs' sole challenge is to the validity of the warning labels as applied to premium cigars. Nor do Plaintiffs contest the fact that

- all premium cigars contain and deliver to their users the same toxins and carcinogens as do other cigars and cigarettes and can cause cancer and other fatal diseases;
- all premium cigars contain and deliver to their users nicotine, a highly addictive substance;
- secondhand tobacco smoke causes death and disease to non-users of tobacco products and the smoke from premium cigars is no less likely to contribute to such death and disease than is the smoke from any other tobacco product.
- the text of the warnings is substantially the same as the text of warnings that the seven largest cigar manufacturers have, by agreement, affixed to all their cigars, including premium cigars, for 18 years;

Plaintiffs therefore do not and could not plausibly maintain that premium cigars are, intrinsically, any less hazardous than other cigars. Rather, their entire argument is premised on the contention that warnings appropriate for other cigars cannot constitutionally be required for premium cigars because consumers do not use them frequently enough to cause the adverse health consequences cited in the warnings and those who do use them are already aware that "excessive" use of premium cigars can cause those consequences. The data Plaintiffs cite, however, support none of those propositions.

B. Data Produced Subsequent to the Close of the Administrative Record Does Not Support the Exemption of Premium Cigars from the Required Warnings.

Plaintiffs cite no scientific studies in the administrative record to support their contention that the use of premium cigars is too infrequent to justify the warnings FDA has required. Rather, Plaintiffs rely on a few data points cherry-picked from a handful of studies published

subsequent to the close of the administrative record for the rule imposing the requirement for warning labels and explicitly rejecting an exemption for premium cigars. They rely principally on data points derived from the PATH Study regarding the frequency of use for premium cigar smokers[49] and data points from a recently published analysis of data derived from the National Longitudinal Mortality Study.[50] In essence, Plaintiffs' argument is that, although daily premium cigar smoking increases the risk of death and disease, it has not been shown that premium cigar smoking on a less than daily basis does so; thus, warnings should not be required on packaging or advertising for premium cigars because most premium cigar smokers do not smoke them on a daily basis.

The data Plaintiffs cite regarding frequency of use show that many smokers of premium cigars use them less frequently than users of other types of cigars, including other large, traditional cigars. In one study of premium cigar smokers who had used the product within the past 30 days, the median number of days on which they used premium cigars was 1.7 days per month, compared to a median number of 9.2 days for traditional non-premium cigars.[51] However, the same study showed that 6.7% of premium cigar smokers used premium cigars every single day in the past 30 days.[52] According to the Corey study cited by Plaintiffs, 0.7% of the adult population were smokers of premium cigars, the equivalent of about 1.8 million

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[49] 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, 2013-14, Nicotine and Tobacco Res., Sept. 15, 2017; Faten Sabry, Report Regarding Consumption Patterns of Premium Cigars, July 18, 2018, attached as a Declaration to Plaintiffs' Initial Brief. The Sabry study is not a published, peer-reviewed study but rather is in the nature of an expert report submitted on behalf of Plaintiffs.

[50] Carol Christensen, et al., Association of Cigarette, Cigar, and Pipe Use with Mortality Risk in the U.S. Population, JAMA Internal Medicine, Feb. 19, 2018.

[51] Corey, *supra,* note 49, at 1461.

[52] *Id.* at 1461. The Sabry report submitted as a declaration in support of Plaintiffs' Initial Brief shows that 7.5% of exclusive premium cigar smokers were daily smokers. Sabry, *supra,* note 49.

people.[53] If 6.7% of these people were daily users, then more than 118,000 people are daily users of premium cigars and the very studies cited by Plaintiffs confirm that they are at an elevated risk of mortality.[54] Even if these 118,000 people were the only ones at risk of cigar-related disease, a number of this magnitude easily justifies the requirement for warnings.

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 for premium cigar smokers was only 1.7 days per month means that half of all premium cigar smokers—900,000 people-- used the product on more than 1.7 days. Apart from showing that a disproportionately large percentage of this group smoked premium cigars every single day,[55] the data do not reveal the number of days on which any of these users were smoking premium cigars. The likelihood is that, in addition to the many premium cigars smokers who smoke premium cigars every day, tens if not hundreds of thousands of premium cigar smokers who are not daily smokers still use premium cigars on a frequent basis.

Moreover, the data cited by the Plaintiffs do not demonstrate that infrequent smokers of premium cigar smokers are free from substantial risk of tobacco-related disease. The same study relied upon by the Plaintiffs shows that 29.9% of the smokers of premium cigars were also current cigarette smokers, 16.8% also smoked cigars in addition to premium cigars, and 33.7% used another non-cigar, non-cigarette product in addition to premium cigars.[56] Thus, for this

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[53] Corey, *supra*, note 49 at 1460; According to the U.S. Census Bureau, the adult population of the United States is approximately 253 million.

[54] FDA's Cross-Motion for Summary Judgment, using figures from the non-peer-reviewed Sabry declaration, concludes that there are at least 132,000 daily smokers of premium cigars. Br. at 24, n.14. Regardless of which figure is used, it is clear that the number of such smokers is substantial.

[55] If the distribution of such users was spread proportionally over 30 days, the number of daily users would only have been about 3.3%.

[56] Corey, *supra*, note 49 at 1461.

large portion of premium cigar smokers, the risk posed by the use premium cigars is cumulative of the risk posed by the use of other tobacco products.

In sum, the data relied on by the Plaintiffs do not support their argument that the health risks posed by the use of premium cigars are insubstantial.

Plaintiffs also rely on a 2018 analysis of data from the National Longitudinal Mortality Study to determine the association of cigarette, cigar and pipe use with mortality risks. Plaintiffs fail to mention that the study concluded that "exclusive use of cigars, pipes, and cigarettes each confers significant mortality risks," and that "[t]he data underscore the importance of cessation to reduce morbidity and mortality from combustible tobacco use."[57]

The study followed only "exclusive" users of cigars, cigarettes or pipes. Thus, it excluded the substantial number of cigar smokers who also smoke cigarettes. Nevertheless, the study found that "current exclusive cigar smokers have increased all-cause mortality risk."[58] More specifically, the study found that "among daily [exclusive] cigar users, mortality risks from tobacco-related cancer..., lung cancer..., and COPD...were elevated and statistically significant."[59] Thus, the study confirms that, at a minimum, the more than 100,000 daily users of premium cigars have an elevated risk of dying from these diseases. Moreover, data from the Christensen study shows that 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.[60]

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57 Christensen, *supra*, note 50, at 469, 475.
58 *Id.* at 473.
59 *Id.* at 472.
60 *Id.*

Finally, Plaintiffs dispute FDA's conclusion that youth also use premium cigars. However, as demonstrated in FDA's Memorandum in Support of its Cross-Motion for Summary Judgement, the study that the Plaintiffs cite indicates that large, traditional cigars are used by at more than 31,000 underage users.[61] Moreover, a demonstration that youth use premium cigars is not necessary to support the validity of the warning label requirement. As FDA stated,

> FDA is concerned with tobacco use by all age groups, including young adults and adults who may lawfully purchase these products. The Tobacco Control Act charges FDA with protecting the public health generally, not only the health of minors.[62]

Far from supporting an exemption from the warnings, these studies support the validity of the warnings required by the FDA for all cigars and do not provide evidence sufficient to invalidate the warnings as to premium cigars.

C. Other Studies Published Subsequent to the Close of the Administrative Record Demonstrate the Health Hazards of Large Cigars.

Recent studies published subsequent to the close of the administrative record continue to demonstrate that large and premium cigars pose substantial health risks. A 2017 study concluded that cigar smokers have a higher risk of disease and mortality than never smokers[63] and all cigars, including large cigars (some of which are premium cigars) deliver significant amounts of toxins and nicotine.[64] Thus, 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

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61 FDA Br. at 32.

62 81 Fed. Reg. at 29,024.

63 Malhotra, J. et al., "Association between Cigar or Pipe Smoking and Cancer risk in Men: A Pooled Analysis of Five Cohort Studies," *Cancer Prevention Research*, DOI:10.1158/1940-6207. CAPR-17-0084 (Published Online First September 28, 2017) (finding increased risk of smoking-related cancers with exclusive use of cigars or pipe when compared to never smokers, with both products contributing independently to cancer risk; lung cancer showed strongest association with smoking both these products); Christensen, *supra*, note 49 (finding exclusive cigar smokers "had higher all-cause mortality risks than never tobacco users" and "had an elevated risk of dying from a tobacco-related cancer (including bladder, esophagus, larynx, lung, oral cavity, and pancreas)."

64 Pickworth, WB, et al., "Dual Use of Cigarettes, Little Cigars, Cigarillos, and Large Cigars: Smoking Topography and Toxicant Exposure," *Tobacco Regulatory Science* 3(Supp. 1):S72-S83, April 2017.

cigarillo and large cigar users) expose themselves to toxicant levels of CO [carbon monoxide] and potentially other components of mainstream tobacco smoke," concluding that "it is clear that all cigar products delivered significant and addictive quantities of nicotine and CO – findings that support the rationale for their regulation."[65]

Another recent study of dual users of cigarettes and large cigars examined toxicant delivery and addictive potential. It found that by smoking large cigars, dual users "expose themselves to toxic components that have been linked with the addiction risk, morbidity, and mortality of cigarette smoking."[66] 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."[67] "These findings," the authors continued, "support the rationale for regulation of cigar products as has recently been enacted by the FDA."[68]

IV. PLAINTIFFS' DATA DO NOT SHOW THAT PREMIUM CIGAR SMOKERS UNDERSTAND THE RISK OF EXCESSIVE USE.

Plaintiffs also draw conclusions that are unsupported by any data. For example, they argue that "premium cigars are used infrequently, in a manner showing that consumers understand the risks of excessive use."[69] However, Plaintiffs cite no evidence to support the argument that the relative infrequency of premium cigar use must be the result of consumers' recognition of the risks of excessive use. Infrequency of use might well reflect the high relative price of premium cigars, or that premium cigars are larger and take longer to smoke, or that

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65 *Id* at 7, 8.

66 Rosenberry, ZR, Pickworth, WB, and Koszowski, B, "Large Cigars: Smoking Topography and Toxicant Exposure," *Nicotine & Tobacco Research* 20(2):183-191, 2018.

67 *Id* at 188.

68 *Id* at 188.

69 Plaintiffs' Br. at 28.

premium cigars provide larger doses of nicotine over a longer period of time. Moreover, the fact that hundreds of thousands of smokers of premium cigars also use cigarettes and other tobacco products—based on data from the same studies Plaintiffs rely on—indicates that many users of premium cigars do not understand the risks of tobacco use. Perhaps most important, since premium cigar use exposes users to all the same toxins and carcinogens as cigarettes, there is no level of usage that can be deemed "not excessive." Plaintiffs' argument does nothing to refute FDA's extensively supported conclusion that consumers mistakenly believe cigars are less harmful than other tobacco products.[70]

Furthermore, the same study that Plaintiffs rely on to show the infrequency of premium cigar use demonstrates that nearly one-third (31.4%) of premium cigar smokers smoke them because they believe premium cigars "might be less harmful than cigarettes."[71] The health hazards of premium cigars and the widespread public perception that premium cigars are "safer" support the need for warning labels on premium cigars.

V. EXEMPTING CIGARS FROM THE WARNING REQUIREMENT WOULD CREATE THE MISIMPRESSION THAT SOME CIGARS DO NOT PRESENT HEALTH RISKS.

FDA found that requiring warnings on cigar packaging and advertisements was appropriate for the protection of the public health. Exempting premium cigars from this requirement would foster the misimpression that premium cigars are less toxic, carcinogenic, or addictive than other cigars and thus would be contrary to the protection of the public health. In deciding not to exempt premium cigars from regulation, FDA explicitly agreed with the comment,

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[70] 81 Fed. Reg. at 29,070; 79 Fed. Reg. 23,158-59.

[71] Corey, *et al.*, at Supplemental Table B.

> "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."[72]

If warning labels were required on some but not all cigar packages and advertisement, consumers entering a store, or opening a website where cigars are sold, would encounter an array of products only some which carried warnings. Such a striking disparity would likely create the misimpression that premium cigars do not carry the same health risks as other cigars.

VI. CREATION OF AN EXEMPTION FROM THE WARNING REQUIREMENTS FOR PREMIUM CIGARS WOULD INVITE PRODUCT MANIPULATION TO QUALIFY FOR THE EXEMPTION.

Creation of an exemption from warning label requirements for "premium cigars" would require FDA to establish a definition of "premium cigars." In fact, there is no agreed-upon definition for "premium cigars" and different studies have defined them with reference to various characteristics. The difficulty of finding an agreed-upon definition is demonstrated by Plaintiffs' own disagreement with aspects of the definition FDA used in its discussion.[73] Regardless of what definition is used, however, creation of an exemption would invite manufacturers to manipulate their product to qualify. The record is replete with instances in which manufacturers of tobacco products have manipulated their products to circumvent regulation. For example, when a lower federal excise tax rate was established for "large" cigars rather than "little cigars," manufacturers added weight to filters to allow for reclassification of their products. 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

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[72] 81 Fed. Reg. at 29,021. See also, 79 Fed. Reg. at 23,166, where FDA stated that "the absence of a health warning for other tobacco products could reinforce the existing false sense of security that youth have about the safety of these products."

[73] Initial Brief of Plaintiffs at 8, n. 1.

with the labeled product type;[74] indeed, some products called cigarillos weighed more than products called large cigars.[75] In addition, nicotine content was not necessarily associated with the size of the cigar and determining which products might deliver more nicotine than others is not an intuitive process. Thus, although some cigarillo products weighed less than some large cigars, some of those cigarillos had the "greatest amount of free nicotine on a per-mass of tobacco basis."[76] The study indicated that "consumers smoking the same brand of cigar may unintentionally be exposed to varying doses of nicotine and potentially other smoke constituents."[77] Thus, given the wide variability among cigars and the absence of consistent features defining categories of cigars, recent research reaffirms that efforts by FDA to exempt a category of cigars from regulatory requirements would create real public health risks.

CONCLUSION

For the reasons stated herein, *Amici* urge this Court to deny the Plaintiffs' Motion for Summary Judgment and a Permanent Injunction and to grant Defendants' Cross-Motion for Summary Judgment.

Dated: May 3, 2019

Respectfully submitted,

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[74] Koszowski, B. et al., "Nicotine Content and Physical Properties of Large Cigars and Cigarillos in the United States," *Nicotine & Tobacco Research* 20(3):393-398, 2018.

[75] *Id* at 395.

[76] *Id* at 395, 397.

[77] *Id* at 397.

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APPENDIX A

Description of *Amici Curiae*

1. The American Academy of Pediatrics

The American Academy of Pediatrics (AAP), founded in 1930, is a national, not-for-profit organization dedicated to furthering the interests of children's health and the pediatric specialty. Since its inception, the membership of the AAP has grown from the original group of 60 physicians specializing in children's health to 66,000 pediatricians. Over the past 85 years, the AAP has become a powerful voice for children's health through education, research, advocacy, and expert advice, and has demonstrated a continuing commitment to protect the well-being of America's children. The AAP has engaged in broad and continuous efforts to prevent harm to the health of children and adolescents caused by the use of tobacco products and exposure to secondhand tobacco smoke.

2. The American Cancer Society Cancer Action Network

The American Cancer Society Cancer Action Network (ACS CAN) is the nation's leading cancer advocacy organization dedicated to making cancer issues a priority. Created in 2001 as the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, ACS CAN educates the public, government officials, and candidates about cancer's devastating impact on public health and encourages them to make fighting cancer a top priority. ACS CAN has more than one million volunteers nationwide, many of whom advocate for effective tobacco control at the federal, state, and local levels. In 2015, an estimated 221,000 people in the US will be diagnosed with lung and bronchus cancer, the vast majority of which is attributable to tobacco use. This devastating impact makes regulation of tobacco products critical to our mission.

3. The American Heart Association

The American Heart Association (AHA) is the nation's oldest and largest voluntary organization dedicated to fighting heart disease and stroke. Founded in 1924, AHA now includes more than 30 million volunteers and supporters, with local chapters in all 50 states, as well as in Washington D.C., and Puerto Rico. The association invests in research, professional and public education, and advocacy so people across American can live stronger, longer lives. AHA has long been active before Congress and regulatory agencies on tobacco and other health-related matters and has petitioned the Food and Drug Administration on several occasions seeking regulation of cigarette and other tobacco products under the Federal Food, Drug, and Cosmetic Act.

4. The American Lung Association

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

5. The American Thoracic Society

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

6. The Campaign for Tobacco-Free Kids

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

7. Public Health Law Center

The Public Health Law Center is a public interest legal resource center dedicated to improving health through the power of law and policy, grounded in the belief that everyone deserves to be healthy. Located at the Mitchell Hamline School of Law in Saint Paul, Minnesota, the Center helps local, state, national, Tribal, and global leaders promote health by strengthening public policies. For almost twenty years, the Center has worked with public officials and community leaders to develop, implement, and defend effective public health laws and policies, including those designed to reduce commercial tobacco use, improve the nation's diet, encourage physical activity, protect the nation's public health infrastructure, and promote health equity. The Center has filed more than sixty briefs as amicus curiae in the highest courts in the United States and before international bodies, including many briefs filed by the Center's tobacco program, the Tobacco Control Legal Consortium.[1]

[1] The Consortium's affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, at University of Maryland Francis King Carey School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Center for Public Health and Tobacco Policy,

8. The Truth Initiative

The Truth Initiative envisions an America where tobacco is a thing of the past and where all youth and young adults reject tobacco use. Truth Initiative's proven-effective and nationally recognized public education programs include truth®, the national youth smoking prevention campaign that has been cited as contributing to significant declines in youth smoking; EX®, an innovative smoking cessation program; and research initiatives exploring the causes, consequences, and approaches to reducing tobacco use. Truth Initiative also develops programs to address the health effects of tobacco use–with a focus on priority populations disproportionately affected by the toll of tobacco–through alliances, youth activism, training, and technical assistance. Located in Washington, D.C., Truth Initiative was created as a result of the November 1998 Master Settlement Agreement between attorneys general from 46 states, five U.S. territories, and the tobacco industry.

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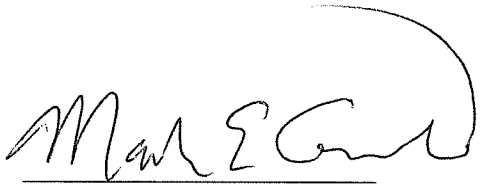
both at Northeastern University School of Law, Boston, Massachusetts; Smoke-Free Environments Law Project, at the University of Michigan, Ann Arbor, Michigan; and Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey.

CERTIFICATE OF SERVICE

I hereby certify that on May 3, 2019, I electronically filed the foregoing Amicus Curiae Brief with the Clerk of the Court for the United States District Court for the District of Columbia by using the CM/ECF system. All participants in the case are registered CM/ECF users and will be served by the CM/ECF system.



MARK GREENWOLD