IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANTS' CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT

For the reasons stated in the accompanying memorandum of law, Defendants respectfully cross-move for partial summary judgment on all claims raised in Plaintiffs' partial motion for summary judgment. *See* Fed. R. Civ. P. 56.

Dated: October 24, 2017

Respectfully submitted,

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

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION AND FOR PARTIAL SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT

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INTRODUCTION

The use of cigars and pipe tobacco has persisted even as the use of other tobacco products has declined. Indeed, more than 8% of high school students currently smoke cigars, comparable to the 9% who smoke cigarettes. In contrast to popular perception, the typical cigar is not a luxury indulgence hand-rolled by an artisan, but instead a relatively inexpensive, machine-made product, likely in a kid-friendly fruit flavor. And while cigars are often perceived to be a safe alternative to cigarettes, there is abundant evidence that they pose significant health risks. To begin, they can deliver nicotine—one of the most addictive substances known to man—as effectively as cigarettes. Nicotine is also toxic—it impairs brain development in youth, and causes pre-term delivery and stillbirth. And because cigar smoke contains essentially the same toxins and carcinogens as cigarette smoke, it causes cancer, lung disease, and death.

Plaintiffs acknowledge none of these risks. Their brief gives no inkling that nicotine is highly addictive, that cigar and pipe tobacco smoke is carcinogenic, or that their products, when used as directed, may be lethal. Instead, Plaintiffs contend that cigars and pipe tobacco should be exempted from regulation under several key provisions of the Tobacco Control Act—if not from the entire Act, a question they reserve for later briefing. Congress saw the matter differently; it expressly authorized the FDA to regulate cigars and pipe tobacco under the Tobacco Control Act, 21 U.S.C. §§ 387g(d)(3)(A), 387s(b)(2)(B), and it plainly expected that the agency would do so. The FDA reasonably exercised that authority here, and its expert judgment merits substantial deference.[1]

[1] The agency has announced that it intends to issue an Advance Notice of Proposed Rulemaking seeking public comment on the patterns of use and resulting public health impacts of premium cigars. *See* FDA, Press Release, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 28, 2017), *available at*

As an initial matter, Plaintiffs' request for preliminary relief should be rejected out of hand. The deeming rule was promulgated in May 2016. Yet Plaintiffs waited nearly 17 months, until October 2017, to move for a preliminary injunction. That lengthy delay undercuts any claim of irreparable harm, and it should not be rewarded by a favorable exercise of equitable discretion. Besides, there is no practical reason for preliminary relief: The parties are simultaneously seeking summary judgment on the same claims, using the same briefs. Those claims can be decided now based not on their likelihood of success, but on their actual merits.

In any event, Plaintiffs' claims fail at each turn. Their First Amendment challenge to the health warnings that the deeming rule requires on packages and advertisements of cigars and pipe tobacco lacks merit. Plaintiffs do not dispute that the warnings are accurate, and the standard of review applicable to such disclosure requirements is amply satisfied by the evidence that consumers—especially youth—commonly misperceive the health risks of these products. Indeed, the warnings would easily pass muster even if scrutinized as commercial speech, as they are narrowly tailored to mitigate the harms that Congress foresaw. And this challenge fares no better when dressed in the garb of prior restraint—a claim not raised in Plaintiffs' complaint that should be dismissed for that reason alone.

Plaintiffs' other challenges likewise lack merit. The agency reasonably considered pipes to be "components" or "parts" of tobacco products. 21 U.S.C. § 321(rr)(1); 21 C.F.R. § 1140.3. It permissibly found that retailers who blend tobacco are regulable as manufacturers, given that

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https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM568923.htm. Plaintiffs contend that this announcement suggests that the FDA's regulation of premium cigars "is not supportable on the current record." Pls.' Br. 14. That is not correct. Rather, the FDA expressed willingness to consider the appropriate regulatory status of premium cigars based on any new information that might be submitted relevant to that question. *See* Remarks by Scott Gottlieb, M.D., Protecting American Families: Comprehensive Approach to Nicotine and Tobacco (July 28, 2017), *available at* https://www.fda.gov/newsevents/speeches/ucm569024.htm.

they "assemble[]" or "process[]" tobacco products. 21 U.S.C. § 387(20). And its assessment of user fees on manufacturers of cigars and pipe tobacco faithfully tracks the statute, and implements the funding scheme that Congress itself designed.

Cigars and pipe tobacco are addictive and pose significant public health risks—and those risks are widely underappreciated. The regulations challenged here are entirely reasonable in view of those grave risks and the scheme established by Congress, and summary judgment should be granted to Defendants.

BACKGROUND

A. Statutory Background

Congress crafted the Tobacco Control Act ("TCA") based on evidence gathered over decades by all three branches of government regarding the health risks of tobacco products and the tobacco industry's marketing practices. That evidence established four key points.

First, "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). "Each year, 440,000 people die of diseases caused by smoking or other forms of tobacco use—that is about 20 percent of all deaths in our nation." Statement of Vice Admiral Richard H. Carmona, U.S. Surgeon General, *reprinted at* 155 Cong. Rec. S6000 (June 3, 2009).

Second, the magnitude of the public health harm caused by tobacco use is "inextricably linked" to nicotine addiction. 75 Fed. Reg. 69,524, 69,528 (Nov. 12, 2010). "The pharmacologic and behavioral processes that determine tobacco addiction are similar to those that determine addiction to drugs such as heroin and cocaine." *Id.* The power of nicotine addiction is perhaps best illustrated by the failure rate of individual cessation efforts. In 2004,

for example, "although approximately 40.5 percent of adult smokers reported attempting to quit . . . , only between 3 and 5 percent were successful." *Id*. at 69,529. The tobacco industry has long appreciated the importance of nicotine addiction to their sales. In an internal 1972 memo, one company acknowledged that "a tobacco product is, in essence, a vehicle for the delivery of nicotine"—a "potent drug with a variety of physiologic effects"—and that the "industry is then based upon the design, manufacture, and sale of attractive forms of nicotine." 146 Cong. Rec. H1849 (Apr. 5, 2000) (statement of Rep. Ganske) (quoting an R.J. Reynolds memo).

Third, the tobacco industry has long depended on recruiting underage users who become addicted before age 18. Congress found that, despite laws prohibiting the sale of tobacco products to minors, the "overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18." Pub. L. No. 111-31, § 2(31), 123 Stat. 1776 (2009). Congress additionally 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." Pub. L. No. 111-31, § 2(15); *see also United States v. Philip Morris USA, Inc.*, 449 F. Supp. 2d 1, 572 (D.D.C. 2006) (the "central purpose of the tobacco companies' image advertising is motivating adolescents to smoke"), *aff'd in part*, 566 F.3d 1095 (D.C. Cir. 2009).

B. The Tobacco Control Act

Against this backdrop, Congress enacted the TCA as a comprehensive scheme for the regulation of tobacco products. Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 301 *et seq.*). The Act addresses the manufacture and marketing of tobacco products in three principal ways.

First, Congress enacted measures to ensure that the FDA has accurate information about the ingredients of tobacco products and their health risks. For example, manufacturers of tobacco products subject to the Act must disclose to the FDA the identity and quantity of all ingredients—including nicotine and any other additives—in each product. 21 U.S.C. § 387d(a)(1)–(2). The labels on their products must accurately describe their contents. *Id.* § 387c. Smokeless tobacco must bear a warning label—such as "WARNING: Smokeless tobacco is addictive," 15 U.S.C. § 4402(a)(1)—and other tobacco products may be required to bear similar warnings, 21 U.S.C. § 387f(d)(1)–(2). And to ensure that products marketed as presenting reduced health risks actually do so, Congress required premarket FDA review of tobacco products purportedly posing "modified risks," such as a lower risk of disease, or reduced exposure to a harmful substance. *Id.* § 387k.

Second, Congress took steps to control the contents and quality of tobacco products. Manufacturers must register with the FDA, *id.* § 387e(b), and file a list of tobacco products they make, *id.* § 387f(e). For all tobacco products, Congress authorized the FDA to adopt standards regulating the level of any ingredient, including nicotine. *Id.* § 387g(a)(3). And to avoid allowing potentially harmful tobacco products to saturate the market before regulators can catch up, as happened with cigarettes, Congress provided for premarket FDA review of new tobacco products, including those entering the U.S. market after February 15, 2007, as well as any modification of a tobacco product commercially marketed after that date. *Id.* § 387j.

Third, Congress directed the FDA to reissue, with certain changes, provisions of a 1996 rule that restricted several marketing practices used by the tobacco industry to recruit children and adolescents. 21 U.S.C. § 387a–1(a) (directing reissuance of portions of 21 C.F.R. part 897, now codified at 21 C.F.R. part 1140). Among other things, the reissued rule bars the sale of

cigarettes and smokeless tobacco to minors, and restricts the distribution of free samples. 21 C.F.R. §§ 1140.14(a), 1140.16(d) (2010).

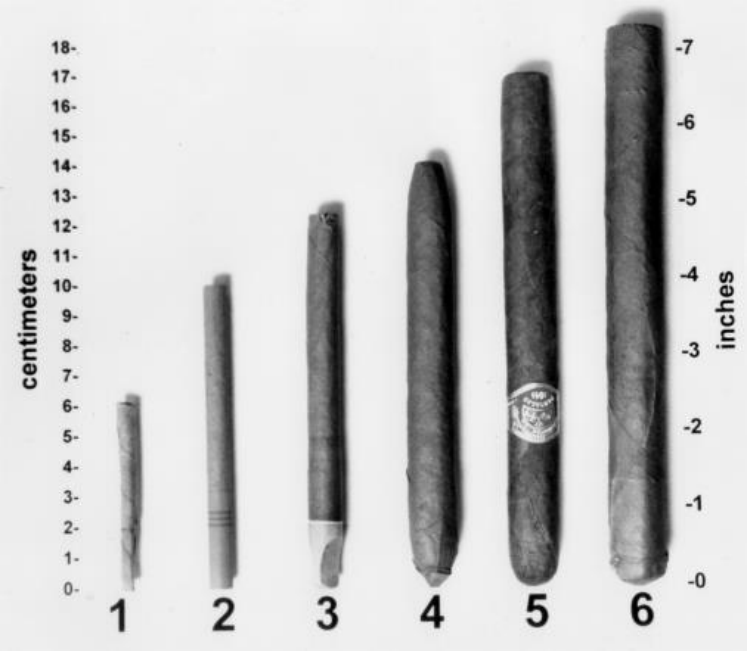
Together, these provisions effectuate several of the Act's principal goals: to make "consumers . . . better informed" about "the health and dependency effects or safety of tobacco products"; to permit the FDA to "regulate the levels of tar, nicotine, and other harmful components" of tobacco products; and to ensure "effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." Pub. L. No. 111-31, § 3(4)–(6).

C. Regulatory Background

Congress made the TCA applicable to four categories of tobacco products—"all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco"—as well as "to any other tobacco products that the Secretary by regulation *deems* to be subject to this chapter." 21 U.S.C. § 387a(b) (emphasis added). In the deeming rule, the FDA exercised that authority, subjecting cigars and pipe tobacco, among other products, to regulation under the TCA.

A "cigar" is any "roll of tobacco" that is "wrapped in leaf tobacco or any substance containing tobacco" and is not a cigarette. 21 C.F.R. § 1143.1; *cf.* 21 U.S.C. § 387(3) (defining "cigarette"). There are three major categories of cigar products: little cigars, cigarillos, and traditional cigars, labeled as numbers 2, 3, and 4-6 (respectively) in the figure below.[2]

[2] This figure is from Cigars: Health Effects and Trends, NCI Smoking and Tobacco Control Monograph, at 57 (AR 742), which describes (1) as a bidi, (2) as a little cigar with a filter tip, (3) as a small cigar or cigarillo with a plastic mouth piece, (4) as a regular cigar, and (5)-(6) as premium cigars.



Little cigars resemble cigarettes and are often smoked in the same manner. They are about the same size as cigarettes, containing about 1 gram of tobacco; they are commonly sold in packs of 20; and they often have filters:

Delnevo (2006) at 116–17 (AR 308–09); *see also* 21 U.S.C. § 387(11) (defining "little cigar" as a tobacco product that meets the definition of a "little cigar" in [15 U.S.C. § 1332(7)], which is "any roll of tobacco wrapped in leaf tobacco or any substance containing tobacco (other than any roll of tobacco which is a cigarette within the meaning of subsection (1)) and as to which one thousand units weigh not more than three pounds"). Indeed, little cigars are positioned as cheaper substitutes for cigarettes, given that they have avoided the stricter regulations applied to cigarettes. *Id.* at 116–18 (AR 308–10); Delnevo & Hrywna (2007) at 1368–73 (AR 300–05).

Cigarillos are shorter, slimmer versions of traditional cigars, and generally contain between 3 and 10 pounds of tobacco per thousand units. Kozlowski et al. (AR 7703). They may have wooden or plastic tips. AR 742.

Traditional cigars vary in length and diameter, and are generally larger than cigarillos. Kozlowski et al. (AR 7703). While little cigars and cigarillos are generally machine-rolled, traditional cigars may be either machine-rolled or hand-rolled. AR 882. The term "premium cigar" is not defined by federal law, and does not have an agreed-upon definition, but is sometimes used to refer to traditional cigars that are hand-rolled, made with higher-grade tobacco, or more expensive. *See, e.g.*, Corey et al. (2014) at 650 (AR 22,253).

Cigar use in the United States has persisted even as the use of other tobacco products has declined. In 2012–13, 7.4% of adults reported current cigar use. Coleman et al. (2014) at 1 (AR 960). That figure is even higher among youth: In 2014, 8.2% of high school students—some 1.2 million youth—were current cigar users, 81 Fed. Reg. at 29,960, 28,985 (2016) (citing Ref. 22 at AR 15,634), comparable to the 9.2% of high school students who smoked cigarettes, *id*.

Just as cigar use skews young, it also skews poor. While the "stereotypical public image of the cigar tends to be one of premium handmade products," in reality, "machine-manufactured cigars dominate" the market, "accounting for 90% of retail volume sales." Euromonitor (2014) at 1, 3 (AR Supp. 2870, 2872). These mass-produced cigars are "typically much less expensive than handmade cigars" and "tend to be purchased by a younger, less affluent demographic." *Id*.

The industry structure reflects these market trends. The U.S. cigar industry is dominated by four large manufacturers, which together account for 75% of total sales volume. Euromonitor at 3 (AR Supp. 2872). The industry leader, Swisher International—a member of Plaintiff Cigar

Association of America—controls a full 33% of the domestic cigar market, "due mainly to its strength in machine-manufactured" products. *Id.*

In contrast to cigarettes, which since 2009 have been permitted in only two characterizing flavors—tobacco and menthol—most machine-manufactured cigars are flavored, magnifying their appeal to youth. Delnevo et al. (2015) at 391 tbl. 2, 393 (AR 20,899); 81 Fed. Reg. at 29,014, 29,027. For example, Swisher International's industry-leading "Swisher Sweets" product line includes flavors ranging from "peach" and "chocolate" to "cherry dynamite" and "banana smash." *See* http://swishersweets.com; Euromonitor at 8 tbl. 8 (AR Supp. 2877). It is these sorts of products marketed as flavored cigars that are principally driving growth in the cigar industry: Between 2008 and 2011, flavored cigars were responsible for 75% of the total increase in cigar sales. Delnevo et al. (2015) at 390 (AR 20,898). While 63.2% of cigar smokers over age 35 report using a brand that makes flavored cigars, fully 95.1% of youth under age 17 do. *Id.* at 392–93 & tbl. 4 (AR 20,900–01).[3]

The record before the agency demonstrates that cigars and pipe tobacco present significant risks to public health—chief among them, addiction, cancer, and heart disease.

First, cigars and pipe tobacco contain nicotine, "one of the most addictive substances used by humans," 81 Fed. Reg. at 28,988, and "a powerful pharmacologic agent that acts in the brain and throughout the body," Surgeon General's Report (1988) at 14 (AR 1183). "[N]icotine is psychoactive ('mood altering') and can provide pleasurable effects," and "causes physical dependence characterized by a withdrawal syndrome that usually accompanies nicotine

[3] The agency has announced that it intends to issue an Advance Notice of Proposed Rulemaking seeking public comment on, *inter alia*, the role that flavors in tobacco products play in attracting youth. *See* FDA, Press Release, FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death (July 28, 2017), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM568923.htm.

abstinence." *Id.* Youth and young adults have a "unique susceptibility" to these addictive effects. 81 Fed. Reg. at 29,023, 29,047 (citing multiple studies). Cigars can deliver as much nicotine as cigarettes—sometimes much more. *Id.* at 29,022.

Second, nicotine is also toxic at high doses, and can harm adolescents, pregnant women, and fetuses. *Id.* at 29,033. The Surgeon General has concluded that nicotine exposure during pregnancy "contribut[es] to multiple adverse outcomes, such as pre-term delivery and stillbirth," and "has lasting consequences for [fetal] brain development." Surgeon General's Report (2014) at 126 (AR 14,708). Likewise, nicotine exposure during adolescence "may have lasting adverse consequences for brain development." *Id.*

Third, cigars and pipe tobacco cause cancer and other fatal diseases. Cigar and pipe smoke contain many of the same harmful constituents as cigarette smoke and may have higher levels of several harmful compounds. 81 Fed. Reg. at 29,020, 29,070; Nat'l Cancer Inst. (1998) at 17–18 (AR 21,109-10). Indeed, in comparison to cigarette smoke, cigar smoke contains more tar, carbon monoxide, ammonia, lead, cadmium, and nitrosamines. 81 Fed. Reg. at 29,070; Baker et al. (2000) at 737 (AR 18,741). Cigar smokers have an increased risk of a variety of fatal diseases, including lung cancer, oral cancer, laryngeal cancer, esophageal cancer, stomach cancer, heart disease, aortic aneurysm, stroke, and chronic obstructive pulmonary disease ("COPD"). 81 Fed. Reg. at 29,020, 29,024. All told, cigar smoking is "responsible for approximately 9,000 premature deaths"—or the loss of "almost 140,000 years of potential life"—every year. *Id.* at 29,020.

While pipe tobacco use is less common, the risk of disease and death is comparable. Pipe smokers have an "increased risk of death from cancers of the lung, oropharynx, esophagus, colorectum, pancreas, and larynx, and from coronary heart disease, cerebrovascular disease, and

COPD." *Id*. at 29,049. Indeed, "their risk of tobacco-related disease is similar to the risk in those who . . . smoke cigarettes." *Id.*

Fourth, the secondhand smoke from cigars and pipes causes disease and death in nonusers. Exposure to secondhand cigar and pipe smoke "can cause the same or similarly dangerous effects as exposure to secondhand cigarette smoke" given its similar chemical composition. 81 Fed. Reg. at 29,071. And secondhand smoke has long been known to cause lung cancer and heart disease in nonsmokers, resulting in tens of thousands of deaths each year. *Id*. at 29,070–71; Surgeon General's Rpt. (2014) at 660 tbl 12.4 (AR 15,244).

Fifth, the health risks of cigar and pipe tobacco are widely underappreciated. For example, there is a common misconception, repeated by some commenters, that cigars are not addictive unless the user inhales. 81 Fed. Reg. at 28,988 (comment 11). In fact, most cigar users inhale some smoke even if they do not intend to; regardless, because cigar smoke dissolves in saliva, "sufficient nicotine to create dependence" is absorbed through the oral mucosa. *Id*. at 28,988, 29,069. Likewise, there is a widespread misperception that cigars are a safe alternative to cigarettes. *Id*. at 29,070. Indeed, in one nationwide survey, less than half of cigar smokers believed that "cigar smoking is a high-risk behavior for developing cancer." Baker et al. (2000) at 737 (AR 18,741).

The scientific evidence is overwhelming: cigars and pipe tobacco pose significant public health risks. In view of this record, the FDA concluded that regulatory oversight would mitigate the underappreciated risks that these products pose to public health.

D. The Deeming Rule

Congress authorized the FDA to subject "any" "tobacco product" (except certain raw tobacco leaf) to the TCA as it "deems" fit. 21 U.S.C. § 387a(b). The Act "broadly defines

tobacco products as extending to '*any* product made *or derived from* tobacco,'" *Sottera Inc. v. FDA*, 627 F.3d 891, 897 (D.C. Cir. 2010) (quoting 21 U.S.C. § 321(rr)(1)) (emphasis in original), "including any component, part, or accessory of a tobacco product," 21 U.S.C. § 321(rr)(1).

In the challenged rule, the FDA deemed cigars, pipe tobacco, and other tobacco products—including their components and parts, but not accessories—subject to the TCA. The FDA defined the statutory term "component or part" to mean:

> any software or assembly of materials intended or reasonably expected:
> (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or
> (2) To be used with or for the human consumption of a tobacco product.
> Component or part excludes anything that is an accessory of a tobacco product.

81 Fed. Reg. at 29,102. The preamble to the rule explains that this definition includes filters, mouthpieces, removable tips, and pipes. *Id*. at 29,019, 29,042.

At the same time, the FDA determined *not* to exercise its statutory authority to deem "accessories" of the newly deemed products subject to the TCA. *Id*. at 28,974. It defined "accessories" to mean items used with, but not made or derived from, tobacco that are "not intended or reasonably expected to affect or alter" a tobacco product (or that are expected to have such an effect solely by controlling moisture, temperature, or initial combustion). *Id*. at 29,102. Such accessories include conventional matches and lighters, ashtrays, cigar cutters, permeable humidor buttons, pipe pouches, lanyards, and carrying cases. *Id*. at 28,975, 29,015–16, 29,019.

Although the deeming rule subjected cigars, pipe tobacco, and other newly deemed products to the TCA effective August 8, 2016, for many provisions the FDA has announced lengthy compliance periods. For example, for manufacturers in operation when the rule took effect, the FDA did not enforce the requirements that they register with the agency and submit a

list of products until October 12, 2017, and it does not intend to enforce the requirement that they submit a list of ingredients until November 2017 (or, for small-scale manufacturers, May 2018).[4] And although after August 8, 2016, *new* products may not enter the market without FDA authorization, for products *already* on the market then, the FDA does not intend to enforce the premarket review requirement for combustible products until August 2021, while manufacturers submit applications, and expects that manufacturers would continue to market products while their applications are under review.[5]

In addition, for "covered tobacco products"—which include newly deemed products but "exclude[] any component or part that is not made or derived from tobacco," *id*. at 29,103, such as pipes—the FDA exercised its authority to regulate distribution, marketing, and labeling in two ways, 21 U.S.C. § 387f(d)(1)–(2). First, to reduce youth access, the rule bans sales to those under age 18, requires identification checks of purchasers age 26 and under, and bars vending-machine sales except in adult-only facilities. 81 Fed. Reg. at 29,103 (codified at 21 C.F.R. § 1140.14(b)(1)–(3)). These provisions took effect on August 8, 2016. Second, to help consumers better understand the implications of using these products, the rule requires packages and advertisements of cigarette tobacco, roll-your-own tobacco, and covered tobacco products *other* than cigars to state: "WARNING: This product contains nicotine. Nicotine is an addictive chemical." *Id*. at 29,104–05 (codified at 21 C.F.R. § 1143.3(a)–(b)).

For cigars, the rule requires the same addictiveness warning to be rotated with five other warnings:

[4] https://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/ucm557716.pdf (revising earlier compliance dates set forth at 81 Fed. Reg. at 29,006).

[5] *Id.*

- WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- WARNING: Cigar smoking can cause lung cancer and heart disease.
- WARNING: Cigars are not a safe alternative to cigarettes.
- WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- WARNING: Cigar use while pregnant can harm you and your baby.

Id. at 29,061 (codified at 21 C.F.R. § 1143.5).[6] The same warnings are "already included on most cigar packages and in most cigar advertisements as a result of settlement agreements between the FTC and the seven largest U.S. cigar manufacturers," 81 Fed. Reg. at 29,071, "represent[ing] approximately 95 percent of the U.S. cigar market" at the time of the agreements.[7] The warning must generally occupy 30 percent of the two principal display panels on packages and 20 percent of advertisements beginning in August 2018.[8]

STANDARD OF REVIEW

Under the Administrative Procedure Act ("APA"), an agency's decision must be upheld unless arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *See* 5 U.S.C. § 706(2)(A). Under this deferential standard, the agency's decision is presumed valid, and the Court considers only whether it "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park v. Volpe*,

[6] For the last of these warnings, there is an optional alternative: "SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth, and Low Birth Weight." *Id.* at 29,061. There is also an exception for cigars sold individually without a package, for which all six warnings must be on a sign at the point of sale. 21 C.F.R. § 1143.5(a)(3).

[7] Press Release, FTC, Nationwide Labeling Rules for Cigar Packaging and Ads Take Effect Today (Feb. 13, 2001), *at* https://www.ftc.gov/news-events/press-releases/2001/02/nationwide-labeling-rules-cigar-packaging-and-ads-take-effect.

[8] *Id*. at 29,061 (codified at 21 C.F.R. § 1143.5); https://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/ucm557716.pdf.

401 U.S. 402, 416 (1971). An agency's decision may be deemed arbitrary and capricious only in circumstances where the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency," or its decision "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983). The Court may not "substitute its judgment for that of the agency." *Id.*

This deference is heightened even further in cases like this one involving scientific or technical decisions. "We will give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise," *West Virginia v. EPA*, 362 F.3d 861, 871 (D.C. Cir. 2004), for "we cannot decide . . . whether technical evidence beyond our ken supports the proposition it is asserted to support," *Simpson v. Young*, 854 F.2d 1429, 1434 (D.C. Cir. 1988). "When examining this kind of scientific determination . . . a reviewing court must generally be at its most deferential." *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983). Indeed, "[i]n the face of conflicting evidence at the frontiers of science, courts' deference to expert determinations should be at its greatest." *Cellular Phone Task Force v. FCC*, 205 F.2d 82, 90 (2d Cir. 2000).

ARGUMENT

There is no dispute that Congress expressly authorized the FDA to deem cigars and pipe tobacco subject to the TCA. The statute requires the agency to regulate "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." 21 U.S.C. § 387a(b). It permits the agency to regulate "any other tobacco products" (except certain raw tobacco leaf) that it "deems" fit. *Id*. And the statute specifically identifies "cigars" and "pipe tobacco" as two such products.

It provides that, if "cigars" or "pipe tobacco" are deemed, they may be regulated but not "bann[ed]" outright, *id*. § 387g(d)(3)(A), and "shall" be subject to user fees to fund the statutory scheme, *id*. § 387s(b)(2)(B).

It is equally clear that the FDA's decision to deem cigars and pipe tobacco was an appropriate exercise of its deeming authority—an issue that Plaintiffs' brief does not contest. As an initial matter, the FDA's exercise of its deeming authority is committed to agency discretion and not subject to review. *Cf. Webster v. Doe*, 486 U.S. 592, 600 (1988) (use of the word "deem" indicates that statute's implementation is "committed to agency discretion"). But it would in any event readily withstand scrutiny under the APA, as Judge Jackson recently concluded in an analogous case concerning the deeming of electronic cigarettes. *See Nicopure Labs LLC v. FDA*, --- F. Supp. 3d ---, No. 16-878, 2017 WL 3130312, at *26–31 (July 21, 2017), *appeal docketed*, No. 17-2509 (D.C. Cir. Aug 31, 2017).

The FDA's deeming rule marked the culmination of a comprehensive 5-year review of the scientific literature on cigars, pipe tobacco, and other newly deemed products, including more than 275 scientific studies and other reports and 135,000 public comments. As that vast record makes clear, cigars and pipe tobacco present grave risks to the public health, including addiction, disease, and death. It is against that backdrop that Plaintiffs' challenges come to the Court.

I. THE DEEMING RULE'S HEALTH WARNING REQUIREMENTS ARE CONSISTENT WITH THE FIRST AMENDMENT AND THE TCA

Plaintiffs do not deny that the health warnings that the deeming rule requires on packages and advertisements of cigars and pipe tobacco are accurate. Nor could they: The same statements have long been required on most cigar products by consent decree, and each is firmly supported by the scientific evidence. *See* 79 Fed. Reg. at 23,142, 23,168–70 (2014). Instead,

Plaintiffs take issue with the size of these warnings, claiming that they will "crowd[] out manufacturer communication with consumers." Pls.' Br. 16. But as the Supreme Court has made clear, warnings and other disclosure requirements "trench much more narrowly on an advertiser's interests than do flat prohibitions on speech," and Plaintiffs have a "minimal" interest in avoiding them. *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 651 (1985). The FDA acted well within the bounds of the First Amendment in requiring the health warnings at issue here.

A. The Health Warnings Are Consistent with the First Amendment

1. The Health Warnings Are Properly Analyzed under *Zauderer*

Rather than restricting what manufacturers may say, the deeming rule requires them to make disclosures. And there is no dispute with respect to the accuracy of the required statements. As mandated disclosures of "purely factual and uncontroversial information," the health warnings are subject to the relatively relaxed standard of review set forth in *Zauderer*, which reflects the "material differences between disclosure requirements and outright prohibitions on speech." *Id.* at 650, 651. Unlike restrictions on commercial speech, disclosure requirements do not prevent sellers "from conveying information to the public"; they merely require sellers to provide "more factual information than they might otherwise be inclined to present." *Id.* Because a party's "constitutionally protected interest in *not* providing any particular factual information in his advertising is minimal," the applicable test is accordingly more lenient, asking only whether the disclosure requirement is reasonably related to the government's interest. *Id.*

Plaintiffs attempt to evade this test by claiming that the size of the required health warnings crowds out their speech and therefore must be subject to the standard of review set

forth in *Central Hudson* for commercial speech restrictions. Pls.' Br. 17–18 (citing *Central Hudson Gas & Elec. Co. v. Pub. Serv. Comm'n of N.Y.*, 447 U.S. 557 (1980)). But Plaintiffs point to no case analyzing such a disclosure requirement under *Central Hudson* rather than *Zauderer*. Indeed, the best citation they muster is to a footnote in a recent D.C. Circuit opinion contemplating that there may be a point at which "the compulsion to speak becomes more like a speech restriction than a disclosure." *Pursuing Am.'s Greatness v. FEC*, 831 F.3d 500, 507 n.3 (D.C. Cir. 2016).[9] But Plaintiffs offer no basis to conclude that the health warnings here cross that undefined line, or that they are prevented from conveying any particular information in the available 70 percent of their packages and 80 percent of advertisements. There is thus no reason to depart from the standard practice of applying *Zauderer* to disclosure requirements.

2. The Health Warning Requirements Are Rationally Related to the Government's Interests

Under *Zauderer*, the Court must uphold a disclosure requirement so long as it is "reasonably related" to an identified government interest, and not so "[u]njustified or unduly burdensome" as to "chill[] protected speech." *Milavetz, Gallop & Millavetz, P.S. v. United States*, 559 U.S. 229, 250 (2010) (quoting *Zauderer*, 471 U.S. at 651). That test is readily satisfied here.

[9] Plaintiffs' reliance on *Dwyer v. Cappell*, 762 F.3d 275, 284 (3d Cir. 2014), is even further off the mark. Pls.' Br. 18. There, the court considered a regulation that barred attorneys from quoting judicial opinions in advertisements unless they disclosed the full text of the entire opinion. While the court remarked that a disclosure requirement "inten[ded] . . . to [be] so burdensome" as to amount to "an outright ban" on commercial speech might properly be analyzed under *Central Hudson*, it ultimately analyzed the disclosure requirement at issue under *Zauderer*. *Dwyer*, 762 F.3d at 284 (noting "its holding under the less-stringent *Zauderer* standard"). Likewise, while Plaintiffs cite *Edenfield v. Fane*, 507 U.S. 761 (1993), for the proposition that the FDA must justify "a regulation restricting the space and prominence of a company's communication with consumers," Pls.' Br. 18, that case concerned an outright prohibition on personal solicitation, not a compelled disclosure.

The FDA promulgated the health warning requirements to "help consumers better understand and appreciate the risks and characteristics of tobacco products" and to help correct current misperceptions about the newly deemed products. 81 Fed. Reg. at 28,981; 79 Fed. Reg. at 23,166. The record is replete with evidence that people, especially youth, "are not receiving sufficiently explicit information to clearly articulate the true health hazards of cigars." OIG Report (1999) at 20 (AR 987). Cigar smokers often misperceive cigars as less addictive, more natural, and less harmful than cigarettes. Cullen et al. (2011) at 1955 (AR 7708). Moreover, cigar packaging "does not always contain a warning label, and so health warnings may go unnoticed by cigar users." *Id*. In requiring that all cigar and pipe tobacco products carry the health warnings, the FDA aims to inform consumers and to help disabuse them of any misperceptions regarding the risks of these products.

The health warning requirements are reasonably related to that goal. The format of the warnings accords with the international consensus reflected in the World Health Organization's Framework Convention on Tobacco Control, which calls for warnings that "shall be rotating," "shall be large, clear, visible and legible," and "should be 50% or more of the principal display areas but shall be no less than 30% of the principal display areas." WHO Framework Convention on Tobacco Control, art. 11.1(b) (2003). The Convention has been signed by the United States and ratified by 167 countries. And the record in this case overwhelmingly established that "[u]sers are more likely to recall warnings that are in a larger size and that appear on the front/major surfaces of the tobacco product package." 81 Fed. Reg. 29,989; *see, e.g.*, IOM Report (2007) at 294 (AR 5149) ("In general, the evidence shows that the salience of warnings is affected by their placement, sizes, and other design features, and that salient warnings affect the consumer's awareness of risks."); Hammond et al. (2007) at 202 (AR 18757)

("[L]arge, comprehensive warnings" are "more likely to be noticed and rated as effective by smokers.").[10] As the FDA explained, "[b]efore a warning label can help a consumer better understand and appreciate the risks against which it warns, the consumer must notice and pay attention to the warning. The likelihood that a consumer will do so depends upon [the] warning's size and position." 81 Fed. Reg. at 28,989.

Plaintiffs contend that the warning labels fail the *Zauderer* test for three reasons. They are wrong at each turn.

First, Plaintiffs complain that "there has been no charge of consumer 'deception' by cigar or pipe tobacco manufacturers." Pls.' Br. 28. But as the en banc D.C. Circuit has clarified, *Zauderer* "sweeps far more broadly than the interest in remedying deception," so the government's interest need not be so limited. *Am. Meat Inst. v. USDA*, 760 F.3d 18, 22 (D.C. Cir. 2014) (en banc).

Second, Plaintiffs claim that the FDA's asserted interest is insufficient unless tied to data demonstrating that the increased understanding will lead to lower smoking rates. Pls.' Br. 28–29. They begin by citing *American Meat Institute*'s observation that it is "not . . . clear whether *Zauderer* would permit government reliance on interests that do not qualify as substantial under *Central Hudson*." *Am. Meat Inst.*, 760 F.3d at 23; *see* Pls.' Br. 28. From that statement,

[10] *See also* Bansal-Travers et al. (2011) at 674 (AR 18832) ("[L]arger warnings [are] most effective in communicating health risks to U.S. adults."); Hammond (2011) at 327 (AR 18745) ("[T]he evidence indicates that the impact of health warnings depends upon their size and design . . . . [P]rominent health warnings on the face of packages serve as a prominent source of health information for smokers and non-smokers, can increase health knowledge and perceptions of risk and can promote smoking cessation."); Elliott & Shanahan Research (2009) at 2 (AR 18770) (noting "specific features which have emerged from the literature review and are important to the effectiveness of the warning include the size of the warning (the larger the better, as this promotes visibility and enables warnings to compete with other pack elements)").

Plaintiffs infer that only substantial interests are sufficient; that the only possible substantial interest the FDA could assert is in reducing the incidence of smoking; and that the FDA has failed to show that the warnings further that interest. *See* Pls.' Br. 28–29. Even if Plaintiffs' first premise were correct,[11] the additional conclusions they draw are not, as the FDA's asserted interests here are indeed substantial. In *American Meat Institute*, the D.C. Circuit held that the government's interest in country-of-origin labeling for food was substantial. In so holding, the court noted "the context and long history of country-of-origin disclosures to enable consumers to choose American-made products; the demonstrated consumer interest in extending country-of-origin labeling to food products; and the individual health concerns and market impacts that can arise in the event of a food-borne illness outbreak." *Am. Meat Inst.*, 760 F.3d at 23. Similar interests justify the warnings here.

Like country-of-origin labeling, warning statements for tobacco products have a lengthy history. Congress has required such warnings for cigarettes since 1965 and for smokeless tobacco since 1986.[12] Indeed, large, extensive disclosures are also required in drug labeling and advertisements, even for generally less dangerous, over-the-counter drugs. 21 C.F.R. § 201.66. For many products, the required disclosures comprise more than 50 percent of the packaging.

[11] Other courts have not so held. *See, e.g.*, *New York State Restaurant Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 131 (2d Cir. 2009) ("In light of *Zauderer*, this Circuit thus held that rules mandating that commercial actors disclose commercial information are subject to the rational basis test."); *Discount Tobacco City & Lottery, Inc. v. United States*, 674 F.3d 509, 561, 564 (6th Cir. 2012) (evaluating cigarette and smokeless tobacco warning requirements "under *Zauderer*'s rational-basis rule" and finding them "reasonably related to promoting greater public understanding of the risks [of tobacco use]").

[12] *See* Federal Cigarette Labeling and Advertising Act of 1965, Pub. L. 89-92, 79 Stat. 282 (1965); Comprehensive Smoking Education Act of 1984, Pub. L. 98-474, 98 Stat. 2200 (1984); Comprehensive Smokeless Tobacco Health Education Act of 1986, Pub. L. 99-252. 100 Stat. 30 (1986).

Moreover, the warnings here are obviously addressed to "individual health concerns," *Am. Meat Inst.*, 760 F.3d at 23, as the information provided explicitly informs consumers of the health risks posed by the products. Finally, the warnings here serve to help correct consumer misconceptions about the risks for these products. *See* 81 Fed. Reg. at 29,070; RIA 59; AR 23970. As in *American Meat*, the combination of these factors creates a substantial interest.

Plaintiffs' reliance on *R.J. Reynolds Tobacco Co. v. FDA*, 696 F.3d 1205 (D.C. Cir. 2012), is therefore misplaced. Pls.' Br. 19–22. There, the court assessed the government's interest under *Central Hudson* only after concluding that *Zauderer* was inapplicable absent a charge of consumer deception. *Id.* at 1214. As just noted, however, the en banc D.C. Circuit overruled that portion of the decision, thereby undermining the *Central Hudson* analysis, which the court would not have reached had it properly applied *Zauderer*. *Am. Meat Inst.*, 760 F.3d at 22. In any event, in *R.J. Reynolds* the court determined that "[t]he *only* explicitly asserted interest in either the Proposed or Final Rule is an interest in reducing smoking rates." *R.J. Reynolds*, 696 F.3d at 1218. The court thus evaluated the interest in communicating health information as a means by which the FDA attempted to reduce smoking rates and found insufficient evidence that the warning labels at issue would accomplish that goal. *Id.* at 1221. Here, by contrast, the FDA has made clear throughout the rulemaking that its goal is to help consumers appreciate health consequences and correct their misperceptions.

Plaintiffs also miss the mark in asserting that the only possible legitimate interest is "the reduction of underaged cigar and pipe tobacco use," Pls.' Br. 20.[13] True, that is an interest that

[13] The Court should disregard the opinions of Plaintiffs' "expert" on this and all other issues. *See* Decl. of Cecil Reynolds, Dkt. No. 62-27; *Beyond Nuclear v. U.S. Dep't of Energy*, 233 F. Supp. 3d 40, 47 (D.D.C. 2017) (striking extra-record declarations).

both the Supreme Court and the D.C. Circuit have repeatedly recognized. But neither court has ever suggested that this is the only possible legitimate interest.[14] Indeed, as just discussed, the D.C. Circuit has recognized a variety of substantial interests that justify disclosure requirements of this type. *See Am. Meat Inst.*, 760 F.3d at 23; *Spirit Airlines, Inc. v. U.S. Dep't of Transp.*, 687 F.3d 403, 415 (D.C. Cir. 2012) ("[T]here is no question that [the government's] interest in ensuring the accuracy of commercial information in the marketplace is substantial."); *Pearson v. Shalala*, 164 F.3d 650, 656 (D.C. Cir. 1999) (holding that the government "has a substantial interest in promoting the health, safety, and welfare of its citizens").[15]

On this score, Plaintiffs' reliance on *International Dairy Foods Ass'n v. Amestoy*, 92 F.2d 67 (2d Cir. 1996), is particularly misguided. Pls.' Br. 20, 28–29. In that case, the court enjoined a Vermont law requiring dairy manufacturers to label milk from cows treated with a growth hormone (recombinant bovine somatotropin, or rBST), finding the state's asserted interest insubstantial. 92 F.2d at 73. But there, the state's "sole expressed interest" was mere "'consumer curiosity,'" *id*. at 73 n.1—indeed, it was "undisputed" that milk from treated and untreated cows was "indistinguishable," *id*. at 69, and "the FDA ha[d] 'concluded that . . . there are no human safety or health concerns associated with food products derived from cows treated

[14] *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), does not bear the weight that Plaintiffs place on it. There, the only interest asserted by the state was to prevent the use of tobacco by minors, and the Court found that the advertising ban was not reasonably tailored to that interest. *Id.* at 555, 562, 565. The Court's analysis thus did not consider whether a state could have a substantial interest beyond preventing use by minors.

[15] *See also Kansas v. United States*, 16 F.3d 436, 443 (D.C. Cir. 1994) (holding that "ensuring adequate facilities for interstate air travel in the Dallas-Fort Worth area" is a substantial interest); *Board of Trustees v. Fox*, 492 U.S. 469, 475 (1989) (finding a ban applied to "Tupperware parties" in a college dormitory to be permissibly based on the state's substantial interest in "promoting an educational rather than commercial atmosphere on SUNY's campuses, promoting safety and security, preventing commercial exploitation of students, and preserving residential tranquility").

with rBST,'" *id*. at 73. The same can hardly be said for cigars and pipe tobacco, for which the health concerns are well documented.

Finally, Plaintiffs are mistaken to contend that the warning labels constitute an undue burden. The court in *American Meat Institute* explained that "[t]o the extent that the government's interest is in assuring that consumers receive particular information . . . , the means-end fit is self-evidently satisfied when the government acts only through a reasonably crafted mandate to disclose 'purely factual and uncontroversial information' about attributes of the product or service being offered." *Am. Meat Inst.*, 760 F.3d at 26. Thus, the kinds of disclosures at issue here "will almost always demonstrate a reasonable means-ends relationship, absent a showing that the disclosure is 'unduly burdensome' in a way that 'chill[s] protected commercial speech.'" *Id.* (quoting *Zauderer*, 471 U.S. at 651). But Plaintiffs have not established that any of their speech is chilled. Nor have they shown that they are prevented from communicating their products' "qualities" and "craftsmanship," Pls.' Br. 17, in the available 70 percent of the packaging and 80 percent of the advertisements. To be sure, the warnings may reduce the space available for the communication of these messages and cause Plaintiffs to alter the design of the decorative boxes. But as the Sixth Circuit held in upholding similar warnings for smokeless tobacco—and even larger warnings for cigarettes—"[a]mple evidence supports the size requirements for the new warnings . . . and Plaintiffs have not shown that the remaining portions of their packages are insufficient for them to market their products." *Discount Tobacco City & Lottery, Inc.*, 674 F.3d 509, 567 (6th Cir. 2012); *see also Consolidated Cigar Corp. v. Reilly*, 218 F.3d 30, 55 (1st Cir. 2000), *rev'd in part on other grounds sub nom. Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001).

The out-of-circuit cases cited by Plaintiffs do not compel a different result. They lean most heavily on *American Beverage Association v. City and County of San Francisco*, 871 F.3d 884 (9th Cir. 2017) (petition for rehearing en banc filed Oct. 17, 2017), which considered an ordinance requiring advertisements for sugar-sweetened drinks to bear a warning, occupying 20 percent of the advertisement, reading: "Drinking beverages with added sugar(s) contributes to obesity, diabetes, and tooth decay." *Id*. at 888. But there, the court enjoined the ordinance not because the warning was "just too big," as Plaintiffs suggest. Pls.' Br. 22. Rather, it did so after concluding that the warning was "deceptive in light of the current state of research," *Am. Beverage*, 871 F.3d at 895, and further, that having to "counter[] San Francisco's misleading message would leave [the plaintiffs] little room to communicate their intended message"—effectively "turning [the advertisement] into a vehicle for a debate about the health effects of sugar-sweetened beverages," *id*. at 897. There is no such debate here: Plaintiffs do not deny that the warnings are accurate, and, as the *American Beverage* court recognized, tobacco products are distinguishable from sugar-sweetened drinks given their "physiologically addictive qualities." *Id*. at 897 n.11.

Plaintiffs' reliance on *Entertainment Software Association v. Blagojevich*, 469 F.3d 641 (7th Cir. 2006), is similarly misplaced. Pls.' Br. 22. There, the court enjoined an Illinois law requiring retailers to label "sexually explicit" video games with a four-inch square sticker bearing the number "18." *Id*. at 643. But it did so by "[a]pplying strict scrutiny," having concluded that *Zauderer* was inapplicable because the sticker was not "purely factual" but instead bore a "subjective and highly controversial message—that the game's content is sexually explicit." *Id*. at 652. Indeed, the court expressly distinguished tobacco warnings, explaining that "[t]his is unlike a surgeon general's warning of the carcinogenic properties of cigarettes." *Id*.

Thus, as the Sixth Circuit explained, "*Blagojevich* is distinguishable from this case" and "the standards it articulates are inapplicable here." *Discount Tobacco*, 674 F.3d at 561.

The other cases that Plaintiffs cite are equally unpersuasive, Pls.' Br. 29–30, as they concern disclosures either insufficiently tethered to the product being sold,[16] or far lengthier or more detailed than those required here.[17] Indeed, some of the same cases expressly recognize that short disclosures like the warnings here are permissible. *See, e.g.*, *Dwyer*, 762 F.3d at 283 (a "statement such as 'This is an excerpt of a judicial opinion from a specific legal dispute. It is not an endorsement of my abilities'" "would . . . likely suffice under *Zauderer*"); *see also Borgner v. Brooks*, 284 F.3d 1204, 1209 n.5, 1215 (11th Cir. 2002) (disclosure that "implant dentistry" is "not a recognized specialty area by the American Dental Association or the Florida Board of Dentistry" is "not especially long or cumbersome, but simply an effective manner to convey necessary information to the public").

[16] *Tillman v. Miller*, 133 F.3d 1402, 1403 (11th Cir. 1998) (requirement that an attorney's television advertisement soliciting workers' compensation claims include a "notice" about criminal penalties for making false statements fails scrutiny under *Zauderer* because it is "not tied to an inherent quality of the thing he is trying to sell—his legal services").

[17] *See, e.g.*, *Dwyer*, 762 F.3d at 278 (requiring disclosure of "full text of [judicial] opinions"); *Public Citizen, Inc. v. La. Att'y Disciplinary Bd.*, 632 F.3d 212, 229 (5th Cir. 2011) (an "attorney advertisement must include, both written in a large font and spoken slowly, at least all of the following information: (1) the lawyer's name and office location . . . ; (2) a client's responsibility for costs . . . ; (3) all jurisdictions in which the lawyer is licensed . . . ; (4) the use of simulated scenes or pictures or actors portraying clients . . . ; and (5) the use of a spokesperson, whether the spokesperson is a lawyer, and whether the spokesperson is paid"); *Ibanez v. Fla. Dep't of Bus. & Prof'l Regulation*, 512 U.S. 134, 146 (1994) ("disclaimer must 'stat[e] that the recognizing agency is not affiliated with or sanctioned by the state or federal government,' and it must set out the recognizing agency's 'requirements for recognition, including, but not limited to, educatio[n], experience[,] and testing'").

For all of these reasons, the "argument that the warnings are unduly burdensome because their size drowns out [Plaintiffs'] speech is unpersuasive," *Discount Tobacco*, 674 F.3d at 567, and the warnings should therefore be sustained under *Zauderer*.

3. Even if *Central Hudson* Applies, the Health Warnings Withstand Review

Even if the Court were to agree with Plaintiffs that the health warnings exceed some as-yet undefined limit and must be considered a restriction on speech, they would survive scrutiny under *Central Hudson*.

"The Constitution . . . accords a lesser protection to commercial speech than to other constitutionally guaranteed expression." *Central Hudson*, 447 U.S. at 562–63. "In commercial speech cases, then, a four-part analysis has developed." *Id.* at 566. First, the court determines whether the speech at issue is misleading or related to unlawful activity. If so, the speech is entitled to no protection. If not, the court "ask[s] whether the asserted governmental interest is substantial." *Id*. Finally, under the third and fourth steps, the court "must determine whether the regulation directly advances the governmental interest asserted, and whether it is not more extensive than is necessary to serve that interest." *Id.* Courts do not require the government to employ "the least restrictive means" of regulation or to achieve a perfect fit between means and ends. *Boards of Trustees v. Fox*, 492 U.S. 469, 480 (1989). It is sufficient that the legislature achieve a "reasonable" fit by adopting regulations "in proportion to the interest served." *Id*.

For the reasons already described, the government's interests in helping consumers understand and appreciate health risks and in curing the misperceptions that have arisen about the health and safety of these products are substantial.

Moreover, the warning requirements directly and materially advance the government's interest in correcting misperceptions and helping consumers understand the health consequences

of using cigars and pipe tobacco. As explained above, studies have shown that larger, more prominent warnings are more likely to be noticed and serve to "increase health knowledge and perceptions of risk." Hammond (2011) at 327 (AR 18745). Plaintiffs do not dispute these studies, but claim that the FDA conceded that it lacked "[r]eliable evidence on the impacts of warnings labels" for cigars and pipe tobacco. Pls.' Br. 20 (quoting RIA at 62). Plaintiffs lift that quote from the agency's cost-benefit analysis,[18] where it explained the obvious fact that there is no specific quantitative evidence on the benefits of the warning labels because they have not yet been implemented. The FDA therefore estimated the benefits by extrapolating from its experience with other products. As the studies examining cigarette labels have stated, there is "no reason to doubt that the principles identified in this work could be applied to other tobacco products" including cigars and pipe tobacco. Centre for Behavioral Research in Cancer (1992) at 6 (AR 18848); *see also* 79 Fed. Reg. at 23,165 ("FDA believes that the fundamental similarities between cigarettes and smokeless tobacco and other products allow for the application of data regarding the effectiveness of cigarette and smokeless tobacco warnings to warnings for other tobacco products."). Plaintiffs' demand for evidence directly from cigar and pipe tobacco studies is therefore misguided. As the Supreme Court has made clear, the government may "justify speech restrictions by reference to studies and anecdotes pertaining to different locales altogether, or even, in a case applying strict scrutiny . . . based solely on history, consensus, and simple common sense." *Florida Bar v. Went For It, Inc.*, 515 U.S. 618, 628–29 (1995); *accord Lorillard*, 533 U.S. at 555; *see also Hutchins v. District of Columbia*, 188 F.3d 531, 544 (D.C.

[18] The State of Arizona has submitted an amicus brief, asking that the Court set aside the rule pursuant to the APA. Dkt. No. 66. That brief focuses on the FDA's cost-benefit analysis, *id.*, which is not at issue for purposes of the pending motions. Accordingly, the Court need not consider the arguments raised by the State, *see Eldred v. Ashcroft*, 255 F.3d 849, 850-51 (D.C. Cir. 2001).

Cir. 1999) (under intermediate First Amendment scrutiny, a city may rely on evidence from other cities that "is reasonably believed to be relevant to the problem").

The warning labels are also sufficiently tailored. The Supreme Court has made clear that "the 'least restrictive means' test has no role in the commercial speech context." *Florida Bar*, 515 U.S. at 632. Instead, all that is required is "a fit that is not necessarily perfect, but reasonable; that represents not necessarily the single best disposition but one whose scope is 'in proportion to the interest served,' and that employs not necessarily the least restrictive means but . . . a means narrowly tailored to achieve the desired objective.'" *Id.* (citations omitted). In requiring that the labels cover 30 percent of the principal display panels and 20 percent of advertisements, the FDA ensured that the warnings are consistent with what Congress determined to be appropriate for smokeless tobacco, *see* 15 U.S.C. § 4402(a)(2)(A), and with the Institute of Medicine's findings, *see* IOM Report (2007) at 290–95 (AR 5145–50); 81 Fed. Reg. at 29,065; *see also Discount Tobacco*, 674 F.3d at 568 (opinion of Stranch, J.) ("Ample evidence supports the size requirements for the new warnings."); *id.* at 530-31 (opinion of Clay, J.) (concluding that "[t]he government has provided ample evidence supporting the size requirement for the new labels" and that "Plaintiffs have not shown that the remaining portions of their packaging are insufficient for them to place their brand names, logos or other information").

This also explains why the FDA did not simply adopt the warning requirements mandated by the FTC consent decree or California law. The size of those warnings is inconsistent with the consensus and judgment described above. The FDA took the FTC's warnings into account and decided to keep five of them as part of its six-warning rotating system, which will likely benefit those subject to the FTC consent decree. 81 Fed. Reg. at 28,979. Moreover, the FDA expects that the specific size it has chosen will provide increased clarity to the industry as compared with

the FTC's requirement that warnings be "clear and conspicuous." *Id.* at 28,988. Plaintiffs' other proposals for alternatives that are less restrictive of speech also fail, as they are premised on the faulty assumption that the FDA's purpose is to "reduce underage tobacco use." Pls.' Br. 27. As already explained, however, the warnings are instead intended to inform consumers and correct misperceptions—a goal that is not limited to youth, but applies equally to adults, *see* 81 Fed. Reg. at 28, 981, 28,988-89, 79 Fed. Reg. at 23,163, 23,148. Plaintiffs' proposals for increasing the legal age to buy products, making changes in enforcement, and raising tobacco prices would do nothing to further the FDA's stated interest, even setting aside the fact that many are outside the bounds of the FDA's regulatory authority. *See, e.g.*, 21 U.S.C. § 387f(d)(3) (barring FDA from raising the minimum age of sale). The FDA has reasonably sought to make use of the authority it possesses to solve the informational failures it sees.

Finally, Plaintiffs' complaints about the effect of the labels on their "ornate packaging" do not alter the correct outcome. *See* Pls.' Br. 23. First, it is important to note that the majority of cigars are mass-market products that are packaged more like cigarettes than the premium cigars shown in Plaintiffs' declarations. Euromonitor (2014) at 1, 3 (AR Supp. 2870, 2872); Delnevo (2006) at 116–17 (AR 308–09). In addition, the projections of the FDA-required warning labels Plaintiffs attach in their declarations are misleading because they appear to cover more than the required 30 percent of the panels by area.[19] In the Trowbridge Declaration, for example, one warning appears to cover about 40 percent of the panel by area. *See* Trowbridge Decl. C-3. Moreover, the warning projections are distorted, such that the warning area of the package

[19] 21 C.F.R. § 1143.5(a)(2)(i) requires that the warning comprise "at least 30 percent" of each of the principal display panels, so warnings could be larger, of course. But Plaintiffs appear to suggest, incorrectly, that the regulation requires labels to be as large as those in the projections that they attached.

appears more prominent than the background detail of the cigar boxes. *See* Trowbridge Decl. B-2. In any event, the warning labels restrict the amount of the packaging that can be devoted to "brand competition," but do not "destroy this medium," as Plaintiffs contend. Pls.' Br. 23. The remaining 70 percent of the principal display panels—and the rest of the box—can be used to indicate brand or quality or for ornate design. Indeed, because of the deeming rule, all cigar products will now be subject to the warning requirements rather than only the seven companies subject to the FTC consent decree. Thus, the cigar manufacturers are all on the same playing field, with the same amount of packaging space to devote to design, branding, or any other means of attracting customers.

In sum, the health warnings are consistent with the First Amendment, regardless of the standard used to examine them. The warning labels further a substantial government interest in providing important health information and also serve to help counteract prevalent misperceptions. In adopting the size requirements that Congress chose, the FDA joined an overwhelming consensus built around the research-backed understanding that larger warnings are more effective in making consumers aware of health risks. These labels are sufficiently tailored and leave open ample space for manufacturers to convey their own messages to the public. The labeling requirements should be upheld.

B. The Requirement to Submit a Plan for Rotating the Health Warnings Does Not Constitute a Prior Restraint

In addition to challenging the *size* of the health warnings, Plaintiffs alternatively challenge—for the first time in their opening brief—the requirement that they "submit a proposed warning plan" explaining how they will *rotate* those warnings "no later than either 12 months after [August] 10, 2016, or 12 months before advertising or commercially marketing a product that is subject to such requirement." 21 C.F.R. § 1143.5(c).[20] According to Plaintiffs, the requirement for FDA approval of a warning plan constitutes an unlawful prior restraint and restriction on speech in violation of the First Amendment. Pls.' Br. 30–33. This argument should be rejected for several independent reasons.

First, Plaintiffs' complaint raised no such claim, and it is axiomatic that they cannot amend their complaint by way of their opening brief. While Plaintiffs' complaint plainly challenged the size of the health warnings, it said nothing whatsoever about the submission of a plan explaining how those warnings would be rotated. *See* Compl. ¶ 136 (alleging that the "Final Rule imposes warning label format requirements of 20% disclosure space for advertising and 30% disclosure space for the two principal display areas for product"); *see also id.* ¶¶ 4(e), 34, 53, prayer for relief (e)–(f). Those requirements are contained in separate regulatory subsections. *Compare* 21 C.F.R. § 1143.5(a) *with id.* § 1143.5(c). And the principal basis on which Plaintiffs challenge the warning plan requirement—that it constitutes a prior *restraint* on speech—appears nowhere in the complaint, and is fundamentally distinct from their claims that the warning requirements constitute *compelled* speech. *Cf., e.g.*, *Brammer-Hoelter v. Twin Peaks Charter Acad.*, 492 F.3d 1192, 1209 (10th Cir. 2007) (recognizing that a "prior restraint claim . . .

[20] *See also* https://www.fda.gov/downloads/tobaccoproducts/labeling/rulesregulationsguidance/ucm557716.pdf (revising earlier compliance dates set forth at 81 Fed. Reg. at 29,006).

is separate and distinct from [plaintiffs'] freedom of speech and freedom of association retaliation theories"). Plaintiffs' attempt to raise this claim for the first time in their summary judgment brief is improper, and it should be dismissed for that reason alone. *See, e.g.*, *Quick v. U.S. Dep't of Commerce*, 775 F. Supp. 2d 174, 183 (D.D.C. 2011) ("[I]t is axiomatic that a party cannot amend its complaint merely by injecting new claims in the course of briefing a dispositive motion.").

Second, Plaintiffs' claim is not ripe for review. "The ripeness doctrine is drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Nat'l Park Hosp. Ass'n v. Dep't of the Interior*, 538 U.S. 803, 808 (2003) (citation omitted). "In deciding whether a case is ripe, [courts] consider '(1) the fitness of the issues for judicial decision' and (2) 'the hardship to the parties of withholding court consideration.'" *Cobell v. Jewell*, 802 F.3d 12, 21 (D.C. Cir. 2015) (citation omitted); *see also Full Value Advisors, LLC v. SEC*, 633 F.3d 1101, 1106 (D.C. Cir. 2011) (cautioning restraint where "the issue is one of constitutional import").

Plaintiffs' claim, even if "predominantly legal in character," *Devia v. NRC*, 492 F.3d 421, 424-25 (D.C. Cir. 2007), speculates about threatened harm and therefore is not fit for a judicial decision, *see Nevada v. Dep't of Energy*, 457 F.3d 78, 87 (D.C. Cir. 2006). Plaintiffs state that they are prevented from "speaking" because they are subject to an "indefinite" waiting period for FDA approval of their warning plans. *See* Pls.' Br. 31. But this harm is entirely conjectural, given Plaintiffs' failure to allege that they have suffered any injury from waiting for FDA review of a warning plan. As the FDA has explained, it "believes that it will be able to complete its review of the submitted warning plans by the effective date of the required cigar warnings," and if it receives a higher volume than expected, it will consider a compliance policy "to ensure that

cigar entities are not delayed or prevented from advertising or distributing cigars due to FDA's review of their warning plans." 81 Fed. Reg. at 29,073; *see also id.* (noting that review of warning plans for smokeless tobacco products did not delay or prevent advertising, "and FDA does not anticipate a different outcome here"); Submission of Warning Plans for Cigars, Guidance for Industry, at 7 (estimating "that it will take up to 12 months for the Agency to review a submission").

Withholding judicial review also presents no meaningful risk of hardship to Plaintiffs. For ripeness purposes, the "paradigm case of 'hardship'" is where parties are presented with the "choice . . . between taking immediate action to their detriment and risking substantial future penalties for non-compliance." *Chamber of Commerce of U.S. v. Reich*, 57 F.3d 1099, 1101 (D.C. Cir. 1995); *Friends of Animals v. Haugrud*, 236 F. Supp. 3d 131, 135 (D.D.C. 2017) ("Generally speaking, hardship will establish ripeness only where 'postponing review . . . impose[s] a hardship on the complaining party that is immediate, direct, and significant.'" (citation omitted)). But here, Plaintiffs have failed to demonstrate that they confront any such dilemma, particularly given that the compliance deadline for the warnings they dislike is not until August 10, 2018.[21] Thus, Plaintiffs' claim is not ripe for review.

Third, even if Plaintiffs' claim were ripe, FDA's warning plan submission requirement is consistent with the First Amendment. To begin, Plaintiffs have not established that the prior restraint doctrine even extends to commercial speech—a question about which the Supreme Court has expressed doubt, *Central Hudson.*, 447 U.S. at 571 n.13 (1980) ("[C]ommercial

[21] *See* https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM557716.pdf, at 6-7.

speech is such a sturdy brand of expression that traditional prior restraint doctrine may not apply to it."), and that the D.C. Circuit has not decided, *Pearson v. Shalala*, 164 F.3d 650, 660 & n.11 (D.C. Cir. 1999); *see also Discount Tobacco*, 674 F.3d at 537 (declining to apply the prior restraint doctrine to commercial speech).[22] Indeed, as the FDA's review centers not on the content of warnings but rather on their rotation, *see* 21 C.F.R. 1143.5(c)(3), Plaintiffs' invocation of traditional prior restraint scenarios, Pls.' Br. 30–32 (citing, among other cases, *FW/PBS, Inc. v. City of Dall.*, 493 U.S. 215, 225 (1990)), is particularly inapt. *Cf. Thomas v. Chicago Park Dist.*, 534 U.S. 316, 322 (2002) (declining to apply traditional prior restraint test to content-neutral pre-approval requirement).

Even assuming that the prior restraint doctrine applies to commercial speech, it requires only that a restraint on commercial speech be a narrowly tailored means of advancing a substantial governmental interest. *See Nutritional Health Alliance v. Shalala*, 144 F.3d 220, 228 (2d Cir. 1998) (applying *Central Hudson* test when considering whether 540-day period provided for FDA review of labeling claims was an unconstitutional prior restraint, and holding period was permissible "given the need to protect consumers before any harm occurs," to "evaluate the evidence in support of labeling claims," and to develop "a record on the matter so that a court can determine whether the regulated speech is, in fact, truthful and non-misleading").

[22] The cases relied upon by Plaintiffs, Pls.' Br. 31, do not demonstrate that the Court should analyze the purely commercial speech at issue here through the prior restraint lens. For example, *N.Y. Magazine v. Metro. Transp. Auth.* involved "both commercial and political elements present in speech." 136 F.3d 123, 131 (2d Cir. 1998). Further, the Ninth Circuit's decision in *Desert Outdoor Adver., Inc. v. City of Moreno Valley*, 103 F.3d 814, 818 (9th Cir. 1996), predates *Hunt v. City of Los Angeles*, where the court stated that "[i]t is an open question whether the prior restraint doctrine even applies to commercial speech." 638 F.3d 703, 718 n.7 (9th Cir. 2011). And the Tenth Circuit's analysis in *In re Search of Kitty's E.* is of limited persuasive value, given that it did not acknowledge the aforementioned dicta in *Central Hudson*. *See* 905 F.2d 1367, 1371 (10th Cir. 1990).

The twelve-month period estimated by the FDA for action on a warning plan submission is permissible under that test. The agency's review of warning plan submissions ensures that warnings will be adequately rotated and distributed as of the compliance date, contributing to its larger regulatory strategy for mitigating the public health risks posed by tobacco products. *See* 81 Fed. Reg. at 29,072–73 (explaining that the World Health Organization "has recognized the need to rotate health warnings for tobacco products"); *id.* at 29,072 ("Relying on random distribution would not ensure that the different health warning messages are reaching as many individuals as possible, and the health warnings may grow stale from overuse if repeated too many times for the same individual."). Accordingly, the pre-approval requirement implicates a substantial government interest. *See Pearson*, 164 F.3d at 656. Further, "the regulation directly advances the governmental interest asserted," *Central Hudson*, 447 U.S. at 566, as the "FDA's review and approval of a warning plan enables the Agency to more effectively conduct surveillance and inspection activities to ensure compliance with the warning label requirements," 81 Fed. Reg. at 29,072. Many of the entities may be unfamiliar with implementing rotation plans, and the FDA's advance review will pave the way for immediate proper compliance by ensuring there is adequate time to communicate and correct deficiencies. Finally, even if conceived of as a restriction on speech, the length of the FDA's review—estimated not to exceed 12 months—is "not more extensive than is necessary," *Central Hudson*, 447 U.S. at 566; *see Nutritional Health Alliance*, 144 F.3d at 228; *Commonwealth Brands, Inc. v. United States*, 678 F. Supp. 2d 512, 533 (W.D. Ky. 2010), *aff'd on other grounds sub nom. Discount Tobacco*, 674 F.3d 509; *see also* 5 U.S.C. § 555(b) (imposing requirement that "within a reasonable time, each agency shall proceed to conclude a matter presented to it").

Plaintiffs' arguments to the contrary are unpersuasive. Doubling down on *International Dairy*, they contend that the warning plan requirement "does not directly advance any 'substantial' governmental interest." Pls.' Br. 33. But, as previously noted, in that case the only asserted interest was mere "consumer curiosity" and "there [we]re no human safety or health concerns" at stake. *Int'l Dairy*, 92 F.2d at 73 & n.1. Here, by contrast, the FDA's requirement addresses risks to public health, 81 Fed. Reg. at 29,072–73, which courts regularly recognize as a substantial interest, *e.g.*, *Pearson*, 164 F.3d at 656. Plaintiffs also claim that the FDA has not "demonstrated any 'reasonable fit' between means and ends." Pls.' Br. 32 (citing *Lorillard*, 533 U.S. at 562). But *Lorillard* is likewise not on point. There, the Supreme Court held that outdoor advertising regulations lacked a reasonable fit because they would "constitute nearly a complete ban on the communication of truthful information about smokeless tobacco and cigars to adult consumers." *Lorillard*, 533 U.S. at 562. By contrast, here the warning plan requirement effectuates no such ban, instead imposing a pre-approval process for the rotation plan to ensure compliance. 81 Fed. Reg. at 29,072.[23]

Plaintiffs' challenge to the warning plan requirement should therefore be rejected, if it is not dismissed at the outset as speculative, premature, and improperly raised.

C. The FDA Made the Requisite Statutory Findings Before Adopting the Health Warning Requirements

Unable to show that the health warning requirements run afoul of the First Amendment, Plaintiffs half-heartedly argue that the FDA adopted those requirements without making the requisite statutory findings. Pls.' Br. 34. That claim is demonstrably false and should be rejected.

[23] For the reasons described above, the process would also survive scrutiny under the typical prior restraint test.

Congress authorized the FDA to regulate the advertising and promotion of tobacco products "if the Secretary determines that such regulation would be appropriate for the protection of the public health." 21 U.S.C. § 387f(d)(1). Whether this standard is met "shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products." *Id.*

The FDA made the required findings. In the notice of proposed rulemaking, the agency unequivocally stated that it "believes the sale and distribution restrictions the Agency is proposing," including the "health warning requirements," "meet the public health standard set forth" in the statute. 79 Fed. Reg. at 23,146. It then provided further detail, "conclud[ing] that the restrictions would be appropriate for the protection of the public health with respect to the risks and benefits to the population as a whole, including the increased likelihood that existing users will quit using tobacco products and the decreased likelihood that new users will initiate tobacco product use." *Id.* The FDA based this determination on "several factors," including the addictive properties of nicotine and its effects on adolescents; the fact that "combustible products like cigars, pipes, and waterpipes, are known causes of adverse health effects, including certain cancers and heart disease"; that users of products like cigars may "migrate to cigarettes" and that the rule may "avert that cigarette usage"; and the "risk that failure to act will reinforce consumers' existing confusion and misinformation about these products' safety or lack of harmfulness." *Id.* And in the preamble to the final rule, the FDA reiterated its finding that the

health warnings are "appropriate for the protection of the public health" pursuant to the statute's requirements. *See, e.g.*, 81 Fed. Reg. at 28,982, 28,988–89, 29,062, 29,066, 29,069.

Ignoring this, Plaintiffs instead claim that the FDA "admitted it could not make the statutorily mandated finding" in stating that "'[r]eliable evidence on the impacts of warning labels . . . on users of cigars . . . [and] pipe tobacco . . . does not, to our knowledge, exist.'" Pls.' Br. 34 (quoting RIA 62 (AR 23973)). That quotation comes from the FDA's regulatory impact analysis, where the agency makes the unremarkable point that it cannot quantify the benefits based on specific evidence because the warnings are new to these products, so it must extrapolate from its experience with other products. *See* RIA 62. But that will always be the case when an agency imposes new requirements, so it is unsurprising that the statute does not require the evidence that Plaintiffs demand. Instead, the agency properly took into account the likelihood of increased or decreased use of tobacco products based on what it knows of the products (including that they contain nicotine and cause disease), of the way in which they are used (often with cigarettes and other tobacco products), and of the way they are perceived (*e.g.*, that they are incorrectly seen as less addictive). *See* 81 Fed. Reg. at 29,062-63; *see also* 79 Fed. Reg. 23,167-170. Taking these things together, the FDA determined that warning labels are appropriate for the public health.[24] The agency thus made the findings that Congress required, and Plaintiffs are mistaken to contend otherwise.

[24] Plaintiffs also argue that the agency disregarded expertise from the Tobacco Products Scientific Advisory Committee before subjecting cigars and pipe tobacco to the warning label requirements. Pls.' Br. 36 n.9. The comment to which Plaintiffs refer came from the National Hookah Alliance and pointed out that no research has been done to determine if there is a threshold level below which nicotine yields do not produce dependence on the tobacco product involved, and that hookah smokers partake of the product once a week or less. AR 160,638. By contrast, for cigars, the FDA has evidence that nicotine levels are comparably high to cigarettes, and in some cases much higher. 81 Fed. Reg. at 29,022, 29,069.

D. Preliminary Relief Is Unwarranted

Plaintiffs have failed to demonstrate that they are entitled to preliminary relief regarding enforcement of the warning requirements. "A preliminary injunction is an extraordinary and drastic remedy; it is never awarded as of right." *Munaf v. Geren*, 128 S. Ct. 2207, 2219 (2008) (citations and internal quotation marks omitted). A party seeking such relief "must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest." *Winter v. NRDC*, 555 U.S. 7, 20 (2008).

As a threshold matter, the parties are briefing the merits on summary judgment, and this Court can evaluate actual success on the merits, not likelihood of success. And for the reasons discussed above, Plaintiffs cannot show success on the merits. Nor can Plaintiffs establish the remaining *Winter* elements. First, they have not demonstrated irreparable harm. To begin, Plaintiffs invoke "serious compliance costs," Pls.' Br. 37, but "[m]ere injuries, however substantial, in terms of money, time and energy necessarily expended in the absence of a stay are not enough." *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006). Plaintiffs also suggest that "the difficulty of recovering" costs from the agency makes them irreparable. Pls.' Br. 38. However, costs that are "irretrievable" must still be "serious in terms of its effect on the plaintiff." *Gulf Oil Corp. v. Dep't of Energy*, 514 F. Supp. 1019, 1026 (D.D.C. 1981); *N. Air Cargo v. USPS*, 756 F. Supp. 2d 116, 125 n.6 (D.D.C. 2010).

Further, a mere incantation of the First Amendment, *see* Pls.' Br. 38, is not enough, *Chaplaincy of Full Gospel Churches*, 454 F.3d at 301 ("[I]n this court, as in several others, there is no *per se* rule that a violation of freedom of expression automatically constitutes irreparable harm."). Moreover, Plaintiffs' lengthy delay in seeking preliminary relief undermines their

contention that the Court should exercise its equitable powers to enter an injunction immediately, instead of proceeding in the normal course. *Davis v. Billington*, 76 F. Supp. 3d 59, 66 n.11 (D.D.C. 2014).

The equities and public interest also tilt against preliminary injunctive relief. Congress intended for the FDA to deem and regulate additional tobacco products, as well as to provide for appropriate restrictions such as health warnings. 21 U.S.C. §§ 387a(b); 387f(d). The FDA has determined that these warnings are appropriate to protect the public from products that present a significant risk to health, and the public will be harmed if the warnings are enjoined. *Cf. Serono Labs. Inc. v. Shalala*, 158 F.3d 1313, 1326 (D.C. Cir. 1998) (determining that the public interest is "inextricably linked" to the merits and Congressional purpose).

Accordingly, there is no basis to award Plaintiffs a preliminary injunction.[25]

II. THE FDA'S ASSESSMENT OF USER FEES IS CONSISTENT WITH STATUTORY AUTHORITY

Plaintiffs do not dispute that, by statute, cigars and pipe tobacco must be assessed user fees. Their claim that the FDA arbitrarily declined to assess user fees on *other* newly deemed products, like e-cigarettes, misreads the statute. The user fee rule is not "economic favoritism" aimed at "avoiding a few more paragraphs in the final rule," Pls.' Br. 43, but the promulgation of

[25] Plaintiffs also suggest that the Court vacate all aspects of the rule implicating labeling changes, including requirements under § 903(a)(2) and (a)(4) that are unrelated to their merits arguments. Pls.' Br. 36 n.10. But the cases Plaintiffs cite do not support granting an injunction far beyond the scope of their claims. *See API v. EPA*, 862 F.3d 50, 71 (D.C. Cir. 2017) (declining to sever and affirm a portion of the rule that plaintiffs favored because the court could not say without "substantial doubt" that EPA would have adopted the severed portion on its own); *see also Ass'n of Private Colleges & Univs. v. Duncan*, 870 F. Supp. 2d 133, 154 (D.D.C. 2012) (similarly declining to sever provisions without clear knowledge of agency's intent). Here, the agency made clear its intent that any provisions found unlawful be severed from other provisions. *See* 81 Fed. Reg. at 28,974. *See North Carolina v. FERC*, 730 F.2d 790, 795–96 (D.C. Cir. 1984).

the precise scheme that Congress set up. Plaintiffs' arguments to the contrary ignore the statute's plain text and misconstrue the agency's interpretation of it.

In interpreting a statute that the FDA is entrusted to administer, the Court follows "the familiar two-step framework of *Chevron*." *Sherley v. Sebelius*, 644 F.3d 388, 393 (D.C. Cir. 2011). Under *Chevron* step one, if Congress has "'directly spoken to the precise question at issue,'" then the Court must "'give effect to [its] unambiguously expressed intent.'" *Id.* (quoting *Chevron*, 467 U.S. at 843). If instead the "'statute is silent or ambiguous with respect to the specific issue,'" then, under *Chevron* step two, the Court must "defer to the administering agency's interpretation as long as it reflects 'a permissible construction of the statute.'" *Id.* (quoting *Chevron*, 467 U.S. at 843). Here, the statute is clear and the FDA has acted in accordance with its commands.

The TCA requires the FDA to "assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products" subject to chapter IX "in accordance with" the requirements of Section 919 of the FDCA. 21 U.S.C. § 387s(a). The fees are to be used as the sole source of funding for the FDA's regulation of tobacco products. *Id.* § 387s(c)(2). The statute sets forth the total amount of user fees to be assessed in each fiscal year and then provides that the fees shall be allocated among six classes of tobacco products—cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco—by the "percentage determined under section 625(c) of [the Fair and Equitable Tobacco Reform Act ("FETRA")] for each such class of product for such fiscal year." *Id.* § 387s(b)(2)(B)(ii). The incorporated section of FETRA, in turn, lists percentage allocations for the same six tobacco products. 7 U.S.C. § 518d(c)(1). Unsurprisingly, these percentages add up to 100 percent. *Id.* FETRA further makes clear that the allocations among the tobacco manufacturers and importers within each

class of products shall be based on the manufacturer's or importer's "share of gross domestic volume," which is defined as the volume of tobacco products "removed," as defined by the Internal Revenue Code ("IRC"). *Id.* § 518d(a)(2), (e). The IRC limits its definition of "removal" to the same six tobacco products listed in FETRA and in the FDCA. 26 U.S.C. § 5702(c), (j).

In incorporating FETRA's methodology for user fee calculations, Congress set out a complete and complex system. As the FDA explained in the user fee rule, FETRA provides an initial class percentage for the six classes, totaling 100 percent, and requires that subsequent allocations be made only among these same six classes. In addition, FETRA's calculations require information on removal of tobacco products for federal excise tax purposes and the payment of such taxes. Since tobacco products outside of the six classes are not currently subject to federal excise taxes, FETRA cannot yield percentages for such products and consequently the FDA is necessarily limited to assessing user fees on the six enumerated classes. 81 Fed. Reg. at 28,709–10. The FDA has thus assessed user fees "in accordance with" the instructions set out in the statute, as Congress required. 21 U.S.C. § 387s(a).

In pressing their contrary interpretation, Plaintiffs focus on language referring to "'each manufacturer and importer of tobacco products subject to'" chapter IX. Pls.' Br. 40 (quoting 21 U.S.C. § 387s(a)). But their reading of this language would nullify the remainder of Section 919. If the FDA were to attempt to assess fees on e-cigarettes, as Plaintiffs urge, it would be unable to do so "in accordance with" the statutory scheme because FETRA's carefully laid out methodology for determining applicable percentages simply does not allow for it.[26] Adding an additional class of products not contemplated by FETRA would therefore completely depart

[26] Put another way, if FDA were to assess fees on e-cigarettes "in accordance with" 21 U.S.C. § 387s, their fees would necessarily be zero.

from this methodology for determining percentages listed therein, making Congress's incorporation of that standard meaningless. Nor does FETRA provide a means to determine the allocation among e-cigarette manufacturers and importers, as e-cigarettes are not "removed" for federal tax purposes. *See* 26 U.S.C. § 5702(c), (j). By contrast, the FDA's interpretation gives effect to all of the statute, assessing user fees "in accordance with" the method laid out by the statutory section, to the products listed in the section, but only when those "manufacturer[s] and importer[s] of tobacco products" are actually "subject to" the FDCA, whether because originally regulated or later deemed by the FDA.

Indeed, in promulgating the user fee rule, the FDA explained that any other interpretation of "each manufacturer and importer of tobacco products" would lead to absurd results. 81 Fed. Reg. at 28,711. For example, if the FDA used the definition of "tobacco product manufacturer" from 21 U.S.C. § 387(20), it would have to include repackers and relabelers, which are not accounted for in FETRA because they do not "remove" products as defined by the IRC. *Id.* Additionally, using the definitions in section 387 would result in duplicative assessments for certain tobacco products, since the definition of a "cigarette" includes roll-your-own tobacco for cigarettes—two products that are separately accounted for in FETRA. *Id.* Nor would it make sense to use the definition of "tobacco product" in 21 U.S.C. § 321(rr), which includes any "component, part or accessory" and is therefore significantly broader than what is provided for in the IRC and FETRA. *Id.*

Plaintiffs do not even attempt to grapple with the agency's reading of the statute, and the arguments they do make are unavailing. Plaintiffs first contend that the FDA's allocations are impermissible because the fees now function as a tax rather than a user fee, which they claim Congress did not intend. Pls.' Br. 42-43. But the FDA is simply administering the statutory fee

assessment method that Congress enacted. Plaintiffs do not claim that the "tax" is a forbidden delegation of legislative power, nor could they. As the Supreme Court made clear in *National Cable Television Ass'n v. United States*, 415 U.S. 336, 342 (1974), "[i]f Congress shall lay down by legislative act an intelligible principle to which the person or body authorized to fix such rates is directed to conform, such legislative action is not a forbidden delegation of legislative power." *See also Skinner v. Mid-America Pipeline Co.*, 490 U.S. 212, 220 (1989). Here, Congress has clearly laid out a detailed scheme that the FDA is authorized to use to assess fees. The FDA has complied with that scheme. That Plaintiffs here are dissatisfied with what Congress set out does not make it contrary to law.

Plaintiffs' statutory argument fares no better. Plaintiffs contend that Congress nowhere says that user fees should be imposed "only" on the six product classes identified in Section 919(b)(1)–(2). But by requiring the FDA to apply FETRA's percentages and methodology, Congress effectively accomplished the same thing. Adding another class of tobacco products would mean exceeding 100 percent of the user fees Congress permitted the FDA to collect using FETRA's allocations, which would violate Section 919(b)(1). *See* 81 Fed. Reg. at 28,709. Plaintiffs also point to section 919(b)(2)(B)(iii), claiming that it allows the FDA to assess user fees on products originally regulated or "'deemed by the Secretary in a regulation.'" Pls.' Br. 41. But that provision does not authorize the FDA to assess user fees on *any* newly deemed product. Rather, it makes clear that "no user fees shall be assessed" on product classes otherwise listed in Section 919 where such classes were not originally regulated or later deemed. 21 U.S.C. § 387s(b)(2)(B)(iii). Thus, while cigars and pipe tobacco are provided for in Section 919(b)(2)(B)(i) and in FETRA, because those products were not originally regulated, the FDA could not assess user fees on them unless and until they were deemed. Underscoring this point,

the statute provides that any fees that would have been assessed pursuant to the FETRA methodology "shall be reallocated to the classes of tobacco products that are subject to [chapter IX] in the same manner and based on the same relative percentages otherwise determined under [§ 387s(b)(2)(B)(ii)]." *Id.* § 387s(b)(2)(B)(iv). Thus, the statute provides for reallocation of fees where the FDA has declined to deem all six product classes listed in the statute and in FETRA. But Congress provided no way of allocating fees to tobacco products beyond the six product classes listed.

Even if the statute were ambiguous, the FDA's interpretation is, at a minimum, a reasonable one that merits deference under *Chevron*. Plaintiffs claim that the FDA's construction is unreasonable because the agency relied on "administrative convenience" without sufficient explanation. Pls.' Br. 42-43. This argument reveals a fundamental misunderstanding of both the FDA's reasoning and *Chevron*'s requirements. Under *Chevron* step two, the reasonableness of the agency's interpretation is determined "by reference to both the agency's textual analysis (broadly defined, including where appropriate resort to legislative history) and to the compatibility of that interpretation with the Congressional purposes informing the measure." *Cont'l Air Lines, Inc. v. DOT*, 843 F.2d 1444, 1449 (D.C. Cir. 1988). Thus, the agency's own interpretive path remains relevant.

Because the text of the statute clearly references FETRA's allocative scheme and nowhere in the text or legislative history is there any hint at how the agency would be able to make use of that scheme should it attempt to allocate fees among a seventh category, the agency's interpretation is reasonable. Plaintiffs imply that the user fee rule was merely a way for the agency to avoid the extra work of reallocating fees. To the contrary, the FDA clearly explained in the rule itself that it based its interpretation on the statute's text and structure, as

well as the fact that neither it, nor any other federal agency, collects the data that would be needed to compute share calculations for tobacco products in classes other than the six classes. 81 Fed. Reg. at 28,710 & n.2 (citing 21 U.S.C. § 387s(b)(7)(A)). Even if the FDA's interpretation were not compelled by the statute's text, it "is in no way contrary to the text, structure, or purpose of the statute" and should therefore be upheld under *Chevron* step two. *UC Health v. NLRB*, 803 F.3d 669, 675 (D.C. Cir. 2015); *see also Dep't of Treasury v. Fed. Labor Relations Auth.*, 494 U.S. 922, 928 (1990) (explaining that the agency's view is deemed to be permissible so long as it is not "flatly contradicted" by the statute).

Plaintiffs cannot save this claim by invoking the canon of constitutional avoidance. Pls.' Br. 43. While they claim that the statute's distinctions among different tobacco products raise potential equal-protection concerns, "a court's review of a pure economic regulation has been called the 'toothless rationality' test." *Boat Owners Ass'n of U.S. v. United States*, 834 F. Supp. 7, 11 (D.D.C. 1993) (citation omitted). In applying this test, the Court is not bound by the record before Congress, but instead considers whether "Congress *could have* rationally concluded" that the distinction was appropriate. *United States v. Sperry Corp.*, 493 U.S. 52, 65 (1989) (rejecting due process claim based on Congress's decision to assess user fees against only some claimants to the Iran-United States Claims Tribunal); *see also Kadrmas v. Dickinson Pub. Schools*, 487 U.S. 450, 462 (upholding user fees for bus services only in nonreorganized school districts). "[E]conomic regulation like the statute at issue in this case . . . 'carries with it a presumption of rationality that can only be overcome by a clear showing of arbitrariness and irrationality.'" *Id.* Plaintiffs cannot carry that "heavy burden" here. *Id.* at 463.

Congress's decision to incorporate the FETRA scheme without providing for user fees for certain newly deemed products is decidedly rational. When Congress enacted the statute,

FETRA was already established and enabled the FDA to obtain all the data necessary for the FDA to assess the fees. This not only benefitted the FDA by allowing easier implementation, addressing a concern that regulating tobacco would draw money away from the FDA's other regulatory efforts, *see* H.R. Rep. No. 111-58, at 127 (2009), but also minimized the burden for manufacturers and importers who were already required to provide information regarding product removal under FETRA. In enacting the scheme, Congress could have rationally determined that tobacco products outside the six listed classes were unlikely to gain a sufficient market share to justify the changes that would be required to assess user fees on them through changes to the TCA, FETRA, and the IRC. These kinds of "administrative considerations" can serve as a rational basis. *See Armour v. City of Indianapolis*, 566 U.S. 673, 682 (2012).[27]

It is exceedingly rare for courts to strike down economic regulations as a violation of the equal protection clause. Plaintiffs' attempt to pose this as a "serious constitutional problem" that requires the Court to interpret the statute contrary to its apparent meaning should be rejected. *See Cubaexport v.Dep't of Treasury*, 638 F.3d 794, 801 (D.C. Cir. 2011) ("A clear statute and a weak constitutional claim are not a recipe for a successful invocation of the constitutional avoidance canon.").

[27] Plaintiffs are incorrect in asserting that the FDA must make a showing that the administrative inconvenience would obviate potential benefits. Pls.' Br. 43. Though the Court in *Armour* determined that the costs would not have been justified, it did not require such a showing. Indeed, the Court made clear that "a legislature need not actually articulate at any time the purpose or rationale supporting its classification. Rather, the burden is on the one attacking the legislative arrangement to negative every conceivable basis which might support it." *Armour*, 132 S. Ct. at 2082 (internal quotation marks and citations omitted); *see also Carmichael v. Southern Coal & Coke Co.*, 301 U.S. 495, 511 (1937) (upholding distinction between business with seven employees and those who have eight in light of administrative convenience with no showing that expense and inconvenience would be "disproportionate to the revenue obtained").

III. THE FDA REASONABLY INTERPRETED THE TCA TO TREAT TOBACCO BLENDERS AS MANUFACTURERS

Plaintiffs next contend that the FDA erred in concluding that retailers who blend pipe tobacco for customers are considered tobacco "manufacturers" under the statute. Pls.' Br. 44-46. But the agency's interpretation is necessitated by the statutory language itself. *See* 81 Fed. Reg. at 29,049. Moreover, even if the statute did not clearly require it, the FDA's interpretation is reasonable and warrants deference under *Chevron*.

The TCA defines a tobacco product manufacturer as "any person, including any repacker, or relabeler, who—(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States." 21 U.S.C. § 387(20). Plaintiffs make no argument that retailers who blend tobacco do not qualify as manufacturers under this statutory definition. Nor could they. At a minimum, blending pipe tobacco clearly qualifies as "assembling" or "processing" the product, as such retailers repack two distinct products into one and thus assemble a new product for sale to a consumer. This application of the definition is consistent with courts' practice of applying the FDCA "'as broad[ly] as its literal language indicates.'" *United States v. Regenerative Scis., LLC*, 741 F.3d 1314, 1320 (D.C. Cir. 2014) (citation omitted).[28]

Instead of consulting the relevant statutory language, Plaintiffs turn to a separate section of the statute that defines "manufactur[ing]" and related activities as including certain acts "in furtherance of the distribution of the product from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user." 21 U.S.C. § 387e(a)(1).

[28] *See also De Freese v. United States*, 270 F.2d 730, 735 (5th Cir. 1959) ("The purpose of the Act is to safeguard the consumer by applying its requirements to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer." (internal quotation marks and citations omitted)).

Plaintiffs improperly conclude from this section that a manufacturer and retailer must be distinct entities. Thus, under Plaintiffs' reading, an entity could undertake the full and complete manufacture of a tobacco product, but so long as that same entity actually made the sale to the consumer, it could not be considered a tobacco manufacturer. Clearly this is not what Congress intended, and that is likely why the definition of a manufacturer contains no such limitation. In fact, Congress instructed that the relevant definition be applicable throughout the subchapter, *id.* § 387, while limiting the definition on which Plaintiffs rely to § 387e alone, a section focused on annual registration by owners and operators of establishments engaged in the manufacture, preparation, compounding, or processing of a tobacco product, *id.* § 387e(a). And Congress's definition is perfectly sensible. In blending the tobacco, the retailers are serving as a link between the original manufacturer and the ultimate consumer and are altering the product sold. Indeed, it may well be the case that the person who blends the tobacco is not the same person who mans the cash register and "makes the final delivery or sale to the ultimate consumer or user." *Id.* § 387e(a)(1). The application of the statute does not turn on precisely how the retailer is staffed, but on whether the retailer engages in any of the listed activities before delivering the product to the consumer. Where retailers blend pipe tobacco, the statute plainly applies.

Even if the statute were ambiguous as to its application to retailers, the FDA's interpretation is reasonable. Plaintiffs incorrectly assert that the FDA failed to show "that blending of finished pipe tobacco chemically or physically alters the tobacco in any way." Pls.' Br. 45. In the deeming rule, however, the FDA noted that blending changes may "alter the chemical or perception properties of the new product (*e.g.*, nicotine level, pH, smoothness, harshness, etc.)," 81 Fed. Reg. at 28,996, and may also "raise levels of HPHCs [harmful or potentially harmful constituents] in the product," *id*. at 28,995. Such changes can therefore result

in different risk profiles, "raising different questions of public health" among products. Thus, even aside from the FDA's legitimate reading of the statutory text, the agency has ample rationale to regulate the blending process.

IV. THE FDA PERMISSIBLY CONSIDERED PIPES TO BE "COMPONENTS" OR "PARTS" OF TOBACCO PRODUCTS

Finally, Plaintiffs take issue with the FDA's regulation of pipes as "components" or "parts" of tobacco products. Pls.' Br. 46-49. But the agency's interpretation is "entirely consistent with the plain meaning" of those terms, and thus satisfies *Chevron* at step one. *See Nicopure*, 2017 WL 3130312, at *16. The *Nicopure* court concluded that "the device plus the liquid are undeniably the two essential components of an open vaping system: a consumer cannot use a vaping device for its primary purpose without adding the liquid," *id.*, just as consumers cannot use a pipe for its primary purpose without adding pipe tobacco. In any event, the FDA's interpretation of these terms, which Congress left undefined, is reasonable and merits deference.

A. The FDA's Interpretation of the TCA Is Entitled to *Chevron* Deference

The TCA "broadly defines" the term "tobacco product," *Sottera*, 627 F.3d at 897, as extending to "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product," 21 U.S.C. § 321(rr)(1). Congress did not further define the terms "component, part, or accessory," and thus "left a gap for the agency to fill." *Chevron*, 467 U.S. at 843. The agency's expert judgment about how to fill that gap merits substantial deference under *Chevron*. *Nicopure*, 2017 WL 3130312, at *18.

At *Chevron* step two, an agency need not establish that its construction of the statute "was the only one it permissibly could have adopted," *Rust v. Sullivan*, 500 U.S. 173, 184

(1991); *Northpoint Tech. v. FCC*, 414 F.3d 61, 69 (D.C. Cir. 2005), or that it is "the best interpretation of the statute," *United States v. Haggar Apparel Co.*, 526 U.S. 380, 394 (1999), or that it is "the most natural reading," *Pauley v. Beth Energy Mines*, 501 U.S. 680, 702 (1991). Rather, the agency's view is permissible so long as it is not "flatly contradicted" by the statute. *Dep't of Treasury v. Fed. Labor Relations Auth.*, 494 U.S. 922, 928 (1990). This deference is heightened in "'a complex and highly technical regulatory program'" like this one, where "the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994). For Plaintiffs to prevail, they must demonstrate that the statute "cannot bear the interpretation adopted by the [FDA]" and that their alternative reading is the "only possible interpretation" of the statute. *Sullivan v. Everhart*, 494 U.S. 83, 89 (1990).

B. The FDA's Definition of "Component or Part" Is a Permissible Interpretation of the Statute

Under the TCA, it is not only things "made or derived from tobacco" that are tobacco products. 21 U.S.C. § 321(rr)(1). Any "component, part, or accessory" is also a tobacco product—whether or not it is made or derived from tobacco. *Id.* In the deeming rule, the FDA defined "component or part" to mean:

> any software or assembly of materials intended or reasonably expected:
> (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or
> (2) To be used with or for the human consumption of a tobacco product.
> Component or part excludes anything that is an accessory of a tobacco product.

81 Fed. Reg. at 29,102 (codified at 21 C.F.R. § 1100.3). That interpretation is faithful to the statutory text, and is supported by the TCA's structure, legislative history, and purpose.

The statutory text should be liberally construed, consistent with the FDCA's primary purpose "to protect consumers from dangerous products." *United States v. Sullivan*, 332 U.S.

689, 696 (1948). As the Supreme Court has explained, "Congress fully intended that the [FDCA]'s coverage be as broad as its literal language indicates . . . . [R]emedial legislation such as the [FDCA] is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health." *United States v. Article of Drug Bacto-Unidisk*, 394 U.S. 784, 798 (1969).[29] And indeed the statute's text bears this out, as Congress made the definition of tobacco product expansive, extending to "any" component, part, or accessory of "any" product merely "derived" from tobacco.

In defining a "component or part" to include things intended or reasonably expected to "affect a product's performance, composition, constituents, or characteristics," 81 Fed. Reg. at 29,102, the FDA acted consistently with Congress's understanding of these terms as used elsewhere in the statute. For example, in banning the use of characterizing flavorings (except tobacco and menthol) in cigarettes, Congress understood the "component parts" of a cigarette to include its "tobacco, filter, [and] paper." 21 U.S.C. § 387g(a)(1)(A) (referring to "a cigarette and any of its component parts (including the tobacco, filter, or paper)"). A cigarette's filter and paper obviously affect not only its physical "composition," but also its "performance" and "constituents." 81 Fed. Reg. at 29,102. In particular, the filter changes the mixture of chemicals delivered to the user by screening out certain particles, affects inhalation depending on its density and porousness, and makes smoke taste less harsh and therefore more tolerable. Likewise, the paper affects the burn rate and thus the rate of chemical delivery. Indeed, cigarette

[29] *See also United States v. Cassaro, Inc.*, 443 F.2d 153, 155 (1st Cir. 1971) ("[T]he Supreme Court has consistently accorded the [FDCA] a broad construction."); *De Freese v. United States*, 270 F.2d 730, 735 (5th Cir. 1959) (FDCA must be "liberally construed" to give effect to its "comprehensive scope").

companies have long manipulated these components or parts to affect the performance of their products. *See, e.g., United States v. Philip Morris USA Inc.*, 801 F.3d 250, 259 (D.C. Cir. 2015).

Plaintiffs claim, however, that a pipe cannot be a component or part of a tobacco product because it is not "integrated with a product made of tobacco." Pls.' Br. 48. But that argument has no basis in the text of the statute, which places no such limitation on the terms "component, part, or accessory." Congress could easily have defined tobacco products to include only "inseparable" components or parts, but instead it said "any."

Moreover, by Plaintiffs' logic, even the filter and paper of a cigarette would not qualify as components or parts, because they are not actually "inseparable." Some smokers empty the tobacco from a manufactured cigarette and refill its shell with other ingredients.[30] Others remove the filters of manufactured cigarettes and smoke them filterless.[31] And filters can be taken from manufactured cigarettes and repurposed in rolled cigarettes, with or without other ingredients.[32] Congress nevertheless considered the filter and paper of a cigarette to be components or parts, even if they are not made or derived from tobacco. *See* 21 U.S.C. § 387g(a)(1)(A) (referring to "a cigarette and any of its *component parts* (*including* the tobacco, filter, or paper)") (emphasis added). Indeed, it contemplated that cigarettes and other tobacco products would have still *other*, unspecified components and parts. *See id*. § 387d(a)(1) (requiring listing of substances added "to the tobacco, paper, filter, *or other part* of each tobacco

[30] *See, e.g.*, Weedist, How To Make a Cigarette Spliff (Feb. 20, 2013), *at* http://www.weedist.com/2013/02/how-to-make-a-cigarette-spliff; spliffy1329, How To Roll a Spliff Using a Regular Cigarette (Jan. 13, 2011), *at* https://www.youtube.com/watch?v=rJ2Oxbkoc4g.

[31] *See, e.g.*, smokyeyes3, How To Remove the Filter of Your Cigarettes (Oct. 14, 2015), at https://www.youtube.com/watch?v=yyQV451Wgm4.

[32] *See, e.g.*, wikiHow, How to Roll a Cigarette ("Remove the filter from a store-bought cigarette. . . . Lay this filter into your rolled cigarette."), *at* http://www.wikihow.com/Roll-a-Cigarette.

product") (emphasis added). Thus, the statutory definition of "tobacco product" contains no such limitation, and the FDA reasonably declined to add one. *See Nicopure*, 2017 WL 3130312, at *18 (rejecting argument that e-cigarettes sold separately from liquid nicotine do not qualify as components or parts).

Plaintiffs next contend that even if the statute is ambiguous, defining "component or part" in a way that includes pipes is unreasonable because "[t]here is nothing in the record to suggest that pipe architecture is being manipulated to make tobacco more addictive or dangerous and have any other direct effect on public health." Pls.' Br. 48. According to Plaintiffs, "differentiation among pipes is almost all for aesthetic reasons." *Id.* But a simple internet search reveals that this is not the case: Pipe shape affects smoking characteristics, taste, temperature, and moisture. *See, e.g.*, *Does the Shape Affect the Smoking Characteristics of a Pipe?*, *at* https://www.pipesandcigars.com/faq/does-the-shape-affect-the-smoking-characteristics-of-a-pipe/1818111; *How to Pick a Pipe with a Purpose*, *at* http://www.talkingtobacco.com/2012/08/how-to-pick-a-pipe-with-a-purpose-2. And changes in characteristics like moisture can "significantly impact consumers' exposure to nicotine and other constituents." 81 Fed. Reg. at 29,015. Thus, the FDA reasonably defined a "component or part" of a tobacco product, and its basis for the chosen definition supports regulating pipes.[33]

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiffs' motions for a preliminary injunction and partial summary judgment, grant Defendants' cross-motion for partial summary judgment, and enter judgment in favor of Defendants on all claims discussed above.

[33] The FDA adequately considered these costs, and Plaintiffs are not entitled to any particular outcome. *See, e.g.*, AR 23,986; 23,989; 23,995.

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