UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, et al.,	)	
Plaintiffs,	)	
v.	)	**Case No. 1:16-cv-01460 (APM)**
U.S. FOOD AND DRUG ADMINISTRATION, et al.,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

I. INTRODUCTION

On May 10, 2016, the U.S. Food and Drug Administration ("FDA") published a final rule "deeming" cigars, pipe tobacco, and certain other products (e.g., e-cigarettes) subject to the federal Food, Drug, and Cosmetic Act ("FD&C Act"), 21 U.S.C. §§ 301, *et seq.*, as amended by the Family Smoking Prevention and Tobacco Control Act of 2009 ("TCA"). Known as the "Deeming Rule," the FDA's action subjects these newly "deemed" products to comparable statutory and regulatory requirements already imposed on cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. At the same time, the FDA promulgated a separate rule, referred to as the "User Fee Rule," which assesses "user fees" on manufacturers and importers of cigars and pipe tobacco, but not other newly deemed products, like e-cigarettes. The FDA is statutorily authorized to collect user fees for the purpose of funding the FDA's regulation of tobacco products under the FD&C Act and the TCA.[1]

[1] Hereinafter, for ease of reference, the court refers to the FD&C Act, as amended by the TCA, as the "TCA."

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Plaintiffs in this case are three non-profit associations that represent cigar manufacturers, importers, distributors, suppliers, and consumers, as well as premium cigar and tobacco retail shops. They brought this action in July 2016 against the FDA and its Commissioner, and the U.S. Department of Health and Human Services ("HHS") and its Secretary (collectively, "Defendants"), challenging the Deeming Rule and the User Fee Rule on a host of grounds.[2] For reasons explained later in this opinion, not all of Plaintiffs' challenges to the Rules are presently before the court. Instead, the court addresses only the following subset of challenges: (1) the imposition of health warning requirements for cigar packaging and advertisements; (2) the assessment of user fees on cigar and pipe tobacco products, but not on another newly deemed product, e-cigarettes; (3) the treatment of retailers who blend pipe tobacco in-store as "manufacturers" subject to the regulatory requirements of 21 U.S.C. § 387e; and (4) the classification of pipes as "components" of tobacco products, thereby subjecting pipe makers to regulation. Plaintiffs also have moved to preliminarily enjoin implementation and enforcement of the Deeming Rule's health warning requirements.

For the reasons set forth below, the court grants in part and denies in part the parties' cross-motions for partial summary judgment and denies Plaintiffs' motion for a preliminary injunction as moot. The Deeming Rule's health warning requirements are upheld in all respects, as is the User Fee Rule in its entirety. The court also affirms the agency's classification of pipes as "components or parts" of tobacco products under the TCA. The court, however, concludes that Defendants' rationale for subjecting retailers who blend pipe tobacco in-store to the requirements of 21 U.S.C. § 387e is arbitrary and capricious and therefore remands that issue to the FDA for further consideration.

[2] Pursuant to Federal Rule of Civil Procedure 25(d), Alex M. Azar II, Secretary of Health and Human Services, and Dr. Scott Gottlieb, Commissioner of Food and Drugs, are substituted for their predecessors in office.

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II. BACKGROUND

A. Statutory Background

In 2009, Congress enacted the TCA to "provide authority to the [FDA] to regulate tobacco products under the [FD&C Act] by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products," and "to authorize the [FDA] to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products," among other purposes. Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 3, 123 Stat. 1776, 1781–82 (2009). Congress made 49 legislative findings in the Act, in which it acknowledged the "inherent dangerous[ness]" of tobacco products and nicotine and the strong public interest in regulating tobacco products and their advertising and promotion, and discussed Congress's interest in reducing youth tobacco use, in light of judicial findings that major U.S. tobacco companies specifically targeted and marketed their products to youth. TCA § 2. Congress further recognized that no other federal agency except the FDA "possesses the scientific expertise needed to implement effectively all provisions of the [TCA]." TCA § 2(45).

In light of those findings, the TCA authorized the Secretary of Health and Human Services to regulate the manufacture, distribution, and marketing of tobacco products. TCA § 901, codified at 21 U.S.C. § 387a (entitled "FDA authority over tobacco products"). The legislation immediately subjected "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco" to a panoply of statutory and regulatory requirements, and also reserved future application of the TCA to "any other tobacco products that the Secretary [of Health and Human Services] by regulation *deems* to be subject to this chapter." 21 U.S.C. § 387a(b) (emphasis added). Congress defined "tobacco product" to mean "any product made or derived from tobacco

that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr)(1). The FDA's decision in 2016 to "deem" cigars and pipe tobacco as "tobacco products," and thus subject them to regulation, gave rise to this litigation.

B. Regulatory Background

1. The Cigar Product

Federal regulations define "cigar" to mean any "roll of tobacco that is wrapped in leaf tobacco or any substance containing tobacco" that is "not a cigarette." 21 C.F.R. § 1143.1. There are three major categories of cigar products: (1) little cigars, (2) cigarillos, and (3) traditional cigars. *See* Defs.' Cross-Mot. for Partial Summ. J. & Mem. in Support, ECF No. 74 [hereinafter Defs.' Cross-Mot.], at 6–7. Little cigars resemble cigarettes in size and tobacco content and thus "are positioned as cheaper substitutes for cigarettes." *See id.* at 7. Cigarillos are a shorter, slimmer version of traditional cigars and, generally speaking, contain between 3 and 10 pounds of tobacco per thousand units. *See id.* at 8. Traditional cigars are the largest cigar product, varying in length and diameter. *See id.* While little cigars and cigarillos are machine-rolled, traditional cigars may be either machine-rolled or hand-rolled. *See id.*

Within the category of traditional cigars are a sub-category known as "premium cigars." *See id.* Premium cigars typically are hand-rolled, made with a higher-grade tobacco, or are more expensive. *See id.* The term "premium cigar" is not, however, defined by federal statute or regulation. *See id.*

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2. The Existing FTC Health Warning Statements Regime

Long before the FDA's action in 2016, cigar products already were subject to some federal regulation. More than a decade earlier, in 2000, in settlements with the Federal Trade Commission ("FTC"), the seven largest U.S. cigar companies agreed to include warnings about significant adverse health risks on their packaging and advertisements. *See, e.g.*, Decision & Order, *In the Matter of Swedish Match N. Am., Inc.*, Docket No. C-3970 (F.T.C. Aug. 18, 2000), 2000 WL 1207446. The FTC settlements represented the first national requirements for health warnings on cigar products and applied to approximately 95 percent of the U.S. cigar market at the time. *See* Press Release, FTC, Nationwide Labeling Rules for Cigar Packaging and Ads Take Effect Today (Feb. 13, 2001), https://www.ftc.gov/news-events/press-releases/2001/02/nationwide-labeling-rules-cigar-packaging-and-ads-take-effect.

Pursuant to the consent orders, which remain in effect today, the covered cigar companies must display one of the five following health warning statements "clearly and conspicuously" on their advertising and packaging:

> SURGEON GENERAL WARNING: Cigar Smoking Can Cause Cancers Of The Mouth And Throat, Even If You Do Not Inhale.
>
> SURGEON GENERAL WARNING: Cigar Smoking Can Cause Lung Cancer And Heart Disease.
>
> SURGEON GENERAL WARNING: Tobacco Use Increases The Risk Of Infertility, Stillbirth And Low Birth Weight.
>
> SURGEON GENERAL WARNING: Cigars Are Not A Safe Alternative To Cigarettes.
>
> SURGEON GENERAL WARNING: Tobacco Smoke Increases The Risk Of Lung Cancer And Heart Disease, Even In Nonsmokers.

See Decision & Order, *In the Matter of Swedish Match N. Am., Inc.*, 2000 WL 1207446, at *3. The FTC consent orders specify the size and formatting of the health warnings, and require that

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