IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

BIG TIME VAPES, INC. and UNITED STATES VAPING ASSOCIATION, INC. **PLAINTIFFS**

v. **CAUSE NO. 1:19cv531-LG-JCG**

FOOD AND DRUG ADMINISTRATION, et al. **DEFENDANTS**

MEMORANDUM OPINION AND ORDER GRANTING DEFENDANTS' MOTION TO DISMISS AND DENYING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

BEFORE THE COURT are the [15] Motion for Preliminary Injunction filed by the plaintiffs Big Time Vapes, Inc., and United States Vaping Association, Inc., and [24] Motion to Dismiss filed by the defendants Food and Drug Administration, Admiral Brett P. Giroir, M.D. in his official capacity as Acting Commissioner of Food and Drug Administration, and Alex M. Azar, II, in his official capacity as Secretary of Health and Human Services. The parties have fully briefed both Motions. The plaintiffs raise a constitutional delegation challenge to part of the Family Smoking Prevention and Tobacco Control Act ("TCA"), and the defendants counter that the plaintiffs have failed to state a plausible claim for relief. After reviewing the submissions of the parties, the record in this matter, and the applicable law, the Court finds that the defendants' Motion to Dismiss should be granted, and the plaintiffs' Motion for Preliminary Injunction should be denied.

BACKGROUND

In 2009, Congress amended the Federal Food, Drug, and Cosmetic Act to include the TCA, which vests the FDA with regulatory authority over the design, production, marketing, and advertising of tobacco products. Congress listed the following purposes of the Act:

> (1) to provide authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act . . . by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products as provided for in this division . . . ;
> (2) to ensure that the Food and Drug Administration has the authority to address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco;
> (3) to authorize the Food and Drug Administration to set national standards controlling the manufacture of tobacco products and the identity, public disclosure, and amount of ingredients used in such products;
> (4) to provide new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products;
> (5) to vest the Food and Drug Administration with the authority to regulate the levels of tar, nicotine, and other harmful components of tobacco products;
> (6) in order to ensure that consumers are better informed, to require tobacco product manufacturers to disclose research which has not previously been made available, as well as research generated in the future, relating to the health and dependency effects or safety of tobacco products;
> (7) to continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers;
> (8) to impose appropriate regulatory controls on the tobacco industry;
> (9) to promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases; and
> (10) to strengthen legislation against illicit trade in tobacco products.

Pub. L. No. 111-31, 123 Stat. 1778 (2009). Congress clarified, however, that the TCA is not intended to affect the growing, cultivation, or curing of raw tobacco. *Id.*

Congress specified that the TCA "shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco and to any other tobacco products that the Secretary by regulation deems to be subject to this subchapter." 21 U.S.C. § 387a(b).[1] Congress defines "tobacco product" as "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).

On May 10, 2016, the FDA issued a final rule deeming electronic nicotine delivery systems ("ENDS") to be subject to the Federal Food, Drug, and Cosmetic Act.[2] Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,973-01 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143). This deeming rule clarified that "establishments that mix or prepare e-liquids or create of modify aerosolizing apparatus for direct sale to consumers are tobacco product manufacturers under the definition set forth in the

[1] The Secretary referred to in the statute is the Secretary of Health and Human Services. 21 U.S.C. § 321(d). The Secretary redelegated his authority to the FDA Commissioner, who in turn redelegated his authority to the Associate Commissioner for Policy. FDA Staff Manual Guide 1410.10, 1410.21.

[2] ENDS include e-cigarettes, e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,973-01, 29,028 (May 10, 2016) (to be codified at 21 C.F.R. pts. 1100, 1140, and 1143).

FD&C Act and, accordingly, are subject to the same legal requirements that apply to other tobacco product manufacturers." *Id.* at 28,979. As a result, these establishments must obtain premarket approval of all products not commercially marketed in the United States as of February 15, 2007. 21 U.S.C. § 387j. Any products not preapproved by the FDA are banned. *See* 21 U.S.C. § 387b; 21 U.S.C. § 387c.

The deeming rule went into effect on August 8, 2016, but the FDA provided time periods during which the FDA did not intend to enforce compliance with premarket review requirements. *Id.* at 29,006. In August 2017, the FDA issued *Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* (Aug. 2017), which is available at https://www.fda.gov/media/105346 /download, stating that it did not intend to enforce the Act's premarket review provisions "as a matter of enforcement discretion" until August 2022. 2017 Guidance at 3-4.

The American Academy of Pediatrics and others filed a lawsuit against the FDA in the United States District Court for the District of Maryland, arguing that the 2017 Guidance violated the Administrative Procedure Act, exceeded the FDA's statutory authority, and violated U.S. Const. art. II, § 3. *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461, 490 (D. Md. 2019). The plaintiffs alleged that the FDA violated the APA by failing to comply with the notice and comment requirements for rule-making when it issued the 2017 Guidance. *Id.* The court held that the Guidance was "tantamount to an amendment to the Tobacco Control

Act," such that the FDA was required to comply with the APA's notice and comment requirements. *Id.* at 497-98. As a result, the court vacated the 2017 Guidance. *Id.* at 498. In a subsequent order dated July 12, 2019, the court established a ten-month deadline for submitting marketing order applications for new tobacco products and a one-year deadline for products for which applications were already filed to remain on market without enforcement action. *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 399 F. Supp. 3d 479 (D. Md. 2019). As a result, premarket review applications for ENDS products must be submitted by August 2022. The *American Academy of Pediatrics* decision is currently on appeal before the United States Court of Appeals for the Fourth Circuit.

Faced with accelerated deadlines for complying with the TCA, Big Time Vapes, Inc., and United States Vaping Association, Inc., filed this lawsuit on August 19, 2019, against the FDA, the Secretary of Health and Human Services, and the Acting Commissioner of the FDA. The plaintiffs assert that 21 U.S.C. § 387a(b) violates the United States Constitution by impermissibly delegating legislative authority to the executive branch.[3] *See* U.S. Const., art. I, § 1 ("All legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives.") The plaintiffs seek a

[3] Big Time Vapes is a Mississippi corporation that sells and manufactures vaping products in Picayune, Mississippi. United States Vaping Association is a trade association "organized in July and August 2019 to represent small-business vaping manufacturers (who make e-liquid) and retail vape shops that sell e-liquid manufactured by other firms and mix and produce their own in-house e-liquid." (Compl. 4-5, ECF No. 1.)

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