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,	§	
	§	Civil Case No. 1:19-cv-531-HSO-JCG
v.	§	
FOOD AND DRUG ADMINISTRATION; NORMAN E. "NED" SHARPLESS, M.D., in his official capacity as Acting Commissioner of Food and Drugs; and ALEX M. AZAR, II, in his official capacity as Secretary of Health and Human Services,	§	DECLARATORY AND INJUNCTIVE RELIEF REQUESTED
Defendants.	§	

COMPLAINT

Plaintiffs Big Time Vapes, Inc. and United States Vaping Association bring this action for declaratory and injunctive relief, and will show as follows:

INTRODUCTION

1. This is an action for declaratory and injunctive relief arising under the Constitution of the United States. Plaintiffs find themselves pleading for the vindication of their rights in the federal court system because a Final Rule promulgated under the auspices of the Food and Drug Administration ("FDA") imposes severe—even insurmountable—burdens that will harm Plaintiffs and their customers.

2. These burdens were imposed not by Congress, but as a result of the policy decisions of the FDA exercising its statutory authority. In 2009, Congress imposed a new regulatory regime

on cigarettes and smokeless tobacco via the Family Smoking Prevention & Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1777 (2009) (the "Tobacco Control Act" or "TCA"), *codified at* 21 U.S.C. 387 *et seq*. Notably, Congress left other types of tobacco—including such widely-used products as cigars and hookah—unregulated. While Congress *itself* declined to impose the new statutory regime on these other products, it purported to transfer the discretion to do so across Independence Avenue, vesting the Executive branch (the Secretary of Health and Human Services) with the authority to impose the Act on "any other tobacco products that the Secretary by regulation deems to be subject to [the Act]." 21 U.S.C. § 387a(b).

3. This statute grants the Secretary authority to deem—or to not deem—any "tobacco product" to be subject to the strictures of the Tobacco Control Act, with no guidance as to how the Secretary is expected to exercise such discretion.

4. On May 10, 2016, the FDA published a Final Rule deeming *all* products meeting the statutory definition of "tobacco product" to be subject to the Tobacco Control Act.[1] This Rule expressly included not only those products like cigars that are (relatively) similar to cigarettes in their composition and in wide and longstanding use at the time Congress passed the Act (and which Congress declined to regulate), but also products of a materially different nature comprising the vaping industry.[2] Given the *carte blanche* statutory discretion to deem "tobacco products" subject

[1] "Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products," No. FDA-2014-N-0189, 81 Fed. Reg. 28,973 (May 10, 2016) ("Deeming Rule" or "the Rule"). The Rule went into effect 90 days after its publication. 81 Fed. Reg. at 28,976.

[2] Through the Deeming Rule, FDA interpreted the definition of a "tobacco product" so broadly that it also chose to define as a "tobacco product" the electronic components of a vapor device like lithium-ion batteries, software, and electronic circuitry. 81 Fed. Reg. at 28,975. This is just one more aspect of FDA's deployment of its discretion under the provision of the TCA challenged here

to regulation without reference to any factors or standards, and assuming *arguendo* that vaping liquids containing nicotine derived from tobacco satisfy the statutory definition, the Secretary could have decided to regulate only cigars and leave vaping and hookah products untouched. Or, the Secretary could have done the opposite, regulating vaping and hookah but not cigars. Ultimately, the Secretary could have "deemed" any product or combination of products, and not deemed others, based on whatever factors she wanted to consider.

5. Such standardless discretion violates the United States Constitution. The power to make policy is the legislative power, and that power has been vested exclusively in the "Congress of the United States[.]" U.S. Const., art. I, § 1. It is by design that the power to make policy—to set priorities among competing interests—was vested in the Congress, an institution comprised of two Houses, selected at different times from different constituencies. While broad delegations to the Executive branch have been upheld by the judiciary, the provision here goes further than prior delegations. Section 387a(b) of the Tobacco Control Act violates Article I of the Constitution, and the Deeming Rule—promulgated pursuant to this invalid delegation of legislative power—may not be enforced.

JURISDICTION AND VENUE

6. This civil action arises under the United States Constitution. This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1331 (federal question jurisdiction). Declaratory relief is authorized by 28 U.S.C. § 2201, and injunctive relief by 28 U.S.C. § 2202 and Federal Rule of Civil Procedure 65.

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that further demonstrates why delegating standardless legislative power to the Executive branch is untenable.

7. Venue is proper under 28 U.S.C. § 1391(e)(1) because Plaintiff Big Time Vapes resides in this district and Division.

PARTIES

8. Plaintiff Big Time Vapes is an S-Corporation organized under the laws of Mississippi, with its principal place of business at 711 Memorial Boulevard, Picayune, Mississippi 39466. Belinda Dudziak is the sole owner. Ms. Dudziak began smoking traditional cigarettes at the age of sixteen. From the age of nineteen to forty-six, she smoked one-and-a-half to three packs a day. After picking up her first e-cigarette in 2011 or 2012, she quit smoking traditional cigarettes entirely within *three to four days*. She started with a blend of 18% nicotine and gradually reduced to zero nicotine content. She now vapes exclusively without nicotine. She established Big Time Vapes, a retailer and "manufacturer" of vaping products, in 2015, and now employs six full-time employees, not including herself. She has approximately 4,000 customers, 98% of whom have quit smoking cigarettes completely. Big Time Vapes makes its own flavors—350 of them—which can be sold with various levels of nicotine content (from 0-24 mils), and in six different bottle sizes. Due to the various combinations possible with these variables (all the flavors, with all variations of nicotine content, in six different bottle sizes), she has registered 98,000 stock keeping units (SKUs) with FDA. It is impossible for Big Time Vapes to submit the premarket review applications that would be required for it to comply with the Tobacco Control Act.

9. Plaintiff United States Vaping Association (USVA) is a trade association organized in accordance with Section 501(c)(6) of the Internal Revenue Code, with its principal place of business at 100 E. Whitestone Blvd., 148, Cedar Park, Texas 78613. USVA was 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. The Deeming Rule's effects were a primary motivation for organization of the USVA. The USVA currently has approximately three dozen paid members, and is growing. With a focus on representing the needs of small-business vaping industry participants, the USVA also furthers its mission by developing recommended industry best practices, and assisting its members in efforts to prepare for and comply with the new regulatory environment. The USVA has standing to bring this suit because (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *United Food and Commercial Workers Union Local 751 v. Brown Group, Inc.*, 517 U.S. 544, 553 (quoting *Hunt v. Washington State Apple Advertising Com'n*, 432 U.S. 333, 432 (1977)).

10. Defendant Food and Drug Administration is an agency of the United States government within the Department of Health and Human Services, with an office at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993. The Secretary of Health and Human Services has purported to delegate to FDA the authority to administer the Tobacco Control Act.

11. Defendant Norman E. "Ned" Sharpless, M.D., is Acting Commissioner of Food and Drugs and is the senior official of the FDA. He is sued in his official capacity. Dr. Sharpless maintains an office at 10903 New Hampshire Avenue, Silver Spring, Maryland 20993.

12. Alex M. Azar, II is Secretary of Health and Human Services and the official charged by law with administering the Act. He is sued in his official capacity. Secretary Azar maintains an office at 200 Independence Avenue SW, Washington, D.C. 20201.

13. All Defendants are collectively referred to hereinafter as "FDA."

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