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."

LEGAL BACKGROUND

The "Nondelegation" Doctrine in General

14. The Constitution provides that "*[a]ll* legislative Powers herein granted shall be vested in a Congress of the United States." U.S. Const., Art. I, § 1 (emphasis added).

15. "From this language the [Supreme] Court has derived the nondelegation doctrine: that Congress may not constitutionally delegate its legislative power to another branch of government." *Touby v. United States*, 500 U.S. 160, 165 (1991). While "all legislative powers" were granted to the people's representatives in Congress, Article II vests the "[t]he executive Power" in the President, and Article III vests "[t]he judicial power" in the courts. Thus, "'[t]he nondelegation doctrine is rooted in the principle of separation of powers that underlies our tripartite system of Government.'" *Touby*, 500 U.S. at 165 (quoting *Mistretta v. United States*, 488 U.S. 361, 371 (1989)).

16. The essence of "legislative power" is the power to set out *the policy* by which private conduct is to be governed. In 1810, the Supreme Court described the legislative power as the power to "prescribe general rules for the government of society." *Fletcher v. Peck*, 10 U.S. (6 Cranch) 87, 136 (1810). While the imposition of a particular policy can be made conditional on the Executive's finding of the existence of a designated fact or circumstance, the designation of those circumstances—the circumstances in which such policy shall become effective—is fundamentally legislative. *See Marshall Field & Co. v. Clark*, 143 U.S. 649, 693 (1892) ("Legislative power was exercised when congress declared that the suspension should take effect *upon a named contingency*.") (emphasis added).

17. The Supreme Court's statement of the relevant inquiry in *Panama Refining Company v. Ryan* illustrates the fundamental character of the legislative power:

> [T]he question whether th[e interstate] transportation [of "hot oil" extracted in violation of state standard's] shall be prohibited by [federal] law is obviously one of legislative policy. Accordingly, we look to the statute to see whether the Congress has declared a policy with respect to that subject; whether the Congress has set up a standard for the President's action; whether the Congress has required any finding by the President in the exercise of the authority to enact the prohibition.

293 U.S. 388, 415 (1935) (holding certain Executive Orders and regulations issued by Secretary of the Interior to be invalid under the nondelegation doctrine).

The Tobacco Control Act

18. In 2009, Congress amended the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq.* ("FD&C Act") by passing 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*.[3] The Tobacco Control Act mandates that "[t]obacco products … shall be regulated by the Secretary [of Health and Human Services] under this subchapter and shall not be subject to the provisions of subchapter V." 21 U.S.C. § 387a. (Subchapter V of the FD&C Act governs "drugs" and "devices.").

19. "Tobacco product" is defined 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).

20. The terms "component," "part," and "accessory" are not further defined by statute.

21. While tobacco products fitting the statutory definition were extant in many and long-established forms when Congress enacted the TCA—including cigarettes, cigars, smokeless

[3] The TCA comprises subchapter IX of the Food, Drug, and Cosmetic Act (FDCA), which is codified in chapter 9 of title 21 of the United States Code.

tobacco, and hookah—Congress did not choose to impose the Act's requirements on all such forms of tobacco products. Instead, Section 901 of the TCA provides that "[t]his chapter 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 chapter." *Id.*, *codified at* 21 U.S.C. § 387a(b).

22. "Roll-your-own tobacco" is defined to mean "any tobacco product which … is suitable for use and likely to be offered to, or purchased by, consumers as tobacco *for making cigarettes*." 21 U.S.C. § 387(15) (emphasis added).

23. Therefore, Congress itself imposed the TCA only upon cigarettes and cigarette tobacco, and "smokeless tobacco," which is limited to "any tobacco product that consists of cut, ground, powdered, or leaf tobacco and that is intended to be placed in the oral or nasal cavity." *Id.* § 387(18). Left unregulated were all other forms of tobacco products, including such widely used products as cigars (premium and all other varieties) and hookah.

24. While Congress itself declined to impose the TCA's requirements on anything other than cigarettes or "smokeless tobacco," it purported to vest the Secretary of Health and Human Services with the authority impose the Act on "any other tobacco products that the Secretary by regulation deems to be subject to [the TCA]." 21 U.S.C. § 387a(b).[4]

25. The TCA imposes a variety of regulatory requirements on tobacco products subject to it.

[4] While the statute delegates deeming authority to "the Secretary [of HHS]," through a staff manual, the Secretary sub-delegated this power to the FDA Commissioner. FDA Staff Manual Guide 1410.10. The FDA Commissioner, in turn, sub-delegated this power to the Associate Commissioner for Policy. FDA Staff Manual Guide 1410.21 (authorizing the Associate Commissioner for Policy to assume the FDA Commissioner's authority to issue "proposed and final regulations").

26. Many of the most onerous burdens apply to "tobacco product manufacturers," a term whose application is broader than it might first appear. The TCA defines "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).

27. In the Deeming Rule, FDA's application of the term "manufacturer" captures the vast majority of "e-cigarette retail stores and vape establishments." 81 Fed. Reg. at 28,979. FDA explained that "establishments that mix or prepare e-liquids or create or modify aerosolizing apparatus for direct sale to consumers are tobacco product manufacturers under the definition set forth in the FD&C Act and, accordingly, are subject to the same legal requirements that apply to other tobacco product manufacturers." *Id.*

28. The Act requires each covered manufacturer, including Plaintiff Big Time Vapes and the businesses represented by the USVA, to provide FDA a list of all ingredients and compounds added to its products, as well as any and all documentation pertaining to the products' health and related effects. 21 U.S.C. § 387d(a)-(b). The Act also requires manufacturers to register their places of business and their product listing with the agency. *Id.* § 387e. It prohibits, among other things, the marketing of any covered "new tobacco product" without the FDA's approval, unless the product is grandfathered. *Id.* § 387j. The effect of this provision is that any covered tobacco product that was "not commercially marketed in the United States as of February 15, 2007" is banned from the marketplace without prior FDA approval. *See id.* § 387j(a).

29. There are two main pathways for FDA approval to market a "new tobacco product" covered by the TCA.

30. The less onerous pathway is to demonstrate that the new product is "substantially equivalent" to a product that was being commercially marketed in the United States on the February 2007 grandfather date. 21 U.S.C. § 387j(b). Substantial equivalence is demonstrated if the product "(i) has the same characteristics[5] of the predicate tobacco product; or (ii) has different characteristics and the information submitted [in the substantial equivalence report] contains information … that demonstrates that it is not appropriate to regulate the product … because the product does not raise different questions of public health." *Id.* § 387j(a)(3)(A). If the FDA concludes that the new product is substantially equivalent to the predicate product, it must issue an order allowing the product to be commercially marketed. *Id.* § 387j(c).

31. If the sponsor of a covered new product cannot invoke the substantial equivalence pathway because there was no predicate product on the market as of February 15, 2007, it must seek FDA approval through a "premarket tobacco application," sometimes referred to as a "PMTA."[6] This process requires the development and submission of substantial amounts of data, *see* 21 U.S.C. § 387j(b), an arduous undertaking that FDA itself has estimated may cost the vaping industry hundreds of thousands of dollars or more *per product*. *See* FDA, Final Regulatory Impact Analysis 87-88 Tbls. 11(a) & 11(b) (2016).

32. The TCA requires the FDA either approve or deny a premarket review application within 180 days. 21 U.S.C. § 387j(c)(1)(A).

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[5] "Characteristics" means "the materials, ingredients, design, composition, heating source, or other features of a tobacco product." 21 U.S.C. § 387j(a)(3)(B).

[6] *See* U.S. DEP'T OF HEALTH AND HUMAN SERVICES, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry* at 1 (Jun. 2019), https://www.fda.gov/media/127853/download.

33. Failure to comply with the above-described provisions can result in a variety of serious consequences for manufacturers and retailers, including designation of one's products as misbranded or adulterated, *see* 21 U.S.C. §§ 387b, 387c, which in turn can trigger substantial civil penalties and imprisonment, 21 U.S.C. §§ 331, 333, as well as seizure of the offending products, 21 U.S.C. § 334.

STATEMENT OF FACTS

The Deeming Rule

34. FDA published the Deeming Rule in the Federal Register on May 10, 2016.

35. In the Deeming Rule, FDA exercised its authority under 21 U.S.C. § 387a(b), decreeing that it "deems all products meeting the statutory definition of 'tobacco product,' except accessories of the newly deemed tobacco products, to be subject to FDA's tobacco product authorities under chapter IX" of the FD&C Act. 21 Fed. Reg. 28,976 (emphasis added). FDA explained the breadth of the Rule:

> Products that meet the statutory definition of "tobacco products" include currently marketed products such as dissolvables not already regulated by FDA, gels, waterpipe tobacco, ENDS (including e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes), cigars, and pipe tobacco.
>
> In addition, this final rule deems any additional current and future tobacco products that meet the statutory definition of "tobacco product," except accessories of such newly deemed products, to be subject to FDA's authorities under chapter IX of the FD&C Act. For example, FDA envisions that there could be tobacco products developed in the future that provide nicotine delivery through means (e.g., via dermal absorption or intranasal spray) similar to currently marketed medicinal nicotine products, but which are not drugs or devices. These products would be "tobacco products" and subject to FDA's chapter IX authorities in accordance with this final deeming rule.

81 Fed. Reg. 28,976.[7]

36. Application of the TCA to ENDS and all other newly-deemed products imposed immediate restrictions upon the effective date of the Rule (August 8, 2016), including the required submission of ingredient listing, "manufacturer" registration and product listing, prohibition of the sale or distribution of products bearing 'modified risk' descriptions (such as 'light,' 'low,' or 'mild') without FDA approval (subject to a separate "Modified Risk" approval process), and a prohibition on distribution of free samples. *See* Deeming Rule, 81 Fed. Reg. at 28,976.

37. The TCA also would have authorized FDA to halt sales of newly-deemed products until the TCA-required premarket review applications were processed and approved. *See* 21 U.S.C. § 387b (finding a tobacco product is adulterated if it is required to have a premarket review order but does not have one); *id.* § 331(a) (making it unlawful to introduce an adulterated tobacco product into interstate commerce). But as part of the Deeming Rule, FDA opted to implement the statutory requirement more gradually, establishing a "staggered initial compliance period":

> [M]anufacturers of all newly deemed, new tobacco products will have a 12-, 18- or 24-month initial compliance period in which to prepare applications for marketing authorization, as well as a 12-month continued compliance period after those dates in which to obtain authorization from FDA (resulting in total compliance periods of 24, 30, or 36 months). After the close of the continued compliance period, products will be subject to enforcement unless they are grandfathered or are the subject of a marketing authorization order.

81 Fed. Reg. at 28978.

38. Because ENDS products are not eligible for grandfathering or the "substantial equivalence" pathway, the FDA acknowledged that "nearly all ENDS products will be subject to

[7] Plaintiffs note the acronym "ENDS"—short for "electronic nicotine delivery systems" and deployed by FDA in the Deeming Rule—can be misleading, given that many persons who vape cease using nicotine blends at at all, and vape only the flavors. Nonetheless, Plaintiffs utilize the term interchangeably herein with "vaping" products.

premarket review," and the FDA candidly predicted "considerable product consolidation and [market] exit." Regulatory Impact Analysis, AR 23,912-24,067 ("RIA"). This is because any variation, however slight, of any ingredient or component of either an e-liquid or an ENDS delivery device, would render the product a unique "new tobacco product" as defined in the TCA and therefore require its own unique premarket review application.

39. FDA itself estimated that an initial premarket review application for e-liquids would cost between $181,686 and $2,014,120 per application, and applications for delivery devices it estimated would cost between $285,656 and $2,622,224 per application. RIA, AR 23,998 (Table 11a), AR 24,001-02 (Table 12a).

40. Under the "staggered compliance policy," a manufacturer submitting a premarket review application was initially required to do so by August 8, 2018—24 months after the Rule became effective. *Id.* at 28,977-78 (describing compliance periods for the different pathways). FDA stated that it would then allow an additional 12-month period for review and approval of the PMTA before enforcement would commence, and would defer enforcement even further on a case-by-case basis. *Id.* at 28,978 ("However, if at the time of the conclusion of the continued compliance period, the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.").

41. FDA subsequently extended the compliance deadlines. First, in May 2017, it extended the deadlines outlined in the Deeming Rule by three months.[8] Then, in August 2017,

[8] *Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry* (May 2017).

FDA announced another extension applying "only to compliance deadlines relating to premarket review requirements." *Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry (Revised)* ("August 2017 Guidance"). The August 2017 Guidance amended the FDA's prior compliance approach in substantive ways.

42. For example, whereas the Deeming Rule's "staggered compliance schedule" set out different deadlines for submission of applications by *application type* (substantial equivalence, exception to substantial equivalence, or premarket review), the August 2017 Guidance distinguished between *product type*. The deadline for any type of application regarding a newly deemed combustible tobacco product was established as August 8, 2021, and the deadline for any type of application for a noncombustible product was established as August 8, 2022. *See August 2017 Guidance* at 3, 8.

43. Additionally, the August 2017 Guidance "revis[ed] the compliance policy relating to the period after FDA receipt" of product applications. *Id.* at 3. In the Deeming Rule, FDA had established a 12-month compliance period for FDA review. The August 2017 Guidance reverted to a less definite compliance period pending review of submitted applications. *Id.* ("Under this new compliance policy, there will be a continued compliance period pending review of [marketing] applications … [t]his compliance period will continue until the agency renders a decision on an application … or the application is withdrawn.").

44. However, FDA has now been ordered by the federal district court for the District of Maryland to severely accelerate the compliance deadlines. In *American Academy of Pediatrics v. Food and Drug Administration*, the district court held that the Administrative Procedures Act applied to the FDA's compliance guidance establishing the deadlines, and that FDA had failed to abide by the notice and comment requirements. 379 F. Supp. 3d 461 (D. Md. 2019). After briefing

by the parties as to the appropriate remedy, in a subsequent order issued July 12, 2019, the District Court for the District of Maryland vacated FDA's August 2017 Guidance, and ordered as follows:

> 1. [T]he FDA shall require that, for new tobacco products on the market as of the August 8, 2016 effective date of the Deeming Rule ("New Products"), applications for marketing orders must be filed within 10 months of the date of this Memorandum Opinion and Order;
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> 2. New Products for which applications have not been filed within this period shall be subject to FDA enforcement actions, in the FDA's discretion;
>
> 3. New Products for which applications have been timely filed may remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application;
>
> 4. The FDA shall have the ability to exempt New Products from filing requirements for good cause on a case-by-case basis.

American Academy of Pediatrics v. Food and Drug Administration, No. 8:18-cv-00883-PWG, 2019 WL 3067492, at *7 (D. Md. Jul. 12, 2019).

45. In other words, rather than allowing premarket review applications to be submitted for ENDS products by August 2022, FDA has been ordered to require their submission by May 2020.[9] This severely accelerates the period within which Plaintiffs and others similarly situated are expected to prepare and file the complex PMTAs that even the FDA acknowledges are prohibitively expensive, and predicted would prompt "considerable product consolidation and [market] exit." RIA, AR 23,989-90 (FDA itself assuming that "54 percent of delivery systems and somewhere between 50 and 87.5 percent of e-liquids [would] not submit a marketing application and will exit the market after the initial compliance period … ends.").

[9] No formal order effectuating the court-mandated deadlines has yet been promulgated by FDA, as the Maryland court held that such guidance will be subject to the APA's notice and comment requirements. *See* 2019 WL 3067492, at *1 (indicating that while FDA need not effectuate the court's order through a formal rulemaking, it must do so through guidance following the notice and comment period).

Impact of the Deeming Rule on Plaintiffs

46. The Deeming Rule went into effect on August 8, 2016, subjecting all "retailers" and "manufacturers" (as defined in the TCA) of vaping industry products immediately to all of the requirements of the Tobacco Control Act, including the premarket approval, reporting, recordkeeping, inspection, labeling, manufacturing, and testing requirements.

47. Such regulations severely burden Plaintiffs and all businesses active in the vaping industry, from the larger firms and those that concentrate on manufacturing e-liquids and devices down to the smallest retail shops, many or most of which are also regulated as "manufacturers" under the TCA.

48. The Deeming Rule's premarket approval requirement has effectively frozen the vaping industry in time as of August 8, 2016, the Rule's effective date. This is because FDA's compliance policy only permits the continued marketing of vaping products that were "on the market on the effective date of [the Deeming Rule]." 81 Fed. Reg. at 28,978. "Manufacturers" are therefore prohibited from introducing any variations on their e-liquids or other products unless they request and receive a marketing authorization order permitting marketing of any new products.

49. For vaping products that *were* on the market as of August 8, 2016, "manufacturers" are required to either submit the required premarket approval applications or face an effective ban on the continued marketing of their products. *See* Deeming Rule, 81 Fed. Reg. at 28,978 ("Any such newly deemed tobacco product for which an application…has not been submitted…will not benefit from this continued compliance policy and will be subject to enforcement as of that date."). While FDA's August 2017 Guidance had allowed until August 2022 for such applications, FDA has been ordered to accelerate that deadline to May 2020. Plaintiff Big Time Vapes, the businesses

represented by the USVA, and countless other similarly situated small businesses regulated as "manufacturers" must either submit a premarket application for each of their products or face enforcement action, including injunction and seizure of their products, and other civil and criminal penalties. The premarket approval requirement is prohibitively arduous, expensive, and complicated, and will force significant disruption and "market exit," just as FDA itself predicted. Many businesses will be extinguished completely, and any that survive will be forced to reduce product offerings simply because they cannot afford to submit the required premarket applications.

50. Even if Plaintiff Big Time Vapes or others represented by the USVA attempt to complete and submit the requisite premarket applications by the May 2020 deadline, doing so will force a major redirection of resources from day to day business operations and research and development to compliance.

51. For these reasons and for others given in this Complaint, there exists an actual and justiciable controversy between Plaintiffs and Defendants requiring resolution by this Court.

FIRST CLAIM FOR RELIEF

The Tobacco Control Act Cedes Legislative Authority to the Executive in Violation of Article I of the Constitution

52. Plaintiffs re-allege and incorporate by reference all of the allegations contained in the preceding paragraphs.

53. The Constitution provides that "[a]ll legislative Powers herein granted shall be vested in a Congress of the United States, which shall consist of a Senate and House of Representatives." U.S. Const., art. I, § 1.

54. The Constitution authorizes Congress "[t]o make all Laws which shall be necessary and proper for carrying into Execution" its general powers. U.S. Const., art. I, § 8, cl. 18.

55. The Constitution bars Congress from delegating to others the essential legislative functions with which it is vested.

56. The essence of "legislative power" is the power to set out *the policy* by which private conduct is to be governed.

57. Section 901 of the TCA provides that "[t]his chapter 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 chapter**." *Id.*, *codified at* 21 U.S.C. § 387a(b) (emphasis added). Congress itself chose only to impose the TCA's onerous requirements on cigarettes and smokeless chewing tobacco, leaving unregulated cigars, hookah, and myriad other "tobacco products" in wide use at the time the Act was passed. Congress punted to the "Secretary [of HHS]" the question whether, and if so, when, to subject any other "tobacco products" to the TCA's strictures. Congress provided no guidelines, no factors, no parameters, and no hints to guide the Secretary's deeming discretion.

58. While it is true that statutes vesting the Executive branch with authority in broad terms have been upheld by the Supreme Court, § 387a takes the delegation of legislative power to new territory. It does not even impose the minimal, broadly-worded guidance that has allowed other statutes to survive.

59. That Congress vested the Secretary with absolute discretion to deem or not deem any given "tobacco product" has been recognized by the federal district court for the District of Columbia. In *Nicopure Labs, LLC v. Food and Drug Administration*, the district court noted that "the statute did not provide standards for when and how the agency was to exercise its discretion

to deem[.]" 266 F. Supp. 3d 360 (D.D.C. 2017), *appeal docketed*, No. 17-5196 (D.C. Cir.).[10] This is commensurate with FDA's express argument: that "Congress's choice of the deferential word 'deems' *and the absence of any standard*—beyond the requirement that the product meet the definition of a 'tobacco product'—demonstrate that Congress committed the exercise of this authority to the agency's broad discretion." *See id.* at 392 (quoting FDA's argument) (emphasis added).

60. The absence of any standard is something the FDA had already relied upon in its rulemaking, in the course of rejecting commenters' suggestions that deeming ENDS should be deferred. FDA rejected the suggestion to defer, stating that it did not have to "meet a particular public health standard to deem tobacco products." *See* Deeming Rule, 81 Fed. Reg. at 28,983.[11]

61. Therefore, absent any statutory limitations, the Secretary was free to deem, or to not deem, one type of tobacco product or another, to deem all of them or none of them, at his or her executive whim.

62. Free of any statutory standards or parameters to guide its deeming decisions, FDA's own public statements reflect that it has made its deeming decisions and the follow-on compliance guidance based on its own conception of the public interest, considering and weighing whatever

[10] The *Nicopure* court made this statement in the course of holding that the only substantive limitation on the Secretary's deeming authority, and thus justiciable for purposes of Nicopure's APA challenge, is that deeming extends only to "tobacco products." 266 F. Supp. 3d at 393. Nicopure did not allege that the statute violates the nondelegation principle. To counsel's knowledge, the nondelegation doctrine has not been asserted in any other litigation involving the Deeming Rule.

[11] This statement was also relied upon by the district court in *Nicopure*, in the course of holding that FDA was not required to accept any suggested regulatory alternatives under the APA. 266 F. Supp. 3d at 398; *see also id.* at 401 (holding that "[t]he statute does not limit the Secretary's authority to deem to when he finds it 'appropriate and necessary' to do so," and therefore there is "no source for a requirement that costs be taken into account when the deeming power is exercised").

factors and interests it wants, in whatever manner it believes best. So, while former Commissioner Scott Gottlieb recognized that "what primarily causes death and disease from tobacco use isn't the nicotine" but "the act of lighting tobacco on fire to free that drug for inhalation," and "E-cigarettes may present an important opportunity for adult smokers to transition off combustible tobacco products," he also explained that FDA was concerned with the incidence of youth use of (certain) ENDS products. FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use* (Sept. 12, 2018). Announcing an expected modified approach to its manner of reviewing premarket applications for ENDS products, Gottlieb frankly acknowledged:

> This may create some obstacles for some adults who also enjoy e-cigs. **These are the hard tradeoffs that we're grappling with.** But the youth risk is paramount.
>
> It's now clear to me, that in closing the on-ramp to kids, we're going to have to narrow the off-ramp for adults who want to migrate off combustible tobacco and onto e-cigs.

Id. (emphasis added).

63. Whatever the merits of the factors considered relevant or compelling by former Commissioner Gottlieb, or the current Commissioner, or the next Commissioner, or the current or the next Secretary of HHS, those considerations and trade-offs are the essence of the legislative power, and that power is vested solely with the elected representatives in Congress. Article I requires that this debate occur in the House and the Senate, and it cannot be punted to the policy-development offices of Executive branch functionaries unbound by statutory guidance.

64. Plaintiffs have no adequate remedy at law to redress the injuries they are suffering under 21 U.S.C. § 387a, as the FDA has seized on the boundless authority ceded to it under that provision to issue the Deeming Rule.

65. Plaintiffs thus seek a declaration that 21 U.S.C. § 387a and the Deeming Rule, and any guidance or compliance requirements issued pursuant to the Deeming Rule, violate Article I, Section 1 of the Constitution and are unenforceable, and an injunction barring Defendants from implementing or administering the Deeming Rule.

SECOND CLAIM FOR RELIEF

Declaratory Judgment (28 U.SC. § 2201)

66. Plaintiffs re-allege and incorporate by reference all of the allegations contained in the preceding paragraphs.

67. There is an actual controversy of sufficient immediacy and concreteness relating to the legal rights and duties of the Plaintiffs and their legal relations with the Defendants to warrant relief under 28 U.S.C. § 2201.

68. The harm to the Plaintiffs as a direct result of the application of the TCA is sufficiently real and imminent to warrant the issuance of a conclusive declaratory judgment clarifying the legal relations of the parties.

PRAYER

Wherefore, Plaintiffs pray for relief as follows:

1. Declare Section 901 of the TCA, *codified at* 21 U.S.C. § 387a, to be in violation of Article I of the Constitution of the United States, and, consequently, the Deeming Rule promulgated under its authority to be invalid;
2. Declare Defendants to have violated the Plaintiffs' rights;
3. Enjoin Defendants and any other agency or employee acting on behalf of the United States from enforcing the TCA against the Plaintiffs or any other similarly situated

businesses, and to take such actions as are necessary and proper to remedy their violations deriving from any such actual or attempted enforcement; and

4. Award Plaintiffs their reasonable attorney's fees and costs, and grant such other relief as the Court may deem just and proper.

Respectfully submitted,

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*Motion for admission and for admission *pro hac vice* forthcoming.
+Motion for admission forthcoming.