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.)

declaratory judgment that 21 U.S.C. § 387a(b) violates the Constitution, such that the deeming rule is invalid. The plaintiffs also ask the Court to enjoin the defendants from enforcing the TCA against the plaintiffs or any other similarly situated businesses. The plaintiffs have filed a motion for preliminary injunction, and the defendants have filed a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6).

DISCUSSION

I. DEFENDANTS' MOTION TO DISMISS

When considering a motion under Rule 12(b)(6), the "court accepts 'all well-pleaded facts as true, viewing them in the light most favorable to the plaintiff.'" *Martin K. Eby Constr. Co. v. Dall. Area Rapid Transit*, 369 F.3d 464, 467 (5th Cir. 2004) (quoting *Jones v. Greninger*, 188 F.3d 322, 324 (5th Cir. 1999) (per curiam)). But "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007)). To overcome a Rule 12(b)(6) motion, a plaintiff must plead "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. "Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* at 555 (citations and footnote omitted).

Ordinarily, in considering a motion to dismiss under Rule 12(b)(6), the Court "must limit itself to the contents of the pleadings, including attachments thereto." *Collins v. Morgan Stanley Dean Witter*, 224 F.3d 496, 498 (5th Cir. 2000). An exception to this rule exists for "matters of public record," of which the Court may take judicial notice. *Norris v. Hearst Tr.*, 500 F.3d 454, 461 n.9 (5th Cir. 2007). Additionally, "[d]ocuments that a defendant attaches to a motion to dismiss are considered part of the pleadings if they are referred to in the plaintiff's complaint and are central to her claim." *Causey v. Sewell Cadillac-Chevrolet, Inc.*, 394 F.3d 285, 288 (5th Cir. 2004). "If . . . matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56." Fed. R. Civ. P. 12. The Court has not considered any matters outside of the pleadings while deciding the defendants' Motion; therefore, it is not necessary to treat the defendants' Motion to Dismiss as a motion for summary judgment.[4]

Article I, section 1 of the Constitution provides, "All legislative powers herein granted shall be vested in a Congress of the United States . . . ." U.S. Const. art. I, § 1. As a result, "Congress generally cannot delegate its power to another Branch." *Mistretta v. United States*, 488 U.S. 361, 372 (1989). Nevertheless, this

[4] The plaintiffs ask the Court to permit them to conduct discovery prior to ruling on the defendants' Motion to Dismiss, because the plaintiffs contend that the defendants have relied on documents outside the pleadings in support of their Motion. Because the Court has not considered any documents outside the pleadings, discovery is not necessary to determine whether the plaintiffs have stated plausible claims for relief.

nondelegation doctrine does not prevent Congress from delegating "at least some authority that it could exercise itself." *Loving v. United States*, 517 U.S. 748, 758 (1996). "So long as Congress shall lay down by legislative act an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform, such legislative action is not a forbidden delegation of legislative power." *Mistretta*, 488 U.S. at 372 (alterations in original). "Applying this 'intelligible principle' test to congressional delegations, our jurisprudence has been driven by a practical understanding that in our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives." *Id.* "The true distinction . . . is between the delegation of power to make the law, which necessarily involves discretion as to what it shall be, and conferring authority or discretion as to its execution, to be exercised under and in pursuance of the law. The first cannot be done; to the latter no valid objection can be made." *Loving*, 517 U.S. at 758-59. Apart from two 1935 cases, *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935), and *A.L.A. Schechter Poultry Corp. v. United States*, 295 U.S. 495 (1935), the Supreme Court has upheld every challenge to a congressional delegation of power that has been presented to it. *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 474 (2001).

Courts considering whether Congress has supplied an intelligible principle must "construe the challenged statute to figure out what task it delegates and what instructions it provides." *Gundy v. United States*, 139 S. Ct. 2116, 2123

(2019). The delegation of legislative authority is "constitutionally sufficient if Congress clearly delineates the general policy, the public agency which is to apply it, and the boundaries of this delegated authority." *Mistretta*, 488 U.S. at 372-73 (quoting *Am. Power & Light Co. v. SEC*, 329 U.S. 90, 105 (1946)). "The standards of the statute are not to be tested in isolation but must derive meaningful content from the purpose of the statute and its factual background and the statutory context in which the standards appear." *United States v. Womack*, 654 F.2d 1034, 1037 (5th Cir. 1981) (citing *Am. Power & Light Corp.,* 329 U.S. at 105). "[T]he degree of agency discretion that is acceptable varies according to the scope of the power congressionally conferred." *Am. Trucking Ass'ns*, 531 U.S. at 475.

The plaintiffs argue that the TCA is unconstitutional, because it gives the FDA no guidance for determining whether a tobacco product should be governed by the TCA. Contrary to the plaintiffs' assertions, Congress did not give the FDA unlimited discretion but restricted the FDA's discretion with a controlling definition of "tobacco product."[5] In addition, Congress, itself, designated certain tobacco products as governed by the TCA[6] and presented detailed policies behind its enactment of the TCA. For example, Congress clearly expressed a desire to protect the public health and to prevent, to the extent possible, underaged persons from

[5] 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).

[6] Congress specified that the TCA "shall apply to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco . . . ." 21 U.S.C. § 387a(b).

having access to tobacco products. These listed policies and covered products provide additional guidance to the FDA for determining which additional tobacco products should be governed by the TCA. This case is analogous to *United States v. Womack*, wherein the Fifth Circuit held that Title XI of the Organized Crime Control Act of 1970 provided the Secretary of the Treasury with adequate standards for listing additional explosives covered by the Act where Congress provided a definition of the term "explosives" and gave an illustrative list of explosives subject to the Act. 654 F.2d at 1037. In the opinion of the Court the TCA does not violate the Constitution, and the plaintiffs have not stated a plausible claim for relief.

II. PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

> A movant is entitled to a preliminary injunction only if he establishes:
>
> (1) a substantial likelihood of success on the merits, (2) a substantial threat of irreparable injury if the injunction is not issued, (3) that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted, and (4) that the grant of an injunction will not disserve the public interest.

Byrum v. Landreth, 566 F.3d 442, 444 (5th Cir. 2009). The plaintiffs cannot demonstrate a substantial likelihood of success on the merits because they have not stated a plausible claim for relief. As a result, it is not necessary to consider the additional preliminary injunction elements. The plaintiffs' Motion for Preliminary Injunction is denied.

CONCLUSION

Congress provided sufficient guidance when it delegated authority to the FDA to designate which products should be governed by the TCA. Thus, the TCA

does not violate the United States Constitution. The defendants' Motion to Dismiss is granted, and the plaintiffs' Motion for Preliminary Injunction is denied.

IT IS, THEREFORE, ORDERED AND ADJUDGED that the [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 is **GRANTED**. This lawsuit is hereby **DISMISSED WITH PREJUDICE**. The Court will enter a separate judgment pursuant to Fed. R. Civ. P. 58.

IT IS, FURTHER, ORDERED AND ADJUDGED that the [15] Motion for Preliminary Injunction filed by the plaintiffs, Big Time Vapes, Inc., and United States Vaping Association, Inc., is **DENIED**.

SO ORDERED AND ADJUDGED this the 16th day of December, 2019.

s/ *Louis Guirola, Jr.*

LOUIS GUIROLA, JR.
UNITED STATES DISTRICT JUDGE