UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION
AT LEXINGTON

VAPOR TECHNOLOGY ASSOCIATION and VAPOR STOCKROOM, LLC, **Plaintiffs,** **V.** **UNITED STATES FOOD AND DRUG ADMINISTRATION, *et. al.*,** **Defendants.**	**CIVIL ACTION NO. 5:19-330-KKC** **OPINION AND ORDER**

*** *** ***

This matter is before the Court on several motions. Plaintiffs Vapor Technology Association and Vapor Stockroom, LLC brought suit in this Court seeking a declaratory judgment and injunctive relief and filed a separate motion for a preliminary injunction. (DE 1; DE 13.) Defendants United States Food and Drug Administration, United States Department of Health and Human Services, Dr. Norman E. Sharpless, in his official capacity as Acting Commissioner of Food and Drugs, and Alex Azar, in his official capacity as Secretary of Health and Human Services, filed a combined motion to dismiss the complaint and opposition to the preliminary injunction, as well as a motion to transfer the case. (DE 23; DE 24.) For the reasons stated below, the Court grants Defendants' motion to dismiss and, accordingly, denies Defendants' motion to transfer and Plaintiff's motion for a preliminary injunction as moot. Further, because the Court rules in Defendants' favor without consideration of *amici curiae's* proposed brief, it denies *amici curiae's* motion for leave to file (DE 27) as moot.

Background

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) ("Tobacco Control Act"), which amended the Food, Drug, and Cosmetic Act and gave the Food and Drug Administration the authority to regulate tobacco products. (DE 1 at 12.) Pursuant 21 U.S.C. § 387a(b), the Tobacco Control Act only explicitly applies to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco; however, that provision also grants the Secretary of Health and Human Services the authority to "deem[]" "any other tobacco products" subject to the statute's regulations. Among those regulations is § 387j(a), which requires that a manufacturer obtain authorization from the FDA *before* introducing a new tobacco product into interstate commerce. (DE 23 at 8-9.) There are three pathways for seeking such authorization; most relevant here is a premarket tobacco application ("PMTA") demonstrating that sale of the product would be appropriate for the public health. (DE 1 at 14-16; DE 23 at 9.)

Exercising its authority under § 387a(b), on May 10, 2016, the FDA issued a "deeming rule" that brought "e-liquids containing, and vapor devices containing or intended to be used with, nicotine derived from tobacco plants" under the purview of the Tobacco Control Act's regulations. (DE 1 at 13.) When the deeming rule took effect in August 2016, as many as 25,000 e-liquids and vaping products already on the market became subject to, and would suddenly be in violation of, § 387j(a). (DE 23 at 15.) However, in what the government calls "an exercise of its enforcement discretion," the FDA announced "compliance periods" – periods of time during which it would not bring enforcement actions against manufacturers of newly-regulated products for failure to obtain marketing authorization. (DE 23 at 15.) First the FDA said that PMTA submissions must be filed by August 8, 2018. (DE 1 at 16.) Then, in May 2017, the FDA extended the compliance periods by three months. (DE 23 at 16.) Finally, in August 2017, the FDA issued industry guidance that extended the deadline to

August 8, 2022 for noncombustible products, including most e-cigarettes. (DE 1 at 22; DE 23 at 16-17.)

On March 27, 2018, a group of physicians and public health organizations brought suit against the FDA in the United States District Court for the District of Maryland, challenging the August 2017 guidance's extension of the deadline to file PMTAs. (DE 1 at 32-33.) The plaintiffs in that suit asked the court "to vacate the August 2017 Guidance," arguing "that it is unlawful in that it exceeds the agency's statutory authority and is an express and deliberate abdication of FDA's responsibilities under the Tobacco Control Act;… was not promulgated in accordance with the [Administrative Procedure Act's] notice and comment requirements, despite being a substantive rule…; and is arbitrary and capricious and not the product of reasoned decisionmaking." *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461, 469 (D. Md. 2019) ("*AAP I*"). On May 15, 2019, Judge Paul W. Grimm ruled in favor of the plaintiffs. *Id.* at 470. Judge Grimm found that the FDA was "required to, but did not, follow the APA's notice and comment requirements [when it] issu[ed] the August 2017 Guidance, and therefore Defendants violated the APA by issuing it." *Id.* Judge Grimm granted the plaintiffs' motion for summary judgment and vacated the August 2017 guidance. *Id.* at 498. He also ordered that, since the original deadlines set in the deeming rule and previous FDA guidance had by then passed, the parties should "submit additional briefing regarding a remedy (which should be specific, rather than generalized)." *Id.* He instructed that –

> [a]ny Guidance providing for a compliance period will, of course, have to adhere to the notice and comment requirements of the APA. Even so, manufacturers long have been on notice that they will have to file premarket approval applications, substantial equivalence reports, and exemption requests, and if they have chosen to delay their preparations to do so, then any hardship occasioned by their now having to comply is of their own making. And, in adopting new Guidance, the APA can propose that the deadlines can be set sufficiently soon beyond the end of the

> notice and comment period to afford relief to Plaintiffs and to attempt to combat the epidemic-level use of new tobacco products like e-cigarettes, especially by teenagers.

Id.

On July 12, 2019, Judge Grimm issued the remedy opinion. *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 399 F. Supp. 3d 479 (D. Md. 2019) ("*AAP II*"). Judge Grimm determined that the court had "the authority to impose… a deadline under the extraordinary circumstances of this case in which prompt action is necessary to combat the epidemic-level rise in youth e-cigarette use, which undisputedly is a mounting public health crisis." *Id.* at 486 (citations and internal quotation marks omitted). The court ordered that –

> 1. the 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;
>
> 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.

Id. at 487. Both *AAP I* and *AAP II* are currently on appeal before the United States Court of Appeals for the Fourth Circuit. *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 379 F. Supp. 3d 461, *appeal docketed*, No. 19-2198 (4th Cir. Oct. 30, 2019); *Am. Acad. of Pediatrics v. Food & Drug Admin.*, 399 F. Supp. 3d 479, *appeal docketed*, No. 19-2198 (4th Cir. Oct. 30, 2019).

On August 14, 2019, Plaintiffs brought suit in this Court. (DE 1.) Plaintiff Vapor Technology Association ("VTA") is a trade association whose members, according to its own description, "are dedicated to developing and selling high quality vapor product [sic] that

provide adult consumers with a safer alternative to traditional combustible cigarettes." (DE 1 at 6.) Plaintiff Vapor Stockroom, LLC, a VTA member, is a Kentucky limited liability company that manufactures and sells nicotine-containing e-liquids. (DE 1 at 7.) Plaintiffs argue that the FDA having suggested a ten-month deadline in its briefing to the Maryland court "constituted a transparent attempt at regulation by litigation" and that "[i]n so doing, FDA circumvented the proper notice-and-comment procedure required by the Administrative Procedure Act… and deprived Vapor Stockroom and the VTA's other members of any realistic possibility of submitting a complete PMTA by the new deadline." (DE 1 at 37.) Plaintiffs seek a declaratory judgment that the "FDA's proposal and/or enforcement of the ten-month (i.e., May 2020) deadline" violated the Administrative Procedure Act and the Fifth Amendment's Due Process Clause, as well as injunctive relief –

> [p]reliminarily and permanently enjoining FDA to: (a) establish a proposed and final rule governing the submission of [PMTAs] and product standards for vapor products pursuant to a mandatory notice-and-comment rulemaking process; (b) set a reasonable, science-based, non-arbitrary deadline for the filing of PMTAs pursuant to the finalized rule after notice and comment; (c) refrain from taking enforcement action against any vapor products on the U.S. market as of August 8, 2016, until after the new filing deadline for PMTAs; and (d) refrain from taking enforcement action based on the failure of a vapor product manufacturer to submit a complete PMTA by May 11, 2020.

(DE 1 at 45-47.) Plaintiffs filed their motion for a preliminary injunction on September 2, 2019. (DE 13.)

On October 11, 2019, Defendants filed a combined motion to dismiss the complaint and opposition to the motion for a preliminary injunction, as well as a motion to transfer the case to the District of Maryland. (DE 23; DE 24.) In their motion to dismiss, Defendants argue, *inter alia*, that Plaintiffs do not have standing to pursue their claims and, therefore, the Court lacks jurisdiction. (DE 23.)

Analysis

I. Motion to Dismiss

Because Plaintiffs have failed to establish that the conduct which they challenge is sufficiently causally connected to their alleged injuries, they do not have standing to sue. Accordingly, the Court must dismiss the complaint for lack of subject-matter jurisdiction.

A. Standard

Defendants appear to move to dismiss Plaintiffs' complaint for both lack of subject-matter jurisdiction pursuant to FED. R. CIV. P. 12(b)(1), and for a failure to state a claim upon which relief can be granted pursuant to FED. R. CIV. P. 12(b)(6).[1] (DE 23 at 27-28.) The Court must consider the 12(b)(1) motion first – finding in Defendants' favor would render the 12(b)(6) motion moot, since determining the validity of a claim would itself be an exercise of jurisdiction. *Moir v. Greater Cleveland Reg'l Transit Auth.*, 895 F.2d 266, 269 (6th Cir. 1990) (citing *Bell v. Hood*, 327 U.S. 678, 682 (1946)).

"Standing goes to a court's subject matter jurisdiction." *Kepley v. Lanz*, 715 F.3d 969, 972 (6th Cir. 2013) (citation, internal quotation marks, and brackets omitted). "Plaintiffs have the burden of establishing standing," and "[i]f they cannot do so, their claims must be dismissed for lack of subject matter jurisdiction." *In re Foreclosure Cases*, 521 F. Supp. 2d 650, 653 (S.D. Ohio 2007) (citing *Loren v. Blue Cross & Blue Shield of Mich.*, 505 F.3d 598, 606-07 (6th Cir. 2007)). There are three elements to "the irreducible constitutional minimum of standing," *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992) –

> [f]irst, the plaintiff must have suffered an injury in fact – an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical. Second, there must be a causal connection between the injury and the conduct complained of – the injury has to be fairly... traceable to the challenged action of the defendant, and

[1] Even though this is not entirely clear, FED. R. CIV. P. 12(h) empowers the Court to *sua sponte* dismiss an action for lack of subject matter jurisdiction. *Wagenknecht v. United States*, 533 F.3d 412, 416 (6th Cir. 2008).

> not... the result of the independent action of some third party not before the court. Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Id. at 560-61 (citations, internal quotation marks, and brackets omitted).

B. Discussion

With its best interpretation of the briefings, the Court understands that the "challenged action," *Lujan*, 504 U.S. at 560, which Plaintiffs allege has caused them injury is Defendants having proposed the ten-month deadline to the District Court for the District of Maryland. (DE 1 at 37, 44-47.) As a result of this proposal, the complaint asserts, Plaintiffs now face the "conundrum," or "Hobson's choice," of deciding whether to "spend millions of dollars" on regulatory filings – which they claim will "of necessity" be impossible to complete by the deadline – or, chance potential enforcement actions while they await further, possible regulations or guidance. (DE 1 at 5, 42, 45, 47.) Plaintiffs further allege that if the Court does not grant the relief that they seek, "the overwhelming majority of the vaping industry, including over 160,000 jobs at small- and medium-sized businesses, will be destroyed" (DE 1 at 5-6), and that "the net result will be the virtual overnight elimination of the vapor industry as it currently exists in the United States" (DE 1 at 42). In sum, they argue that Defendants' proposal to the Maryland court, because it led to a revised regulatory deadline – which Plaintiffs are unprepared and without sufficient guidance to meet – created injurious financial consequences in the present and future.

Even assuming that Plaintiffs have properly alleged an injury for standing purposes, they, at the least, fail to make the requisite showing of causation. Because the alleged injuries are "the result of the independent action of some third party not before the court" – Judge Grimm's orders in *AAP I* and *AAP II* – Plaintiffs have failed to show the appropriate causal connection between their injuries and Defendants' conduct. *Lujan*, 504 U.S. at 560 (citation,

internal quotation marks, and brackets omitted). For the present purposes, it is of no consequence if it is the Defendants, rather than Judge Grimm, who will literally impose and enforce the regulatory deadline against Plaintiffs (DE 31-1 at 1, 10-11) because "[a] party must obey an order entered by a court with proper jurisdiction, even if the order is clearly incorrect." *Johnson v. Merrill Lynch*, 719 F.3d 601, 606-07 (7th Cir. 2013) (citation, internal quotation marks, and emphasis omitted); *see also Howat v. Kansas*, 258 U.S. 181, 190 (1922) ("It is for the court of first instance to determine the question of the validity of the law, and until its decision is reversed for error by orderly review… its orders based on its decision are to be respected.") As the District Court for the District of Columbia held in a recent, similar suit brought by cigar industry plaintiffs, "the predicament in which Plaintiffs find themselves… was caused not by any action or inaction by the [FDA]; rather, it is entirely a function of a judicial ruling." *Cigar Ass'n of America v. U.S. Food & Drug Admin.*, No. 1:16-cv-01460 (APM), 2019 WL 6647261, at *1 (D.D.C. Oct. 18, 2019). The Court finds that it was the District Court for the District of Maryland, and not the FDA, which set the deadline that gives rise to Plaintiffs' alleged injuries.

Plaintiffs assert that the FDA's "proposal of the ten-month deadline was… a 'motivating factor' in the setting of [the] accelerated timetable and demonstrably increased the risk that the Maryland District Court would establish an accelerated timetable," citing *Parsons v. U.S. Dep't of Justice*, 801 F.3d 701, 714 (6th Cir. 2015). (DE 31-1 at 12-13.) The Sixth Circuit in *Parsons* noted, in the relevant part, that "it is still possible to motivate harmful conduct without giving a direct order to engage in said conduct," and that "[i]n the nebulous land of 'fairly traceable,' where causation means more than speculative but less than but-for, the allegation that a defendant's conduct was a motivating factor in the third party's injurious actions satisfies the requisite standard." *Id.* Plaintiffs in that case – several fans of the music group Insane Clown Posse who self-identify as "Juggalos" – brought suit

against the Justice Department and the FBI after they were stopped, detained, and/or questioned by law enforcement officers. *Id.* at 705, 713-14. The plaintiffs alleged that their injuries were caused by the FBI's National Gang Intelligence Center having classified Juggalos "as a 'loosely-organized hybrid gang;'" for example, an officer who "considered Juggalos to be a criminal gang based on the DOJ's designation" had stopped, detained, and searched one of the plaintiffs because of a logo on his truck associated with Juggalos. *Id.* at 707, 713. The genesis of the "motivating factor" standard that Plaintiffs cite is in that court's discussion of whether causation was broken by the "officers' voluntary conduct," considering that the FBI never "direct[ed]" officers to take action against Juggalos. *Id.* at 714.

According to Plaintiffs, "the fact that FDA's suggestion motivated the court to establish precisely the deadline proposed is sufficient." (DE 31-1 at 14.) The Court rejects both the premise and the conclusion. First, and although it is not dispositive here, the reality of the government's briefing in *AAP II* significantly undercuts Plaintiffs' argument. Contrary to Plaintiffs' characterizations, the government argued to the Maryland court that the "bedrock principles of administrative law constrain [that] Court's authority" to enforce a specific deadline, and that the court should, instead, remand to the FDA. (DE 23 at 21.) According to Defendants, because the government "recognized the practical reality… that there was a substantial risk that Judge Grimm would disagree with the FDA's legal position about the court's limited authority to impose a specific remedy," it therefore "include[ed] a backstop argument… couched explicitly in the alternative" that the court should impose a deadline of no sooner than ten months from the date of its decision. (DE 23 at 21-22.)

Second, and more importantly, Plaintiffs' line of reasoning, including the reference to *Parsons*, is inapplicable here. Reliance on Plaintiffs' distorted analogy to that case renders an inaccurate conception of judicial decision-making. Even if the government had vigorously argued for the ten-month deadline, courts are not "motivated" by parties to rule in a certain

way. For example, this Court, after considering Defendants' and Plaintiffs' arguments on justiciability, is now dismissing Plaintiffs' suit, but not because it has been "motivated" to do so by Defendants; rather, because that is what it has determined the law requires.

II. Motion to Transfer

Defendants also move to transfer the case, under either the first-to-file rule or, alternatively, under 28 U.S.C. § 1404(a). (DE 24.) However, because Plaintiffs lack standing to sue, the Court will dismiss the case for lack of subject-matter jurisdiction and deny the motion to transfer as moot. *See IPXpharma, LLC v. Millennium Pharm., Inc.*, No. 3:14-cv-1545, 2014 WL 6977662, at *9 (M.D. Tenn. Dec. 9, 2014). "The 'first to file' rule is not an independent source of jurisdiction, and only becomes relevant if the transferor court has jurisdiction over the case." *Patterson v. John Drews, Invirion Diagnostics LLC*, No. C 09-2741 SI, 2009 WL 2474687, at *4 (N.D. Cal. Aug. 11, 2009). Similarly, "a court without subject matter jurisdiction cannot transfer a case to another court under 28 U.S.C. § 1404(a)." *Integrated Health Serv. of Cliff Manor, Inc. v. THCI Co.*, 417 F.3d 953, 957 (8th Cir. 2005).

Conclusion

Accordingly, the Court hereby ORDERS that:

1) Defendants' motion to dismiss (DE 23) is GRANTED;

2) Defendants' motion to transfer (DE 24) is DENIED as moot;

3) Plaintiffs' motion for a preliminary injunction (DE 13) is DENIED as moot;

4) *amici curiae's* motion for leave to file (DE 27) is DENIED as moot; and

5) a judgment will be entered contemporaneously with this order.

Dated January 16, 2020

Karen K. Caldwell

KAREN K. CALDWELL
UNITED STATES DISTRICT JUDGE
EASTERN DISTRICT OF KENTUCKY