UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
Lexington Division

VAPOR TECHNOLOGY ASSOCIATION, et al., Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, et al., Defendants.	)	Case No. 5:19-cv-00330-KKC

PLAINTIFFS' RESPONSE TO DEFENDANTS' NOTICE REGARDING NEW FDA ENFORCEMENT GUIDANCE DATED JANUARY 2, 2020, AND REQUEST FOR STATUS CONFERENCE AT THE EARLIEST AVAILABLE DATE

Plaintiffs Vapor Technology Association ("VTA") and Vapor Stockroom, LLC ("Vapor Stockroom"), respectfully submit this response to Defendants' notice (Doc. 46) advising the Court that on January 2, 2020, FDA released a new Guidance for Industry entitled "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization" ("Enforcement Priorities Guidance") (Doc. 46-1).

The Enforcement Priorities Guidance is a profoundly important document for the issues before the Court. Currently at issue in this litigation is whether FDA engaged in unlawful regulation by litigation when it superfluously suggested a highly accelerated PMTA deadline to the U.S. District Court for the District of Maryland in *American Academy of Pediatrics, et al. v. FDA, et al.*, Case No. 8:18-cv-883 (D. Md.). The Enforcement Priorities Guidance confirms that is exactly what FDA did, because FDA now has adopted the exact same date that the Maryland District Court ordered at FDA's suggestion. Specifically, on January 2, 2020, the FDA declared:

> The U.S. District Court for the District of Maryland has ordered that premarket applications for all deemed new tobacco products on the market as of August 8, 2016, be submitted by May 12, 2020. ***Even in the absence of this court***

> ***order, FDA would prioritize enforcement of any ENDS product that lacks a premarket application after May 12, 2020, for the reasons described in this guidance.*** . . . .

Enforcement Priorities Guidance, Doc. 46-1, at 27-28 (emphasis added). Lest there be any doubt, FDA further states that it "is prioritizing enforcement of premarket review requirements for ENDS products . . . and is doing so ***independently*** of the [Maryland] court order." *Id*. (emphasis added).

FDA's latest regulatory action therefore eviscerates its own core contention in this litigation—that FDA's suggestion of a highly accelerated PMTA deadline to the Maryland District Court was a mere "routine litigation precaution of including a backstop argument." Defs.' Combined Mot. to Dismiss and Opp'n to Pls.' Mot. for Prelim. Inj., Doc. 23 at 22; *see also* Defs.' Reply in Support of Mot. to Dismiss, Doc. 43 ("it is indisputable that the May 2020 deadline . . . was not set by the FDA").[1] Clearly, the May 2020 deadline is not a "backstop"; the accelerated deadline is the action FDA will take "[e]ven in the absence of" the Maryland litigation.

The Enforcement Guidance Document also eviscerates FDA's various other arguments, further undermining the motions it has presented to this Court. For example, FDA claimed Plaintiffs lacked Article III standing because it was the Maryland District Court, not FDA, that was to blame for Plaintiffs' untenable predicament of being forced to spend millions of dollars on PMTAs, the requirements for which are unclear and cannot be met by May 12, 2020, or face enforcement action that would put Plaintiffs out of business. *See, e.g.*, Doc. 23 at 30, 32-33. Those arguments are gone now that FDA has admitted that it has been planning enforcement action based

[1] Indeed, as evidence of Defendants' "heads we win, tails you lose" position, FDA has indicated in the appeal from the Maryland District Court's order pending in the United States Court of Appeals for the Fourth Circuit that the appeal is moot because, even if the remedy order had not been entered or was vacated, FDA would still take enforcement action after May 12, 2020. *See* Letter dated January 2, 2020, from Joshua Revesz, Esq. to Patricia S. Connor, Clerk, in *American Academy of Pediatrics v. United States Food and Drug Administration*, Appeal No. 19-2130 (4th Cir. Jan. 2, 2020), a copy of which is attached hereto as Exhibit A.

on the accelerated deadlines "independently" from the Maryland District Court's order. Enforcement Priorities Guidance, Doc. 46-1, at 28.

FDA's Enforcement Guidance Document also makes a mockery of Defendants' argument that the PMTA deadline could not constitute "final agency action," and thus could not be subject to review under 5 U.S.C. § 702, because the "10-month deadline was not set by the FDA." Doc. 23 at 36. FDA has now *set the exact same deadline* in the Enforcement Priorities Guidance.[2]

In short, FDA's publication of the Enforcement Priorities Guidance upends the issues in this litigation—all with the enforcement date of May 12, 2020, rapidly approaching. In light of this latest and most dramatic shift in FDA's constantly shifting regulatory positions, Plaintiffs intend to file a motion for leave to file an amended complaint to include new counts addressing the Enforcement Priorities Guidance and wish to file supplemental briefing on their pending motion for preliminary injunction. VTA, Vapor Stockroom and the VTA's other members continue to be irreparably harmed by the Hobson's choice with which FDA's actions present them.

Plaintiffs respectfully request that the Court convene a status conference at the earliest possible date to discuss how it would like the parties to proceed and to set a supplemental briefing schedule.

[2] The Enforcement Guidance Document eliminates most of Defendants' arguments to date in this litigation. For example, they have claimed that Plaintiffs' lawsuit is an impermissible collateral attack on the Maryland District Court's remedy order. *Id*. at 39-41. Yet, enjoining FDA from taking enforcement action against vapor products that FDA itself now readily admits it would take after May 12, 2020, "even in the absence of the [Maryland District] court order" cannot be reasonably contended to constitute a collateral attack on another district court's order. Finally, Defendants have tried to escape review of the accelerated PMTA deadline on the grounds that the "decisionmaker" setting the May 12, 2020 enforcement deadline "would have been FDA's litigation counsel at DOJ" or the Maryland District Court, rather than FDA itself. *Id*. at 47. That argument also falls by the wayside now that it is FDA itself that is enforcing the deadline.

Respectfully submitted,

THOMPSON HINE LLP

Dated: January 10, 2020

By: /s/ Eric N. Heyer

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CERTIFICATE OF SERVICE

I hereby certify that on this 10th day of January, 2020, I will cause the foregoing to be electronically filed via the Court's ECM/ECF system and thereby served on the following:

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Exhibit A

U.S. Department of Justice
Civil Division

Washington, D.C. 20530

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January 2, 2020

Ms. Patricia S. Connor, Clerk
United States Court of Appeals for the Fourth Circuit
1100 East Main Street, Suite 501
Richmond, VA 23219

Via CM/ECF

RE: *American Academy of Pediatrics v. United States Food and Drug Administration*, No. 19-2130 (4th Cir.)

Dear Ms. Connor:

Pursuant to Federal Rule of Appellate Procedure 28(j), we write to notify the Court that the Food and Drug Administration (FDA) today issued a new guidance document (attached), entitled Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization. In all relevant respects, FDA's new guidance supersedes the August 2017 guidance that is the subject of this litigation. The new guidance states how FDA intends to prioritize enforcement beginning 30 days after notice of its availability publishes in the Federal Register.

FDA's new guidance document states that FDA will prioritize enforcement of the Tobacco Control Act's premarket review requirements beginning on May 12, 2020 for all ENDS products. FDA will prioritize enforcement sooner for flavored, cartridge-based ENDS products (except for menthol and tobacco flavors); all other ENDS products for which the manufacturer fails to take adequate measures to prevent minors' access; and all ENDS products that are targeted to, or whose marketing is likely to promote use by, minors. FDA explained that it issued the guidance largely in response to increasing evidence of youth e-cigarette use. And it stated that it chose to prioritize enforcement of the Act's premarket review requirements for all e-cigarette products by May 12, 2020, independent of the district court's order in this case. FDA also explained that with respect to all other deemed products, after May 12, 2020, it intends to prioritize enforcement based on the likelihood of youth use or initiation, in order to make the most efficient use of its resources and address its most pressing public health concerns.

The new guidance confirms that the industry groups' motions for stays pending appeal should be denied. FDA's decision to reconsider its enforcement priorities underscores that the industry groups have no legally protected interest in any enforcement timetable, and are therefore not entitled to a stay. *See* Gov't Stay Opp'n 9-10.

Indeed, the government respectfully suggests that FDA's new guidance document may well moot the intervenors' appeals in this case. The government will address the question of mootness in its opening brief.

Sincerely,

/s/ *Joshua Revesz*
JOSHUA REVESZ
Attorney for the Federal Appellants

CERTIFICATE OF SERVICE

I hereby certify that on January 2, 2020, I electronically filed the foregoing with the Clerk of the Court by using the appellate CM/ECF system. I certify that the participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ *Joshua Revesz*
JOSHUA REVESZ
Attorney for the Federal Appellants

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

VAPOR TECHNOLOGY ASSOCIATION, *et al.*,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.[1]

Civil Action No. 5:19-cv-00330-KKC

NOTICE

In Defendants' motion to dismiss, Defendants stated that "while the *AAP* court ordered premarket applications for all new deemed products to be filed by May 12, 2020, in the meantime the FDA intends to finalize a compliance policy in the coming weeks that would prioritize the agency's enforcement of the premarket authorization requirements for flavored e-cigarettes that appeal to youth." ECF No. 23 at 27. "As of the date of th[at] filing, that new compliance policy ha[d] not yet been issued." *Id.* at 27 n.26.

Defendants respectfully notify the Court that, on January 2, 2020, the Food and Drug Administration issued a new guidance document titled *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization*. "The guidance describes, among other things, how FDA intends to prioritize its enforcement resources with regard

[1] Dr. Stephen M. Hahn is automatically substituted as a Defendant in his official capacity as Commissioner of Food and Drugs, pursuant to Federal Rule of Civil Procedure 25(d).

to the marketing of ENDS products that do not have premarket authorization." 85 Fed. Reg. 720 (Jan. 7, 2020) (notice of availability). The full guidance document is attached to this filing as Exhibit 1.

January 7, 2020

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