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-LG-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,	§	ORAL ARGUMENT REQUESTED
Defendants.	§	

PLAINTIFFS' RESPONSE TO DEFENDANTS'
MOTION FOR EXTENSION OF TIME AND TO MODIFY BRIEFING SCHEDULE

Defendants have announced their intent to "clear the market" of more than 90% of the products Plaintiffs sell within 30 days of the announcement of a revised policy,[1] and that announcement has been promised such that it may come at any moment now. *Id.* at 26-27. The mere announcement of this policy will cause immediate and irreparable harm—as Plaintiffs decide whether to order more inventory or simply begin winding down—and their businesses will be permanently destroyed upon the effective date of the policy absent an injunction. *Id.* at 29-33. While the briefing on Plaintiffs' injunction motion would be complete by November 5 under the default local rules, Defendants now ask to extend the briefing schedule by a full month so that they

[1] *See generally Plfs' Memorandum in Support of Mtn. for Prelim. Inj.* ("Prelim. Inj. Memo") at 26-32.

can have more time to respond to Plaintiffs' motion, and even incorporate their own dispositive motion. They make this request without making any commitment that they will withhold the policy, or even shedding any light as to the date on which they intend to release it. Plaintiffs cannot agree to a schedule that may guarantee their destruction, and respectfully ask the Court to deny the request unless and until the Defendants commit to delay the announcement or implementation of the policy to accommodate the delay they seek.

Given the brevity of this response, Plaintiffs further request that the Court waive the requirement under the Uniform Local Rules to file a memorandum by separate document.

I. Background Relevant to This Motion

Plaintiffs filed suit on August 19, 2019. Service of process was completed as to all Defendants by September 11, 2019.

On September 11, the President of the United States, along with Defendants Azar and Sharpless, held a nationally-televised press conference announcing that they would revise the Deeming Rule enforcement policy to remove all flavored vapor products other than tobacco flavors from the U.S. market within 30 days of the finalization of the policy, which was promised within "weeks." *Prelim. Inj. Memo* at 27.

On October 3, counsel for Plaintiffs emailed Eric Beckenhauer, the Assistant Director of the Federal Programs Branch at the Department of Justice's Civil Division, as Mr. Beckenhauer is the attorney who has signed the most recent documents on behalf of these same Defendants in other Deeming Rule litigation. **Exhibit A** (email chain, J. Najvar and E. Beckenhauer). By this email, Plaintiffs provided advance notice that they would be moving for an injunction, and that, given the necessity of reaching a decision before the effective date of the new flavor policy, Plaintiffs would not be able to agree to an extended briefing schedule:

> I have seen that in other cases, such as the VTA v. FDA case in KY, the government has sought a briefing schedule extending time for responses and incorporating time for your own motion to dismiss to be combined with the briefing. While I certainly look forward to talking with you (or the appropriate counsel who will appear) and am always amenable to accommodations where possible, we will have to request a schedule consonant with the expected flavor ban. My clients are already being forced to make decisions about their businesses, and the flavor ban will destroy most of their businesses entirely if it becomes effective.

Id. Therefore, counsel wrote that he was "writing to give you advanced notice because, while I do not anticipate seeking a TRO, I will need to request disposition of the request for preliminary relief on a schedule that would allow for an appeal to the Fifth Circuit before the anticipated flavor ban becomes effective." *Id.* Plaintiffs indicated that the motion would follow the outline of the claim asserted in the Complaint, "based primarily on *Panama Refining*." *Id.*

Mr. Beckenhauer responded the same day. *Id.* He indicated that "this case may be handled by our office, [but] it hasn't been assigned to an attorney yet." *Id.*

Plaintiffs filed their motion for preliminary injunction seven days later (October 10) and emailed a courtesy copy of the motion and all accompanying documents (including the memorandum) the same day to Mr. Beckenhauer. All documents were personally served upon Defendants the following day.

II. Defendants' Request for Extension Should Be Denied

Under the normal deadlines set forth in the local rules, Defendants' response to the injunction motion is due Tuesday, October 29, and Plaintiffs' reply is due Tuesday, November 5. Local Uniform Civ. R. 7(b)(4).[2] Defendants now seek a significantly extended schedule calculated

[2] Plaintiffs' motion, exhibits, and proposed memorandum of law with its accompanying motion for leave were all served on Defendants October 11, but the Court granted Plaintiffs leave to file the over-length memorandum on October 15. While it may be uncertain whether the response deadline should be calculated from October 11 or October 15, Plaintiffs have agreed to Defendants' request to calculate it from October 15, resulting in additional time for Defendants to respond.

not only to allow more time for them to respond to Plaintiffs' motion, but to incorporate their own dispositive motion. *Defs' Mtn. for Extension* at 4. Defendants claim that this "combined briefing schedule would be most efficient for the parties and the Court." *Id.* Defendants' proposed schedule would extend the briefing on Plaintiffs' injunction request by an entire month, although they have not offered any assurance that their revised flavor enforcement policy will not be released or become effective in the interim.

Plaintiffs thus far have not asked for anything apart from the normal procedures under the Local Rules. They provided advance notice to the Defendants' counsel, and filed their motion in a manner so as to allow for orderly litigation of the preliminary injunction request under the normal deadlines without creating an absolute emergency for the Court. While it often makes sense to combine briefing on certain motions, it is unreasonable for Defendants to request a month-long delay while at the same time leaving Plaintiffs and the Court in the dark as to when Defendants anticipate publishing their promised flavor ban. The mere *release* of the revised policy will cause immediate irreparable injury, and, upon its effective date—which Secretary Azar has suggested will be 30 days after its announcement—will literally destroy Plaintiffs' businesses and cause cascading financial ruin for many persons associated with these businesses. *Prelim. Inj. Memo* at 28-31.

Defendants have not presented any persuasive justification for delaying the disposition of Plaintiffs' motion. Defendants rely on the fact that counsel was not assigned to this case until October 16, *Defs' Mtn. for Extension* at 4, but Plaintiffs provided advanced notice of the forthcoming motion—including notice that the substantive argument would rely heavily on *Panama Refining*—on October 3. No explanation is offered as to why Defendants waited nearly

five weeks after they were served with the lawsuit, and thirteen days after Plaintiffs emailed to advise of the forthcoming injunction motion, to assign counsel.

Defendants' other purported justifications for extending the schedule are likewise unavailing.

As to the imminent revised flavor policy that will remove Plaintiffs "from the market," Defendants invite the impression that this new policy, promised in a nationally-televised Presidential press conference on September 11, was merely a resurrection or proposed finalization of draft guidance issued in March 2019. *See Defs' Mtn. for Extension* ¶6. This is not the case. The March 2019 draft guidance, expressly "nonbinding" and "not for implementation," proposed a much more targeted enforcement policy, aimed, e.g., at products that are "offered for sale in ways that pose a greater risk for minors to access such products," and certain new flavored ENDS products introduced to the market after August 8, 2021 (i.e., *not* targeting those products that were already safe from enforcement under the pre-existing enforcement policy because they were on the market before the effective date of the Deeming Rule in August 2016).[3] This proposal was never finalized. The new policy, by contrast, will "clear the market" of "all flavored e-cigarettes, other than tobacco flavor," including those on the market since 2016 and regardless of how they are marketed. *See* Compl. at 27 (quoting Sec'y Azar's comments at White House). Moreover, this policy is indeed challenged in Plaintiffs' Complaint (contrary to the suggestion at *Defs' Mtn. for Extension* ¶6) because the Complaint challenges the deeming provision of the Tobacco Control Act and the Deeming Rule issued pursuant to that provision. Compl. at 21. The proposed flavor

[3] *See* FDA, Draft Guidance for Industry, *Modifications to Compliance Policy for Certain Deemed Tobacco Products* at 12-13 (March 2019), available at https://www.fda.gov/media/121384/download.

ban is a revised policy of enforcement premised on the Defendants' authority under the Deeming Rule.

Regarding the impending harm from the premarket review application (PMTA) requirements, Defendants' suggestion that somehow Plaintiffs' request is tardy because they have "been on notice of the obligation to prepare those applications…since at least 2016" is misplaced. The FDA had put off the PMTA deadline for ENDS products until August 2022, recognizing that the "rules of the road" were not even finalized yet, until—as their motion acknowledges—the deadline was accelerated in July 2019 by 27 months. *See Defs' Mtn. for Extension* ¶5. If Plaintiffs had requested an injunction before the acceleration of that deadline, or even after its acceleration but before the FDA had finally proposed its final rule setting out the requirements for ENDS PMTAs, Defendants would have argued that the request was premature. Now that Plaintiffs sought an injunction approximately two weeks after FDA finally proposed its final PMTA rule, Defendants argue Plaintiffs are too late to request preliminary relief.

CONCLUSION

Plaintiffs would not hesitate to agree to more time for the Defendants to prepare a response to the preliminary injunction motion if the Defendants would commit to not finalize the promised flavor ban until a date certain. But as it stands, the FDA has promised to finalize the policy any day now, to become effective only 30 days later. Plaintiffs have proactively acted in a manner to permit this Court to consider their motion under the default deadlines in the local rules without creating an absolute emergency, and Plaintiffs must ensure that there remains at least a reasonable amount of time for an emergency appeal to the Fifth Circuit in the event that appeal is necessary before their businesses are permanently destroyed. The Defendants are free to file a motion to

dismiss at any time; indeed, they could have done so already.[4] But it is unreasonable to seek a delay that could effectively deny Plaintiffs the ability to seek to forestall irreparable and permanent harm through the courts.

Respectfully submitted,

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Counsel for Plaintiffs

[4] Should the Defendants move to dismiss, Plaintiffs can respond as appropriate in the normal course. Part of Plaintiffs' response will be that at least some discovery is necessary in this case. Plaintiffs anticipate resistance to such discovery from Defendants.

CERTIFICATE OF SERVICE

I do hereby certify that I have electronically served the foregoing Response using the Court's ECF System, which sent notification to all known counsel of record.

THIS, the 23nd day of October, 2019.

/s/ Spencer M. Ritchie
SPENCER M. RITCHIE