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VIA CM/ECF

August 9, 2019

The Honorable Paul W. Grimm
United States District Court
For the District of Maryland
6500 Cherrywood Lane, Suite 465A
Greenbelt, MD 20770

Re: *American Academy of Pediatrics v. FDA*, No. 18-cv-00883-PWG

Dear Judge Grimm:

On behalf of the vapor industry trade associations listed below,[1] we respectfully provide notice of intent to file a motion to intervene under Fed. R. Civ. P. 24(a) and (b), as well as a motion to stay this Court's remedy decision pending appeal. Unlike the trade associations' earlier effort to intervene in the remedy phase, the intervention sought here is for the purpose of appealing this Court's final judgment, including its May 15, 2019 merits opinion and the July 12, 2019 remedy order, and to participate in any post-judgment proceedings. The trade associations are prepared to file their motions on a schedule set by the Court.

The trade associations represent a broad spectrum of small U.S. businesses, including manufacturers, distributors, and retailers, that make up the grassroots vapor industry. These entities are not owned or operated by cigarette companies and, in fact, many are "Mom and Pop" businesses, *see* Anton Decl., ECF No. 113-F at ¶ 18. Further, these entities are focused primarily on the "open tank" e-liquid and device market, which the Food and Drug Administration (FDA) indicated is *not* the source of recent increases in underage e-cigarette use.[2]

[1] American E-Liquid Manufacturing Standards Association; American Vaping Association; Arizona Smoke-Free Business Alliance; Indiana Smoke-Free Association; Iowans for Alternative to Smoking and Tobacco; Kentucky Smoke-Free Association; Maryland Vapor Alliance; New York State Vapor Association; Ohio Vapor Trade Association; Right to be Smoke-Free Coalition; Smoke-Free Alternatives Trade Association (SFATA); SFATA-California; SFATA-Connecticut; SFATA-Hawaii; SFATA-Louisiana; SFATA-Rhode Island; SFATA-Texas; SFATA-Wisconsin; Tennessee Smoke-Free Association; Texas Vapor Coalition.

[2] FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use* (September 12, 2018), *available at* https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620185.htm.

Each of the four intervention requirements are met here. *First*, the trade associations and their members have a clear "interest in the subject matter of the action." *Stuart v. Huff*, 706 F.3d 345, 349 (4th Cir. 2013). They must comply with the pre-market tobacco application (PMTA) requirements and any filing deadlines. Their businesses and the products they sell to adult consumers are the very subject of the Plaintiffs' lawsuit. Accordingly, this Court was correct to "assume" in response to the previous motion to intervene that the trade associations satisfy this first element. Letter Order at 2, ECF No. 84.

Second, their interests are now clearly "impaired." *Stuart*, 706 F.3d at 349. When this Court previously denied the trade associations the right to intervene at the remedy stage, it stated that "until a remedy is proposed and ordered by the Court, Applicants cannot show that their rights will be impaired." Letter Order at 2, ECF No. 84. That condition is now met as the Court's rulings replace an August 2022 deadline for vapor manufacturers to submit PMTAs with a May 2020 deadline. Indeed, declarations submitted by the trade associations as part of several amicus briefs explain in detail why manufacturers will undoubtedly need time beyond May 2020 to submit complete applications that the FDA would likely approve. *See, e.g.*, Benson Decl., ECF No. 37-4 at ¶¶ 9-10 and Table 1 (*e.g.*, showing average historical times to complete federally-funded, tobacco-related clinical and epidemiological studies to be 6.67 years and 5.11 years, respectively); Anton Decl., ECF No. 113-F at ¶¶ 8-15; Benson Decl., ECF No. 113-G at ¶¶ 8-26. Moreover, the trade associations no longer have any other opportunity to participate in an FDA decision regarding a PMTA deadline. The Court initially seemed to contemplate that FDA would take further notice and comment on an appropriate PMTA filing cutoff, *see* Mem. Op., ECF 73 at 53-54/Letter Order at 2, ECF No. 84, but the Court's remedy order, setting a May 2020 deadline, leaves manufacturers no chance to play any further role in that process.

Third, the trade associations' interests are no longer "adequately represented by existing parties to the litigation." *Stuart*, 706 F.3d at 350. To whatever extent the FDA's interest originally may have aligned with the vapor industry, Letter Order at 2, ECF No. 84, they currently "seek divergent objectives," *Stuart*, 706 F.3d at 352. At a minimum, the FDA proposed, after this Court denied industry's original motion to intervene, a 10-month PMTA deadline, Defs.' Remedy Br., ECF No. 120 at 6, in direct contradiction to declarations previously submitted by the trade associations, all of which indicated that more time would be required to file compliant PMTAs. *See, e.g.*, Benson Decl., ECF No. 37-4 at ¶ 17; Anton Decl., ECF No. 113-F at ¶¶ 8-15; Benson Decl., ECF No. 113-G at ¶¶ 8-26. In fact, this Court has now acknowledged that the "FDA's position is strongly at odds with the Industry's" in several respects. Mem. and Order, ECF No. 127 at 7-8 n.6 (*e.g.*, noting differences regarding whether vacatur of the August 2017 guidance was appropriate or if "further formal guidance" is necessary to complete a compliant application).

Additionally, FDA has sent strong signals that it will not appeal the final judgment because the Court imposed a remedy that the FDA proposed as viable. In a recent press release, the FDA's acting Commissioner Ned Sharpless, after referencing this Court's 10-month remedy,

stated that "FDA stands ready to accelerate the review of e-cigarettes."[3] A decision by the FDA not to appeal would leave the trade associations with no recourse to challenge the validity of the final judgment and defend their interests. Courts often grant post-judgment motions to intervene where a government defendant may no longer adequately represent the interests of the proposed intervenor. *See, e.g.*, *Smoke v. Norton*, 252 F.3d 468, 471 (D.C. Cir. 2001) (allowing intervention for purposes of appeal where government defendant "equivocated" on its intent to appeal summary judgment ruling). Indeed, "the Government's refusal to appeal" is "evidence [that it] inadequate[ly] represent[s]" the interests of would-be intervenors. *United States v. AT&T*, 642 F.2d 1285, 1294 (D.C. 1980); *see also, e.g.*, *United Airlines, Inc. v. McDonald*, 432 U.S. 385, 396 (1977) (permitting "post-judgment intervention for the purpose of appeal").[4]

Fourth, granting intervention for the sole purpose of appeal does not prejudice the parties. *See, e.g.*, *Flying J, Inc. v. Van Hollen*, 578 F.3d 569, 573-74 (7th Cir. 2009) (post-judgment intervention for purposes of appeal causes no prejudice). This Court has no further proceedings scheduled and all that remains is entry of final judgment.

Finally, consideration of the four factors governing a stay request tip in favor of the trade associations. *See U.S. v. Various Articles of Drugs*, 1996 U.S. Dist. LEXIS 22868, at *3-4 (D. Md. 1996). As noted above, they will be irreparably injured absent a stay, with the public interest also harmed if adult smokers no longer have adequate access to vapor products. Also, based on the arguments presented in the joint amicus brief on remedy, the "issues presented on appeal could be 'rationally resolved' in favor of the" proposed intervenors, thus showing a likelihood of success on the merits. *Id.* at *6.

We greatly appreciate the Court's attention to these matters.

Sincerely,

Eric P. Gotting
Bar ID #20278

[3] FDA, *Statement on the agency's actions to tackle the epidemic of youth vaping and court ruling on application of submission deadlines for certain tobacco products, including e-cigarettes* (July 15, 2019), *available at* https://www.fda.gov/news-events/press-announcements/statement-agencys-actions-tackle-epidemic-youth-vaping-and-court-ruling-application-submission.

[4] The intervention motion would also be timely as it would be filed within the 60-day time period for noticing an appeal (which has not even commenced, as the Court has not yet entered final judgment). *See* Fed. R. Civ. P. 58; *Smoke*, 252 F.3d at 471 (noting timeliness if motion filed within time period for appeal).