UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

CHAMBERS OF
PAUL W. GRIMM
UNITED STATES DISTRICT JUDGE

6500 CHERRYWOOD LANE
GREENBELT, MARYLAND 20770
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May 31, 2019

LETTER ORDER

RE: *AAP v. FDA*
PWG-18-883

ITG Brands, John Middleton Co., JUUL Labs., Right to be Smoke-Free Coalition, and NJOY LLC ("Applicants") have filed letters in this case, asking "to file a motion to intervene in this case for the purpose of addressing the appropriate remedy in light of the Court's May 15, 2019 Order." *E.g.*, ITG Brands Ltr. 1, ECF No. 76; *see also* ECF Nos. 77, 79, 80, 81. They seek to intervene as of right pursuant to Fed. R. Civ. P. 24(a) or, alternatively, they seek permissive intervention pursuant to Fed. R. Cir. P. 24(b). In its letter, NJOY LLC states that it and "others who have provided such notice [of an intent to intervene] or intend to do so soon are conferring with each other, and . . . will meet and confer with the parties as well, to endeavor to arrive at a mutually agreeable proposal to streamline the number of intervenor briefs filed." NJOY LLC Ltr. 1, ECF No. 81. It is unclear from these filings whether Applicants are seeking to intervene beyond stating their views regarding a potential remedy, which I note they also could do through *amici curiae* briefs.

To the extent these third parties seek to intervene, their letters are construed as letter motions to intervene, *see* Fed. R. Civ. P. 1, and denied. Where, as here, a would-be intervenor seeks to join a suit on the same side as the Government, it "must mount a strong showing" that the Government cannot adequately represent its interest. *Stuart v. Huff*, 706 F.3d 345, 352 (4th Cir. 2013). Applicants have not met their burden. Nor have they shown that the protection of their interests would be impaired without intervention. Therefore, they are not entitled to intervene as of right under Rule 24(a) of the Federal Rules of Civil Procedure. I also decline to exercise my discretion to permit their intervention under Rule 24(b). I will, however, authorize the groups to submit a consolidated *amicus curiae* brief.

Intervention as of Right

Pursuant to Rule 24(a), a third party who submits a timely motion to intervene is entitled to intervenor status if he or she "can demonstrate '(1) an interest in the subject matter of the action; (2) that the protection of this interest would be impaired because of the action; and (3) that the applicants' interest is not adequately represented by existing parties to the litigation.'" *Stuart v. Huff*, 706 F.3d 345, 349 (4th Cir. 2013) (quoting *Teague v. Bakker*, 931 F.2d 259, 260–61 (4th Cir. 1991)); *see* Fed. R. Civ. P. 24(a)(2). "In addition to the three factors listed in *Stuart*, 'timeliness is [also] a "cardinal consideration" of whether to permit intervention . . . .'" *CX Reinsurance Co. Ltd. v. B&R Mgmt.*, No. ELH-15-3364, 2017 WL 371800, at *3 (D. Md. Jan. 26, 2017) (quoting *Houston Gen. Ins. Co. v. Moore*, 193 F.3d 838, 839 (4th Cir. 1999)). I assume, without deciding, that Applicants have satisfied the first element.

With regard to both timeliness and protecting their interests, I note that Applicants were content to let the Government shoulder the burden of protecting their interests in maintaining the status quo of the FDA Guidance that Plaintiffs challenged in their suit, from the inception of this case in March 2018 through May 15, 2019, when I granted summary judgment in Plaintiffs' favor and vacated the FDA's August 2017 Guidance. ECF Nos. 73, 74. It was not until this Court's ruling that Applicants expressed any concern about the outcome of this litigation, despite the fact that if the Plaintiffs prevailed, the impact on the Applicants was readily apparent. Thus, the Applicants' efforts to intervene at this late date is anything but timely. Moreover, until a remedy is proposed and ordered by the Court, Applicants cannot show that their rights will be impaired. Indeed, any remedy will involve further action by the FDA, which may well have to comply with the APA notice and comment process. At such time, Applicants would have ample opportunity to be heard regarding the deadlines the FDA proposes to implement and the opportunity to protect their interests. Thus, they cannot show that "the disposition of [this] case would, as a practical matter, impair the applicant's ability to protect his interest in the [subject matter of the litigation]." *Spring Constr. Co. v. Harris*, 614 F.2d 374, 377 (4th Cir. 1980).

As for the third element, when, as here, a movant shares its objective with a governmental party, "a more exacting showing of inadequacy" than typically is required is necessary. *Stuart*, 706 F.3d at 351. This is because the Government "is simply the most natural party to shoulder the responsibility of defending the fruits of the democratic process." *Id.* To determine whether the movant has met its burden, the court may first assess whether the would-be intervenor and the Government shared the "same ultimate objective." *Id.* at 349. Stated differently, the question is whether the would-be intervenor and the Government seek the same outcome in the litigation. *See Outdoor Amusement Bus. Ass'n v. Dep't of Homeland Sec.*, No. ELH-16-1015, 2017 WL 2778820, at *11 (D. Md. June 26, 2017). If so, "a presumption arises that [the applicant's] interests are adequately represented." *Stuart*, 706 F.3d at 349. To rebut this presumption, the applicant would have to show that the Government's representation was compromised by "adversity of interest, collusion, or nonfeasance." *Id.* Here, Applicants and the Government both seek a longer period for premarket approval applications, substantial equivalence reports, and exemption requests to be filed and approved. Thus, the presumption of adequate representation applies, and the issue is whether Applicants have rebutted it. *See Stuart*, 706 F.3d at 349.

To rebut the presumption, Applicants must demonstrate that they have "identifiable adverse interests with the existing government party; the existing parties have engaged in collusion; or the government has committed nonfeasance." *Ohio Valley Envtl.*, 313 F.R.D. at 29. Applicants have not demonstrated any adverse interests, collusion, or nonfeasance. Therefore, Applicants are not entitled to intervention as of right under Rule 24(a).

Permissive Intervention

Applicants ask the Court, in the alternative, to permit their intervention under Rule 24(b). Under this provision, a court may, in its discretion, allow a third party to intervene in a case if he or she "has a claim or defense that shares with the main action a common question of law or fact." Fed. R. Civ. P. 24(b)(1). The provision requires the court, in the course of its analysis, to "consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3).

Although Applicants filed their letter motions promptly after this Court directed the parties to submit briefs addressing an appropriate remedy, their request to intervene came well over a year

after Plaintiffs filed suit, when all that remained for resolution was determination of an appropriate remedy. And, Applicants suggest that additional non-parties have not yet but will seek to intervene at an unknown date in the future. Adding four private companies, "the U.S. electronic vapor ('e-vapor') industry,"[1] and whatever other non-parties may seek to intervene certainly would unavoidably complicate the proceedings and result in further delay. Notwithstanding delay, the Court only should deny intervention if the ensuing delay would be "undue." Fed. R. Civ. P. 24(b)(3); *see Ohio Valley Envtl.*, 313 F.R.D. at 30. In making this assessment, "the court must balance the delay threatened by intervention against the advantages promised by it." *Ohio Valley Envtl.*, 313 F.R.D. at 30; *see Va. Uranium, Inc. v. McAuliffe*, No. 4:15-cv-00031, 2015 WL 6143105, at *4 (W.D. Va. Oct. 19, 2015).

My conclusion that the Government adequately represents Applicants' interests, while not decisive, militates against permissive intervention, *see Va. Uranium*, 2015 WL 6143105, at *4, because it suggests that the opportunities for Applicants to make meaningful contributions to the case are likely to be limited. Further, I already found that the Government is in violation of the law. Any delay in determining a remedy for that violation would not be in the public interest. Moreover, "[t]he decision to grant or deny permissive intervention 'lies within the sound discretion of the trial court.'" *Md. Restorative Justice Initiative v. Hogan*, 316 F.R.D. 106, 112 (D. Md. 2016) (quoting *Smith v. Pennington*, 352 F.3d 884, 892 (4th Cir. 2003)). Under the circumstances of this particular case, Applicants' intervention is unwarranted. Their request for permissive intervention under Rule 24(b) is denied.

***Amicus Curiae* Status**

Although they may not intervene, Applicants are not "without recourse." *See Stuart*, 706 F.3d at 355. In appropriate cases, a court may authorize a non-party to submit an *amicus curiae* brief, providing the non-party an opportunity to weigh in on the legal issues presented in a case. *See Outdoor Amusement*, 2017 WL 2778820, at *13; *Ohio Valley Envtl.*, 313 F.R.D. at 32. Here, it is abundantly clear that Applicants are knowledgeable about the filing and approval processes for premarket approval applications, substantial equivalence reports, and exemption requests. I choose, therefore, to grant Applicants *amici curiae* status in this action, limited to the purpose of filing a single, consolidated *amicus* brief, addressing a potential remedy only, by June 12, 2019.

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[1] In their letter motion to intervene, the representatives of the e-vapor industry identify themselves as

> American E-Liquid Manufacturing Standards Association, the American Vaping Association, the Arizona Smoke-Free Association, the Indiana Smoke-Free Association, Iowans for Alternative to Smoking and Tobacco, the Kentucky Smoke-Free Association, the Maryland Vapor Alliance, the New York State Vapor Association, the Ohio Vapor Trade Association, the Right to be Smoke-Free Coalition, Smoke-Free Pennsylvania, the Smoke-Free Alternatives Trade Association (SFATA), SFATA-California, SFATA-Connecticut, SFATA-Hawaii, SFATA-Louisiana, SFATA-Rhode Island, SFATA-Texas, SFATA-Wisconsin, the Tennessee Smoke-Free Association, the Texas Vapor Coalition, and numerous individual vapor businesses from across the country.

Indus. Ltr. 1, ECF No. 80.

The Plaintiffs' and the Government's briefs on a remedy are limited to 15 pages, and therefore the third parties' consolidated *amicus* brief is limited to 15 pages as well. The Plaintiffs and the Government each may respond to the consolidated *amicus* brief in 15 pages or less by June 26, 2019. In accordance with this Court's Standing Order re Amicus Briefs, which adopts Federal Rule of Appellate Procedure 29, the *amicus* brief must comply with Local Rules 102.2 (format of court documents) and 105.1(a) (electronic filing); no reply is permitted; *amici* may not participate in any oral argument, hearings or conference calls unless requested by the Court; and any amicus curiae that is a corporation must file a disclosure statement like that required of parties by Local Rule 103.3(a).

Although informal, this is an Order of Court and will be docketed accordingly.

Sincerely,

/S/

Paul W. Grimm
United States District Judge

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