IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

CYCLOPS VAPOR 2, LLC, *et al.*, *Plaintiffs*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Civil Action No. 2:16-cv-556-MHT-CSC

MOTION TO INTERVENE AS DEFENDANTS

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Ambrose, B.K., et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014*, 314 J. Am. Med. Ass'n 1871 (2015), *available at* http://jamanetwork.com/journals/jama/fullarticle/2464690.....5

U.S. Centers for Disease Control and Prevention, *Tobacco Use Among Middle and High School Students—United States, 2011-2016*, 66 Morbidity & Mortality Weekly Rep. 597 (2017), *available at* https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6623a1.pdf.....2

Pursuant to Federal Rule of Civil Procedure 24, the American Academy of Pediatrics, the American Cancer Society Cancer Action Network, the American Heart Association, the American Lung Association, the Campaign for Tobacco-Free Kids, and the Truth Initiative (collectively, "Public Health Intervenors") hereby move for leave to intervene as Defendants in this case.[1] Public Health Intervenors seek intervention as of right under Rule 24(a)(2) or, in the alternative, permissive intervention under Rule 24(b)(1).[2]

Public Health Intervenors have contacted counsel for all parties to determine whether they consent to intervention. Plaintiffs have stated that they oppose intervention. Defendants reserve the right to oppose the motion.

I. INTRODUCTION

In this case, manufacturers and distributors of e-cigarettes and e-liquids ask the Court to set aside the "Deeming Rule,"[3] through which defendant U.S. Food and Drug Administration ("FDA") determined that e-cigarettes[4] and related products should be deemed subject to FDA regulation as "tobacco products" under the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. §§ 387-387u) ("TCA"). In the TCA, Congress required the FDA to regulate certain types of tobacco products, such as cigarettes and smokeless tobacco, and gave the FDA authority to regulate other tobacco

[1] A proposed pleading has been lodged together with this motion. *See* Answer (Ex. 2).

[2] The court previously granted the motion of the Campaign for Tobacco-Free Kids to file an amicus brief in this case. If this motion to intervene is granted, the Campaign for Tobacco-Free Kids will not file an amicus brief and will instead participate jointly with Public Health Intervenors as intervenor-defendants in this case.

[3] Final Rule Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,974 (May 10, 2016).

[4] The Deeming Rule applies not only to e-cigarettes and other types of "electronic nicotine delivery systems" but to their components and parts as well. *See* 81 Fed. Reg. 28,975. For simplicity, this brief refers to all such products as "e-cigarettes."

products, including e-cigarettes, if the FDA first deemed them to be subject to regulation. 21 U.S.C. § 387a(b). On July 21, 2017, the U.S. District Court for the District of Columbia upheld the Deeming Rule against a challenge raising issues virtually identical to those here. *See Nicopure Labs, LLC v. FDA*, No. 1:16-cv-00878-ABJ (D.D.C. July 21, 2017) ("Slip Op.").

The TCA banned flavorings in cigarettes other than menthol and cigarette advertising practices targeted at minors in an effort to reduce the prevalence of youth smoking. *See* 21 U.S.C. § 387g; 21 U.S.C. § 387a-1. But because these prohibitions did not apply to e-cigarettes in the absence of a final rule deeming them subject to FDA regulation, manufacturers of tobacco products could still create and market flavored e-cigarettes and design products and marketing strategies that appeal particularly to young people. This is exactly what happened: The availability of flavored e-liquids—addictive nicotine products that taste like candy, fruit, or chocolate and have names like "Unicorn Milk" or "I Love Donuts"—has risen dramatically. *See* Defs.' Cross-MSJ 10, *Nicopure*, No. 1:16-cv-00878-ABJ (Aug. 17, 2016), ECF No. 43 ("FDA's *Nicopure* Br."). As a result, e-cigarettes became the most widely used tobacco product among youth, spiking from 1.5% of high school students to 13.4% from 2011 to 2014. *See* 81 Fed. Reg. at 28,984.[5]

The Deeming Rule is a necessary predicate for FDA regulation of e-cigarettes. Without it FDA could not take the measures necessary to address the public health risks that the unregulated promotion and sale of e-cigarettes have created. Setting aside the Deeming Rule, as Plaintiffs request, would have a direct adverse effect on public health, particularly among youth. Public Health Intervenors are non-profit organizations that have worked for decades to protect

[5] More recent data show that current use of e-cigarettes among youth increased to 16% in 2015, before declining to 11.3% in 2016, a rate that still exceeds use of conventional cigarettes. U.S. Centers for Disease Control and Prevention, *Tobacco Use Among Middle and High School Students—United States, 2011-2016*, 66 Morbidity & Mortality Weekly Rep. 597, 600 (2017).

the public from the devastating harms caused by tobacco products. Each of the organizations engages in public education programs designed to discourage initiation of tobacco usage, to encourage cessation and to counter the aggressive marketing of tobacco products by manufacturers, particularly marketing that targets youth. *See* Myers Aff. ¶ 3 (Ex. 4); Schoeberl Aff. ¶¶ 4, 9 (Ex.6); Vargyas Aff. ¶¶ 5-6 (Ex. 7); Wimmer Aff. ¶ 7 (Ex. 8); Phillips Aff. ¶ 5 (Ex. 5); Del Monte Aff. ¶¶ 6-8 (Ex. 3).

Dismantling the regulatory structure adopted by the FDA in the Deeming Rule would increase the risk of those harms, particularly to young people, and thus force Public Health Intervenors to expend greater resources to accomplish their shared mission than if the Rule were preserved and fully implemented. The proliferation of new products and new flavors—none of which would have been subjected to regulatory review—would greatly increase the burden of organizations, such as Public Health Intervenors, to effectively counter these marketing efforts. *See* Myers Aff. ¶ 10; Schoeberl Aff. ¶ 15; Vargyas Aff. ¶ 12; Wimmer Aff. ¶ 10; Phillips Aff. ¶ 11; Del Monte Aff. ¶¶ 14. Moreover, the absence of any requirement that manufacturers demonstrate the truth of claims that their products are less hazardous than other tobacco products would make it more difficult for Public Health Intervenors to provide effective public education concerning the consequences of tobacco use. *See* Myers Aff. ¶ 13; Schoeberl Aff. ¶ 18; Vargyas Aff. ¶ 12; Wimmer Aff. ¶ 13; Phillips Aff. ¶ 14; Del Monte Aff. ¶ 17. Public Health Intervenors therefore have a strong interest in preserving the Deeming Rule.

Intervention by certain of these Public Health Intervenors has been permitted in other tobacco cases. *See, e.g.*, *United States v. Philip Morris USA Inc.* ("*Philip Morris II*"), 566 F.3d 1095, 1098, 1146 (D.C. Cir. 2009). In this case, the necessity of intervention is particularly strong, given the recent indications that Defendants may not aggressively defend the Deeming

Rule, or may seek to alter or rescind the Rule, after their recent changes in leadership. Public Health Intervenors have filed their motion prior to the filing of Defendants' response to Plaintiffs' summary judgment motion to ensure that at least some parties to this case will vigorously defend the Deeming Rule and to enable the motion to intervene to be decided promptly after Defendants make known whether and how they will defend the Rule.

Public Health Intervenors therefore respectfully request that this Court grant leave to intervene as defendants to protect their and their members' interests in ensuring that the Deeming Rule is not weakened, vacated, or rendered ineffective.

II. FACTUAL AND LEGAL BACKGROUND

A. The Deeming Rule

"[T]obacco use, particularly among children and adolescents, poses perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000). Nonetheless, the Supreme Court held in 2000 that Congress had not authorized the FDA to regulate tobacco products. *Id.* In response, Congress enacted the TCA, providing that "[t]obacco products … shall be regulated by the Secretary [of the Department of Health and Human Services]." 21 U.S.C. § 387a(a). Congress applied the TCA to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco" as well as "any other tobacco products that the Secretary by regulation deems to be subject to this subchapter." *Id.* § 387a(b).

After passage of the TCA, several types of tobacco products remained unregulated, including e-cigarettes and the e-liquids they deliver. 81 Fed. Reg. at 28,982. To determine whether to exercise the deeming authority granted by Congress, the FDA engaged in a comprehensive five-year review of the scientific literature on unregulated tobacco products, analyzing more than 275 scientific studies and other reports and 135,000 public comments. It

concluded that e-cigarettes "may deliver as much nicotine as other tobacco products." *Id*. The prevalence of e-cigarettes among youth is particularly concerning because "adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system," and "nicotine exposure during adolescence may have lasting adverse consequences for brain development" as well as "detrimental effects on the cardiovascular system." *Id.* at 29,029, 29,033. Moreover, "flavored e-liquids contain chemicals that could be dangerous to consumers when inhaled." *Id.* at 39,029. These risks are compounded by the "significant variability in the concentration of chemicals amongst products—including variability between labeled content and concentration and actual content and concentration." *Id.* at 28,984. For example, some combinations of e-cigarette delivery systems and e-liquids "deliver more formaldehyde than … conventional cigarettes." *Id.* at 29,031.

Moreover, as noted above, the fruit- and candy-flavored e-cigarettes not only may pose health risks to individual users, but also make these products attractive to kids. According to FDA's Population Assessment of Tobacco and Health study, 85.3% of current e-cigarette users aged 12-17 had used a flavored e-cigarette in the past month and 81.5% of current youth e-cigarette users said they used e-cigarettes "because they come in flavors I like." Ambrose et al., *Flavored Tobacco Product Use Among US Youth Aged 12-17 Years, 2013-2014*, 314 J. Am. Med. Ass'n 1871, 1873 (2015); *see* 81 Fed. Reg. at 29,014 (citing Ambrose et al.).

In light of these and other findings, the FDA "extend[ed] the Agency's 'tobacco product' authorities in the FD&C Act to all other categories of products that meet the statutory definition of 'tobacco product' in the FD&C Act, except accessories of such newly deemed tobacco products." 81 Fed. Reg. at 28,974. Because the FDA deemed e-cigarettes subject to regulation under the TCA, e-cigarettes became subject to the provisions of the TCA, including, among

other things, prohibitions on adulteration and misbranding, 21 U.S.C. §§ 387b-387c; reporting and registration requirements, *id.* §§ 387d-387e; ingredient disclosure, *id.* § 387c; protections against misleading health claims, *id.*; and, most notably for this case, mandatory premarket review of "any tobacco product … that was not commercially marketed in the United States as of February 15, 2007," *id.* § 387j(a)(1)(A). The FDA also "establish[ed] specific restrictions that are appropriate to the protection of the public health for the newly deemed tobacco products," including prohibiting the sale of covered tobacco products (including e-cigarettes) to individuals under the age of 18 and requiring the display of health warnings on tobacco product labels and advertisements. 81 Fed. Reg. at 28,974-75.

As the district court in *Nicopure* explained in rejecting a challenge virtually identical to the one here:

> [t]he Rule requires manufacturers to subject their products to review before marketing them, to tell the truth when making any claims about their health benefits, and to warn consumers about the dangers of nicotine when offering a means to deliver the nicotine to consumers. In short, the manufacturers of e-cigarettes are now required to tell the 30 million people who use the devices what is actually in the liquid being vaporized and inhaled.

Slip Op. 4.

The FDA "concluded that the benefits of the final rule justify the costs," 81 Fed. Reg. at 29,075, a determination upheld in *Nicopure* as a "careful assessment of the costs and benefits," Slip Op. 70. The rule would "reduce the death and disease from tobacco products" and "afford[] FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use." *Id.* In order to give manufacturers ample time to obtain FDA authorization, the FDA announced lengthy compliance periods—and FDA has since extended these deadlines further. *See* FDA, *Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* 4-11 (May 2017) ("*Guidance*").

B. Plaintiffs' Challenge to the Deeming Rule

Three sellers or distributors of e-cigarettes—Cyclops Vapor 2, LLC, Tiger Vapor, LLC, and Karma S Clouds, LLC (collectively, "Plaintiffs")—filed suit to challenge the Deeming Rule. Arguing that the Deeming Rule is arbitrary and capricious and violates the Administrative Procedure Act and the First Amendment, they seek, among other things, vacatur of the Rule.

C. Defendants' Responses to Challenges to the Deeming Rule

Similar suits challenging the Deeming Rule have been brought by e-cigarette and cigar manufacturers and retailers.[6] The furthest along is *Nicopure Labs, LLC v. FDA*, No. 16-cv-878 (D.D.C.),[7] in which the Court, on July 21, 2017, granted summary judgment to the government and upheld the Deeming Rule against a challenge by e-cigarette manufacturers virtually identical to the one here.[8] In *Nicopure*, FDA had filed an 85-page cross-motion for summary judgment, vigorously defending the Deeming Rule in full as it applies to e-cigarettes. *See* FDA's *Nicopure* Br. In its motion, FDA argued that the recent "explosion in virtually unregulated [e-cigarette] products raises significant public health concerns." *Id.* at 10. It pointed to the growing prevalence of e-cigarette use among youth, the use of marketing techniques designed to attract youth, the addictiveness of e-cigarettes due to nicotine delivery comparable to conventional cigarettes, the toxicity of nicotine and its significant risk of adverse effects on pregnant women and the still-developing adolescent brain, the divergence of actual nicotine content from labeled

[6] *See Nicopure Labs, LLC v. FDA*, No. 16-cv-878 (D.D.C.); *Right to be Smoke-Free Coalition v. FDA*, No. 16-cv-1210 (D.D.C.); *Cigar Ass'n of Am. v. FDA*, No. 16-cv-1460 (D.D.C.); *Lost Art Liquids, LLC v. FDA*, No. 16-cv-3468 (C.D. Cal.); *Faircloth v. FDA*, No. 16-cv-5267 (S.D. W. Va.); *Sanchez Icaza & Global Premium Cigars v. FDA*, No. 16-cv-21967 (S.D. Fla.).

[7] A second suit, *Right to Be Smoke-Free Coalition v. FDA*, No. 16-cv-1210 (D.D.C.), is consolidated with *Nicopure*. For simplicity, Public Health Intervenors will refer to the consolidated cases as "*Nicopure*."

[8] Indeed, Plaintiffs' summary judgment brief in this case raises issues identical to those in *Nicopure*, and the large majority of it copies the plaintiffs' brief in *Nicopure* verbatim.

content, the inhalation risks of certain e-liquid ingredients (including certain flavorings), the risk of battery explosion and resulting injury, and the potential harm to nonusers of secondhand aerosol containing nicotine. *Id.* at 9-15. The government's arguments were successful in persuading the district court in *Nicopure* to uphold the Rule as a permissible exercise of FDA's discretion. Slip Op. 48-51.

In recent months, however, it has become apparent that Defendants, in spite of the arguments made by FDA in *Nicopure*, may not adequately defend the Deeming Rule and may seek to weaken or rescind it. Twice in recent months Defendants have requested extensions of time to oppose Plaintiffs' motion for summary judgment and/or to file a cross-motion for summary judgment. The first such motion was filed by Defendants jointly with the industry Plaintiffs on March 1, 2017. On May 1, 2017, facing a deadline for their summary judgment motion, Defendants filed a joint motion with the industry Plaintiffs requesting that all deadlines in this case be extended three months so that "new leadership personnel at the Department of Health and Human Services" can "more fully consider the Rule and the issues raised in this case and determine how to proceed." Doc. 31 at 2.

Two days later, the FDA delayed a May 10 compliance deadline and indicated its intent "to defer enforcement of all future compliance deadlines for all categories of newly regulated products for three months." FDA, *May 2017: Web Statement* ("*Web Statement*"), *available at* https://www.fda.gov/TobaccoProducts/NewsEvents/ucm556562.htm (last updated May 3, 2017); *see also Guidance* 4-11. This extension was ostensibly for the purpose of "allow[ing] new leadership at the FDA and the Department of Health and Human Services additional time to more fully consider issues raised by the final rule that are now the subject of multiple lawsuits in federal court." *Web Statement.* The FDA announcement states that its action will extend

compliance dates for such fundamental regulatory requirements as ingredient listing, the production of documents on the health effects of new tobacco products, substantial equivalence and premarket tobacco applications, and the reporting of harmful and potentially harmful product constituents to FDA. *Id*.

Accordingly, it is currently unclear whether Defendants will defend the Deeming Rule in this litigation when their cross-motion for summary judgment and opposition to Plaintiffs' summary judgment motion are due on August 2.

III. PUBLIC HEALTH INTERVENORS

Public Health Intervenors include six public health organizations dedicated to combatting the diseases and other adverse health effects caused by use of tobacco products, including e-cigarettes. Each of the proposed intervenors expends substantial resources to educate the public about the risks of tobacco products, to help users quit smoking, and to advise the government on effective regulation of tobacco products.

For example, the American Academy of Pediatrics ("AAP") publishes a Clinical Practice Policy to Protect Children from Tobacco, Nicotine, and Tobacco Smoke, which "describes clinical practice recommendations to physicians on how to screen for tobacco use and counsel their patients and patients' parents" and contains extensive recommendations regarding the counseling of patients about the consequences of e-cigarette usage. Del Monte Aff. ¶ 7. The American Lung Association ("ALA") expends substantial resources to support its highly-acclaimed Freedom From Smoking® program, which has in-person, online and telephonic options to help smokers quit, including access by telephone to certified tobacco treatment specialists at [ALA's] Lung Helpline. Wimmer Aff. ¶ 5. In addition, ALA provides information regarding the consequences of e-cigarette usage in its numerous publications and through online social media outlets. *Id*. ¶ 6.

Similarly, the American Heart Association ("AHA") maintains a quality improvement program "to ensure that hospitals are screening for tobacco use among patients and providing cessation resources when needed," and it provides information on the consequences of e-cigarette usage on its website. Schoeberl Aff. ¶ 6. AHA also works directly with local health care providers, church leaders, and school administrators, as well as historically black colleges and universities, "to ensure that strong tobacco-free policies are in place and to provide tobacco users with the resources they need to quit." *Id*. ¶¶ 4-5. The American Cancer Society Cancer Action Network ("ACS CAN") has been a leader in educating the public about the dangers of using tobacco products and in advocating policies and programs to discourage tobacco initiation and encourage cessation. Phillips Aff. ¶ 5. ACS CAN and its members provide information to the public and to policymakers regarding the consequences of e-cigarette usage. *Id.* ¶ 5.

The Campaign for Tobacco-Free Kids ("Tobacco-Free Kids") "has developed research and public education material about the marketing of e-cigarettes to youth," along with youth activities designed to "educate young people about the dangers of tobacco use, including use of e-cigarettes." Myers Aff. ¶¶ 3. Truth Initiative's nationally recognized **truth®** campaign has reached hundreds of millions of teens and young adults with information about the health effects and social costs of tobacco and, through its on-line tobacco cessation intervention, Become an Ex®, has reached over 700,000 persons to date with information to help adults quit using tobacco products. Truth Initiative provides researched-based information regarding the consequences of e-cigarette usage in its publications on its website and through social media to explain to young people that e-cigarettes are not harmless, are addictive, and are not approved for use as a cessation aid. Vargyas Aff. ¶¶ 6-7.

Because of their substantial interests in the regulation, each of the Public Health Intervenors also participated in the administrative process leading to the Deeming Rule, helping the FDA devise a reasoned regulation that appropriately protected public health. Public Health Intervenors met with the FDA and other government agencies and submitted extensive public comments evaluating the criticisms raised by Plaintiffs. *See* Myers Aff. ¶¶ 5-6; Schoeberl Aff. ¶¶ 12-13; Vargyas Aff. ¶¶ 10-11; Wimmer Aff. ¶ 9; Phillips Aff. ¶¶ 7-8; Del Monte Aff. ¶¶ 11-12. The comments filed by Public Health Intervenors and other public health and medical groups were cited in upholding the Deeming Rule in *Nicopure*. *See* Slip Op. 53. And each of the Public Health Intervenors has a long history of participating as amicus curiae, plaintiffs, or intervenors in cases related to government regulation of the tobacco industry. *See, e.g.*, Myers Aff. ¶ 4; Schoeberl Aff. ¶ 10; Vargyas Aff. ¶ 9; Wimmer Aff. ¶ 8; Phillips Aff. ¶ 6; Del Monte Aff. ¶ 11. Indeed, each of them participated as amicus curiae in the case that established the status of e-cigarettes as "tobacco products" subject to regulation under the TCA. *See Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2011). Each also joined an amicus brief defending the Deeming Rule in the *Nicopure* case.

Additionally, AAP "is a professional membership organization of 66,000 pediatricians, pediatric medical sub-specialists and pediatric surgical specialists." Del Monte Aff. ¶ 3. Their "mission is to attain optimal physical, mental and social health and well-being for all infants, children, adolescents and young adults." *Id.* ¶ 5. As part of this mission, AAP's members "actively screen their patients for use of tobacco and provide counseling to their patients and patients' parents about the health hazards of tobacco use, in an effort to prevent tobacco initiation." *Id.* ¶ 6. "The presence of unregulated tobacco products undermines these efforts by increasing the opportunities for young people to begin or continue using tobacco products." *Id.*

¶ 8. The prevalence of products such as flavored e-cigarettes forces AAP and its members to expend additional resources to effectively pursue the critical preventive objective of discouraging the use of these addictive products by young people. *Id.* ¶ 9.

IV. ARGUMENT

Public Health Intervenors seek leave to intervene as defendants to protect their interests and, in the case of AAP, the interests of their pediatrician members. The failure to subject harmful and addictive e-cigarettes to regulation under the full implementation of the Deeming Rule will force Public Health Intervenors to expend substantial additional resources combatting the public health risks these products create. Public Health Intervenors readily satisfy the requirements of Article III and Federal Rule of Civil Procedure 24; indeed, several of these very organizations repeatedly have been held to have standing to participate in tobacco-related litigation.

A. Public Health Intervenors Have Standing to Intervene as Defendants

Public Health Intervenors do not need to establish that they have standing as long as Defendants "maintain[] an adversarial litigating position vis-a-vis the opposing parties." *Dillard v. Chilton Cnty. Comm'n*, 495 F.3d 1324, 1337 (11th Cir. 2007). If, as Public Health Intervenors fear, Defendants cease defending the Deeming Rule, or seek to limit or weaken its application to e-cigarettes, Plaintiffs can readily establish standing.

To establish Article III standing, a party must show (1) "an 'injury in fact' that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Florida Wildlife Federation, Inc. v. South Fla. Water Mgmt. Dist.*, 647 F.3d 1296, 1302 (11th

Cir. 2011).[9] Where "a party benefits from agency action, the action is then challenged in court, and an unfavorable decision would remove the party's benefit," the standing requirement is typically satisfied. *Crossroads Grassroots Policy Strategies v. FEC*, 788 F.3d 312, 317 (D.C. Cir. 2015). If at least one proposed intervenor has standing, the court "need not decide the standing issue as to the remaining intervening public health organizations." *Philip Morris II*, 566 F.3d at 1146. Well-pleaded allegations supporting a motion to intervene are assumed to be true. *See, e.g.*, *United States v. Baxter Int'l, Inc.*, 345 F.3d 866, 881 (11th Cir. 2003).

As courts have repeatedly held, public health organizations have standing to bring or intervene in cases regarding regulation of tobacco products. *See Philip Morris II*, 566 F.3d at 1146; *Public Citizen*, 869 F.2d at 1546-53. Indeed, appellate courts have previously held that several of the specific organizations seeking to intervene here have standing in such cases. *See Philip Morris II*, 566 F.3d at 1108, 1146 (holding that American Cancer Society, AHA, ALA, and Tobacco-Free Kids Action Fund had standing as intervenors); *Public Citizen*, 869 F.2d at 1545, 1553 (holding that American Cancer Society, AHA, and ALA had standing as plaintiffs).[10]

All Public Health Intervenors have organizational standing. AAP has associational standing as well.

1. Organizational Standing

"[A]n organization has standing to sue on its own behalf if the [challenged actions] impair its ability to engage in its projects by forcing the organization to divert resources to

[9] This traditional standing test for plaintiffs applies where intervenor-defendants "seek relief from a federal court." *Florida Med. Ass'n, Inc. v. HEW*, No. 78-cv-178, 2011 WL 4459387, at *10 n.12 (M.D. Fla. Sept. 26, 2011). Although Public Health Intervenors are not seeking relief from a federal court, they will assume that the same standing requirements apply.

[10] ACS CAN, one of the proposed intervenors here, is a nonpartisan 501(c)(4) affiliate of American Cancer Society, the party in *Philip Morris* and *Public Citizen*. Tobacco-Free Kids, another proposed intervenor here, is the nonpartisan 501(c)(3) affiliate of Tobacco-Free Kids Action Fund.

counteract those [actions]." *Florida State Conference of NAACP v. Browning*, 522 F.3d 1153, 1165 (11th Cir. 2008). An organization that "will divert resources from its regular activities to educate" individuals affected by a regulatory change has standing to challenge that change. *Common Cause/Ga. v. Billups*, 554 F.3d 1340, 1350 (11th Cir. 2009); *see also, e.g.*, *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982) (standing shown where the challenged conduct "perceptibly impair[s] [an organization's] ability to provide counseling … with the consequent drain on the organization's resources").

Public Health Intervenors expend substantial resources to gather information on, educate the public about, and protect their members and other members of the public whom they serve from the harms of tobacco products. As one district judge found in evaluating the organizational standing of some of these same Public Health Intervenors:

> [t]here can be no question, based upon the declarations submitted and the long history of these organizations in the public health arena, that they devote much of their time and resources to convincing young people not to smoke and to educating the public about the dangers of addiction and the difficulties of quitting smoking. As John Kirkland, President and Chief Executive Officer of American Lung Association, explained, the organization "has long been active in research, education and public policy advocacy on the adverse effects of tobacco products." These are precisely the "discrete programmatic concerns [that] are being directly and adversely affected by the challenged action," which the Court of Appeals ruled would demonstrate the requisite institutional injury to satisfy Article III standing requirements.

United States v. Philip Morris USA Inc. ("*Philip Morris I*"), No. 99-cv-2496, 2005 WL 1830815, at *4 (D.D.C. July 22, 2005).

The availability of unregulated e-cigarettes makes these efforts more difficult and more expensive. Easy access to e-cigarettes—particularly youth-friendly flavored e-cigarettes—increases the risk of youth e-cigarette initiation and continuation of use, thus increasing the amount of public education and counseling needed to combat e-cigarette use among minors. *See, e.g.*, Schoeberl Aff. ¶ 16. Moreover, as the court noted in

Nicopure, "the manufacturers, if they remain unregulated, are free to mislabel their products without consequence." Slip Op. 50. The significant increase of youth usage of e-cigarettes since 2011, accompanied by unregulated marketing and the proliferation of thousands of products and flavors—many of them designed to appeal to youth and with both unknown and potentially widely varying levels of toxicants, carcinogens, and nicotine—has made it much harder for Public Health Intervenors "to be effective in (a) giving the public, and particularly young people, an accurate understanding of the dangers of e-cigarette usage; (b) discouraging initiation of e-cigarettes by young people; and (c) encouraging e-cigarette users, particularly young people, to quit." Schoeberl Aff. ¶ 18. The Deeming Rule would reduce youth access to e-cigarettes and give FDA the authority to take youth-focused e-cigarettes off the market, easing the challenge of fulfilling Public Health Intervenors' mission. Eliminating the Deeming Rule would allow manufacturers to continue to target youth in the design, advertising, marketing, and promotion of e-cigarettes, making Public Health Intervenors' mission harder.

Vacating the Deeming Rule would thus "forc[e] [Public Health Intervenors] to divert resources to counteract" the prevalence of e-cigarettes in kid-friendly flavors, supported by marketing directed at young people and by unverified claims. *Browning*, 522 F.3d at 1165. By contrast, upholding the Deeming Rule would slow the flood of highly addictive e-cigarettes to young people, providing Public Health Intervenors meaningful redress by allowing them to focus their resources on protecting the public health from other tobacco products. Accordingly, Public Health Intervenors have standing to intervene.

2. Associational Standing

In addition, AAP has associational standing. "[A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their

own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977).

AAP is a membership organization of 66,000 pediatricians and pediatric specialists dedicated to improving the physical, mental, and social health and well-being of infants, children, adolescents, and young adults. Del Monte Aff. ¶ 5. To fulfill this mission, AAP's members "actively screen their patients for use of tobacco and provide counseling to their patients and patients' parents about the health hazards of tobacco use, in an effort to prevent tobacco initiation." *Id.* at ¶ 6. The more available e-cigarettes are to youth, and the more tobacco manufacturers are able to market candy- and fruit-flavored e-cigarettes that appeal to youth, the more of their limited time and resources AAP's members must spend on counseling patients and their parents not to use these products—and the less they can devote to improving children's health in other ways. They thus have a significant interest in ensuring the survival of the Deeming Rule.

The other requirements of associational standing are similarly satisfied. The interests AAP seeks to protect "are germane to [its] purpose[]," namely, advancing the health of infants, children, adolescents, and young adults. *Hunt*, 432 U.S. at 343. And the proposed defense does not "require[] the participation of individual members in the lawsuit," *id.*, because the outcome of the case will not affect the rights or obligations of any particular individual member differently from AAP's other members.[11] Accordingly, even if Public Health Intervenors did not

[11] This third requirement "is merely prudential." *Dunn v. Dunn*, 219 F. Supp. 3d 1163, 1167 (M.D. Ala. 2016). Some courts have held that intervenor-defendants need not satisfy prudential standing considerations. *See, e.g.*, *Crossroads*, 788 F.3d at 320. The Court need not reach this issue because the third requirement is satisfied, whether it is necessary or not.

have organizational standing in their own right, AAP would have standing to intervene on behalf of its members.

B. Public Health Intervenors Are Entitled to Intervene as of Right

Under Federal Rule of Civil Procedure 24(a), a proposed intervenor is entitled to intervention as of right if it (1) makes a timely motion, (2) has "an interest relating to the property or transaction which is the subject of the action," (3) "is so situated that the disposition of the action, as a practical matter, may impede or impair [the intervenor's] ability to protect that interest," and (4) may not be "adequately represented by existing parties." *Athens Lumber Co. v. FEC*, 690 F.2d 1364, 1366 (11th Cir. 1982) (quoting Fed. R. Civ. P. 24(a)(2)). Applications for intervention as of right are given "liberal treatment." *Diaz v. South Drilling Corp.*, 427 F.2d 1118, 1126 (5th Cir. 1970).[12]

Public Health Intervenors satisfy all four prongs of this test.

1. Public Health Intervenors' Motion to Intervene Is Timely

To determine whether an application to intervene is timely, courts consider "all of the circumstances." *NAACP v. New York*, 413 U.S. 345, 365-66 (1973). The court must consider:

> (1) the length of time during which the would-be intervenor knew or reasonably should have known of his interest in the case before he petitioned for leave to intervene; (2) the extent of prejudice to the existing parties as a result of the would-be intervenor's failure to apply as soon as he knew or reasonably should have known of his interest; (3) the extent of prejudice to the would-be intervenor if his petition is denied; and (4) the existence of unusual circumstances militating either for or against a determination that the application is timely.

United States v. Jefferson Cty., 720 F.2d 1511, 1516 (11th Cir. 1983) (citations omitted).

[12] *Accord, e.g.*, *Public Serv. Co. of N.M. v. Barboan*, 857 F.3d 1101, 1113 (10th Cir. 2017) (taking "a liberal view of Rule 24(a)"); *Wilderness Soc'y v. U.S. Forest Serv.*, 630 F.3d 1173, 1179 (9th Cir. 2011) ("A liberal policy in favor of intervention serves both efficient resolution of issues and broadened access to the courts." (internal quotation marks omitted)).

This motion is timely. It comes at an early stage of the proceedings, before the Court has made any substantive rulings or the first substantive motion has been fully briefed. No discovery has taken place (or likely will take place), given that this case is based on the administrative record. Courts routinely grant motions to intervene at similar or even later stages. *See, e.g.*, *Diaz*, 427 F.2d at 1125 (affirming grant of intervention where intervenor intervened "approximately a year after the date that [it] clearly knew of the suit" but before there had been any "legally significant events"); *Bellito v. Snipes*, No. 16-cv-61474, 2016 WL 5118568, at *2 (S.D. Fla. Sept. 21, 2016) (granting motion to intervene filed after first dispositive motion became ripe); *Ohio Sec. Ins. Co. v. Newsome*, No. 14-cv-125, 2015 WL 1419341, at *6 (S.D. Ga. Mar. 27, 2015) (collecting cases showing that "courts have routinely found that a several month delay does not render a motion to intervene 'untimely'"); *Lancer Ins. Co. v. Hitts*, No. 09-cv-302, 2010 WL 2867836, at *3 (M.D. Ga. July 20, 2010); (granting motion to intervene filed after filing of summary judgment motion).[13]

Moreover, the need to intervene has grown increasingly clear since Plaintiffs filed their motion for summary judgment on February 13. Before the change in administrations, FDA strongly defended the Deeming Rule against an industry challenge in the *Nicopure* case. *See* FDA's *Nicopure* Br. But since February, FDA has sought and received two extensions of time to file summary judgment papers in this and other challenges to the Deeming Rule because it needed additional time to "more fully consider" the issues raised by those legal challenges. Of

[13] *See also, e.g.*, *Williams & Humbert Ltd. v. W. & H. Trade Marks (Jersey) Ltd.*, 840 F.2d 72, 74, 77 (D.C. Cir. 1988) (reversing denial of motion to intervene filed after summary judgment briefing); *Williams & Humbert Ltd. v. Ruiz-Mateos*, No. 83-cv-1905, 1991 WL 148283, at *2 (D.D.C. Jan. 29, 1991) (noting grant on remand of motion to intervene); *Hardin v. Jackson*, 600 F. Supp. 2d 13, 14, 16 (D.D.C. 2009) (granting intervention filed on same day defendant agency filed opposition to plaintiffs' motion and cross-motion for summary judgment).

even greater significance, FDA in May announced a postponement of all industry compliance deadlines set for May 10, 2017 or thereafter, including deadlines for such crucial public health protections as ingredient listing, premarket tobacco applications, the reporting of harmful and potentially harmful constituents, and the submission of documents to FDA concerning the health effects of the deemed products. Intervention is sought here only after it has become apparent that the government may not adequately represent the interest of Public Health Intervenors. *Cf. Smoke v. Norton*, 252 F.3d 468, 471 (D.C. Cir. 2001) (motion to intervene can be timely even after judgment, as long as that is when "the potential inadequacy of representation came into existence").

There will be no prejudice to the existing parties if intervention is granted. As discussed below, Public Health Intervenors intend to limit their briefing to avoid duplicative arguments in the interest of judicial efficiency and to conserve the Court's and parties' resources. Intervention would likely delay the briefing schedule by no more than several weeks, if a delay proved necessary at all. By contrast, Public Health Intervenors would be prejudiced if they were denied intervention and Defendants chose not to defend the Deeming Rule in full. As explained above, if the Rule went undefended, Public Health Intervenors' interest in reducing the use of e-cigarettes by young people and in minimizing any harm from these products to consumers would be significantly impaired.

Finally, there are no unusual circumstances militating in either direction. Accordingly, all factors are either neutral or support a finding that Public Health Intervenors' application is timely.

2. Public Health Intervenors Have Legally Protected Interests at Stake

For the same reasons that Public Health Intervenors have Article III standing, they possess an interest relating to the property or transaction that is the subject matter of the

litigation. *See, e.g.*, *Meek v. Metro. Dade Cnty.*, 985 F.2d 1471, 1480 (11th Cir. 1993) ("In this circuit, a movant who shows standing is deemed to have a sufficiently substantial interest to intervene."), *abrogated on other grounds as stated in Dillard*, 495 F.3d at 1331-1332; *Watkins v. Vestil Mfg. Corp.*, No. 07-cv-152, 2008 WL 5102885, at *1 (N.D. Ga. Dec. 1, 2008) (same).[14] The same factual allegations that establish Public Health Intervenors' standing, discussed above, establish a sufficient interest for intervention. *See supra* pp. 12-17.

3. If Successful, Plaintiffs' Action Would Impair Public Health Intervenors' Interests

Under Rule 24(a)'s third prong, "[a]ll that is required … is that the would-be interven[or] be practically disadvantaged by his exclusion from the proceedings." *Huff v. Commissioner*, 743 F.3d 790, 800 (11th Cir. 2014). Only a "possibility" that the intervenor's interest may be impaired is required, not a certainty. *Diaz*, 427 F.2d at 1124; *accord, e.g.*, *Foster v. Gueory*, 655 F.2d 1319, 1325 (D.C. Cir. 1981) (third prong satisfied by "possibility" that intervenors' "interests may be practically impaired or impeded by the disposition of the plaintiffs' suit"). Where a party seeks to intervene in a suit to oppose or defend regulation, courts look to "the 'practical consequences' of denying intervention, even where the possibility of future challenge to the regulation remain[s] available." *Fund for Animals*, 322 F.3d at 735 (D.C. Cir. 2003) (quoting *Natural Res. Def. Council v. Costle*, 561 F.2d 904, 909 (D.C. Cir. 1977)).

If Plaintiffs' suit succeeds, the e-cigarette industry may remain unregulated (or at a minimum, less rigorously regulated) for years to come, while the FDA determines whether to issue a new rule. Such a result would undermine, in several ways, Public Health Intervenors'

[14] *See also, e.g.*, *Philip Morris II*, 566 F.3d at 1146 ("[B]y demonstrating Article III standing, the intervenors adduce a sufficient interest."); *Fund for Animals, Inc. v. Norton*, 322 F.3d 728, 735 (D.C. Cir. 2003) ("Our conclusion that [proposed intervenor] has constitutional standing is alone sufficient to establish that the [it] has 'an interest relating to the property or transaction which is the subject of the action.'" (quoting Fed. R. Civ. P. 24(a)(2))).

efforts to reduce the public health harms resulting from e-cigarette use: by exposing youth and other consumers to e-cigarettes marketed without the addictiveness warning mandated by the Deeming Rule; by depriving FDA of the authority to review e-cigarettes under the public health standard and take off the market candy- and fruit-flavored e-cigarettes that appeal to young people, and instead allowing all e-cigarette products, regardless of their levels of harmful substances, to remain on the market with no review of their effect on public health; by preventing FDA from setting product standards for e-cigarettes to reduce their harmfulness; by allowing e-cigarette manufacturers and retailers to make unproven and misleading health claims; and by eliminating restrictions on sale of e-cigarettes to minors and other public health protections under the Rule. All of these changes would materially undermine Public Health Intervenors' efforts, requiring Public Health Intervenors to expend additional time and resources to accomplish their shared mission of reducing the use of e-cigarettes by the young and any harmful effects of these unregulated products on consumers. Accordingly, the third prong is also satisfied.

4. Public Health Intervenors' Interests May Not Be Adequately Represented by Defendants

The fourth requirement of Rule 24(a) is satisfied as long as the proposed intervenors can "show that representation of [their] interest '*may* be' inadequate; and the burden of making that showing should be treated as minimal." *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10 (1972) (emphasis added); *accord, e.g.*, *Huff*, 743 F.3d at 800 ("The 'inadequate representation' requirement 'should be treated as minimal' and is satisfied 'unless it is clear that the existing parties will provide adequate representation.'"). "[T]his is not an onerous burden." *Govan v. Yale Carolinas, Inc.*, No. 15-cv-624, 2015 WL 12979094, at *3 (N.D. Ala. Aug. 13, 2015) (quoting *Defenders of Wildlife v. Bureau of Ocean Energy Mgmt.*, No. 10-cv-254, 2010

WL 5139101, at *3 (S.D. Ala. Dec. 9, 2010)). Courts "look skeptically on government entities serving as adequate advocates for private parties." *Crossroads*, 788 F.3d at 321.

None of the current parties adequately represents Public Health Intervenors' interests in this matter. First, as explained above, FDA has postponed various compliance deadlines to "more fully consider" issues raised by the legal challenges to the Deeming Rule, when previously the agency had strongly defended the Rule as applied to e-cigarettes. Thus, it is not clear that Defendants' new leadership plans to defend the Deeming Rule at all, let alone defend it in full. *See, e.g.*, *Kootenai Tribe of Idaho v. Veneman*, 313 F.3d 1094, 1107 (9th Cir. 2002) (relying on change in administration in granting intervention of right), *abrogated on other grounds by Wilderness Soc'y v. U.S. Forest Serv.*, 630 F.3d 1173 (9th Cir. 2011); *Kleissler v. U.S. Forest Serv.*, 157 F.3d 964, 974 (3d Cir. 1998) (same).

Even without this postponement of compliance, there would be no guarantee of adequate representation. "[E]ven when the interest of a federal agency and potential intervenor can be expected to coincide, 'that does not necessarily mean … adequacy of representation is ensured for purpose of Rule 24(a)(2).'" *Crossroads*, 788 F.3d at 321 (quoting *Costle*, 561 F.2d at 912). Although "there may be a partial congruence of interests, that does not guarantee the adequacy of representation." *Fund for Animals*, 322 F.3d at 736-37. For example, Public Health Intervenors may have different perspectives than FDA in assessing various aspects of the challenged Rule, such as the scope of FDA's authority to extend compliance deadlines established in the rule. *See* Final Regulatory Impact Analysis, Docket No. FDA-2014-N-1089 (May 2016).[15] Given the minimal showing required to satisfy this prong of the test, this potential divergence of interests

[15] To be clear, Public Health Intervenors do not intend to argue that the Deeming Rule should be made more rigorous. Rather, the point is that Public Health Intervenors and Defendants may come from different perspectives in assessing the propriety of the challenged Rule.

suffices to raise the possibility that representation "may be inadequate." *Trbovich*, 404 U.S. at 538 n.10 (internal quotation marks omitted).

Accordingly, the Court should grant intervention as of right under Rule 24(a).

C. Alternatively, the Court Should Permit Applicants to Intervene Permissively

In the alternative, Public Health Intervenors request leave to intervene under Rule 24(b). Where a motion is timely filed, "[p]ermissive intervention under Fed. R. Civ. Proc. 24(b) is appropriate where a party's claim or defense and the main action have a question of law or fact in common and the intervention will not unduly prejudice or delay the adjudication of the rights of the original parties." *Georgia v. U.S. Army Corps of Eng'rs*, 302 F.3d 1242, 1250 (11th Cir. 2002). Public Health Intervenors respectfully submit that the Court should exercise its discretion to permit intervention if it denies intervention as of right.

First, as explained above, Public Health Intervenors' motion is timely. *Supra* pp. 17-19.

Second, Public Health Intervenors' defense plainly has "a question of law or fact in common" with the underlying action, *U.S. Army Corps of Eng'rs*, 302 F.3d at 1250, given that it concerns the same questions of law at issue in the Plaintiffs' suit—namely, whether the Deeming Rule is consistent with the statute, arbitrary and capricious, or unconstitutional.

Third, as explained above, intervention will not unduly delay or prejudice the rights of the original parties. It would not inject any new issues into the case, as Public Health Intervenors intend to address, if necessary, the same issues currently scheduled to be briefed—namely, whether Plaintiffs or Defendants are entitled to summary judgment on Plaintiffs' claims against the Deeming Rule. Indeed, Public Health Intervenors' views will *already* be at issue in this case, because the Court has granted leave to file an amicus brief. *See* Doc. 28. At most, as discussed

below, intervention might require a delay of several weeks in an already extended briefing schedule[16]—and potentially even less, if Defendants adequately defend the Deeming Rule.

Public Health Intervenors therefore meet the criteria for permissive intervention. Moreover, intervention would provide the Court with a valuable perspective on the issues at the heart of this case. These organizations have spent decades analyzing the public health impacts of tobacco products (including, since their introduction, e-cigarettes), working to help individuals overcome their dependency on nicotine, developing effective programs to curb tobacco use, and working for regulations to reduce the incidence of tobacco-product use in the United States. This substantial expertise will contribute to reaching an informed conclusion on an issue that affects the health of millions of Americans.

Accordingly, at a minimum, the Court should permit Public Health Intervenors to intervene under Rule 24(b).

V. PROPOSED TIMELINE FOR INTERVENTION

Public Health Intervenors will not burden the Court with duplicative briefing, and it is possible that they will need only to supplement Defendants' arguments. Public Health Intervenors have moved to intervene now, before Defendants' filing, so that the Court can resolve the intervention motion expeditiously and set an appropriate briefing schedule after Public Health Intervenors have reviewed Defendants' summary judgment or other filings.

Accordingly, Public Health Intervenors propose that the Court set a status conference shortly after August 2 so that the Court and parties can discuss the most efficient way to proceed once it is known whether and how Defendants are defending the Deeming Rule. Public Health Intervenors will be available any time from August 4 through August 12 for a status conference.

[16] The briefing schedule already has been significantly extended by the joint action of Defendants and the industry Plaintiffs.

If the Court prefers, they will also be prepared to submit a short statement proposing a briefing schedule on August 3, once they review Defendants' filing.

VI. CONCLUSION

For the foregoing reasons, the Court should grant Public Health Intervenors' motion to intervene.

Dated: July 24, 2017

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 24th day of July, 2017, I electronically transmitted the foregoing document to the Clerk's Office using the CM/ECF system, which will send a notice of filing to the following counsel of record:

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