IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, *et al.*, *Plaintiffs*, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, *Defendants*.	Civil Action No. 16-1460 (APM)

MOTION TO INTERVENE AS DEFENDANTS

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Pursuant to Federal Rule of Civil Procedure 24 and Local Rule 7(j), 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]

Pursuant to Local Rule 7(m), Public Health Intervenors have contacted counsel for all parties to determine whether they consent to intervention. Plaintiffs have stated that they oppose this motion. Defendants reserve the right to oppose the motion.

I. INTRODUCTION

In this case, representatives of the tobacco industry ask the Court to set aside the "Deeming Rule,"[3] through which defendant U.S. Food and Drug Administration ("FDA")

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

[2] On April 3, 2017, the Court granted the Campaign for Tobacco-Free Kids' ("Tobacco-Free Kids") unopposed motion for leave to a file an amicus brief in this action. That same day, the Court sent a Notice to Parties disclosing that its former law firm, Zuckerman Spaeder LLP, has, from time to time, represented Tobacco-Free Kids, and requesting that the organization disclose any actual or planned involvement of the Zuckerman Spaeder firm in the amicus brief intended to be filed. Tobacco-Free Kids responded to the Court's notice on April 5, disclosing the number of hours worked by the firm on this matter and the expectation that the firm would provide substantial assistance in drafting the amicus brief going forward. Due to the extensions of the pleading schedule described below, that amicus brief has not been filed with the Court. Tobacco-Free Kids hereby informs the Court that the Zuckerman Spaeder firm is not representing Tobacco-Free Kids or the other prospective intervenors in connection with this motion to intervene and will not be involved in the case going forward. Carlos T. Angulo and Andrew N. Goldfarb of the firm did provide advice and guidance to Tobacco-Free Kids on legal issues relating to possible intervention in this case, but did not participate in the preparation of the instant motion and supporting materials. Should the present motion to intervene be granted, 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).

determined that cigars should be deemed subject to FDA regulation as "tobacco products" for the purposes of 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"). The regulation applied to all cigars, including so-called "premium" cigars, little cigars, and cigarillos. 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 products, including cigars, if the FDA first deemed them to be subject to regulation. 21 U.S.C. § 387a(b). On July 21, 2017, Judge Jackson upheld the Deeming Rule, granting the government summary judgment and rejecting a similar challenge to the Rule by e-cigarette companies. *See Nicopure Labs, LLC v. FDA*, No. 1:16-cv-00878-ABJ (D.D.C. July 21, 2017) ("Slip Op.").

The TCA banned flavored cigarettes (except for menthol) and cigarette advertising practices targeted at minors in an effort to reduce the prevalence of youth smoking. *See* 21 U.S.C. §§ 387g, 387a-1. But because these prohibitions did not apply to cigars in the absence of a final rule deeming them subject to FDA regulation, manufacturers of tobacco products could still create and market flavored cigars and design products and marketing strategies that appeal particularly to young people. The cigar industry responded immediately. Manufacturers consciously reoriented the market, resulting in a dramatic rise in the availability of flavored cigars—cigars that taste like candy, fruit, or chocolate and have names like "Banana Split" or "Wild Rush"—in order to appeal powerfully to minors. As a result, many studies find that cigar smoking is more prevalent than cigarette smoking, or as prevalent, among youth. *See* 81 Fed. Reg. at 29,023.

The Deeming Rule is a necessary predicate to FDA regulation of cigars and thus the only way for the FDA to reverse this trend and reduce the public health risks that the unregulated

promotion and sale of cigars has 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 the public from the devastating harms caused by tobacco products. 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. Public Health Intervenors therefore have a strong interest in defending 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 cigars, pipe tobacco, [and] waterpipe tobacco." 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 "[a]ll cigars pose serious negative health risks," with regular cigar smoking "responsible for approximately 9,000 premature deaths or almost 140,000 years of potential life lost among adults 35 years or older in 2010." *Id.* at 29,020. "All cigar smokers have an increased risk of oral, esophageal, laryngeal, and lung cancer compared to non-tobacco users," as well as "other adverse health effects, such as increased risk of heart and pulmonary disease," "a marked increase in risk for chronic obstructive pulmonary disease," and "a higher risk of fatal and nonfatal stroke." *Id.* In addition, "[a]ll cigars produce secondhand smoke, which causes negative health effects such as heart disease and lung cancer in bystanders." *Id.*[4]

[4] Indeed, as Public Health Intervenors along with several other public health groups noted in commenting on the proposed rule, cigars emit significantly more harmful secondhand smoke than cigarettes. *See* Campaign for Tobacco-Free Kids et al. Cmt. 14, Docket No. FDA-2014-N-1089 (Aug. 8, 2014) ("'Compared with a [similarly smoked] cigarette …, a large cigar … emits about 20 times the carbon monoxide, five times the respirable particles, and twice the amount of

The FDA explained that it "remains most concerned about use by youth and young adults given their *unique* susceptibility to the addictiveness of nicotine." 81 Fed. Reg. at 29,023.[5] A cigar can contain as much tobacco as an entire pack of cigarettes, and nicotine yields from smoking a cigar can be up to eight times higher than yields from smoking a cigarette. *Id.* at 29,022. It is thus particularly troubling that "youth cigar use has not declined when compared to use of other tobacco products" since the passage of the TCA. *Id.* at 29,023. Data from the 2014 National Youth Tobacco Survey showed that 8.2 percent of high school students (over 1.2 million young people) and 1.9% of middle school students (220,000) had smoked cigars (including cigarillos and little cigars) in the past 30 days. *Id.* at 28,985. The 2014 National Survey on Drug Use and Health revealed that more than 2,500 persons under the age of 18 smoke their first cigar each day. *Id.* Cigar smoking appears to have actually surpassed cigarette smoking among youth in certain areas of the United States: In a survey of 21 cities, 8.6% of high school students smoked cigars, compared to 7.7% who smoked cigarettes. *Id.* at 29,023.

In light of these and other findings, the FDA "extend[ed] the Agency's 'tobacco product' authorities in the [Federal Food, Drug, and Cosmetic Act] to all other categories of products that meet the statutory definition of 'tobacco product' in the … Act, except accessories of such newly deemed tobacco products." 81 Fed. Reg. at 28,974. Because the FDA deemed cigars subject to regulation under the TCA, cigars became subject to the provisions of the TCA, including, among other things, prohibitions on adulteration and misbranding, 21 U.S.C. §§ 387b-387c; reporting

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polycyclic aromatic hydrocarbon.'" (quoting Baker et al., *Health Risks Associated with Cigar Smoking*, 284 J. Am. Med. Ass'n 735, 738 (2000))).

[5] *See, e.g.*, 81 Fed. Reg. at 29,029 ("The Surgeon General has stated that adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system."); *id.* at 29,033 ("[N]icotine exposure during adolescence may have lasting adverse consequences for brain development.").

and registration requirements, *id.* §§ 387d-387e; 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 cigars) to individuals under the age of 18 and requiring the display of health warnings on tobacco product labels and advertisements. 81 Fed. Reg. at 28,974-28,975.

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 to e-cigarettes as a "careful assessment" of the costs and benefits, Slip Op. 70. The FDA explained that 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." 81 Fed. Reg. at 29,075. 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* (May 2017) ("*Guidance*").

B. Plaintiffs' Challenge to the Deeming Rule

Three trade associations of tobacco industry participants—the Cigar Association of America, Inc., International Premium Cigar and Pipe Retailers Association, and Cigar Rights of America (collectively, "Plaintiffs")—filed suit to challenge the Deeming Rule.[6] Arguing that the

[6] Plaintiffs also challenged a related rule dealing with the calculation of user fees levied on tobacco manufacturers and importers under 21 U.S.C. § 387s. *See* Requirements for the Submission of Data Needed to Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco, 81 Fed. Reg. 28,707 (May 10, 2016) (the "User Fee Rule"). Public Health Intervenors do not intend to take a position on Plaintiffs' challenge to the User Fee Rule.

Deeming Rule is arbitrary and capricious and violates the First Amendment, they seek, among other things, vacatur of the Deeming Rule, a permanent injunction restraining its implementation or enforcement, and a declaration that its labeling requirements violate the First Amendment.

C. Defendants' Responses to Challenges to the Deeming Rule

Similar suits challenging the Deeming Rule have been brought by e-cigarette manufacturers and retailers.[7] The furthest along is *Nicopure Labs, LLC v. FDA*, No. 16-cv-878 (D.D.C.),[8] in which Judge Jackson, on July 21, 2017, granted summary judgment to the government and upheld the Deeming Rule against a challenge by e-cigarette manufacturers raising many arguments parallel to those made by Plaintiffs in the present case. In *Nicopure*, Defendants had filed an 85-page cross-motion for summary judgment, vigorously defending the Deeming Rule in full.

In recent months, however, it has become apparent that Defendants may not adequately defend the Deeming Rule and may seek to weaken or rescind it. Twice in recent months the Defendants have requested extensions of time to oppose Plaintiffs' motion for summary judgment and/or file a cross-motion for summary judgment in this case. The first such motion was filed by Defendants jointly with the industry Plaintiffs on March 21, 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

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[7] *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.); *Lost Art Liquids, LLC v. FDA*, No. 16-cv-3468 (C.D. Cal.); *Cyclops Vapor 2, LLC v. FDA*, No. 16-cv-556 (M.D. Ala.); *Faircloth v. FDA*, No. 16-cv-5267 (S.D. W. Va.). A similar suit has also been brought by a cigar manufacturer and its owner. *See Sanchez Icaza & Global Premium Cigars v. FDA*, No. 16-cv-21967 (S.D. Fla.).

[8] 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 refer to the consolidated cases as "*Nicopure.*"

"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. 34 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 its action will extend compliance dates for such fundamental regulatory requirements as the submission of plans for cigar health warning labels, 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 1.

III. PUBLIC HEALTH INTERVENORS

Public Health Intervenors include six public health organizations dedicated to combating smoking and the diseases it causes. Each of the proposed intervenors expends substantial resources to educate the public about the risks of smoking, 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." Del Monte Aff. ¶ 7 (Ex. 3). 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 (Ex. 8).

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." Schoeberl Aff. ¶ 6 (Ex. 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, including cigars, and in advocating policies and programs to discourage smoking initiation and help smokers quit." Phillips Aff. ¶ 5 (Ex. 5).

The Campaign for Tobacco-Free Kids ("Tobacco-Free Kids") "has developed research and public education material about the hazards of cigar smoking and the specific threat of cheap, flavored cigars to young people," along with youth activities designed to "educate young people about the dangers of tobacco use, including cigar smoking." Myers Aff. ¶ 3 (Ex. 4). 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 smoking cessation intervention, Become an Ex®, has reached over 700,000

persons to date with information to help adults stop smoking, including information about the health risks of cigars. Vargyas Aff. ¶¶ 6-7 (Ex. 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, e.g.*, Myers Aff. ¶¶ 7-8; Del Monte Aff. ¶ 10. 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.*, Del Monte Aff. ¶ 9; Phillips Aff. ¶ 6. All of the Public Health Intervenors, moreover, joined in filing an amicus brief in support of 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 cigars forces AAP and its members to expend additional resources to effectuate its policies. *Id.* ¶¶ 8, 15.

IV. ARGUMENT

Public Health Intervenors seek leave to intervene as Defendants so that they may participate in this case to protect their interests and, in the case of AAP, the interests of their pediatrician members. The failure to subject deadly and addictive cigars 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, the D.C. Circuit has repeatedly held that several of these very organizations have standing to participate in tobacco-related litigation.

A. Public Health Intervenors Have Standing to Intervene as Defendants

Public Health Intervenors have standing to intervene in this action. *See Crossroads Grassroots Policy Strategies v. FEC*, 788 F.3d 312, 316, 320 (D.C. Cir. 2015) (holding that intervenor-defendants must show Article III standing, though they need not satisfy prudential standing considerations). Under D.C. Circuit precedent, "[t]he standing inquiry for an intervening-defendant is the same as for a plaintiff: The intervenor must show injury in fact, causation, and redressability." *Id.* at 316. There is generally "a sufficient injury in fact where a party benefits from agency action, the action is then challenged in court, and an unfavorable decision would remove the party's benefit." *Id.* at 317.

On a motion to intervene, "'[c]ourts are to take all well-pleaded, nonconclusory allegations in the motion to intervene, the proposed complaint or answer in intervention, and declarations supporting the motion as true absent sham, frivolity or other objections.'" *Parker v. John Moriarty & Assocs.*, 319 F.R.D. 18, 20 (D.D.C. 2016) (quoting *Southwest Ctr. for Biological Diversity v. Berg*, 268 F.3d 810, 820 (9th Cir. 2001)); *see also, e.g.*, *United States v. AT&T Co.*, 642 F.2d 1285, 1291 (D.C. Cir. 1980) (at intervention stage, courts assess standing

on basis of proposed pleading and "must accept a party's well-pleaded allegations as valid"). Where 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.

As the D.C. Circuit has repeatedly held, public health organizations have standing to bring or intervene in cases regarding regulation of tobacco companies. *See Philip Morris II*, 566 F.3d at 1146; *Public Citizen*, 869 F.2d at 1546-53. Indeed, the D.C. Circuit has 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).[9]

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

1. Organizational Standing

"A plaintiff suffers an organizational injury if the alleged violation 'perceptibly impair[s]' its ability to carry out its activities." *Friends of Animals v. Salazar*, 626 F. Supp. 2d 102, 113 (D.D.C. 2009) (citation omitted). Public Health Intervenors expend substantial resources to gather information on, educate the public about, and protect their members from the

[9] 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.

harms of smoking. As Judge Kessler 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 cigars makes these efforts more difficult and more expensive. Easy access to cigars—particularly youth-friendly flavored cigars—increases the risk of youth initiation and continuation of smoking, thus increasing the amount of public education and counseling needed to combat tobacco use among minors. *See, e.g.*, Schoeberl Aff. ¶¶ 9, 16; Myers Aff. ¶ 13. Moreover, as the court noted in *Nicopure*, the manufacturers of newly deemed products, "if they remain unregulated, are free to mislabel their products without consequence." Slip Op. 50. The burden created by the unregulated marketing of these products makes it harder for Public Health Intervenors "to be effective in (a) giving the public, and particularly young people, an accurate understanding of the dangers of cigar smoking; (b) discouraging initiation of cigar smoking by young people; and (c) encouraging cigar smokers, particularly young people, to quit." Schoeberl Aff. ¶ 16; *see* Phillips Aff. ¶ 11; Myers Aff. ¶ 13. The Deeming Rule would reduce youth access to cigars and give FDA the authority to take youth-focused cigars off the market, easing the challenge of fulfilling Public Health Intervenors'

mission. Eliminating the Deeming Rule would allow tobacco manufacturers to make unverified claims and to continue giving youth ready opportunities to smoke cigars, making Public Health Intervenors' mission harder. Upholding the Deeming Rule would thus provide Public Health Intervenors meaningful redress.

2. Associational Standing

In addition, AAP has associational standing. To show associational standing, an association "must demonstrate that at least one member would have standing under Article III to sue in his or her own right, that the interests it seeks to protect are germane to its purposes, and that neither the claim asserted nor the relief requested requires that an individual member participate in the lawsuit." *Natural Res. Def. Council v. EPA*, 489 F.3d 1364, 1370 (D.C. Cir. 2007).

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. ¶¶ 3, 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.* ¶ 6. AAP's members must spend more time counseling patients and their parents not to smoke when cigar manufacturers are unregulated and therefore permitted to create and market candy-flavored products that appeal to youth. They thus have a significant interest in defending 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. *Natural Res. Def. Council*, 489 F.3d at 1370. And the proposed defense does not "require[] that an individual member

participate 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.

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) "claims 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 may as a practical matter impair or impede the applicant's ability to protect that interest," and (4) may not be "adequately represented by existing parties." *Mova Pharm. Corp. v. Shalala*, 140 F.3d 1060, 1074 (D.C. Cir. 1998) (quoting Fed. R. Civ. P. 24(a)(2)). This Court takes "a liberal approach to intervention." *Wilderness Soc'y v. Babbitt*, 104 F. Supp. 2d 10, 18 (D.D.C. 2000).

Public Health Intervenors satisfy all four prongs of this test.

1. Public Health Intervenors' Motion to Intervene is Timely

Courts determine the timeliness of motions to intervene "in consideration of all the circumstances, especially weighing the factors of time elapsed since the inception of the suit, the purpose for which intervention is sought, the need for intervention as a means of preserving the applicant's rights, and the probability of prejudice to those already parties in the case." *Smoke v. Norton*, 252 F.3d 468, 471 (D.C. Cir. 2001) (quoting *AT&T*, 642 F.2d at 1295).

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.*, *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).

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, and successfully, defended the Deeming Rule against an industry challenge in the *Nicopure* case. 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 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 cigar warning label plans, ingredient listing, 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*, 252 F.3d at 471 (motion to intervene can be timely even after judgment, as long as that is when "the potential inadequacy of representation came into existence").

Finally, there will be no prejudice to the existing parties. If intervention is granted, 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.

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.*, *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))). The same factual allegations establishing Public Health Intervenors' standing, discussed above, establish a sufficient interest for intervention. *See supra* pp. 11-15.

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

Rule 24(a)'s third prong is satisfied if there is a "possibility" that intervenors' "interests may be practically impaired or impeded by the disposition of the plaintiffs' suit." *Foster v. Gueory*, 655 F.2d 1319, 1325 (D.C. Cir. 1981). 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 cigar industry may be unregulated (or at a minimum, less rigorously regulated) for years to come,

while the FDA determines whether to issue a new rule. This would undermine Public Health Intervenors' efforts to reduce cigar smoking in several ways: by exposing youth to cigars marketed without the health warnings mandated by the Deeming Rule; by depriving FDA of the authority to review cigars under the public health standard and take off the market candy- and fruit-flavored cigars that appeal to young people; by preventing FDA from setting product standards for cigars to reduce their harmfulness; by allowing cigar manufacturers and retailers to make unproven and misleading health claims; and by eliminating restrictions on sale of cigars to minors and other public health protections under the Rule. All of these changes would require Public Health Intervenors to expend additional time and resources to their shared mission of reducing the prevalence of cigar smoking, particularly by the young. 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.*, *Fund for Animals*, 322 F.3d at 735. This requirement is "not onerous." *Fund for Animals*, 322 F.3d at 735 (quoting *Dimond v. District of Columbia*, 792 F.2d 179, 192 (D.C. Cir. 1986)). The D.C. Circuit, moreover, "look[s] skeptically on government entities serving as adequate advocates for private parties." *Crossroads*, 788 F.3d at 321. A proposed intervenor "ordinarily should be allowed to intervene unless it is clear that the party will provide adequate representation for the absentee." *Fund for Animals*, 322 F.3d at 735 (quoting *AT&T*, 642 F.2d at 1293).

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. 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. The D.C. Circuit has "stressed that even 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 weight to be given to the economic impact that the Deeming Rule will have on the cigar industry, which Defendants considered in determining the appropriate compliance deadlines and other rules. *See* Final Regulatory Impact Analysis, Docket No. FDA-2014-N-1089 (May 2016).[10] Given the minimal showing required to satisfy this prong,

[10] 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.

this potential divergence of interests 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). Rule 24(b) allows intervention where a party files a timely motion and "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). "In exercising its discretion, the court must consider whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3); *see e.g.*, *Acree v. Republic of Iraq*, 370 F.3d 41, 49 (D.C. Cir. 2004) ("[A]n applicant may be permitted to intervene if his claim shares a question of law or fact in common with the underlying action and if the intervention will not unduly delay or prejudice the rights of the original parties."), *abrogated on other grounds by Republic of Iraq v. Beatry*, 556 U.S. 848 (2009). 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. 15-17.

Second, Public Health Intervenors' defense plainly "shares a question of law or fact in common with the underlying action," *Acree*, 370 F.3d at 49, 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. Public Health Intervenors intend to address, if necessary, the same issues currently scheduled to be briefed—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. 30. At most, as discussed below, intervention might require a delay of several weeks in an already extended briefing schedule[11]—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 smoking (including cigar smoking), 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 smoking 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 1 so that the Court and parties can discuss the most efficient way to proceed

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

once it is known whether and how Defendants are defending the Deeming Rule. Public Health Intervenors will be available any time from August 3 through August 12 for a status conference. If the Court prefers, they will also be prepared to submit a short statement proposing a briefing schedule on August 2, once they review Defendants' filing.

VI. CONCLUSION

For the foregoing reasons, the Court should grant Public Health Intervenors' motion to intervene and enter the attached proposed answer.

Dated: July 24, 2017

Respectfully submitted,

/s/ Kelly P. Dunbar

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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 all counsel of record.

/s/ Kelly P. Dunbar
KELLY P. DUNBAR