ORAL ARGUMENT NOT YET SCHEDULED

No. 17-5196

United States Court of Appeals
for the District of Columbia Circuit

NICOPURE LABS, LLC, RIGHT TO BE SMOKE FREE COALITION

Plaintiffs-Appellants,

AMERICAN E-LIQUID MANUFACTURING STANDARDS ASS'N, *et al.*,

Plaintiffs-Appellees,

v.

FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Columbia,
Docket No. 1:16-CV-00878-ABJ (A. Jackson, J.)

MOTION OF PUBLIC HEALTH ORGANIZATIONS TO INTERVENE AS DEFENDANTS-APPELLEES

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Movants American Association of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative are all non-profit organizations committed to advancing the public health. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

INTRODUCTION

The American Association of Pediatrics, American Cancer Society Cancer Action Network, American Heart Association, American Lung Association, Campaign for Tobacco-Free Kids, and Truth Initiative (collectively, "the Public Health Intervenors") hereby move to intervene as Defendants-Appellees in this appeal.

Plaintiffs-appellants in this case have sought to overturn the U.S. Food and Drug Administration's ("FDA") final "deeming rule," which subjects electronic cigarettes, other types of "electronic nicotine delivery systems," and components of such products (collectively, "e-cigarettes") to regulation as tobacco products under the Family Smoking Prevention and Tobacco Control Act.[1] *See* 81 Fed. Reg. 28,973 (May 10, 2016) (final rule). On July 21, 2017, the district court upheld the deeming rule, granting summary judgment for FDA and the other federal government defendants (collectively, "Defendants"). *Nicopure Labs, LLC, v. FDA*, No. 16-0878 (ABJ), 2017 WL 3130312, at *1 (D.D.C. July 21, 2017) (attached hereto as Exhibit 1). Plaintiffs noticed their appeal of the district court's decision on August 30, 2017.

Notwithstanding Defendants' successful defense of the deeming rule in the district court, their recent actions in other e-cigarette/deeming rule litigation and

[1] Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. §§ 387-387u) (hereafter, "TCA").

FDA's regulatory decisions regarding e-cigarettes raise serious doubts that the government will continue to aggressively defend or implement the rule in its entirety (or as applied to e-cigarettes)—either in connection with this appeal or in any related settlement discussions. Public Health Intervenors participated in this case in the district court as *amici curiae* in support of Defendants.[2] The government's recent actions, however, compel this motion to intervene to protect their strong interests in full and effective implementation of the rule.

BACKGROUND

I. Public Health Intervenors

Public Health Intervenors are six public health organizations dedicated to combating the diseases and other adverse health effects caused by use of tobacco products, including e-cigarettes. These organizations have a strong interest in the preservation and forceful implementation of the deeming rule as applied to e-cigarettes (and otherwise). As set forth in the affidavit from each Public Health Intervenor appended hereto, these organizations expend substantial resources to educate the public about the risks of tobacco products (including e-cigarettes), to help smokers quit, and to advise the government on the effective regulation of these products. For example:

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[2] *See* Brief for Campaign for Tobacco-Free Kids, *et al.*, as *Amici Curiae* Supporting Defendants, *Nicopure*, ECF No. 45 (Aug. 19, 2016).

The American Association 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. Ex. 2 (Del Monte Aff. ¶ 7) and Ex. A thereto.

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. Ex. 3 (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 and Ex. A thereto.

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 provides information on the consequences of e-cigarette usage on its website. Ex. 4 (Schoeberl Aff. ¶ 6). The AHA also works directly with local health care providers, church leaders, and school administrators, including from 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. Ex. 5 (Phillips Aff. ¶ 5). ACS CAN and its members provide information to the public and policymakers regarding the consequences of e-cigarette usage. *Id.*

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." Ex. 6 (Myers Aff. ¶¶ 3, 9).

Truth Initiative's ("Truth Initiative") 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 online tobacco cessation intervention, Become an Ex®, has reached over 700,000 persons to date with information to help adults quit using tobacco products. Ex. 7 (Vargyas Aff. ¶¶ 6-7). Truth Initiative also provides research-based information regarding the consequences of e-cigarette usage in its website publications and

through social media. It explains to young people that e-cigarettes are not harmless, are addictive, and there is much that is not known about the constituents of e-cigarettes and the impact of these constituents. Truth Initiative also includes information in Become an Ex® that e-cigarettes are not approved for use as a smoking cessation aid. *Id* ¶ 7.

Because of their substantial interests in the deeming rule, Public Health Intervenors actively participated in the administrative process leading to FDA's adoption of the rule, meeting with the agency during development of the rule and submitting extensive public comments on the proposed rule. *See, e.g.,* Ex. 6 (Myers Aff. ¶¶ 5-6); Ex. 4 (Schoeberl Aff. ¶¶ 12-13); Ex. 7 (Vargyas Aff. ¶¶ 10-11); Ex. 3 (Wimmer Aff. ¶ 9); Ex. 5 (Phillips Aff. ¶¶ 7-8); Ex. 2 (Del Monte Aff. ¶¶ 11-12). The district court identified these comments as important factors in upholding the deeming rule as in the interest of public health. *Nicopure*, 2017 WL 3130312, at *28. Public Health Intervenors also have long histories participating as *amici* or parties in cases relating to government regulation of the tobacco industry. *See, e.g.,* Ex. 6 (Myers Aff. ¶ 4); Ex. 4 (Schoeberl Aff. ¶ 10); Ex. 7 (Vargyas Aff. ¶ 9); Ex. 3 (Wimmer Aff. ¶ 8); Ex. 5 (Phillips Aff. ¶ 6); Ex. 2 (Del Monte Aff. ¶ 10).

In addition, AAP "is a professional membership organization of 66,000 pediatricians, pediatric medical sub-specialists and pediatric surgical specialists."

Ex. 2 (Del Monte Aff. ¶ 3). AAP members' 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.* at ¶ 6.

II. 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 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. 81 Fed. Reg. at 28,982. To determine whether to extend its TCA authority to these products, FDA undertook 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. FDA found that e-cigarettes "may deliver as much nicotine as other tobacco products." *Id.* at 29,029. The prevalence of e-cigarettes among youth was of particular concern to FDA 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, FDA determined that "flavored e-liquids contain chemicals that could be dangerous to consumers when inhaled" (*id.* at 29,029) and that 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 29,003. For example, some combinations of e-cigarette delivery systems and e-liquids "deliver more formaldehyde than ... conventional cigarettes." *Id.* at 29,031.

FDA also concluded that fruit- and candy-flavored e-cigarettes available in the marketplace not only may pose health risks to individual users, but also make these products attractive to kids. According to one FDA 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).

In light of these and other findings, FDA in the deeming rule extended the Agency's "tobacco product" regulatory authority to e-cigarettes, subjecting them to such TCA provisions as the statute's 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). 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, including a warning on the addictiveness of the nicotine in e-cigarettes. 81 Fed. Reg. at 28,975. In short, the deeming 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." *Nicopure*,

2017 WL 3130312, at *2. FDA determined that the rule would "reduce the death and disease from tobacco products" and would "afford[] FDA additional tools to reduce the number of illnesses and premature deaths associated with tobacco product use" (81 Fed. Reg. at 29,075). FDA concluded that that the benefits of the final rule justify the costs" (*id.*), a determination upheld by the district court. *Nicopure*, 2017 WL 3130312, at *33-37.

III. Plaintiffs' Challenge to the Deeming Rule

This case involves two challenges to the deeming rule that were consolidated in the district court. In one case, Nicopure Labs, an e-cigarette device and liquid manufacturer, sued FDA, the acting FDA Commissioner, and the Secretary of the Department of Health and Human Services claiming that the deeming rule exceeded FDA's authority and was arbitrary and capricious in violation of the Administrative Procedures Act. In the other case, trade associations representing the e-cigarette industry asserted similar challenges to the rule. The district court denied Plaintiffs' summary judgment motions and granted Defendants' cross-motion for summary judgment, upholding the deeming rule in all respects. Plaintiffs filed their corrected notice of appeal on August 30, 2017.

IV. Defendants' Responses to Challenges to the Deeming Rule

Defendants strongly and successfully supported the deeming rule, and the reasoning behind FDA's action, in their 85-page summary judgment brief in the

district court. Defs.' Mem. in Opp'n to Pls.' Mot. for Summ. J. and in Supp. of Defs.' Cross-Mot. for Summ. J., *Nicopure,* ECF No. 42-2 (Aug. 16, 2016) ("FDA Br."). At that stage of the case, Defendants' interests in preserving a robust, complete deeming rule aligned with the Public Health Intervenors' interests.

In recent weeks and months however, it has become increasingly apparent that Defendants, despite their previously robust defense of the deeming rule, may not continue to adequately defend the rule and its e-cigarette provisions, including in any appeal of the district court's judgment, and may in fact seek to weaken or rescind the rule and those provisions. Three times in recent months, Defendants have acted to delay summary judgment briefing in another case challenging the validity of the deeming rule as applied to e-cigarettes. *See Cyclops Vapor 2, LLC v. FDA*, No. 2:16-cv-00556-MHT-CSC (M.D. Ala.), ECF No. 29 (Mar. 1, 2017); *Id.*, ECF No. 31 (May 1, 2017); *Id.*, ECF No. 54 (July 31, 2017). Most recently, barely a month ago, the government Defendants and industry Plaintiffs jointly moved to vacate the summary judgment briefing schedule and stay that case for *two years*. *Id.*[3] This motion explained that with the change of administrations, new leadership at the Department of Health and Human Services needs additional time to "more fully consider the issues raised in this case and determine how best to proceed." *Id.* ¶ 3. The motion is pending.

[3] Public Health Intervenors have moved to intervene in the *Cyclops* case as well, on the same grounds as in this case. That motion is pending.

At the same time that the government has sought to delay litigation deadlines in *Cyclops*, it has repeatedly and significantly postponed important regulatory compliance deadlines under the deeming rule.

For example, on May 2, 2017, a day after seeking to extend the summary judgment briefing deadline in *Cyclops*, FDA delayed a May 10 deeming rule 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 Web Statement (May 3, 2017), https://www.fda.gov/TobaccoProducts/NewEvents/ucm556652.htm. This extension was ostensibly to "allow new leadership at FDA and the Department of Health and Human Services additional time to more fully consider issues raised by the [deeming] rule that are now the subject of multiple lawsuits in federal court." *Id.* FDA announced that it 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 applications, and the reporting of harmful and potentially harmful product constituents to FDA. *Id.*

FDA then announced on July 24—three days after the district court upheld the deeming rule in this case—that it would extend deadlines for premarket submissions for e-cigarettes until August 2022, approximately *four years* later than the current November 2018 premarket submission deadline for these products.

FDA News Release (July 28, 2017), https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm568923.htm. These various extensions are memorialized in an FDA August 2017 guidance document. FDA, EXTENSION OF CERTAIN TOBACCO PRODUCT COMPLIANCE DEADLINES RELATED TO THE FINAL DEEMING RULE: GUIDANCE FOR INDUSTRY (Revised) (2017) (available at https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulations Guidance/UCM557716.pdf).

In short, since it was last required to take a position on the deeming rule in this case, FDA has delayed required industry compliance with many of the rule's provisions that Defendants (and *amici*) had previously defended and that the district court upheld. And in pushing back the deadline by which e-cigarettes must comply with premarket submission requirements, a primary focus of Plaintiffs' attack in this case, FDA is allowing those products to stay on the market for years without meaningful regulatory oversight. These actions directly contradict Defendants' prior, successful argument that the recent "explosion in virtually unregulated [e-cigarette] products raises significant public health concerns" (FDA Br. at 10) that strongly justified FDA's authority "to evaluate the health risks and other characteristics of new, potentially harmful products . . . ." *Id.* at 67. There is thus serious doubt that Defendants will continue to adequately defend the deeming rule in this appeal or in any related contexts (such as settlement discussions).

ARGUMENT

I. Public Health Intervenors Are Entitled To Intervene as of Right.

A party is entitled to intervene in an appeal as of right if: (1) it has a legally protected interest in the action; (2) the outcome of the action threatens to impair that interest; (3) no existing party adequately represents that interest; and (4) its motion is timely. *Crossroads Grassroots Policy Strategies v. FEC*, 788 F.3d 312, 316, 320 (D.C. Cir. 2015). *See* Fed. R. Civ. P. 24(a).[4] Public Health Intervenors satisfy each of these requirements.

A. Public Health Intervenors Have Article III Standing and Therefore Legally Protected Interests at Stake.

The requirement that an intervenor demonstrate a legally-protected interest "is primarily a practical guide to disposing of lawsuits by involving as many apparently concerned persons as is compatible with efficiency and due process." *Nuesse v. Camp*, 385 F.2d 694, 700 (D.C. Cir. 1967). An intervenor's showing of Article III standing necessarily satisfies this factor. *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 [it] has 'an interest relating to the property or transaction which is the subject of the

[4] This Court has routinely applied Rule 24's standards to motions to intervene in an appeal. *E.g., United States House of Representatives v. Price*, No. 16-5202, 2017 WL 3271445 (D.C. Cir. Aug. 1, 2017).

action.'" (quoting Fed. R. Civ. P. 24(a)(2))). A proposed intervenor has standing if it demonstrates that it would "suffer concrete injury if the court were to grant the relief the plaintiffs seek." *Id.* at 733. That is exactly the situation facing Public Health Intervenors here.

As set forth in the accompanying affidavits from each Public Health Intervenor, these organizations expend substantial resources gathering information on, educating the public about, and protecting the public from the harms of smoking and use of other tobacco products, including e-cigarettes. *See also United States v. Philip Morris USA Inc.*, No. 99-cv-2496 (GK), 2005 WL 1830815, at *4 (D.D.C. July 22, 2005) (finding based on declarations and "the long history of these organizations in the public health arena" that proposed public health intervenors in that case, which included the groups seeking to intervene here, "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."). Vacating or otherwise undercutting the deeming rule, and therefore leaving e-cigarettes completely or largely unregulated, would make these programmatic activities much more difficult and expensive. *See* Ex. 7 (Vargyas Aff. ¶ 12);Ex. 6 (Myers Aff. ¶¶ 10-13); Ex. 5 (Phillips Aff. ¶¶ 11-14); Ex. 3 (Wimmer Aff. ¶¶ 10-13); Ex. 2 (Del Monte Aff. ¶¶ 14-17); Ex. 4 (Schoeberl Aff. ¶¶ 15-18). *See also Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982)

(holding that an organizational plaintiff suffers injury if the alleged violation of law "perceptibly impair[s]" its ability to carry out its activities); *Nat'l Taxpayer Union, Inc. v. United States*, 68 F.3d 1428, 1434 (D.C. Cir. 1995).

For example, invalidation or weakening of the deeming rule could result in Public Health Intervenors not having access to key information regarding the constituents and nicotine content of e-cigarettes, either severely limiting their ability to provide reliable information about the constituents, safety hazards, and addictiveness of these products or compelling them to spend considerable resources to develop such information. *E.g.,* Ex. 7 (Vargyas Aff. ¶ 12); Ex. 3 (Wimmer Aff. ¶ 12). Moreover, easy access to e-cigarettes—particularly youth-friendly flavors—increases the risk of youth initiation or continuation of smoking, increasing the amount of public education and counseling needed to combat tobacco use among minors. *E.g.,* Ex. 3 (Wimmer Aff. ¶ 13); Ex. 2 (Del Monte Aff. ¶ 15). Further, as the district court noted, the manufacturers of newly deemed products, "if they remain unregulated, are free to mislabel their products without consequence." *Nicopure*, 2017 WL 3130312, at *26. The burden created by e-cigarettes' unregulated marketing 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 e-cigarette use; (b) discouraging initiation of e-cigarette use by young people; and (c) encouraging users of these products,

particularly young people, to quit." Ex. 2 (Del Monte Aff. ¶ 17); Ex. 5 (Phillips Aff. ¶ 14). Eliminating or weakening the deeming rule would also allow manufacturers to continue targeting youth in the design, advertising, marketing, and promotion of e-cigarettes, making Public Health Intervenors' mission harder. *E.g.*, Ex. 5 (Phillips Aff. ¶ 12); Ex. 6 (Myers Aff. ¶ 11).

In short, vacating the deeming rule would force Public Health Intervenors to "expend resources in response to, and to counteract" the prevalence of e-cigarettes in kid-friendly flavors, supported by marketing directed at young people and by unverified claims. *See PETA v. United States Dep't of Agric.*, 797 F.3d 1087, 1097 (D.C. Cir. 2015) (finding standing where plaintiff organization claimed that defendant federal agency's inaction caused it to expend resources to counteract such inaction) (citations and internal quotations omitted)). Accordingly, Public Health Intervenors have Article III standing and, therefore, a legally protected interest at stake that entitles them to intervene. Indeed, this Court has repeatedly held that public health organizations, including certain of the Public Health Intervenors, have standing to bring or intervene in cases regarding regulation of tobacco companies. *See United States v. Philip Morris USA Inc.*, 566 F.3d 1095, 1108, 1146 (D.C. Cir. 2009) (holding that American Cancer Society, AHA, ALA, and Tobacco-Free Kids Action Fund had standing as intervenors); *Public Citizen v.*

FTC, 869 F.2d 1541, 1545 (D.C. Cir. 1989) (holding that American Cancer Society, AHA, and ALA had standing to intervene as plaintiffs).[5]

In addition, AAP has associational standing, which requires that "at least one member [of the intervenor group] 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." *NRDC 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. Ex. 2 (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 e-cigarette 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. Moreover, the interests AAP seeks to protect "are germane to [its]

[5] ACS CAN, one of the proposed intervenors here, is a nonpartisan 501(c)(4) affiliate of the 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.

purpose[]," namely, advancing the health of infants, children, adolescents, and young adults. *See NRDC*, 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. If Successful, Plaintiffs' Action Would Impair Public Health Intervenors' Interests.

The "impairment of interest" prong of the intervention test 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) (emphasis added). 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 (quoting *NRDC v. Costle*, 561 F.2d 904, 909 (D.C. Cir. 1977)). If Plaintiffs obtain relief they have thus far unsuccessfully sought (either from a court or a favorable settlement), e-cigarettes may be completely or largely unregulated for years to come. As discussed above, this would undermine Public Health Intervenors' programmatic efforts to reduce harmful e-cigarette use in several ways: by exposing consumers to e-cigarettes marketed without the health warnings 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 products that appeal to young people; 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 require Public Health Intervenors to expend additional time and resources as part of their shared mission to reduce the prevalence of e-cigarette use by the young and reducing the risk of harm from e-cigarettes to public health.

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

The "inadequate representation" prong of the intervention test is satisfied if Public Health 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 of Am.*, 404 U.S. 528, 538 n.10 (1972) (emphasis added). 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)). This Court, 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." *United States v. AT&T*, 642 F.2d 1285, 1293 (D.C. Cir. 1980).

As discussed above, Defendants' recent actions in other court challenges to the deeming rule and their postponement for several years of key regulatory deadlines under the rule raise serious questions about their continuing commitment to their previous approach and whether Defendants still share Public Health Intervenors' commitment to a strong deeming rule. This case resembles *Smoke v. Norton*, 252 F.3d 468 (D.C. Cir. 2001), in which the government's potential inadequate representation of the proposed intervenors' interest arose after summary judgment had been entered in the case (in that case, against the government). There, as here, the proposed intervenors "[had] no reason to doubt the adequacy of the Government's commitment to resisting the appellees' motion for summary judgment," but "[t]he Government's representation of the [proposed intervenor's] interests became potentially inadequate only when it equivocated about whether it would appeal the adverse ruling of the district court." *Id.* at 471. That court reversed the district court's denial of the intervention motion on the grounds that the motion was untimely. *See also House of Representatives*, 2017 WL 3271445, at *2 (granting motion to intervene in appeal after "substantial doubts about the inadequacy of representation develop[ed] after the case beg[an]" due to

"accumulating public statements by high-level [administration] officials") (citation omitted).

Here, likewise, Defendants' conduct since they aggressively defended the deeming rule in the district court establishes the potential that they will not aggressively defend the rule going forward. 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). Here, even that expectation is absent.

D. Public Health Intervenors' Motion is Timely.

Whether an intervention motion is timely depends upon "all the circumstances, especially...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*, 252 F.3d at 471 (citation and internal quotation omitted). "Where, as here, substantial doubts about the inadequacy of representation develop after the case has begun, timeliness is measured from when the potential inadequacy of representation develops." *House of Representatives*, 2017 WL 3271445, at *2 (citation omitted) (granting intervention motion after the

government's "accumulating public statements" raised concerns as to whether it would prosecute an appeal of district court injunction).

This motion is timely. Public Health Intervenors seek intervention only after it has become apparent in recent weeks that the government may not adequately represent their interests. *Smoke*, 252 F.3d at 471 (intervention motion can be timely even after judgment, as long as that is when "the potential inadequacy of representation came into existence"). The case for intervention is even stronger here than in *House of Representatives*—in which this Court granted intervention—because here, doubts about the government's representation of intervenors' interests arose not only because of "accumulating public statements," but also by concrete actions by the government regarding its position on the issues addressed in this case. 2017 WL 3271445, at *2. Most importantly, barely one month ago, FDA announced multi-year extensions of key e-cigarette compliance deadlines under the rule, including the deadline for submitting pre-market applications. This delay thoroughly undercuts the rule's premarket review provisions that have been the focus of Plaintiffs' challenge and that Defendants previously defended. This motion has been filed a reasonable time after the government's dramatic change of course, less than a month since it was memorialized in an FDA guidance document, and a week after this appeal was docketed.

Finally, there will be no prejudice to the existing parties from granting the motion. If intervention is allowed, Public Health Intervenors will participate in any appeal like any other party according to all relevant rules and procedures.

II. Alternatively, the Court Should Grant Permissive Intervention.

Alternatively, Public Health Intervenors meet the criteria for permissive intervention. "[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." *Acree v. Republic of Iraq*, 370 F.3d 41, 49 (D.C. Cir. 2004), *abrogated on other grounds by Republic of Iraq v. Beaty*, 556 U.S. 848 (2009). *See* Fed. R. Civ. P. 24(b).

First, as explained above, this motion is timely.

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 legal issues as Plaintiffs' suit—namely, whether the deeming rule is consistent with the statute, is arbitrary and capricious, or is unconstitutional.

Third, as also explained above, intervention will not unduly delay or prejudice the rights of the original parties.

CONCLUSION

For the foregoing reasons, this Court should grant the motion to intervene.

Respectfully submitted,

Dated: September 8, 2017

/s/ Carlos T. Angulo

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CERTIFICATE OF PARTIES AND AMICI

Pursuant to D.C. Circuit Rules 27(a)(4) and 28(a)(1), movants certify that the following entities have appeared as parties or amici before the district court and in this Court in this case:

Parties:

Nicopure Labs, LLC (Plaintiff/Appellant)
American E-Liquid Manufacturing Standards Association (Plaintiff/Appellant)
Electronic Vaping Coalition of America (Plaintiff/Appellee)
Right to be Smoke Free Coalition (Plaintiff/Appellee)
American Vaping Association (Plaintiff/Appellee)
Georgia Smoke Free Association (Plaintiff/Appellee)
Kentucky Vaping Retailers Association (Plaintiff/Appellee)
Louisiana Vaping Association (Plaintiff/Appellee)
Maryland Vaping Professionals, LLC (Plaintiff/Appellee)
New Jersey Vapor Retailers Coalition (Plaintiff/Appellee)
Ohio Vapor Association (Plaintiff/Appellee)
Tennessee Smoke Free Association (Plaintiff/Appellee)
New Jersey Retailers Coalition (Plaintiff/Appellee)
U.S. Food and Drug Administration (Defendant/Appellee)
Commissioner of Food and Drug Administration (Defendant/Appellee) (currently Scott Gottlieb, M.D.)
Secretary of Health and Human Services (Defendant/Appellee) (currently Tom Price)

Amici: American Academy of Pediatrics; the American Cancer Society Cancer Action Network; the American Heart Association; the American Lung Association; the American Thoracic Society; the Campaign for Tobacco-Free Kids; the Tobacco Control Legal Consortium; Truth Initiative; Clive Bates; National Center for Public Policy Research; Smoke Free Alternatives Trade Association; TechFreedom; Vape a Vet Project.

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Carlos T. Angulo

CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 27(d)(2), because it contains 5,180 words, according to the count of Microsoft Word. I further certify that this brief complies with typeface requirements of Rule 27(d)(1)(E) because it has been prepared in 14-point Times New Roman Font.

/s/ Carlos T. Angulo
Carlos T. Angulo

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of September, 2017, I electronically filed the foregoing Motion of Public Health Organizations to Intervene as Defendants-Appellees with the Court by using the CM/ECF system. All parties to the case have been served through the CM/ECF system.

/s/ Carlos T. Angulo
Carlos T. Angulo