IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

NICOPURE LABS, LLC, *et al.*, Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civ. No. 1:16-cv-0878-ABJ
RIGHT TO BE SMOKE-FREE COALITION, *et al.*, Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civ. No. 1:16-cv-1210-ABJ

Brief of *Amici Curiae* Public Health Organizations in Support of Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiffs' Motions for Summary Judgment

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Respectfully submitted,

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CORPORATE AND FINANCIAL DISCLOSURE STATEMENT PURSUANT TO FEDERAL RULES OF APPELLATE PROCEDURE 26.1 AND 29(c) AND LOCAL CIVIL RULE 7(o)(5)

Amici curiae[1] 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.

STATEMENT OF COUNSEL PURSUANT TO FEDERAL RULE OF APPELLATE PROCEDURE 29(c)(5) AND LOCAL CIVIL RULE 7(o)(5)

Counsel for *amici curiae* hereby states that:

- no counsel for any party to this litigation authored this brief in whole or in part;
- no party or party's counsel contributed money that was intended to fund, or did fund, the preparation or submission of this brief; and
- no person, other than *amici curiae*, contributed money that was intended to fund, or did fund, the preparation or submission of this brief.

[1] *Amici* include the following organizations: the 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; and Truth Initiative.

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STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*

Amici include the following organizations: the 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; and Truth Initiative.[2] *Amici* are non-profit organizations that have worked for decades to protect the public from the devastating harms caused by tobacco products, which are the leading cause of preventable death in America, claiming over 480,000 lives every year.[3]

Amici have serious concerns about the short- and long-term public health effects of electronic cigarettes ("e-cigarettes"),[4] concerns driven by: (1) the sharp increase in the use of e-cigarettes, especially among young people; (2) the emergence of thousands of varieties of flavored e-cigarettes, many with strong appeal to young people; (3) the conceded addictiveness of nicotine-containing e-cigarette products; (4) the presence in many e-cigarettes of hazardous or potentially hazardous constituents and ingredients; (5) increasing reports of adverse events, including death, from the use of e-cigarettes or the ingestion of their contents; (6) the thousands of different e-cigarette products on the market, with widely varying nicotine content and design characteristics; (7) the use of e-cigarettes by young people who have never smoked conventional

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[2] Appendix A provides a brief description of each amicus.

[3] *See* Dep't of Health and Human Services, *The Health Consequences of Smoking-50 Years of Progress: A Report of the Surgeon General*, at 659 (2014), *available at* http://www.surgeongeneral.gov/library/reports/50-years-of-progress/full-report.pdf.

[4] As used herein, "e-cigarettes" includes the full range of electronic nicotine delivery devices, and their parts and components, deemed by FDA to fall within the definition of "tobacco product." *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products; Final Rule, 81 Fed. Reg. 28973, 29028 (May 10, 2016) (to be codified at 21 C.F.R. pt. 1100) (the "Deeming Rule").

cigarettes and the potential for them to progress to conventional cigarettes; and (8) the lack of conclusive evidence as to whether e-cigarettes contribute to smoking cessation or abstinence, or instead predominantly encourage "dual use" of e-cigarettes and conventional, deadly cigarettes, instead of helping smokers to quit.

Amici support, and have a strong interest in preserving, the regulatory structure adopted by the defendant Food and Drug Administration ("FDA") in the Deeming Rule extending FDA's regulatory authority over tobacco products under the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1777 (2009) ("TCA") to a range of previously unregulated tobacco products, including e-cigarettes. Through the Deeming Rule, FDA can gather critical, otherwise unavailable information to determine e-cigarettes' long- and short-term individual and population-wide health effects, to subject e-cigarettes on the market, and those seeking to enter the market, to review under a public health standard, and to develop design, manufacturing, and other standards to govern these products. *Amici* strongly oppose Plaintiffs' efforts to dismantle this regulatory framework, which is a critical part of FDA's efforts to advance the TCA's goal of protecting the public health.

SUMMARY OF ARGUMENT

This brief is focused on a single issue that *amici* are particularly well-suited to address: whether the Deeming Rule advances the public health. The answer is indisputably yes.

Absent the Deeming Rule, the e-cigarette industry will continue to be the "Wild West." Currently, hundreds if not thousands of companies market many thousands of e-cigarette products that deliver nicotine in unregulated doses that can create and sustain addiction.[5] These

[5] Nicopure states that it alone markets over 2,400 products, and that it is only one of thousands of companies in the e-cigarette industry. Nicopure Mot. 5, 22.

products present risks to the public health that may vary significantly in type and degree. The use of these products increased significantly between 2011 and 2014, especially among the young; because the industry is relatively new, information about the long-term effects of these products is limited. Yet, prior to the Deeming Rule, anyone could put such products on the market without meeting any regulatory requirement. In the Deeming Rule, FDA has identified numerous significant specific public health concerns about e-cigarettes and established a regulatory framework to ensure, for the first time, that these products do not expose their users to unnecessarily high levels of risk or increase the risk of youth tobacco initiation. The Deeming Rule will also enable FDA to acquire the information needed to answer the many unanswered questions about the health effects of these products and develop standards of product identity, design, manufacturing, packaging, and advertising. The stakes for the next generation are simply too high to allow the unregulated market to continue.

The core of Plaintiffs' argument is that FDA's application of the Deeming Rule to e-cigarettes is arbitrary and capricious because: (1) there is evidence that *exclusive* e-cigarette use is less harmful to the individual than smoking cigarettes;[6] and (2) FDA acknowledges that the long-term public health effects of e-cigarettes cannot currently be determined with certainty.[7]

As to the first point, Congress gave FDA regulatory authority over tobacco products to ensure an objective, scientific assessment of risk by FDA that takes into account both individual

[6] *See, e.g.*, Nicopure Mot. 5 ("Peer-reviewed studies have shown that vaping is much safer than using cigarettes…."); Trade Assocs. Mot. 2 ("During the rulemaking, FDA repeatedly acknowledged that using vaping products likely presents far less risk than smoking cigarettes and that individuals switching from combusted tobacco products to vaping products may significantly reduce their harm.").

[7] *E.g.*, Nicopure Mot. 15 (claiming the Deeming Rule "is at war with itself" because "FDA says that sweeping regulation of vaping products is necessary to protect the public health, while simultaneously conceding that it does not know enough to determine its effect on the public health").

and population-wide effects. FDA has concluded that regulation of e-cigarette products is necessary for it to fulfill that role and protect the public health. The record before the FDA provides a scientific basis that is more than sufficient to support FDA's conclusions. The TCA gave FDA statutory authority to make that assessment precisely because of the agency's scientific expertise. The legal issue before this Court is not whether e-cigarettes, if properly regulated and used by smokers who otherwise cannot or would not quit smoking, might or might not reduce their risk of disease. Rather, the issue is whether the Deeming Rule is a rational regulation based on the current state of scientific knowledge about the individual and population-wide risks from e-cigarettes. It clearly meets that test.

Nor does the scientific uncertainty about the scope and severity of the public health impact of e-cigarettes undermine the Deeming Rule. It is precisely the uncertainty that exists today that makes FDA's assertion of jurisdiction over e-cigarettes, including the requirement for premarket review, reasonable and appropriate under the APA and consistent with Congress's decision to make protection of the public health the TCA's central objective. In short, the presence of nicotine in e-cigarettes, the potential presence of other harmful or potentially harmful substances in e-cigarettes, and the growth of the e-cigarette market demand meaningful regulatory oversight. The Deeming Rule more than meets the test of rational agency decision-making under the APA.

Plaintiffs also contend that the Deeming Rule's prohibition on distribution of free e-cigarettes samples and the requirement that FDA pre-review modified risk claims for e-cigarettes unconstitutionally restrict commercial speech. Restrictions on the free sampling of harmful, potentially addictive and/or potentially harmful substances do not implicate the First Amendment and are well within the FDA's authority to protect the public health. Even if these restrictions

implicate the First Amendment, they satisfy the test for commercial speech regulation set out in *Central Hudson Gas and Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980), because they are appropriately tailored to advance FDA's indisputably substantial public health interests.

ARGUMENT

I. The Deeming Rule is a rational regulatory response to the public health issues associated with e-cigarettes and does not violate the APA.

Plaintiffs claim the Deeming Rule is internally inconsistent and therefore violates the APA. In Plaintiffs' view, FDA cannot regulate e-cigarettes to protect the public health until the agency is certain about the full public health impact of those products. *E.g.*, Nicopure Mot. 15. But there is no inconsistency. FDA has identified numerous important, undisputed public health issues related to e-cigarettes and has adopted the Deeming Rule to address these issues.

A. E-cigarettes raise many significant public health concerns.

Implicit in Plaintiffs' argument is the suggestion that FDA has identified no legitimate public health concerns that justify regulating e-cigarettes. Based on this erroneous premise, Plaintiffs ask the Court to conclude that FDA lacks any rational basis under the APA for the Deeming Rule. In fact, FDA has identified numerous significant public health concerns relating to e-cigarettes, none of which Plaintiffs even discuss, much less attempt to rebut.

1. E-cigarette use among the young has increased.

The unregulated market for e-cigarettes has led to an "alarming" rise in e-cigarette use by middle school and high school students. 81 Fed. Reg. at 29028. FDA cited statistics showing that between 2011 and 2014, the number of high school students who had used e-cigarettes during the previous 30 days increased nearly *800%*, from 1.5% to 13.4% (more than one in eight students). *Id.* at 28984, 29028. Another study relied on by FDA showed that between 2011 and 2013, the

number of youths who had previously never smoked conventional cigarettes but who reported e-cigarette use increased from 79,000 to over 263,000. *Id.* at 29029.

With "current use" defined as use at least once during the past 30 days, in 2015 more than 2.3 million high school students *and 620,000 middle school students* were using e-cigarettes.[8] Plaintiffs do not contest these findings. That millions of young people have gravitated to these new, previously unregulated products is reason enough for the Deeming Rule.[9]

2. Many e-cigarette products deliver addictive doses of nicotine.

Plaintiffs concede that most e-cigarette products contain nicotine. *See* Trade Assocs. Mot. 5 ("Nicotine is used in most, but not all, e-liquids.").[10] Nicotine is indisputably a highly addictive drug. As FDA has pointed out, e-cigarettes "may deliver as much nicotine as other tobacco products" (81 Fed. Reg. at 29029, 29031), and even when they do not, "lower levels of nicotine…still have the potential to addict users…." *Id.* at 29031. Plaintiffs do not challenge this finding.

Plaintiffs also do not deny that "adolescents appear to be particularly vulnerable to the adverse effects of nicotine on the central nervous system [citation omitted]," and that nicotine

[8] U.S. Centers for Disease Control and Prevention (CDC), "Tobacco Use Among Middle and High School Students—United States, 2011-2015," *Morbidity & Mortality Weekly Report* 65(14):361-367, April 14, 2016, *available at* http://www.cdc.gov/mmwr/volumes/65/wr/pdfs/mm6514a1.pdf; *see also* 81 Fed. Reg. at 28984 (over 2.4 million high school and middle school students reported current use of e-cigarettes in 2014).

[9] Adult use of e-cigarettes has also increased significantly in recent years. *See* 81 Fed. Reg. at 28984; *see also* 79 Fed. Reg. 23142, 23152 (Apr. 25, 2014) (proposed Deeming Rule) (citing data on adult use of e-cigarettes).

[10] FDA noted studies have "found that certain types of [e-cigarettes] do not have consistent quality and the labels may not accurately reflect the amount of nicotine in e-liquid." 81 Fed. Reg. at 29032. As discussed below, the Deeming Rule will allow FDA to: (1) identify and verify which e-cigarette products contain nicotine and which do not; (2) determine whether, and if so how, these two product categories should be regulated differently; and (3) ensure accurate labeling regarding the nicotine content of particular e-cigarette products.

may have lasting adverse effects on adolescent brain development. *Id*. at 29029, 29033.[11] These findings, coupled with the dramatic increase of e-cigarette use among this very same population, necessitate FDA's assertion of jurisdiction to protect the public health.

3. E-cigarettes are made and marketed with flavors that appeal to young people.

A particularly troubling feature of the unregulated market for e-cigarettes is the introduction of flavored products, including sweet and fruity flavors obviously calculated to appeal to children—from cotton candy, to gummi bear, to bubble gum. The TCA banned the use of characterizing flavors in conventional cigarettes (with the exception of tobacco flavor and menthol) precisely because of their appeal to kids. It is now apparent that flavored e-cigarettes have a similar appeal to young people. In the proposed Deeming Rule, FDA noted concerns that these types of flavors might appeal to youth. 79 Fed. Reg. at 23157 (citing report that teenagers have expressed a preference for e-cigarette flavors like gummi bears "because it tastes really good."). One study showed that among the 400 brands of e-cigarettes available on the market, 84% offered fruit flavors and 80% offered candy and dessert flavors.[12] According to FDA's 2013-2014 Population Assessment of Tobacco and Health survey, 85.3% of current youth e-cigarette users 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."[13]

[11] *See also* 2014 Surgeon General's Report, *supra* n.3, at 121-22 (noting lasting damage to adolescent brain development from nicotine exposure).

[12] *See* Comments of the Campaign for Tobacco-Free Kids to Docket No. FDA-2014-N-1936 ("CFTFK Comments") at 12 and n.26 (July 2, 2015) (citing Zhu, S-H, *et al.*, "Four Hundred and Sixty Brands of E-Cigarettes and Counting: Implications for Product Regulation," *Tobacco Control*, 23 (Suppl. 3):iii3-iii9 (2014)).

[13] 81 Fed. Reg. at 29014 (citing Ambrose, BK, *et al.*, "Flavored Tobacco Use Among US Youth Aged 12-17 Years, 2013-2014," *Journal of the Am. Med. Assn.* (Oct. 26, 2015)).

Indeed, in 2014, at the time that it was marketing a leading brand of e-cigarettes, Lorillard Inc. stated on its "Real Parents Real Answers" website: "Kids may be particularly vulnerable to trying e-cigarettes due to an abundance of fun flavors such as cherry, vanilla, piña-colada and berry."[14] *See* http://tinyurl.com/ecigstatement (capturing the now-removed webpage). Given the obvious attraction of flavored products, and given that adolescents are particularly vulnerable to social norms, 81 Fed. Reg. at 29036 (citing the Surgeon General's 2012 Report), it is hardly surprising that use of these highly addictive products by kids has increased greatly.

The risks posed by such flavored e-cigarettes are exacerbated by the extensive marketing of e-cigarettes in ways that appeal to kids. Such marketing frequently utilizes the same strategies that cigarette makers used to attract new, young smokers, including use of cartoon characters, endorsements by entertainers popular with kids, sponsorships of athletic events and rock concerts, and characterization of e-cigarette users as cool or glamorous.[15]

4. Many e-cigarette aerosols deliver harmful and/or potentially harmful constituents.

The Deeming Rule relies on substantial scientific evidence about harmful ingredients and constituents in e-cigarettes—evidence that Plaintiffs make no effort to address. For example, FDA cited data that many e-cigarette products "contain chemicals that could be dangerous to consumers when inhaled." *Id*. at 29029. FDA also noted that e-cigarette use involves regular inhalation of toxicants, albeit at lower levels than in cigarette smoke. *Id*. at 29031-32. FDA determined that "[i]n the absence of short- and long-term studies on the potential impact of

[14] *See* Comments of 24 Public Health Organizations to the Proposed Deeming Rule (Docket No. FDA-214-N-0189) at 46-47 (Aug. 8, 2014).

[15] *Id.* at 21-26, 46-49.

secondary exposure to [e-cigarette] aerosol, FDA cannot conclude that the aerosol is harmless." *Id.* at 29032.

Furthermore, FDA found that many of the flavors used in e-cigarette products contain constituents that are hazardous when inhaled. FDA noted, among other data, a study testing 159 sweetly-flavored e-liquids which showed that almost 75% of the tested flavors contained diacetyl or acetyl proponiol, "both of which pose known inhalation risks," and that nearly half of the products that tested positive "could expose users to levels that exceeded recommended workplace limits for breathing these chemicals." *Id.* at 29029. Another study relied on by FDA found that "many [e-cigarette] flavors, including cotton candy and bubble gum, contained aldehydes, a class of chemicals that can cause respiratory irritation, airway constriction, and other effects," and that two flavors in particular (dark chocolate and wild cherry) would expose e-cigarette users to more than twice the recommended workplace safety limit for the aldehydes vanillin and benzaldehyde. *Id.* FDA also cited data showing that several cinnamon-flavored e-liquids contained cinnamaldehyde, a chemical found to be highly toxic to human cells in laboratory tests. *Id.* The risk of harm is compounded because some of the flavors containing these toxicants are the very same flavors that appeal and are marketed to young people, the segment of the e-cigarette user population that is growing most quickly and is most impacted by them.

5. There have been many adverse events related to e-cigarettes.

FDA rightly expressed "concern[] about the risk of nicotine poisoning in both users and nonusers" of e-cigarettes, noting that the CDC reported more than 2,400 calls to U.S. poison control centers for e-liquid exposure between September 2010 and February 2014. *Id.* FDA also referenced another study of 1,700 e-liquid exposures (from 2010 to 2013) showing that children

aged five years or less represented the largest proportion of these exposures and experienced the largest increase in exposures per month in the first three quarters of 2013. *Id.* at 29032. FDA explained that nicotine exposure in sufficient concentrations can cause serious or fatal poisoning, with symptoms including nausea, vomiting, seizures, coma, cardiovascular instability, respiratory arrest, and sometimes death. *Id.* FDA noted that after the close of the comment period, the media had reported the first death of a toddler from e-liquid poisoning. *Id.* at 29036.[16] In addition, FDA also cited reports of adverse events associated with e-cigarette hardware, including overheating and exploding batteries. *Id.* at 29035.

6. E-cigarettes lack quality control and product consistency, and there is wide variability both within the same product and between different products.

"Thousands of small, independent, businesses comprise the vaping industry." Nicopure Mot. 5. And the reality is that the variety of e-cigarette products on the market is almost as wide as the number of companies that make them, with different product types posing many different combinations of risks.

FDA noted that "[a]t present, there is significant variability in the concentration of chemicals amongst products—including variability between labeled content and concentration and actual content and concentration." 81 Fed. Reg. at 28984. Moreover, because many of the thousands of manufacturers of these products lack the training and resources to ensure product consistency, the level of hazardous substances in different batches of the same product may vary significantly. *Id.* at 29034.

[16] Congress has recently acted to address these concerns by vesting jurisdiction in the Consumer Products Safety Commission to regulate the packaging of e-liquids. *See* Childhood Nicotine Poisoning Prevention Act, Pub. L. No. 114-116 (2016). But this law also preserved FDA's authority to address this issue.

As of January 2014, researchers had identified more than 7,700 unique e-cigarette flavors available on-line, with an average of 240 new flavors added per month.[17] As discussed above, many of these flavors pose particular health risks because of the presence or levels of toxicants. FDA also found that "[e]-liquids are available in a wide range of nicotine concentrations," *id.* at 29031, and that "there are some [e-cigarettes] and some power levels of operating [e-cigarettes] that deliver more formaldehyde than other [e-cigarettes] and conventional cigarettes." *Id.* at 29031 and 29036 (noting study showing "large variations in formaldehyde delivery across devices" and that some of the products tested delivered more formaldehyde than combustible cigarettes at every power tested). Moreover, FDA cited evidence that the level of nicotine delivered by some e-cigarettes differed substantially from the level on the label. *Id.* at 29034.

The wide variety of e-cigarette products circulating in a completely unregulated market, in and of itself, poses a serious public health concern. Absent regulation, thousands of different products, including many that may be highly addictive, will continue to be available to and used by consumers, including large numbers of young people (to whom these products are particularly appealing), with FDA unable even to identify what products are on the market, much less to establish basic standards to ensure product consistency and quality. *E.g.*, *id.* at 29029 ("Absent a regulatory standard, FDA acknowledges that it may not be able to account for the wide variability of concentrations and constituents in [e-cigarette] flavors."). Given the documented health risks posed by e-cigarettes, the product inconsistency, and product variability, this "Wild West" state of affairs cannot continue.

[17] CFTFK Comments at 12 and n.25 (citing Zhu, *supra*, at iii3-iii9).

7. The impact of e-cigarettes on smoking is uncertain.

Notwithstanding the substantial public health concerns identified by FDA in connection with e-cigarettes, Plaintiffs claim the Deeming Rule is inconsistent with protection of the public health because there is evidence to suggest that exclusive use of e-cigarettes is safer than smoking cigarettes. *E.g.*, Nicopure Mot. 5; Trade Assocs. Mot. 2. FDA acknowledged in the Deeming Rule that "*completely* switching from combusted cigarettes to [e-cigarettes] may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products." *Id.* at 29030 (emphasis added). As discussed above, that does not mean that e-cigarettes are not harmful. A tobacco product does not need to be as harmful as a cigarette to justify FDA's decision to act in the interests of the public health under the TCA.

Moreover, whether or not e-cigarettes reduce individual health risks when used as a complete substitute for conventional cigarettes, critical public health questions about the population-wide effects of e-cigarette use remain: *To what extent are e-cigarettes in fact used as a complete substitute for cigarettes by smokers trying to quit*? *To what extent do they instead encourage "dual use" among cigarette smokers who would otherwise quit smoking altogether? To what extent are they being used by youth? To what extent do they act as a gateway for the use of cigarettes by new smokers (i.e., young people), or encourage relapse among former smokers*?

FDA found, correctly, that the current evidence on these critical issues is inconclusive. *Id.* at 29028 (noting that "long-term studies are not yet available to determine whether…youth and young adults [using e-cigarettes] are only experimenting with tobacco use, becoming established [e-cigarette] users or dual users, or transitioning to combusted products. In addition, there is not sufficient evidence to conclude that youth and young adults are using [e-cigarettes] as a means to quit smoking."); *id.* at 29037 (noting that some studies showed that using e-

cigarettes helped smokers quit, but noting that "other evidence is to the contrary" and citing studies showing that individuals who were smokers at the start of the study, and who reported e-cigarette use at the end of the study, were more likely to still be smoking and to have unsuccessfully tried to stop smoking than smokers who had not used e-cigarettes); *id.* at 29037 (noting that despite some evidence to suggest that e-cigarettes may be viable smoking cessation devices, "some systematic reviews of available evidence indicate that there is currently insufficient data to draw [this] conclusion."). FDA also noted that notwithstanding some claims that e-cigarettes are used to aid smoking cessation, for a product to be marketed as a smoking cessation device it must be approved as a drug by FDA's Center for Drug Evaluation and Research ("CDER"), and no e-cigarette to date has been so approved. *Id.* at 29036.

In short, the data are inconclusive as to whether or to what extent e-cigarettes reduce the number of people who use conventional tobacco products. One of the key objectives of the Deeming Rule, including premarket review, is to facilitate gathering the information that will help answer this critical question.

B. Regulation under the Deeming Rule is rationally connected to FDA's public health concerns.

As the legislative history of the TCA makes clear, the overall intent of that statute is "to protect the public health," H.R. Rep. 111-58 (Pt. 1) at 1 (2009). The public health standard "is intended to be a flexible standard that focuses on reducing the number of individuals who die or are harmed by tobacco products." *Id.* at 39. The regulatory structure for e-cigarettes set out in the Deeming Rule will advance the TCA's goals by, among other things:

- increasing product consistency by helping "to ensure quality control relative to the chemicals and their quantities being aerosolized and inhaled" (81 Fed. Reg. at 28984);

- "allow[ing] FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market" (*id.*);
- subjecting all e-cigarettes to certain basic labeling requirements, to ensure that their advertising is not false and misleading (*id.*);
- imposing certain critical restrictions on the sale of e-cigarettes, such as minimum age requirements and advertising restrictions (*id.*);
- providing FDA with essential information regarding the health risks of e-cigarettes, including information derived from ingredient listing submissions and reporting of adverse events (*id*.);
- requiring substantiation of any "modified-risk" claims for e-cigarettes (*id.*);
- preventing the marketing of products that lack appropriate design methods and controls (*id.* at 28983); and
- conferring authority on FDA to take enforcement action against manufacturers that do not comply with legal requirements (*id.* at 28984).

In short, FDA's public health concerns and the regulatory measures adopted in the Deeming Rule to address those concerns align completely.

1. Application of the pre-market review procedures to e-cigarettes is necessary to protect the public health.

Application of the pre-market review procedure set out in Section 910 of the Food, Drug, and Cosmetic Act to e-cigarettes is a critical element of FDA's effort to accomplish the above-listed goals. As FDA stated, "Whether [e-cigarettes] generally may eventually be shown to have a net benefit on or harm to public health at the population level . . . *regulation* of [e-cigarettes] will still benefit public health." *Id.* at 28984) (emphasis in original); s*ee also id.* at 28984 ("[R]egulation and product review allows the Agency to help ensure the public health is

protected."). Absent such review, the market will continue to be flooded with thousands of different types of potentially addictive products presenting widely varying risks to the public health. *See also id*. ("Even if a category of products were to prove generally beneficial, individual products within that category may raise concerns.").

Plaintiffs contend that FDA's refusal to change the TCA's February 15, 2007 grandfather date for e-cigarettes is arbitrary and capricious. Trade Assocs. Mot. 18-21. But changing the grandfather date would (i) leave hazardous products on the market merely because they were marketed by a given date regardless of the risks they pose to the public health or their appeal to youth, and (ii) preclude premarket review by FDA of products that might deliver unnecessarily high levels of toxicants or might be particularly likely to lead to youth use and/or addiction and/or initiation of cigarette smoking. While Plaintiffs argue that the date established in the statute does not enable e-cigarettes to be marketed through the "substantial equivalence" pathway, the TCA did not give e-cigarettes (or other deemed products) any "right" to bypass the requirement to show that their marketing is appropriate for the protection of the public health.

Pre-market review of e-cigarettes will, *inter alia*, provide FDA with the information—unavailable to the agency in today's completely unregulated market—that it needs to evaluate the public health effects (at both the individual and population levels) of specific products, including the effect of flavored products; to monitor changes in product development; to promote product consistency through the adoption of common identity, design, production, labeling, packaging and advertising standards against which all e-cigarette products can be measured; and to spur innovation by issuing marketing orders for products that meet these standards while rejecting products that do not. *E.g.*, *id*. at 28983-84 ("FDA's premarket review . . . will increase product consistency."). And pre-market review and other forms of FDA regulation will also

enable FDA to gather information to help it answer the fundamental public health question of the impact (positive or negative) that e-cigarettes have on use of conventional tobacco products.

Plaintiffs argue that FDA failed to consider alternatives and failed to establish a regulatory structure that takes into consideration that the benefits of the marketing of e-cigarettes may outweigh the risks. Trade Assocs. Mot. 3. On the contrary, FDA not only documented its extensive consideration of alternatives, it also exercised its discretion to provide a number of accommodations to e-cigarette makers, including permitting e-cigarette products on the market as of the effective date of the Rule to *remain* on the market for up to two additional years pending the submission of a pre-market tobacco product application ("PMTA"). 81 Fed. Reg. at 29005-06.

2. FDA need not await certainty about short- and long-term effects of e-cigarettes at the individual and population levels before regulating e-cigarettes consistent with the TCA.

Contrary to Plaintiffs' contention, the APA does not require FDA to wait for conclusive evidence about e-cigarettes' adverse long-term effects before fulfilling the role that Congress assigned to it. Nor does it require the invalidation of a regulatory scheme that will allow the agency to obtain a better understanding of these products and public health issues associated with them. As the D.C. Circuit has noted:

> Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge, the regulations designed to protect the public health, and the decision that of an expert administrator, we will not demand rigorous step-by-step proof of cause and effect. Such proof may be impossible to obtain if the precautionary purpose of the statute is to be served.

Ethyl Corp. v. EPA, 541 F.2d 1, 28 (D.C. Cir.) (*en banc*), *cert denied*, 426 U.S. 941 (1976)); s*ee also American Mining Congress v. EPA*, 907 F.2d 1179, 1187 (D.C. Cir. 1990) (noting that federal agencies may apply their expertise to regulate in the face of "imperfect data"). Plaintiffs'

approach, by contrast, would "allow for only reactive, not preventive, regulation," *Ethyl Corp.*, 541 F.2d at 25, an approach that would conflict with the overarching goals of the TCA.

FDA's approach is consistent with its statutory mandate and the "precautionary principle" that informs public health policy generally and that "requires that in the light of scientific uncertainty, when credible evidence is put forth that a risk exists, action should be taken to minimize that risk or eliminate it even though absolute proof has not been obtained which quantifies the risk." *New Mexico v. Gen. Elec. Co.*, 335 F. Supp. 2d 1185, 1221 (D.N.M. 2004); *see also In re Welding Fume Products Liability Litig.*, 2010 WL 7699456, *25 (N.D. Ohio June 4, 2010) (noting that this principle "calls for policies to protect health from potential hazards even when definitive proof and measurement of those hazards is not yet available").

In short, it is inconceivable that FDA would lack a basis for regulating a product that is used by millions of Americans, including many young people, comes in thousands of product types, is highly addictive, affects adolescent brain development, features characterizing flavors with obvious appeal to kids, often contains harmful toxicants associated with product flavors that appeal to young people, has resulted in a spike in poison control center visits involving children, has been the cause of explosions causing serious injuries, and has an as-yet unclear effect on the use of conventional deadly tobacco products—*even if* FDA does not and cannot yet have full knowledge of that product's effects on public health.

3. Plaintiffs' doomsday scenarios for the e-cigarette industry are premature and provide no basis for invalidating the Deeming Rule.

Plaintiffs claim that the Deeming Rule will effectively destroy the e-cigarette industry. *E.g.*, Trade Assocs. Mot. 4 (absent the requested relief, "virtually all manufacturers will exit the vaping market, thus depriving adults of a relatively safer tobacco product and a chance to reduce or, better yet, quit their smoking habits"). They complain that the additional two-year period in

which they can remain on the market does not give them adequate time to conduct the studies required to support a PMTA. Trade Assocs. Mot. 24-27. Plaintiffs' doomsday scenario represents nothing more than premature speculation.

On the day it issued the Deeming Rule, FDA also issued a draft guidance on PMTAs. *See* Draft FDA Guidance for Industry, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems* (May 2016) ("Draft Guidance"). The Draft Guidance makes clear that FDA will take into account the practical constraints on adducing evidence within the time periods established under the rule when it considers such applications.[18] FDA is now considering the public comments it received on the Draft Guidance. No application for premarket approval for an e-cigarette has been submitted to, much less ruled upon, by the agency. Plaintiffs cannot credibly claim at this early stage that the approach chosen by FDA to regulate e-cigarettes, an approach whose precise contours are still uncertain, will extinguish the entire industry.

Moreover, nothing in the Draft Guidance indicates that FDA will require information that cannot reasonably be provided. Contrary to Plaintiffs' contentions, the Draft Guidance does not state that clinical trials will be required to obtain a marketing order. Rather, it explicitly states that in some cases such data will not be required and that other data submitted by the manufacturer may support such an application. Draft Guidance at 44. The Draft Guidance takes into account both the need to protect the public health against unreasonable risks and the objective of making it possible for e-cigarette products that are responsibly manufactured and marketed to be available to consumers.

[18] In addition, it should be noted that manufacturers of e-cigarettes have long been on notice that they would be required to submit new product applications in order to keep their products on the market. FDA announced its intention to assert jurisdiction over e-cigarettes in 2011 and issued the proposed deeming rule in April 2014.

FDA determined that regulation will encourage innovation by incentivizing e-cigarette manufacturers to develop less risky products and by ensuring that such products will not have to compete with more dangerous (and often cheaper) products. The agency explained:

> Greater regulatory certainty created by premarket authorizations should help companies to invest in creating novel products, with greater confidence that improved products will enter the market without having to compete against equally novel, but more dangerous products. For example, a company wishing to invest the additional resources needed to ensure that its e-cigarette is designed and manufactured with appropriate methods and controls will be more likely to do so if the product is not competing against products that are more cheaply and crudely made, yet appear to be identical to the consumer.

81 Fed. Reg. at 28983. This determination clearly aligns with the overall goals of the TCA.

In sum, Plaintiffs and their members are not entitled to an unregulated market in which they can sell any e-cigarette product they want. If certain products cannot meet the standards FDA adopts to protect the public health, they should not be allowed on the market, and this in turn will free the market for, and incentivize development of, products that can meet those standards. Plaintiffs may disagree with FDA's approach and its conclusion that the Deeming Rule will help address legitimate public health concerns about e-cigarettes, but there is no doubt that FDA's chosen approach has "a rational connection" to those concerns. *See Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The Court should reject Plaintiffs' challenge.

II. Even if the Deeming Rule implicates First Amendment interests, it meets the *Central Hudson* test.

Plaintiffs contend that by applying certain of the TCA's marketing and promotion restrictions to e-cigarettes, the Deeming Rule violates the First Amendment. Nicopure Mot. 33-44. In particular, Plaintiffs challenge (i) the prohibition on distribution of free samples of e-cigarette products, and (ii) the application to e-cigarettes of section 911 of the FDCA, which

prohibits statements communicating that an e-cigarette is less harmful than other tobacco products, absent FDA grant of a modified risk application for such a product.

However, even assuming *arguendo* that these restrictions implicate the First Amendment,[19] they are both permissible restrictions on commercial speech under *Central Hudson*, 447 U.S. 557. These two restrictions materially and directly advance the substantial public health interests articulated by FDA. *See* 447 U.S. at 566.

A. Prohibition of free samples is necessary to meet critical public health goal of limiting access to e-cigarettes by young people.

In the TCA, Congress made numerous findings about the significant impact of advertising, promotion, and marketing activities on the use of tobacco products by youth, concluding that "comprehensive restrictions on the sale, promotion, and distribution of such products are needed." TCA § 2 (5), (6), (15), (16), (18), (30)-(33). To counter the well-documented role that marketing and promotion play in attracting youth to tobacco products, Congress directed FDA to re-promulgate its Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents, 61 Fed. Reg. 44396 (Aug. 28, 1996) (the "Tobacco Rule"). *Id.* § 102(a)(2). Among other things, the Tobacco Rule prohibited the distribution of free cigarette samples. 61 Fed. Reg. at 44617. The Deeming Rule extends these same restrictions to e-cigarettes.

Plaintiffs concede that the governmental interest in preventing youth access to tobacco products is substantial and do not suggest that restrictions on free cigarette samples is unconstitutional. Nicopure Mot. 36. Rather, they complain that the Deeming Rule restrictions on

[19] *Amici* agree with Defendants that the distribution of free samples is not an expressive activity that warrants First Amendment protection, but assume for purposes of this brief that these restrictions do trigger the First Amendment scrutiny afforded commercial speech.

free e-cigarette samples do not "directly and materially advance" that substantial interest because the only evidence relied on by FDA related to free sampling of conventional tobacco products, not e-cigarettes. *Id.* at 36-37. But Plaintiffs ignore the agency's evidence specific to e-cigarettes that supports the free sampling ban, and do not explain why the evidence about how young people respond to free sampling in the cigarette context does not justify similar restrictions for e-cigarettes.

FDA found, and Plaintiffs do not deny, that e-cigarettes, like cigarettes, are "physiologically addictive, and socially attractive to youth."[20] FDA also cited evidence that e-cigarettes are marketed in appealing flavors that cause young people to use them. 81 Fed. Reg. at 29014. And FDA presented evidence of e-cigarette companies conducting free-sample promotional activities at youth-oriented events. *Id.* at 28986 (referring to e-cigarette companies' free-sampling activities at youth-oriented events, including six e-cigarette companies distributing free samples or sponsoring at a combined 348 events in 2012 and 2013, including "music festivals and motorsport events geared at young people").

FDA also found that youth are "uniquely susceptible to biological, social, and environmental influences to use and become addicted to tobacco products" and that free samples "encourage experimentation by minors with a risk free and cost-free way to satisfy their curiosity."[21] Plaintiffs make no effort to explain why these considerations are any less valid in

[20] 81 Fed. Reg. at 29031, 29033 (discussing evidence that e-cigarettes deliver addictive doses of nicotine).

[21] *Id.* at 29047, 29054 (quoting 2004 Institute of Medicine report, *Growing Up Tobacco Free: Preventing Nicotine Addiction in Children and Youths*); *see also Discount Tobacco City & Lottery v. United States*, 674 F.3d 509, 541 (6th Cir. 2012), *cert. denied sub nom. Am. Snuff Co., LLC v. United States*, 133 S. Ct. 1996 (2013) (finding that FDA presented "extensive evidence that free samples of tobacco products are 'easily accessible source of these products to young people'") (quoting Tobacco Rule, 61 Fed. Reg. at 44460).

the context of e-cigarettes than conventional tobacco products.

B. FDA review of proposed modified risk claims is essential to protect against serious public health consequences of unsubstantiated reduced risk claims.

Plaintiffs also challenge the application to e-cigarettes of FDA's pre-market review authority, under section 911 of the FDCA, over claims that a tobacco product reduces harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. Nicopure Mot. 39-44. In the TCA, Congress made findings about the risks to public health posed by unsubstantiated reduced-risk claims about tobacco products. *See* TCA § 2(36)-(44). These concerns apply no less to e-cigarettes than to conventional cigarettes, and FDA's regulation of such claims meets the requirements of *Central Hudson*. The Deeming Rule does not prohibit manufacturers from making reduced risk claims; it just requires them to provide adequate scientific evidence supporting such claims so that the public is not misled.

Plaintiffs address only two of the four government interests identified by FDA in the Deeming Rule—"improve[ing]" and "protecting" the public health (*id.* at 28976 & 29053) and "prevent[ing] the use of unsubstantiated modified risk claims, which may mislead consumers and lead them to initiate tobacco product use or to continue using tobacco when they would otherwise quit" (*id.* at 29053).[22] Plaintiffs do not deny these are substantial governmental interests. Rather, they claim that applying section 911 to e-cigarettes will not directly or materially advance those interests and restricts speech more extensively than necessary. Nicopure Mot. 41-44. Plaintiffs are wrong.

[22] The two governmental interests that Plaintiffs ignore are "allowing for better-informed consumers" (81 Fed. Reg. at 29005, 29053), and "help[ing] to prevent the use of misleading marketing targeted to youth populations" (*id.* at 29053).

1. The addictive and potential harmful nature of tobacco products makes consumers particularly susceptible to reduced risk claims.

Applying section 911 to e-cigarettes will directly and materially improve and protect the public health. To support their argument to the contrary, Plaintiffs selectively quote statements from the Deeming Rule (omitting qualifiers and context) to suggest that FDA agrees that e-cigarettes are unqualifiedly safer for individuals. *See* Nicopure Mot. 41-42. But Plaintiffs overlook the questions about who is using these products and how—questions that create substantial uncertainties about the safety of unregulated e-cigarettes, at both the individual and population levels, that FDA details in the Deeming Rule (*see supra* Sec. I.A.).[23]

In upholding the section 911 provisions against a First Amendment challenge, the Sixth Circuit stated that "the government has made a reasonable determination that, *in the context of a deadly and highly addictive product*, it would be a virtual impossibility to unring the bell of misinformation after it has been rung." *Discount Tobacco*, 674 F.3d at 537 (emphasis added). That reasoning applies equally to e-cigarettes. The Deeming Rule documents the delivery by some e-cigarettes of harmful substances, including chemicals in flavorings that attract kids, and e-cigarettes' capacity to deliver potentially addictive doses of nicotine. 81 Fed. Reg. at 29029-33. The existence of evidence to suggest that, on an individual level for an existing smoker, e-

[23] For example, in the comment that referred to a review that "*suggests* substantial reductions in the exposure to harmful constituents typically associated with smoking" from use of e-cigarettes instead of conventional cigarettes, FDA cautioned about limitations of that paper; noted that "study results have been inconsistent about the effects" of e-cigarettes; cited to other studies showing higher delivery of formaldehyde from e-cigarettes versus cigarettes; and emphasized the limits of currently available data. *Id.* at 29030-31. Similarly, Plaintiffs' statement about the comparative quit rate of e-cigarette users versus users of nicotine-replacement therapies (Nicopure Mot. 42), which came from a single survey, ignores FDA's extensive discussion of e-cigarettes' role in cessation, and its statements that the currently small and generally low-quality body of evidence on the subject precludes scientific conclusions. 81 Fed. Reg. at 29037.

cigarettes may be less deadly than a product (conventional cigarettes) that kills half its users does not mean these products are free of risk and thus exempt from reasonable requirements established by Congress to protect the public from unsubstantiated modified risk claims.

2. The history of consumers' response to unsubstantiated reduced risk claims for tobacco products, and the related disastrous public health consequences, justify FDA's decision to apply section 911 to e-cigarettes.

Plaintiffs downplay (Nicopure Mot. 43) FDA's statement that it is important to apply section 911 to e-cigarettes (and other newly deemed products) to prevent "inaccurate and harmful health claims about tobacco products of the sort that the industry has made for many decades." 81 Fed. Reg. at 28987. But Congress and FDA are right to consider that history instructive. Cigarette companies used product descriptors like "light" and "low tar," and advertising statements and imagery, to communicate to health-conscious consumers that their products were less harmful than "full flavor" cigarettes—which the manufacturers knew to be false and which proved to be untrue. *United States v. Philip Morris USA Inc.*, 449 F. Supp. 2d 1, 430, 446-47 (D.D.C. 2006) (citing to consensus scientific evidence that the market shift to cigarettes sold as "light" and "low tar" yielded no reduction in disease risk to smokers or public health benefit), *aff'd in relevant part*, 566 F.3d 1095 (D.C. Cir. 2009). In the TCA, Congress adopted the Federal Trade Commission's finding that "consumers have misinterpreted advertisements in which one product is claimed to be less harmful than a comparable product, even in the presence of disclosures and advisories intended to provide clarification." TCA § 2(41). Congress thus found that "[t]he dangers of products sold or distributed as modified risk tobacco products that do not in fact reduce risk are so high that there is a compelling governmental interest in ensuring that statements about modified risk tobacco products are complete, accurate, and relate to the overall disease risk of the product." *Id.* § 2(40). Congress

concluded that "[t]he *only* way to effectively protect the public health from the dangers of unsubstantiated modified risk tobacco products" was to empower FDA to review such products in advance of marketing and to verify evidence relied on to support claims of modified risk. *Id.* § 2(43) (emphasis added).

Congress's findings about consumer behavior and susceptibility to health-related communications apply beyond just conventional cigarettes marketed with light/low tar descriptors and the companies that marketed them. Given the history of cigarette marketing, and the addictive, potentially harmful nature of tobacco products, including e-cigarettes, requiring that FDA review and approve modified risk claims for a tobacco product before that product can be marketed with such claims is a reasonable response to protect consumers from unsubstantiated, misleading statements.[24]

CONCLUSION

For the foregoing reasons, this Court should grant the Defendants' cross-motion for summary judgment and deny the Plaintiffs' motions for summary judgment.

[24] Indeed, FDA noted that adolescents are particularly vulnerable to "social norms." 81 Fed. Reg. at 29036 (citing to *Preventing Tobacco Use Among Youth and Young Adults*," *A Report of the Surgeon General* (2012), available at http://www.ncbi.nlm.nih.gov/books/NBK99237/Preventing Tobacco Use Among Youth and Young Adults). That report also cited to evidence of young people's susceptibility to cigarette companies' erroneous marketing of "light" and "low tar" cigarettes as less harmful. 2012 Surgeon General's Report at 531.

Respectfully submitted,

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APPENDIX A

Description of *Amici Curiae*

1. The American Academy of Pediatrics

The American Academy of Pediatrics (AAP), founded in 1930, is a national, not-for-profit organization dedicated to furthering the interests of children's health and the pediatric specialty. Since its inception, the membership of the AAP has grown from the original group of 60 physicians specializing in children's health to 62,000 primary care physicians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past 85 years, the AAP has become a powerful voice for children's health through education, research, advocacy, and expert advice and has demonstrated a continuing commitment to protect the well-being of America's children. The AAP has engaged in broad and continuous efforts to prevent harm to the health of children and adolescents caused by the use of tobacco products and exposure to secondhand tobacco smoke.

2. The American Cancer Society Cancer Action Network

The American Cancer Society Cancer Action Network (ACS CAN) is the nation's leading cancer advocacy organization dedicated to making cancer issues a priority. Created in 2001 as the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, ACS CAN educates the public, government officials, and candidates about cancer's devastating impact on public health and encourages them to make fighting cancer a top priority. ACS CAN has more than one million volunteers nationwide, many of whom advocate for effective tobacco control at the federal, state, and local levels. In 2015, an estimated 221,000 people in the US will be diagnosed with lung and bronchus cancer, the vast majority of which is attributable to tobacco use. This devastating impact makes regulation of tobacco products critical to our mission.

3. The American Heart Association

The American Heart Association ("AHA") is a voluntary health organization that, since 1924, has helped protect people of all ages and ethnicities from the ravages of heart disease and stroke. AHA is one of the world's premier health organizations, with local chapters in all 50 states, as well as in Washington D.C., and Puerto Rico. The association invests in research, professional and public education, and advocacy so people across American can live stronger, longer lives. AHA has long been active before Congress and regulatory agencies on tobacco and other health-related matters and has petitioned the Food and Drug Administration on several occasions seeking regulation of cigarette and other tobacco products under the Federal Food, Drug, and Cosmetic Act.

4. The American Lung Association

The American Lung Association is the nation's oldest voluntary health organization. Because smoking is a major cause of lung cancer and chronic obstructive pulmonary disease (COPD), the American Lung Association has long been active in research,

education and public policy advocacy regarding the adverse health effects caused by tobacco use, as well as efforts to regulate the marketing, manufacture and sale of tobacco products.

5. The American Thoracic Society

The American Thoracic Society ("ATS") is an international educational and scientific organization founded in 1905 that represents more than 15,000 health care professionals. ATS works to prevent and fight respiratory disease around the globe through research, education, patient care, and advocacy. ATS publishes three peer-reviewed scientific journals that disseminate groundbreaking research, including studies on the adverse pulmonary health effects of tobacco use.

6. The Campaign for Tobacco-Free Kids

The Campaign for Tobacco-Free Kids is a leading force in the fight to reduce tobacco use and its deadly toll in the United States and around the world. The Campaign envisions a future free of the death and disease caused by tobacco, and it works to save lives by advocating for public policies that prevent kids from smoking, help smokers quit and protect everyone from secondhand smoke.

7. The Tobacco Control Legal Consortium

The Tobacco Control Legal Consortium is a national network of nonprofit legal centers working to protect the public from the devastating health consequences of tobacco use. The Consortium's activities are coordinated by the Public Health Law Center, Inc., at Mitchell Hamline School of Law in St. Paul, Minnesota. Affiliated legal centers include: ChangeLab Solutions, Oakland, California; Legal Resource Center for Tobacco Regulation, Litigation & Advocacy, at University of Maryland School of Law, Baltimore, Maryland; Public Health Advocacy Institute and the Center for Public Health and Tobacco Policy, at Northeastern University School of Law, Boston, Massachusetts; Smoke-Free Environments Law Project, at Center for Social Gerontology, Ann Arbor, Michigan; Tobacco Control Policy and Legal Resource Center at New Jersey GASP, Summit, New Jersey.

8. Truth Initiative

The Truth Initiative envisions an America where tobacco is a thing of the past and where all youth and young adults reject tobacco use. Truth Initiative's proven -effective and nationally recognized public education programs include truth®, the national youth smoking prevention campaign that has been cited as contributing to significant declines in youth smoking; EX®, an innovative smoking cessation program; and research initiatives exploring the causes, consequences, and approaches to reducing tobacco use. Truth Initiative also develops programs to address the health effects of tobacco use–with a focus on priority populations disproportionately affected by the toll of tobacco–through alliances, youth activism, training, and technical assistance. Located in Washington, D.C., Truth Initiative was created as a result of the November 1998 Master Settlement Agreement between attorneys general from 46 states, five U.S. territories, and the tobacco industry.

CERTIFICATE OF SERVICE

Pursuant to Local Civil Rule 5.4, I hereby certify that on this 19th day of August, 2016, I electronically filed the foregoing Brief of *Amici Curiae* Public Health Organizations in Support of Defendants' Cross-Motion for Summary Judgment and in Opposition to Plaintiffs' Motions for Summary Judgment 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
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