IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

RIGHT TO BE SMOKE-FREE COALITION
4049 E. Presidio Street
Mesa, AZ 85215

AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION
P.O. Box 184
Englewood, OH 45322

AMERICAN VAPING ASSOCIATION
736 Washington Street
Hoboken, NJ 07030

ELECTRONIC VAPING COALITION OF AMERICA
P.O. Box 510403
New Berlin, WI 53151

GEORGIA SMOKE FREE ASSOCIATION
3212 Westside Country Drive
Fort Oglethorpe, GA 30742

KENTUCKY VAPING RETAILERS ASSOCIATION, INC., d/b/a KENTUCKY SMOKE FREE ASSOCIATION
9909 Taylorsville Road
Louisville, KY 40299

LOUISIANA VAPING ASSOCIATION
135 W. Genie Street
Chalmette, LA 70043

MARYLAND VAPE PROFESSIONALS, LLC
211 Saint Paul Street
Baltimore, MD 21202

NEW JERSEY VAPOR RETAILERS COALITION
3 Becker Farm Road, Suite 105
Roseland, NJ 07068

Civil Action No. _____

OHIO VAPOR TRADE ASSOCIATION
4251 Lyons Road
Miamisburg, OH 45342

and

TENNESSEE SMOKE FREE ASSOCIATION
7203 Bonny Oaks Drive
Chattanooga, TN 37421,

Plaintiffs,

v.

FOOD AND DRUG ADMINISTRATION
10903 New Hampshire Ave.
Silver Spring, MD 20993

ROBERT CALIFF, M.D.
Commissioner of Food and Drugs
10903 New Hampshire Ave.
Silver Spring, MD 20993

and

SYLVIA MATHEWS BURWELL
Secretary of Health and Human Services
200 Independence Ave., SW
Washington, DC, 20201,

Defendants.

COMPLAINT

The United States Food and Drug Administration ("FDA" or the "Agency") recently promulgated a final rule that, *inter alia*, comprehensively regulates for the first time at the federal level electronic nicotine delivery systems ("ENDS"), commonly known as electronic cigarettes. The regulation was adopted pursuant to the Food, Drug and Cosmetic Act ("FDCA"), as amended by the Family Smoking Prevention and Tobacco Control Act ("TCA"). *See* 81 Fed. Reg. 28,973 (May 10, 2016) (the "Deeming Rule" or "final rule"). The Plaintiffs, consisting of national and state-wide trade associations representing the entire ENDS industry (*i.e.*,

manufacturers, distributors, and retailers), bring this challenge to have portions of the Deeming Rule and TCA declared unlawful and enjoined on constitutional and administrative grounds.

PRELIMINARY STATEMENT

1. Plaintiffs are fully committed to the safety of ENDS products, from manufacturing through distribution and sale, and recognize the need for reasonable regulation at the federal level. As such, Plaintiffs are not challenging herein many of the Deeming Rule's provisions, including those aimed at guarding against youth access to ENDS or providing FDA with extensive health and safety information regarding their products. The final rule in several places, however, sets forth obligations that reach far beyond any reasonable level of regulatory oversight and imposes requirements that are unlawful in their nature and scope.

2. Of particular concern is FDA's decision under the TCA to regulate ENDS as tobacco products in the same fashion as more dangerous products, like cigarettes. FDA recognizes that ENDS are potentially safer products that could lead to reduced smoking levels in this country. But the Agency adopted a "one-size-fits-all" approach even though Congress was clear in the TCA that the Agency should use its regulatory authority in a flexible manner that recognizes the continuum of risk presented by different tobacco products. This is evidenced by the fact that FDA was directed to ensure that adults continue to have access to tobacco products, particularly newer, more innovative products that present less health risk than traditional ones.

3. Yet FDA elected to regulate ENDS in a manner that will all but guarantee, in a direct challenge to Congress' wishes, that the vast majority of such products will be forced to exit the market over the next two years. Driving what will effectively amount to a ban on many categories of ENDS is FDA's use of a particular pre-market authorization process that was designed to prevent the introduction of more harmful tobacco products. Moreover, FDA has

effectively written out of the statute for ENDS products another form of pre-market authorization that Congress intended for the Agency to use in a more flexible exercise of enforcement authority. Despite a statutory obligation to tailor the pre-market process, as well as other provisions, to each specific type of tobacco product, the Agency has adopted an unlawful, uniform approach that fails to recognize the unique position ENDS occupy in the marketplace.

4. Plaintiffs are not opposed to a reasonable form of pre-market authorization and other regulatory safeguards provided that they comply with the TCA. But under FDA's approach, the Agency made no effort to determine where ENDS products fall on the continuum of risk before deeming them covered by the TCA and regulating accordingly. As a result, FDA will have substantially reduced the availability of, if not outright banned, a product in direct contravention of Congressional intent.

PARTIES

5. Plaintiff Right To Be Smoke-Free Coalition, Inc. ("RSF") is a non-profit trade association incorporated under the laws of the District of Columbia. RSF's members consist of e-vapor companies that manufacture, distribute and sell e-liquids and e-vapor devices, including Cosmic Fog Vapors, LLC, located in Newport Beach, California, which qualifies as a small entity under the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. §§ 601, *et seq.* (the "RFA").

6. Plaintiff American E-Liquid Manufacturing Standards Association ("AEMSA") is a non-profit trade association incorporated under the laws of Ohio. Its members consist of e-vapor companies that manufacture, distribute and sell e-liquids and e-vapor devices, including Texas Select Vapor, located in Conroe, Texas, which qualifies as a small entity under the RFA.

7. Plaintiff American Vaping Association ("AVA") is a non-profit organization incorporated under the laws of New Jersey. AVA's members consist of e-vapor companies that manufacture, distribute and sell e-liquids and e-vapor devices, including Mid Cities Vapor LLC, located in North Richland Hills, Texas, which qualifies as a small entity under the RFA.

8. Plaintiff Electronic Vaping Coalition of America ("EVCA") is a non-profit trade association incorporated under the laws of the District of Columbia. Its members consist of e-vapor companies that manufacture, distribute and sell e-liquids and e-vapor devices, including Vape8nr, LLC, located in Sheffield Village, Ohio, which is a small entity under the RFA.

9. Plaintiff Georgia Smoke Free Association ("GSFA") is a non-profit consumer advocacy group and trade organization incorporated under the laws of Georgia. GSFA's members consist of e-vapor companies that manufacture, distribute and sell e-liquids and e-vapor devices, including Emote Vapes LLC, located in Fort Oglethorpe, Georgia, which qualifies as a small entity under the RFA.

10. Plaintiff Kentucky Vaping Retailers Association, Inc., d/b/a Kentucky Smoke Free Association ("KSFA"), is a non-profit consumer advocacy group and trade organization incorporated under the laws of Kentucky. KSFA's members consist of e-vapor companies that manufacture, distribute and sell e-liquids and e-vapor devices, including Derb E-Cigs, located in Louisville, Kentucky, which qualifies as a small entity under the RFA.

11. Plaintiff Louisiana Vaping Association ("LAVA") is a non-profit retail and manufacturing trade organization incorporated under the laws of Louisiana. LAVA's members consist of e-vapor companies that manufacture, distribute and sell e-liquids and e-vapor devices, including Big Chief Vapor Products LLC, located in Chalmette, Louisiana, which qualifies as a small entity under the RFA.

12. Plaintiff Maryland Vape Professionals, LLC ("MD Vape Professionals") is a trade association incorporated under the laws of Maryland. Its members consist of e-vapor companies that manufacture, distribute and sell e-liquids and e-vapor devices, including Liquid Art Inc., located in Glen Burnie, Maryland, which qualifies as a small entity under the RFA.

13. Plaintiff Ohio Vapor Trade Association ("OHVTA") is a non-profit trade association incorporated under the laws of Ohio. OHVTA's members consist of e-vapor companies that manufacture, distribute and sell e-liquids and e-vapor devices, including NicQuid LLC, located in Miamisburg, Ohio, which qualifies as a small entity under the RFA.

14. Plaintiff Tennessee Smoke Free Association ("TSFA") is a non-profit consumer advocacy group and trade organization incorporated under the laws of Tennessee. TSFA's members consist of e-vapor companies that manufacture, distribute and sell e-liquids and e-vapor devices, including Mountain Oak Vapors LLC, located in Cleveland, Tennessee, which qualifies as a small entity under the RFA.

15. Plaintiff New Jersey Vapor Retailers Coalition ("NJVRC") is a non-profit trade association incorporated under the laws of New Jersey. Its members consist of e-vapor companies that manufacture, distribute and sell e-liquids and e-vapor devices, including Quantum Vapor, located in Rockaway, New Jersey, which is a small entity under the RFA.

16. All of the Plaintiffs have as their underlying mission or purpose advocating for reasonable laws and regulations for the ENDS industry.

JURISDICTION AND VENUE

17. This suit alleges violations of the United States Constitution pursuant to 42 U.S.C. § 1983.

18. This suit also arises under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 500 *et seq.*, the FDCA, 21 U.S.C. §§ 301 *et seq.*, the TCA, 21 U.S.C. §§ 387 *et seq.*, and the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601 *et seq.*

19. Judicial review of final agency action under the APA is authorized at 5 U.S.C. §§ 701 *et seq.* Judicial review under the RFA is authorized at 5 U.S.C. § 611.

20. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 2201-02.

21. Venue is proper under 28 U.S.C. § 1391(e).

FACTUAL BACKGROUND

Background

22. ENDS products, including the "e-liquid" used in them, are not traditional tobacco products or cigarettes, as they do not contain tobacco and there is no combustion or smoke. Rather, the aerosol (vapor) produced by an ENDS device is created when a battery activates a heating coil (contained in an atomizer) that vaporizes a flavored e-liquid solution. Some devices are designed to look like a traditional cigarette – often called "cigalikes" – with a small, built-in cartridge containing pre-filled e-liquid. In industry parlance, these are referred to as "closed systems." Other devices differ in size and shape, being somewhat larger than cigalikes, and contain an e-liquid tank that can be refilled by the consumer. These are called "open systems." Regardless, both types have the same purpose and functional utility – they allow the user to mimic the act of smoking, but without the harmful smoke, by inhaling through a mouthpiece the aerosol from the vaporized e-liquid.

23. E-liquids are manufactured using three or four primary ingredients – vegetable glycerin and/or propylene glycol, flavorings, and liquid nicotine. Nicotine is used in most, but

not all, e-liquids. The nicotine, in turn, may be derived from tobacco or non-tobacco sources, or produced synthetically in a lab.

24. A large and growing body of scientific evidence indicates that ENDS devices and e-liquids do not pose the same health risks as traditional cigarettes and are substantially less harmful, in part due to the fact that e-liquids do not contain tobacco and do not result in combustion by-products, like particulate matter (tar) and many other carcinogens and harmful substances. Moreover, as demonstrated by the fast growing number of users, over 20 million in the United States alone, there is considerable evidence that the vast majority of "vapers" are cigarette smokers who have turned to ENDS as a smoke-free alternative to reduce or quit smoking and to avoid the significant health hazards associated with traditional cigarettes.

25. Most recently, in April 2016, the Royal College of Physicians ("RCP") – Britain's professional association dedicated to setting and improving medical standards and the authors of the original groundbreaking report on the dangers of cigarette smoking in 1962 – issued a report lauding the benefits of ENDS products as safer alternatives to combustible tobacco.

26. The RCP report summarizes the science, public policy, regulation, and ethical issues related to ENDS products, and concludes that vaping is not a "gateway" to smoking. On the contrary, "the available evidence to date indicates that e-cigarettes are being used almost exclusively as safer alternatives to smoked tobacco, by confirmed smokers who are trying to reduce harm to themselves or others from smoking, or to quit smoking completely." Specifically, the report estimates that ENDS are only 5% as harmful as traditional cigarettes and that the long-term effects of nicotine from vaping are likely to be minimal.

27. This estimate corresponds with the conclusions of Public Health England, a department of the British Government, which recently determined that, based on the current evidence, ENDS products are 95% less harmful than traditional cigarettes.

28. Here in the United States, a growing number of scientific and public health experts agree that vaping is significantly less harmful than smoking cigarettes and a valuable tool for tobacco harm reduction efforts. Research suggests that because e-liquids and the resulting vapor do not contain the toxic chemicals found in cigarette smoke, the use of these non-combustible, nicotine containing products is safer than combustible tobacco and is expected to result in a vast reduction in tobacco-related disease and death.

The Tobacco Control Act – Generally

29. The TCA was adopted on June 22, 2009, and provides FDA with authority to regulate the "manufacture, marketing, and distribution of tobacco products." Pub. L. No. 111-31, § 3(1), 123 Stat. 1776, 1781 (2009).

30. For purposes of the TCA, the term "tobacco product" is defined to mean, in part, "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr).

31. FDA was initially charged under the TCA with regulating "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." In addition, it was given authority to regulate in the future "any other tobacco products that [the Agency] by regulation deems to be subject to this chapter." 21 U.S.C. § 387a(b). The Deeming Rule subjects a wide range of ENDS products to the TCA's requirements. 81 Fed. Reg. at 28,975.

32. Under the TCA, FDA is provided with regulatory authority over the entire supply chain. This includes:

a. Prohibiting the sale of adulterated or contaminated tobacco products. 21 U.S.C. § 387b.

b. Prohibiting the sale of misbranded tobacco products. 21 U.S.C. § 387c.

c. Requiring manufacturers to submit health information (*e.g.*, health studies) regarding each tobacco product. 21 U.S.C. § 387d.

d. Requiring manufacturers to register with FDA their production facilities. 21 U.S.C. § 387e.

e. Imposing advertising restrictions on the sale and distribution of tobacco products. 21 U.S.C. § 387f(d).

f. Promulgating good manufacturing practices. 21 U.S.C. § 387f(e).

g. Adopting tobacco product standards (*e.g.*, ingredients). 21 U.S.C. § 387g(a).

h. Requiring manufacturers to establish and maintain records. 21 U.S.C. § 387i).

i. Requiring manufacturers of any "new tobacco product" to obtain pre-market approval prior to commercial sale. A "new tobacco product" is defined to mean, in part, "any tobacco product . . . that was not commercially marketed in the United States as of February 15, 2007" ("Grandfather Date"). 21 U.S.C. § 387j.

j. Requiring FDA authorization before a "modified risk" tobacco product (*i.e.*, a product accompanied by claims that it reduces harm or risk of tobacco-related disease, or reduces exposure to harmful substances) may be introduced into interstate commerce. 21 U.S.C. § 387k.

33. Any tobacco product that was on the market "as of" February 15, 2007 is grandfathered and exempt from FDA pre-market review. 21 U.S.C. §§ 387(e(j), 387j(a).

The Tobacco Control Act – Key Provisions

34. The extensive pre-market provisions provide that a "new tobacco product" (*i.e.*, first marketed or modified after the Grandfather Date) must be approved by FDA in one of three ways before being introduced into interstate commerce. These "pathways" include:

a. Pre-Market Tobacco Application ("PMTA") Pathway – This is the most extensive pre-market review process. It requires manufacturers to submit, *inter alia*, substantial amounts of information for each new tobacco product showing that marketing the product is "appropriate for the protection of public health." This "population effects" standard requires FDA to take into account the product's impact on the population as a whole, including the likelihood that people will stop using tobacco products (*i.e.*, cessation), as well as start using them (*i.e.*, initiation). 21 U.S.C. § 387j(c).

b. Substantial Equivalence ("SE") Pathway – This is a more abbreviated form of pre-market review when compared to the PMTA. Under this pathway, a manufacturer must show that the new tobacco product is "substantially equivalent" to a tobacco product that was commercially marketed in the United States as of the Grandfather Date of February 15, 2007 ("predicate product"). 21 U.S.C. § 387e(j). The term "substantially equivalent" means, in turn, that the tobacco product either has the same (identical) "characteristics" (*e.g.*, materials, ingredients, design, composition, heating source, or other features) as the predicate product or has different characteristics but does not raise different questions of public health. 21 U.S.C. § 387j(a).

c. SE Exemption Pathway – FDA may exempt from SE requirements certain minor changes to existing tobacco products. 21 U.S.C. § 387e(j).

35. To satisfy the "population effects" standard, a PMTA submission must contain extensive data regarding the new tobacco product, including all information from investigations on the health risks of such product and data regarding whether the product presents less risk than other tobacco products. 21 U.S.C. § 387j(b). In particular, these investigations "may include . . . clinical" (*i.e.*, human) studies and other "valid scientific evidence" that FDA considers "sufficient to evaluate" the product. 21 U.S.C. § 387j(c).

36. The TCA also requires FDA authorization before any tobacco product may be introduced into interstate commerce with a "modified risk" claim. This includes any label or advertising, as well as statements made in media or other forums, that explicitly state or imply that the product presents a lower risk of tobacco-related disease, the product or its smoke contains a reduced level of a substance or presents a reduced exposure to a substance, or that the product or its smoke does not contain or is free of a substance. To obtain an FDA order permitting such a claim, a manufacturer must submit substantial information to the Agency, including scientific research findings on the ability of the product to reduce risk or exposure, data and information on how consumers actually use the product, and post market surveillance studies. The manufacturer must show that there is a significant reduction in risk of tobacco-related disease and FDA must take into account, on a population level, the health benefit to users of tobacco products and those who do not use such products (the "public health benefit" standard). 21 U.S.C. § 387k.

37. Under the TCA, however, smokeless tobacco products (*e.g.*, chewing tobacco) are not subject to the modified risk requirements if a label or advertising uses phrases like "does not

produce smoke," "smokefree," "smoke-free," "without smoke," "no smoke," or "not smoke." 21 U.S.C. § 387k(b).

38. The TCA prohibits manufacturers and retailers from distributing free samples of tobacco products, but provides an exception for free samples of smokeless tobacco distributed in "qualified adult-only facilities." 21 U.S.C. § 387a-1(a).

39. The TCA also places significant restrictions on FDA's exercise of regulatory authority. For example, the Agency may not ban cigarettes, smokeless tobacco products, cigars, pipe tobacco, or roll-your-own tobacco, and may not require the reduction of nicotine yields of any tobacco product to zero. 21 U.S.C. § 387g(d).

The Deeming Rule – Generally

40. The Deeming Rule becomes effective 90 days from the date of publication. The rule was published on May 10, 2016, thus the effective date is August 8, 2016.

41. Overall, the Deeming Rule subjects all products that meet the definition of "tobacco product" (except "accessories" of deemed products), including ENDS products, to virtually all of the TCA's provisions that were initially applied to cigarettes, cigarette tobacco, roll-your-own tobacco, smokeless tobacco – *i.e.*, subjects ENDS products to a "one-size-fits-all" regulatory regime. These include pre-market review provisions, modified risk claim restrictions, and the ban on free samples. 81 Fed. Reg. at 28,976. The Deeming Rule applies to any manufacturers of ENDS products, including vape shops that mix or prepare e-liquids or modify an ENDS device. 81 Fed. Reg. at 29,044.

42. The Deeming Rule also subjects what are called "covered tobacco products" to additional provisions, including a ban on the sale of such products to any individual under the age of 18 years, a health warning requirement with regard to nicotine, and a ban on the sale of

such products through vending machines unless at a facility that is limited to adult access. The term "covered tobacco products" includes any tobacco product, except components or parts that are not made or derived from tobacco (*e.g.*, an ENDS device). 81 Fed. Reg. at 28,976.

43. Under the Deeming Rule, FDA has taken a broad interpretation as to what items are covered under the definition of "tobacco product." As to ENDS products, these would not only include e-liquids containing nicotine and other ingredients (like flavors), but also products that do not contain tobacco or are not derived from tobacco, including tanks and tank systems, coils, cartomizers, digital display/lights, software, and even batteries. 81 Fed. Reg. at 29,016.

44. FDA also established a pre-market compliance period where manufacturers of "new tobacco products" that are currently on the market will have staggered time-periods to file applications under one of the three marketing approval pathways noted above. Significantly, for PMTAs, ENDS manufacturers will only have two (2) years from the Deeming Rule's effective date to submit an application. As for SE Reports and SE Exemption requests, manufacturers will only have eighteen (18) months and twelve (12) months, respectively, from the effective date to file an application. Following each initial compliance period, manufacturers who have made timely submissions will have an additional twelve (12) months to continue marketing their products; however, if at the end of this continued compliance period FDA has either denied an application or failed to issue a decision, such manufacturers will be subject to enforcement actions for failure to obtain pre-market approval. 81 Fed. Reg. at 28,978.

45. Any "new tobacco products" first marketed after the effective date of the Deeming Rule, however, will not be able to avail themselves of the compliance periods; rather, manufacturers of such products must submit a PMTA, SE Report, or SE Exemption request, and obtain FDA marketing authorization before any such product is commercially sold.

46. FDA also makes a limited number of concessions for small businesses – what FDA calls "small-scale manufacturers" – by extending a few reporting deadlines, such as submitting health-related documents and ingredient lists to the Agency. As such, FDA did not grant small businesses additional time to comply with the more costly and time-consuming obligations under the TCA, such as PMTA submissions. 81 Fed. Reg. at 28,979. The term "small-scale manufacturers" is defined as a manufacturer that has 150 or fewer full-time equivalent employees and has $5 million or less in annual revenues. 81 Fed. Reg. at 28,980.

The Tobacco Control Act – Striking a Balance

47. While the TCA provides FDA with broad regulatory authority over tobacco products, such authority is not unfettered. Indeed, the Agency is circumscribed by the underlying purposes of the statute, as well as additional limitations placed on the exercise of its delegated powers. Specifically, Congress sought to strike a balance in the TCA between, on the one hand, prohibiting FDA from effectively banning tobacco products, and instead ensuring that adults continue to have ready access to such products while, on the other hand, taking steps so that such products are not accessible to underage consumers. Further, Congress instructed FDA to regulate tobacco products in a manner that promotes the introduction and sale of safer and less harmful tobacco products, rather than keeping them off the market.

48. The TCA's "Purposes" section explicitly provides that FDA must "continue to permit the sale of tobacco products to adults in conjunction with measures to ensure that they are not sold or accessible to underage purchasers." Pub. L. No. 111-31, § 3(7), 123 Stat. 1776, 1782 (2009); *see, e.g.*, H. Rep. No. 111-58, Pt. 1, at 33 (2009). While the TCA allows FDA to take action on specific tobacco products, like adopting tobacco product standards that limit the use of

a specified additive, Congress sent a clear message that the regulatory regime cannot be implemented in a way that substantially limits adult access to a category of tobacco product.

49. The TCA also specifically prohibits FDA from taking any action "requiring the reduction of nicotine yields of a tobacco product to zero." 21 U.S.C. § 387g(d); *see, e.g.*, H. Rep. No. 111-58, Pt. 1 at 2, 19. Significantly, as the United States District Court for the District of Columbia stated in *Smoking Everywhere, Inc., et al. v. U.S. Food and Drug Admin.*, 680 F. Supp. 2d 62, 70 n.9 (D.D.C. 2010), this means that FDA cannot, as a practical matter, effectively ban an ENDS product, including nicotine-containing e-liquids used in ENDS devices.

50. Under the TCA, Congress also gave FDA "new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." Pub. L. No. 111-31, § 3(4), 123 Stat. 1776, 1782 (2009). In other words, Congress did not intend for new tobacco products to be subject to a "one-size-fits-all" approach that is also applicable to more risky, traditional tobacco products, like cigarettes. Rather, Congress directed FDA to tailor its regulations to a tobacco product's specific risk profile. For example, the PMTA provisions only require pre-market applications to include clinical studies "when appropriate" and give FDA authority to base a PMTA decision on "valid scientific evidence" other than clinical studies when such evidence "is sufficient to evaluate the tobacco product." 21 U.S.C. § 387j(c); *see also* 21 U.S.C. § 371(a) (granting FDA authority under the FDCA to promulgate regulations "for the efficient enforcement" of the statute); 79 Fed. Reg. 23,142, 23,149 (Apr. 25, 2014) (FDA stating that the "premarket authorities can spur innovation and help to create a market" for less risky products).

51. Indeed, FDA itself acknowledges that the regulation of tobacco products must account for a continuum of risk. For example, Mitch Zeller, Director of FDA's Center for

Tobacco Products, has noted that "[a]nyone who would ponder the endgame must acknowledge that the continuum of risk exists and pursue strategies that are designed to drive consumers from the most deadly and dangerous to the least harmful forms of nicotine delivery." Zeller, *Reflections on the 'Endgame' for Tobacco Control*, Tob. Control 22:i40-i41, at i40 (2013); *see, also* 79 Fed. Reg. at 23,147 (FDA stating that "there are distinctions in the hazards presented by various nicotine-delivering products"); 79 Fed. Reg. at 23,152 ("FDA realizes that while all tobacco products are potentially harmful and potentially addictive, different categories of tobacco products may have the potential for varying effects on public health").

52. FDA also explicitly mentions ENDS products as potentially falling within a lower risk category. *See, e.g.,* 81 Fed. Reg. at 29,027 ("FDA agrees that a continuum of nicotine-delivering products does exist as demonstrated by the lower levels of toxicants in ENDS in comparison to cigarettes, and may warrant different requirements for products at different ends of this continuum"); 81 Fed. Reg. at 29,030 ("FDA recognizes that completely switching from combusted cigarettes to ENDS may reduce the risk of tobacco-related disease for individuals currently using combusted tobacco products, given the products' comparative placements on the continuum of nicotine-delivering products."); *see also id.* at 29,050, 23,152.

53. Moreover, Congress directed FDA to only "impose appropriate regulatory controls on the tobacco industry" and, from that perspective, envisioned regulatory action only after the Agency took into account all relevant costs and benefits on the ENDS industry. Pub. L. No. 111-31, § 3(8), 123 Stat. 1776, 1782 (2009); *see also Michigan v. E.P.A.*, 135 S.Ct. 2699, 2706-07 (2015) (holding term "appropriate" to encompass cost/benefit factors).

54. Finally, the TCA's "Purposes" section provides that the statute is intended to "strengthen legislation against illicit trade in tobacco products." Pub. L. No. 111-31, § 3(10),

123 Stat. 1776, 1782 (2009). This indicates that FDA should not regulate deemed products, including ENDS, in a manner that would foster a black market, such as by banning or severely restricting the legitimate availability of a product category.

ENDS Manufacturers Will Be Required To Use The PMTA Pathway

55. It is critically important to the survival of the ENDS industry regarding how FDA structures the PMTA compliance period and other obligations because, even using the Agency's own numbers, the SE pathway will not be a viable option for ENDS products.

a. FDA estimates that no e-liquids will qualify for grandfathered status and that 0.0% of e-liquid manufacturers will use the SE pathway during the initial compliance period. Final Regulatory Impact Analysis, at 84, 97 (May 2016).

b. FDA concludes that only 1.0% of ENDS devices will qualify for grandfather status and that a mere 11.0% of device manufacturers will use the SE pathway during the initial compliance period (although Plaintiffs allege that even these numbers significantly overstate the facts). Final Regulatory Impact Analysis, at 84, 97 (May 2016). And this says nothing about the number of SE Reports for ENDS devices (or components and parts), if any, that would ultimately be approved by the Agency. As it stands now, FDA claims that it has identified one ENDS product that "may have" been on the market as of the Grandfather Date and "may possibly be able to serve as a valid predicate for purposes of the SE pathway," but then the Agency outright refuses to identify that product. 81 Fed. Reg. at 28,978, 28,991.

56. Indeed, FDA concedes that it will be extremely difficult for those in the ENDS industry to rely on the SE pathway. *See, e.g.*, 81 Fed. Reg. at 28,992 ("However, manufacturers of . . . ENDS would have great difficulty showing that a product is substantially equivalent to a combusted cigarette or a smokeless tobacco product."); *see also id.* at 28,977, 28,994; FDA

PMTA Draft Guidance for Industry, at 4 (May 2016) ("Given the possible absence of valid predicates . . . for use in the substantial equivalence pathway, FDA expects to receive PMTA submissions from manufacturers of newly deemed ENDS".).

The PMTA Pathway Will Require Clinical Studies And Other Extensive Data

57. As a result, ENDS product manufacturers will be required to submit to FDA comprehensive PMTAs that the Agency notes will likely require long-term, clinical (*i.e.*, human) studies on numerous issues. All of this will be necessary for such manufacturers to satisfy the population effects standard set forth in the TCA. The studies, whether sponsored by each product manufacturer itself or conducted by others, will have to provide various human impact data and information regarding each ENDS product, including:

a. Consumer perceptions (*e.g.*, how consumers perceive product risk);

b. Likelihood of initiation and cessation by both users and non-users;

c. Product use patterns (*e.g.*, how frequently consumers use a product);

d. Labeling comprehension (*e.g.*, how consumers understand the label);

e. Human factors (*e.g.*, normal use and foreseeable misuse);

f. Abuse factors (*e.g.*, nicotine addiction and exposures);

g. Biomarkers of harm and exposure (*e.g.*, tracking cotinine in body); and

h. Health outcomes (*e.g.*, health effects from exposure to flavorings).

PMTA Draft Guidance, at 35-39.

58. Indeed, FDA admits that clinical studies will likely be required in PMTAs, particularly for any products that must file a PMTA within the two-year compliance period. *See, e.g.*, 81 Fed. Reg. at 28,997 ("However, in cases where there have been few or no scientific studies of a product's potential impact on the public health, new nonclinical and clinical studies

may be required for [PMTAs]"); PMTA Draft Guidance at 30 ("Due to the emerging nature of ENDS products . . . FDA acknowledges that there may be limited nonclinical or clinical research conducted on specific ENDS products. Thus, it is likely that applicants will conduct certain investigations themselves and submit their own research findings as part of their PMTA"); *id.* at 32 (FDA noting that "nonclinical studies alone are generally not sufficient to support a determination that marketing of the product is appropriate for the protection of public health (PMTAs would generally need clinical data).").

59. In fact, the only PMTAs that have been authorized by FDA to date are for eight (8) smokeless tobacco (snus) products that have already been subject to extensive clinical and long-term epidemiological studies.

60. The clinical study requirements are in addition to a whole host of other non-clinical data that must be generated for each ENDS product in support of the PMTA, including:

a. Toxicological and pharmacological data of all ingredients and aerosols;

b. In-vitro and in-vivo toxicological studies (*e.g.,* genotoxicity, cytotoxicity);

c. Computational modeling of any toxicants;

d. Potential human exposure studies at various device use levels;

e. Aerosolization properties of each ingredient (*e.g.,* particle sizes); and

f. Thorough public health and medical literature review.

PMTA Draft Guidance, at 32-35.

61. Further complicating matters is the fact that each PMTA must be accompanied by data from testing open system e-liquids and devices in a range of conditions. For example, to satisfy the population effects standard, an e-liquid may need to "provide evidence and analysis of the product's likely impact when used in the range of delivery systems available." Likewise, a

device manufacturer may need to "provide evidence and analysis of the product's likely impact when used together with the range of other components and liquids available." 81 Fed. Reg. at 28,994. When considered in light of evidence submitted during the rulemaking comment period that a single manufacturer may have hundreds, if not thousands, of ENDS products on the market, it becomes readily apparent how complying with the PMTA process will be time and cost prohibitive for ENDS manufacturers.

62. In addition to the PMTA requirements under the TCA, ENDS manufacturers must also prepare a comprehensive Environmental Assessment ("EA") pursuant to the National Environmental Policy Act ("NEPA"). Such assessment must contain sufficient information and analysis on, *inter alia*: (i) environmental introduction of the manufacturing, use of, and disposal after use of the new ENDS product; (ii) fate of materials released into the environment; and (iii) use of energy and other resources. FDA then determines whether to prepare an Environmental Impact Statement ("EIS") or issue a Finding of No Significant Impact ("FONSI"). 21 C.F.R. § 25.20; 40 C.F.R. § 1501.4. However, unlike for traditional tobacco products, historical information on the environmental impact of ENDS does not yet exist; moreover, unlike certain types of SE Reports, PMTAs are not categorically exempt from the EA requirement.

FDA Concedes That No Long-Term Clinical Data Exists On ENDS Products

63. Even though FDA is forcing ENDS products manufacturers into a PMTA process that will require long-term clinical and other similar studies, the Agency concedes that such information does not presently exist. *See, e.g.*, 81 Fed. Reg. at 28,984 ("there have not yet been long-term studies conducted"), *id.* at 29,028 ("long-term studies are not yet available"), 29,031 ("no adequate data on long-term health effects"), *id.* at 29,041 ("[l]ong-term studies are not available"); PMTA Draft Guidance at 14 ("Given the relatively new entrance of ENDS on the

U.S. market, FDA understands that limited data may exist from scientific studies and analyses; *id.* at 30 ("Due to the emerging nature of ENDS products . . . FDA acknowledges that there may be limited . . . clinical research"); 79 Fed. Reg. at 23,152, 23,157, 23,166 (FDA noting lack of sufficient data regarding ENDS products).

64. In fact, given the dearth of long-term clinical data and other information, FDA claims that it does not know one way or the other if ENDS products will be able to satisfy the population effects standard under the TCA. *See, e.g.*, 81 Fed. Reg. at 28,984 ("[T]here have not yet been long-term studies conducted" to show whether ENDS "may eventually be shown to have a net benefit on or harm to public health at the population level"); *id.* at 29,010 (FDA acknowledging "uncertainty regarding the positive or negative impact on public health from products like ENDS"); *id.* at 29,028 ("[W]e do not have sufficient data to determine what effects e-cigarettes have on public health at the population level"); *id.* ("Long-term studies are not yet available to determine" the impact of ENDS products on underage use); *id.* at 29,030 ("Given the relatively new entrance of ENDS on the market, consumers have not had the duration of use for researchers to fully assess the morbidity and mortality effects for ENDS on either the individual or the population"); *id.* at 29,041 ("Long-term studies are not available to conclude that ENDS are a proven cessation product"); 79 Fed. Reg. at 23,144, 23,152, 23,157, 23,166 (*e.g.*, "We do not currently have sufficient data about e-cigarettes . . . to determine what effects they have on the public health").

65. In response to concerns expressed by the ENDS industry that, due to the lack of existing data and other factors, complying with the PMTA process will not be possible within the short, two-year compliance period established under the Deeming Rule, FDA has taken the position that someday there will be sufficient long-term clinical and other data to support

PMTAs and that manufacturers will be able to share such information through master files. 81 Fed. Reg. at 28,997 ("FDA expects that, in some cases, it may be possible for an applicant to obtain a PMTA marketing authorization order without conducting any new nonclinical or clinical studies where there is an established body of evidence regarding the public health impact of the product. However, in cases where there have been few or no scientific studies of a product's potential impact on the public health, new nonclinical and clinical studies may be required for market authorization"); *see also* 81 Fed. Reg. at 29,077, 29,080.

66. FDA does not, however, indicate when such studies will be available (whether they are carried-out by manufacturers or others) or if they will exist in time for ENDS manufacturers to prepare and file adequate PMTAs in an efficient and cost-effective manner before the compliance deadline in August 2018. Rather, the Agency simply asserts that the compliance period is sufficient. *See, e.g.*, 81 Fed. Reg. at 29,001 (FDA, without more, stating that "we believe the compliance period is appropriate, and it takes into account the time frame for firms to generate and submit information for a PMTA"); *id.* at 29,012 (FDA noting, without further explanation, that it "believes that [the 2-year compliance period] will give sufficient time for manufacturers of such products to prepare high quality applications").

67. Nor does FDA explain how the eventual development of long-term data will help support the submission of PMTAs for new tobacco products introduced in the market after the Deeming Rule's effective date which are not eligible to take advantage of the compliance period.

68. At the same time, notwithstanding FDA's uncertainty, the Agency acknowledges that additional studies and research may further confirm that ENDS products have a lower risk profile than traditional tobacco products. *See, e.g.*, 81 Fed. Reg. at 29,030 ("FDA recognizes that completely switching from combusted cigarettes to ENDS may reduce the risk of tobacco-

related disease for individuals currently using combusted tobacco products, given the products' comparative placements on the continuum of nicotine-delivering products"); *id.* at 29,032 (FDA "agrees that the exhaled aerosol from ENDS users is potentially less hazardous than secondhand smoke from combusted cigarettes"); *id.* at 29,035 ("FDA agrees that use of ENDS is likely less hazardous for an individual user than continued smoking of traditional cigarettes"); *id.* at 29,039 (FDA conceding that "ENDS may potentially provide cessation benefits").

FDA Adopts One-Size-Fits-All Approach

69. Despite FDA's own statements in the administrative record – *e.g.*, PMTAs and clinical studies will be required for pre-market authorization, but long-term studies do not yet exist; FDA does not know what the science shows, but concedes that ENDS are likely safer than traditional tobacco products – the Agency elected to deem ENDS and regulate them like cigarettes and other tobacco products that, by FDA's own admission, present more significant risks. The Agency rejected virtually all alternatives that, as directed by Congress, would have allowed FDA to regulate with more flexible enforcement authority. The suggestions that were dismissed out right include, but are not limited to:

a. Establishing pre-market criteria based on continuum of risk and ENDS products' lower risk profile;

b. Developing a pre-market process that relies on scientific information other than clinical studies to address population effects;

c. Extending the compliance period for PMTAs so that sufficient long-term clinical and other information can be adequately developed; and

d. Extending or establishing the Grandfather Date.

See, e.g., 81 Fed. Reg. at 28,997, 29,000. Instead, FDA adopted a "one-size-fits-all" approach that equates traditional tobacco products with ENDS, in direct contravention of the careful balance struck by Congress and the underlying purposes set forth in the TCA.

70. As a result, given the lack of long-term data and information needed to support PMTAs within the 2-year compliance period, coupled with the substantial time and expense that would be required to comply with the pre-market obligations as required under the Deeming Rule, FDA will all but ban ENDS from the market, including entire e-liquid and device categories, thus depriving adults of a product that the Agency concedes could help substantially reduce tobacco-related disease and death in this country.

COUNT ONE

Violation of Administrative Procedure Act
Grandfather Date

71. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

72. Under the Administrative Procedure Act ("APA"), a court may hold unlawful and set aside agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law . . . [or] in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706.

73. Pursuant to the TCA, Congress provided tobacco manufacturers with several pre-market pathways, including SE Reports. Congress did not intend for FDA to implement the TCA in a manner that would entirely exclude the SE pathway for deemed products.

74. By virtue of applying the Grandfather Date to ENDS products, and thus preventing ENDS manufacturers from using the SE pathway, FDA will effectively ban ENDS products from the marketplace. Congress did not intend such a result where continuum of risk and continued adult access must be taken into account in any regulatory regime.

75. Accordingly, FDA had the authority and statutory duty to either establish a new Grandfather Date for ENDS products or apply its enforcement authority so that some ENDS manufacturers, including e-liquid companies, would have the opportunity to forego the PMTA pathway and avail themselves of the option to submit SE Reports.

COUNT TWO

Violation of Administrative Procedure Act
Pre-Market Authorization Process

76. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

77. FDA was under an obligation to structure the pre-market authorization process based on the balance struck by Congress in the TCA. The Agency was required to take into account continued access of tobacco products to adults, facilitating the commercial market for less harmful products, and accounting for continuum of risk.

78. FDA failed, however, to exercise the "flexible" enforcement authority mandated by Congress and, instead, applied a "one-size-fits-all" regulatory regime to ENDS products which, by FDA's own admission, have a lower risk profile than traditional cigarettes.

79. FDA has forced ENDS manufacturers into the PMTA process despite the fact that the Agency offers no evidence or explanation as to how such manufacturers will be able to conduct the necessary long-term clinical health studies, which FDA concedes do not exist, within the two year compliance period. The same holds true for completing additional, non-clinical scientific studies, including EAs and other health-related research. The Agency simply assumes, without more, that some manufacturers will be able to file PMTAs by August 2018.

80. FDA rejected regulatory alternatives available under the TCA that would have increased the chances that ENDS manufacturers could successfully file PMTAs and obtain market authorization. These include, but are not limited to, extending the compliance period,

tailoring the type of scientific information required for PMTAs, establishing a new Grandfather Date for ENDS, or delaying the deeming of ENDS for purposes of pre-market review until FDA has more research so that it can impose an "appropriate" regulatory regime.

81. Instead, by subjecting ENDS products to the same requirements as cigarettes and other harmful tobacco products, FDA will all but ban entire e-liquid and device categories, in direct contravention of the regulatory scheme established by Congress under the TCA.

82. Accordingly, FDA's application of the PMTA process to ENDS products violates the APA and, thus, should be set aside as unlawful and enjoined.

COUNT THREE

Violation of Due Process and Equal Protection Clauses Tobacco Control Act

83. The Due Process Clause of the Fifth Amendment of the United States Constitution requires that federal laws must have a rational relationship to a legitimate governmental interest. A federal law whose chosen means do not bear a rational relationship to the asserted governmental interests is arbitrary and thus unconstitutional.

84. The Equal Protection Clause prohibits the federal government from regulating differently situated persons similarly where there is no rational relationship between such similar treatment and a legitimate governmental interest.

85. Congress made clear that adult access to tobacco products must be maintained, that FDA must regulate in a flexible manner so that newer and safer products can enter the market, and that any regulation should be "appropriate" and recognize continuum of risk. *See* Pub. L. No. 111-31, § 3, 123 Stat. 1776, 1782 (2009).

86. FDA repeatedly takes the position, however, that it does not have discretion under the TCA to tailor the PMTA process and other regulatory requirements to ENDS products. In

other words, FDA had no choice but to impose a "one-size-fits-all" regime on ENDS. *See, e.g.*, 81 Fed. Reg. at 28,993 ("FDA concludes that it lacks authority to change the grandfather date for the newly deemed products"); *id.* at 28,997 ("FDA is not authorized to deviate from the premarket requirements"); *id.* at 29,001 (FDA rejecting suggestions that is has authority to tailor PMTA requirements based on continuum of risk).

87. If the TCA does, as a legal matter, compel FDA to impose a "one-size-fits-all" scheme on all tobacco products, then Congress did not provide FDA with the necessary tools and regulatory flexibility to achieve the TCA's stated goals. In fact, the TCA would result in the virtual ban of entire e-liquid and device categories, precisely the outcome that the TCA seeks to avoid. This approach is irrational and fails to meet the stated legislative goals of the TCA.

88. Moreover, in the TCA, Congress made clear that different tobacco products present different risks and that FDA should exercise its enforcement authority in a "flexible" manner. However, FDA treats ENDS products the same as traditional tobacco products, including cigarettes. This holds true despite the fact that, unlike traditional tobacco products, ENDS do not contain tobacco, they do not result in combustion by-products, and do not produce smoke. As FDA also concedes, ENDS present a lower (and different) risk profile than cigarettes and other harmful products. But if the TCA requires a "one-size-fits-all" approach, as FDA argues, then Congress has treated differently situated products in a similar manner.

89. As a result, the TCA is unconstitutional under the Due Process and Equal Protection Clauses.

COUNT FOUR

Violation of First Amendment and Administrative Procedure Act
Ban on Free Samples

90. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

91. Where the federal government restricts commercial speech, it must demonstrate that: (i) the regulated speech is not misleading; (ii) the governmental interest is substantial; (iii) the restriction directly advances the governmental interest; and (iv) the regulation is not more extensive than is necessary to serve that interest. *Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980).

92. Under the APA, a court may hold unlawful and set aside agency action found to be "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706.

93. The Deeming Rule applies the existing ban on the distribution of free samples of traditional tobacco products (*e.g.*, cigarettes) to ENDS products. 81 Fed. Reg. at 28,976; 21 C.F.R. § 1140.16. This ban extends to the sampling of e-liquids by customers in vape shops and at other events that are restricted to adult consumers. 81 Fed. Reg. at 29,054.

94. Allowing adult customers to sample various e-liquids before purchase is integral to the marketing of those products. Surveys of ENDS users demonstrate that flavors, including flavor variety, is a primary reason why vapers continue to vape and move away from combustible tobacco-products. Allowing adult consumers to test various flavors prior to purchase is, therefore, an important part for retaining customers and business.

95. Distributing free samples is a form of non-misleading speech protected by the First Amendment.

96. FDA does not have a substantial interest in prohibiting access to free samples by adult consumers, nor does a complete ban directly advance the government's stated interests. In the preamble to the Deeming Rule, FDA justifies the total ban on free samples on preventing youth access to ENDS. 81 Fed. Reg. at 28,986-87. That interest ceases to exist, however, if free samples are limited to adult consumers.

97. There are also more narrow options available to FDA to advance the government's interest in preventing youth access while still allowing vape shops and others to market using free samples. FDA could have simply restricted free sampling to vape shops and other venues that are subject to minimum age and identification requirements.

98. Under the Deeming Rule, retailers are required to verify that a customer is 18 years or older before selling an e-liquid. 81 Fed. Reg. at 29,057. In fact, the Deeming Rule prohibits the sale of ENDS through vending machines "unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time." *Id.* at 28,976. The same approach should apply to free samples.

99. FDA violated the APA by applying the ban on free samples to ENDS products.

100. The total ban on free samples violates the First Amendment and the APA. Thus, this provision should be declared unconstitutional and enjoined to the extent free samples are prohibited in vape shops and other venues where access is limited to adults only.

COUNT FIVE

Violation of First Amendment and the Administrative Procedure Act Modified Risk Tobacco Products

101. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

102. The TCA's Modified Risk Tobacco Products ("MRTP") provision requires manufacturers of tobacco products to secure FDA's approval before making certain truthful, non-misleading claims about their products, whether or not those claims are made through commercial speech, like advertising and labeling, or through non-commercial speech, such as statements made in the media and other forums. 21 U.S.C. § 387k. As such, this provision is subject to strict scrutiny or, at a minimum, intermediate scrutiny under *Central Hudson*.

103. As interpreted by FDA, the MRTP provision applies to ENDS products. Thus, truthful, non-misleading claims that would be subject to FDA's prior approval would include statements that an ENDS product is "smokefree," contains reduced levels of or does not contain a certain substance, or that it presents a reduced level of risk when compared to traditional tobacco products. 21 U.S.C. § 387k; *see, e.g.*, 81 Fed. Reg. at 28,987.

104. FDA applies the MRTP process to ENDS products, however, despite the fact that such products do not: (i) produce smoke (as e-liquids do not contain tobacco); (ii) combust e-liquid when used as intended (the ENDS device only vaporizes the e-liquid); or (iii) produce an aerosol that contains particulate matter (tar) or other carcinogens and harmful substances seen in traditional tobacco products. Indeed, FDA has repeatedly acknowledged that ENDS products likely present less risks than other tobacco products. *See, e.g.*, 81 Fed. Reg. 29,035.

105. Moreover, while FDA concludes that the MRTP process is needed to guard against misleading health claims, like those the Agency says characterized the marketing of traditional tobacco products over the span of many decades, the ENDS industry (which only emerged in the last 10 years) does not have such a history. *See, e.g.*, 81 Fed. Reg. at 28,987.

106. Accordingly, the MRTP process as applied to ENDS products fails to directly advance any purported government interests (which focus on traditional tobacco products) and captures commercial and non-commercial speech that is clearly not misleading.

107. FDA also has less intrusive options to advance any interests in approving modified risk claims, such as the use of disclaimers to prevent any purported consumer confusion or simply verifying any tests conducted by the manufacturer to confirm that a certain substance has been detected in low amounts or is completely absent from the product.

108. The MRTP process, as well as FDA's application of the provision to ENDS products, also runs afoul of the prior restraint doctrine, including the fact that none of the procedural protections required for a prior restraint (*e.g.*, prompt judicial review) exist.

109. FDA violated the APA by applying the MRTP provision, and its extensive review process (including a showing under the "public health benefit" test), to ENDS products.

110. The MRTP provision, and FDA's application to ENDS products, should therefore be declared unconstitutional and enjoined from enforcement.

COUNT SIX

Violation of Administrative Procedure Act
Definition of "Tobacco Product" and Application to ENDS

111. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

112. Under the TCA, the term "tobacco product" is defined to mean, in part, "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product." 21 U.S.C. § 321(rr).

113. In the Deeming Rule, FDA defines "component or part" as "any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or (2) To be used with or for the human consumption of a tobacco product." 21 U.S.C. § 1100.3. Components and parts are subject to regulation under the Deeming Rule. 81 Fed. Reg. at 28,975.

114. FDA has exercised its discretion, however, and is not regulating "accessories" under the final rule. 81 Fed. Reg. at 28,975.

115. FDA considers a broad range of ENDS products to be regulated as "tobacco products" or "components or parts." These include software used to operate devices, batteries, atomizers, cartomizers, digital display/lights, tanks, and glass e-liquid containers. *See, e.g.*, 81

Fed. Reg. at 28,975. Under the Deeming Rule, such products would be required, *inter alia*, to obtain pre-market approval through SE Reports and PMTAs.

116. FDA intends to regulate these products despite the fact that they do not contain tobacco, are not derived from tobacco, and are not components or parts of an actual tobacco product. The Agency offers no rationale based on the definition of "tobacco product" or the legislative history indicating that such definition can be stretched so far as to capture these types of ENDS products (*e.g.*, merely because they are used to consume a tobacco product).

117. Accordingly, FDA's application of the TCA's definition of "tobacco product" to certain ENDS is unreasonable and unlawful under the APA. Thus, the regulation of such products should be enjoined in its entirety.

COUNT SEVEN

Violation of Regulatory Flexibility Act
Unlawful Cost/Benefit Analysis

118. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

119. The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. §§ 601, *et seq.* (the "RFA"), requires administrative agencies to consider the effects of their regulatory actions on small business entities.

120. For purposes of the RFA, FDA is required to use the Small Business Administration's definition of small entity, which defines small entity tobacco product manufacturers as those having 1,500 or fewer employees, and small entity tobacco retailers are defined as those with annual receipts of $7,500,000 or less. As acknowledged by FDA, the vast majority of ENDS product manufacturers and retailers subject to the Deeming Rule qualify as small businesses. Final Regulatory Impact Analysis, at 128-31 (May 2016).

121. FDA was required to prepare a Final Regulatory Flexibility Analysis ("FRFA") that, *inter alia*: (i) considered all significant alternatives that would minimize the economic impact on small businesses, including a statement of the factual, policy, and legal reasons for rejecting various significant alternatives; (ii) estimated the number of small entities that would be covered by the Deeming Rule; and (iii) provided a description of those small entities that would be subject to filing and other compliance provisions. 5 U.S.C. § 604.

122. The RFA lists significant alternatives as including differing compliance or reporting timetables, tailoring compliance obligations to small entities, and exemptions from coverage of a rule. 5 U.S.C. § 603.

123. FDA failed to consider significant alternatives, including, but not limited to, the impact of any compliance period on the ability of small entities to successfully navigate the PMTA process given that FDA concedes that there are no long-term clinical studies or other data necessary to support such applications. FDA only considered several, modest alternatives focused on discrete issues like labeling burdens. The Agency did not make a reasonable, good faith effort to consider alternatives that would have an overall impact on all small entities.

124. FDA also significantly underestimated the number of small entities and ENDS products that would be subject to the Deeming Rule, as well as substantially overestimated, without any explanation or supporting data, the number of PMTA applications that would be submitted and the number of products that would ultimately be approved by the Agency for marketing. FDA received repeated comments that the vast majority of ENDS manufacturers, most of whom are small businesses with limited resources, would not be able to comply with the expensive and time-consuming PMTA process within the two-year compliance period.

125. FDA substantially overestimates the benefits of the Deeming Rule and underestimates the costs.

126. The RFA permits small entities "adversely affected or aggrieved" by FDA non-compliance with the RFA to seek judicial review. 5 U.S.C. § 611(a)(1)-(2).

127. Accordingly, this Court should take corrective action, set aside and remand the Deeming Rule to FDA, and defer enforcement until the Agency complies with the RFA.

COUNT EIGHT

Violation of Administrative Procedure Act
Unlawful Cost/Benefit Analysis

128. Plaintiffs reassert and incorporate by reference each of the above paragraphs.

129. Under the APA, an agency must engage in "reasoned decisionmaking" that is "logical and rational," which includes "consideration of the relevant factors." *Michigan v. E.P.A.*, 135 S.Ct. 2699, 2706-07 (2015). Adequately considering the costs and benefits of an agency action is integral to that process. *Id.* at 2711 (holding that EPA must consider cost when deciding whether action taken pursuant to the Clean Air Act was "appropriate and necessary").

130. The TCA makes clear that FDA was required to adequately consider the costs and benefits of the Deeming Rule. Among other things, the TCA states that FDA shall only "impose appropriate regulatory controls on the tobacco industry." Pub. L. No. 111-31, § 3(8), 123 Stat. 1776, 1782 (2009); *see also* 21 U.S.C. § 371(a) (granting FDA authority under the FDCA to promulgate regulations "for the efficient enforcement" of the statute). As discussed above, Congress also struck a balance between allowing adult access to tobacco products and encouraging the development and marketing of safer products, while at the same time prohibiting youth access and more dangerous products. Achieving that balance required the Agency to pay close attention to the costs that will be imposed on the ENDS industry.

131. As with the RFA, FDA failed to consider regulatory alternatives, such as an extended compliance period, that would have significantly increased the chance that ENDS manufacturers would be able to comply with the PMTA process, thus avoiding what will be an effective ban on ENDS products. The Agency also failed to properly estimate key factors necessary to an adequate cost/benefit analysis, including the number of entities and products affected, as well as the number of PMTA applications that will be filed. For many of these numbers, FDA did not adequately explain or support its conclusions.

132. FDA substantially overestimates the benefits of the Deeming Rule and underestimates the costs.

133. As a result, FDA violated the APA and, therefore, the Deeming Rule must be remanded to the Agency so that a proper cost/benefit analysis may be conducted.

REQUEST FOR RELIEF

A. A declaration that the challenged portions of the Deeming Rule violate:

a. the Administrative Procedure Act;

b. the Regulatory Flexibility Act; and/or

c. the First Amendment.

B. A declaration that the challenged portions of the TCA violate:

a. the First Amendment;

b. the Due Process Clause; and/or

c. the Equal Protection Clause.

C. A preliminary and permanent injunction vacating and enjoining the enforcement of the challenged portions of the Deeming Rule and TCA.

D. Expedited resolution of this action on the merits.

E. Grant Plaintiffs reasonable attorneys' fees and expenses.

F. Award such further relief as this Court deems appropriate.

Respectfully submitted,

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