UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
Lexington Division

VAPOR TECHNOLOGY ASSOCIATION,
1201 Pennsylvania Avenue, N.W., Suite 530
Washington, DC 20004,

and

VAPOR STOCKROOM, LLC,
2428 Palumbo Drive, Suite 110
Lexington, KY 40509,

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION,
NORMAN E. SHARPLESS, M.D., Acting Commissioner for Food and Drugs,
10903 New Hampshire Avenue
Silver Spring, Maryland 20903,

and

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
ALEX AZAR,
Secretary of Health and Human Services,
200 Independence Avenue, S.W.
Washington, D.C. 20201,

Defendants.

Case No. _____

VERIFIED COMPLAINT
(PRELIMINARY INJUNCTION REQUESTED)

Plaintiffs Vapor Technology Association ("VTA") and Vapor Stockroom, LLC ("Vapor Stockroom"), for their Complaint against the United States Food and Drug Administration, Norman E. Sharpless, M.D., Acting Commissioner for Food and Drugs (collectively, "FDA"), the

United States Department of Health and Human Services, and Alex Azar, Secretary of the Department of Health and Human Services (collectively, "HHS"), hereby state as follows:

NATURE OF THE ACTION

1. This is an action seeking a declaratory judgment and a preliminary and permanent injunction requiring FDA to: (a) establish a proposed and final rule governing the submission of pre-market tobacco applications ("PMTAs") for vapor products pursuant to Section 910 of the federal Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. § 387j, pursuant to a mandatory notice-and-comment rulemaking process; (b) set a reasonable, non-arbitrary deadline for the filing of PMTAs pursuant to the finalized rule after notice and opportunity for public comment; and (c) refrain from taking enforcement action against any vapor products on the U.S. market as of August 8, 2016, until the new filing deadline for PMTAs. Such relief is necessitated by FDA's failure to establish what are, by FDA's own admissions, the necessary "rules of the road" and foundational regulations for the PMTA regulatory pathway in the face of its repeatedly and arbitrarily shifting deadlines—from August 8, 2018, to August 8, 2022, to August 8, 2021 (for a large segment of vapor products), and, finally, to a much earlier deadline of May 11, 2019—for the submission of PMTAs for the *over-three million* vapor products currently on the market

2. Through this action, Plaintiffs seek to enjoin FDA from improperly and simultaneously both abdicating and exceeding its statutorily delegated authority by engaging in regulation by litigation instead of the mandatory notice-and-comment procedure required by the Administrative Procedure Act, 5 U.S.C. § 553, and, in so doing, depriving industry stakeholders, including Plaintiffs, of their statutory and constitutional rights to meaningfully participate in a

regulatory process that, if carried out unlawfully, will close thousands of U.S. small businesses and cause tens of thousands of workers to become unemployed. .

3. Plaintiffs' complaint is necessitated in part by FDA's arbitrary, unfounded, and wholly superfluous proposal to another district court of a revised deadline for the filing of PMTAs—which are complex, multi-year, multi-million dollar undertakings—for *all* vapor products currently legally present on the U.S. market that is some twenty-seven (27) months *earlier* than the deadline announced by FDA in August 2017 and upon which industry stakeholders, including Vapor Stockroom and the VTA's other members, have reasonably relied since that time.

4. Since August 8, 2016, FDA has set five different deadlines for the submission of pre-market tobacco applications. Initially, FDA required that such applications be filed in two years, by August 8, 2018. Then, in May 2017, FDA extended the deadline until November 8, 2018. Just a few months later, in July 2017, FDA extended the deadline until August 8, 2022, to allow time for its Center for Tobacco Products to provide the "rules of the road" to industry stakeholders regarding such applications. In March 2019, FDA then announced it would take enforcement action against certain companies which did not file PMTAs on or before August 8, 2021, thereby shortening the deadline by a full year for vapor products that are not tobacco-, menthol-, or mint-flavored. Finally, only three months later, in June 2019, FDA stunned the industry by asking a district court to grossly accelerate the PMTA deadline by twenty-seven months to May 11, 2020, for all vapor products. FDA failed to give any notice to the public, including industry stakeholders, or to allow public comment prior to proposing the grossly accelerated deadline.

5. The one constant behind for these ever-shifting deadlines has been the FDA's failure or refusal to establish definitive "rules of the road" for acceptable PMTA applications. Throughout 2016, 2017, 2018 and 2019, FDA publicly and repeatedly told all stakeholders that FDA did not have the rules, guidance, and standards in place for companies to move forward with PMTA application submissions. These statements came in the form of major press conferences held by then-Commissioner Gottlieb, FDA press releases, and, as recently as February 27, 2019, sworn testimony from Commissioner Gottlieb before Congress stating that the PMTA deadline had been extended because the FDA had not laid out the rules of the road.

6. Despite having more than three years to do so, FDA has failed to publish even a *draft*, much less final, regulation specifying what must be included in all-important PMTAs for vapor products. Instead, FDA has only put forward a single non-binding PMTA guidance document, the final version of which was published on June 11, 2019—just one day before FDA asked the district court to impose only a ten-month deadline for companies to comply. Unfortunately, the final guidance document contains significant changes regarding recommended product testing from the draft version published earlier and fails to definitively specify what evidence is or is not required for an acceptable PMTA.

7. For all those manufacturers who in good faith waited to commence work on their PMTAs in reliance on FDA's multiple promises of further guidelines by way of a rule governing PMTAs, the ten-month period remaining to submit complete PMTAs is now not attainable. Despite there being thousands of manufacturers and millions of vapor products on the U.S. market, there are only five to six appropriately qualified and credentialed laboratories available to conduct the extensive aerosol testing for harmful and potentially harmful constituents ("HPHCs") that FDA recommends. Upon information and belief, *none* of these laboratories currently have in place

independently validated testing methodologies to test for all of the new HPHCs that FDA just announced on June 11, 2019. Indeed, for certain HPHCs, the limitations of current laboratory technology dictate that the minimum limits of detection exceed the threshold levels of concern that FDA has specified should be referenced. Further, per industry standards, product stability and shelf life testing must take 12 months or more. The clinical studies that FDA recommends also cannot be concluded in fewer than 12 months and are more likely to take well in excess of one year. Further, the few appropriately qualified laboratories in the United States to undertake such clinical studies do not have availability to even start until the last quarter of this year.

8. As a result of FDA's arbitrary and capricious proposal of a new ten-month deadline, Vapor Stockroom and the VTA's other members face the immediate conundrum of whether to: (i) spend millions of dollars on PMTAs for which FDA has admittedly not yet established the "rules of the road" by way of a finalized regulation and which will, of necessity, be impossible to complete by the filing deadline of May 11, 2020; or, alternatively, (ii) wait for additional regulations from FDA that may or may not be forthcoming and run the risk that FDA will treat their products as adulterated under 21 U.S.C. § 387b(6)(A) and take enforcement action to remove them from the market after May 11, 2020.

9. Both preliminary and permanent injunctive relief (a) requiring FDA to propose and finalize a rule governing the submission of PMTAs, (b) requiring FDA to set a reasonable deadline for the filing of PMTAs pursuant to the finalized rule after notice and public comment, (c) prohibiting FDA from taking enforcement action against any vapor products on the U.S. market as of August 8, 2016, until after the new filing deadline for PMTAs is required, and (d) prohibiting FDA from taking enforcement action based on the May 2020 deadline. Absent prompt intervention by the Court, the overwhelming majority of the vaping industry, including over

160,000 jobs at small- and medium-sized businesses, will be destroyed. Further, many former smokers will likely revert back to the use of more harmful combustible cigarettes. As FDA itself has observed, such a precipitous mass market exit "needs to be avoided it at all possible."

PARTIES

10. The Vapor Technology Association is a national non-profit industry trade association whose more than 800 members are dedicated to developing and selling high quality vapor product that provide adult consumers with a safer alternative to traditional combustible cigarettes. The VTA's membership includes manufacturers of aerosolizing apparatuses—commonly known as vapor devices or e-cigarettes—manufacturers of nicotine-containing e-liquids, flavorings, and components, as well as wholesales, importers, and e-commerce and brick-and-mortar retailers. The VTA also counts twenty-seven (27) state-level vapor associations among its membership. Since its founding, the VTA has been as the forefront of the most critical issues confronting the vapor industry, including adopting the industry's first comprehensive set of marketing standards intended to ensure that vapor products are properly marketed towards adults only and are not accessible to minors. The VTA's headquarters are located at 1201 Pennsylvania Avenue, N.W., Suite 530, Washington, DC 20004.

11. In its role as the industry's leading national trade association representing companies from every sector of the vapor industry, the VTA has a vital interest in ensuring that any regulation of vapor products imposed by FDA is consistent with statutory and constitutional requirements, including the Administrative Procedure Act's notice and comment requirements under 5 U.S.C. § 553 and the Fifth Amendment's Due Process Clause.

12. The VTA has standing to bring this suit because (a) its members would otherwise have standing to sue in their own right; (b) the interests the VTA seeks to protect are germane to

the organization's purpose of ensuring the continued availability in the United States of high quality vapor products to adult consumers that are former smokers; and (c) neither the claims asserted nor the relief requested require the participation of individual members in the lawsuit. *E.g., United Food & Commercial Workers Union Local 751 v. Brown Grp., Inc.*, 517 U.S. 544, 552-57 (1996).

13. Vapor Stockroom, LLC is a Kentucky limited liability company headquartered at 2428 Palumbo Drive, Suite 110, Lexington, Kentucky 40509. Vapor Stockroom is a manufacturer of nicotine-containing e-liquids and currently manufactures 40 distinct lines of such products in a variety of nicotine concentrations, propylene glycol and vegetable glycerin ratios, flavors, and bottle sizes. Vapor Stockroom employs thirteen individuals and sells its e-liquids in local retail stores, online, and through distribution to vape shops and tobacco specialty stores nationwide. Vapor Stockroom is a member of the Vapor Technology Association.

14. Defendant United States Food and Drug Administration is a division of Defendant Department of Health and Human Services. The headquarters and principal place of business of the FDA is 10903 New Hampshire Avenue, Silver Spring, Maryland 20903. The headquarters and principal place of business of Defendant HHS is 200 Independence Avenue, S.W., Washington, D.C. 20201.

15. Defendant Norman E. Sharpless, M.D., is the Acting Commissioner of the Food and Drug Administration and is sued in his official capacity. Defendant Alex Azar is the Secretary of Health and Human Services and is sued in his official capacity.

JURISDICTION AND VENUE

16. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1343(a), and 1361. This Court has the authority to grant the declaratory relief requested by Plaintiffs

pursuant to 28 U.S.C. §§ 2201 and 2202. The Court also has the authority to hold unlawful and set aside FDA's actions pursuant to 5 U.S.C. §§ 702 and 706.

17. This Court has personal jurisdiction over Defendants FDA, HHS, Acting Commissioner Sharpless, and Secretary Azar in their official capacities, as each is an agency or official of the United States Government.

18. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) as the district wherein Plaintiff Vapor Stockroom resides.

FACTS

A. A Wide Variety of Innovative Vapor Products Provide an Alternative to Combustible Cigarettes for Existing Smokers and Hold Great Potential to Benefit the Public Health as a Harm Reduction Tool.

19. Vapor devices, also known as "electronic cigarettes," "e-cigarettes," or "electronic nicotine delivery systems (ENDS)" are electronic devices that are used to aerosolize a liquid mixture that contains nicotine (not cannabis or any other active ingredient) by heating it ("e-liquid"). Once the e-liquid is aerosolized, the user of the vapor device inhales the aerosolized "vapor" in a manner similar to that of inhaling actual tobacco smoke, but without the fire, flame, tar, carbon monoxide, ash, stub, or smell associated with traditional cigarettes.

20. Vapor devices are handheld technologies that typically consist of a battery, software, electronics, an atomizer (or heating element), and a fluid-filled cartridge, pod, or empty reservoir tank. In a so-called "closed system," either the device itself or interchangeable pods or cartridges intended for use with that device come pre-filled with a particular type of e-liquid. In a so-called "open system," the device will not come pre-filled; rather, the user will separately buy bottled e-liquid(s) and use them to fill the device's e-liquid reservoir, or "tank," with the e-liquid and nicotine level of her or her choice.

21. E-liquids are typically made with a mixture of propylene glycol and/or vegetable glycerin, flavorings, and pharmaceutical grade nicotine. E-liquids are sold to consumers in a range of nicotine concentrations and flavor combinations for both open and closed systems and in a variety of bottle sizes for use with open systems. Because e-liquids are sold in varying levels of nicotine concentrations, *including zero nicotine products*, users have the option to reduce their nicotine intake and/or wean themselves off of nicotine entirely.

22. Vapor products first became available in the United States in or about 2008. In the more than ten years since, the vapor product market has become remarkably diverse and has grown to meet the varied needs and demands of adult consumers, many of which are current or former smokers. Samples of just a few types of vapor devices and e-liquids are shown below:

23. Upon information and belief, to date, well over 3 million unique e-liquids and vapor devices are registered with the FDA's Center for Tobacco Products.

24. Vapor products also have been the focus of extensive peer-reviewed scientific study and analysis, with a general resulting consensus. FDA itself acknowledges that such products pose far lesser risk to the individual than combustible cigarettes and that they hold great potential to benefit the public health as a harm reduction tool.

25. By way of example, evaluations undertaken by the United Kingdom's internationally recognized and esteemed Royal College of Physicians from 2014 to 2018 concluded that the potential hazard to health arising from long-term use of vapor products is, at

most, five percent (5%) of the comparable harm resulting from the use of traditional combustible cigarettes.[1]

26. A study conducted at Georgetown University, entitled *Potential Deaths Averted in USA by Replacing Cigarettes with E-Cigarettes* and published in the journal *Tobacco Control* in 2017, concluded that switching from traditional cigarettes to vapor products would prevent between 1.6 million and 6.6 million premature deaths over ten years in the United States.[2]

27. A comprehensive study of vapor products commissioned by FDA and published by the National Academies of Sciences, Engineering, and Medicine in January 2018 also confirmed that vapor products pose substantially less risk than combustible cigarettes, concluding, *inter alia*, that:

- "There is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes."
- "There is substantial evidence that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems."
- "The evidence about harm reduction suggests that across a range of studies and outcomes, e-cigarettes pose less risk to an individual than combustible tobacco cigarettes."

[1] Royal College of Physicians Tobacco Advisory Group. Nicotine without smoke: Tobacco harm reduction, April 2016, available at: https://www.rcplondon.ac.uk/projects/outputs/nicotine-without-smoke-tobacco-harm-reduction-0.

[2] Levy DT, Borland R, Lindblom EN, Goniewicz ML, Meza R, Holford TR, Yuan Z, Luo Y, O'Connor R, Niaura R, Abrams DB, 2018 Potential deaths averted in USA by replacing cigarettes with e-cigarettes. Tob. Control 2018 Jan;27(1):18-25. doi: 10.1136/tobaccocontrol-2017-053759. Epub 2017 Oct 2.

- "Laboratory tests of e-cigarette ingredients, in vitro toxicological tests, and short-term human studies suggest that e-cigarettes are likely to be far less harmful that combustible tobacco cigarettes."[3]

28. Further, a randomized clinical study published in the New England Journal of Medicine on February 14, 2019, concluded that cigarette smokers were almost twice as likely to quit smoking when using e-cigarettes than when using nicotine replacement therapies such as lozenges and patches.[4] Another study of over 18,000 smokers published in May 2019 found that those using e-cigarettes as a quitting aid were almost three times more likely to succeeded in their efforts to quit after 12 months than those using nicotine gums, patches, and lozenges.[5]

29. In the United Kingdom, the National Health Service is promoting vapor products as a smoking cessation tool and two NHS hospitals have even opened vape shops on their premises as part of their efforts to eradicate smoking.[6]

30. The Centers for Disease Control reports that the number of smokers as a percentage of the U.S. population has dropped dramatically from 20.6 percent in 2009,[7] when ENDS products

[3] National Academies of Sciences, Engineering, Medicine. 2018. Public Health Consequences of E-Cigarettes, at 1, 11, 487, 604, 617.

[4] Hajek, Peter, et al., A Randomized Trial of E-Cigarettes versus Nicotine Replacement Therapy. N. Engl. J. Med. 2019; 380:629-637 DOI: 10.1056/NEJMoa1808779.

[5] Jackson SE, et al., Moderators of Real-World Effectiveness of Smoking Cessation Aids: A Population Study. Addiction 2019; Vol. 114: 1627-1638; DOI: 10.1111/add.14656.

[6] Laura Donnelly, *Vape Shops Open on NHS Hospital Sites, in Bid to Stub Out Smoking*, The Telegraph, (July 9, 2019), available at https://www.telegraph.co.uk/news/2019/07/09/vape-shops-open-nhs-hospital-sites-bid-stub-smoking.

[7] U.S. Center for Disease Control and Prevention (CDC), Trends in Current Cigarette Smoking Among High School Students and Adults, United States, 1965–2014, available at https://www.cdc.gov/tobacco/data_statistics/tables/trends/cig_smoking/index.htm.

first gained traction in the United States, to only 14 percent as of 2017.[8] Similarly, between June 2018 and June 2019, U.S. cigarette sales volumes fell by more than 10 percent.[9]

31. Despite vapor products' great potential to benefit public health as a harm reduction tool, FDA's recent actions taken in violation of the Administrative Procedure Act's notice and comment requirements imminently threaten the continued existence of a robust tobacco alternatives industry and threaten a return to the day where American smokers' only option to satisfy their nicotine cravings is the leading cause of preventable death and disease in the United States—the combustible cigarette.[10]

B. Vapor Products, Which Do Not Contain Tobacco, Are Disadvantaged Under the Tobacco Control Act Compared to More Harmful Combustible Cigarettes Because *Pre-Market* Tobacco Applications Must be Filed for Vapor Products Already On the Market.

32. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (the "TCA" or the "Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. §§ 387, *et seq.*). The TCA significantly altered federal regulation of tobacco products by, for the first time, granting FDA the statutory authority to regulate tobacco products through the addition of a new Chapter IX to the federal Food, Drug, and Cosmetic Act ("FDCA"), and the creation of a new "center" within FDA, the Center for Tobacco Products.

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[8] CDC Press Release, Smoking is down, almost 38 million American adults still smoke (Jan. 18, 2018); CDC Smoking & Tobacco Use: Fast Facts and Fact Sheets, available at https://www.cdc.gov/tobacco/data_statistics/fact_sheets/index.htm#fast.

[9] Herzog, B. Nielsen: Tobacco All Channel Data Thru 6/15 – Cig Vol Declines Accelerate, Wells Fargo Securities. 29 June 2019.

[10] CDC, Current Cigarette Smoking Among Adults in the United States, available at https://www.cdc.gov/tobacco/data_statistics/fact_sheets/adult_data/cig_smoking/index.htm.

33. The FDCA, as amended by the TCA, defines a "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr).

34. Under Section 901 of the FDCA, the requirements of the TCA originally applied only to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco (the "Originally Regulated Products"). 21 U.S.C. § 387a(b). The TCA's requirements would only apply to other products meeting the statutory definition of a "tobacco product" if and when the Secretary of Health and Human Services "by regulation deems" such products to be "tobacco products." *Id.*

35. On May 10, 2016, FDA finalized its so-called "Deeming Rule"[11] that, for the first time, deemed e-liquids containing, and vapor devices containing or intended to be used with, nicotine derived from tobacco plants to be "tobacco products" under the FDCA's definition (the "Newly Deemed Products"). *See* 81 Fed. Reg. 28,974 – 29,106 (May 10, 2016).

36. Through the Deeming Rule, FDA interpreted the definition of a "tobacco product" so broadly that it also chose to define as a "tobacco product" the electronic components of a vapor device like lithium-ion batteries, software, and electronic circuitry. In so doing, FDA superimposed a regulatory scheme designed for a 19th century agricultural product on to a 21st century technology.

[11] U.S. Food & Drug Admin., *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; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,973 (May 10, 2016) (codified at 21 C.F.R. § 1143.1) (hereafter, "Deeming Rule").

37. In addition to expanding the definition of a "tobacco product" to an unprecedented breadth, FDA also intentionally swept into its ambit of authority as many businesses as possible, regardless of how small and regardless of whether they actually manufacture vapor products when it defined "manufacturer" so broadly that the term includes even persons who merely assemble or label prefabricated vapor products. See 21 U.S.C. § 387(20)(A).

38. The TCA, as extended to manufacturers of vapor products through the Deeming Rule, imposed a variety of duties and prohibitions on manufacturers—whether large or small and whether they manufacture a product or merely assemble and label it—including a complex, multi-million-dollar, multi-year pre-market tobacco application requirement.

39. While the TCA was considered landmark legislation and heralded by public health groups, the TCA expressly exempted cigarette products on the market as of February 15, 2007, from the onerous PMTA requirements. All combustible cigarette products were "grandfathered," or allowed to remain on the market without any requirement that their manufacturers spend millions of dollars on PMTA applications. In stark contrast, no vapor products are "grandfathered," and all vapor products are subject to the onerous PMTA process.

40. For all new tobacco products that were not on the market as of February 15, 2007, the date of the Act's introduction in Congress, and for grandfathered products that were modified after that date, Section 910 of the FDCA requires obtaining an authorization order from FDA permitting the marketing of such products (referred to as a "marketing authorization order") before such products can be legally sold in the United States. *See* 21 U.S.C. § 387j.

41. The TCA created three pathways to obtaining a marketing authorization order for non-grandfathered tobacco products: substantial equivalence exemption reports, substantial equivalence reports, and PMTAs.

42. The substantial equivalence pathway allows manufacturers of tobacco products to obtain a marketing authorization order if they can show that the new tobacco product is "substantially equivalent" to a "grandfathered" tobacco product commercially marketed in the United States as of February 15, 2007, or a tobacco product that FDA has already determined was substantially equivalent to such a product. 21 U.S.C. §§ 387e(j)(1)(A)(i). The substantial equivalence exemption pathway similarly requires reference to a grandfathered predicate tobacco product. As FDA has publicly stated, the less expensive and less onerous substantial equivalence pathway is not available to vapor product manufacturers because no grandfathered vapor products that could serve as the predicate for a substantial equivalence application were marketed in the United States as of February 15, 2007. *See* Fed. Reg. at 28990-97.

43. The TCA allowed manufacturers of the Originally Regulated Products to continue marketing their tobacco products that were on the market as of June 22, 2009, when they first became subject to regulation, and allowed them to "look back" only two and a half years—to February 15, 2007—for predicate products.[12]

44. Under the Act, manufacturers of Originally Regulated Products, including combustible cigarettes, were permitted to change existing products and introduce new products until March 22, 2011, when pre-market and substantial equivalence applications were first due. *See* 21 U.S.C. § 387e(j)(2).

45. Originally Regulated Products for which applications were filed by March 22, 2011, could remain on the market (subject to compliance with the other provisions of the Act) unless and until FDA rejected a product's application. *See* 21 U.S.C. §§ 387e, 387j.

[12] *See* 21 U.S.C. § 387e(j)(1)(A)(i); U.S. Food & Drug Admin., Guidance for Industry, *Establishing That a Tobacco Product Was Commercially Marketed in the United States as of February 15, 2017* (September 2014), at https://www.fda.gov/media/116764/download.

46. However, under the Deeming Rule, in contrast, manufacturers of Newly Deemed Products, are forced to "look back" over nine years for predicate products. This distinction places Newly Deemed Products, including less harmful vapor products, in a significantly different and less advantageous regulatory category compared to Originally Regulated Products such as combustible cigarettes.

47. FDA's promulgation and implementation of the Deeming Rule pursuant to its authority under 21 U.S.C. § 387a(b), subjected "all products meeting the statutory definition of 'tobacco product,' except accessories of the newly deemed tobacco products," to regulation under the FDCA.

48. The Deeming Rule thus commands that not only e-liquids, but also vapor devices and the constituent parts or components of vapor devices are "tobacco products" subject to the TCA's requirements, **including the PMTA requirement**.

49. The Deeming Rule also provided staggered compliance periods for Newly Deemed Products that were introduced after February 15, 2007, and on the market on the effective date of the Deeming Rule, August 8, 2016. PMTA submissions were required to be filed in 24 months, or by August 8, 2018. 81 Fed. Reg. at 28977-78.

50. The Deeming Rule took effect on August 8, 2016. 81 Fed. Reg. at 28,974.

C. Since August 8, 2016, When the Deeming Rule Took Effect, Vapor Companies Have Been Subject To and Have Complied With an Extensive Series of FDA Regulations.

51. In the three years since the Deeming Rule took effect, all Newly Deemed Products, including vapor products, have been heavily regulated by FDA. Vapor industry stakeholders, including Vapor Stockroom and the VTA's other members, have steadily complied with a series

of rigorous regulatory requirements progressively imposed by FDA under the Tobacco Control Act.

52. On August 8, 2016, all vapor companies became subject to the FDCA, as amended by the TCA, and FDA immediately imposed numerous requirements and obligations, including:

a. making it unlawful to market misbranded or adulterated tobacco products;

b. requiring the preservation of certain records;

c. authorizing FDA to regulate the methods used in manufacturing and testing tobacco products;

d. granting FDA authority to mandate new product standards regarding the composition and characteristics of vapor products; and

e. requiring manufacturers to obtain advance approval from FDA before making a variety of advertising and labeling claims—so called "modified risk" claims.

See 81 Fed. Reg. at 28974, 28976.

53. By February 8, 2017 (or November 8, 2017, for small-scale manufacturers), vapor product manufacturers were required to file with FDA copies of "health documents" relating to "health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents . . . , ingredients, components, and additives" as required under Section 904 of the FDCA, 21 U.S.C. § 387d(a)(4).

54. By October 30, 2017, every business in the United States engaged in the "manufacture, preparation, compounding, or processing" of vapor products was required to register their establishment(s) with FDA and open their establishment(s) to inspection by FDA

once every two years as required under Section 905 of the FDCA, 21 U.S.C. § 387e(a)(1), (b), (g). To date, approximately 3,686 vapor product manufacturing establishments have been registered.[13]

55. By October 30, 2017, every business in the United States engaged in the manufacturing of vapor products was required to identify every one of its products with FDA, including providing copies of product labels and samples of advertisements, as required under Section 905 of the FDCA, 21 U.S.C. § 387e(i)(1). As of today, upon information and belief, there are more than 3,500,000 vapor products (i.e., e-liquids and devices) that have been registered with FDA. A PMTA, as discussed in greater detail below, is required to be filed for every one of them.

56. By May 8, 2018 (or November 8, 2018, for small-scale manufacturers), manufacturers and importers submitted to FDA all ingredients found in their finished tobacco products pursuant to Section 904 of the FDCA, 21 U.S.C. § 387d(a)(3). Today, FDA has detailed information on the ingredients contained in millions of vapor products.

57. By August 10, 2018, manufacturers complied with comprehensive new labeling, packaging and advertising requirements, including the nicotine warning requirement set forth in 21 C.F.R. § 1143.3(a)(1)-(2), which requires prominently placing the following nicotine addiction warning on any vapor products containing e-liquid: **"WARNING: This product contains nicotine. Nicotine is an addictive chemical."** Companies spent considerable time and funds to change their product labels, their product packaging, and their advertising to comply with the FDA's new regulation. Also, manufacturers uploaded to the FDA's database, or otherwise submitted, samples of their new labels and packaging.

[13] *See* U.S. Food & Drug Admin., Establishment Registration & Tobacco Product Listing, as of August 3, 2019, "Download Establishment Registration," at https://ctpocerl.fda.gov/rlapp/home.html.

58. As a result of the implementation of the Deeming Rule, FDA now has robust information regarding the vapor industry and vapor products, including those of Vapor Stockroom, to allow it to effectively carry out its mandate to protect the public health, including information regarding: (i) the identities and locations of vapor product manufacturers; (ii) the products manufactured and sold by those manufacturers; (iii) the ingredients found in those products; and (iv) studies performed by vapor businesses regarding the health effects of those products. In a public statement released on July 10, 2019, Acting Commissioner Sharpless stated that "[t]hese submissions are a key step in FDA's efforts to learn more about these products and to develop future regulations regarding ENDS manufacturing and marketing."

59. Despite vapor manufacturers spending tens if not hundreds of thousands of dollars to comply with each of the foregoing requirements, the most significant regulatory hurdle for every stakeholder in the vapor industry—including Vapor Stockroom and the VTA's other members—remains: the securing of premarket approval for the products it sells from FDA. And, unlike each of the foregoing requirements, FDA has either failed or refused to provide the clear rules or guidelines that would enable companies to comply with the onerous PMTA requirements.

D. FDA Repeatedly Promised, But Has Failed to Deliver, Foundational Rules or Clear Guidance Setting Forth the "Rules of the Road" Upon Which Vapor Manufacturers Could Rely for the Mandatory Pre-Market Tobacco Application Process.

60. Along with its sweeping Deeming Rule, on May 10, 2016, FDA issued a draft industry guidance for ENDS manufacturers titled "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Draft Guidance" ("Draft ENDS PMTA Guidance").[14]

[14] *See* Draft Guidance, Premarket Tobacco Product Applications for ENDS, 81 Fed. Reg. 2871 (May 10, 2016).

However, from the outset, FDA promised that additional and final guidance would be forthcoming well in advance of the deadline for filing PMTAs.

61. More importantly, since passage of the TCA, FDA has repeatedly confirmed that it must take a number of other preliminary regulatory actions to ensure that manufacturers know how to comply with the pre-market filing requirements established by the Act. Specifically, FDA confirmed that further guidance and a formal "foundational rule" would be necessary to provide the "rules of the road" for vapor manufacturers to properly comply with the Act's, the Deeming Rule's, and FDA's PMTA filing requirements.

62. In 2016 and 2017, industry eagerly awaited FDA's action on these items since the PMTA application deadline was a short time away in August 2018.

63. Then, in late July 2017, FDA made a major announcement. FDA announced a dramatic change in its regulatory priorities through a new comprehensive plan for the regulation of tobacco and nicotine-containing products that would include reducing the permissible amount of nicotine in combustible cigarettes to minimally addictive or non-addictive levels. In announcing its new comprehensive plan, FDA emphasized that nicotine is delivered through products that present a continuum of risk and that nicotine is most harmful when delivered through smoke particles in combustible cigarettes—not through aerosol generated by vapor products.[15]

64. In his July 28, 2017 speech announcing the new comprehensive plan, former FDA Commissioner Scott Gottlieb, M.D., announced that, to make certain FDA was striking an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than combustible cigarettes, FDA was providing relief on

[15] FDA Comm'r S. Gottlieb, Protecting American Families: Comprehensive Plan for Nicotine and Tobacco (July 28, 2017), at https://www.fda.gov/news-events/speeches-fda-officials/protecting-american-families-comprehensive-approach-nicotine-and-tobacco-06282017.

some deadlines described in the May 2016 Deeming Rule. Then-Commissioner Gottlieb stated: "Envisioning a world where cigarettes would no longer create or sustain addiction, and where adults who still need or want nicotine could get it from alternative and less harmful sources, needs to be the cornerstone of our efforts – and we believe it's vital that we pursue this common ground."[16]

65. Then-Commissioner Gottlieb also stated: "Our approach to nicotine must be accompanied by a firm foundation of rules and standards for newly-regulated products. To be successful all of these steps must be done in concert and not in isolation." Gottlieb acknowledged that FDA did not yet have the proper regulations in placed for newly deemed ENDS products when he stated: "One area of emphasis will be to make sure we have the foundational regulatory architecture to ensure proper oversight of ENDS . . . . Part of this will be developing regulations that we have not yet pursued because the Agency's tobacco program itself is so new."[17]

66. In conjunction with the comprehensive plan's announcement, Center for Tobacco Products Director Mitch Zeller also emphasized the importance of public and stakeholder input in the process of developing appropriate regulations governing PMTAs: "This comprehensive plan and sweeping approach to tobacco and nicotine allows the FDA to apply the powerful tools given by Congress to achieve the most significant public health impact. . . . Public input on these complex issues will help ensure the agency has the proper science-based policies in place to meaningfully reduce the harms caused by tobacco use."[18]

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[16] *Id*.

[17] *Id*.

[18] News Release, U.S. Food & Drug Admin., FDA announces comprehensive regulatory plan to shift trajectory of tobacco-related disease, death (July 28, 2017), at https://www.fda.gov/news-

67. Most importantly, as part of its July 2017 announcement, FDA stated that it planned to issue foundational rules to "make the product review process more efficient, predictable, and transparent for manufacturers, while upholding the agency's public health mission. ***Among other things, the FDA intends to issue regulations outlining what information the agency expects to be included in Premarket Tobacco Applications (PMTAs)***, Modified Risk Tobacco Product (MRTP) applications and reports to demonstrate Substantial Equivalence (SE). The FDA also plans to finalize guidance on how it intends to review PMTAs for ENDS" (emphasis added).[19]

68. Following the public announcement of its new comprehensive plan, in or about August 2017, FDA issued a Guidance for Industry entitled "Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule" (the "August 2017 Guidance"). The August 2017 Guidance extended the compliance deadline for manufacturers to submit SE exemption requests, SE reports, and, most significantly for Plaintiffs, PMTAs for vapor products that were on the market as of August 8, 2016. Specifically, FDA's August 2017 Guidance extended the PMTA deadline for vapor products from August 8, 2018, to August 8, 2022.[20] Other than the deadline extension, the August 2017 Guidance did not offer any new guidelines or direction on the PMTA application requirements or process.

69. Given the complexity, costs, and time associated with filing a PMTA, and because of the absence of any PMTA foundational rule or finalized guidance, VTA advocated for an extension of the PMTA deadline by two years from the date of the final foundational rule. Instead,

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events/press-announcements/fda-announces-comprehensive-regulatory-plan-shift-trajectory-tobacco-related-disease-death.

[19] *Id.*

[20] *See* U.S. Food & Drug Admin., Guidance for Industry, Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule (August 2017), at 8.

FDA extended the deadline out for four years (from August 8, 2018, to August 8, 2022), presumably because FDA was aware that its internal work on crafting the foundational rules, guidance, and product standards would take a significant amount of time, as would manufacturers' compliance with whatever foundational rules and finalized guidance FDA would ultimately publish.

70. Thereafter, FDA repeatedly affirmed that additional regulation and guidance were necessary for the vapor industry to satisfactorily comply with the filing requirements and submit the information necessary to successfully complete a PMTA.

71. On November 3, 2017, then-Commissioner Gottlieb stated that "[t]he foundational regulations for the tobacco program were never put in place and so we're going to take the time to put those in place so we have a firm foundation from which to regulate."[21]

72. By the end of 2017, FDA had clearly instructed stakeholders that it was pursuing a new comprehensive plan, that there would be new rules forthcoming, and that FDA was going to take the time necessary to get the process for PMTAs for vapor products right.

73. FDA continued its assurances throughout 2018. For example, in a press release on March 15, 2018, then-Commissioner Gottlieb stated:

> "For example, our plan demonstrates a greater awareness that nicotine, while highly addictive, is delivered through products on a continuum of risk, and that in order to successfully address cigarette addiction, we must make it possible for current adult smokers who still seek nicotine to get it from alternative and less harmful sources. To that end, the agency's regulation of both novel nicotine delivery products such as e-cigarettes and traditional tobacco products will encourage the innovation of less harmful products while still ensuring that all tobacco products are put through an appropriate series of regulatory gates to maximize any public health benefits and minimize their harms. This will be achieved through our ongoing regulatory work to develop several foundational rules, guidances, product standards and other regulations.

[21] FDA Comm'r S. Gottlieb, Remarks at the National Press Club (Nov. 3, 2017), at https://www.fda.gov/news-events/speeches-fda-officials/remarks-national-press-club-11032017.

> . . . .
>
> Finally, we also plan to take new steps to make sure that our policies and processes for the regulation of tobacco products are efficient and predictable, and consistent with the mandate Congress gave us under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). We're committed to making sure that we have transparent regulatory policies and best practices in place to maximize our public health impact. ***To these ends, we plan to issue a series of foundational rules and guidance documents that will delineate key requirements of the regulatory process, such as the demonstration of substantial equivalence and the submission of applications for new tobacco products.***
>
> . . . .
>
> ***As we move forward with these efforts,*** we have an opportunity to more formally solicit feedback, and we'll continue to foster a public dialogue to re-shape our country's relationship with nicotine and seek public input on policies that will guide us toward a healthier future. (Emphasis added.)[22]

74. Then, on August 2, 2018, FDA released a statement titled "Advancing Tobacco Regulation to Protect Children and Families, which stated that "foundational proposed rules" are needed "regarding the basic rules of the road, especially when it comes to what's expected in premarket applications."[23]

75. Just five months ago, on February 27, 2019, FDA Commissioner Gottlieb, in sworn testimony before Congress, defended and affirmed that extending the PMTA deadline to August 2022 was necessary "to give [FDA] the time to put in place the implementing regulations and

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[22] *Statement from FDA Comm'r S. Gottlieb, M.D., on pivotal public health step to dramatically reduce smoking rates by lowering nicotine in combustible cigarettes to minimally or non-addictive levels* (Mar. 15, 2018), at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-pivotal-public-health-step-dramatically-reduce-smoking.

[23] U.S. Food & Drug Admin., *Advancing Tobacco Regulation to Protect Children and Families: Update & New Initiatives from the FDA on the Anniversary of the Tobacco Control Act & FDA's Comprehensive Plan for Nicotine* (Aug. 2, 2018), at https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/advancing-tobacco-regulation-protect-children-and-families-updates-and-new-initiatives-fda.

guidance that would . . . provide the rules of the road for how to effectively traverse the PMTA process[.]"[24] Thus, as recently as February of this year, the FDA Commissioner noted the absence of any implementing regulation governing PMTAs for ENDS and that neither FDA, nor any industry stakeholder, knew the "rules of the road" for the PMTA process.

76. Significantly, despite FDA's repeated statements over the course of almost two years emphasizing the importance of a foundational rule for PMTAs for ENDS products and product standards, as of the date of the filing of this complaint, FDA has yet to publish even a *draft* rule on PMTAs for vapor products, much less a final rule, has failed to articulate any product standards, and has failed to propose any good manufacturing practices.

77. Rather, FDA shifted its focus almost exclusively to addressing what it called an "epidemic" regarding the illegal use of vapor products by underage teens. For example, on March 21, 2018, FDA published an Advance Notice of Proposed Rulemaking entitled "Regulation of Flavors in Tobacco Products" (the "Flavor ANPRM").[25] In July 2018, VTA and thousands of other stakeholders provided comments, consistent with the Administrative Procedure Act, regarding the role of flavors in vapor products. Since that time, FDA has not responded to the thousands of comments submitted in response to its Flavor ANPRM, nor has FDA published any proposed rule for comment regarding if and how it might regulate flavors in tobacco products, including vapor products.

78. Instead of completing the scientific review of the comments received in response to the Flavor ANPRM, in March 2019, FDA published another draft guidance document entitled

[24] *Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations for 2020: Hearings Before a Subcomm. of the H. Comm. on Appropriations*, 116th Cong. 35 (2019) (statement of FDA Comm'r S. Gottlieb).

[25] 83 Fed. Reg. 12,294 (Mar. 21, 2018)

"Modifications to Compliance Policy for Certain Deemed Tobacco Products" (the "March 2019 Guidance") in which, *inter alia*, FDA announced that it was changing the PMTA deadline for *certain* flavored tobacco products.[26] **Remarkably, FDA stated that it was issuing the March 2019 guidance so that "manufacturers will be *prompted* to move up their filing of premarket submission for certain deemed tobacco products," – the same PMTA applications for which Commissioner Gottlieb testified there were no regulations or rules of the road just a few weeks earlier** (emphasis supplied).[27] Specifically, FDA indicated that it was shortening the deadline for filing PMTAs for a large number of vapor products that had a flavor other than tobacco flavor, menthol flavor, or mint flavor by one year to August 8, 2021.[28]

79. To add to the arbitrariness of its actions, FDA stated that it would be selectively enforcing the new August 2021 deadline on a "case-by-case" basis against certain companies that sold products in certain ways not defined in the March 2019 Guidance.[29] However, FDA did not shorten the PMTA filing deadline for other non-combustible tobacco products from the then-existing August 8, 2022 deadline set forth in FDA's August 2017 Guidance.

80. The VTA filed comments on the March 2019 Guidance that raised serious procedural and substantive legal problems. Specifically, VTA asserted:

> The Draft Guidance raises substantial concern that FDA is trying to effectively implement a tobacco product standard by compelling affected industry stakeholders to act in accordance with the Guidance's prescriptions under threat of agency enforcement in violation of Congress's explicit direction in Section 907 of the

[26] 84 Fed. Reg. 9345, U.S. Food & Drug Admin., Draft Guidance for Industry, Modification to Compliance Policy for Certain Deemed Tobacco Products (March 14, 2019).

[27] *Id*. at 7.

[28] *Id*. at 14.

[29] *Id*.

FDCA, 21 U.S.C. § 387g, to only enact tobacco product standards through formal notice and comment rulemaking.

On March 21, 2018, FDA published in the Federal Register an advance notice of proposed rulemaking entitled Regulation of Flavors in Tobacco Products (the "Flavors ANPRM"). The Flavors ANPRM suggested that FDA was initializing the process for the proposal of a tobacco product standard regarding the role of flavors in tobacco products under Section 907 of the federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 387g. On July 19, 2018, the VTA submitted extensive and highly detailed comments in response to the Flavors ANPRM that summarized the state of the existing peer-reviewed scientific literature on flavors and responded to each of the questions posed by FDA regarding the role of flavors in vaping products.

Rather than request further industry and public input on the still-developing science around OTMM[30] Flavored ENDS Products as part of a formal notice-and-comment rulemaking process, however, FDA has now published the Draft Guidance. The VTA and its members are greatly concerned that the Draft Guidance appears to be an illegal attempt by FDA to circumvent the procedural safeguards and statutory standards applicable to the issuance of a tobacco product standard under Section 907 of the FDCA under the guise of a discretionary change to the agency's enforcement policy.

If finalized, the language in the Draft Guidance may well be illegal under the Administrative Procedure Act because FDA proposes to restrict the availability of OTMM Flavored ENDS Products, while leaving unchanged the compliance policy for menthol, mint, and tobacco-flavored ENDS products:

> • without satisfying the substantive test of Section 907 of the federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 387g;
> • without satisfying the procedural obligations of Section 553(b) of the APA, 5 U.S.C. § 553(b); and
> • through a vehicle that FDA may contend does not constitute a final agency action subject to judicial review under Section 706(2) of the APA, 5 U.S.C. § 706(2).[31]

81. Importantly, the March 2019 Guidance imposing the new August 2021 deadline for "certain" flavored products was not based on FDA's review of the reams of science supplied in

[30] "Other than Tobacco, Menthol and Mint."

[31] Vapor Technology Association's Comments in Response to FDA's Draft Guidance: Modifications to Compliance Policy for Certain deemed Tobacco Products (April 30, 2019), Dkt. No. FDA-2019-D-0661.

response to FDA's Flavor ANPRM. To be sure, FDA has not even proposed a draft rule that would govern flavors, choosing instead to avoid the rulemaking process that it started by choosing to arbitrarily enforce the PMTA deadlines differently for certain products and companies.

82. Once again, FDA has not responded to the thousands of comments it received on the March 2019 Guidance and has not finalized that guidance.

83. More importantly, of the laundry list of promised PMTA foundational rules, PMTA guidance, product standards, and good manufacturing practices, FDA has only produced a single "Final" PMTA Guidance document within the last two months, but has not published the crucial foundational rules or other promised documents.

E. Vapor Stockroom and the VTA's Members Delayed Working on Their PMTAs in Reasonable and Detrimental Reliance on FDA's Oft-Repeated Promises That Further Guidance and a Foundational Rule Setting the "Rules of the Road" for PMTAs Would be Forthcoming and FDA's Public Statements and Guidance Stating that Stakeholders Would Have Until August 2022 to File Their PMTAs.

84. Relying on FDA's August 2017 Guidance providing that manufacturers would have until August 2022 to submit PMTAs for vapor products that were on the market prior to August 8, 2016, and on FDA's repeated representations between August 2016 and February 2019 that detailed guidance for PMTAs for vapor products *and* foundational rules setting the "rules of the road" for such applications would be forthcoming, many VTA member entities, including Vapor Stockroom and other vapor device and e-liquid manufacturers, smartly waited for the new comprehensive regulatory plan FDA kept promising.

85. Waiting for the oft-promised guidance and rules without which FDA suggested PMTA applications could not be properly prepared was wise for a number of reasons. First, preparing a PMTA is an extremely costly and time-consuming endeavor, with estimated costs for only five e-liquid flavors running between $2.5 million and $3.5 million. Costs for only HPHC

testing, stability testing, and environmental assessments for one unique e-liquid product are over $300,000 (without consideration of the many other elements of a PMTA described in greater detail below). For only 10 unique e-liquid products, a company would spend $1,629,470 on these 3 components. For 50 unique e-liquid products, the cost would be in excess of $7 million, and for 100 unique e-liquid products, the cost would be more than $14 million on these three components alone. These actual costs are exponentially greater than the $300,000 to $500,000 total PMTA cost per product that FDA estimated in its Regulatory Impact Analysis.

86. Second, as discussed below, a PMTA is a highly complex undertaking requiring the coordination of services of multiple outside scientific and laboratories and the development and implementation of a wide variety of research studies.

87. Third, FDA had historically rejected 100 percent of PMTAs that vapor product manufacturers had attempted to file due to incompleteness or a lack of necessary information or data.

88. In the ten years since the TCA was enacted, FDA has approved PMTAs for only two types of tobacco products, neither of which is a vapor product. One of the approved types of products—a smokeless tobacco product known as snus—relied primarily on over 30 years of epidemiology data from Sweden—a feat that cannot be replicated for any newly deemed vapor products, as such products have only been on the U.S. market since approximately 2008.[32] Similarly, the other approved PMTA—for Philip Morris's IQOS Tobacco Heating System—

[32]Brief on Remedies for John Middleton, Co., et al. as Amicus Curiae, p. 13, *Am. Acad. of Pediatrics, et al. v. FDA, et al.*, No. 8:18-cv-883, 2019 U.S. Dist. LEXIS 116003 (D. Md. July 12, 2019), at ECF No. 113.

included about two million pages of submissions, over 35 studies, and required over two years of FDA review.[33]

89. Finally, until the "rules of the road" were finalized, there were no assurances that FDA would not change its recommendations regarding product testing—a concern that later materialized in dramatic fashion with respect to the onerous Harmful and Potentially Harmful Constituent testing requirements.

F. FDA Materially Changed its Recommendations Regarding Harmful and Potentially Harmful Constituent Testing Between the Draft ENDS PMTA Guidance Published in 2016 and the Final ENDS PMTA Guidance Published on June 11, 2019.

90. After years of delay, on June 11, 2019, FDA finalized its ENDS PMTA Guidance (the "Final ENDS PMTA Guidance").[34] (A true and correct copy of the Final ENDS PMTA Guidance is attached hereto as **Exhibit 1**.) In the process, FDA made significant changes from the Draft ENDS PMTA Guidance that had been published over three years earlier in May 2016.

91. By way of example, in the Final ENDS PMTA Guidance, FDA changed materially the list of harmful and potentially harmful constituents, or "HPHCs," for which it recommends extensive testing be conducted. Of the 29 HPHCs for which FDA recommended extensive testing in the Draft ENDS PMTA Guidance, eight HPHCs (4-Aminobiphenyl, 1-Aminonaphthalne, 2-Aminonaphthalne, ammonia, anabasine, benzo[a]pyrene, 1,3-butadiene, and isoprene) were removed from the Final ENDS PMTA Guidance and eleven new HPHCs (benzyl acetate,

[33] *Id.*

[34] U.S. Food & Drug Admin., Guidance for Industry, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (June 2019), 28-29, at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/premarket-tobacco-product-applications-electronic-nicotine-delivery-systems-ends.

butyraldehyde, ethyl acetate, furfural, glycidol, isoamyl acetate, isobutyl acetate, methyl acetate, N-butanol, priopionic acid, and propylene oxide) were added.[35]

92. Upon information and belief, over the course of 2018 and early 2019, testing laboratories had already conducted HPHC testing using the original list on hundreds, if not thousands, of e-liquid products at the cost of hundreds of thousands, if not millions, of dollars, that has now proven worthless as a result of the elimination of eight HPHCs from the Draft ENDS PMTA Guidance.

93. To further complicate matters with respect to HPHCs, on August 5, 2019, FDA published a notice in the Federal Register seeking comments on whether, *inter alia*, two additional potential constituents not previously identified in either the 2016 Draft ENDS PMTA Guidance or the June 11, 2019 Final ENDS PMTA Guidance—acetic acid and acetoin—should also be included in the list of HPHCs for ENDS products because of their potential adverse respiratory effects.[36]

94. With respect to all HPHCs, FDA has never published recommended methodologies for aerosol testing under "intense" and "non-intense" use conditions, despite recommended such testing in the Final ENDS PMTA Guidance.[37]

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[35] *Compare* Guidance for Industry, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (June 2019), *with* U.S. Food & Drug Admin., Draft Guidance, Premarket Tobacco Product Applications for ENDS, 81 Fed. Reg. 2871 (May 10, 2016).

[36] U.S. Food & Drug Admin., Harmful and Potentially Harmful Constituents in Tobacco Products; Established List; Proposed Additions; Request for Comments, 84 Fed. Reg. 38032 – 38035 (Aug. 5, 2019).

[37] Guidance for Industry, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (June 2019), at 28.

95. FDA's Final ENDS PMTA Guidance also suggests that, in addition to an extensive review and analysis of the relevant existing scientific literature, extensive product testing (including aerosol testing), toxicological analysis, stability testing, materials testing, and environmental and behavioral testing and analysis is required.[38] An environmental assessment prepared in accordance with 21 C.F.R. § 25.40 is also required for each PMTA.[39] Many facets of the recommended testing cannot be completed in fewer than one to two years.

96. The Final ENDS PMTA Guidance also suggests that applicants conduct "nonclinical in vitro assays that assess . . . toxicities" for comparison to other tobacco products and human clinical studies to study patterns of use (i.e., number of puffs per use, puff duration, puff intensity, frequency of use, and duration of use) and biomarkers of nicotine exposure (i.e., pharamacokinetic studies) and health outcomes such as heart rate, blood pressure, and changes in lung function. Indeed, FDA observes that "[n]onclinical studies alone are generally not sufficient to support a determination that permitting the marketing of a tobacco product would be appropriate for the protection of the public health."[40]

G. FDA Engaged in Unlawful "Regulation by Litigation" By Superfluously Suggesting a Grossly Accelerated Ten-Month Deadline for the Submission of PMTAs Without Any Advance Notice or Opportunity for Comment by VTA or Industry Stakeholders.

97. On March 27, 2018, following FDA's announcement of its new comprehensive plan for the regulation of tobacco and nicotine-containing products, various organizations filed a lawsuit in the United States District Court for the District of Maryland challenging the PMTA

[38] *Id*. at 12.

[39] *Id*. at 23.

[40] *Id*. at 12.

deadline extension under the August 2017 Guidance. The case was captioned as *American Academy of Pediatrics v. Food and Drug Administration*, Case No. 8:18-cv-00883-PWG (D. Md.).

98. On May 15, 2019, the United States District Court for the District of Maryland (Grimm, J.) granted summary judgment for the plaintiffs, holding that FDA had exceeded the scope of its statutory authority and had failed to comply with the APA's mandatory notice and comment requirements in extending the deadline for receipt of PMTAs for newly deemed products, including vapor products, to August 8, 2022. *See Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461, 2019 U.S. Dist. LEXIS 81652, 2019 WL 2123397 (D. Md. May 15, 2019). The Maryland District Court's order vacated FDA's August 2017 Guidance and directed further briefing by the parties as to appropriate remedies. *Id.* at 498, **82-83.

99. In directing the parties to file briefs concerning an appropriate remedy, the Maryland District Court noted that "[a]ny Guidance providing for a compliance period will, of course, have to adhere to the notice and comment requirements of the APA." *Id.*

100. On May 29, 2019, the plaintiffs in that case filed their remedy brief and requested that, because the plaintiffs and FDA "agreed" that there was a "public health crisis," the Maryland District Court should enjoin FDA to set a deadline of 120 days from the date of the court's order for the filing of PMTAs.[41]

101. Neither Vapor Stockroom nor the VTA was a party to the Maryland District Court litigation. Indeed, while a limited number of manufacturers and other organizations sought leave to intervene and file briefs on an appropriate remedy after that court's summary judgment decision, on May 31, 2019—well before FDA filed its remedy brief—the Maryland District Court denied

[41] Opening Brief on Remedies for Plaintiffs Am. Acad. of Pediatrics, et al., *Am. Acad. of Pediatrics, et al. v. FDA, et al.*, No. 8:18-cv-883, 2019 U.S. Dist. LEXIS 116003 (D. Md. July 12, 2019), at ECF No. 78.

their requests on the ground that they had failed to show that the Government could not adequately represent their interests and instead limited them to filing a joint amicus brief of only 15 pages.[42] The Maryland District Court also held that "until a remedy is proposed and ordered by the Court, [the proposed vapor industry intervenors] cannot show that their rights will be impaired. ***Indeed, any remedy will involve further action by the FDA, which may well have to comply with the APA notice and comment process. At such time, [the proposed vapor industry intervenors] would have ample opportunity to be heard regarding the deadlines the FDA proposes to implement*** and the opportunity to protect their interests" (emphasis added).[43]

102. On June 12, 2019, FDA filed its remedy brief. In its remedy brief, FDA initially argued that the Maryland District Court should remand the matter to FDA so that FDA could follow the proper rulemaking procedures prescribed by the Administrative Procedure Act to establish a new PMTA deadline for Newly Deemed Products, including vapor products.[44] In so doing, FDA contended that "Plaintiffs' proposed timeframe [of four months] could adversely affect the public health by abruptly clearing the market of e-cigarette products, creating a genuine risk that former smokers addicted to nicotine could migrate back to conventional cigarettes."[45] FDA supported its position with a declaration from CTP Director Zeller in which he stated that it was the agency's "firm belief" that an accelerated deadline would "create[] a genuine risk of migration from potentially less harmful ENDS products back to combustible tobacco products

[42] Letter Order, *Am. Acad. of Pediatrics, et al. v. FDA, et al.*, No. 8:18-cv-883, (D. Md. May 31, 2019) at ECF 84.

[43] *Id*.

[44] Remedy Brief for Defendants FDA, et al., *Am. Acad. of Pediatrics, et al. v. FDA, et al.*, No. 8:18-cv-883, 2019 U.S. Dist. LEXIS 116003 (D. Md. July 12, 2019), at ECF No. 120.

[45] *Id*. at 1.

within the population of addicted adult smokers who have completely switched to ENDS." Moreover, the Director warned that a four month deadline would prevent most companies from filing PMTA applications such that "it is likely that there would be a mass market exit of ENDS products" that "could adversely affect the public health." (A true and correct copy of the Declaration of Mitchell Zeller is attached hereto as **Exhibit 2**.)

103. Despite the fact that, as noted above, more than 3 million vapor products have been registered with FDA, FDA inexplicably estimated that PMTAs would only be submitted for approximately 1,610 to 2,950 vapor products. FDA also stressed that it was still in the process of creating the actual draft rule concerning PMTAs.[46]

104. Among the concerns Director Zeller cited for opposing the plaintiff's proposed 120-day deadline were that "many ENDS manufacturers will be unlikely to submit quality PMTA applications (e.g., applications that are sufficiently complete and organized to enable CTP to efficiently conduct the required scientific review) for deemed products within a 120-day period" and that "[m]any applicants will be newly regulated entities lacking experience with FDA, and based on our experience to date, the applications are anticipated to be lower in quality and less complete than current-day applications for other FDA regulated products." (Zeller Declaration, Ex. 2, at ¶ 18.)

105. However, instead of simply arguing against the plaintiffs' proposed 120-day deadline and for remand to FDA for proper rulemaking consistent with notice and comment requirements under the APA, and despite being under no compulsion to do so, FDA proposed an arbitrary ten-month deadline for PMTA submissions—a fifth, new deadline some 27 months

[46] *Id*. at 11.

earlier than the previously existing deadline.[47] FDA's explanation of why a four-month deadline posed a threat to public health, but a ten-month deadline was appropriate was FDA's "belief" that a ten-month deadline "would at least *reduce* the potential for administrative disruption [to FDA] and the risk of a mass market exit that would adversely affect public health." (Zeller Declaration, Ex. 2, at ¶ 22.)

106. In support of its ten-month PMTA deadline recommendation, FDA stressed that it had published the Final ENDS PMTA Guidance. In reality, the Final ENDS PMTA Guidance was conveniently published only *one day* earlier—on June 11, 2019—and, like all of FDA's guidance documents, contains only "nonbinding recommendations." (Zeller Declaration, Ex. 2, at ¶ 5.) Further, as noted above, FDA substantially changed the list of HPHCs for which extensive methodological development, validation, and aerosol testing is required.

107. In his declaration, Director Zeller also indicated that "FDA intends to issue a proposed rule in the near future to further specify [PMTA] application contents and FDA's review and communication procedures under this pathway." (Zeller Declaration, Ex. 2, at ¶ 5.) As of the date of filing of this complaint, some two months later, even the draft version of this foundational rule—touted by FDA as critical to setting the "rules of the road" for PMTAs for ENDS—has yet to be published. Indeed, even a proposed version of the rule is not expected to be published any earlier than September 2019.[48]

108. Director Zeller also attempted to justify the suggestion of a ten-month deadline by claiming that such a deadline "would at least make it feasible for more manufacturers to develop

[47] Remedy Brief for Defendants FDA, et al., *Am. Acad. of Pediatrics, et al. v. FDA, et al.,* No. 8:18-cv-883, 2019 U.S. Dist. LEXIS 116003 (D. Md. July 12, 2019), at ECF No. 120.

[48] *See* OMB RIN 0910-AH44, HHS-FDA Proposed Rule, Premarket Tobacco Applications and Recordkeeping Requirements (May 31, 2019).

and submit complete and high quality applications, and for FDA to publish a proposed PMTA rule and be close to finalizing . . . [the] PMTA rule[]." (Zeller Declaration, Ex. 2, at ¶ 13.) Director Zeller also noted that the 120-day deadline proposed by the plaintiffs "would cause significant public health concerns," including "a mass market exit of such products [that] would limit the availability of a potentially less harmful alternative for adult smokers seeking to transition or stay away from combustible tobacco products. Dramatically and precipitously reducing availability of these products could present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products." (*Id*. at ¶ 15.)

109. Unsurprisingly, the Maryland District Court adopted FDA's ten-month proposal in its July 12, 2019 Order, setting May 11, 2020, as the new deadline for submission of PMTAs. *Am. Acad. of Pediatrics v. FDA,* 2019 U.S. Dist. LEXIS 116003 (D. Md. July 12, 2019).

H. FDA's Arbitrary and Capricious Suggestion of a Ten-Month Deadline Presents Vapor Manufacturers like Vapor Stockroom with a Hobson's Choice of Either Spending Millions of Dollars on PMTAs that They Know Will Be Incomplete by May 11, 2020, or Waiting for Additional Regulations from FDA and Running the Risk that Their Products Will Face Enforcement Action After May 11, 2020.

110. FDA's wholly unnecessary and superfluous proposal of a ten-month deadline for the filing of PMTAs for all vapor products legally present on the U.S. market constituted a transparent attempt at regulation by litigation without any notice to, or request for input from, the very industry stakeholders that would be so profoundly prejudiced by the extremely truncated period in which to generate a PMTA. In so doing, FDA circumvented the proper notice-and-comment procedure required by the Administrative Procedure Act, 5 U.S.C. § 553, and deprived Vapor Stockroom and the VTA's other members of any realistic possibility of submitting a complete PMTA by the new deadline.

111. Because FDA sought no input from industry prior to offering its superfluous ten-month proposal to the Maryland District Court, FDA was either unaware of or willfully ignored the reality that many manufacturers had yet to start, or had only recently begun, the extensive literature reviews, testing, studies, and analyses required for a PMTA specifically because of FDA's repeated representations that additional clarification on PMTAs would be forthcoming. FDA's unsupported and arbitrary ten-month deadline was proposed without any consideration for the irreparable and potentially fatal harm that the VTA's members would suffer to their businesses as a result.

112. In proposing a ten-month deadline for the filing of PMTAs, FDA also failed to consider the length of time the FDA-recommended testing and clinical studies will require for an applicant to collect all necessary information for a sufficient PMTA. There are multiple reasons why vapor product manufacturers cannot comply with all of FDA's recommendations for PMTAs set out in its Final ENDS PMTA Guidance on the ten-month timeframe that they currently face:

a. First, as regards HPHC testing, FDA has indicated that it will only accept results from testing laboratories that are in compliance with good laboratory practices regulations. Upon information and belief, there are only five to six such qualified laboratories total in the United States, Canada, and the United Kingdom with any meaningful experience conducting aerosol testing of vapor products. Of these, one laboratory does not even have the capability of generating its own aerosol in-house. The capacity of these laboratories will thus fall far short of that required by the industry to meet the ten-month filing deadline suggested by FDA.

b. Second, upon information and belief, none of these qualified laboratories currently have in place independently validated testing methodologies or assays for detecting and quantifying all of the newly added HPHCs announced by FDA on June 11, 2019, in its Final ENDS

PMTA Guidance. Upon information and belief, the process for obtaining approval for such methodologies from accrediting laboratory organizations such as the American Association for Laboratory Accreditation may take weeks or even months.

c. Third, FDA has still not published a long-promised guidance document on an approved methodology for the testing of vapor device aerosol for HPHCs, leaving both e-liquid and vapor device manufacturers to only guess as to what testing methodologies might be appropriate and then spend hundreds of thousands, if not millions, of dollars on executing on an approach that may or may not be accepted by FDA.

d. Fourth, with respect to the HPHCs for which applicants are required to test, FDA has indicated that the exposure levels should be compared against threshold levels of concern for the general population. However, the limits of detection with currently available laboratory equipment are substantially greater than the general population-level threshold levels of concern for a number of the HPHCs, meaning that laboratories cannot meaningfully determine whether HPHCs emitted in the aerosol from such products exceed the threshold levels of concern without performing thousands of puffs on a single device, which is neither realistic nor feasible.

e. Fifth, upon information and belief, the industry standard minimum duration for product stability and shelf life testing (which FDA recommends in its Final ENDS PMTA Guidance) for inhaled consumer products is at least twelve (12) months, and typically must exceed the stated shelf life of the product by approximately 30 percent. FDA has also indicated that it will not accept accelerated storage and stability testing results.

f. Sixth, although FDA recommends studies on vaping topography (i.e., patterns of product use) and pharmacokinetics (or nicotine uptake), such studies must be performed clinically, and, upon information and belief, the shortest time frame in which such a study can be

completed is 12 months. This is because even a small study requires: (i) development of a study protocol, review and approval by an institutional review board, or IRB, execution of the study (which will often require subjects to stay overnight at the clinical laboratory facility for a period of approximately a week), capture and presentation of the resulting data in a format appropriate for FDA review, and analysis, interpretation, and explanation of the data in a detailed written report.

g. Seventh, upon information and belief, there are six or fewer clinical laboratories in the United States with the expertise and experience to execute the type of clinical studies recommended by FDA. As of the time of the filing of this complaint, the earliest any of these laboratories is even available to *begin* such a study is not until the end of October 2019. Even if an applicant had hired a clinical testing lab to prepare a clinical study framework on June 11, 2019, such studies would not have been able to be completed by the ten-month deadline of May 11, 2020. As it is, the few clinical laboratories in the United States with extensive experience with tobacco products are not able to even start new clinical studies until the end of 2019, much less complete the studies, write up the results, and incorporate them into a complete PMTA package by May 11, 2020. Further, these few clinical laboratories with appropriate capabilities do not have nearly sufficient capacity to handle all of the PMTAs that industry stakeholders will need to file.

h. Eighth, upon information and belief, a nationally representative behavioral study, as recommended by FDA, cannot be completed in fewer than ten months. Such is the case because, to be truly nationally representative, such a survey requires a sampling plan and thousands of participants.

113. Indeed, upon information and belief, the final PMTA submission of any applicant who complies with each of the facets of a PMTA recommended by FDA in its Final ENDS PMTA

Guidance is expected to be at least 50,000 pages in length and will compile hundreds, if not thousands, of individual documents. Upon information and belief, the consulting firms that specialize in compiling and organizing such submissions for FDA's review require that all relevant documents be provided to them at least three (3) months prior to the deadline for filing so that they have time to appropriately organize, collate, and create internal cross-references and links in the final submission package. A ten-month deadline is woefully inadequate to perform appropriate product testing and studies and to synthesize and present the data and conclusions in the massive submission that FDA recommends.

114. Consistent with its testimony that four months is insufficient time to avoid the public health crisis that would be caused by the precipitous removal of vapor products from the marketplace for failure to comply with an accelerated PMTA deadline, FDA knows that its arbitrarily selected ten-month deadline is equally insufficient. Indeed, such a deadline is likely to, at best, lead only to the "low-quality" PMTA submissions about which Director Zeller expressed such concern because, given the industry's reliance on FDA's repeated promises of further guidelines regarding the PMTA process, no meaningful distinction exists between a four-month and a ten-month deadline. Further, with the possible exception of the behavioral studies that cannot be completed in less than ten months in any event, none of the recommended tests or studies associated with a PMTA is likely to have any meaningful role in addressing any purported "epidemic" associated with illegal underage use of vapor products.

115. Through its wholly unnecessary and superfluous proposal of a ten-month deadline for the submission of PMTAs, FDA deprived industry stakeholders, including Plaintiffs, of any opportunity to provide input as to a reasonable time period for the submission of PMTAs.

116. As a result, Vapor Stockroom and the VTA's other members now find themselves in a position where they face a Hobson's choice of spending tens of millions of dollars on literature reviews, product testing, and clinical and non-clinical studies that they know they will not be able to complete and incorporate into a PMTA by the ten-month deadline or, alternatively, not submit a PMTA until FDA provides further guidelines and run the risk that FDA will cause all of their products to be removed from the US market due to the lack of a pending PMTA come May 11, 2020.

117. FDA ignored these and other factors by proposing the ten-month deadline. Rather than proceed under the notice-and-comment process mandated by the Administrative Procedure Act, FDA chose to, in effect, propose and implement a new rule (and insulate the same by cloaking it in a district court order) without any input or comment from the affected parties.

118. If FDA is permitted to enforce the ten-month deadline for PMTAs by taking enforcement action against manufacturers who have not yet submitted a complete PMTA by the May 2020 deadline, virtually all of the VTA's manufacturer members, including Vapor Stockroom, will lose access to the U.S. market for their products and would likely go out of business entirely. In short, the net result will be the virtual overnight elimination of the vapor industry as it currently exists in the United States—precisely what FDA warned could precipitate a public health crisis and precisely what FDA said must be "avoided if at all possible."

119. Not only would such an outcome be financially ruinous for what has become a 9-billion-dollar industry that employs over 160,000 people in small businesses across the country but, as noted by FDA in its briefing before the Maryland District Court, the public health consequences for former smokers who have successfully turned to vapor products would likely be devastating.

120. In sharp contrast to FDA's repeated earlier public statements regarding the need for a foundational rule to establish the "rules of the road" with respect to PMTAs for vapor products and his own July 10, 2019 statement that FDA's "policies and procedures [with respect to vapor products] are still evolving," in a statement released only five days later, on July 15, 2019, in the wake of the Maryland District Court's decision, Acting Commissioner Sharpless claimed that the Maryland District Court "recognized the agency's work to provide a framework and clear guidance for companies seeking to market e-cigarette and ENDS products as they prepare their product applications" and that "we've outlined our recommendations for what the FDA expects to be included in e-cigarette premarket applications."[49]

121. As of the date of the filing of this Complaint, FDA has not filed a notice of appeal of the Maryland District Court's decision to the United States Court of Appeals for the Fourth Circuit nor sought a stay of that court's order. Instead, on August 9, 2019, FDA requested permission to file a motion for clarification with the Maryland District Court to confirm that FDA may continue to take enforcement action against vapor products currently on the market that were not on the market as of August 8, 2016—thus suggesting that FDA has no plans to appeal the Maryland District Court's ruling.[50]

122. Moreover, Acting Commissioner Sharpless has publicly stated that FDA stands ready to enforce the grossly accelerated May 2020 deadline. And, remarkably, FDA also has

[49] *Statement from Acting FDA Commissioner Norman E. Sharpless, M.D., on the agency's actions to tackle the epidemic of youth vaping and court ruling on application submission deadlines for certain tobacco products, including e-cigarettes* (July 15, 2019) at https://www.fda.gov/news-events/press-announcements/statement-agencys-actions-tackle-epidemic-youth-vaping-and-court-ruling-application-submission.

[50] Letter Request from Defendants FDA, et al., *Am. Acad. of Pediatrics, et al. v. FDA, et al.,* No. 8:18-cv-883 (D. Md. Aug. 9, 2019), at ECF No. 129.

announced that it is changing the HPHC requirements again with the deadline clock rapidly counting down.

123. Court intervention declaring that FDA's proposal of the ten-month deadline in the Maryland District Court case constitutes unlawful agency action in violation of the notice-and-comment requirements of the Administrative Procedure Act and preliminarily and permanently enjoining FDA from taking any enforcement action based on the failure of a vapor product manufacturer to submit a complete PMTA by May 11, 2020, and requiring FDA to engage in a proper notice and comment procedure to finalize a foundational rule for PMTAs and establish a new filing deadline is both necessary and appropriate.

COUNT I
(Declaratory Judgment that FDA Violated the Administrative Procedure Act)

124. Plaintiffs incorporate herein by reference the allegations set forth in paragraphs 1 through 123, above.

125. As a federal agency, FDA is subject to the requirements of the Administrative Procedure Act, including the notice and comment requirements imposed by 5 U.S.C. § 553.

126. As recently as June of this year, the United States Supreme Court pointedly warned about agency actions that create "unfair surprise" to regulated parties because of the potential for such actions to disrupt expectations. *Kisor v. Wilkie*, 139 S. Ct. 2400, 2417-18 (June 26, 2019). By proposing an abbreviated ten-month deadline for the filing of PMTAs for Newly Deemed Products, including vapor products, when it had previously established a deadline some 27 months longer upon which industry stakeholders had relied and had (and still has) failed to publish long-promised and necessary rules setting forth the requirements for the preparation of PMTAs, FDA engaged in arbitrary and capricious agency action that this Court should declare unlawful pursuant to 5 U.S.C. § 706(2)(A) and set aside.

127. By engaging in the aforementioned conduct without engaging in any notice and comment procedure as required by 5 U.S.C. § 553, FDA engaged in agency action without observance of procedure required by law that this Court should declare unlawful pursuant to 5 U.S.C. § 706(2)(D) and set aside.

128. An actionable controversy of a justiciable nature exists between Plaintiffs and FDA regarding whether FDA's aforementioned conduct constitutes a violation of the Administrative Procedure Act and, if so, the proper remedy therefor.

129. FDA's conduct is ongoing and immediate. As a result of FDA's actions in violation of the requirements of the Administrative Procedure Act, Vapor Stockroom and the VTA's members are suffering ongoing and irreparable harm in that they face the impossible choice of either (a) spending millions of dollars on testing and studies that they know will still not allow for a complete PMTA submission by the May 11, 2020 deadline and may not ultimately be accepted by FDA, or (b) waiting for further guidance which may or may not be forthcoming and running the risk that FDA will take enforcement action to remove their products from the U.S. market after May 11, 2020, because they will not have complete PMTAs on file.

WHEREFORE, Plaintiffs Vapor Technology Association and Vapor Stockroom request a preliminary and permanent injunction and a declaratory judgment:

A. Declaring that FDA's proposal and/or enforcement of the ten-month (i.e., May 2020) deadline constitutes unlawful agency action in violation of the Administrative Procedure Act;

B. Preliminarily and permanently enjoining FDA to: (a) establish a proposed and final rule governing the submission of pre-market tobacco applications and product standards for vapor products pursuant to a mandatory notice-and-comment rulemaking process; (b) set a reasonable,

science-based, non-arbitrary deadline for the filing of PMTAs pursuant to the finalized rule after notice and comment; (c) refrain from taking enforcement action against any vapor products on the U.S. market as of August 8, 2016, until after the new filing deadline for PMTAs; and (d) refrain from taking enforcement action based on the failure of a vapor product manufacturer to submit a complete PMTA by May 11, 2020;

C. Awarding Plaintiffs their costs and expenses;

D. Awarding Plaintiffs their reasonable attorneys' fees under 28 U.S.C. § 2412; and

E. Granting such further and other relief as is necessary and appropriate.

COUNT II
(Declaratory Judgment that FDA Violated the Fifth Amendment's Due Process Clause)

130. Plaintiffs incorporate herein by reference the allegations set forth in paragraphs 1 through 129, above.

131. The Fifth Amendment's Due Process Clause protects, *inter alia*, against the deprivation of property without due process of law.

132. A violation of a person's procedural due process rights occurs when the person is deprived of a property interest without sufficient procedural protections.

133. The VTA's members have constitutionally protected property interests in their continued ability to operate their businesses of manufacturing and selling vapor products in interstate commerce. Indeed, Congress has generally recognized this right by forbidding FDA from banning the sale of such products as a class. 21 U.S.C. § 387g(d)(3)(A)-(B).

134. As regards the procedural protections that were due the VTA's members in conjunction with the Maryland District Court litigation and FDA's remedy proposal therein, "there is a 'failure of due process' where 'it cannot be said that the procedure adopted, fairly insures the

protection of the interests of absent parties who are to be bound by it.'" *Hansberry v. Lee*, 311 U.S. 32, 42-43 (1940)).

135. By superfluously proposing a ten-month deadline for the filing of PMTAs for Newly Deemed Products to the Maryland District Court without notice or any opportunity for comment by Plaintiffs, FDA engaged in a deprivation of Vapor Stockroom's and the VTA's other members' property interests.

136. An actionable controversy of a justiciable nature exists between Plaintiffs and FDA regarding whether FDA's aforementioned conduct constitutes a violation of the Fifth Amendment's Due Process Clause and, if so, the proper remedy therefor.

137. FDA's deprivation of the VTA's members' due process rights is ongoing and immediate. As a result of FDA's actions, Vapor Stockroom and the VTA's other members are suffering ongoing and irreparable harm in that they face the impossible choice of either (a) spending tens of millions of dollars on testing and studies that they know will still not allow for a complete PMTA submission by the May 11, 2020 deadline and may not ultimately be accepted by FDA, or (b) waiting for further guidance which may or may not be forthcoming and running the risk that FDA will take enforcement action to remove their products from the U.S. market after May 11, 2020, because they will not have complete PMTAs on file.

WHEREFORE, Plaintiff Vapor Technology Association and Vapor Stockroom request a preliminary and permanent injunction and a declaratory judgment:

A. Declaring that FDA's proposal and/or enforcement of the ten-month (i.e., May 2020) deadline violates the procedural due process rights of Vapor Stockroom and the VTA's other members;

B. Preliminarily and permanently enjoining FDA to: (a) establish a proposed and final rule governing the submission of pre-market tobacco applications and product standards for vapor products pursuant to a mandatory notice-and-comment rulemaking process; (b) set a reasonable, science-based, non-arbitrary deadline for the filing of PMTAs pursuant to the finalized rule after notice and comment; (c) refrain from taking enforcement action against any vapor products on the U.S. market as of August 8, 2016, until the new filing deadline for PMTAs; and (d) refrain from taking enforcement action based on the failure of a vapor product manufacturer to submit a complete PMTA by May 11, 2020;

C. Awarding Plaintiffs their costs and expenses;

D. Awarding Plaintiffs their reasonable attorneys' fees under 28 U.S.C. § 2412; and

E. Granting such further and other relief as is necessary and appropriate.

Respectfully submitted,

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Dated: August 14, 2019

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VERIFICATION

I verify under penalty of perjury that the facts set forth in the foregoing complaint, other than those facts relating to Vapor Stockroom, LLC, which Tony Florence is separately verifying, are true and correct to the best of my information, knowledge, and belief.

Anthony L. Abboud
Executive Director
Vapor Technology Association

VERIFICATION

I verify under penalty of perjury that the facts set forth in the foregoing complaint regarding Vapor Stockroom, LLC are true and correct to the best of my information, knowledge, and belief.

Tony Florence
President
Vapor Stockroom, LLC