UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

CAMPAIGN FOR TOBACCO-FREE KIDS,
1400 I Street NW, Suite 1200
Washington, DC 20005

AMERICAN ACADEMY OF PEDIATRICS,
345 Park Boulevard
Itasca, IL 60143

AMERICAN CANCER SOCIETY CANCER ACTION NETWORK,
555 11th Street NW, Suite 300
Washington, DC 20004

AMERICAN HEART ASSOCIATION,
7272 Greenville Avenue
Dallas, TX 75231

AMERICAN LUNG ASSOCIATION,
55 W. Wacker Drive, Suite 1150
Chicago, IL 60601

PARENTS AGAINST VAPING E-CIGARETTES,
105 West 86th Street, Suite 360
New York, NY 10024

TRUTH INITIATIVE,
900 G Street NW, Fourth Floor
Washington, DC 20001

DR. SUSAN WALLEY,
c/o Campaign for Tobacco-Free Kids
1400 I Street NW, Suite 1200
Washington, DC 20005

and

JANE DOE,

Plaintiffs,

v.

COMPLAINT
FOR DECLARATORY AND INJUNCTIVE RELIEF

Case No. _____

FOOD AND DRUG ADMINISTRATION,
10903 New Hampshire Avenue
Silver Spring, Montgomery County, MD 20993

KYLE DIAMANTAS, in his official capacity as Acting Commissioner of Food and Drugs,
10903 New Hampshire Avenue
Silver Spring, Montgomery County, MD 20993

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue SW
Washington, D.C. 20001

and

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, D.C. 20001

Defendants.

1. The Supreme Court has described the catastrophic health risks created by tobacco products as "perhaps the single most significant threat to public health in the United States." *FDA v. Brown & Williamson Tobacco Corp*., 529 U.S. 120, 161 (2000). To protect the public, especially youth, against these risks, Congress enacted the Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) ("Tobacco Control Act"), in 2009. The Tobacco Control Act established a comprehensive scheme for the regulation of tobacco products by the U.S. Food and Drug Administration ("FDA"). At the core of this scheme is FDA premarket review, which requires all "new tobacco products" (those introduced after February 15, 2007) to receive an FDA marketing granted order ("MGO") before entering the market. 21 U.S.C. § 387j(a)(1)-(2). To receive an MGO, a manufacturer must demonstrate that its product is "appropriate for the protection of the public health," considering the impact of the product to the population as a whole, including both users and non-users of tobacco products. *Id.*

2. Now FDA is attempting to allow large numbers of new tobacco products to enter the market without complying with the statutory premarket review requirement. On May 8, 2026, FDA issued a six-page Guidance for Industry titled "Enforcement Priorities for Certain New Tobacco Products Without Premarket Authorization" ("2026 Guidance" or "Guidance"), https://perma.cc/VK24-GSDN. Issued without prior notice or opportunity for public comment, the Guidance announced a major and unlawful change to FDA's implementation of the Tobacco Control Act. The Guidance permits potentially thousands of tobacco products to enter and remain on the market for an indefinite period of time without the MGO required by the Tobacco Control Act. The products affected are the two tobacco products most commonly used by youth, e-cigarettes[1] and nicotine pouches, including in flavors that undeniably appeal to youth.

3. Under the Guidance, e-cigarettes and nicotine pouches are eligible for safe harbor from enforcement so long as they are the subject of a *pending* premarket tobacco product

[1] The Guidance refers to "ENDS" (electronic nicotine delivery systems) "that include e-liquids and products that deliver aerosolized e-liquid when inhaled . . . ." Guidance at 2. This Complaint uses "ENDS" and "e-cigarettes" interchangeably.

application ("PMTA") filed after November 3, 2021, that has completed FDA's "threshold" acceptance and filing review. FDA's threshold review does not entail a substantive scientific review of the PMTA nor any assessment of a product's public health implications. And a product's safe harbor status will be no secret: FDA will issue a public list of products subject to this safe harbor, publicly broadcasting that their sale will not be subject to enforcement, notwithstanding the express language of the Tobacco Control Act.

4. This has happened before. In 2017, the FDA issued a guidance that allowed most e-cigarettes to be marketed without authorization for an indefinite period. A court in this district vacated that guidance[2]—but not before the unlawful guidance had contributed to an "epidemic-level rise in youth e-cigarette use" and a "mounting public health crisis," as the FDA Commissioner who had issued the guidance acknowledged.[3] If the new Guidance stands, it will cause similar harm to our nation's youth and the parents and doctors who care for them.

5. The Guidance exceeds FDA's statutory authority and is not in accordance with law because it is an express and deliberate abdication of FDA's responsibilities under the Tobacco Control Act. The Guidance effectively rewrites the Tobacco Control Act to presumptively permit marketing by replacing its premarket review provisions with an extra-statutory, *post-market* review system for a significant category of new tobacco products. And by publishing a list of products subject to the new system and thereby facilitating their unlawful sale, the Guidance "in practice, provides a measure of 'cover'" to the industry.[4] Accordingly, the Guidance must be vacated because it is not in accordance with law, exceeds FDA's statutory authority, and is *ultra vires*.

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[2] *Am. Acad. of Pediatrics v. FDA*, 379 F. Supp. 3d 461 (D. Md. 2019) ("*AAP I*"), *aff'd in part, dismissed by appellants' req. in part*, *In re Cigar Ass'n of Am.*, 812 Fed. App'x 128 (4th Cir. 2020).

[3] *Am. Acad. of Pediatrics v. FDA*, 399 F. Supp. 3d 479, 483 (D. Md. 2019) ("*AAP II*") (quoting FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on advancing new policies aimed at preventing youth access to, and appeal of, flavored tobacco products, including e-cigarettes and cigars* (Mar. 13, 2019)).

[4] New FDA Guidance Clarifies Enforcement Discretion Policy for Certain ENDS and Nicotine Pouch Products (May 15, 2026), https://perma.cc/DR8C-9VN9.

6. The Guidance is also arbitrary and capricious and not the product of reasoned decisionmaking by FDA. The Administrative Procedure Act ("APA") requires that a federal agency consider "important aspects" of a problem it is seeking to solve and "cogently explain why it has exercised its discretion in a given manner." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43, 48 (1983). In issuing the Guidance, FDA breached these obligations. The Guidance offers no meaningful justification for the creation of the safe harbor or the criteria that determine which products are eligible for the safe harbor. Nor does it display awareness of its previous position and explain why it is reversing its consistent recognition that non-tobacco flavors are a significant driver of youth tobacco use, which it has long relied on in its prior enforcement policy and in marketing denial orders ("MDOs") for millions of flavored products.

7. Finally, the Guidance is unlawful because it is a substantive rule that was not promulgated in accordance with the APA's notice and comment requirements. The Guidance effectively amends the Tobacco Control Act by altering the core statutory requirement of *pre*market review. The Guidance also affects the substantive rights of manufacturers by effectively granting them the right to sell certain new tobacco products without the statutorily required marketing authorization. Even if this change were not barred under the Tobacco Control Act, the APA would nevertheless independently require FDA to follow notice and comment procedures to make this change, ensuring adequate public input and agency deliberation. And the Food, Drug, and Cosmetic Act ("FD&C Act") and FDA's own regulations separately required the agency to allow prior public participation in this change because it sets forth a major change in policy and addresses a highly controversial issue. 21 U.S.C. § 371(h)(1)(C)(i); *accord* 21 C.F.R. § 10.115. FDA's failure to follow these procedural requirements resulted in an ill-advised action that will have devastating public health effects, particularly on young people. FDA's violation of the APA's notice-and-comment and FD&C Act's public participation requirements thus independently require vacatur of the Guidance.

8. Plaintiffs include public health organizations, a pediatrician, and a parent. Each Plaintiff is harmed by the increased availability of unauthorized products and the inability to publicly comment on the changes announced in the Guidance. They seek vacatur of the Guidance and other declaratory and injunctive relief.

PARTIES

9. Plaintiff Campaign for Tobacco-Free Kids ("Tobacco-Free Kids") is a 501(c)(3) nonprofit organized under the laws of the District of Columbia with its principal place of business in Washington, D.C.

10. Plaintiff American Academy of Pediatrics ("AAP") is a 501(c)(3) nonprofit organization with membership comprising 67,000 pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. AAP is incorporated in the State of Illinois with its principal place of business in Itasca, Illinois.

11. Plaintiff American Cancer Society Cancer Action Network ("ACS CAN") is a 501(c)(4) social welfare organization incorporated in the District of Columbia with its principal places of business in Washington, D.C.

12. Plaintiff American Heart Association ("AHA") is a 501(c)(3) nonprofit corporation incorporated in the State of New York with its principal place of business in Dallas, Texas.

13. Plaintiff American Lung Association ("Lung Association") is a 501(c)(3) nonprofit voluntary health organization incorporated in the State of Maine with its principal place of business in Chicago, Illinois.

14. Plaintiff Parents Against Vaping e-Cigarettes, Inc. ("Parents Against Vaping") is a 501(c)(3) nonprofit incorporated under the laws of the District of Columbia and based in the City of New York.

15. Plaintiff Truth Initiative Foundation, d/b/a Truth Initiative ("Truth Initiative") is a 501(c)(3) nonprofit incorporated in Delaware with its principal place of business in Washington, D.C.

16. Plaintiff Dr. Susan Walley is a natural person and pediatrician, domiciled in Montgomery County, Maryland, and practicing medicine in Washington, D.C.

17. Plaintiff Jane Doe is a natural person and mother of three minor children, domiciled in Chester County, Pennsylvania.

18. Defendant FDA is an agency of the United States government, within the United States Department of Health and Human Services ("HHS"). FDA administers the relevant provisions of the Tobacco Control Act, pursuant to authority delegated to it by HHS. *See* 21 U.S.C. § 387a. FDA is headquartered at 10903 New Hampshire Avenue, Silver Spring, MD 20903.

19. Defendant Kyle Diamantas is Acting Commissioner of the FDA and is the senior official of FDA. In this capacity, he has ultimate responsibility for activities at FDA, including the actions complained of herein. He is sued in his official capacity. Acting Commissioner Diamantas maintains an office at 10903 New Hampshire Avenue, Silver Spring, MD 20903.

20. Defendant HHS is an agency of the United States government. HHS is headquartered at 200 Independence Avenue S.W., Washington, D.C. 20201.

21. Defendant Robert F. Kennedy, Jr. is Secretary of HHS and is the official charged by law with administering the Tobacco Control Act. *Id.* § 387a. He is sued in his official capacity. Secretary Kennedy maintains an office at 200 Independence Avenue S.W., Washington, D.C. 20201.

JURISDICTION AND VENUE

22. This Court has jurisdiction over this case pursuant to 28 U.S.C. §§ 1331, 1361, 2201, and 2202 and 5 U.S.C. § 702.

23. Venue is proper under 28 U.S.C. § 1391(e)(1). Defendants FDA and Diamantas have headquarters and reside in this district. Moreover, a substantial part of the events or omissions giving rise to this action occurred in this district.

FACTS

I. STATUTORY AND REGULATORY BACKGROUND

A. Tobacco Control Act

24. In 2009, Congress enacted the Tobacco Control Act, establishing FDA as the "primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products." Pub. L. No. 111-31, § 3(1), 123 Stat. at 1781.[5] Recognizing the extraordinary public health risks posed by tobacco products, Congress explained that "comprehensive restrictions on the sale, promotion, and distribution of [tobacco] products are needed," and determined that "[i]t is in the public interest" to "provide[] the Food and Drug Administration with the authority to regulate tobacco products." *Id.* § 2(6), (12), 123 Stat. at 1777.

25. Congress applied the requirements of the Tobacco Control Act immediately to four types of tobacco products (cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco) and authorized the Secretary of HHS to "deem[]," through regulation, other tobacco products subject to its jurisdiction. 21 U.S.C. § 387a(b).

26. A central requirement of the Tobacco Control Act is FDA premarket review of new tobacco products. Specifically, every "new tobacco product"—defined to include any tobacco product not on the market in the United States as of February 15, 2007—must be authorized by FDA for sale in the United States before it may enter the marketplace. *Id.* § 387j(a)(1)-(2). The premarket authorization requirement allows FDA to review the public health implications of tobacco products and, with certain exceptions not relevant here, allows market access only to those products FDA has found appropriate for the protection of the public health.

[5] As originally enacted, the statute defined "tobacco product" as "any product made or derived from tobacco that is intended for human consumption . . . ," which includes products with nicotine derived from tobacco. Pub. L. No. 111-31, § 101(a), 123 Stat. at 1783.

27. The Tobacco Control Act establishes three pathways to premarket authorization, only one of which—the PMTA pathway—is directly implicated by the Guidance or the products at issue in this case.[6]

28. Under the PMTA pathway, a manufacturer may submit for FDA review a PMTA for a new tobacco product. *Id.* § 387j(b) (listing PMTA requirements). FDA must deny the PMTA if it fails to demonstrate that "permitting such tobacco product to be marketed would be appropriate for the protection of the public health." *Id.* § 387j(c)(2)(A). Under the Tobacco Control Act, whether a product is appropriate for the protection of the public health:

> shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account: (A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

Id. § 387j(c)(4).

29. FDA must issue an MGO or MDO within 180 days of receiving the PMTA. *Id.* § 387j(c)(1)(A). Regardless of whether FDA meets that statutory deadline, any new tobacco product that is sold without an MGO "shall be deemed to be adulterated," *id.* § 387b(6), and is subject to seizure and injunctive action, *id.* §§ 331(a), 332, 334, 372, unless it satisfies one of the statute's two alternative pathways to legal distribution.

B. Deeming Rule

30. In 2016, FDA issued a regulation deeming all products (besides those already included by Congress) that met the statutory definition of "tobacco product," including e-

[6] The second pathway allows a manufacturer to introduce a new tobacco product if FDA issues an order finding that the new product is "substantially equivalent" to a product that was on the market as of February 15, 2007. 21 U.S.C. §§ 387e(j)(1), 387j(a)(3). The third allows a manufacturer to market a product if the FDA issues an exemption from the substantial equivalence requirements upon finding that the product makes only minor modifications to a legally marketed tobacco product. *Id.* §§ 387e(j)(3). Because no e-cigarette or nicotine pouch products were on the market prior to 2007, and new e-cigarette and nicotine pouches are typically not minor modifications to tobacco additives, neither pathway is typically available to these products. All FDA-authorized e-cigarette or nicotine pouch products to date have obtained authorization through the PMTA pathway.

cigarettes and nicotine pouches, subject to the premarket authorization and other requirements of the Tobacco Control Act. Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, 81 Fed. Reg. 28,973 (May 10, 2016) ("Deeming Rule").

31. FDA promulgated the final Deeming Rule on May 10, 2016, and the Rule went into effect 90 days later, on August 8, 2016.

32. In the Deeming Rule, FDA deemed e-cigarettes, nicotine pouches, and all other current and future products meeting the statutory "tobacco product" definition, except accessories of such newly deemed products, as subject to the agency's tobacco control authorities and implementing regulations. FDA supported its deeming determination with detailed findings regarding the health risks of newly deemed tobacco products and the crucial need for regulatory oversight of those products, including premarket review.

33. FDA explained, for example, that "[t]he Surgeon General has long recognized that the addictive nature of tobacco products is due to the presence of highly addictive nicotine that can be absorbed into the bloodstream." 81 Fed. Reg. at 28,981. Citing available scientific evidence, FDA found that nicotine addiction often begins in adolescence and extends throughout adulthood. *Id.* Thus, "addiction to nicotine is often lifelong." *Id.* Moreover, FDA cited research demonstrating that nicotine exposure "may have long-term consequences on executive cognitive function and on the risk of developing a substance abuse disorder and various mental health problems as an adult." *Id.* "[B]ased on scientific data," FDA found that "the newly deemed products should be regulated due to their potential for public harm" and that "regulation is necessary to learn more about that potential." *Id.* at 28,983.

34. FDA explained that premarket review is a critical part of this regulatory regime because, among other things, it allows "FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market." *Id.* at 28,984. FDA also reasoned that premarket review has the potential to incentivize "producers to develop products that are less dangerous when consumed, less likely to lead to initiation of tobacco use, and/or easier to quit." *Id.* at 28,983. Moreover, FDA found that "premarket review . . . will increase

product consistency" by "ensuring quality control relative to the chemicals and their quantities" that consumers are being exposed to. *Id.* at 28,983-84.

35. Rather than immediately subjecting newly deemed tobacco products to the Tobacco Control Act's premarket review requirement—which would have rendered them immediately illegal as unauthorized new tobacco products—the Deeming Rule established staggered "compliance periods" during which FDA intended to exercise "enforcement discretion" and defer enforcement against newly deemed, new tobacco products that were on the market as of the Rule's effective date (August 8, 2016).

36. The Deeming Rule initially provided a two-year compliance period (later extended to November 8, 2018) for companies to file PMTAs, followed by an additional 12-month "continued compliance period" during which the products would be free from enforcement while the PMTAs were pending. FDA established time-limited compliance periods because it "determined that exercising enforcement discretion indefinitely could put youth and young adults at risk for tobacco-related death and disease." 81 Fed. Reg. at 28,977.

C. 2017 Guidance, Subsequent Litigation, and 2020 Guidance

37. In August 2017, FDA issued guidance, without allowing for notice and comment, that extended the compliance period for filing PMTAs for noncombustible products (*e.g.,* e-cigarettes and nicotine pouches) by four years (to 2022), and for combustible products (*e.g.,* cigars) by three years (to 2021). Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry; Availability, 82 Fed. Reg. 37,459 (Aug. 10, 2017) ("2017 Guidance"). The 2017 Guidance also extended compliance periods indefinitely after application "until the agency renders a decision on an application." *AAP I*, 379 F. Supp. 3d at 472. Thus, the 2017 Guidance allowed e-cigarettes already on the market in 2016 to remain on the market for an indefinite period without the MGO required by the Tobacco Control Act.

38. A court in this district invalidated the 2017 Guidance, determining that FDA had both exceeded its statutory authority and violated the APA by issuing the 2017 Guidance without following notice-and-comment rulemaking. *Id.*

39. After vacating the 2017 Guidance, the court ultimately set September 9, 2020, as the final deadline for manufacturers to submit PMTAs for new tobacco products that were on the market as of the August 8, 2016 effective date of the Deeming Rule.[7] It further provided that products for which applications were timely filed could "remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application." *AAP II*, 399 F. Supp. 3d at 487.

40. By the time the court invalidated the 2017 Guidance, FDA leadership had already recognized the damage that it had done. In March 2019, then-Commissioner Scott Gottlieb acknowledged that there had been an "epidemic-level rise in youth e-cigarette use" since its prior action, which constituted a "mounting public health crisis."[8] That epidemic "required [FDA] to take a critical look at [its] policies and regulatory priorities" and led it to abandon the 2017 Guidance. Because "[e]vidence shows that youth are especially attracted to flavored e-cigarette products," FDA ended its compliance policy "as it applies to flavored [ENDS] products (other than tobacco-, mint-, and menthol-flavored)." In particular, it ended its "previous policy . . . deferring enforcement while an ENDS product's application was pending review."

41. FDA promulgated a new compliance policy for notice and comment, receiving and responding to more than 15,000 comments. *See* FDA, "Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market without Premarket Authorization (Revised)" ("2020 Guidance") (April 2020); Modifications to Compliance Policy for Certain Deemed Tobacco Products; Draft Guidance for Industry; Availability, 84 Fed. Reg. 9,345 (Mar. 14, 2019). It issued a 52-page guidance document justifying the new policy, much of which focused on the role of flavors in encouraging youth use.

42. The 2020 Guidance prioritized enforcement against:

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[7] *AAP II*, 399 F. Supp. 3d at 487; *Am. Acad. of Pediatrics v. FDA*, No. 8:18-cv-883 (D. Md. Apr. 22, 2020), ECF No. 182.

[8] FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on advancing new policies aimed at preventing youth access to, and appeal of, flavored tobacco products, including e-cigarettes and cigars* (Mar. 13, 2019) ("2019 Statement").

- Any flavored, cartridge-based ENDS product (other than a tobacco- or menthol-flavored ENDS product);
- All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
- Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors.

2020 Guidance at 3.

43. FDA subsequently recognized that the 2020 Guidance's focus on cartridge-based flavored products was too narrowly focused because it led youth to begin using flavored products that were not cartridge-based, including disposable products. Following the 2020 Guidance, FDA observed a "ten-fold increase" in use of disposable flavored e-cigarettes among high schoolers.[9] This "trend illustrates that the removal of one flavored product option prompted youth to migrate to another ENDS type that offered the desired flavor options, *underscoring the fundamental role of flavor in driving appeal*." *Id.* (emphasis added).

D. PMTA Rule

44. FDA issued a Final Rule titled "Premarket Tobacco Product Applications and Recordkeeping Requirements," 86 Fed. Reg. 55,300 ("PMTA Rule"), on October 5, 2021. The PMTA Rule, which took effect November 4, 2021, "describes and sets forth requirements related to the content and format of PMTAs" and "also addresses issues such as the procedures by which FDA reviews a PMTA." 86 Fed. Reg. at 55,301. The PMTA Rule establishes three sequential reviews of a PMTA.

45. According to the PMTA Rule, when an applicant submits a PMTA, FDA first conducts an "acceptance review of the submission," *id.* at 55,379, in which it assesses the submission based upon the criteria in 21 C.F.R. § 1105.10. Under the rule, FDA may refuse to accept a PMTA if, for example, the PMTA does "not comply with the applicable format requirements." *Id.* The PMTA Rule clarifies, however, that FDA's acceptance review assesses "the facial completeness of a submission only" and is not an "in-depth, technical review." *Id.*

[9] FDA, *Technical Project Lead (TPL) Review of PMTAs*, 8 (Sep. 17, 2021), https://perma.cc/T72W-ZDZK.

46. If FDA accepts a PMTA for review, it will notify the applicant and then "conduct a filing review to determine whether the application contains sufficient information to permit a full substantive review of the application." *Id.* FDA may refuse to file a PMTA if the PMTA does not include the information required by 21 C.F.R. §§ 1114.7, 1114.15, or 1114.17, as applicable, such as health risk investigations of the product including "the potential impact that the marketing of the new tobacco product would have on" both users and non-users of tobacco products. *Id.* at 55,379-80. Whereas the acceptance review "considers whether a submission meets basic content, format, and jurisdiction requirements . . . the filing review is a more in-depth review to ensure the applications contains sufficient information for initiating substantive review." *Id.* at 55,379.

47. PMTAs that successfully complete FDA filing review are then substantively reviewed by FDA. *Id.* at 55,382. Following substantive review, FDA will issue an MGO for a product if it finds that none of the statutory grounds for a denial apply, *see* 21 U.S.C. § 387j(c)(2). As discussed above, one requirement for an MGO is that the applicant demonstrate that the marketing of its product would be appropriate for the protection of the public health. *See id.* § 387j(c)(2)(A); *see also* 86 Fed. Reg. at 55,384.

48. The PMTA Rule also codified, in FDA's regulations, the statutory premarket order requirement: "A new tobacco product may not be introduced or delivered for introduction into interstate commerce under this part until FDA has issued a marketing granted order for the product." *Id.* at 55,414 (codified at 21 C.F.R. 1114.5).

E. Synthetic Nicotine Amendment

49. In 2022, Congress amended the Tobacco Control Act's definition of "tobacco product" to include products containing nicotine from any source. Consolidated Appropriations Act, 2022, Pub. L. No. 117-103, § 111, 136 Stat. 49, 789-90 (2022). This enactment followed an increase in products that were marketed as containing nicotine derived from a source other than

tobacco, or "synthetic nicotine," which their manufacturers claimed placed them outside FDA's tobacco regulatory jurisdiction.[10]

50. The 2022 amendment included an explicit "transition period" for synthetic nicotine-containing products. *Id.* § 111(d)(1) (codified at 21 U.S.C. § 387j note (1)). In general, the law allowed synthetic nicotine products that were on the market as of the effective date, April 14, 2022, to remain on the market until May 14, 2022 (i.e., 30 days after the effective date), without being considered in violation of the Tobacco Control Act. *Id.* § 111(d)(1).[11] If a PMTA was submitted for a product during that time, the product could remain on the market until July 13, 2022 (i.e., 90 days after the effective date). *Id.* at note (2). However, after that period, all synthetic nicotine products remaining on the market without an MGO, including products that are "the subject of a pending application," would be in violation of the Tobacco Control Act. *Id.* at note (3). This legislatively specified timetable effectively precluded FDA from allowing synthetic nicotine products with pending applications to remain on the market for an indefinite period, as the agency had previously attempted to do with tobacco-derived nicotine products that were the subject of the Deeming Rule before the court in this district vacated that attempt.

II. FDA HAS GRANTED A LIMITED NUMBER OF MGOS, AND DENIED MGOS TO ALL FLAVORED PRODUCTS UNTIL MAY 2026

51. Since the 2019 decision in *AAP* invalidating the 2017 Guidance, FDA has denied PMTAs for millions of deemed products, primarily flavored e-cigarettes. *See, e.g.*, *FDA v. Wages & White Lions Invs., L.L.C.*, 604 U.S. 542, 562-63 (2025); Brian King, Dir., FDA Ctr. for Tobacco Prods., *A Year in Review: FDA's Progress on Tobacco Product Regulation in 2024* (Jan. 14, 2025), https://perma.cc/GQ4K-T428. FDA has generally denied flavored e-cigarette PMTAs on the ground that they did not contain "reliable and robust evidence of a potential benefit to

[10] Letter from American Academy of Pediatrics, et al. to Acting FDA Commissioner Janet Woodcock, September 2, 2021, at 3, https://perma.cc/22AA-8DQS.

[11] Products were not eligible for this transition period—and thus immediately considered in violation of the Tobacco Control Act—if FDA had previously denied a PMTA, refused to file a PMTA, or withdrew an MGO for a prior version of the product which used tobacco-derived nicotine. 21 U.S.C. § 387j note (2)(C).

adult smokers" that would be sufficient to offset the "known and substantial risk of flavored e-cigarettes with respect to youth appeal, uptake, and use."[12]

52. FDA's reports accompanying the denial orders, called Technical Project Lead Reviews ("TPL Reviews"), document the overwhelming evidence that any flavored product poses a significant risk to youth.[13] For example, FDA's model TPL Review ("Model TPL"), reflecting the agency's general approach to evaluating flavored e-cigarettes under the public health standard, states that "the flavoring in tobacco products (including ENDS) make them more palatable for novice youth and young adults, which can lead to initiation, more frequent and repeated use, and eventually established regular use." Model TPL at 13, https://perma.cc/T72W-ZDZK. It also found that "the preference for use of flavored ENDS among youth is consistently demonstrated across large, national surveys and longitudinal cohort studies." *Id.* at 7.

53. To date, FDA has authorized 45 e-cigarettes. Prior to May 5, 2026, none of them had flavors other than menthol or tobacco. FDA publishes a list of the authorized e-cigarettes on a public-facing webpage. According to that page, "[t]hese are the only e-cigarettes that may be lawfully sold in the U.S."[14] Prior to May 5, 2026, each MGO was accompanied by a publicly available TPL Review and other documentation that provided extensive details about the authorized product, including its chemical composition, health impacts, and other information that is relevant to both medical and lay understanding of the product's effects and usage.[15]

54. To date, FDA has authorized 26 nicotine pouches. As with its marketing decisions on flavored e-cigarettes, the TPL Reviews for the authorized nicotine pouches discuss the literature

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[12] FDA, *Technical Project Lead (TPL) Review of PMTAs*, 3 (Sep. 17, 2021), https://perma.cc/T72W-ZDZK.

[13] When this Complaint refers to "flavors" or "flavored products" it is referring to flavors other than tobacco, reflecting FDA's view that the non-tobacco flavors are more appealing to youth than tobacco-flavored e-cigarettes.

[14] FDA, *E-Cigarettes, "Vapes" and Other Electronic Nicotine Delivery Systems (ENDS) Authorized by the FDA* (May 05, 2026), https://perma.cc/FM25-633K.

[15] FDA, *Tobacco Products Marketing Orders* (May 06, 2026),https://perma.cc/MED8-A4YF.

showing "that in general, non-tobacco flavors increase the appeal of tobacco products, particularly for youth, and, as such, increase the risk of youth initiation."[16]

III. FDA'S PRIOR STATEMENTS HAVE CONSISTENTLY UNDERSCORED ITS LACK OF AUTHORITY TO EXEMPT ENTIRE CATEGORIES OF PRODUCTS FROM PREMARKET REVIEW

55. FDA has repeatedly rejected industry attempts to exempt new tobacco products with pending PMTAs from agency enforcement. As discussed below, the agency has previously taken the position that it lacks the statutory authority to exercise enforcement discretion of entire categories of new tobacco products, particularly in light of this court's *AAP* decision.

A. 2023 Citizen Petition Response

56. For example, on June 16, 2022, an e-cigarette trade association filed a citizen petition with FDA requesting, in part, that the agency "exercise enforcement discretion" to "allow manufacturers of synthetic nicotine e-liquids used in open-system ENDS devices who submitted timely PMTAs that meet FDA's criteria for application acceptance . . . and filing . . . to keep those products on the market . . . until FDA reaches a final marketing authorization determination."[17]

57. FDA denied the petition on February 2, 2023. The agency's response specifically noted that the agency was denying the petition to the extent it "request[ed] that FDA issue a statement of policy to exercise enforcement discretion with respect to certain synthetic nicotine-liquid products."[18] The agency wrote that such a "proposal . . . raises significant issues,"

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[16] *See, e.g.*, FDA, Technical Project Lead Review of Zyn Nicotine Pouches (Jan. 16, 2025), https://perma.cc/Q27R-QFCH.

[17] Citizen Petition by American Vapor Manufacturers Requesting the Food and Drug Administration Exercise Enforcement Discretion to Manufacturers of Open-System Synthetic Nicotine E-Liquid Products, Regulations.gov Docket No. FDA-2022-P-1211, at 2, (Jun. 17, 2022), https://perma.cc/3RMP-CJH8.

[18] FDA Final Response to American Vapor Manufacturers Citizen Petition, Regulations.gov Docket No. FDA-2022-P-1211, at 4, (Feb. 2, 2023), https://perma.cc/6HWZ-2PT5.

including that it would require FDA to "permit" the marketing of products that cannot be legally marketed, which is "outside of its statutory authority."[19]

58. FDA noted that another issue with the petition's request "is highlighted by the decision in" *AAP* invalidating the 2017 Guidance. FDA wrote of the *AAP* decision:

> The court concluded that the guidance was *ultra vires* and conflicted with the FD&C Act. The Court found that the guidance conflicted with the purpose of the FD&C Act by "allow[ing] unapproved tobacco products to be manufactured, advertised, and sold for five years or longer." *AAP*, 379 F. Supp. 3d at 492. In addition, it found that "FDA's across-the-board suspension of the Tobacco Control Act's premarket approval process . . . amount[ed] to a rule amendment or revocation, as it is inconsistent with the statute." *Id*. According to the court, by delaying enforcement, FDA was "abdicating its statutory duty to review new tobacco products," by implementing what was in effect a *post*market review of such products rather than a *pre*market review as required by the Act, thus exceeding FDA's statutory authority.[20]

59. Thus, FDA recognized that it did not have the authority to permit an entire category of products to be marketed without the statutorily required premarket MGO.

B. 2025 Letters

60. In 2025, two major tobacco companies—R.J. Reynolds Vapor Co. and Helix, an Altria subsidiary—announced their plans to begin marketing e-cigarette and nicotine pouch products, respectively, that lacked MGOs but were the subject of pending PMTAs.[21]

61. FDA, in response to a letter sent by six of the Plaintiffs, stated that the agency was "aware of the announcement from the two companies . . . and has communicated with both," including by "issuing an It has Come to Our Attention (IHCTOA) letter to R.J. Reynolds Vapor Company *reiterating the illegality of selling* Vuse One [e-cigarette] *without an MGO*," along with similar letters to retailers that had been advertising that the product was "coming soon."[22] Thus, as recently as October 2025, FDA had publicly taken the position that no unauthorized e-

[19] *Id.* at 3.
[20] *Id.* at 4.
[21] Letter to the Honorable Martin Makary, M.D., FDA Commissioner, by American Academy of Pediatrics, et al, on Marketing of unauthorized new tobacco products by Reynolds and Altria (Sept. 25, 2025), https://perma.cc/TQ47-LFST.
[22] Letter from CTP Acting Dir. Koplow to Dennis Henigan (Oct. 15, 2025) (emphasis supplied).

cigarette or nicotine pouch, including those with pending PMTAs, should be on the market without an MGO—a position completely at odds with the 2026 Guidance.

C. March 2026 Draft Guidance and CTP Acting Director Koplow's March 2026 Comments

62. On March 11, 2026, FDA issued for notice and comment a Draft Guidance on "Considerations Related to Youth Risk" in flavored ENDS PMTAs.[23] The Draft Guidance explained that "FDA has gained considerable experience in regulating ENDS and has determined that the evidence shows that flavored ENDS products pose a substantial risk to youth, and they pose a greater risk to youth than tobacco-flavored ENDS." Mar. 2026 Draft Guidance at 4. It included a lengthy discussion of the evidence regarding flavored tobacco products, youth use, and tobacco initiation, and the reasons that, among the millions of products it has reviewed, "FDA has not identified any ENDS product with a flavor that is highly appealing to youth for which the applicant presented a magnitude of evidence of public health benefit sufficient to overcome the risk to youth." *Id.* at 8; *see generally id.* at 8-17.

63. Among other things, the Draft Guidance noted that many non-tobacco flavors have "greater appeal to youth (e.g., fruit and candy/dessert/other sweet)" and "pose a substantial health risk," and that they therefore "face a correspondingly high evidentiary burden to demonstrate that the benefits to adult smokers in terms of quitting or significantly reducing cigarette use outweigh the risks of youth initiation and use." *Id.* at 4-5, 8.

64. It also explained that "advertising and promotion restrictions intended to limit youth exposure to and appeal of tobacco product marketing," such as "using advertising content and methods that are not known to resonate with youth . . . may not in themselves provide enough

[23] FDA, Draft Guidance, "Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications—Considerations Related to Youth Risk" ("Mar. 2026 Draft Guidance"), https://perma.cc/44RE-YZ88; Flavored Electronic Nicotine Delivery Systems (ENDS) Premarket Applications—Considerations Related to Youth Risk; Draft Guidance for Industry; Availability, 91 Fed. Reg. 11,980 (Mar. 11, 2026).

assurance of a sufficient reduction in youth use to mitigate the substantial risk that flavored ENDS pose to youth." *Id.* at 16.

65. Around the same time, at a March 2026 conference, CTP Acting Director Bret Koplow was asked whether FDA would issue a list of tobacco products with pending PMTAs. Dr. Koplow made a strong case against the issuance of such a list. For example, he reiterated that FDA did not "consider the pendency of an application to have any justification for marketing" and that state laws that permit the sale of unauthorized products with pending applications are "inconsistent" with federal law.[24]

66. Dr. Koplow also worried that such a list "would potentially facilitate sales of products that have not undergone any type of scientific review," which would undercut FDA's goal of "protecting the public by trying to ensure that" authorized products "are appropriate for the protection of the public health and trying to . . . clear the market of the products that aren't." He went on to note FDA's position that "the pendency of an application does not mean that a product is appropriate for the protection of the public health."[25]

IV. THE 2026 GUIDANCE RADICALLY DEPARTED FROM PRIOR FDA POSITIONS

67. On May 8, 2026, before the comment period for the March 2026 Draft Guidance had even concluded, FDA issued the 2026 Guidance.[26]

68. The 2026 Guidance was not the finalization of the March 2026 Draft Guidance, but rather an entirely new guidance issued "without prior public comment." Enforcement Priorities for Certain New Tobacco Products Marketed Without Premarket Authorization; Guidance for Industry; Availability, 91 Fed. Reg. 25,983, 25,983 (May 12, 2026).

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[24] FDA, Ctr. for Tobacco Prods., *FDA CTP Special Session – 1*, at 1:11:15–1:11:20, 1:13:05–1:13:25 (Vimeo, Mar. 18, 2026), https://vimeo.com/1174851040/bfc7666ce5.
[25] *Id.* (1:11:45–1:11:55, 1:12:10–1:12:30, 1:13:15–1:13:25).
[26] *See* FDA, *FDA Issues Guidance on Enforcement Priorities for Unauthorized ENDS and Nicotine Pouch Products* (May 8, 2026), https://perma.cc/T7HT-7LLA.

69. Despite acknowledging that federal law "provides that new tobacco products may not legally be marketed without premarket authorization," 2026 Guidance at 3, the Guidance nevertheless announced that for unauthorized e-cigarettes and nicotine pouch products:

> FDA generally does not intend to prioritize enforcement of the premarket authorization requirement, where the product:
>
> - is subject to an application that is pending, and the application has been accepted and filed or is subject to a supplemental application (sPMTA) that has been accepted and pending for more than 180 days; and
>
> - for nontobacco-flavored ENDS products, if FDA has determined that the application also includes data necessary to evaluate whether such product is appropriate for the protection of the public health.

Id.

70. As explained *supra* ¶¶ 45–46, the "accepted and filed" review is not a technical or substantive review, but only a threshold review to ensure that the application complies with formatting and similar requirements and contains sufficient data for FDA to subsequently review.

71. The Guidance applies to PMTAs filed on or after November 4, 2021, the effective date of the PMTA Rule. *Id.* n.7.

72. The Guidance sets forth only two exceptions under which FDA would consider prioritizing enforcement against products that satisfied the threshold criteria:

- Products with "presumptively underage-appealing elements such as depicting a cartoon-like fictional character, disguising its nature as a vaping product or resembling a children's toy, phone, or gaming platform;" or

- Products that "present[] a significant public health or safety concern that is greater than generally presented by ENDS or nicotine pouch products or other tobacco products, such as a product that has high nicotine content, has serious adverse experiences or a larger number of unexpected associated adverse experiences compared with authorized ENDS or nicotine pouch products, lacks child-resistant packaging (CRP) in accordance with Child Nicotine Poisoning Prevention Act of 2015, or that is a potential fire hazard."

Id. at 4.

73. The Guidance also provides that to "promote transparency to consumers, retailers and other industry stakeholders and to assist FDA in efficiently allocating enforcement resources,"

FDA "will create and maintain a public-facing webpage identifying manufacturers and their associated products that FDA generally does not intend to prioritize enforcement against." *Id.* The Guidance recommends that manufacturers of products that qualify under the identified criteria contact FDA for inclusion on the list, which FDA will update on a "rolling basis." *Id.*

74. The Guidance's only rationale for choosing its deprioritization criteria is that PMTAs "that include the types of studies, data, and evidence identified above are more likely to . . . have the information necessary for the agency to determine if the tobacco products in such applications meet the required standards under the law for granting marketing authorization." *Id.* at 3. Allowing these products to be marketed without authorization, according to the Guidance, will enable FDA "to better allocate its enforcement resources." *Id.*

75. The Guidance, however, disclaims any connection between the enforcement policy and ultimate authorization: "The fact that an ENDS or nicotine pouch product falls within this enforcement policy in this guidance in no way has a bearing on whether the product is likely to receive premarket authorization." *Id.* at 5.

76. The Federal Register notice announcing the Guidance claimed that the Guidance was "intended to facilitate an orderly shift toward a regulated market in which compliant products, supported by appropriate evidence and subject to meaningful oversight, can replace unauthorized offerings." 91 Fed. Reg. at 25,893. It did not explain how the Guidance, which specifically only *eases* the marketing of unauthorized offerings, furthers this goal.

77. FDA also announced in the Guidance that it was withdrawing the agency's 2020 Guidance, without providing any rationale. At the same time, it included the 2020 Guidance as a reference because it "has information and discussions that continue to be relevant and helpful, such as about the history leading up to those enforcement policies." 2026 Guidance at 5.

78. Unlike the 2020 Guidance, the 2026 Guidance includes no public health justification for its enforcement deprioritization criteria, and it makes no attempt to explain why it was rejecting the findings and analysis underlying the 2020 Guidance. Nor does it acknowledge its

prior recognition that an "epidemic-level rise" followed the similar 2017 Guidance, much less provide a basis for concluding that the 2026 Guidance will not have the same effect.

79. The 2026 Guidance also does not explain, or even acknowledge, its rejection of the statements made just two months earlier in the 2026 Draft Guidance that FDA had never found an e-cigarette product flavored with anything but tobacco or menthol to have sufficient benefits to outweigh the risk of youth use. Nor does it explain how its reliance on the absence of marketing elements appealing to youth is consistent with the concerns noted in the 2026 Draft Guidance about the inadequacy of such marketing restrictions.

HARM TO PLAINTIFFS

I. CAMPAIGN FOR TOBACCO-FREE KIDS

80. Tobacco-Free Kids works to reduce tobacco use and its deadly toll in the United States and around the world. It devotes substantial resources to educating the public and those working to improve public health about the addictiveness and other health harms of e-cigarettes and nicotine pouches, including flavored e-cigarettes and nicotine pouches that studies have shown to be especially appealing and hazardous to youth.

81. Through its youth initiatives, Tobacco-Free Kids engages in activities designed to discourage youth from initiating use of e-cigarettes, nicotine pouches, and other tobacco products, including coordinating the Take Down Tobacco National Day of Action and co-leading the Youth Engagement Alliance for Tobacco Control. The National Day of Action is a national day of activities that, as part of its overall programming, engages youth to speak out against the dangers of tobacco use, including e-cigarettes and nicotine pouches. The Youth Engagement Alliance supports adult coordinators to empower youth engagement in tobacco control and public health, including communicating the dangers of tobacco products. The 2026 Guidance, by allowing the marketing of e-cigarettes and nicotine pouches that lack FDA marketing authorization, especially flavored products with a powerful appeal to young people, will reduce the effectiveness of those activities directed at discouraging youth initiation of those tobacco

products, thereby requiring a diversion of organizational resources to maintain the efficacy of these youth programs.

82. Tobacco-Free Kids also provides information, education, and technical assistance to health departments and other groups, including assistance regarding the lawfulness of various tobacco products. The 2026 Guidance, because it is action by FDA to allow the marketing of e-cigarettes and nicotine pouches without the legally required marketing authorization, will create confusion as to the legal status of the products subject to the Guidance, requiring a greater investment of Tobacco-Free Kids' resources to provide accurate and understandable technical assistance, including by updating its educational resources to specifically address the new category of products entering the market due to the Guidance.

II. AMERICAN ACADEMY OF PEDIATRICS

83. AAP's mission is to attain optimal physical, mental, and social health and wellbeing for all infants, children, adolescents, and young adults. To accomplish this goal, AAP's pediatrician members actively screen their patients for use of tobacco products and provide counseling to their patients and patients' family/caregivers about the health hazards of tobacco use, in an effort to prevent initiation and promote cessation. AAP expends substantial resources in providing its physician members with education and tools for screening and counseling, including through the Section on Nicotine and Tobacco Prevention and Treatment and the Julius B. Richmond Center of Excellence. These educational materials and tools include:

i. A Clinical Report and accompanying Policy Statement and Technical Report titled Protecting Children and Adolescents from Tobacco and Nicotine that describe, respectively, clinical practice recommendations for screening and counseling, tobacco policy recommendations, and the evidence underlying those recommendations;

ii. A Youth Tobacco Cessation progressive web application designed for use during clinical encounters that assists physicians and other clinicians with screening for, counseling, and treating youth tobacco use.

iii. An online course titled EQIPP: Addressing Vaping and Tobacco Use with Patients and Families that educates pediatricians on techniques to screen youth at every visit for tobacco use and to provide those who screen positive with counseling and cessation support;

iv. In-person programs and webinars that provide training to help pediatricians and pediatric care team members promote youth tobacco cessation and address second- and third-hand smoke; and

v. Technical assistance to AAP state chapters that are looking to educate their members about addressing tobacco in pediatric practice.

84. AAP also expends substantial resources educating parents and the wider public about tobacco use, research, policy, and events, including through publications on Healthychildren.org, AAP's official parenting website, and monthly publicly accessible newsletters from the Richmond Center.

85. In developing and updating its educational materials and tools, AAP depends upon the availability of accurate, science-based information about tobacco products made available in FDA marketing orders and accompanying reports.

86. The 2026 Guidance will increase youth usage of e-cigarettes and nicotine pouches. Through experience and research, AAP knows that the overwhelming majority of youth tobacco users initiate use with a flavored product and that e-cigarettes and nicotine pouch products have levels of highly addictive nicotine that make it easier for adolescents and young adults to develop nicotine dependence and harder to quit. Moreover, FDA's publication of products that may be sold pursuant to the Enforcement Guidance will inaccurately suggest to patients that the listed products pose fewer risks than other similar products.

87. The Guidance will also result in these e-cigarettes and nicotine pouches being on the market without the accompanying information that FDA provides when it authorizes a new tobacco product.

88. As a result, the 2026 Guidance will directly and negatively impact AAP's efforts to educate its members as well as patients and their families/caregivers on discouraging tobacco use by decreasing the effectiveness of AAP's tools and increasing AAP's administrative burdens. AAP's existing tools and resources will be rendered less effective by the introduction and marketing of new highly appealing flavored e-cigarettes and pouches. Moreover, the tools AAP provides its members on screening and counseling for tobacco use will not sufficiently train

pediatricians to address misconceptions by adolescents, young adults, and their families or caregivers about the safety of tobacco products that will enter the market as the result of the Guidance, including flavored products that will be heavily advertised. The Guidance will force AAP to make costly changes to its tools and to provide additional resources to specifically address the new products entering the market as a result of the Guidance and to prepare pediatricians for a surge in patients who are using tobacco products and may be addicted to multiple types of products as a result of the Guidance.

89. Moreover, AAP will need to expend considerable resources researching the products and their associated health risks when developing and updating its tools and resources. These efforts will impose concrete and significant costs on AAP, including the diversion of staff from existing assignments to research and develop new training and educational resources for pediatricians, the inability of the Section to complete planned activities and achieve planned outcomes, and the reallocation of funds away from budgeted activities.

90. The Guidance also directly harms AAP's pediatrician members, such as Dr. Susan Walley, by interfering with their practice of medicine, interrupting existing clinical workflows and negating the effectiveness of established patient care protocols. By allowing significant numbers of nicotine-laden, youth-appealing flavored e-cigarettes and nicotine pouches to be marketed for an indefinite period, the 2026 Guidance will increase the volume and complexity of patient needs AAP's members must confront, thus increasing the time these members must spend to provide effective prevention and counseling services. The Guidance will also make it harder for members to treat their patients who have been or are currently addicted, as they may be attracted to and use these new products. Moreover, FDA's publication of permitted products will inaccurately suggest to patients that the listed products pose fewer risks than other similar products, requiring more of the members' time to correct their patients' misperceptions. Finally, the Guidance will additionally harm pediatricians by depriving them of health information that would otherwise be available for authorized tobacco products, thus undercutting their ability to provide effective patient care.

III. AMERICAN CANCER SOCIETY CANCER ACTION NETWORK

91. ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society. ACS CAN promotes evidence-based public policies to reduce the cancer burden for everyone. Because tobacco usage is a leading cause of lung and other forms of cancer, ACS CAN has, since its founding, been a leader in educating the public about the dangers of using tobacco products and advocating for policies and programs that discourage initiation of tobacco use and encourage cessation. ACS CAN is a membership organization with 12,000 members in 2026.

92. ACS CAN devotes significant resources to educating the public, volunteers, and policymakers at the federal, state and local levels to help them understand the market around tobacco products in order to properly regulate them. The Guidance directly harms ACS CAN members because it will lead to a flood of tobacco products on the market, without scientific review, that will require significantly more resources to monitor, analyze, and educate members, policymakers, and the public on. The lack of information from FDA for products available on the market without a scientific review would result in more staff time and potential research dollars to fill the void.

IV. AMERICAN HEART ASSOCIATION

93. AHA's mission is to be a relentless force for a world of longer, healthier lives. In pursuit of this mission, AHA works with health care clinicians, employers, community groups, and school administrators to provide education and counseling to help prevent youth initiation of tobacco use and to encourage current tobacco users to quit. This work includes:

i. AHA's Scientific Statements on topics including e-cigarettes and nicotine pouches, which are used to promote greater awareness and represent a synthesis of the latest data and consensus of leading experts, and its Clinical Practice Guidelines, which translate research into practical guidance for healthcare professionals;

ii. AHA's "Get With The Guidelines" quality improvement program that seeks to ensure hospitals and other healthcare clinicians are providing the most effective tobacco use screening and cessation resources;

iii. The Tobacco Cessation Specialist Certification that AHA offers, which validates that tobacco treatment specialists are providing clear and effective screening and cessation services; and

iv. The Tobacco Endgame Movement, which is an initiative to bring together advocates aged 13-24 to lead efforts to end tobacco use and nicotine addiction.

94. AHA also develops and distributes a large array of material for individuals on cessation strategies and resources as well as the dangers of using tobacco, including e-cigarettes and nicotine pouches. In addition, AHA is the largest non-profit, non-governmental funder of cardiovascular and cerebrovascular research in the U.S., and currently funds research on the health impact of e-cigarettes, nicotine pouches, and other tobacco and nicotine products.

95. In developing and updating the resources described above, AHA regularly publishes and relies on research that uses information about tobacco products contained in FDA marketing orders and accompanying TPL Reviews and related documentation.

96. The 2026 Guidance interferes with AHA's ability to provide complete, accurate, and effective prevention and cessation materials and programs. AHA's prevention and cessation resources are evidence-based and require substantial AHA staff and volunteer time to ensure they account for the most relevant and recent scientific findings as well as the current tobacco product marketplace. The Guidance, which will allow e-cigarettes and nicotine pouches to be marketed without the information FDA generally discloses when it authorizes a new tobacco product, will make this work more burdensome and less effective. AHA will be forced to expend significant resources, including staff time, assessing the composition and risk profile of these new products in order to maintain the effectiveness and credibility of AHA's materials and programs—information that would otherwise be available were the products to reach the market only if authorized. However, any external analysis of the products is necessarily more limited than what FDA publishes with an MGO given the amount of information FDA receives from an applicant about the product. Thus, in response to the Guidance, AHA will not only have to expend additional resources, but its effectiveness in achieving its mission by providing complete,

accurate, and effective prevention and cessation materials and programs will be materially hampered.

97. The Guidance will also force AHA to make costly changes to its materials and programs to specifically address the new products that will enter the market as a result of the Guidance and to correct misperceptions and confusion—among both clinicians and the public—around the meaning of the list of products that FDA will publish pursuant to this Guidance, namely whether inclusion on the list signifies that a product has undergone FDA review or poses fewer risks than other similar products. AHA's educational materials, clinical guidance, and cessation resources will have to be modified to explain that inclusion on FDA's public list does not constitute FDA authorization and does not reflect a determination that the product is appropriate for the protection of the public health.

98. The Guidance will also require AHA to invest additional resources to evaluate potential changes to its Tobacco Cessation Specialist Certification in order to ensure that the Certification continues to be an effective tool to maintain high standards among healthcare professionals in promoting tobacco cessation efforts, particularly to address the confusion that will result from FDA's publication of the list of products under the Guidance.

99. As a result of the Guidance, AHA will be required to reduce staffing on other projects, delay new programs, and spend additional funds in order to continue this aspect of its mission.

V. AMERICAN LUNG ASSOCIATION

100. The Lung Association's mission is to save lives by improving lung health and preventing lung disease. The prevention and cessation of the use of tobacco products, including e-cigarettes and nicotine pouches, is an integral part of this mission. In furtherance of this, the Lung Association engages in various programs and activities to prevent people, especially youth, from starting to use tobacco products, and to help those who are using tobacco products to quit. These program and activities include:

i. Not-On-Tobacco®, a voluntary program offering cessation counseling and other programming for youth ages 13-19;

ii. Freedom from Smoking, an evidence-based cessation program for adults seeking a structured, systematic approach to quitting, which has helped over one million people across the U.S. end their addiction to nicotine and begin new smokefree lives since it was introduced more than 40 years ago;

iii. ACT to Address Youth Cessation Training, an online course to educate school counselors, teachers, coaches and administrators on effective intervention to prevent youth from initiating e-cigarette use and to help youth e-cigarette users to stop using e-cigarettes;

iv. Vape-Free Schools Initiative, an initiative to ensure that schools implement evidence-based policies to prevent youth from initiating e-cigarette use and to help youth e-cigarette users to stop using e-cigarettes and all tobacco products;

v. Talking to Your Child About Vaping, a program designed to reinforce prevention messages and effective intervention strategies with resources for parents and other caregivers of youth ages 8 to 20;

vi. The INDEPTH program, a program that offers direct intervention with students who have violated school tobacco-free policies as an alternative to suspension and is designed to motivate students to stop using e-cigarettes and other tobacco products; and

vii. Mass media campaigns, conducted in partnership with the Ad Council, to engage parents in helping to prevent youth vaping.

101. The 2026 Guidance, through which FDA will permit new tobacco products, including many flavored products with great appeal to youth, to enter the market even though they lack legally required marketing orders, will cause youth to misperceive the relative risk of these e-cigarettes and nicotine pouches, as well as increase the social appeal of e-cigarettes and nicotine pouches overall, and therefore increase youth usage of these products. Through experience and research, the Lung Association knows that e-cigarettes and nicotine pouch products have levels of highly addictive nicotine that make it difficult for youth and adults to quit.

102. As a result, the 2026 Guidance will directly and negatively impact the Lung Association's prevention and cessation programs and activities by decreasing their effectiveness and increasing their administrative burdens. The Lung Association will bear a higher burden of demonstrating the risks of addiction and other health harms from e-cigarettes and nicotine pouches sufficient to discourage youth initiation of use. Further, it will be more difficult and costly for the Lung Association to successfully help youth to achieve cessation, because there

will be more youth users, and because more intensive treatment plans are needed when tobacco product users use more than one type of tobacco product. In addition, the Lung Association will be required to make costly changes to its programs and activities, including its trainings and surveys, to specifically address the new products entering the market as a result of the 2026 Guidance. These various impacts will require the Lung Association to divert resources from other critical lung health efforts.

VI. PARENTS AGAINST VAPING E-CIGARETTES

103. Parents Against Vaping is a national, grassroots organization of parents committed to protecting children from the dangers of vaping and other flavored tobacco use. Parents Against Vaping helps parents, educators, and communities fight the youth vaping crisis by engaging in powerful, research-based educational programs. Parents Against Vaping's priorities and educational initiatives are shaped by parent volunteers, such as Jane Doe.

104. Its signature offerings include its "Core Presentation" on health risks and industry tactics directed at young people, "Clear the Vapor" conversations regarding the latest tobacco product trends, deep-dive "Ask the Expert" sessions, and youth-focused programs like "Vapes Are Trash." Parents Against Vaping also offers "Train the Trainer" programming to enable parents, public health professionals and other interested adults to present Parents Against Vaping's educational programming in their own communities. In addition to its educational work, Parents Against Vaping offers support to parents whose children suffer from the serious and adverse effects of tobacco product addiction, including through online resources.

105. The 2026 Guidance will make it substantially harder and more costly for Parents Against Vaping to deliver its educational and parental support programs. Parents Against Vaping responds individually to every parent who reaches out for help. The increased availability of flavored e-cigarette and nicotine pouches cause more parents to reach out to Parents Against Vaping for assistance, straining Parents Against Vaping's parental support services. The proliferation of new products will also require Parents Against Vaping to expend more of its limited resources to understand and explain products that children are using.

106. Through its Parents Opposing Illegal Sales of Nicotine ("POISON") initiative, Parents Against Vaping also supports parents in filing reports with authorities about e-commerce stores and retailers that are carrying illegal products and/or selling to minors. The 2026 Guidance and the public list will further burden Parents Against Vaping by increasing the number of available flavored products that parents need to monitor and report, creating confusion about their regulatory status, and making it harder for Parents Against Vaping and its parent volunteers to accurately report illegal products that are harmful to youth.

VII. TRUTH INITIATIVE

107. Truth Initiative is a non-profit organization created out of the Tobacco Master Settlement Agreement ("MSA") in 1998. Established by 47 state attorneys general to combat youth tobacco usage and substance abuse, the MSA directs Truth Initiative to create nationwide education and prevention campaigns to counter the use of tobacco and nicotine, disseminate educational programs for schools, develop criteria for effective cessation programs, and publish research on the factors that influence youth tobacco usage and develop strategies to counter such usage.

108. When a novel nicotine product (such as an e-cigarette or oral nicotine pouch) is allowed to enter and stay on the market illegally, Truth Initiative's work becomes more complex and more expensive. To combat youth usage of e-cigarettes and nicotine pouches allowed to enter and stay on the market without FDA authorization as a result of the 2026 Guidance, Truth Initiative must first understand how young people perceive the products covered by the Guidance, their attitudes and beliefs about the risks, the marketing they are exposed to through social media, and test messaging that might change their knowledge, attitudes, beliefs and behaviors about the products. Further, Truth Initiative operates one of the largest nicotine cessation programs in the country, enrolling over 134,000 13-24 year olds in 2025. Truth Initiative will need to constantly adjust the messaging that young people receive as part of the program to address the unauthorized products. In addition, it must adjust both its marketing program designed to prevent youth usage and to encourage those already caught in the cycle of

addiction to quit. All of this work will require an investment of significant staff time, contracting with external consultants, engagement of new social media talent, and modification of our tracking of youth usage, all for products that should not be allowed to stay on the market.

VIII. DR. SUSAN WALLEY

109. Dr. Susan Walley is a pediatric hospitalist and an expert in adolescent tobacco use. She is an AAP member and the outgoing chair of AAP's Section on Nicotine and Tobacco Prevention and Treatment. She is certified in nicotine and tobacco treatment, which involves special training on how to help patients quit using tobacco products and how to discourage the initiation of tobacco products. As a pediatric hospitalist, she treats adolescent patients, including patients where vaping caused their hospitalization or worsened their illness. In addition, because nicotine addiction is a mental health disorder, her responsibilities as a pediatrician include treating her patients' addictions and counseling her patients who do not currently use tobacco products to avoid using them.

110. The 2026 Guidance will result in many unauthorized and flavored e-cigarette and nicotine pouch products with high nicotine content entering the market and remaining on the market indefinitely. Because flavors in e-cigarettes and nicotine pouches are among the major factors attracting youth to these products, the 2026 Guidance will make Dr. Walley's practice of pediatric medicine more difficult, increasing the time it takes for effective prevention and counseling. In addition, FDA's planned publicizing of a list of the products allowed, by FDA's own action, to enter the market, will inaccurately suggest to her patients that the listed products pose fewer risks to youth than other similar products, requiring more of Dr. Walley's time to correct her patients' misperceptions. The 2026 Guidance will also make it harder to treat her patients who already have addictions, as that they may use, or at least be tempted by, these new products.

IX. JANE DOE

111. Jane Doe suffers from the serious and adverse consequences of tobacco product addiction to her and her family. Jane Doe is the mother of three teenage boys, two of whom

struggle with nicotine vaping and its harmful effects on their health. Jane first learned that her two older sons were vaping several years ago when she found vapes hidden under their mattresses and the corners of their bedrooms. Both children prefer flavored vapes, especially fruity flavors like mango and blueberry (although there are numerous other flavors that entice them as well). Although her sons are significantly under the legal purchasing age for tobacco products, they are able to acquire vapes from a variety of sources, including local vape shops or from friends with mustaches who look older.

112. Both of her sons openly acknowledge that they are addicted to nicotine and feel powerless to stop vaping despite repeated attempts to quit. The oldest child and another addicted friend committed to quitting together, yet both relapsed, illustrating the extraordinary hold nicotine addiction has on her children and all adolescents.

113. Her oldest son believes that quitting during high school is nearly impossible because vaping is deeply embedded in the social environment and so readily accessible.

114. In addition, both children have started using nicotine pouches as a strategy to try and quit using nicotine. However, this highlights that the addiction has not ended—it has simply shifted to another nicotine delivery system.

115. Since starting to vape, both boys' academic performance has suffered. Jane describes the past two years of trying to overcome their addictions as difficult, challenging, and worrisome.

116. Given the products her children prefer and their ongoing and active tobacco product use, Jane fears that the new flavored vapes and nicotine pouches that are marketed as a result of the 2026 Guidance will further entice her sons and make it even more difficult for them to quit. She also worries that these new products will entice her youngest son, who has already been offered vapes by his friends, to start on a path of nicotine addiction.

COUNT ONE

(Tobacco Control Act, 21 U.S.C. § 387j; Administrative Procedure Act, 5 U.S.C. § 706)

THE GUIDANCE IS NOT IN ACCORDANCE WITH LAW AND EXCEEDS STATUTORY AUTHORITY

117. Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

118. The guidance is final agency action subject to review under the Administrative Procedure Act, 5 U.S.C. § 706.

119. The APA requires the Court to hold unlawful and set aside any agency action which is "not in accordance with law" or "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706 (2)(A), (C).

120. The Guidance conflicts with the Tobacco Control Act and exceeds FDA's statutory authority because it permits e-cigarettes and nicotine pouches to enter and remain on the market for an indefinite period without the statutorily required MGO.

121. With certain exceptions not relevant here, *see supra* n.6, the Tobacco Control Act does not allow FDA to authorize the marketing of a new tobacco product, for even a single day, without an MGO finding that the company has demonstrated that the product is appropriate for the protection of the public health. 21 U.S.C. § 387j; *see also* 21 C.F.R. § 1114.5.

122. The Guidance suffers from the same core defects as the 2017 Guidance that a court in this district previously vacated. By allowing products to enter the market before they have been authorized, the Guidance transforms the Tobacco Control Act's *premarket* review into "a form of *postmarket* review," which "clearly was contrary to the Tobacco Control Act's purpose and therefore an ultra vires action." *AAP I*, 379 F. Supp. 3d at 492.

123. FDA itself has previously recognized that it does not have the authority under the Tobacco Control Act or this court's *AAP* decision to exercise its enforcement discretion so as to permit an entire category of products to be marketed without the statutorily required MGO.

124. FDA has also previously raised concerns about issuing a list of new tobacco products that are the subject of pending PMTAs.

125. Despite the plain text of the statute, this court's *AAP* decision, and FDA's prior positions, the Guidance permits the marketing of unauthorized e-cigarettes and nicotine pouches without MGOs for an indefinite period of time. It also creates a public list of unauthorized products that the agency permits to be sold free from enforcement. The Guidance does not include a sunset date for that safe harbor.

126. The Guidance will result in potentially thousands of e-cigarettes and nicotine pouches, including youth-appealing flavored products, that have not been scientifically reviewed by FDA, being on the market free from FDA enforcement for potentially years on end.

127. The Guidance is not an exercise of permissible, and unreviewable, enforcement discretion. Rather, in direct contravention of the statute's premarket review requirements, the Guidance affirmatively authorizes manufacturers of e-cigarettes and nicotine pouches with pending PMTAs filed after November 3, 2021, to keep those products on the market while FDA reviews their PMTAs. In fact, FDA even intends to create, maintain, and update on a rolling basis a public list of products that qualify for deprioritized enforcement—presumably to indicate to retailers and distributors which products may be sold free from FDA enforcement.

128. In abandoning the premarket authorization requirement for a broad category of tobacco products, FDA "has 'consciously and expressly adopted a general policy' that is so extreme as to amount to an abdication of its statutory responsibilities." *Heckler v. Chaney*, 470 U.S. 821, 833 n.4 (1985) (quoting *Adams v. Richardson*, 480 F.2d 1159 (D.C. Cir. 1973)). Here, the Guidance purports to override, rewrite, and annul—for years or even indefinitely—the detailed premarket review scheme established by Congress, replacing it with a postmarket review scheme which directly contradicts the Tobacco Control Act and thereby allows products to be introduced into the market without statutorily required authorizations.

129. For these reasons, the Guidance must be vacated and "set aside" because it is "not in accordance with law," and is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C § 706(2)(A), (C).

COUNT TWO
(Administrative Procedure Act, 5 U.S.C. § 706)
THE GUIDANCE IS ARBITRARY AND CAPRICIOUS

130. Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

131. The APA requires this Court to hold unlawful and set aside any agency action that is "arbitrary, capricious, . . . or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

Agency action that is not the product of reasoned decision-making is arbitrary and capricious. *Motor Vehicle Manuf. Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). To qualify as reasoned decision-making, an agency "must examine the relevant data and articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Id.* (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168 (1962)).

132. The Guidance fails the APA's reasoned decision-making requirement multiple times over. It fails to give a reasoned explanation for its choice of the criteria that will be used to determine the products that will receive a safe harbor from enforcement, fails to give a reasoned explanation for publicizing the list of products that will receive a safe harbor from enforcement, fails to adequately explain why (or even acknowledge that) FDA has changed policies, particularly around flavors, and fails to explain the connection between the data before FDA and the choice made.

133. The Guidance's only explanation for why FDA will not pursue enforcement against certain products is that FDA has limited resources and these products' PMTAs are more likely to contain the "information necessary for the Agency to determine if the tobacco products…meet the required standard" for authorization. Guidance at 3-4. Notably, the Guidance does not assert that the products qualifying for the safe harbor are more likely to *satisfy* the statutory standard of appropriateness for the protection of the public health or present a lower public health risk than other unauthorized products, and explicitly disclaims any connection between being on the list and ultimately receiving authorization.

134. The Guidance's criteria is also arbitrary because it is not tied to the purposes of the Tobacco Control Act. *See Judulang v. Holder*, 565 U.S. 42, 55 (2011) (agency action "must be tied, even if loosely, to the purposes of the" governing statute.). The Guidance creates an extra-statutory pathway for unauthorized products to reach the market with no indication that the agency will balance, even preliminarily, the risks that these products will pose to users and non-

users of tobacco products—the two factors at the center of the statutory standard of being appropriate for the protection of the public health. *See* 21 U.S.C. 387j(c)(4).

135. Significantly, the Guidance includes no consideration of the risk that *flavored* e-cigarettes and nicotine pouches specifically pose to youth. This is a stark, unexplained departure from the 2020 Guidance it replaces and from other recent FDA actions, including actions taken shortly before the Guidance was issued. The lack of explanation for (or even acknowledgment of) this departure, much less a reasoned one, is arbitrary and capricious.

136. The Guidance must be vacated and set aside.

COUNT THREE
(Administrative Procedure Act, 5 U.S.C. §§ 553, 706)
THE GUIDANCE VIOLATES THE APA'S REQUIREMENT FOR NOTICE-AND-COMMENT RULEMAKING

137. Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

138. The APA requires this Court to hold unlawful and set aside any agency action taken "without observance of procedure required by law." 5 U.S.C. § 706(2)(D).

139. The Guidance issued by FDA is a "rule" within the meaning of the APA because it is "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). With exceptions not applicable here, the "agency process for formulating, amending, or repealing [such] a rule," *id.* § 551(5), must comply with the requirements of notice-and-comment rulemaking, *see id.* § 553.

140. The Guidance is not an "interpretative rule[], general statement[] of policy, or rule[] of agency organization, procedure, or practice." 5 U.S.C. § 553(b)(A). To the contrary, it is a substantive rule because it "is tantamount to an amendment" of the Tobacco Control Act's premarket review provisions. *AAP I*, 379 F. Supp. 3d at 497. Whereas the statute and FDA's regulations governing premarket review require the premarket review process to be completed successfully by a PMTA applicant before a product can be marketed, the Guidance alters this

core requirement by allowing products to be marketed—potentially for years—pending the completion of application review processes.

141. In purpose and effect, the Guidance ties FDA's hands, limiting its discretion to prosecute acts prohibited by statute and expressly allowing certain new e-cigarettes and nicotine pouches to enter the market without statutorily required prerequisite marketing orders from FDA. Pursuant to the Guidance, the agency will even publish a list of products against which the agency will not enforce the law.

142. The Guidance also effectively immunizes conduct that would otherwise be manifestly illegal under federal law, changing the rights of regulated entities and conferring benefits onto manufacturers for which there is no legislative basis—the right to sell certain new tobacco products without statutorily required marketing authorization.

143. Absent "good cause," FDA was required to provide notice of its proposal, an opportunity for public comment, and an explanation of the rule ultimately adopted, see 5 U.S.C. § 553(b), (c)—none of which FDA did. FDA lacked good cause to forgo notice and comment.

144. Because FDA promulgated the Guidance without notice and comment, in violation of 5 U.S.C. § 553, it is unlawful and must be vacated.

COUNT FOUR
(Administrative Procedure Act, 5 U.S.C. § 706; Food, Drug, and Cosmetic Act, 21 U.S.C. § 371(h)(1)(C)(i))
THE GUIDANCE WAS ADOPTED CONTRARY TO THE FOOD, DRUG, AND COSMETIC ACT'S REQUIREMENT OF PUBLIC PARTICIPATION

145. Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

146. The FD&C Act required FDA to permit prior public participation before issuing the Guidance. "For guidance documents that set forth … changes in interpretation or policy that are of more than a minor nature" or that address "highly controversial issues, the Secretary shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate." 21 U.S.C. § 371(h)(1)(C)(i).

147. Here, the Guidance amends a core component of the Tobacco Control Act's regulatory system—premarket review—which is a major and highly controversial policy shift that will allow potentially thousands of e-cigarettes and nicotine pouches, including flavored products, to be on the market without the required authorization.

148. FDA issued the Guidance without prior public comment. Its only attempt to justify this decision was a single conclusory sentence that does not demonstrate that public participation was either infeasible or inappropriate. *See* 91 Fed. Reg. at 25,893.

149. FDA's promulgation of the Guidance without complying with the FD&C Act's requirement of public participation was "not in accordance with law," 5 U.S.C. § 706(2)(A), and was undertaken "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). The Guidance should therefore be vacated and set aside.

COUNT FIVE
(*Accardi* Doctrine, 21 C.F.R. § 10.115(g)(1)(iv))
THE GUIDANCE WAS ADOPTED PURSUANT TO A PROCESS CONTRARY TO FDA'S REGULATIONS

150. Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

151. "[W]hen an agency fails to follow its own procedures or regulations, that agency's actions are generally invalid." *Nader v. Blair*, 549 F.3d 953, 962 (4th Cir. 2008) (citing *United States ex rel. Accardi v. Shaughnessy*, 347 U.S. 260 (1954)).

152. FDA maintains "policies and procedures for developing, issuing, and using guidance documents." 21 C.F.R. § 10.115.

153. For "Level 1 guidance documents," which includes documents that "[s]et forth changes in interpretation or policy that are of more than a minor nature," 21 C.F.R. § 10.115(c)(1)(ii), or documents that "[c]over highly controversial issues," 21 C.F.R. § 10.115(c)(1)(iv), FDA must publish a draft of the guidance and invite public comment. 21 C.F.R. § 10.115(g)(1).

154. The Guidance is a Level 1 guidance document within the meaning of 21 C.F.R. § 10.115(c)(1).

155. FDA issued the Guidance without prior public comment. Its only attempt to justify this decision was a single conclusory sentence that did not demonstrate prior public participation to be either infeasible or inappropriate.

156. FDA therefore violated its own procedures and regulations when it issued the Guidance without following notice and comment procedures. The Guidance is therefore invalid.

COUNT SIX
(Tobacco Control Act, 21 U.S.C. § 387j; Administrative Procedure Act, 5 U.S.C. § 706)
THE GUIDANCE IS *ULTRA VIRES*

157. Plaintiffs incorporate by reference the allegations of the preceding paragraphs.

158. Non-statutory *ultra vires* review is available when an agency takes action "entirely in excess of its delegated powers and contrary to a specific prohibition in a statute," unless a statutory review scheme "provides aggrieved persons with a meaningful and adequate opportunity for judicial review" or "forecloses all other forms of judicial review." *Nuclear Regul. Comm'n v. Texas*, 605 U.S. 665, 681 (2025) (cleaned up).

159. As a federal agency, FDA has no power to act unless and until Congress confers that power. Actions taken by FDA that are unauthorized by Congress or inconsistent with congressional direction are *ultra vires* and must be set aside.

160. The Guidance is more than a non-enforcement policy; it established an alternative regulatory regime, with the force of law, that is not authorized by Congress and is squarely contrary to the one Congress established and directed.

161. Similarly, Congress has not authorized FDA to issue a list of unauthorized tobacco products that can be marketed without fear of FDA enforcement.

162. The Guidance and the accompanying list are *ultra vires*, and must be set aside.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court:

a) Vacate and set aside the Guidance;

b) Declare that the Guidance is contrary to law and exceeds FDA's statutory authority; is arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law; and was promulgated without observance of procedure required by law and in violation of the *Accardi* doctrine;

c) Enjoin Defendants from enforcement or implementation of the Guidance, including creation and maintenance of a public-facing list identifying manufacturers and products protected from enforcement pursuant to the Guidance;

d) Award Plaintiffs their costs, disbursements, and reasonable attorney's fees associated with this litigation pursuant to 28 U.S.C. § 2412 and other applicable authority; and

e) Grant such other relief as this Court may deem just and proper.

Dated: July 14, 2026

Respectfully submitted,

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