IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN ACADEMY OF PEDIATRICS
141 Northwest Point Boulevard
Elk Grove Village, IL 60007

MARYLAND CHAPTER – AMERICAN ACADEMY OF PEDIATRICS
1211 Cathedral Street
Baltimore, MD 21201

AMERICAN CANCER SOCIETY CANCER ACTION NETWORK
555 11th Street NW, Suite 300
Washington, D.C. 20004

AMERICAN HEART ASSOCIATION
7272 Greenville Avenue
Dallas, TX 75231

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

CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I Street NW, Suite 1200
Washington, D.C. 20005

TRUTH INITIATIVE
900 G Street NW, Fourth Floor
Washington, D.C. 20001

DR. LEAH BRASCH, MD
Montgomery County, MD

DR. CYNTHIA FISHMAN, MD
Montgomery County, MD

DR. LINDA GOLDSTEIN, MD
Washington, D.C.

DR. STEVEN HIRSCH, MD
Montgomery County, MD and

Civil Action No. 8:18-cv-883

DR. DAVID MYLES, MD
Montgomery County, MD

Plaintiffs,

v.

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

SCOTT GOTTLIEB, in his official capacity as Commissioner of Food and Drugs,
10903 New Hampshire Avenue
Silver Spring, MD 20993

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
200 Independence Avenue SW
Washington, D.C. 20201
and

ALEX M. AZAR II, in his official capacity as Secretary of Health and Human Services,
200 Independence Avenue SW
Washington, D.C. 20201

Defendants.

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiffs the AMERICAN ACADEMY OF PEDIATRICS, the MARYLAND CHAPTER – AMERICAN ACADEMY OF PEDIATRICS, the AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, the AMERICAN HEART ASSOCIATION, the AMERICAN LUNG ASSOCIATION, the CAMPAIGN FOR TOBACCO-FREE KIDS, the TRUTH INITIATIVE, DR. LEAH BRASH, MD, DR. CYNTHIA FISHMAN, MD, DR. LINDA GOLDSTEIN, MD, DR. STEVEN HIRSCH, MD, and DR. DAVID MYLES, MD (collectively, "Plaintiffs") allege as follows:

INTRODUCTION

1. To protect the public, especially youth, against the catastrophic health risks created by tobacco products—risks the Supreme Court has described 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)—Congress enacted the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act") in 2009 as a comprehensive scheme for the regulation of tobacco products. 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), as well as all other "tobacco products" the Secretary of the Department of Health and Human Services ("HHS") deems to be subject to regulation. 21 U.S.C. § 387a(b). Congress further specified a range of requirements for "tobacco products," including, as relevant here, premarket review requirements that must be satisfied before any "new tobacco product" may be marketed or sold. *Id.* § 387j(a).

2. After notice and comment and based on a well-developed administrative record, in 2016 the Food and Drug Administration ("FDA" or "the agency") exercised the Secretary's statutory authority to deem electronic nicotine device systems (referred to here as "e-cigarettes"), cigars, and pipe tobacco "tobacco products" subject to regulatory controls under the Tobacco Control Act.[1] In doing so, FDA made comprehensive and specific findings about the health risks of the newly deemed tobacco products, and it adopted a compliance and enforcement regime it believed would best accomplish the statute's public health objectives. Known as the "Deeming Rule," FDA's regulation became effective on August 8, 2016. *See* Final Rule, *Deeming Tobacco*

[1] In the rulemaking leading to the Deeming Rule, FDA referred to e-cigarettes and other vaping devices as "electronic nicotine delivery systems" ("ENDS"). In this Complaint, the term "e-cigarette" is used synonymously with the term "ENDS."

Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act, 81 Fed. Reg. 28,973 (May 10, 2016).

3. After the change in presidential administration, FDA deferred for 90 days certain statutory and regulatory deadlines established by the Deeming Rule and the Tobacco Control Act. The purpose of this delay, ostensibly, was for the new Administration to reconsider its approach to the Deeming Rule. Then, in August 2017, without inviting public or stakeholder comment as required by the Administrative Procedure Act ("APA") or building a new administrative record to guide its decision, FDA issued what it labeled a "Guidance" that fundamentally altered the statutory duties and responsibilities of manufacturers of newly deemed tobacco products. *See Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry* 3 (Aug. 2017) ("Guidance") (Ex. A). Perhaps most significantly, FDA purported to exempt, on a categorical basis, manufacturers of newly deemed products from the Tobacco Control Act's premarket review regime for up to *six years* beyond the effective date of the Deeming Rule (and, in practice, indefinitely beyond that time)—notwithstanding Congress's statutory mandate that, subject to exceptions not relevant here, premarket review is "required" before newly deemed products may be marketed or distributed to consumers. 21 U.S.C. § 387j(a)(2)(A).

4. FDA's "Guidance" is manifestly unlawful in multiple respects and must be vacated. *First*, the Guidance exceeds the agency'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. Although FDA seeks to ground its Guidance in agency non-enforcement discretion, the Guidance is nothing like a traditional case-by-case agency enforcement decision. It is categorical, covering all newly deemed products; it extends key deadlines for multiple years;

and it does far more than decline to enforce a statutory requirement. Rather, it effectively rewrites the statute Congress enacted by exempting manufacturers of newly deemed tobacco products for years from the statutory premarket review regime that Congress imposed. In doing so, FDA effectively arrogated to itself sweeping statutory forbearance authority that Congress nowhere delegated to the agency. The Guidance is accordingly ultra vires and must be vacated.

5. *Second*, the Guidance is unlawful because it is a substantive rule that was not promulgated in accordance with the APA's notice and comment requirements. FDA's position that the Guidance does not affect substantive rights and is not subject to notice and comment fails as a matter of law because the multi-year exemption created by the "Guidance" alters the rights and responsibilities of manufacturers of newly deemed tobacco products for an extended period of time. Even if the statute could be read to permit FDA to exempt manufacturers from premarket review requirements for up to six years (or longer), the APA required FDA to make any such substantial change through notice and comment procedures, ensuring adequate public input and agency deliberation. FDA's failure to follow that procedural path here resulted in an ill-advised action that will have devastating and substantial public health effects. FDA's violation of the APA's notice and comment requirements thus independently requires vacatur of the Guidance.

6. *Third*, the Guidance is arbitrary and capricious and not the product of reasoned decisionmaking. The 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 United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 48 (1983). In issuing the Guidance, FDA flagrantly breached that obligation. It offered no meaningful justification for ripping a hole in the statutory framework by exempting,

for more than half a decade, newly deemed products from premarket review—review FDA previously described as "central" to the regulatory scheme Congress enacted for tobacco products. Moreover, FDA failed to grapple with, much less reasonably explain, how its decision was warranted in light of previous findings FDA itself had made—such as FDA's determination that its prior, and much shorter, compliance deadlines were sufficient to give industry time to come into compliance. Although an agency may change its mind, it must contemporaneously address prior findings and decisions and explain *why* it is nonetheless changing course. FDA did not comply with that basic responsibility here.

7. Plaintiffs, public health organizations and pediatricians with vital and concrete stakes in seeing the Tobacco Control Act's mandates fully implemented, bring this action under the APA, seeking vacatur of FDA's Guidance and other declaratory and injunctive relief.

PARTIES

8. Plaintiff the American Academy of Pediatrics ("AAP") is a professional membership organization of 66,000 pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists. AAP is incorporated under the laws of Illinois, headquartered in Elk Grove Village, Illinois, and operated exclusively for charitable and educational purposes under section 501(c)(3) of the Internal Revenue Code. 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 and provide counseling to their patients and patients' parents about the health hazards of tobacco use, in an effort to prevent tobacco initiation. AAP expends substantial resources in providing its physician members tools for screening and counseling, including by publishing and distributing a *Clinical Practice Policy to Protect Children from Tobacco, Nicotine, and Tobacco*

Smoke, which describes clinical practice recommendations for screening and counseling. AAP participated extensively in the development and promulgation of the Deeming Rule. In the past, and as described further below, AAP has reviewed and used information about tobacco products contained in FDA marketing orders as part of its advocacy and educational efforts; it would do so further were FDA to engage in statutorily required premarket review of newly deemed tobacco products.

9. Plaintiff the Maryland Chapter – American Academy of Pediatrics ("MDAAP") is a section 501(c)(6) professional membership organization located in Maryland, and is separately incorporated from AAP. Since the inception of MDAAP in 1950, the organization has had a long and distinguished history of advocacy and support of Maryland children and their health care needs. Its mission is to support and encourage pediatricians in the promotion of optimal health for all of Maryland's children and adolescents, as part of MDAAP's commitment to the health and wellbeing of all children. MDAAP initiates and supports numerous programs that respond to the needs of children. Through collaborative and creative programming with other public and private agencies throughout Maryland, MDAAP seeks to be a positive change agent in the lives of children, recognizing the unique role pediatricians can play in primary prevention efforts. For example, MDAAP provides resources and information to pediatrician members through a weekly newsletter and regularly scheduled meetings that are focused on public health issues, including youth tobacco use. MDAAP has also worked closely with other stakeholders to promote legislation that protects children and youth from the hazards of tobacco exposure and tobacco use. MDAAP has recently partnered with NCD Child, a global multi-stakeholder coalition, to champion the rights and needs of children and adolescents who are living with, at risk of developing, or affected by non-communicable diseases—including cancer, cardiovascular

disease, and chronic respiratory diseases. Through this partnership MDAAP will continue to focus on the risks of tobacco use and exposure and their effects on the life course of children.

10. Plaintiff the American Cancer Society Cancer Action Network, Inc. ("ACS CAN") is a nonprofit organization incorporated in the District of Columbia, with its principal place of business in Washington, D.C. Created in 2001, ACS CAN is the nonpartisan advocacy affiliate of the American Cancer Society, a nationwide, community-based voluntary health nonprofit organization. It is incorporated separately under section 501(c)(4) of the Internal Revenue Code. Because smoking is a principal cause of lung and other forms of cancer, ACS CAN has been a leader in educating the public about the dangers of using tobacco products and in advocating for policies and programs to discourage tobacco initiation and encourage cessation. ACS CAN advocates for effective tobacco control at every level of government. It has been an active participant in FDA tobacco regulatory proceedings since FDA was given regulatory authority in 2009, including by filing comments in the rulemaking proceeding that led to FDA's issuance of the Deeming Rule. In the past, and as described further below, ACS CAN has reviewed and used information about tobacco contained in FDA marketing orders as part of its advocacy and educational efforts; it would do so further were FDA to engage in statutorily required premarket review of newly deemed tobacco products.

11. Plaintiff the American Heart Association, Inc. ("AHA") is a 501(c)(3) nonprofit corporation organized under the laws of New York with its principal place of business in Dallas, Texas. AHA works with local health care providers, church leaders, and school administrators to provide education and counseling in hospitals, churches, and schools to help prevent youth initiation of tobacco use and to encourage current tobacco users to quit. This involves contact with individuals about the consequences of tobacco use. One of the principal goals of AHA's

programs is to ensure that the individuals who receive counseling fully understand the consequences of tobacco use.

12. For example, through its multicultural initiatives department, AHA works with historically black colleges and universities as well as churches to ensure that strong tobacco-free policies are in place and to provide tobacco users with the resources they need to quit. Through its "Get With The Guidelines" quality improvement program, AHA seeks to ensure that hospitals are screening for tobacco use among patients and providing cessation resources when needed. In addition, AHA's website provides individuals with a large array of information about the long-term consequences of smoking and strategies to promote cessation. Through these and other efforts, AHA expends substantial resources to help prevent young people from beginning to use tobacco products and to encourage current users to quit. AHA participated extensively in the development and promulgation of the Deeming Rule. In the past, and as described further below, AHA has reviewed and used information about tobacco products contained in FDA marketing orders as part of its advocacy and educational efforts; it would do so further were FDA to engage in statutorily required premarket review of newly deemed tobacco products.

13. Plaintiff the American Lung Association ("ALA") is a 501(c)(3) nonprofit voluntary health organization incorporated in the State of Maine with its principal place of business in Chicago, Illinois. Its mission is to save lives by improving lung health and preventing lung disease. The prevention and cessation of the use of tobacco products is an integral part of this mission. Providing effective assistance to tobacco users who are trying to quit is one of ALA's top priorities. For example, ALA expends substantial resources to support its highly acclaimed Freedom From Smoking® program, which has in-person, online, and telephonic options to help tobacco users quit, including access by telephone to certified tobacco

treatment specialists at ALA's Lung Helpline. Similarly, ALA expends substantial resources to operate a "Not on Tobacco (N-O-T)" program aimed at helping teens quit smoking.

14. Moreover, ALA actively participated in urging FDA to issue the proposed Deeming Rule. In the past, and as described further below, ALA has reviewed and used information about tobacco products contained in FDA marketing orders as part of its advocacy and educational efforts; it would do so further were FDA to engage in statutorily required premarket review of newly deemed tobacco products. Finally, ALA engages in substantial public education efforts, including by producing an annual "State of Tobacco Control Report" that grades all fifty states and the federal government on tobacco control policies.

15. Plaintiff the Campaign for Tobacco-Free Kids ("TFK") is a 501(c)(3) non-profit corporation organized under the laws of the District of Columbia with its principal place of business is Washington, D.C. TFK works to reduce tobacco use and its deadly toll in the United States and around the world. TFK engages in public education about the dangers of cigarettes, as well as advocates public policies and sponsors activities to prevent kids from smoking, to help smokers quit, and to protect everyone from secondhand smoke.

16. Through its youth initiatives, TFK sponsors youth activities to educate young people about the dangers of smoking and to engage them in activities designed to discourage youth from initiating cigarette use and encourage youth smokers to quit smoking. For example, TFK sponsors Kick Butts Day, a national day of activities that engage youth to speak up against the dangers of tobacco use, generating more than 1,000 events across the United States, including many in Maryland. The youth participants plan and conduct events that focus attention on the deadly dangers of tobacco use and urge their peers to be tobacco-free. TFK participated extensively in the development and promulgation of the Deeming Rule. In the past, and as

described further below, TFK has reviewed and used information about tobacco products contained in FDA marketing orders as part of its advocacy and educational efforts. It would do so further were FDA to engage in statutorily required premarket review of newly deemed tobacco products.

17. Plaintiff the Truth Initiative Foundation, d/b/a Truth Initiative ("Truth Initiative") is a 501(c)(3) Delaware corporation created in 1999 out of a 1998 master settlement agreement that resolved litigation brought by 46 states, five U.S. territories, and the District of Columbia against the major U.S. cigarette companies. Headquartered in Washington, D.C., Truth Initiative studies and supports programs in the United States to reduce youth tobacco use and to prevent diseases associated with tobacco use. Its nationally recognized truth® campaign has educated hundreds of millions of young people about the health effects and social costs of tobacco, and through its online smoking cessation intervention, Become an Ex®, Truth Initiative has reached over 700,000 people to date with information to help tobacco users quit.

18. Truth Initiative also conducts youth activism programs to educate low-income, minority, and LGBTQ youth about the health risks of tobacco and to encourage them to take an active role in helping their communities become tobacco-free. Truth Initiative participated extensively in the development and promulgation of the Deeming Rule. In the past, and as described further below, Truth Initiative has reviewed and used information about tobacco products contained in FDA marketing orders as part of its advocacy and educational efforts; it would do so further were FDA to engage in statutorily required premarket review of newly deemed tobacco products.

19. Plaintiff Dr. Leah Brasch is a Clinical Associate Professor at George Washington Medical School and a practicing pediatrician at Friendship Pediatrics, located in Montgomery

County, Maryland. Dr. Brasch is a member of AAP, is active in the Montgomery-PG County Pediatric Society, and previously served as president of the Montgomery County Pediatric Society. Dr. Brasch resides in Montgomery County, Maryland.

20. Plaintiff Dr. Cynthia Fishman is a practicing pediatrician at Children First Pediatrics, located in Montgomery County, Maryland. Dr. Fishman is a member of AAP and the Montgomery County Medical Society. Dr. Fishman resides in Montgomery County, Maryland.

21. Plaintiff Dr. Linda Goldstein is a Clinical Associate Professor at George Washington Medical School and a practicing pediatrician at Friendship Pediatrics, located in Montgomery County, Maryland. Dr. Goldstein is a member of AAP, is active in the Montgomery-PG County Pediatric Society, and previously served as president of the Montgomery County Pediatric Society and vice president of the board of directors of the Children's National Health Network. Dr. Goldstein resides in Washington, D.C..

22. Plaintiff Dr. Steven Hirsch is an Assistant Clinical Professor of Pediatrics at Georgetown University and the George Washington University, a practicing pediatrician, and the founder of Hirsch Pediatrics, located in Montgomery County, Maryland. Dr. Hirsch is a member of AAP, sits on the board of directors of the Children's National Health Network, and previously served as president of the Montgomery County Pediatric Society. Dr. Hirsch resides in Montgomery County, Maryland.

23. Plaintiff Dr. David Myles is a practicing pediatrician at Holy Cross Germantown Hospital in Montgomery County, Maryland. Dr. Myles is a member of AAP and the Montgomery County Medical Society, and currently sits on AAP's Committee on State Government Affairs. Dr. Myles resides in Montgomery County, Maryland.

24. Plaintiffs Drs. Brasch, Fishman, Goldstein, Hirsch, and Myles (together the "Pediatrician Plaintiffs") are members of MDAAP and AAP, described above. As part of their regular professional practice, the Pediatrician Plaintiffs provide medical care and advice to patients from infancy through college age, as well as medical advice to patients' parents. The Pediatrician Plaintiffs actively screen their patients for use of tobacco products and provide counseling to their patients and patients' parents about the health hazards of tobacco and nicotine use, in an effort to prevent tobacco initiation. They also provide counseling and resources, when necessary, to help in tobacco cessation efforts. In providing these services, the Pediatrician Plaintiffs rely on information provided by the organizations described above, among others.

25. Defendant the Food and Drug Administration is an agency of the United States government within the Department of Health and Human Services, with an office at 10903 New Hampshire Ave., Silver Spring, MD 20993. The Secretary of Health and Human Services has delegated to FDA the authority to administer the relevant provisions of the Tobacco Control Act, 21 U.S.C. §§ 387a, 387a–1.

26. Defendant Scott Gottlieb is Commissioner of Food and Drugs and is the senior official of FDA. He is sued in his official capacity. Dr. Gottlieb maintains an office at 10903 New Hampshire Ave., Silver Spring, MD 20993.

27. Defendant Department of Health and Human Services is an agency of the United States government with an office at 200 Independence Ave. SW, Washington, D.C. 20201.

28. Defendant Alex M. Azar II is Secretary of Health and Human Services and is the official charged by law with administering the Tobacco Control Act. He is sued in his official capacity. Secretary Azar maintains an office at 200 Independence Ave. SW, Washington, D.C. 20201.

JURISDICTION AND VENUE

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

30. The Guidance issued by FDA in August 2017 is final agency action for which there is no other adequate remedy in a court. 5 U.S.C. § 704. It marks the consummation of the agency's decisionmaking process with respect to the compliance regime applicable to newly deemed tobacco products, and it has direct and appreciable legal consequences.

31. Venue is proper under 28 U.S.C. § 1391(e)(1). Defendant FDA and Defendant Gottlieb have headquarters and reside in this district. Four of the Pediatrician Plaintiffs reside in this district. Moreover, a substantial part of the events or omissions giving rise to this action occurred in this district. Assignment is proper in the Southern Division because a majority of Maryland residents who are parties to this action reside in that division. D. Md. Local R. 501(b)(ii).

STANDING

32. Plaintiffs having standing to bring these claims. Plaintiffs are seven public health organizations dedicated to combating tobacco use and the diseases it causes (together, the "Public Health Organization Plaintiffs") and five individual pediatricians who counsel young people about the health effects of tobacco products and treat the conditions, including nicotine dependence, resulting from tobacco use. Plaintiffs have standing to bring this action on behalf of themselves as well as, in the case of MDAAP and AAP, their members.

33. The Guidance perceptibly impairs the Public Health Organization Plaintiffs' ability to carry out their missions and otherwise injures them in at least two respects.

34. ***First***, FDA's categorical exemption of newly deemed tobacco products from statutorily mandated premarket review for multiple years deprives the Public Health Organization Plaintiffs of access to vital information they rely on (and would rely on) to educate the public about the use of tobacco products and to press for regulatory actions with respect to those products.

35. As structured by Congress, the Tobacco Control Act's premarket review process requires manufacturers to submit substantial information and data about newly deemed products to FDA. *See, e.g.*, 21 U.S.C. § 387j(b). After reviewing a premarket tobacco application, FDA must issue an order approving or denying the application and setting forth the basis for its determination. *See, e.g.*, *id.* § 387j(c)(1)(A). FDA's decision, including a summary of its findings, must then be made publicly available. *See, e.g.*, FDA, Marketing Orders for PMTA, https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/PremarketTobaccoApplications/ucm472108.htm; 21 C.F.R. § 20.20(b); *cf.* 21 C.F.R. § 814.9 (mandating public disclosure of premarket approval information for medical devices). These orders provide a wealth of scientific and other data and information about newly deemed tobacco products to Plaintiffs. In the past, various Plaintiffs have reviewed and used this information to advocate for tobacco product standards and to advise the public on the health risks (or benefits) associated with the product's use, and they would do so further were FDA not abdicating its statutory responsibilities.

36. For example, various Public Health Organization Plaintiffs have recently used information disclosed by FDA as a result of the premarket review process with respect to smokeless tobacco. In November 2015, FDA issued an order authorizing the marketing of eight smokeless tobacco products by Swedish Match North America, Inc. In that order, FDA found

that these products exposed users to significantly lower cancer risks than other smokeless products on the U.S. market. In February 2016, Plaintiffs TFK and Truth Initiative used that information to urge FDA to establish a product standard reducing certain carcinogens in smokeless tobacco products. And in January and July 2017, AAP, ACS CAN, AHA, ALA, TFK, and Truth Initiative again relied on FDA's disclosures in the Swedish Match order in comments they submitted in support of a proposed rule mandating reduction in the carcinogen N-nitrosonornicotine in smokeless tobacco. Plaintiff TFK also issued press releases using FDA's disclosures in the Swedish Match marketing order to educate the public about the relative risk of these smokeless products and the need for a product standard reducing this carcinogen in all smokeless tobacco products.

37. Absent statutorily mandated premarket review of newly deemed tobacco products, the Public Health Organization Plaintiffs lack access to similar scientific or other information about these products that FDA would otherwise make publicly available through its marketing orders. This denial of information is no small matter. Not only do Plaintiffs themselves view educating the public about the health effects of tobacco products as central to their missions, but the public, too, looks to and relies on various Plaintiffs to fill that critical role.[2] By depriving Plaintiffs of FDA marketing orders—an important source of information about newly deemed products—the Guidance impedes Plaintiffs' ability to carry out this vital function.

38. Given the regulatory vacuum created by the Guidance, many of the Public Health Organization Plaintiffs are compelled to conduct their own studies or otherwise evaluate the

[2] *See, e.g.*, D. Vallone et al., *The Effect of Branding to Promote Healthy Behavior: Reducing Tobacco Use Among Youth and Young Adults*, 14 Int. J. Environ. Res. Public Health 1517, 1520 (2017) (demonstrating high levels of public trust in Plaintiff Truth Initiative's truth® campaign), *available at* www.mdpi.com/1660-4601/14/12/1517/pdf.

dangers of newly deemed tobacco products. *See, e.g.*, Truth Initiative, Latest Research: Tobacco Products, https://truthinitiative.org/research/tobacco-products. But given the sheer number and wide variety of products in an unregulated market—which contains hundreds of cigar products and thousands of e-cigarette products—FDA's failure to perform premarket review makes it far more difficult and costly to evaluate the health risks of newly deemed products. In that way as well, the Guidance directly impairs Plaintiffs' efforts to use research-based information to educate the public about the relative health dangers of tobacco products, to advocate for product standards, and to seek regulatory action with respect to especially harmful products.

39. For example, were FDA to engage in premarket review of newly deemed products, as the statute requires, many of the Public Health Organization Plaintiffs would use information about products for which marketing orders had been granted to educate consumers about which products (if any) might assist in reducing addiction. It may be that, for adults, certain e-cigarette products are less dangerous or more effective than others in enabling smokers to quit using cigarettes completely. However, in the absence of premarket review, there is little incentive for manufacturers to conduct well-conceived, independently reviewed studies of e-cigarettes under conditions of actual use—studies that would enable Plaintiffs to educate the public, including existing users, about which products (if any) are most effective in helping adult users quit using cigarettes. Premarket review gives companies an incentive to perform the research to demonstrate that their product facilitates smoking cessation, and to present that science to FDA and the public. Plaintiffs are deprived of the ability to educate the public regarding these important public health matters because of FDA's unlawful refusal to implement the clear statutory requirement for premarket review.

40. The Guidance accordingly will hinder the development of the science needed to understand and educate the public about which products actually do promote smoking cessation and how they can be marketed without exposing young people to unnecessary risk. Premarket review requires manufacturers to develop and submit to FDA their best available data and other information on the individual and population-wide effects of their products. Much of that information may be unavailable to FDA or others absent premarket review. The absence of premarket review thus directly slows and impedes the development of the science needed to understand fully and explain the health effects of newly deemed tobacco products—information critical to Plaintiffs' missions.

41. In addition, FDA's failure to exercise its statutorily mandated oversight role requires many of the Public Health Organization Plaintiffs to dedicate time and resources to monitor the marketplace for dangerous tobacco products, particularly those targeted at children and teenagers. As just one example, ALA—based on its own monitoring of the tobacco product marketplace—has filed a complaint with FDA based on an "Apple Juice" e-cigarette product:

Were FDA performing its premarket review responsibilities, Plaintiffs themselves would not be compelled to expend the same level of resources to monitor the marketplace for newly deemed tobacco products aimed at children. Moreover, were FDA performing its premarket review responsibilities, Plaintiffs would have an additional source of information to use in filing administrative or other complaints to protect the public health.

42. ***Second***, the Guidance perceptibly impairs the Public Health Organization Plaintiffs' ability to carry out their missions because it requires those Plaintiffs to spend substantial resources to counter the effects of FDA's decision to exempt, for years, manufacturers of newly deemed products from statutory premarket approval requirements. In performing their counseling and education functions, Plaintiffs must confront widespread public confusion, acknowledged by FDA, about the health consequences of using newly deemed tobacco products, and particularly e-cigarettes, and the ability of e-cigarettes to enable smokers to quit smoking completely. The Guidance prolongs and compounds this confusion, and requires many Plaintiffs to engage in additional public education efforts and dedicate substantial additional resources to address the confusion caused by the absence of regulatory oversight.

43. Were FDA to perform its statutory responsibilities, its premarket review should remove from the commercial marketplace those tobacco products that pose the greatest public health risks, particularly those targeted at children and teenagers. Moreover, premarket review would create substantial incentives for manufacturers to market and sell products that are capable of meeting FDA's requirements and that are not targeted at children and teenagers. Postponing premarket review prolongs the period during which regulators, consumers, and public health professionals are all denied the basic facts needed to make informed judgments—facts that would become known through statutory compliance. Enforcing premarket review would thus

necessarily reduce the scope of the obstacles and challenges many of the Public Health Organization Plaintiffs confront in counseling and educating the public about newly deemed tobacco products.

44. Absent premarket review, many of the Public Health Organization Plaintiffs must now dedicate, as a result of the Guidance, substantial additional resources to their efforts to counter the deleterious effects of an unregulated marketplace. Put simply, it is far more difficult and resource-intensive for many Plaintiffs to advise the public about the health risks of hundreds or thousands of different products when FDA, by declining to require premarket review, does not make specific information about each of those products available to Plaintiffs, and when manufacturers will face no oversight, for years, in marketing and selling the unhealthiest and most addictive products in ways that appeal to children and teenagers. By design, premarket review limits the presence of such products on the market and creates incentives for manufacturers to develop and market products that reduce public health harms and to jettison products that are more dangerous and likely to attract children and teenagers. *Cf.* 81 Fed. Reg. at 28,983 ("FDA believes the employment of the premarket authorities could create incentives for producers to develop products that are less dangerous when consumed, less likely to lead to initiation of tobacco use, and/or easier to quit."). Premarket review would thus decrease the resources Plaintiffs currently need to dedicate to their tobacco prevention and cessation efforts. Conversely, by exempting manufacturers of newly deemed tobacco products from premarket review requirements, the Guidance leaves young people unprotected from even the most irresponsibly manufactured and marketed products, expanding the work many Plaintiffs must perform with limited resources and impairing their ability to carry out their missions.

45. Indeed, due to the proliferation of previously unregulated tobacco products and their continued marketing especially to youth, the need for tobacco prevention and cessation efforts is more important and more difficult than ever and places added demands on many Public Health Organization Plaintiffs' constrained resources. For example, so long as FDA continues to abdicate its premarket review duties—an indefinite prospect under the Guidance—many Plaintiffs must themselves dedicate significant resources to studying the dangers presented by newly deemed tobacco products to carry out their public-education functions. *See, e.g.*, Truth Initiative, Latest Research: Tobacco Products, https://truthinitiative.org/research/tobacco-products; American Lung Association, Popcorn Lung: A Dangerous Risk of Flavored E-Cigarettes (last updated Aug. 9, 2016), http://www.lung.org/about-us/blog/2016/07/popcorn-lung-risk-ecigs.html?referrer=https://www.google.com.

46. Were FDA performing its premarket review responsibilities, as required by Congress, those Public Health Organization Plaintiffs could instead direct those resources to other policy and intervention efforts. In particular, if FDA, after reviewing application materials for a newly deemed product, issued a marketing order, the findings contained in that order could obviate the need for Plaintiffs to conduct their own studies or, at the very least, expedite Plaintiffs' independent analyses; and if FDA denied the marketing application, there would be no reason for Plaintiffs to undertake their own research, for the product in question would not be permitted on the market.

47. Each of these direct consequences of the Guidance demonstrates a concrete and particularized injury to the Public Health Organization Plaintiffs' daily operations and public health missions that is sufficient for purposes of organizational standing.

48. In addition to organizational standing, AAP and MDAAP have independent standing to sue on behalf of their members. AAP and MDAAP represent pediatricians across Maryland and the nation who counsel, advise, and treat patients (sometimes on a daily basis) regarding tobacco use, e-cigarettes, and cigars, as well as smoking cessation, and whose practice of medicine is directly undermined by the Guidance. For many of AAP's and MDAAP's members, the Guidance makes it more difficult, time-consuming, and resource-intensive to counsel, advise, and treat patients by, among other things, (i) depriving pediatricians of access to valuable information that would be used in counseling, advising, and treating patients and (ii) fostering public confusion regarding newly deemed tobacco products.

49. The Pediatrician Plaintiffs have independent standing to sue in their own right. The Pediatrician Plaintiffs—who are also members of AAP and MDAAP—routinely discuss tobacco use with their patients, and those talks are informed by information disseminated by FDA, among others. FDA's failure to carry out its premarket review responsibilities directly injures the Pediatrician Plaintiffs and other members of MDAAP and AAP. The Guidance deprives the Pediatrician Plaintiffs of important information—information provided to them by MDAAP, AAP, or otherwise—about the characteristics and health effects of newly deemed tobacco products. Such information would be very useful to the Pediatrician Plaintiffs' efforts to counsel their patients about the health hazards of tobacco use to prevent tobacco initiation or, when necessary, to promote cessation. Such information would also enable the Pediatrician Plaintiffs to offer more accurate medical advice and counseling, including about which newly deemed tobacco products carry the greatest health risks and which—if it could be provided in premarket product applications—might facilitate smoking cessation.

50. Conversely, depriving the Pediatrician Plaintiffs of access to that information makes it more difficult and time-consuming to counsel or treat patients or to advise their parents regarding the health effects of e-cigarettes and other newly deemed tobacco products. Relatedly, by depriving the public of access to information about newly deemed tobacco products, the Guidance makes it more difficult and time-consuming for the Pediatrician Plaintiffs to treat and counsel patients because patients are less receptive or responsive to counseling.

51. In these ways, the Guidance—by allowing the proliferation of newly deemed tobacco products to continue unchecked, and by denying the Pediatrician Plaintiffs and the public information that would be provided by the premarket review process—the Guidance interferes with and undermines the Pediatrician Plaintiffs' ability to counsel and treat their patients, making it more difficult to provide the highest level of medical care to their patients.

STATUTORY AND REGULATORY BACKGROUND

I. THE TOBACCO CONTROL ACT

52. Congress enacted the Tobacco Control Act in 2009. Recognizing the extraordinary public health risks posed by the use of 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." Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2(6), (12), 123 Stat. 1776, 1777 (2009).

53. The Tobacco Control Act amended the Food, Drug, and Cosmetic Act ("the FD&C Act" or "the 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. Among other things, the Tobacco Control Act empowered FDA to set national standards governing the manufacture of tobacco products, to limit levels of harmful

components in tobacco products, and to require manufacturers to disclose information and research relating to the products' health effects. *See generally id.* § 3, 123 Stat. at 1782.

54. To achieve its public health objectives, Congress authorized FDA to regulate not only "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," but also "any other tobacco products that the Secretary [of FDA] by regulation deems to be subject" to the FD&C Act. 21 U.S.C. § 387a(b). The Tobacco Control Act's requirements apply equally to congressionally enumerated tobacco products and those products "deem[ed]" subject to the Act by FDA. *Id.* FDA's deeming authority was operative immediately when the statute took effect.

55. A central requirement of the Tobacco Control Act is premarket review of all 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. 21 U.S.C. § 387j(a)(1)-(2). With a single exception described below, premarket authorization is therefore required for any "deem[ed]" tobacco product that was commercially unavailable as of February 15, 2007. *Id.* §§ 387a(b), 387j.

56. The Tobacco Control Act establishes three pathways to premarket authorization.

57. *Premarket tobacco application*. A manufacturer may submit for FDA review a premarket tobacco application, or "PMTA." 21 U.S.C. § 387j(b) (listing PMTA requirements). If the agency determines, among other things, that "permitting such tobacco product to be marketed would be appropriate for the protection of the public health," *id.* § 387j(c)(2)(A), it may issue a new product order authorizing the product to enter the marketplace, *id.* § 387j(c)(1)(A)(i). FDA must issue such an order, or an order denying the PMTA, within 180 days of receiving the application. *Id.* § 387j(c)(1)(A). If a manufacturer proceeds to sell a new

tobacco product without obtaining a new product order—and without satisfying one of the statute's two alternative pathways to legal distribution—the product "shall be deemed to be adulterated," *id.* § 387b(6), and is therefore subject to seizure and injunctive action, *id.* §§ 331(a), 332, 334, 372.

58. *Substantial equivalence report*. Alternatively, a manufacturer may submit a substantial equivalence report, or "SE Report," demonstrating that the new tobacco product is "substantially equivalent" to a grandfathered product—that is, a product on the market as of February 15, 2007. 21 U.S.C. §§ 387e(j)(1), 387j(a)(3). If FDA determines that the new product is in fact substantially equivalent to a predicate product and otherwise "in compliance with the requirements of [the FD&C Act]," the agency may issue an order to that effect, and the new product may enter the market. *Id.* § 387j(a)(2)(A)(i). SE Reports must be submitted to FDA at least 90 days before the manufacturer begins to distribute the new product. *Id.* § 387e(j)(1).

59. *Substantial equivalence exemption*. Finally, in certain circumstances, a manufacturer may request an exemption from the substantial equivalence requirements, or an "SE Exemption." 21 U.S.C. § 387e(j)(3) (outlining narrow exemption for products that, among other things, constitute only "minor modification[s]" of grandfathered products). If FDA issues an order authorizing an SE exemption, the new product may proceed to market. *Id.* § 387j(a)(2)(A)(ii).

60. In the Tobacco Control Act, Congress created a single exception to this premarket review regime—for products (1) commercially marketed in the United States after February 15, 2007 but within "21 months after" the date of enactment of the Tobacco Control Act, that is, by March 22, 2011, and (2) for which an SE report was submitted within that 21-month period. 21 U.S.C. §§ 387j(a)(2)(B), 387e(j)(2). Products meeting both of these requirements could continue

to be marketed unless and until FDA denied the substantial equivalence application. No other "new tobacco products" can be marketed until FDA has found that the product is (1) "appropriate for the protection of the public health" upon review of a PMTA, *id.* § 387j(c)(2)(A); (2) substantially equivalent to a grandfathered product; or (3) exempt from SE requirements, *id.* § 387j(a). In view of these statutory provisions, had FDA exercised its deeming authority promptly after passage of the Tobacco Control Act, newly deemed tobacco products would have benefited from that 21-month grace period.

61. Congress gave FDA no authority to modify either the February 2007 date for grandfathered products or the requirement that all new tobacco products obtain an FDA marketing order via one of the three authorized pathways (PMTA, SE Report, or SE Exemption) before entering the U.S. market.

II. THE PROPOSED RULEMAKING

62. In April 2014, FDA proposed a rule to deem certain unregulated tobacco products—including e-cigarettes, cigars, and pipe tobacco—to be subject to the FD&C Act, and in turn, to FDA oversight. *See* 79 Fed. Reg. 23,142 (Apr. 25, 2014); 21 U.S.C. § 387a(b). The agency explained that it was taking such action "to address the public health concerns associated with the use" of these products. 79 Fed. Reg. at 23,142

63. Consistent with the Tobacco Control Act, FDA recognized that new tobacco products "deemed" under a final rule would thereby become subject to the statute's premarket review requirements. The agency explained that premarket review "improve[s] the public health" by, among other things, "preventing new products from entering the market if they are not appropriate for the protection of public health or found substantially equivalent to an identified predicate product." 79 Fed. Reg. at 23,143.

64. In its proposed rulemaking, FDA acknowledged that Congress provided only "three pathways for legally marketing a new tobacco product"—PMTA, SE Report, and SE Exemption—and explained that, under the statute, "most proposed deemed tobacco products would be considered new tobacco products and would be required to obtain an order from FDA prior to marketing under one of the three pathways." 79 Fed. Reg. at 23,174.

65. Despite those statutory requirements, FDA proposed a 24-month "compliance policy" for manufacturers of deemed products to submit marketing applications of any kind, during which time, the agency stated, newly deemed products already for sale in the United States could remain on the market. 79 Fed. Reg. at 23,174; *see also id.* at 23,175-23,176 (explaining that manufacturers would have 24 months after the effective date of a final rule to submit PMTAs, SE Reports, and SE Exemption requests).

66. FDA offered no explanation of its statutory authority to adopt this "compliance policy." However, according to FDA, its proposed compliance regime was "similar to" the narrow carveout created by Congress exclusively for tobacco products brought to market after February 15, 2007, but within 21 months after the date of the statute's enactment. 79 Fed. Reg. at 23,174-23,176. Because Congress had permitted this small and defined class of products to remain on the market so long as the manufacturer had submitted a successful SE application during the 21-month period, 21 U.S.C. §§ 387j(a)(2)(B), 387e(j)(2), FDA apparently believed that it too could create an exemption from the statute's premarket requirements—and a broader one at that, persisting for 24 months, encompassing all deemed products brought to market since the end of the 21-month grace period, and covering all types of marketing applications.

67. In addition to the 24-month submission window, FDA proposed extending the compliance policy indefinitely "pending [agency] review of marketing applications," as long as

applications were received within 24 months of the final rule's promulgation. 79 Fed. Reg. at 23,174. Thus, under the proposed rule, products for which applications were submitted during that compliance period could remain on the market without a marketing order unless and until FDA denied the application. As it did with the proposed rule generally, FDA solicited comments on its proposed compliance regime, explaining that it would revise its policy "should the Agency find that doing so is warranted … to better protect the public health." *Id.* at 23,177.

III. COMMENTS SUBMITTED IN RESPONSE TO THE PROPOSED RULEMAKING

68. FDA received numerous comments on the proposed rule generally, the costs and benefits of regulating e-cigarettes, cigars, and pipe tobacco under the Tobacco Control Act, and its proposed compliance regime. *See* Dkt. ID FDA-2014-N-0189.[3]

69. For example, the Public Health Organization Plaintiffs here joined in comments explaining why "[t]he deeming of all tobacco products as subject to FDA's regulatory authority is critical to protecting the public health against the risks posed by an increasingly dynamic and diverse marketplace in tobacco products and ensuring continued, and accelerated, progress toward eliminating tobacco-related disease and death." Comment No. FDA-2014-N-0189-79772, at 4 ("Public Health Groups Cmt."). Plaintiffs explained that "[p]remarket review is an essential authority under the Tobacco Control Act. Prior to the Act, there was no limitation on the introduction of new products or the modification of existing tobacco products. As a result, in the absence of regulation manufacturers continually introduced new products that were more addictive, more lethal, and more appealing to kids." *Id.* at 58. Plaintiffs stressed that "unless manufacturers are required to comply with these [premarket review] provisions," "FDA cannot protect the public health," as the statute requires. *Id.*

[3] Comments are available at https://www.regulations.gov/docket?D=FDA-2014-N-0189.

70. Many stakeholders criticized FDA's 24-month submission period as contrary to the Tobacco Control Act's premarket review requirements and, in any event, longer than necessary for manufacturers to prepare marketing applications. The Tobacco Control Legal Consortium, for example, stated that FDA's proposal would create a dangerous "loophole in the premarket review process" and "seriously diminish the potential benefits to public health that would result" from the proposed rule. Comment No. FDA-2014-N-0189-81044, at 40-45.

71. The Public Health Organization Plaintiffs' comments also addressed FDA's proposed "compliance policy." Plaintiffs explained that "[t]he policy of the statute is to require premarket authorization for the marketing of new tobacco products," a requirement reflecting that "over the course of many decades the introduction of new tobacco products has been detrimental to public health." Public Health Groups Cmt. 61. They further stated that FDA's approach would "prolong[] the public's exposure to products that contain nicotine, a highly addictive substance, and that do not meet the statutory standard for the grant of a marketing order." *Id.* at 61. They added that FDA's proposed approach would effectively "permit deemed products" to be marketed that "would otherwise be illegal." *Id.* at 62. Were the agency to take such an extraordinary step, Plaintiffs argued, it must do so only after imposing restrictions to help safeguard the public health—the extension should be no more than 12 months; marketing during that time should be conditioned on ensuring a "product is not being manufactured or marketed in ways that appeal to minors"; and FDA should ensure that products do not remain on the market for "unreasonably long" periods of time pending review. *Id.*

72. The Public Health Organization Plaintiffs and others also strongly objected to FDA's proposed indefinite compliance period pending agency review of premarket applications. That approach, Plaintiffs explained, would mean that "[m]anufacturers, knowing that submission

of an application—however incomplete or deficient—will permit them to market products for years, have every incentive to file as many applications as possible." Public Health Groups Cmt. 67; *see id.* at 66-67. Similarly, the Tobacco Control Legal Consortium observed that a shortened submission window and limited period for FDA review would give manufacturers "an incentive to generate high-quality, complete reports as quickly as possible." Comment No. FDA-2014-N-0189-81044, at 48; *see also id.* at 35, 42-43 (noting that initial 21-month grace period created by Congress was "for the creation, staffing, and training of a previously non-existent FDA center" and explaining that the grace period has been exploited by manufacturers).

73. Tobacco product manufacturers, by contrast, sought a wholesale exemption from Congress's premarket review mandate, lengthier "compliance periods," and different application requirements for different product categories. The American E-Liquid Manufacturing Standards Association, for example, stated that FDA should "allow deemed tobacco products that were on the market as of the NPRM publication date (*i.e.*, April 25, 2014) to remain on the market" indefinitely without submitting any type of marketing application. Comment No. FDA-2014-N-0189-10852, at 25. RAIS, a subsidiary of Reynolds American Inc., urged FDA to extend the proposed PMTA deadline for "at least five years after the regulation's effective date." Comment No. FDA-2014-N-0189-79096, at 26; *see also* Comment No. FDA-2014-N-0189-81859, at 8-11.

IV. THE FINAL DEEMING RULE

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

75. As relevant here, FDA deemed e-cigarettes, cigars, and pipe tobacco to be "tobacco products" subject to the Tobacco Control Act. FDA supported its deeming determination with detailed findings regarding the health risks of newly deemed products as well as the crucial need for regulatory oversight, including premarket review.

76. 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.*

77. Furthermore, FDA made express findings that "tobacco products unregulated by FDA are widely available and come in many forms," 81 Fed. Reg. at 28,982, and that there had been a "dramatic rise in youth and young adult use of tobacco products such as e-cigarettes and waterpipe tobacco, and continued youth and young adult use of cigars," *id.* at 28,984. FDA thus concluded that "regulation of the newly deemed products will be beneficial to public health." *Id.* at 28,983. "[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.*

78. Premarket review, FDA explained, is a critical part of this regulatory regime because, among other things, "employment of the premarket authorities could create incentives for producers to develop products that are less dangerous when consumed, less likely to lead to initiation of tobacco use, and/or easier to quit." 81 Fed. Reg. at 28,983. In addition, FDA found "premarket review … will increase product consistency"; absent such consistency, "variability in nicotine content among products" would "rais[e] potential public health and safety issues." *Id.* at 28,983-28,984. Moreover, FDA reasoned, "[i]mplementation of the premarket review

requirements … will allow FDA to monitor product development and changes and to prevent more harmful or addictive products from reaching the market." *Id.*

79. In addition, in light of the comments outlined above, FDA announced a revised compliance policy. Abandoning its proposed approach of an across-the-board 24-month submission window in favor of "staggered initial compliance periods based on the expected complexity of the applications," 81 Fed. Reg. at 29,010, FDA maintained a 24-month deadline only for PMTAs. Compliance periods for SE Reports and SE Exemption requests were reduced to 18 and 12 months, respectively. *Id.* at 29,011; *see also id.* at 29,010 (recognizing that "the time it takes to prepare premarket applications is dependent upon the type of application and complexity of the product"). Staggered timelines based on product type are not appropriate, FDA determined, because of the "uncertainty regarding the positive or negative impact on public health from products likes [e-cigarettes]." *Id.* at 29,010. The new compliance regime applied to all products on the market as of the Rule's effective date, August 8, 2016.

80. Although FDA failed to explain the legal authority for extending "compliance deadlines" under the statute, FDA did offer substantial explanations for why it structured its compliance approach the way it did. FDA explained, for example, that although "many industry comments sought additional time to comply with [premarket] requirements," the agency had determined that the chosen compliance periods were "sufficient to allow manufacturers of previously unregulated tobacco products to submit applications," particularly given FDA's many "steps to provide helpful feedback to industry to encourage more complete, streamlined submissions and reviews." 81 Fed. Reg. at 29,012 (detailing FDA's assistance to industry, including publishing guidance documents, streamlining the SE process, and facilitating teleconferences between FDA project managers and applicants).

81. FDA also modified the agency's proposed compliance approach governing the marketing of the newly deemed products during the period FDA was considering the applications. Informed by the concerns of the Public Health Organization Plaintiffs and others regarding the dangers of an indefinite presumption of compliance pending review, FDA announced that "products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months" only. 81 Fed. Reg. at 29,011. After that, FDA advised, the agency "may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period." *Id.* at 29,010.

82. This revised compliance regime, FDA stated, "aims to balance the public health concerns raised in the comments, allow [FDA] to more efficiently manage the flow of incoming applications, and encourage high-quality premarket submissions from applicants." 81 Fed. Reg. at 29,010. And while FDA acknowledged that "a new tobacco product may be legally marketed [under the Tobacco Control Act] only if FDA has authorized its marketing under one of the three premarket pathways," FDA stated that, "[a]s a result of the compliance policy being announced," manufacturers of "newly deemed, new tobacco products will continue to market their products without FDA authorization." *Id.*

V. SUBSEQUENT DEVELOPMENTS AND THE AUGUST 2017 GUIDANCE

83. The Deeming Rule became effective on August 8, 2016.

84. On May 15, 2017, several months after the change in presidential administration, FDA advised that it was extending by three months all "effective dates and compliance deadlines for requirements under the [deeming] rule." 82 Fed. Reg. 22,338, 22,340 (May 15, 2017). FDA also sought to stay litigation in pending judicial challenges to the Deeming Rule.

85. Three months later, on August 10, 2017, FDA announced a new and greatly expanded "extension" applying "only to compliance deadlines relating to premarket review requirements," in the form of the challenged "Guidance." Guidance 3; *see also* 82 Fed. Reg. 37,459 (Aug. 10, 2017). FDA issued the new Guidance "without prior public comment," asserting that public participation was "not feasible or appropriate." 82 Fed. Reg. at 37,460.

86. The Guidance applies broadly to "all categories of newly regulated products that were on the market on August 8, 2016, including ENDS (e.g., e-cigarettes and e-cigars), hookah, pipe tobacco, and cigars." Guidance 3. The Guidance amends FDA's prior approach as well as statutory premarket review requirements in significant and substantive ways.

87. *First*, the Guidance dramatically extends the submission period for premarket applications, effectively rewriting the statute to exempt tobacco product manufacturers from the premarket authorization mandate for up to six years from the date of the Deeming Rule. Under FDA's prior approach, SE Exemption requests were due on August 8, 2017 (12 months after the rule's effective date); SE Reports were due on February 8, 2018 (18 months after the rule's effective date); and PMTAs were due on August 8, 2018 (24 months after the rule's effective date). The deadline for combustible product applications of any kind is now August 8, 2021—60 months from the Deeming Rule's effective date. The deadline for all noncombustible product applications is pushed off even further, 72 months, until August 8, 2022. *See* Guidance 3, 8.

88. *Second*, the Guidance "revis[es] the compliance policy relating to the period after FDA receipt" of product applications. Guidance 3. In the Deeming Rule, FDA carefully considered and rejected the indefinite compliance policy it had initially proposed in response to compelling concerns raised by commenters, instead establishing a 12-month compliance period for FDA review. The Guidance reverts to the previously rejected approach. *Id.* ("Under this

new compliance policy, there will be a continued compliance period pending review of [marketing] applications … [t]his compliance period will continue until the agency renders a decision on an application … or the application is withdrawn.").

89. Under the Guidance, an unapproved product can stay on the market indefinitely, potentially for years past the unexplained 2021 and 2022 deadlines. Indeed, the indefinite compliance approach essentially guarantees that Congress's mandate that unapproved products be removed from the market will remain thwarted well past 2021 and 2022. As commenters previously explained, it will create incentives for many manufacturers to wait until the deadline arrives to submit their PMTA applications, SE Reports, or SE Exemption requests, so that their products can remain on the market as long as possible in the event that their application is ultimately rejected. The Guidance offers no rationale for this about-face and no explanation of how it can be squared with the statute's plain text.

90. *Third*, instead of staggering submission deadlines based on *application* type (that is, PMTA, SE Report, or SE Exemption request), the Guidance now staggers compliance deadlines based on *product* type, setting different deadlines for combustible and noncombustible tobacco products. All types of marketing applications (PMTAs, SE Reports, and SE Exemption requests) for combustible products now share a single "compliance deadline," as do all types of marketing applications for noncombustible products. Guidance 3, 8. FDA does not acknowledge, much less explain, this changed approach.

91. In addition to offering no explanation for the agency's radical policy shift, the Guidance does not even attempt to explain how FDA is authorized under the Tobacco Control Act to approve conduct Congress has plainly made unlawful—namely, the distribution of newly deemed tobacco products without premarket authorization. As the Guidance makes clear, but

nowhere justifies, FDA has expressly and deliberately abdicated its statutory duties under the Tobacco Control Act for up to six years, and likely much longer.

COUNT ONE
(Tobacco Control Act, 21 U.S.C. § 387j; Administrative Procedure Act, 5 U.S.C. § 706; U.S. Const. art. II, § 3)

THE GUIDANCE IS ULTRA VIRES AND UNCONSTITUTIONAL

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

93. As a federal agency, FDA has no power to act unless and until Congress confers that power, and actions that are unauthorized by Congress or inconsistent with congressional direction are ultra vires and must be set aside. *See* 5 U.S.C. § 706(2)(A), (C).

94. In purporting to exempt manufacturers of newly deemed tobacco products from statutory premarket approval requirements for up to six years (and indefinitely beyond that), the Guidance conflicts with the Tobacco Control Act; exceeds FDA's statutory authority; and violates the Constitution's Take Care clause, U.S. Const. art. II, § 3.

95. Under the Tobacco Control Act, before any new tobacco product may enter the market, the manufacturer must demonstrate that its product is "appropriate for the protection of the public health," substantially equivalent to a grandfathered product, or exempt from SE requirements. 21 U.S.C. § 387j(a). Congress thus made clear that, absent an SE Report or SE Exemption request, a premarket approval order "for a new tobacco product is *required*." *Id.* § 387j(a)(2)(A) (emphasis added).

96. FDA has repeatedly acknowledged as much. For example, in responding to a manufacturer's argument that FDA should forego premarket review for newly deemed tobacco products, FDA explained that "Congress carefully crafted a system whereby 'new' tobacco products would be prevented from entering the market unless found" to have satisfied one of the three pathways to legal distribution. FDA Cross-MSJ 67, *Nicopure Labs, LLC* v. *FDA*, No. 16-

878 (D.D.C. Aug. 17, 2016), ECF No. 43; *see also id.* at 46 ("premarket review 'is *required*' for new tobacco products"). As FDA recognized, "there are no exemptions," *id*. at 67 (quoting 81 Fed. Reg. at 29,004), and "the statute itself admits of no other reading," *id.* at 49; *see also* 81 Fed. Reg. at 29,010 (under the TCA, "a new tobacco product may be legally marketed only if FDA has authorized its marketing").

97. Despite the plain text of the statute as well as FDA's prior position, the Guidance categorically suspends the Tobacco Control Act's premarket review requirements for manufacturers of newly deemed products until August 2021 or 2022 (depending on the type of product), and indefinitely after those dates so long as a marketing application of any kind has been submitted to the agency and has not been denied. As a result of the Guidance, consumers will continue to be exposed for many years to thousands of tobacco products containing lethal and addictive components that have not met the statutory requirements. FDA has no legal authority to absolve regulated entities of their legal obligation to comply with statutory mandates in that manner. Congress plainly knew how to exempt new tobacco products from its premarket review regime. *See* 21 U.S.C. §§ 387j(a)(2)(B), 387e(j)(2). But it created no such exemption for any new tobacco product, including newly deemed products.

98. FDA's apparent belief that newly deemed products already on the market should enjoy a sustained "grace" period (and an indefinite one at that) is irrelevant; the agency has no "power to revise clear statutory terms that," in its view, "turn out not to work in practice." *Util. Air Regulatory Grp.* v. *EPA*, 134 S. Ct. 2427, 2446 (2014). The Guidance impermissibly arrogates to FDA a statutory forbearance authority that Congress has not delegated to it. In fact, FDA previously recognized that any burden imposed on manufacturers by premarket review does not permit the agency to alter those requirements. *See, e.g.*, FDA Reply Br. 9, *Nicopure*,

No. 16-878 (D.D.C. Sept. 9, 2016), ECF No. 48 ("Congress was well aware that requiring premarket review of innovative types of nicotine delivery devices would limit their access to the market. Yet it made premarket review a central feature of the statute[.]" (internal quotation marks and citations omitted)).

99. Nor is the Guidance an exercise of permissible, and unreviewable, enforcement discretion. Indeed, the Guidance is not an exercise of enforcement discretion at all. Rather, in direct contravention of the statute's premarket review requirements, the Guidance affirmatively, conclusively, and categorically authorizes manufacturers of newly deemed products to keep those products on the market without agency review—for more than half a decade and perhaps indefinitely. This FDA cannot do: Agencies may not modify unambiguous requirements imposed by a federal statute. The Guidance does not simply fail to enforce statutory requirements; it purports to alter those requirements and to establish, with the force of law, that otherwise prohibited conduct does not violate the Tobacco Control Act.

100. Even were the Guidance an exercise of enforcement discretion, it would be subject to judicial review. In abandoning premarket review of all newly deemed products for years, the agency "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 regime established by Congress.

101. FDA's abdication of its statutory duties is so flagrant, in fact, that the Guidance violates the duty of the Executive Branch to "take care that the Laws be faithfully executed." U.S. Const., art. II, § 3. Crafted expressly to preclude the President from suspending or

dispensing with Acts of Congress, the Take Care Clause forbids the Executive Branch from declaring that conduct Congress made unlawful through the legislative process is now lawful by means of an executive policy of non-enforcement. Any other conclusion would vest in the President a legislative power to revoke and rewrite laws. Yet FDA has done just that, declaring, despite Congress's clear instruction to the contrary, that manufacturers may market newly deemed tobacco products without FDA review and premarket approval. Under the Constitution, FDA, as an Executive Branch agency, cannot exercise such legislative power.

102. For these reasons, the Guidance must be vacated and "set aside" because it is "not in accordance with law," 5 U.S.C. § 706(2)(A); it is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right," *id.* § 706(2)(C); and it is "contrary to constitutional right, power, privilege, or immunity," *id.* § 706(2)(B).

COUNT TWO
(Administrative Procedure Act, 5 U.S.C. §§ 553, 706)

THE GUIDANCE VIOLATES THE APA'S REQUIREMENTS FOR NOTICE-AND-COMMENT RULEMAKING

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

104. 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).

105. 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.

106. 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). To the contrary, it is a

substantive rule that categorically exempts newly deemed tobacco products from statutory premarket review requirements until August 2021 or 2022 (depending on the type of product), and perhaps indefinitely. In purpose and effect, the Guidance stays FDA's hand, eliminating its discretion to prosecute acts prohibited by statute and authorizing newly deemed tobacco products to continue being marketed without the statutorily required marketing order from FDA. The Guidance also purports to immunize conduct that would otherwise be manifestly illegal under federal law, changing the rights of regulated entities. For these and other reasons, the Guidance is a legislative rule.

107. Absent "good cause" for not doing so, 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. By contrast, although FDA disclaimed being bound by the APA's requirements for notice-and-comment rulemaking when promulgating the prior "Compliance Policy for Premarket Review" set forth in the Deeming Rule, 81 Fed. Reg. at 28,977, it gave prior notice, *see* 79 Fed. Reg. at 23,174-23,177; "received many comments … on possible compliance approaches," 81 Fed. Reg. at 29,010; and thoroughly explained its reasons for adopting the approach it did, *id*. at 29,009-29,015.

108. FDA made no reasoned "good cause" finding for failing to follow the same approach here, 5 U.S.C. § 553(b), nor was there good cause.

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

110. In any event, even were the Guidance not a substantive rule—which it is—both the FD&C Act and FDA's own regulations for good guidance procedures required FDA to permit prior public participation. "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); *accord* 21 C.F.R. § 10.115. Because FDA's conclusory assertion that "prior public participation [was] not feasible or appropriate" lacks any plausible basis, FDA's failure to comply with statutory and regulatory procedures for issuing guidance documents independently compels vacatur of the Guidance here.

COUNT THREE
(Administrative Procedure Act, 5 U.S.C. § 706)

THE GUIDANCE IS ARBITRARY AND CAPRICIOUS

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

112. 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 decisionmaking is arbitrary and capricious. *State Farm*, 463 U.S. at 43. To satisfy that core requirement of reasoned decisionmaking, an agency must "cogently explain why it has exercised its discretion in a given manner." *Id.* at 48. Separately, under the Tobacco Control Act, Congress mandated that, "[t]o facilitate judicial review, a regulation or order issued under section … 387j … shall contain a statement of the reasons for the issuance of such regulation or order." 21 U.S.C. § 387*l*(e).

113. The Guidance fails the critical statutory standards governing agency decisionmaking under both the APA and the Tobacco Control Act. As explained above, the Guidance purports (1) to forbear from and substantially revise the premarket review structure that Congress enacted; (2) to change FDA's prior approach to compliance deadlines, using the type of product rather than the type of application as the basis for the length of time a

manufacturer may market newly deemed products without seeking premarket review; and (3) to reverse FDA's prior decision *not* to permit indefinite marketing of a newly deemed product pending FDA review. Despite those substantial changes, FDA offered *no* contemporaneous explanation whatsoever in the Guidance to justify those decisions or to explain how those decisions are remotely consistent with FDA's statutory obligations to protect the public health from the dangers of tobacco products, the purposes of the Tobacco Control Act, the administrative record before the agency in the Deeming Rule, or FDA's own prior findings.

114. For example, in the Guidance, FDA failed to address—much less explain—how an indefinite review period comports with the 180-day review period prescribed by Congress in the Tobacco Control Act. 21 U.S.C. § 387j(c)(1)(A). Moreover, FDA nowhere identified any basis on which it determined the length of the newly announced compliance periods, nor has it provided any reasoned basis for establishing different compliance periods for different product types—an approach it had previously rejected.

115. Beyond that, in issuing the Deeming Rule, FDA expressly found that "manufacturers of the newly deemed products have been on notice for more than 4 years that these products could and likely would be regulated," 81 Fed. Reg. at 28,993, and that the much shorter compliance deadlines initially adopted were "sufficient to allow manufacturers of previously unregulated tobacco products to submit applications without unduly delaying compliance," *id.* at 29,012; *see id.* at 29,014 ("FDA believes that these time periods are sufficient for manufacturers to prepare high quality applications addressing the requirements in the statute."). Those findings substantially undercut FDA's apparent position in the Guidance that there is now a pressing need for extended compliance deadlines, and FDA offered no factual or legal explanation in the Guidance for its abrupt departure from its prior positions. *See FCC v.*

Fox Television Stations, Inc., 556 U.S. 502, 516 (2009) ("[A] reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy.").

116. Moreover, the Guidance is arbitrary and capricious because it exempts combustible products (such as cigars) from premarket review for several additional years, despite FDA statements elsewhere that the motivation behind exempting newly deemed products from premarket review was a desire to strengthen regulation of combustible tobacco. This unexplained agency inconsistency independently renders the Guidance unlawful.

117. Finally, in announcing the Guidance, FDA failed to acknowledge, much less explain, its abandonment of its prior compliance policy. As part of the Deeming Rule, FDA offered a lengthy explanation for why the "comments and data submitted in response to the compliance policy in the NPRM" justified the final "compliance policy" that FDA adopted. 81 Fed. Reg. at 29,010. Based on the record before it, FDA found that much shorter compliance deadlines properly "balance[d] the public health concerns raised in the comments, allow[ed] the Agency to more efficiently manage the flow of incoming applications, and encourage[d] high-quality premarket submissions from applicants." *Id.* The Guidance cites no changed circumstances, no new evidence, and no additional considerations that would justify FDA's about-face. In that way, the Guidance is a textbook example of unreasoned agency decisionmaking.

118. For these reasons and others, the Guidance must be vacated and "set aside" as "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

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 and constitutional authority; was promulgated without observance of procedure required by law; and is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

c) Enjoin Defendants from enforcement or implementation of 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: March 27, 2018

Respectfully submitted,

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