UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, Plaintiffs, v. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Case No. 8:18-cv-883-PWG

AMICUS CURIAE BRIEF OF JOHN MIDDLETON, CO., ITG BRANDS LLC, JUUL LABS, INC., THE CONSUMER ADVOCATES FOR SMOKE-FREE ALTERNATIVES ASSOCIATION, NJOY LLC, THE AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION, THE AMERICAN VAPING ASSOCIATION, THE ARIZONA SMOKE FREE BUSINESS ALLIANCE, THE INDIANA SMOKE FREE ASSOCIATION, IOWANS FOR ALTERNATIVE TO SMOKING AND TOBACCO, THE KENTUCKY SMOKE FREE ASSOCIATION, THE MARYLAND VAPOR ALLIANCE, THE NEW YORK STATE VAPOR ASSOCIATION, THE OHIO VAPOR TRADE ASSOCIATION, THE RIGHT TO BE SMOKE-FREE COALTION, THE SMOKE FREE ALTERNATIVES TRADE ASSOCIATION (SFATA), SFATA-CALIFORNIA, SFATA-CONNECTICUT, SFATA-HAWAII, SFATA-LOUSIANA, SFATA-RHODE ISLAND, SFATA-TEXAS, SFATA-WISCONSIN, THE TENNESSEE SMOKE FREE ASSOCIATION, AND THE TEXAS VAPOR COALITION

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INTERESTS OF *AMICI CURIAE*

The interests of *amici* are set forth in the letters they filed expressing their intent to move to intervene. *Amici* are manufacturers of cigars covered by the Deeming Rule, and manufacturers, retailers, and users of electronic nicotine delivery system (ENDS) products also covered by that Rule. For most cigar products, the pathway to FDA approval is through Substantial Equivalence (SE) Reports, *i.e.*, applications establishing substantial equivalence to products already on the market. For ENDS products, the path involves Premarket Tobacco Applications (PMTAs), *i.e.*, applications establishing that the product is appropriate for the protection of public health. *Amici* have direct, substantial, and varying interests that will be affected by any remedy the Court imposes. It is also "abundantly clear" that *amici* are knowledgeable about the practical realities of the "filing and approval processes" that any remedy will affect. May 31, 2019 Letter Order.[1]

INTRODUCTION

For years, FDA has issued, then extended, deadlines for when ENDS and cigar manufacturers must submit premarket review applications to keep existing products on the market. That iterative process did not happen because FDA sat on its hands. Rather, one of the cornerstones of the Deeming Rule—the rule that subjected ENDS and cigars to FDA's powers under the Tobacco Control Act (TCA)—was FDA's flexibility to extend enforcement timetables so it could lay out regulatory stepping stones that would instruct manufacturers what tests to undertake, what studies to provide, and what other information FDA needs to assess their applications. This process turned out to be staggeringly complicated, especially due to a host of

[1] *Amici* submit this joint brief pursuant to the Court's May 31, 2019 Letter Order, Dkt. No. 84, without prejudice to their rights to appeal the denial of intervention or their ability to make arguments in further proceedings based on their own interests. As the accompanying declarations illustrate, *amici* are disparate entities in disparate industries with multiple disparate interests.

novel and disparate technical issues affecting ENDS products and cigars. FDA has made progress: in April 2019, it issued a notice of proposed rulemaking to clarify the contents of SE Reports, and it recently announced that a proposed rule for PMTAs is under review at the Office of Management and Budget (OMB). Just yesterday, FDA issued 52-page final guidance to ENDS manufacturers regarding what their PMTA applications should include. *See* FDA Guidance, Premarket Tobacco Product Applications for ENDS (June 11, 2019), available at https://tinyurl.com/yybbk93z (Final Guidance). But all along the way, FDA has assured manufacturers that they would be given both the guidance and the time necessary to successfully navigate its premarket approval process. Manufacturers can hardly be faulted for having taken FDA at its word.

All agree that this Court's holding invalidating FDA's August 2017 Guidance cannot suddenly subject ENDS and cigar products to TCA enforcement actions for failure to file the very applications that FDA authorized manufacturers to file later. Remanding that Guidance to FDA without vacatur would avoid upending FDA's massive existing regulatory efforts and causing unwarranted harm to consumers and manufacturers. Such a remand would allow FDA to continue fleshing out parameters for premarket applications and would give manufacturers sufficient time to prepare the technical data necessary for quality applications that include the kind of information that Plaintiffs themselves claim to want and need. Such a remand would also provide FDA sufficient time to resolve each completed application without products being forced off the market in the interim. A remand is the customary remedy in these circumstances.

By contrast, any court-fixed timetable would defy black-letter law prohibiting judicial intervention in the substance of agency rulemaking. Dictating a timetable to FDA would risk invalidating the Deeming Rule itself, which presupposed that FDA retains the flexibility to ensure that newly deemed products have the time and means to successfully navigate premarket review.

Plaintiffs' unrealistic proposed timetable would also cause this Court to preside over a regulatory train wreck that would unlawfully deprive manufacturers of a meaningful ability to submit thousands of anticipated PMTA applications and SE Reports and would short-circuit FDA review. To satisfy Plaintiffs' timelines, FDA would be forced to act precipitately, without regard for the law, public health, FDA's pending rulemakings, or devastating economic consequences.

Make no mistake: *amici* share the Court's concerns about youth usage, which they are strongly combatting and consider unacceptable at any level. Youth cigar usage continues to decline. And ENDS manufacturers have taken a number of steps, and spent tens of millions of dollars on programs, to prevent youth usage. But the answer is not to force from the market products on which millions of American adults rely in their efforts to quit smoking cigarettes.

ARGUMENT

I. This Court Must Remand for FDA to Complete Essential Regulatory Steps

A. FDA Must Fill Significant Regulatory Gaps, and Allow the Time Necessary for Manufacturer Testing and Applications, Before It Can Review Applications

1. As FDA has frequently acknowledged, it must undertake a host of preliminary regulatory actions to ensure that manufacturers know what to file and have time to prepare their applications. Starting in 2011, FDA acknowledged (with respect to cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco) that "interested parties need clarity as to FDA's expectations regarding [SE] reports," pledging to "initiate a rulemaking that would establish requirements and standards for SE." Guidance for Industry and FDA Staff (Jan. 2011) at 1–2. FDA's initial efforts focused on the four tobacco product types identified in the TCA; FDA only began devoting comparable efforts to the SE requirements for newly-deemed products after FDA issued the 2016 Deeming Rule. Time and again, FDA has insisted that further regulatory action

is imperative before ENDS and cigar manufacturers face compliance deadlines.[2] And rightly so. FDA could not conceivably satisfy the APA by requiring applicants to submit applications without first telling them what rules applications must follow. Yet despite FDA's decision to deem cigars and ENDS products subject to the TCA, manufacturers remain in dire need of clarity to this day.

2. For ENDS products, significant pieces of the application puzzle are still missing. ENDS products generally require PMTAs. But manufacturers have had little to go on in preparing them. FDA has approved *two* PMTAs ever, and has never approved a PMTA for an ENDS product. Bauersachs Decl. ¶ 20; FDA, Premarket Tobacco Product Marketing Orders (June 11, 2019), https://tinyurl.com/yyxfqzdw (approval of two PMTA applications comprising 12 products). The estimated timeframe to prepare a PMTA for any type of tobacco product is at least two years. Bauersachs Decl. ¶ 23; Engelke Decl. ¶ 20; Benson Decl. ¶ 25.

Fleshing out the rules for ENDS products has proven particularly challenging given the newness of those products and the dearth of existing studies. For starters, until only yesterday,

[2] *See* Guidance for Industry and FDA Staff: Demonstrating Substantial Equivalence for Tobacco Products (Jan. 2011) at 1–2, https://tinyurl.com/y4x3dd62 (pledging to initiate a "[new] rulemaking that would establish requirements and standards for [SE]"); FDA Comm'r S. Gottlieb, Protecting American Families: Comprehensive Plan for Nicotine and Tobacco (Jul. 28, 2017), https://tinyurl.com/y5lsxn4o ("One area of emphasis will be to make sure we have the foundational regulatory architecture to ensure proper oversight of ENDS . . . . Part of this will be developing regulations that we have not yet pursued because the Agency's tobacco program itself is so new."); FDA Comm'r S. Gottlieb, Address at National Press Club (Nov. 3, 2017), https://tinyurl.com/y5hdqbu3 (33:15) ("The foundational regulations for the tobacco program were never put in place and so we're going to take the time to put those in place so we have a firm foundation from which to regulate."); FDA, *Advancing Tobacco Regulation to Protect Children and Families* (Aug. 2, 2018) (stating that "foundational proposed rules" are needed "regarding the basic rules of the road, especially when it comes to what's expected in premarket applications."), https://tinyurl.com/yysms73g; FDA Comm'r S. Gottlieb, Testimony to House Approp. Subcomm. for Agriculture, Rural Development, Food and Drug Administration, and Related Agencies (Feb. 27, 2019), https://tinyurl.com/y62ps5pe (1:51:05) (August 2017 Guidance is needed "to give [FDA] the time to put in place the implementing regulations and guidance that would . . . provide the rules of the road for how to effectively traverse the PMTA process[.]").

FDA had not issued final guidance on what PMTAs for ENDS products should include, and it had expressly warned that its draft guidance did not necessarily reflect FDA's current thinking. *See* Draft Guidance, Premarket Tobacco Product Applications for ENDS, 81 Fed. Reg. 28,781 (May 10, 2016). Manufacturers have barely had time to digest that 52-page "nonbinding" document, but it plainly does not resolve many open questions. The guidance contemplates the need for further rulemaking, *see, e.g.*, Final Guidance at 1, 11, and that PMTAs will not be a one-size-fits-all process. FDA still has not specified the kind of testing (if any) ENDS manufacturers should conduct to produce reliable data regarding product characteristics or public health consequences. The Final Guidance identifies a wide variety of studies or materials that "should" or "could" be conducted or included, but acknowledges limits on what is actually feasible, and encourages manufacturers to meet with FDA before submitting an application to discuss what to include. *Id.* at 3, 50–52. That reflects the reality that there is substantial variation among ENDS products, which come in different configurations and flavors and are sold or distributed in different ways. Woessner Decl. ¶¶ 4–8. What FDA requires for one product may prove different than for another.

FDA also appears poised to clarify what PMTAs for all tobacco products must include, but much work remains on that front as well. The government just announced that OMB is reviewing FDA's draft Notice of Proposed Rulemaking on PMTAs—but that notice is not expected to issue until at least September 2019. *See* OMB RIN 0910-AH44, HHS-FDA Proposed Rule, Premarket Tobacco Product Applications and Recordkeeping Requirements (May 31, 2019). Then would come the comment period, which would likely produce tens of thousands of comments—all of which FDA must carefully consider in its final rule to avoid invalidation. *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 626 F.3d 84, 94 (D.C. Cir. 2010).

Even when manufacturers know what tests or studies FDA wants, that is just the first step

in a long process. FDA must allow manufacturers time to conduct and analyze those studies before they can be submitted. Human clinical studies are time-consuming. Determining whether and how the chemical composition of liquid in an ENDS pod changes during a year of shelf-life requires study preparation, then the required year of observation. Surveys tracking consumers' consumption patterns take time to set up. Engelke Decl. ¶¶ 37, 42–50; Graham Decl. ¶¶ 10, 14.

Finally, in determining what applications should include and when manufacturers should submit them, FDA must continue considering substantial reliance interests—not just of manufacturers who have been promised a path to demonstrate that their products should remain on the market, but of the millions of American adults who use ENDS products to help them quit smoking cigarettes. Manufacturers cannot be faulted for not prematurely committing resources to costly studies they may have to redo if they guessed wrongly as to what FDA would want. And forcing manufacturers into a process where they would lack a meaningful opportunity to submit applications would be quintessential arbitrary and capricious agency action given the reliance interests FDA has created. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016).

That said, ENDS manufacturers have not just sat around. They have done what they can to prepare for the PMTA process. Engelke Decl. ¶¶ 21–56; Graham Decl. ¶¶ 10–11, 16–17. But as the signatories to this brief reflect, ENDS manufacturers come in different shapes and sizes, with vastly different levels of resources to devote to trying to anticipate what FDA would require. For example, there are not enough accredited third-party laboratories qualified to conduct various types of testing, and small manufacturers lack the resources to do those tests themselves. Engelke Decl. ¶ 35; Woessner Decl. ¶¶ 9, 12; Anton Decl. ¶ 12; Benton Decl. ¶¶ 6, 24.

ENDS manufacturers have not been dilatory in addressing youth usage, either. *Amici* reject *any* youth use of nicotine-containing products, and ENDS manufacturers have been tackling youth

usage head-on. They have spent tens of millions of dollars on programs to prevent youth usage, have proposed limits on how their products can be sold, and have spearheaded youth education initiatives, among other efforts. Many have supported a nationwide increase in the minimum age for buying tobacco products. *E.g.*, Engelke Decl. ¶ 9. But as FDA has stated, ENDS products present fewer health risks than cigarettes and help many adult smokers move down the "continuum of risk" for nicotine use,[3] and the premarket review process must fully account for this.

3. Seeking approval for cigars poses its own challenges. FDA has substantially more experience with SE Reports, having received over 5,000 of these types of applications for other tobacco products. Folmar Decl. ¶ 6. But that experience does not bode well for efforts to prescribe a fixed timetable. FDA as of April 2018 has issued final orders for only about 191 provisional products, in no small part because FDA's current SE process involves a litany of time-consuming back-and-forth steps (including multi-disciplinary scientific review).[4]

Here, too, regulatory gaps abound. Cigars are different than cigarettes and present unique additional challenges. There are currently no standardized testing methodologies for cigar smoke; cigars do not fit standardized cigarette testing machines, and may have other unique attributes (like plastic tips that affect inhalation). As with ENDS products, FDA has not yet provided guidance as to which Harmful and Potentially Harmful Constituents ("HPHC") manufacturers should test for in cigars or how such testing should be conducted, *see* 21 U.S.C. § 387d(a)(3), and there is a lack of accepted HPHC testing standards, methods, and equipment for these products. Bauersachs Decl. ¶ 15; *see* Final Guidance at 28 & n.35. Nor has FDA grappled with how to standardize

[3] *See* Protecting American Families: Comprehensive Plan for Nicotine and Tobacco, *supra* n.2; Engelke Decl. ¶¶ 6–7.

[4] *See* FDA, Substantial Equivalence: The Review Process, https://tinyurl.com/y3sm3lvt; Update on Provisional Substantial Equivalence Review (Apr. 5, 2018), https://tinyurl.com/yyrhcwjt.

testing results for cigar tobacco leaf, which displays much higher variability with respect to HPHC yields than cigarette tobacco. FDA thus instructed manufacturers to stop submitting applications on a trial-and-error basis pending further FDA action. Bauersachs Decl. ¶ 26.[5]

FDA is now amidst a rulemaking that may substantially affect all SE Reports. In April 2019, FDA issued a notice of proposed rulemaking to clarify what SE Reports should generally include. Content and Format of Substantial Equivalence Reports, 84 Fed. Reg. 12,740 (April 2, 2019). The comment period (which FDA is extending) will close on July 17, 2019. FDA then must decide how to finalize the rule in response to comments, as well as undergo OMB review. Those processes will take time. And the proposed rule does not elucidate what cigar manufacturers should submit for this unique product category, instead inviting "comments and information [regarding] the parameters that may be needed to support an SE Report." 84 Fed. Reg. 12,762. Meanwhile, FDA is still weighing comments submitted in response to advance notices of proposed rulemakings on "Regulation of Flavors in Tobacco Products," 83 Fed. Reg. 12,294 (Mar. 21, 2018), and "Regulation of Premium Cigars," 83 Fed. Reg. 12,901 (Mar. 26, 2018).

B. A Remand Is Necessary for FDA to Complete the Requisite Regulatory Steps

Given these considerations, the only proper remedy is a remand of the Guidance. FDA cannot lawfully enforce any application deadline before it takes needed steps to flesh out the premarket review process for ENDS and cigar products, and determines how much time is needed for acceptable applications to obtain approval. But that process defies any predetermined

[5] Trade associations have challenged the Deeming Rule's premarket authorization provisions for cigars and pipe tobacco. *Cigar Ass'n of Am. v. FDA*, No. 1:16-cv-1460, ECF No. 1 (D.D.C.). After FDA announced the August 2017 Guidance, the parties, with court approval, agreed to defer those challenges to give FDA time to act. *Id.*, ECF No. 51 at 2–3. That suit has proceeded on the understanding that FDA would undertake regulatory actions, including issuing a substantial equivalence rule, to clarify the premarket review process for newly deemed products. *Id.*, ECF Nos. 53, 110, 112, 115, 119. The Court should not interfere with that process.

timetable, not least because hard technical problems cannot be resolved at will. A remand is needed so that FDA is not straitjacketed into a timetable that precludes reasoned deliberations.

1. No one argues that invalidating the August 2017 Guidance means that ENDS and cigar products that were on the market as of August 8, 2016 (which are the only products to which that guidance applies) should suddenly be forced off the market. As the Court recognized, that Guidance replaced earlier guidance documents setting application deadlines that have already passed. Op. at 9–10, 53. And, as the Court noted, "[i]t is undisputed that the FDA has some discretion to adapt [TCA] provisions to the special circumstances of products that become subject to the TCA . . . by virtue of deeming and, to that end, to permit a compliance period for newly deemed products." *Id.* at 8. Even Plaintiffs' remedy presupposes that manufacturers and FDA must have *some* period to submit and review applications, respectively.

But FDA, not the courts, must set that timetable in the first instance. "If courts were empowered to enter general orders compelling compliance with broad statutory mandates, they would necessarily be empowered, as well, to determine whether compliance was achieved." *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 66 (2004). If so, "it would ultimately become the task of the supervising court, rather than the agency, to work out compliance with the broad statutory mandate, injecting the judge into day-to-day agency management." *Id.* at 66–67. But "[t]he prospect of pervasive oversight by federal courts over the manner and pace of agency compliance with such congressional directives is not contemplated by the APA." *Id.* at 67; *see City of New York v. DOD*, 913 F.3d 423, 429–31 (4th Cir. 2019) (similar).

2. A remand without vacatur is the only appropriate remedy under the APA. Black-letter administrative law dictates that "set[ting] aside" unlawful agency action under 5 U.S.C. § 706(2) is limited to either remanding the action to the agency (i.e., allowing the action to remain in effect

while the agency considers next steps) or vacating it (i.e., preventing the action from having further force or effect). *See Sierra Club v. Army Corps of Eng's*, 909 F.3d 635, 655 (4th Cir. 2018). And courts have chosen remands when eliminating the agency action would leave a destabilizing void or uncertainty while the agency determines what further action to take. *E.g.*, *N. Carolina v. EPA*, 550 F.3d 1176, 1177–78 (D.C. Cir. 2008) (remanding without vacating an EPA rule despite having concluded that EPA could not lawfully re-enact virtually any of it); *see also Cal. Communities Against Toxics v. EPA*, 688 F.3d 989, 993–94 (9th Cir. 2012) (remanding without vacating rule with concededly flawed rationale where vacatur "could well delay a much needed power plant").

This case fits the same mold. The pre-Guidance deadlines cannot spring back into effect; they have since expired (and also were not issued by rulemaking). *See* Op. at 53. But the Court has concluded that any future timetable to replace the August 2017 Guidance likely must go through notice-and-comment rulemaking. *Id.* at 53–54. To avoid confusion over the vacuum created by vacating the existing Guidance in the interim, the Court should remand without vacatur. At a minimum, the Court should avoid "impairing the interim administration" of the Deeming Rule by staying any order to vacate the Guidance until FDA takes necessary next steps. *See Northern Pipeline Constr. Co. v. Marathon Pipe Line Co.*, 458 U.S. 50, 88–89 (1982).[6]

II. Plaintiffs' Proposed Remedy Is Unlawful

A. Plaintiffs' Timeframe Would Invalidate the Deeming Rule

Plaintiffs would give manufacturers a mere 120 days from the Court's order to submit applications, and would give FDA twelve more months to process those applications. Any proposed remedy that could force *amici*'s products off the market without a full and fair

[6] While the Court has indicated that it is vacating the Guidance, Op. at 53, courts have shifted from vacatur to remand in similar circumstances. *E.g.*, *N. Carolina*, 550 F.3d at 1177–78.

opportunity to obtain marketing orders would expose the Deeming Rule to legal challenge under the APA. The TCA does not empower FDA to summarily declare entire classes of tobacco (or "deemed tobacco") products illegal. *See, e.g.*, 21 U.S.C. § 387g(d)(3); H.R. Rep. No. 111–58, pt. 1, at 2 (2009) (Act does not grant authority to "ban[] a class of nicotine products, such as all cigarettes"). To the contrary, the TCA only gives FDA the power to deem products subject to the statute. And the TCA plainly anticipates a process by which manufacturers may submit applications seeking approval of those products—approval that FDA may deny only upon specific consideration and findings. *See, e.g.*, 21 U.S.C. § 387j(c)(2).

Cognizant of that reality, FDA did not contemplate in the Deeming Rule that it could force existing products from the market before PMTAs or SE Reports could be submitted, reviewed, and acted upon. Nor did that Rule address the impact of such a drastic outcome. Rather, one of FDA's core assumptions in that Rule was that FDA could consider and address these potential impacts during the application review process, and after FDA clarified what the application process should entail. *See* 81 Fed. Reg. 28,974, 29,010/1-2 (May 10, 2016). Indeed, when commenters emphasized the public health benefits of ENDS and "argued that restrictions on access to the newly deemed products would be detrimental to public health," FDA responded that its "consideration of [the] public health benefits" of the products "*will be included in FDA's review of PMTAs based on the evidence*." *Id*. at 28,995/1 (emphasis added).

If, as plaintiffs maintain, the Deeming Rule may be administered in a way that pulls thousands of products off the market without a real opportunity to seek FDA review, then the Rule violates the TCA and the APA's requirement that agencies consider an "important aspect of the problem," *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)—namely, the economic consequences of devastating multi-billion dollar industries, and the

attendant adverse effects on public health that FDA said it would assess before barring products.

Further, the Deeming Rule would fail for having "misconceived the law." *SEC v. Chenery Corp.*, 318 U.S. 80, 94 (1943). The Rule rests on FDA's legal view that "[a]gency compliance/ enforcement policies"—including "the relevant time periods" by which *amici* would be required to submit a PMTA—are "not subject to the requirements that govern notice-and-comment rulemaking," and that FDA could extend those periods as needed. 81 Fed. Reg. at 28,977. If FDA lacks the flexibility to allow products to remain on the market during the period needed to finalize the application process and for applications to be received and reviewed, an essential legal premise of the Rule is invalid, as is the Rule itself.

B. Plaintiffs' Remedy Would Otherwise Violate the APA

1. Plaintiffs' proposed court-imposed timetable would flout the APA by impermissibly dictating the outcome of notice-and-comment rulemaking. Under the Court's opinion, FDA cannot impose such a "compliance period" without "adher[ing] to the notice and comment requirements of the APA." Op. 53; *see id.* at 54 (contemplating "notice and comment period" for the adoption of "new Guidance"); Dkt. No. 84, at 2 (similar). Agencies cannot render the rulemaking process a sham by pre-judging the outcome before commenters can convey concerns. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). Forcing FDA to adopt a fixed timetable would ensure that such a final rule is invalidated, which would only delay FDA.

2. Plaintiffs' proposed remedy would also be arbitrary and capricious, for several reasons. First, forcing manufacturers into a process where they would lack a meaningful opportunity to submit applications or were abruptly forced to pull their products from the shelves would be quintessential arbitrary and capricious agency action, particularly given the reliance interests FDA has created. *See Encino*, 136 S. Ct. at 2126. FDA, after all, deemed products before establishing

a process to review them, and assured manufacturers that they will have meaningful guidance and meaningful time to submit applications. Forcing FDA to abandon those assurances and adopt a timetable that makes a mockery of deliberation during the premarket review process would subject FDA's ensuing actions to invalidation.

Second, a key part of premarket review is what applications must contain for FDA to meaningfully review them. But, despite the new PMTA Guidance, FDA still has not made clear what it wants PMTAs to include, let alone filled gaps for SE Reports. In the next 120 days, FDA cannot conceivably fill all of those holes. But it would be arbitrary and capricious to order FDA to conduct premarket review in a manner that precludes it from considering centrally "important aspect[s] of" what it seeks to regulate. *State Farm*, 463 U.S. at 43.

Third, Plaintiffs' artificial 120-day deadline to file applications would ensure arbitrary and capricious determinations by depriving manufacturers of a meaningful opportunity to submit quality applications. ENDS products are novel and generally require time-consuming and exhaustive PMTA applications, which require population-level data beyond individual safety. The first PMTA for a smokeless tobacco product relied heavily on long-term (30+ year) epidemiology data from Sweden, and the most recent PMTA, for the IQOS Tobacco Heating System, involved about two million pages of submissions, over 35 studies, and over two years of FDA review (when no other application had been accepted for filing). Engelke Decl. ¶ 20; Benson Decl. ¶¶ 15–17; IQOS Briefing Document for Tobacco Prod. Sci. Advisory Comm. at 8 (Dec. 2017), https://tinyurl.com/yy63pdl4. Ordering ENDS manufacturers to submit PMTA applications with 120 days thus may force FDA to forgo requests for studies and tests that it otherwise would consider. Likewise, SE Reports involve amassing studies and technical data—but until FDA says what it wants, cigar manufacturers would have to either forgo the information or take a kitchen-

sink approach to their applications. Either way, this rushed process would unfairly hamper their chances of navigating the premarket review process for products that have been on the market in largely the same form for decades. Folmar Decl. ¶ 14; Bauersachs Decl. ¶¶ 2, 29, 31–33.

Fourth, Plaintiffs' compressed timetable would deprive FDA of any meaningful time to review applications. Plaintiffs would give FDA twelve months from receipt of an application to review FDA's existing backlog and all new applications, and would force any unapproved products off the market thereafter. But, to date, FDA has resolved only 5% of some 5,000 PMTA and SE Report submissions; any pending ENDS or cigar applications would apparently be swept into Plaintiffs' one-year timetable for an FDA decision. Folmar Decl. ¶ 6. There is reason to doubt even one ENDS PMTA could be resolved under Plaintiffs' schedule, let alone the thousands that would be expected were the Court to enter Plaintiffs' proposed remedial order. FDA has never resolved a PMTA for an ENDS product, and the most recent PMTA for a non-ENDS product took over two years to process (at a time when hardly any other PMTAs were pending). Engelke Decl. ¶ 20. Yet estimates of expected ENDS PMTAs range from 750 to *tens of thousands*. *See* Preamble, Deeming Rule, 81 Fed. Reg. 29,078 (May 16, 2016); Deeming Rule, 81 Fed. Reg. 29,091 (May 10, 2016). As for cigars, Plaintiffs' timetable similarly fails to allow for meaningful review given FDA's backlog of thousands of SE Reports and the agency's track record of processing such applications to date. Bauersachs Decl. ¶¶ 16–17; Folmar Decl. ¶¶ 6–8. But Plaintiffs' proposal would flood FDA with an unpreceded deluge of applications, all on a one-year clock.

III. Plaintiffs' Proposal Would Devastate Industry and Jeopardize Public Health

Plaintiffs' abrupt timetable would risk forcing ENDS products off the market and destroying the multibillion-dollar ENDS industry. Manufacturers have planned the onset and duration of long-term studies to correspond with FDA's deadlines in the August 2017 Guidance.

Hobbling manufacturers' ability to file adequate PMTAs, and forcing FDA to deny applications it fails to complete on an unrealistic timetable, could drive ENDS products off the market. Wiping out that industry would endanger public health, risking a significant reversal in the historic downward trend of cancer-causing cigarette consumption. Many of the roughly 14 million ENDS users have switched, or are transitioning, from very harmful cigarettes to ENDS products. Woessner Decl. ¶ 15; Engelke Decl. ¶¶ 6-7.

Plaintiffs similarly overlook the serious hardships their proposal would inflict on the cigar industry. Needless to say, forcing cigar products off the market if FDA could not complete its premarket review process within a year would significantly harm manufacturers, and that could translate into job losses, loss of tax revenue, and other unpredictable consequences. Bauersachs Decl. ¶¶ 32—33; Anton Decl. ¶ 19. Meanwhile, Plaintiffs have not even tried to assert that their proposal would somehow promote access to reliable public-health data, creating doubts about whether their proposal redresses the injuries they claim. *See Lewis v. Casey*, 518 U.S. 343 (1996).

CONCLUSION

This Court should remand the Guidance to give FDA the flexibility it needs—and which the APA demands—to clarify critical aspects of the TCA as applied to ENDS and cigar products and to complete pending rulemakings. If instead the Court orders vacatur, it should stay that ruling until FDA imposes another timetable, or otherwise make clear that deemed products may remain on the market as an orderly process is established for their application and review.

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Dated: June 12, 2019

CERTIFICATE OF SERVICE

I hereby certify that on June 12, 2019, I electronically filed the foregoing document with the Clerk of the Court of the District of Maryland by using the CM/ECF system, which filing will provide service to all parties and *amici*.

/s/ David J. Ryan
David J. Ryan (20484)