IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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

PLAINTIFFS' REPLY TO AMICUS BRIEF OF JOHN MIDDLETON, CO. ET AL.

When Congress enacted the Tobacco Control Act ("TCA") in 2009, it prohibited the marketing of new tobacco products (i.e., products not commercially marketed on February 15, 2007) unless their manufacturer could prove to FDA that the products were "appropriate for the protection of the public health" or "substantially equivalent" to a product marketed on February 15, 2007. 21 U.S.C. §§ 387j(a)(2)-(3), (c)(2)(A). Congress applied this requirement to four specific types of tobacco products, as well as any other tobacco products FDA subjected to the TCA through regulation. *Id.* § 387a(b). The prospect of new tobacco products becoming subject to premarket review after they entered the market was thus explicit in the statutory structure.

In the August 2017 Guidance, FDA set Congress's design aside for at least five years. This Court correctly found this action unlawful because it conflicted with the TCA and vacated the Guidance. *Amici curiae*[1]—tobacco companies and industry associations representing e-cigarette and cigar interests[2]—ask the Court to reverse itself by remanding to FDA without vacatur, thus reinstating the August 2017 Guidance despite its manifest unlawfulness.

Amici tellingly do not cite the standard for remanding without vacatur, a remedy that the Fourth Circuit "has never formally embraced" but at a minimum requires "a serious possibility that the [agency] will be able to substantiate its decision on remand." *Sierra Club v. U.S. Army Corps of Eng'rs*, 909 F.3d 635, 655 (4th Cir. 2018) (quoting *Allied-Signal, Inc. v. U.S. Nuclear Reg. Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993)). *Amici* do not even attempt to argue that this standard is satisfied, and thus the Court should follow the settled rule that "Section 706(2)(A) 'requires federal courts to set aside federal agency action' that is 'not in accordance with law.'"

[1] In this brief, "*amici*" refers to the signatories to the Amicus Curiae Brief of John Middleton, Co. et al. ("Amicus Br."), ECF No. 113, not to the State of Maryland, which filed a brief in support of Plaintiffs' proposal, ECF No. 97.
[2] *Amicus* CASAA, while not formally an industry trade association, is funded at least in part by tobacco companies. *See, e.g.*, CASAA, *Re: USSTC MRTP Application for Copenhagen Snuff Fine Cut*, 3 (Jan. 22, 2019), https://tinyurl.com/y4cw26p8 (acknowledging donation from Altria); CASAA, *Re: Modified risk tobacco product applications (MRTPAs), submitted by R.J. Reynolds Tobacco Company (RJRT) for six Camel SNUS tobacco products*, 5 (Aug. 28, 2018), https://tinyurl.com/y28vml32 (acknowledging donation from R.J. Reynolds).

Id. (quoting *FCC v. NextWave Pers. Commc'ns Inc.*, 537 U.S. 293, 300 (2003)).

Even if *amici* could clear this hurdle, remand without vacatur would be inappropriate. Their entire argument hinges on replacing Congress's judgments with their own. They assume that new tobacco products should continue to be sold until FDA has rejected their applications, when Congress expressly required an FDA marketing order *before* marketing. They insist that they should not be required to submit applications for years more, until FDA has answered to their satisfaction every question about the premarket process, even though Congress did not make the application requirement contingent on FDA guidance and FDA has issued numerous guidances on application content since promulgating the Deeming Rule. Nothing in the TCA gives manufacturers a right to keep new products on the market without a marketing order. *Amici*'s proposal would leave thousands of new tobacco products on the market indefinitely without statutorily required FDA review, including ENDS that are causing an epidemic of youth nicotine addiction and flavored cigars that have become more popular among youth than cigarettes. The Court should reject *amici*'s proposal and enter Plaintiffs' proposed order.

I. Remand Without Vacatur Is Inappropriate for ENDS Products

Amici ask this Court to order "remand without vacatur." Amicus Br. at 2-10. This is a remedial option used by some courts in limited circumstances but "never formally embraced" by the Fourth Circuit. *Sierra Club*, 909 F.3d at 655. It is of questionable validity because "[t]he Supreme Court has recognized that Section 706(2)(A) 'requires federal courts to set aside federal agency action' that is 'not in accordance with law.'" *Id.* (quoting *NextWave*, 537 U.S. at 300). To the extent remand without vacatur is statutorily permissible, it is as an exercise of courts' remedial discretion—the same remedial discretion that *amici* and Defendants deny the Court has when responding to Plaintiffs' proposal. *See, e.g.*, *Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Eng'rs*, 781 F.3d 1271, 1289-90 (11th Cir. 2015) (collecting cases).

Assuming *arguendo* that remand without vacatur is permitted under the APA, *amici* have not come close to justifying its use—and cannot. "[W]hen a reviewing court determines that agency regulations are unlawful, the ordinary result is that the rules are vacated[.]" *NAACP v. Trump*, 298 F. Supp. 3d 209, 243 (D.D.C. 2018) (quoting *Harmon v. Thornburgh*, 878 F.2d 484, 495 n.21 (D.C. Cir. 1989)). To determine whether an exception should be made, courts consider the *Allied-Signal* factors: whether (1) "there is at least a serious possibility that the [agency] will be able to substantiate its decision on remand" and (2) "the consequences of vacating may be quite disruptive." 988 F.2d at 151. Exceptions are principally permitted where agencies have "inadequately supported rule[s]," *Sierra Club*, 909 F.3d at 655 (quoting *Allied-Signal*, 988 F.2d at 150)—not where they flatly contravened a statute, *see, e.g.*, *NRDC v. EPA*, 489 F.3d 1364, 1374 (D.C. Cir. 2007) ("The agency's errors could not be more serious insofar as it acted unlawfully, which is more than sufficient reason to vacate the rules."). As then-Judge Ginsburg explained, when there is "little or no prospect of the rule's being readopted upon the basis of a more adequate explanation of the agency's reasoning, the practice of the court is ordinarily to vacate the rule." *Ill. Pub. Telecom. Ass'n v. FCC*, 123 F.3d 693, 693 (D.C. Cir. 1997).

A. FDA Cannot Substantiate the August 2017 Guidance on Remand

Amici do not acknowledge the first requirement of *Allied-Signal*, perhaps because it is impossible for them to satisfy. The Court found the August 2017 Guidance contrary to law, not merely inadequately justified. There is thus no possibility that the agency will be able to substantiate its decision on remand. Indeed, FDA has already proposed abandoning the deadlines established in the August 2017 Guidance. As Acting Commissioner Sharpless recently admitted, "nobody in the FDA anymore really thinks the 2022 date was a good idea … ."[3]

[3] Interview with Dr. Ned Sharpless, Acting Comm'r, FDA, Wash. Post, June 21, 2019, https://tinyurl.com/y5jjbbuq.

The cases cited by *amici* provide them no help. In one, the sole flaw was faulty *reasoning* and the agency had the ability to provide "new reasoning to support its final rule" on remand. *Cal. Cmtys. Against Toxics v. EPA*, 688 F.3d 989, 993 (9th Cir. 2012). The other falls into a special subset of cases where a court strikes down an environmental regulation because it is not strict enough. *See North Carolina v. EPA*, 550 F.3d 1176, 1178 (D.C. Cir. 2008) ("[I]t is appropriate to remand without vacatur in particular occasions where vacatur would at least temporarily defeat … the enhanced protection of the environmental values covered by [the challenged rule]." (internal quotation marks omitted). Where a rule "does not go far enough," courts may leave it in place during remand because having a "plainly inadequate" rule is better than having no rule at all. *Advocs for Hwy. & Auto Safety v. Fed. Motor Carrier Safety Admin.*, 429 F.3d 1136, 1151-2 (D.C. Cir. 2005). That situation does not exist here, where the rule contradicted the public interest prescribed by Congress rather than insufficiently advancing it.

B. The Consequences of Vacatur Do Not Support Remanding Without Vacatur

Even if *amici* could satisfy *Allied-Signal*, they fail to show that the drastic remedy they propose is warranted. *Amici*'s principal arguments are that the TCA cannot be applied without further guidance from FDA, and that they relied on the vacated Guidance. Amicus Br. at 3-10. In support, *amici* advance two extraordinary propositions. First, they assert that, despite the clear provisions of the statute, they should be able to keep their products on the market indefinitely without even filing an application until FDA has resolved all of industry's questions about what they will need to prove in an application and given them several more years to prepare it. Second, they assert that after submitting applications they should be permitted to keep their products on the market indefinitely unless and until FDA rejects the application. Both these propositions are contrary to the clear statutory language providing that no new product may

legally remain on the market in the absence of a marketing order. Moreover, if *amici*'s positions are accepted, many more years will pass before the provisions of the statute are actually applied—with potentially severe consequences for public health.

1. *Amici*'s Desire for More Guidance Does Not Justify Remand Without Vacatur

Tobacco manufacturers have long known FDA would apply the TCA to ENDS and have received ample guidance and ample time to prepare premarket applications. When Congress enacted the TCA on June 22, 2009, it applied the premarket review ("PMTA") or substantial equivalence ("SE") requirements to every cigarette, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco product "that was not commercially marketed in the United States as of February 15, 2007." 21 U.S.C. § 387j(a)(1)(A). It also authorized FDA to subject additional tobacco products to the TCA by promulgating a rule deeming them subject to the law. *Id.* § 387a(b). It did not vary the grandfather date for deemed products or authorize FDA to do so. *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 398-99 (D.D.C. 2017), *appeal filed*, No. 17-5196. Nor did it make the requirements contingent on FDA issuing further guidance. Instead, the TCA "authorized the agency to impose the premarket review requirement on manufacturers immediately, thereby halting sales until premarket applications were approved." *Id* at 376.[4]

The TCA provided detailed criteria that FDA must apply in evaluating a PMTA application. 21 U.S.C. § 387j(b)(1). Manufacturers were placed on notice that they would have to demonstrate that the marketing of their products was appropriate for the protection of the public health—taking into account not only existing users who might stop using tobacco products but also non-users who might begin—in order for them to remain on the market. *Id.* § 387j(c)(4).

[4] The *Nicopure* court was not presented with the question of whether the Deeming Rule's compliance period was consistent with the TCA; the only challenge related to the compliance period was industry's claim that the period was arbitrarily short. *See Nicopure Labs*, 266 F. Supp. 3d at 399-400

As early as 2011, ENDS manufacturers knew they would have to satisfy this standard. In April 2011, FDA announced its intent to deem ENDS products subject to the TCA.[5] Since virtually no ENDS products were commercially marketed on February 15, 2007, it was clear in early 2011 that they would have to comply with the PMTA provisions once deemed. That same year, FDA issued guidance on the preparation of PMTAs for new products after notice-and-comment rulemaking,[6] as well as detailed guidance on SE applications.[7]

In April 2014, FDA issued a proposed deeming rule, which made clear that the PMTA provisions would be applied to all deemed products, including ENDS products. 79 Fed. Reg. 23,142 (Apr. 25, 2014). In proposing the deeming rule, FDA proposed a compliance period of two years from the promulgation of the final rule for manufacturers to submit applications. *Id.* at 23,144. Thus, ENDS manufacturers were once again notified that they would be required to prepare and submit PMTA applications in order to keep their products on the market.

In May 2016, after receiving thousands of comments, FDA promulgated the Deeming Rule and simultaneously published a detailed draft guidance on the preparation of PMTA applications for ENDS products.[8] The issuance of the Deeming Rule, combined with the draft guidance, gave ENDS product manufacturers a roadmap for preparing PMTA applications. Although FDA invited comments on the draft guidance, few ENDS manufacturers submitted comments. In June 2019, FDA finalized the guidance with "substantially similar"

[5] Letter to Stakeholders from Lawrence Deyton, Dir., FDA Ctr. for Tobacco Prods. & Janet Woodcock, Dir., FDA Ctr. for Drug Evaluation & Research, *Regulation of E-Cigarettes and Other Tobacco Products* (Apr. 25, 2011).
[6] FDA, Guidance for Industry, Applications for Premarket Review of New Tobacco Products—Draft Guidance (Sept. 2011), https://tinyurl.com/y4v82tc3.
[7] FDA, Guidance for Industry and FDA Staff, Section 905(j) Reports: Demonstrating Substantial Equivalence for Tobacco Products ("2011 SE Guidance") (2011), https://tinyurl.com/y3xzcca2.
[8] FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Guidance for Industry, Draft Guidance (May 2016), https://tinyurl.com/y6pmzl5o.

recommendations as the proposed guidance issued more than three years earlier.[9]

In addition to issuing guidance, FDA has conducted public seminars and workshops to inform manufacturers about the PMTA requirements and offered to meet with any manufacturers with questions about the application process and content. Zeller Decl. ¶¶ 5(d), 15, ECF No. 120-1. Fewer than 10 manufacturers have availed themselves of that opportunity. *Id.* at ¶ 15. Moreover, FDA has repeatedly invited manufacturers to submit applications in advance of the deadline. Defs.' Remedy Br. at 8, ECF No. 120. But as former FDA Commissioner Scott Gottlieb observed, "the vaping and e-cig industry doesn't have a single association, company, or other entity that's engaged consistently and constructively with the regulatory process. The entire apparatus seems focused on fighting FDA. That hurts progress long term[.]"[10]

The fact that FDA can always issue more guidance cannot justify "hold[ing] in abeyance enforcement of mandatory provisions of a statute … all the while affording those manufacturers responsible for the public harm a holiday from meeting the obligations of the law." Op. at 46, ECF No. 73. FDA itself has rejected the claim that manufacturers cannot comply without more guidance. As FDA has said, there has never been an "excuse for manufacturers not to file applications with the FDA because the agency hasn't told them what they are expected to do." Defs.' Remedy Br. at 8 (quoting Press Release, FDA, *Statement from FDA Comm'r Scott Gottlieb, M.D., on New Steps to Address Epidemic of Youth E-Cigarette Use* (Sept. 12, 2018)).

ENDS product manufacturers have known for years that they would be required to obtain marketing orders to keep their products on the market, and have already received a compliance period of more than five years since the Deeming Rule's proposal and three years since its final

[9] FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems, Guidance for Industry, at 2 (June 2019), https://tinyurl.com/y3s62jno.
[10] Scott Gottlieb (@ScottGottliebMD), Twitter, https://tinyurl.com/y6pskrql (June 11, 2019).

issuance. Rather than prepare to make the required public health showing, manufacturers simply continued to introduce products to the market; the large majority of ENDS products currently on the market were introduced after FDA had announced its intention to apply the provisions of the TCA to ENDS products. They have no legitimate complaint that they have not been given adequate time to prepare their applications or adequate notice of the required contents.

2. *Amici* Have No Legitimate Reliance Interests

Amici also claim to have relied on being "promised a path to demonstrate that their products should remain on the market." Amicus Br. at 6. This "path," in the form of the August 2017 Guidance, was, as this Court found, beyond FDA's statutory authority. "The Supreme Court … has generally resisted protecting reliance on mistaken assurances about the law or its application" even when "regulated parties relied to their detriment on federal officials' guidance." Zachary S. Price, *Reliance on Nonenforcement*, 58 Wm & Mary L. Rev. 937, 949 (2017). No agency can immunize unlawful conduct prospectively; even true exercises of enforcement discretion "entail[] authority to ignore completed violations but not to excuse future ones." *Id.* at 945. Giving an agency the ability not only to withhold enforcement currently but to make future enforcement impossible due to reliance interests would violate the very separation of powers principles *amici* purport to protect. *Id.*; *see also, e.g.*, *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 327 (2014) ("An agency confronting resource constraints may change its own conduct, but it cannot change the law."); *cf. Heckler v. Cmty Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 60 (1984) ("When the Government is unable to enforce the law because the conduct of its agents has given rise to an estoppel, the interest of the citizenry as a whole in obedience to the rule of law is undermined. It is for this reason that it is well settled that the Government may not be estopped on the same terms as any other litigant.").

Moreover, a party asserting reliance interests must have clean hands. *See, e.g.*, *Food Lion, Inc. v. S.L. Nusbaum Ins. Agency, Inc.*, 202 F.3d 223, 228 (4th Cir. 2000) ("Unclean hands bars a party from receiving equitable relief … ."). Leaving aside the role tobacco manufacturers (including some *amici*) have played in making their products attractive and available to youth,[11] they have consistently failed to take advantage of the agency's repeated offers of assistance in preparing their applications or to use the longstanding draft guidance to prepare applications. *See supra* p. 7; *see* Op. at 53-54 ("[M]anufacturers long have been on notice that they will have to file premarket approval applications, substantial equivalence reports, and exemption requests, and if they have chosen to delay their preparations to do so, then any hardship occasioned by their now having to comply is of their making."). Manufacturers' collective refusal to engage with FDA's efforts to provide assistance renders any claim of unfairness hollow.

C. The Public Interest Weighs Against Remand Without Vacatur

Having received a long holiday from regulation never contemplated by the statute, and having used that holiday "to attract new, young users and get them addicted to nicotine," Op. at 44, ENDS manufacturers nevertheless want more. They demanded more time from FDA when it considered the Deeming Rule and from the *Nicopure* court when they challenged the Deeming Rule as arbitrary and capricious. *See* 266 F. Supp. 3d at 399-400. After being denied in the rulemaking process and on the merits, they cannot overcome the law in this last-ditch manner.

No equitable considerations could justify reinstating the August 2017 Guidance. As the Court has found, the lengthy compliance period manufacturers have already enjoyed was not

[11] According to the Centers for Disease Control and Prevention, "[t]he rise in e-cigarette use during 2017-2018 is likely because of the recent popularity of e-cigarettes shaped like a USB flash drive, such as JUUL; these products can be used discreetly, have a high nicotine content, and come in flavors that appeal to youths." Karen A. Cullen et al., Use of Electronic Cigarettes and Any Tobacco Products Among Middle and High School Students—United States, 2011-2018, 67 *Morbidity & Mortality Weekly Rep.* 1276, 1277 (Nov. 16, 2018).

authorized by the TCA. Congress determined that advance review by FDA was necessary to safeguard public health—a decision borne out by the surging epidemic of ENDS use by young people in the absence of that review. *Amici* ask the Court to presume that, as a category, ENDS products are helping smokers to quit. *See, e.g.*, Amicus Br. at 3, 15. Not only is the proposition that ENDS products help smokers quit subject to considerable doubt,[12] the salient point is that Congress chose to place the burden on manufacturers to demonstrate that their products produce that kind of benefit and that such benefits outweigh any risks to public health. *Amici* would have FDA and this Court presume precisely what the statute requires the manufacturers to prove, and substitute *amici*'s self-interested assertions for Congress's statutory choices.

II. Remand Without Vacatur Is Even Less Appropriate for Cigars

Amici's arguments are meritless as to all deemed products, but are particularly egregious—and often outright misleading—when it comes to cigars. Unlike ENDS products, many cigars were commercially marketed on February 15, 2007 and hence are "grandfathered" past the premarket review requirements. *See* 21 U.S.C. § 387j(a)(1). Additionally, cigars with the "same characteristics" as grandfathered products or that "do[] not raise different questions of public health" are eligible for clearance through the already established SE process, and at least one *amicus* has already had SE reports for cigars granted. *See* Zeller Decl. ¶ 5(b)-(c) nn.11-12. Hundreds if not thousands of cigar varieties are lawfully on the market today, and will remain on the market with no need for further application no matter what the Court does here.[13]

But since Congress took up the TCA, a new type of "cigar" has flourished: small, fruit- or

[12] According to a 2018 Report from the National Academies of Sciences, Engineering and Medicine ("NASEM"), "[o]verall, there is limited evidence that e-cigarettes may be effective aids to promote smoking cessation." NASEM, *Public Health Consequences of E-Cigarettes*, Washington, D.C. 4. (Jan. 2018).

[13] The Regulatory Impact Analysis for the Deeming Rule estimated that 60% of cigars on the market, or about 4500 cigar varieties, would be grandfathered. FDA. Docket No. FDA-2014-N-0189, Final Regulatory Impact Analysis, at 84 (May 2016), https://tinyurl.com/yy7h8txr.

candy-flavored products with names like "SwagBerry" or "Da Bomb Blueberry" that are transparently designed to get around the TCA's ban on youth-friendly flavored cigarettes.[14] These products are virtually indistinguishable from cigarettes and disproportionately appeal to youth. *See* 79 Fed. Reg. 23,146, 23,158 (Apr. 25, 2014). As a result of these products, cigar smoking is now roughly as prevalent among youth as cigarette smoking. 81 Fed. Reg. 28,974, 29,023 (May 10, 2016). As FDA explained in March 2019, these products

> are associated with significant risk and provide no public health benefit. Like other combustible tobacco products, cigars—including flavored cigars—expose users to toxic and carcinogenic chemicals. Although little cigars deliver similar levels of nicotine compared to cigarettes, the levels of some carcinogens in the mainstream smoke exceed those in cigarettes.[15]

Most of *amici*'s arguments—public health, the TCA's prohibition on "banning" products, the difficulty of proving the statutory PMTA requirements—are thus wholly inapplicable to cigars. *Amici*'s only relevant arguments—that manufacturers do not know what to include in SE reports and that it is unfair to move up an unlawful deadline on which they "relied"—are even less compelling for cigars than for ENDS products.

The first argument cannot withstand even modest scrutiny. Unlike for ENDS products, the most realistic pathway to market for non-grandfathered cigars is through substantial equivalence, as amici acknowledge. Amicus Br. at 1. This requirement is straightforward, asking only whether the new product has "the same characteristics" as a predicate product or "has different characteristics [but] does not raise different questions of public health." 21 U.S.C. §§ 387e(j), 387j(a)(3). Thousands of new tobacco products have completed this process already.

Both FDA and manufacturers have already had extensive experience with SE reports,

[14] *See* Campaign for Tobacco-Free Kids, Not Your Grandfather's Cigar: A New Generation of Cheap and Sweet Cigars Threatens a New Generation of Kids, at 9, 12-14 (Mar. 13, 2013), https://tinyurl.com/y6nu66zx.
[15] FDA, Modifications to Compliance Policy for Certain Deemed Tobacco Products, Guidance for Industry, Draft Guidance (Mar. 2019), https://tinyurl.com/yyywgoat.

giving manufacturers abundant information about how to meet the standard. *Amici* claim that FDA has "issued final orders for only about 191 provisional [SE] products," out of over 5000 SE submissions, leaving a "backlog of thousands of SE reports." Amicus Br. at 7, 14; *see also* Folmar Decl. ¶ 6, ECF No. 133-5 (claiming "FDA appears to have issued final orders on only approximately 5.1 percent of known SE Reports"); Bauersachs Decl. ¶ 17, ECF No. 113-2 (same). This is a complete distortion of the facts. The source they cite says FDA has "resolved 93 percent" of the more than 2500 SE submissions filed since March 22, 2011, issuing among other things "601 SE orders" and "202 [not SE] orders," leaving "no backlog of new regular SE applications."[16] Only products that were the subject of "provisional applications" filed before March 22, 2011 remain in any significant number—but the TCA did not require FDA to grant or deny these reports by a date certain, permitting products for which SE reports were filed by that date to remain on the market indefinitely unless FDA denied the application. 2018 SE Update; *see also* 21 U.S.C. § 387j(a)(2)(B). Even so, FDA has resolved "over 1,000" of the "nearly 3,600 provisional SE applications submitted." 2018 SE Update. *Amici*'s "5.1 percent" figure is pure fiction.[17]

Along with this well-established process, FDA has provided voluminous information about the requirements for substantial equivalence, issuing numerous guidance documents and convening several workshops informing manufacturers of the requirements for SE Reports.[18] FDA publishes detailed scientific review documents for products found substantially equivalent

[16] FDA, Update on Provisional Substantial (SE) Equivalence Review Process ("2018 SE Update") (Apr. 5, 2018), https://tinyurl.com/yyrhcwjt.
[17] *Amici* similarly mislead by describing 1,500 SE Reports FDA "indefinitely remove[d] from review" as a "backlog" Folmar Decl. ¶ 6; *see also* Bauersachs Decl. ¶ 17. FDA removed these products because it determined they were "less likely" to "raise different questions of public health" and therefore were unlikely to be denied. 2018 SE Update. Their removal was tantamount to a tacit resolution in the applicants' favor, not a backlog.
[18] *See supra* pp. 6-7; Zeller Decl. ¶¶ 5(b), 5(d), 15; FDA, Guidance, https://tinyurl.com/y4eka9yv (listing relevant guidance in January 2011, September 2011, September 2014, July 2016, and December 2016).

and issues general summaries of denied applications that explain the reasons for denial, providing a roadmap for the filing of future reports. Most recently, FDA issued a detailed proposed rule[19] establishing requirements for SE reports, closely tracking the standards FDA has published since the first reports were filed in 2011. Notably, this same proposed rule governs SE filings for cigarettes and other non-deemed tobacco products, and the lack of final guidance to date has not impeded the submission and resolution of thousands of SE reports for such products. Indeed, it has not even stopped *amici* themselves. *See* Zeller Decl. at ¶ 5(b)-(c) nn.11-12.

Moreover, FDA's inclusion of cigars in the Deeming Rule was based in part on overwhelming evidence that the toxic and carcinogenic constituents in cigar smoke are the same, or even more harmful, as those in cigarette smoke. 81 Fed. Reg. at 29,020. Cigar manufacturers cannot plausibly claim ignorance of the product characteristics they have to report in their applications. If cigar manufacturers have legitimate questions about the details of reports, FDA has been and continues to be available to address their questions. *See* Zeller Decl. ¶ 15. The claim that they lack sufficient information is thus thoroughly unconvincing.

Nor do cigar manufacturers have any plausible reliance argument. Under the Deeming Rule, cigar manufacturers would have had to file SE reports by February 8, 2018 in order to keep their products on the market pending FDA action on their applications. 81 Fed. Reg. at 28,978. That deadline was just months away when FDA extended it in May and August 2017. Cigar manufacturers thus should have been close by that time to having the data necessary for their reports—and have now had an additional two years to prepare. Any cigar manufacturer planning to file an SE report has had ample opportunity and information to prepare it.

Amici also mischaracterize FDA's advice regarding submitting SE reports. Although the

[19] Content and Format of Substantial Equivalence Reports; Food and Drug Administration Action on Substantial Equivalence Reports, 84 Fed. Reg. 12740 (Apr. 2, 2019).

August 2017 Guidance extended the submission deadline, FDA did not "instruct manufacturers to stop submitting applications ... pending further FDA action." Amicus Br. at 8. On the contrary, Commissioner Gottlieb encouraged prompt submission of such reports. *See* Defs.' Remedy Br. at 8.[20] Cigar manufacturers had no legitimate basis for postponing the preparation of information for their SE reports and their choice to do so does not create a cognizable reliance interest.

III. Vacatur Would Not Jeopardize the Deeming Rule or Violate the TCA

Amici's arguments that vacatur would somehow retroactively taint the Deeming Rule are meritless. Their first argument, that vacatur would "ban" an entire class of products and thus violate 21 U.S.C. § 387g(d)(3), Amicus Br. at 11,[21] is an absurd reading of the TCA. Under this construction, FDA could not deem a class of new tobacco products if none of its members could satisfy the "protection of public health" standard, because that would "ban" the entire class. The worse the product, the more powerless FDA would be. This is plainly not Congress's intent, and is not a plausible reading of the TCA. *See Delany v. Moraitis*, 136 F.2d 129, 131 (4th Cir. 1943) ("[I]t is well settled that statutes should be construed, if possible, so as to effectuate the purpose intended and avoid absurd consequences."). In reality, no class of products is being banned. ENDS that are shown to meet the public health standard will be allowed on the market, and those that are not will be prohibited. That is the statutory design, not a violation of the statute.

Amici's second argument, that the Deeming Rule would have been arbitrary and capricious if it gave ENDS products only a 120-day (or even 10-month) window to prepare

[20] Similarly, while *amici* claim that "[t]ime and again, FDA has insisted that further regulatory action is imperative before ENDS and cigar manufacturers face compliance deadlines[.]" Amicus Br. at 3-4 & n.2, the documents they cite tell a different story. Far from stating that SE reports should be held back until FDA took new action, the 2011 guidance made clear that SE reports should be submitted even before FDA "initate[d] a rulemaking that would establish requirements and standards for substantial equivalence." 2011 SE Guidance at 1; *see also id.* at 5-6. The rest of *amici*'s citations are connected to the unlawful August 2017 Guidance and show that FDA did not offer that rationale until well after it issued the Deeming Rule and its initial guidance and timelines. *See* Amicus Br. at 4 n.2.

[21] Although *amici* do not acknowledge it, this argument does not apply to cigars, because many cigars were grandfathered in or successfully showed their substantial equivalence. *See supra* p. 10 & n.13.

applications, Amicus Br. at 11-12, fares no better. *Amici* identify no precedent for suggesting that a rule could become arbitrary and capricious years after the fact because of judicial invalidation of a subsequent rule, and Plaintiffs are aware of none. More importantly, though, as noted previously, the TCA authorized FDA to issue a deeming rule with no compliance period whatsoever. *See Nicopure*, 266 F. Supp. 3d at 376. Far from being arbitrary and capricious, such a rule would have been entirely consistent with the TCA. Again, under the TCA, there is no right for a deemed product to be on the market without a marketing order.

IV. Plaintiffs' Proposal Would Not Violate the APA

Amici's argument that Plaintiffs' proposal would violate the APA, Amicus Br. at 12-14, is similarly meritless.[22] The proposed order explicitly requires that to the extent any FDA rule is issued in response to the order, it should be implemented in accordance with the APA. *See* Pls.' Proposed Remedial Order at 1, ECF No. 78-1. This process would include notice-and-comment procedures, as applicable. Nor does the proposed order prejudge the outcome of any rulemaking or individual applications. It merely requires that the outcome of that rulemaking restore the parties to the status quo before the illegal August 2017 Guidance as nearly as possible, and that FDA meet its legal obligations to enforce the TCA. The proposal does not mandate how FDA assesses individual applications. Manufacturers can submit whatever evidence they choose and FDA can process applications however it sees fit; the only change is that manufacturers cannot keep their products on the market indefinitely in derogation of Congressional intent and design.

V. Conclusion

For the foregoing reasons and those stated in Plaintiffs' other briefs, the Court should order the remedy proposed by Plaintiffs.

[22] *Amici* also argue that the Court lacks the authority to adopt Plaintiffs' proposal. Plaintiffs addressed these arguments in response to Defendants' brief. *See* Pls.' Reply to Defs.' Remedy Br. at 2-3, 6-8, ECF No. 123.

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Respectfully submitted,

/s/ Jeffrey B. Dubner

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