IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CIGAR ASSOCIATION OF AMERICA, *et al.*, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	Civil Action No. 16-1460 (APM)

AMICUS CURIAE BRIEF OF AMERICAN ACADEMY OF PEDIATRICS, MARYLAND CHAPTER—AMERICAN ACADEMY OF PEDIATRICS, AMERICAN CANCER SOCIETY CANCER ACTION NETWORK, AMERICAN HEART ASSOCIATION, AMERICAN LUNG ASSOCIATION, CAMPAIGN FOR TOBACCO-FREE KIDS, TRUTH INITIATIVE, DR. LEAH BRASCH, DR. CYNTHIA FISHMAN, DR. LINDA GOLDSTEIN, DR. STEVEN HIRSCH, AND DR. DAVID MYLES REGARDING PLAINTIFFS' MOTIONS FOR LEAVE TO AMEND AND FOR SUMMARY JUDGMENT

CORPORATE AND FINANCIAL DISCLOSURE STATEMENT

Amici curiae are non-profit organizations committed to advancing the public health, and pediatricians who actively treat patients for and counsel patients on the use of tobacco products. No party to this filing has a parent corporation, and no publicly held corporation owns 10% or more of the stock of any of the parties to this filing.

STATEMENT OF COUNSEL PURSUANT TO FEDERAL RULE OF APPELLATE PROCEDURE 29(a)(4)(E) AND LOCAL CIVIL RULE 7(o)(5)

Counsel for *amici curiae* hereby states that no counsel for any party to this litigation authored this brief in whole or in part; no party or party's counsel contributed money that was intended to fund, or did fund, the preparation or submission of this brief; and no person, other than *amici curiae*, contributed money that was intended to fund, or did fund, the preparation or submission of this brief.

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STATEMENT OF IDENTITY AND INTEREST OF *AMICI CURIAE*

Amici[1] include the American Academy of Pediatrics, the Maryland Chapter of the 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, and Truth Initiative (the "*Amicus* Organizations"), as well as Dr. Leah Brasch, M.D., Dr. Cynthia Fishman, M.D., Dr. Linda Goldstein, M.D., Dr. Steven Hirsch, M.D., and Dr. David Myles, M.D. (the "*Amicus* Pediatricians"). The *Amicus* Organizations are non-profit organizations that have worked for decades to protect the public from the devastating harms caused by tobacco products, which are the leading cause of preventable death in America, claiming over 480,000 lives every year. *See* ECF No. 76-1. The *Amicus* Pediatricians all screen, counsel, and treat youth patients for tobacco use.

Amici work daily on the front lines of a multi-faceted effort to eradicate tobacco addiction and to avert the creation of new generations of addicted children and adults. *Amicus* Organizations' membership includes many of the country's preeminent researchers into the impacts and incidence of tobacco use, particularly among youth. *Amicus* Organizations use the information produced during FDA's premarket review process to advise their members, including *Amicus* Pediatricians, on the best ways to counsel and treat patients who use newly authorized products.

In August 2017, FDA issued a Guidance in which it announced that it would suspend, for at least four years, the Family Smoking Prevention and Tobacco Control Act's ("TCA") premarket review requirements for cigars, pipe tobacco, and other deemed tobacco products introduced into the market between February 16, 2007 and August 8, 2016. To protect their interest in having the

[1] For clarity, this brief uses "*amici*" to refer to the plaintiffs in *AAP* even when discussing their filings in that case, and uses "Plaintiffs" to refer to the plaintiffs in this case even when discussing their *amicus* filing in *AAP*. To distinguish citations to this case's docket from the *AAP* docket, the brief will refer to docket entries in this case as "ECF No. ##" and to docket entries in *AAP* as "*AAP*, Dkt. No. ##." If the Court would like to receive physical copies of any or all of the *AAP* documents cited by the parties, *amici* would be happy to provide them.

premarket review requirements enforced, *amici* filed suit against FDA on March 27, 2018, arguing that the August 2017 Guidance was inconsistent with the Tobacco Control Act, arbitrary and capricious, and unlawfully issued without complying with the notice-and-comment requirements of the Administrative Procedure Act. District Judge Paul W. Grimm of the U.S. District Court for the District of Maryland granted summary judgment to *amici* and vacated the Guidance on May 15, 2019. On July 12, 2019, Judge Grimm entered a remedial order effectively restarting the premarket review process. *Amici* have a clear and strong interest in ensuring that the judgment and orders they obtained after hard-fought litigation are not nullified through a collateral attack in another court.

INTRODUCTION AND SUMMARY OF ARGUMENT

Plaintiffs in this case seek to add a claim for declaratory relief effectively nullifying the judgment in a case that has been pending before Judge Grimm for more than a year. *See Am. Acad. of Pediatrics* ("*AAP*") *v. FDA*, No. 18-883 (D. Md. filed Mar. 27, 2018). They request this extraordinary relief even though they voluntarily deferred their claims in this case throughout the entire pendency of the *AAP* litigation; never informed either court that the relief requested in *AAP* would in any way interfere with proceedings in this Court; and have not even now asked this Court to schedule briefing on the supposedly affected claims.

As Defendants suggest, the proposed new claim would be futile, as it is neither permissible nor appropriate under the Declaratory Judgment Act, Section 705 of the Administrative Procedure Act, or the law-of-the-case doctrine. *Amici* write to address three subjects relevant to the Court's consideration of whether "justice … requires" granting Plaintiffs leave to amend, Fed. R. Civ. P. 15(a)(2): (1) the Plaintiffs' misleading description of the *AAP* case and its relationship to this case, along with Plaintiffs' conscious decision not to raise the supposed conflict in either Court before now; (2) FDA's proposal, first announced several months ago, to replace the August 2017 Guidance

in the near future and subject many cigars to enforcement within 30 days of issuance, which Plaintiffs never raised with this Court despite the supposed centrality of the Guidance to this Court's case management orders; and (3) the public health impact of reinstating cigar manufacturers' unlawful holiday from the statutory requirements for premarket review. These facts undermine any claim that Plaintiffs acted diligently in amending their complaint or that justice requires allowing amendment at this stage. Additionally, Plaintiffs will briefly expand on the unsuitability of relief under the three sources of law that Defendants identified, focusing largely on the equitable considerations that must be evaluated under all of these discretionary doctrines.

Amici respectfully submit that these facts and arguments, and those in Defendants' brief, provide ample basis to deny Plaintiffs' motion for leave to amend; or, in the alternative, to deny Plaintiffs' motion for summary judgment and provide Plaintiffs an opportunity to demonstrate why summary judgment should not be granted to Defendants *sua sponte* under Federal Rule of Civil Procedure 56(f). *See, e.g.*, *Robbins v. Dist. of Columbia*, 650 F. App'x 37, 40-41 (D.C. Cir. 2016).[2]

I. Plaintiffs Omit or Misstate Key Facts Related to Their Motions

A. Plaintiffs Misrepresent the Relationship Between This Case and *AAP*

Plaintiffs' depiction of *AAP* and its relationship to this case is misleading in numerous respects, most notably the propriety of *amici* filing that lawsuit and the diligence of Plaintiffs in raising their concerns. Plaintiffs repeatedly insinuate that *amici* acted improperly by filing a lawsuit to challenge FDA's delay of the TCA's premarket review requirements after this Court denied *amici*'s motion to intervene to defend the Deeming Rule against Plaintiffs' challenge to its warning

[2] While the motion for summary judgment is not yet before this Court, as explained by Defendants, *see* ECF No. 139, *amici* will address both summary judgment and the motion for leave to amend simultaneously due to the overlap between the two, in lieu of filing a second, duplicative *amicus* brief if the motion for leave is granted. Barring unanticipated developments, *amici* do not expect to file a separate *amicus* brief on summary judgment. While Plaintiffs' motions can be resolved without oral argument, *amici* would be pleased to participate in oral argument if the Court would like them to address any questions regarding *AAP* or the other issues presented in these motions.

requirements. *See, e.g.*, ECF No. 136-1 at 2, 8, 11, 17. However, Plaintiffs took the opposite position earlier in this case. When Plaintiffs opposed intervention, they explicitly and repeatedly argued that *amici* should "*fil[e] their own lawsuit against the Government*" if they wished to challenge the then-imminent issuance of the Guidance. ECF No. 44 at 3 (emphasis in original). Assuming that *amici's* "real concern [was] that the agency will change the [Deeming] Rule," they insisted that "if [*amici*] become unsatisfied with alterations to the rule made through the administrative process, they can file their own lawsuits against the FDA at the appropriate time." *Id.* at 11.

On this issue, *amici* and Plaintiffs agreed. As *amici* explained, Plaintiffs' speculation that *amici* wanted to use intervention in this case to challenge the imminent Guidance was wrong. Instead, *amici* sought in this Court only "to defend the Deeming Rule against Plaintiffs' legal challenges," and confirmed that "[i]f the FDA issues new rules that weaken the Deeming Rule in a manner inconsistent with legal requirements, [*amici*] will oppose such changes in separate proceedings." ECF No. 46 at 1; *see also id.* at 7 ("[*Amici*] have no intention of using Plaintiffs' case as a vehicle for challenging … the FDA's delayed compliance deadlines."); *accord id.* at 12 n.7. *Amici*'s suit in Maryland was thus not an end-run around this Court's ruling on intervention, but rather *the exact process the Plaintiffs recommended*.

Nor did this Court's standing ruling render the *AAP* litigation or Judge Grimm's ruling improper. Because all that *amici* sought to do in this case was defend the Deeming Rule and the only material challenges then at issue were the warning label requirements, *amici*'s standing to intervene turned entirely on "one interest": their interest *vel non* in "preserving the Rule's warning requirements." ECF No. 68 at 7. This Court found *amici*'s showing as to this sole issue wanting and

therefore denied intervention, *id.* at 13-20, but recognized that *amici* could have "standing in other matters concerning tobacco regulation." *Id.* at 15.

AAP concerned an entirely different action—FDA's extension of "compliance periods" that exempted all deemed products from statutorily mandated premarket review requirements for at least several years—and an entirely different record. *See AAP*, Dkt. No. 39 at 11-12 (distinguishing the standing issues in *AAP* from those in *CAA*). *Amici* submitted more than 150 pages of specific, detailed, and concrete declarations in *AAP* explaining the exact kind of data that premarket review created, how *amici* would use it, and specific programs that were impeded without it. *See AAP*, Dkt. No. 39-1 to 39-14; *see also AAP*, Dkt. No. 39 at 2-14 (discussing standing allegations). Judge Grimm analyzed this record at length and found that it established standing. *AAP v. FDA*, 379 F. Supp. 3d 461, 475-80 (D. Md. 2019). Plaintiffs here do not suggest any flaw in that analysis, and their disparagement of *amici* as "outside entities that had no standing to be in this lawsuit," ECF No. 136-1 at 11, is irrelevant to the propriety and validity of Judge Grimm's holding or of the Maryland litigation more broadly.

Plaintiffs' characterization of *AAP* as the "e-cigarette" case and this as the "cigar" case is also incorrect. From the beginning, *AAP* challenged the delay of premarket review as to *all* deemed products, including both cigars and e-cigarettes. *See, e.g.*, *AAP*, Dkt. No. 1 ¶¶ 38, 77, 87, 116. *Amici*'s summary judgment briefing and declarations specifically discussed cigars. *See, e.g.*, *AAP*, Dkt. No. 31-2 at 2, 25; *AAP*, Dkt. No. 39 at 33, 36; *AAP*, Dkt. No. 39-5 ¶¶ 11, 14-15; *AAP*, Dkt. No. 39-10 ¶¶ 16-22; *see also AAP*, Dkt. No. 34 at 1, 4-9 (*amicus* brief discussing how "[t]he proliferation of flavored and mini cigars threatens public health, particularly for youth").

Critically, Plaintiffs here knew all along that *AAP* implicated cigars. They discussed *AAP* with this Court at an August 16, 2018 status conference while summary judgment was being briefed

in Maryland, yet did not suggest to this Court that its case management was jeopardized. *See* ECF No. 109 at 43-44.[3] Plaintiffs then submitted an *amicus* brief in *AAP* in which they made no mention of any supposed conflict between that litigation and this Court's proceedings. *AAP*, Dkt. No. 45-1.[4] Indeed, they explained that they consciously chose not to intervene in *AAP* because "[t]he Government has raised the key legal reasons why Plaintiffs' effort to force agency action should be denied," *id.* at 1, even though the government had made no arguments based on any conflict between the two cases, *see AAP*, Dkt. Nos. 36-1, 43.

Even now, Plaintiffs have *never* advised Judge Grimm of any supposed problem with his ruling vis-à-vis this case, much less that his "opinion threatens this Court's management of the instant case[.]" ECF No. 136-1 at 3. After Judge Grimm vacated the Guidance and requested briefing on whether further remedial measures were appropriate, several industry associations and tobacco manufacturers, including cigar manufacturers, sought to intervene and filed amicus briefs. *See AAP*, Dkt. Nos. 76, 77, 79, 80, 81, 87, 113. Plaintiffs here were not among them.[5] Instead, Plaintiffs waited seven weeks after Judge Grimm vacated the Guidance before seeking relief in this Court—conveniently waiting until a week after remedial briefing was complete in *AAP*.

B. Plaintiffs Omit FDA's Plans to Replace the Guidance

Plaintiffs also fail to mention regulatory developments of considerable significance to their claim that the elimination of the Guidance would cause a "judicial emergency." ECF No. 136-1 at

[3] The *ad hominem* criticism that *amici* were "trying to re-litigate Your Honor's ruling" is attributed in the transcript to counsel for Defendants, but that appears to be an error; the speaker calls it "strange" that "the government didn't try to transfer this case back to Your Honor," which would make little sense for the government's counsel to say. ECF No. 109 at 44:1-7. That speaker also made the same overly broad description of this Court's standing ruling as Plaintiffs' brief, claiming that the Court ruled "[t]hat there's no standing for [*amici*] to challenge these type of things," *id.* at 44:3-4, when in fact the Court explicitly recognized that *amici* could have standing to challenge some FDA tobacco regulations but not others, *see supra* pp. 6-7.

[4] Judge Grimm found Plaintiffs' *amicus* brief untimely and duplicative of an earlier industry *amicus* brief, and therefore denied leave to file. *AAP*, Dkt. No. 50 at 2.

[5] Much of the remedial briefing addressed cigars directly. *See, e.g.*, *AAP*, Dkt. No. 113 at 7-8; *AAP,* (Dkt. No. 113-2, 113-5 (declarations by cigar manufacturers); *AAP*, No. 124 at 10-14.

11. In November 2018, FDA announced that it intended to "revisit" the Guidance, specifically stating that "flavored cigars should no longer be subject to the extended compliance date for premarket authorization."[6] Then, on March 13, 2019, it issued a Draft Guidance that, if finalized, would subject many cigars to premarket review requirements 30 days after issuance.[7] Defendants told Judge Grimm that FDA "plan[ned] to finalize the draft guidance as quickly as possible." *AAP*, Dkt. No. 71 at 5. As recently as July 15, after Judge Grimm's remedial order, FDA's acting commissioner reiterated FDA's intention to finalize a new compliance policy subjecting flavored cigars to premarket review, calling it "one of the most critical public health steps that the FDA can take to curb youth vaping and address youth use of flavored cigars."[8]

Plaintiffs have known for months that Defendants were planning to abandon the Guidance that is supposedly "an indispensable feature of the Court's case management efforts," ECF No. 136-1 at 11—yet have said nothing to this Court about the proposed changes in any of the numerous status reports they have filed during that time. *See* ECF Nos. 112, 115, 119, 127.[9] Plaintiffs did not ask for emergency relief, nor even request a briefing schedule for their deferred claims.

These facts undermine Plaintiffs' claim that they suddenly need unprecedented declaratory relief countermanding a coordinate court's order. Plaintiffs were content to allow *AAP* to proceed without any action in either court for more than a year, have made no effort to advise Judge Grimm of the supposed conflict, and even now—more than two months after Judge Grimm vacated the

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[6] Scott Gottlieb, M.D., Comm'r, FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes Nov. 15, 2018, https://tinyurl.com/y4kn533v.

[7] FDA, *Modifications to Compliance Policy for Certain Deemed Tobacco Products—Guidance for Industry—Draft Guidance* 15-19 (Mar. 2019), ("March 2019 Draft Guidance"), https://tinyurl.com/yyywgoat.

[8] Norman E. Sharpless, M.D., Acting Comm'r, FDA, Statement on the Agency's Actions to Tackle the Epidemic of Youth Vaping and Court Ruling on Application Submission Deadlines for Certain Tobacco Products, Including E-Cigarettes, July 15, 2019, ("Sharpless Statement"), https://tinyurl.com/y6bk24kq.

[9] These status reports stated that Plaintiffs were "monitor[ing] regulatory developments," *see, e.g.*, ECF No. 112 at 2, but never suggested to the Court that any pending developments could require resumption of the briefing on the deferred counts, much less emergency relief.

Guidance, and more than *eight* months after FDA indicated that it was likely to replace the Guidance—have not asked this Court to begin proceedings on their deferred claims. If there is any "'fire drill' situation" here, ECF No. 136-1 at 3, it is entirely of Plaintiffs' making. *Cf., e.g.*, *McCoy v. Iberdrola Renewables, Inc.*, 760 F.3d 674, 687 (7th Cir. 2014) (courts have discretion to deny leave where "the unexplained delay looks more like procedural gamesmanship than legitimate ignorance or oversight").

II. Plaintiffs' Proposed Relief Would Violate the TCA and Harm Public Health

Because each of the statutes or doctrines supposedly authorizing Plaintiffs' proposed relief involves the Court's equitable discretion, it is important to recognize exactly what Plaintiffs are requesting: blanket immunity from the mandatory premarket review requirements of the Tobacco Control Act for as long as they can keep their deferred claims alive. Congress designed the TCA to prevent manufacturers from marketing new tobacco products—like Plaintiffs' members' kid-friendly flavored cigars—without first proving to FDA that they are "appropriate for the protection of public health" or are substantially equivalent to a product marketed on February 15, 2007. *See* 21 U.S.C. § 387j(a)(3), (c)(2). The relief Plaintiffs request would expose hundreds of thousands of young people to deadly, addictive products designed to appeal to them, while postponing the requirement for manufacturers to demonstrate that their products meet the statutory criteria.

The TCA prohibits any manufacturer from marketing any tobacco product not commercially marketed on February 15, 2007, unless and until the manufacturer proves to FDA that the product is "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). As Judge Grimm explained in *AAP*, the TCA "require[s] premarket review (involving applications and decisions on those applications) within a specific timeframe," and "prohibits products from entering the market

without the FDA's approval." *AAP*, 379 F. Supp. 3d at 485. He found that the Guidance was an "across-the-board suspension of the Tobacco Control Act's premarket approval process" that was "inconsistent with the statute." *Id.* at 492. Crucially, the Guidance "h[e]ld in abeyance enforcement of mandatory provisions of a statute that Congress viewed as integral to address public health dangers that the agency itself acknowledges are alarming … , all the while affording those manufacturers responsible for the public harm a holiday from meeting the obligations of the law." *Id.* at 493. The Guidance invalidated by the AAP decision allowed manufacturers "to attract new, young users and get them addicted to nicotine before any of their products, labels, or flavors are pulled from the market, at which time the youth are likely to switch to one of the other thousands of tobacco products that already are approved—results entirely contrary to the express purpose of the Tobacco Control Act." *Id.* at 492.[10]

Plaintiffs do not acknowledge, much less engage with, Judge Grimm's holding. All that they offer in any of their filings about the legality of the Guidance or the substance of Judge Grimm's opinion is a scant one-page restatement of arguments that Defendants made in *AAP* and Judge Grimm rejected at length. *Compare* ECF No. 136-1 at 14-15 *with AAP*, 379 F. Supp. 3d at 480-87, 491-94. Neither their claim for relief nor their argument for granting them summary judgment thereon even mention the TCA, let alone attempt to square their requested relief with it. *See* ECF No. 135 at ¶¶ 161-70; ECF No. 136-1 at 10-17. And they do not mention, much less refute, Judge Grimm's holding that the Guidance was unlawful without notice-and-comment rulemaking. *See AAP*, 379 F. Supp. 3d at 47-53. The idea that justice requires allowing plaintiffs to amend a

[10] To be sure, Judge Grimm's opinion only explicitly referred to e-cigarettes. But nothing in his analysis or the TCA supports any distinction between e-cigarettes and cigars, and the public health case against cigars is if anything *stronger* than against e-cigarettes: whereas e-cigarettes could theoretically bring some public health benefit *if* they could be proven less deadly than combustible tobacco products and effective at helping individual users quit smoking without leading to youth initiation, cigars have no potential public health benefits whatsoever. *Cf. AAP*, Dkt No. 124 at 10-14 (explaining why cigar manufacturers have even less basis for relief from the *AAP* decree than e-cigarette manufacturers).

complaint three years into a case whose remaining claims Plaintiffs have deferred for years, for the sole purpose of reinstating a separate agency action that has been held unlawful by a coordinate court, without any suggestion that that court overstepped its jurisdiction or even erred in its conclusion, is without any precedent.

Just as they ignore the TCA and the unprecedented nature of their requested relief, Plaintiffs do not mention the public health effects of exempting all cigars from the premarket review requirements of the TCA. While Plaintiffs seek to focus the Court's attention on premium cigars, the majority of products at issue are cheap, kid-friendly, flavored cigarette-like products, consciously designed to circumvent prohibitions on flavored cigarettes and attract youth users. *See* ECF No. 76 at 1-2, 6-8; ECF No. 74 at 9; *AAP*, Dkt. No. 124 at 10-14; AR 154660-67. As FDA recently explained when it proposed to eliminate the Guidance's compliance period for flavored cigars, 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.[11]

Thanks in large part to these new kid-friendly products, roughly a million youth each year begin cigar use, and youth cigar use has become as prevalent as cigarette use. ECF No. 76 at 9 (citing 79 Fed. Reg. 23,141, 23,156 (Apr. 25, 2014)); *see also* ECF No. 74 at 9-11 (explaining why "[t]he scientific evidence is overwhelming: cigars and pipe tobacco pose significant public health risks").

Delaying premarket review for these products has harmed public health and endangers the health of children exposed to these products. As FDA explained in the Deeming Rule, "[a]ll cigars pose serious negative health risks" because "[a]ll cigar smokers have an increased risk of oral,

[11] March 2019 Draft Guidance, *supra* n.7, at 16.

esophageal, laryngeal, and lung cancer compared to non-tobacco users," as well as "other adverse health effects, such as increased risk of heart and pulmonary disease," "a marked increase in risk for chronic obstructive pulmonary disease," a higher risk of death from COPD, and "a higher risk of fatal and nonfatal stroke compared to non-smokers." 81 Fed. Reg. 28,973, 29,020 (May 10, 2016); *see also, e.g.*, ECF No. 94 at 8, 20, 34-35 (noting health risks of cigar use). And while FDA is "concerned about the use of all tobacco products, particularly combusted products like cigars and cigarettes, . . . [it] remains most concerned about use by youth and young adults given their *unique* susceptibility to the addictiveness of nicotine." 81 Fed. Reg. at 29,023; *see generally* ECF No. 76 at 3-5.

Even the cigar manufacturers who filed an *amicus* brief on the remedy in *AAP* acknowledged that their new products could *only* be authorized through "applications establishing substantial equivalence to products already on the market," *AAP*, Dkt. No. 113 at 1, presumably because they recognize that they cannot possibly show that their authorization is "appropriate for the protection of public health," 21 U.S.C. § 387j(c)(2)(A). And substantial equivalence requires that a new product has "the same characteristics as [a pre-2007] tobacco product," or "has different characteristics" from a predicate product but "does not raise different questions of public health." *Id.* § 387j(a)(3). Given the blatant dangers that FDA has recognized, it is hard to imagine how new fruit- or candy-flavored products like "SwagBerry" or "Da Bomb Blueberry" could possibly meet these standards. *See* AR 154662.

Plaintiffs also suggest that FDA's intention of providing more guidance on the content of substantial equivalence applications makes it impossible for them to comply with the TCA's requirements. This assertion is, as Judge Grimm put it, "disingenuous[]."*AAP v. FDA*, No. 18-cv-883, 2019 WL 3067492, at *5 (D. Md. July 12, 2019). As FDA has repeatedly explained, it has

issued ample guidance on applications, and manufacturers can submit applications without any further rulemaking. *See, e.g.*, *AAP*, Dkt. No. 125 at 2-5; *AAP*, Dkt. No. 120-1 ¶¶ 5(b)-(c); Sharpless Statement, *supra* n.8 ("Let me be clear with the tobacco industry: responsible manufacturers certainly don't need to wait 10 months to act."); *see also AAP*, Dkt. No. 124 at 5-8, 10-14. Indeed, the existing guidance has been sufficient for at least one cigar manufacturer to obtain a substantial equivalence determination. *See AAP*, Dkt. No. 120-1 ¶¶ 5(b)-(c) nn.11-12. Moreover, the TCA did not condition the requirement that all new products submit premarket review or substantial equivalence applications on the issuance of guidance by FDA elaborating on Congress's clearly specified requirements. *See AAP*, Dkt. No. 124 at 5-6, 11-12.

Plaintiffs' proposed claim for relief would therefore result in a wholesale reversal of Congress's policy determinations and mandatory requirements, with the effect of prolonging the exposure of hundreds of thousands of youth to deadly, addictive, kid-friendly products. Any equitable analysis must take this reality into account, yet Plaintiffs' briefs ignore it completely.

III. None of the Claimed Sources of Authority Allow Plaintiffs' Proposed Relief

The relief Plaintiffs request is, as far as their citations show or *amici* can find, unprecedented. Plaintiffs identify no cases where one district court has held that an agency action found unlawful and vacated by another district court must nonetheless remain lawful as to some of its subjects, much less for the sake of the court's case management orders. They identify three hypothetical sources of law, each less plausible than the previous one: the Declaratory Judgment Act, Section 705 of the APA, and the law of the case doctrine. None of these sources of authority remotely support the bold relief Plaintiffs demand.

Amici agree with the FDA's evaluation of the merits of the proposed Count X and add additional reasons that the amendment should be found futile or summary judgment denied and Rule 56(f) proceedings initiated.

A. Plaintiffs' Claim Does Not Satisfy the Declaratory Judgment Act

Plaintiffs' proposed amended complaint identifies the Declaratory Judgment Act as the legal basis for relief, 28 U.S.C. § 2201(a). *See* ECF No. 135-1 ¶ 170. Yet in their summary judgment brief, the Declaratory Judgment Act is nowhere to be found. *See, e.g.*, ECF No. 136-1 at iii. This omission is perhaps understandable, as the Declaratory Judgment Act does not remotely authorize Plaintiffs' claim. As FDA explains, the Declaratory Judgment Act requires that claimants show "a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Md. Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941); *accord, e.g.*, *Glenn v. Fay*, 222 F. Supp. 3d 31, 35 (D.D.C. 2016). The lack of adversity between Plaintiffs and FDA on the lawfulness of the Guidance precludes any declaration, much less the improper collateral attack sought here. *See* ECF No. 140 at 7-9.

But even if the Declaratory Judgment Act authorized Plaintiffs' proposed relief, it would only "confer[] a discretion on the court[] rather than an absolute right upon the litigant." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 287 (1995) (quoting *Pub. Serv. Comm'n of Utah v. Wycoff Co.*, 344 U.S. 237, 241 (1952)). The court's "discretion to withhold declaratory judgment" is of "singular breadth." *Jackson v. Culinary Sch. of Wash., Ltd.*, 59 F.3d 254, 256 (D.C. Cir. 1995). A court may "dismiss a declaratory action for equitable, prudential, or policy arguments." *Glenn*, 222 F. Supp. 3d at 35 (citing *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 136 (2007). While courts may consider any relevant factors, the analysis typically includes:

> [1] Whether a declaratory judgment would finally settle the controversy between the parties; [2] whether other remedies are available or other proceedings pending; [3]

> the convenience of the parties; [4] the equity of the conduct of the declaratory judgment plaintiff; [5] prevention of "procedural fencing"; [6] the state of the record; [7] the degree of adverseness between the parties; and [8] the public importance of the question to be decided.

Hanes Corp. v. Millard, 531 F.2d 585, 591 n.4 (D.C. Cir. 1976).

Here, the *Hanes* factors point uniformly point toward denial of Plaintiffs' requested relief—as do the equitable and policy concerns with overriding Congress's design and allowing Plaintiffs' members' to sell deadly, addictive, kid-friendly products. *See supra* pp. 10-14

1. A declaratory judgment would not "finally settle the controversy between the parties." *Hanes*, 531 F.2d at 591 n.4. The controversy between Plaintiffs and Defendants is not about the Guidance; it is principally about whether the FDA acted arbitrarily and capriciously in subjecting cigars (whether all cigars or premium cigars) to the mandatory premarket review requirements of the TCA. *See, e.g.*, ECF No. 22 at 18-30. Plaintiffs do not identify a single case where a declaratory judgment has been issued to buy a party time to litigate other claims, rather than to "settle [a] controversy between the parties," *Hanes*, 531 F.2d at 591 n.4, and *amici* have found none.

2. Other proceedings have been pending and other remedies are—or at least were—available to Plaintiffs. *Amici* filed the Maryland case on March 27, 2018, more than a year before Plaintiffs filed the instant motion. The *AAP* complaint specifically requested that Judge Grimm "[v]acate and set aside the Guidance." *AAP*, Dkt. No. 1 at 44. Plaintiffs were aware of the case no later than August 2018, ECF No. 109 at 43-44, and summary judgment briefing concluded in September 2018, *AAP* Dkt. No. 43. Thus, for nearly a year, Plaintiffs have known that the Guidance could be vacated at any time. Yet they chose to defer resolution of their premarket review claims month after month, never once warning the Court that doing so would create a "judicial emergency" if Judge Grimm found in *amici*'s favor. Even when FDA announced its intent to replace the Guidance with a new compliance scheme subjecting new flavored cigars to potential enforcement

within 30 days of issuance, *see supra* pp. 8-10, Plaintiffs continued asking this Court to defer resolution of their claims about the premarket review requirements.

Just as concerning, Plaintiffs have never requested *any* relief from Judge Grimm related to this case or the schedule in this Court. *See Patton Boggs, LLP v. Chevron Corp.*, 791 F. Supp. 2d 13, 25 (D.D.C. 2011) (if "the dispute in question would be 'better settled' by a court before which parallel proceedings are pending," whether state or federal, courts typically abstain from issuing a declaratory judgment (quoting *Cinci. Indem. Co. v. A&K Const. Co.*, 542 F.3d 623, 625 (8th Cir. 2008))). They never sought to intervene in the Maryland case, to transfer the Maryland case to this Court, or even to inform Judge Grimm that proceedings in his case might affect case management in this case. Even after Judge Grimm vacated the Guidance and asked whether further remedial action was appropriate (either to correct the harm caused by the Guidance or to mitigate disruption caused by its vacatur), they did not so much as file an *amicus* brief to propose relief that would accommodate the supposed scheduling emergency vacatur had caused. Having resolutely ignored every opportunity to request relief or raise their concerns in the Maryland proceedings and willfully delayed resolution in this Court despite knowing that this situation could arise, they can hardly be heard to demand an exceptional declaratory remedy at this late stage.

3. The convenience of the parties would not be served by the proposed relief, because, as Defendants explained, it would subject FDA to contradictory obligations to two different district courts. *See* ECF No. 140 at 9-11.

4. Plaintiffs' unreasonable delay eliminates any equity in their favor. *See, e.g.*, *CarrAmerica Realty Corp. v. Kaidanow*, 321 F.3d 165, 171-73 (D.C. Cir. 2003) (equitable defense of laches bars declaratory judgment claim). Their delay has prejudiced both *amici* and Defendants, who litigated an entire case without any indication that they needed to address Plaintiffs' supposed concerns. It

has further prejudiced *amici* by forcing them to expend resources defending Judge Grimm's decision outside of the normal appellate process in this collateral attack. And their motion wastes judicial resources by forcing multiple courts to consider the validity of the Guidance, when earlier action might have allowed some form of streamlining or coordination.[12] Additionally, their insistence that this case *was not* about the validity of the Guidance when it suited their purposes makes it inequitable for them to argue now that they need a declaration about the validity of the Guidance. *See supra* pp. 5-6; *cf. Comcast Corp. v. FCC*, 600 F.3d 642, 647 (D.C. Cir. 2010) ("Courts may invoke judicial estoppel where a party assumes a certain position in a legal proceeding, succeeds in maintaining that position, and then, simply because his interests have changed, assumes a contrary position." (alterations adopted and internal quotation marks omitted)).

5. While the traditional concern about "procedural fencing" (i.e., a race to the courthouse to get a more favorable forum) does not directly apply here, Plaintiffs' gamesmanship is clearly of a piece with it. Rather than raise their concerns with either this Court or Judge Grimm while the validity of the Guidance was being litigated, they waited until they could invoke the specter of a supposed "judicial emergency," ECF No. 136-1 at 11, to justify relitigating the Guidance's validity in a second forum on truncated briefing with manufactured exigency.

6. The state of the record and the merits-free nature of Plaintiffs' briefing makes a declaratory judgment inappropriate. No Joint Appendix has been submitted to this Court on the Guidance; even Plaintiffs' proposed amended complaint does not discuss the Guidance in its factual allegations, merely tacking a new declaratory judgment claim onto a complaint about a different agency action. More disturbingly, they are asking this Court to adjudicate the "validity and effectiveness" of an agency action already held unlawful with just one scant page about the validity

[12] This is to say nothing of the gross inequity of what they are seeking here: an open-ended license to market their deadly and addictive products in violation of the TCA. *See supra* pp. 10-14

and legality of that action. *See* ECF No. 136-1 at 14-15. This question was the subject of nearly 200 pages of briefing in the Maryland case, resulting in a 54-page opinion by a District Judge. Plaintiffs' breezy assertion that the Guidance was "within the agency's discretion" and "hardly an instance of the FDA abdicating its statutory responsibilities," ECF No. 136-1 at 14 (internal quotation marks omitted), does not even attempt to engage with Judge Grimm's rejection of these exact arguments. *See AAP*, 379 F. Supp. 3d at 480-87, 491-94. Nor do Plaintiffs mention, let alone refute, Judge Grimm's holding that the Guidance was unlawful without notice-and-comment rulemaking. *Id.* at 47-53.[13]

7. As FDA explained, there is little if any adverseness between the parties on the specific issue in proposed Count X.

8. There is little if any public importance to the question Plaintiffs raise. FDA has already announced that it has no intention of maintaining the Guidance, and apparently would not return to it even if Judge Grimm's ruling were reversed. Plaintiffs effectively request an advisory opinion stating that an agency action from which they benefited was lawful, even though the agency would abandon it even if it were lawful.

And all this, of course, is before the Court even considers the severe public health impact of the requested declaration and the impropriety of overriding Congress's prescriptions in this context. *See supra* pp. 10-14. Thus, even if the Declaratory Judgment Act somehow allowed the relief Plaintiffs request, "equitable, prudential, and policy arguments," *MedImmune*, 549 U.S. at 136, all make that relief unwarranted.

[13] Even if Plaintiffs' blithe rejection of Judge Grimm's conclusions were convincing, they would still need to overcome *amici*'s argument that the Guidance was arbitrary and capricious, which Judge Grimm did not reach. *See AAP*, Dkt. No. 31-2 at 21-25; *AAP*, Dkt. No. 39 at 30-37; *AAP*, 379 F. Supp. 3d at 491 n.10.

B. Section 705 and the Law of the Case Do Not Authorize Plaintiffs' Requested Relief

With the Declaratory Judgment Act plainly unavailable to them, Plaintiffs turn to two even less plausible sources of authority: Section 705 of the APA and the law of the case doctrine. Neither bears even a passing resemblance to Plaintiffs' brazen claim for a declaration of validity.

1. Section 705 Does Not Allow the Relief Plaintiffs Request

Section 705 of the APA authorizes a court that is reviewing an agency action to stay the effective date *of the action under review*. As Plaintiffs' own authority explains, courts do not have jurisdiction to grant a motion to stay an agency action unless the motion is "accompanied by a petition to review the underlying [action][.]" *In re GTE Serv. Corp.*, 762 F.2d 1024, 1026 (D.C. Cir. 1985); *see also, e.g.*, *Bauer v. DeVos*, 325 F. Supp. 3d 74, 106-07 (D.D.C. 2018) ("[W]hen a court issues a stay, … under § 705[, it] should be imposed for one—and only one—reason: to maintain the status quo in order to allow judicial review *of the underlying regulation* to proceed in a 'just' manner." (emphasis added)). All of Plaintiffs' Section 705 cases—like all other Section 705 cases, as far as *amici* have found—involve stays of the precise agency action under judicial review. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 155-56 (1967); *In re GTE*, 762 F.2d at 1026; *FBME Bank Ltd. v. Lew*, 209 F. Supp. 3d 299, 310 (D.D.C. 2016).

While Plaintiffs describe the relief they seek as "a lesser judicial intervention than the injunctions authorized by Section 705 of the APA," ECF No. 136-1 at 16, what they propose would expand Section 705 to an unprecedented scope. They are not seeking to stay an agency action temporarily so that a court can determine whether that action was lawful. Instead, they request an open-ended declaration that an agency action (the August 2017 Guidance) *is* "valid and effective" from a court that otherwise would never consider its legality at all—and after another court has

already found that action unlawful. Neither Section 705 nor any other source of authority provides this advisory power.

Even if Section 705 were somehow relevant here, Plaintiffs' showing would be insufficient to invoke it. As Defendants explained, motions to stay agency action under Section 705 "are reviewed under the same standards used to evaluate requests for interim injunctive relief." *Affinity Healthcare Servs., Inc. v. Sebelius*, 720 F. Supp. 2d 12, 15 n.4 (D.D.C. 2010). Plaintiffs do not attempt to satisfy and could not satisfy the traditional four-factor test.

First and most obviously, they have shown *no* likelihood of success on the merits; their paltry arguments were specifically rejected in *AAP*, yet they have not even attempted to refute Judge Grimm's analysis. *See supra* pp. 10-11. Nor have they tried to show a likelihood of success on the merits of their claims against the Deeming Rule itself—and would have a difficult time doing so, given the rejection of nearly identical arguments in *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 393-407 (D.D.C. 2017), *appeal filed*, No. 17-5196.

Second, they have not argued and could not argue that they are irreparably harmed by the Guidance or its elimination. While they repeatedly cite to this Court's finding that it would be "grossly unfair" to subject manufacturers of premium cigars to warning requirements while FDA was itself reconsidering the need for health warnings on premium cigars, *see* ECF No. 106 at 10, that reasoning does not apply in this situation. The "unfairness" they decry now is that FDA has "announced or opened rulemaking proceedings to adjust and to clarify the premarket approval and substantial equivalence process for cigars and pipe tobacco." ECF No. 136-1 at 3-4. This same argument was made to Judge Grimm by cigar manufacturers, *see AAP*, Dkt. No. 113 at 7-8, and he found it "disingenuous[]," *AAP*, 2019 WL 3067492, at *5. Plaintiffs complain of having to submit applications while FDA might issue *more* guidance on the content of applications, but Congress,

FDA, and Judge Grimm—and even cigar manufacturers themselves—have all found the statutory standards and existing guidance sufficient to allow successful applications. *See supra* pp. 13-14. As to Plaintiffs' desire to stave off enforcement indefinitely while they litigate the deferred counts of their complaint, there is nothing unfair—grossly or otherwise—about subjecting a regulated party to a regulation that it challenges pending judicial review; to the contrary, that is the ordinary course of things, absent the difficult showing required by Section 705.

Finally, the last two factors of the four-factor test, the balance of equities and the public interest, outweigh any shred of equity in Plaintiffs' favor. *See supra* pp. 10-14. As Plaintiffs' own authority says, "[i]t is scarcely to be doubted that a court would refuse to [grant relief under Section 705] if … delay would be detrimental to the public health or safety." *Abbott Labs.*, 387 U.S. at 156. Plaintiffs request exactly what the Supreme Court says no court would grant.

2. The Law of the Case Does Not Allow the Relief Plaintiffs Request

Finally, Plaintiffs appeal to the law of the case. As their authority explains, the law of the case doctrine holds that "when a court *decides upon a rule of law*, that decision should continue to govern the same issues in subsequent stages in the same case." *Arizona v. California*, 460 U.S. 605, 618 (1983) (emphasis added); *accord Burlington Ins. Co. v. Okie Dokie, Inc.*, 439 F. Supp. 2d 124, 132 (D.D.C. 2006). This Court has made no decision about the validity of the Guidance and there is therefore no rule of law on which to base an application of the law of the case doctrine. As one District Court put it, "a ruling regarding scheduling is not a substantive ruling that somehow becomes the law of the case, never to be altered." *Hansen v. Native Am. Oil Refinery Co.*, No. 06-cv-109, 2008 WL 2405947, at *2 (D. Utah June 11, 2008)).[14]

[14] *See, e.g.*, *Beale v. District of Columbia*, 545 F. Supp. 2d 8, 16 (D.D.C .2008) ("The law-of-the-case doctrine has little to do with docket management."); *see also, e.g.*, *In re Lynch*, 430 F.3d 600, 604 (2d Cir. 2005) (rejecting argument that scheduling order determined an issue and thus established law of the case); *In re Air Crash Disaster*, 86 F.3d 498, 517-

In any event, the law of the case doctrine "is a prudential rule rather than a jurisdictional one." *U.S. on Behalf of Dep't of Labor v. Ins. Co. of N. Am.*, 131 F.3d 1037, 1043 n.12 (D.C. Cir. 1997) (internal citation omitted). For all the reasons explained above, equity would dictate denying Plaintiffs' motion even if the law of the case somehow applied.

IV. Conclusion

Plaintiffs lack even a nonfrivolous argument for extending the doctrines they invoke to this context, much less a compelling argument. For the foregoing reasons, the Court should deny the motion for leave to amend as futile or, alternatively, deny summary judgment to Plaintiffs and begin proceedings to grant summary judgment *sua sponte* to Defendants under Federal Rule of Civil Procedure 56(f).

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Respectfully submitted,

/s/ Jeffrey B. Dubner

Jeffrey B. Dubner (D.C. Bar No. 1013399)
Javier M. Guzman (D.C. Bar No. 462679)
DEMOCRACY FORWARD FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
jdubner@democracyforward.org
jguzman@democracyforward.org
(202) 448-9090

Eve L. Hill (Fed. Bar No. 19938)
BROWN GOLDSTEIN & LEVY, LLP
120 East Baltimore Street, Suite 1700
Baltimore, Maryland 21202
ehill@browngold.com
T: (410) 962-1030
F: (410) 385-0869

18 (6th Cir. 1996) (same); *Stonecrest Partners, LLC v. Bank of Hampton Roads*, 770 F. Supp. 2d 778, 785 n.5 (E.D.N.C. 2011) (same)

Dennis A. Henigan (*pro hac vice*)
Mark E. Greenwold (*pro hac vice*)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I Street NW, Suite 1200
Washington, D.C. 20005
dhenigan@tobaccofreekids.org
mgreenwold@tobaccofreekids.org
(202) 296-5469

Counsel for Plaintiffs