In The

United States Court of Appeals

For the Fourth Circuit

No. 19-2130
(8:18-cv-00883-PWG)

In re: CIGAR ASSOCIATION OF AMERICA; CIGAR RIGHTS OF AMERICA; PREMIUM CIGAR ASSOCIATION, f/k/a International Premium Cigar and Pipe Retailers Association

Appellants

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, MD; DR. CYNTHIA FISHMAN, MD; DR. LINDA GOLDSTEIN, MD; DR. STEVEN HIRSCH, MD; DR. DAVID MYLES, MD

Plaintiffs – Appellees

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; SCOTT GOTTLIEB, in his Official capacity as Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; ALEX M. AZAR, II, in his Official capacity as Secretary of Health and Human Services

Defendant

PLAINTIFFS-APPELLEES' OPPOSITION TO NON-PARTY-APPELLANTS' MOTION TO STAY

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The Non-Party-Appellants' ("Cigar Associations") motion to stay is entirely without merit. They were denied party status for purposes of intervention, yet seek relief that only a party may obtain. They seek to stay the Summary Judgment Order,[1] but did not move to stay that order in the District Court. They base their stay request on arguments that they never raised below. And they challenge the denial of their motion to intervene, without even acknowledging the plainly untimely grounds on which they sought to intervene. None of these arguments should be entertained on appeal, and none would have merit even if the Court did consider them.

A stay pending appeal is extraordinary relief that cannot be granted unless all four factors point in the movant's favor. As demonstrated below, *none* of the four factors support the motion, and the Court should deny it.

BACKGROUND

The background of the TCA, the Deeming Rule, and the Guidance is summarized in Plaintiffs' Opposition to the E-Cigarette Stay Motion. *See* ECF 47 at 3-8. Here, Plaintiffs provide additional details of particular relevance to the Cigar Associations' motion.

[1] All terms in this brief have the same definition as in Plaintiffs-Appellees' Opposition to Intervenors-Appellants' Motion to Stay Pending Appeal, ECF 47 ("Pls.' Opp. to E-Cig. Stay Mot.").

I. The Tobacco Control Act's Substantial Equivalence Pathway

FDA deemed cigars subject to the TCA at the same time as e-cigarettes. 81 Fed. Reg. 28,973, 29,011 (May 10, 2016). Thus, as of August 2016, cigar products introduced after February 15, 2007 could not be lawfully marketed without FDA authorization under 21 U.S.C. § 387j.

Cigar manufacturers can obtain such authorization through the "substantial equivalence" ("SE") pathway, which requires that manufacturers submit an "SE Report" establishing that their products are "substantially equivalent" to cigars marketed on February 15, 2007, a far simpler showing than that required for a PMTA. *Id.* §§ 387e(j), 387j(a)(2)-(3). Unlike a PMTA, all a manufacturer needs to demonstrate for a substantial equivalence order is that the product either "has the same characteristics" as a product marketed on February 15, 2007 or that it "has different characteristics [but] does not raise different questions of public health." *Id.* § 387j(a)(3)(A).

Although this requirement has applied to cigars since August 2016, FDA has never enforced it against products on the market at that time, and cigar manufacturers have continued to sell new products without FDA authorization. The Deeming Rule established a compliance period under which FDA would withhold enforcement against products requiring an SE Report until February 8, 2018 (six months earlier than for PMTAs). 81 Fed. Reg. at 29,011. Manufacturers

who submitted SE Reports by that date would receive a further one-year period without enforcement, pending FDA review. *Id.* In August 2017, only six months before the compliance period was to end, FDA issued the Guidance, extending the enforcement holiday for cigars until August 2021 and providing that an SE Report filed by the deadline entitled the manufacturer to market the product indefinitely unless FDA rejected the application. Summ. J. Op. at 10.

The process for submitting SE Reports is well established. *See* D.Ct. Dkt. 125 at 2-4.[2] FDA has granted more than 1000 SE applications, including at least 11 for cigars.[3]

II. The Current Cigar Market Is Dominated by Small, Flavored Cigars That Appeal to Children.

The tobacco industry has long understood that sweetly flavored products are critical to attracting and addicting children to tobacco products. "Flavors have been used for decades to attract youth to tobacco products and to mask the flavor and harshness of tobacco."[4] To end this harmful practice, Congress prohibited all flavors in cigarettes other than tobacco and menthol, banning the various candy- and fruit-flavored cigarettes most popular with children. 21 U.S.C. §

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[2] *See also* Lauren DeBerry, Ctr. for Tobacco Prods., "Substantial Equivalence—2019 Update," Oct. 28-29, 2019, https://tinyurl.com/ta6d8ue.
[3] *Id.* at 28-29.
[4] D.Ct. Dkt. 34-1 at 6 (quoting Office of Smoking & Health, Dep't of Health & Human Servs., *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General*, vii (2016), https://tinyurl.com/y5awzccw ("SG's Report")).

387g(a)(1)(A). The tobacco industry responded to this regulation, as it has done in the past,[5] by reformulating cigarette products into cigarette-like cigars, so that it could continue marketing kid-friendly products despite Congress's efforts.

The only essential difference between a cigar and a cigarette is that a cigar contains tobacco in the wrapper, while a cigarette typically does not. See 15 U.S.C. § 1332(1)(a) (defining "cigarette"); 21 C.F.R. § 1143.1 (defining "cigar"). As the possibility of a flavored cigarette ban neared, the Cigar Associations' members dramatically increased production of small flavored cigars that are more like the now-banned flavored cigarettes than traditional cigars. AR 3515. Today, the Cigar Associations' members produce flavored cigars by the millions, lacing them with sugary flavors from candy to chocolate to lemonade and giving them names like "SwagBerry" or "Da Bomb Blueberry." AR 3515, 154662; *see also* D.Ct. Dkt. 34-1 at 7-8 (displaying examples of flavored cigars and their packaging); AR 154655 (same). These products overwhelmingly appeal to youth. As one of the Cigar Associations' members acknowledged, "[i]t is mainly new recruits to cigar smoking who take to the new flavors," AR 145585—and "new

[5] *See, e.g.*, AR 30022 ("Industry documents indicate that tobacco firms have been aware of disparities in the legal treatment of cigarettes and cigars and have made efforts to develop cigars that cigarette smokers would smoke."); *see also* Cristine Delnevo *et al.*, "Close, But No Cigar: Certain Cigars Are Pseudo-Cigarettes Designed to Evade Regulation," 26 *Tobacco Control* 349 (2017), https://tinyurl.com/uf7gmlv.

recruits" are almost exclusively minors. *See* 79 Fed. Reg. 23,142, 23,155 (Apr. 25, 2014) ("Virtually all new users of most tobacco products are youth … .").[6]

As a result of the cigar industry's strategy of targeting minors and its insulation from the law created by the Guidance, youth cigar use has become at least as much of a public health threat as youth cigarette use. Today, more high school students smoke cigars than cigarettes[7] and 1,350 persons under the age of 18 smoke their first cigar each day.[8]

The adverse health effects of cigar use are significant. *See, e.g.*, D.Ct. Dkt. 59-1 at 16; D.Ct. Dkt. 34-1 at 4-6. These health risks include "an increased risk of oral, esophageal, laryngeal, and lung cancer," "heart and pulmonary disease," "chronic obstructive pulmonary disease," and "fatal and nonfatal stroke." 81 Fed. Reg. at 29,020.

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[6] *See also, e.g.*, AR 154660 ("While different cigars target a variety of markets, all flavored tobacco products tend to appeal primarily to younger consumers."); D.Ct. Dkt. 34-1 at 7 ("[T]obacco companies marketed flavored little cigars and cigarillos to youth and to African Americans to facilitate their uptake of cigarettes." (quoting SG's Report at 11)); 79 Fed. Reg. at 23,146 ("Research has shown that … sugar preference is strongest among youth and young adults and declines with age.").

[7] U.S. Centers for Disease Control & Prevention, "Tobacco Product Use and Associated Factors Among Middle and High School Students — United States, 2019," *Morbidity and Mortality Weekly Report* 68(12), Dec. 6, 2019, https://tinyurl.com/saeozuz.

[8] Substance Abuse and Mental Health Services Administration, HHS, "Key Substance Use and Mental Health Indicators in the United States: Results from the 2018 National Survey on Drug Use and Health," Aug. 2019, tbl. A.3A, https://tinyurl.com/t5qkbc7.

III. Procedural History Below and in the District Court for the District of Columbia

In the District Court, the Cigar Associations premised their motion to intervene on a supposed conflict between the District Court's orders and the schedule in a case they brought in the U.S. District Court for the District of Columbia, *Cigar Association of America v. FDA* ("*CAA*"), No. 16-cv-1460 (D.D.C.). To evaluate the merits *vel non* of their motion to stay, some background on that case is necessary.

In *CAA*, the Cigar Associations brought nine claims seeking to invalidate the Deeming Rule in whole or in part, including one claim challenging the premarket review requirement. *CAA* Dkt. 1 at ¶¶ 82-99. In September 2017, after FDA issued the Guidance, they chose to defer their premarket review claim, prioritizing instead claims about the Deeming Rule's warning labels. *CAA* Dkt. 56. The trial court rejected those claims, which are currently on appeal to the D.C. Circuit. *CAA v. FDA*, 315 F. Supp. 3d 143 (D.D.C. 2018).

A year and a half later, after Judge Grimm issued the Summary Judgment Order vacating the Guidance, numerous industry participants sought to intervene in this case to brief remedial issues. *See* D.Ct. Dkt. 76-81. By contrast, the Cigar Associations chose not to seek intervention or make any argument on the appropriate remedy. Instead, they waited until remedial briefing in this case was complete and then amended their complaint in *CAA* to request a declaratory

judgment holding the Guidance "valid and effective" as to all cigars notwithstanding the District Court's ruling here. *CAA* Dkt. 135-1 at ¶¶ 161-70. As grounds for relief, they asserted that the Guidance invalidated by the Summary Judgment Order had been an "indispensable feature of … case management efforts" in *CAA*, such that vacatur could create "an entirely unnecessary and unwarranted judicial emergency, requiring expedited consideration of the merits" of their long-deferred claim. *CAA* Dkt. 136-1 at 11. The Cigar Associations thus sought to invalidate the rulings of the District of Maryland not by opposing them in that court or by appeal, but by collaterally attacking them in a coordinate court.

Judge Mehta, presiding over *CAA*, observed that the Cigar Associations were asking him to "in effect, partially countermand" or "roll … back" the Summary Judgment Order in this case. D.Ct. Dkt. 142-1 at 20:4-5 & 15-1. He expressed "concerns about the relief that they're asking for … infringing upon the scope of [Judge Grimm's] order, to put it candidly." *Id.* at 30:9-12. He recommended that the Cigar Associations seek relief from Judge Grimm, rather than attacking his ruling collaterally in the District of Columbia. *See* D.Ct. Dkt. 142 at 5 & n.6 (collecting transcript citations).

Nearly two months after the Remedial Order's issuance, the Cigar Associations finally informed Judge Grimm of their supposed belief that there was a conflict between his rulings and case management in *CAA*. On September 4,

2019, they sought leave to intervene for purposes of appeal. D.Ct. Dkt. 135. Five days later, they moved to stay the Remedial Order (but not the Summary Judgment Order) pending appeal. ECF 37-2.

In their motion to intervene, the *only* issue the Cigar Associations raised was that the proceedings in this case "could disrupt the long-settled course of proceedings in the *Cigar Associations* case, requiring a substantially accelerated resolution" of their claims in that case. D.Ct. Dkt. 135 at 2-3. Their motion to stay similarly argued that "a stay would eliminate any potential interference with Judge Mehta's management of the [CAA] litigation." ECF 37-2 at 2. They did not identify any putative defects in Judge Grimm's orders that they believed were likely to be reversed on appeal. *See id.*

Plaintiffs and FDA opposed these motions. *See* D.Ct. Dkt. 142, 147, 148. Among other things, Plaintiffs noted that the Cigar Associations had been aware of the supposed relationship between Plaintiffs' claims in this case and case management in *CAA* since at least August 2018, but never suggested in either forum that a conflict existed. D.Ct. Dkt. 142 at 3; D.Ct. Dkt. 147 at 1-2.

The District Court denied the Cigar Associations' motion to intervene as untimely. ECF 37-3 at 5-7. As it observed, "the Cigar Associations have been aware for months that this litigation challenged the deadlines" in the Guidance, "[y]et they chose not to seek leave to intervene previously, waiting instead to see if

the case would survive Defendants' motion to dismiss and, when it did, to see what the remedy would be." *Id.*at 6 (citing *Alt v. U.S. E.P.A.*, 758 F.3d 588, 591-92 (4th Cir. 2014) ("Such deliberate forbearance understandably engenders little sympathy.")). Moreover, the Cigar Associations motion "c[ame] too late" because it sought to "litigat[e] new issues," which "the Fourth Circuit does not hear … on appeal." *Id.* (citing *Gen. Ins. Co. of Am. v. U.S. Fire Ins. Co.*, 886 F.3d 346, 356 (4th Cir. 2018), *as amended* (Mar. 28, 2018)). Because it denied the motion to intervene, the District Court denied the motion to stay as moot. *Id.* at 7.[9]

The Cigar Associations noticed their appeal on October 10, 2019. D.Ct. Dkt. 157. They then waited more than two months, until December 14, 2019, to move this Court for a stay. *See* ECF 37-1.

LEGAL STANDARD

The standard of review is stated in Plaintiffs' Opposition to the E-Cigarette Stay Motion. *See* ECF 47 at 12-13.

[9] Judge Mehta subsequently denied the Cigar Associations' request for a declaratory judgment, finding that (1) "[s]uch an order would be tantamount to permitting a collateral attack on the *AAP* court's order, which this court cannot do"; (2) "the novel declaration that Plaintiffs seek is not premised on any claimed violation of law by the FDA"; and (3) the Cigar Associations "delayed in raising their concerns before the *AAP* court, … conduct [that] weighs against granting the extraordinary relief they now request." *CAA v. FDA*, --- F. Supp. 3d ----, 2019 WL 6647261, at *1-2 (D.D.C. Oct. 18, 2019).

ARGUMENT

I. The Cigar Associations Are Not Parties to the Summary Judgment and Remedial Orders and Cannot Stay Them

Because the Cigar Associations were denied intervention, they are parties only for the limited purpose of appealing the denial of their motion to intervene. *See, e.g.*, *Robert Ito Farm, Inc. v. County of Maui*, 842 F.3d 681, 688 (9th Cir. 2016) (a denied intervenor "is a party for purposes of appealing the specific [intervention] order at issue" but is "not a party for purposes of the final judgment" (quoting *Eisenstein v. City of New York*, 556 U.S. 928, 931 n.2 (2009)); *Pub. Serv. Comm'n of State of N.Y. v. Fed. Power Comm'n*, 284 F.2d 200, 204 (D.C. Cir. 1960) ("A would-be intervenor is a party to a proceeding in a limited sense, restricted to the proceedings upon the application for intervention; … he is not a party to the proceeding in the full sense of the term and is not aggrieved by the final order upon the merits of the controversy.") As to the District Court's orders on the merits of Plaintiffs' claims and the appropriate remedy, they are non-parties.

Federal Rule of Appellate Procedure 8(a)(1) only authorizes a "party" to seek a stay pending appeal, and thus a denied intervenor can only seek to stay the order to which they are a party—i.e., the order denying their motion to intervene. Numerous courts have held that denied intervenors "ha[ve] no legal standing to move th[e] court for any form of relief other than intervention." *United States v.*

Atl. Wood Indus., Inc., 330 F.R.D. 435, 438 n.3 (E.D. Va. 2019); *Boothe v. Northstar Realty Fin. Corp., Inc.*, No. 16-cv-3742, 2019 WL 587419, at *10 (D. Md. Feb. 13, 2019) (citing cases for the proposition that a "nonparty proposed intervenor must first succeed in intervening before seeking relief from [a] court order"). In particular, a denied intervenor cannot "move for a stay pending his appeal." *Fair Political Practices Comm'n v. U.S. Postal Serv.*, No. 12-cv-93, 2012 WL 5398789, at *2 (E.D. Cal. Nov. 2, 2012); *see also* D.Ct. Dkt. 154 at 7 ("Because their Motion to Intervene is denied, their Motion to Stay pending their appeal is … moot."). Accordingly, the Cigar Associations' motion cannot be granted.

II. The Cigar Associations Have No Likelihood of Success on the Merits

A. The Cigar Associations Did Not Move to Stay the Summary Judgment Order

The Cigar Associations ask this Court to stay the Summary Judgment Order. *See* ECF 37-1 at 4, 10. However, neither they nor any other party asked the District Court to stay that Order. *See* ECF 36-6 at 1 (requesting to "stay pending appeal the July 12, 2019 … Remedies Order"); ECF 37-2 (joining E-Cigarette Associations' stay motion); D.Ct. Dkt. 152 at 1 ("Unless a stay of the Court's remedial order is granted …"). "A party must ordinarily move first in the district court for … a stay of the judgment or order of a district court pending appeal." Fed. R. App. P. 8(a)(1). Under Rule 8, a party asking a Court of Appeals to stay an

order must have asked the District Court to stay "*the … order*"—not merely some subsequent order providing additional relief. Because the Cigar Associations did not move in the District Court to stay the Summary Judgment Order, their motion should be denied.[10]

B. The Cigar Associations Have Waived Any Arguments to Stay the Remedial Order

In the first sentence of their brief, the Cigar Associations also ask the Court to stay the Remedial Order. ECF 37-1 at 1. But they do not claim they are likely to succeed on the merits of an appeal from that order. *See id.* at 9 ("Appellants are likely to succeed on their appeals *from the District Court's summary judgment and intervention orders*." (emphasis added)). Nor does their merits discussion suggest any legal error in the Remedial Order. *Id.* at 9-17. Nor do they join the E-Cigarettes' motion to stay the Remedial Order; to the contrary, the Cigar Associations have affirmatively stated that they "will be briefing separate legal issues with virtually no duplication," as "evident from the arguments each movant made in their … motions to stay." ECF 41 at 5; *see also id.* at 5-6 ("[T]he cigar associations' briefing will focus on demonstrating that the district court erred in

[10] The Cigar Associations' arguments against the Summary Judgment Order are substantively meritless, for the reasons stated by the District Court. *See* Summ. J. Order at 23-53. Plaintiffs will address those arguments if raised in the Appellants' merits briefing.

granting summary judgment for plaintiffs, and on the denial of their motion to intervene.").

Because the Cigar Associations make no argument that the Remedial Order is erroneous, they cannot obtain relief from that order. *See* Fed. R. App. P. 8(a)(2)(B)(i) (requiring that a motion to stay include "the reasons for granting the relief requested"); *Grayson O Co. v. Agadir Int'l LLC*, 856 F.3d 307, 316 (4th Cir. 2017) ("A party waives an argument by failing to present in its opening brief or by failing to develop its argument—even if its brief takes a passing shot at the issue." (internal quotation marks and brackets omitted)).

To the extent the Cigar Associations propose putative flaws in the Summary Judgment Order as a basis for staying the Remedial Order, the Court could not consider their motion because they did not make these arguments when seeking a stay from the District Court. The Cigar Associations now argue that "[FDA's] decision to delay enforcement of parts of the Deeming Rule is unreviewable," "the decision to set an enforcement date after the effective date of the Deeming Rule does not violate the TCA," and "[t]he Guidance was a policy statement to which APA's notice-and-comment requirements do not apply." ECF 37-1 at 9-13. Neither of the stay motions in the district court included even a passing mention of these arguments. *See* ECF 36-6, 37-2.[11] The E-Cigarette Associations exclusively

[11] The fact that FDA made similar merits arguments when opposing summary

argued that the Remedial Order exceeded the District Court's authority, *see* ECF 36-6 at 3-4, while the Cigar Associations eschewed merits arguments altogether, *see* ECF 37-2 at 2-3.

An argument not made in the District Court cannot be raised on appeal. *See, e.g.*, *In re Under Seal*, 749 F.3d 276, 285 (4th Cir. 2014) ("Our settled rule is simple: absent exceptional circumstances, … we do not consider issues raised for the first time on appeal." (quotations omitted)). The Cigar Associations waived any argument to stay the Remedial Order, and their motion cannot be granted.

C. The Cigar Associations Have No Likelihood of Success on the Merits of Their Challenge to the Denial of Their Motion to Intervene

The Cigar Associations also assert that they are likely to show that the District Court abused its discretion in denying their motion to intervene. *See* ECF 37-1 at 14-17. However, the sole basis on which they asked the District Court for permission to intervene was the purported conflict between this case and the case management orders in *CAA*. *See supra* pp. 7-8. They do not acknowledge the actual issue presented by their motion to intervene, much less dispute the District Court's resolution of that issue. *See* D.Ct. Dkt. 154 at 6. Indeed, even the one

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judgment is irrelevant. The argument the Cigar Associations make now is that the four-factor analysis for preliminary relief requires a stay. No party gave the District Court an opportunity to consider any putative errors in the Summary Judgment Order as part of that analysis.

argument they make to this Court—that they are "similarly-situated" to the E-Cigarette Associations and that the District Court abused its discretion in granting leave to one but not the other, ECF 37-1 at 15—is made without reference to the grounds on which the District Court distinguished the two groups. *See* D.Ct. Dkt. 154 at 6 ("[U]nlike the Vapor Associations that could not previously show harm to their interests, the Cigar Associations have been aware for months that this litigation challenged the deadlines that they believed they had negotiated to extend. Yet they chose not to seek leave to intervene previously … .").

The District Court's holdings, unchallenged in any substance here, were well within the District Court's "wide discretion." *Gould v. Alleco, Inc.*, 883 F.2d 281, 286 (4th Cir. 1989). The Cigar Associations thus have not made a "strong showing that [they are] likely to succeed on the merits," and their motion must be denied. *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987).[12]

III. The Cigar Associations Have Not Shown a Likelihood of Irreparable Harm

The Cigar Associations argue irreparable harm on a completely different—but equally unavailing—basis than they did in the District Court. There, they

[12] Even if the Cigar Associations had shown that they were likely to succeed on their appeal of the denial to intervene, that would not warrant a stay without an additional showing that they were likely to succeed on the merits of their challenge to the Summary Judgment Order—a showing they have not made, as explained above.

focused only on the putative conflict with *CAA* and did not explain how the Remedial Order caused them harm, saying only that an order by Judge Mehta in *CAA* was "instructive." ECF 37-2 at 3. And while they joined the E-Cigarette Associations' motion to stay, that motion did not suggest any harm to cigar manufacturers, focusing on issues that they themselves say are irrelevant to their claims. *See* ECF 41 at 7-8 (stating that discussion of PMTA issues is not "relevant to the cigar industry's SE Report process" because "[t]he cigar associations' members … will … not use the PMTA process … ."). Thus the Cigar Associations' claims of harm are waived. *See In re Under Seal*, 749 F.3d at 285.[13]

Even if the Court were to consider the Cigar Associations' newly raised arguments, they fail to make the required "clear showing" of irreparable harm. *Direx Israel, Ltd. v. Breakthrough Med. Corp.*, 952 F.2d 802, 812 (4th Cir. 1991). The Cigar Associations make two arguments: first, that the Remedial Order "will require hundreds of millions of dollars in preparation even before FDA has provided 'foundational rules,'" and second, that "the District Court's erroneous Remedy Order could lead to products being pulled from the market, causing … lost sales." ECF 37-1 at 17, 19. Much like the E-Cigarette Associations'

[13] The Cigar Associations did make some similar points in their reply brief below. *See* D.Ct. Dkt. 152 at 1-2. However, arguments raised for the first time in a reply brief are waived. *See, e.g.*, *Moseley v. Branker*, 550 F.3d 312, 325 n.7 (4th Cir. 2008).

comparable arguments, these contentions lack merit. *See* Pls.' Opp. to E-Cig. Stay Mot. at 16-18.

First, the District Court rightly found that the industry's contention "that it cannot complete its applications without further formal guidance" is "disingenuous[]." Remedial Order at 8; *see* Pls.' Opp. to E-Cig. Stay Mot. at 17-18. Such a claim is especially implausible coming from the Cigar Associations, because their members file SE Reports, which are far simpler and less costly to complete than PMTAs. *See, e.g.*, AR 030047, 030367-68 (Regulatory Impact Analysis estimating SE Reports require 5-20% as many hours as PMTAs and cost 3-17% as much). Moreover, as the District Court noted, the TCA "itself sets forth the baseline requirements for … SE reports"; the FDA "has issued a number of lengthy guidance documents discussing these statutory requirements"; and the agency "has authorized the marketing of *more than a thousand* tobacco products" under the SE pathway. Remedial Order at 8 (quoting D.Ct. Dkt. 125 at 2-3). The FDA has already approved at least 11 SE Reports for new cigars, contradicting any claim that cigar manufacturers cannot submit SE Reports without further guidance. *See supra* p. 3. Moreover, FDA's website includes hundreds of FDA orders explaining how it evaluated each order.[14]

[14] *See* FDA, "Marketing Orders for SE," https://tinyurl.com/rmnm9cr.

Second, thousands of cigars were on the market before February 15, 2007. The Cigar Associations' members can continue to sell these "grandfathered" products without obtaining marketing orders. The costs that the Cigar Associations' members incur flow from their choice to market new, and largely flavored, products that appeal to young people. Tellingly, the Cigar Associations do not claim that *any* of their members is at risk of going out of business if the District Court's orders are upheld.

Third, the two-plus months that the Cigar Associations waited to file their stay motion belie their supposed concern about the ongoing costs of preparing SE Reports. Those costs have presumably been accruing—yet the Cigar Associations waited months without explanation before seeking relief. "[A] party's failure to act with speed or urgency in moving for [temporary injunctive relief] necessarily undermines a finding of irreparable harm." *Wreal, LLC v. Amazon.com, Inc.*, 840 F.3d 1244, 1248 (11th Cir. 2016) ("A delay in seeking a preliminary injunction of even only a few months … militates against a finding of irreparable harm."); *see also Quince Orchard Valley Citizens Ass'n, Inc. v. Hodel*, 872 F.2d 75, 80 (4th Cir. 1989) (collecting cases).[15]

[15] *See also, e.g., Citibank, N.A. v. Citytrust*, 756 F.2d 273, 277 (2d Cir. 1985) (10-week delay "undercuts the sense of urgency … and suggests that there is, in fact, no irreparable injury); *Fund for Animals v. Frizzell*, 530 F.2d 982, 987 (D.C. Cir. 1975) (denying preliminary injunctive relief due to "inexcusable" 44-day delay); *Gidatex, S.R.L. v. Campaniello Imps., Ltd.*, 13 F. Supp. 2d 417, 419 (S.D.N.Y.

Fourth, the Cigar Associations argue that the pendency of FDA's advance notice of proposed rulemaking ("ANPRM") addressing the regulation of premium cigars should preclude application of the premarket review requirement to all new cigars. ECF 37-1 at 22. This argument ignores the fact that the Deeming Rule addressed application of the TCA to premium cigars at length and subjected them to the TCA. 81 Fed. Reg. at 29,020-27. The comment period in the ANPRM ended more than two years ago, and FDA has given no indication that it intends to exempt premium cigars in response. That an agency may be considering a future regulatory change is not a valid reason for suspending application of the law in anticipation of a change that may never happen. Moreover, premium cigars represent less than 3% of the cigar market. AR 130336. It would be unconscionable to prevent enforcement of the TCA over all cigars, and nullify the public health benefits of premarket review, because of the bare possibility that FDA might at some future date choose a different regulatory strategy for a small segment of the cigar market.

Finally, the Cigar Associations' description of Judge Mehta's stay pending appeal in *CAA* is particularly misleading. In *CAA*, the Cigar Associations brought an unsuccessful First Amendment challenge to the Deeming Rule's warning label

1998) ("[C]ourts typically decline to grant preliminary injunctions in the face of unexplained delays of more than two months.").

requirement. *See CAA*, 315 F. Supp. 3d at 163-74. A month after Judge Mehta granted summary judgment to FDA, the Supreme Court reversed a case that had rejected a First Amendment challenge to compelled disclosures. *See Nat'l Inst. of Fam. & Life Advocs. v. Becerra*, 138 S. Ct. 2361 (2018). Judge Mehta subsequently stayed portions of his order pending appeal in light of this intervening precedent and the "host of complex … difficult legal questions" posed by the First Amendment claim. *Cigar Ass'n of Am. v. FDA*, 317 F. Supp. 3d 555, 561 (D.D.C. 2018). The principal harm he cited was the possible impairment of the Cigar Associations' First Amendment rights. *Id.* at 562-63. While he briefly discussed financial harm as a secondary injury, he did not hold that such harm would have warranted a stay in the absence of the First Amendment issues—much less that it would overcome as weak a showing of success on the merits as the Cigar Associations have made here. *Id.* at 563.

IV. A Stay Would Substantially Harm Plaintiffs

The Cigar Associations barely address the harm a stay would cause Plaintiffs and their members. *See* ECF 37-1 at 21-22. In the District Court, Plaintiffs submitted detailed declarations by the American Academy of Pediatricians' members on the harm that unauthorized flavored cigars do to their practices (and, more importantly, their patients). *See, e.g.*, D.Ct. Dkt. 39-10 ¶¶ 16-22. The widespread availability of flavored cigars significantly complicates the

counseling and treating of children who are attracted to those products, increasing the cost and time of that necessary treatment. *Id.* The proliferation of products similarly thwarts the organizational Plaintiffs' "efforts to examine the effect of flavored cigars on youth uptake." D.Ct. Dkt. 39-6 ¶ 17. Any delay would prolong these harms—to say nothing of the effect on the young people using the products that the Cigar Associations wish to continue unlawfully marketing without FDA authorization.

V. A Stay Would Harm the Public Interest

A stay would harm the public interest for much the same reasons explained in Plaintiffs' Opposition to the E-Cigarette Stay Motion. *See* ECF 47 at 20-21. Widespread youth usage of cigars demonstrates that application of the premarket review requirements to cigars is an important public health priority. The Cigar Associations present virtually no argument regarding the public health impact of exempting cigars from the TCA beyond asserting that the epidemic of e-cigarette use presents an even greater public danger. ECF 37-1 at 22. Moreover, unlike e-cigarettes, cigar manufacturers cannot claim even an unproven hope of potential health benefits compared to cigarettes; as the FDA has said, these products "are associated with significant risk and provide no public health benefit." D.Ct. Dkt. 59-1 at 16; *see supra* p. 5. There is a compelling public interest in finally applying

to cigars Congress's requirement that new products be marketed only if they receive FDA authorization.

CONCLUSION

The Cigar Associations seek relief they cannot obtain from orders they did not challenge and on arguments they never raised. Their motion should be denied.

Respectfully submitted,

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/s/ Jeffrey B. Dubner

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UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT
Effective 12/01/2016

No. 19-2130 **Caption:** In re Cigar Association of America

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Party Name AAP, et al.

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I certify that on December 31, 2019, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/ Jeffrey B. Dubner
Jeffrey B. Dubner