UNPUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 19-2130

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; NORMAN E. SHARPLESS, in his official capacity as Acting 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,

Defendants.

STATE OF MARYLAND; MARYLAND ASSOCIATION OF COUNTY HEALTH OFFICERS,

Amicus Supporting Appellees.

No. 19-2132

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.

AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION; AMERICAN VAPING ASSOCIATION; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- CALIFORNIA; ARIZONA SMOKE FREE BUSINESS ALLIANCE; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION-CONNECTICUT; INDIANA SMOKE FREE ASSOCIATION; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- HAWAII; IOWANS FOR ALTERNATIVE TO SMOKING AND TOBACCO; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- LOUISIANA; KENTUCKY SMOKE FREE ASSOCIATION; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- RHODE ISLAND; MARYLAND VAPOR ALLIANCE; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- TEXAS; NEW YORK STATE VAPOR ASSOCIATION; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- WISCONSIN; OHIO VAPOR TRADE ASSOCIATION; RIGHT TO BE SMOKE-FREE COALITION; SMOKE FREE ALTERNATIVES TRADE ASSOCIATION; TENNESSEE SMOKE FREE ASSOCIATION; TEXAS VAPOR COALITION,

Intervenors - Appellants,

and

UNITED STATES FOOD AND DRUG ADMINISTRATION; NORMAN E. SHARPLESS, in his official capacity as Acting 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,

Defendants,

WASHINGTON LEGAL FOUNDATION; CONSUMER ADVOCATES FOR SMOKE-FREE ALTERNATIVES ASSOCIATION; MICHAEL SIEGEL,

Amici Supporting Appellants.

STATE OF MARYLAND,

Amicus Supporting Appellees.

No. 19-2198

AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY CANCER ACTION NETWORK; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; LEAH BRASCH, MD; CAMPAIGN FOR TOBACCO-FREE KIDS; CYNTHIA FISHMAN, MD; LINDA GOLDSTEIN, MD; STEVEN HIRSCH, MD; DAVID MYLES, MD; TRUTH INITIATIVE; MARYLAND CHAPTER- AMERICAN ACADEMY OF PEDIATRICS,

Plaintiffs - Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; NORMAN E. SHARPLESS, 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,

Defendants - Appellants.

STATE OF MARYLAND; MARYLAND ASSOCIATION OF COUNTY HEALTH OFFICERS,

Amici Supporting Appellees.

No. 19-2242

In re: AMERICAN E-LIQUID MANUFACTURING STANDARDS ASSOCIATION; AMERICAN VAPING ASSOCIATION; ARIZONA SMOKE FREE BUSINESS ALLIANCE; INDIANA SMOKE FREE ASSOCIATION; IOWANS FOR ALTERNATIVE TO SMOKING AND TOBACCO; KENTUCKY SMOKE FREE ASSOCIATION; MARYLAND VAPOR ALLIANCE; NEW YORK STATE VAPOR ASSOCIATION; OHIO VAPOR TRADE ASSOCIATION; RIGHT TO BE SMOKE-FREE COALITION; SMOKE FREE ALTERNATIVES TRADE ASSOCIATION; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- CALIFORNIA; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- CONNECTICUT; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- HAWAII; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- LOUISIANA; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- RHODE ISLAND; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- TEXAS; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION- WISCONSIN; TENNESSEE SMOKE FREE ASSOCIATION; TEXAS VAPOR COALITION,

Appellants.

AMERICAN ACADEMY OF PEDIATRICS; AMERICAN CANCER SOCIETY CANCER ACTION NETWORK; AMERICAN HEART ASSOCIATION; AMERICAN LUNG ASSOCIATION; LEAH BRASCH; CAMPAIGN FOR TOBACCO-FREE KIDS; CYNTHIA FISHMAN; LINDA GOLDSTEIN; STEVEN HIRSCH; DAVID MYLES; MARYLAND CHAPTER- AMERICAN ACADEMY OF PEDIATRICS; TRUTH INITIATIVE,

Plaintiffs - Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; SCOTT GOTTLIEB, in his Official capacity as Commissioner of Food and Drugs; NORMAN E. SHARPLESS, 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; AMERICAN ASSOCIATION FOR RESPIRATORY CARE,

Defendants.

WASHINGTON LEGAL FOUNDATION; CONSUMER ADVOCATES FOR SMOKE-FREE ALTERNATIVES; MICHAEL SIEGEL,

Amici Supporting Appellants.

STATE OF MARYLAND; MARYLAND ASSOCIATION OF COUNTY HEALTH OFFICERS,

Amici Supporting Appellees.

Appeals from the United States District Court for the District of Maryland, at Greenbelt. Paul W. Grimm, District Judge. (8:18-cv-00883-PWG)

Argued: March 18, 2020 Decided: May 4, 2020

Before AGEE, THACKER, and RUSHING, Circuit Judges.

Affirmed in part, dismissed in part by unpublished per curiam opinion.

ARGUED: Eric P. Gotting, KELLER AND HECKMAN LLP, Washington, D.C., for Intervenor-Appellants. Mark S. Raffman, GOODWIN PROCTER LLP, Washington, D.C, for Appellants. Joshua Revesz, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellant United States Food and Drug Administration. Jeffrey B. Dubner, DEMOCRACY FORWARD FOUNDATION, Washington, D.C., for Appellees. **ON BRIEF:** Joseph H. Hunt, Assistant Attorney General, Mark B. Stern, Lindsey Powell, Civil Division, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Robert P. Charrow, General Counsel, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Washington, D.C.; Stacy Cline Amin, Chief Counsel, Annamarie Kempic, Deputy Chief Counsel for Litigation, Wendy S. Vicente, Senior Counsel, Peter G. Dickos, Associate Chief Counsel, UNITED STATES FOOD AND DRUG ADMINISTRATION, Rockville, Maryland, for Appellants. Andrew Kim,

Benjamin Hayes, GOODWIN PROCTER LLP, Washington, D.C., for Appellant Cigar Association of America. Azim Chowdhury, KELLER AND HECKMAN LLP, Washington, D.C., for Intervenor-Appellants. Michael J. Edney, STEPTOE & JOHNSON LLP, Washington, D.C., for Appellants Premium Cigar Association and Cigar Rights of America. Dennis A. Henigan, Swati Rawani, CAMPAIGN FOR TOBACCO-FREE KIDS, Washington, D.C.; Mark E. Greenwold, Washington, D.C.; Sean A. Lev, Nitin Shah, DEMOCRACY FORWARD FOUNDATION, Washington, D.C.; Eve L. Hill, BROWN GOLDSTEIN & LEVY, LLP, Baltimore, Maryland, for Appellees. Corbin K. Barthold, Cory L. Andrews, WASHINGTON LEGAL FOUNDATION, Washington, D.C., for Amicus Washington Legal Foundation. Keith D. Price, Andrew D. Ryan, Timothy C. Sansone, Zachary S. Merkle, SANDBERG PHOENIX & VON GONTARD, P.C., St. Louis, Missouri, for Amici Consumer Advocates for Smoke-Free Alternatives Association and Michael Siegel, M.D., M.P.H. Kathleen Hoke, UNIVERSITY OF MARYLAND SCHOOL OF LAW, Baltimore, Maryland, for Amicus Maryland Association of County Health Officers. Brian E. Frosh, Attorney General, Steven M. Sullivan, Solicitor General, John M. Leovy, Assistant Attorney General, Sarah W. Rice, Assistant Attorney General, OFFICE OF THE ATTORNEY GENERAL OF MARYLAND, Baltimore, Maryland, for Amicus State of Maryland. Rachel S. Bloomekatz, Columbus, Ohio, for Amici Public Health Law Center; Action on Smoking and Health; American Academy of Allergy, Asthma and Immunology; American College of Chest Physicians; American College of Occupational and Environmental Medicine; Americans for Nonsmokers' Rights; American Medical Association; American Public Health Association; American Thoracic Society; NAATPN, Inc.; National Association for the Medical Direction of Respiratory Care; and National Medical Association.

Unpublished opinions are not binding precedent in this circuit.

PER CURIAM:

This case involves a challenge to an August 2017 Guidance issued by the Food and Drug Administration ("FDA") which set a compliance deadline for certain newly deemed tobacco products. That Guidance was superseded by another Guidance issued by the FDA in January 2020. Industry groups representing e-cigarettes and other vapor products (the "Vapor Appellants") and cigars (the "Cigar Appellants"), along with the FDA, challenge the district court's determination that the August 2017 Guidance was unlawful, as well as the district court's decision to set its own replacement compliance deadline for the August 2017 Guidance rather than remand for the FDA to issue a new Guidance.

As to the Cigar Appellants, we affirm the district court's denial of their motion to intervene. As to the Vapor Appellants, the 2020 Guidance moots the merits of their appeal. And, because the FDA asks us to dismiss its appeal if we reach the foregoing conclusions, we dismiss the remainder of the appeal.

I.

A.

Relevant Background

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (the "TCA"), which aims, in part, to reduce the use of tobacco products by children and adolescents. *See* 21 U.S.C. § 387 note. The TCA authorizes the FDA to regulate tobacco products, including "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," as well as "any other tobacco products that the Secretary by regulation deems to be subject" to the TCA. *Id.* § 387a(b). Relevant here, the TCA requires

manufacturers of new tobacco products[1] to submit a Premarket Tobacco Application ("PMTA") and receive authorization from the FDA prior to marketing these products.

The PMTA must contain information about the product's health risks, a statement of the product's ingredients, specified manufacturing information, samples of the product, and the product's proposed labeling. *Id.* § 387j(b)(1). A manufacturer of a new tobacco product may only avoid filing a PMTA if the product "is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007." *Id.* § 382j(a)(2)(A)(i)(I).

In accordance with its authority to "deem" new products subject to the TCA, the FDA issued a final "Deeming Rule" in May 2016 which deemed products such as cigars, pipe tobacco, and electronic nicotine delivery systems[2] ("vapor products") to be subject to the TCA. 81 Fed. Reg. 28974, 28982. Recognizing that the Deeming Rule meant that the newly deemed products may already be on the market without having submitted a PMTA, the Deeming Rule included a provision giving manufacturers of the newly deemed products time to come into compliance. Relevant here, the Deeming Rule included "staggered" twelve to twenty-four month compliance periods for manufacturers of newly deemed products already on the market. *Id*. at 29010. The Deeming Rule also specified

[1] "New tobacco products" are "product[s] (including those products in test markets) that w[ere] not commercially marketed in the United States as of February 15, 2007," or tobacco products that were modified after that date. 21 U.S.C. § 387j(a)(1).

[2] Electronic nicotine delivery systems are often referred to as "vaping" devices, including e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. *See* 81 Fed. Reg. at 29028. We refer to these products collectively as "vapor products."

that the FDA would continue to exercise "enforcement discretion" for an additional one-year period while it processed PMTAs. *Id.* at 29014. The FDA explained that, during that time, it did not intend to seek to administratively or judicially enforce the statutory premarket review requirements for products with submitted PMTAs during the initial compliance period. *Id.* Together, these two periods, that is, the initial staggered compliance periods combined with the additional one year of enforcement discretion, meant that the FDA did not intend to enforce the TCA's PMTA requirements for most deemed tobacco products until 2018.

However, in May 2017, the FDA issued guidance that it would not prioritize enforcement of PMTA requirements for an additional three months beyond the initial staggered compliance dates set forth in the Deeming Rule. Then, in August 2017, the FDA again switched course. It issued a new Guidance (the August 2017 Guidance) extending the compliance period for combustible products like cigars until August 2021, and until August 2022 for noncombustible products, including most vapor products. Further, the August 2017 Guidance indicated that the FDA did not intend to prioritize enforcement of the PMTA requirements "until the agency renders a decision on [the manufacturer's] application . . . or the application is withdrawn." J.A. 143.[3]

This case arises out of a challenge to the FDA's August 2017 Guidance, which the FDA issued without any notice and comment period or other opportunity for public input.

[3] Citations to the "J.A." refer to the Joint Appendix filed by the parties in this appeal.

B.

Procedural History

On March 27, 2018, Appellees, six public-health organizations and five pediatricians, filed their complaint in the district court alleging the August 2017 Guidance violated the TCA and the Take Care Clause, U.S. Const. art. II, § 3, should have been issued through the Administrative Procedure Act's ("APA") notice and comment procedures, and was, therefore, arbitrary and capricious. In September 2018, during the course of litigation, the FDA announced it was considering whether to revisit the enforcement priorities set forth in the August 2017 Guidance. And in March 2019, the FDA published a draft superseding guidance in the Federal Register and initiated a notice and comment period. *See* 84 FR 9345.

In May 2019, the district court granted summary judgment in favor of Appellees, holding the August 2017 Guidance was unlawful because it was inconsistent with the TCA's mandatory language, and because it was "a legislative, rather than interpretive, rule" that required notice and comment. J.A. 86–97. However, because the original Deeming Rule compliance deadline of 2018 had passed during the pendency of litigation, the district court asked the parties to separately brief the question of an appropriate remedy. While the supplemental briefs were pending, numerous interest groups, including the Vapor

Appellants (but not the Cigar Appellants) moved to intervene. Those motions were denied.[4]

In July 2019, the district court entered its "Remedy Order" which directed the FDA to require all PMTAs to be filed by May 12, 2020, consistent with one of the FDA's requests in its briefing. Less than one month later, the Vapor Appellants again moved to intervene -- this time, for purposes of appeal. Two months after the Remedy Order issued, the Cigar Appellants filed a motion to intervene. The district granted the Vapor Appellants' motion but denied the Cigar Appellants' motion as untimely.

The FDA and the Vapor Appellants appealed from the district court's Summary Judgment and Remedy Orders. Appellees and the FDA argue that the Vapor Appellants' appeal is moot. The Cigar Appellants appeal the district court's denial of their motion to intervene and, should they be successful, raise merits issues for consideration on appeal.

On January 2, 2020, while these appeals were pending, the FDA finalized its new Guidance after receiving over 15,000 comments during the comment period (the "2020 Guidance"). The 2020 Guidance replaced the August 2017 Guidance and set the PMTA compliance deadline as May 12, 2020.

[4] The Vapor Appellants appealed the district court's denial of their first motion to intervene in Case No. 19-2242. However, they did not include any argument for reversing that decision in their opening brief. Therefore, we affirm the district court's denial. *See, e.g.*, *IGEN Int'l, Inc. v. Roche Diagnostics GmbH*, 335 F.3d 303, 308 (4th Cir. 2003) ("Failure to present or argue assignments of error in opening appellate briefs constitutes a waiver of those issues.").

II.

This Court considers questions of jurisdiction de novo. *Lee Graham Shopping Ctr., LLC v. Estate of Kirsch*, 777 F.3d 678, 680 (4th Cir. 2015). We review the denial of a motion to intervene for abuse of discretion. *Stuart v. Huff*, 706 F.3d 345, 349 (4th Cir. 2013).

III.

Mootness

A.

Before considering the merits of this appeal, we must first consider whether the Vapor Appellants' appeal is moot now that the FDA has replaced the challenged August 2017 Guidance.

"[T]he parties' stake in the outcome of the case must exist not only at the case's inception, but for the entire duration of the proceedings." *CVLR Performance Horses, Inc. v. Wynne*, 792 F.3d 469, 474 (4th Cir. 2015). Thus, "[l]itigation may become moot during the pendency of an appeal when an intervening event makes it impossible for the court to grant effective relief to the prevailing party." *Id.* And "'[i]f an event occurs while a case is pending on appeal that makes it impossible for the court to grant any effectual relief whatever to a prevailing party, the appeal must be dismissed.'" *Incumaa v. Ozmint*, 507 F.3d 281, 286 (4th Cir. 2007) (quoting *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992)) (alteration omitted).

In similar cases, when statutes or regulatory rules have changed during the course of litigation, courts have found the changes may render the initial suit moot. *See, e.g.*,

Valero Terrestrial Corp. v. Paige, 211 F.3d 112, 116 (4th Cir. 2000); *Esposito v. S.C. Coastal Council*, 939 F.2d 165, 171 (4th Cir. 1991); *Disabled in Action of Baltimore v. Bridwell*, 820 F.2d 1219, at *4 (4th Cir. 1987) (unpublished); *see also Ctr. for Sci. in the Pub. Interest v. Regan* ("*CSPI*"), 727 F.2d 1161, 1167 (D.C. Cir. 1984). In *Valero*, the appellants initially sued in the district court challenging the constitutionality of several provisions of West Virginia law related to waste disposal. *See Valero*, 211 F.3d at 115. The district court initially agreed that the provisions were unconstitutional and entered an injunction prohibiting their enforcement. *See id.* While the case was still pending in the district court on several motions to reconsider, the West Virginia legislature revised the implicated provisions of West Virginia law. *See id.* The appellees moved the district court to dismiss the complaint as moot in light of the revisions, and the district court did so. *See id.* We affirmed on appeal because "[t]he amendments repealed the former requirement[s]" that were the subject of the lawsuit. *Id.* at 116. Further, we determined that the revisions did not preclude a mootness finding on the grounds of voluntary cessation by the State. *See id.* That doctrine, we held, "is generally limited to the circumstance . . . in which a defendant openly announces its intention to reenact 'precisely the same provision' held unconstitutional below." *Id.* (citing *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 & n.11 (1982)).

Considering a similar case involving a change in an agency rule, the D.C. Circuit held that an intervening change moots a challenge to the prior rule. *See CSPI*, 727 F.2d at 1167. Importantly, the D.C. Circuit recognized that the agency in that case "was legitimately empowered to initiate further rulemaking to correct the deficiencies that the

district court found in [the prior rule]." *Id.* at 1164–65. Because the prior rule, which was the alleged source of the plaintiffs' harm, had been superseded, the D.C. Circuit determined "[a]ny appellate pronouncement on the validity of that rule would be meaningless" and dismissed the appeal. *Id.* at 1165. Relevant here, the D.C. Circuit also explained that any challenges to the amended rule "present[ed] a new case" and that any attacks on the new rule should be "by a separate action." *Id.* at 1166.

The FDA and Appellees argue the 2020 Guidance issued by the FDA moots the Vapor Appellants' appeal because it expressly replaces the August 2017 Guidance. As they see it, any relief this court might grant in relation to the August 2017 Guidance would be useless as that Guidance no longer exists. Specifically, in the 2020 Guidance, the FDA explains that it is "prioritizing enforcement of premarket review requirements for [vapor] products, as described in this section, and is doing so independently of the [district] court order" regarding the August 2017 Guidance. J.A. 215. Interestingly, the Vapor Appellants do not dispute that the 2020 Guidance supersedes the August 2017 Guidance. Instead, they argue that the 2020 Guidance was enacted without proper APA notice and comment, in violation of the district court's order. Because, in their view, the 2020 Guidance repeats the same notice and comment error as the August 2017 Guidance, the Vapor Appellants argue it does not moot this appeal. The FDA counters, arguing that the 2020 Guidance is procedurally sound and that, in any event, a challenge to the 2020 Guidance must be made in a separate action.

B.

We hold that the 2020 Guidance moots the Vapor Appellants' appeal because it supersedes the August 2017 Guidance, leaving no possible meaningful relief that this court could grant. In other words, any ruling by this court as to the procedural or substantive reasonableness of the August 2017 Guidance would amount to nothing more than an advisory opinion.

"Under any conceivable disposition of the [Vapor Appellants' appeal], it is clear that an ultimate determination of the rights and obligations of the parties concerning" the 2020 Guidance's procedural adequacy "can emerge only upon consideration of the validity of" that policy. *CSPI*, 727 F.2d at 1164. "That is unquestionably a matter for the district court initially, because a determination of the validity of [the 2020 Guidance] necessarily requires review of the new administrative record." *Id.* As the FDA has represented, the August 2017 Guidance "is a dead letter, and cannot be revived in favor of intervenors. Any appellate pronouncement on the validity of that rule would be meaningless." *Id.* at 1165. Because this court can offer no relief to the Vapor Appellants in the context of this litigation, their appeal has become moot. *See Lamprecht v. F.C.C.*, 958 F.2d 382, 389 (D.C. Cir. 1992).

Accordingly, we hold the Vapor Appellants' appeal is moot and dismiss it.[5]

[5] Of course, the Vapor Appellants may challenge the 2020 Guidance, if they so choose, in a separate action brought in the appropriate district court.

IV.

Motion to Intervene

A.

Next, we consider whether the district court abused its discretion when it denied the Cigar Appellants' motion to intervene. We hold it did not.

Pursuant to Federal Rule of Civil Procedure 24(a)(2), intervention as of right is only appropriate when "[o]n timely motion" an intervenor "claims an interest relating to the property or transaction that is the subject of the action, and is so situated that disposing of the action may as a practical matter impair or impede the movant's ability to protect its interest unless existing parties adequately represent that interest." Fed. R. Civ. P. 24(a)(2). "Thus, *in addition to timeliness*, intervention of right is dependent on the moving party's fulfillment of three requirements: interest, impairment of interest and inadequate representation." *Gould v. Alleco, Inc.*, 883 F.2d 281, 284 (4th Cir. 1989) (emphasis supplied).

"[T]imeliness is a 'cardinal consideration' of whether to permit intervention." *Houston Gen. Ins. Co. v. Moore*, 193 F.3d 838, 839 (4th Cir. 1999); *see also id.* ("The determination of timeliness is committed to the discretion of the district court and will not be disturbed on appeal except for an abuse of that discretion."). The purpose of the timeliness exception is to "prevent a tardy intervenor from derailing a lawsuit within sight of the terminal." *Alt v. U.S. EPA*, 758 F.3d 588, 591 (4th Cir. 2014) (citation omitted).

Thus, a movant's failure to seek intervention in a timely manner is sufficient to justify denial of a motion to intervene. *See Gould v. Alleco, Inc.*, 883 F.2d 281, 286 (4th

Cir. 1989). When assessing the timeliness of a motion to intervene in a civil action, "a trial court in this Circuit is obliged to assess three factors: first, how far the underlying suit has progressed; second, the prejudice any resulting delay might cause the other parties; and third, why the movant was tardy in filing its motion." *Alt*, 758 F.3d at 591. And in considering these three *Alt* factors, we have stressed that courts should be reluctant to stall "the momentum of [a] lawsuit" that is in the advanced stages of litigation. *Id.*

B.

The district court recognized that the Cigar Appellants sought to intervene because this case "potentially could disrupt the long-settled course of proceedings" in *Cigar Association of America v. FDA*, No. 16-1460, in the United States District Court for the District of Columbia, "an ongoing case in which they filed a challenge to the Deeming Rule in 2016." J.A. 122. The district court determined the motion was untimely:

> The litigation in the District of Columbia preceded this case and they could have sought to intervene months earlier. And, unlike 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, waiting instead to see if the case would survive Defendants' motion to dismiss and, when it did, to see what the remedy would be. "Such deliberate forbearance understandably engenders little sympathy."

Id. at 123 (quoting *Alt*, 758 F.3d at 591). Indeed, unlike the Vapor Appellants and other interested groups, the Cigar Appellants did not move to intervene at any point during the pendency of the district court litigation. Instead, their motion was not filed until September 4, 2019 -- nearly 18 months after the complaint was filed, four months after the district

court granted summary judgment on May 15, 2019, and two months after the district court entered its remedy order on July 12, 2019.

As to the first *Alt* factor, the underlying suit had progressed literally to its end. *See, e.g.*, *Houston Gen. Ins. Co.*, 193 F.3d at 840 (affirming denial of motion to intervene filed more than two months after the district court entered its final order of judgment). Though a party may intervene for purposes of appeal, *Marino v. Ortiz*, 484 U.S. 301, 304 (1988), none of the parties here raised the Cigar Appellants' idiosyncratic interest in preserving the deadlines in the D.C. case during the course of the underlying litigation. That further undercuts the appropriateness of intervention at such a late stage of the present litigation. *See Alt*, 758 F.3d at 591 ("In such circumstances, the court was reasonably reluctant to arrest the momentum of the lawsuit so near its final resolution.").

As to the second factor, the district court noted that the parties had not argued or briefed any of the issues raised by the Cigar Appellants throughout the course of the litigation and "the delay that litigating new issues theoretically would cause after the issuance of a final judgment is not outweighed by the Cigar Associations' potential success on appeal." J.A. 123. The district court did not abuse its discretion in reaching this conclusion. Indeed, we have previously found that the expenditure of "extra effort[s]" on the part of the parties could amount to prejudice on which a district court may base its denial of a motion to intervene. *See Alt*, 758 F.3d at 591 ("Affording the court its proper deference, we are in no position to disagree."). The same is true here.

And as to the third *Alt* factor, the district court held "[t]he Cigar Associations have not provided any justification for their delay in raising their issues in this litigation." *Id.*

Though the Cigar Appellants argue they had no opportunity to move to intervene earlier because the district court had already denied the Vapor Appellants' motion to intervene, this argument fails to recognize that the Cigar Appellants were seeking to intervene for different reasons. Indeed, the Cigar Appellants were on notice that the FDA was seeking to alter the PMTA compliance deadlines at least as early as March 2019, when the FDA published its draft superseding guidance. J.A. 182 (noting that the FDA was "reconsidering the compliance policy with respect to other deemed tobacco products," including "flavored cigars"). Yet, the Cigar Appellants did not move to intervene for another six months. Instead, they filed a motion in the pending District of Columbia case seeking a declaration from that court that the deadlines put in place by the district court here did not apply to cigar products. *See Cigar Ass'n of Am. v. FDA*, Mem. in Supp. of Pls.' Motion for a Decl., No. 16-1460, ECF No. 136-1. The District of Columbia court rightly rejected the Cigar Appellants' attempted maneuvering. *See Cig Ass'n of Am. v. FDA*, 411 F. Supp. 3d 1, 4 (D.D.C. 2019). Therefore, against this backdrop, it appears the Cigar Appellants "gambled and lost in the execution of [their] litigation strategy," which "engenders little sympathy." *Alt*, 758 F.3d at 591. We thus decline to disturb the district court's ruling, which was well within its discretion.

Accordingly, we affirm the district court and hold that that it did not abuse its discretion when it denied the motion to intervene.

V.

For the foregoing reasons, the district court's denial of the Cigar Appellants' Motion to Intervene is affirmed. And because the 2020 Guidance moots the merits of the Vapor

Appellants' appeal, it is dismissed. The FDA has requested its appeal be dismissed if we reach the foregoing conclusions about the Appellants' arguments; therefore, we dismiss the remainder of this appeal.

AFFIRMED IN PART, DISMISSED IN PART