UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 19-2130(L)

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.

On Appeal from the United States District Court
for the District of Maryland, No. 8:18-cv-883 (Grimm, J.)

CONSOLIDATED OPENING BRIEF OF APPELLANTS (NO. 19-2130) AND INTERVENORS-APPELLANTS (NOS. 19-2132, 19-2242)

(CAPTION CONTINUED ON INSIDE COVER)

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.

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.

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.

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January 23, 2020

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The District Court's orders threaten the viability of manufacturers of e-cigarettes, and of cigars and pipe tobacco. The challenges to those orders asserted by each industry, however, are distinct and in tension with each other. E-cigarettes were the focus of the proceedings below, while cigar and pipe tobacco products were barely mentioned by the District Court. Moreover, recent guidance issued by the Food and Drug Administration ("FDA") addresses the two industries in different ways that dramatically affect their respective arguments here. Accordingly, although this brief is filed on behalf of both the Vapor Appellants[1] and Cigar Appellants,[2] their respective arguments are stated separately, and neither industry group joins the arguments asserted by the other, unless otherwise specified.

VAPOR APPELLANTS' INTRODUCTION

Over the last decade, countless adult smokers have relied on e-cigarettes ("vapor products") to transition away from substantially more dangerous cigarettes. For most addicted smokers, other nicotine replacement products, like gums and patches, have failed miserably. These adults use vapor products that are produced and sold by thousands of small companies and family-owned businesses, like Vapor Appellants here. While all agree aggressive steps must be taken to eliminate

[1] The Vapor Appellants are the intervenor-appellants in Nos. 19-2132 and 19-2242.
[2] The Cigar Appellants are the three appellants in No. 19-2130.

underage use, there are significant public health interests impacting current and former adult smokers that must be taken into account.

The District Court's remedy decision not only threatens the very existence of these small businesses, but also the continued availability of products used by adults to improve their health. By imposing a May 12, 2020 deadline under the Family Smoking Prevention and Tobacco Control Act ("TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), *codified at* 21 U.S.C. §§ 387 *et seq*., for submission of pre-market applications to FDA, the court left manufacturers insufficient time to file complete applications. The court was, instead, obligated to remand this matter to FDA so the agency could fully consider these interests through formal notice-and-comment rulemaking under the Administrative Procedure Act ("APA"). Nothing less than a mass market exit of these products and companies is at stake.

CIGAR APPELLANTS' INTRODUCTION

In 2016, the FDA for the first time regulated cigars and pipe tobacco, as well as e-cigarettes. This was a discretionary decision, not mandated by the TCA. At the same time FDA decided to regulate cigars and pipe tobacco, it announced an initial set of tentative deadlines for manufacturers and retailers to comply with aspects of the new regulatory scheme. The agency set these deadlines on the express assumption that it had the authority to later revise them.

In August 2017, FDA exercised this authority by extending the deadlines for manufacturers of newly-regulated products to submit premarket review applications for products that entered the market after 2007. For cigar and pipe tobacco manufacturers, the so-called "Guidance" document extended the deadline until August 2021; for e-cigarettes, the deadline was extended until August 2022.

In 2018, several private health organizations challenged the August 2017 Guidance. In an opinion focused almost exclusively on e-cigarettes, the District Court held the agency's action unlawful and vacated the Guidance. Then, the District Court set its own deadline for premarket review submissions—May 12, 2020—finding that "extraordinary circumstances" pertaining only to e-cigarettes justified this remedy.

This Court should vacate the District Court's orders, without reaching the merits. The fundamental basis for those orders—a finding that e-cigarettes and their novel health effects needed urgent review that FDA was not undertaking—has been completely overtaken by events. On January 2, 2020, FDA exercised discretion to require certain e-cigarette products to exit the market in 30 days, allowing them to re-enter only after FDA receives and approves their premarket review applications. Remaining e-cigarette products must submit applications by May 2020. Significantly, the agency stated it would have exercised its discretion to require these deadlines *regardless* of the District Court's orders. FDA made no such finding

regarding cigars and pipe tobacco. When the basis for a lower court's order is completely undermined by an intervening event, the correct result is to vacate that order and remand it for reconsideration under current circumstances. In any event, in reaching the merits, the District Court erred, transgressing long-standing administrative law principles insulating from judicial review an agency's decision not to enforce a regulation for a limited period of time.

Should this Court reach the merits, it should find the District Court profoundly erred. To the extent the District Court set its own deadline for cigars and pipe tobacco, it had *no basis* for doing so, focusing its entire remedial analysis on e-cigarettes. The remedial order should be reversed to the extent it applies to cigars and pipe tobacco. Moreover, the District Court based its decision on an incorrect interpretation of the TCA, under which the Act would require the agency to remove from the market any newly-regulated product that had entered the market after 2007 as soon as the Deeming Rule took effect, and require such products to stay off the market until manufacturers applied for and received FDA approval. By that reasoning, even the original compliance deadlines provided alongside the Final Deeming Rule—allowing manufacturers to apply for an FDA substantial equivalence order 18 months after the Deeming Rule's effective date—contravened the Act. The District Court's analysis completely missed that Congress gave the

FDA discretion whether *and when* to regulate tobacco products other than cigarettes and smokeless tobacco.

STATEMENT OF JURISDICTION

The District Court had jurisdiction under 28 U.S.C. § 1331. The District Court issued a decision granting summary judgment in Appellees' favor on May 1, 2019 and a decision ordering injunctive relief on July 12, 2019. JA45, 105. The District Court entered final judgment on November 5, 2019. JA125. Both Cigar Appellants and Vapor Appellants timely appealed. JA765, 768. This Court has jurisdiction under 28 U.S.C. § 1291.

VAPOR APPELLANTS' STATEMENT OF ISSUES

The District Court held that an informal guidance issued by FDA setting a Pre-Market Tobacco Product Application ("PMTA") deadline for vapor product manufacturers under the TCA constituted a legislative rule requiring compliance with the APA's formal notice-and-comment rulemaking procedures.

1. Did the District Court abuse its discretion when it imposed a new PMTA deadline without remanding to FDA so the agency could establish a deadline in compliance with APA rulemaking requirements?

2. Did the District Court abuse its discretion when it refused to temporarily reinstate the prior PMTA deadline pending further FDA proceedings where vacatur will result in: a mass exit of vapor products used by adults to transition

away from more dangerous cigarettes; thousands of small vapor businesses closing their doors; and FDA being denied the chance to correct its APA procedural errors?

CIGAR APPELLANTS' STATEMENT OF ISSUES

1. Whether this Court should vacate the decisions below due to FDA's intervening January 2, 2020 Guidance accelerating enforcement of the premarket review process for e-cigarettes and entirely changing the factual circumstances addressed by the District Court.

2. Whether the District Court erred in holding that FDA's decision to extend the deadlines by which manufacturers must submit regulatory filings was not an unreviewable exercise of FDA's discretion to refrain from enforcing a regulation for a limited period of time.

3. Whether the District Court erred in finding the private organizational plaintiffs had standing to challenge the agency's delay of the premarket review deadlines with respect to cigars and pipe tobacco.

4. Whether the District Court erred in ordering a remedy beyond vacating the August 2017 guidance, and in setting its own May 2020 deadline, even though it made no findings justifying this remedy for cigars and pipe tobacco.

5. Whether the District Court erred in holding that the TCA prevented FDA from setting compliance dates for the Act's premarket review provisions that are later in time than the effective date of FDA's Deeming Rule.

6. Whether the District Court erred in denying the Cigar Appellants' motion to intervene as untimely despite their inability to have intervened earlier.

VAPOR APPELLANTS' STANDARD OF REVIEW

This Court reviews a district court's award of equitable relief for abuse of discretion, accepting the court's factual findings absent clear error, and reviewing issues of law de novo. *Solis v. Malkani*, 638 F.3d 269, 274 (4th Cir. 2011) (*see* standard of review for summary judgment below).

CIGAR APPELLANTS' STANDARD OF REVIEW

This Court reviews a grant of summary judgment de novo. *JKC Holding Co. LLC v. Wash. Sports Ventures, Inc.*, 264 F.3d 459, 465 (4th Cir. 2001). The Court reviews the denial of a motion to intervene for an abuse of discretion. *Stuart v. Huff*, 706 F.3d 345, 349 (4th Cir. 2013).

STATEMENT OF RELATED CASE AND PROCEEDINGS

This case has not previously been before this Court. The following pending case is related to these appeals: *Cigar Ass'n of America, et al. v. FDA*, No. 1:16-cv-1460 (D.D.C.).

VAPOR APPELLANTS' STATEMENT OF THE CASE

I. Manufacturers Must Comply With Extensive PMTA Requirements

By virtue of FDA's Deeming Rule, 81 Fed. Reg. 28,973 (May 10, 2016), vapor products are subject to regulation under the TCA.

Specifically, vapor product manufacturers must submit a PMTA for each product and secure FDA approval to remain on the market. 21 U.S.C. § 387j(a). PMTAs are the most time-consuming, costly, and complex pathway to commercialization under the TCA. JA515, 518; JA546, JA529. They require substantial amounts of information for each product to assess human health and population-level impacts—*e.g.*, extensive testing on constituents, toxicological and pharmacological properties, and storage/stability performance, as well as consumer perception studies, environmental assessments, and literature reviews. JA265-292.

Most PMTAs will also require long-term data from human clinical and epidemiological (population-level) studies showing a given product is "appropriate for the protection of the public health." 21 U.S.C. § 387j(c). This "population effects" standard assesses the product's impact on the population as a whole, including the likelihood people will stop using tobacco products or start using them. *Id*.

Particularly concerning is the substantial time required to complete these studies. Based on a PMTA expert's review of timetables for e-cigarette health studies that were federally-funded in 2017, the average time to finish randomized-controlled clinical trials and cohort observational studies (*i.e.*, epidemiological studies) was 6.67 and 5.11 years, respectively. JA349-350. Thus, even if manufacturers had started conducting such research in August 2016, the effective

date of the Deeming Rule, many would still not be done. Indeed, FDA's own epidemiological study of e-cigarettes, which examines the same issues as a PMTA, has taken eight years and is still on-going. JA354.

Not surprisingly, PMTA experts and rulemaking comments submitted on the Deeming Rule concluded that manufacturers would need years to conduct the required studies and submit complete PMTAs. JA529; JA668, 701.

II. Open System Vapor Products Are Used By Adult Smokers To Transition From Cigarettes

Vapor Appellants are national and state trade associations representing hundreds of vapor product manufacturers, distributors, and retailers, many of whom are small "Mom and Pop" businesses. JA513, 518; JA561. They are located in all 50 states and employ thousands. JA513. Many businesses were started by vapers who quit using cigarettes and nicotine altogether with the goal of helping others. JA561; JA519. It is estimated there are over 15,000 brick-and-mortar vape shops across the country. JA518.

These businesses focus on "open" (*i.e.*, refillable) e-cigarette systems that adult smokers rely on to move away from more dangerous cigarettes. For instance, a 2018 survey of 20,836 U.S. adult vapers found the vast majority of respondents (76%) who had completely substituted vapor products for cigarettes used open

systems. JA599 n.5.[3] Another 2018 survey of 69,000 adult vapers, the largest of its kind to date, revealed almost 90% of the respondents started vaping to quit smoking and 76% were using open systems. JA599-600 n.6.[4]

Open systems also have not driven the recent increase in underage use. A review of Nielson data from 2017-18 indicates this upward trend, which notably followed two years of falling or steady use by minors, corresponds almost exactly with the introduction of "closed" (*i.e.*, non-refillable) pod/cartridge systems, like JUULs, into the convenience store/gas station ("c-store") distribution network normally reserved for cigarettes. JA601 n.11; JA539.

FDA Commissioner Scott Gottlieb acknowledged this fact in September 2018 when he noted "open tank" vapor products are not the source of rising underage use. JA601 n.12. In fact, the majority of FDA enforcement actions for illegal sales to minors involve c-stores, not independently-owned vape shops. JA601. It is not surprising that FDA, in recently issued guidance setting various enforcement priorities, repeatedly states, based on 2019 data, that youth "overwhelmingly prefer cartridge-based" vapor products. JA202. This is because, unlike open systems that

[3] *See* Russell study at 1.
[4] *See* Farsalinos survey at 11 (Table 4), 14 (Table 6).

are bulky and require separately bottled e-liquids, pods/cartridges are easy to use and conceal.[5] *Id.*

III. Vapor Products Offer Substantial Health Benefits To Adult Smokers

Leading governmental health organizations and research bodies have concluded vaping is far less risky than smoking cigarettes. This is because e-cigarettes do not burn tobacco leaf or involve the inhalation of tar and other pyrolyzed tobacco constituents associated with cigarettes, many of which are known human carcinogens and toxicants. JA684-685. According to FDA, the "use of [vapor products] is likely less hazardous for an individual user than continued smoking of traditional cigarettes." 81 Fed. Reg. at 29,035; *see* 81 Fed. Reg. at 29,030, 29,032. The National Academies of Sciences, based on a recent review of over 4,000 studies, found there is "conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in" cigarettes. JA611.

Likewise, FDA's Center for Tobacco Products Director, Mitch Zeller, concluded in a sworn statement in this litigation "it is likely that some [vapor] products may reduce harm at the individual level." JA542. Along with

[5] FDA and Centers for Disease Control ("CDC") have also determined that the recent outbreak of "vaping" related lung illnesses is being driven by illicit tetrahydrocannabinol ("THC") products containing vitamin E acetate. *See* FDA at https://tinyurl.com/y3bgtdtx; CDC at https://tinyurl.com/sxx48th. Commercial nicotine products do not contain THC or vitamin E acetate.

Commissioner Gottlieb, he also wrote that vapor products, when combined with measures to reduce nicotine levels in cigarettes, "represent[] a promising foundation for a comprehensive approach to tobacco harm reduction." JA611. Public Health England, an arm of the British government, and the Royal College of Physicians found vaping is "95% safer" than smoking. JA633.

Extensive research also shows vaping can be an effective quit aid. A recent one-year clinical trial published in the *New England Journal of Medicine* found vaping is nearly twice as effective as other cessation products (*i.e.*, nicotine replacement therapies) when both are combined with behavioral support. JA599 n.1. The National Academies of Sciences report concluded "[w]hile overall evidence from observational trials are mixed, there is moderate evidence from observational studies that more frequent use of e-cigarettes [is] associated with an increased likelihood of cessation." JA611. Two recent surveys of almost 100,000 U.S. vapers (combined) found the vast majority had completely replaced smoking with vaping. JA344; JA612. Public Health England reported almost all of the one-million-plus adult vapers in England are current or ex-smokers, many of whom are vaping to help transition away from cigarettes. JA703.

Director Zeller's declaration also stated "some addicted adult smokers use these products with a goal to end" their smoking habits and that a "mass market exit of [vapor] products would limit the availability of a potentially less harmful

alternative for adult smokers seeking to transition or stay away from" cigarettes. JA542. In fact, he stated that "[d]ramatically and precipitously reducing availability of these products could present a serious risk that adults, especially former smokers, who currently use [vapor] products and are addicted to nicotine would migrate to [cigarettes]." JA542. He warned this was a "public health outcome that should be avoided if at all possible." JA541; JA207 (recent FDA enforcement guidance balancing various interests, including the "availability of potentially less harmful options for current and former adult smokers who have transitioned or wish to transition completely away from" cigarettes).

Accordingly, open-system vaping products fit squarely within the TCA's goals of promoting products with a relatively favorable position on the continuum of risk. The TCA "provide[s] new and flexible enforcement authority to ensure there is effective oversight of the tobacco industry's efforts to develop, introduce, and promote less harmful tobacco products." TCA § 3(4). FDA must also "promote cessation to reduce disease risk and the social costs associated with tobacco-related diseases" while "continu[ing] to permit the sale of tobacco products to adults in conjunction with measures to ensure they are not sold or accessible to underage purchasers." TCA §§ 3(7), (9). The TCA, therefore, seeks to advance the interests of adult smokers looking for harm reduction tools.

IV. FDA's PMTA Deadlines Have Accounted For Manufacturer And Adult Interests

Beginning with 2016's Deeming Rule, FDA has extended the PMTA filing deadline on several occasions in an effort to balance numerous stakeholder interests, including those of vapor product manufacturers and adult consumers.

The Deeming Rule initially established an August 8, 2018 deadline for vapor products on the market as of August 8, 2016. If a timely PMTA was filed, the product could remain on the market for up to an additional year pending FDA review. 81 Fed. Reg. at 28,978. FDA said this approach balanced concerns regarding underage use, manufacturers' need for adequate time to comply and file high-quality PMTAs, and the recognition that vapor products may help adults move away from more dangerous cigarettes. *Id.* at 28,977-78; JA537-538.

In July 2017, FDA issued the guidance challenged here which extended the deadline to August 2022. JA772-782; JA153-166. Again, FDA highlighted the importance of balancing competing interests. FDA also stressed it needed sufficient time to develop additional "foundational" rules and guidance for manufacturers to follow when navigating the complex PMTA process. FDA further noted an extension was necessary to avoid forcing vapor products off the market and depriving addicted smokers of a potentially less risky alternative. And it reiterated the importance of providing manufacturers adequate time to submit complete

PMTAs. JA772-782. Products meeting the deadline could remain on the market pending FDA review. JA538.

In March 2019, FDA published draft guidance that proposed changing the PMTA cutoff yet again to August 8, 2021. JA167-186. This was done in response to recent data showing increased underage use of certain types of vapor products. In doing so, FDA again balanced concerns regarding minors with the potential benefit of giving adult smokers safer options to transition from cigarettes. JA539. However, as discussed below, the District Court eventually imposed a May 12, 2020 deadline, which was recently adopted by FDA in guidance finalized on January 2, 2020 ("2020 Guidance"). JA187.

V. Manufacturers Reasonably Relied On FDA Promises To Provide Adequate PMTA Guidance

As FDA extended the PMTA deadline beyond 2018, the agency consistently indicated it required additional time to develop and issue further guidance and regulations detailing the types of information required for PMTAs and, importantly, how to conduct extensive testing and clinical research.

In 2017, Commissioner Gottlieb, when setting the August 2022 deadline, stated "[o]ne area of emphasis will be to make sure we have the foundational regulatory architecture to ensure proper oversight of [vapor products] . . . Part of this will be developing regulations that we have not yet pursued because the Agency's tobacco program is so new." JA726 n.2. A year later, he acknowledged "[a] key

part of achieving [FDA's] goals is issuing foundational rules and guidances to help industry better understand what is needed to submit product applications." JA523. He explained "in the coming months," FDA would "propose new rules to help industry on topics including" PMTAs that would "lay out a transparent, modern, and science-based framework for manufacturing practices and the development of [PMTAs] that meet the legal requirements." JA523. And in 2019, he again indicated the August 2022 deadline gave FDA "the time to put in place the implementing regulations and guidance that would . . . provide the rules of the road for how to effectively traverse the PMTA process." JA726 n.2.

Until recently, vapor manufacturers had to rely on a *draft* PMTA guidance document issued along with the Deeming Rule. But FDA warned the draft did not necessarily reflect FDA's current thinking, which would only be set forth in a final guidance document. 81 Fed. Reg. at 28,991. The draft itself explicitly stated it only represented FDA's current thinking when finalized, and was stamped "Contains Nonbinding Recommendations" and "Draft – Not for Implementation". JA635-665. FDA's website contained the same representations. JA522-523.

Vapor product manufacturers, and particularly the thousands of small businesses with limited monetary resources and technical know-how, could not reasonably be expected to complete the PMTAs based on only draft guidance. JA515-516; JA522. As Director Zeller stated in this litigation, the applications

involve "previously novel" products and "newly regulated entities lacking experience with FDA." JA544. PMTAs also center around the population effects standard, a test that is entirely new to both manufacturers and FDA. JA515 (noting FDA regulation of drugs and devices focuses on different concepts of safety and effectiveness). Without final guidance, it was not only difficult for small companies to understand what was required for each application, but also to manage risk, including significant financial and time demands. JA515; JA529.

VI. FDA Has Not Resolved Significant Uncertainties In The PMTA Process

While FDA eventually finalized the PMTA guidance in June 2019, three years after the draft was issued, it still falls well short of providing manufacturers with details needed to complete PMTAs. JA240-294. Although the document provides recommendations for "what" manufacturers may include in a PMTA, it leaves unanswered questions regarding "how" to test products and develop required information, and ignores realities on the ground. JA513-517; JA558; JA523-525.

Significantly, it does not set forth testing protocols for devices or e-liquids. JA524. Variables like power settings, airflow settings, humectant composition, nicotine concentrations, and flavors can greatly influence the cost and time to perform clinical and non-clinical studies. For instance, a clinical study of an open-system device with two power settings, two airflow settings, three flavors, various ingredient ratios, and three nicotine concentrations would result in 108 possible

consumer use scenarios and would take several years to complete. Yet FDA only tells manufacturers to conduct tests with a range of conditions. JA270. Relying on such ambiguous instructions runs a serious risk of falling short of FDA's expectations. JA524.

Similarly, FDA has not provided any standardized testing methods for assessing Harmful and Potentially Harmful Constituents ("HPHCs"). JA516; JA558. PMTAs must identify HPHCs contained in each product. JA270-271. Unlike testing regimes for cigarettes, FDA does not specify for vapor products any testing protocols, sample sizes, validation methods, limits of detection, or how to conduct exposure assessments. JA516; JA558. To complicate matters, FDA recently added new HPHCs to the list of reportable substances. Now labs must develop more testing methodologies that will need to be validated and go through third-party accrediting processes. JA558.

The final guidance also fails to establish Good Manufacturing Practices ("GMPs"), which must be verified in each PMTA as having been implemented. 21 U.S.C. § 387j(b)(1)(C); JA516; JA523-524. While the guidance summarizes information about manufacturing processes that will need to be included in a PMTA, it does not provide details on what practices or procedures are appropriate for the protection of human health when, for example, manufacturing e-liquids. JA516.

Finally, yet another source of uncertainty involves the process of conducting an Environmental Assessment ("EA") for each product, which applicants must submit under the National Environmental Policy Act. JA517. For instance, it is not clear how companies need to assess the potential greenhouse gas emissions resulting from the use and disposal of millions of vapor products, JA517, or what GMPs need to be incorporated into the EA, JA523-524.

Even FDA concedes it has not fully articulated what must go into a PMTA. An additional regulation, also designed to specify PMTA contents, was only proposed at the end of September 2019, with a public comment deadline of December 16, 2019.[6] JA541. It will be months before it is finalized.

VII. FDA Has Not Resolved Key Sources Of Delay In The PMTA Process

Significant bottlenecks in the PMTA process also expand the time required to complete the applications. To fill-in critical gaps discussed above, the final PMTA guidance essentially requires manufacturers to attend pre-application meetings with FDA. JA225, 292-294; JA517; JA525. FDA expects them to meet "well in advance of planned premarket applications" so manufacturers can "consider [FDA] feedback prior to preparing the application" and to "ensure the application will be complete at

[6] Premarket Tobacco Product Application and Recordkeeping Requirements (Proposed Rule) (September 2019), *available at* https://tinyurl.com/tezsy8k.

the time of submission and likely to provide data and information" so FDA can "make a final authorization decision." JA293.

FDA needs time to flesh out parameters and resolve difficult technical questions for each application. JA517. This back-and-forth takes months, even years, to play out for even a single manufacturer. JA517; JA525. For instance, there were nearly two years of such communications with Philip Morris for a heat-not-burn product called IQOS *after* the company submitted its initial application, with FDA requesting additional information and/or corrections at least 12 times. JA526. And this review period does not include pre-application meetings leading up to the submission.

Recently, there is also growing concern regarding significant inefficiencies in this process. Many manufacturers had tried, without success, to schedule meetings for late 2019. JA557. Given that FDA anticipates hundreds of PMTAs, at a minimum, it will be impossible for FDA to confer with all manufacturers and provide adequate guidance well before the District Court's May 2020 deadline. JA557; JA517. And even if FDA could do so, manufacturers would still need sufficient time after the pre-submission meetings to actually conduct the necessary studies per FDA's instructions. JA517.

Finally, another source of delay is a severe shortage of third-party lab capacity for clinical and non-clinical testing. JA529; JA516-517. Small manufacturers do

not have resources to conduct testing in-house. JA516-517. Labs should be accredited, follow good laboratory practices, and have technical expertise to develop testing protocols necessary to demonstrate a product is protective of public health. JA529. Yet there are only five known qualified labs in the US, UK, and Canada. JA557. As small manufacturers collectively produce millions of vapor products, space at these labs will quickly run out. JA529.

VIII. The Merits Decision, Remedies Order, And 2020 Guidance

In this case, Plaintiffs challenged the August 2022 filing deadline in federal District Court. They argued the cutoff was set through informal guidance that actually constituted a legislative rule which was required to go through formal notice-and-comment rulemaking under the APA. JA85. In a Merits Decision, the court agreed and vacated the deadline. JA45, 50, 86 n.10.

The court recognized, however, FDA has some discretion to set a deadline beyond the Deeming Rule's effective date (*i.e.*, August 2016) and that Plaintiffs had long conceded this point. JA52, 73-74. While the court determined FDA's discretion is "circumscribed" by the TCA, and therefore the August 2022 cutoff was set too far into the future, JA89, the agency still has authority to establish a new deadline provided it complies with APA notice-and-comment procedures. "Any Guidance providing for a compliance period will, of course, have to adhere to the notice and comment requirements of the APA." JA97.

The District Court then asked for briefing on a remedy and the vapor associations moved to intervene in the remedies phase. JA97; JA715-717. The court denied the motion, finding FDA adequately represented the associations' interests and, significantly, they would be protected going forward through additional notice-and-comment. The court stated:

> Indeed, any remedy will involve further action by the FDA, which may well have to comply with the APA notice and comment process. At such time, [the vapor associations] would have ample opportunity to be heard regarding the deadlines the FDA proposes to implement and the opportunity to protect their interests.

JA102. The associations were then granted *amicus* status. JA103.

In its remedies brief, FDA initially urged the court to reject calls from Plaintiffs to set a 4-month PMTA deadline (*i.e.*, November 2019) with a one-year grace period for products subject to timely filed applications and, instead, remand the issue for further proceedings. JA107, 109-110. Director Zeller expressed concerns with such a short cutoff date. JA541. These included the risk of a "mass market exit" of vapor products, which offer "a potentially less harmful alternative for adult smokers seeking to transition or stay away from combustible tobacco products." JA542. He also said more time was required so FDA could finalize additional PMTA rules and guidance, manufacturers could complete the complex PMTA process and file high-quality applications, and FDA could review PMTAs within a statutorily-mandated 180-day period. JA543-546.

Despite having pushed for remand, FDA then did an about-face and proposed in the alternative a 10-month deadline (*i.e.*, May 2020), essentially making a settlement offer. JA541. This proposed deadline was based on Director Zeller's own belief that a May 2020 cutoff would better address competing interests. JA541, 546. His affidavit was filed one day before the vapor associations' joint *amicus* brief, in which they presented numerous reasons why a longer time-period would be required. JA723-728.

In response, the court ignored its prior decision and imposed the 10-month deadline. JA105. It acknowledged "[u]nder settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the corrected legal standards." JA109-110 (*quoting PPG Indus. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995)). However, the court stated it may "issue detailed remedial orders" under "extraordinary circumstances." JA116 (*quoting N.C. Fisheries Ass'n v. Gutierrez*, 550 F.3d 16, 20 (D.C. Cir. 2008)). It cited a recent rise in underage vaping as constituting "extraordinary circumstances" and justifying a court-imposed deadline. JA114. Finally, the court found additional authority in the APA, Sections 706(1) and (2). *Id.*; 5 U.S.C. §§ 706(1), (2).

Because the 10-month cutoff works against the interests of manufacturers and adult smokers, the vapor associations filed a motion to intervene for purposes of appeal and to stay the decision. JA742. The court granted intervention, finding FDA's views "have diverged" from those of the associations, but denied the stay. JA122. These appeals followed.

Then, just two weeks before opening briefs were due, FDA issued the 2020 Guidance, adopting the same May 12, 2020, PMTA deadline set by the court. JA187. This was issued without formal notice-and-comment rulemaking despite the Merits Decision's APA holding. FDA maintained the 2020 Guidance was done "independent" of the court's ruling and that formal notice-and-comment rulemaking was not required. Doc. 50 at 1; JA204-205.

IX. The District Court's PMTA Deadline Will Adversely Impact Small Businesses

If the May 2020 deadline stands, thousands of small manufacturers will be forced out of business, and any remaining manufacturers meeting the filing deadline will likely have submitted incomplete PMTAs.

To begin, small companies will have no choice but to close their doors given severe time constraints and PMTA uncertainties. JA557-558 (*e.g.*, enclosing letter to FDA from 1,464 small businesses indicating they will likely go out of business); JA518. Manufacturers will not be able to pay bills or overhead, purchase equipment, or extend leases. JA518. Likewise, thousands of vape shops will be severely

impacted by a shortage of approved products and will have to shut down. JA518. Small business owners who invested their life savings, mortgaged their homes, and personally guaranteed leases and Small Business Administration loans will lose sizable investments, including equipment used to outfit advanced e-liquid clean rooms and production labs. JA518-519; JA561-562. They will be forced to sell their remaining assets for pennies on the dollar. JA562. Countless jobs will be lost. JA518-519; JA561.

Moreover, there is a substantial risk that PMTAs filed in May 2020 will be quickly rejected by FDA as incomplete. Director Zeller warned in this litigation that manufacturers, under Plaintiffs' proposed 4-month cutoff, were "unlikely to submit quality PMTA applications (*e.g.*, applications that are sufficiently complete and organized to enable [FDA] to efficiently conduct the required scientific review)." JA 543. There is no reason to believe the court-imposed May 2020 deadline will be any better. As one PMTA expert observed, given the complexity of these applications and the need to resolve complicated issues, like protocols for testing and research, manufacturers will require longer than 10 months to file high-quality PMTAs. JA529; JA546 (Director Zeller acknowledging the "complexity of [these] applications and the scientific review process"). To date, FDA has rejected 98% of the applications filed as incomplete. JA536-537.

CIGAR APPELLANTS' STATEMENT OF THE CASE

I. FDA Decides To Regulate Cigars And Pipe Tobacco, Prompting Industry Challenge And Adjustment Of Compliance Dates

The TCA established a comprehensive framework for regulating cigarettes, smokeless tobacco, and roll-your-own tobacco. Pub. L. 111-31, 123 Stat. 1776 *et seq.* (codified at 21 U.S.C. §§ 387 *et seq.*). The Act also authorized, but did not require, FDA to regulate other tobacco products by "deem[ing]" them subject to the Act. *Id*. § 387a(b).

In May 2016, FDA published a final rule through which it chose to regulate cigars, pipe tobacco, e-cigarettes, and several other tobacco products for the first time. *See* 81 Fed. Reg. 28,973 (May 10, 2016). Accordingly, products in these categories that had not been "commercially marketed in the United States as of February 15, 2007" would henceforth need to seek and obtain FDA approval to remain on the market. 21 U.S.C. § 387j(a)(1)(A).

The Act provides several avenues for obtaining such approval. Because cigars and pipe tobacco were abundantly marketed before 2007, cigar and pipe tobacco manufacturers could submit reports to FDA demonstrating that a cigar or pipe tobacco product entering the market after 2007 was "substantially equivalent" to a product on the market before 2007 ("SE Report"). To do so, manufacturers would need to show that the product "has the same characteristics as" that of a pre-2007

product or "has different characteristics" that "do[] not raise different questions of public health." *Id*. §§ 387e(j), 387j(a)(2)(A)(i), 387j(3)(A).

E-cigarette products, by contrast, were novel, and not on the market in 2007. As a result, e-cigarette manufacturers would need to go through an entirely different process, seeking FDA approval by submitting a PMTA demonstrating that the e-cigarette was "appropriate for the protection of the public health," often through clinical studies. *Id*. § 387j(c)(2).

FDA set an effective date for the Deeming Rule of August 8, 2016, just three months after publication. 81 Fed. Reg. at 29,003. FDA selected this effective date even though it was aware that the cigar industry could not comply with the new regulatory scheme in just three months. *Id*. at 29,008. For example, the cigar and pipe tobacco industries would need to assemble thousands, if not tens of thousands, of SE Reports and FDA would need to review and approve them. *Id*. at 29,079. FDA determined that the August 2016 effective date was appropriate, however, because it understood that it had discretion to set and subsequently adjust compliance dates that were later than the Deeming Rule's effective date. *See id*. at 29,005-06, 29,008. For the premarket review process, FDA originally required SE Reports to be filed in February 2018—18 months after the Deeming Rule's effective date—and allowed products to remain on the market for an additional year while FDA considered the reports. *Id*. at 28,974, 28,977-78.

FDA's assessment of how long this process would take, and when it would be ready to enforce aspects of the regulatory scheme, was preliminary. The agency recognized, among other things, that it had work to do in finalizing implementing regulations and guidance to facilitate efficient compliance. *Id.* at 28,980, 28,996, 29,001, 29,004-05, 29,008, 29,012, 29,026, 29,046, 29,051-52, 29,078. FDA had not yet issued a rule specifying the content and form of SE Reports, despite a statutory obligation to do so. 21 U.S.C. § 387e(j). Crucial to FDA's analysis was its determination that it could delay compliance dates in the future and that its discretionary action to deem cigars and pipe tobacco subject to the Act did not hamstring its ability to do so. 81 Fed. Reg. at 29,006 (distinguishing "effective dates" from "compliance periods," recognizing the latter as the date on which the burdens of the regulatory scheme would occur); *id*. at 29,010 (noting its discretion to further delay compliance dates); *id.* at 29,011-12.

The Cigar Appellants filed suit in DC federal court to challenge the Deeming Rule, including the substantial equivalence process. *See Cigar Ass'n of Am. et al. v. FDA*, 1:16-cv-01460 (D.D.C. July 15, 2016) (*"CAA"*). The agency extended compliance deadlines in exchange for extending litigation deadlines, *id.*, ECF 34 ¶¶ 3-4, and the court acted on FDA's representation that it "will extend and defer enforcement of all future compliance dates." *Id*., ECF 35 at 1; *see* JA126-38 (three-month extension in May 2017).

By July 2017, FDA recognized that it needed additional time to finalize necessary implementing rules and guidance for the premarket review scheme and to determine how, if at all, premium cigars would be subject to this process. FDA, Press Release, *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death* (July 27, 2017) ("FDA Press Release").[7] To address this agency need, FDA announced it would delay the requirement for cigar and pipe tobacco manufacturers to submit SE Reports until August 2021 and the requirement for e-cigarette manufacturers to submit PMTAs until August 2022. *Id.* FDA said it would use this time to issue "foundational rules" regarding the form and content of SE Reports in order to make the review process "more efficient, predictable, and transparent for manufacturers." *Id.* FDA also said it would open a rulemaking docket to reconsider whether premium cigars should be regulated at all and, if so, how. *Id.* The agency memorialized these compliance extensions in the August 2017 compliance document. JA139-52. And the agency used these extensions to forestall adjudication of many cigar industry claims against the Deeming Rule. *CAA,* ECF 53 at 2-3.

Consistent with the August 2021 extension for cigars and pipe tobacco, the agency has commenced, but has not finished, these rulemakings. In April 2019,

[7] https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/UCM568923.htm.

FDA issued a proposed rule on the form and content of SE Reports, 84 Fed. Reg. 12,740, 12,741 (Apr. 2, 2019), and FDA projects a final rule in April 2020 at the earliest.[8] FDA also opened a rulemaking docket to address whether and how premium cigars should be regulated, citing evidence from its own staff that premium cigars are used infrequently by adults and almost never by children. *See* 83 Fed. Reg. 12,901 (Mar. 26, 2018). It is clear that this docket will not be resolved before the May 2020 compliance deadline.

II. Private Pro-Regulation Organizations, Citing Rising Youth Usage Of E-Cigarettes, Sue To Overturn The Guidance

In May 2018, a group of private organizations and individual physicians sued FDA in federal court in Maryland to overturn the Guidance. *See* JA295-339. Their challenge focused almost exclusively on e-cigarettes, claiming that the health effects of these new products were unknown and that the agency must not allow them to stay on the market without FDA's prior review and approval.

The District Court initially denied Appellees' summary judgment motion without prejudice, JA42-44, but following a motion for reconsideration it changed course and vacated the Guidance. JA97, 99 ¶ 5. The District Court's opinion focused on e-cigarettes, observing that new data showed a spike in youth usage of

[8] Unified Regulatory Agenda, Format and Content of Reports Intended to Demonstrate Substantial Equivalence, RIN 0910-AH89, available at https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201910&RIN=0910-AH89.

those new products. JA45-47, 55, 60-61, 63-64, 88, 98. In its decision, the District Court found that the private organizations had standing, focusing almost entirely on the information they would learn about novel e-cigarette products as they pass through the PMTA process. JA58-64. The District Court went on to rule, among other things, that the agency lacked discretion to delay compliance even a day beyond the Deeming Rule's effective date, explaining that once a tobacco product is deemed subject to the Act, it must have an FDA order approving it or it is illegal. JA87-90.

The District Court then ordered additional briefing on the appropriate remedy. JA97, 99 ¶ 6. In a second opinion focused again almost entirely on e-cigarettes and what the Court believed to be the urgent need for a government agency to review them promptly, the District Court set a deadline of May 12, 2020, and provided that those who do "may remain on the market without being subject to FDA enforcement action for a period not to exceed on year." *See* JA116.

After the court's summary judgment decision, various cigar and vapor-product manufacturers moved to intervene to participate in the remedy briefing, JA706, 709, 712, 718, but the court denied the motions. The court concluded that the manufacturers' interests were adequately represented by FDA. JA102. On August 8, 2019, FDA filed a motion to clarify the court's remedial order, asking whether it could set earlier deadlines than May 2020, rather than immediately

appealing it. JA739-40. Given this first indication that FDA might not vigorously to resist efforts to overturn the Guidance, the Cigar Appellants and the Vapor Appellants separately moved to intervene for purposes of appeal. JA745-48; JA742-44. The court granted the Vapor Appellants' motion to intervene, correctly concluding that they "could not, practically speaking" have "successfully intervene[d]" "before the Remedy Order issued." JA120. In the same order, however, the court denied the Cigar Appellants' motion to intervene as untimely—even though it had only recently denied intervention on the ground that FDA was adequately protecting cigar manufacturers' interests. JA123.

Appellants timely appealed. JA768.

III. On The First Business Day Of 2020, FDA Radically Changes The Premarket Review Compliance Deadlines Addressed By The District Court

One of the principal reasons the District Court vacated the Guidance and issued its remedial order was that FDA would not tell the Court when it planned to finalize new guidance it was preparing to accelerate compliance deadlines for e-cigarettes. JA49-50; *see* JA114-16. On January 2, 2020, the agency finalized that new guidance. JA187-239. The new Guidance required that premarket review applications for certain e-cigarette products be submitted within 30 days and barred those products until FDA approves the application. JA190, 205. For all other e-cigarettes, FDA set a May 12, 2020 deadline. JA215-18. The agency expressly said

it was exercising its independent discretion to require these new deadlines for e-cigarettes and would do so "even in the absence of" the District Court's order. JA214.

FDA made no such finding regarding the deadline for cigars and pipe tobacco. Instead, it observed that substantial equivalence reports for cigars and pipe tobacco were due on May 12, 2020 *solely* because of the District Court's orders under appeal here. JA217 (observing the deadline is "consistent with the U.S. District Court for the District of Maryland's order directing FDA to require that applications be submitted to the Agency by May 12, 2020"). FDA also suggested that the District Court's order was impeding its preferred treatment of "relatively expensive, large hand rolled cigars that do not have flavors," which would be "FDA's lowest priority" for enforcement "given what FDA understands to be their comparatively lower youth usage rates." JA218.

VAPOR APPELLANTS' SUMMARY OF THE ARGUMENT

1. This appeal seeks to enforce FDA's notice-and-comment rulemaking obligations under the APA, 5 U.S.C. § 553, and avoid a regulatory train wreck that could remove from the market virtually all e-cigarette (or vapor) products adult smokers rely on to move away from their smoking habits and force thousands of small businesses to close.

2. Vapor Appellants are national and state trade associations representing vapor product manufacturers, distributors, and retailers across the country. Many of these businesses are "Mom and Pop" vape shops frequented by adults looking for an alternative to more dangerous cigarettes. Significantly, these companies make and sell "open" (*i.e.*, refillable) e-cigarette systems. They do not focus on "closed" (*i.e.*, non-refillable) cartridge/pod-based systems, like JUUL, that FDA blames for the recent increase in underage use.

3. These manufacturers agree vaping by minors must be addressed head-on. But regulating access to vapor products cannot be done at the total expense of adult smokers. FDA and other prominent governmental and academic institutions have concluded vaping is far less risky to health than smoking cigarettes. And extensive research indicates vaping helps current and former adult smokers reduce or eliminate cigarettes from their daily lives.

4. Under the TCA, manufacturers must submit to FDA a PMTA for each and every device or e-liquid product, and obtain agency approval to remain on the market. These applications are time-consuming and complex, requiring extensive product testing and long-term, human clinical and epidemiological (or population-based) studies that take years to complete. PMTAs are so complicated that FDA has yet to publish all of the agency documents setting forth what information is required for each application and how to conduct the requisite testing. Manufacturers remain

in the dark regarding key aspects of the PMTAs and what is needed to file a complete application.

5. Adding to the confusion, FDA has, through the exercise of enforcement discretion and guidance, established or proposed four different deadlines for manufacturers to file PMTAs. Beginning in August 2016, when FDA promulgated the Deeming Rule (the regulation that subjected vapor products to the TCA's requirements), the agency said applications must be filed by August 2018. Then, about a year later, the agency extended the cutoff to August 2022, to give manufacturers more time to comply and file high-quality applications. But earlier this year, FDA signaled it would shorten the period to August 2021, and just this month published final guidance knocking 15 months off that date and setting a May 2020 deadline. Needless to say, these small businesses (and the adults who rely on their products) have suffered a form of regulatory whiplash.

6. In 2018, Plaintiffs challenged the August 2022 deadline. They argued the deadline, which was set forth in informal guidance, violated the APA's formal notice-and-comment rulemaking procedures. In a Merits Decision, the District Court agreed, vacated the deadline, and stated that manufacturers would have an opportunity to protect their interests on remand through notice-and-comment procedures. Significantly, the court found FDA had discretion under the TCA to establish a reasonable deadline that was not set too far into the future. But then the

court suddenly reversed course in a Remedies Order and imposed a deadline, 10 months from the date of the order (*i.e.*, May 2020), a date that was suggested by FDA as part of the remedies phase. As such, the matter was not remanded and the court adopted what essentially amounts to an interpretive rule or guidance pushed by FDA at the last minute to resolve this litigation. FDA then compounded this failure by adopting that date in new 2020 guidance without notice-and-comment.

7. The district court far exceeded its authority when imposing a 10-month PMTA deadline. As a matter of law, the Merits Decision and Remedies Order are irreconcilable. An across-the-board PMTA deadline cannot be both a legislative rule governed by the APA and interpretive guidance falling outside the statute. The District Court ruled it is the former and therefore could not shortcut the process by imposing a deadline offered by FDA during briefing on an appropriate remedy. Moreover, courts do not have authority to completely supplant an agency's discretion and policy-making judgment, particularly where stakeholders have a right to APA notice-and-comment rulemaking. To hold otherwise would be to hand courts unchecked authority to weigh complex and competing stakeholder interests and relieve agencies of any duty to do so within the confines of the APA. Stakeholders would be deprived of their rights to have an agency, like FDA, fairly address comments and justify any action upon judicial review.

8. This Court should vacate the District Court's Remedies Order, temporarily stay vacatur of the August 2022 deadline, and remand to FDA for further proceedings consistent with the APA.

CIGAR APPELLANTS' SUMMARY OF THE ARGUMENT

1. This Court should vacate the District Court's opinions without reaching the merits of whether the August 2017 Guidance was proper.

a. The decision below was fundamentally based on equitable concerns that FDA would not review novel e-cigarette products with sufficient promptness. That basis for the District Court's decision has been vitiated in its entirety by FDA's January 2, 2020 guidance accelerating the review of e-cigarettes, in some cases well before the District Court's deadline. The proper result, in such circumstances, is to vacate and remand the District Court's order. The District Court never considered whether its summary judgment and remedial orders were proper if the only issue were, as it is today, when cigar and pipe tobacco manufacturers should be required to submit SE Reports.

b. The District Court never should have considered whether the compliance extension was proper. That is because it erred by reviewing the agency's decision not to enforce an aspect of the regulatory scheme for a discrete period of time. In stark contrast to a decision to enforce a regulation, long-standing principles of administrative law make a decision to delay enforcement unreviewable, as it

concerns an agency's assessment of when it is ready to act balanced with its other responsibilities.

c. The private organizational plaintiffs lacked standing to challenge the agency's delay of the premarket review deadlines. The District Court's analysis focused on e-cigarettes and the information generated by those products' passage through the premarket review process. The District Court engaged in no analysis of whether the organizations had standing to challenge compliance extensions for cigars and pipe tobacco, which will pass through the separate substantial equivalence process, presenting entirely different issues.

2. The District Court's rulings regarding the legality of the Guidance, the proper remedy, and the ability of the Cigar Associations to intervene were erroneous.

a. The District Court erred by extending its remedial order, and its May 2020 premarket review deadline, to all "newly deemed products," without having supplied any explanation for why it should reach cigars and pipe tobacco. Even the District Court recognized that setting new deadlines for products—instead of merely vacating the Guidance—would require a finding of "extraordinary circumstances," but its analysis of such circumstances focused solely on e-cigarettes. The District Court's orders should thus be reversed insofar as they apply to cigars and pipe tobacco.

b. The District Court wrongly held that the Guidance violated the TCA. According to the District Court, the Act required that all post-2007 tobacco products be pulled from the market the minute the Deeming Rule took effect. Of course, that was not FDA's understanding in the Deeming Rule itself, which set compliance dates 18 months or more after the effective dates. Further, the District Court overlooked that FDA's decision to regulate the new products in the first place was *discretionary*.

c. The District Court abused its discretion in denying the Cigar Appellants' motion to intervene as untimely. The timeliness of intervention turns on when parties to litigation are not adequately defending the intervenor's interests. In June 2019, the District Court rejected cigar industry participants' intervention because FDA was adequately protecting their interests. It was improper for the court to deny the Cigar Appellants' motion to intervene shortly thereafter.

VAPOR APPELLANTS' ARGUMENT

I. The District Court Was Required To Remand The PMTA Deadline For APA Notice-And-Comment Rulemaking

The District Court made three relevant findings in the Merits Decision: (i) FDA committed a procedural error under the APA when it adopted a PMTA deadline without notice-and-comment rulemaking (JA50, 97); (ii) FDA nevertheless retained some discretion to set a shorter compliance period (JA52, 73-74); and (iii) any future PMTA deadline must go through notice-and-comment proceedings (JA97). Under

these circumstances, the court had no authority to set a May 12, 2020 PMTA deadline in lieu of a remand.

To its credit, the District Court acknowledged it had pushed the envelope. It recognized "[u]nder settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the corrected legal standards." JA109-110 (quoting *PPG Indus. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995)). This is because a district court is acting not as a trial court, but rather as an appellate tribunal. *Bennett v. Donovan*, 703 F.3d 582, 589 (D.C. Cir. 2013); *Hill Dermaceuticals, Inc. v. FDA*, 709 F.3d 44, 46 n.1 (D.C. Cir. 2013).

Where the agency retains discretion in the matter, and the procedural error is a failure of notice-and-comment rulemaking, then a remand is required. *Gurrola v. United States*, 751 F.3d 629, 634 (D.C. Cir. 2014); *Am. Medical Ass'n v. Reno*, 57 F.3d 1129, 1130-31 (D.C. Cir. 1995). APA Section 706(1) is the only provision allowing a court to "compel agency action" unlawfully withheld. But as the Supreme Court made clear in *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 65 (2004), this only applies where the agency has no discretion to act. *City of New York v. United States DoD*, 913 F.3d 423, 432 (4th Cir. 2019) (same). Given the District Court concluded (and Plaintiffs agreed) FDA has discretion to set a new

PMTA deadline, the court lacked authority to impose the 10-month compliance period on its own.

Further, APA Section 706(2) does not save the District Court. That provision only allows a court to "set aside" unlawful agency action. The District Court did that here when vacating the August 2022 deadline as inconsistent with the TCA. But to interpret Section 706(2) as further permitting injunctive relief, particularly where the agency would retain discretion on remand, would be to read Section 706(1) out of the statute and render *Norton* a dead letter. *Hibbs v. Winn*, 542 U.S. 88, 101 (2004) (courts must avoid rendering statutory terms inoperative or superfluous). Indeed, as the D.C. Circuit held in *Gurrola*, when those two provisions are read together, agency "discretion forecloses a detailed order" when the "statutory failure was of notice and comment." 751 F.3d at 634.

And courts take this approach for good reason. Notice-and-comment "serve[s] important purposes of agency accountability and reasoned decisionmaking." *Am. Medical Ass'n*, 57 F.3d at 1132. "[It] allow[s] the agency to benefit from the experience and input of the parties who file comments . . . thereby helping to ensure informed agency decisionmaking." *Chocolate Mfrs. Ass'n v. Block*, 755 F.2d 1098, 1103 (4th Cir. 1985) (citations and internal quotations omitted). It ensures an agency considers all relevant factors and explains its decision, *Motor Vehicle Mfrs Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29,

43-44, 52-53 (1983), and it is subject to meaningful judicial review, *Am. Medical Ass'n*, 57 F.3d at 1134.

Unfortunately, that did not happen here. Nowhere did Director Zeller's declaration consider any of the concerns raised by the vapor associations as *amici* (and could not have given his declaration was submitted one day before the industry *amici* brief). *Supra* at 17-21. All of these issues (*e.g.*, required long-term studies, lack of testing protocols, pre-application meetings, pending PMTA rulemaking) are relevant factors FDA would have been obligated to consider on remand when explaining how it selected a new filing deadline.

Furthermore, small businesses reasonably relied on public statements made by FDA between 2017-19 indicating the agency had yet to fully articulate "foundational" guidance and regulations (*i.e.*, "rules of the road") for completing PMTAs. *Supra* at 15-17. Substantial financial, personnel, and time commitments have been impacted by FDA's representations that it will provide a clear path to PMTA approval before requiring any filings. JA515-516; JA529. Manufacturers cannot be faulted for planning in light of significant uncertainties and delays.

This holds true even where FDA has indicated more recently it might shorten the filing deadline given the rise in underage use. It would still be arbitrary and capricious under the APA for the agency to set a PMTA cutoff without considering the reliance interests engendered by what has proven to be FDA's lengthy process

of adopting much needed PMTA rules and guidance. *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016); *Nat'l Lifeline Ass'n v. FCC*, 915 F.3d 19, 28 (D.C. Cir. 2018). And even after those instructions have been finalized, manufacturers will still need sufficient time to understand and implement them (*e.g.*, actually testing products). JA518; JA525.

Finally, perhaps the most worrisome aspect of Director Zeller's declaration is that it is premised on nothing more than his mere belief a 10-month deadline is sufficient. JA541, 546. He never explains why a 4-month deadline, as proposed by Plaintiffs, could lead to a public health and administrative disaster – with a mass exit of products and businesses, former smokers migrating back to cigarettes, manufacturers filing incomplete and low quality PMTAs, FDA struggling to finish PMTA rulemakings and guidance needed by the regulated community, and a backlog of unreviewed applications (JA540-546) – but a modestly longer 10-month period would not. This is a glaring omission, as just a few months before FDA had concluded August 2021 was the appropriate cutoff. JA539-540.

Regrettably, the District Court, by adopting what was essentially a 10-month litigation settlement offer by FDA, absolved the agency of any responsibility or accountability to ensure these issues were considered and appropriately resolved under the APA. This is not permitted. *Conservation Northwest v. Sherman*, 715 F.3d 1181, 1187 (9th Cir. 2013) ("a district court abuses its discretion when it enters

a consent decree that permanently and substantially amends an agency rule that would have otherwise been subject to statutory rulemaking procedures").

In setting a PMTA deadline, the District Court relied, in part, on its perceived equitable powers and cited non-Fourth Circuit cases where courts imposed injunctive relief. JA108-109, 114-115. But none of those decisions hold that a court, where an agency violated APA notice-and-comment requirements, can award injunctive relief that completely strips the agency of all discretion. There was simply no occasion for those courts to consider whether they had authority, under the APA or otherwise, to replace stakeholder rights to notice-and-comment rulemaking.

In fact, the only case that involved notice-and-comment issues – *Coal. for Gov't Procurement v. Fed. Prison Indus., Inc.*, 365 F.3d 435, 459-60, 473-75 (6th Cir. 2004) – considered imposing injunctive relief that would have preserved agency discretion on remand. There, the court would have ordered the federal defendants to take comment and calculate how much office furniture produced by prison workforces could be introduced into the commercial marketplace. *Id.* at 473-77. In contrast, the District Court stripped FDA of all discretion.

Moreover, the District Court discussed several Fair Housing Act cases (which did not involve a failure of notice-and-comment) that concluded the "words 'set aside' [in APA Section 706(2)] need not be interpreted narrowly" when "devising an appropriate remedy." JA115 (citing *Thompson v. United States Dep't of HUD*,

348 F. Supp. 2d 398, 464 (D. Md. 2005) which in turn quoted *NAACP v. Secretary of HUD*, 817 F.2d 149, 160 (1st Cir. 1987)). JA115. The District Court read this expansively to permit injunctive relief that completely supplanted any discretion FDA would have had on remand. But the court failed to note the *NAACP* court explicitly warned the lower court, that when fashioning any injunctive relief, it must "preserv[e] for the agency its discretionary options." 817 F.2d at 159.

Finally, the court took the unprecedented step of relying on an "extraordinary circumstances" exception that was briefly mentioned by the D.C. Circuit in *N.C. Fisheries Ass'n v. Gutierrez*, 550 F.3d 16, 20 (D.C. Cir. 2008). JA110. The court cited no cases affirmatively applying the exception (and we are not aware of any) or any Fourth Circuit decision that even references the doctrine. In the few cases that have cited to it, the courts focused on the authority of the agency and refused to order injunctive relief where the agency retained some discretion on remand. *See Gurrola*, 751 F.3d at 634-35 (refusing to impose on remand a specific tax refund procedure where the IRS retained discretion to "design the [procedure's] details"); *Baptist Med. Ctr. v. Sebelius*, 855 F. Supp. 2d 1, 3 (D.D.C. 2012) (refusing to dictate specific standards for recalculating Medicare payments where agency was entitled to have an "opportunity to reconsider the issues on remand").

The District Court did not cite to any cases where the exception was applied based on public policy concerns – a virtually limitless expansion of the doctrine –

which are better addressed through agency decision-making. Indeed, the instant case is about more than just extending a filing date. As the foregoing demonstrates, it involves a complicated balancing of scientific, technical, administrative, and public policy matters that should be accomplished through notice-and-comment rulemaking, with FDA's ultimate decision subject to judicial review.

II. FDA's 2020 Guidance Does Not Moot This Appeal

The recently issued 2020 Guidance does not change this analysis. FDA indicated its opening brief will argue the guidance moots this appeal. Doc. 50 at 2. To the contrary, it highlights why the District Court's decision is flawed. The 2020 Guidance, which adopted the May 2020 deadline, was published without formal notice-and-comment rulemaking. Doc. 50 at 1; JA204-205. As such, this violates the court's finding that an across-the-board PMTA deadline is a legislative rule that must comply with formal notice-and-comment procedures. If the court had remanded, FDA would have been compelled to address manufacturers' specific concerns and establish a deadline subject to judicial review. Instead, this guidance not only flies in the face of the relief sought here, it is also an unlawful end-around of manufacturers' APA procedural rights.[9]

[9] The Merits Decision suggested FDA would only need to adopt "Guidance" using notice-and-comment. JA97. But that directly contradicts the court's own APA ruling. Again, an across-the-board deadline cannot, as a matter of law, be both a legislative rule and an interpretive rule.

III. The District Court Should Have Temporarily Stayed Vacatur Of The August 2022 PMTA Deadline

This Court should also temporarily reinstate the August 2022 deadline while FDA properly adopts a new cutoff through formal rulemaking. Remanding without vacatur is particularly warranted here as FDA's unlawful 2020 Guidance will likely create even more confusion as to the actual filing deadline.

Courts may forego vacatur and, in doing so, consider several factors when exercising such discretion, including instances where there is a failure of notice-and-comment. *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 98 (D.C. Cir. 2002). First, courts look to whether the agency can justify its action on remand. *Id.* (citation omitted); *N. Air Cargo v. United States Postal Serv.*, 674 F.3d 852, 860-61 (D.C. Cir. 2012) (same). Second, courts ask whether vacatur could have "disruptive consequences" or impose significant costs. *Id.* Both factors warrant temporarily suspending vacatur here.

As to the second factor, Director Zeller set forth the significant public health risks to adult smokers if there is a premature mass market exit of vapor products. He concluded that a truncated filing deadline would limit the availability of products that individual vapers use to end their smoking habits and thus forcing them back to combustible cigarettes. JA542-543. According to Director Zeller, this is a "public health outcome that should be avoided if at all possible." JA541. Indeed, extensive

research demonstrates vaping is far less risky than smoking and that vapor products may help adults quit. *Supra* at 11-13.

While underage use must also be considered, we note that, according to FDA, open systems used by adults and manufactured by the vapor associations' members are not driving underage use. Indeed, the federal government has recently taken steps to address underage use involving products of concern. The 2020 Guidance, in a section that does not involve the PMTA deadline, is designed to immediately remove questionable products, namely flavored, closed (*i.e.*, cartridge-based/pod) systems like JUUL, from the market. JA197-198. The government also just adopted a 21-and-over restriction for tobacco products, including e-cigarettes. All of this should temper concerns when not immediately vacating the prior deadline.

Moreover, courts eschew vacatur where substantial economic interests could be jeopardized. *Cal. Cmtys. Against Toxics v. United States EPA*, 688 F.3d 989, 994 (9th Cir. 2012) (weighing employment losses). The record shows countless small businesses will have to close if they are unable to file complete PMTAs by May 2020. Employees will be let go, owners will lose significant investments and savings, loans will go into default, and leases will be broken. *Supra* at 24-25. This could be avoided by keeping the vacated guidance temporarily in place and sending a clear message to the market that open systems will not be immediately subject to enforcement actions as FDA decides on a new deadline.

Finally, with regard to the first factor, while FDA is prohibited by the District Court's ruling from adopting something akin to an August 2022 deadline, it can obviously correct the notice-and-comment failure on remand. Further, this is not a case where an agency acted completely outside its authority. The court found (and Plaintiffs agree) FDA has some discretion to set a new cutoff. JA52, 73-74. FDA can do so after taking comment from all stakeholders, including manufacturers, and complying with all APA rulemaking procedures.

CIGAR APPELLANTS' ARGUMENT

I. This Court Should Vacate The District Court's Orders Without Reaching The Merits

There is no need for this Court to reach the merits of the District Court's rulings that the August 2017 Guidance—including its compliance extensions—is invalid. This Court rather should vacate the District Court's orders because: the January 2020 Guidance has fundamentally has changed the circumstances addressed by the District Court; the extensions were judicially unreviewable; and Appellees had not established Article III standing with regard to cigars and pipe tobacco.

A. FDA's Intervening January 2020 Guidance Requires That The District Court's Orders Be Vacated

The District Court's orders should be vacated in light of FDA's intervening January 2020 Guidance. That Guidance has so fundamentally changed the circumstances evaluated by the District Court that the District Court should now determine whether its orders are still warranted. *E.g.*, *Douglas v. Indep. Living Ctr.*

of S. Cal., Inc., 565 U.S. 606, 610, 616 (2012) (vacating and remanding lower court opinion after the agency changed its determination and "the relevant circumstances have changed").

The District Court's orders stemmed from its determination that, because e-cigarettes were being used by youth in alarming numbers and had unknown public health effects, FDA should review these products before allowing them to remain on the market. JA55, 98. These concerns animated the District Court's remedial order. JA106-07, 110-16. More than once the District Court cited uncertainty about when FDA would follow through with a proposed acceleration of premarket review deadlines for e-cigarettes. JA50. The District Court also invoked exceptions to the general rule that an agency's non-enforcement decision is immune from judicial review, *see infra* at 53-57, on the ground that the agency was not enforcing the premarket review provisions against *any* of the newly deemed products, while conceding it would be a different case if the agency were prioritizing enforcement among the newly deemed products, for example, by accelerating review of e-cigarettes. JA89.

FDA's January 2020 guidance changed all these core factors driving the District Court's orders. The agency has now promised immediate enforcement—far earlier than May 2020—against a class of e-cigarette products that the agency determined are particularly attractive to youth. JA205. The agency also set a May

12, 2020 deadline for all other e-cigarette products to submit premarket review applications or to pull them from the market. JA216-17. Importantly, the agency set these new e-cigarette deadlines strictly as an exercise of its own discretion and said it would have done so "even in the absence of" the District Court's orders. JA214.

The new 2020 guidance treats cigars and pipe tobacco differently from e-cigarettes. For cigars and pipe tobacco, the agency only observed that the May 12, 2020 deadline for premarket review submissions is "consistent with" the District Court's orders. JA217. The agency made no claim that it would set a May 2020 deadline for cigars and pipe tobacco in the absence of those orders. Today, the District Court's orders are only driving enforcement against cigars and pipe tobacco.

There is no evidence that the District Court would have granted summary judgment against FDA, much less ordered a May 2020 deadline for premarket review submissions, if the agency had delayed only the premarket review compliance deadlines for cigars and pipe tobacco. Cigars and pipe tobacco were barely mentioned in either of the District Court's orders. To the extent they were mentioned, it was only to describe the coverage of the Deeming Rule. JA46 n.3; JA51.

The District Court identified no public health crisis arising from delayed enforcement against cigars and pipe tobacco. Indeed, cigars and pipe tobacco are

situated very differently from e-cigarettes. Enforcement of the premarket review scheme would not have affected thousands of cigar and pipe tobacco products on the market because they existed before 2007. Moreover, the extension of the compliance deadline for cigars and pipe tobacco was a year shorter, only to August 2021. The extension also governed an entirely different agency inquiry—the substantial equivalence process—under which manufacturers would be required to show only that their post-2007 products were not materially different from cigar and pipe tobacco products long on the market. By contrast, e-cigarettes would have to, but had yet to, demonstrate that their products were appropriate for protection of the public health—a much more rigorous standard.

When intervening agency action has so materially changed the conditions considered by the District Court, the correct result is to vacate the District Court's orders and remand the case, both so that aggrieved parties may consider whether they have a claim and so that the District Court may determine whether its approach remains warranted. *See, e.g.*, *Douglas*, 565 U.S. at 610, 616; *Madison Cty. v. Oneida Indian Nation of N.Y.*, 562 U.S. 42 (2011) (per curiam) (vacating and remanding to address a "new factual development"); *Slekis v. Thomas*, 525 U.S. 1098 (1999) (vacating and remanding in light of new "interpretive guidance" issued by the agency); *Long Island Care at Home, Ltd. v. Coke*, 546 U.S. 1147 (2006) (vacating and remanding in light of new agency advisory opinion); *Greater Boston Television*

Corp. v. FCC, 463 F.2d 268, 283 (D.C. Cir. 1971) (vacatur of a lower court decision warranted "where there has been a change in circumstances, subsequent to administrative decision and prior to court decision, that is not merely 'material' but rises to the level of a change in 'core' circumstances, the kind of change that goes to the very heart of the case"); *Concerned Citizens of Vicksburg v. Sills*, 567 F.2d 646, 649-50 (5th Cir. 1978) ("[W]here circumstances have changed between the ruling below and the decision on appeal, the preferred procedure is to remand to give the district court an opportunity to pass on the changed circumstances.") (citation omitted).

That is what should happen here. This Court should vacate the District Court's summary judgment and remedial orders in light of FDA's January 2020 guidance.

B. The Guidance Is An Unreviewable Exercise Of FDA's Non-Enforcement Discretion

The District Court also erred by contravening longstanding principles of administrative law that insulate from judicial review an agency decision *not to enforce* a regulation for a discrete period of time. *Cf.* JA67-79. Such a decision stands in stark contrast to an agency decision to enforce a regulation, including as to

the timing of its enforcement, which regulated entities may challenge in the judicial system.[10]

The Supreme Court made these fundamental administrative law principles clear in *Heckler v. Chaney*, 470 U.S. 821, 831 (1985). There, the Court held that "an agency's decision not to prosecute or enforce . . . is a decision generally committed to [its] absolute discretion," and is "presumed immune from judicial review." *Id.* at 831, 832. The Court explained that "an agency decision *not to enforce* often involves complicated balancing of a number of factors which are peculiarly within its expertise," and agencies are "far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities." *Id.* at 831-32 (emphasis added). The Court distinguished decisions to enforce or accelerate enforcement of a regulation, reasoning that "when an agency refuses to act it generally does not exercise its *coercive* power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect." *Id.* at 832.

FDA's limited extension of compliance deadlines was clearly a decision not to enforce a regulation. The District Court erred by holding that the "presumption of unreviewability" that attaches to such decision was rebutted here. JA68-79, 89-

[10] In this regard, FDA has been and would be incorrect to contend that judicial review is forbidden where the agency makes a decision to *accelerate* enforcement after leading regulated entities to believe they had time to comply.

90. *First*, the extension of the premarket review deadlines clearly was not an "abdication" of FDA's statutory responsibilities. *Cf.* JA89 (citing *Chaney*, 470 U.S. at 833 n.4). The Guidance extended the compliance deadline for only one portion—the premarket review provisions—of a massive regulatory scheme imposed on the newly deemed products. It did not alter compliance deadlines for manufacturer registration, product listings, ingredient listings, health information submissions, and warning labels, among many other requirements. JA143. Even with regard to premarket review, the extension applied only to a subset of the newly deemed products, those that were on the market as of August 8, 2016, the Deeming Rule's effective date. JA143-44. Moreover, the Guidance did not say that the premarket review provisions would never be enforced against these newly deemed products; it instead established a limited extension of the compliance dates. *Compare Jerome Stevens Pharmaceuticals, Inc. v. FDA*, 402 F.3d 1249, 1250-51 (D.C. Cir. 2005) (holding unreviewable an agency determination allowing a class of drugs to be sold without FDA approval for three years) *with Kenney v. Glickman*, 96 F.3d 1118, 1123 (8th Cir. 1996) (holding that *Chaney* does not apply to "permanent policies or standards").

Moreover, FDA extended the Deeming Rule's compliance deadlines to advance—not undermine—the Act's regulatory regime. Specifically, the extension was to allow FDA time to prepare what it described as "foundational" rules on the

form and content of SE Reports. *See* FDA Press Release, *supra* n. 7. These rules were required by statute, 21 U.S.C. § 387e(j)(1), and were needed to clear up "confusion about what information FDA needs from applications to make a substantial equivalence finding," 84 Fed. Reg. at 12,741, and to provide an "efficient, predictable, and transparent" review process, FDA Press Release, *supra* n. 7.

The District Court further erred by claiming that *Chaney*'s "presumption of unreviewability" applied only when the agency decides not to enforce "on a case-by-case basis." *See* JA89-90. Courts regularly have declined to review agency extensions of compliance deadline for classes of products. *Jerome*, 402 F.3d at 1250-51 (holding that a three-year deferral of enforcement was unreviewable agency action); *Ass'n of Irritated Residents v. EPA*, 494 F.3d 1027, 1031-32 (D.C. Cir. 2007) (holding unreviewable the deferral of enforcement across an entire industry). The key is whether the deferral of enforcement is limited in duration. *Jerome*, 402 F.3d at 1257.

Second, the District Court erred by holding that the statute "provided guidelines for the agency to follow in exercising its enforcement powers," "circumscribing [FDA's] power." *Chaney*, 470 U.S. at 832, 833; *see also Sierra Club v. Larson*, 882 F.2d 128, 131 (4th Cir. 1989). The Food, Drug and Cosmetics

Act's enforcement provisions are at issue here and were in *Chaney*, and the Supreme Court held they give FDA wide berth. *Chaney*, 470 U.S. at 835.

Moreover, none of the specific statutory provisions identified by the District Court barred enforcement delays. *See* JA74-78. One provision simply required the agency to rule on a premarket application within "180 days after the receipt" of the application. 21 U.S.C. § 387j(c)(1)(A). This provision, however, protects the regulated entities, dictating how quickly the agency should process an application, not when the agency must require the applications or take enforcement action to remove products from the market. The other provides that the Secretary "shall deny an application" if certain statutory criteria are met. *Id*. § 387j(c)(2). Again, however, this says nothing about when the agency must require such applications. In addition, reflecting the District Court's singular focus on e-cigarettes, these provisions concern only premarket tobacco product applications that e-cigarette companies will submit, not the substantial equivalence reports that cigars and pipe tobacco products will provide. *See id*. § 387j(c)(2).

C. The Private Organizations Lacked Article III Standing To Seek Redress Against The Cigar And Pipe Tobacco Deadlines

To the limited extent FDA argues that private parties seeking to force an agency to regulate more aggressively or quickly lack standing, the Cigar Appellants adopt those arguments. In addition to the agency's arguments, Article III standing is particularly lacking for seeking any redress against the August 2021 deadline

extension *for cigars and pipe tobacco* because the District Court never identified how a ruling in Appellees' favor would redress the harms they asserted.

Instead, the District Court's standing analysis focused on the PMTA process for e-cigarettes, observing that these would include new studies and that FDA would have to respond within 180 days and thereby disclose these data to the public. *See* JA66 (citing 21 U.S.C. § 387j(c)(1)(A), which explains the government action deadline for premarket tobacco applications, not SE reports). Indeed, PMTAs require the creation of new information, including "well-controlled investigations, which may include [one] or more clinical investigations by experts." 21 U.S.C. § 387j(c)(5).

But the District Court did not show how judicial intervention accelerating the *substantial equivalence* deadline *for cigars and pipe tobacco* would inevitably provide FDA or Plaintiffs with any information to which they did not already have access. Nor could it have. Although the statute requires disclosure of certain "health information" shortly after the FDA approval of an SE report, 21 U.S.C. § 387j(a)(4), there are other statutory provisions that also contain health information disclosure requirements. *See* 21 U.S.C. § 387d(a); *see also* 21 U.S.C. §§ 387d(c)(1), 387e(j)(1) (aligning timing of health information disclosures for new products with that for substantial equivalence reports). The various "health information" requirements for products on the market—as all products affected by the substantial equivalence

extension are—took effect in 2017 and 2018. Neither the District Court nor any Appellee demonstrated what information enforcement of the *substantial equivalence process*—the only meaningful pathway for cigars and pipe tobacco—will add.

II. The District Court's Rulings Setting Its Own Compliance Deadline And Holding The Guidance Illegal Were Erroneous

The District Court should not have reached questions of whether FDA's compliance extension was legally valid, nor should this Court, as explained above. But should this Court address these questions, it should reverse the District Court's summary judgment and remedial orders, both of which were erroneous.

A. The District Court Erred In Granting Injunctive Relief Against Cigars And Pipe Tobacco

For the reasons stated in the Vapor Appellants' argument above, the District Court's remedial order was erroneous in that the District Court simply had no authority to set its own deadline for premarket review applications; its only option was to remand to the agency. The remedial order should be reversed.

The remedial order is especially erroneous in that it purports to reach all newly deemed products, including cigars and pipe tobacco, while only providing analysis regarding e-cigarettes. JA111-14, 116. The District Court attempted to build a case for invoking its inherent equitable authority to mandate its own compliance deadline, but did so entirely by reference to e-cigarettes. JA111-14, 116. According to the District Court, e-cigarettes were an acute public health crisis because of a spike in

youth usage, and experts did not yet know the health effects of using these brand new products. JA111, 113-14. No e-cigarettes were on the market before 2007 and therefore none were grandfathered. Thus, the question before the agency in enforcing the premarket review was whether any e-cigarette should be available for sale in the United States. *See* 81 Fed. Reg. at 28,991; JA46-48. On this issue, the District Court expressed profound frustration about FDA's unwillingness to commit on the timing of its proposed policy to accelerate enforcement of the premarket review process against e-cigarettes. JA49-50. After repeated inquiries by the Court regarding e-cigarettes, the District Court held that it had lost confidence that the agency would promptly handle the e-cigarette issue. *See* JA113-16.

The District Court, however, said nothing about cigars or pipe tobacco. It provided no explanation for using its equitable authority to set a compliance date for those products. Of course, the issues with those products were much different. Cigars and pipe tobacco have been on the market for decades and therefore are not subject to the premarket review provisions. Whether or not the premarket review provisions were enforced, thousands if not tens of thousands would remain on the market. The District Court did not claim that there was a public health crisis arising from cigars and pipe tobacco.

Further, to the extent the private advocacy organizations have concerns about cigars, no organization submitted evidence in the record concerning handmade

premium cigars, for which there is no evidence of youth usage or even frequent use by adults. At the same time, enforcement of the premarket review process particularly hits premium cigars, which have many varieties due to their handmade nature. 81 Fed. Reg. at 29,079; JA830-32. The District Court's orders are particularly improper given the agency's statements regarding these cigars: on January 2, FDA characterized "relatively expensive, large hand-rolled cigars" as its "lowest priority" for enforcement "given what FDA understands to be their comparatively lower youth usage rates." JA218.

Similarly erroneous is the District Court's mandate that newly deemed products may remain on the market for one year after having submitted a substantial equivalence report. JA115. The remedial order contains no analysis of whether FDA will be able to process those reports within one year—a symptom of the court's failure to mention cigars—much less grappled with the thousands of reports the cigar industry is likely to submit. This aspect of the order underscores the District Court's breathtaking incursion into FDA's assessment of how quickly it will be able to process applications and when enforcement is warranted.

The District Court's remedial order supplies no basis to impose a May 2020 deadline against cigars and pipe tobacco. Accordingly, this Court should vacate the District Court's remedial order as to cigars and pipe tobacco.

B. The Guidance Does Not Conflict With The TCA

The District Court also erred in holding that the Guidance's extension of compliance deadlines for submitting premarket review applications violates the TCA. JA86-90. By the logic of the District Court's ruling, the moment an FDA rule deeming a tobacco product "subject to the Act" becomes effective, any such product marketed for the first time after 2007 is illegal until the agency reviews and approves a premarket review application. As the District Court would have it, the agency had no discretion to set a compliance period later than the effective date of the Final Deeming Rule. JA76-79, 87-90.

That interpretation of the TCA is plainly wrong. *First,* the District Court completely missed the discretion the Act gives FDA to decide *whether* to regulate any tobacco product other than cigarettes, smokeless tobacco, and roll-your-own tobacco. 21 U.S.C. § 387a(b). Congress expressed no view on whether cigars and pipe tobacco, for example, should be regulated at all, leaving that question entirely to the FDA. The greater discretion of whether to regulate a tobacco product clearly entails the lesser discretion of when and how to begin regulating it. *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1052 (D.C. Cir. 1987).

Second, the District Court never reconciled its interpretation of the Act with the compliance periods set forth alongside the Deeming Rule. By the District Court's logic, every one of the products covered by the Deeming Rule was

"unlawfully" on the market without FDA approval when the rule became effective. The District Court, however, never suggested the TCA barred FDA from permitting initial compliance periods of 18 months to submit SE Reports and 24 months to submit PMTAs, plus 12 months during which manufacturers could market their products pending FDA review. *See* 81 Fed. Reg. at 28,974, 28,977-78. The court failed to explain how the TCA allowed FDA to establish initial compliance periods in the Deeming Rule, but not to extend those compliance periods when circumstances warranted.

III. The District Court Abused Its Discretion In Denying The Cigar Appellants' Motion To Intervene

This Court should also reverse the District Court's denial of the Cigar Appellants' motion to intervene, a decision this Court reviews for abuse of discretion. *Stuart v. Huff*, 706 F.3d 345, 349 (4th Cir. 2013). "A district court abuses its discretion when it relies on incorrect legal conclusions . . . or otherwise acts arbitrarily or irrationally in its ruling." *SAS Inst., Inc. v. World Programming Ltd.*, 874 F.3d 370, 385 (4th Cir. 2017) (citation and quotation marks omitted).

The District Court denied the Cigar Appellants' motion to intervene as untimely, faulting them for not seeking "to intervene months earlier" when they were "aware . . . that [the] litigation challenged" the Guidance's compliance dates. *See* JA123. This was a clear abuse of discretion because Appellants *could not* have

intervened then, as the court had found FDA was "adequately represent[ing]" their interests at that time. Fed. R. Civ. P. 24(a).

The timeliness of a motion to intervene is measured from the time at which the prospective-intervenor "was on notice that its interests may not be protected by a party already in the case." *Okla. ex rel. Edmondson v. Tyson Foods, Inc.*, 619 F.3d 1223, 1232 (10th Cir. 2010) (collecting cases); *see also Hill v. W. Elec. Co.*, 672 F.2d 381, 386 (4th Cir. 1982). Thus, a prospective-intervenor cannot "be said to have unduly delayed in moving to intervene if its interests had been adequately represented until shortly before the motion to intervene" was filed. *Edmondson*, 619 F.3d at 1232; *see Reich v. ABC/York-Estes Corp.*, 64 F.3d 316, 322 (7th Cir. 1995).

Shortly after the District Court's summary judgment order, two cigar manufacturers and two vapor-product manufacturers sought intervention to participate in the remedy briefing. JA706, 709, 712, 718. The court denied the manufacturers' motions because their interests in preserving the Guidance were adequately represented by FDA. JA102. Taking this clear language at face value, Appellants declined to seek intervention at that time. Then FDA sought to amend the Remedy Order rather than immediately appealing it. JA739-40. So uncertain was FDA's zeal to overturn the District Court's orders that it waited to almost the last day possible to appeal. JA117, 770. The Cigar Appellants thus concluded that

FDA might leave their interests undefended, and so they moved to intervene less than a month after FDA moved to clarify the order rather than appeal it. JA745-47.

The District Court, however, denied the Cigar Appellants' motion to intervene on the theory that they should have "sought to intervene months earlier." *See* JA123. This ruling directly contradicts the District Court's previous finding that FDA was adequately representing the interests of those seeking to preserve the Guidance. JA102-03. Had Cigar Appellants sought intervention when the District Court suggested, they "would [have been] laughed out of court." *Reich*, 64 F.3d at 322.

The District Court's error is made plain by its decision granting the Vapor Appellants' separate motion to intervene. JA742-44; JA119-22. The Court deemed these entities' motion timely on the theory that they "could not . . . [have] successfully intervene[d]" earlier because they were unable to show "harm to their interests" prior to the Remedy Order being issued. JA120. The same is true of Cigar Appellants: they could not have "successfully intervene[d]" at the time the District Court suggested because FDA was adequately defending their interests at that time.

VAPOR APPELLANTS' CONCLUSION

This Court should: (i) vacate the Remedies Order; (ii) temporarily stay vacatur of the August 2022 deadline; and (iii) remand to FDA for further proceedings consistent with the APA.

CIGAR APPELLANTS' CONCLUSION

The Court should vacate the District Court's orders in light of FDA's January 2020 Guidance and remand to the District Court to consider the effect of that Guidance. Should this Court reach the merits, this Court should reverse the District Court's grant of summary judgment in Appellees' favor and the ensuing remedy order. Alternatively, this Court should reverse and vacate both orders as they apply to cigars and pipe tobacco. The Court also should reverse the District Court's denial of the Cigar Appellants' motion to intervene.

Respectfully submitted,

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Dated: January 23, 2020

CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B), as modified by this Court's January 21, 2020 Order (Dkt. 64), because the brief contains 14,769 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the typestyle requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally-spaced typeface using Microsoft Word 365 in 14-point font.

Dated: January 23, 2020

/s/ Mark S. Raffman
Mark S. Raffman

CERTIFICATE OF SERVICE

I certify that on January 23, 2020, 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/ Mark S. Raffman
Mark S. Raffman