Nos. 19-2130(L), 19-2132, 19-2198, 19-2242 (Consolidated)

IN THE 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; STEPHEN HAHN, 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.

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

PLAINTIFFS-APPELLEES' BRIEF

(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; STEPHEN HAHN, 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.

No. 19-2198

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; STEPHEN HAHN, 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; STEPHEN HAHN, 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,

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INTRODUCTION

Plaintiffs-Appellees ("Plaintiffs") filed this lawsuit to challenge a 2017 Food and Drug Administration ("FDA") guidance document (the "2017 Guidance"). That Guidance gave manufacturers of e-cigarettes and cigars a holiday from the premarket review provisions of the Family Smoking Prevention and Tobacco Control Act ("Act" or "TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (2009), without notice, comment, or justification.

The district court found that the 2017 Guidance violated the TCA and the Administrative Procedure Act ("APA") and therefore vacated it. Because the original deadline for premarket review submissions had passed during the litigation's pendency, the district court subsequently extended that deadline for 10 months.

Before the district court resolved Plaintiffs' claims, however, FDA announced plans to abandon the 2017 Guidance. It issued new draft guidance in March 2019 and provided an extended notice-and-comment period. In January 2020, FDA finalized and issued new guidance (the "2020 Guidance") that explicitly superseded the 2017 Guidance.

FDA now recognizes that these appeals should be dismissed. Several trade associations for manufacturers of tobacco products ("Industry Appellants"),[1] which sought to intervene only after the district court ruled, disagree. Even though FDA has disavowed and superseded the 2017 Guidance, the Industry Appellants ask the Court to reinstate it and prevent FDA from proceeding with the 2020 Guidance—an agency action that was not at issue in the district court and is not part of this appeal. But the E-Cigarette Associations' claims are moot in light of the 2020 Guidance, and the Cigar Associations' motion to intervene was properly denied. The district court's orders therefore present no live issues, and the appeals should be dismissed.

Nor do Appellants' other arguments fare better. *First*, the district court correctly held that Plaintiffs have standing. Plaintiffs are six leading public health organizations, including an association of 67,000 pediatricians, and several individual pediatricians. The 2017 Guidance contributed to an epidemic of youth tobacco use that upended Plaintiffs'

[1] The Industry Appellants include the Intervenors-Appellants in Nos. 19-2132 and 19-2242 ("E-Cigarette Associations") and the Non-Party-Appellants in No. 19-2130 ("Cigar Associations").

operations, compelling substantial expenditures and impairing mission-critical activities.

Second, the district court correctly held that the 2017 Guidance exceeded FDA's authority, violated the Act, and required notice and comment under the APA. Contrary to Appellants' arguments, a categorical suspension of a statutory obligation is not an unreviewable exercise of enforcement discretion; it is final agency action that contravenes FDA's and manufacturers' duties under the Act.

Third, the district court did not abuse its discretion by issuing a remedial order allowing manufacturers to continue marketing their products without fear of enforcement for an additional ten months. Courts have authority to adjust their relief to the exigencies of a given case, particularly where otherwise-applicable deadlines have passed during the pendency of litigation. All that the district court did was require FDA to cease making blanket exemptions to the TCA's premarket review provisions within ten months, a decision well within the court's authority.

Accordingly, the Court should dismiss the appeals or, in the alternative, affirm the district court's orders.

STATEMENT OF JURISDICTION

Plaintiffs concur with the Government's Statement of Jurisdiction. *See* Gov't Br. 5; Fed. R. App. P. 28(b).

STATEMENT OF THE ISSUES

1. Whether the Court should dismiss the appeals because (a) FDA's 2020 Guidance moots the E-Cigarette Associations' appeal, and (b) the district court's denial of the Cigar Associations' motion to intervene was not an abuse of discretion.

2. Whether, in the alternative, the judgment of the district court should be affirmed because (a) Plaintiffs had standing to challenge the 2017 Guidance; (b) FDA's decision to categorically exempt manufacturers from compliance with the TCA is reviewable final agency action; (c) the 2017 Guidance violated the TCA and the APA; and (d) its remedial order was not an abuse of discretion.

PERTINENT STATUTES

Pertinent statutes are reproduced in the Addendum.

STATEMENT OF THE CASE

Plaintiffs largely concur with the Government's statement of the case. Two exceptions—its characterizations of Plaintiffs' standing

evidence and the district court's merits holding—are dealt with in the argument section below. In addition to the regulatory and procedural facts in the Government's statement, the following facts are relevant to the issues before the Court.

I. The Substantial Public Health Concerns Raised by E-Cigarettes and Cigars

A. E-Cigarettes

1. FDA's Announcement of Its Intention to Regulate E-Cigarettes

In April 2011, after the D.C. Circuit held that it could not regulate e-cigarettes as drugs under the Federal Food, Drug and Cosmetic Act absent therapeutic claims, *see Sottera, Inc. v. FDA*, 627 F.3d 891 (D.C. Cir. 2010), FDA announced its intention to deem e-cigarettes subject to the TCA, as provided by 21 U.S.C. § 387a(b).

FDA based its decision to subject e-cigarettes to the TCA on its recognition that e-cigarettes are addictive and harmful to the user's health. An e-cigarette "delivers nicotine by vaporizing a liquid that includes other chemicals and flavorings. The device heats the liquid until it generates an aerosol—or 'vapor'—that can be inhaled." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). Rather than water vapor, users inhale "ultrafine particulate aerosols"—

"atomized chemicals" that "are often not safe for inhalation in the lungs." App.549; *see Nicopure*, 944 F.3d at 274-76.

E-cigarettes also contain nicotine, "one of the most addictive substances used by humans." 81 Fed. Reg. 28,973, 28,988 (May 10, 2016) (the "Deeming Rule"). Adolescents are "uniquely susceptible to … becom[ing] addicted to tobacco products," *id.* at 29,047, an addiction that often becomes permanent, *Nicopure*, 944 F.3d at 274. Nicotine can have "lasting adverse consequences for brain development," 81 Fed. Reg. at 29,033, causing "detrimental effects on the cardiovascular system and potentially disrupt[ing] the central nervous system," *id.*—effects to which adolescents are "particularly vulnerable," *id.* at 29,029. *See also, e.g.*, App.223.[2]

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[2] The E-Cigarette Associations' appellate arguments focus heavily on so-called "open-tank" e-cigarettes. *See, e.g.*, Industry Br. 9-11. The first time they suggested the difference between "open" and "closed" systems had any relevance was in the reply in support of their stay pending appeal, months after the rulings on appeal here. App.760; *see also* App.606-30 (e-cigarette summary judgment *amicus* brief not distinguishing between open- and closed-tank products); App.721-38 (same, remedy brief). Any argument based on this purported distinction is thus waived. *See, e.g.*, *Holland v. Big River Mins. Corp.*, 181 F.3d 597, 605 (4th Cir. 1999) (issue raised for the first time after judgment "not preserved for appellate review").

In any event, nothing in the record indicates that the E-Cigarette

2. Growth of Youth E-Cigarette Use in the Absence of Regulation

Although FDA announced its intention to regulate e-cigarettes in early 2011, it did not issue a proposed rule to do so until 2014 or a final Deeming Rule until May 2016. In that five-year interval, while e-cigarettes were totally unregulated, thousands of varieties of e-cigarettes were introduced into the market, and youth use increased exponentially. Key to this increase were youth-oriented advertising and the promotion of youth-friendly flavors. E-cigarette manufacturers "introduced many sweet flavors particularly appealing to children, including 'gummy bear' and 'bubblegum,'" *Nicopure*, 944 F.3d at 274-275 (citing 79 Fed. Reg. 23,142, 23,157 (Apr. 25, 2014)), gave them names like "Cherri Bombz" and "Cereal Treats Loopz," App.112, and sometimes marketed them in packaging resembling juice boxes or candy, App.47 n.5. FDA found "substantial evidence that

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Associations' members only or even primarily sell open-tank products. Moreover, their arguments are misleading. For example, FDA Commissioner Scott Gottlieb did not suggest that open-tank products played no role in underage use, but only that "the *biggest* youth use seems to be among cartridge-based e-cigarettes." FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on new steps to address epidemic of youth e-cigarette use* (Sept. 11, 2018) (emphasis added), https://tinyurl.com/y32z4yb2 (cited at App.601).

manufacturers have specifically targeted youth, both with kid-friendly fruit and candy flavors and youth-directed advertising." App.113.

As a result, between the time FDA announced its intention to regulate e-cigarettes and the time it actually proposed the Deeming Rule, "e-cigarette use among high school students rose 'nearly 800 percent from 1.5 percent in 2011 to 13.4 percent in 2014.'" *Nicopure*, 944 F.3d at 275 (quoting 81 Fed. Reg. at 28,984).

3. FDA's Issuance of the Final Deeming Rule

After notice-and-comment rulemaking, FDA issued the final Deeming Rule on May 10, 2016, making it effective August 8, 2016. 81 Fed. Reg. at 28,974. Because the TCA required all new tobacco products (*i.e.,* products introduced after the "grandfather date" of February 15, 2007, 21 U.S.C. § 387j(a)(1)) to obtain marketing orders from FDA prior to entering the market, as of the effective date of the Deeming Rule, all the e-cigarettes on the market were immediately out of compliance with the TCA because they lacked such premarket orders. FDA established a "compliance period" during which it would not enforce the premarket review requirements for up to two years (*i.e.*, until August 8, 2018) against products on the market as of the effective date. *Id.* at 29,011. E-

cigarettes for which premarket tobacco applications ("PMTAs") were filed by August 8, 2018 would receive an additional one-year compliance period while FDA reviewed their applications. *Id.*

The Deeming Rule—and particularly the application of premarket review to e-cigarettes—has been upheld on judicial review. *See Nicopure*, 944 F.3d 267. The validity of the Deeming Rule and its compliance schedule are not challenged in this case.

4. The 2017 Guidance and the Youth E-Cigarette Epidemic

In August 2017, FDA, without notice-and-comment rulemaking, extended the compliance period for e-cigarettes by four years, from August 2018 to August 2022, and replaced the one-year post-filing compliance period with a policy of indefinite non-enforcement unless and until FDA rejected an application. App.54.

Following the 2017 Guidance, youth e-cigarette use exploded. From 2017-2019, e-cigarette use more than doubled among both high schoolers and middle schoolers, to 27.5% and 10.5%, respectively. App.199. In 2019, five million people aged 18 and under used e-cigarettes, with 1.6 million of them reporting using e-cigarettes

frequently—an indication of addiction. App.199-200. FDA has characterized this level of usage as an "epidemic." *E.g.*, App.45, 110.

Moreover, "studies show that youth who use e-cigarettes are more likely to smoke conventional cigarettes." *Nicopure*, 944 F.3d at 275 (quoting 81 Fed. Reg. at 28,985, 29,040-41). E-cigarettes provide "a trendy on-ramp to tobacco use for people who otherwise might never have used it." *Id.* (citing 81 Fed. Reg. at 29,036-37).

At the same time, "[e]-cigarettes have not been shown to reduce the incidence of conventional smoking." *Id.* (citing 81 Fed. Reg. at 29,041 and 79 Fed. Reg. at 23,147, 23,152); *see also* App.113. Although youth use of e-cigarettes has exploded since 2017, adult use of e-cigarettes has not increased.[3] In short, suspending premarket review of

[3] *Compare* MeLisa R. Creamer et al., CDC, *Tobacco Product Use and Cessation Indicators Among Adults—United States, 2018*, Morbidity and Mortality Wkly. Rep. 68(45) (Nov. 15, 2019), https://tinyurl.com/u954gvf (3.2% adult use in 2018) *with* CDC, *QuickStats: Percentage of Adults Who Ever Used an E-Cigarette and Percentage Who Currently Use E-Cigarettes, by Age Group*, Morbidity and Mortality Wkly. Rep. (Aug. 25, 2017), https://tinyurl.com/yx64xk5a (3.2% adult use in 2016). (Judicial notice of information contained on government websites is appropriate. *See United States v. Garcia*, 855 F.3d 615, 621 (4th Cir. 2017).)

e-cigarettes has produced a public health catastrophe, fueling a youth vaping epidemic with no countervailing health benefits.

B. Cigars

The tobacco industry has long understood that sweetly-flavored products are critical to attracting and addicting children to tobacco. To end this harmful practice, Congress prohibited all flavors in cigarettes other than tobacco and menthol, banning the various candy- and fruit-flavored cigarettes most popular with children. 21 U.S.C. § 387g(a)(1)(A). The tobacco industry responded to this regulation, as it has done in the past, App.802-06, by producing and marketing cigarette-like cigars, so that it could continue marketing kid-friendly products despite Congress's efforts. App.804, 882.

The only significant definitional difference between a cigar and a cigarette is that a cigar contains tobacco in the wrapper, while a cigarette typically does not. *See* 15 U.S.C. § 1332(1)(a) (defining "cigarette"); 21 C.F.R. § 1143.1 (defining "cigar"). As the possibility of a flavored cigarette ban neared, the Cigar Associations' members dramatically increased production of small flavored cigars that are more like the now-banned flavored cigarettes than traditional cigars.

App.791, 804, 882. Today, the Cigar Associations' members produce flavored cigars by the billions, adding sugary flavors from candy to chocolate to lemonade and giving them names like "SwagBerry" or "Da Bomb Blueberry." App.793-94, 799, 882; *see also* App.783, 800-01 (displaying examples of flavored cigars' colorful packaging). By contrast, traditional "premium" cigars constitute less than 3% of today's market. App.885.

Flavored products overwhelmingly appeal to youth. As one of the Cigar Associations' members acknowledged, "It is mainly new recruits to cigar smoking who take to the new flavors," App.888—and "new recruits" are almost exclusively minors. *See* 79 Fed. Reg at 23,155 ("Virtually all new users of most tobacco products are youth … .").

As a result of the cigar industry's strategy of targeting minors and the insulation from premarket review established by the 2017 Guidance, youth cigar use has become at least as much of a public health threat as youth cigarette use. In issuing the Deeming Rule, FDA found that more than 2500 persons under the age of 18 smoke their

first cigar each day. 81 Fed. Reg. at 28,985. Today, more high school students smoke cigars than cigarettes.[4]

The adverse health effects of cigar use are significant. *See, e.g.*, App.183 ("Cigars are associated with significant risk and provide no public health benefit."). These health risks include "an increased risk of oral, esophageal, laryngeal, and lung cancer," "heart and pulmonary disease," "chronic obstructive pulmonary disease," and "fatal and nonfatal stroke." 81 Fed. Reg. at 29,020; *see also* App.183.

II. The Impact on Plaintiffs of Allowing New Tobacco Products to Proliferate Without Premarket Review and the Information Accompanying Marketing Orders

Plaintiffs include six of the country's leading public health organizations: the American Academy of Pediatrics ("AAP") and its Maryland chapter, the American Cancer Society Cancer Action Network ("ACS CAN"), the American Heart Association ("AHA"), the American Lung Association ("ALA"), the Campaign for Tobacco-Free Kids ("CTFK"), and the Truth Initiative (collectively, "Organizational

[4] Teresa W. Wang et al., CDC, *Tobacco Product Use and Associated Factors Among Middle and High School Students—United States, 2019*, Morbidity and Mortality Wkly. Rep. 68(12) (Dec. 6, 2019), https://tinyurl.com/saeozuz.

Plaintiffs"). App.358-472. These organizations are joined by five individual pediatricians who regularly treat children who use e-cigarettes and/or cigars ("Pediatrician Plaintiffs"). App.486-511.

The Organizational and Pediatrician Plaintiffs submitted sworn declarations describing at length the ways in which the 2017 Guidance adversely affected their day-to-day activities, as did three additional pediatricians who are members of AAP. App.358-511. No party, intervenor, or *amicus* challenged the veracity of these declarations below. In summary, the Plaintiffs showed the following:

American Academy of Pediatrics: AAP is a membership organization of 67,000 pediatricians. App.460. To assist its members, "AAP dedicates a substantial amount of staff time and financial resources to researching tobacco products, educating its members about tobacco use and treatment, and creating resources that members can use in their practice." App.461. Without premarket review, AAP has had to expend thousands of staff hours and hundreds of thousands of dollars to deal with the exponential growth in e-cigarette use. App.461-72.

Among other things, AAP has needed to conduct its "Asking the Right Questions" pediatrician training session more often than usual, at a cost of $25,000-$30,000 per session, App.463; purchase a wide variety of e-cigarette products for study and for use in training sessions, App.464; issue numerous factsheets and articles to assist pediatricians and provide educational sessions at professional conferences and meetings, App.466-67; and devote more than 1000 hours of staff time to drafting a Policy Statement providing guidance to pediatricians ahead of schedule. App.467-69. All of these necessary responses to the absence of premarket review have prevented AAP "from engaging in numerous activities that would otherwise be at the core of [its] mission." App.469; *see* App.470-71 (describing impact on grant opportunities, research, global child health initiatives, and other activities).

American Cancer Society Cancer Action Network: ACS CAN is a membership organization devoted to defeating cancer by supporting groundbreaking medical research and ensuring access to the latest prevention and treatment measures. App.435-36. ACS CAN has used the data disclosed in previous premarket review orders to advocate for product standards that can lower the risk of cancer. App.436-37. The

premarket review orders are critical to ACS CAN's efforts: "Scientific data on the contents of novel tobacco products and their physiological consequences are crucial to [ACS CAN's] ability to identify effective and feasible product standards." App.437. Moreover, by "increas[ing] the sheer number of potentially dangerous products on the market," the 2017 Guidance "significantly increase[d] the costs to [ACS CAN] of monitoring the marketplace for such products." App.438. This "hinders [ACS CAN] from working on other priorities" and forces it to pursue "vastly more expensive and onerous solutions." *Id.*

American Heart Association: AHA works with "local health care providers, church leaders, employers, and school administrators to provide education and counseling … to help prevent youth initiation of tobacco use, including e-cigarette and cigar use, and to encourage tobacco users to quit." App.441. The proliferation of unauthorized products in the absence of premarket review "impedes these efforts in numerous ways," costing AHA in time, resources, and income. *Id.* For example, hospitals pay AHA for its "Get With the Guidelines" quality improvement program. App.442. "The proliferation of unregulated, unapproved e-cigarettes and cigar products has … imped[ed] AHA from

offering authoritative, medically accurate material." App.443. This makes "hospitals … less likely to purchase" this program. *Id.*; *see also* App.442-44 (describing impairment of AHA's continuing education and CEO Roundtable efforts).

To make up for the absence of premarket review, AHA has needed to conduct its own research and literature reviews. However, due to "the paucity of published information, the variable contents of the unregulated products, and the sheer number of products on the market," that work "is not only a completely inadequate substitute for premarket review, but also expensive." App.444.

American Lung Association: "ALA's mission is to save lives by promoting lung health and preventing lung disease. The prevention and cessation of the use of tobacco products is an integral part of this mission." App.447. "ALA expends substantial resources to support its highly acclaimed Freedom From Smoking program, which has in-person, online, self-help, and telephonic options to help tobacco users quit." *Id.* "These efforts are made substantially more complicated, more expensive, and less effective because of the proliferation of unregulated tobacco products such as e-cigarettes." App.448.

Because "[t]here is a significant amount of misinformation and consumer confusion about e-cigarettes," and "consumers' baseline understanding of the risks of nicotine addiction and lung injury from e-cigarettes is nowhere close to that of traditional cigarettes," counseling e-cigarette users is particularly burdensome, "taking up time and money that would otherwise be used to reach more users and innovate to improve [ALA's] offerings." App.448-49. Similarly, the "lack of public understanding about the health harms of cigar use," coupled with the unchecked rise of cigars that followed from tobacco manufacturers converting flavored products to cigars, "require[s] additional resources from [ALA] to provide patient support services." *Id.*

Campaign for Tobacco-Free Kids: CTFK "engage[s] in public education about the dangers of … tobacco products, including sponsoring activities to prevent kids from using tobacco products, help users quit, and protect everyone from secondhand smoke." App.359. It also "researches and advocates [for] public policies that reduce kids' exposure to the dangers of tobacco products." *Id.*

CTFK uses the information created by the premarket review process in both of these efforts. App.361-62. For example, after FDA

authorized a new smokeless tobacco product with relatively low levels of the carcinogen N-Nitrosonornicotine, CTFK (along with other Plaintiffs) used the scientific data accompanying that marketing order to propose a new product standard regulating the level of that carcinogen in all smokeless tobacco products. App.362-63; *see also* App.367-433 (marketing order decision summary). FDA subsequently proposed a similar product standard. App.363; 82 Fed. Reg. 8004 (Jan. 23, 2017). Without such data, CTFK cannot as effectively propose comparable product standards for e-cigarettes, nor can it educate the public adequately about specific e-cigarette products, impeding its mission and making it more costly to pursue. App.364-65.

Truth Initiative: Truth Initiative is a non-profit corporation created out of the Master Settlement Agreement between 52 states, territories, and the District of Columbia and major U.S. tobacco companies. App.453.

The rise of e-cigarettes and flavored cigars without the standardization and information that would result from premarket review has required Truth Initiative to conduct "a tremendous amount of research into popular e-cigarette products …, as well as many of the

less common e-cigarette products" and cigars. App.454, 457. This research is "more expensive" than it would be if premarket review were in effect. App.457.

AAP Members and Individual Pediatricians: The undisputed evidence also shows how FDA's decision to exempt e-cigarettes and cigars from the premarket review provisions harmed the Pediatrician Plaintiffs and AAP's members. The proliferation of novel products without the information provided by premarket review undercuts pediatricians' ability to counsel and treat their patients effectively, forcing them to reduce either the time they spend on other important issues or the number of patients they see.

For Dr. Sharon Levy, for example, "[n]early every child [she] treat[s] or assess[es] uses some form of e-cigarette product." App.475. Without concrete information about the products their patients use, pediatricians lose "credibility and authority with [their] patients," making it far harder to provide effective advice and treatment. App.476. Dr. Levy must spend a significant amount of time researching new products "just to be able to perform [her] duties as a medical professional." *Id.*; *see also, e.g.*, App.499 (Dr. Leah Brasch describing

information gap "limiting [her] ability to carry out [her] responsibilit[y] to [her patients] as their physician"); App.491-93 (Dr. Jonathan Winickoff describing similar problems from cigars).

The 2017 Guidance also harmed AAP members by increasing the volume and complexity of patient needs they must confront. The number of patients who present respiratory ailments and symptoms of nicotine addiction, as well as comorbid addiction to multiple substances, has increased alongside the rise of e-cigarettes. *See* App.490. As Dr. Winickoff explained, the rise of unauthorized tobacco products has forced him to spend "as much as a third of a visit" counseling patients on tobacco use. App.489-90.

And for pediatricians who conduct clinical research, the absence of premarket review and the proliferation of unstandardized products makes their research "difficult if not impossible" in some respects. App.484.

SUMMARY OF ARGUMENT

The E-Cigarette Associations' challenges to the orders below are moot because FDA has explicitly superseded the guidance at issue here. *See, e.g.*, *Valero Terrestrial Corp. v. Paige*, 211 F.3d 112, 116 (4th Cir.

2000). Those entities are free to bring a new case challenging that distinct agency decision, but they cannot use this case to challenge it. *See Ctr. for Sci. in the Pub. Interest v. Regan* ("*CSPI*"), 727 F.2d 1161, 1167 (D.C. Cir. 1984).

The Cigar Associations' appeal should also be dismissed because they do not even attempt to dispute the grounds on which the district court denied their motion to intervene. The sole basis the Cigar Associations asserted for intervention was a purported conflict with case management in other litigation—a purported conflict they had been aware of for over a year, but chose not to bring to the district court's attention until well after it resolved this case. The district court plainly acted within its discretion in rejecting the Cigar Associations' belated attempt to insert themselves into this case.

Although it need not do so, if the Court does reach the merits of any of the appeals, it should affirm the district court's rulings. The district court rightly found that Plaintiffs—six of the country's leading public health organizations and several individual pediatricians—had standing. The 2017 Guidance contributed to an epidemic of youth tobacco use that these pediatricians and others who combat tobacco use

had to confront, while denying them critical information that otherwise would have been available to help them execute their missions. It compelled significant expenditures and radical shifts in their day-to-day operations, harms that readily satisfy the requirements of standing. *See, e.g.*, *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982).

The district court also correctly held that the 2017 Guidance exceeded FDA's statutory authority, violated the TCA, and required notice and comment. The FDA announced a policy of not enforcing mandatory provisions of a statute *at all* and informed manufacturers that they were free to disregard an unconditional statutory command for an additional four years—and for an indefinite period after that. This policy was an unlawful abrogation of statutory requirements. *See, e.g.*, *Pub. Citizen Health Res. Grp. v. Acosta*, 363 F. Supp. 3d 1, 18 (D.D.C. 2018). The court correctly found the 2017 Guidance to be a reviewable final agency action and correctly vacated it.

Finally, the district court did not abuse its discretion in entering the Remedial Order. Vacating the 2017 Guidance restored the Deeming Rule's compliance deadlines, but those deadlines had already passed. The court had ample authority to reset those deadlines to account for

their expiration. *See Zambrana v. Califano*, 651 F.2d 842, 844 (2d Cir. 1981). Indeed, the Remedial Order *benefitted* the Industry Appellants, as it protected them from the possibility of immediate enforcement. Nor did the court improperly eliminate or supervise FDA's future exercises of discretion. The only thing it prohibited FDA from doing was resuming its unlawful blanket policy, an action well within its authority.

STANDARD OF REVIEW

The Court reviews a district court's grant of summary judgment de novo. *Ray Commc'ns, Inc. v. Clear Channel Commc'ns, Inc.*, 673 F.3d 294, 297 (4th Cir. 2012). It reviews the denial of a motion to intervene for abuse of discretion. *Stuart v. Huff*, 706 F.3d 345, 349 (4th Cir. 2013). And it reviews a district court's grant of equitable relief for abuse of discretion. *Solis v. Malkani*, 638 F.3d 269, 274 (4th Cir. 2011).

ARGUMENT

I. The Court Should Dismiss the Appeals

A. The E-Cigarette Associations' Appeal Is Moot

Plaintiffs' lawsuit challenged one agency action: the 2017 Guidance. The Government has now issued a new guidance that "supersedes" the 2017 Guidance "[i]n all relevant respects." Gov't Br.

22; *see* App.187-239. For substantially the reasons explained by the Government, the E-Cigarette Associations' appeal is moot. *See* Gov't Br. 22-23; *see also, e.g.*, *Valero*, 211 F.3d at 115 (case became moot when government "substantially revised the enjoined … provisions" after summary judgment); *CSPI*, 727 F.2d at 1165 (after agency superseded rule challenged by plaintiff, intervenors' appeal became moot because the challenged rule "is a dead letter, and cannot be revived in favor of intervenors").[5]

The E-Cigarette Associations deny that the 2020 Guidance moots their appeal by disputing the legality of the 2020 Guidance. Industry Br. 46. But the lawfulness of the 2020 Guidance is not before this Court. An intervenor "may only join issue on a matter that has been brought before the court by another party. They cannot expand the proceedings." *Lamprecht v. FCC*, 958 F.2d 382, 389 (D.C. Cir. 1992) (citation omitted). If the E-Cigarette Associations or any other entities want to challenge the 2020 Guidance, the proper vehicle for doing so is a new lawsuit filed in district court—not an appellate brief asserting claims that were not

[5] The Court need not decide whether the Cigar Associations' appeal is also moot, as the District Court plainly did not abuse its discretion in denying their motion to intervene. *See infra* Part I.B.

raised by any party below and thus have never been adjudicated by the district court. *See, e.g.*, *CSPI*, 727 F.2d at 1167 ("The Department's promulgation of [a superseding rule], which rescinded [the rule challenged below], presents a new case . … Any person complaining of the procedures or provisions of [the new rule] should attack it by a separate action.").

Accordingly, because the 2020 Guidance superseded the 2017 Guidance challenged below, the Court should dismiss the E-Cigarette Associations' appeal. Because mootness resulted from the Government's voluntary action, dismissal should be without vacatur of the district court's orders. *See U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18, 26 (1994) (vacatur is an "extraordinary remedy" typically unavailable where the losing party voluntarily moots a case); *CSPI*, 727 F.2d at 66-67 (denying intervenors' request for vacatur because "review was prevented, not by 'happenstance,' but by the deliberate action of the losing party before the district court, the [agency]").[6]

[6] In addition to being moot, the E-Cigarette Associations' separate appeal from the denial of their first motion to intervene, No. 19-2242, should be dismissed because their brief did not suggest any reason it should be reversed. *See Brown v. Nucor Corp.*, 785 F.3d 895, 923 (4th

B. The District Court Did Not Abuse Its Discretion in Denying the Cigar Associations' Motion to Intervene

The district court did not abuse its "wide discretion" to deny the Cigar Associations' motion for leave to intervene as untimely, given the Associations' choice to wait more than a year and through all critical stages of the case before seeking intervention. *See Gould v. Alleco, Inc.*, 883 F.2d 281, 286 (4th Cir. 1989). They now assert that the district court's decision was erroneous because it had previously found other intervenors' interests adequately represented by the Government and because it granted the E-Cigarette Associations' second motion to intervene. Industry Br. 64-65. This argument omits any mention of the Cigar Associations' proposed basis for intervention below, as well as the district court's sound reasons for denying intervention on that basis.

Unlike the E-Cigarette Associations, the Cigar Associations did not intervene to defend their members' ability to sell their products without fear of enforcement, nor did they argue that they had a different view of any issue in this case from FDA. *Compare* App.745-48 (Cigar Associations' motion to intervene) *with* App.742-44 (E-Cigarette

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Cir. 2015) ("An appellant must raise every issue that he wishes to press in his opening brief.").

Associations' motion to intervene). Instead, the Cigar Associations asserted one idiosyncratic interest: that they had "relied on the deadline relief in the [2017] Guidance in managing the litigation" in a challenge to the Deeming Rule that they had filed in another district court, *Cigar Association of America v. FDA* ("*CAA*"), No. 16-1460 (D.D.C.) (filed July 15, 2016). App.745-46. According to the Cigar Associations, the proceedings in this case "potentially could disrupt the long-settled course of proceedings in the *Cigar Associations* [sic] case, requiring a substantially accelerated resolution of" the Cigar Associations' claims in *CAA*. App.746-47. These interests were supposedly "'impaired' to the extent that [the Cigar Associations] potentially must now litigate to preserve the deadline extensions that the FDA had previously agreed to in *CAA* and address the claims of some that the long-settled extensions underlying the *CAA* case may be affected by this Court's orders." App.747.

As the district court observed, this supposed basis for intervention was untimely:

> [T]he Cigar Associations ha[d] been aware for months that this litigation challenged the deadlines that they believed that they had negotiated to extend. Yet they chose not to seek leave to intervene previously, waiting instead to see if

> the case would survive Defendants' motion to dismiss and, when it did, to see what the remedy would be. "Such deliberate forbearance understandably engenders little sympathy." *Alt v. EPA*, 758 F.3d 588, 591-92 (4th Cir. 2014).

App.123.

The court's finding was amply justified and certainly not an abuse of discretion. The Cigar Associations were aware of this case at least as early as August 16, 2018. *See CAA*, Dkt. No. 109, at 43. They recognized in a September 28, 2018 *amicus* brief in this case that Plaintiffs sought to "[v]acat[e] the [2017] Guidance and reinstat[e] the original effective dates and compliance policy." D. Ct. Dkt. No. 45-1 at 15. Nonetheless, they consciously chose *not* to intervene because the Government had "raised the key legal reasons why Plaintiffs' efforts to force agency action should be denied," *id.* at 3—even though the Government never suggested any conflict between this case and *CAA* or even mentioned *CAA*. In short, the Cigar Associations were fully aware that no party had suggested that *CAA* provided any reason not to proceed, and yet they chose not to intervene.

The Cigar Associations remained silent even in May 2019, when the district court granted summary judgment to Plaintiffs in this case and explicitly invited briefing on further remedial measures that could

either correct the harm caused by the 2017 Guidance or mitigate any disruption caused by its vacatur. Although several industry associations and tobacco manufacturers sought to intervene and filed an *amicus* brief at that point, App.706-38, the Cigar Associations were not among them. Instead, they waited until September 4, 2019, nearly four months after the district court's request for remedial briefing and nearly two months after the resulting Remedial Order, to inform the court of the supposed conflict for the first time. App.745.

Given that the Cigar Associations had known about the supposed conflict between this case and *CAA* since at least August 16, 2018, but consciously chose not to alert the court to that supposed conflict for more than a year, until September 4, 2019, the district court plainly acted within its discretion to find the motion to intervene untimely. *See, e.g.*, *Alt*, 758 F.3d at 591-92. The district court's resolution of other applicants' motions to intervene on a wholly different basis is simply irrelevant.

The district court was also correct in denying the Cigar Associations' motion for the independent reason that "issues raised for the first time on appeal generally will not be considered." App.123

(quoting *Gen. Ins. Co. of Am. v. U.S. Fire Ins. Co.*, 886 F.3d 346, 356 (4th Cir. 2018), *as amended* (Mar. 28, 2018)). Nobody—no party, no *amicus*, and no proposed intervenor—had suggested that the putative conflict with *CAA* was in any way relevant to the issues before the district court. And the Cigar Associations did not suggest any intention to challenge the district court's decisions on any other ground. *See* App.745-48. Thus, the Cigar Associations attempted to intervene *only* to inject new issues into the case long after the Court vacated the 2017 Guidance and ordered a remedy. Even if the supposed conflict with *CAA* gave the Cigar Associations some interest relevant to intervention under Federal Rule of Civil Procedure 24(a)(2),[7] "the protection of this interest would [not] be impaired" by denying intervention, *Stuart*, 706 F.3d at 349 (4th Cir. 2013) (quoting *Teague v. Bakker*, 931 F.2d 259,

[7] The Cigar Associations have never specified whether they sought intervention as of right or permissive intervention, but their motion below purported to address the Rule 24(a) factors. App.746-47. To the extent they now claim to have requested permissive intervention, their claim has even less merit, as review of a denial of permissive intervention is "particularly deferential," requiring a "*clear* abuse of discretion." *McHenry v. Comm'r of Internal Revenue*, 677 F.3d 214, 219 (4th Cir. 2012) (citations omitted) (describing reversal as "extremely rare, bordering on nonexistent").

260-61 (4th Cir. 1991)), because it could not be advanced on appeal, *Gen. Ins. Co.*, 886 F.3d at 356.

Because the Cigar Associations' brief does not even acknowledge the grounds on which they sought, and the district court denied, intervention, they necessarily cannot show that the denial was an abuse of the district court's "wide discretion." *Gould*, 883 F.2d at 286. Accordingly, the Court should affirm the order denying the Cigar Associations' motion to intervene and dismiss the Cigar Associations' appeal as to all other issues. *See Francis v. Chamber of Commerce of U.S.*, 481 F.2d 192, 196 (4th Cir. 1973) (dismissing appeal upon finding denial of intervention was within district court's discretion).

II. Alternatively, the Court Should Affirm the District Court's Orders

For the foregoing reasons, the appeals should be dismissed. However, if the Court concludes that some aspect of these appeals remains live, it should affirm the orders below. The district court correctly held that Plaintiffs had standing and the 2017 Guidance was unlawful, and did not abuse its discretion in ordering equitable relief designed to restore the status quo before the 2017 Guidance.

A. Plaintiffs Had Standing to Challenge the 2017 Guidance

The district court held that the Organizational Plaintiffs had standing based on their "concrete and particularized," "non-speculative" interest in the information that would have been made available if FDA had conducted the premarket review process as required. App.62, 64. It further found that the injury was traceable to the 2017 Guidance and redressable by a decision in Plaintiffs' favor. App.65-66. Because that injury sufficed to demonstrate standing, the court had no need to pass upon Organizational Plaintiffs' other injuries, nor on the standing of the Pediatrician Plaintiffs or AAP as a membership organization. App.66-67; *see Bostic v. Schaefer*, 760 F.3d 352, 370 (4th Cir. 2014) (courts need only find that one plaintiff has standing).

The Government has never contested any of the facts in Plaintiffs' 13 detailed declarations. *See supra* at 14; App.358-511. It does not dispute that those declarations demonstrated a non-speculative injury that was traceable to the 2017 Guidance and are redressable by vacatur. And it likewise does not contest that FDA's own regulations required disclosure of the information at issue.

Instead, it makes just two arguments: *first*, that injuries due to the deprivation of information can create standing only where there is a statutory right to such information, and no such statute exists here, Gov't Br. 28-32; and *second*, that Plaintiffs' injuries based on the proliferation of new tobacco products are merely a "generalized" interest in the problem, Gov't Br. 33. Neither argument has merit.

1. Organizational Plaintiffs Have Standing Based on the Deprivation of Information Created by the Suspension of Premarket Review Requirements

The Government's main argument is that Plaintiffs' injuries from the deprivation of the information accompanying premarket review authorizations do not qualify as injuries-in-fact. According to the Government, deprivation of information can support standing *only* if Congress has expressly required provision of that information, no matter how concretely that deprivation harms a plaintiff and no matter how likely it is that the agency action will cause the deprivation. This argument is wrong as a matter of law, and incorrectly describes FDA's obligations and practices regarding marketing orders.

1. "[T]he 'irreducible constitutional minimum' of standing consists of three elements. The plaintiff must have (1)

suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Only injury in fact is at issue here.

Injury in fact requires "'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Id.* at 1548 (quoting *Lujan*, 504 U.S. at 560). The inquiry is the same for organizations and individuals. *Lane v. Holder*, 703 F.3d 668, 674 (4th Cir. 2012). "An organization may suffer an injury in fact when a defendant's actions impede its efforts to carry out its mission." *Id.* An organization typically meets that test by showing that it suffered a "concrete and demonstrable injury to the organization's activities—with the consequent drain on the organization's resources[.]" *Havens Realty*, 455 U.S. at 379.

To determine whether a plaintiff has made this showing, courts ask "first, whether the agency's action or omission to act injured the [organization's] interest and, second, whether the organization used its resources to counteract that harm." *Food & Water Watch, Inc. v.*

Vilsack, 808 F.3d 905, 919 (D.C. Cir. 2015) (citation omitted); *see also Havens Realty*, 455 U.S. at 379. As the D.C. Circuit recently explained, where a plaintiff claims that a legal violation deprived it of information it otherwise would have received, causing a concrete, particularized, and actual or imminent injury, the plaintiff "ha[s] standing even though it had no legal right to the ... reports it sought." *Am. Anti-Vivisection Soc'y v. USDA*, 946 F.3d 615, 619 (D.C. Cir. 2020); *see also, e.g.*, *People for the Ethical Treatment of Animals v. USDA* ("*PETA*"), 797 F.3d 1087, 1094-95 (D.C. Cir. 2015) (plaintiff had standing where agency refused to issue inspection reports that plaintiff used to raise awareness and formulate complaints); *Action All. of Senior Citizens of Greater Phila. v. Heckler*, 789 F.2d 931, 937-38 (D.C. Cir. 1986) (plaintiffs had standing to challenge regulatory change "significantly restrict[ing]" information that would "enhance [their] capacity … to refer members to appropriate services and to counsel members," where they "alleged inhibition of their daily operations, an injury both concrete and specific to the work in which they [were] engaged").

2. The Government does not dispute that the numerous ways Plaintiffs would have used the information lost due to the 2017

Guidance create concrete, particularized, and actual injuries. As this silence suggests, the district court's finding of concrete and particularized injury is plainly correct. *See* App.59-64. To pick just three examples, the 2017 Guidance:

- Increased the costs of the Organizational Plaintiffs' various efforts to educate smokers, physicians, and parents about the dangers of tobacco products, "requir[ing] additional resources … to provide patient support services," App.449, and "entail[ing] a tremendous amount of research into popular e-cigarette products" at the cost of "substantial expenditure of resources," App.454.

- Prevented the Organizational Plaintiffs from effectively proposing product standards that could improve the safety of new tobacco products market-wide. App.362-63, 436-37.

- Impeded multiple Organizational Plaintiffs from providing effective services to hospitals and employers. App.443 (2017 Guidance impaired AHA's ability to "offer[] authoritative, medically accurate material on the diverse products that health care providers encounter and their most effective treatments" in its Get With the Guidelines program, making "hospitals … less likely to purchase Get With the Guidelines[,] reducing AHA's revenues from the program and decreasing its resources for maintaining and improving the program"); App.456-57 (describing similar impediments to Truth Initiative's programs).

As the district court correctly observed, "this injury to the organizations' daily operations due to agency action limiting their access to the information is the type of injury that courts have

recognized as both concrete and particularized." App.62; *see, e.g.*, *Havens Realty*, 455 U.S. at 379; *PETA*, 797 F.3d at 1094-95 (denial of "access to information and avenues of redress they wish to use in their routine information-dispensing, counseling, and referral activities" is an "inhibition of … daily operations" that is "an injury both concrete and specific to the work in which they are engaged").

3. Instead of disputing the concrete, particularized, and actual nature of Plaintiffs' injuries, the Government suggests that the "three elements" identified by the Supreme Court as the "'irreducible constitutional minimum' of standing," *Spokeo*, 136 S. Ct. at 1547 (quoting *Lujan*, 504 U.S. at 560), are an incomplete set. According to the Government, there is a fourth element, applicable only in cases where an injury is caused by the deprivation of information: that the information was "required to be disclosed by statute." Gov't Br. 29 (quoting *Dreher v. Experian Info. Sols., Inc.*, 856 F.3d 337, 345 (4th Cir. 2017)).

This argument is premised on a misreading of the distinct doctrine of "informational standing" applicable in cases brought under information-focused statutes such as the Freedom of Information Act

("FOIA") and the Federal Advisory Committee Act ("FACA"). That doctrine allows plaintiffs that are denied access to information to sue the federal government for that information without showing (as Plaintiffs have here) that the loss of information injures them—but it applies only if Congress has created a legal entitlement to the information.

Informational standing in that context is based on the principle that "the violation of a procedural right granted by statute can be sufficient in some circumstances to constitute injury in fact." *Spokeo*, 136 S. Ct. at 1549. For such congressionally created entitlements, deprivation of the information *itself* is a sufficiently concrete harm to meet the requirements of Article III; "[i]n other words, a plaintiff in such a case need not allege any *additional* harm beyond the one Congress has identified." *Id.*; *see also, e.g.*, *FEC v. Akins*, 524 U.S. 11, 21 (1998) ("[T]his Court has previously held that a plaintiff suffers an 'injury in fact' when the plaintiff fails to obtain information which must be publicly disclosed pursuant to a statute.").

In elevating information in certain contexts to an actionable entitlement without any further showing, however, Congress did not set

aside the conventional rules of standing for other injuries that involve information. Where a legal violation deprives a plaintiff of information, and that deprivation causes a concrete and particularized injury, a plaintiff may sue just as it can for any other type of violation. *See Am. Anti-Vivisection Soc'y*, 946 F.3d at 619 (plaintiff can "ha[ve] standing even though it had no legal right to the … reports it sought"); *see supra* at 36 (collecting cases).

The Government attempts to turn the sword created in statutes such as FOIA and FACA into a shield in all other contexts, asserting that Congress's enactment of statutes creating standalone informational injuries precludes all other claims involving information. This doctrinal innovation is based on a misreading of *Dreher* and *Spokeo*.

Spokeo distinguished statutes where Congress created an informational cause of action against the federal government (such as FOIA and FACA) from other statutes where Congress sought to curb a particular harm by mandating information disclosures. The statute at issue in *Spokeo*, the Fair Credit Reporting Act ("FCRA"), fell in the latter category, creating a cause of action related to nondisclosure not

for the purpose of information *qua* information, but instead "to ensure 'fair and accurate credit reporting.'" *Spokeo*, 136 S. Ct. at 1545. Under statutes such as FCRA, *Spokeo* explained, a "bare procedural violation" is insufficient to create Article III standing; unlike FOIA and FACA, the plaintiff must also show a concrete and particularized injury resulting from the violation. *Id.*

Dreher is a FCRA case in which the plaintiff attempted to do exactly what *Spokeo* foreclosed: "allege a bare procedural violation, divorced from any concrete harm, [to] satisfy the injury-in-fact requirement." *Dreher*, 856 F.3d at 344 (quoting *Spokeo*, 136 S. Ct. at 1549). *Dreher* thus found standing lacking, explaining that, under FCRA, a plaintiff must show "information to which he is legally entitled *and* that the denial of that information creates a 'real' harm with an adverse effect." *Id.* at 345 (quoting *Spokeo*, 136 S. Ct. at 1548).

The Government divorces *Dreher*'s statement of FCRA law from that context, portraying it as a blanket statement that a statutory entitlement is necessary in all cases involving the loss of information. Nothing in *Dreher* suggests such a broad reading. *Dreher* was discussing "a constitutionally cognizable informational injury" *created*

by Congress, not holding that all injuries involving information must be created by Congress. *Id.* Indeed, if the Government were correct that *Dreher*'s holding regarding FCRA was in fact a rule for all information-related cases, *Dreher* would be in direct conflict with the FOIA line of cases discussed above. *See, e.g.*, *Akins*, 524 U.S. at 21.

Moreover, even read as the Government prefers, *Dreher* requires only that the plaintiff be "*legally* entitled" to the information, 856 F.3d at 345 (emphasis added), not *statutorily* entitled. Nothing in *Dreher* suggests that this legal entitlement must be created by statute, rather than by regulation. The only way the Government can read a requirement of a specifically *statutory* entitlement is to miscast the Court's summary of a case where the only asserted entitlement was statutory as a case where regulatory or other entitlements were ruled out. *See id.* (discussing *Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016)). Because the Government concedes that "its own regulations" compel disclosure, Gov't Br. 29 (citing 21 C.F.R. § 814.9); *see also* 21 C.F.R. § 20.20(a) ("The Food and Drug Administration will make the fullest possible disclosure of records to the public … ."), Plaintiffs have standing even under a broad reading of *Dreher*. *See also*

Action All., 789 F.2d at 937-38 (plaintiffs had standing to challenge denial of two categories of information, one required by regulation and one not required by regulation or statute).

The Government's other cases are no more availing. *Nader v. FEC*, 725 F.3d 226 (D.C. Cir. 2013), concerned a FCRA-like statute, where the question was not whether the statute required disclosure, but whether the plaintiff (who only sought "to force the FEC to get the bad guys," *id.* at 230 (citation omitted)), had shown a concrete injury. *Salt Institute v. Leavitt*, 440 F.3d 156 (4th Cir. 2006), dealt with a plaintiff that argued unsuccessfully that the Information Quality Act created an explicit entitlement to information, *à la* FOIA; it was undisputed that such a cause of action was a prerequisite to suit.

4. Even if the Government were correct that the loss of information can confer standing only when Congress has specifically created a legal entitlement to that information, FDA's statutory obligations supply such an entitlement. As the Government acknowledges, the TCA "requires FDA to issue 'an order' on premarket tobacco applications." Gov't Br. 32 n.4 (quoting 21 U.S.C. § 387j(c)). The order must be based on the FDA's findings regarding four statutorily

specified questions, including whether "permitting such tobacco product to be marketed would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(1)(A), (c)(2). By statute, such an order must be made public. Gov't Br. 32 n.4 (citing 5 U.S.C. § 552(a)(2)).

This statutory obligation provides exactly the entitlement the Government claims is lacking. Its claim that it only makes those orders publicly available "as a matter of practice and its own regulations," Gov't Br. 29, is wrong, as its footnoted concession shows, *see id.* at 32 n.4. And while the Government suggests that orders only report "the mere fact of an application's grant or denial," *id.*, FDA uniformly publishes its marketing orders with detailed decision summaries containing a wealth of scientific, medical, and epidemiological data. *See* App.367-433 (example of PMTA order summary); *cf.* App.362-63, 436-38 (discussing utility of PMTA information); Gov't Br. 29 (conceding that marketing orders "increas[e] the availability of certain information potentially useful to plaintiffs in advancing their organizational interests and in treating their patients").

Additionally, as the Government concedes, Congress required it to disclose summaries of substantial equivalence reports. Gov't Br. 30

(citing 21 U.S.C. § 387j(a)(2)). The Government downplays the value of the health information in these reports. To be sure, the information is less comprehensive than that disclosed in marketing orders following PMTAs, given the relative novelty of the products subject to each and the differing scope of FDA's inquiry, but that does not mean they are so valueless that Plaintiffs lack any interest in them. Just like PMTA orders, substantial equivalence reports can reveal information that enables the Organizational Plaintiffs to propose product standards for all products in that category.[8] *Cf.* App.362, 437 (explaining the type of information useful in proposing product standards).[9]

[8] Substantial equivalence reports are available at https://www.fda.gov/tobacco-products/substantial-equivalence/marketing-orders-se.

[9] The Cigar Associations make a slightly different argument, claiming that Plaintiffs needed standing specifically to challenge the 2017 Guidance's "deadline extension *for cigars and pipe tobacco*." Industry Br. 57-58. Nobody suggested below that the 2017 Guidance might be unlawful as to e-cigarettes but lawful as to cigars, and any such argument would now be waived. *See Gen. Ins. Co.*, 886 F.3d at 356. In any event, Plaintiffs demonstrated harm from the marketing of kid-friendly, flavored cigars without marketing authorization. *See, e.g.*, App.449, 457, 477, 485, 491-93.

Thus, even if there were a requirement of a legal entitlement—and even if that legal entitlement must be created by statute—that requirement would be satisfied here.

2. Organizational Plaintiffs Have Standing Based on the Government's Decision to Exempt Tens of Thousands of New Tobacco Products

Even if the Government's information-focused arguments were correct, Plaintiffs would have standing based on the injuries that flow from the Government's decision to suspend indefinitely premarket review of new tobacco products.[10] These injuries readily satisfy the requirement of a "concrete and particularized," "actual or imminent" injury in fact. *Lujan*, 504 U.S. at 560.

1. In the 2017 Guidance, FDA informed all tobacco manufacturers that tens of thousands of products—every e-cigarette and cigar on the market when the Deeming Rule took effect—could be marketed whether or not their manufacturer complied with the TCA's premarket review provisions, and whether or not they were appropriate for the protection

[10] Because the district court found standing based on the deprivation of information, it did not consider this separate theory, which Plaintiffs raised below. *See* D. Ct. Dkt. 39 at 6-7. The Court may affirm the district court on alternative grounds. *Cochran v. Morris*, 73 F.3d 1310, 1315 (4th Cir. 1996).

of public health or substantially equivalent to a grandfathered product. As a direct result, the market was inundated with novel e-cigarette and cigar products in thousands of flavors.

As outlined above, *see supra* at 14-21, Defendants' actions substantially impeded the Organizational Plaintiffs' ability to carry out their missions. Organizational Plaintiffs' missions are, in various forms, to "reduce tobacco use and its deadly toll in the United States and around the world." App.359. The introduction of thousands of new tobacco products is not just a matter in which they have an "abstract social interest[]." *Havens Realty*, 455 U.S. at 379. Rather, as Plaintiffs demonstrated in 13 detailed and undisputed declarations, the 2017 Guidance radically altered the work they perform and required a substantial redirection and investment of resources in order to continue the services they have long provided.

Take, for example, the American Academy of Pediatrics. AAP's mission is to support the country's 67,000 pediatricians in promoting their patients' health. App.460-61. "One of the most important tasks that AAP undertakes" as part of that mission is to train its pediatrician members on clinical issues and provide them with resources to use

when treating patients. App.463-67. Pediatricians rely on these resources to provide medical services to the country's youth. *E.g.*, App.503. And screening and counseling patients for tobacco use is an integral part of every pediatrician's duties. App.461.

When new tobacco products spark an exponential growth in youth use, AAP does not have the choice to ignore them. Analyzing the products on the market, developing guidelines for pediatricians, and conducting training sessions, *see* App.463-69, are not "budgetary choices" that AAP makes. *Lane*, 703 F.3d at 675 (quoting *Fair Emp't Council of Greater Wash., Inc. v. BMC Mktg. Corp.*, 28 F.3d 1268, 1276 (D.C. Cir. 1994)). They are professional and medical imperatives. The only other "choice" the 2017 Guidance left to AAP was to abandon its mission and ignore the requests it receives "from countless members for resources to educate them and their patients about" the "dozens if not hundreds of different e-cigarette products" they encounter when treating patients. App.472.[11] This kind of "choice" does not defeat

[11] The same is true for the other Organizational Plaintiffs. *See, e.g.*, App.442-44 (explaining mission-critical aspects of AHA's work that require more resources to sustain due to the 2017 Guidance); App.448-49 (same, ALA); App.454-57 (same, Truth Initiative).

standing; if the option of simply giving up on one's mission defeated standing, then Havens Realty and other organizational plaintiffs that have prevailed on this issue would have lost as well. *See, e.g.*, *PETA*, 797 F.3d at 1095 (standing where organization had "expended resources to counter" impairment of its ability to address violations of statute and "continue to educate the public").

It is largely undisputed that these imperatives have come at tremendous cost to AAP, requiring significant outlays of money, App.463-65;[12] precluding AAP from pursuing grant opportunities, App.470; and forcing AAP to abandon, downgrade, or delay activities as diverse as supporting early-career researchers, improving adolescent health services, and working on its global child health initiatives, App.469-71. This is the exact type of harm recognized by the Supreme

[12] For the first time on appeal, the Government claims Plaintiffs "did not allege … that they have had to expend any specified sum of money because of FDA's evolving enforcement priorities." Gov't Br. 35. There is no requirement that a plaintiff identify a "specified sum of money," and the Government cites no case suggesting otherwise. But even if there were, AAP's declaration shows exactly that. *See* App.471 (AAP has spent "more than $150,000" due to the need to provide tobacco trainings more often); *compare* Gov't Br. 35 (attempting to distinguish *PETA* because plaintiffs spent "more than $3,000 per year"). Plaintiffs' declarations describe numerous other examples of substantial commitments of financial resources as well. *E.g.*, App.444, 450, 454-57.

Court in *Havens Realty*. FDA's decision to condone the widespread marketing of novel tobacco products "perceptibly impaired [AAP's] ability to provide counseling and [other] services" to its pediatrician members "with the consequent drain on the organization's resources." *Havens Realty*, 455 U.S. at 379. There is therefore "no question that the organization has suffered injury in fact. Such concrete and demonstrable injury to the organization's activities … constitutes far more than simply a setback to the organization's abstract social interests." *Id.*

2. The Government attempts to minimize such injuries as mere "generalized statements." Gov't Br. 33. This description does not fairly characterize Plaintiffs' 13 detailed and unchallenged declarations. *See supra* at 14-21. Compare, for example, *Sierra Club v. Morton*, 405 U.S. 727 (1972), with the facts of this case. Sierra Club sought to challenge a proposed development in a national forest. But "Sierra Club failed to allege that it or its members would be affected in any of their activities or pastimes by the … development"; it did not even "state that its members use [the site] for any purpose, much less that they use it in any way that would be significantly affected by the proposed actions of

the respondents." *Id.* at 735. Instead, Sierra Club proceeded as a "representative of the public" and nothing more. *Id.* at 736. This is what the Supreme Court was rejecting when it said that "a mere 'interest in a problem,'" *id.* at 739, is insufficient: not a significant retooling of an organization's day-to-day operations at substantial cost necessitated by the defendants' actions, but a pure and abstract social interest.

Nor is this case like *International Primate Protection League v. Institute for Behavioral Research, Inc.*, 799 F.2d 934 (4th Cir. 1986), Defendants' sole Fourth Circuit case on this point. There, the plaintiffs based their claim on their tax payments used to fund the defendants' work, their voluntary offer to care for monkeys being used for research, and their personal relationship with the monkeys that had arisen because of the litigation. *Id.* at 937-38. That those allegations failed to show standing says nothing about whether the Organizational Plaintiffs' detailed, concrete, and particularized injuries suffice.

The Government also relies on the general principle that a plaintiff cannot force the government to initiate a particular enforcement action. *See* Gov't Br. 33-34; *see, e.g.*, *Linda R.S. v. Richard D.*, 410 U.S. 614, 619 (1973) (plaintiff lacked standing to compel state to

prosecute father of her child for failure to pay child support). But Plaintiffs did not seek to compel FDA to enforce the TCA against a particular violator; they sought to prevent FDA from suspending the operation of a legal mandate that applies to every tobacco product manufacturer. As the district court explained, the action challenged here "does not 'share … the characteristics of the decision of a prosecutor … not to indict' to any extent." App.90 (quoting *Heckler v. Chaney*, 470 U.S. 821, 832 (1985)).

The cases the Government seeks to distinguish are directly on point. In *PETA*, the plaintiff argued that it had standing because the agency's failure to act meant that "USDA was not creating bird-related inspection reports that PETA could use to raise public awareness." 797 F.3d at 1091. The D.C. Circuit agreed, explaining that "USDA's allegedly unlawful failure to apply" the Animal Welfare Act ("AWA") had denied PETA access to "bird-related AWA information" and thereby "'perceptibly impaired [PETA's] ability' to both bring AWA violations to the attention of the agency charged with preventing avian cruelty and continue to educate the public." *Id.* at 1095 (citation omitted). Plaintiffs have shown comparable harms and more: obligations to their members,

partners, and customers that are more difficult and more expensive to fulfill as a direct result of the challenged action. *See supra* at 14-21.

Similarly, in *Centro de la Comunidad Hispana de Locust Valley v. Town of Oyster Bay*, 868 F.3d 104 (2d Cir. 2017), the court recognized that an organization has standing when an action that does not directly regulate it nonetheless causes it to "inevitably face increased difficulty" in mission-critical activities, if the organization "offered unrebutted testimony that it has already had to devote attention, time, and personnel to prepare its response to the [challenged policy]." *Id.* at 110-11. The court made clear that these injuries were "sufficient to constitute an injury-in-fact," *id.* at 111, even though they did not involve any direct effect on the plaintiff's operations. The Government's attempt to distinguish *Centro de la Comunidad* as a case requiring a "direct" impairment of an organization's work is thus incorrect—and, moreover, incompatible with binding precedent. *See Warth v. Seldin*, 422 U.S. 490, 504-05 (1975) ("The fact that the harm to petitioners may have resulted indirectly does not in itself preclude standing.").

3. Pediatrician Plaintiffs and AAP as a Membership Organization Have Standing Due to the Impairment to Their Businesses and Patients

In addition to their organizational injuries, Plaintiffs established standing on behalf of the Pediatrician Plaintiffs and AAP as a membership organization. *See generally Lane*, 703 F.3d at 674 n.6 (membership organization may sue where its members would have standing to sue, the interests it seeks to protect are germane to its purpose, and participation of individual members is not required).

The influx of tens of thousands of new products harms pediatricians' practices—their professional obligations and livelihoods—by undercutting their ability to counsel and treat their patients effectively. *See supra* at 20-21. It has forced them to conduct substantial additional research "just to be able to perform [their] duties as … medical professional[s]." App.476. Even with that additional work, the proliferation of products and the dearth of product-specific, evidence-based resources limits pediatricians' "ability to carry out [their] responsibilit[y] to [their patients] as their physician." App.499. It has also increased the volume and complexity of patients they treat, forcing them to either reduce time spent "on other important health issues … or

lengthen[] [their] sessions so that [they] can see fewer patients"—with, for some pediatricians, "a corresponding effect on both [their] patients' health and [their] practice[s'] income." App.489-90.

The increased burdens on physicians caused by the lack of product-specific information has been vividly illustrated by the recent outbreak of vaping-related illness, which has caused at least 64 deaths.[13] One of the major reasons why the Centers for Disease Control had such difficulty identifying the cause of the outbreak and recommending a course of treatment was the variety of products potentially implicated and the lack of information about specific products. App.551-52. If lack of product-specific information impeded diagnosis and treatment by even the most sophisticated epidemiologists, the impediments for practicing pediatricians caused by such a lack of information are even more severe. FDA's failure to require reporting of product-specific information that would be required in the course of premarket review and the consequent absence of information for physicians actually treating and advising patients has

[13] *See* CDC, "Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products" (last updated Feb. 11, 2020), https://tinyurl.com/y2yrb5bc.

already impeded their ability to serve their patients, illustrating why courts recognize such injuries.

These impairments harm pediatric patients—and they harm pediatricians' "interests, both financial and professional, in practicing medicine pursuant to [their] best medical judgment[.]" *Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 917 (9th Cir. 2004); *see also Pa. Psych. Soc'y v. Green Spring Health Servs., Inc.*, 280 F.3d 278, 289 (3d Cir. 2002) (medical association had standing where "defendants' policies and procedures have economically injured its member psychiatrists and undermined their ability to provide quality health care").

B. The 2017 Guidance Is Reviewable

1. The 2017 Guidance Is Not an Exercise of Enforcement Discretion

Rather than defend the 2017 Guidance on the merits, the Government argues that the district court lacked authority to review it. It contends that whether FDA can categorically exempt all manufacturers from complying with the Act's premarket review requirement is "committed to agency discretion by law," 5 U.S.C. §

701(a)(2), and is an unreviewable exercise of enforcement discretion under *Heckler v. Chaney*, 470 U.S. 821 (1985).

The Government cannot hide behind *Chaney* for three related reasons: *first*, because the TCA provides "law to apply" with respect to FDA's authority to exempt manufacturers from the Act's requirements; *second*, because *Chaney* does not apply to generally applicable policies where, as here, Plaintiffs allege that the challenged policy is contrary to law; and *third*, because FDA's policy represents a wholesale abdication of its statutory duties under the Act.

1. The 2017 Guidance was not about agency enforcement priorities. Rather, as the district court held, App.76-79, it created unlawful, categorical exemptions from the clear and mandatory duties imposed by the TCA. Put another way, there is a difference between exercising enforcement discretion and instructing an entire industry that it need not comply with mandatory statutory duties. The latter does not fall within *Chaney*'s exception to the normal presumption of reviewability. *See Clean Air Council v. Pruitt*, 862 F.3d 1, 6 (D.C. Cir. 2017) (stay of rule's effective date was "tantamount to amending or revoking a rule"). Here, FDA effectively rendered the regulated entities

"not legally obligated to submit" to the premarket review process, "regardless of whether [the agency] decide[d] to take action against them for not doing so." *Pub. Citizen Health Res. Grp.*, 363 F. Supp. 3d at 18.

Although *Chaney* precludes review of an agency's decision not to undertake an enforcement action where such a decision is "committed to agency discretion by law," 470 U.S. at 828-29 (quoting 5 U.S.C. § 701(a)(2)), it does not allow an agency to "disregard legislative direction in the statutory scheme that [it] administers." *Id.* at 833. Accordingly, courts have rejected efforts to cloak *ultra vires* acts within the framework of "enforcement discretion" where, as here, the substantive statute imposes mandatory duties. *See, e.g.*, *Delta Air Lines, Inc. v. Export-Import Bank of the U.S.*, 718 F.3d 974, 977 (D.C. Cir. 2013) (rejecting *Chaney* argument where statute cabined scope of agency discretion by using mandatory "shall").

With respect to whether manufacturers are required to comply with the premarket review provisions for new tobacco products, the Act provides explicit direction. It "require[s]" premarket review for new tobacco products. 21 U.S.C. § 387j(a)(2)(A); *see also Nicopure*, 944 F.3d

at 276 ("In general, all new tobacco products must be cleared by the FDA before they can be marketed and sold in the United States."). It provides that the Secretary "shall" issue an order granting or denying a new tobacco product application within 180 days of receipt. *Id.* § 387j(c)(1)(A). Moreover, an application that fails to meet the enumerated statutory criteria pertaining to public safety "shall" be denied. *Id.* § 387j(c)(2). These provisions are plainly mandatory. *See Bennett v. Spear*, 520 U.S. 154, 175 (1997) ("[A]ny contention that the relevant provision … is discretionary would fly in the face of its text, which uses the imperative 'shall.'").

Congress also carefully considered the extent to which products should be exempt from the premarket authorization requirement and allowed exemptions in only two specific circumstances: where a substantial equivalence report was filed before March 22, 2011; or where the products are "intended for investigational use." *Id.* §§ 387e(j)(2), 387j(a)(2)(B), 387j(g).[14] In all other cases, products introduced

[14] Although the TCA provides an "exemption" from substantial equivalence requirements for a narrow category of specific "minor modification[s]," 21 U.S.C. § 387e(j)(3), this is not an exemption from the premarket authorization requirement, but rather an alternative means of satisfying it.

after February 15, 2007 are subject to mandatory premarket review and must receive FDA authorization as prescribed by the statute to be sold lawfully. Where Congress has considered which exceptions to permit to a generally applicable requirement, the agency "ha[s] no authority to create exceptions not explicitly listed in the statute[.]" *Nat'l Ass'n of Clean Water Agencies v. EPA*, 734 F.3d 1115, 1128 (D.C. Cir. 2013).

The 2017 Guidance eviscerated this carefully crafted legislative design. In granting a sweeping, extended exemption for "*all* categories of newly regulated products that were on the market on August 8, 2016," App.157 (emphasis added), the 2017 Guidance rendered the Act's mandatory premarket review process a legal nullity. In other words, the 2017 Guidance purports to "establish with the force of law that otherwise-prohibited conduct will not violate the Act." *Util. Air Reg. Grp. v. EPA*, 134 S. Ct. 2427, 2445 (2014); *cf. Nicopure*, 944 F.3d at 281 (FDA could not permissibly create a "blanket rule excusing e-cigarettes from the premarket authorization requirement"). Such a blanket rule is not an exercise of enforcement discretion; it is the revocation of a statutory mandate. To accept the Government's argument that the 2017 Guidance is unreviewable would be to allow agencies to pick and choose

which legislative commands have the force of law. This the law does not allow.

The Government argues that the statutory provisions relied on by the district court do not pertain to the agency's authority to decide whether and how to enforce the Act's requirements, and that they impose mandatory duties on manufacturers, but not the Government. Gov't Br. 41-42. This argument misses the point: even if it were true that the TCA did not mandate action by FDA, FDA's 2017 Guidance effectively suspended *manufacturers'* mandatory duties. FDA fully expected manufacturers to treat the extension as a suspension of the Act's substantive requirements; hence FDA's statement, regarding the original compliance period provided in the Deeming Rule, that "manufacturers … will continue to market their products without FDA authorization." 81 Fed. Reg. at 29,010. Suspending those mandatory requirements is not an exercise of enforcement discretion at all, but rather an unlawful, *de facto* amendment to the substantive provisions of the Act. *See Delta Air Lines*, 718 F.3d at 977. And although the Government now argues that manufacturers remain obligated to comply with the Act, Gov't Br. 45-46, no such indication can be found on

the face of the 2017 Guidance, App.141-52 and the agency's own pronouncement in the Deeming Rule on the effect of these "compliance periods" indicates the contrary expectation.

Notwithstanding the Government's protests, Gov't Br. 46-47, the *Public Citizen Health Research Group* decision, on which the district court relied, is directly on point. There, an agency had effectively suspended a reporting requirement while casting its action as a matter of enforcement discretion. 363 F. Supp. 3d at 18. The court correctly rejected the *Chaney* argument, noting that "[s]uch decisions … 'are tantamount to amending or revoking a rule.'" *Id.* (quoting *Clean Air Council*, 862 F.3d at 6).

Here, similarly, the 2017 Guidance was intended to be and was treated as the suspension of manufacturers' obligation to comply with the Act. In response, the Government can only cite a newspaper article indicating that a manufacturer voluntarily submitted an application in Fall 2019. Gov't Br. 46. But that application was filed after the district court vacated the 2017 Guidance, and says nothing about the effect of the 2017 Guidance on manufacturers' *legal obligation* to comply.

2. Even if the 2017 Guidance were an exercise of enforcement discretion, *Chaney* would be inapplicable where, as here, Plaintiffs have challenged whether an agency's *general policy* exceeds its statutory authority.

The D.C. Circuit and other courts have distinguished between a "*single-shot* non-enforcement decision," such as that at issue in *Chaney*, and "an agency's statement of a general enforcement policy," holding that only the former is covered by *Chaney*'s presumption of non-reviewability. *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 676 (D.C. Cir. 1994); *see also OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808 (D.C. Cir. 1998) (general non-enforcement policy was subject to review); *Kenney v. Glickman*, 96 F.3d 1118, 1123 (8th Cir. 1996) ("*Chaney* applies to individual, case-by-case determinations of when to enforce existing regulations"). Last year, this Court recognized this very distinction. *See Casa De Maryland v. DHS*, 924 F.3d 684, 699 (4th Cir. 2019), *petition for cert. filed* (U.S. May 24, 2019) (No. 18-1469).

These cases recognize that a general enforcement policy is an agency action susceptible to review in a way that a one-off enforcement determination is not. Whereas individual non-enforcement decisions

may "involve[] a complicated balancing of a number of factors which are peculiarly within its expertise," *Chaney*, 470 U.S. at 831, blanket determinations not to enforce a statutory requirement do not. *See Kenney*, 96 F.3d at 1123 (distinguishing *Chaney* where "[t]he Secretary has not decided 'whether a violation has occurred,' has not decided whether he will 'succeed' if he acts, and has not determined which 'technical violations' to act against" (quoting *Chaney*, 470 U.S. at 831-32)). FDA's 2017 Guidance is not, for example, based on consideration of "whether agency resources are best spent on this violation or another"; "whether the particular enforcement action requested best fits the agency's overall policies"; or "whether the agency has enough resources to undertake the action at all." *Chaney*, 470 U.S. at 831.

Rather, FDA granted manufacturers a categorical, nearly half-decade-long exemption from their nondiscretionary premarket review obligations, based on the erroneous view that it was authorized to suspend the Act's premarket review requirements. The legality of that decision is a question entirely fit for judicial review. The Government seeks to distinguish the body of cases acknowledging this *Chaney* exception, including this Court's decision in *Casa De Maryland*, by

arguing that the exception only applies when the claim challenges the validity of "the agency's legal interpretation." Gov't Br. 45 (quoting *Casa De Md.*, 924 F.3d at 699). But even if so, whether the agency exceeded its legal authority under the Act is at issue in this case. *See infra* Part II.C.

3. The 2017 Guidance is independently reviewable because, by categorically exempting manufacturers from the Act's premarket review requirements, FDA has "'consciously and expressly adopted a general policy' that is so extreme as to amount to an abdication of its statutory responsibilities." *Chaney*, 470 U.S. at 833 n.4 (quoting *Adams v. Richardson*, 480 F.2d 1159 (D.C. Cir. 1973)). By refusing to administer the premarket review regime with respect to this broad swath of new tobacco products, FDA has abdicated its mandatory duty to enforce the Act.

In similar circumstances, courts have found jurisdiction to review an agency's general policy or practice of nonenforcement. In *Adams v. Richardson*—a case cited in *Chaney*—the D.C. Circuit held that a "consistent failure" to enforce Title VI of the Civil Rights Act with respect to segregated school districts constituted a "dereliction of duty

reviewable in the courts." 480 F.2d at 1163. And in *NAACP v. Secretary of HUD*, 817 F.2d 149 (1st Cir. 1987) (Breyer, J.), the court held that the agency's broad pattern of failing to enforce the Fair Housing Act was reviewable, even though individual instances of non-enforcement may not be. The court held that difficult questions of discretion were not implicated where a case "call[s] for a more straightforward evaluation of whether agency activity over time has furthered the statutory goal, and, if not, for an explanation of why not and a determination of whether a given explanation, in light of the statute, is satisfactory." *Id.* at 158.

FDA's actions here are a far cry from a careful calibration of enforcement priorities that would arguably fall within *Chaney*'s presumption of nonreviewability. Rather, FDA categorically exempted some 25,000 products from the Act's requirements—immunizing an entire industry from compliance with a statutory mandate—for years. App.830. That is precisely the sort of wholesale "abdication of … statutory responsibilities" that *Chaney* suggested may not be committed to agency discretion. 470 U.S. at 833 n.4.

In response, the Government points to the Deeming Rule, enacted during the prior Administration, as evidence that it has not abdicated

its duties. Gov't Br. 43. But the Deeming Rule has no bearing on the lawfulness of the agency's subsequent decision to exempt manufacturers from a critical statutory duty. It then points to the 2020 Guidance as further evidence that it has not abdicated its statutory duty. But that later guidance, although relevant to mootness, cannot retroactively shield the 2017 Guidance from judicial review under *Chaney*.

To the contrary, the differences between the 2020 Guidance and the 2017 Guidance bring the latter's core defect into sharp relief. The 2020 Guidance—whatever its merits from a policy perspective—identifies characteristics of different products that will make FDA more or less likely to pursue action against violators. *E.g.*, App.205 (identifying three categorizes of e-cigarettes it "intends to prioritize enforcement" against); App.218 (identifying facts FDA will consider when "mak[ing] enforcement decisions on a case-by-case basis" against cigars). It explicitly affirms that "it is illegal to market any new tobacco product without premarket authorization," App.190, while stating that it retains enforcement discretion to pursue any violation.

The 2017 Guidance, by contrast, stated that FDA was providing an "extension of premarket review compliance deadlines" for all manufacturers. App.143. It explicitly stated that FDA "d[id] not intend to enforce [the premarket review] requirement" and that "there *will be* a continued compliance period." App.143-44 (emphasis added). The 2017 Guidance did not describe enforcement priorities; it instead announced there would be no enforcement, statutory requirement notwithstanding.

4. The Government and Cigar Associations insist that this case is on all fours with *Chaney*. Gov't Br. 39; Industry Br. 54-56. But *Chaney* involved a challenge to the FDA's response to a *specific* petition (submitted by death row inmates) requesting that FDA initiate an enforcement action against the manufacturers of *specific* drugs when used for a *specific* purpose (lethal injections). 470 U.S. at 824. That is entirely distinct from FDA's affirmative decision here to issue a sweeping, categorical exemption of an entire class of products. And unlike here, in *Chaney*, the Commissioner's refusal was based on consideration of typical resource prioritization factors. *Id.* Accordingly, it is the exceptions to *Chaney*, discussed above, that lead the way here.

The Government and Cigar Associations also cite *Jerome Stevens Pharms., Inc. v. FDA*, 402 F.3d 1249, 1258 (D.C. Cir. 2005). That case, however, involved an extension to a new drug application deadline for a specific product, not for a sweeping category of some 25,000 products. Moreover, the appellant did not dispute the district court's decision on the nonreviewability of deadline extensions and did not identify any contrary statutory provisions. *Id.* at 1257-58. Plaintiffs here have done both.[15]

2. The 2017 Guidance Is Final Agency Action

The Government also argues that the 2017 Guidance is not final agency action subject to review under the APA. Gov't Br. 47; *see* 5 U.S.C. § 704. In order to qualify as "final," agency action must (1) "mark the 'consummation' of the agency's decisionmaking process," and (2) be "one by which 'rights or obligations have been determined,' or from

[15] The Government and Cigar Associations both cite cases challenging settlement agreements in which an agency agreed not to bring an enforcement action against individual entities that were parties to the agreements. Industry Br. 56 (citing *Ass'n of Irritated Residents v. EPA*, 494 F.3d 1027, 1031-32 (D.C. Cir. 2007)); Gov't Br. 40 (citing *Schering Corp. v. Heckler*, 779 F.2d 683, 685 (D.C. Cir. 1985)). It is no surprise that consent agreements with specific parties, grounded in an interest in avoiding the time and expense of litigation, fall within the scope of *Chaney*. Such a rule has no bearing here.

which 'legal consequences will flow.'" *Bennett*, 520 U.S. at 177-78. The Government contends that neither prong is satisfied, but its arguments miss the mark.

With respect to the first *Bennett* prong, there was nothing "tentative" about the 2017 Guidance. *Bennett*, 520 U.S. at 178. It allowed manufacturers to continue to market newly deemed tobacco products without premarket review, going so far as to set new deadlines years into the future. App.148. Indeed, FDA acknowledged forthrightly in the Deeming Rule itself that the anticipated effect of extending compliance periods would be that "manufacturers … will continue to market their products without FDA authorization." 81 Fed. Reg. at 29,010.

The Government points to boilerplate language that the 2017 Guidance reflected the agency's "current thinking." Gov't Br. 47 (citing App.141). But that is definitionally true of any agency action, whether explicitly stated or merely implicit. FDA's 2020 Guidance states that the agency decided to revisit the 2017 Guidance in light of new factual developments and information regarding the use of new tobacco products, App.193-94, not as a necessary culmination of the original

process. An agency revision based on "'new information[]' … does not make an otherwise definitive decision nonfinal." *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1814 (2016). Rather, the 2017 Guidance stood on its own as a "final and binding determination." *Safari Club Int'l v. Jewell*, 842 F.3d 1280, 1289 (D.C. Cir. 2016); *see also Real Truth About Abortion, Inc. v. FEC*, 681 F.3d 544, 555 n.4 (4th Cir. 2012).

On the second *Bennett* prong, there can be no question that the 2017 Guidance determined the rights and obligations of manufacturers by exempting them from statutory premarket review requirements for a period of years. "The definitive nature" of the 2017 Guidance "gives rise to 'direct and appreciable legal consequences.'" *Hawkes*, 136 S. Ct. at 1814 (quoting *Bennett*, 520 U.S. at 178). Although the Government now argues that the 2017 Guidance had no legal consequences, Gov't. Br. 48, that position is unpersuasive for the reasons discussed above. *See supra* at 60-62. Without the 2017 Guidance, manufacturers would have been exposed to severe consequences if they marketed their products without an order from FDA, *see* App.52; the 2017 Guidance allowed them to do just that with no fear of repercussion.

As with the first *Bennett* prong, the Government again relies principally on the generic disclaimers contained in the 2017 Guidance about its effect. But such "boilerplate," contained in "all [of FDA's] guidance documents," do not nullify the legal consequences of the 2017 Guidance. *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000). What matters is "the effect" of the agency's action, not the label the agency chooses to attach to it. *Hawkes*, 136 S. Ct. at 1814. As in *Hawkes*, the bright-line deadlines provided by FDA afforded manufacturers a *de facto* "safe harbor"—"a 'legal consequence[]' satisfying the second *Bennett* prong." *Id.* at 1810 (quoting *Bennett*, 520 U.S. at 177-78).

C. The 2017 Guidance Violated the TCA

In issuing the 2017 Guidance, FDA granted a categorical multi-year extension of "compliance deadlines" for some 25,000 new tobacco products. App.830. It did so with the understanding and expectation that as a result of extending compliance periods, "manufacturers … will continue to market their products without FDA authorization." 81 Fed. Reg. at 29,010 (discussing effect of initial Deeming Rule compliance periods). The 2017 Guidance relieved manufacturers and FDA of the

Act's mandatory premarket review requirements. In so doing, the 2017 Guidance contravened the purpose of the Act, as (to quote the district court) "[i]nstead of addressing public health concerns associated with tobacco use by minors and others, the August 2017 Guidance exacerbate[d] the situation by stating, in essence, that manufacturers can continue to advertise and sell products that are addictive and target a youth market." App.88. The Act permits no such exemption for manufacturers.

Indeed, the Government does not meaningfully challenge the district court's merits decision, merely asserting in a single sentence that some of its same arguments regarding reviewability also apply to the merits. *See* Gov't Br. 49 n.6. It has therefore abandoned any other merits contentions on appeal. *See Brown*, 785 F.3d at 923.[16]

The Cigar Associations contest only two points of the district court's decision on its merits. First, they argue that the Act gives FDA discretion to decide, in the first place, whether or not to regulate a tobacco product, and thus FDA has discretion to decide the conditions of

[16] In particular, no Appellant disputes the district court's holding that the 2017 Guidance was a legislative rule requiring notice-and-comment rulemaking. *See* App.91-97.

compliance. Industry Br. 62. This is simply another flavor of an argument the D.C. Circuit rejected in *Nicopure*. As that court explained, whatever discretion the agency had in the first instance, FDA did, through notice-and-comment rulemaking, deem these products to be subject to the Act, and thus the requirements the Act imposes are nondiscretionary as to the deemed products. "Once the FDA deemed e-cigarettes [and cigars] to be 'tobacco products'—a decision Appellants no longer challenge—e-cigarettes [and cigars] became subject to premarket authorization," and FDA had no discretion to make any exceptions. *Nicopure*, 944 F.3d at 281; *see also Clean Air Council*, 862 F.3d at 9 ("'[A]n agency issuing a legislative rule is itself bound by the rule until that rule is amended or revoked' and 'may not alter [such a rule] without notice and comment.'" (quoting *Nat'l Family Planning & Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227, 234 (D.C. Cir. 1992))).

Second, the Cigar Associations note that the Deeming Rule contained timelines for submitting premarket applications and other actions. Industry Br. 62-63. That is irrelevant. The validity of the time periods set by the Deeming Rule—which have long since expired—is

not at issue in this litigation. In any event, there is a stark difference between the Deeming Rule, which provided a 24-month initial window for submitting premarket applications followed by a time-limited one-year grace period for products that submitted such applications, and the 2017 Guidance, which extended application deadlines by an additional four years and then created an *indefinite* exemption for all manufacturers who submitted applications. *See* App.143. While the former may have been a reasonable response to the impossibility of filing and processing applications instantaneously, the latter effectively suspended one of the most critical portions of the Act itself.

D. The Remedial Order Was Not an Abuse of Discretion

1. The District Court Had Discretion to Reset the Deeming Rule's Lapsed Deadline

When the district court vacated the 2017 Guidance, the previous compliance deadlines for premarket review applications went back into effect. Because those deadlines had passed, the district court "ordered the parties to submit additional briefing regarding a remedy." App.106.

After briefing, the court exercised its remedial discretion to provide Industry Appellants' members with up to ten additional months to market their products without the possibility of FDA

enforcing the Act's premarket review requirements. Not satisfied, the Industry Appellants now challenge that discretionary grant, asking this Court not only to reverse the district court's order, but also to hold that the district court was *required* to remand the 2017 Guidance without vacatur.

This argument should be rejected. Industry Appellants' arguments misstate the district court's rulings, the factual context, and the governing law. The district court acted well within its remedial discretion to account for the expiration of the deadlines that were in effect before the unlawful 2017 Guidance.

1. "It is well-established that federal courts possess broad discretion to fashion equitable remedies." *Coal. for Gov't Procurement v. Fed. Prison Indus., Inc.*, 365 F.3d 435, 460 (6th Cir. 2004). This discretion allows a court to "adjust its relief to the exigencies of the case in accordance with the equitable principles governing judicial action." *Zambrana*, 651 F.2d at 844 (quoting *Ford Motor Co. v. NLRB*, 305 U.S. 364, 373 (1939)). As part of their discretion, courts "may craft declaratory and injunctive relief designed to preclude a federal agency from acting in contravention of its statutory and regulatory authority."

Coal. for Gov't Procurement, 365 F.3d at 460. "Furthermore, the court may require an agency to modify its current or future practices in order to account for past violations of its statutes or regulations." *Id.*

Of course, this discretion is not boundless. "When a district court reverses agency action and determines that the agency acted unlawfully, *ordinarily* the appropriate course is simply to identify a legal error and then remand to the agency … ." *N. Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012) (emphasis added). One common exception is where the expiration of deadlines during litigation makes remedial discretion necessary to restore something resembling the status quo before the unlawful activity. In such circumstances, a court "may when appropriate set a time limit for action by the administrative tribunal, and this is often done." *Zambrana*, 651 F.2d at 844; *see, e.g.*, *Andrulis Research Corp. v. U.S. Small Bus. Admin.*, No. 90-cv-2569, 1990 WL 169318, at *2 (D.D.C. Oct. 19, 1990) (collecting cases). In "extraordinary circumstances," courts may go even further and "issue detailed remedial orders." *N.C. Fisheries Ass'n v. Gutierrez*, 550 F.3d 16, 20 (D.C. Cir. 2008).

2. When the district court issued the Summary Judgment

Opinion, it vacated the 2017 Guidance. App.99; *see also* 5 U.S.C. § 706(2) (directing courts to "hold unlawful and set aside agency action" found to be "in excess of statutory jurisdiction, authority, or limitations," or "without observance of procedure required by law"). Ordinarily, this would mean a return to the pre-Guidance status quo: "the application deadlines set in the Deeming Rule," as briefly extended in May 2017. App.106. As the district court explained, these deadlines "otherwise would have applied following the vacatur," but "had passed." *Id.*

The expiration of the previous deadlines meant that, once the 2017 Guidance was vacated, there was *no* compliance period for any deemed product: every single e-cigarette and post-2007 cigar was immediately exposed to the possibility of an FDA action. This raised the possibility that, at least temporarily, no e-cigarettes would be available. *See* App.106-07. The district court, suggesting a "need to avoid creating an additional public health crisis if e-cigarette availability dropped so precipitously as to push users to combusted tobacco products," *id.*, requested remedial briefing to determine whether it should "adjust its relief to the exigencies of the case,"

Zambrana, 651 F.2d at 844.

After hearing from Plaintiffs, the Government, the E-Cigarette Associations, and several e-cigarette and cigar manufacturers, the court made several factual findings. Vacating the 2017 Guidance without any further remedy would risk pushing e-cigarette users to potentially more dangerous combustible tobacco products. App.106-07. Based on the evidence before it, the court found that Plaintiffs' proposal that the lapsed Deeming Rule deadline be reset for four months out would have the same risk. App.111. But, at the same time, FDA could not revert to its unlawful policy of assuring manufacturers it would not enforce the TCA against them indefinitely. App.90, 111 n.6. And as the Government emphasized, "there is currently insufficient data to draw a conclusion about the efficacy of e-cigarettes as a cessation device." App.113 (quotation omitted). Moreover, the evidence in the record suggested that "in the absence of a deadline for filing, the Industry will … raise every roadblock it can and take every available dilatory measure to keep its products on the market without approval." App.113-14.

In light of these facts, the district court determined that

"'extraordinary circumstances' … call[ed] for more than a simple remand or vacatur." App.110; *see also* App.114. Rejecting Plaintiffs' proposal, the court adopted the Government's suggestion, supported by a detailed declaration by the Director of FDA's Center for Tobacco Products, that the Deeming Rule's deadline be pushed back ten months. App.114 ("The Industry insists that 'FDA, not the courts, must set that timetable in the first instance.' In fact, it has." (citation omitted)). Based on the evidentiary record, the court determined that this schedule "allow[ed] sufficient time for application submissions that present the information that the FDA needs to assess the e-cigarette products, while not delaying longer than necessary." *Id.*

The resulting order provided that any new products for which applications were filed within 10 months "may remain on the market without being subject to FDA enforcement actions for a period not to exceed one year," while products for which an application was not submitted by that date would "be subject to FDA enforcement actions, in the FDA's discretion." App.116. The court made clear that its remedy was designed to "allow the FDA to continue with its existing regulatory efforts." App.111 n.6 (quotation omitted). It subsequently clarified its

order to confirm FDA's authority to enforce the premarket review provisions earlier against any products. App.117.

Notably, the district court *rejected* Plaintiffs' request for further relief. Plaintiffs had requested "that the Court require the FDA to file quarterly reports with the Court 'on the measures it is taking to carry out its premarket review responsibilities under the TCA.'" App.107. The court found no "present need to require court monitoring through quarterly reports," App.116, trusting FDA to exercise its enforcement discretion as it saw fit.

Thus, the effect of the district court's orders was: (1) to reinstate the compliance policy of the Deeming Rule (*i.e.,* enforcement withheld up to a certain date and for a one-year period thereafter), but with a new deadline of May 12, 2020 to replace the lapsed 2018 deadlines; (2) FDA could accelerate those dates as it saw fit within its discretion; (3) FDA could not issue a blanket non-enforcement policy exempting *all* manufacturers, but otherwise retained its standard enforcement discretion; and (4) the district court would not supervise FDA's exercise of its enforcement discretion.

3. The Remedial Order fell squarely within the district court's

discretion to "adjust its relief to the exigencies of the case in accordance with the equitable principles governing judicial action." *Zambrana*, 651 F.2d at 844. It recognized the special circumstances of the case—the universally recognized "epidemic-level rise in youth e-cigarette use" and "mounting public health crisis," App.110 (quoting FDA Commissioner's statement)—and evaluated the equities of the evidence before it, including the supposed unfairness to Industry Appellants' members of facing the possibility of enforcement for marketing products that undisputedly were unlawful to market. It crafted tailored relief that prevented FDA from resuming its prior unlawful behavior and provided some accommodation to manufacturers, while ensuring the unlawful delay wrought by the 2017 Guidance would end relatively promptly. It left FDA discretion to set enforcement priorities—any priorities except the categorical suspension that it had erroneously tried to characterize as discretion. *See supra* Part II.B.1. And it refused to superintend FDA's enforcement of the TCA.

4. The E-Cigarette Associations' arguments that the Remedial Order exceeded the district court's authority or abused its discretion are unavailing.

As a preliminary matter, the Remedial Order (as opposed to the Summary Judgment Order) did not impair any interest of Industry Appellants or their members. The Summary Judgment Order vacated the 2017 Guidance. Without that guidance, every new product on the market was currently at risk of enforcement. The Remedial Order effectively stayed vacatur by ten months, granting a *benefit* to Industry Appellants.

The only way the Remedial Order could be viewed as harmful to Industry Appellants is if their members had some entitlement to an exemption from the premarket review provisions. But as already explained, FDA lacked authority to exempt products from the TCA's clear requirements. *See supra* Part II.C.; *Nicopure*, 944 F.3d at 281 (FDA cannot make a "blanket rule excusing e-cigarettes from the premarket authorization requirement"). Industry Appellants' members have neither an entitlement to, nor a reasonable expectation of, FDA categorically withholding enforcement.

The E-Cigarette Associations contend that the district court lacked discretion to do anything but remand because "the procedural error" in this case was "a failure of notice-and-comment rulemaking."

Industry Br. 40. But their authority explicitly deals with cases where "*the only* statutory failure was of notice and comment." *In re Long-Distance Tel. Serv. Fed. Excise Tax Refund Litig.*, 751 F.3d 629, 634 (D.C. Cir. 2014) (emphasis added); *compare* Industry Br. 41 (quoting same language but omitting "the only"). While the E-Cigarette Associations consistently pretend that the only error in the 2017 Guidance was the failure to use notice-and-comment procedures, *e.g.*, Industry Br. 39-41, 44, the district court explicitly found far more. *E.g.*, App.90 ("[T]he FDA's action … is inconsistent with the Tobacco Control Act and in excess of its statutory authority, and it cannot stand.").

The E-Cigarette Associations' attempts to distinguish the authority relied upon by the district court fare no better. They ignore the caselaw showing that resetting lapsed deadlines is common. *See* App.109. They note that *Coalition for Government Procurement* "preserved agency discretion on remand," Industry Br. 44, but fail to acknowledge that the district court here *did* preserve the agency's discretion to do anything except issue another blanket exemption. And they disparage the "extraordinary circumstances" doctrine without identifying even a single case suggesting it is erroneous. Industry Br.

45-46.

The E-Cigarette Associations' contention that the district court was "obligated to remand this matter" for "formal notice-and-comment rulemaking under the Administrative Procedure Act," Industry Br. 2, is similarly wrong. They compare this case to entry of a consent decree negotiated by the parties, *see* Industry Br. 43-44, but such a comparison has no bearing on the validity of a court's order of limited injunctive relief after considering the adversarial positions of multiple parties.

This argument also misconstrues the district court's Summary Judgment Opinion. The court did not say that any guidance FDA ever issued would need to go through "notice-and-comment proceedings." Industry Br. 39. It merely observed that, if FDA wished to issue a new categorical "compliance period," it would need to "adhere to the notice and comment requirements of the APA." App.97; *see also* App.106 n.4 ("I did not suggest that the FDA needed to issue a formal regulation in lieu of guidance as it had done previously."). The fact that FDA would need to go through a notice-and-comment process if it wished to afford all manufacturers *more* than ten months does not preclude the district court from giving them that period as an exercise of equitable

authority.

The E-Cigarette Associations' argument is particularly ill-taken because the 2020 Guidance *was* accompanied by notice and comment. FDA issued a draft guidance in March 2019 and solicited comments in a Federal Register notice. 84 Fed. Reg. 9,345 (Mar. 14, 2019). It extended that period at manufacturers' request. 84 Fed. Reg. 14,120 (Apr. 9, 2019). And it ultimately received "approximately 15,467 comments," App.50, which it addressed in detail in the 2020 Guidance, App.219-39. If the E-Cigarette Associations see some way that this process failed to comply with the APA, they have not identified it.[17]

The E-Cigarette Associations insist that their products offer significant health benefits and help smokers quit, and that affirming the district court's orders would eliminate these benefits. They ask the Court to accept the possible benefits of e-cigarettes as an entire category, but Congress made the opposite choice. Congress required *individual products* to be authorized by the FDA, and only after they

[17] As noted above, the E-Cigarette Associations cannot use this case to challenge the 2020 Guidance. *See supra* at 25-26. Even if they could, they cannot propose flaws in the 2020 Guidance for the first time on reply. *See Brown*, 785 F.3d at 923.

prove themselves "appropriate for the protection of public health." 21 U.S.C. § 387j(c)(2)(A); *see Nicopure*, 944 F.3d at 281 ("There is no exemption in the Act for certain new tobacco products speculated to be less risky than other new tobacco products.").

Indeed, Congress went even further for products that claim to be healthier than cigarettes or useful as smoking cessation aids. Those claims need to be proven through even more rigorous standards. *See* 21 U.S.C. §§ 355, 387k; *see generally Nicopure*, 944 F.3d at 277-79, 284-90 (rejecting E-Cigarette Associations' challenge to these requirements). The E-Cigarette Associations ask this Court to do something Congress expressly chose not to do, and bless their wholesale entry into the market on the basis of claims FDA has not substantiated. Every prior smoking cessation aid—nicotine patches, nicotine gum, nicotine lozenges—has had to prove itself product-by-product to FDA, despite the potential health benefits they clearly represented. E-cigarette manufacturers, whose products have already caused an epidemic of nicotine use, are not entitled to an easier, judicially created path to market.

Moreover, as FDA has repeatedly said, "there is currently

insufficient data to draw a conclusion about the efficacy of e-cigarettes as a cessation device." App.113. While "*some* [e-cigarette] products may reduce harm at the individual level," App.542 (emphasis added), nobody knows which ones—and it is at least as well established that many e-cigarette products are extremely harmful. *See, e.g.*, 81 Fed. Reg. at 29,031; *Nicopure*, 944 F.3d at 274. In this regard, the E-Cigarette Associations and their *amici* rely on cherry-picked factoids and out-of-context statements, many of them outside the Administrative Record and some of them specifically criticized by the FDA.[18] Indeed, much of this purported data (including the E-Cigarette Associations' "open system" claims, Industry Br. 10, 13) was not presented to the district court until well after the Remedial Order, and is not properly before the Court. *See supra* at 6 n.2. And even if e-cigarettes' benefits had been established, several e-cigarette manufacturers have *already* filed premarket applications, eliminating any risk that smokers using e-cigarettes to quit combustible cigarettes will be left without any products whatsoever under the district court's order. *See* No. 19-2130,

[18] *Compare, e.g.*, Industry Br. 12 (relying on Public Health England paper) *with* 81 Fed. Reg. at 29,030 (extensively critiquing the paper).

ECF No. 47 (Plaintiffs' Opposition to E-Cigarette Associations' Motion for Stay Pending Appeal) at 18 & n.13.

Perhaps most importantly, *FDA itself* considered all of these assertions in the comment process for the 2020 Guidance, yet nevertheless decided—independent of the district court's order—to require e-cigarette manufacturers to submit *all* e-cigarette products to premarket review. App.214-15. The E-Cigarette Associations would thus have this Court overrule both Congress and FDA—in a matter in which the relevant FDA guidance is not even under review—for purely policy reasons directly contrary to the TCA.

Finally, the E-Cigarette Associations suggest that the district court did not properly weight its members' equities. But the only supposed equity they can identify is their members' interest in selling products *that cannot be lawfully sold*. The relief they demand is permission to violate the law with impunity; the harm they declaim is the possibility of facing consequences for these unlawful acts. There is no cognizable equity in such a request. Even if there were, the claim that manufacturers cannot comply with the TCA until FDA issues more guidance is "disingenuous[]," as the district court found. App.112.

Congress did not make the applicability of the premarket review provisions contingent on FDA issuing more guidance—and, in any event, FDA has provided ample guidance. *Id.*

5. The Cigar Associations' brief attack on the Remedial Order fails for essentially the same reasons.

There is no argument that the 2017 Guidance was lawful as to e-cigarettes but not as to cigars. Once that guidance was vacated, the Remedial Order was the only thing standing between the Cigar Associations' members and immediate enforcement, so they are not harmed in any way by the Remedial Order.

Moreover, contrary to the Cigar Associations' portrayal, the district court did evaluate the application of the Remedial Order to cigar products. In rejecting industry *amici*'s arguments below, it discussed the substantial equivalence process. App.112. All parties have agreed that this process generally applies to cigars but *not* e-cigarettes. *E.g.*, Industry Br. 38, 52.

If anything, cigar manufacturers have an even weaker claim to legitimate equities here than e-cigarette manufacturers. Thousands of cigars were on the market before February 15, 2007, meaning that the

Cigar Associations' members can continue to sell these "grandfathered" products without obtaining marketing orders. Any harm to cigar manufacturers from the possibility of enforcement flows from their choice to market new products. *See supra* at 11-13. And as the 2020 Guidance states, the "premium" cigars that the Cigar Associations emphasize are "FDA's lowest priority" for enforcement going forward. App.218. The only possible equity that the Cigar Associations can cite is their desire for *immunity* from enforcement. This is no equity at all.

2. The District Court's Decision Not to Remand Without Vacatur Was Not an Abuse of Discretion

Finally, the District Court did not abuse its discretion in rejecting the E-Cigarette Associations' request for remand without vacatur. *See* App.111 n.6. This Court has explicitly declined to "formally embrace[]" remand without vacatur and questioned its validity. *Sierra Club v. U.S. Army Corps of Eng'rs*, 909 F.3d 635, 655 (4th Cir. 2018). More importantly, it explained that, if remand without vacatur is permissible, it is unavailable where agency action "exceed[ed] [the agency's] statutory authority." *Id.* The E-Cigarette Associations ignore this binding precedent, just as they ignore the fact that the district court explicitly found that the 2017 Guidance was "in excess of [FDA's]

statutory authority." App.90; *see also* App.111 n.6.

CONCLUSION

For the foregoing reasons, the appeals should be dismissed; or, in the alternative, the district court's orders should be affirmed.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) and this Court's February 10, 2020 Order granting Plaintiffs-Appellees' Motion to Exceed Length Limitations, which authorized Plaintiffs-Appellees to file a brief containing 17,500 words, because it contains 17,491 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word for Office 365 in Century Schoolbook 14-point font, a proportionally spaced typeface.

/s/ Jeffrey B. Dubner
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ADDENDUM

TABLE OF CONTENTS

21 U.S.C. 387j – Application for review of certain tobacco products

(a) In general

(1) New tobacco product defined

For purposes of this section the term "new tobacco product" means--

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required

(A) New products

An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless--

(i) the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product--

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products

Subparagraph (A) shall not apply to a tobacco product--

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15,

2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period, except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

(3) Substantially equivalent defined

(A) In general

In this section and section 387e(j) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product--

(i) has the same characteristics as the predicate tobacco product; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

(B) Characteristics

In subparagraph (A), the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) Limitation

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(4) Health information

(A) Summary

As part of a submission under section 387e(j) of this title respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the

tobacco product or state that such information will be made available upon request by any person.

(B) Required information

Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

(b) Application

(1) Contents

An application under this section shall contain--

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 387g of this title which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

(2) Referral to Tobacco Products Scientific Advisory Committee

Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary--

(A) may, on the Secretary's own initiative; or

(B) may, upon the request of an applicant,

refer such application to the Tobacco Products Scientific Advisory Committee for reference and for submission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) Action on application

(1) Deadline

(A) In general

As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall--

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) Restrictions on sale and distribution

An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title.

(2) Denial of application

The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that--

(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard.

* * *

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