Nos. 19-2130, -2132, -2198 & -2242

IN THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

AMERICAN ACADEMY OF PEDIATRICS, et al.,

Plaintiffs-Appellees,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants-Appellants,

E-LIQUID MANUFACTURING STANDARDS ASSOCIATION, et al.,

Intervenors-Appellants, and

CIGAR ASSOCIATION OF AMERICA, et al.,

Appellants.

On Appeal from the United States District Court
for the District of Maryland

BRIEF FOR THE FEDERAL APPELLANTS

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INTRODUCTION

This suit concerns the timetable on which the Food and Drug Administration (FDA) was previously enforcing certain provisions of the Family Smoking Prevention and Tobacco Control Act that require manufacturers of e-cigarettes, cigars, and other tobacco products to submit applications for FDA review prior to selling or marketing their products. The validity of those statutory provisions, and the validity of an implementing regulation issued by FDA in 2016, are not at issue in this suit.

Plaintiffs challenge an August 2017 guidance in which FDA stated that it planned to defer enforcement of certain of these requirements until 2021 for combustible products (like cigars), and until 2022 for noncombustible products (like most e-cigarettes). The district court vacated the August 2017 guidance, and later directed FDA to require manufacturers to submit premarket-review applications by May 12, 2020 or face the threat of enforcement proceedings. The government and a number of tobacco-industry groups that sought to intervene in district court appealed.

Subsequent to the district court's decision, FDA issued a new guidance in January 2020. That guidance describes how FDA intends to prioritize enforcement for statutory premarket-review requirements for deemed products that were on the market as of August 8, 2016. FDA intends to enforce premarket-review requirements beginning on February 6, 2020 for flavored, cartridge-based e-cigarette products (other than tobacco- or menthol-flavored products) because they pose a particular risk of youth use. FDA also intends to prioritize enforcement of requirements for those

e-cigarette products for which manufacturers have failed to take adequate measures to prevent minors' access or that are targeted to minors or whose marketing is likely to promote use by minors. For all other e-cigarette products, FDA intends to prioritize enforcement of the premarket-review requirements by May 12, 2020, the same date as the district court's remedy order. The guidance makes clear that FDA retains discretion to pursue enforcement action "at any time against any deemed new tobacco product marketed without premarket authorization, regardless of whether it falls within one of these categories of enforcement priorities," App. 198, and that, for cigar products in particular, it will "make enforcement decisions on a case-by-case basis" after May 12, 2020, and that it intends to prioritize based on "the likelihood of youth use or initiation," App. 218. FDA explained that it "is continuously evaluating new information and adjusting its enforcement priorities in light of the best available data," and that it "will take appropriate action regarding tobacco products that are marketed without premarket authorization, including as warranted based on changed circumstances, new information, or to better address minors' use of those products." *Id.*

1. The January 2020 guidance fundamentally alters the previous premises of this litigation. The district court's order vacated a guidance document that has now been superseded. Because the enforcement timetable for e-cigarettes set out in the January 2020 guidance is independent of the district court's order, an order by this Court reversing the district court would have no effect on FDA's enforcement of the

statute and regulations against e-cigarette manufacturers. The e-cigarette organizations' appeal from the district court's orders is thus moot and should be dismissed.

2. Although the cigar associations' appeal may not be entirely moot, there is no reason to consider their contentions with respect to the district court's timetable because the court did not abuse its discretion in denying the cigar associations' motion to intervene. The cigar associations sought to intervene four months after the district court's summary judgment order and two months after its remedy order. And they were aware that the 2017 guidance was always subject to change and that FDA had, in fact, proposed changes to its enforcement policy with regard to flavored cigars in March 2019. Moreover, the cigar associations have no legally protectable interest of the kind that would support intervention: they have always been subject to the requirements of the Tobacco Control Act, and the 2017 guidance provided no legal entitlement to be free from FDA enforcement.

3. If this Court agrees that the e-cigarette organizations' appeal is moot and that the cigar associations' attempt to intervene was properly denied, the government respectfully requests that the Court dismiss the government's appeal rather than adjudicating the merits of this case. Otherwise, the Court should reverse the judgment of the district court on three threshold grounds.

First, the district court erred in concluding that plaintiffs had demonstrated standing on the basis of an asserted "informational" injury. Plaintiffs have identified

no statutory right to information provided in premarket-review applications. Indeed, the sole provision of the Tobacco Control Act that the district court cited in concluding that plaintiffs have a right to information does not govern the premarket tobacco application pathway applicable to the products (like e-cigarettes) with which plaintiffs are principally concerned and thus has no bearing on the public disclosure of information provided to the agency through that process. Plaintiffs' claim to standing on non-informational grounds, which the district court did not address, likewise lacks merit.

Second, FDA's choice of when and how to enforce a particular statutory provision is committed to its discretion by law. Such choices involve the consideration of many factors that the agency is uniquely positioned to evaluate, and it is well established that such decisions are therefore generally not subject to judicial review. The district court identified no circumstances that implicate an exception to the general rule that courts will not intrude into the exercise of an agency's enforcement discretion.

Third, FDA's August 2017 guidance is not final agency action subject to judicial review. The guidance reflected the agency's then-current thinking about its enforcement policy that by its terms was subject to change and did not alter the legal obligations of any party. As the district court recognized, FDA retained authority to enforce the provisions it administers at any time and for any reason. The court erred

in concluding that the guidance was a rule that suspended the substantive requirements of the Tobacco Control Act.

STATEMENT OF JURISDICTION

Plaintiffs assert claims against FDA under the Administrative Procedure Act (APA), 5 U.S.C. § 706. The jurisdiction of the district court was invoked under 28 U.S.C. § 1331. The district court entered an injunction on July 12, 2019, App. 105, and entered a judgment order on November 5, 2019, App. 125. The industry groups filed timely notices of appeal on October 10, 2019. App. 765, 768. The government filed a timely notice of appeal on October 24, 2019. *See* App. 770; Fed. R. App. P. 4(a)(1)(B), (a)(3). This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

1. Whether FDA's January 2020 guidance moots the e-cigarette organizations' appeal.
2. Whether the district court abused its discretion in denying the cigar associations' motion to intervene.
3. Whether the district court's judgment should be reversed because:

   (a) plaintiffs lack standing to challenge FDA's August 2017 guidance; (b) the determination of enforcement priorities set out in the August 2017 guidance is action committed to agency discretion by law and thus unreviewable under the APA; and (c) the August 2017 guidance was not final agency action subject to review.

PERTINENT STATUTES

Pertinent statutes are reproduced in the addendum to this brief.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background

1. The Family Smoking Prevention and Tobacco Control Act

This case involves a challenge to an August 2017 FDA guidance that was superseded by another FDA guidance issued in January 2020. This case does not involve the merits of the statutory or regulatory provisions that impose substantive requirements on tobacco-product manufacturers. We provide that statutory and regulatory background to place the suit in context.

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (TCA) to (among other goals) reduce the use of tobacco products by children and adolescents, concluding that the use of such products constituted a "pediatric disease of considerable proportions." Pub. L. No. 111-31, div. A, § 2(1), 123 Stat. 1776, 1777 (2009) (reprinted at 21 U.S.C. § 387 note). Congress sought to address this critical problem by "provid[ing] authority to the Food and Drug Administration to regulate tobacco products . . . , by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products." *Id.* § 3(1), 123 Stat. at 1781 (reprinted at 21 U.S.C. § 387 note). The statute accordingly "provide[d] new and flexible enforcement authority to ensure that there is effective oversight of the tobacco industry's efforts to

develop, introduce, and promote less harmful tobacco products." *Id.* § 3(4), 123 Stat. at 1782.

As the D.C. Circuit recently explained, Congress in enacting the statute "insisted on 'comprehensive restrictions on the sale, promotion, and distribution' of tobacco products." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 272 (D.C. Cir. 2019) (quoting TCA § 2(6), 123 Stat. at 1777). The Tobacco Control Act therefore requires tobacco manufacturers to obtain premarket authorization before introducing a "new tobacco product" into interstate commerce. 21 U.S.C. § 387j(a)(1)-(2). A "tobacco product" is "any product made or derived from tobacco that is intended for human consumption." *Id.* § 321(rr)(1). And a "tobacco product" is "new" if it was not commercially marketed in the United States on or before February 15, 2007, or if it was modified after that date. *Id.* § 387j(a)(1)(A)-(B).

The statute sets forth multiple paths for tobacco manufacturers to seek premarket authorization.

First, a manufacturer may file a premarket tobacco application. 21 U.S.C. § 387j(b)-(c). That application must contain information concerning the product's health risks, a statement of the product's ingredients, specified manufacturing information, and samples of the product and its proposed labeling. *Id.* § 387j(b). "As

promptly as possible," and no later than 180 days after receiving the application, FDA shall grant or deny the application.[1] *Id.* § 387j(c).

Second, a manufacturer may avoid filing a premarket tobacco application if it can demonstrate that its product is "substantially equivalent" to a product that was marketed on or before February 15, 2007 (or a product that has already been found to be substantially equivalent). 21 U.S.C. §§ 387e(j)(1), 387j(a)(2)(A).

Third, if FDA concludes, among other requirements, that a change to a tobacco additive in a tobacco product is a "minor modification" of a tobacco product that can be sold under the TCA, the agency may exempt manufacturers from demonstrating substantial equivalence. 21 U.S.C. § 387e(j)(3)(A). More novel products such as e-cigarette products generally cannot claim to be substantially equivalent to a tobacco product on the market as of February 15, 2007, and it is expected they will proceed through the first premarket tobacco application pathway.

Failure to obtain authorization pursuant to an appropriate pathway may carry serious consequences. A tobacco product that is marketed without appropriate authorization is "adulterated" and "misbranded" within the meaning of the TCA and the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.* 21 U.S.C. §§ 387b(6), 387c(a)(6). FDA may file a civil action to enjoin illegal conduct, *id.* § 332,

[1] The Act gives various responsibilities to the Secretary of the U.S. Department of Health and Human Services. The Secretary carries out these responsibilities through the FDA Commissioner. *See* 21 U.S.C. § 393(d)(2). This brief therefore refers to FDA rather than to the Secretary.

or to seize the adulterated and misbranded products, *id.* § 334. The agency may also seek criminal penalties. *Id.* § 333.

2. FDA's Deeming Rule

Congress did not make the Tobacco Control Act's many provisions immediately applicable to all "tobacco products." Instead, it determined that the provisions in Chapter IX of the statute would apply to "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," as well as to "any other tobacco products that [FDA] by regulation deems to be subject" to the Act's requirements. 21 U.S.C. § 387a(b).

In May 2016, FDA exercised its authority to promulgate a rule (the "deeming rule") that deemed all products that meet the definition of "tobacco product" (except accessories) to be subject to Chapter IX of the statute. 81 Fed. Reg. 28,973, 28,975 (May 10, 2016); *see* 21 C.F.R. § 1100.1. These products include cigars, pipe tobacco, and electronic nicotine delivery systems (e-cigarettes).[2] 81 Fed. Reg. at 28,982.

Recognizing the demands that the rule placed on its own enforcement resources as well as the resources of manufacturers, in the preamble to the deeming rule, FDA announced "staggered compliance periods" for certain provisions as applied to deemed tobacco products that were already on the market on the effective

[2] This brief uses "e-cigarettes" to refer to all electronic nicotine delivery systems, often referred to as "vaping" devices, including e-cigars, e-hookah, vape pens, personal vaporizers, and electronic pipes. *See* 81 Fed. Reg. at 29,028.

date of the rule. 81 Fed. Reg. at 29,010. As relevant here, FDA announced initial twelve-to-twenty-four-month compliance periods for manufacturers of "new tobacco products" regarding the requirement to seek premarket authorization. *Id.* FDA also announced that it would continue to exercise "enforcement discretion" for an additional one-year period. *Id.* at 29,014. During that time, FDA explained that it did not intend to seek to administratively or judicially enforce the statutory premarket-review requirements for products for which premarket submissions were made during the initial compliance period. *Id.* Together, these two periods meant that FDA did not intend to enforce the TCA's premarket-review requirements for most deemed tobacco products until 2018. FDA explained that its decision to defer enforcement of premarket-review requirements was informed by, among other things, the possibility that some products could play a role in helping tobacco users transition away from combusted tobacco products, like cigarettes, which are likely the most harmful form of nicotine delivery for an individual user. *Id.* at 29,011.

Tobacco manufacturers and associations filed multiple challenges to the deeming rule. In December 2019, the D.C. Circuit rejected the remaining challenges on appeal in the leading e-cigarette case, *Nicopure*, explaining that the deeming rule reasonably subjected e-cigarettes to the TCA's premarket-review requirements, 944 F.3d at 281-82, and that extending other requirements of the TCA to e-cigarettes did not violate the First Amendment, *id.* at 282-91. *See id.* at 273 ("FDA's Deeming Rule cited to a robust body of scientific evidence about the uses and risks of e-cigarettes

and explained in detail how the evidence informed the agency's decision to subject them to the Act's requirements.").

B. FDA's 2017 Enforcement Guidance And The Present Suit

1. The 2017 Guidance

In May and August 2017, FDA announced changes to the agency's priorities with respect to enforcement of premarket-review requirements for particular products. In May 2017, FDA announced that it would not prioritize enforcement of premarket-review requirements (and other requirements not at issue here) for an additional three months beyond the dates set forth in the preamble to the deeming rule. App. 126-38.

In August 2017, FDA again revised its enforcement priorities, App. 139-52, resulting in "a further extension of certain future compliance deadlines for requirements under the final deeming rule," App. 143. This further extension applied only to products on the market as of the effective date of the deeming rule, and "only to compliance deadlines relating to" the TCA's "premarket review requirements." *Id.* Under the revised guidance, FDA did not intend to enforce premarket-review requirements for combustible products (like cigars) until August 2021, or until August 2022 for noncombustible products (like most e-cigarettes). *Id.* The guidance also announced that FDA did not intend to initiate enforcement against a tobacco manufacturer "until the agency renders a decision on [the manufacturer's] application . . . or the application is withdrawn." *Id.* The guidance emphasized that it "represents

the current thinking" of the agency, "do[es] not establish legally enforceable responsibilities," and "is not binding on FDA or the public." App 141.

2. Proceedings Below

a. Plaintiffs are six public-health organizations and five pediatricians. App. 299-304 (Compl. ¶¶ 8-13). They filed this action in March 2018, contending that the August 2017 guidance violated the TCA and the Take Care Clause, U.S. Const. art. II, § 3, should have been issued through the APA's notice-and-comment procedures, and was arbitrary and capricious.

To establish standing, plaintiffs alleged two categories of injury. First, they claimed that the guidance caused a delay in premarket tobacco applications, and that those applications would have provided plaintiffs with useful information. App. 309-13 (Compl. ¶¶ 34-41). Second, plaintiffs asserted that the guidance required them to "spend substantial resources to counter the effects of FDA's decision to exempt, for years, manufacturers of deemed products from statutory premarket approval requirements." App. 313 (Compl. ¶ 42); *see* App. 313-17 (Compl. ¶¶ 42-51). Plaintiffs moved for summary judgment, and the government moved to dismiss or, in the alternative, for summary judgment. *See* App. 48.

b. The district court granted plaintiffs' motion for summary judgment in May 2019. App. 51.

The court first concluded that plaintiffs had Article III standing. App. 57-67. It began its analysis by noting that the Tobacco Control Act requires FDA to disclose

to the public certain information and data thirty days after the agency determines whether a deemed tobacco product is substantially equivalent to a product that was on the market when the TCA was enacted. App. 61 (citing 21 U.S.C. § 387j(a)(4)(B)). The court therefore determined that, by allowing manufacturers to delay in submitting premarket applications, FDA's guidance denied plaintiffs "access to information required to be disclosed by statute." App. 61-62 (quoting *Dreher v. Experian Info. Sols., Inc.*, 856 F.3d 337, 345 (4th Cir. 2017)). The court concluded that plaintiffs suffer "the type of harm Congress sought to prevent by requiring disclosure," because Congress enacted the TCA in part to ensure that consumers are better informed about tobacco risks. App. 62 (quoting *Dreher*, 856 F.3d at 345 (emphasis omitted)). The court thus found it unnecessary to reach plaintiffs' claimed injury based on the alleged expenditure of additional funds.

The district court also concluded that the August 2017 guidance was subject to judicial review under the APA. App. 67-79. The court acknowledged that "the presumption is that judicial review is not available" for an agency's "[r]efusal to take enforcement steps." App. 67 (quoting *Heckler v. Chaney*, 470 U.S. 821, 831 (1985) (alteration in original)). But the court concluded that, in this case, "statutory language . . . constrains the agency's exercise of its enforcement discretion." App. 68 (quotation marks and citation omitted). That was so, the district court believed, because the Tobacco Control Act requires tobacco manufacturers to submit premarket applications, requires FDA to act on those applications within a set time,

and requires FDA to deny those applications if certain criteria are not met. App. 75-76. The court concluded that those mandatory provisions governing FDA's review of submitted applications were unlike the permissive enforcement provisions in *Chaney* and fettered FDA's enforcement discretion in establishing an enforcement timetable. The district court also concluded that the August 2017 guidance was final agency action and therefore reviewable under the APA. App. 79-85.

Having concluded that the case was justiciable, the district court held that the August 2017 guidance was unlawful because it was inconsistent with the TCA's mandatory language, App. 86-90, and because it found it was "a legislative, rather than interpretive, rule" that required notice and comment, App. 91-97.

c. After further briefing, the district court issued its remedy order in July 2019. The district court acknowledged "FDA's laudable efforts to guide the premarket approval process," App. 107, and observed that FDA created a "commendable record detailing [its] own resources and ability" to review premarket applications, App. 110. At the same time, the court noted "purposeful avoidance by the [tobacco] industry of complying with the premarket requirements." App. 113. The court therefore directed FDA to require all premarket applications to be filed by May 12, 2020, consistent with FDA's alternative request, in the event remand were denied, that the court not adopt an application deadline sooner than ten months after its order. App. 114. The court's order provided that:

> 1. The FDA shall require that, for new tobacco products on the market as of the August 8, 2016 effective date of the Deeming Rule ("New Products"), applications for marketing orders must be filed within 10 months of the date of this Memorandum Opinion and Order;
>
> 2. New Products for which applications have not been filed within this period shall be subject to FDA enforcement actions, in the FDA's discretion;
>
> 3. New Products for which applications have been timely filed may remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application;
>
> 4. The FDA shall have the ability to exempt New Products from filing requirements for good cause on a case-by-case basis.

App. 116.

The district court later modified the order to clarify that it "does not restrict the FDA's authority to enforce the premarket-review provision against deemed products, or categories of deemed products, before the close of either the 10-month application submission period or the FDA application review period described above." App. 117. The government filed a timely notice of appeal from the district court's orders. App. 770; *see* Fed. R. App. P. 4(a)(3).

d. After the district court issued its merits decision, the e-cigarette organizations and other tobacco manufacturers and trade associations (but not the cigar associations that have appealed here) moved to intervene. The district court denied many of those motions, in part because they were not timely, and reasoned that the industry groups could effectively participate as amici. App. 101-04; *see also* Dkt. No. 91 (paperless order). The e-cigarette organizations joined with other

tobacco industry members to file an amicus brief; the cigar associations did not join that brief. Following the entry of the remedy order, the court granted a motion to intervene filed by e-cigarette organizations, concluding that the briefing on the court's remedy order showed that the government's interests were not entirely aligned with those organizations' interests. App. 119-22. At the same time, the court denied an intervention motion filed by cigar associations (who also represent the interests of the pipe-tobacco industry), ruling that the motion was "untimely" because the cigar associations "have been aware for months" of their stated need to intervene, and because "final judgment has been entered in this case." App. 123-24. Both the e-cigarette organizations and the cigar associations filed timely notices of appeal. App. 768; App. 770.

C. FDA's Reevaluation and the January 2020 Guidance

1. After issuing its August 2017 guidance, FDA continued to assess the public health impact of various tobacco products. In late 2017, FDA saw a marked increase in complaints about e-cigarettes, particularly in connection with minors' access and use. FDA responded by taking a number of regulatory and enforcement actions, and in September 2018 it announced it was considering whether to revisit the enforcement priorities set forth in the 2017 guidance. *See* Press Release, FDA, *FDA Takes New Steps To Address Epidemic of Youth E-Cigarette Use* (Sept. 11, 2018), https://go.usa.gov/xdrB6.

Before the district court's decision, in March 2019, citing recent evidence of increased youth use, FDA requested public comment on a draft guidance proposing revised enforcement priorities for certain deemed tobacco products that present a heightened risk of youth use. *See* App. 167-86. FDA received more than 15,000 comments on the draft guidance.

2. On January 2, 2020, FDA finalized its new guidance. App. 187-239. The new guidance notes data showing that e-cigarette use more than doubled among middle- and high-school students from 2017 to 2019. App. 199 (citing Richard Miech et al., *Trends in Adolescent Vaping, 2017-2019*, 381 New Eng. J. Med. 1490 (2019)). FDA's new guidance states that FDA intends to prioritize enforcement of the Tobacco Control Act's premarket-review requirements beginning on May 12, 2020 for all e-cigarette products. App. 198. FDA intends to prioritize enforcement sooner for flavored, cartridge-based e-cigarette products (except for menthol and tobacco flavors); all other e-cigarette products for which the manufacturer fails to take adequate measures to prevent minors' access; and all e-cigarette products that are targeted to, or whose marketing is likely to promote use by, minors. App. 197. FDA also explained that with respect to all other deemed products, after May 12, 2020, it intends to "make enforcement decisions on a case-by-case basis" based on "the likelihood of youth use or initiation." App. 218. The guidance also confirms that FDA "retains discretion to pursue enforcement action at any time against any deemed new tobacco product marketed without premarket authorization, regardless of

whether it falls within one of these categories of enforcement priorities." App. 198. FDA's January 2020 guidance issued after these appeals were docketed.

SUMMARY OF ARGUMENT

I. The Court should dismiss the e-cigarette organizations' appeal as moot. The January 2020 guidance supersedes the challenged guidance in all relevant aspects. The new guidance prioritizes enforcement for all e-cigarette products that lack a premarket application starting in May 2020. The guidance will continue to reflect the agency's enforcement priorities as to e-cigarettes regardless of a ruling by this Court vacating the district court's decision. Thus, even if the district court's orders were reversed, FDA would still enforce the Tobacco Control Act's requirements in May 2020 (or sooner) as to all e-cigarettes according to the agency's newly announced guidance. Because the Court cannot grant effective relief to the e-cigarette organizations, dismissal is required.

II. The district court did not abuse its discretion in denying the cigar associations' motion to intervene. The cigar associations sought to intervene only after the district court ruled on summary judgment and entered an injunction; unlike the other industry representatives, the cigar associations declined to participate in the remedy proceedings below. The cigar associations attempt to excuse their late filing on the ground that they were previously unaware of any divergence between their interests and those of the government. But FDA had made clear that the 2017 guidance was subject to change, and it had announced more than nine months prior

to the associations' intervention motion that the agency was considering prioritizing enforcement of flavored cigars. In any event, the cigar associations have no legally protected interest of the kind necessary to support intervention. Since the deeming rule was promulgated, they have been subject to the requirements of the Tobacco Control Act, and the 2017 guidance conferred no right to be free from FDA enforcement of those provisions.

III. If the Court dismisses the e-cigarette organizations' appeal as moot and rejects the cigar associations' appeal of their intervention order, there is no occasion to consider other issues potentially raised by these appeals. If the Court decides it does need to reach those issues, it should reverse for three threshold reasons.

A. The district court erred in concluding that plaintiffs demonstrated Article III standing on the basis of an asserted informational injury. Such an injury is judicially cognizable only if a statute gives a plaintiff the right to the information that it seeks. In this case, plaintiffs have no statutory right to the information that they seek, and they have never alleged that they would benefit from the limited categories of information for which the statute requires disclosure.

The district court did not address plaintiffs' claim of organizational standing based on non-informational interests, and that argument fares no better. Plaintiffs contend that enforcement of premarket-review requirements for new tobacco products limits those products' presence on the market and decreases plaintiffs' need to inform the public of the dangers of tobacco use. But plaintiffs cannot challenge

the FDA's decision to enforce or not enforce the TCA against any tobacco manufacturer. And their claims that they have lost resources due to FDA's August 2017 guidance are far too attenuated to suffice for Article III standing.

B. The district court also erred in concluding that FDA's August 2017 guidance was subject to judicial review. In *Heckler v. Chaney*, 470 U.S. 821 (1985), the Supreme Court made clear that an agency's decisions concerning when not to enforce the laws that it administers are committed to the agency's discretion and presumptively unreviewable by the federal courts. That presumption, the Court explained, was warranted in light of the many policy factors that go into each decision whether to enforce the law, which agencies traditionally resolve for themselves. Here, as in *Chaney*, FDA has consistently explained that its enforcement priorities are shaped by complex and frequently changing public-health considerations, as well as resource constraints, which entail policy decisions unsuited to judicial review.

No exception to the *Chaney* presumption applies to this case. The text of the Tobacco Control Act does not constrain the agency's discretion in any relevant respect because it nowhere directs the agency when to enforce (or not enforce) any of its substantive provisions. Likewise, this is not a case in which an agency has wholly abdicated its statutory responsibilities. FDA has consistently worked to protect the public health through its tobacco policy and has regularly revised its enforcement priorities to reflect new information regarding the risks presented by these products.

C. The August 2017 guidance is not final agency action subject to judicial review. The guidance reflected the agency's then-current enforcement policy and did not alter or impose any substantive requirements on any entity. The relevant substantive requirements have always been those established by the TCA and the deeming rule, which are not at issue in this case. The guidance, which expressed FDA's thinking regarding the appropriate approach to enforcement of those requirements, was, by its terms, subject to change. Indeed, FDA had provided notice that it was reevaluating that guidance well before the district court issued its orders, and it has since announced new enforcement priorities based on new information regarding the public risks presented by these products.

STANDARD OF REVIEW

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

ARGUMENT

I. FDA's January 2020 guidance moots the e-cigarette organizations' appeal.

The district court concluded that FDA's August 2017 guidance was final agency action subject to judicial review. It set aside that guidance and ordered the agency to act on a timetable entered by the court.

The FDA guidance issued on January 2, 2020 supersedes the enforcement priorities set forth in FDA's August 2017 guidance in all relevant aspects. Specifically, beginning on February 6, 2020, FDA intends to prioritize enforcement with respect to flavored, cartridge-based e-cigarette products (except for menthol and tobacco flavors); other e-cigarette products for which the manufacturer fails to take adequate measures to prevent minors' access; and all e-cigarette products that are targeted to, or whose marketing is likely to promote use by, minors. App. 190. The new guidance reflects FDA's particular concern with the rising use of e-cigarettes by youth by prioritizing enforcement with respect to those products and circumstances that present the greatest risk of youth use. For all other e-cigarettes, the new guidance will prioritize enforcement with respect to any product for which the manufacturer has not filed a premarket tobacco application by May 12, 2020. *Id.*

This new guidance moots the e-cigarette organizations' appeal. "[T]he parties' stake in the outcome of the case must exist not only at the case's inception, but for the entire duration of the proceedings." *CVLR Performance Horses, Inc. v. Wynne*, 792

F.3d 469, 474 (4th Cir. 2015). Thus, "[l]itigation may become moot during the pendency of an appeal when an intervening event makes it impossible for the court to grant effective relief to the prevailing party." *Id.* And "[i]f an event occurs while a case is pending on appeal that makes it impossible for the court to grant any effectual relief whatever to a prevailing party, the appeal must be dismissed." *Incumaa v. Ozmint*, 507 F.3d 281, 286 (4th Cir. 2007) (quoting *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992)) (alteration omitted).

At this juncture, reversal of the district court's orders would afford no relief to the e-cigarette organizations. The January 2020 guidance adopts the May 2020 compliance deadline as the agency's own, "independent[]" of the district court's order. App. 215. Because the enforcement priorities set out in the January 2020 guidance would be in place even if this Court were to reverse the district court's order, reversal would have no practical effect on FDA's enforcement of the statute. "The subject matter" of the e-cigarette organizations' appeal "no longer has any force," and the "controversy surrounding it has been mooted." *Center for Sci. in the Pub. Interest v. Regan*, 727 F.2d 1161, 1164 (D.C. Cir. 1984). The e-cigarette organizations' appeal should therefore be dismissed.

II. The district court correctly denied the cigar associations' motion to intervene.

Although the January 2020 guidance may not moot all aspects of the district court's order with respect to cigars, the Court need not reach the cigar manufacturers'

challenge to the merits of the district court's ruling because the court did not abuse its discretion in denying their motion to intervene. App. 122-24.

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

Although the complaint in this case was filed in March 2018, the cigar associations did not seek to intervene until September 2019, App. 745, two months after the district court entered its remedy order, and four months after it entered its summary judgment order. Unlike the e-cigarette organizations and other groups, the cigar associations did not participate in any remedies briefing before the district court. "In such circumstances, the court was reasonably reluctant to arrest the momentum of the lawsuit so near to its final resolution." *Alt*, 758 F.3d at 591. At the very least, the district court did not abuse its discretion in refusing to entertain the cigar associations' late-breaking motions.

The cigar associations have sought to excuse their delay on the ground that they previously believed that the government was adequately representing their

interests, and there was thus no basis for seeking leave to intervene. Cigar Associations' Stay Reply 8; *see Stuart*, 706 F.3d at 348. That assertion mistakes the nature of FDA's enforcement guidance and the agency's statements. Since August 2016, manufacturers of deemed products have been legally required to submit applications for premarket review or demonstrate substantial equivalence. While the 2017 guidance stated that FDA at that point did not intend to prioritize enforcement of those requirements for combustible products like cigars until 2021, the guidance made clear that the agency's priorities were subject to change. In November 2018, FDA issued a statement announcing its intent to modify the August 2017 enforcement policy, including to begin prioritizing enforcement of flavored cigars. FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on Proposed New Steps To Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes* (Nov. 15, 2018), https://go.usa.gov/xdrKU. And in March 2019, FDA published a draft guidance document that proposed, *inter alia*, to "prioritize enforcement of actions with respect to flavored cigars," App. 182, thereby putting manufacturers on notice that FDA was considering altering its enforcement priorities.

Despite FDA's repeated announcements that the agency's priorities might be shifting and that FDA might be considering the appropriateness of enforcement prior to 2021, the cigar associations waited an additional nine months before contending that their interests were not aligned with the government's insofar as this litigation is concerned. Their behavior is in marked contrast with the other would-be intervenors,

including the e-cigarette organizations, that sought intervention promptly after the district court entered its merits ruling, and that participated as amici before the district court.[3] Under these circumstances, the district court reasonably concluded that the cigar associations should not be allowed to intervene after the proceedings had concluded, thereby disrupting the parties' expectations and the orderly proceeding of the litigation.

B. Even apart from issues of timeliness, the industry groups lack a "significantly protectable interest" in this litigation. *Teague v. Bakker*, 931 F.2d 259, 261 (4th Cir. 1991). They have no substantive right to avoid the Tobacco Control Act's premarket-review provision, which has applied to them since the deeming rule took effect in August 2016. And nothing in the challenged August 2017 guidance conferred any legal entitlement to deferred enforcement of that provision. On the contrary, the guidance emphasized that it "reflect[ed] the current thinking" of the agency and was "not binding on FDA or the public." App. 141; *see supra* p. 12. As the district court recognized in response to the government's request for clarification, FDA retained the authority to enforce the TCA's requirements at any time, regardless

[3] In an action pending in the United States District Court for the District of Columbia, the cigar associations requested that the court exempt them from the district court's judgment in this case. That request was unsuccessful; the district court there noted that, "[b]ecause Plaintiffs delayed in raising their concerns before the *AAP* court, their conduct weighs against granting the extraordinary relief they now request." *Cigar Ass'n of Am. v. FDA*, No. 1:16-cv-1460, 2019 WL 6647261, at *2 (D.D.C. Oct. 18, 2019).

of any guidance document. *See* App. 117. The industry groups therefore have no "legally protected interest" in any enforcement timetable, *SEC v. Prudential Securities Inc.*, 136 F.3d 153, 156 (D.C. Cir. 1998), and the district court's denial of the cigar associations' motion to intervene should alternatively be affirmed on that ground. For similar reasons, the district court erred in permitting the e-cigarette organizations to intervene.

III. In the alternative, this Court should reverse the district court's judgment.

Because the e-cigarette organizations' appeal is moot, and because the cigar associations' motion to intervene was properly denied, neither of the intervenor groups may appeal the district court's summary-judgment and remedy orders. If this Court agrees, the government does not wish to maintain its separate appeal, and it thus respectfully requests that the Court dismiss the government's appeal rather than adjudicating the merits of this case. *See* Fed. R. App. P. 42(b). If, however, the Court determines that either group of intervenors is entitled to challenge the district court's orders, then the government wishes to maintain its appeal to protect its interests, and urges that this Court reverse three of the district court's threshold determinations.

A. Plaintiffs lack standing to challenge the August 2017 guidance.

To satisfy Article III's standing requirements, plaintiffs must show, *inter alia*, that they have "suffered an 'injury in fact'" that is "concrete and particularized" and "actual or imminent." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). If a

plaintiff "is himself an object of the action" challenged, there is "ordinarily little question" that the plaintiff can demonstrate an injury. *Id.* at 561. But where, as here, "a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else*, much more is needed." *Id.* at 562; *see also id.* (noting that standing in those circumstances is "substantially more difficult" to establish).

In this case, the public-health organizations and pediatricians allege two species of injury. First, they claim that the August 2017 guidance deprives them of information that would further the interests of their respective organizations or medical practice. *See* App. 309-13 (Compl. ¶¶ 34-41). Second, they assert that the guidance forces them to expend additional resources to address the health risks presented by tobacco products. *See* App. 313-17 (Compl. ¶¶ 42-51). Neither of these assertions gives rise to a concrete and imminent harm fairly traceable to the August 2017 guidance sufficient to establish standing.

1. Plaintiffs cannot demonstrate informational standing.

Both the organizational and individual plaintiffs argue that they have suffered an "informational injury," a type of intangible injury that can, in some circumstances, suffice for standing purposes. *See FEC v. Akins*, 524 U.S. 11, 24 (1988). As this Court recently explained, a "constitutionally cognizable informational injury" requires the plaintiff to demonstrate (1) that it "lack[s] access to information to which [it] is legally entitled," and (2) "that the denial of that information creates a 'real' harm with

an adverse effect." *Dreher v. Experian Info. Sols., Inc.*, 856 F.3d 337, 345 (4th Cir. 2017) (quoting *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016)). In order to satisfy the first requirement, a plaintiff must show that it "is denied access to information required to be disclosed by statute." *Id.*

That requirement is fatal to plaintiffs' claims of informational injury. Plaintiffs principally contend that they are injured because the August 2017 guidance makes it less likely that tobacco manufacturers will submit premarket tobacco applications to FDA, which in turn makes it less likely that FDA will issue orders approving or denying those applications. App. 309 (Compl. ¶ 35). And plaintiffs observe that FDA, as a matter of practice and its own regulations, makes those orders available to the public, thereby increasing the availability of certain information potentially useful to plaintiffs in advancing their organizational interests and in treating their patients. App. 309, 316 (Compl. ¶¶ 35, 49); *see* 21 C.F.R. § 814.9. But plaintiffs do not cite any statute that requires the disclosure of that information to plaintiffs or to the general public, and no such statute exists. Accordingly, plaintiffs cannot demonstrate that they have been "denied access to information required to be disclosed by statute." *Dreher*, 856 F.3d at 345; *see Salt Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006) ("Because the statute upon which appellants rely does not grant the rights that appellants claim were invaded, appellants cannot establish an injury in fact."); *cf. Nader v. FEC*, 725 F.3d 226, 229 (D.C. Cir. 2013) ("Only if the statute grants a plaintiff a concrete interest in the information sought will he be able to assert an injury in fact.").

The district court concluded that plaintiffs have informational standing because a provision of the TCA provides that tobacco manufacturers that seek to market their products on the grounds that the products are substantially equivalent to a product on the market in 2007 must "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." 21 U.S.C. § 387j(a)(4)(A); *see id.* § 387e(j); *see also supra* p. 8 (explaining the substantial-equivalence pathway). That "summary . . . shall be made available to the public by [FDA] within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product." 21 U.S.C. § 387j(a)(4)(B).

By its terms, the disclosure provision on which the district court based its ruling applies only to manufacturers who do not file premarket tobacco applications, and who instead seek to demonstrate that their products are "substantially equivalent" to products previously on the market. 21 U.S.C. § 387j(a)(2); *see supra* p. 8. The summaries of health information in authorized substantial-equivalence reports (which are the only summaries that are disclosed by statute) will not contain information about new or previously unknown risks; the entire premise of that pathway is that the product for which the manufacturer is seeking authorization is not new in any relevant sense and does not present novel risks. Provisions governing the substantial-equivalence pathway have no bearing on the injury alleged in plaintiffs' complaint, which concerned only the information that they might gain from FDA's processing of

"premarket tobacco application[s]." App. 309 (Compl. ¶ 35). Plaintiffs nowhere alleged that the "summary" accompanying substantial-equivalence applications would be helpful to their medical practices or organizational missions.

Indeed, such an assertion would be surprising inasmuch as plaintiffs' complaint focuses on the dangers posed by products that are unlikely to be subject to a substantial-equivalence application. The complaint emphasizes the dangers of e-cigarettes and a unique smokeless tobacco product for which a premarket tobacco application was filed. *See* App. 309-10 (Compl. ¶ 36) (focusing on unique smokeless tobacco product); App. 311, 313 (Compl. ¶¶ 39, 42) ("e-cigarettes"). Because e-cigarettes were not marketed in the United States prior to February 2007, FDA does not expect that e-cigarette manufacturers will attempt to demonstrate that their products are substantially equivalent to a product that was lawfully marketed at that time. Plaintiffs have not suggested that any manufacturer of an e-cigarette product will file a substantial-equivalence application (which could lead to the disclosure of health-information summaries), rather than a premarket tobacco application (which would not). Because the only information to which plaintiffs are arguably entitled by statute is information that is not alleged to be relevant to their interests, plaintiffs have

not carried their burden to demonstrate a concrete, particularized, and actual informational injury to support Article III standing.[4]

As the foregoing analysis shows, the district court swept far too broadly in asserting that "Congress intended for the research provided pursuant to the Tobacco Control Act to be publicly available promptly after product approval." App. 62. The TCA's disclosure requirement is limited to information provided in applications for substantial-equivalence review, which are not implicated by plaintiffs' complaint, and would in any event provide no new information about the health risks caused by tobacco products because the entire premise of the substantial-equivalence pathway is that authorized products present no new risks. Plaintiffs have alleged no statutory entitlement to information provided through the premarket-review pathway that e-cigarette manufacturers will use, and they therefore cannot establish informational standing based on an interest in accessing information that might be provided through such applications. The district court thus erred in holding that plaintiffs have a cognizable interest in such information.

[4] Below, plaintiffs also pointed to 21 U.S.C. § 387j(c), which requires FDA to issue "an order" on premarket tobacco applications. *See also* 5 U.S.C. § 552(a)(2) (requiring agencies to make "orders" available to the public). But plaintiffs never alleged in their complaint that the mere fact of an application's grant or denial would provide them with any information of interest.

2. Plaintiffs cannot demonstrate standing based on non-informational interests.

Plaintiffs also assert that they have suffered a cognizable injury based on their allegation that they must "dedicate time and resources to monitor the marketplace for dangerous tobacco products," App. 312-13 (Compl. ¶ 41), and "to address the confusion caused by the absence of regulatory oversight" that plaintiffs claim the August 2017 guidance engendered, App. 313 (Compl. ¶ 42). More specifically, plaintiffs contend that FDA's deferred enforcement of premarket-review requirements has caused them to expend "substantial additional resources to their efforts to counter the deleterious effects of an unregulated marketplace," App. 313 (Compl. ¶ 44), and that they could "instead direct those resources to other policy and intervention efforts" if FDA enforced the TCA's premarket-review requirements more assiduously, App. 315 (Compl. ¶ 46). The individual plaintiffs allege that, by allowing the proliferation of deemed tobacco products, the guidance has complicated plaintiffs' practice of medicine. *See* App. 317 (Compl. ¶ 51).

These generalized statements are not sufficient to demonstrate standing. As an initial matter, it is "settled doctrine that the exercise of prosecutorial discretion cannot be challenged by one who is himself neither prosecuted nor threatened with prosecution." *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 37 (1976); *Linda R.S. v. Richard D.*, 410 U.S. 614, 619 (1973) ("[I]n American jurisprudence at least, a private citizen lacks a judicially cognizable interest in the prosecution or

nonprosecution of another."); *cf. Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance . . . ."). To the extent that plaintiffs' complaint is that FDA is not filing enough enforcement actions, plaintiffs necessarily lack standing to press that alleged interest.

Furthermore, the Supreme Court has long made clear that "a mere 'interest in a problem,' no matter how longstanding the interest and no matter how qualified the organization is in evaluating the problem," is not sufficient for standing purposes. *Sierra Club v. Morton*, 405 U.S. 727, 739 (1972); *see also Foundation on Econ. Trends v. Lyng*, 943 F.2d 79, 85 (D.C. Cir. 1991) ("It is not apparent why an organization's desire for information about the same . . . problem should rest on a different footing."). Plaintiffs' interest in addressing the public-health risks caused by tobacco, and in informing their patients of such risks, is laudable. But that interest does not permit plaintiffs to sue FDA in an attempt to force the agency to pursue enforcement on any set timetable. *See International Primate Prot. League v. Institute for Behavioral Research, Inc.*, 799 F.2d 934, 938 (4th Cir. 1986) ("The commitment of an organization may enhance its legislative access; it does not, by itself, provide entry to a federal court.").

Plaintiffs cannot circumvent this bedrock rule by pointing to an alleged shift in resources. As the D.C. Circuit and other courts have held, the "diversion of resources" from one cause to another is a "self-inflicted" harm insufficient to establish standing. *Fair Emp't Council of Greater Washington, Inc. v. BMC Mktg. Corp.*, 28

F.3d 1268, 1277 (D.C. Cir. 1994); *see Williams v. Parker*, 843 F.3d 617, 621 (5th Cir. 2016); *cf. Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 418 (2013) (holding that "self-inflicted" injuries are not sufficient for standing).

Indeed, plaintiffs' threadbare allegations would fail under every one of the extra-circuit cases on which plaintiffs relied below. For example, plaintiffs' district court filings heavily relied on *PETA v. USDA*, 797 F.3d 1087 (D.C. Cir. 2015). In that case, the D.C. Circuit found that the organizational plaintiff had standing because the plaintiff "has expended resources to counteract [its] injuries." *Id.* at 1094. Specifically, the D.C. Circuit held, the plaintiff alleged that it "submitted numerous formal . . . complaints" to the agency about the challenged policy. *Id.* at 1095-96; *see also id.* at 1096 (estimating that the government's actions cost plaintiff "more than $3,000 per year"). Here, in contrast, plaintiffs did not allege that they have spent any resources engaging with FDA's processes, nor that they have had to expend any specified sum of money because of FDA's evolving enforcement priorities. Thus, even assuming *PETA* were correct, it does not support plaintiffs' standing here. And besides, as one member of the *PETA* panel observed in concurring *dubitante*, it is "hard to reconcile [that decision] with the general rule that a plaintiff's voluntary expenditure of resources to counteract governmental action that only indirectly affects the plaintiff does not support standing." *See id.* at 1099 (Millett, J., dubitante).

Centro de la Comunidad Hispana de Locust Valley v. Town of Oyster Bay, 868 F.3d 104 (2d Cir. 2017), also relied on by plaintiffs, further underscores the lack of standing in

these circumstances. In that case, a municipal defendant enacted an ordinance prohibiting roadside solicitation of employment. *Id.* at 107. The plaintiff, an organization that advanced the interests of day workers in the area, asserted that the ordinance would make it more difficult for the organization to meet with day workers, that the organization "has already had to devote attention, time, and personnel to prepare its response to the Ordinance," and that the organization's own employees might run afoul of the ordinance. *Id.* at 110-11. As the Second Circuit noted, such allegations describe the type of injury sufficient to confer standing in *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), where the defendants' "racial steering practices" directly "impaired" the organization's ability to provide accurate information. *Id.* at 379; *see PETA*, 797 F.3d at 1100 (Millett, J., dubitante) ("Put simply, what HOME used its own resources, information, and client base to build up, Havens Realty's racist lies tore down. That is the type of direct, concrete, and immediate injury that Article III recognizes."). Here, in contrast, there is no allegation that the government is doing anything to directly impair plaintiffs' work, and plaintiffs' vague allegations regarding expenditure of resources do not satisfy Article III's requirement of concrete injury.

B. FDA's enforcement priorities are committed to its discretion by law.

The district court also erred in concluding that it could review the FDA's August 2017 guidance under the APA. The APA's judicial-review provisions do not

apply to the extent that agency action is "committed to agency discretion by law." 5 U.S.C. § 701(a)(2); *see Angelex Ltd. v. United States*, 723 F.3d 500, 502 (4th Cir. 2013) (explaining that, where agency actions are "committed to agency discretion by law," the courts lack jurisdiction over challenges to those actions).

1. An agency's non-enforcement decisions are presumptively unreviewable.

In *Heckler v. Chaney*, 470 U.S. 821 (1985), the Supreme Court made clear that "an agency's decision not to prosecute or enforce, whether through civil or criminal process," is "generally committed to an agency's absolute discretion" and presumptively "unsuitab[le] for judicial review." *Id.* at 831; *see id.* at 838 ("The general exception to reviewability provided by § 701(a)(2) for action 'committed to agency discretion' remains a narrow one, but within that exception are included agency refusals to institute investigative or enforcement proceedings, unless Congress has indicated otherwise." (citation omitted)). Applying this principle, the *Chaney* Court rejected an attempt by prisoners to direct FDA to take enforcement action against the creators of unapproved drugs used in lethal injections. *Id.* at 823-24, 827.

Chaney identified several reasons undergirding this presumption of unreviewability. First, it observed that an agency's decision to enforce has "traditionally been 'committed to agency discretion,'" and that "Congress [in] enacting the APA did not intend to alter that tradition." 470 U.S. at 832; *see Lincoln v. Vigil*, 508 U.S. 182, 191 (1993) ("Over the years, we have read § 701(a)(2) to preclude judicial

review of certain categories of administrative decisions that courts traditionally have regarded as 'committed to agency discretion.'"). Second, the *Chaney* Court observed that an agency's decision to forgo enforcement involves "a complicated balancing of a number of factors which are peculiarly within [an agency's] expertise." 470 U.S. at 831. Those factors include not only "whether a violation has occurred," but also "whether agency resources are best spent on this violation or another," whether "the agency is likely to succeed if it acts," whether "the "particular enforcement action requested best fits the agency's overall policies," and "whether the agency has enough resources to undertake the action at all." *Id.* As the Supreme Court observed, "the agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities." *Id.* at 831-32.

Third, "[i]n addition to these administrative concerns," the *Chaney* Court "note[d] that when an agency refuses to act it generally does not exercise its *coercive* power over an individual's liberty or property rights, and thus does not infringe upon areas that courts often are called upon to protect." 470 U.S. at 832. By contrast, the Court explained, when an agency "*does* act to enforce, that action itself provides a focus for judicial review." *Id.* And finally, the Supreme Court "recognize[d] that an agency's refusal to institute proceedings shares to some extent the characteristics of the decision of a prosecutor in the Executive Branch not to indict," a decision "which has long been regarded as the special province of the Executive Branch, inasmuch as

it is the Executive who is charged by the Constitution to 'take Care that the Laws be faithfully executed.'" *Id.* (quoting U.S. Const. art. II, § 3).

This case is on all fours with *Chaney*. Here, as in *Chaney*, plaintiffs have sued FDA and asked the courts to compel the agency to take enforcement action when the agency explained that the enforcement actions that plaintiffs demand are not consistent with the agency's enforcement priorities. *See* 81 Fed. Reg. at 29,014 ("In developing this compliance period, FDA balanced three important public health considerations."). And in this case, like *Chaney*, FDA has not exercised coercive power to infringe on any entity's liberty or property rights. It is the TCA and the deeming rule—neither of which is challenged here—that together impose requirements on manufacturers. And plaintiffs themselves are under no legal obligation as a result of the challenged guidance or the broader regulatory scheme. As in *Chaney*, the agency is best situated to decide whether and when to enforce the laws that Congress entrusted it to administer, and plaintiffs cannot overcome the presumption against allowing the courts to police the agency's exercise of its discretion in these circumstances.

The D.C. Circuit's analysis in *Jerome Stevens Pharmaceuticals v. FDA*, 402 F.3d 1249 (D.C. Cir. 2005), further underscores the unreviewability of FDA's guidance. There, FDA had published a notice in the Federal Register extending the compliance period for drug manufacturers to obtain approval for all drugs containing levothyroxine sodium. *Id.* at 1250-51. A drug manufacturer that had already filed an

application sued, claiming that the extension benefited the manufacturer's competitors and violated the APA. *Id.* at 1251. The D.C. Circuit had little trouble finding the suit unreviewable, noting that "FDA's extensions of the [compliance] deadlines qualify as decisions not to prosecute or enforce, and therefore enjoy a presumption of unreviewability." *Id.* at 1257 (quotation marks omitted); *see also Schering Corp. v. Heckler*, 779 F.2d 683, 685 (D.C. Cir. 1985) (holding that a settlement agreement that committed FDA not to sue a drug manufacturer for eighteen months was unreviewable). That principle applies with equal force here, and confirms that the August 2017 guidance is not properly subject to judicial review.

2. No exception applies that rebuts the presumption against reviewability.

Once the *Chaney* presumption of unreviewability is established, the question shifts to whether any feature of the agency action or statutory scheme can overcome that presumption. The *Chaney* Court held that the presumption may be rebutted if Congress has either "set[] enforcement priorities" or otherwise "circumscrib[ed] an agency's power to discriminate among issues or cases it will pursue." 470 U.S. at 833. There is no argument that Congress has done so here, nor is there any other reason not to apply the holding of *Chaney*.

a. Nothing in the Tobacco Control Act "supplie[s] sufficient standards to rebut the presumption of unreviewability." *Chaney*, 470 U.S. at 833. Although the Act

contains various substantive standards, it contains no enforcement standards that require the agency to seek to restrain violations in any particular circumstances.

In particular, as discussed above, *supra* pp. 8-9, the statute provides that a manufacturer's failure to seek premarket review shall result in its product being deemed "adulterated," 21 U.S.C. § 387b(6), and "misbranded," *id.* § 387c(a)(6). As with adulterated and misbranded drugs, adulterated and misbranded tobacco products "shall be liable to be proceeded against" and seized. 21 U.S.C. § 334(a)(2). The FDA's statutes also provide for criminal penalties, *id.* § 333(a), and grant the district courts jurisdiction over motions to enjoin illegal conduct, *id.* § 332. Those provisions hardly "indicate[] an intent to circumscribe agency enforcement discretion." *Chaney*, 470 U.S. at 834. They are not, for example, like the statute at issue in *Dunlop v. Bachowski*, 421 U.S. 560 (1975), discussed in *Chaney*, 470 U.S. at 833-35, which directed that the Secretary of Labor "shall investigate" all complaints filed by union members and "shall . . . bring a civil action" if the complaint is supported by probable cause. *Chaney*, 470 U.S. at 833 (quoting 29 U.S.C. § 482 (alterations in original)). That statute "quite clearly withdrew discretion from the agency and provided guidelines for exercise of its enforcement power." *Id.* at 834. Here, by contrast, none of the statutes authorizing FDA enforcement require FDA to take any enforcement action at any time—indeed, they are the same enforcement provisions at issue in *Chaney* itself.

The district court correctly recognized that whether the Tobacco Control Act fetters FDA's discretion is a "matter of statutory interpretation." App. 74. But its

determination that the TCA circumscribes FDA's enforcement authority, App. 74-79, is flatly incorrect. None of the provisions that the district court invoked indicate any intent by Congress to withdraw enforcement discretion from FDA.

First, the district court relied on a provision stating that premarket review is "required" for all tobacco products. 21 U.S.C. § 387j(a)(2); *see* App. 74. As *Chaney* indicates, that argument "may be dealt with summarily." 470 U.S. at 835. The statute's premarket-review requirement is a "substantive prohibition[]" on regulated entities, not a directive to the agency to enforce or forbear enforcement with respect to entities that violate the prohibition. *Id.* at 836. Provisions of that nature, *Chaney* held, "are simply irrelevant to the agency's discretion to refuse to initiate proceedings." *Id.* at 836.

Second, the district court cited two provisions stating that FDA "shall" grant or deny a premarket-review application within 180 days after receiving an application, 21 U.S.C. § 387j(c)(1)(A), and that FDA "shall" deny such an application unless various health and safety criteria are met, *id.* § 387j(c)(2). *See* App. 77-78 (describing this language as "show[ing] Congressional intent to circumscribe agency enforcement discretion" (quotation marks omitted)). This directive does not constrain FDA's discretion in any respect relevant here. The cited provisions limit FDA's discretion to grant or deny premarket-review applications that have been submitted. *Cf.* 21 U.S.C. § 355(c)(1) (providing that FDA "shall" approve or reject new drug applications within 180 days, the requirement at issue in *Chaney*, *see* 470 U.S. at 824). They say

nothing whatsoever about FDA's discretion to enforce, or decline to enforce, the statute against tobacco manufacturers that have not submitted applications for the agency's review in the first place.

b. The Supreme Court in *Chaney* left open the question whether an agency has exceeded its statutory enforcement discretion if it "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 (quotation marks omitted). This Court need not decide that question because it is not plausible to characterize the August 2017 guidance in that manner. Through the deeming rule, FDA exercised the authority delegated by Congress and made all tobacco products subject to regulation. *See supra* pp. 9-11. And the agency successfully defended that rule against challenges from tobacco manufacturers. *See Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 271-72 (D.C. Cir. 2019). FDA has continued to monitor the developing scientific evidence concerning deemed tobacco products and to adjust its enforcement priorities in response to those developments. In the January 2020 guidance, FDA announced that it intended to prioritize enforcing the Tobacco Control Act's premarket-review requirements against e-cigarette products that particularly appeal to youth. *See supra* pp. 17-18. But even before that new guidance, FDA was taking enforcement and regulatory action for other statutory provisions against deemed products.[5] In short,

[5] *See* App. 195 (noting that FDA has issued more than 1400 complaints to retailers for selling e-cigarette products to minors).

its decision to temporarily defer enforcement of the premarket-review provision—just one of the many TCA provisions made applicable by the deeming rule—was "precisely the sort of balancing of agency priorities and objectives, informed by judgments based on agency expertise, that . . . should not be second-guessed by a court." *Association of Irritated Residents v. EPA*, 494 F.3d 1027, 1033 (D.C. Cir. 2007) (quoting *Schering*, 779 F.2d at 687).

c. There is likewise no merit to the suggestion that FDA's discretionary enforcement decisions somehow became subject to judicial review because they are set forth in a general guidance document. That is clear from *Chaney* itself, which concerned FDA's categorical policy determination not to enforce its statutes with respect to drugs used to administer the death penalty. *See* 470 U.S. at 824-25. Decisions about how an agency's "resources are best spent," or how certain enforcement activity "best fits the agency's overall policies," are readily susceptible to explanation through guidance, and an agency's use of such means to announce its priorities does not alter the discretionary nature of its judgment. *Id.* at 831; *see, e.g.*, *Wayte v. United States*, 470 U.S. 598, 601-03 (1985) (describing the announcement by the President of a "grace period to afford nonregistrants [to the Selective Service] a further opportunity to register.").

Casa De Maryland v. U.S. Department of Homeland Security, 924 F.3d 684 (4th Cir. 2019), *petition for cert. filed*, No. 18-1469 (U.S. May 24, 2019) (No. 18-1469), is not to the contrary. There, this Court held that the Department of Homeland Security's

rescission of the DACA policy was reviewable under the APA. *Id.* at 697-701. It did so after determining that the Department's decision was "not a *Chaney*-type enforcement action," *id.* at 698 (quotation marks omitted), because "an agency's expression of a broad or general enforcement policy based on the agency's legal interpretation is subject to review," *id.* at 699. *See also id.* at 699-700 (holding that the Department's policy did not "involve[] discretionary balancing"). Even if that decision is correct—a question that the Supreme Court is currently considering in a parallel DACA case—it does not apply here, where no one argues that FDA's enforcement policy is "based on the agency's legal interpretation." Instead, it is based on a "discretionary balancing" of FDA's enforcement priorities. *See supra* pp. 39-40. *Chaney*, not *Casa De Maryland*, thus controls.

d. Finally, this is not the sort of case in which an agency purports to exercise its enforcement discretion but actually rewrites the substantive provisions of a statute. An agency may not invoke "enforcement discretion" in order "to *alter* [a law's] requirements and to establish with the force of law that otherwise-prohibited conduct will not violate" that law. *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302, 326 (2014). But FDA has never stated that its guidance documents excuse tobacco manufacturers from complying with provisions of the Tobacco Control Act; nor does the agency's guidance purport to alter the statute's substantive requirements. FDA has made clear that the Act requires manufacturers to submit applications for premarket review or to demonstrate the applicability of another review pathway. FDA's guidance documents,

which repeatedly state that they create no legally enforceable right, *see supra* pp. 12, 17-18, simply give manufacturers more time to comply with existing legal requirements as a practical matter. They in no way alter or obviate the requirements themselves. Consistent with the guidance, FDA always retained discretion to take enforcement action as appropriate. And, at FDA's request, the district court clarified that its order preserves FDA's ability to enforce the TCA before May 2020. *See supra* p. 15. FDA now intends to do so, guided by the priorities set forth in the January 2020 guidance.

For this reason, the district court erred in relying on *Public Citizen Health Research Group v. Acosta*, 363 F. Supp. 3d 1, 18 (D.D.C. 2018). *See* App. 71-73. In that case, a Department of Labor rule required employers to submit certain forms. *See* 363 F. Supp. 3d at 8. The agency then announced that it would "not accept[]" the submission of certain of those forms, and that it would "not enforce" the rule's submission requirements. *Id.* That announcement, the D.C. district court held, was reviewable because the agency "suspended [the rule's] reporting requirement entirely" by forbidding the submission of the relevant forms. *Id.* at 18; *see also id.* ("The amendment or revocation of an agency rule . . . [is] generally reviewable by courts.").

This case is entirely distinct. FDA has not suspended the premarket-review requirements. It continues to accept premarket-review applications and to process those applications, which are legally required notwithstanding the August 2017 guidance. *See, e.g.*, Jennifer Maloney, *Reynolds Files for FDA Review of Vuse E-Cigarettes*, Wall St. J., Oct. 11, 2019, wsj.com/articles/reynolds-files-for-fda-review-of-vuse-e-

cigarettes-11570808409. And FDA has repeatedly affirmed its commitment to the orderly implementation of this regulatory scheme. There is no credible claim that FDA's August 2017 guidance sought to alter the substantive provisions of the statute. It is therefore not the appropriate object of judicial review.

C. The August 2017 guidance is not final agency action.

For the reasons discussed, FDA's exercise of its enforcement discretion was committed to the agency's discretion by law. For very similar reasons, the August 2017 guidance is not final agency action subject to review. 5 U.S.C. § 704; *see Invention Submission Corp. v. Rogan*, 357 F.3d 452, 458 (4th Cir. 2004) (holding that this is a "question of subject matter jurisdiction").

To satisfy the APA's finality test, agency action must satisfy two independent requirements. *See Bennett v. Spear*, 520 U.S. 154, 177 (1997). First, the action must "mark the consummation of the agency's decisionmaking process" and not be "of a merely tentative or interlocutory nature." *Id.* at 178 (citation omitted). Second, the action must be one "by which rights or obligations have been determined, or from which legal consequences will flow." *Id.*

The challenged guidance satisfies neither *Bennett* prong. As discussed above, the August 2017 guidance stated that it reflected only the agency's "current thinking" on the proper enforcement timetable, and was subject to change. App. 141. *See supra* p. 12. FDA had begun to reevaluate aspects of the guidance even prior to the district court's order, and, as the district court recognized, FDA retained authority to enforce

the provisions it administers at any time according to its discretion. App. 117. That FDA has continued to reevaluate its enforcement priorities and announced revised priorities in the January 2020 guidance confirms that the August 2017 guidance did not "mark the consummation" of any decisionmaking process. *Bennett*, 520 U.S. at 178.

The August 2017 guidance also has no "legal consequences." *Bennett*, 520 U.S. at 178. As explained above, the guidance reflects an exercise of agency enforcement discretion and does not alter the substantive requirements of the Tobacco Control Act. *See supra* pp. 45-47. The relevant substantive requirements are established by the TCA and the deeming rule, neither of which are at issue in this case. The guidance does not "tell regulated parties what they must do or may not do in order to avoid liability," nor does it "impose any requirements" on any entity. *National Mining Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) (Kavanaugh, J.). It is therefore "not a final agency action subject to pre-enforcement review." *Id.* at 253.

The district court's contrary ruling rested on the mistaken view that the August 2017 guidance "suspended" requirements in the Tobacco Control Act, App. 81, and that FDA took "a definitive legal position regarding its statutory authority" in the guidance, App. 83 (quotation marks omitted). These conclusions were plainly mistaken for the reasons set forth above: the 2017 guidance was committed to agency discretion by law and was not final agency action in any event, because it concerned the agency's enforcement priorities rather than the industry's legal obligations. *See*

supra pp. 36-47. The failure to recognize that fundamental point likewise explains the court's erroneous merits rulings.[6]

[6] The district court's ruling that FDA lacked statutory authority for its August 2017 guidance was based on its view that FDA's actions marked an "abdication of its statutory responsibilities." App. 89 (quoting *Chaney*, 470 U.S. at 833 n.4). Its ruling that FDA was required to follow the APA's notice-and-comment process overlapped almost entirely with its final-agency-action analysis. App. 91-97. The district court did not rule on the argument that the August 2017 guidance was arbitrary and capricious, App. 86 n.10, and there is no cause for this Court to reach that question, particularly given that the guidance at issue no longer represents FDA's current thinking on the proper enforcement timetable for the TCA's premarket-review requirements.

CONCLUSION

The e-cigarette organizations' appeal should be dismissed as moot, the judgment of the district court denying the cigar associations' motion to intervene should be affirmed, and the government's appeal should be voluntarily dismissed. In the alternative, the judgment of the district court vacating the August 2017 guidance and entering an injunction should be reversed.

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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) because it contains 12,021 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 2016 in Garamond 14-point font, a proportionally spaced typeface.

s/ Joshua Revesz
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CERTIFICATE OF SERVICE

I hereby certify that on January 23, 2020, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fourth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Joshua Revesz
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ADDENDUM

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21 U.S.C. § 387e

§ 387e. Annual registration

* * *

(j) **Report preceding introduction of certain substantially equivalent products into interstate commerce**

(1) **In general.** Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a tobacco product intended for human use that was not commercially marketed (other than for test marketing) in the United States as of February 15, 2007, shall, at least 90 days prior to making such introduction or delivery, report to the Secretary (in such form and manner as the Secretary shall prescribe)—

(A) the basis for such person's determination that—

(i) the tobacco product is substantially equivalent, within the meaning of section 387j of this title, to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007, or to a tobacco product that the Secretary has previously determined, pursuant to subsection (a)(3) of section 387j of this title, is substantially equivalent and that is in compliance with the requirements of this chapter; or

(ii) the tobacco product is modified within the meaning of paragraph (3), the modifications are to a product that is commercially marketed and in compliance with the requirements of this chapter, and all of the modifications are covered by exemptions granted by the Secretary pursuant to paragraph (3); and

(B) action taken by such person to comply with the requirements under section 387g of this title that are applicable to the tobacco product.

(2) **Application to certain post–February 15, 2007, products**

A report under this subsection for a tobacco product 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, shall be submitted to the Secretary not later than 21 months after June 22, 2009.

(3) **Exemptions**

(A) **In general.** The Secretary may exempt from the requirements of this subsection relating to the demonstration that a tobacco product is substantially equivalent within the meaning of section 387j of this title, tobacco products that are modified by adding or deleting a tobacco additive, or increasing or decreasing the quantity of an existing tobacco additive, if the Secretary determines that—

(i) such modification would be a minor modification of a tobacco product that can be sold under this chapter;

(ii) a report under this subsection is not necessary to ensure that permitting the tobacco product to be marketed would be appropriate for protection of the public health; and

(iii) an exemption is otherwise appropriate.

(B) **Regulations**

Not later than 15 months after June 22, 2009, the Secretary shall issue regulations to implement this paragraph.

21 U.S.C. § 387j

§ 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 CommitteeUpon 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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