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,

AMERICAN 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

REPLY BRIEF FOR THE FEDERAL APPELLANTS

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SUMMARY OF ARGUMENT

I. The industry groups' brief confirms that the e-cigarette organizations' appeal is moot and that the district court appropriately denied the cigar associations' motion to intervene.

The e-cigarette organizations do not dispute that, in light of the Food and Drug Administration (FDA) guidance issued in January 2020, an order setting aside the district court's injunction will not redress their asserted injuries. Instead, they argue that the newly issued guidance is unlawful. That argument is not properly before this Court: the complaint in this suit does not challenge the 2020 guidance, and the district court did not consider that question. Moreover, even if the 2020 guidance were at issue, the e-cigarette organizations' argument would fail on multiple grounds: the organizations lack standing to challenge the guidance, the guidance is not subject to judicial review, and the guidance is lawful in all respects. The e-cigarette organizations' appeal should therefore be dismissed.

The industry brief provides no reason to conclude that the district court abused its discretion in denying the cigar associations' motion to intervene. The cigar associations argue only that, had they sought to intervene earlier, the district court might have denied their motion at that time. That calculation, even if it were correct, would not excuse their failure to move for intervention in a timely manner. And, had such a motion been denied, they could have appealed the denial to this Court. In all events, the cigar associations' choice to collaterally attack the district court's judgment

in a different venue months before they sought to intervene confirms that the associations understood the need to protect their interests earlier than their intervention motion suggests.

Finally, there is no basis for the cigar associations' claim that this Court should dissolve the district court's injunction without even addressing whether the district court's legal conclusions were correct. No precedent supports the extraordinary suggestion that this Court can revive the now-superseded 2017 guidance without considering whether the district court erred in holding the guidance invalid.

II. If, as the government urges, neither set of industry groups can attack the judgment below, the government respectfully requests that this Court dismiss the government's appeal and end the case there. If the Court instead reaches the underlying dispute, it should hold that the district court erred in reaching the merits, and should reverse the judgment below. Three independent, jurisdictional doctrines dictate that result.

First, plaintiffs' response brief underscores their failure to demonstrate standing in their complaint. The allegations in the complaint do not show that any of the information subject to disclosure under the statute would help plaintiffs advance their stated goals, and they do not show that that plaintiffs suffered any economic injury as a result of FDA's actions. Plaintiffs make no serious argument to the contrary, and instead focus almost entirely on the declarations that they submitted to the district court at the summary-judgment stage. Those allegations cannot salvage

the fact that plaintiffs failed to establish standing in their complaint. Supreme Court precedent in any event precludes plaintiffs' contention that they may allege informational injuries stemming from a lack of access to information to which they have no statutory right.

Second, FDA's enforcement priorities are committed to the agency's discretion by law. Plaintiffs point to no provision in the Tobacco Control Act (TCA) that fetters FDA's enforcement discretion. Their argument that any decision to delay enforcement of a statute is tantamount to an unlawful repeal of the statute misunderstands the nature of enforcement discretion, which is subject to change at any time. As the 2020 guidance shows, there is no basis for plaintiffs' suggestion that FDA has abdicated its responsibility in enforcing the tobacco laws. In addition, plaintiffs' view that an agency subjects its enforcement priorities to judicial review only when it sets them out in a public document undermines administrative law's transparency goals and is without precedential support.

Finally, the challenged guidance is not final agency action subject to judicial review. Plaintiffs' contrary argument depends entirely on the theory that, had the guidance not been issued, FDA would have lacked discretion to enforce the relevant provisions of the TCA. But that is not correct. With or without the guidance, FDA retained discretion as to when and how to enforce the TCA's premarket-review requirements. While the guidance explained FDA's then-current thinking about when

it was likely to take certain types of enforcement action, it did not alter the rights or responsibilities of any regulated entity.

ARGUMENT

I. The e-cigarette organizations' appeal is moot.

The district court's injunction orders FDA to require manufacturers of new tobacco products to submit premarket-review applications by May 2020. App. 116. The government's opening brief demonstrated that FDA's January 2020 guidance, which adopts a May 2020 compliance date for e-cigarettes independent of the district court's injunction, moots the e-cigarette organizations' appeal. *See* FDA Br. 22-23.

The e-cigarette organizations do not dispute that the 2020 guidance "makes it impossible for the court to grant any effectual relief" to the organizations. *Incumaa v. Ozmint*, 507 F.3d 281, 286 (4th Cir. 2007). Instead, they argue (at 46) that the 2020 guidance is procedurally infirm, and therefore that their appeal remains live. That argument is wrong for two reasons: first, any procedural defect in the 2020 guidance would not bear on the mootness inquiry, and second, the 2020 guidance is lawful in all respects.

A. The legality of the 2020 guidance does not bear on these appeals.

The e-cigarette organizations' arguments fail at the threshold because the validity of FDA's 2020 guidance is not at issue in this case. Rather than litigating based on the complaint filed below, the e-cigarette organizations improperly attempt

to initiate a new suit before this Court. FDA's new guidance has not been challenged in any complaint and has not been the subject of district court review. It is axiomatic that, without some special statutory provision, agency action must first be challenged in district court. 28 U.S.C. § 1331; *see* 5 U.S.C. § 703. That principle would apply fully to the 2020 guidance, assuming that it were reviewable at all. The e-cigarette organizations' attempts to short-circuit these procedures mean that they have never filed a complaint and cannot even demonstrate standing to challenge the new guidance. *See Maryland Highways Contractors Ass'n v. Maryland*, 933 F.2d 1246, 1249 (4th Cir. 1991) ("In order to determine if someone has been injured by the new statute, we would need more information about the new statute than is presently before us.").

Nor is there any basis for this Court to consider a hypothetical challenge to the 2020 guidance in this case. It is settled that the enactment of superseding legislation or administrative action typically moots a controversy concerning the prior enactment. *Esposito v. South Carolina Coastal Council*, 939 F.2d 165, 171 (4th Cir. 1991). That is true even if it is possible that the new enactment "will likely be the subject of a challenge," even by the same plaintiffs. *Maryland Highways Contractors Ass'n*, 933 F.2d at 1250; *see* 13C Charles Alan Wright et al., *Federal Practice & Procedure* § 3533.6 (3d ed. 2019 update) ("The fact that independent litigation challenges the new enactment that satisfies the claims in the present action is not likely to defeat mootness. Courts are not interested in predicting the outcome or consequences of proceedings in another court, nor in retaining jurisdiction as an opportunity for collateral attack on another

court's eventual judgment."). Regardless of the outcome of an eventual challenge, there is no question that FDA's prior guidance has been superseded. To pass on the legality of that guidance would at this point be to "render[] an advisory opinion." *Maryland Highway Contractors Ass'n*, 933 F.2d at 1249. Accordingly, this Court should dismiss the e-cigarette organizations' appeal concerning the now-superseded guidance.

B. Any challenge to the 2020 guidance would fail.

If the Court were to reach the issue, intervenors offer no basis for setting the 2020 guidance aside.

1. As a threshold matter, the e-cigarette organizations would lack standing to challenge the 2020 guidance because—regardless of what they might allege in a hypothetical complaint—the industry groups can identify no "legally protected interest" in any enforcement timetable, as is necessary to demonstrate injury. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992); *see* FDA Br. 26-27. The industry groups' stated interest is in having "time beyond May 2020 to submit complete applications," App. 743, but the applications at issue are required by statute, and the industry groups have no cognizable interest in continuing to market their products in violation of Congress's clear directive.

In addition, any injury alleged by the e-cigarette organizations would not be redressable. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 103 (1998). FDA's 2020 guidance is clear that it does not "alter the fact that it is illegal to market any new tobacco product without premarket authorization," and it does "not establish legally

enforceable responsibilities." App. 190. Nothing in the 2020 guidance (or in any prior guidance) alters the substantive requirements of the Tobacco Control Act. Nor does any guidance bar FDA from enforcing those requirements at any time. *See* App. 189 (noting that the 2020 guidance "is not binding on FDA or the public"). A court order vacating the 2020 guidance would not change those facts: any marketing of tobacco products without premarket authorization would still be illegal, and FDA would still have discretion to enforce the TCA against any tobacco manufacturer that violated the law. Accordingly, an order vacating the 2020 guidance would not leave the e-cigarette organizations any better off than they are now.

2. Any challenge to the 2020 guidance would also fail because the guidance is not final agency action and because it represents an exercise of enforcement discretion that is not subject to judicial review. Those jurisdictional arguments are identical to the arguments FDA has made in defending the challenged August 2017 guidance, *see* FDA Br. 36-49, and we therefore do not elaborate on them here.

The cigar associations contend that the reviewability analysis would be different for the 2020 guidance than for the August 2017 guidance because a decision to "*accelerate* enforcement" is categorically different from a decision to delay enforcement. Industry Br. 54 n.10. The cigar associations cite no holding from any court to support that extraordinary assertion, and it is squarely contrary to this Court's decision in *Speed Mining, Inc. v. Federal Mine Safety & Health Review Comm'n*, 528 F.3d 310 (4th Cir. 2008), which held that the "discretionary decision" to cite an operator for a Mine Act

violation was unreviewable. *Id.* at 318. And, while intervenors quote the statement in *Heckler v. Chaney* that "when an agency refuses to act it generally does not exercise its *coercive* power," the very next sentence of *Chaney* states that "when an agency *does* act to enforce, that action itself provides a focus for judicial review." 470 U.S. 821, 832 (1985). Thus, if FDA denied a premarket tobacco application or sought to enjoin the marketing of a tobacco product without authorization, the tobacco manufacturer could seek judicial review of that agency action. *See* 21 U.S.C. §§ 332, 387j(c)(2). *Chaney* thus makes clear that particular enforcement actions are reviewable, but decisions about whether and when to enforce the law are not. 470 U.S. at 831; *accord Speed Mining*, 528 F.3d at 318 (noting that an "agency's exercise of its enforcement discretion" is "an area in which the courts have traditionally been most reluctant to interfere"). Like the now-superseded August 2017 guidance, the 2020 guidance addresses only FDA's current thinking regarding when it will enforce certain provisions of the TCA and is plainly not the type of enforcement action that the *Chaney* Court suggested would be reviewable.

3. Finally, on the merits, the e-cigarette organizations are wrong to argue (at 46) that the new guidance required notice-and-comment rulemaking. An agency action that simply serves to "apprise the regulated community of the agency's intentions" and "inform[] the exercise of discretion by agents and officers in the field" is a statement of policy that need not go through the Administrative Procedure Act's (APA's) informal rulemaking procedures. *Association of Flight Attendants v. Huerta*, 785

F.3d 710, 716 (D.C. Cir. 2015) (alteration omitted); *see* 5 U.S.C. § 553(b). As long as a statement is "binding on neither the public nor the agency," and as long as the agency "retains the discretion and the authority to change its position," no notice and comment is required. *Syncor Int'l Corp. v. Shalala*, 127 F.3d 90, 94 (D.C. Cir. 1997) (citations omitted); *see Chen Zhou Chai v. Carroll*, 48 F.3d 1331, 1341 (4th Cir. 1995) (policy statements announce "tentative intentions for the future without binding" an agency). The 2020 guidance, which makes clear that it is not binding and that FDA retains discretion to enforce the TCA at any time, falls within those precedents. *See supra* pp. 6-7.

In reviewing the 2017 guidance, the district court found that any future FDA guidance would have to adhere to the notice-and-comment requirements in the APA. App. 97. As discussed below, the court erred in vacating the 2017 guidance. *See infra* pp. 17-24; FDA Br. 27-50. But even assuming that the court's ruling with regard to notice and comment were correct, its rationale would not dictate a similar result for the 2020 guidance for two independent reasons. First, the 2020 guidance did go through the notice-and-comment procedures set forth by statute and in FDA's regulations. 21 U.S.C. § 371(h); 21 C.F.R. § 10.115(g); *see* Pls.' Br. 86. Particularly given that the district court emphasized that FDA would not have to issue new guidance through "formal regulation," there is every reason to believe that the process for the 2020 guidance would be sufficient under the district court's view. App. 106 n.4.

Second, a core part of the district court's reasoning was its view that the August 2017 guidance was a legislative rule because it ran "180 degrees counter" to the plain meaning of the TCA, which "set much more stringent deadlines." App. 97. That reasoning has no application to the 2020 guidance, which announced that FDA plans to prioritize enforcement of the TCA's premarket-review requirements for certain products beginning now, and for certain other products in the near future. The May 2020 date in the guidance for prioritizing enforcement of premarket-review requirements for many e-cigarette products is the same date that the district court recognized allowed sufficient time for application submissions but did not delay longer than was necessary. *See* App. 114. Even under the district court's analytical framework, therefore, there would be no reason to conclude that notice-and-comment requirements would apply to the 2020 guidance.

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

The government's opening brief also showed that the district court did not abuse its discretion in denying the cigar associations' belated attempt to intervene. FDA Br. 23-26; *see also* FDA Br. 26-27 (noting that all industry appellants lack a significantly protected interest in this litigation). In arguing to the contrary, the cigar associations state (at 63-65) that they could not have intervened earlier because the district court had previously denied intervention motions from other tobacco

manufacturers. *See* App. 101-04. This argument is misplaced for three independent reasons.

First, the cigar associations' theory rests on a misunderstanding of the district court's order denying the earlier intervention motions. The associations claim that the district court denied those motions "because their interests in preserving the Guidance were adequately represented by FDA." Industry Br. 64 (citing App. 102). In fact, however, the district court denied those intervention motions largely because those motions were untimely. The court stated that the would-be intervenors "were content to let the Government shoulder the burden of protecting their interests" for nearly all of the litigation, and that their "efforts to intervene at this late date [are] anything but timely." App. 102; *see* App. 102-03 (noting that the "request to intervene came well over a year after Plaintiffs filed suit"); App. 103 (noting that "the opportunities for Applicants to make meaningful contributions to the case are likely to be limited"). The district court's reasoning in no way suggests that the cigar associations should not have sought to intervene earlier because their interests were adequately represented. If anything, the district court's reasoning underscores that it did not abuse its discretion in denying the cigar associations' motion to intervene in September 2019, four months after the intervention motions it already considered untimely. *See* App. 123.

Second, the cigar associations are wrong to state that they "could not" have sought to intervene "months earlier," again due to the denial of other putative

intervenors' earlier motions. Industry Br. 63-64 (emphasis omitted). Even if the cigar associations suspected that the district court would have denied their motion as it did the others, nothing prevented them from moving to intervene and then taking an appeal to this Court. *See* 15B Charles Alan Wright et al., *Federal Practice and Procedure* § 3914.18 (2d ed. 2019 update) (noting that denials of motions to intervene are appealable). Had they done so, their motion would have been several months less untimely.

Third, regardless of the district court's reasoning, the cigar associations are incorrect to suggest that FDA was adequately representing their interests during any of the time periods when they might have sought to intervene. As the government's opening brief recounts, FDA issued a draft guidance in March 2019—two months before anyone sought to intervene in this case—that proposed in part to "prioritize enforcement of actions with respect to flavored cigars." App. 182; *see* FDA Br. 25 (collecting examples of earlier FDA statements). Given that FDA had told cigar manufacturers that it intended to alter its enforcement priorities in this way, it is hard to understand how the cigar associations could reasonably have thought that FDA adequately represented their interests in this litigation.

Indeed, there is evidence that the cigar associations understood the need to protect their interests here months before they sought to intervene. In July 2019, the cigar associations sought a declaratory judgment from the United States District Court for the District of Columbia that the district court's ruling in this case did not apply to

them. Mem. in Supp. of Pls.' Mot. for Partial Summ. J. at 3-4, *Cigar Ass'n of Am. v. FDA*, No. 1:16-cv-1460 (D.D.C. July 2, 2019), ECF No. 136-1. That district court properly denied the associations' request, observing that it "would be tantamount to permitting a collateral attack on the *AAP* court's order, which this court cannot do." *Cigar Ass'n of Am. v. FDA*, 411 F. Supp. 3d 1, 3 (D.D.C. 2019). The court also observed that "[o]ther remedies have been available to [the cigar associations] for some time—namely, seeking relief before the court in *AAP*." *Id.* at 4; *see id.* ("Because [the cigar associations] delayed in raising their concerns before the *AAP* court, their conduct weighs against granting the extraordinary relief they now request.").

The cigar associations cannot reconcile their filings elsewhere with their contentions that they saw no need to assert their interests until the late point at which they sought to intervene. *See* Pls.' Br. 27-32 (further exploring the inconsistencies in the cigar associations' various filings). The D.C. district court made clear to the associations that the proper means to assert those interests was to attempt to intervene in this litigation. Because the cigar associations failed to do so, the district court here "was reasonably reluctant to arrest the momentum of the lawsuit so near to its final resolution." *Alt v. U.S. EPA*, 758 F.3d 588, 591 (4th Cir. 2014); *see also Scardelletti v. Debarr*, 265 F.3d 195, 203 (4th Cir. 2001), *rev'd on other grounds sub nom. Devlin v. Scardeletti*, 536 U.S. 1 (2002) (denying intervention on timeliness grounds because, "[a]lthough Devlin argue[d] that he was not aware of his interest in the

settlement until the notice of proposed settlement, Devlin's argument is belied by his participation in the New York case").

III. There is no precedent to support the cigar associations' request that the Court vacate the district court's orders without reaching the merits.

Because the e-cigarette organizations' appeal is moot, and because the district court properly denied the cigar associations' motion to intervene, those appeals should be resolved without reaching the merits. If this Court agrees, the government respectfully requests that the Court voluntarily dismiss its appeal without reaching any other issues. FDA Br. 27; *see* Fed. R. App. P. 42(b). If the Court disagrees, it should conclude that the district court erred in reviewing and vacating FDA's guidance. There is no scenario in which it would be appropriate to accept the cigar associations' invitation (at 49-53) to dissolve the district court's injunction without considering whether it was entered improperly. Unless the Court determines that the injunction was issued in error, there is no proper basis to vacate it.

There is no merit to the cigar associations' position that the district court's judgment should be vacated in light of the 2020 guidance. The cigar associations note (at 50-51) that the 2020 guidance supersedes the August 2017 guidance insofar as it applies to e-cigarettes. Thus, they contend, the district court's order no longer affects enforcement regarding e-cigarettes. That is certainly correct. But the rest of their argument is difficult to fathom. The associations ask that the district court's injunction be vacated because it now covers only products other than e-cigarettes.

They do not argue that this fact constitutes a legal ground for setting the injunction aside. They suggest instead that that the district court *might* not have entered the order in these changed circumstances.

Nothing in the district court's order supports that suggestion. On the contrary, the district court's injunction declined to distinguish among various classes of deemed tobacco products. *See* App. 116. And it based the need for an injunction principally on its view that, without an injunction, industry groups would "take every available dilatory measure to keep [their] products on the market without approval." App. 114. Because the district court's reasoning applies equally to all industry groups, there is no basis to accept the cigar associations' hypothesis.

In any event, this Court is not the proper venue to urge that the injunction be altered. If there were reason for the district court to reassess the appropriateness of the injunction in light of changed circumstances, this Court can remand without vacating the injunction, and the cigar associations may present their request to the district court. *See* Fed. R. Civ. P. 60(b). None of the precedents that the cigar associations cite support undoing a district court's injunction without first holding that the court erred as a matter of law. In many of the cases that they invoke (at 52-53), the Supreme Court returned a case to the court of appeals to account for some changed circumstance. *See, e.g.*, *Douglas v. Independent Living Ctr. of S. Cal., Inc.*, 565 U.S. 606, 616 (2012). That sort of remand to a court of appeals does not disturb the district court's judgment or otherwise alter the status quo, and so does not implicate

any equitable concerns. Similarly, in *Concerned Citizens of Vicksburg v. Sills*, in which the court of appeals ordered the district court to reconsider its dismissal of the case in light of changed circumstances, the court of appeals did not alter the status quo; it left the parties in the same position as before. 567 F.2d 646, 648, 650 (5th Cir. 1978).[1]

By contrast, the entire purpose of the cigar associations' request for vacatur in this case is to alter the status quo. That request is without precedential support, and would be particularly inappropriate here, where FDA, which is the party subject to the injunction in this case, caused the changed circumstances by voluntarily issuing the 2020 guidance. *See Anderson v. Greene*, 513 U.S. 557, 560 (1995) (courts will not "disturb prior judgments" if the "party seeking relief from the judgment below caused the [nonjusticiability] by voluntary action" (quoting *U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18, 25 (1994) (alteration in original)). The cigar associations' request should therefore be rejected.

[1] The cigar associations also cite *Greater Boston Television Corp. v. FCC*, 463 F.2d 268 (D.C. Cir. 1971), but it is unclear why. In that case, the D.C. Circuit declined to recall its mandate to permit the Federal Communications Commission to further consider its administrative proceedings. *Id.* at 290-91. The court's analysis turned on administrative-law principles that are not relevant here. *See id.* at 283 (discussing "a doctrine favoring remand . . . subsequent to administrative decision and prior to court decision").

IV. If this Court reaches the underlying dispute, the Court should reverse on threshold grounds.

If this Court determines that either set of intervenors' appeal should proceed, then it should reach the underlying dispute and reverse the district court on any of three jurisdictional grounds.

A. Plaintiffs lack standing.

1. Plaintiffs err in contending (at 34-43) that they can demonstrate informational standing even if they are not "denied access to information required to be disclosed by statute." *Dreher v. Experian Info. Sols., Inc.*, 856 F.3d 337, 345 (4th Cir. 2017). The Supreme Court has limited informational-standing claims to cases in which "the plaintiff fails to obtain information which must be publicly disclosed pursuant to a statute." *Federal Election Comm'n v. Akins*, 524 U.S. 11, 21 (1998). That requirement is no mere technicality, but reflects the bedrock rule that only Congress has "power to create new interests the invasion of which will confer standing." *Simon v. Eastern Ky. Welfare Rights Org.*, 426 U.S. 26, 41 n.22 (1976). Because agencies lack that power, FDA's regulations—on which plaintiffs principally premise their claim to informational standing—do not bear on this case. And all of the cases that plaintiffs cite to the contrary do not assist them because, in those cases, plaintiffs were able to establish an economic injury, not just a mere denial of information. *E.g.*, *American Anti-Vivisection Soc'y v. USDA*, 946 F.3d 615, 619 (D.C. Cir. 2020); *see infra* p. 19; FDA Br. 33-36; (explaining why plaintiffs fail to demonstrate any non-informational injury).

2. There is likewise no merit to plaintiffs' contention (at 43-46) that they may demonstrate informational standing based on the limited categories of information that are subject to statutory disclosure. Plaintiffs argue that FDA must make public any "order" concerning premarket tobacco applications, 21 U.S.C. § 387j(c), but they ignore the clear limitations of this requirement. That provision requires only that FDA disclose whether "the new product may be introduced" into interstate commerce. *Id.* Plaintiffs nowhere allege that this minimal information would be useful to them, much less that it would redress their alleged injury. The fact that FDA has chosen, as a matter of practice, to provide information beyond that required by statute does not bear on the informational-standing inquiry, which looks to the requirements established by Congress.

The statutory availability of certain information related to substantial-equivalence reports likewise fails to support standing. Although plaintiffs point to declarations stating that they would benefit from substantial-equivalence reports, they never respond to the government's showing that their complaint fails to allege that plaintiffs have any interests relating to those reports. *See* FDA Br. 31-32. That fact is dispositive, because "the party invoking the jurisdiction of the court must include the necessary factual allegations" in their complaint. *Bishop v. Bartlett*, 575 F.3d 419, 424 (4th Cir. 2009); *cf. Summers v. Earth Island Inst.*, 555 U.S. 488, 500 (2009) (declining to consider "late-filed affidavits"). And even the declarations that plaintiffs cite do not

state that any of the plaintiffs seek information contained in the substantial-equivalence reports.

3. Plaintiffs also assert (at 46-56) that they have standing based on non-informational, economic interests. The government's opening brief explained that plaintiffs do not fall within any precedents recognizing standing on that basis. FDA Br. 33-36. Nothing in the complaint alleges any economic injury or resource drain, except for the sort of "self-inflicted" injury that is not sufficient for standing. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 418 (2013). For example, the complaint alleges that plaintiffs are "compelled to expend . . . resources to monitor the marketplace for newly deemed tobacco products aimed at children," App. 313 (Compl. ¶ 41), but that reflects a voluntary choice by plaintiffs, not an expenditure caused by any FDA action. *Fair Emp't Council of Greater Washington, Inc. v. BMC Mktg. Corp.*, 28 F.3d 1268, 1276-77 (D.C. Cir. 1994). Plaintiffs' response, which focuses solely on their "declarations," Pls.' Br. 50, does not absolve them of their obligation to demonstrate standing in their complaint.

B. The August 2017 guidance is not reviewable.

The government's opening brief also showed that the challenged guidance was "committed to [the] agency's absolute discretion" and therefore "unsuitab[le] for judicial review." *Heckler v. Chaney*, 470 U.S. 821, 831 (1985); *see* FDA Br. 36-47. Plaintiffs have three responses. None is convincing.

1. Plaintiffs suggest (at 57-62) that the Tobacco Control Act indicates "an intent to circumscribe agency enforcement discretion" and therefore provides "law to apply." *Chaney*, 470 U.S. at 834 (quoting 5 U.S.C. § 701(a)(2)). FDA's opening brief rebutted that argument, FDA Br. 40-43, explaining that, unlike in other statutes, nothing in the TCA indicates that FDA "shall investigate" any alleged violations, much less take enforcement action, *e.g.*, *Dunlop v. Bachowski*, 421 U.S. 560, 563 n.2 (1975). Instead, the TCA contains the sort of substantive commands that "are simply irrelevant to the agency's discretion to refuse to initiate proceedings." *Chaney*, 470 U.S. at 836.

Plaintiffs' contrary argument depends on the notion that temporarily delaying enforcement of a provision is legally equivalent to excusing regulated entities from following that provision. *See* Pls.' Br. 60 (suggesting that the August 2017 guidance rendered the "mandatory premarket review process a legal nullity"). Plaintiffs cite no authority for that position, and it is foreclosed both by *Chaney* and by common sense. In *Chaney*, none of the Justices thought that FDA's categorical refusal to enforce statutory requirements against drugs used in lethal injections made those statutes "a legal nullity" as to those drugs. And it of course would not have been true, because FDA would have retained discretion to change its mind and to enforce the law against those drugs, even if it had earlier said that it would not.

The same is true here. FDA is not excusing any manufacturer from any requirement of the TCA, because—as the 2020 guidance shows—FDA retains

discretion to enforce the law's requirements at any time. The situation might be different if FDA had declared it would no longer accept premarket-review applications, *see Public Citizen Health Research Grp. v. Acosta*, 363 F. Supp. 3d 1, 18 (D.D.C. 2018), or if it had declared a "safe harbor" from "civil enforcement proceedings" that was "binding for five years" on the government, *U.S. Army Corps of Eng'rs v. Hawkes Co., Inc.*, 136 S. Ct. 1807, 1809, 1814 (2016). But the agency did not do so, and subsequent events confirmed that FDA retained discretion to enforce the TCA on any timetable it chose. Accordingly, there is no basis to contend that anything in the August 2017 guidance altered the substantive requirements of the TCA.

2. Plaintiffs also theorize (at 63-65) that the August 2017 guidance is reviewable because it is not a mere "*single-shot* non-enforcement decision." *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 676 (D.C. Cir. 1994). Neither was the enforcement decision at issue in *Chaney*, which concerned a programmatic determination not to enforce statutes with respect to drugs used to administer the death penalty, and which did not address the particular circumstances of any individual case. 470 U.S. at 824-25; *see* FDA Br. 43-44. There is therefore no support for the distinction that plaintiffs draw.

Plaintiffs' reliance on *Casa De Maryland v. United States Department of Homeland Security*, 924 F.3d 684 (4th Cir. 2019), *petition for cert. filed* (U.S. May 24, 2019) (No. 18-1469), is also misplaced. In that case, this Court held that an agency's enforcement

decisions are reviewable if they are "based on the agency's legal interpretation." *Id.* at 699. Here, FDA based its enforcement decisions on policy objectives and resource constraints and did not make any statement interpreting the scope or applicability of the TCA. The exception to the presumption of reviewability that *Casa De Maryland* created accordingly does not apply. And plaintiffs' counterargument (at 65), that a policy is reviewable whenever a plaintiff contends that the policy is unlawful, misapprehends principles of reviewability and has no grounding in the decisions that plaintiffs cite.

Finally, it is hard to see why plaintiffs' position makes sense as a practical matter. On plaintiffs' view, FDA's decision temporarily not to enforce premarket-review provisions would be unreviewable as long as the agency did not make that decision public. Only when FDA seeks to give guidance to the public would it subject its discretionary enforcement choices to judicial review. That position, if adopted, would only harm plaintiffs and others who benefit from agencies speaking clearly. It certainly would not advance "transparency of the administrative process," a "critical goal judicial review is meant to further." *North Slope Borough v. Andrus*, 642 F.2d 589, 603 (D.C. Cir. 1980).

3. Plaintiffs also claim that 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 (quotation marks omitted). There is simply no authority for the proposition that an agency's temporary delay in enforcing

a handful of provisions for a subset of products in a complex statutory scheme is an "abdication" of the agency's responsibilities. *See* FDA Br. 43-44. This is a far cry from the cases on which plaintiffs rely, in which agencies entirely failed to enforce desegregation statutes and offered no indication that they would ever do so. *See, e.g.*, *Adams v. Richardson*, 480 F.2d 1159, 1164 (D.C. Cir. 1973) (en banc). And, as events both prior and subsequent to the August 2017 guidance show, FDA has repeatedly recalibrated its enforcement priorities consistent with its commitment to enforcing the TCA and protecting the public health. FDA Br. 43.

C. The challenged guidance was not final agency action.

Finally, the government's opening brief explained why the challenged guidance is not final agency action subject to judicial review. FDA Br. 47-49; *see* 5 U.S.C. § 704. The challenged guidance satisfies neither of the two prongs that the Supreme Court identified in *Bennett v. Spear*, 520 U.S. 154 (1997), because it was a tentative policy that had no legal consequences for anyone.

Plaintiffs contend otherwise principally on the ground that, "[w]ithout the 2017 Guidance, manufacturers would have been exposed to severe consequences if they marketed their products without an order from FDA." Pls.' Br. 71. That is incorrect. Plaintiffs do not dispute that neither the TCA nor the Federal Food, Drug, and Cosmetic Act create a private right of action; it is only "the Federal Government rather than private litigants who are authorized to file suit for noncompliance." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001); *see* 21 U.S.C.

§ 337(a). Therefore, the only potential "severe consequences" would have come if FDA had chosen, in its enforcement discretion, to seek to restrain those violations of the TCA. FDA would have possessed precisely the same enforcement discretion with or without the guidance, confirming that the guidance has no "legal consequences." *Bennett*, 520 U.S. at 178.

Plaintiffs' invocation (at 72) of *Hawkes* is therefore inapposite. The letters at issue in *Hawkes* were final agency action because they were "binding for five years on both the Corps and the Environmental Protection Agency." 136 S. Ct. at 1809. Here, the challenged guidance did not bind FDA, as FDA's decision to issue the 2020 guidance confirms.

In sum, plaintiffs cannot point to any actual legal consequence of the challenged guidance. With or without the guidance, FDA had discretion to enforce, or not enforce, the TCA's premarket-review requirements at any time. Even though the guidance announced FDA's "current thinking," App. 141, that thinking was always subject to change (and indeed has changed). Accordingly, the guidance has no legal consequence and is not subject to judicial review.

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.

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) because it contains 6081 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.

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CERTIFICATE OF SERVICE

I hereby certify that on February 27, 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.

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