IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, *et al.*,

Defendants.

Civil Action No. 8:18-cv-883-PWG

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS OR, IN THE ALTERNATIVE, FOR SUMMARY JUDGMENT

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INTRODUCTION

The Tobacco Control Act (TCA or Act) sets forth a comprehensive scheme for the regulation of tobacco products. Manufacturers of products subject to the Act must generally register with the FDA, submit lists of their products and ingredients, obtain premarket authorization before marketing new products, and include health warnings on packaging and advertisements. Products marketed in violation of these requirements are considered "adulterated" or "misbranded."

Congress made the TCA immediately applicable to four products—cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco—and authorized the FDA to later "deem" other products subject to the Act. The FDA exercised that authority in 2016, issuing a regulation—known as the "deeming rule"—that subjected cigars and e-cigarettes, among other products, to its regulatory oversight.

This case concerns the FDA's enforcement of the TCA's premarket review provision. When it passed the Act in 2009, Congress included a statutory grace period that applied to the four originally regulated products: it required the FDA to allow those products to remain on the market during premarket review so long as their manufacturers submitted premarket applications by March 2011. But there is no statutory grace period for products later deemed subject to the Act. Thus, when the deeming rule took effect in August 2016, all newly deemed products then on the market were suddenly noncompliant with the statute. This was no small matter: as many as 7,500 cigars, 11,000 e-cigarette products, and 5,710 pipe tobacco products were affected. Final Regulatory Impact Analysis (RIA) at 84 (AR 23,995).[1]

[1] Citations to the "AR" are to the Administrative Record for the deeming rule. Citations to "GAR" are to the supplemental Administrative Record for the Guidance.

In their comments on the deeming rule, the Plaintiff public-health organizations "recognize[d] . . . the need for FDA to use its enforcement discretion to adapt those provisions to the special circumstances of products that become subject to the TCA by virtue of deeming." AR 145,551. While they urged the FDA to select a relatively short compliance period, they acknowledged that "[p]ermitting a compliance period for newly deemed products is discretionary with FDA." AR 145,607. Accordingly, the FDA used its enforcement discretion—discretion that the Supreme Court has described as "complete," *Heckler v. Chaney*, 470 U.S. 831, 835 (1985)—to defer enforcement of various provisions, including the premarket review provision, to give manufacturers time to come into compliance. In the preamble to the final deeming rule, the FDA thus announced that it intended to defer enforcement of the premarket review provision for most newly deemed products until at least February 2018, to allow manufacturers to submit applications, and for an additional year while those applications were reviewed.

In July 2017, the FDA revised this compliance policy as part of a new comprehensive regulatory strategy. The agency announced that it would further defer enforcement of the premarket review provision with respect to combustible products (like cigars) until 2021, and noncombustible products (like most e-cigarettes) until 2022—but only for products that were on the market when the deeming rule took effect in August 2016. In the meantime, the agency plans to issue regulations governing the information to be included in premarket applications, to develop standards that certain products must meet, and to publish additional guidance explaining what applications should contain and how they will be reviewed. This approach is part of a broader comprehensive plan for the regulation of tobacco and nicotine, and is intended to help foster a smooth transition to a properly regulated marketplace and to pave the way for higher-quality applications informed by the forthcoming regulations and guidance. Here, Plaintiffs

challenge an August 2017 FDA guidance document (the Guidance) that describes the revised compliance policy.

This case should be dismissed for a number of independent threshold defects. First, Plaintiffs lack standing, as they are not regulated by the TCA and are not cognizably harmed by the Guidance. They principally claim that the FDA's enforcement policy indirectly impairs their missions, requiring them to monitor the market for dangerous tobacco products. But a neighboring district court recently found that most of the same Plaintiffs lacked standing to intervene in a related challenge to the deeming rule, holding that these alleged harms were too "abstract" to confer standing. *Cigar Ass'n of Am. v. FDA*, 323 F.R.D. 54 (D.D.C. 2017). So too here.

Second, 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 is therefore "presumed immune from judicial review." *Chaney*, 470 U.S. at 831–32. Such decisions involve "a complicated balancing of . . . factors which are peculiarly within [an agency's] expertise," including "whether the particular enforcement action requested best fits the agency's overall policies." *Id*. at 831. Indeed, such decisions "resemble[] a prosecutor's prerogative not to indict—'a decision which has long been regarded as the special province of the Executive Branch.'" *Baltimore Gas & Elec. Co. v. FERC*, 252 F.3d 456, 459 (D.C. Cir. 2001) (quoting *Chaney*, 470 U.S. at 832). Plaintiffs cannot overcome that presumption here. As the Supreme Court has squarely held, the enforcement provisions of the Federal Food, Drug, and Cosmetic Act—of which the TCA is part—"commit *complete discretion* to the Secretary to decide how and when they should be exercised." *Chaney*, 470 U.S. at 835 (emphasis added).

Third, the Guidance is not final agency action subject to review under the Administrative Procedure Act (APA). It reflects only the FDA's current enforcement strategy, and imposes no substantive obligations on any regulated party or member of the public, much less Plaintiffs.

Even if Plaintiffs could overcome these justiciability hurdles, their claims would fail on the merits. To begin, the Guidance does not conflict with the TCA. While the statute requires manufacturers to obtain premarket authorization before marketing their products, it does not command the FDA to enforce those provisions in any particular way. And that Congress set forth a statutory grace period for originally regulated products in no way curtails the agency's inherent discretion to extend a similar grace period to newly deemed products—if anything, it shows that deferring enforcement of this provision for newly regulated products is entirely sensible. Plaintiffs' contentions to the contrary simply cannot be squared with their earlier acknowledgment of "the need for FDA to use its enforcement discretion to adapt those provisions" to newly deemed products. AR 145,551.

Plaintiffs' notice-and-comment claim is equally unavailing. The APA explicitly exempts "general statements of policy" from notice and comment, 5 U.S.C. § 553(b), and the revised compliance policy described in the Guidance readily qualifies. It imposes no substantive obligations on regulated parties, but merely "explains how the agency will enforce a statute or regulation—in other words, how it will exercise its broad enforcement discretion," *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251 (D.C. Cir. 2014)—a paradigmatic statement of policy.

Finally, Plaintiffs' claim that the revised compliance policy is arbitrary and capricious likewise lacks merit. Agencies are always free to change course on policy matters so long as they provide a rational explanation. Here, the FDA's decision to further defer enforcement of

the TCA's premarket review provision, while it issues regulations and guidance intended to improve the quality of premarket applications, amply meets that deferential standard.

The Court should dismiss this case or, in the alternative, grant summary judgment to Defendants.

BACKGROUND

A. The Tobacco Control Act and the Deeming Rule

This case concerns an FDA regulation—known as the "deeming rule"—that deems electronic cigarettes, cigars, and pipe tobacco (among other products) subject to regulation under Chapter IX of the Federal Food, Drug, and Cosmetic Act (FDCA). The deeming rule generally subjects these products to the same regulatory scheme that has applied to conventional cigarettes since the Tobacco Control Act was enacted in 2009.

The TCA establishes a comprehensive scheme for the regulation of tobacco products, which Congress broadly defined to include "any product made or derived from tobacco that is intended for human consumption." 21 U.S.C § 321(rr)(1). Among other things, the TCA requires a manufacturer to obtain premarket authorization before introducing a "new tobacco product"—that is, a product not commercially marketed in the United States as of February 15, 2007, or modified after that date—into interstate commerce. *Id*. § 387j(a)(1)–(2).

A manufacturer may seek premarket authorization through one of three pathways: by submitting (1) a "premarket tobacco application" demonstrating that the product would be appropriate for the protection of the public health, *id*. § 387j(b)–(c); (2) a "report" establishing that the product is "substantially equivalent" to a predicate product, *id*. §§ 387j(a)(2)(A)(i), 387e(j)(1); or (3) a request for an "exemption" from the substantial equivalence requirement, *id*. §§ 387j(a)(2)(A)(ii), 387e(j)(3). For simplicity, this brief generally refers to each route as

requiring a "premarket application."

A tobacco product that is marketed without a necessary premarket authorization is considered "adulterated" or "misbranded." *Id*. §§ 387b(6), 387c(a)(6). The FDA "is authorized to conduct examinations and investigations" to enforce these and other provisions of the FDCA. *Id*. § 372(a)(1)(A). Violations may lead to enforcement action, including the seizure of offending products, *id*. § 334, injunctions against manufacturers, distributors, and retailers, *id*. § 332, and criminal prosecution, *id*. §§ 331(a)–(c), 333(a), 335.

In the TCA, Congress made Chapter IX of the FDCA immediately applicable to four categories of tobacco products: "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." *Id*. § 387a(b). It also made Chapter IX applicable to any "other tobacco products that the Secretary by regulation deems to be subject to this chapter," *id*.—the authority that the FDA exercised in the deeming rule. As noted above, *supra* at 1, once the deeming rule took effect in August 2016, the newly regulated products immediately became subject to Chapter IX—meaning that as many as 25,000 products were suddenly out of compliance with its provisions. RIA at 84 (AR 23,995). Accordingly, in the preamble to the deeming rule, the FDA announced "compliance periods" during which it did not intend to enforce certain provisions, 81 Fed. Reg. at 29,003–15 & tbls. 2–3, adopting with some modifications the anticipated compliance policy it had set forth in the preamble to the proposed rule.[2] In the meantime, the agency explained, it was "committed to helping industry better understand the tobacco product premarket review process." *Id*. at 29,013.

[2] FDA, *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Regulations on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 79 Fed. Reg. 23,142, 23,172–74 & tbl. 1B (Apr. 25, 2014).

B. The Original Compliance Policy

Although "[a]gency compliance/enforcement policies are not subject to the requirements that govern notice-and-comment rulemaking," *id*. at 29,010 (citations omitted), the FDA published and sought comment on its compliance policy "because the relevant time periods [we]re of obvious interest" to industry and the public, *id*. Unsurprisingly, it received conflicting comments. On the one hand, "many industry comments sought additional time to comply with the[] requirements" imposed by the rule, *id*. at 29,012, asserting, for example, that "small and medium-sized businesses . . . lack the resources to tackle [its] high administrative burden," *id*. at 29,014. On the other hand, "many other comments stated that the contemplated . . . compliance period[s] w[ere] too long," *id*. at 29,013, and could be "detrimental to the public health," *id*. at 29,012. Notably, no commenter suggested that the FDA lacks the authority to adopt such compliance periods. Indeed, the Plaintiff public-health organizations submitted a comment urging the agency to "exercise . . . its enforcement discretion" to select shorter compliance periods, but acknowledging that "[p]ermitting a compliance period for newly deemed tobacco products is discretionary with FDA." AR 145,604, 145,607.

After weighing these considerations, the FDA set forth its original compliance policy in the preamble to the final deeming rule, seeking to "strike[] an appropriate balance between providing industry time to transition and protecting the public health." 81 Fed. Reg. at 29,014. As the agency explained, as an exercise of "enforcement discretion," it did "not intend to take enforcement action" under certain provisions for specified periods. *Id*. at 29,010. For example, it planned to defer enforcement of the requirements to register as a manufacturer and submit a list of products until December 2016. *Id*. at 29,006. It expected to defer enforcement of the requirement to submit a list of ingredients until February 2017. *Id*. And, for most products, it

intended to defer enforcement of the premarket review requirement until at least February 2018. *Id*. at 29,010–11. With respect to premarket review in particular, the FDA sought to "balance the Agency's concern about the continued marketing of new tobacco products that have not been reviewed by FDA . . . and the possibility that some of those products are playing a role in helping some tobacco users transition away from what is likely the most harmful form of nicotine delivery for an individual user, combusted tobacco products." *Id*. at 29,011. The FDA noted, however, that "[a]s with any such policy, the Agency will review and revise this policy as appropriate." *Id*. at 29,008.

C. Deeming Rule Litigation

Within months of the deeming rule's issuance, it was challenged by manufacturers, trade associations, and consumers in eight separate lawsuits—many of which focused on the burden and expense of the premarket review requirement. Some of the earlier cases quickly proceeded to merits briefing. For example, in the leading case, *Nicopure Labs, LLC v. FDA*, No. 16-878 (D.D.C.), the plaintiffs argued (among other things) that the premarket review compliance periods were irrationally short, and that the agency had provided insufficient guidance for manufacturers to prepare successful applications. Although the district court rejected these arguments, noting "the range of viewpoints that had been presented during the notice and comment period," it observed that "other approaches may have been reasonable as well." *Nicopure Labs, LLC v. FDA*, 266 F. Supp. 3d 360, 400 (D.D.C. 2017), *appeal docketed*, No. 17-5196 (D.C. Cir. Aug. 31, 2017).[3] And members of the public and industry continued to press the agency to adopt another approach. *See infra* at 44 & n.15.

[3] *Nicopure*, brought by a manufacturer of e-cigarettes and e-liquids, was consolidated and decided with *Right to Be Smoke-Free Coalition v. FDA*, No. 16-1210 (D.D.C.), brought by a

After the change in administrations, briefing in several other challenges to the deeming rule was delayed to give new leadership at the Department of Health and Human Services time to more fully consider the issues and determine how best to proceed.[4] At the same time, the FDA announced a 3-month extension of all compliance periods under the deeming rule that had not yet elapsed.[5]

D. The FDA's Comprehensive Regulatory Plan and Updated Compliance Policy

On July 28, 2017, the FDA announced a "new comprehensive plan" for the regulation of tobacco products.[6] The agency explained that its new approach would place "nicotine, and the issue of addiction, at the center of [its] tobacco regulation efforts." Press Release at 1 (GAR 411). In particular, the agency set a new public health goal of "lowering nicotine levels in combustible cigarettes to non-addictive levels through achievable product standards," which would "decrease the likelihood that future generations become addicted to cigarettes and allow more currently addicted smokers to quit." *Id.* at 1–2 (GAR 411–12). The agency issued an

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coalition of e-cigarette industry trade associations. In a second case, the district court largely granted a motion to dismiss for lack of standing. *Faircloth v. FDA*, No. 16-5267, 2017 U.S. Dist. LEXIS 159641 (S.D.W. Va. Sep. 28, 2017) (e-cigarette consumer and state legislator). A third case quickly settled. *John Middleton Co., LLC v. FDA*, No. 16-996 (D.D.C.) (cigar manufacturer).

[4] *See Cigar Ass'n of Am. v. FDA*, No. 16-1460 (D.D.C.) (cigar and pipe tobacco manufacturer trade groups); *Sanchez Icaza v. FDA*, No. 16-21967 (S.D. Fla.) (cigar manufacturer); *Cyclops Vapor 2, LLC v. FDA*, No. 16-556 (M.D. Ala.) (e-liquid manufacturers and e-cigarette vendors); *Lost Art Liquids, LLC v. FDA*, No. 16-3468 (C.D. Cal.) (e-liquid manufacturer).

[5] FDA, *Guidance for Industry: Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* (May 2017) (GAR 206–18).

[6] FDA, Press Release, *FDA Announces Comprehensive Regulatory Plan to Shift Trajectory of Tobacco-Related Disease, Death*, at 1 (July 28, 2017) ("Press Release") (GAR 411–13).

Advance Notice of Proposed Rulemaking (ANPRM) seeking public comment on this issue in March 2018. *See* 83 Fed. Reg. 11,818 (Mar. 16, 2018).

The agency also explained that, while it is pursuing the goal of reducing the nicotine levels in combustible cigarettes, it is "committed to encouraging innovations that have the potential to make a notable public health difference," Press Release at 2 (GAR 412)—such as e-cigarettes, which may present a reduced risk of tobacco-related disease because they generally do not produce the smoke delivered by combustible tobacco products, 81 Fed. Reg. at 28,981.[7] As part of that effort, the agency:

- Announced that it "intends to issue regulations outlining what information the agency expects to be included in [p]remarket [t]obacco [a]pplications," Press Release at 2 (GAR 412)—the type of premarket application most likely to be submitted by e-cigarette manufacturers, RIA at 97 & tbl. 16 (AR 24,008).

- Plans "to develop product standards" that certain newly regulated products must meet—for example, "to protect against known public health risks such as [e-cigarette] battery issues and concerns about children's exposure to liquid nicotine." Press Release at 2 (GAR 412).

- Has issued ANPRMs seeking public comment on, among other things, the role that flavors play in tobacco products, including "whether and how certain flavors may help adult cigarette smokers reduce cigarette use and switch to potentially less harmful products." 83 Fed. Reg. 12,294 (Mar. 21, 2018); *see* Press Release at 2 (GAR 412).

- Will "finalize guidance on how it intends to review" premarket applications for e-cigarettes. Press Release at 2 (GAR 412).

In addition, the agency explained that, "to make this effort successful," *id.*, it intended to further defer enforcement of the TCA's premarket review provision for a subset of newly regulated products—namely, those that were on the market as of August 8, 2016, when the

[7] This brief uses the term "e-cigarette" to refer to any sort of electronic nicotine delivery system (ENDS), including so-called "vaping" devices. *See* 81 Fed. Reg. at 28,976 ("ENDS" includes "e-cigarettes, ehookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes").

deeming rule took effect.[8] Under this "new compliance policy," the compliance period for seeking premarket authorization was extended to August 2021 for combustible products (like cigars) and to August 2022 for noncombustible products (like most e-cigarettes). During these periods, the TCA's premarket review provision remains in effect, but the FDA "does not intend to enforce" that requirement "as a matter of enforcement discretion." Guidance at 4 (GAR 425). This "targeted relief" was intended to "make certain that the FDA is striking an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes," and to "provide manufacturers additional time to develop higher quality, more complete applications informed by additional guidance from the agency." Press Release at 1–2 (GAR 411–12). The Guidance notes, however, that it merely "represents the current thinking of the [FDA] on this topic," and "does not establish any rights for any person and is not binding on [the] FDA or the public." Guidance at 1 (GAR 422).

Notably, the Guidance left the compliance periods for the vast majority of TCA provisions unchanged. It did "not apply to provisions of the final rule for which compliance deadlines already ha[d] passed, such as mandatory age and photo-ID checks to prevent illegal sales to minors." Press Release at 2 (GAR 412). It likewise did "not affect future deadlines for other provisions of the rule, including, but not limited to, required warning statements, ingredient listing, health document submissions, harmful and potentially harmful constituent reports, and the removal of modified risk claims, i.e., 'light,' 'low,' or 'mild,' or similar descriptors." *Id*. And even with respect to the premarket review provision, the Guidance did not alter the fact that many newly regulated products—namely, those that entered the market *after* August 8, 2016—

[8] FDA, *Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* (Aug. 2017) ("Guidance"), https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm557714.htm (GAR 420–33).

are not subject to the compliance policy at all, and must go through the premarket review process before entering the market.

E. This Action

Plaintiffs bring three claims under the APA. First, they allege that the Guidance conflicts with the TCA and amounts to an "abdication of . . . statutory responsibilities" "so flagrant" as to offend the Take Care Clause. Compl. ¶¶ 94–95, 100–01 (citing 21 U.S.C. § 387j and U.S. Const. art. II, § 3). Second, they contend that the Guidance was improperly issued without notice and comment. *Id*. ¶¶ 103–10 (citing 5 U.S.C. § 553(b)). Third, they assert that the Guidance reflects a change in agency policy so inadequately explained as to be arbitrary and capricious. *Id*. ¶¶ 111–18 (citing 5 U.S.C. § 706).

ARGUMENT

I. THIS CASE IS NOT JUSTICIABLE

A. Plaintiffs Lack Standing

Plaintiffs are not the object of the challenged Guidance. Rather, their principal claim of injury is that the Guidance conflicts with their mission to combat tobacco use and to educate the public and their patients about the health effects of tobacco products. That is precisely the type of abstract policy concern that is insufficient to confer standing.

To satisfy Article III's standing requirements, a plaintiff—whether an organization or an individual—must (1) have suffered an injury in fact; (2) that is caused by the defendant's conduct; and (3) that is likely to be redressed by a favorable ruling. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992); *Lane v. Holder*, 703 F.3d 668, 672, 674 (4th Cir. 2012). The plaintiff bears the burden of alleging facts to establish each element, *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990), and, at the summary judgment stage, "must set forth *evidence*

of an injury in fact in addition to [the allegations] provided in the complaint," *Pye v. United States*, 269 F.3d 459, 467 (4th Cir. 2001) (citing *Lujan*, 504 U.S. at 561) (emphasis added). An organization seeking to sue on behalf of its members must demonstrate that "its members would otherwise have standing to sue in their own right, the interests at stake are germane to the organization's purpose, and neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

An injury in fact is "an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent, not conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (citation omitted). To be particularized, an injury "must affect the plaintiff in a personal and individual way." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016) (citation omitted); *accord Lujan*, 504 U.S. at 560 n.1. It is not enough that the plaintiff "suffers in some indefinite way in common with people generally." *Hein v. Freedom from Religion Found.*, 551 U.S. 587, 599 (2007) (citation omitted). Concreteness is an independent requirement. *See Spokeo*, 136 S. Ct. at 1548. To be concrete, an injury must "actually exist" rather than being merely "abstract." *Id.*

1. Plaintiffs Cannot Show a Cognizable Injury Caused by the Guidance

Plaintiffs have not satisfied the requirements for standing because they have not alleged a concrete, particularized, and imminent injury to a legally protected interest that is fairly traceable to the Guidance. The Organizational Plaintiffs assert that the Guidance "impairs [their] ability to carry out their missions" because they will have to expend resources to "monitor the marketplace for dangerous tobacco products" and "conduct . . . studies or otherwise evaluate the dangers of newly deemed tobacco products" in order to "carry out their public-education functions." Compl. ¶¶ 33, 38, 41, 45. The Individual Plaintiffs similarly allege that the Guidance will make

it "more difficult, time-consuming, and resource-intensive to counsel, advise, and treat patients." *Id*. ¶ 48. But another district court already determined that similar allegations by most of the same Plaintiffs were not sufficient to establish standing to intervene in a challenge to the deeming rule.

In *Cigar Association of America v. FDA*, 323 F.R.D. 54 (D.D.C. 2017), six of the public-health organizations that are Plaintiffs here sought to intervene (both on their own and on behalf of their physician members) in a suit brought by trade associations challenging, among other things, the deeming rule's requirement to include certain health warnings on cigar and pipe tobacco packages and advertisements. The proposed intervenors alleged that, if the plaintiffs in *Cigar Association* were successful in invaliding the warning requirements, the organizations would be "compelled to expend additional resources to communicate information to the public that would otherwise appear on the products themselves." *Id*. at 62. The court denied the motion to intervene based on its determination that the organizations lacked standing. *See id*. at 57.

The court explained that the proposed intervenors had not demonstrated that their activities would be "'perceptibly impaired' as required to make out a concrete and demonstrable injury for purposes of Article III." *Id*. at 62. Instead, the organizations' assertion that they would "have to expend some undefined amount of additional resources if the Rule is vacated" was merely a "generalized harm" and an "abstract injury to [the organizations'] interests." *Id*. at 62–63 (citation omitted). The court noted that, at most, the organizations had shown that "the Rule [would] help them achieve their organizational objectives and that the Rule's demise would make it harder to achieve those objectives." *Id*. at 63. Such a showing, however, did not amount to a legally sufficient injury in fact. *See id*. The court also held that the organizations did not have standing to sue on behalf of their physician members for the same reasons. *See id*. at 64–

65. The members' assertion that, in the absence of the Rule, they would have to "expend additional time and resources counseling patients about the dangers of tobacco use" was not sufficiently particularized or concrete. *Id*. at 65.

Plaintiffs' standing allegations here are flawed for the same reasons. The Organizational Plaintiffs contend that, like the warning requirements at issue in *Cigar Association*, the premarket review process at issue here would "help them achieve their organizational objectives" and the Guidance, which extends the compliance dates for certain products, may "make it harder [for the organizations] to achieve those objectives" because manufacturers may decide not to conduct studies on the effects of certain newly deemed tobacco products and the FDA's authorization (or denial) of certain premarket applications may be delayed. *Id*. at 63; *see* Compl. ¶¶ 34–46. As in *Cigar Association*, however, these alleged injuries are merely generalized and abstract harms to the organizations' interests in educating the public and combating tobacco use. The Organizational Plaintiffs have not alleged a concrete, particularized, and imminent injury stemming from the Guidance.

The Individual Plaintiffs fare no better. They make the same allegations that the proposed intervenors made in *Cigar Association* in an effort to establish standing on behalf of their physician members—i.e., that it will be more difficult and resource intensive for the Individual Plaintiffs to counsel and treat their patients with the Guidance than without. *Compare Cigar Association*, 323 F.R.D. at 64–65, *with* Compl. ¶¶ 48–51. The *Cigar Association* court concluded that these allegations were "abstract societal interests" that did not "connect . . . to Plaintiffs' present challenges to the Rule." 323 F.R.D. at 65. That is equally true here.

Plaintiffs' allegations of injury in this case also fail for additional reasons. First, it is well established that standing is "substantially more difficult" to show "[w]hen a plaintiff is not the

direct subject of government action, but rather . . . the 'asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of someone else." *Lane*, 703 F.3d at 673 (citation omitted). That is the case here. The Guidance extends compliance dates for *manufacturers* to submit certain premarket review applications; it does not regulate Plaintiffs, who are public-health organizations and physicians, in any way. Accordingly, Plaintiffs' alleged injuries are premised on speculation about what manufacturers will do in response to the Guidance and assumes that Plaintiffs will find the information provided by manufacturers in the applications to be useful.

Specifically, Plaintiffs allege that the Guidance will cause manufacturers to (1) delay submission of premarket review applications for products covered by the Guidance; (2) decide not to conduct research that they otherwise would have conducted on the effects of their products in order to support their premarket review applications; and (3) continue to market products they otherwise would have discontinued, knowing those products would not likely obtain marketing authorization. *See* Compl. ¶¶ 37, 39–40, 43–44. These "[a]llegations of *possible* future injury" are too speculative to constitute injury in fact. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013) (citation omitted) (emphasis added). Plaintiffs can only hypothesize about the actions manufacturers may take (or not take) in response to the Guidance, which the FDA issued as part of an effort to *improve* the quality of the applications and data manufacturers will submit. *See supra* 10–11. Similarly, Plaintiffs' allegations about what manufacturers would have done in the absence of the Guidance (e.g., conducting unspecified studies or removing certain unspecified products from the market) is pure conjecture. Their "standing theories" "rest on speculation about the [future] decisions of independent actors" and should be rejected. *Clapper*, 568 U.S. at 414.

Second, even if manufacturers were to respond to the Guidance in the ways that Plaintiffs predict, Plaintiffs have not alleged that it would result in any concrete and particularized injury to them. Plaintiffs assert that, if manufacturers delay submission of premarket review applications as a result of the Guidance, the FDA's decisions on those applications will be delayed, depriving Plaintiffs of the information contained in those decision documents and requiring them to spend resources to obtain similar information from other sources in order to educate their members and the public. *See* Compl. ¶¶ 34–38, 42–46. But Plaintiffs do not claim (nor could they) that the Guidance puts them in a worse position than the one in which they have always been. The products at issue in this litigation were not previously deemed tobacco products under the FDCA, and thus, manufacturers have never been required to obtain premarket authorization from the FDA for these products. To the extent Plaintiffs are expending resources to obtain information about these products, those are resources that Plaintiffs have always had to spend for these purposes. *See, e.g.*, Am. Acad. Pediatrics, Fact Sheets, https://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Richmond-Center/Pages/Fact-Sheets.aspx (last visited Aug. 7, 2018) (providing "fact sheets" on tobacco products, including e-cigarettes).

Plaintiffs' complaint, then, is that they may have to *continue* spending resources on these endeavors under the Guidance. *See* Compl. ¶ 44 (asserting that premarket review would "decrease the resources Plaintiffs currently need to dedicate to their tobacco prevention and cessation efforts"). An organization, however, "does not suffer an injury in fact where it 'expend[s] resources to educate its members and others' unless doing so subjects the organization to 'operational costs *beyond those normally expended*.'" *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 920 (D.C. Cir. 2015) (citation omitted) (emphasis added); *see also Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982) (an organization must show

"concrete and demonstrable injury to [its] activities—with the consequent drain on the organization's resources"). Because Plaintiffs have not alleged that the Guidance has caused them to "spend anything beyond their typical annual expenditures," Plaintiffs have not alleged a cognizable injury. *Envtl. Working Grp. v. FDA*, 301 F. Supp. 3d 165, 172 (D.D.C. 2018) (holding that organizations "focused on warning the public about the health hazards in consumer products" lacked standing to challenge the FDA's denial of a petition to regulate hair products that allegedly contained formaldehyde because the organizations' anti-formaldehyde educational efforts were "exactly" the "type of work . . . these organizations always do" and the organizations had not alleged that they incurred "operational costs beyond those normally expended" in response to the agency's decision); *see also Lane*, 703 F.3d at 675 (an organization's decision to "spend its money on educating members . . . in response to legislation [or agency action]" is not a cognizable injury).[9]

Indeed, Plaintiffs' future expenditures on efforts to obtain product information to educate the public and its members may decrease below past levels even under the Guidance. Because the Guidance does not apply to newly deemed tobacco products that were not on the market as of August 8, 2016, manufacturers that wish to sell those products are subject to the agency's usual policies regarding the requirement to obtain premarket authorization from the FDA. *See* Guidance at 3 (GAR 424). Plaintiffs will thus have access to the FDA's marketing orders and decision summaries regarding these products, which Plaintiffs never had before, even while the

[9] Plaintiffs also allege that they rely on information in FDA marketing orders and decision summaries to "press for regulatory actions." Compl. ¶ 34; *see id.* ¶ 36. But purported impacts on an organization's lobbying activities are not cognizable injuries. *See, e.g.*, *Ctr. for Law & Educ. v. Dep't of Educ.*, 396 F.3d 1152, 1161 (D.C. Cir. 2005); *Envtl. Working Grp.*, 301 F. Supp. 3d at 171 (explaining that a contrary rule "would allow lobbyists on either side of virtually any issue to take the Government to court").

compliance dates for other products are extended. The Guidance, moreover, does not *prevent* manufacturers from submitting premarket applications: a manufacturer may submit such an application at any time while the compliance period is in effect and the FDA would review that application.

Third, to the extent Plaintiffs attempt to allege an informational injury, their allegations fail because the TCA "does not create a legal right to access to [the] information" Plaintiffs seek. *Salt Inst. v. Leavitt*, 440 F.3d 156, 159 (4th Cir. 2006). As noted above, Plaintiffs' alleged injuries stem largely from their assertion that the FDA's authorization (or denial) of premarket review applications for products covered by the Guidance will be delayed, depriving Plaintiffs of the information contained in the FDA's marketing orders and decision summaries.[10] *See* Compl. ¶¶ 34–37. To establish standing based on a denial of access to information, however, a plaintiff must demonstrate (among other things) that "the statute upon which [it] rel[ies] . . . create[s] a legal right to access to information." *Salt Inst.*, 440 F.3d at 159. Absent such a showing, a plaintiff cannot establish injury to "a legally protected interest," which is necessary to confer standing. *Lane*, 703 F.3d at 672 (citation omitted); *see Salt Inst.*, 440 F.3d at 159.

The TCA's provisions governing premarket review do not create any legal rights in third parties, much less a right to public disclosure of the FDA's marketing orders and decision summaries. *See* 21 U.S.C. § 387j. And Plaintiffs do not claim otherwise. Instead, Plaintiffs cite a regulation setting forth the agency's general records policies, which provides that FDA records shall be made available for public disclosure absent certain exceptions. *See* Compl. ¶ 35 (citing

[10] The FDA's marketing orders do not contain any "scientific [or] other data," but the decision summaries do. Compl. ¶ 35; *see* FDA, Premarket Tobacco Product Marketing Orders, https://www.fda.gov/TobaccoProducts/Labeling/TobaccoProductReviewEvaluation/PremarketTobaccoApplications/ucm472108.htm (last visited Aug. 7, 2018).

21 C.F.R. § 20.20(b)). This *regulation*, however, is not sufficient to create a *statutory* right to information. *See Salt Inst.*, 440 F.3d at 159 (asking "whether Congress has granted a legal right to the information in question"); *New Eng. Anti-Vivisection Soc'y v. U.S. Fish & Wildlife Serv.*, 208 F. Supp. 3d 142, 156, 159 (D.D.C. 2016) (rejecting a claim of informational injury in part because it relied on a regulation, not a statute). Furthermore, even if a regulation could provide the basis for an informational injury, the regulation Plaintiffs cite was not promulgated pursuant to the "statute upon which" Plaintiffs' claims rest (i.e., the TCA), and thus, the regulation cannot create the necessary legal right to access to information that is a predicate for Plaintiffs' alleged informational injury. *Salt Inst.*, 440 F.3d at 159.[11]

In any event, even if Plaintiffs could demonstrate a legal right to access to the FDA's marketing orders and decision summaries, Plaintiffs still have not alleged an informational injury because the Guidance does not deprive them of access to such information. Under the Guidance, the FDA will continue to review and act upon premarket review applications that are submitted to the agency, and the FDA plans to continue to make its marketing orders and decision summaries available to the public as it has in the past. Thus, Plaintiffs' claim is not that they have been denied access to information that exists, but rather, that the FDA may not be creating the information as quickly as Plaintiffs desire as a result of the Guidance. Such allegations cannot form the basis for an informational injury. *See Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016) (concluding that the plaintiff lacked standing where the statute on which it relied did not require the agency to publish information until later in the process); *New*

[11] The fact that, in practice, the FDA has historically made its marketing orders and decision summaries available to the public also does not demonstrate that "the statute upon which [Plaintiffs] rely . . . create[s] a legal right to access to [this] information." *Salt Institute*, 440 F.3d at 159.

Eng. Anti-Vivisection Soc'y, 208 F. Supp. 3d at 157 (rejecting the plaintiff's attempt to rely on a statute that required the agency to disclose information it *received* to support an alleged injury stemming from the agency's failure to *collect* the information).

Because Plaintiffs have not alleged a cognizable injury that is fairly traceable to the Guidance, the Court lacks jurisdiction.

2. Plaintiffs Cannot Demonstrate Redressability

Plaintiffs also cannot show that their alleged injury is likely to be redressed by a favorable decision. *See Lujan*, 504 U.S. at 560. Plaintiffs ask the Court to "[v]acate and set aside the Guidance" and to "[e]njoin Defendants from enforcement or implementation of the Guidance." Compl., Prayer for Relief. This relief, however, would not provide Plaintiffs with the information they seek from FDA marketing orders and decision summaries. Notably, Plaintiffs do not ask the Court to force manufacturers to submit premarket applications or to compel the FDA to take enforcement action against any manufacturer that fails to do so. And there would be no basis for such a request, as the FDCA contains no private right of action. *See* 21 U.S.C. § 337(a); *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Accordingly, Plaintiffs also lack standing because their alleged injury is not redressable.

B. The Court Lacks Jurisdiction To Review FDA's Compliance Policy

Even if Plaintiffs had standing, the Court would lack jurisdiction for another reason: It is well established that an executive branch agency's nonenforcement decisions, such as the compliance policy here, are committed to agency discretion, and thus presumptively immune from judicial review. Plaintiffs cannot overcome that presumption here.

1. An Agency's Nonenforcement Decisions Are Presumptively Unreviewable

The APA grants a cause of action to "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute." 5 U.S.C. § 702. It withdraws that cause of action "to the extent that . . . agency action is committed to agency discretion by law." *Id.* § 701(a)(2). In *Heckler v. Chaney*, 470 U.S. 821 (1985), the Supreme Court held 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 is therefore "presumed immune from judicial review under § 701(a)(2)." *Id.* at 831–32; *see Angelex Ltd. v. United States*, 723 F.3d 500, 502 (4th Cir. 2013) (where agency "actions [a]re committed to agency discretion by law . . . , the district court lack[s] jurisdiction" and "dismissal under Federal Rule of Civil Procedure 12(b)(1)" is required).

The *Chaney* Court identified three reasons for the presumption of nonreviewability. First, an agency's decision not to enforce involves "a complicated balancing of a number of factors which are peculiarly within [an agency's] expertise." 470 U.S. at 831. An agency:

> must not only assess whether a violation has occurred, but 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, indeed, whether the agency has enough resources to undertake the action at all.

Id. "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. Second, "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 are often called upon to protect." *Id.* at 832. "Third, and perhaps most importantly, an agency's decision not to enforce resembles a prosecutor's prerogative not to indict—'a decision which has long been regarded as the special

province of the Executive Branch.'" *Baltimore Gas*, 252 F.3d at 459 (quoting *Chaney*, 470 U.S. at 832).

Chaney is on all fours here, as it rejected a challenge to an FDA nonenforcement decision much like this one. There, the plaintiffs argued that certain drugs used for lethal injections had not been approved by the FDA as "safe and effective" for that purpose, and were therefore "misbranded" under the FDCA. 470 U.S. at 823–24. The plaintiffs thus argued that the FDA was required to take "various investigatory and enforcement actions" to prevent these violations—including to "affix warnings to the labels of all the drugs," to "send statements to the drug manufacturers and prison administrators" stating that the drugs should not be used, to "adopt procedures for seizing the drugs," and to "recommend the prosecution of all those in the chain of distribution." *Id*. at 824. The Court flatly disagreed, concluding that "[t]he Act's enforcement provisions . . . commit *complete discretion* to the Secretary to decide how and when they should be exercised." *Id*. at 835 (emphasis added); *see also Jerome Stevens Pharm., Inc. v. FDA*, 402 F.3d 1249, 1258 (D.C. Cir. 2005) (concluding that the FDA's extension of a new drug application approval deadline was "an exercise of FDA's enforcement discretion"); *United States v. Sage Pharm. Inc.*, 210 F.3d 475, 480 (5th Cir. 2000) ("[T]he APA prohibits review of the FDA's enforcement decisions, at least when the FDA declines to enforce the Act against a manufacturer."); *Int'l Ctr. for Tech. Assessment v. Thompson*, 421 F. Supp. 2d 1, 7 (D.D.C. 2006) (upholding the FDA's exercise of enforcement discretion concerning new animal drug applications).

The compliance policy challenged here—under which the FDA has announced that it intends to defer enforcement action against certain products that have not obtained premarket

approval—cannot meaningfully be distinguished. Thus, under *Chaney*, this Court lacks jurisdiction to review the challenged Guidance.

2. Plaintiffs Fail to Rebut the Presumption of Nonreviewability

Although the Supreme Court has identified three circumstances in which a plaintiff "might" be able to overcome the presumption of nonreviewability, *Chaney*, 470 U.S. at 833 n.4, none is present here.

a. The FDCA vests the FDA with "complete discretion" over how and when to exercise its enforcement provisions

To begin, the presumption of nonreviewability may be overcome "where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers." *Id*. at 833. But, as explained above, *Chaney* itself found that the FDCA provides no such "guidelines." *Id*. at 835. That conclusion is binding here.

"Congress may limit an agency's exercise of enforcement power if it wishes, either by setting substantive priorities, or by otherwise circumscribing an agency's power to discriminate among issues or cases it will pursue." *Id*. at 833. The key inquiry is whether "the statute . . . lay[s] out any circumstances in which the agency is required to undertake or to continue an enforcement action." *N.Y. State Dep't of Law v. FCC*, 984 F.2d 1209, 1215 (D.C. Cir. 1993); *Baltimore Gas*, 252 F.3d at 460. An agency retains its enforcement discretion where the statute gives no "indication that violators must be pursued in every case, or that one particular enforcement strategy must be chosen over another." *Ass'n of Irritated Residents v. EPA*, 494 F.3d 1027, 1033 (D.C. Cir. 2007). The touchstone is congressional intent. *See Chaney*, 470 U.S. at 838.

Here, the TCA's premarket review provision states that, before a new tobacco product may enter the market, its manufacturer must submit an application demonstrating that the

product is either "appropriate for the protection of the public health," 21 U.S.C. § 387j(c)(2)(A), substantially equivalent (SE) to a grandfathered product or other predicate, *id*. §§ 387j(a)(2)(A)(i), 387e(j)(1)(A), or exempt from SE requirements, *id*. § 387j(a)(2)(A)(ii). In other words, unless the manufacturer submits an SE application or is exempt from SE requirements, then a premarket authorization "order" affirming that the product is appropriate for the protection of the public health "is required." *Id*. § 387j(c)(2)(A).

Plaintiffs' contention that this provision provides a "clear" expression of Congress's intent to circumscribe the FDA's enforcement discretion lacks merit. Compl. ¶ 95. To be sure, the provision imposes a substantive requirement on tobacco product *manufacturers*. But the Supreme Court has "reject[ed] [the] argument that the [FDCA's] substantive prohibitions . . . supply us with 'law to apply'" to constrain the enforcement discretion of *the FDA*. *Chaney*, 470 U.S. at 835–36. Such "provisions are simply irrelevant to the agency's discretion to refuse to initiate proceedings." *Id*. at 836. Critically, Plaintiffs point to nothing in the statutory text that purports to require the FDA to take enforcement action under these circumstances—which is the key question under *Chaney*. *See, e.g.*, *Schering Corp. v. Heckler*, 779 F.2d 683, 686 (D.C. Cir. 1985) ("These provisions authorize, but do not compel the FDA to undertake enforcement activity; they 'commit complete discretion to the Secretary to decide how and when they should be exercised.'") (citation omitted); *Irritated Residents*, 494 F.3d at 1033 (enforcement discretion not curtailed where statute gives no "indication that violators must be pursued in every case").

Indeed, courts have consistently declined to attribute sweeping meaning to the sort of unremarkable statutory language that Plaintiffs emphasize even when featured in enforcement provisions. For example, *Chaney* rejected the argument that an FDCA provision stating that certain offenders "shall be imprisoned . . . or fined" would "mandate[] criminal prosecution of

every violator of the Act." 470 U.S. at 835. The Court noted that there was "no indication in case law or legislative history that such was Congress' intention in using this language"—the same language that is "commonly found" throughout the criminal code, where it is understood that the prosecution of every offender is not required. *Id.* (citing, *inter alia*, 18 U.S.C. §§ 1001 (false statement), 1341 (mail fraud)).

Chaney also illustrates that the FDCA does not limit the FDA's enforcement discretion by offering a contrasting example of a statute that *does*. As *Chaney* explains, the statute at issue in an earlier case, *Dunlop v. Bachowski*, 421 U.S. 560 (1975), provided that, upon the filing of a complaint by a union member, the Secretary of Labor "'shall investigate such complaint and, if he finds probable cause to believe that a violation . . . has occurred . . . he shall . . . bring a civil action.'" *Chaney*, 470 U.S. at 833 (quoting 29 U.S.C. § 482). That statutory language, the Court in *Chaney* explained, "quite clearly withdrew discretion from the agency and provided guidelines for exercise of its enforcement power." *Id.* at 834. Even there, however, the Court held that the Secretary retained "a degree of discretion to select cases" based on his "subjective judgment," and required only that he set forth a statement of reasons for not bringing suit, subject to review for arbitrariness. *Dunlop*, 421 U.S. at 572. Here, by contrast, Plaintiffs point to no comparably clear language purporting to limit the FDA's "complete discretion." *Chaney*, 470 U.S. at 835.

b. The FDA's compliance policy is not based on a mistaken belief that it lacks jurisdiction to bring an enforcement action

The presumption of nonreviewability may also be overcome where an agency "refus[es] . . . to institute proceedings based solely on the belief that it lacks jurisdiction." *Chaney*, 470 U.S. at 833 n.4. Plaintiffs make no such allegation here—nor could they. The FDA has vigorously defended its authority to subject newly regulated products to this provision, *see, e.g.*, *Nicopure*, 266 F. Supp. 3d at 396–400, has announced plans to enforce it beginning in 2021, and

has published guidance describing how it intends to do so, *see supra* at 10–11. Thus, there is no concern here that the FDA has extended the premarket compliance periods out of a mistaken belief that it lacked jurisdiction.

c. The FDA's compliance policy is not an "abdication" of its statutory responsibilities

Finally, while the Supreme Court has left open the possibility that the presumption of nonreviewability "may" be overcome if an agency 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 (citation omitted), Plaintiffs fall well short of showing that the FDA could "justifiably be found" to have done so here, *id*. Not only is the revised compliance policy explicitly limited in duration, but it is part and parcel of a broader regulatory plan designed to allow the agency to issue regulations and other guidance expected to improve the quality of premarket applications—hardly "abdication" by any reasonable measure.

Contrary to Plaintiffs' claims, the compliance policy abdicates no "duty assigned to [the FDA] by statute." Mem. in Supp. of Pls.' Mot. for Summ. J. ("Pls.' Br.") at 9, ECF No. 31-2. Plaintiffs observe that, under the TCA, a manufacturer "is required" to obtain premarket authorization, 21 U.S.C. § 387j(a)(2)(A), before a "new product may be introduced . . . into interstate commerce," *id.* § 387j(c)(1)(A)(i); *see* Pls.' Br. at 9. But that provision places a requirement on *manufacturers*, not the FDA, as Plaintiffs themselves recognize. Pls.' Br. at 9 (acknowledging that "the Act directs" this requirement "[a]s to manufacturers"). Plaintiffs also note that the statute says the FDA "shall . . . issue an order" granting or denying premarket authorization within "180 days after receipt of an application." 21 U.S.C. § 387j(c)(1)(A)(i), (ii); *see* Pls.' Br. at 10. But the FDA has not abdicated any duty imposed by that provision: manufacturers remain free to submit premarket applications in advance of the compliance date,

and the agency intends to process such applications within the statutory timeframe. Indeed, there is no material difference between these provisions and those governing the premarket approval process for new drugs in *Chaney*, where they were "simply irrelevant to the agency's discretion to refuse to initiate proceedings." 470 U.S. at 824, 836 (citing 21 U.S.C. § 355).[12]

The cases cited by Plaintiffs are inapposite, *see* Pls.' Br. at 14, as each involved an unambiguous statutory command to the agency. For example, in *Adams v. Richardson*, 480 F.2d 1159 (D.C. Cir. 1973) (en banc), the agency refused to cut off federal funding under Title VI of the Civil Rights Act to schools that had failed to take sufficient action to end segregation. The court held that this was not an enforcement decision committed to agency discretion, as the statute "not only requires the agency to enforce the Act, but also sets forth specific enforcement procedures." *Id*. at 1162. Similarly, in *NAACP v. Secretary of Housing and Urban Development*, 817 F.2d 149 (1st Cir. 1987), the agency declined to take steps "to affirmatively further" the policies of the Fair Housing Act, claiming that this statutory directive was satisfied so long as the agency did not engage in discriminatory conduct itself. The court found *Chaney* inapplicable, noting that "as a matter of language and logic" the statute "impose[d] an obligation [on the agency] to do more." *Id*. at 154. And in *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013), the court held that the FDA did not have unreviewable discretion to permit the *importation* of misbranded drugs, explaining that another FDCA provision required that "the FDA [1] must request samples of all drugs offered for import that have been made in an unregistered

[12] *See also* 21 U.S.C. § 355(a) ("Necessity of effective approval of application. No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."); *id*. § 355(c) (within "one hundred and eighty days after the filing of an application," the FDA "shall either . . . approve the application . . . or . . . give the applicant notice of an opportunity for a hearing"); *id*. § 355(d) (if "after . . . an opportunity for a hearing" the drug is not approvable, the FDA "shall issue an order refusing to approve the application").

establishment, [2] must examine those samples for a violation of the FDCA, and [3] must refuse admission to any drug that appears, through the sampling process or otherwise, to violate the FDCA." *Id*. at 7–8 (citing 21 U.S.C. § 381). But the court took pains to distinguish the FDA's "enforcement discretion to allow the *domestic* distribution of a misbranded or unapproved new drug, as the Supreme Court recognized in *Chaney*." *Id*. at 10 (emphasis added) (citing 21 U.S.C. § 355). Thus, in each of these cases, a clear statutory directive curtailed the agency's enforcement discretion. Here, by contrast, the "[t]he Act's enforcement provisions . . . commit *complete discretion*" to the agency. *Chaney*, 470 U.S. at 835 (emphasis added).

That discretion is not nullified by what Plaintiffs describe as the "categorical" nature of the compliance policy. Pls.' Br. at 14. For starters, the policy is hardly all-encompassing: it has no effect on the many other TCA provisions made applicable by the deeming rule, and even with respect to the premarket review provision, the policy does not apply to products that entered the market *after* August 8, 2016, when the deeming rule took effect. *See supra* at 11–12. Regardless, *Chaney* itself involved a similarly "categorical" nonenforcement policy. There, the plaintiffs sought to compel enforcement of the FDCA's misbranding provision with respect to drugs used for capital punishment, requesting "various investigatory and enforcement actions" against "drug manufacturers," "prison administrators," and "all [others] in the chain of distribution" throughout Texas, Oklahoma, and potentially "several other[]" states that had adopted lethal injection. 470 U.S. at 823–24. The Supreme Court rejected this wide-ranging request, holding that the FDA's categorical conclusion that its enforcement discretion "should not be exercised to interfere with this particular aspect of state criminal justice systems" was unreviewable. *Id*. at 824. Similarly, in *Irritated Residents*, the plaintiffs sought to force the EPA to enforce Clean Air Act limits on pollutants emitted from animal feed lots. The EPA, having

found the emissions difficult to measure, had agreed to "several thousand . . . identical" consent decrees promising to defer enforcement for "about four years" while it completed a methodological study. 494 F.3d at 1029–30. The court found this an unreviewable exercise of enforcement discretion, noting the agency's "judgment that immediate compliance [wa]s impossible or impracticable" and that this "broader strategy" would improve "industry-wide compliance." *Id*. at 1031. The policy thus gave "no indication that [the agency] ha[d] abandoned its responsibility to enforce" the statute; "to the contrary, it is part of the agency's attempt to ensure that [the industry members] comply." *Id*. at 1035.

So too here. The compliance policy should be understood in its proper context, as an integral part of the comprehensive tobacco regulatory plan with which it was announced. *See supra* at 9–12. That plan does not extend the premarket review compliance period simply to benefit industry, as Plaintiffs intimate. The extension is also designed to build in time for the FDA "to issue regulations outlining what information the agency expects to be included in [p]remarket" applications, "to develop product standards" that certain newly regulated products must meet, and to "finalize guidance on how it intends to review" premarket applications for e-cigarettes. Press Release at 2 (GAR 412). Those steps are expected to pave the way toward "higher quality, more complete applications," which would benefit not just industry, but the agency and the public alike. *Id*. As *Chaney* teaches, these are "precisely the sort of balancing of agency priorities and objectives, informed by judgments based on expertise, that, absent some 'law to apply,' should not be second-guessed by a court." *Irritated Residents*, 494 F.3d at 1032 (citation omitted).

C. The Guidance Is Not Final Agency Action Subject to Judicial Review

Finality is another prerequisite to judicial review of agency action. *See* 5 U.S.C. § 704; *Invention Submission Corp. v. Rogan*, 357 F.3d 452, 458 (4th Cir. 2004) (noting that the APA's final agency action requirement is a "question of subject matter jurisdiction"). To be final, 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*. Even if the Guidance were more than the FDA's "current thinking" on enforcement of the premarket authorization requirement, Guidance at 1 (GAR 422); *see BBK Tobacco & Foods, LLP v. FDA*, 672 F. Supp. 2d 969, 975–76 (D. Ariz. 2009), it does not satisfy the second criterion because it does not determine any rights or obligations, nor will any legal consequences flow from it.

As the FDCA and its implementing regulations explain, FDA guidance documents do not establish legally enforceable rights or responsibilities, and do not legally bind the public or the agency. *See* 21 U.S.C. § 371(h)(1)(A); 21 C.F.R. § 10.115(d). The Guidance itself states that "[i]t does not establish any rights for any person," "do[es] not establish legally enforceable responsibilities," and "is not binding on FDA or the public." Guidance at 1 (GAR 422). Instead, the Guidance merely explains that the agency "does not intend to enforce a particular requirement," for a limited period. *Id*. at 4 (GAR 425). The Guidance sets forth the FDA's current thinking on how it intends to exercise its enforcement discretion in the future with respect to premarket review for certain products. Such non-binding enforcement guidance is not final agency action. *See Am. Tort Reform Ass'n v. Occupational Safety & Health Admin*., 738

F.3d 387, 395 (D.C. Cir. 2013) (explaining that non-legislative rules, such as guidance documents, typically are not final agency action); *Ctr. for Auto Safety, Inc. v. Nat'l Highway Traffic Safety Admin.*, 342 F. Supp. 2d 1, 24 (D.D.C. 2004) (holding that "non-binding" letter containing "prospective enforcement policies designed to inform the industry and agency personnel regarding how the agency intends to exercise its enforcement discretion" was not final agency action); *see also BBK Tobacco*, 672 F. Supp. 2d at 975 (concluding that FDA guidance documents were not final agency action because no legal consequences flowed from them).

Plaintiffs claim that they may suffer practical consequences if manufacturers postpone the submission of their premarket review applications as a result of the Guidance, but the Fourth Circuit has made clear that this alleged harm is not the sort of *legal* consequence that can render agency action final. In *Flue-Cured Tobacco Coop. Stabilization Corp. v. EPA*, 313 F.3d 852 (4th Cir. 2002), the plaintiffs sought to challenge a report issued by the EPA regarding the health hazards of second-hand tobacco smoke. Like the Guidance here, the report was not legally binding on anyone. *See id*. at 859. The plaintiffs nevertheless argued that the report imposed "coercive pressures" on third parties to act in ways that could harm the plaintiffs. *Id*. In particular, the plaintiffs claimed that the report exerted significant pressure on private groups and other government agencies to impose restrictions on tobacco, which in turn would be detrimental to the plaintiffs' businesses. *See id*. at 860–61. The court rejected the plaintiffs' theory that "agency action producing only coercive pressures on third parties is reviewable under the APA." *Id*. at 859. The court noted that, if it were to adopt such an expansive approach, "almost any agency policy . . . would be subject to judicial review" because all agency statements—even non-binding ones—are likely to influence the actions of others. *Id*. at 861.

Because the Guidance does not impose "legally enforceable responsibilities" on regulated entities and is "not binding on FDA or the public," Guidance at 1 (GAR 422), it is not final agency action subject to judicial review.

II. PLAINTIFFS' CLAIMS FAIL ON THE MERITS

Even if this case were justiciable, Plaintiffs' claims would fail on the merits, as the Guidance is fully consistent with the statutory text, is a policy statement exempt from notice and comment, and reflects an entirely reasonable enforcement strategy.

A. The Guidance Does Not Conflict with the TCA

Plaintiffs principally claim that the Guidance "violates the Tobacco Control Act." Pls.' Br. at 9. It does no such thing. The Guidance does not purport to modify or interpret any provision of the TCA. Rather, it simply states that the FDA "does not intend to enforce a particular requirement" of the statute for a limited period, Guidance at 4 (GAR 425)—an entirely unexceptional exercise of enforcement discretion that conflicts with no legislative directive.

To begin, the compliance policy in no way "countermand[s] a duty assigned to [the FDA] by statute." Pls.' Br. at 9. As already explained, while the statutory text provides that premarket authorization "is required," 21 U.S.C. § 387j(a)(2)(A), that provision places an obligation on the *manufacturer*, not the FDA, and the agency intends to process any such applications within the statutory timeframe. *See supra* at 24–25, 27–28. Plaintiffs' appeal to the TCA's legislative history gets them no further, Pls.' Br. at 9, as the House Report simply confirms this understanding.[13]

[13] *See, e.g.*, H.R. Rep. No. 111-58, pt. 1, at 41 (2009) ("Section 910(c) requires the Secretary, within 180 days after receipt of an application, to make a determination of whether to allow the new product to enter the market or deny the application.").

Equally unpersuasive is Plaintiffs' argument that the Guidance "rewrite[s] clear provisions" of the TCA, replacing the statutory text with words "of [the FDA's] own choosing." Pls.' Br. at 11. Here, they point to a statutory exception to the general rule that a manufacturer must obtain premarket authorization before marketing a new tobacco product: if the product entered the market by March 22, 2011, and the manufacturer submitted an SE application by the same date, then the product can be marketed while that application is pending without being deemed misbranded. *See* 21 U.S.C. § 387j(a)(2)(B). This provision, Plaintiffs claim, impliedly precludes the FDA from crafting other exceptions to the premarket review requirement. Pls.' Br. at 11–12. But the Guidance nowhere purports to create any exceptions to the substantive requirements of the statute; it merely indicates that the agency does not intend to take action to enforce those requirements for a limited time.

Plaintiffs' reliance on *Utility Air Regulation Group v. EPA*, 134 S. Ct. 2427, 2445 (2014), is therefore misplaced. There, the EPA's decision to regulate greenhouses gases swept millions of parties into the Clean Air Act's statutory scheme, which requires sources that emit more than 100–250 tons per year of a regulated pollutant to obtain permits, *id*. at 2435–36; to mitigate these costs, the agency issued a regulation changing this statutory threshold to 100,000 tons per year for greenhouse gases, *id*. at 2444–45. The Supreme Court held that the EPA's regulatory "rewriting of the statutory thresholds was [an] impermissible" effort "to *alter* those requirements and to establish with the force of law that otherwise-prohibited conduct will not violate the Act." *Id*. at 2445. The Court noted, however, that were it not for the Clean Air Act's citizen-suit provision, the EPA might well have achieved the same ends by "merely exercising its enforcement discretion," *id.*, as the FDA did here.

Moreover, Plaintiffs' suggestion that the Guidance somehow converts the premarket review process into "a form of *post*market review" blinks reality. Pls.' Br. at 11. When the deeming rule took effect in August 2016, there were, for example, as many as 11,000 e-cigarette products on the market, RIA at 84 (AR 23,995)—all of which were suddenly out of compliance with the TCA's premarket review provision. *See supra* at 1. Even under the original compliance policy, which is unchallenged here, all of these products would necessarily have undergone review *after* entering the market. And because all of these products would have been immediately subject to enforcement action as of the deeming rule's effective date, few favored forgoing a compliance period, given the potential these products may have for reducing the risk of tobacco-related disease, the benefits of allowing the agency to more efficiently manage the flow of incoming applications, and the benefits of having high-quality premarket submissions. Indeed, during the comment period for the deeming rule, Plaintiffs themselves submitted a comment urging the agency to "exercise . . . its enforcement discretion" to select shorter compliance periods, but acknowledging that "[p]ermitting a compliance period for newly deemed tobacco products is discretionary with FDA." AR 145,604, 145,607. They should not be heard to take a contrary position now. *See, e.g.*, *Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002) ("It is well established that issues not raised in comments before the agency are waived and this Court will not consider them.").

Plaintiffs' nod to the Take Care Clause, Pls.' Br. at 13, offers them no aid. First, that clause provides that *the President* "shall take Care that the Laws be faithfully executed," U.S. Const., art. II, § 3; it does not direct *subordinate officers or agencies* in the performance of their duties, *see Printz v. United States*, 521 U.S. 898, 922 (1997). Because Plaintiffs challenge guidance issued by the FDA, not an action (or inaction) of the President, their invocation of the

Take Care Clause stalls at the threshold. Second, even if the Take Care Clause applied to subordinate officers and agencies, it does not provide an independent cause of action. *See Mississippi v. Johnson*, 71 U.S. (4 Wall.) 475, 499 (1867) (observing that "the duty of the President in the exercise of the power to see that the laws are faithfully executed" is "purely executive and political" and so not subject to judicial review); *cf. Armstrong v. Exceptional Child Ctr., Inc.*, 135 S. Ct. 1378, 1383–84 (2015) (holding that the Supremacy Clause does not confer an implied right of action). Third, it is not the case that if an agency violates a statute it automatically violates the Constitution as well. As the Supreme Court has explained, its "cases do not support the proposition that every action by the President, or by another executive official, in excess of his statutory authority is ipso facto in violation of the Constitution." *Dalton v. Specter*, 511 U.S. 462, 472 (1994). To hold otherwise would flip the doctrine of constitutional avoidance on its head, as relief under the APA would remedy the purported constitutional violation and therefore make resolution of the constitutional claim unnecessary and inadvisable. *See, e.g., Nw. Austin Mun. Util. Dist. No. One v. Holder*, 557 U.S. 193, 204–06 (2009) (discussing doctrine of constitutional avoidance). Because Plaintiffs' reliance on the Take Care Clause is grounded solely in the FDA's alleged violation of 21 U.S.C. § 387j(a), it simply has no independent force. *See, e.g., South Carolina v. United States*, No. 16-391, 2017 WL 976298, at *29 (D.S.C. Mar. 14, 2017) (dismissing Take Care Clause claim premised solely on the defendant's alleged violation of a statute).

Regardless, Plaintiffs' suggestion that recognizing the FDA's enforcement discretion here "would unconstitutionally vest in the Executive Branch legislative power to rewrite laws," Pls.' Br. at 13, gets things exactly backward. Under Article II, the power to "take care that the laws be faithfully executed" is "entrusted to the executive branch—and only to the executive branch."

Baltimore Gas, 252 F.3d at 459 (citing U.S. Const. art. II, § 3). "One aspect of that power is the prerogative to decline to enforce a law, or to enforce a law in a particular way." *Id*. Thus, "[w]hen the judiciary orders an executive agency to enforce the law it risks arrogating to itself a power that the Constitution commits to the executive branch." *Id*. Indeed, as the D.C. Circuit has explained, "*Chaney*'s recognition that the courts must not require agencies to initiate enforcement actions may well be a requirement of the separation of powers commanded by our constitution." *Id*.

B. The Guidance Is a Policy Statement Exempt from Notice and Comment

Plaintiffs likewise miss the mark in arguing that the Guidance must be set aside because it is a substantive rule issued without notice and comment. *See* Compl. ¶¶ 103–10. Under the APA, before adopting a "substantive" (or "legislative") rule, an agency generally must publish a notice of proposed rulemaking in the Federal Register and accept public comment. 5 U.S.C. § 553(b)–(c). "[G]eneral statements of policy," however, are exempt from these notice-and-comment requirements. *Id*. § 553(b). And the Guidance is a paradigmatic statement of policy.

A "substantive rule establishes a standard of conduct which has the force of law." *Pac. Gas & Elec. Co. v. Fed. Power Comm'n*, 506 F.2d 33, 38 (D.C. Cir. 1974); *see Jerri's Ceramic Arts, Inc. v. Consumer Prod. Safety Comm'n*, 874 F.2d 205, 207 (4th Cir. 1989) ("[A] substantive or legislative rule, pursuant to properly delegated authority, has the force of law, and creates new law or imposes new rights or duties."). Thus, an "agency action that purports to impose legally binding obligations or prohibitions on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements—is a legislative rule." *Nat'l Mining*, 758 F.3d at 251.

A statement of policy, by contrast, "advise[s] the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Lincoln v. Vigil*, 508 U.S. 182, 197 (1993) (quoting *Attorney General's Manual on the Administrative Procedure Act* 30 n.3 (1947)). It "explains how the agency will enforce a statute or regulation—in other words, how it will exercise its broad enforcement discretion or permitting discretion under some extant statute or rule." *Nat'l Mining*, 758 F.3d at 252. It serves to "appris[e] the regulated community of the agency's intentions" and "inform[] the exercise of discretion by agents and officers in the field." *Ass'n of Flight Attendants-CWA, AFL-CIO v. Huerta*, 785 F.3d 710, 716 (D.C. Cir. 2015). Policy statements "are binding on neither the public nor the agency," and the agency "retains the discretion and the authority to change its position . . . in any specific case." *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]"; they do not "establish a binding norm and leave[] agency officials free to exercise their discretion").

The Guidance is a quintessential statement of policy, as its text repeatedly reinforces. It was issued as a "matter of enforcement discretion." Guidance at 4 (GAR 425). It imposes "no[] . . . legally enforceable responsibilities" on regulated parties. *Id*. at 1 (GAR 422). Rather, it simply announces that the agency "does not intend to enforce a particular requirement" for a limited period. *Id*. at 4 (GAR 425). Indeed, as is characteristic of policy statements, it merely represents the agency's "current thinking" and "is not binding on FDA or the public." *Id*. at 1 (GAR 422); *see* 21 U.S.C. § 371(h)(1)(A)–(B); 21 C.F.R. § 10.115(d). Because the Guidance establishes no rights or obligations but merely advises the public of how the FDA intends to exercise its enforcement discretion, it is a policy statement exempt from notice and comment.

Contrary to Plaintiffs' assertion, the Guidance's status as a policy statement is not merely a function of the FDA's "characterization" of it as such. *See* Pls.' Br. at 18. The Guidance is a policy statement because of what it says and "the substance of what [the FDA] has purported to do and has done." *Nat'l Knitwear Mfrs. Ass'n v. Consumer Prod. Safety Comm'n*, 666 F.2d 81, 83 (4th Cir. 1981) (citation omitted); *see Prof'ls & Patients for Customized Care v. Shalala*, 56 F.3d 592, 596–97 (5th Cir. 1995); *All. for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166, 172 (D.D.C. 2000) ("courts will look to the actual language of [an agency's] statement," in addition to giving the "agency's own characterization of its statement . . . some weight"). Indeed, it is Plaintiffs that attempt to characterize the Guidance as something other than what it is, by ignoring its plain terms. Plaintiffs say the Guidance creates a "categorical[] exempt[ion]," Pls.' Br. at 17, but it is neither categorical, nor an exemption. *See* Guidance at 3 (GAR 424) (describing limited circumstances to which the Guidance applies); *id*. at 1 (GAR 422) (explaining that the Guidance "does not establish any rights" or any "legally enforceable responsibilities"). And Plaintiffs assert that the Guidance "constrains FDA's discretion," Pls.' Br. at 17, but the Guidance expressly disclaims any such intent or effect by making clear that it is "not binding on FDA," Guidance at 1 (GAR 422). In short, the Guidance is—in terms and in substance—a statement of policy.

Courts have routinely held that enforcement guidance, like that contained in the Guidance, is a statement of policy exempt from notice and comment, not a substantive rule. *See, e.g.*, *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 357 (D.C. Cir. 2017) (concluding that non-binding instructions setting forth "agency's enforcement priorities" constituted a statement of policy); *Prof'ls & Patients for Customized Care*, 56 F.3d at 593 (holding an FDA Compliance Policy Guide was not a substantive rule); *Int'l Union, UAW v. Brock*, 783 F.2d 237, 251 n.18

(D.C. Cir. 1986); *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 537–38 (D.C. Cir. 1986) (holding that non-binding guidance for the exercise of an agency's enforcement discretion was not subject to notice-and-comment rulemaking); *NAACP v. Trump*, 298 F. Supp. 3d 209, 237 (D.D.C. 2018) (concluding that memorandum rescinding Deferred Action for Childhood Arrivals program (DACA) was a "clear example" of a policy statement because it merely "advise[d] the public prospectively of the manner in which the agency propose[d] to exercise [its enforcement discretion]"); *Casa de Maryland v. U.S. Dep't of Homeland Sec.*, 284 F. Supp. 3d 758, 772 (D. Md. 2018) (same); *see also Ctr. for Auto Safety, Inc. v. Nat'l Highway Traffic Safety Admin.*, 342 F. Supp. 2d 1, 20 (D.D.C. 2004) ("[C]ourts have uniformly construed enforcement guidelines as policy statements."). This Court should do the same.

The cases on which Plaintiffs rely are inapposite. *See* Pls.' Br. at 17–19. Unlike the Guidance, the agency pronouncements at issue in those cases created new rights or obligations that were binding on the agency and the public. In many of Plaintiffs' cases, the agency "indefinitely postpone[ed] the *effective date*" of a rule, which "effectively repeal[ed]" the rule. *Nat. Res. Def. Council, Inc. v. EPA*, 683 F.2d 752, 753, 762 (3d Cir. 1982) (emphasis added); *see Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 100 (2d Cir. 2018) (agency "indefinitely delay[ed] the effective date" of rule); *Nat. Res. Def. Council v. Abraham*, 355 F.3d 179, 194, 195 (2d Cir. 2004) (agency "suspended the effective date of [the rule] indefinitely," which was "in substance, tantamount to an amendment or rescission of the [rule]"); *Envtl. Def. Fund, Inc. v. Gorsuch*, 713 F.2d 802, 814 (D.C. Cir. 1983) (explaining that the agency's decision had the effect of "indefinitely suspend[ing] the effective date of the [rule]" while the agency considered a proposed rule that would in fact "suspend the effective date[]" of the existing rule); *Envtl. Def. Fund, Inc. v. EPA*, 716 F.2d 915, 917 (D.C. Cir. 1983) (agency

"suspended" regulation); *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 575 (D.C. Cir. 1981) ("deferred implementation" of rule). Suspending a rule's effective date alters the underlying legal norm—thus establishing new rights or obligations—in a way that binds the agency; an agency cannot enforce a rule that is not in effect. The Guidance, in contrast, does not delay or otherwise alter the effective date of the deeming rule. *See* 81 Fed. Reg. at 28,974. The August 8, 2016, effective date of the premarket review requirements remains the same, and the Guidance "simply lets the public know [the FDA's] current enforcement . . . approach" with respect to those requirements. *Syncor Int'l*, 127 F.3d at 94. The FDA "retains the discretion and the authority to change its position" because the Guidance "does not affect the legal norm." *Id*.; *see also Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1046 (D.C. Cir. 1987) (a general policy statement "allow[s] agencies to announce their tentative intentions for the future, without binding themselves") (citation omitted).

Plaintiffs' remaining cases all involved agency pronouncements that imposed legally binding obligations or prohibitions on regulated parties. *See Gen. Elec. Co. v. EPA*, 290 F.3d 377, 385 (D.C. Cir. 2002) (concluding that agency statement that "impose[d] binding obligations upon applicants," and directed "Agency not to question" applications that complied, was a substantive rule because it "ha[d] the force of law"); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1024–28 (D.C. Cir. 2000) (rejecting classification of agency statement as interpretative rule where it imposed new duties on regulated entities that were not found in the regulations, i.e., it "direct[ed] State permitting authorities to conduct wide-ranging sufficiency reviews and to enhance the monitoring required in individual permits"); *Alaska v. U.S. Dep't of Transp.*, 868 F.2d 441, 442 (D.C. Cir. 1989) (concluding that "Order Granting Exemption" from federal regulations had the force of law because "exemptions" were mandatory and preempted any

contrary state laws); *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 945, 947–49 (D.C. Cir. 1987) (agency's issuance of "action level," which informed producers of the allowable level of unavoidable contaminants in food, was substantive rule; "agency's own words" established that levels created binding norms, as they defined the level at which food would become unlawful and required producers to obtain an exemption before exceeding the level). Unlike the binding norms at issue in those cases, the Guidance merely advises the public of how the FDA intends to exercise its enforcement discretion. It "do[es] not establish legally enforceable responsibilities," and it is "not binding on FDA or the public." Guidance at 1 (GAR 422). Accordingly, even if the cases on which Plaintiffs rely were binding on this Court (and none of them are), they would not control here.

Furthermore, the FDA's decision to solicit comments, in conjunction with promulgation of the deeming rule, before announcing its prior premarket review enforcement policy does not somehow transform the Guidance into a substantive rule. *See* Pls.' Br. at 19–20; Compl. ¶ 107. The FDA made clear that the enforcement policy was not a substantive rule, and that it described the proposed policy and revised policy in the preambles to the proposed and final rule, rather than a separate guidance document, because of the obvious interest. *See* 81 Fed. Reg. at 28,977. And Plaintiffs cite no authority for their novel theory that an agency converts a statement of policy into a substantive rule by voluntarily subjecting prior iterations to notice and comment. The absence of such authority is not surprising; requiring an agency to forgo voluntarily seeking public input in order to preserve its right to issue policy statements without such procedures in the future would create perverse incentives.[14]

[14] Contrary to Plaintiffs' argument, which they raise in a footnote, *see* Pls.' Br. at 20 n.8, the FDA acted in accordance with its statute and regulations. The statute and regulations provide

C. The FDA Rationally Explained Its Updated Enforcement Policy

It is black-letter law that an agency is free to change course on policy matters so long as it provides a rational explanation. Here, the FDA's decision to revise its compliance policy—for a single TCA provision, for a subset of newly deemed products, for a limited time—readily meets that deferential standard.

From the beginning, the FDA's proposed compliance policy was the subject of conflicting comments. On the one hand, "many industry comments sought additional time to comply with the[] requirements" imposed by the rule, 81 Fed. Reg. at 29,012, asserting, for example, that "small and medium-sized businesses lack the . . . resources to tackle [its] high administrative burden," *id*. at 29,014. On the other hand, "many other comments stated that the contemplated . . . compliance period[s] w[ere] too long," *id*. at 29,013, and could be "detrimental to the public health," *id*. at 20,012. In the preamble to the final deeming rule, the FDA "str[uck] an appropriate balance" between these competing interests, *id*. at 29,014, announcing that it did not intend to enforce certain provisions for specified periods, *id*. at 29,006 tbl. 2. With respect to the premarket review provision, the agency intended to defer enforcement for products already on the market as of the deeming rule's effective date if the manufacturer submitted an application by one of three compliance dates—for SE exemption requests, August 2017; for SE reports, February 2018; and for premarket tobacco applications, August 2018—and would

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that the "FDA will not seek . . . comment before it implements a . . . guidance document if the agency determines that prior public participation is not feasible or appropriate." 21 C.F.R. § 10.115(g)(2); *see also* 21 U.S.C. § 371(h)(1)(C)(i). The FDA reasonably made that determination here. *See* 82 Fed. Reg. 37,459, 37,460 (Aug. 10, 2017) (explaining that the FDA could not delay issuance of the Guidance given "the upcoming compliance deadlines and the amount of time needed for [regulated entities] to prepare for them"). And the FDA provided the public with an opportunity to submit comments after issuance of the Guidance, as required by the agency's regulations. *See* 21 C.F.R. § 10.115(g)(3); *see also* 21 U.S.C. § 371(h)(1)(C)(i).

continue deferring enforcement for up to another year while the application was under review. *Id*. at 29,011. The FDA noted, however, that "[a]s with any such policy, the Agency will review and revise this policy as appropriate." *Id*. at 29,008.

Shortly after the deeming rule's publication, it was challenged by manufacturers, trade associations, and consumers in a number of lawsuits, many of which targeted the premarket review provision—which for most products is expected to be the TCA's most burdensome requirement. *See* RIA at 114–15 & tbl. 32 (AR 24,025–26). In *Nicopure*, for example, the plaintiffs argued that the premarket review compliance periods were irrationally short, and that the agency had provided insufficient guidance for manufacturers to prepare successful applications. While the district court rejected these arguments, emphasizing "the range of viewpoints that had been presented during the notice and comment period," it noted that "other approaches may have been reasonable as well." *Nicopure*, 266 F. Supp. 3d at 399–400. And members of the public and industry continued to urge the agency to adopt another approach.[15]

After the change in administrations, as part of a "new comprehensive plan" for the regulation of tobacco products, *see supra* at 9–12, the FDA indeed revised its approach. Under its "new compliance policy," the agency now intends to defer enforcement of the premarket review provision until August 2021 for combustible products (like cigars) and until August 2022 for noncombustible products (like most e-cigarettes). Guidance at 3 (GAR 424). In the meantime, it plans "to issue regulations outlining what information the agency expects to be included in [p]remarket" applications, "to develop product standards" that certain newly regulated products must meet, and to "finalize guidance on how it intends to review" premarket

[15] *See, e.g.*, GAR 166–79 (urging the FDA to extend compliance dates generally); GAR 303 (urging the FDA to extend compliance dates for two years); GAR 159 (urging the FDA to extend compliance dates until August 2022).

applications for e-cigarettes. Press Release at 2 (GAR 412). As the FDA explained in a July 28, 2017, press release—and as the Commissioner of Food and Drugs underscored in a lengthy policy address the same day—this "targeted relief" was intended to "make certain that the FDA is striking an appropriate balance between regulation and encouraging the development of innovative tobacco products that may be less dangerous than cigarettes," and to facilitate the submission of "higher quality, more complete applications informed by additional guidance from the agency." *Id.* at 1, 2.

That explanation was more than sufficient. Under the APA, an agency's decision must be upheld unless arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. *See* 5 U.S.C. § 706(2)(A). The agency's decision is presumed valid, and the Court considers only whether it "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). An agency decision may be deemed arbitrary and capricious only in circumstances where the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983). The Court may not "substitute its judgment for that of the agency." *Id*.

Here, the FDA's decision amply meets these "minimal standards of rationality," *Troy Corp. v. Browner*, 120 F.3d 277, 283 (D.C. Cir. 1997), and Plaintiffs' arguments to the contrary fail at each turn. Indeed, none of the cases Plaintiffs cite in support of their argument that the

Guidance is arbitrary and capricious, *see* Pls.' Br. at 21–25, involves a challenge to an agency enforcement policy.

First, Plaintiffs contend that the FDA "failed to provide *any* explanation" for revising its compliance policy. Pls.' Br. at 21. But as Plaintiffs well know, the revised compliance policy was part and parcel of the comprehensive regulatory strategy set forth in the agency's July 28, 2017, press release, and discussed in the Commissioner's equally comprehensive policy address. The Court should not indulge their head-in-the-sand approach, least of all based on their mistaken interpretation of *Dow AgroSciences LLC v. National Marine Fisheries Service*, 707 F.3d 462 (4th Cir. 2013), which in fact stands for the unremarkable proposition that "'*post hoc* rationalizations'" are disfavored, *id*. at 468 (citation omitted)—not that agency action cannot be supported by *earlier* materials properly in the record. Here, the "agency's path may reasonably be discerned," which would be enough under the APA even if the "decision [were] of less than ideal clarity." *Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974).

Second, Plaintiffs argue that the FDA pointed to no "good reasons" for its decision, claiming that the agency cited "no changed circumstances" or "new evidence" justifying a policy shift. Pls.' Br. at 22–23. That misstates the agency's burden. When an agency makes a policy change, it "need not demonstrate to a court's satisfaction that the reasons for the new policy are *better* than the reasons for the old one." *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515 (2009). Rather, "it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates." *Id*. Under this standard, an agency could well reweigh the same evidence and come to a different policy judgment, so long as it explains why. In any event, here, the FDA

set forth ample reasons for revising its compliance policy—including to pave the way for higher-quality applications informed by the forthcoming regulations and guidance. And contrary to Plaintiffs' claim, there is nothing at all "bizarre" about the agency's decision to more fully develop a framework for conducting premarket review for certain products already on the market before enforcing the premarket review requirement as to those products, Pls.' Br. at 23, including by developing tobacco product standards to be applied as additional prerequisites for premarket approval, *see* 21 U.S.C. § 387j(b)(1)(D) (requiring a premarket tobacco application "to show that [the] product fully meets [any applicable] tobacco product standard"). Regardless, an "agency enjoys broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures and priorities," and need not "solve every problem before it in the same proceeding." *Mobil Oil Exploration & Producing, S.E., Inc. v. United Distrib. Cos.*, 498 U.S. 211, 231 (1991). Nothing in the TCA—or the APA, for that matter—purports to limit that discretion.

Third, Plaintiffs argue that the FDA failed to explain subsidiary aspects of the updated compliance policy, such as its staggering of compliance periods based on product type (combustible or noncombustible) rather than type of premarket application. Pls.' Br. at 24. But those categories largely overlap. *See, e.g.*, RIA at 95–97 & tbls. 15, 16 (AR 24,006–08) (noting that most non-grandfathered cigar and pipe tobacco products are expected to submit SE applications, while most e-cigarette products are expected to submit premarket tobacco applications). And the agency did explain the differences between combustible and noncombustible products that informed its approach:

> [I]t's the other chemical compounds in tobacco, and in the smoke created by setting tobacco on fire, that directly and primarily cause the illness and death, not the nicotine. So we need to take a fresh look at nicotine itself, and how the addiction that it causes relates to the potential harm of its delivery mechanism. . . . Looking at ways to reduce nicotine levels in cigarettes so that they are minimally or non-addictive, while not altering the nicotine content of noncombustible

> products such as e-cigarettes, is a cornerstone of our new and more comprehensive approach to effective tobacco regulation. . . . But, as we move forward with this approach, we must also take a new and fresh look at the noncombustible side of the house.

Scott Gottlieb, Protecting American Families: Comprehensive Approach to Nicotine and Tobacco, https://www.fda.gov/NewsEvents/Speeches/ucm569024.htm (July 28, 2018) (GAR 405–10). Given the potential of noncombustible products to present a reduced risk of tobacco-related disease, and the more onerous premarket application pathway that most noncombustible products are expected to use, *see* RIA at 94 & tbl. 14 (AR 24,005) (summarizing differences in average cost among application pathways), the agency's staggering of compliance deadlines was entirely sensible. And despite Plaintiffs' suggestion to the contrary, the updated compliance policy's deferral of enforcement is not properly understood as "indefinite." The TCA provides that the FDA "shall . . . issue an order" granting or denying premarket authorization within "180 days after receipt of an application," 21 U.S.C. § 387j(c)(1)(A)(i), (ii), and the agency intends to process such applications within the statutory timeframe.

The FDA also considered the potential public health effects of its updated compliance policy. *See* Pls.' Br. at 24–25. The extended compliance periods are a component of the FDA's larger comprehensive regulatory strategy to protect the public health, in part by reducing the addictiveness of combustible cigarettes while temporarily delaying the immediate market exit of innovative, potentially less harmful tobacco products. *See* GAR 405–10 ("In a world where FDA is pursuing how to regulate nicotine levels in cigarettes, and combustible cigarettes are one day far less addictive, we can take the time to make sure we have in place the foundational elements of a robust and sustainable framework for regulating the non-combustible forms of nicotine delivery. That means extending further some of the current compliance deadlines for newly deemed products."). The FDA determined that these benefits, along with the "higher

quality, more complete applications informed by additional guidance from the agency" it now anticipates receiving, Press Release at 1–2 (GAR 411–12), warranted a further, limited deferral of enforcement of the premarket review provisions. That expert policy judgment merits deference here—if it is even subject to judicial review at all.

CONCLUSION

For the foregoing reasons, the Court should dismiss this case or, in the alternative, grant summary judgment to Defendants.

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Respectfully submitted,

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