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

DEFENDANTS' REMEDY BRIEF

INTRODUCTION

The FDA believes that the recent "epidemic-level rise in youth e-cigarette use" is a "mounting public health crisis."[1] It agrees that this crisis demands a robust regulatory response, including through enforcement of the Tobacco Control Act's premarket review provision. And, as reflected in its March 2019 draft guidance, it is taking steps to accelerate enforcement of that provision, particularly with respect to the products driving this crisis: e-cigarettes targeted to youth or easily accessible to them, especially those in kid-friendly fruit or candy flavors. *See* Defs.' Notice (Mar. 15, 2019) (ECF No. 59). To address this public health crisis, the FDA is committed to finalizing that guidance within 120 days.

Nevertheless, bedrock principles of administrative law constrain the Court's authority to enter the specific relief that Plaintiffs request. Having already set aside the challenged August 2017 guidance—the remedy authorized by the terms of the Administrative Procedure Act—the Court should simply remand to the FDA to permit it to choose a course of action consistent with the Court's opinion. But even if the Court determines to go further, it should not enter the specific relief that Plaintiffs request, and certainly not on the dramatically accelerated timetable they suggest. In particular, requiring premarket applications for all deemed products—an expected 5,424 to 6,764 applications—to be submitted within 4 months would create massive administrative burdens at the agency that would ultimately be counterproductive. More importantly, such a precipitous deadline would threaten to abruptly clear the market of e-cigarette products, creating a "genuine risk" that adult former smokers addicted to nicotine would "migrat[e] from potentially less harmful ENDS products [*i.e.*, e-cigarettes] back to combustible tobacco products"—a "public health outcome that should be avoided if at all possible, while still achieving the public health benefits of earlier premarket review for

[1] FDA, *Statement from FDA Commissioner Scott Gottlieb, M.D., on advancing new policies aimed at preventing youth access to, and appeal of, flavored tobacco products, including e-cigarettes and cigars* (Mar. 13, 2019), at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-advancing-new-policies-aimed-preventing-youth-access.

deemed products, especially with respect to curtailing youth use." Declaration of Mitchell Zeller, Director, Center for Tobacco Products, FDA ("Zeller Decl.") ¶ 12.

Thus, should the Court order premarket applications to be submitted by a date certain, it should set that deadline no sooner than 10 months from the date of its decision, along with a one-year period for FDA review. *See id.* ¶ 13. That would strike a better balance among public health considerations, and allow the agency some time to prepare to absorb a flood of applications significantly sooner than anticipated. It would also permit the FDA to finalize the March 2019 draft guidance setting forth its enforcement priorities in the meantime. That is "one of the most critical public health steps that [the] FDA can take to curb youth vaping," Zeller Decl. ¶ 11, and the agency plans to complete it within 120 days.

DISCUSSION

I. The Court should not go beyond vacating the August 2017 guidance.

In this case, Plaintiffs challenged a single, discrete agency action: the issuance of an August 2017 guidance document describing the FDA's intention to temporarily defer enforcement of the Tobacco Control Act's (TCA) premarket review provision with respect to a subset of deemed products. Compl. ¶ 30. The relief they sought was accordingly narrow: they asked the Court to declare the guidance unlawful, and to "[v]acate [it] and set [it] aside." *Id.* ¶¶ (a)–(b) (prayer for relief). And the Court has now granted that relief, holding that the guidance exceeded the agency's statutory authority, was improperly issued without notice and comment, and must therefore be vacated. Mem. Op. at 44, 53 (ECF No. 73); Order at 1 (ECF No. 74).

Under longstanding principles of administrative law, that should be the end of the matter. By its terms, the Administrative Procedure Act (APA) authorizes courts only to "set aside" unlawful agency action. 5 U.S.C. § 706(2); *see* Compl. ¶¶ 93, 102, 104, 118. And "[u]nlike a district court managing a 'garden variety civil suit,' a district court reviewing a final agency action" under the APA

"'does not perform its normal role' but instead 'sits as an appellate tribunal.'" *Palisades Gen'l Hosp. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005). "Thus, under settled principles of administrative law, when a court reviewing agency action determines that an agency made an error of law, the court's inquiry is at an end: the case must be remanded to the agency for further action consistent with the correct legal standards." *Id.* Relief in an APA case is therefore ordinarily "limited only to vacating the unlawful action," and courts should not enjoin an agency to implement a specific remedy that "preclud[es] future agency decisionmaking." *Hill Dermaceuticals v. FDA*, 709 F.3d 44, 46 n.1 (D.C. Cir. 2013).

Nevertheless, Plaintiffs now ask the Court to do just that. They urge the Court to enter an injunction requiring that: (1) premarket applications be submitted within 120 days; (2) products with timely applications on file be allowed to remain on the market for no more than one year pending FDA review; (3) the FDA take "any and all actions necessary" to ensure that "no" newly deemed product remains on the market "without being subject to FDA enforcement action"; and (4) the FDA make quarterly reports about the number of premarket applications it has processed and the "number and nature of enforcement actions it has commenced." Pls.' Proposed Order at 1–2 (ECF No. 78-1). But absent unusual circumstances not present here,[2] it is inappropriate to issue an injunction imposing specific duties on the agency—a principle that courts have adhered to time and again.

For example, in *Hill Dermaceuticals*, the court considered a challenge to the FDA's approval of a supplemental new drug application for a generic corticosteroid. In rejecting the challenge, the court

[2] This case bears no resemblance to the few Plaintiffs cite where courts entered injunctive relief. Pls.' Remedy Br. at 7, 9. In *NAACP v. HUD*, 817 F.2d 149 (1st Cir. 1987), for example, the court found that "over time, HUD's pattern of activity" reflected a failure to enforce the nondiscrimination policies of the Fair Housing Act, despite a demonstrated history of racial segregation in housing in Boston. *Id.* at 151 (citing 42 U.S.C. § 3608(e)(5)). Similarly, in *Thompson v. HUD*, No. 95-309, 2006 WL 581260 (D. Md. Jan. 10, 2006), the agency's "long-term practice" and "pattern of actions" "perpetuated Region-wide segregation" in housing in the Baltimore area. *Id.* at *4. And in *Cobell v. Norton*, 240 F.3d 1081 (D.C. Cir. 2001), the court cited "the government's 'historical record of recalcitrance' in performing its trust duties" toward Native Americans. *Id.* at 1108. There is nothing comparable here.

criticized the plaintiff for requesting "injunctive relief[] seeking to enjoin the FDA from approving [the generic competitor's] new drugs." 709 F.3d at 46 n.1. It explained: "where a district court reviews agency action under the APA, it acts as an appellate tribunal, so the appropriate remedy for a violation is 'simply to identify a legal error and then remand to the agency.'" *Id.* Thus, any relief "would need to be limited only to vacating the unlawful action, not precluding future agency decisionmaking." *Id.*

Similarly, in *Palisades*, the plaintiff hospital claimed that the Department of Health and Human Services had failed to correct certain data, leading to improperly low reimbursement rates, and urged the court to "exercise its equitable powers" to award it "make-whole relief including an adjusted reimbursement." 426 F.3d at 401, 403. The court concluded that the "district court had no jurisdiction to order specific relief": although it could "vacate the Secretary's decision rejecting the hospital's revised wage data and . . . remand for further action consistent with its opinion," it "did not . . . have jurisdiction to order reclassification based upon those adjusted wage data or an adjusted reimbursement payment." *Id.*; *see also, e.g.*, *Bennett v. Donovan*, 703 F.3d 582 (D.C. Cir. 2013) ("We do not hold, of course, that HUD is required to take this precise series of steps, nor do we suggest that the district court should issue an injunction to that effect. Appellants brought a complaint under the Administrative Procedure Act to set aside an unlawful agency action, and in such circumstances, it is the prerogative of the agency to decide in the first instance how best to provide relief.").

These cases point the way here. The Court has held that the August 2017 guidance exceeded the FDA's statutory authority and was improperly issued without notice and comment. But the remedy is not to issue an injunction constraining the agency to undertake a judicially prescribed course of action, as Plaintiffs now argue. It is instead to remand to the FDA to permit it to choose a course consistent with the Court's opinion, as Plaintiffs previously suggested. *See* Pls.' Letter Mot. to Reconsider at 1 (ECF No. 63) ("if the Court strikes down the operative Guidance, FDA would know the legal rules it must follow to make its forthcoming guidance valid"). That is particularly true given

the range of remedial options open to the FDA, which Congress has recognized as the "regulatory agency with the scientific expertise" to "evaluate scientific studies supporting claims about the safety of products" and "make[] decisions about how whether and how [tobacco] products may be marketed." TCA § 2(44). The Court should not substitute its judgment for the scientific expertise of the agency on these matters.

Moreover, an injunction would be particularly anomalous here given that Plaintiffs make no attempt to meet the standard prerequisites for such relief. "An injunction is an equitable remedy that 'does not follow from success on the merits as a matter of course.'" *SAS Institute, Inc. v. World Programming Ltd.*, 874 F.3d 370, 384 (4th Cir. 2017) (citation omitted). Rather, Plaintiffs must show that: (1) they have suffered irreparable injury; (2) remedies available at law are inadequate; (3) a remedy in equity is warranted considering the balance of hardships; and (4) the public interest would not be disserved by a permanent injunction. *Id.* Here, Plaintiffs fail to show that any harm to them is irreparable—a traditional prerequisite to any injunction, whether preliminary or final. *Bethesda Softworks, LLC v. Interplay Entm't Corp.*, 452 F. App'x 351, 354 (4th Cir. 2011). They assert harm from a "deprivation of information" to be made available upon approval of premarket applications. Mem. Op. at 18. But presumably they already have sufficient information to counsel their patients and the public to avoid e-cigarettes and cigars. *See* Pls.' Remedy Br. at 1 (arguing that these products are "highly addictive and harmful"). And under their own remedial proposal, Plaintiffs would not receive the additional information they seek here for some 17 months: 4 months for the submission of premarket applications, a year for review, and an additional month for information to be released, *see* Pls.' Remedy Br. at 8; 21 U.S.C. § 387j(a)(4)(B), so they provide no reason to think they would be irreparably harmed by not having that information for some hypothetical period of time beyond that point. *See, e.g.*, *Elec. Privacy Info. Ctr. v. Presidential Advisory Comm'n on Election Integrity*, 266 F. Supp. 3d 297, 319 (D.D.C. 2017) (it "cannot be" "that whenever a statute provides for potential disclosure, a

party claiming entitlement to that information in the midst of a substantial public debate would be entitled to a finding of irreparable informational injury").

The equities and public interest also tilt against injunctive relief. *See Nken v. Holder*, 556 U.S. 418, 435 (2009) (these "factors merge when the Government is the opposing party"). To "set aside" the challenged guidance, as contemplated by the text of the APA, 5 U.S.C. § 706(2), would adequately remedy their asserted harm. And Plaintiffs' proposed timeframe could adversely affect the public health by abruptly clearing the market of e-cigarette products, creating a genuine risk that former smokers addicted to nicotine could migrate back to conventional cigarettes. Zeller Decl. ¶ 15; *see Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312–13 (1982) ("[C]ourts of equity should pay particular regard for the public consequences in employing the extraordinary remedy of injunction."). Plaintiffs' request for this extraordinary form of relief should therefore be rejected.

II. Plaintiffs' proposed 120-day deadline for the submission of premarket applications could adversely affect the public health and would be administratively infeasible.

If the Court nevertheless enters an injunction requiring premarket applications to be submitted by a date certain, it should not adopt the 120-day deadline that Plaintiffs propose. As explained in the attached declaration of Mitchell Zeller, Director of the FDA's Center for Tobacco Products, that precipitous deadline "would cause significant public health concerns, as well as implementation challenges." Zeller Decl. ¶ 15. It could suddenly clear the market of thousands of e-cigarette products, raising the risk that some former smokers addicted to nicotine might migrate back to conventional cigarettes, and is likely to flood the agency with thousands of low-quality applications that would strain agency resources and significantly delay processing. *Id.* ¶¶ 15, 18. Thus, if the Court orders a deadline for the submission of premarket applications, it should set that deadline no sooner than 10 months from the date of its decision (with a one-year period for FDA review, without limiting the agency's discretion to take enforcement action in the meantime). These dates, while still significantly accelerated, would at least reduce the expected abrupt and massive market exit of e-cigarette products,

and give the FDA an opportunity to administratively prepare for and review a massive influx of applications sooner than anticipated. Critically, they would also allow the agency to finalize the March 2019 draft guidance setting forth its enforcement priorities in the interim—particularly with respect to e-cigarettes targeted to minors or sold in ways that heighten the risk of youth access. In the FDA's judgment, finalizing that guidance is "one of the most critical public health steps that [the agency] can take to curb youth vaping," *id.* ¶ 11, and it plans to do so within 120 days, *id.* ¶ 10. And it is the FDA, not Plaintiffs, who are in the best position to balance the important public health and agency resource considerations interests at stake.

"First and foremost, from the public health perspective," a 120-day deadline would "likely" lead to a "mass market exit of ENDS products." Zeller Decl. ¶ 15. Because e-cigarette products are relatively novel, their manufacturers are likely to seek premarket authorization by filing a "premarket tobacco application" (PMTA)—the most complex of the three possible pathways. *See* Defs.' Br. at 5–6 (ECF No. 36-1) (describing premarket pathways); *see also* Zeller Decl. ¶ 5(d). There are currently no authorized PMTAs for e-cigarette products, and the FDA believes that Plaintiffs' proposed 120-day deadline would lead to "mass market exit"—a "significant public health concern." Zeller Decl. ¶ 15. To be sure, the "[o]verall population level impact" of e-cigarettes "remains uncertain today, especially given youth uptake of ENDS." *Id.* But for "cigarette smokers who completely switch to ENDS, these products may be less harmful at an individual level than combustible tobacco products." *Id.* The "mass market exit" of e-cigarette products thus "would limit the availability of a potentially less harmful alternative for adult smokers seeking to transition or stay away from combustible tobacco products." *Id.* In the FDA's judgment, "[d]ramatically and precipitously reducing availability of these products could present a serious risk that adults, especially former smokers, who currently use ENDS products and are addicted to nicotine would migrate to combustible tobacco products, even if particular ENDS products ultimately receive marketing authorization and return to the market later."

Id. "And although there has been great recent progress in declining use of cigarettes for all age groups," the FDA is "concerned that these declines could be slowed or reversed in the case of very sudden and very dramatic reductions in availability." *Id.* The FDA's expert judgment on this issue merits substantial deference. *See, e.g.*, *West Virginia v. EPA*, 362 F.3d 861, 871 (D.C. Cir. 2004) ("We will give an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise.").

Second, on top of this public health concern, Plaintiffs' proposed 120-day deadline would likely inundate the agency with low-quality applications that would strain agency resources and result in significant delays. For starters, the FDA would be receiving an estimated 5,424 to 6,764 premarket applications. Zeller Decl. ¶ 19. When the deeming rule was issued in May 2016, there were approximately 20,504 to 25,704 deemed tobacco products on the market, including 4,640 to 8,800 e-cigarette products and 7,500 cigars. RIA at 84 tbl.9. The FDA expected the manufacturers of about 5,424 to 6,764 of those products, including some 1,610 to 2,950 e-cigarette products and 2,625 cigars, to apply for premarket review. *Id.* Although the August 2017 guidance explained that the agency generally intended to defer enforcement of the premarket review provision until 2021 or 2022, manufacturers were not precluded from submitting applications earlier—in fact, the agency has repeatedly encouraged them to do so. *See, e.g.*, Press Release, FDA, *Statement from FDA Comm'r Scott Gottlieb, M.D., On New Steps to Address Epidemic of Youth E-Cigarette Use* (Sept. 12, 2018) (there is "no excuse for manufacturers not to file applications with the FDA because the agency hasn't told them what they are expected to do").[3] Nevertheless, given the sheer number of products at issue, requiring all manufacturers to submit premarket applications within 120 days would be counterproductive.

[3] *Available at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use; *see also* Press Release, FDA, *Statement From FDA Comm'r Scott Gottlieb, M.D., On Proposed New Steps to Protect Youth by*

The PMTA pathway requires a manufacturer to establish that the product is "appropriate for the protection of the public health," 21 U.S.C. § 387j(c)(2)(A), considering "the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products," *id.* § 387j(c)(4). By statute, a PMTA must include, among other things:

- "full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;"
- "a full statement of the components, ingredients, additives, and properties, and of the principle or principles of operation, of such tobacco product;" and
- "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product."

Id. § 387j(b)(1); *see also* Zeller Decl. ¶¶ 20–21. A PMTA must also include an adequate environmental assessment (or a claim of categorical exclusion). 25 C.F.R. § 25.15. To assist manufacturers in navigating these requirements, in May 2016 the FDA released a 50-page draft guidance document for

Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes (Nov. 15, 2018) (expressing hope that FDA would "soon see manufacturers of ENDS [Electronic Nicotine Delivery Systems] products preparing, with FDA input as appropriate, premarket tobacco product applications (PMTAs) to demonstrate that their products meet the public health standard in the Tobacco Control Act"), *at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access; Press Release, FDA, *Statement From FDA Comm'r Scott Gottlieb, M.D., On Advancing New Policies Aimed At Preventing Youth Access to, and Appeal of Flavored Tobacco Products, Including E-Cigarettes and Cigars* (Mar. 13, 2019) ("manufacturers need not wait to submit premarket tobacco product applications for ENDS products, flavored or otherwise"), *at* https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-advancing-new-policies-aimed-preventing-youth-access.

the submission of PMTAs for e-cigarette products.[4] The final, 52-page version of that guidance document was released on June 11, 2019.[5]

To date, the FDA has received few PMTAs that meet even the basic requirements for them to be considered properly filed. As of April 30, 2019, the agency had received 401 PMTAs, 373 of which were for deemed products. Zeller Decl. ¶ 5(d). Of those 373, more than 99% (369/373) were closed as insufficient to accept or file, largely for failure to include an environmental assessment, and the manufacturers have not refiled corrected versions. *Id.* Overall, just 12 PMTAs have been authorized, for smokeless tobacco and noncombustible, "heated" cigarettes (which differ from e-cigarettes in that they vaporize actual tobacco, rather than an e-liquid). *See id.* And only 4 PMTAs remain pending for deemed products, none of them for e-cigarette products. *Id.* Moreover, as part of the premarket authorization process, tobacco manufacturers routinely consult with FDA, similar to the analogous process for new drug or device applications under the Federal Food, Drug, and Cosmetic Act (FDCA). *See id.* ¶ 5(d). Yet only a handful of manufacturers—"fewer than 10"—"have sought pre-submission meetings with FDA to discuss potential premarket applications for ENDS products." *Id.* ¶ 15.

Perhaps the best analogue to this expected influx of premarket applications took place in March 2011, in the days preceding a statutory deadline for manufacturers to submit "provisional" substantial equivalence (SE) applications. *See* 21 U.S.C. § 387j(a)(2)(B) (discussed in Defs.' Br. at 34). In total, manufacturers submitted nearly 3,600 provisional SE applications—about 3,000 of them (more than 83%) "within the last several days leading up to" the deadline. Zeller Decl. ¶ 19. While

[4] FDA, Draft Guidance for Industry, *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems* (May 2016), *at* https://www.fda.gov/media/97652/download.

[5] FDA, Guidance for Industry, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (June 2019), *at* https://www.fda.gov/media/127853/download.

the "FDA has put many more systems in place since then, and has created a robust application review process within CTP's Office of Science, there is no doubt that the agency will be flooded with applications in the final days leading up to any court-ordered submission deadline" entered here. *Id.*

Such a large number of premarket applications would threaten to overwhelm the FDA's resources if submitted *en masse* by a deadline much earlier than the agency had anticipated. This resource problem is likely to be compounded by the fact that "[m]any applicants will be newly regulated entities lacking experience with FDA"—which is particularly likely for e-cigarette products, which are relatively novel. *Id.* ¶ 18. "[B]ased on [the agency's] experience to date, the applications are anticipated to be lower in quality and less complete than current-day applications for other FDA-regulated products." *Id.* A "large volume of incomplete or haphazard applications in which the information is not clearly presented or is missing data will cause further delay because it will divert valuable agency resources into the painstaking effort of reviewing those submissions and communicating deficiencies." *Id.* ¶ 18.

Finally, the FDA only recently published the final version of its guidance document for the submission of PMTAs for e-cigarette products, *see supra* at 9–10, and is still in the process of issuing a rule concerning PMTAs. *See* Zeller Decl. ¶ 4(d). Of course, "manufacturers may submit premarket applications for these products at any time, and there is no legal barrier to filing." *Id.* ¶ 16. "Indeed, CTP has accepted, filed, and authorized applications through each of the available pathways based on statutory criteria even in the absence of rules or product-specific guidance." *Id.* But such guidance can assist manufacturers in preparing applications that are of high enough quality to facilitate efficient review. *See id.*

For all of these reasons, Plaintiffs' proposed 120-day deadline for the submission of premarket applications would threaten to harm the public health and is administratively infeasible. Indeed, it is the FDA's "firm belief" that such an accelerated deadline would "create[] a genuine risk of migration

from potentially less harmful ENDS products back to combustible tobacco products within the population of addicted adult smokers who have completely switched to ENDS." *Id.* ¶ 12. "This is a public health outcome that should be avoided if at all possible, while still achieving the public health benefits of earlier premarket review for deemed products, especially with respect to curtailing youth use." *Id.*

Thus, should the Court order premarket applications to be submitted by a date certain—and it should not, *see supra* at 2–6—under no circumstances should it set that deadline sooner than 10 months from the date of its decision (with a one-year period for FDA review, without limiting the agency's discretion to take enforcement action in the meantime). *See* Zeller Decl. ¶ 13.[6] While perhaps not the dates that the FDA would select if permitted to exercise its own discretion, such a deadline would at least reduce the expected abrupt and massive market exit; avoid flooding the FDA with thousands of premarket applications on a nearly immediate basis; and allow the agency at least some time to prepare to receive and review applications much more quickly than it had anticipated. *See id.* ¶¶ 15, 16. It would also enable manufacturers to strengthen their applications based on the recently issued PMTA guidance. *See id.* ¶ 16. And this relief would permit the FDA to finalize the March 2019

[6] Plaintiffs also ask the Court to order that products with timely premarket applications on file be allowed to remain on the market for no more than one year pending FDA review. *See* Pls.' Proposed Order ¶ 2. The original compliance policy, set forth in the preamble to the final deeming rule, contained a similar one-year compliance period for products with timely premarket applications. 81 Fed. Reg. 28,974, 29,011 (May 10, 2016) ("Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period[.]"). That policy also provided that, "if at the time of the conclusion of the continued compliance period," authorization has not yet been granted but "the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period." *Id.* at 29,012. If the Court determines to enter an injunction limiting the compliance period for products with timely premarket applications on file to one year, it should not disturb the FDA's discretion to similarly defer enforcement on a case-by-case basis with respect to specific products in light of the relevant circumstances.

draft guidance setting forth its enforcement priorities in the meantime, which it plans to do within 120 days. *Id.* ¶ 10. Notably, that draft guidance proposes that the FDA would target several categories of deemed products for earlier enforcement of the premarket review provision—including e-cigarette products targeted to minors or sold in ways that heighten the risk of youth access. *See* Defs.' Notice (Mar. 15, 2019) (ECF No. 59). And that enforcement could take place before any deadline for the submission of premarket applications that the Court were to order.

III. The Court should not order the FDA to enforce the premarket review provision—a step that would raise significant separation of powers concerns.

In all events, the Court should flatly reject Plaintiffs' suggestion that it order the FDA to take "any and all actions necessary" to ensure that "no" newly deemed product remains on the market "without being subject to FDA enforcement action," Pls.' Proposed Order ¶ 1, and make quarterly reports about the number of premarket applications it has processed and the "number and nature of enforcement actions it has commenced," *id.* ¶ 4. The FDCA contains no private right of action, which is effectively what Plaintiffs seek. *See* 21 U.S.C. § 337(a); *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). Moreover, such an order would plainly intrude on the prerogatives of the executive branch and raise significant separation of powers concerns.

The Court has held that, under the Tobacco Control Act, "the FDA '*must*' require filings from manufacturers and approve or deny those filings." Mem. Op. at 33 (citations omitted). But it is one thing to say that the agency must require the submission of premarket applications and adjudicate any applications submitted. It would be quite another to order the agency to take enforcement action against noncompliant products—and the Court's opinion rightly stopped short of doing so.

As Defendants have explained, a tobacco product that is marketed without a necessary premarket authorization is considered "adulterated" or "misbranded." Defs.' Br. at 6 (quoting 21 U.S.C. §§ 387b(6), 387c(a)(6)). The FDA "is *authorized* to conduct examinations and investigations" to enforce these and other provisions of the FDCA, 21 U.S.C. § 372(a)(1)(A) (emphasis added), and

violations may lead to enforcement action, including the seizure of offending products, *id.* § 334 (products "shall be *liable* to be proceeded against" (emphasis added)), injunctions against manufacturers, distributors, and retailers, *id.* § 332, and potentially criminal prosecution, *id.* §§ 331(a)–(c), 333(a), 336. These enforcement provisions are *precisely the same* as those at issue in *Heckler v. Chaney*, 470 U.S. 831 (1985), where the Supreme Court held that they "commit *complete discretion* to the Secretary to decide how and when they should be exercised." *Id.* at 835 (emphasis added). Thus, even if the Court enters a deadline for the submission of premarket applications, it should not purport to order the agency to take enforcement action against manufacturers that fail to meet that requirement.

The "basic principle" underlying the separation of powers doctrine is that "one branch of the Government may not intrude upon the central prerogatives of another." *Loving v. United States*, 517 U.S. 748, 757 (1996). 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 & Elec. Co. v. FERC*, 252 F.3d 456, 459 (D.C. Cir. 2001) (citing U.S. Const. art. II, § 3). "One aspect of that power is the prerogative to decline to enforce a law, or to enforce the 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, "*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.*

That is reason enough to reject Plaintiffs' requested relief. But here, Plaintiffs offer more, as they would have the Court intrude even further into the executive sphere. Plaintiffs seek not only to compel the FDA to take enforcement action, but also for the Court to second-guess the nature, scope, and thoroughness of the agency's enforcement efforts. Indeed, their remedy brief and proposed order make clear that Plaintiffs envision an invasive inquiry into the FDA's decisionmaking process, including quarterly reports on: (a) "all steps" the agency is taking to enforce the premarket review

provision; (b) the "number of applications . . . it has received"; (c) the "status of its processing of those applications"; (d) the "number of . . . enforcement actions it has commenced"; and (e) the "nature" of those enforcement actions. Pls.' Proposed Order ¶ 4. Presumably, then, Plaintiffs anticipate continual judicial supervision of the FDA's processing of an expected 5,424 to 6,764 premarket applications, and intend to ask the Court to manage the agency's enforcement efforts should they be thought unsatisfactory.

Such inquiries fall outside the judicial role—a province that "a district judge must be careful not to exceed" "when the government is challenged for not bringing as extensive an action as it might." *United States v. Microsoft Corp.*, 56 F.3d 1448, 1462 (D.C. Cir. 1995).[7] In *Microsoft*, for example, the district court refused to enter a consent decree after the government declined to provide it with details akin to those sought by Plaintiffs here, such as (a) the "broad contours of the investigation"; (b) the "conclusions reached by the Government" about the company's practices; (c) why "areas were bargained away" during settlement discussions; and (d) what the government's future investigative plans were. *Id.* at 1455. The D.C. Circuit reversed—and reassigned the case—explaining that the district "judge's demand that he be informed [of these matters] indicates that the judge impermissibly arrogated to himself the President's role to 'take care that the laws be faithfully executed.'" *Id.* at 1457 (quoting U.S. Const. art. II, § 3). This Court should decline Plaintiffs' invitation to similarly encroach on the executive power.

CONCLUSION

For the foregoing reasons, the Court should decline to issue further relief in this case.

[7] Nor do Plaintiffs cite any relevant support for requiring agencies to report their *enforcement* activities to a court. *See* Pls.' Remedy Br. at 9. In *Cobell*—the only case they cite—reporting requirements were imposed for a breach of trust, and only in light of a "history of destruction of documents," "government malfeasance," and a "longstanding inability or unwillingness of government officials to discharge their fiduciary obligations." 240 F.3d at 1109.

Dated: June 12, 2019

Respectfully submitted,

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