**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MARYLAND**

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| AMERICAN ACADEMY OF PEDIATRICS, *et al.*,<br>Plaintiffs,<br>v.<br>FOOD AND DRUG ADMINISTRATION, *et al.*,<br>Defendants. | Civ. Action No. 8:18-cv-883-PWG |

**PLAINTIFFS' REPLY TO DEFENDANTS' REMEDY BRIEF**

Defendants misapprehend Plaintiffs' proposal, the scope of the Court's authority, and the consequences of forgoing a further remedial order. As the Court explained, vacating the August 2017 Guidance means that "manufacturers [are] required to submit their applications immediately … or by a reasonable date" imposed by the Court. Op. at 22, ECF No. 73. Without further order, the effect of the existing Order is to make all ENDS products and newly marketed cigars immediately subject to an enforcement action.

Because the compliance period established by the Deeming Rule was still in effect at the time FDA issued the unlawful August 2017 Guidance, Plaintiffs' proposal would come as close as possible to restoring the status quo ante prior to the guidance. Like the Deeming Rule, it would give manufacturers time to prepare and submit the required applications and allow manufacturers who submit applications the same one-year window while the application is pending. It thus would not "abruptly clear[] the market of e-cigarette products," Defs.' Remedy Br. ("Defs.' Br.") at 6, ECF No. 120; to the contrary, it would allow products for which applications had been timely submitted to stay on the market for the same one-year period as that permitted by the Deeming Rule. Moreover, making clear that deemed products are subject to enforcement actions does not require FDA to bring an enforcement action against every non-complying product or implicate the separation of powers. It merely affirms what both Plaintiffs and FDA recognize: that any company marketing unlawfully does so at its own peril.

Finally, there is nothing inappropriate about ordering reports on compliance with a Court order. The Court held that the FDA cannot choose "not to enforce the premarket review requirements against any manufacturers," Op. at 46, and reporting is an appropriate and standard means of responding to agency inaction. Defendants' suggestion that Plaintiffs are seeking judicial supervision of the PMTA process is unfounded. Plaintiffs do not seek any relief related

to how FDA evaluates applications; they seek only to ensure that FDA cannot evade its statutory obligations and the Court's judgment through inaction.

## I. The Court Should Exercise Its Remedial Discretion to Provide 120 Days to File Applications and Restore the Deeming Rule's One-Year Post-Submission Period.

The Court's Order vacated the 2017 Guidance, thus leaving the Deeming Rule as the governing law on the TCA's application to deemed products. Under the Deeming Rule, "[t]he compliance period for submission and FDA receipt of [PMTA] applications" expired "24 months from the effective date of" the Deeming Rule, *i.e.* August 8, 2018. 81 Fed. Reg. at 29,011. As FDA explained, "[n]ew products for which no application has been submitted by 24 months from the effective date of this rule will … be subject to enforcement." *Id.* August 8, 2018 has come and gone, and not a single ENDS product has a PMTA application on file. Decl. of Mitchell Zeller ("Zeller Decl."), ¶ 5(d), ECF No. 120-1. Thus, no ENDS product can lawfully be marketed, and every single one is "subject to enforcement." 81 Fed. Reg. at 29,011.

If ENDS manufacturers remove products from the market once they cannot be lawfully marketed—as Defendants assume when discussing Plaintiffs' proposal, *id.* at 6-7—all ENDS products would imminently leave the market *unless* the Court issues a further remedial order. By contrast, Plaintiffs' proposed remedy provides time for manufacturers to file applications, coming as close as possible to what the Deeming Rule and the TCA require in light of the reality created by FDA's unlawful actions.

There is ample authority for a Court to structure its remedy to account for the realities of immediate vacatur or reinstate the status quo. *See, e.g.*, *Andrulis Res. Corp. v. U.S. Small Bus. Admin.*, No. 90-cv-2569, 1990 WL 169318, at *2 (D.D.C. Oct. 19, 1990) (collecting cases where

courts extended statutory deadlines).[1] While Defendants' concerns about the scope of the Court's authority are unfounded across the board, *see infra* pp. 6-8, they are particularly misplaced here.

Moreover, the prospect of consumers suddenly losing all availability to ENDS products is baseless. Such an outcome would occur only if *no* manufacturers submitted PMTA applications, which Defendants do not suggest is plausible.[2] Manufacturers have strong financial incentives to submit applications, enabling them to market their products for an additional year while their applications are under consideration.[3] Defendants estimate that there were "4,640 to 8,800 e-cigarette products" on the market as of May 2016. Defs.' Br. at 8. FDA expected manufacturers of roughly one-third of those products (1,610 to 2,950 ENDS) to submit applications—but even if manufacturers of 95% of those products failed to submit complete applications by the 120-day mark, consumers would still have hundreds of ENDS products to choose from.

Nor should the Court simply rely on FDA's "commitment" to issue a new Guidance within 120 days setting out the agency's "enforcement priorities." Defs.' Br. at 1. While the agency has now, for the first time, suggested when it *hopes* to act, it gives no assurance of when that Guidance will issue nor what its substance will be. The Court has already rejected the possibility of allowing FDA to leave the statute entirely unenforced while it finalizes its next guidance. *See* Op. at 46 (agency cannot "hold in abeyance enforcement of mandatory provisions

[1] *See generally Nat'l Wildlife Fed'n v. Nat'l Marine Fisheries Serv.*, 886 F.3d 803, 823-24 (9th Cir. 2018) ("In fashioning equitable relief, a court 'must act within the bounds of the statute and without intruding upon the administrative province,' but it 'may adjust its relief to the exigencies of the case in accordance with the equitable principles governing judicial action.'" (quoting *Sierra Pac. Indus. v. Lyng*, 866 F.2d 1099, 1111 (9th Cir. 1989)); *Thompson v. HUD*, No. 95-cv-309, 2006 WL 581260, at *10 (D. Md. Jan. 10, 2006) (same); *Zambrana v. Califano*, 651 F.2d 842, 844 (2d Cir. 1981) (courts "may when appropriate set a time limit for action by the [agency], and this is often done").

[2] Even the declarations from executives of ENDS companies do not assert that their employers would be unable or unwilling to submit PMTA applications within 120 days if required to do so. *See* Decl. of Joanna Engelke, ECF No. 113-4; Decl. of David M. Graham, ECF No. 113-6.

[3] The parties appear to agree that the Deeming Rule's one-year window following the application cutoff is appropriate. *See* Pls.' Opening Br. on Remedies ("Pls.' Br.") at 8; Defs.' Br. at 12.

of a statute" while it "tries to figure out how it will implement the statute, all the while affording those manufacturers responsible for the public harm a holiday from meeting the obligations of the law"). Even if the proposed draft guidance were legal and adequate (which it is not, *see* ECF No. 61 at 2), FDA's unlawful abdication and the current crisis of youth nicotine addiction that it helped cause would render a remedial order entirely appropriate.

Defendants' alternative arguments for a ten-month application period instead of four are unpersuasive. First, they argue—inconsistently with their argument that manufacturers will leave the market rather than file applications—that manufacturers will flood FDA with applications at the last minute. But Defendants offer no reason to think this problem would be any different with a ten-month deadline. As Defendants point out, in the "best analogue," the vast majority of manufacturers submitted applications "'within the last several days leading up to' the deadline," Defs.' Br. at 10 (quoting Zeller Decl. ¶ 19), suggesting that they will do so regardless of the amount of time they had to prepare.

Defendants' argument that many applications will be low quality is equally ill-conceived. Manufacturers have already had more than three years since the issuance of the Deeming Rule and a detailed draft guidance regarding the content of a PMTA application—a much longer period to prepare applications than the 24 months established by the Deeming Rule. The public health burden of products that are the subject of "haphazard" applications, Defs.' Br. at 11, should not fall on young people. Manufacturers who are unable, more than three years after the issuance of the Deeming Rule, to submit complete applications should not be enabled to continue to sell addictive products. To the contrary, eliminating such products will help consumers identify those products that may meet the statutory standards. Defendants' argument that FDA lacks the resources to process applications is similarly unpersuasive in light of the fact that FDA

receives more than $700 million annually from user fees, which it can only spend on administering the Tobacco Control Act. *See* 21 U.S.C. § 387s(b)(1)(K), (c)(2)(A).

Finally, while FDA states that it wishes to issue a new rule providing guidance on PMTAs, Defs.' Br. at 11, it concedes that its existing guidance allows manufacturers to submit viable applications, and has repeatedly encouraged manufacturers to file them, *id.* at 8, 11. FDA's substantive expectations for such applications have been clear for more than three years. Simultaneously with the issuance of the Deeming Rule, FDA issued a lengthy draft guidance detailing the requirements for the submission of premarket applications for ENDS products.[4] FDA finalized this guidance last week, acknowledging that the final recommendations "are substantially similar to those set forth in the draft guidance issued on May 5, 2016."[5]

## II. The Other Elements of Plaintiffs' Proposal Are Appropriate and Within the Court's Authority

Much of Defendants' response to Plaintiffs' proposal is based on a fundamental misunderstanding of that proposal. Plaintiffs' Proposed Remedial Order, ECF No. 78-1, would require FDA to "take any and all actions necessary, and in accord with the Administrative Procedure Act, to ensure that no new tobacco product … may remain on the market without being subject to FDA enforcement action unless an application for a Marketing Order for such product is received by FDA within 120 days of this Remedial Order." *Id.* at 1. Defendants interpret this language to require FDA to initiate an enforcement action against *every* product that is marketed in violation of the TCA. It was not Plaintiffs' intention to require any such thing, nor is any such conclusion suggested by the language Plaintiffs proposed.

[4] *See* FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems—Guidance for Industry, Draft Guidance (May 2016), https://www.fda.gov/media/97652/download.
[5] FDA, Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems—Guidance for Industry, at 2 (June 2019), https://www.fda.gov/media/127853/download.

Rather, Plaintiffs' proposal makes clear that any unlawfully marketed products (i.e., any deemed new products that are not the subject of a timely filed application or as to which an application has not timely been granted) are *subject to* enforcement action—that is, exposed to the possibility of enforcement. Defendants' declarant uses the same language to mean the same thing. *See* Zeller Decl. ¶ 14 ("Products lacking an application after 10 months would be subject to enforcement … ."). Plaintiffs are not asking the Court to order Defendants to initiate enforcement actions against all noncompliant manufacturers, much less to "second-guess the nature, scope, and thoroughness of the agency's enforcement efforts." Defs.' Br. at 14. Defendants' separation of powers objection is thus entirely misplaced.

The cases Defendants cite all involve plaintiffs seeking to dictate a *particular* enforcement action.[6] None of them deal with the situation here, where a government agency "'consciously and expressly adopted a general policy' that is so extreme as to amount to an abdication of its statutory responsibilities." Op. at 45 (quoting *Chaney*, 470 U.S. at 833 n.4). In such a case, eliminating the violation necessarily entails prohibiting the agency from continuing to leave a statutory requirement entirely unenforced. It is well established that "federal courts possess broad discretion to fashion equitable remedies" and "may craft declaratory and injunctive relief designed to preclude a federal agency from acting in contravention of its statutory and regulatory authority." *Coal. for Gov't Procurement v. Fed. Prison Indus.*, 365 F.3d 435, 460 (6th Cir. 2004). "Furthermore, the court may require an agency to modify its current or future practices in order to account for past violations of its statutes or regulations." *Id.*[7]

[6] *See Heckler v. Chaney*, 470 U.S. 821, 824-25 (1985) (seeking to compel enforcement against particular products); *Hill Dermeuticals v. FDA*, 709 F.3d 44, 46 (D.C. Cir. 2013) (seeking to enjoin approval of a particular product); *Palisades Gen. Hosp. v. Leavitt*, 426 F.3d 400, 403 (D.C. Cir. 2005) (seeking to compel reclassification of a particular beneficiary of a government program); *Balt. Gas & Elec. Co. v. FERC*, 252 F.3d 456, 457 (D.C. Cir. 2001) (seeking to block settlement of a particular enforcement action).

[7] *See, e.g.*, *Howard v. Pierce*, 738 F.2d 722, 730 (6th Cir. 1984) (relief that "do[es] no more than preclude illegal activity on the part of a federal agency" is "limited relief [that] would not interfere seriously with the agency's scope

Plaintiffs' proposal would do no more than confirm what the Court's Opinion concluded: FDA may not abdicate its enforcement responsibilities under the TCA. *See* Opinion at 42-46. It does not require the Court to "substitute its judgment for the scientific expertise of the agency," much less "supervis[e] the FDA's processing of … premarket applications" or "manage the agency's enforcement efforts." Defs.' Br. at 5, 15. It merely makes clear that FDA cannot immunize products from enforcement in contravention of the TCA.

Plaintiffs' proposed reporting requirement is similarly a limited, narrowly tailored requirement allowing the Court and Plaintiffs to ensure that FDA does not continue to abdicate its enforcement responsibilities through a policy (whether explicit or implicit) of blanket inaction. Without such reports, neither the Court nor Plaintiffs would be able to confirm that FDA is in fact enforcing Congress's premarket review requirement. While Defendants portray reporting as an "invasive inquiry" that is "[p]resumably" a precursor to supervision of application processing and individual enforcement decisions, Defs.' Br. at 14-15, this specter is baseless. The Court is more than capable of distinguishing between *abdication* of enforcement and the wide range of enforcement discretion that agencies possess.

Defendants imply that reporting requirements are only appropriate where an agency has a history of misconduct. Defs.' Br. at 15 n.7. On the contrary, reporting requirements are common not only where an agency has acted in bad faith but in cases of "unreasonable delay of agency action or failure to comply with a statutory deadline," *Baystate Med. Ctr. v. Leavitt*, 587 F. Supp. 2d 37, 41 (D.D.C. 2008), which is the case here.[8] The sole case Defendants proffer to cast doubt

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of responsibilities"); *Thompson*, 2006 WL 581260, at *10 ("Federal agencies are not immune from the federal court's traditional equitable powers. 'While the court must act within the bounds of the statute and without intruding upon the administrative province, it may adjust its relief to the exigencies of the case in accordance with the equitable principles governing judicial action.'" (quoting *Ford Motor Co. v. NLRB*, 305 U.S. 364, 373 (1939)).

[8] *See also, e.g.*, *Alaska Ctr. for Env't v. Browner*, 20 F.3d 981, 986-87 (9th Cir. 1994); *Clark v. Perdue*, No. 19-cv-394, 2019 WL 2476614, at *4 (D.D.C. June 13, 2019); *Baptist Med. Ctr. v. Burwell*, No. 11-cv-899, 2019 WL 978957, at *9 (D.D.C. Feb. 28, 2019).

on a court's ability to require such information is far afield, to say the least; it is about whether a court evaluating the settlement of an antitrust complaint under the Tunney Act may "ask[] whether the complaint itself was adequate." *United States v. Microsoft Corp.*, 56 F.3d 1448, 1457 (D.C. Cir. 1995). It sheds absolutely no light on the range of remedies that is acceptable when a court finds a violation of the APA, much less when a court concludes that an agency completely abdicated its statutory responsibilities.

**III. To the Extent the Four-Factor Permanent Injunction Test Applies, It Is Satisfied**

Finally, Defendants raise a red herring: the four-factor test for a permanent injunction. Courts have explained that in "devising an appropriate remedy [under 5 U.S.C. § 706(2)], the words 'set aside' need not be interpreted narrowly," and a court "may tailor its remedy to the unlawful agency behavior." *Thompson v. HUD*, 348 F. Supp. 2d 398, 464 (D. Md. 2005) (internal citation omitted). Courts routinely exercise this remedial discretion without applying the permanent injunction test.[9] Moreover, the relief Plaintiffs propose here is principally declaratory, confirming what it means for the Deeming Rule to apply in light of Defendants' unlawful delay. The reporting requirement is merely a means of ensuring that Defendants observe the Court's mandate, rather than an injunction requiring the application of the test. *See, e.g.*, *Alaska Ctr. for Env't*, 20 F.3d at 986-87 (approving reporting requirement without application of injunctive test).

Even if the four-factor test applied, it is readily satisfied. First, Plaintiffs' standing declarations amply demonstrate irreparable injury to Plaintiffs. *See* Op. at 14-20. Among other things, these injuries include thousands of hours of work requiring plaintiffs to "reduce staffing on other projects, postpone new initiatives, spend funds that [they] would not have otherwise had to, and forgo grant funding." *Id.* at 16-17 (quoting Pls.' Summ. J. Reply at 7, ECF No. 39). There

[9] *See, e.g.*, *Thompson*, 2006 WL 581260, at *10; *Beechwood Restorative Care Ctr. v. Thompson*, 494 F. Supp. 2d 181, 202 (W.D.N.Y. 2007); *NAACP, Boston Chapter v. Kemp*, 721 F. Supp. 361, 368 (D. Mass. 1989).

is no mechanism for Plaintiffs to recoup these resources, rendering the harm irreparable. *See, e.g.*, *E. Bay Sanctuary Covenant v. Trump*, 354 F. Supp. 3d 1094, 1116 (N.D. Cal. 2018) ("[T]he general rule that '[e]conomic harm is not normally considered irreparable' does not apply where there is no adequate remedy to recover those damages, such as in APA cases." (quoting *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018))); *Mansfield v. Orr*, 545 F. Supp. 118, 125-26 (D. Md. 1982) (irreparable injury shown where "there is no remedy—monetary or otherwise—which could compensate plaintiff for the losses he will have sustained").

Even more importantly, the premarket review process is critical to Plaintiffs' ability to advise physicians and the public on the relative dangers of the particular products on the markets and the consequences of their use. *See* Pls.' Summ. J. Reply at 5. The denial of this information constitutes irreparable injury. For example, whenever a pediatrician is unable to provide the best available information to a young patient, an opportunity to avoid serious potential harm is irrevocably lost. Defendants do not explain how any of Plaintiffs' injuries can be repaired, instead merely rehashing their already-rejected arguments that they are not cognizable injuries at all. *Compare* Defs.' Br. at 5-6 *with* Defs.' Mot. to Dismiss at 12-21, ECF No. 36-1.

The second factor, whether remedies available at law are adequate, also weighs in favor of an injunction. As Plaintiffs explained previously, "[v]acatur alone … cannot remedy all the harm that has resulted from FDA's unlawful action." Pls.' Br. at 5. To the extent the limited additional provisions Plaintiffs propose are considered injunctive, they are necessary to restore the status quo ante and extinguish the violation, and thus satisfy the second factor.

The balance of equities and the public interest, however, are the most important factors here—and they definitively support Plaintiffs' proposal. The principal purpose of the remedy proposed by the Plaintiffs is to protect the public health—and especially the health of children—

by ensuring agency adherence to the requirements of a significant public health statute. In the face of an epidemic of youth usage of e-cigarettes, none of which has been subjected to the premarket review required by law, Plaintiffs' proposal would advance the public interest by ensuring that the public—and particularly youth—are protected from addictive products that FDA has not found "appropriate for the protection of public health." 21 U.S.C. § 387j(c)(4). Requiring manufacturers to comply with the statutory requirement of filing an application for a marketing order serves the public interest; indeed, it is the very definition of the public interest, as specified by Congress. *Cf. Roe v. Shanahan*, 359 F. Supp. 3d 382, 421 (E.D. Va. 2019) ("The public undoubtedly has an interest in seeing its governmental institutions follow the law … .").

Congress did not create a presumption that ENDS, cigars, or any other deemed product was appropriate for the protection of public health. To the contrary, it required manufacturers to prove their products' appropriateness *before* bringing them to market. There is thus no public interest in ensuring that products remain on the market where manufacturers have not established that they protect public health, even after years of "notice that they will have to file premarket approval applications." Op. at 53. The burden of FDA's failure to enforce its statutory responsibilities and manufacturers' failure to ensure their own products' suitability should not fall on the millions of youth whose health is at stake.

## IV. Conclusion

For the foregoing reasons and those stated in Plaintiffs' opening brief, the Court should enter Plaintiffs' proposed remedial order.

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Respectfully submitted,

*/s/ Jeffrey B. Dubner*

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