IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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

PLAINTIFFS' OPENING BRIEF ON REMEDIES

In accord with the Court's May 15, 2019 Memorandum Opinion, ECF No. 73 ("the Court's Opinion") and Order, ECF No. 74 ("the Court's Order"), Plaintiffs submit this brief regarding the appropriate remedial order to be entered by the Court consistent with the Court's Opinion. A proposed order accompanies the brief.

The U.S. Food and Drug Administration's ("FDA") unlawful August 2017 Extension of Certain Tobacco Product Compliance Deadlines Relating to the Final Deeming Rule: Guidance for Industry (Revised) ("August 2017 Guidance"), found by this Court to have exceeded the agency's statutory authority by suspending the premarket review process, has caused immeasurable harm to the public health, and particularly to the health of the nation's children, by allowing highly addictive and harmful tobacco products to remain on the market without public health review. The Court's Opinion and Order have the effect of returning the agency and the industry to the status quo ante under the Deeming Rule, in which deemed products were permitted to stay on the market not subject to enforcement actions only if their manufacturers applied for marketing orders by a specific deadline and then only for a further specified period for FDA to consider the applications. *See Am. Acad. of Pediatrics ("AAP") v. FDA*, No. PWG-

18-883, 2019 WL 2123397 (D. Md. May 15, 2019); Deeming Rule, 81 Fed. Reg. 28,974, 28,976 (May 10, 2016). However, those deadlines and time limits have long ago expired. This Court should implement a remedy that sets a new timetable for premarket review that effectuates the intent of the Deeming Rule to the extent possible and thus serves the public health objectives of the TCA. Thus, the appropriate remedy is an order that promptly restarts the premarket review process and prevents any further postponement of the effective dates for premarket review that would continue to expose the public, and particularly our young people, to precisely the health risks that the Family Smoking Prevention and Tobacco Control Act was enacted to prevent. *See* Family Smoking Prevention and Tobacco Control Act ("TCA" or "Tobacco Control Act"), Pub. L. No. 111-31, § 2(1), 123 Stat. 1776, 1777 (2009).

As set out in detail below, it is Plaintiffs' position that the Court's action vacating the August 2017 Guidance should be accompanied by the entry of a remedial order that (1) prevents FDA from further delaying the prompt implementation of the premarket review provisions of the statute; (2) limits the time period during which any newly deemed tobacco product on the market as of the effective date of the Deeming Rule can stay on the market without a marketing order; and (3) requires FDA to report regularly to the Court on its implementation of premarket review and enforcement of the TCA requirements against companies marketing their products without a required marketing order, to ensure that FDA does not accomplish through inaction what it has sought to do through unlawful regulation. The Court should also retain jurisdiction to enforce the order. A remedy built on these objectives is required to implement, albeit belatedly, the mandatory premarket review provisions of the TCA and enable FDA to meet the Act's public health objectives.

I. The Court's Opinion Provides The Framework For The Appropriate Remedial Order.

The Court's opinion reached four legal conclusions that provide the framework for the entry of an appropriate remedial order.[1]

First, the Court concluded that FDA's "wholesale suspension" of the mandatory statutory premarket application filing and FDA authorization requirements until 2021 (for cigars and other combustible products) and 2022 (for e-cigarettes), or later, in the August 2017 Guidance, was not an exercise of agency enforcement discretion insulated from judicial review, but rather constituted a reviewable rule amendment or revocation. S*ee AAP*, 2019 WL 2123397, at *16. In this connection, the Court noted that the August 2017 Guidance not only extended the deadlines for premarket applications to be filed, it also provided for a "continued compliance period" pending review of certain applications, that would run until the agency rendered a decision. *See id.* at *5. In contrast, the Deeming Rule had generally limited the "continued compliance period" to one year following the submission of the application, regardless of whether FDA had yet acted. Deeming Rule, 81 Fed. Reg. at 28, 978.

Second, the Court concluded that, despite the boilerplate language in the August 2017 Guidance that it was "not binding" and does not "establish legally enforceable responsibilities," the Guidance represented a completed agency decision-making process, had sufficient legal consequences and imposed a sufficient burden on Plaintiffs, that it constituted final agency action subject to judicial review. *See AAP*, 2019 WL 2123397, at *18-19.

Third, and of greatest relevance to the remedial stage of this proceeding, the Court concluded that the August 2017 Guidance was not a permissible exercise of agency enforcement discretion, but rather was an abdication of FDA's statutory responsibility to review new tobacco

[1] This discussion will not review the Court's determination that the Plaintiffs had standing to bring this action, as it is less relevant to the remedies issue.

products "in the prompt fashion dictated by Congress" to protect the public health before they can do harm. *Id.* at *21. The Court explained the public health implications of the "holiday" FDA had afforded manufacturers in issuing the August 2017 Guidance – implications that also should inform the Court's determination of the appropriate remedial order:

> Instead of addressing public health concerns associated with tobacco use by minors and others, the August 2017 Guidance exacerbates the situation by stating, in essence, that manufacturers can continue to advertise and sell products that are addictive and that target a youth market, like the "Apple Juice" e-cigarette discussed in Plaintiffs' Complaint, at a time when minors' use of tobacco products like e-cigarettes is at an epidemic level and rising. Arguably, the five-year compliance safe-harbor has allowed the manufacturers enough time to attract new, young users and get them addicted to nicotine before any of their products, labels, or flavors are pulled from the market, at which time the youth are likely to switch to one of the other thousands of tobacco products that already are approved – result entirely contrary to the express purpose of the Tobacco Control Act.

Id. Thus, the Court found the August 2017 Guidance inconsistent with the Tobacco Control Act and in excess of FDA's statutory authority.[2] *Id.* at *21-22.

Finally, the Court concluded that the August 2017 Guidance constituted a legislative rule, not simply a policy statement, as argued by FDA, and therefore was required to comply with the notice and public comment requirements of the Administrative Procedure Act ("APA"). *Id.* at *25-26. Thus, in directing the parties to file briefs concerning the appropriate remedial order, the Court indicated that any future Guidance providing for a compliance period must account for

[2] As the Court is aware, on March 13, 2019, FDA issued for public comment a Draft Guidance proposing to modify the August 17, 2017 Guidance. *See* Defendants' Notice (Mar. 15, 2019), ECF No. 59; Modifications to Compliance Policy for Certain Deemed Tobacco Products, Guidance for Industry, Draft Guidance (Mar. 2019), https://www.fda.gov/media/121384/download. The March 13 Draft Guidance, if made final, would also be inconsistent with the TCA and beyond the authority of FDA under the reasoning of the Court's opinion. Like the August 2017 Guidance now vacated by this Court, the March 13 Draft Guidance does not represent a case-by-case exercise of enforcement discretion by FDA, but rather simply redefines the categories of products exempt from premarket review application requirements, shortens the compliance period by only a single year, and permits products to be marketed for an indefinite period during FDA's consideration of the applications. *Id.* In addition, as Plaintiffs have argued in comments filed with FDA, the March 13 Draft Guidance is an inadequate response by FDA to the youth e-cigarette epidemic.

notice and comment required by the APA. *Id.* at *26. For these reasons the Court vacated the August 2017 Guidance. *Id.*

II. Vacating The August 2017 Guidance Restores Premarket Review To Its Central Role In The Regulation Of New Tobacco Products.

By vacating the August 2017 Guidance, this Court's Opinion and Order establishes that all deemed tobacco products, including new e-cigarettes and cigars, on the market as of August 8, 2016, are not being lawfully marketed because they lack a premarket order and are subject to FDA enforcement if they remain on the market.

The Court's Opinion thus restores the premarket review process to the central role it was designed to play under the Tobacco Control Act. Manufacturers of new tobacco products who wish to continue marketing those products in the future now are required, and have a strong incentive, to submit high quality premarket applications as quickly as possible in order to avoid the possibility of FDA enforcement proceedings. Moreover, by returning to the status quo before the August 2017 Guidance and in contrast to the situation created by that Guidance, any undue delay caused by manufacturers' failure to file full and complete applications, or delays by FDA in responding to them, would not result in an indefinite period during which new tobacco products are allowed to be marketed without obtaining the required FDA marketing order.

III. The Court Should Issue A Remedial Order To Minimize The Future Harm Resulting From FDA's Illegal Action.

Vacatur alone, however, cannot remedy all the harm that has resulted from FDA's unlawful action. This Court found that the "safe harbor" created for manufacturers under the August 2017 Guidance has contributed to the current epidemic of e-cigarette use among teens because it "allowed the manufacturers enough time to attract new, young users and get them addicted to nicotine. . . ." *See AAP*, 2019 WL 2123397, at *21. Even the FDA Commissioner

who promulgated the August 2017 Guidance recently expressed regret that the agency did not require applications to be submitted earlier, admitted the agency had "struck the wrong balance" on e-cigarettes, and expressed hope that FDA would consider removing from the market the nicotine pod e-cigarettes like JUUL that have contributed most to the current crisis.[3]

Had the Deeming Rule been allowed to take full effect, newly-deemed products would have remained on the market only if their manufacturers had filed their applications by August 2018 and generally would have remained on the market only until August 2019 if FDA had not granted the applications by then. Deeming Rule, 81 Fed. Reg. at 28,978. Thus, under the Deeming Rule, the August 2019 deadline would be approaching and any products for which applications had not been filed presumably would have been off the market for nearly a year. *Id.*

Instead, by virtue of the now-vacated August 2017 Guidance, all the products that have created this crisis remain on the market and, with no incentive for filing applications, manufacturers have not done so. Furthermore, the Draft Guidance issued by FDA in March 2019 would not remedy the problem. Even if that Guidance is finalized at some time in the future, all the products that have given rise to this crisis would remain on the market with no FDA review for all or nearly all the same time as under the August 2017 Guidance. Furthermore, once an application is filed, those products would still remain on the market indefinitely pending FDA's eventual disposition of those applications, no matter how long it takes FDA to reach a decision or even if the delay is caused by the actions of the manufacturer.

Thus, given that FDA's illegal action in abrogating the deadlines established by the Deeming Rule has created a public health crisis and left a multitude of products on the market with no legal authorization, this Court should exercise its broad equitable authority to effectuate

[3] *See, e.g.*, Angelica LaVito, *Former FDA Chief Gottlieb: 'We Struck the Wrong Balance' On E-Cigarettes*, CNBC (May 21, 2019), https://www.cnbc.com/2019/05/21/former-fda-chief-gottlieb-we-struck-the-wrong-balance-on-e-cigarettes.html.

the terms of FDA's original Deeming Rule requirements and restore the agency, the industry and the public to the positions they would have held if FDA has not acted illegally. Unfortunately for the young people who have become addicted to nicotine in the last two years as a result of the FDA's action, no action taken now can undo the harm that has been done. However, prompt reimplementation of the premarket review requirements can at least stop the damage from impacting more and more people, especially youth. The effectiveness of a remedial order will be negated if a new, lengthy regulatory process is permitted, leading to an extended period during which manufacturers again operate with a "safe harbor," protected from premarket review. FDA's original requirement is now back in effect.

In devising an appropriate remedy in a case involving an agency's abdication of statutory responsibilities, the "Court may tailor its remedy to the unlawful agency behavior" and "while the court must act within the bounds of the statute and without intruding into the administrative province, it may adjust its relief to the exigencies of the case in accordance with the equitable principles governing judicial action." *See Thompson v. U.S. Dep't of Hous. & Urban Dev.*, 348 F. Supp. 2d 398, 464-65 (D. Md. 2005) (quoting *Indiana & Mich. Elec. Co. v. Fed. Power Comm'n*, 502 F.2d 336, 346 (D.C. Cir. 1974); *see also NAACP v. Sec'y of Hous. & Urban Dev.*, 817 F.2d 149, 160 (1st Cir. 1987) (holding with respect to 5 U.S.C. § 706(2)(A) that a court, "where it finds unlawful agency behavior, may tailor its remedy to the occasion"); *Thompson v. U.S. Dep't of Hous. & Urban Dev.*, 2006 WL 581260, at *9-10 (D. Md. Jan. 10, 2006) (rejecting argument that where the APA is violated "there is no judicial power to compel [an agency] to do, or consider, anything at all," and affirming that "[f]ederal agencies are not immune from the federal court's traditional equitable powers"). Thus, this Court has broad remedial authority to

require that the premarket review process be restored in a manner consistent with the deadlines and time limits in the Deeming Rule, to effectuate the public health objectives of the TCA.

Accordingly, to address what Plaintiffs and FDA agree is a public health crisis, and consistent with the principles set forth in the Court's Opinion, Plaintiffs propose that the Court enter an order with the following provisions:

First, FDA must take whatever actions are necessary and in accord with the APA, to allow new tobacco products on the market as of the August 8, 2016 effective date of the Deeming Rule to remain on the market without being subject to FDA enforcement actions, *only* under the following conditions:

1. Applications for marketing orders must be filed within 120 days of issuance of this Court's order and products for which applications have not been filed within this period shall be subject to FDA enforcement actions;
2. Products for which applications have been timely filed may remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application.[4]

These dual requirements are consistent with the Court's holdings that FDA's enforcement discretion does not extend to an across-the-board suspension of enforcement of the TCA's mandatory premarket approval process. *AAP*, 2019 WL 2123397, at *21-22. In directly addressing that abdication, these requirements are tailored to fit the specific legal violation found by the Court. *Thompson*, 348 F. Supp. 2d at 464-65.

[4] Under this order, FDA would be free to impose sales or other restrictions on the products as further conditions to their remaining on the market during the premarket review process. The agency also would be free to deny certain deemed products or categories of deemed products any period of time during which they could stay on the market without a marketing order.

Second, FDA shall report to the Court quarterly on the measures it is taking to carry out its premarket review responsibilities under the TCA, including reporting the number and nature of the enforcement actions it has undertaken against companies for marketing their products without a marketing order. Given FDA's record of non-compliance with the TCA's mandatory premarket review requirements, there is considerable reason to be concerned that, in the absence of Court supervision, FDA would accomplish through inaction what it has sought to permit through postponement of regulation. This regular reporting will permit the Court to monitor FDA's enforcement activity to ensure that the agency does not create a de facto "safe harbor" for companies by simply refraining from bringing enforcement actions. *See Cobell v. Norton*, 240 F.3d 1081, 2209 (D.C. Cir 2001) (citing examples and explaining that federal courts "regularly retain jurisdiction until a federal agency has complied with its legal obligations, and have the authority to require regular progress reports in the meantime.").

Third, and for the same reasons, the Court should retain jurisdiction of this matter to ensure compliance with its vacatur and remedial orders. *Id.*

IV. A Remedial Order Mandating Compliance With The Premarket Review Requirements Of The Tobacco Control Act Would Not Be Unfair To The Regulated Companies.

The Court's Opinion and Order, which mandate that FDA apply the Tobacco Control Act's premarket review provisions to deemed products, and the additional remedial measures proposed above, are not unfair to the regulated companies.

Manufacturers of new tobacco products first subject to FDA regulation through issuance of the Deeming Rule have long been on notice that the premarket review provisions of the statute would apply to their products. FDA announced its intention to subject such products to

regulation in 2011,[5] issued a proposed rule doing so in 2014,[6] and promulgated a final Deeming Rule in 2016.[7] Virtually every e-cigarette product currently on the market was introduced subsequent to FDA's declaration of intention to subject such products to regulations that include premarket review and the vast majority were introduced subsequent to issuance of the proposed rule. Thus, manufacturers of deemed products introduced their products knowing that they would be subject to the premarket review provisions of the statute and that the filing of applications would be mandatory.

Indeed, for over a year after the issuance of the Deeming Rule (until issuance of the August 2017 Guidance), those manufacturers understood that their applications would have to be filed by August 8, 2018 for their products to remain on the market. Moreover, as of the March 2018 filing of the Complaint in this case, manufacturers knew that FDA's action extending the compliance period for years into the future was under legal attack in this Court. Under the circumstances, the only prudent course for a manufacturer would be to prepare the required premarket applications long before expiration of the compliance periods set out in the August 2017 Guidance.

Nothing in the August 2017 Guidance prohibited, or even inhibited, manufacturers from developing the needed information or submitting applications for premarket review. Indeed, the agency, at the highest level, has repeatedly implored companies to file premarket applications far in advance of the compliance deadlines in the August 2017 Guidance. In September of last year, Commissioner Gottlieb made it clear that there is "no excuse for manufacturers not to file

[5] *See* Letter to Stakeholders from Lawrence R. Deyton, Dir., FDA Ctr. for Tobacco Products, & Janet Woodcock, Dir., FDA Ctr. for Drug Evaluation and Research, *Regulation of E-Cigarettes and Other Tobacco Products* (Apr. 25, 2011).
[6] *See* Dep't of Health & Human Servs., 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 Statement for Tobacco Products; Proposed Rule, 79 Fed. Reg. 23,142 (Apr. 25, 2014).
[7] Deeming Rule, 81 Fed. Reg. 28,974.

applications with the FDA because the agency hasn't told them what they are expected to do."[8] When Commissioner Gottlieb announced the FDA's intention to revise the August 2017 Guidance in November of last year, he expressed hope that he would "soon see manufacturers of ENDS [Electronic Nicotine Delivery Systems] products preparing, with the FDA input as appropriate, premarket tobacco product applications (PMTAs) to demonstrate that their products meet the public health standard in the Tobacco Control Act."[9] As recently as March 13 of this year, when FDA unveiled its new Draft Guidance, Commissioner Gottlieb noted the multiple guidances already issued by FDA to aid industry premarket submissions and stated that "manufacturers need not wait to submit premarket tobacco product applications for ENDS products, flavored or otherwise."[10] Moreover, any responsible company selling products with potentially serious health consequences for youth and adults should, as a matter of course, be gathering health-related information about its products. They should need little time to complete the applications based on the evidence they have gathered over the last nearly three years.

As this Court wrote, "manufacturers long have been on notice that they will have to file premarket approval applications, substantial equivalence reports, and exemption requests, and if they have chosen to delay their preparations to do so, then any hardship occasioned by their now having to comply is of their own making." *See AAP*, 2019 WL 2123397, at *26. Nor is there

[8] 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), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-new-steps-address-epidemic-youth-e-cigarette-use.
[9] Press Release, FDA, Statement From FDA Comm'r Scott Gottlieb, M.D., On Proposed New Steps to Protect Youth by Preventing Access to Flavored Tobacco Products and Banning Menthol in Cigarettes (Nov. 15, 2018), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-proposed-new-steps-protect-youth-preventing-access.
[10] 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), https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-advancing-new-policies-aimed-preventing-youth-access.

any barrier to FDA making decisions to grant or deny those applications. Indeed, it recently granted a Premarket Tobacco Application for a heated cigarette tobacco product.[11]

Thus, prudent manufacturers should be in a position to file the required premarket applications and FDA should be in a position to determine their sufficiency under the standards in the Tobacco Control Act. No further compliance period or other "safe harbor" is necessary or desirable.

CONCLUSION

For these reasons, Plaintiffs urge the Court to enter a remedial order that seeks to ameliorate the harm caused to public health by the unlawful August 2017 Guidance by requiring FDA to adhere to the statutorily mandated premarket review process, and regularly report to the Court on implementation steps taken and enforcement activities directed at companies marketing tobacco products without required marketing orders. The Court should also retain jurisdiction to enforce the terms of the order.

[11] Press Release, FDA, FDA Permits Sale of IQOS Tobacco Heating System Through Premarket Tobacco Product Application Pathway (Apr. 30, 2019), https://www.fda.gov/news-events/press-announcements/fda-permits-sale-iqos-tobacco-heating-system-through-premarket-tobacco-product-application-pathway.

Dated: May 29, 2019

Respectfully submitted,

/s/ Jeffery B. Dubner

Javier M. Guzman (*pro hac vice*)
Jeffrey B. Dubner (*pro hac vice*)
DEMOCRACY FORWARD FOUNDATION
P.O. Box 34553
Washington, D.C. 20043
jguzman@democracyforward.org
jdubner@democracyforward.org
(202) 448-9090

Eve L. Hill (Fed. Bar No. 19938)
BROWN GOLDSTEIN & LEVY, LLP
120 East Baltimore Street, Suite 1700
Baltimore, Maryland 21202
T: (410) 962-1030
F: (410) 385-0869
ehill@browngold.com

Dennis A. Henigan (*pro hac vice*)
Mark E. Greenwold (*pro hac vice* to be filed)
CAMPAIGN FOR TOBACCO-FREE KIDS
1400 I Street NW, Suite 1200
Washington, D.C. 20005
dhenigan@tobaccofreekids.org
mgreenwold@tobaccofreekids.org
(202) 296-5469

Counsel for Plaintiffs