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-DLB

DEFENDANTS' STATUS REPORT AND MOTION FOR RELIEF UNDER RULE 60(b) FROM OBLIGATION TO FILE FURTHER STATUS REPORTS

In accordance with the Court's Revised Remedial Order (ECF No. 202), Defendants respectfully submit the following status report. In addition, for the reasons that follow, pursuant to Federal Rule of Civil Procedure 60(b)(5)-(6), Defendants respectfully move for relief from the obligation to file any further status reports in this case. That obligation has now outlived its original purpose (as the Food and Drug Administration (FDA) has acted upon 185 out of 186 applications subject to the Revised Remedial Order), and now risks forcing unnecessary and inappropriate disclosure of sensitive information about FDA's ongoing review of a single application submitted by a single private company.

Background

Plaintiffs—a variety of physicians and advocacy groups—filed this lawsuit over six years ago, in March 2018. *See* Compl., ECF No. 1. Plaintiffs challenged August 2017 enforcement guidance from the FDA, *see* Ex. A to Compl., ECF No. 1-1, *Guidance for Industry: Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule* (Aug. 2017), arguing that it violated both the substantive and procedural requirements of the Administrative Procedure Act. That August 2017 guidance had memorialized FDA's intent to further delay enforcement of certain regulatory requirements against manufacturers of certain tobacco products,

while those manufacturers came into compliance with significant new regulatory requirements imposed by the combination of the Tobacco Control Act, 21 U.S.C. §§ 387a-1 *et seq.*, and the FDA's "deeming rule," FDA Final Rule, *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*, 81 Fed. Reg. 28,974 (May 10, 2016). The parties fully briefed dispositive motions by September 2018. *See* ECF Nos. 31-2, 36-1, 39, 43.

Before Judge Grimm ruled on those motions, however, the FDA "released a statement proposing" a new "'policy framework' for the regulation of tobacco products, including flavored e-cigarettes and cigars," Defs' Notice at 1, ECF No. 51 (citation omitted), products that have been a particular focus of Plaintiffs' concerns in this litigation. "As the Commissioner explained, at the time the Guidance challenged in this case was issued in August 2017, trends in youth use [of e-cigarettes] appeared to be changing in the right direction." *Id.* (citation omitted). But by the fall of 2018, "[n]ewly published data . . . show[ed] astonishing increases in kids' use of e-cigarettes" between 2017 and 2018. *Id.* (citation omitted). In fact, "from 2017 to 2018, there was a 78 percent increase in current e-cigarette use among high school students and a 48 percent increase among middle school students. . . . [and] [m]ore than two-thirds (67.8 percent) [were] using flavored e-cigarettes." FDA Statement at 3, ECF No. 51-1. Eventually, as anticipated, on March 13, 2019, FDA released new draft guidance that, among other things, modified the agency's policy of deferred enforcement to instead prioritize enforcement of the premarket review requirement against certain flavored e-cigarette products. *See* Defs.' 2d Notice at 2, ECF No. 59.

In a letter order on March 26, 2019, Judge Grimm noted that "Plaintiffs cannot challenge the Draft Guidance before it is finalized because, as Plaintiffs note, it is the 2017 Guidance, not the Draft Guidance, that is in effect." Letter Order of March 26, 2019 at 3, ECF No. 62. And Judge Grimm concluded that it "would be neither efficient nor a wise allocation of resources to consider Plaintiffs' Motion for Summary Judgment at this time, when the very guidance that Plaintiffs' challenge is subject to possible imminent revision." *Id.* So Judge Grimm denied all

parties' dispositive motions without prejudice, "until such time that any decision regarding the revision of the 2017 Guidance has been made." *Id.*

Before FDA could finalize the new guidance, however, Plaintiffs moved for reconsideration of Judge Grimm's order denying their dispositive motion without prejudice. Pls.' Ltr. Mot., ECF No. 63. On May 15, 2019, Judge Grimm granted Plaintiffs' motion for reconsideration, denied Defendants' dispositive motion, granted Plaintiffs' dispositive motion, and vacated the FDA's August 2017 enforcement guidance in its entirety. Mem. Op., ECF No. 73; Order, ECF No. 74. Judge Grimm also ordered the parties to submit separate briefing regarding an appropriate remedy, given that the operative compliance deadlines had (even by then) already passed. *See id.* After receiving that remedy briefing, in July 2019, Judge Grimm ordered the following relief:

> 1. [T]he FDA shall require that, for new tobacco products on the market as of the August 8, 2016 effective date of the Deeming Rule ("New Products"), applications for marketing orders must be filed within 10 months of the date of this Memorandum Opinion and Order;
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> 2. New Products for which applications have not been filed within this period shall be subject to FDA enforcement actions, in the FDA's discretion;
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> 3. New 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;
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> 4. The FDA shall have the ability to exempt New Products from filing requirements for good cause on a case-by-case basis.

Mem. Op. & Order at 12, ECF No. 127. A fifth paragraph was added shortly thereafter, in response to a motion for clarification filed by Defendants, which Plaintiffs did not oppose, ECF No. 129:

> 5. This order does not restrict the FDA's authority to enforce the premarket review provision against deemed products, or categories of deemed products, before the close of either the 10-month application submission period or the FDA application review period described above.

Order, ECF No. 132. As required by Federal Rule of Civil Procedure 58, Judge Grimm entered a final judgment in a separate document on November 5, 2019. ECF No. 171. Several years of additional district-court and appellate litigation then ensued, regarding issues largely not relevant here, including some brought by intervenors (and proposed intervenors) from various segments of the tobacco industry.

Over two years after final judgment (and almost three years ago), on November 15, 2021, Plaintiffs moved to reopen this case, to request modification of the remedial order. ECF No. 195 at 1. Plaintiffs explained their intent to "seek a modification that would require FDA to provide regular status reports to the Court giving FDA's estimate of the date(s) by which it expects to complete its review of the Premarket Tobacco Product Applications (PMTAs) for all products for which PMTAs were filed by Juul, Vuse, NJOY, Blu, SMOK, Suorin, and any other brands that rank among the top 10 brands in market share" for e-cigarettes. *Id.* To justify this request, Plaintiffs argued that "[t]here have been significant changes in factual circumstances since the July 2019 issuance of the Remedial Order that warrant modification of that Order." *Id.* In Plaintiffs' words:

> FDA has issued marketing orders or marketing denial orders only for products with minimal market share, withholding decisions on any of the e-cigarette products sold in significant quantities, including the products most responsible for the youth vaping epidemic. Second, FDA appears not to have enforced premarket review requirements against any companies awaiting PMTA decisions, suggesting they may have renewed their blanket extrastatutory exemption for such companies. Modification would be in the public interest because regular reporting by FDA would allow the Court to assess, on a continuing basis, the extent to which FDA is prolonging the unlawful regulatory holiday that contributed to the ongoing epidemic of youth e-cigarette use.

Id. Defendants opposed. ECF No. 197.

On April 15, 2022, Judge Grimm granted in part and denied in part Plaintiffs' request to modify the prior remedy order. First, Judge Grimm noted that "[t]he Court has discretion to modify a final order when 'applying it prospectively is no longer equitable,' Fed. R. Civ. P. 60(b)(5), or

for 'any other reason that justifies relief,' *id.* at (b)(6)." Letter Order at 1, ECF No. 201 (citing *Hensley v. Chesapeake & O. Ry. Co.*, 651 F.2d 226, 229 (4th Cir. 1981) (noting a trial court's discretion on a Rule 60(b) motion)). Judge Grimm further explained that "[t]he party seeking modification bears the burden of showing that there has been 'a significant change either in factual conditions or in the law.' *Horne v. Flores*, 557 U.S. 433, 447 (2009)." *Id.*

The fact that "the popular products used by young people remain on the market unreviewed" was, in Judge Grimm's view, "inconsistent with the purpose of this Court's judgment." *Id.* at 2. Judge Grimm ultimately concluded that "Plaintiffs' proposed reporting requirement will inform the Court and public when the FDA expects to take action on those products that account for the largest share of the market." *Id.* Accordingly, he "grant[ed] Plaintiffs' motion to modify the order to add a limited reporting requirement," though did not go as far as Plaintiffs had requested, concluding that some portions of Plaintiffs' proposal were "too burdensome to impose on FDA at this time." *Id.* Judge Grimm then issued the Revised Remedial Order, ECF No. 202, which added three new requirements to the previous order:

> 6. Beginning two weeks from this date, FDA will submit a status report to Plaintiffs and the Court every 90 days;
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> 7. For the purpose of the following paragraph, "Covered Applications" means all applications for New Products for which pending applications for marketing orders were filed by September 9, 2020 that are (a) sold under the brand names JUUL, Vuse, NJOY, Logic, Blu, SMOK, Suorin, or Puff Bar, or (b) reach 2% of total "Retail $ Sales" in Nielsen's "Total E-Cig Market & Players" or "Disposable E-Cig Market & Players" reports before FDA has completed its review of existing Status Report Products;
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> 8. The first status report will state the percentage of Covered Applications on which FDA expects to have taken action (defined as the issuance of a marketing order, refuse-to-accept letter, refuse-to-file letter, or marketing denial order) by June 2022, and quarterly thereafter. Subsequent status reports will report any revisions to prior estimates.

Revised Remedial Order at 1-2, ECF No. 202. In the two-plus years since, FDA has consistently complied with these requirements. *See* ECF Nos. 205, 207, 209, 211, 213, 215, 216, 218, 220. Plaintiffs have never argued to the contrary.

FDA's most recent status report, filed on April 19, 2024, confirmed that it had taken "action on 94% of Covered Applications by March 31, 2024." ECF No. 220. It also reported that "[t]he FDA's best forecast based on current information continues to be that it will take action on all remaining Covered Applications by June 30, 2024." *Id.*

Status Report

Covered Applications: This report includes information about "Covered Applications" as defined in Paragraph 7 of the Court's revised remedial order. The FDA has used the same method for determining which applications constitute Covered Applications as it did in its most recent status report (ECF No. 220). Before filing this status report, Defendants conferred with Plaintiffs, who agreed that the set of brands covered by paragraph 7 of the revised remedial order is the same as in that status report.

Overall Progress: The FDA remains committed to completing review of the applications it has received as soon as feasible to protect and promote the public health. The FDA took action on 95.7% of Covered Applications by June 30, 2024. As of the date of this filing, the FDA has taken action on 99.5% of Covered Applications—that is, 185 out of 186 Covered Applications. It will take action on the final Covered Application—which was the subject of a recent, major amendment submitted by the applicant that will require significant scientific review—as quickly as possible.

Motion

It is well-settled (and law of the case) that, at any time, "[t]he Court has discretion to modify a final order when 'applying it prospectively is no longer equitable,' Fed. R. Civ. P. 60(b)(5), or for 'any other reason that justifies relief,' *id.* at (b)(6)." Letter Order at 1, ECF No. 201 (citing *Hensley v. Chesapeake & O. Ry. Co.*, 651 F.2d 226, 229 (4th Cir. 1981)). Accordingly, under Federal Rule of Civil Procedure 60(b)(5)-(6), Defendants respectfully request relief from the

obligation to file further status reports in this case. For the reasons that follow, "applying" that obligation "prospectively is no longer equitable" or necessary. Fed. R. Civ. P. 60(b)(5). The Revised Remedial Order has now long outlived its original purpose—as the FDA has acted upon 99.5% of Covered Applications—and now risks forcing unnecessary and inappropriate disclosure of sensitive information about FDA's review of a single application submitted by a single private company. It is long past time for this matter to be fully closed.[1]

1. Judge Grimm issued the Revised Remedial Order over two years ago, in April 2022. At that time, FDA faced a massive backlog of long-pending premarket tobacco applications upon which it had not yet taken action. And that backlog was particularly acute with respect to the e-cigarette applications on which Plaintiffs and Judge Grimm had focused their attention—those from the companies with the largest market share, and whose products were heavily used by youth.

On Plaintiffs' view, that backlog threatened to undermine the regulatory scheme that Congress created in the Tobacco Control Act, especially with respect to flavored e-cigarette products that were most appealing to youth. And Plaintiffs' concerns were exacerbated by what they perceived as a general lack of FDA enforcement of the requirements of the Tobacco Control Act. Indeed, at that time, FDA did not dispute that it had not "enforced the premarket review requirements against *any* product still awaiting a PMTA decision, including products with the greatest market share and those most used by youth." ECF No. 195.

But the world looks very different today, across a wide variety of metrics. First, although youth usage of tobacco products remains unacceptably high, trends are positive. In the most recent annual National Youth Tobacco Survey, 2.1 million youth reported using e-cigarettes, which is less than half of the usage reported at the 2019 peak, when 5.4 million youth reported using e-cigarettes. *Compare* CDC, *Morbidity and Mortality Weekly Report, Tobacco Product Use Among Middle and High School Students – Nat'l Youth Tobacco Survey* (Nov. 3, 2023), https://www.cdc.gov/mmwr/volumes/72/wr/mm7244a1.htm; and CDC, *Morbidity and Mortality*

[1] Before filing this motion, counsel for Defendants conferred with counsel for Plaintiffs, who reported that Plaintiffs oppose the relief requested in this motion.

Weekly Report, Tobacco Product Use and Associated Factors Among Middle and High School Students (Dec. 6, 2019), https://www.cdc.gov/mmwr/volumes/68/ss/ss6812a1.htm.

Second, as of this filing, FDA has resolved more than 26 million of the approximately 27 million PMTAs received to date. *See* Ex. 1, *Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes: Hearing Before the S. Comm. on the Judiciary*, 118th Cong. 5 (June 12, 2024) (statement of Brian A. King, Director, FDA Center for Tobacco Products) ("King Testimony"). Since the issuance of the Revised Remedial Order, for e-cigarette products, FDA has issued over 18 million refuse-to-accept decisions, over 67,000 refuse-to-file decisions, and approximately 46,000 marketing denial orders. To date, FDA has also issued marketing granted orders for 34 e-cigarette products.

Most importantly for current purposes, FDA has now taken action on 185 of the 186 Covered Applications subject to the Revised Remedial Order, demonstrating the agency's progress in applying the premarket review requirement to the brands with the largest market share. And the only reason that FDA has not yet taken action on the final Covered Application is due to a recent, major amendment submitted by the applicant, which will require significant scientific review. But for that amendment, FDA is confident that it would have already achieved 100% completion, as it projected in the most recent status report. *See* ECF No. 220. Further, FDA has taken action on 100% of the Covered Applications that were for flavored e-cigarette products.

FDA has also taken significant enforcement actions and other steps to encourage compliance with the Tobacco Control Act and FDA's implementing regulations. For example, as of June 2024, FDA had conducted over 6,600 inspections of tobacco manufacturers and distributors (including e-cigarette manufacturers and vape shops) for sales of unauthorized new tobacco products, resulting in more than 880 warning letters, 57 civil money penalty actions, six injunctions, and one seizure. *See* Ex. 1, King Testimony at 3-4.[2] FDA has also taken concrete

[2] FDA regularly updates its website with compliance and enforcement action information related to unauthorized new tobacco products. *See* FDA, *Advisory and Enforcement Actions Against Industry for Unauthorized Tobacco Products*, https://www.fda.gov/tobacco-products/compliance-enforcement-training/advisory-and-

steps to address sales of tobacco products to underage purchasers, including conducting (with partner agencies) nearly 1.5 million inspections of tobacco retailers that resulted in FDA issuing more than 138,000 warning letters, 33,000 civil money penalties, and 228 No-Tobacco-Sale Orders. *Id.* at 4.

These actions have included many "first of their kind" escalated enforcement actions. For example, in April 2024, in coordination with the U.S. Marshals Service, FDA and the Department of Justice conducted the first civil seizure of tobacco products under the Federal Food, Drug, and Cosmetic Act. *Id.* at 4. More than 45,000 unauthorized e-cigarettes valued at more than $700,000 were seized at a warehouse in California. *Id.* The seized products were mostly the sort of flavored, youth-appealing e-cigarettes about which Plaintiffs have expressed particular concern. *Id.* Further, over the past year, FDA took escalating action by filing complaints seeking civil money penalties against 140 retailers for continuing to sell unauthorized products after receiving a warning letter. *Id.* The total amount of civil penalties sought is over $2,600,000. *Id.*

Finally, FDA is also continuing to collaborate with other agencies to stop the flow of unauthorized e-cigarettes into the United States. For example, last year, FDA participated in a joint operation with U.S. Customs and Border Protection (CBP) at Los Angeles International Airport that resulted in the seizure of approximately 1.4 million units of unauthorized e-cigarette products, with an estimated retail value of more than $18 million. *Id.* FDA has likewise issued two Import Alerts that inform FDA field staff and CBP about unauthorized tobacco products that can be detained without physical examination. *Id.* These Import Alerts address over 40 firms importing e-cigarettes, each of which covers multiple products. *Id.*

After this "significant change . . . in factual conditions," *Horne v. Flores*, 557 U.S. 433, 447 (2009), Plaintiffs cannot credibly maintain that there is any ongoing "abdication of [FDA]'s statutory duties" to enforce the Tobacco Control Act's premarket review requirement, as they

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enforcement-actions-against-industry-unauthorized-tobacco-products. Since the time of the testimony provided in Ex. 1, FDA has, for example, obtained injunctive relief against two additional manufacturers (for a total of 8), and initiated additional civil money penalty actions (for a total of 61).

alleged in their complaint over six years ago. Compl. ¶ 100-01. The compliance and enforcement efforts detailed above cannot fairly be described (to use Plaintiffs' words) as part of any "unlawful regulatory holiday" for manufacturers, retailers, or importers of unauthorized e-cigarette products. ECF No. 195 at 1. And most importantly here, the core factual predicate for the Revised Remedial Order has now been overtaken by events: it is no longer the case that "the popular products used by young people remain on the market unreviewed," including "the most popular e-cigarette brands that are most deleterious to youthful populations." ECF No. 201 at 1, 2 n.3. Instead, FDA has taken action on 185 of those 186 applications.[3]

Accordingly, now, years after final judgment in this case—and roughly six years after the FDA made clear that the enforcement policy reflected in the challenged August 2017 guidance was no longer reflective of agency policy—it is time for this case to be fully and completely closed. There is no longer any factual or legal basis to keep this case alive indefinitely, solely as a vehicle for monitoring FDA's day-to-day work in adjudicating a single application about a single product.

2. Terminating the reporting requirement would also avoid significant practical problems for Defendants, for the Court, and for a single private company that is not a party to this case. Because FDA has now taken action on 185 out of 186 Covered Applications, only one remains. And, based on publicly available information combined with the prior status reports in this case, *see, e.g.*, FDA, *Tobacco Product Applications: Metrics & Reporting*, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting, FDA's expectation is that informed observers will be able to identify the final applicant (and the specific product at issue) by name.

An obligation to publicly disclose when FDA expects to issue a decision on the final pending application would be inequitable—for FDA, for the applicant, and for the public. FDA

[3] FDA continues to devote significant resources to defending its actions on PMTAs, including in administrative appeals and in litigation in the federal courts. Some of the agency's actions on Covered Applications have been subsequently stayed, vacated, or rescinded, including in connection with litigation. *See*, *e.g.*, *Wages & White Lion Invs., LLC v. FDA*, 90 F.4th 357, 362 (5th Cir. 2024), *cert. granted*, No. 23-1038, 2024 WL 3259693 (U.S. July 2, 2024).

generally does not reveal its timing estimates regarding action on individual applications—to protect the integrity of the premarket review process, as a matter of fairness to applicants, and to avoid unpredictable effects on securities markets, which may be affected by public disclosure of expected timing of FDA action. That sort of market-moving information can have significant and unpredictable effects on securities prices. *See, e.g.*, *Why Investors and Traders Need to Track PDUFA Dates*, WallStreetHorizon.com, https://perma.cc/WCH4-849A ("The value for an investor or trader in some cases is dramatic . . . . [T]he expected date for an FDA approval, or non-approval, of a drug is a significant corporate event that should be known and observed if you want to make informed investment and/or trading decisions . . . .").

Thus far, because of the large group of pending applications, these concerns have not arisen in prior status reports. But unlike the aggregate, percentage-based reporting that FDA has been providing in its status reports to date—in which there was minimal risk that FDA's timing estimates could be associated with specific applicants or specific products—providing a specific timing estimate for *one* product could affect the financial interests of that one applicant or its competitors.

Defendants acknowledge that it might be possible to mitigate some of these concerns by filing only a redacted version of each future status report on the public docket, with an unredacted version—including a specific timing estimate about the final pending application—filed only under seal. And in theory, there is a procedural mechanism for that approach under the Local Rules and Fourth Circuit precedent. *See* Local Rule 105.11; *Ashcraft v. Conoco, Inc.*, 218 F.3d 282, 288 (4th Cir. 2000) ("Under established Fourth Circuit precedent, before a district court may seal any court documents, it must (1) give public notice of the request to seal and allow interested parties a reasonable opportunity to object, (2) consider less drastic alternatives to sealing the documents, and (3) provide specific reasons and factual findings supporting its decision to seal the documents and for rejecting the alternatives."). Defendants respectfully submit, however, that the additional logistical complexity (for the parties and the Court), as well as the general presumption in favor of full public access to court filings, *Va. Dep't of State Police v. Wash. Post*, 386 F.3d

567, 575 (4th Cir. 2004), recommend in favor of simply terminating the reporting obligation altogether, rather than incurring these atypical and unnecessary burdens in what is otherwise a long-closed case. And for all the reasons above, continued reporting on FDA's estimation of when the agency expects to act on a single, recently amended application bears little relationship to the original purpose of the Revised Remedial Order.

Conclusion

For these reasons, the Court should relieve Defendants of the obligation to file any further status reports in this case.

DATE: July 22, 2024

Respectfully submitted,

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