DEMOCRACY FORWARD FOUNDATION

November 15, 2021

Hon. Paul W. Grimm
United States District Judge
6500 Cherrywood Lane
Greenbelt, MD 20770

RE: American Academy of Pediatrics, et al., v. FDA (No. 8:18-cv-883-PWG)

Dear Judge Grimm:

Pursuant to the Court's Letter Order Regarding the Filing of Motions, Dkt. No. 15, Plaintiffs respectfully request that the case be reopened and provide notice of their intent to file a motion to amend this Court's Remedial Order ("Order"), Dkt No. 127, pursuant to Rule 60(b)(5). Specifically, Plaintiffs will 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, according to FDA. Plaintiffs are prepared to have this letter serve as their motion.

There have been significant changes in factual circumstances since the July 2019 issuance of the Remedial Order that warrant modification of that Order. 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. Moreover, the requested reporting requirement is narrow and suitably tailored to the changed circumstances.

I. Prior Rulings

On May 15, 2019, this Court held that FDA's unlawful 2017 Guidance had created a years-long regulatory "holiday" for manufacturers of new tobacco products, during which time their products were allowed to stay on the market despite not having gone through the statutorily required premarket authorization process. Dkt. No. 73 at 46. The Court found a direct connection between FDA's suspension of the marketing authorization requirement and the e-cigarette epidemic among youth. *Id.* at 44. Based on FDA's representations that it would put an end to this holiday by certain dates, the Court issued a Remedial Order memorializing FDA's intentions on July 12, 2019. Under FDA's stated plans and the Remedial Order (as subsequently modified due to COVID-19, *see* Dkt. No. 182), PMTAs for new tobacco products that were on the market as of the effective date of the Deeming Rule had to be filed by September 9, 2020,

and products with timely filed applications could "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," a period that expired on September 9, 2021. Dkt. No. 127 at 12; Dkt. No. 182 at 1. Notably, in crafting the Remedial Order, the Court denied Plaintiffs' request for FDA to file status reports, determining that, in light of FDA's plans, while there was not a "present need" to require regular FDA reports to the Court, the Court would "retain jurisdiction to ensure that, *if the need arises, further action could be taken by the Court*." Dkt. No. 127 at 12 (emphasis added). That need has now arisen.

II. Legal Standard

District courts enjoy broad discretion under Rule 60(b) to modify a final order when "applying it prospectively is no longer equitable; or [for] any other reason that justifies relief." F.R.C.P. 60(b)(5)&(6); *see also E.E.O.C. v. Baltimore & Ohio Railroad. Co.*, 557 F. Supp. 1112, 1117 (D. Md. 1983) (noting "the broad discretion to which District Courts are generally entitled when deciding Rule 60(b) motions"). An order is no longer equitable when, as here, "a significant change . . . in factual conditions . . . renders continued enforcement detrimental to the public interest." *Horne v. Flores*, 557 U.S. 433, 447 (2009) (quoting *Rufo v. Inmates of Suffolk Cnty. Jail*, 502 U.S. 367, 384 (1992) (internal quotations omitted). Modification is also appropriate to "protect the purpose" of a judgment. *Duvall v. Hogan*, No. ELH-94-2541, 2021 WL 2042295, at *16 (D. Md. May 21, 2021). Any modification, however, must be "suitably tailored" to the changed circumstance. *Rufo*, 502 U.S. at 383.

III. Significant Factual Changes Support Modifying the Remedial Order

FDA's September 9, 2021 deadline has now passed, yet the vast majority of products, as measured by market share, remain on the market with neither the required marketing order nor enforcement. While FDA announced that it has taken action on 98% of timely filed PMTAs, most of these actions simply rejected "one company's applications for approximately 4.5 million products because required contents were missing."[1] FDA has not issued a single PMTA decision on any of the products with the largest market share in the market as a whole or in the youth market.[2] This inaction is inconsistent with FDA's previous statement that it was "ensuring first review" of the applications for "products that account for most of the current market."[3] As the

[1] *FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More Than 6.5 Million 'Deemed' New Tobacco Products Submitted*, FDA (Sept. 9, 2021), https://bit.ly/3iDmCp9; *see also FDA Permits Marketing of E-Cigarette Products, Marking First Authorization of Its Kind by the Agency*, FDA (Oct. 12, 2021), https://bit.ly/3FEc3w3.

[2] *See* Richard Craver, *Vuse closing in on Juul for top U.S. electronic cigarette market share*, Winston Salem Journal (Oct. 8, 2021), https://bit.ly/2ZeFRyU (finding that the top four e-cigarette brands (Juul, Vuse, NJOY, and Blu) make up over 80% of the market); Eunice Park-Lee et al., Notes from the Field: *E-Cigarette Use Among Middle and High School Students – National Youth Tobacco Survey, United States, 2021*, 70 Morbidity & Mortality Wkly. Rep. 1387, 1388 tbl. (2021), https://bit.ly/3BBMXLT (listing Vuse, SMOK, JUUL, and Suorin as the most-used products among high schoolers, out of products subject to the Court's rulings). While FDA has acted on one product sold by Vuse, the "Vuse Solo," that product has minimal market share; the JUUL-like "Vuse Alto," which is currently the leading product among youth of products subject to the Court's orders, remains on the market without a marketing order.

[3] Mitch Zeller, *Perspective: FDA's Progress on Review of Tobacco Product Applications Submitted by the Sept. 9, 2020 Deadline*, FDA (Feb. 16, 2021), https://bit.ly/2WIq2za.

agency recognized, prioritizing "these products has the potential to have the greatest public health impact—either positively or negatively."[4] FDA has offered no explanation for its failure to complete its review of these products.

Moreover, FDA does not appear to have 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. This suggests that FDA may be continuing its unlawful, indefinite holiday despite the absence of any such statutory exemption. Indeed, on September 9, 2021, FDA Acting Commissioner Janet Woodcock explained that FDA's "highest enforcement priorities" include "products for which no application is pending, including, for example, those with a Marketing Denial Order and those for which no application was submitted."[5] Thus the Court's Remedial Order memorializing FDA's prior intentions may be inadequate to cure the harm caused by its statutory violations.

IV. Limited Modification of the Remedial Order Is Appropriate

The e-cigarette products with the greatest public health impact – both overall and among kids – remain on the market for an indeterminate amount of time, despite receiving no FDA authorization. FDA has effectively granted these products an indefinite extrastatutory "safe harbor," the very result this Court foreclosed when it vacated the 2017 Guidance's indefinite exemption. Modifying the Remedial Order to require FDA reporting would be in the public interest and "protect the purpose" of the Court's conclusions on the merits, judgment, and Remedial Order, *Duvall*, 2021 WL 2042295, at *16, by permitting the Court to determine whether FDA is in fact prolonging the unlawful holiday that the Court found must end.

Moreover, Plaintiffs' "proposed modification is tailored to resolve the problems created by the change in circumstances." *Thompson v. U.S. Dep't of Hous. & Urb. Dev.*, 404 F.3d 821, 831 (4th Cir. 2005) (quoting *Rufo*, 502 U.S. at 391). Plaintiffs request regular status reports, akin to those they originally requested in 2019, that simply provide an estimate of when FDA expects to take action on the products that account for the largest share of the market. The changed circumstances vitiate the merits judgment granted to Plaintiffs by allowing the products with the greatest public health impact to remain on the market indefinitely without authorization, while leaving manufacturers effectively immune from FDA enforcement for the illegal marketing of an unauthorized, and thus adulterated, product. The requested modification responds to this change in circumstances by clarifying whether FDA's actions to date amount to an effective extension of the unlawful regulatory holiday for the largest products, and identifying when any such effective holiday will end. Plaintiffs are not asking the Court to order FDA to issue decisions on these products by a date certain, nor to bring any particular enforcement actions; they are simply asking for basic information about when FDA expects to complete action it is already obligated to perform. This requested modification is as tightly tailored as possible to account for the changed circumstances. Accordingly, modification of the Remedial Order is warranted.

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[4] *Id.*

[5] Janet Woodcock, *FDA Makes Significant Progress in Science-Based Public Health Application Review, Taking Action on Over 90% of More than 6.5 Million 'Deemed' New Tobacco Products Submitted*, FDA (Sept. 9, 2021), https://bit.ly/3DjTMlL.

Respectfully Submitted,

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