IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND
Southern Division

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

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MEMORANDUM OPINION AND ORDER

In a Memorandum Opinion and Order issued on May 15, 2019, I concluded that Defendants the Food and Drug Administration ("FDA"), then-Commissioner of Food and Drugs Scott Gottlieb, the U.S. Department of Health and Human Services, and Secretary of Health and Human Services Alex M. Azar II violated the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.* by issuing the Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry (Revised) ("August 2017 Guidance") without following the APA's notice and comment requirements. ECF Nos. 73, 74. Accordingly, I granted Plaintiffs'[1] motion for summary judgment and vacated the FDA's August 2017 Guidance.

[1] Plaintiffs are the American Academy of Pediatrics; the Maryland Chapter – American Academy of Pediatrics; the American Cancer Society Cancer Action Network; the American Heart Association; the American Lung Association; the Campaign for Tobacco-Free Kids; the Truth Initiative; Dr. Leah Brash, MD; Dr. Cynthia Fishman, MD; Dr. Linda Goldstein, MD; Dr. Steven Hirsch, MD; and Dr. David Myles, MD.

Because the application deadlines set in the Deeming Rule[2] and the May 2017 Guidance[3] (which otherwise would have applied following the vacatur) had passed, I ordered the parties to submit additional briefing regarding a remedy, while noting that "[a]ny Guidance providing for a compliance period will, of course, have to adhere to the notice and comment requirements of the APA." May 15, 2019 Mem. Op. 53.[4] The parties have completed their briefing and responded to *amicus curiae* briefs that the State of Maryland and various organizations[5] filed on behalf of the e-cigarette industry ("Industry"). Pls.' Remedy Br., ECF No. 78; Maryland Br., ECF No. 97; Defs.' Remedy Br., ECF No. 120; Indus. Br., ECF No. 121-1; Pls.' Reply, ECF No. 123; Pls.' Resp. to Indus. Br., ECF No. 124; Defs.' Resp. to Indus. Br., ECF No. 125. A hearing is not necessary. *See* Loc. R. 105.6. Balancing the need to address the existing public health crisis among today's youth, which both parties acknowledge, and the need to avoid creating an additional

[2] On May 10, 2016, the FDA issued the "Deeming Rule," bringing approximately 25,000 new tobacco products, including various cigars, e-cigarettes, pipe tobacco products, and hookah within the purview of the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), Pub. L. No. 111-31, 123 Stat. 1776 (2009) (enacting 21 U.S.C. §§ 387 – 387u and amending and redesignating other statutes). May 15, 2019 Mem. Op. 7; Guidance 2, ECF No. 48-1, at 715, GAR 423. The Deeming Rule went into effect 90 days after its publication. Deeming Rule, 81 Fed. Reg. 28,974-01, 28,976 (May 10, 2016).

[3] In May 2017, the FDA extended the compliance deadline by three months in the "May 2017 Guidance." Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry (May 2017), GAR 206, ECF No. 48-1, at 687.

[4] As Defendants note, I did not suggest that the FDA needed to issue a formal regulation in lieu of guidance as it has done previously. *See* May 15, 2019 Mem. Op. 53; Defs.' Resp. to Indus. Br. 6, ECF No. 125. *Contra* Indus. Br. 10 (referring to a need to "go through notice-and-comment rulemaking").

[5] The Industry includes American E-Liquid Manufacturing Standards Association, American Vaping Association, Arizona Smoke Free Business Alliance, Consumer Advocates for Smoke-Free Alternatives Association ("CASAA"), ITG Brands LLC, Indiana Smoke Free Association, Iowans for Alternative to Smoking and Tobacco, JUUL Labs, Inc., John Middleton Co., Kentucky Smoke Free Association, Maryland Vapor Alliance, NJOY LLC, New York State Vapor Association, Ohio Vapor Trade Association, RIGHT TO BE SMOKE-FREE COALITION, Smoke Free Alternatives Trade Association, Tennessee Smoke Free Association, and Texas Vapor Coalition.

public health crisis if e-cigarette availability dropped so precipitously as to push users to combusted tobacco products, and considering both the FDA's laudable efforts to guide the premarket approval process and the Industry's lack of effort to obtain approval without an imminent deadline, I will impose a ten-month deadline for submissions and a one-year deadline for approval, as the FDA suggested.

Plaintiffs' Requests

> Plaintiffs propose that the Court first order the FDA to
>
> > 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.

Pls.' Remedy Br. 8, ECF No. 78. In their view, the four-month deadline for manufacturers is both reasonable and feasible because the manufacturers have been on notice that the deadline was looming and could be accelerated, and the FDA has encouraged them to move forward with their submissions before the deadline. *Id.* at 10–11. Second, Plaintiffs propose that the Court require the FDA to file quarterly reports with the Court "on the measures it is taking to carry out its premarket review responsibilities under the TCA [Tobacco Control Act], including reporting the number and nature of the enforcement actions it has undertaken against companies for marketing their products without a marketing order." *Id.* at 9. And third, Plaintiffs ask the Court to retain jurisdiction over this case. *Id.* The State of Maryland filed an *amicus curiae* brief in support of Plaintiffs' position, noting the health risks e-cigarettes pose to Maryland's youth and the

consequential medical expenses the State will incur "[a]s these young Marylanders age and sicken" and seek treatment through Medicaid. Maryland Br. 1–2, ECF No. 97.

Plaintiffs argue that this relief is within the Court's "broad remedial authority," insisting that "the 'Court may tailor its remedy to the unlawful agency behavior'" and "'adjust its relief to the exigencies of the case in accordance with the equitable principles governing judicial action.'" Pls.' Remedy Br. 7 (quoting *Thompson v. U.S. Dep't of Hous. & Urban Dev.*, 348 F. Supp. 2d 398, 464–65 (D. Md. 2005)). Plaintiffs also acknowledge that "the court must act within the bounds of the statute and without intruding into the administrative province." *See id.* (quoting *Thompson*, 348 F. Supp. 2d at 465). Still, in Plaintiffs' view, "[t]here is ample authority for a Court to structure its remedy to account for the realities of immediate vacatur or reinstate the status quo." Pls.' Reply 2, ECF No. 123 (citing *Andrulis Res. Corp. v. U.S. Small Bus. Admin.*, No. 9-2569, 1990 WL 169318, at *2 (D.D.C. Oct. 19, 1990)). They insist that the Court "may craft declaratory and injunctive relief designed to preclude a federal agency from acting in contravention of its statutory and regulatory authority." *Id.* at 6 (quoting *Coal. For Gov't Procurement v. Fed. Prison Indus.*, 365 F.3d 435, 460 (6th Cir. 2004)).

Legal Precedent

The Sixth Circuit has noted the courts' authority to order injunctive relief to address agency action or inaction:

> It is well-established that federal courts possess broad discretion to fashion equitable remedies. *See United States v. R.W. Meyer, Inc.*, 932 F.2d 568, 572–73 (6th Cir.1991) (observing the "principle of equity that the chancellor has broad discretion to frame a decree"). It also is established that we may craft declaratory and injunctive relief designed to preclude a federal agency from acting in contravention of its statutory and regulatory authority. *See Howard v. Pierce*, 738 F.2d 722, 730 (6th Cir.1984) (holding that the court may award declaratory and injunctive relief in order to ensure that the Department of Housing and Urban Development adopted regulations consistent with its enabling statute).

> 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. *See Charter Township of Huron, Michigan v. Richards*, 997 F.2d 1168, 1175 (acknowledging the court's authority to issue an injunction requiring the agency to conduct an environmental assessment notwithstanding the implementation of the completed action); *Northwest Envtl. Def. Ctr. v. Gordon*, 849 F.2d 1241, 1245 (9th Cir. 1988) (determining that claims asserted against federal agencies alleging that the agencies unlawfully authorized the overfishing of coho salmon during the 1986 season were not moot because the court could award injunctive relief in the form of "higher escapement provisions and lower quotas in 1989").

Coal. for Gov't Procurement v. Fed. Prison Indus., Inc., 365 F.3d 435, 460 (6th Cir. 2004). And, in 1990, the District of the District of Columbia noted that "various appellate court decisions [have] affirm[ed] a district court's power to extend statutory deadlines to remedy improper agency delay." *Andrulis Research Corp. v. U.S. Small Bus. Admin.*, No. 90-2569(CRR), 1990 WL 169318, at *2 (D.D.C. Oct. 19, 1990) (citing *Connecticut v. Schweiker*, 684 F.2d 979, 997–99 (D.C. Cir. 1982); *Burr v. Ambach*, 863 F.2d 1071, 1077–78 (2d Cir. 1988), *vacated*, 109 S. Ct. 3209 (1989), *aff'd on remand sub nom., Burr v. Sobel*, 888 F.2d 258 (2d Cir. 1989); *Smith v. Miller*, 665 F.2d 172, 180 (7th Cir. 1981); *Carey v. Klutznick*, 637 F.2d 834, 837 (2d Cir. 1980) (per curiam)).

More recently the D.C. Circuit has held that "[w]hen a district court reverses agency action and determines that the agency acted unlawfully, ordinarily the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal." *N. Air Cargo v. U.S. Postal Serv.*, 674 F.3d 852, 861 (D.C. Cir. 2012) (citing *PPG Indus., Inc. v. United States*, 52 F.3d 363, 365 (D.C. Cir. 1995)); *see N.C. Fisheries Ass'n v. Gutierrez*, 550 F.3d 16, 20 (D.C. Cir. 2008) ("To be sure, the district court, sitting as a court in review of agency action under the Act and APA, should have done what a court of appeals normally does when it identifies an agency error: remand to the agency for further proceedings. As we have said, '[u]nder 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 corrected legal standards.'" (quoting *PPG Indus.*, 52 F.3d at 365)); *see also Maine Med. Ctr. v. Burwell*, 841 F.3d 10, 16 (1st Cir. 2016) (quoting *PPG Indus.*, 52 F.3d at 365). But, the D.C. Circuit also acknowledged that, "in extraordinary circumstances," district courts reviewing agency action will "issue detailed remedial orders." *N.C. Fisheries*, 550 F.3d at 20.

Discussion

The issue is whether this case presents those "extraordinary circumstances" that call for more than a simple remand or vacatur. Defendants agree with Plaintiffs (and the Court) that "the recent 'epidemic-level rise in youth e-cigarette use' is a 'mounting public health crisis'" that "demands a robust regulatory response, including through enforcement of the Tobacco Control Act's premarket review provision." Defs.' Remedy Br. 1 (quoting 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). But, they argue that, nonetheless, "bedrock principles of administrative law constrain the Court's authority to enter the specific relief the Plaintiffs request." *Id.* In their view, "the Court should simply remand to the FDA to permit it to choose a course of action consistent with the Court's opinion." *Id.*

Additionally, Defendants insist that the timeframe Plaintiffs propose "would create massive administrative burdens at the agency that would ultimately be counterproductive." Defs.' Remedy Br. 1. Defendants have made a commendable record detailing their own resources and ability, as well as the negative impact of rushed, unguided applications that would exacerbate their difficulties in timely approving—or denying—applications.

Also, Defendants, along with the *amici* that filed a joint brief in support of Defendants' position, Indus. Br.,[6] contend that the four-month timeframe for applications "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.'" Defs.' Remedy Br. 1 (quoting Zeller Decl. ¶ 12, ECF No. 120-1) (emendation in Defs.' Remedy Br.). Aware of these potential public health implications in not only the presence of e-cigarettes, but also in what could be a precipitous absence, Defendants have carefully calibrated a plan to deal with nicotine addiction throughout the public health sector. Their goal of not driving e-cigarette products out of the market appears to be part of a broader attack on tobacco by encouraging the availability of potentially less addictive products. And, it appears that, in the new guidance that the FDA expects to approve within 120 days, the FDA plans to accelerate the premarket review requirements for the products that are most attractive to youth, such as flavored products, consistent with the Tobacco Control Act. The factual record here is unlike in *Cobell v. Norton*, 240 F.3d 1081, 1095, 1096 (D.C. Cir.

[6] The Industry goes so far as to propose that the Court should remand the August 2017 Guidance to "FDA without vacatur [to] avoid upending FDA's massive existing regulatory efforts and causing unwarranted harm to consumers and manufacturers." Indus. Br. 2. Plaintiffs oppose this approach at length in their Response to Industry Brief, and Defendants note in their Response that they "have not asked the Court to revisit its vacatur of the August 2017 guidance." Defs.' Resp. to Indus. Br. 1. As Defendants note, I already have vacated the August 2017 Guidance, *see* May 15, 2019 Mem. Op. 53, and I will not accept an amicus brief as a motion for reconsideration of an existing order. In any event, remand without vacatur is not appropriate under the circumstances of this case. *See Sierra Club v. U.S. Army Corps of Eng'rs*, 909 F.3d 635, 655 (4th Cir. 2018) (noting that remand without vacatur is only appropriate (if at all) when "a serious possibility" exists that an agency "will be able to substantiate its decision on remand," that is, under circumstances in which the agency has rules that are "inadequately supported," rather than rules that are "legally deficient" because "they exceed[] [the agency's] statutory authority" (quoting *Allied-Signal, Inc. v. U.S. Nuclear Reg. Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993))). Nor is it necessary, since the Court can (and in this Memorandum Opinion and Order does) order a remedy that, in the Industry's words, *see* Indus. Br. 2, will allow the FDA to continue with its "existing regulatory efforts" and will not "caus[e] unwarranted harm to consumers and manufacturers."

2001), where the agency completely failed to act, or in *Nat. Res. Def. Council v. EPA*, 489 F.3d 1364, 1374 (D.C. Cir. 2007), where the agency actively undermined a statute. The record does not show contumacious behavior by the FDA, which is not actively thwarting the law. Nor does the record support a conclusion that the FDA is a puppet to the tobacco industry.

Indeed, the FDA's position is strongly at odds with the Industry's in two significant respects. First, the Industry contends disingenuously that it cannot complete its applications without further formal guidance. *See* Indus. Br. 3–6, Yet, according to Defendants, it is commonplace for companies and individuals to call the FDA for guidance, and the FDA has made clear that it is willing to work with manufacturers in the interim to provide informal guidance. Defs.' Resp. to Indus. Br. 2–3. Specifically,

> the FDA disagrees with amici's suggestion that the premarket review provision could not be enforced before the completion of planned rulemakings concerning the premarket tobacco application (PMTA) and substantial equivalence (SE) pathways. Industry Br. at 3–4. The statute itself sets forth the baseline requirements for PMTAs and SE reports, *see* Defs.' Remedy Br. at 9; 21 U.S.C. §§ 387d(j), 387j(b)(1), and the agency has issued a number of lengthy guidance documents discussing these statutory requirements: it issued final guidance concerning the SE process in January 2011, long before the deeming rule was finalized; three versions of a frequently asked questions document concerning the SE process, most recently in December 2016; and draft guidance concerning PMTAs for electronic nicotine delivery systems (ENDS, or e-cigarettes) in May 2016, which it finalized in substantially similar form in June 2019. The FDA has authorized the marketing of *more than a thousand* tobacco products under the statute alone, without the rulemakings that amici suggest are essential: since 2013, it has issued 1,070 SE marketing orders and 12 PMTA marketing orders, Zeller Decl. ¶ 5(b), (d)—including for some of amici's own products. And it has in fact issued warning letters for the unauthorized marketing of deemed new tobacco products that were not on the market as of August 8, 2016—among them, such kid-friendly e-liquid flavors as "Cherri Bombz," "Cereal Treats Loopz," and "Heavy Custard Unicorn Cake."

Id. (some citations omitted); *see also id*. at 4–5 (discussing extent of guidance FDA has provided to date and the number of PMTAs and SEs it has resolved).

Second, Defendants acknowledge that, contrary to the Industry's claim that "'millions of American adults . . . use ENDS products to help them quit smoking cigarettes[,]' . . . there is currently insufficient data to draw a conclusion about the efficacy of e-cigarettes as a cessation device," as there is evidence for and against the proposition that e-cigarettes "help some individual users to quit using combusted tobacco products or to reduce their use of such products." Defs.' Resp. to Indus. Br. 5 n.11 (quoting Indus. Br. 6). Further, Defendants note the Industry's "responsibility for fueling the present problem of youth e-cigarette use by allowing dangerous and addictive products to fall into the hands of youth, whether by neglect or design" and assert that "there is substantial evidence that manufacturers have specifically targeted youth, both with kid-friendly fruit and candy flavors and youth-directed advertising." Defs.' Resp. to Indus. Br. 7–8 (citation omitted).

Indeed, however laudable the FDA's intended regulatory response is, the record before me shows a purposeful avoidance by the industry of complying with the premarket requirements despite entreaties from the FDA that it can do so, and it establishes a shockingly low rate of filings. And, it is far from clear how an impending deadline would force some of the more successful companies to withdraw from the market entirely, when they have large purses and the resources to complete promptly the applications that they have had before them for years. *See generally* Indus. Br. 6 ("ENDS manufacturers have not just sat around. They have done what they can to prepare for the PMTA process. But . . . ENDS manufacturers come in in different shapes and sizes, with vastly different levels of resources to devote to trying to anticipate what FDA would require. For example, there are not enough accredited third-party laboratories qualified to conduct various types of testing, and small manufacturers lack the resources to do those tests themselves." (citations to declarations omitted)). Thus, the record offers little assurance that, in the absence of

a deadline for filing, the Industry will do anything other than raise every roadblock it can and take every available dilatory measure to keep its products on the market without approval. *See* Pls.' Remedy Br. 10–11.

Given the uncertainty in the efficacy of e-cigarettes as smoking cessation devices, the overstated effects that a shorter deadline may have on manufacturers, the Industry's recalcitrance, the continued availability of e-cigarettes and their acknowledged appeal to youth, and the clear public health emergency, I find that a deadline is necessary. The Industry insists that "FDA, not the courts, must set that timetable in the first instance." Indus. Br. 9. In fact, it has. Defendants wisely have proposed an alternative to Plaintiffs' suggested four-month application deadline that Defendants view as too short. Defs.' Remedy Br. 2; *see also id.* at 6–7 ("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."). I agree with Defendants that the ten-month deadline for applications would be more reasonable than the four-month deadline, allowing sufficient time for application submissions that present the information that the FDA needs to assess the e-cigarette products, while not delaying longer than necessary.

Moreover, I conclude that this Court has the authority to impose such a deadline under the extraordinary circumstances of this case in which prompt action is necessary to combat the "epidemic-level rise in youth e-cigarette use," which undisputedly is a "mounting public health crisis." Defs.' Remedy Br. 1 (quoting FDA, *Stmt. from FDA Comm'r Gottlieb*). Pursuant to the

APA, a federal district court may "compel agency action unlawfully withheld or unreasonably delayed," 5 U.S.C. § 706(1), or, as Plaintiffs ask this Court to do, "hold unlawful and set aside agency action, findings, and conclusions found to be [unlawful]." 5 U.S.C. § 706(2). "'[A]gency action' . . . include[s] a 'failure to act." *Thompson v. U.S. Dep't of Hous. & Urban Dev.*, No. MJG-95-309, 2006 WL 581260, at *4 (D. Md. Jan. 10, 2006) (quoting 5 U.S.C. § 551(13)). As Plaintiffs assert, this Court has observed that "the words 'set aside' need not be interpreted narrowly" when "devising an appropriate remedy." *Thompson v. U.S. Dep't of Hous. & Urban Dev.*, 348 F. Supp. 2d 398, 464 (D. Md. 2005) (citing *NAACP v. HUD*, 817 F.2d 149, 161 (1st Cir. 1987)); *see also Thompson*, 2006 WL 581260, at *4 (citing *NAACP*, 817 F.2d at 161).

In *Thompson*, the Court noted that, "once a court concludes that an agency failed to remedy past wrongs, the court is required to fashion a remedy that ensures future compliance with the Constitution," and that "[f]ederal agencies are not immune from the federal court's traditional equitable powers," *id.* at *9, *10. After finding that HUD was "unlikely to [comply with its statutory obligations] in the foreseeable future absent judicial compulsion," the Court concluded that "it ha[d] discretion to exercise its equitable powers to tailor a remedy" for HUD's "long-standing failure to meet [its statutory] obligations," *id.* at *5, *6. This is consistent with the Sixth Circuit's stance in *Coalition for Government Procurement*, 365 F.3d at 460, and the District of the District of Columbia's earlier collection of appellate cases "affirming a district court's power to extend statutory deadlines to remedy improper agency delay," *Andrulis*, 1990 WL 169318, at *2. And, it is not inconsistent with the D.C. Circuit's more recent observation that "*ordinarily* the appropriate course is simply to identify a legal error and then remand to the agency, because the role of the district court in such situations is to act as an appellate tribunal," *N. Air Cargo*, 674 F.3d at 861 (emphasis added), because these are the "extraordinary circumstances" in which

district courts reviewing agency action should "issue detailed remedial orders," *see N.C. Fisheries*, 550 F.3d at 20. Given the steps that the FDA has outlined with respect to its coordinated approach to deal with this public health crisis, and the timetable that they have proposed (and I have approved), I do not find that there is any present need to require court monitoring through quarterly reports. However, I will retain jurisdiction to ensure that, if the need arises, further action could be taken by the Court.

Order

Accordingly, it is this 11th day of July, 2019, hereby ORDERED that

1. the 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;
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;
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;
4. The FDA shall have the ability to exempt New Products from filing requirements for good cause on a case-by-case basis.

/S/
Paul W. Grimm
United States District Judge

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