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

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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

It was bound to happen. Just as email and text messages replaced "snail mail," social media made face-to-face communications passé, and the internet rendered libraries all but obsolete, it was only a matter of time before "electronic cigarettes"[1] replaced combustible tobacco products as a desirable means of nicotine delivery. As it turns out, even addiction has become electronic. And not only among adults, but particularly for teenagers (and younger kids). Especially, as manufactures of e-cigarette products have learned, if they are fruit or dessert flavored, and marketed as cool and alluring. Stmt. of FBA Commissioner, ECF No. 43-2.

> Since 2014, [e-cigarettes] have been the most popular nicotine product among American teenagers.
>
> And e-cigarettes' popularity is accelerating: From 2017 to 2018, … the number of high-school-age children reporting use of e-cigarettes rose by more than 75 percent. Use among middle-schoolers also increased nearly 50 percent. That is an epidemic.

[1] These electronic nicotine products are more accurately—and ironically—called "ENDS"—"electronic nicotine delivery systems." *See* Stmt. of FBA Commissioner, ECF No. 43-2.

> The surge in e-cigarette use by teenagers is alarming because nicotine is highly addictive and can harm brain development, which continues into young adulthood. Worse, kids who start on e-cigarettes are actually more likely than non-user peers to migrate to smoking tobacco ….
>
> It is crucial that e-cigarettes do not become an on-ramp for children to become addicted to nicotine.
>
> … [N]early 90 percent of adult smokers started when they were teens.

Alex M. Azar & Scott Gottlieb, *We cannot let e-cigarettes become an on-ramp for teenage addiction*, Wash. Post (Oct. 11, 2018) ("Azar & Gottlieb Op. Ed.").[2]

To address public health concerns associated with tobacco use, and use by minors in particular, Congress enacted 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), which requires manufacturers of various nicotine products, now including e-cigarettes,[3] to apply for and obtain premarket authorization before introducing new products into interstate commerce for commercial distribution. 21 U.S.C. § 387j(a)(1)-(2), (b)(1); *see also* Defs.' Mem. 1, ECF No. 36-1; Pls.' Mem. 3; Guidance 2, ECF No. 48-1, at 715, GAR 423.[4] Yet, although it might come as a surprise to a reader of the Tobacco

[2] Alex M. Azar is the Secretary of the U.S. Department of Health and Human Services. Until April 2019, Scott Gottlieb was the Commissioner of the Food and Drug Administration ("FDA"). E-cigarettes are devices that use "a small battery to heat a liquid that contains nicotine" and then "turn the liquid into an inhalable vapor." Azar & Gottlieb Op. Ed.

[3] On May 10, 2016, the FDA adopted the "Deeming Rule" to deem electronic nicotine device systems ("e-cigarettes"), cigars, and pipe tobacco subject to regulatory controls under the Tobacco Control Act. *See* Deeming Rule, 81 Fed. Reg. 28,974-01 (May 10, 2016), AR 11,882, ECF No. 48-1, at 69. The parties and the Court use "e-cigarette" to refer to "any sort of electronic nicotine delivery system (ENDS), including so-called 'vaping' devices." Defs.' Mem. 10 n.7 (citing 81 Fed. Reg. at 28,976 ("ENDS" includes "e-cigarettes, ehookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes"); Pls.' Mem. 6 n.2, ECF No. 31-2.

[4] "Citations to 'AR' in the parties' briefs are to the Deeming Rule's administrative record, which has 'FDA' Bates-stamped page numbers. Citations to 'GAR' are to the separate administrative record for the Guidance, which is separately paginated with 'FDA GUID' Bates-stamped pages." Notice 2 n.1, ECF No. 48.

Control Act, currently, "certain e-cigarettes—particularly the products with flavors that might appeal to children[5]—can remain on the market without submitting a premarket application to the FDA until 2022," *id.*, and some can remain on the market while their application is pending, Aug. 2017 Guidance 3, ECF No. 48-1, at 716, GAR 424 (emphasis added). This is because the Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry (Revised) ("August 2017 Guidance"), which the FDA issued in August 2017 regarding the statutory requirements for "newly deemed tobacco products" like e-cigarettes, provides that manufacturers of those products can continue to market and distribute these products while they seek FDA approval; they do not have to seek FDA approval until 2021 or 2022; and for some of the products, once the manufacturers have submitted their applications, they can continue to market and distribute the products until the FDA "renders a decision." Aug. 2017 Guidance 3, 8, ECF No. 48-1, at 716, 721, GAR 424, 429; *see* Compl. ¶¶ 1–3, ECF No. 1.

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[5] E-cigarettes come in flavors including maple, vanilla, and coconut. *See Popcorn Lung: A Dangerous Risk of Flavored E-Cigarettes* (ALA July 7, 2016), https://www.lung.org/about-us/blog/2016/07/popcorn-lung-risk-ecigs.html (last updated Sept. 18, 2018). As an example of a tobacco product "targeted at children and teenagers," Plaintiffs note that there is "an 'Apple Juice' e-cigarette product":

Compl. ¶ 41.

Alarmed by this exemption, 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 filed a Complaint for Declaratory and Injunctive Relief against the 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. Compl. 1. In Plaintiffs' view, the exemption violates the Tobacco Control Act's requirement of premarket review of newly deemed products before they are marketed or distributed to consumers. *Id.* They brought three claims for the same relief pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. § 701 *et seq.* Specifically, Plaintiffs ask the Court to vacate the August 2017 Guidance, claiming that it is unlawful in that it "exceeds the agency's statutory authority" and "is an express and deliberate abdication of FDA's responsibilities under the Tobacco Control Act" (Count I); "was not promulgated in accordance with the APA's notice and comment requirements," despite being a substantive rule (Count II); and "is arbitrary and capricious and not the product of reasoned decisionmaking" (Count III). Compl. ¶¶ 4–7, 92–118.

Plaintiffs filed a Motion for Summary Judgment, ECF No. 31, and Defendants filed a Motion to Dismiss or, in the Alternative, for Summary Judgment, ECF No. 36.[6] Defendants argue that the Court lacks subject matter jurisdiction because (1) the August 2017 Guidance does not

[6] The parties fully briefed the motions. ECF Nos. 31-2, 36-1, 39, 43, 44-1. Plaintiffs also filed a Notice of Errata, ECF No. 47, and Notices of Supplemental Authority, ECF Nos. 54, 58, and the parties informally addressed steps that the FDA has taken since the parties filed their motions. ECF Nos. 51, 53, 59, 61. Right to be Smoke-Free Coalition filed an amicus curiae brief. ECF No. 37-1. A hearing is not necessary. *See* Loc. R. 105.6.

cause any cognizable harm to Plaintiffs and therefore they do not have standing to bring this lawsuit; (2) the FDA has unreviewable discretion in deciding how to enforce the Tobacco Control Act and its rules; and (3) the August 2017 Guidance is not final agency action, rendering it beyond the reach of judicial review. Defs.' Mem. 3–4. Alternatively, they contend that Plaintiffs' claims fail on the merits because the August 2017 Guidance does not conflict with the Tobacco Control Act; it is a policy statement, not a rule, and therefore is exempt from the notice and comment requirements; and the FDA provided a rational explanation for the policy. *Id.* at 4–5.

On March 13, 2019, while the motion remained pending, the FDA published draft guidance that, "if finalized, would modify the August 2017 Guidance challenged in this case." Mar. 26, 2019 Ltr. Order, ECF No. 62; *see* Defs.' Second Notice, ECF No. 59. Noting that the agency was "accepting public comments on the draft guidance for a 30-day period that closes on April 15, 2019," with the revisions intended to "take effect 30 days after the publication of a final guidance document," I denied the parties' motions without prejudice to renewal following the FDA's finalization or rejection of the draft guidance. Mar. 26, 2019 Ltr. Order; Defs.' Second Notice; *see also* FDA, Modifications to Compliance Policy for Certain Deemed Tobacco Products: Guidance for Industry: Draft (March 2019), ECF No. 59-1; 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 2 (Mar. 13, 2019), ECF No. 59-2.

Plaintiffs promptly moved for reconsideration, arguing that "[t]here is . . . no reason to expect that a final Guidance is imminent, and substantial reason to doubt that it will issue this year," and that having "the benefit of a ruling on [the August 2017] Guidance" would increase the FDA's "ability to issue a legally sustainable replacement" and "thus obviat[e] or at least simplify[] challenges to that replacement." Pls.' Ltr. Mot. 1, ECF No. 63. Defendants responded in favor of

"postpon[ing] resolution of this case while the draft guidance is finalized, lest the Court unnecessarily expend resources—and potentially issues what could, in practical terms, largely amount to an advisory opinion—on a policy that is under revision and soon stands to change in material ways." Defs.' Ltr. Opp'n 1, ECF No. 71. They contend that, "[i]f finalized, the draft guidance would modify the deferred-enforcement policy set forth in the August 2017 Guidance challenged in this case with respect to . . . the[] same products [that] are the apparent focus of Plaintiffs' public-health concerns," that is, "e-cigarettes targeted to youth and flavored cigars." *Id.* at 1, 2. But, as Plaintiffs note in their reply, ECF No. 72, Defendants do not state, even generally, when the draft guidance will be finalized; they simply state that "the FDA has given every indication that it plans to finalize the draft guidance as quickly as possible," after it finishes reviewing the approximately 15,467 comments it received electronically and the additional comments it received via U.S. mail. Defs.' Ltr. Opp'n 5. Given the pace at which the FDA has implemented the premarket review provisions of the Tobacco Control Act, its notion of "as quickly as possible" must be taken with a grain of salt.

Upon further review of their briefing of Plaintiffs' letter motion for reconsideration, as well as their briefing of their cross-motions for summary judgment, I am persuaded that Plaintiffs have standing and that this Court has jurisdiction to review the August 2017 Guidance, which was not a nonreviewable discretionary decision and which qualifies as final agency action for purposes of the APA. Moreover, the undisputed evidence establishes that Defendants were required to, but did not, follow the APA's notice and comment requirements issuing the August 2017 Guidance, and therefore Defendants violated the APA by issuing it. Accordingly, I will grant Plaintiffs' motion for reconsideration and reopen the parties' cross-motions. Having done so, I deny

Defendants' motion, which I treat as a motion for summary judgment; grant Plaintiffs' motion for summary judgment; and order supplemental briefing on an appropriate remedy.

Background

Congress enacted the Tobacco Control Act in 2009 to "protect the public health and to reduce tobacco use by minors." Guidance 2, ECF No. 48-1, at 715, GAR 423. The Act "granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own tobacco (RYO), and smokeless tobacco products . . . ." *Id.* Additionally, pursuant to the Act the FDA can "deem[] other products that meet the statutory definition of a tobacco product" to be subject to the Act. *Id.* These products are referred to as "new tobacco products." 21 U.S.C. § 387j(a)(1). 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 Act. Defs.' Mem. 1; Pls.' Mem. 6; 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).

The Act requires "[m]anufacturers of products subject to the Act [to] generally register with the FDA, submit lists of their products and ingredients, obtain premarket authorization before marketing new products, and include health warnings on packaging and advertisements." Defs.' Mem. 1. To obtain premarket authorization, a manufacturer must submit to the FDA either

> (1) a "premarket tobacco application" demonstrating that the product would be appropriate for the protection of the public health, [21 U.S.C.] § 387j(b)–(c); (2) a "report" establishing that the product is "substantially equivalent" to a predicate product, *id*. §§ 387j(a)(2)(A)(i), 387e(j)(1); or (3) a request for an "exemption" from the substantial equivalence requirement, *id* §§ 387j(a)(2)(A)(ii), 387e(j)(3).

Id. at 5.

If products are marketed without adhering to these requirements, they may be considered "adulterated" and seized, and the manufacturers, distributors and retailers may be subject to civil injunctions and/or criminal prosecutions. 21 U.S.C. §§ 331(a)–(c) (prohibited acts), 332 (court jurisdiction to issue injunction), 333(a) (criminal penalties), 334 (seizure), 387b(6) ("A tobacco product shall be deemed to be adulterated if . . . it is required by section 387j(a) . . . to have premarket review and does not have an order in effect under section 387j(c)(1)(A)(i); or . . . it is in violation of an order under section 387j(c)(1)(A).").

> Initially, the Act required the FDA to permit the four products then subject to the Act to remain on the market during premarket review so long as their manufacturers submitted premarket applications by March 2011. But there is no statutory grace period for products later deemed subject to the Act. Thus, when the deeming rule took effect in August 2016, all newly deemed products then on the market were suddenly noncompliant with the statute.

Defs.' Mem. 1.

It is undisputed that the FDA has some "discretion to adapt those provisions to the special circumstances of products that become subject to the TCA [Tobacco Control Act] by virtue of deeming" and, to that end, to "[p]ermit[] a compliance period for newly deemed products." *Id.* at 2 (quoting Organizational Plaintiffs' comments on the proposed deeming rule, AR 145,551, 145,607, ECF No. 48-1, at 566, 622). And, when it published the Deeming Rule, the FDA, in what it called an "exercise of enforcement discretion," stated that "newly deemed, new tobacco products" would not "be subject to enforcement" during "compliance period[s]" that the Deeming Rule established. Deeming Rule, 81 Fed. Reg. at 28,978. Specifically, the Deeming Rule "establish[ed] staggered initial compliance periods based on the expected complexity of the applications to be submitted, followed by continued compliance periods for FDA review," with the FDA's "exercise of enforcement discretion [set to] end twelve months after each initial compliance period." *Id.* Thus, the Deeming Rule provided that

> manufacturers of all newly deemed, new tobacco products [would] have a 12-, 18- or 24-month initial compliance period in which to prepare applications for marketing authorization, as well as a 12-month continued compliance period after those dates in which to obtain authorization from FDA (resulting in total compliance periods of 24, 30, or 36 months).

Id.

The FDA established these specific compliance periods because it "determined that exercising enforcement discretion indefinitely could put youth and young adults at risk for tobacco-related death and disease." *Id.* at 28,977; *see also* Aug. 2017 Guidance 3, ECF No. 48-1, at 716, GAR 424 ("Unless FDA has issued an order denying or refusing to accept the submission, products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described previously. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during this continued compliance period." (quoting 81 Fed. Reg. at 29,011)). The "compliance policy did not apply to any new tobacco product that was not on the market on August 8, 2016." Aug. 2017 Guidance 3, ECF No. 48-1, at 716, GAR 424.

In May 2017, the FDA extended the compliance deadline by three months. 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. Specifically, it provided that

- the "compliance period for manufacturers to submit a substantial equivalence exemption request" was November 8, 2017;
- the "compliance period for manufacturers that have submitted substantial equivalence exemption requests by November 8, 2017 (unless they have received an order denying, or FDA has refused to accept their submission)" was one year later, November 8, 2018;
- the "compliance period for manufacturers to submit a substantial equivalence report" was May 8, 2018;
- the "compliance period for manufacturers that have submitted substantial equivalence reports by May 8, 2018 (unless they have received an order denying, or FDA has refused to accept their submission)" was one year later, May 8, 2019;

- the "compliance period for manufacturers to submit a premarket tobacco product application (PMTA)" was November 8, 2018;
- the "compliance period for manufacturers that have submitted PMTAs by November 8, 2018 (unless they have received an order denying, or FDA has refused to accept their submission)" was one year later, November 8, 2019.

May 2017 Guidance 7–8, GAR 214–15, ECF No. 48-1, at 695–96.

Then, in August 2017, without allowing for a notice and comment period, Pls.' Mem. 7, the FDA issued the August 2017 Guidance (which revised its May 2017 Guidance), "announc[ing] that it would further defer enforcement of the premarket review provision with respect to combustible products (like cigars) until 2021, and noncombustible products (like most e-cigarettes) until 2022—but only for products that were on the market when the deeming rule took effect in August 2016." Defs.' Mem. 2; *see* Aug. 2017 Guidance 8, GAR 429, ECF No. 48-1, at 721. The August 2017 Guidance explained that the FDA had set "compliance date[s] . . . as a matter of enforcement discretion, stating that it does not intend to enforce [] particular requirement[s] that [were] already in effect for a period of time in order to give industry more time to comply." Aug. 2017 Guidance 4, ECF No. 48-1, at 717, GAR 425. Notably, pursuant to the August 2017 Guidance, "there will be a continued compliance period pending review of [certain] applications," and "[t]his compliance period will continue *until the agency renders a decision on an application* (i.e., issuance of: a Marketing Order; a No Marketing Order; a Refuse to File; or Refuse to Accept) or the application is withdrawn." *Id.* at 3, GAR 424, ECF No. 48-1, at 716 (emphasis added). The chart of compliance deadlines only identified the end of the compliance periods for manufacturers to make their submissions; it no longer included a deadline for the compliance period for manufacturers that had made their submissions. *Id.* at 8, GAR 429, ECF No. 48-1, at 721.

During the compliance period, "the agency plans to issue regulations governing the information to be included in premarket applications, to develop standards that certain products must meet, and to publish additional guidance explaining what applications should contain and how they will be reviewed." Defs.' Mem. 2.

The effect of this deferred enforcement is that the products subject to the Act pursuant to the Deeming Rule may remain on the market until 2021 or 2022 without submitting an application or having it reviewed and approved. These products include e-cigarettes. As noted, youth use of e-cigarettes has reached epidemic proportions. Azar & Gottlieb Op. Ed. The FDA recognizes this and professes to be "deeply concerned about the risks that e-cigarettes pose for children, given how quickly teenage use of these products has accelerated." *Id.* It also "believe[s] e-cigarettes can be an important off-ramp for adults who are addicted to combustible cigarettes," but asserts that "[t]he technology that might help adults end one addiction cannot [be permitted to] pull a generation of kids into a new one." *Id.* In fact, the FDA has stated that it is "actively reconsidering our policy under which certain e-cigarettes — particularly the products with flavors that might appeal to children — can remain on the market without submitting a premarket application to the FDA until 2022," noting that "products such as e-cigarettes need to be put through an appropriate regulatory process. Under the most likely path for marketing authorization, they must show that their marketing is appropriate for protecting the public health, taking into account their risks and benefits to the population as a whole," and that "[r]ising e-cigarette use by children makes the marketing of this product especially deserving of close attention." *Id.*

Standard of Review

Defendants challenge this Court's subject matter jurisdiction based on Plaintiffs' purported lack of standing and their view that the August 2017 Guidance is not subject to judicial review

because it was an action within agency discretion and not a final agency action.[7] They also move to dismiss under Fed. R. Civ. P. 12(b)(6) for failure to state a claim. When a defendant moves to dismiss pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction, asserting a facial challenge that "a complaint simply fails to allege facts upon which subject matter jurisdiction can be based," as Defendants do here, "the facts alleged in the complaint are assumed to be true and the plaintiff, in effect, is afforded the same procedural protection as he would receive under a 12(b)(6) consideration." *Adams v. Bain*, 697 F.2d 1213, 1219 (4th Cir. 1982); *see Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (noting that, on a motion to dismiss, a plaintiff's pleading of the elements of standing are "presum[ed] [to] embrace those specific facts that are necessary to support the claim" (quoting *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 889 (1990))). But when, as here, a motion is styled in the alternative as one for summary judgment, both parties file their briefs along with evidence that is not integral to the pleadings, and the Court considers that evidence in reaching a decision, the Court must treat the motion as one for summary judgment. *See* Fed. R. Civ. P. 12(d); *Laughlin v. Metro. Wash. Airports Auth.*, 149 F.3d 253, 261 (4th Cir. 1998) (observing that, while the parties must have notice that a motion will be treated as one for summary judgment, the styling of a motion in the alternative, as well as the filing of evidence in support of the parties' arguments, provides sufficient notice).

Summary judgment is proper when the moving party demonstrates, through "particular parts of materials in the record, including depositions, documents, electronically stored

[7] When a plaintiff does not have standing, its claim is not justiciable. *Flast v. Cohen*, 392 U.S. 83, 95 (1968); *Lansdowne on the Potomac Homeowners Ass'n, Inc. v. OpenBand at Lansdowne, LLC*, 713 F.3d 187, 198 (4th Cir. 2013). "Justiciability is an issue of subject-matter jurisdiction." *Hamilton v. Pallozzi*, 848 F.3d 614, 619 (4th Cir.), *cert. denied*, 138 S. Ct. 500 (2017). Likewise, whether an agency's action "constituted final agency action under the APA so as to be reviewable in court" is "a question of subject matter jurisdiction." *Invention Submission Corp. v. Rogan*, 357 F.3d 452, 458 (4th Cir. 2004).

information, affidavits or declarations, stipulations . . . admissions, interrogatory answers, or other materials," that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a), (c)(1)(A); *see Baldwin v. City of Greensboro*, 714 F.3d 828, 833 (4th Cir. 2013). If the party seeking summary judgment demonstrates that there is no evidence to support the nonmoving party's case, the burden shifts to the nonmoving party to identify evidence that shows that a genuine dispute exists as to material facts. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 585–87 & n.10 (1986). When considering cross-motions for summary judgment, "the court must view each motion in a light most favorable to the non-movant." *Linzer v. Sebelius*, No. AW-07-597, 2009 WL 2778269, at *4 (D. Md. Aug. 28, 2009); *see Mellen v. Bunting*, 327 F.3d 355, 363 (4th Cir. 2003).

Standing

This Court may "adjudicate only actual cases and controversies." *Zaycer v. Sturm Foods, Inc.*, 896 F. Supp. 2d 399, 407 (D. Md. 2012) (citing U.S. Const. art. III, § 2; *O'Shea v. Littleton*, 414 U.S. 488, 493 (1974); *Bishop v. Bartlett*, 575 F.3d 419, 423 (4th Cir. 2009)). This "constraint of Article III" has two distinct but overlapping facets that must be satisfied for a federal district court to have subject matter jurisdiction: standing (which addresses who may sue and which is at issue here) and ripeness (which addresses when a party may bring a suit). *See South Carolina v. United States*, 912 F.3d 720, 730 (4th Cir. 2019) (quoting *Scoggins v. Lee's Crossing Homeowners Ass'n*, 718 F.3d 262, 269 (4th Cir. 2013)).

A plaintiff has standing if

> (1) [the plaintiff] has suffered an "injury in fact" that is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical; (2) the injury is fairly traceable to the challenged action of the defendant; and (3) it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Zaycer, 896 F. Supp. 2d at 408 (quoting *Bishop*, 575 F.3d at 423)); *see also Lujan*, 504 U.S. at 560–61 (same). Notably, while a plaintiff must plead these elements to allege standing, these elements are more than "mere pleading requirements"; they are "an indispensable part of the plaintiff's case," and "each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Lujan*, 504 U.S. at 561. In response to Defendants' Motion for Summary Judgment, Plaintiffs cannot "rest on . . . 'mere allegations'" of injury resulting from Defendants' conduct. *Id*. Rather, they have to "'set forth' by affidavit or other evidence 'specific facts.'" *Id.* (citing Fed. R. Civ. P. 56). If one of multiple plaintiffs has standing for a claim, then the claim can proceed. *Kenny v. Wilson*, 885 F.3d 280, 287 (4th Cir. 2018). Here, the three claims are each brought by all Plaintiffs. Compl. ¶¶ 92–118.

Injury in Fact

The Fourth Circuit has held that, where an organization's "efforts to carry out its mission" are impeded, that impediment is a concrete and particularized injury. *Lane v. Holder*, 703 F.3d 668, 674 (4th Cir. 2012). Likewise, "an organization suffers an injury in fact when it is deprived of information integral to its core activities." *Pub. Citizen Health Research Grp. v. Acosta*, 363 F. Supp. 3d 1, 12 (D.D.C. 2018) (finding that plaintiffs alleged injury in fact sufficiently by "alleg[ing] that [their] 'activities [are] impeded' when [they] cannot rely on the information OSHA would ordinarily collect under the Electronic Reporting Rule"). The Supreme Court refers to this as an "informational injury." *Dreher v. Experian Info. Sols., Inc.*, 856 F.3d 337, 345 (4th Cir. 2017) (quoting *Fed. Election Comm'n v. Akins*, 524 U.S. 11, 24 (1998)).

For a plaintiff to have standing based on an informational injury, the plaintiff must "lack access to information to which he is legally entitled *and* . . . the denial of that information [must]

create[] a 'real' harm with an adverse effect." *Id.* (quoting *Spokeo, Inc. v. Robins*, --- U.S. ----, 136 S. Ct. 1540, 1549 (2016) (internal quotation marks omitted)). Thus, "a plaintiff suffers a concrete informational injury where he is denied access to information required to be disclosed by statute, *and* he 'suffers, by being denied access to that information, the type of harm *Congress sought to prevent* by requiring disclosure.'" *Id.* (quoting *Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016) (emphasis supplied)). In *Spokeo*, the respondents' injury in fact "'consist[ed] of their inability to obtain information . . . that . . . [a] statute require[d] [to be] ma[d]e public' where that information 'would help them . . . evaluate candidates for public office.'" *Id.* (quoting *Spokeo*, 136 S. Ct. at 1548).

The injury also must be "imminent," that is "not too speculative"; in other words, it must be "*certainly* impending." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 564 (1992) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990)). Injury cannot be predicted "at some indefinite future time" or expected to result from acts "partly within the plaintiff's own control." *Id.*

Six Plaintiffs are "Organizational Plaintiffs": American Academy of Pediatrics ("AAP"), the American Cancer Society Cancer Action Network ("ACS CAN"), the American Heart Association ("AHA"), the American Lung Association ("ALA"), the Campaign for Tobacco-Free Kids ("CTFK"), and the Truth Initiative. Pls.' Rely & Opp'n 3. Plaintiffs assert that the Organizational Plaintiffs' "missions center on educating the public about the dangers of [new tobacco products]" and "advancing the public health." *Id.* at 6, 7. To this end, the Organizational Plaintiffs "work daily on the front lines of a multi-faceted effort to eradicate tobacco addiction and to avert the creation of new generations of addicted children and adults." *Id.* at 2.

Plaintiffs offer evidence that,

> [a]s implemented by the Deeming Rule, the Act would have enabled sustained progress toward that goal by subjecting hazardous and addictive products such as cigars and e-cigarettes to premarket review—requiring manufacturers to supply data and other information to FDA showing that the products they seek to market advance the public health, directing FDA to issue public orders determining whether the statutory public health standard has been met, and prohibiting the marketing of those products for which premarket orders have not been issued.
> . . .
> . . . Were FDA performing its statutorily required premarket review responsibilities, FDA would be disclosing to the public significant information about new tobacco products that Organizational Plaintiffs would use to further their missions.

Id. at 2–3 (citing Myers (CTFK) Decl. ¶¶ 10-17, ECF No. 39-1); *see also*, *e.g.*, Myers (CTFK) Decl. ¶ 11 (noting that one FDA "premarket review order disclosed a wealth of information that aid[ed] Tobacco-Free Kids in understanding and educating about the risks of tobacco products and the relative risk among products," such as "how standards in [one producer]'s manufacturing process help ensure lower levels of certain carcinogens; the relative disease risk of [its product] vs. cigarettes and other forms of smokeless tobacco; and the contribution of various harmful and potentially harmful constituents to disease risk"). Plaintiffs assert that they suffered informational injury because

> FDA's suspension of premarket review requirements for approximately 25,000 new tobacco products deprives Organizational Plaintiffs of access to vital scientific and health information necessarily generated as a part of that process—information Plaintiffs need to carry out their missions.

Pls.' Reply & Opp'n 3.

Additionally, Plaintiffs argue, "the Guidance interferes with Organization Plaintiffs' missions of advancing the public health by allowing nearly 25,000 unreviewed products to remain on the market—requiring Plaintiffs to expend more resources to monitor the marketplace and to counsel and educate the public about e-cigarettes, cigars, or both." *Id.* at 7. Specifically,

> Plaintiff AAP, for instance, has expended "approximately 2000 hours on e-cigarette work" since FDA issued the Guidance, AAP Decl. ¶ 15—hours spent updating and offering educational programs focused on e-cigarettes, *id.* ¶¶ 16-25;

> developing and issuing educational curricula and clinical materials, *id.* ¶¶ 30-34; and researching and publishing a policy statement on e-cigarettes, *id.* ¶¶ 35-44. The "massive increase in time that [AAP has] had to spend on e-cigarette work in light of the proliferation of products without premarket review" has required the organization to reduce staffing on other projects, postpone new initiatives, spend funds that it would not have otherwise had to, and forgo grant funding—all as a direct result of the Guidance. *Id.* ¶¶ 45-51. Other Organizational Plaintiffs attest to similar resource expenditures. *See, e.g.*, ALA Decl. ¶¶ 11-14; ACS CAN Decl. ¶ 15; AHA Decl. ¶¶ 15, 17.

Id.; *see also, e.g.*, Phillips (ACS CAN) Decl. ¶ 15, ECF No. 39-3 ("Without a prohibition on marketing newly deemed products until review is complete, hundreds of products in thousands of flavors are currently being sold without a decision from FDA on those products' effect on public health. This situation forces ACS CAN to invest considerably more resources in monitoring the market and the products in the market so that we can determine where the greatest risks to public health are arising. This work hinders ACS CAN from working on other priorities in our evidence-based tobacco prevention and control efforts.").

Notably, the Tobacco Control Act is quite clear that its purpose is, in part, "to ensure that consumers are better informed," and, to that end, it "require[s] tobacco product manufacturers to disclose research which has not previously been made available . . . relating to the health and dependency effects or safety of tobacco products." Pub. Law. 111-31, at § 3(6), 123 Stat 1776, 1782. It recognizes that "the use of tobacco by young people and dependence on tobacco" are "of particular concern to public health officials." *Id.* § 3(2), 123 Stat. 1776, 1781. And, the Act unambiguously established the public's right to the information by requiring the FDA to disclose products' "detailed information regarding data concerning adverse health effects . . . within 30 days" of any substantial equivalence determination. 21 U.S.C. § 387j(a)(4)(B).

The August 2017 Guidance's provisions, which do not require manufacturers to submit their applications (accompanied by research in support) for five or more years and announce that the FDA will defer enforcement during that period, deny the Organizational Plaintiffs "access to

information required to be disclosed by statute." *Dreher*, 856 F.3d at 345; *Friends of Animals*, 828 F.3d at 992; *see, e.g.*, Phillips (ACS CAN) Decl. ¶¶ 12–13 ("When FDA does not conduct premarket review, it is far more difficult for ACS CAN to advocate effectively for its members. Scientific data on the contents of novel tobacco products and their physiological consequences are crucial to ACS CAN's ability to identify effective and feasible product standards. Without such data, designing and proposing a product standard is akin to building a highway without knowing how to make asphalt. And such data largely comes from FDA, because tobacco manufacturers typically release as little information about their products' specific contents and interactions as possible. For example, JUUL, currently one of the most popular e-cigarettes among school-aged youth, has not gone through the premarket review process. If it did, it would have to provide information to FDA about its contents and their effects, and FDA would make that information public if it approved JUUL. Having that information would allow ACS CAN to determine whether there were specific aspects of JUUL that were troublingly carcinogenic and determine whether there are product standards that would minimize the carcinogenic effects of all e-cigarettes. Without premarket review, however, that information is simply unavailable."). Further, Congress intended for the research provided pursuant to the Tobacco Control Act to be publicly available promptly after product approval. 21 U.S.C. § 387j(a)(4)(B); Pub. Law. 111-31, at § 3(2), (6), 123 Stat 1776, 1781, 1782. Therefore, through this deprivation of information, Plaintiffs are suffering "the type of harm *Congress sought to prevent* by requiring disclosure." *Dreher*, 856 F.3d at 345; *Friends of Animals*, 828 F.3d at 992.

Moreover, this injury to the organizations' daily operations due to agency action limiting their access to the information is the type of injury that courts have recognized as both concrete and particularized. *E.g.*, *Acosta*, 363 F. Supp. 3d at 12; *People for the Ethical Treatment of*

Animals v. U.S. Dep't of Agric. (*PETA*), 797 F.3d 1087, 1095 (D.C. Cir. 2015) ("Because PETA's alleged injuries—denial of access to bird-related AWA information including, in particular, investigatory information, and a means by which to seek redress for bird abuse—are 'concrete and specific to the work in which they are engaged,' we find that PETA has alleged a cognizable injury sufficient to support standing." (citation omitted)); *see id*. at 1094 (noting that, when "the challenged regulations den[ied] the [organization plaintiffs] access to information and avenues of redress they wish to use in their routine information-dispensing, counseling, and referral activities," that "inhibition of [plaintiff organizations'] daily operations" is "an injury both concrete and specific to the work in which they are engaged"); *Lane*, 703 F.3d at 674 ("An organization may suffer an injury in fact when a defendant's actions impede its efforts to carry out its mission.").

Further, the injury is not speculative, as the FDA currently is not requiring applications for new products and therefore is not making available the information it otherwise would make available. Additionally, Plaintiffs already have spent time and resources researching and educating the public on e-cigarettes due to the dearth of such information from the FDA. *See* Phillips (ACS CAN) Decl. ¶ 15 ("Without a prohibition on marketing newly deemed products until review is complete, hundreds of products in thousands of flavors are currently being sold without a decision from FDA on those products' effect on public health. This situation forces ACS CAN to invest considerably more resources in monitoring the market and the products in the market so that we can determine where the greatest risks to public health are arising."); Schoeberl (AHA) Decl. ¶¶ 15–16, ECF No. 39-4 ("In lieu of premarket review, AHA must do its own research and review published research on e-cigarettes and cigars. But due to the paucity of published information, the variable contents of the unregulated products, and the sheer number of products on the market, this

endeavor is not only a completely inadequate substitute for premarket review, but also expensive. Similarly, AHA develops resources for individuals, including its 40 million volunteers and supporters. It is currently developing or updating materials on topics such as resources to help quit smoking, whether vaping is safer than smoking, common products such as JUUL, and the public health implications of e-cigarettes. All of this material is more costly to develop—and less complete—due to the absence of premarket review and the information it would provide, as well as the immense diversity of products in the absence of premarket review.").

This Court has held that an organization has standing where, as here, "the defendants' actions 'have caused the organization to divert resources to identify and counteract the defendants' unlawful practices,' and thereby impede[d] and frustrate[d] its core mission." *Equal Rights Ctr. v. Equity Residential*, 483 F. Supp. 2d 482, 487 (D. Md. 2007) (plaintiff's mission was "through 'education, counseling, advocacy, enforcement, and referral services to aid protected individuals'"); *see also Equal Rights Ctr. v. Abercrombie & Fitch Co.*, 767 F. Supp. 2d 510, 519–20 (D. Md. 2010) ("[D]iversion of funds and frustration of an organization's missions are injuries sufficient to establish standing under Article III . . . ."); *Shield Our Constitutional Rights & Justice v. Hicks*, No. DKC-09-940, 2009 WL 3747199, at *5 (D. Md. Nov. 4, 2009) (noting that "Plaintiffs' complaint [wa]s devoid of any facts . . . similar to those in *Equity Residential*," and concluding that plaintiffs failed to establish organizational standing). Therefore, Plaintiffs have demonstrated a concrete, non-speculative injury. *See PETA*, 797 F.3d 1087, 1094–95; *Lane*, 703 F.3d at 674; *Acosta*, 363 F. Supp. 3d at 12; *Abercrombie & Fitch Co.*, 767 F. Supp. 2d at 519–20; *Equity Residential*, 483 F. Supp. 2d at 487.

Traceable Injury

If "the alleged injury is solely 'th[e] result [of] the independent action of some third party not before the court,'" then the "plaintiff may not have standing." *Kravitz v. U.S. Dep't of Commerce*, 336 F. Supp. 3d 545, 559 (D. Md. 2018) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992)). But, "[f]or an injury to be 'fairly traceable' to the defendant, the defendant's actions need not be 'the very last step in the chain of causation.'" *Id.* (quoting *Bennett v. Spear*, 520 U.S. 154, 168–69 (1997)). Rather, "the causation element of standing is satisfied . . . where the plaintiff suffers an injury that is 'produced by [the] determinative or coercive effect' of the defendants' conduct 'upon the action of someone else.'" *Id.* (quoting *Lansdowne on the Potomac Homeowners Ass'n, Inc. v. OpenBand at Lansdowne, LLC*, 713 F.3d 187, 197 (4th Cir. 2013) (quoting *Bennett*, 520 U.S. at 169)).

Here, Plaintiffs' injuries result from the FDA's actions to exempt certain products from premarket review for years. Certainly, the FDA's actions arguably are not "the very last step in the chain of causation," as the manufacturers theoretically could have chosen to submit applications promptly or to remove their products from the market in response to the August 2017 Guidance stating that they were exempt from premarket review and enforcement for five or six years or more. But theory and reality are not always in harmony, and the record before me contains no facts to suggest that manufacturers actually have done so, nor would it be the slightest bit surprising to learn that they have not. And, it is telling that the FDA has not issued any orders on premarket tobacco product applications since 2015 or taken any final action on any premarket tobacco product applications since June 2017. *See* FDA, Summary of Premarket Tobacco Product Application Final Actions, https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-marketing-orders; *see also* Fed. R. Evid. 201(b)(2). Under these

circumstances, the injury is undeniably traceable to Defendants' August 2017 Guidance. *See Pub. Citizen Health Research Grp. v. Acosta*, 363 F. Supp. 3d 1, 12 (D.D.C. 2018) ("Here, the causal relationship is quite clear. Plaintiffs allege that OSHA, in violation of the APA, indefinitely suspended the Electronic Reporting Rule without following proscribed statutory procedures and without adequate justification. As a result of that suspension, employers are not required to submit Forms 300 and 301, nor will OSHA even accept those forms if submitted, and thus OSHA no longer collects the occupational health and injury data on which Plaintiffs profess to rely.").

Redressability

A plaintiff's allegations satisfy the redressability prong if it is "likely, and not merely speculative, that a favorable decision will remedy the injury." *Friends of the Earth, Inc. v. Gaston Cooper Recycling Corp.*, 204 F.3d 149, 154 (4th Cir. 2000). Here, if the Court vacated the August 2017 Guidance as Plaintiffs request, then the manufacturers would be required to submit their applications immediately (as the deadlines in the Deeming Rule and the May 2017 Guidance have passed) or by a reasonable date proposed by FDA, if the Court orders supplemental briefing on a remedy, and then imposes one. *See* Pls.' Reply & Opp'n 40 n.14. Either way, the deadline would be sooner than under the August 2017 Guidance. Once applications are submitted, the FDA would have to respond in 180 days. 21 U.S.C. § 387j(c)(1)(A). This would generate the information Plaintiffs seek and eliminate the need for them to expend time and resources obtaining the information and educating the public. Thus, it is likely that a decision in Plaintiffs' favor would redress their injury. *See Friends of the Earth*, 204 F.3d at 154.

Therefore, the Organizational Plaintiffs have standing. *See Lujan*, 504 U.S. at 560–61; *Bishop*, 575 F.3d at 423. Because these Plaintiffs have standing, I need not consider whether the other Plaintiffs have standing. *See Kenny v. Wilson*, 885 F.3d 280, 287 (4th Cir. 2018); *see also*

Pub. Citizen Health Research Grp. v. Acosta, 363 F. Supp. 3d 1, 11 (D.D.C. 2018) ("Since Plaintiffs' organizational standing alone would suffice to satisfy Article III's requirements, however, the Court will focus its analysis there." (citing *Bowsher v. Synar*, 478 U.S. 714, 721 (1986))).

Judicial Review of Nonenforcement Decision

The actions of an agency such as the FDA "are presumptively subject to judicial review." *Elecs. of N.C., Inc. v. Se. Power Admin.*, 774 F.2d 1262, 1266 (4th Cir. 1985) (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 140–41 (1967)). Two exceptions exist. First, "where Congress manifests its intent to preclude such review," the action is nonreviewable. *Id.*; *see* 5 U.S.C. § 701(a)(1). Second, if the agency's action "is 'committed to agency discretion by law,'" then it is nonreviewable. *Id.* (quoting 5 U.S.C. § 701(a)(2)). For this second "very narrow exception" to apply, the statute must be "drawn in such broad terms that in a given case there is no law to apply." *Id.* (quoting *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (quoting legislative history of the APA, S. Rep. No. 752, 79th Cong., 1st Sess., 26 (1945))). That is, under § 701(a)(2), "review is not to be had if the statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985).

Further, because an agency's "[r]efusal to take enforcement steps" is "generally . . . precisely the opposite" of an agency's actions in accordance with "a statute that set[s] clear guidelines for [such actions]," the "presumption of reviewability" does not apply to that refusal. *Chaney*, 470 U.S. at 831. Indeed, "in that situation . . . the presumption is that judicial review is not available." *Id.*; *see also Elecs. of N.C.*, 774 F.2d at 1266.

Relying on the U.S. District Court for the District of Columbia's decision in *National Association for the Advancement of Colored People v. Trump*, 298 F. Supp. 3d 209 (D.D.C. 2018), Defendants insist that "a 'general enforcement policy,'" such as an agency's decision not to enforce a statute, "is reviewable *only* where it announces an agency's 'legal interpretation' of a statute." Defs.' Reply 7 (quoting *Nat'l Ass'n for the Advancement of Colored People v. Trump*, 298 F. Supp. 3d 209, 231 (D.D.C. 2018), *adhered to on denial of reconsideration*, 315 F. Supp. 3d 457 (D.D.C. 2018)) (emphasis added). Indeed, *Trump* held that "legal interpretations couched as broad enforcement policies . . . are reviewable, . . . individual enforcement decisions . . . are presumptively unreviewable, . . . and *discretionary enforcement policies . . . are presumptively unreviewable. . . .*" *Trump*, 298 F. Supp. 3d at 231 (emphasis added). Significantly, however, this holding defines the applicable *presumption*; the *Trump* Court also noted that the presumption of unreviewability of agency discretionary enforcement policies is rebuttable under two circumstances. *Trump*, 298 F. Supp. 3d at 234; *see also Chaney*, 470 U.S. at 832–33 (discussing when presumption of unreviewability of broad refusal to take enforcement action can be rebutted).

First, while "an agency's decision whether to take an enforcement action is presumptively unreviewable, . . . that presumption can normally be rebutted . . . by pointing to statutory language that constrains the agency's exercise of its enforcement discretion." *Trump*, 298 F. Supp. 3d at 234 (citing *Chaney*, 470 U.S. at 832–33). In other words, the presumption that "an agency's decision not to take enforcement action [is] immune from judicial review under § 701(a)(2) . . . may be rebutted where the substantive statute has provided guidelines for the agency to follow in exercising its enforcement powers." *Chaney*, 470 U.S. at 832–33. To determine whether this exception to the presumption of unreviewability applies, the court considers whether Congress "has indicated an intent to circumscribe agency enforcement discretion, and has provided

meaningful standards for defining the limits of that discretion." *Chaney*, 470 at 834–35. If so, "there is 'law to apply' under § 701(a)(2), and courts may require that the agency follow that law." *Id.* If Congress has not demonstrated such an "intent to circumscribe agency enforcement discretion, . . . then an agency refusal to institute proceedings is a decision 'committed to agency discretion by law'" and is not reviewable in court. *Id.* Second, the *Chaney* "presumption of unreviewability does not apply to 'an agency's announcement of its interpretation of a statute even when that interpretation is advanced in the context of a decision not to take enforcement action.'" *Trump*, 298 F. Supp. 3d at 228 (quoting *Edison Elec. Inst. v. EPA*, 996 F.2d 326, 333 (D.C. Cir. 1993) (citations and internal quotation marks omitted)).

Additionally, if the agency's decision is "'tantamount to amending or revoking a rule,'" then it "amounts to substantive rulemaking subject to the APA's constraints and generally reviewable by courts." *Public Citizen Health Research Group v. Acosta*, 363 F. Supp. 3d 1, 18 (D.D.C. 2018) (quoting *Clean Air Council v. Pruitt*, 862 F.3d 1, 6 (D.C. Cir. 2017) (per curiam)). Thus, an agency enforcement decision, including a refusal to take enforcement action, may be reviewed in court (1) if the agency's decision is a statement of statutory interpretation, albeit couched as an exercise of enforcement discretion; (2) if Congress indicated, such as through the language of the statute itself, that it intended to circumscribe the agency's enforcement discretion, *see Trump*, 298 F. Supp. 3d at 228, 234; *Chaney*, 470 U.S. at 832–35, or (3) if it amounts to a rule amendment or revocation, *see Acosta*, 363 F. Supp. 3d at 18.

In *Chaney* (on which the FDA heavily relies), prison inmates who had been sentenced to death by lethal injection asked the FDA to "take various enforcement actions" regarding the use of drugs for lethal injection; the inmates asserted that the use violated the Federal Food, Drug, and

Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"),[8] but the FDA refused to take action. 470 U.S. at 823. The inmates filed suit, and the Supreme Court considered "the extent to which a decision of an administrative agency to exercise its 'discretion' not to undertake certain enforcement actions is subject to judicial review under the Administrative Procedure Act, 5 U.S.C. § 501 *et seq.* (APA)." 470 U.S. at 823.

Specifically, the *Chaney* Court considered the language of the FDCA, noting that one part "provide[d] only that [t]he Secretary is *authorized* to conduct examinations and investigations" and did not give any "indication of when an injunction should be sought," and another was "framed in the permissive." *Id.* at 835.[9] Also, while "[t]he section on criminal sanctions state[d] baldly that any person who violates the Act's substantive provisions '*shall* be imprisoned . . . or fined,'" the Court was "unwilling" to construe that language to "mandate[] criminal prosecution of every violator of the Act . . . particularly since the Act charges the Secretary only with recommending prosecution; any criminal prosecutions must be instituted by the Attorney General." *Id.* (emphasis added). It concluded that "[t]he Act's enforcement provisions thus commit complete discretion to the Secretary to decide how and when they should be exercised." *Id.* The Court also stated that "the Act's substantive prohibitions of 'misbranding' and the introduction of 'new drugs' absent agency approval" were "simply irrelevant to the agency's discretion to refuse to initiate

[8] The Tobacco Control Act has been codified, in part, as part of the FDCA. *See* 21 U.S.C. §§ 387 – 387(u).

[9] On most occasions, the Act refers to the authority of the Secretary of the Department Health and Human Services (HHS) to take certain actions. However, the Secretary acts through the Commissioner of Food and Drugs. 21 U.S.C. § 393(d)(2). For simplicity, [the court] will refer to any legislative delegation as if made directly to the FDA.

Brown & Williamson Tobacco Corp. v. Food & Drug Admin., 153 F.3d 155, 161 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000).

proceedings." *Id.* at 836. And, it rejected the argument that another provision of the act, stating that nothing in the act would "be construed as requiring the Secretary to report for prosecution . . . *minor* violations of this chapter" gave "rise to the negative implication" that "the Secretary is *required* to report for prosecution all '*major*' violations of the Act." *Id.* at 837 (some emphases added).

In sum, the Court "conclude[d] that the presumption that agency decisions not to institute proceedings are unreviewable under 5 U.S.C. § 701(a)(2) is not overcome by the enforcement provisions of the FDCA," such that "[t]he FDA's decision not to take the enforcement actions requested by [the inmates] is therefore not subject to judicial review under the APA." *Id*. at 837-38. But, as Plaintiffs are quick to point out, *Chaney* is not the last word on how to interpret an agency's professed reliance on the presumption of judicial unreviewability of its exercise of enforcement discretion, because the Circuit and District Courts have examined this subject extensively. Pls.' Reply & Opp'n 28–29.

For example, *Public Citizen Health Research Group v. Acosta*, 363 F. Supp. 3d 1 (D.D.C. 2018), has a fact pattern that is quite similar to the facts in this case. There, the District Court for the District of Columbia considered the justiciability of an action that the Occupational Safety and Health Administration ("OSHA") took that set the requirements for "qualifying employers to record work-related injuries and illnesses on a set of standardized forms." 363 F. Supp. 3d at 6.

> Initially, OSHA only occasionally collected these forms from employers, either during on-site inspections or as part of broader industry surveys. But in May 2016, OSHA issued a new rule requiring employers to submit them—three in total—electronically each year. In May 2018, however, and after the first filing deadline had passed, OSHA announced employers were only required to submit one of the three forms while it considered revising or rescinding the existing rule, citing privacy and waste concerns. In fact, OSHA stated that, until it completed its review, it would not accept two of the three forms from employers at all.

Id. Three public-health advocacy groups that "view[ed] these forms as valuable sources of workplace health data, and . . . allege[d] that they intended to use that data in their research and advocacy efforts once OSHA collected it," filed suit pursuant to the APA, claiming that OSHA's conduct "unlawfully deprived them of access to an important source of workplace health data." *Id.* at 6–7. They asked the court to "require[] OSHA to lift its suspension of the filing deadlines and to accept all three forms." *Id.* at 7.

The court concluded that the plaintiffs sufficiently alleged that "OSHA did not simply exercise its discretion not to enforce the Rule, but suspended its reporting requirement entirely such that covered employers are not legally obligated to submit the forms, regardless of whether OSHA decides to take action against them for not doing so." *Id.* at 18 ("Plaintiffs' complaint plausibly alleges that the May 2018 OSHA action they challenge was a wholesale *suspension* of the Electronic Reporting Rule, not merely a policy statement regarding OSHA's enforcement discretion."). It noted that, in the District of Columbia Circuit, "[s]uch decisions . . . 'are tantamount to amending or revoking a rule,'" which "amounts to substantive rulemaking subject to the APA's constraints and generally reviewable by courts." *Id.* (quoting *Clean Air Council v. Pruitt*, 862 F.3d 1, 6 (D.C. Cir. 2017) (per curiam)). Therefore "OSHA's action d[id] not warrant a presumption against reviewability." *Id.*

The court also considered the mandatory requirements within the statutory language of the Occupational Safety and Health Act ("OSH Act"). Specifically,

> Section 673(a) of the OSH Act mandates that OSHA "*shall* develop and maintain an effective program of collection, compilation, and analysis of occupation safety and health statistics." 29 U.S.C. § 673(a). Similarly, § 657(c)(2) mandates that OSHA "*shall* prescribe regulations requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries and illnesses." *Id.* § 657(c)(2). And § 673(e) further provides that "[o]n the basis of the records made and kept pursuant to section 657(c) . . . , employers *shall* file such

> reports with [OSHA] as [it] *shall* prescribe by regulation, as necessary to carry out [its] functions under this chapter." *Id.* § 673(e).

Id. at 19 (emphases added). The court concluded that these provisions "do not rest unfettered discretion with OSHA to promulgate—or not promulgate—regulations concerning reporting requirements and data compilation. OSHA *must* issue regulations necessary to fulfilling the purposes of the OSH Act and its administrative functions." *Id.*

Here, the parties agree that, pursuant to the August 2017 Guidance, the FDA currently does not have to undertake premarket review for e-cigarettes, cigars, and other newly deemed tobacco products, and manufacturers currently do not have to file applications with the FDA for those products to remain on the market. Pls.' Mem. 1; Defs.' Mem. & Opp'n 2. Defendants acknowledge that Congress did not establish a statutory grace period for new tobacco products as it did "for originally regulated products," but they argue that the inclusion of such a provision in another section of the Act "in no way curtails the agency's inherent discretion to extend a similar grace period to newly deemed products—if anything, it shows that deferring enforcement of this provision for newly regulated products is entirely sensible." Defs.' Mem. 4. But, "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Nat'l Ass'n of Mfrs. v. Dep't of Def.*, —— U.S. ——, 138 S. Ct. 617, 631 (2018) (quoting *Russello v. United States,* 464 U.S. 16, 23 (1983) (internal quotation marks and brackets omitted)).

In Defendants' view, the August 2017 Guidance is a nonenforcement decision that is "committed to agency discretion, and thus presumptively immune from judicial review," as explained in *Chaney*. Defs.' Mem. 21. Certainly, the parties agree that the FDA has some discretion to allow for a compliance period for new tobacco products, and the FDA did just that in the

Deeming Rule. But, Plaintiffs insist that "Congress cabined any FDA discretion under the [Tobacco Control] Act," and therefore the Court may review the August 2017 Guidance. Pls.' Reply & Opp'n 23 (quoting *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971)). As Plaintiffs see it, "[t]he Tobacco Control Act plainly makes premarket review mandatory, not discretionary, for both regulated entities and FDA." Pls.' Mem. 9.

The extent of the FDA's discretion under the Tobacco Control Act is a matter of statutory interpretation.

> "The 'first step' of statutory interpretation 'is to determine whether the language at issue has a plain and unambiguous meaning' by looking to 'the language itself, the specific context in which that language is used, and the broader context of the statute as a whole.' " *Orquera v. Ashcroft*, 357 F.3d 413, 418 (4th Cir. 2003) (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 340–41, 117 S.Ct. 843, 136 L.Ed.2d 808 (1997)). When the words of the statute are "sufficient in and of themselves to determine the purpose of the legislation" and do not produce unreasonable results "plainly at variance with the policy of the legislation as a whole," courts must follow their plain meaning. *United States v. Am. Trucking Ass'ns*, 310 U.S. 534, 60 S.Ct. 1059, 84 L.Ed. 1345 (1940) (quoting *Ozawa v. United States*, 260 U.S. 178, 194, 43 S.Ct. 65, 67 L.Ed. 199 (1922)). Indeed, "[t]here is ... no more persuasive evidence of the purpose of a statute than the words by which the legislature undertook to give expression to its wishes." *Am. Trucking Ass'ns*, 310 U.S. at 543, 60 S.Ct. 1059.

Nat'l Ass'n for the Advancement of Colored People v. U.S. Dep't of Homeland Sec., 364 F. Supp. 3d 568, 574–75 (D. Md. 2019).

Plaintiffs rely on 21 U.S.C. § 387j(a)(2) and (c)(1)(A)(i), which provide:

> (a) In general
>
> . . .
>
> (2) Premarket review required
>
> (A) New products
>
> An order under subsection (c)(1)(A)(i) for a new tobacco product *is required* unless--
>
> (i) the manufacturer has submitted a report under section 387e(j) of this title; and the Secretary has issued an order that the tobacco product--

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products

Subparagraph (A) shall not apply to a tobacco product--

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

. . .

(c) Action on application

(1) Deadline

(A) In general

As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), *shall*--

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) Restrictions on sale and distribution

An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title.

(2) Denial of application

The Secretary *shall* deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that--

> (A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;
>
> (B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;
>
> (C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or
>
> (D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard.

21 U.S.C. § 387j(a)(2), (c)(1)(A)(i), (2) (emphases added).

These statutes include mandatory language like that in *Acosta*, not the permissive language at issue in *Chaney*. The term "shall," which appears repeatedly in these statutory provisions, "normally creates an obligation impervious to . . . discretion." *Lexecon Inc. v. Milberg Weiss Bershad Hynes & Lynch*, 523 U.S. 26, 35 (1998); *see also Cook v. Food & Drug Admin.*, 733 F.3d 1, 7 (D.C. Cir. 2013) (applying *Lexecon* holding with regard to judicial discretion to conclude that agency did not have absolute discretion where mandatory language appeared in the statute). Giving the statute's language its ordinary meaning, these provisions require premarket review (involving applications and decisions on those applications) within a specific timeframe, and the August 2017 Guidance suspends the deadlines for both until 2021 or 2022 *or later*. Moreover, the plain language of the statute prohibits products from entering the market without the FDA's approval. Therefore, the FDA's "wholesale suspension" of the application filing and approval requirements constitutes a rule amendment or revocation that is subject to review by this Court. *Acosta*, 363 F. Supp. 3d at 18; *see also Elecs. of N.C.*, 774 F.2d at 1266.

And, even if the agency's deferral of the premarket approval process constituted an enforcement decision, which would be presumptively unreviewable by the Court, *see Chaney*, 470 U.S. at 831, I note that, as the *Acosta* Court concluded regarding the OSH Act and OSHA's actions,

these provisions of the Tobacco Control Act "do not rest unfettered discretion" with the FDA to modify or suspend the product approval process. *Acosta*, 363 F. Supp. 3d at 19. Rather, the FDA "*must*" require filings from manufacturers and approve or deny those filings, that is, it must take actions that are "necessary to fulfilling the purposes of the [Tobacco Control] Act." *See id.*; *see also Cook*, 733 F.3d at 7 (concluding that any presumption of immunity from judicial review was "rebutted by the specific 'legislative direction in the statutory scheme'" that "set[] forth precisely when the [FDA] must determine whether a drug offered for import appears to violate the FDCA, and what the agency must do with such a drug"). Thus, the Tobacco Control Act was not "drawn in such broad terms that . . . there is no law to apply" in this case, *see Citizens to Preserve Overton Park*, 401 U.S. at 410; *Elecs. of N.C.*, 774 F.2d at 1266, and therefore the FDA's actions were not "committed to agency discretion by law," *see* 5 U.S.C. § 701(a)(2). Neither has Congress "manifest[ed] its intent to preclude [judicial] review" of the FDA's action under the Tobacco Control Act. *See Elecs. of N.C.*, 774 F.2d at 1266; 5 U.S.C. § 701(a)(1).

I further note that the Tobacco Control Act "has provided guidelines for the agency to follow in exercising its enforcement powers," *Chaney*, 470 U.S. at 832–33, and the Act's language shows Congressional "intent to circumscribe agency enforcement discretion"; also, it "has provided meaningful standards for defining the limits of that discretion," *id.* at 834–35. Specifically, the statute provides that, "[a]s promptly as possible, but in no event later than 180 days after the receipt of an application . . . the Secretary . . . shall" consider the report and recommendation submitted with the application and issue an order, either allowing the product into interstate commerce, if the Secretary makes certain findings that the statute identifies, or issue an order prohibiting the product from interstate commerce, if the Secretary makes certain other findings, which also are identified. 21 U.S.C. §§ 387j(c)(1)(A). One of these orders "is required

unless" the Secretary issues an order that the product "is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007" and meets certain statutory requirements, or is exempt from the requirements. 21 U.S.C. §§ 387j(a)(2). Also, "[t]he Secretary shall deny an application" if it makes certain findings identified in the statute. 21 U.S.C. §§ 387j(c)(2). This is "statutory language that constrains the agency's exercise of its enforcement discretion." *Trump*, 298 F. Supp. 3d at 234 (citing *Chaney*, 470 U.S. at 832–33).

Defendants disagree, arguing that these provisions "do not circumscribe the agency's enforcement discretion." Defs.' Reply 6. They reason that "[w]ords like 'required' and 'shall' are common throughout the U.S. Code, yet they have never been thought to 'mandate . . . prosecution of every violator.'" *Id.* (quoting *Chaney*, 470 U.S. at 835). But, as noted, when the *Chaney* Court refused to construe the phrase "shall be imprisoned . . . or fined" to "mandate[] criminal prosecution of every violator of the Act" and concluded that the Secretary had "complete discretion . . . to decide how and when [the enforcement provisions] should be exercised," it was not because the term "shall" is not mandatory. *Chaney*, 470 U.S. at 835. Rather, the Court reasoned that the statute at issue "charge[d] the Secretary only with *recommending* prosecution" and provided that "any criminal prosecutions must be instituted *by the Attorney General*." *Id.* (emphases added). This language differs from the language of § 387j(a)(2) and (c), which expressly directs the Secretary to approve or deny applications.

Insofar as mandatory language may not "mandate[] criminal prosecution of *every* violator" of a given statute, to hold that such language does not mandate that the agency enforce the statute against *any* violator would render the language surplusage. The Court "cannot adopt a reading of [the statute] that renders part of the statute superfluous over one that gives effect to its 'every

clause and word,'" as doing so would violate the "well-established rule against surplusage." *United States v. Simms*, 914 F.3d 229, 241 (4th Cir. 2019) (quoting *United States v. Menasche*, 348 U.S. 528, 538–39 (1955)) (quoting *Inhabitants of Montclair Twp. v. Ramsdell*, 107 U.S. 147, 152 (1883)). Thus, to hold that the FDA's discretion was not circumscribed by the Tobacco Control Act's mandatory language would "violat[e] a cardinal rule of statutory construction." *Id.* Accordingly, any presumption that the August 2017 Guidance is unreviewable under § 701(a)(2) is overcome by these provisions, and therefore, the FDA's decision in the August 2017 Guidance not to undertake premarket review is subject to judicial review under the APA. *See Chaney*, 470 U.S. at 837–38; *Trump*, 298 F. Supp. 3d at 234; *Acosta*, 363 F. Supp. 3d at 18.

Final Agency Action

"Judicial review under the APA . . . is limited to 'final agency actions.'" *City of New York v. U.S. Dep't of Def.*, 913 F.3d 423, 430 (4th Cir. 2019) (quoting 5 U.S.C. § 704). Generally, "two conditions must be satisfied for agency action to be 'final.'" *Vill. of Bald Head Island v. U.S. Army Corps of Eng'rs*, 714 F.3d 186, 194–95 (4th Cir. 2013) (quoting *Bennett v. Spear*, 520 U.S. 154 (1997)). The first requirement is that "the action must mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature." *Id.* (quoting *Bennett*, 520 U.S. at 177–78 (citation and quotation marks omitted)). The second is that "the action must be one by which rights or obligations have been determined or from which legal consequences will flow." *Id.* (quoting *Bennett*, 520 U.S. at 178 (citation and quotation marks omitted)). Stated differently, "[t]he core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties." *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992). "[T]he measure of finality is also 'pragmatic'; an agency action is 'immediately reviewable' when it gives notice of how a certain

statute will be applied even if no action has yet been brought." *Int'l Refugee Assistance Project v. Trump*, 883 F.3d 233, 285 (4th Cir.), *as amended* (Feb. 28, 2018) (quoting *U.S. Army Corps of Eng'rs v. Hawkes Co.*, ––– U.S. ––––, 136 S. Ct. 1807, 1815 (2016)), *cert. granted, judgment vacated on other grounds*, 138 S. Ct. 2710 (2018).

Defendants argue that, "[e]ven if the Guidance were more than the FDA's 'current thinking' on enforcement of the premarket authorization requirement, Guidance at 1 (GAR 422), it does not satisfy the second criterion because it does not determine any rights or obligations, nor will any legal consequences flow from it." Defs.' Mem. 31 (citation omitted). Defendants cite *BBK Tobacco & Foods, LLP v. FDA*, 672 F. Supp. 2d 969, 975–76 (D. Ariz. 2009), in which the U.S. District Court for the District of Arizona held that the FDA's guidance documents at issue in that case, which included the same boilerplate disclaimer about "not creat[ing] or confer[ring] any rights" that appears in the August 2017 Guidance, "d[id] not constitute final agency action within the meaning of the ripeness inquiry" because the guidance documents at issue in that case "d[id] not provide any legal basis from which the FDA [could] institute civil or criminal legal proceedings" and therefore 'legal consequences' [could not] flow" from the documents. But, that case is not on point because here the issue does not concern the FDA *instituting* legal proceedings based on a provision in the August 2017 Guidance but rather failing to take any action, and justifying its decision with the language of the August 2017 Guidance. If the August 2017 Guidance is not a final action, then the FDA's rationale for its inaction is that much less plausible.

In any event, case law from the District of Arizona is not binding on this Court, and the only Fourth Circuit case Defendants cite is *Flue-Cured Tobacco Coop. Stabilization Corp. v. U.S.E.P.A.*, 313 F.3d 852 (4th Cir. 2002). There, the Fourth Circuit concluded that the EPA's report was not a final agency action. *Id.* at 858–59. That case is readily distinguished from this

one because when the Fourth Circuit "first look[ed] for direction to the Radon Act," it noted that "section 404 of the Radon Act prohibits the EPA (and the courts) from giving the Report 'any regulatory' effect." *See id.* at 858. Defendants have not identified any equivalent provision of the Tobacco Control Act.

The Fourth Circuit's recent decision in *Sanitary Board of City of Charleston v. Wheeler*, 918 F.3d 324 (4th Cir. 2019), likewise is not on point. There, the court reasoned that "'advisory,' 'pre-decisional,' or 'staff'" letters that "clearly state[] that the comments contained therein 'do not constitute approval or disapproval decisions[]' . . . do not, in fact, reflect the agency's final position" because "[a]gencies need the ability to designate the import of the information they disseminate, and this includes the ability to clearly communicate when a decision is final." 918 F.3d at 337–38. Here, in contrast, the Guidance is not a letter, and it is not labeled "advisory" or "pre-decisional." *Compare* Aug. 2017 Guidance, GAR 420, ECF No. 48-1, at 712 ("Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule: Guidance for Industry (Revised) (Aug. 2017)"), *with* Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems (ENDS): Guidance for Industry: *Draft Guidance* (May 1, 2016), AR 28350, ECF No. 48-1, at 358.

Certainly, the Guidance includes boilerplate language that it "does not establish any rights for any person and is not binding on FDA or the public" and that it "do[es] not establish legally enforceable responsibilities . . . and should be viewed only as [a] recommendation[ ]." Aug. 2017 Guidance 1, GAR 422, ECF No. 48-1, at 714. But it also states: "You can use an alternative approach *if* it satisfies the requirements of the applicable statutes and regulations." *Id.* (emphasis added). Given that the applicable statutes and regulations imposed a deadline and the August 2017 Guidance suspended it, the *only* acceptable alternative approach would be to adhere to a more

stringent schedule. *See id.* Thus, if a manufacturer sought additional time to submit an application, the only approach was to follow the Guidance. *See id. Contra Mallinckrodt Inc. v. U.S. Food & Drug Admin.*, No. DKC-14-3607, 2015 WL 13091366, at *13–14 (D. Md. July 29, 2015) (concluding that FDA's draft guidance that reclassified the plaintiff's drug was not binding because "the language used by FDA in the documents itself [including the same boilerplate language in the August 2017 Guidance, quoted above] d[id] not purport to 'impose legally binding obligations' . . . or to 'set forth legally binding requirements" and "[m]oreover, . . . the document itself is devoid of commands, orders, or binding requirements" and "alternative approaches may satisfy the [relevant] statutes and regulations"; also reasoning that the draft guidance "did not effectively amend a prior legistative rule because it 'neither repudiate[d] nor [wa]s inconsistent with any pre-existing FDA regulations").

Moreover, with regard to the language purporting to limit the effects of the Guidance, *Philip Morris USA Inc. v. United States Food & Drug Administration*, 202 F. Supp. 3d 31 (D.D.C. 2016), provides helpful guidance, even if it is not controlling authority. There, the District Court for the District of Columbia considered the finality of "Demonstrating the Substantial Equivalence of a New Tobacco Product: Responses to Frequently Asked Questions (Edition 2)" ("Second SE Guidance"), a document that the FDA had released regarding the term "new tobacco product" and "how label and quantity changes could result in a 'new tobacco product.'" 202 F. Supp. 3d at 43, 46. Specifically, the court addressed whether the Second SE Guidance "determine[d] rights or obligations or establish[ed] legal consequences" so as to "fulfill the second requirement of finality." *Id.* at 46.

It noted that "boilerplate language" in the Second SE Guidance stating that it "'do[es] not establish legally enforceable responsibilities . . . and should be viewed only as [a]

recommendation[ ]'" and that it "'does not establish any rights for any person and is not binding on FDA or the public'"—language that is identical to language Defendants cite in the August 2017 Guidance, *see* Defs.' Mem. 31 (quoting Aug. 2017 Guidance, ECF No. 48-1, at 714)—could not "dictate whether the Second SE Guidance is a final agency action fit for review." *Philip Morris*, 202 F. Supp. 3d at 46 (citing *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022–23 (D.C. Cir. 2000) (concluding that "boilerplate" language in guidance released by an agency does not determine whether an agency action has legal consequences)).

Rather, the court determines whether the guidance has legal consequences based on "the context and form in which the agency action arises." *Id.* at 46. The *Philip Morris* Court observed that, while "[n]on-legislative agency statements of the type at issue . . . generally do not qualify as a final agency action[,] . . . [t]hat does not mean, however, that such statements can *never* constitute final agency action." *Id.* (citing *Appalachian Power*, 208 F.3d at 1023). Indeed, agency statements "'can, as a practical matter, having a binding effect' which contributes to a finding that the action is 'final.'" *Id.* (quoting *Pharm. Research*, 138 F. Supp. 3d at 41).

> To determine if an agency's interpretive rule or guidance is sufficiently final to warrant pre-enforcement review, the court may consider a host of factors. The three most important factors are: (1) whether the agency has taken a "definitive legal position" regarding its statutory authority; (2) whether the case presents a "purely legal question of statutory interpretation;" and (3) whether the action "imposes an immediate and significant practical burden on the regulated entity."

Id. (quoting *Pharm. Research*, 138 F. Supp. 3d at 41–43).

In *Philip Morris*, the court concluded that "the first two factors [we]re easily met," and it focused on "whether the action imposes a significant burden on tobacco companies." *Id.* As for that factor, it concluded that the action did impose a significant burden because "[t]he fact that the FDA is purporting merely to interpret a statute that vests it with regulatory authority does not mean . . . that its action is not final," and "the 'distinction' between whether the statute or the guidance

is the actual source of binding authority is 'a hollow one without any meaningful difference.'" *Id.* at 47 (quoting *Pharm. Research*, 138 F. Supp. 3d at 44).

Here, the statute requires premarket review for all tobacco products, 21 U.S.C. § 387j(a)(2), (c)(1)(A), and the FDA announced in the August 2017 Guidance that certain products that had been deemed to be tobacco products could remain on the market for five years or more without premarket review. Aug. 2017 Guidance 8, GAR 429, ECF No. 48-1, at 721. Thus, the FDA has "taken a 'definitive legal position' regarding its statutory authority," asserting that it has the authority under the Tobacco Control Act to delay the premarket review requirement. *See Philip*, 202 F. Supp. 3d at 46. Indeed, the August 2017 Guidance gave "notice of how [the Tobacco Control Act] will be applied . . . ." *See Int'l Refugee Assistance Project*, 883 F.3d at 285. And, this case concerns a legal question of statutory interpretation: can premarket review be postponed, permitting a product to be on the market prior to approval, and if so, for how long? The FDA's action did not "impose[] an immediate and significant practical *burden* on the regulated entity." *Id.* (quoting *Pharm. Research*, 138 F. Supp. 3d at 41–43). In fact, it did the exact opposite—it removed the burden of premarket review, allowing products to be on the market for five years or longer prior to approval. Aug. 2017 Guidance 8, GAR 429, ECF No. 48-1, at 721. But, this factor still weighs in favor of finality under the circumstances, as the effects (welcomed by the manufacturers) on the regulated entities were "immediate and significant." And, the agency action does impose a burden; it simply is on Plaintiffs, rather than the regulated agencies. Further, the August 2017 Guidance marked the culmination of the FDA's decision-making process, as it served as a definitive statement that immediately brought a number of new tobacco products into compliance. Thus, the answer is "yes" to the "core question" of "whether the agency has completed its decisionmaking process, and whether the result of that process is one that will

directly affect the parties." *See Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992). Therefore, the August 2017 Guidance constitutes final agency action subject to this Court's review. *See id.; Int'l Refugee Assistance Project*, 883 F.3d at 285; *Philip Morris*, 202 F. Supp. 3d at 46–47.

APA Claims

Plaintiffs claim that the August 2017 Guidance "is ultra vires and unconstitutional," in violation of the APA, in that it "conflicts with the Tobacco Control Act; exceeds FDA's statutory authority; and violates the Constitution's Take Care clause, U.S. Const. art. II, § 3." Compl. ¶ 94; *see also id.* ¶¶ 92–102 (Count I). They also claim that, because the August 2017 Guidance "is a 'rule' within the meaning of the APA," the FDA violated the APA by issuing it without complying with the notice and comment requirements for rule-making. *Id.* ¶¶ 105–07; *see also id.* ¶¶ 103–10 (Count II). Additionally, Plaintiffs claim that the August 2017 Guidance "is arbitrary and capricious" because

> FDA offered *no* contemporaneous explanation whatsoever in the Guidance to justify [its] decisions [regarding deadlines] or to explain how those decisions are remotely consistent with FDA's statutory obligations to protect the public health from the dangers of tobacco products, the purposes of the Tobacco Control Act, the administrative record before the agency in the Deeming Rule, or FDA's own prior findings.

Id. ¶ 113; *see id.* ¶¶ 111–18 (Count III); *see also id.* ¶¶ 115–17 (August 2017 Guidance is inconsistent with compliance policy adopted in Deeming Rule and the findings in the Deeming Rule and other FDA statements, and the inconsistencies are unexplained). Specifically, they claim that "FDA failed to address—much less explain—how an indefinite review period comports with the 180-day review period prescribed by Congress in the Tobacco Control Act. 21 U.S.C. § 387j(c)(1)(A)," and did not "identif[y] any basis on which it determined the length of the newly announced compliance periods, nor has it provided any reasoned basis for establishing different

compliance periods for different product types—an approach it had previously rejected." *Id.* ¶ 114. On these bases, Plaintiffs ask the Court to vacate the August 2017 Guidance.

Defendants counter that the August 2017 Guidance "is fully consistent with the statutory text, is a policy statement exempt from notice and comment, and reflects an entirely reasonable enforcement strategy." Defs.' Mem. 33. As they see it, the Guidance "does not purport to modify or interpret any provision of the TCA [Tobacco Control Act]. Rather, it simply states that the FDA 'does not intend to enforce a particular requirement' of the statute for a limited period," which they insist is "an entirely unexceptional exercise of enforcement discretion that conflicts with no legislative directive." *Id.* (citing Aug. 2017 Guidance 4, ECF No. 48-1, at 717, GAR 425). And, Defendants insist that its publication of the August 2017 Guidance was neither arbitrary nor capricious because it "rationally explained its updated enforcement policy," and its "explanation was more than sufficient." *Id.* at 43, 45.[10]

Tobacco Control Act's Provisions and Extent of FDA's Statutory Authority

The power of an agency like the FDA "is 'not the power to make law. Rather, it is "the power to adopt regulations to carry into effect the will of Congress as expressed by the statute."'" *Brown & Williamson Tobacco Corp. v. Food & Drug Admin.*, 153 F.3d 155, 161 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000) (quoting *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 213–14 (1976) (citation omitted)). Moreover, "neither federal agencies [like the FDA] nor the courts can substitute their policy judgments for those of Congress." *Id.* at 176. Stated differently, the court's "estimations, and the [agency's] estimations, of desirable policy cannot alter the meaning of [a

[10] Because the undisputed evidence establishes that the August 2017 Guidance conflicts with the Tobacco Control Act and needed to follow the APA's notice and comment requirements, but failed to do so, I will grant Plaintiffs' motion on those grounds. Therefore, I need not consider their argument regarding whether Defendants' actions were arbitrary and capricious.

federal statute]." *Id.* (quoting *MCI Telecomm'cns Corp. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 234 (1994)). Thus, when the FDA takes action contrary to the FDCA, through that *ultra vires* action the FDA "exceed[s] the authority granted to it by Congress, and its . . . action cannot stand." *Id.*

In *Brown*, decided more than a decade before the Tobacco Control Act went into effect and authorized the FDA to regulate tobacco products' manufacture and distribution, the Fourth Circuit considered a final rule that the FDA published that "set out regulations restricting the sale and distribution of cigarettes and smokeless tobacco (collectively referred to as tobacco products) to minors and limiting the advertising and promotion of tobacco products." *Id.* The court concluded that publishing the rule was *ultra vires* action, reasoning that, even though "Congress . . . charged the FDA with protecting the public health and . . . tobacco products present serious health risks for the public," Congress did not intend for the FDA to regulate tobacco products. *Id*. at 167. The court noted that "neither the [FDCA] nor its legislative history mention[s] tobacco products," and "[f]rom 1914 until the present rulemaking attempt, the FDA had consistently stated that tobacco products were outside the scope of its jurisdiction." *Id.* at 168. The court observed:

> This is not a case about whether additional or different regulations are needed to address legitimate concerns about the serious health problems related to tobacco use, and particularly youth tobacco use, in this country. At its core, this case is about who has the power to make this type of major policy decision.

Id. at 176.

Here, as noted, FDA's across-the-board suspension of the Tobacco Control Act's premarket approval process, with regard to applications, substantial equivalence reports, exemption requests, approval and enforcement of these requirements, amounts to a rule amendment or revocation, as it is inconsistent with the statute. *See Acosta*, 363 F. Supp. 3d at 18. Through the August 2017 Guidance, the FDA is abdicating its statutory duty to review new tobacco products in the prompt fashion dictated by Congress in its *premarket* review requirements; as

Plaintiffs asserted, the FDA "will conduct a form of *post*market review, analyzing whether products should be introduced after they have been on the market for years." Pls.' Mem. 11. This is not simply a policy statement about how the FDA will act, within the confines of the Tobacco Control Act. I agree with Plaintiffs that "[t]hat is not the scheme envisioned by Congress and created by the Act," as "premarket review no longer operates as the gateway to the market that Congress intended." *Id.*

Moreover, the August 2017 Guidance defeats, rather than furthers, the purpose of the Tobacco Control Act by allowing unapproved tobacco products to be manufactured, advertised, and sold for five years or longer, and informing the manufacturers that the Tobacco Control Act requirements for premarket review will not be enforced. 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—results entirely contrary to the express purpose of the Tobacco Control Act. The publication of the August 2017 Guidance clearly was contrary to the Tobacco Control Act's purpose and therefore an *ultra vires* action through which the FDA "exceeded the authority granted to it by Congress, and its . . . action cannot stand." *See Brown & Williamson*, 153 F.3d at 176.

Defendants argue—and indeed the August 2017 Guidance itself states—that it is an exercise of "enforcement discretion." *See* Defs.' Mem. 33; Aug. 2017 Guidance 4, ECF No. 48-1, at 717, GAR 425. Certainly, Plaintiffs themselves refer to Defendants' enforcement discretion, but Plaintiffs' use of the term does not mean that it is applicable under the facts of this case.

It is true that the Supreme Court "has recognized on several occasions over many years that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion." *Chaney*, 470 U.S. at 831 (collecting cases). Therefore, as a matter of its "enforcement discretion," the FDA may decide not to enforce the provisions of the Tobacco Control Act with regard to specific products. *See id.* But, "if the court could find that "the agency ha[d] 'consciously and expressly adopted a general policy' that is so extreme as to amount to an abdication of its statutory responsibilities[,] . . . the statute conferring authority on the agency might indicate that such decisions were not 'committed to agency discretion.'" *Chaney*, 470 U.S. at 833 n.4. Such is the case here. Defendants are not deciding, on a case-by-case basis, to enforce or not enforce provisions of the Tobacco Control Act. Rather, they decided not to enforce the premarket review provisions *at all* for five years or longer. Moreover, the Tobacco Control Act makes clear that, insofar as the FDA has enforcement discretion, that discretion is circumscribed by the language of the Act itself, requiring applications, requests, and reports to be filed *before* products enter commerce and requiring an agency ruling within 180 days of the filing.

Further, the "enforcement discretion" argument is a red herring, because the August 2017 Guidance does not fulfill the purpose for which an agency is granted enforcement discretion. As for why an agency has enforcement discretion, the Supreme Court explained:

> [A]n agency decision not to enforce often involves a complicated balancing of a number of factors which are peculiarly within its expertise. Thus, the agency must

> not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all. An agency generally cannot act against each technical violation of the statute it is charged with enforcing. The agency is far better equipped than the courts to deal with the many variables involved in the proper ordering of its priorities. . . .

Chaney, 470 U.S. at 831–32. Simply put, an agency may decide whether to exercise its enforcement discretion as to one or more discrete violations, in light of the circumstances surrounding a particular violation and considering other responsibilities and resources that the agency has at that time. But this bears no relation to a decision to hold in abeyance enforcement of mandatory provisions of a statute that Congress viewed as integral to address public health dangers that the agency itself acknowledges are alarming for five or more years 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.

The *Chaney* Court also observed that

> an agency's refusal to institute proceedings shares to some extent the characteristics of the decision of a prosecutor in the Executive Branch not to indict—a decision which has long been regarded as the special province of the Executive Branch, inasmuch as it is the Executive who is charged by the Constitution to "take Care that the Laws be faithfully executed." U.S. Const., Art. II, § 3.

Chaney, 470 U.S. at 832. But, the decision here, not to enforce the premarket review requirements against any manufacturers, does not "share . . . the characteristics of the decision of a prosecutor . . . not to indict" to any extent; it is more akin to an across-the-board statement that *no one* will be indicted for a certain crime for a period of time. In sum, the FDA's action cannot fall within its enforcement discretion. Its action is inconsistent with the Tobacco Control Act and in excess of its statutory authority, and it cannot stand.

Notice and Comment

Plaintiffs contend that the August 2017 Guidance must be vacated because the FDA did not follow the APA's notice and comment requirements in issuing it. Pls.' Mem. 16. Defendants counter that the August 2017 Guidance "is a policy statement exempt from notice and comment." Defs.' Mem. 33.

"[W]hen an agency issues new 'legislative' or 'substantive' rules that establish binding norms having the force of law," it must follow the APA's notice and comment requirements. *Mallinckrodt Inc. v. United States Food & Drug Admin.*, No. DKC-14-3607, 2015 WL 13091366, at *11 (D. Md. July 29, 2015) (quoting *Berlex Labs., Inc. v. Food & Drug Admin.*, 942 F. Supp. 19, 26 (D.D.C. 1996) (quoting 5 U.S.C. § 553)); *see also Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1206 (2015). In contrast, "'[i]nterpretive' rules . . . are expressly excused from the notice-and-comment requirements." *Mallinckrodt*, 2015 WL 13091366, at *11 (quoting *Berlex Labs.*, 942 F. Supp. at 26 (quoting 5 U.S.C. § 553(b)(3)(A))). Thus, the issue is whether the August 2017 Guidance qualifies as a legislative rule or an interpretive rule.

A rule is "the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." 5 U.S.C. § 551(4). A rule is interpretive if it is "issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Mallinckrodt*, 2015 WL 13091366, at *11 (quoting *Berlex*, 942 F. Supp. at 26 (quoting *Shalala v. Guernsey Memorial Hosp.*, 514 U.S. 87, —— (1995))). A rule is legislative

> if any one of the following four questions is answered in the affirmative:
>
> > (1) whether in the absence of the rule there would not be an adequate legislative basis for ... agency action to confer benefits or ensure the performance of duties,

> (2) whether the agency has published the rule in the Code of Federal Regulations,
>
> (3) whether the agency has explicitly invoked its general legislative authority, or
>
> (4) whether the rule effectively amends a prior legislative rule.

Id. at *11–12 (quoting *Berlex*, 942 F. Supp. at 26 (quoting *American Mining Congress v. Mine Safety & Health Admin.*, 995 F.2d 1106, 1112 (D.C. Cir. 1993))). The answer to the fourth question is "yes" if, through the rule, the "agency adopts a new position inconsistent with an existing regulation, or effects a substantive change in the regulation." *Nat'l Mining Ass'n v. Jackson*, 768 F. Supp. 2d 34, 48 (D.D.C. 2011) (observing that, under these circumstances, "notice and comment are required") (quoting *U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 35 (D.C. Cir. 2005)). "Such a rule 'grant[s] rights, impose[s] obligations, or *produce[s] other significant effects on private interests*;' 'narrowly constrict [s] the discretion of agency officials by largely determining the issue addressed'; and '[has] substantive legal effect.'" *Id.* (quoting *Batterton v. Marshall*, 648 F.2d 694, 701–02 (D.C. Cir. 1980)) (emphasis added). Notably, "the standard for determining whether an agency pronouncement is a legislative rule is very similar to the second element of the *Bennett* finality analysis."[11] *Id.*

In *Mallinckrodt*, 2015 WL 13091366, this Court turned to *Berlex*, 942 F. Supp. 19, and *National Mining Ass'n v. McCarthy*, 758 F.3d 243 (D.C. Cir. 2014), for guidance. The *Berlex* Court had considered whether an FDA guidance document was an interpretive or legislative rule and had determined that it was an interpretive rule "because all four of the criteria articulated in *American Mining Congress* were answered in the negative." *Mallinckrodt*, 2015 WL 13091366,

[11] As noted above, the second requirement for finality is that "the action must be one by which rights or obligations have been determined or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 178 (1997).

at *12. In concluding that the rule did not "effectively amend[] a prior legislative rule," the court reasoned:

> The existing FDA regulation requires the submission of "data derived from nonclinical laboratory and clinical studies." 21 C.F.R. § 601.2(a). In the guidance document, FDA interpreted that language to include data from clinical studies completed on "comparable" biological products. Comparability Guidance Document, 3. That interpretation extended the boundaries of previous FDA actions and policies, to be sure, but it did not "run[ ] 180 degrees counter to the plain meaning of the regulation," as did the agency directive at issue in *National Family Planning and Reproductive Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227, 235 (D.C. Cir. 1992).

Id. (quoting *Berlex*, 942 F. Supp. at 26). Thus, the guidance document "neither repudiate[d] nor [wa]s inconsistent with any pre-existing FDA regulations." *Berlex*, 942 F. Supp. at 26.

In *McCarthy*, the appellate court similarly had considered whether an Environmental Protection Agency ("EPA") guidance document "was a general policy statement or a legislative rule subject to judicial review," concluding that it was a policy statement. *Mallinckrodt*, 2015 WL 13091366, at *12.

> The court emphasized that in determining whether something is a legislative rule "[t]he most important factor concerns the actual legal effect (or lack thereof) of the agency action in question on regulated entities." The court noted that the guidance document in question . . . did "not tell regulated parties what they must do or may not do in order to avoid liability[,]" did not impose "obligations or prohibitions on regulated entities[,]" could not serve as "the basis for an enforcement action against a regulated entity[,]" and did "not impose[] any requirements in order to obtain a permit or license." In addition, the court assessed the agency's characterization of the guidance, and noted that the document itself "disclaims any intent to require anyone to do anything" and the language used throughout the document was devoid of commands, requirements, or orders.

Id. (quoting *McCarthy*, 758 F.3d at 252–53).

The *Mallinckrodt* Court likewise concluded that the FDA draft guidance document before it, which reclassified a drug of Mallinckrodt's, "was an interpretive rule rather than a legislative rule." *Id.* at *13. It reasoned that the FDA had a pre-existing duty to determine whether

bioequivalence had been established and therefore had "the authority to require Mallinckrodt to establish the bioequivalence of its drug using the criteria and measurements FDA f[ound] necessary for the given product"; the "FDA did not invoke its general authority" to publish the draft guidance document; the language of the draft guidance document stated that it did "not create or confer any right"; and "the document itself [wa]s devoid of commands, orders, or binding requirements." *Id.* Additionally, it found that the draft guidance document "did not effectively amend a prior legislative rule because it 'neither repudiate[d] nor [wa]s inconsistent with any pre-existing FDA regulations"; rather, it "merely fine-tuned the measurements and metrics it believe[d] [we]re most useful in measuring bioequivalence" in the drug at issue. *Id.* at *14. The court explained:

> It has done so by altering its 2012 Guidance Document to tweak its recommendations on what measures are most helpful in determining this particular product's bioequivalence. The recommended studies and metrics in the 2014 Guidance Document are consistent with the agency's regulations on bioequivalence and with the recommendations made in the 2012 Guidance Document. The revised 2014 Guidance Document merely requests some additional metrics to ensure the drug's bioequivalence, as the prior metrics may not adequately capture the bioequivalence and efficacy of the drug in the later phases of the twelve-hour dose. The additional metrics requested by FDA fall within the normal range of evidence and measures that FDA may request as part of its process of assessing bioequivalence. Accordingly, FDA's 2014 Guidance Document is not irreconcilable with nor does it repudiate FDA's regulations on bioequivalence or FDA's prior 2012 Guidance Document. The Guidance Document merely clarifies the metrics FDA believes are helpful in showing bioequivalence.

Id. (citations to record and C.F.R. omitted).

National Mining Association v. Jackson, 768 F. Supp. 2d 34 (D.D.C. 2011), is on point with circumstances of the case before me. There, the plaintiff filed suit because the EPA had issued "a series of memoranda and a detailed guidance," which the plaintiff believed "unlawfully obstructed the Clean Water Act permitting process for coal mining." 768 F. Supp. 2d at 38. The court observed that, through the documents, "the EPA seem[ed] to be imposing an additional step

to the permitting process that [wa]s not contemplated or set forth in the [Clean Water Act Section] 404(b)(1) guidelines," and "these changes to the statutorily established process g[a]ve rise to the legal consequences necessary to satisfy the second prong of the *Bennett* finality analysis." *Id.* at 44, 45. It noted that the EPA was applying the guidance memorandum "in a binding manner" and implementing it "in its current version even though the EPA continue[d] to receive comments about it," such that it "qualifie[d] as final agency action . . . despite the [EPA's] representation that it [wa]s an interim document." *Id.* at 45. The court concluded that, on the same basis, the documents constituted "legislative rules that were adopted in violation of the APA's notice and comment requirements." *Id.* at 49. It reasoned:

> As explained above in regard to the Court's finality analysis, based on the record currently before the Court the MCIR Assessment, the EC Process Memoranda, and the Guidance Memorandum all appear to qualify as legislative rules because they seemingly have altered the permitting procedures under the Clean Water Act by changing the codified administrative review process. Thus, the MCIR Assessment, the EC Process, and the Guidance Memorandum all seem to "effectively amend" the Clean Water Act's permitting process, *Am. Mining Cong.*, 995 F.2d at 1112, and represent the EPA's adoption of a new position inconsistent with an existing regulation. *U.S. Telecom Ass'n*, 400 F.3d at 34–35.

Id.

Finally, in *National Family Planning and Reproductive Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227 (D.C. Cir. 1992), the plaintiff challenged a Department of Health and Human Services ("HHS") directive that, in its view, amended a 1998 HHS regulation. The regulation provided that a "Title X project may not provide counseling concerning the use of abortion as a method of family planning or provide referral for abortion as a method of family planning." 979 F.2d at 234 (quoting 42 C.F.R. § 59(a)(1)). The Department of Health and Human Services previously "interpreted [that] 1988 regulation . . . not to permit physicians to counsel patients on abortion." *Id.* The Supreme Court agreed. *Id.* at 236. Then, HHS issued a directive, without adhering to the APA

notice and comment requirements, "announcing that [the] 1988 regulation . . . would thereafter be interpreted to permit doctors to counsel on abortion within the context of the doctor–patient relationship." *Id.* at 228–29; *see id.* at 234–35 ("The Directives say that Title X physicians may, pursuant to the same regulations, provide counseling and referrals for abortions when their medical judgment so dictates.").

Observing that "[i]t is a maxim of administrative law that: 'If a second rule repudiates or is irreconcilable with [a prior legislative rule], the second rule must be an amendment of the first; and, of course, an amendment to a legislative rule must itself be legislative,'" the court concluded that the directive was a legislative rule because its "interpretation of the [regulation ran] 180 degrees counter to the plain meaning of the regulation" and its earlier interpretation of the regulation. *Id*. at 235 (quoting Michael Asimow, *Nonlegislative Rulemaking and Regulatory Reform*, 1985 Duke L.J. 381, 396). The appellate court held that HHS could not "proceed[] with the enforcement of the new Directives without first adhering to the requirements of § 553 of the APA." *Id.* at 229.

Here, as discussed with regard to finality, the August 2017 Guidance is not a policy statement; it is tantamount to an amendment to the Tobacco Control Act. As with the guidance and other documents at issue in *Jackson*, the August 2017 Guidance implements "changes to the statutorily established process." 768 F. Supp. 2d at 45. Those changes have "legal consequences," and the agency has put the process established in the August 2017 Guidance into effect. *See id.* at 44–45. Certainly, its requirements are *more* favorable to manufacturers than the Tobacco Control Act, essentially lifting statutory prohibitions for five or more years and imposing obligations across a longer timeframe. Nevertheless, the language used in the August 2017 Guidance includes commands, requirements, and order: It tells manufacturers when they must submit their

applications, reports, and requests for new tobacco products. More fundamentally, these requirements cannot be reconciled with the Tobacco Control Act, as they "run[ ] 180 degrees counter to the plain meaning of the [statute]," which set much more stringent deadlines. *See Nat'l Family Planning*, 979 F.2d at 235; *see also Mallinckrodt*, 2015 WL 13091366, at *12; *Berlex*, 942 F. Supp. at 26. Thus, applying the factors identified in *Mallinckrodt* confirms that the August 2017 Guidance is a rule amendment and therefore a legislative, rather than interpretive, rule. *See Mallinckrodt*, 2015 WL 13091366, at *12. Even if the half-decade or longer extension were a rational decision within the FDA's discretion, the FDA could not have made that decision without adhering to the APA. Accordingly, the August 2017 Guidance must be vacated.

Conclusion

In sum, Plaintiffs' Motion for Reconsideration, ECF No. 63, IS GRANTED and the parties' cross-motions, ECF Nos. 31 and 36, ARE REOPENED; Defendants' Motion to Dismiss or, in the Alternative, for Summary Judgment, treated as a motion for summary judgment, IS DENIED; and Plaintiffs' Motion for Summary Judgment, ECF No. 31, IS GRANTED. This Memorandum Opinion and the accompanying Order vacate the FDA's August 2017 Guidance.

Given that the application deadlines set in the Deeming Rule and the May 2017 Guidance have passed, Plaintiffs will submit additional briefing regarding a remedy (which should be specific, rather than generalized), in fifteen pages or less, within fourteen days of the date of this Memorandum Opinion. Defendants will have fourteen days to respond, in fifteen pages or less, and Plaintiffs will have five business days to reply, in ten pages or less. Any Guidance providing for a compliance period will, of course, have to adhere to the notice and comment requirements of the APA. Even so, 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. And, in adopting new Guidance, the APA can propose that the deadlines can be set sufficiently soon beyond the end of the notice and comment period to afford relief to Plaintiffs and to attempt to combat the epidemic-level use of new tobacco products like e-cigarettes, especially by teenagers.

A separate order will issue.

Date: May 15, 2019

/S/
Paul W. Grimm
United States District Judge

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