IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

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

MEMORANDUM IN SUPPORT OF
PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

The challenged "Guidance for Industry," issued by the Food and Drug Administration ("FDA") in August 2017, enables manufacturers of e-cigarettes, cigars, and other newly deemed tobacco products to continue marketing those products to children and the public for years (potentially indefinitely) without seeking or obtaining the premarket review by FDA that Congress unambiguously required. The Guidance thus unlawfully nullifies a central feature of the regime Congress established to ensure that new tobacco products satisfy basic public health standards by suspending premarket review until sometime in the next decade. FDA's deliberate decision to grant blanket permission to the continued marketing of unreviewed new tobacco products is in direct violation of federal law and defeats critical congressional objectives.

The Guidance is contrary not only to the substantive statute that it purports to implement, but also to the Administrative Procedure Act ("APA"). The Guidance is a binding substantive rule that required prior notice and an opportunity for public comment because it gives industry the right to market products without an FDA marketing order and precludes FDA from enforcing critical statutory mandates for years to come. Yet FDA rushed to promulgate the Guidance in violation of the APA's bedrock notice-and-comment requirements. Given FDA's defiance of those procedures—which are designed to ensure deliberative agency decisionmaking—it is unsurprising that FDA failed to provide a reasoned, supported justification for its sweeping exemption of newly deemed tobacco products from premarket review. FDA's failure to explain its choice, or to account for the costs to public health from allowing unreviewed new tobacco products to remain on the market, renders the Guidance arbitrary and capricious.

The real-world consequences of FDA's unlawful actions are momentous. As Congress has found, the "use of tobacco products by the Nation's children is a pediatric disease of considerable proportions that results in new generations of tobacco-dependent children and

adults," and "[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products." Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, § 2, 123 Stat. 1776, 1777 (2009). Even as cigarette use has declined, overall youth use of tobacco products has actually increased in recent years because the use of e-cigarettes and flavored cigars has skyrocketed.

Indeed, FDA has recently explained that "[e]-cigarettes are the fastest growing segment of the tobacco market." Brief for Appellees 16, *Nicopure Labs, LLC v. FDA*, No. 17-5197 (D.C. Cir. May 2, 2018). Citing its own findings, FDA stated that "[t]he use of these products has surged among middle and high school students in particular, including those with no history of smoking." *Id.* Adding to this problem, FDA has recognized that manufacturers have introduced hundreds of flavored cigars to attract underage users and that the use of cigars by young males in some age groups now exceeds use of cigarettes in many States. AR11,931.[1] Under the statutory regime Congress designed, the lion's share of these products could not be lawfully marketed today absent FDA premarket review. But the new policy announced in the Guidance allows whole classes of the very products that are creating and sustaining this epidemic to remain on the market for years without the public-health review mandated by Congress.

This Court should vacate the Guidance and grant appropriate equitable relief.

BACKGROUND

A. The Tobacco Control Act

To protect the public, especially children, against the catastrophic health risks created by tobacco products—"perhaps the single most significant threat to public health in the United

[1] Citations to "AR" are to the Deeming Rule's administrative record. Citations to "GAR" are to the Guidance's separate administrative record, which is separately paginated. Defendants have informed Plaintiffs that a copy of the administrative record will be lodged with the Court shortly.

States," *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 161 (2000)—Congress enacted the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act," "TCA," or "Act") in 2009 as a comprehensive scheme for the regulation of tobacco products.

Congress enacted the statute based on detailed findings about the public-health risks posed by tobacco products. In addition to finding that "use of tobacco products by the Nation's children is a pediatric disease of considerable proportions," Congress concluded that "[n]icotine is an addictive drug"; that "comprehensive restrictions on the sale, promotion, and distribution of [tobacco] products are needed"; and that "[i]t is in the public interest" to "provide[] [FDA] with the authority to regulate" in this area. TCA § 2, 123 Stat. at 1777.

The Tobacco Control Act thus amended the Food, Drug, and Cosmetic Act ("FD&C Act") to authorize FDA to regulate not only "all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," but "any other tobacco products that [HHS] by regulation deems to be subject" to the FD&C Act. 21 U.S.C. § 387a(b). FDA's authority to "deem" tobacco products took effect immediately upon the enactment of the Act. The requirements of the Act at issue here apply equally to those tobacco products enumerated by the Act itself, *id.*, and to those tobacco products "deemed" subject to regulation by FDA.

A key component of the Act's regulatory requirements is a premarket review process administered by FDA and designed to prevent the marketing of new tobacco products unless FDA finds that the sale of such products is consistent with protection of the public health as defined in the Tobacco Control Act. Under the premarket review process, every "new tobacco product"—meaning any tobacco product not on the market in the United States as of February 15, 2007—must be authorized by FDA for sale in the United States before it may enter the commercial marketplace. 21 U.S.C. § 387j(a)(1)-(2). With a single exception described below,

premarket authorization is thus required for any "deem[ed]" tobacco product that was not commercially marketed on February 15, 2007. *Id.* §§ 387a(b), 387j. Products commercially marketed on or before that date are grandfathered and need not receive premarket authorization.

The Tobacco Control Act establishes three permissible pathways to authorization:

Premarket tobacco application for new products. A manufacturer may submit a premarket tobacco application, or "PMTA," 21 U.S.C. § 387j(b), which must include, among other things, information about the product's ingredients, properties, health risks, manufacturing and labeling, *id.* § 387j(b)(1). Congress required FDA promptly to review such applications, mandating that it "shall deny" an application unless it finds that marketing the product "would be appropriate for the protection of the public health." *Id.* § 387j(c)(2)(A). If a manufacturer sells a new tobacco product without obtaining such an order or satisfying one of the two alternative pathways to distribution, the product "shall be deemed to be adulterated," *id.* § 387b(6), and is subject to seizure and injunctive action, *id.* §§ 331(a), 332, 334, 372.

Substantial equivalence report. Alternatively, a manufacturer may submit a substantial equivalence report, or "SE Report," demonstrating that a new tobacco product is "substantially equivalent" to a grandfathered product that was on the market as of February 15, 2007. 21 U.S.C. §§ 387e(j)(1), 387j(a)(3). If FDA determines that the new product is substantially equivalent and otherwise "in compliance with the requirements of [the FD&C Act]," FDA may issue an order to that effect, and the new product may enter the market. *Id.* § 387j(a)(2)(A)(i).

Substantial equivalence exemption. Finally, a manufacturer may request an exemption from the substantial equivalence requirements, or an "SE Exemption." 21 U.S.C. § 387e(j)(3). This pathway is available for products that, among other things, constitute only "minor modification[s]" of grandfathered products. *Id.* If FDA issues an order authorizing an SE

exemption, the new product may proceed to market. *Id.* § 387j(a)(2)(A)(ii).

Congress created only one exception to this regime. A manufacturer that placed a new tobacco product on the market *and* submitted an SE Report by March 22, 2011—i.e., within "21 months after" the effective date of the Act—was permitted to market the product unless and until FDA found the product not substantially equivalent. 21 U.S.C. §§ 387j(a)(2)(B), 387e(j)(2). No other "new tobacco products" may be marketed until FDA finds that they are (1) "appropriate for the protection of the public health," *id.* § 387j(c)(2)(A); (2) substantially equivalent to a grandfathered product, *id.* § 387e(j)(1); or (3) exempt from SE requirements, *id.* § 387e(j)(3).

B. The Deeming Rule

In April 2014, almost five years after the Tobacco Control Act's effective date, FDA proposed a rule to deem certain unregulated tobacco products—including e-cigarettes, cigars, and pipe tobacco—to be subject to the FD&C Act and FDA regulation. *See* AR2.

Despite statutory premarket review requirements, FDA also proposed what it called a "compliance policy" that would allow manufacturers of deemed products to submit applications of any kind within a 24-month window, during which newly deemed products could remain on the market. AR34; *see also* AR35-36. FDA proposed extending this exemption period indefinitely "pending [agency] review of marketing applications," as long as applications were submitted within this period. AR34. Thus, under the proposed rule, manufacturers that submitted timely applications for their newly deemed tobacco products could leave those products on the market without a marketing order unless and until FDA denied the application.

FDA received numerous comments on the proposed rule. As relevant here, the public-health organization Plaintiffs, among others, strongly objected to many aspects of FDA's "compliance policy," including the length of time given to manufacturers to file premarket applications and the proposal that newly deemed tobacco products remain on the market

indefinitely pending FDA's review. *E.g.*, Compl. ¶¶ 69-72 (citing comments). They explained that FDA's proposed approach would "permit deemed products" to be sold that "would otherwise be illegal," AR145,604, and that if the agency were to take such an extraordinary step, it must do so only after imposing restrictions to safeguard the public health, *id.* Tobacco product manufacturers, by contrast, sought a wholesale exemption from Congress's premarket review mandate, lengthier statutory exemption periods, and different application requirements for different product categories. *E.g.*, AR45,132; AR140,977; AR158,189-158,192.

FDA promulgated the Deeming Rule on May 10, 2016. AR11,882. The Rule deemed e-cigarettes,[2] cigars, and hookah and pipe tobacco to be subject to the Tobacco Control Act. FDA supported that determination with detailed findings regarding the health risks of newly deemed products as well as the vital need for regulatory oversight, including premarket review. *See, e.g.*, AR11,928-11,935 (cigars); AR11,936-11,944 (e-cigarettes). FDA found that the "public health benefits that will accrue from the premarket review provisions are substantial," explaining that "review is especially critical given the changing nature of the [vaping] technology and industry and the increasing interest in these products from youth and young adults." AR11,911.

After considering the extensive comments submitted, FDA modified the exemption period described in its proposed rule. Instead of providing 24 months to manufacturers of any new tobacco products, FDA provided a 24-month exemption period only to manufacturers planning to submit PMTAs. AR11,918. Compliance periods for SE Reports and SE Exemption requests were reduced to 18 and 12 months, respectively. AR11,919. FDA also modified the proposed compliance approach governing newly deemed products during the period FDA was

[2] E-cigarettes and other "vaping" devices are sometimes referred to as "electronic nicotine delivery systems," or "ENDS." Plaintiffs use the terms synonymously here.

considering the applications. FDA announced that "products for which timely premarket submissions have been submitted [would] be subject to a continued compliance period for 12 months" only. *Id.* After that, the agency would "consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period." AR11,918. FDA explained in detail the reasons why these changes were necessary for the protection of the public health. AR11,920-11,923.

C. FDA's "Guidance"

On May 15, 2017, FDA advised that it would extend by three months all "future compliance deadlines for requirements under the final deeming rule." GAR210. Then, on August 10, 2017, FDA announced a new and significantly revised compliance policy in the form of "Guidance for Industry." GAR420; *see also* 82 Fed. Reg. 37,459 (Aug. 10, 2017). FDA issued the Guidance without prior public comment or a finding of "good cause" to dispense with the APA's requirements of notice and comment—and thus without building a record to evaluate and justify FDA's abrupt change in regulatory policy.

The Guidance applies to "all categories of newly regulated products that were on the market on August 8, 2016," the effective date of the Deeming Rule, "including ENDS (e.g., e-cigarettes and e-cigars), hookah, pipe tobacco, and cigars." GAR424. The Guidance amends the Deeming Rule's exemption period and premarket review requirements in significant ways. First, the Guidance extends the "deadlines" associated with the prior exemption period established by the Deeming Rule, exempting manufacturers of new tobacco products from premarket review for many years. Under the prior approach, manufacturers faced staggered deadlines depending on the type of application: SE Exemption requests were due on August 8, 2017 (12 months after the rule's effective date); SE Reports on February 8, 2018 (18 months); and PMTAs on August 8, 2018 (24 months). The Guidance establishes a longer set of deadlines that vary based not on

application but product type. The deadline for any application for authorization to market cigars and other combustible products is now August 8, 2021—*five* years from the Deeming Rule's effective date. GAR429. The deadline for all e-cigarette and other non-combustible product applications is August 8, 2022—*six* years from the Rule's effective date. *Id.*

Second, the Guidance "revis[es] the compliance policy relating to the period after FDA receipt" of applications. GAR424. In promulgating the Deeming Rule, FDA had decided against adopting its initial proposal, which would have allowed products to remain on the market indefinitely; instead, it had established a limited 12-month period in which manufacturers could continue to market their products pending FDA review. The Guidance reverts to the previously rejected approach. As a result, a manufacturer that submits an application before the new deadlines in 2021 or 2022 can continue to market unapproved tobacco products *indefinitely*.

Plaintiffs—seven public-health organizations on the front line of efforts to prevent tobacco use, particularly by youth, and five pediatricians whose practice of medicine is directly affected by FDA's failure to regulate new tobacco products, especially e-cigarettes and cigars—brought this action under the APA challenging the Guidance. *See* Compl. ¶¶ 8-24, 32-51.

ARGUMENT

The Guidance effectively annuls FDA's statutory review obligations for a significant number of new tobacco products for years and permits manufacturers to sell those products (including e-cigarettes and cigars targeted at youth) indefinitely without complying with the premarket review requirements Congress designed to safeguard public health. The Guidance is contrary to law, as it rips a hole in the statutory framework that Congress established to govern new tobacco products. Even if the Guidance could be squared with the Tobacco Control Act, it accomplishes a seismic shift in the responsibilities of tobacco product manufacturers, permitting

the sale of addictive and potentially deadly products that would otherwise have been unlawful—and so could only be issued pursuant to the APA's notice-and-comment requirements, which FDA failed to follow. Finally, the Guidance is arbitrary and capricious because FDA offered no contemporaneous explanations, much less reasonable ones, for sudden changes in its compliance policy, and failed to account for the devastating public-health consequences that would result.[3]

I. THE GUIDANCE IS CONTRARY TO LAW

A. FDA's Suspension Of Premarket Review Violates The Tobacco Control Act

FDA is "a creature of statute. It has no constitutional or common law existence or authority, but only those authorities conferred upon it by Congress." *Michigan v. EPA*, 268 F.3d 1075, 1081 (D.C. Cir. 2001). Consistent with basic separation-of-powers principles, FDA's "power to act and how [it is] to act is authoritatively prescribed by Congress, so that when [it] act[s] improperly … what [it] do[es] is ultra vires." *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013). By defying FDA's statutory review obligations and also authorizing manufacturers to sell classes of new tobacco products absent required FDA premarket review for an indefinite period, the Guidance exceeds FDA's authority and contravenes these basic principles.

First, the Guidance announces FDA's intent to countermand a duty assigned to it by statute: its responsibility to conduct premarket review of new tobacco products on the market as of August 2016. The Tobacco Control Act plainly makes premarket review mandatory, not discretionary, for both regulated entities and FDA. As to manufacturers, the Act directs, in a section entitled "[p]remarket review required," that an FDA order authorizing a manufacturer to sell a new tobacco product "is *required*" before that product "may be introduced or delivered for introduction into interstate commerce." 21 U.S.C. §§ 387j(a)(2), (c)(1)(A)(i) (emphasis added).

[3] A standard of review section is included as a separate attachment to Plaintiffs' motion.

Quite obviously, "required" imposes a mandatory duty, not a liberty. *See, e.g.*, *New Oxford American Dictionary* 1439 (2d ed. 2005) (defining "require" as "specify as compulsory").

The Tobacco Control Act likewise commands FDA to undertake premarket review. Congress required that, "[a]s promptly as possible, but in no event later than 180 days after receipt of [a PMTA]," FDA "*shall*" either "issue an order that the new product may be introduced … if [it] finds that" none of the grounds for exclusion apply or "issue an order that the new product may not be introduced" if it finds that any one of those grounds does apply. 21 U.S.C. § 387j(c)(1)(A) (emphasis added). The Act also states that FDA "*shall* deny an application" if FDA makes any of the statutory findings. *Id.* § 387j(c)(2) (emphasis added). The text and structure of the Tobacco Control Act thus firmly establish that premarket review is mandatory, not discretionary, for regulated entities and FDA alike.

The Act's legislative history confirms this basic statutory point. The House Report states that the Act "*requires* premarket review for *all* new tobacco products entering the market[] unless … the product is substantially equivalent to an existing product." H.R. Rep. No. 111-58, pt. 1, at 40 (2009) (emphasis added). The Report similarly describes FDA's responsibilities in mandatory terms: The Act "requires" FDA "to make a determination of whether to allow the new product to enter the market or deny the application." *Id.* at 41.[4]

The Guidance plainly violates these legislative directives. Under the Guidance, FDA will not conduct premarket review for any new tobacco product introduced to the market by August

[4] Indeed, FDA has acknowledged this mandate. In responding to an argument that FDA should forego premarket review, FDA explained that "Congress carefully crafted a system whereby 'new' tobacco products would be prevented from entering the market unless found" to have satisfied one of the pathways to distribution. Defs.' Cross-Mot. for Summ. J. 67, *Nicopure Labs, LLC v. FDA*, No. 16-cv-878 (D.D.C. Aug. 17, 2016), ECF No. 43. "There are no exemptions," *id*. at 46, and "[t]he statute itself admits of no other reading," *id.* at 49.

8, 2016; at best, more than a half-decade later, it will conduct a form of *post*market review, analyzing whether products should be introduced after they have been on the market for years. That is not the scheme envisioned by Congress and created by the Act.

Second, the Guidance purports to authorize manufacturers of new tobacco products to sell them for an indefinite period of time by establishing an exemption period found nowhere in the Tobacco Control Act. Under the Act, a limited class of new tobacco products could be marketed before FDA had conducted premarket review: products introduced to the market before March 22, 2011 for which a timely SE Report was submitted. 21 U.S.C. §§ 387j(a)(2)(B), 387e(j)(2). "It is hard to imagine a statutory term less ambiguous" than the exemption period authorized by the statute, which applied only to a defined number of products and only for a limited duration. *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2445 (2014) ("*UARG*"). But FDA has replaced those terms "with others of its own choosing," and in doing so has gone "well beyond the 'bounds of its statutory authority.'" *Id.* Indeed, "the need to rewrite clear provisions of the statute should have alerted [FDA] that it had taken a wrong interpretive turn." *Id.* at 2456.

The Guidance takes a statutory exemption limited in multiple ways—including that it had already expired—and transforms it through regulatory fiat into a sweeping immunity from core statutory requirements. Under the Guidance, a manufacturer of *any* new tobacco product placed on the market by August 8, 2016 can continue to advertise and sell that product to consumers *indefinitely* as long as it submits an application of *any* kind to FDA by 2021 or 2022. The result is a regulatory regime antithetical to the statutory scheme, one in which premarket review no longer operates as the gateway to the market that Congress intended. Indeed, were FDA correct that it had unfettered authority to suspend premarket review requirements for whole classes of products, Congress's purposes of protecting public health would go unrealized in critical

respects. *See Citizens Bank of Maryland v. Strumpf*, 516 U.S. 16, 20 (1995) ("It is an elementary rule of construction that 'the act cannot be held to destroy itself.'"); *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. Ruckelshaus*, 719 F.2d 1159, 1165 (D.C. Cir. 1983) ("A statute should ordinarily be read to effectuate its purposes rather than to frustrate them.").

Moreover, the statutory structure makes plain Congress's intent to preclude FDA from creating exemptions of this kind. The Act establishes one (and only one) exemption to premarket review: the 21-month exemption period afforded to manufacturers that submitted an SE Report by March 22, 2011. *See* 21 U.S.C. §§ 387j(a)(2)(B), 387e(j)(2). The Act likewise provides FDA with one (and only one) source of authority to craft its own exemptions to premarket review: a narrow provision that authorizes the agency to "exempt tobacco products intended for investigational use from the provisions of this subchapter." *Id.* § 387j(g). These tailored provisions are powerful evidence that Congress did not impliedly intend to authorize FDA to craft other exemptions to suit its preferences. *See Hillman v. Maretta*, 569 U.S. 483, 496 (2013) ("[W]here Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent."); *Roy v. Cnty. of Lexington*, 141 F.3d 533, 539 (4th Cir. 1998) (same).[5]

Finally, even were the Act ambiguous (and it is not), any ambiguity would be resolved against FDA under the canon of constitutional avoidance. *See United States v. Hamilton*, 699 F.3d 356, 367 (4th Cir. 2012). "There is no provision in the Constitution that authorizes the President … to amend … or to repeal statutes." *Clinton v. City of New York*, 524 U.S. 417, 438

[5] The absence of an express restriction on FDA disregarding its statutory responsibilities is of no moment. "Courts will not presume a delegation of power based solely on the fact that there is not an express withholding of such power." *Chamber of Commerce of U.S. v. NLRB*, 721 F.3d 152, 159 (4th Cir. 2013) (internal quotation marks omitted); *see also Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 161 (4th Cir. 1998), *aff'd*, 529 U.S. 120 (2000).

(1998). Yet FDA's interpretation would do just that—arrogating to the agency a statutory dispensing power that could be exercised simply by invoking the magic words of "enforcement discretion," in derogation of the command that the Executive Branch "take Care that the Laws be faithfully executed." U.S. Const., art. II, § 3. At a minimum, the Constitution forbids the Executive Branch from declaring that conduct made unlawful by Congress through the "finely wrought" procedures of bicameralism and presentment is somehow lawful through unilateral enforcement policy. *Clinton*, 524 U.S. at 440. Any other reading of the Tobacco Control Act would unconstitutionally vest in the Executive Branch legislative power to rewrite laws.

In short, through the Guidance, FDA has attempted to amend the Tobacco Control Act by suspending the premarket review system Congress viewed as essential to accomplish the public-health objectives of the Act for whole classes of products, thereby authorizing illegal sales of those products. The Guidance is thus *ultra vires* and should be vacated.

B. FDA's Invocation Of "Enforcement Discretion" Is No Defense

Finding no recourse in the statutory text, FDA grounds the Guidance in "enforcement discretion." GAR425. FDA's reliance on such discretion is misplaced.

At a basic level, FDA's invocation of "enforcement discretion" is a sleight of hand. "Enforcement discretion" is what a prosecutor exercises in deciding whether to bring a criminal case or an agency exercises in deciding whether to initiate an enforcement action. That is what the Supreme Court meant in *Heckler v. Chaney*, which involved novel demands by death row inmates for FDA to "take various enforcement actions" against lethal injection drugs. 470 U.S. 821, 823 (1985). The question here is different: Can FDA decline to perform a statutorily mandated function for years for entire categories of products? Fairly understood, that is not *enforcement* discretion any more than would be, for example, an agency's failure to perform required licensing duties or to issue a mandated report to Congress; it is instead a question of an

agency's duty to obey the law. *Chaney* thus has no application.

Moreover, even if FDA's across-the-board refusal to engage in premarket review of classes of new products could be framed as "enforcement discretion," Congress unambiguously cabined that discretion. The Act, as described above, *requires* FDA to conduct this review, subject only to a single (now-expired) exemption. In the face of those duties, FDA lacks the authority to "abdicat[e] … its statutory [review] responsibilities" in the manner envisioned by the Guidance. *Chaney*, 470 U.S. at 833 n.4; *see id.* at 833 ("Congress did not set agencies free to disregard legislative direction in the statutory scheme that the agency administers"); *id.* at 839 (Brennan, J., concurring) (*Chaney* does not apply where "agency engages in a pattern of nonenforcement of clear statutory language"). The Guidance is plainly a "policy" that reflects a "conscious[]" and "express[]" statutory abdication—it is categorical; it applies broadly to all classes of newly deemed products on the market as of August 2016; and it is long-term, lasting at least half a decade. *See Adams v. Richardson*, 480 F.2d 1159, 1162 (D.C. Cir. 1973) (en banc). *Chaney* is inapplicable in such circumstances. *See id.*; *see also Cook v. FDA*, 733 F.3d 1, 7 (D.C. Cir. 2013); *NAACP v. Sec'y of HUD*, 817 F.2d 149 (1st Cir. 1987) (Breyer, J.).

Indeed, the Guidance does far more than announce FDA's intent to forebear from conducting premarket review or bringing enforcement actions. Rather, it sets forth a broad policy of *authorizing* conduct Congress made unlawful. *Chaney* distinguished "[r]efusals to take enforcement steps" from an agency's "affirmative act of approval." 470 U.S. at 831. Here, the Act provides that a new tobacco product cannot be lawfully marketed absent an order from FDA. *See* 21 U.S.C. § 387j(a)(2). The Guidance, however, overrides that statutory requirement for every new product introduced prior to the effective date of the Deeming Rule, authorizing manufacturers to market thousands of new tobacco products for years absent premarket review.

The Guidance is thus tantamount to affirmative approval—a purpose FDA has not bothered to conceal. In adopting the initial "compliance policy," for example, FDA justified its decision by stating "that manufacturers … *will continue to market their products without FDA authorization*." AR11,918 (emphasis added). That is the language of approval, not enforcement discretion. *See UARG*, 134 S. Ct. at 2445 (action was not "refusal to enforce" statutory requirements where it "purport[ed] to alter those requirements and to establish … that otherwise-prohibited conduct will not violate the Act").

Finally, the Guidance exhibits none of the traditional characteristics of enforcement discretion. "[A]n agency's decision not to prosecute or enforce" is typically characterized by the "balancing of a number of factors … peculiarly within its expertise," including:

> 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.

Chaney, 470 U.S. at 831. FDA has justified the Guidance by reference to *none* of these factors. FDA does not claim that it lacks the resources to review applications. It has justified its policy instead by programmatic considerations that turn not on the details of a "particular enforcement action," *id.*, but on FDA's view of what would benefit the industry as a whole. *See, e.g.*, AR11,922 (expressing "cognizan[ce] of the transition that will be required for regulated entities"). Nor does the Guidance set out a policy that would differentiate between "this violation" or that one, *Chaney*, 470 U.S. at 831; instead, the Guidance purports to excuse all prospective violations, and for a significant time. The Guidance, in other words, does not rest on "the sort of mingled assessments of fact, policy, and law that drive an individual enforcement decision and that are, as *Chaney* recognizes, peculiarly within [an] agency's expertise and discretion," *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 677 (D.C. Cir. 1994); rather,

it reflects the agency's deliberate decision not to carry out an obligation imposed on it by Congress. It thus cannot be defended as a "day-to-day agency nonenforcement decision[]." *Nat'l Treasury Emps. Union v. Horner*, 854 F.2d 490, 496 (D.C. Cir. 1988).

II. THE GUIDANCE VIOLATES THE APA'S NOTICE-AND-COMMENT REQUIREMENTS

"[C]ourts are charged with ensuring that agencies comply with the procedural requirements of the APA," *N.C. Growers' Ass'n, Inc. v. UFW*, 702 F.3d 755, 764 (4th Cir. 2012), and a "reviewing court shall … set aside agency action" that was taken "without observance of procedure required by law," 5 U.S.C. § 706. The Guidance is a "rule" within the meaning of the APA because it is "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy." *Id*. § 551(4). In general, the "agency process for formulating, amending, or repealing [such] a rule" (*id.* § 551(5)) must comply with the APA's requirements of notice-and-comment rulemaking. *See id.* § 553. While the APA exempts certain rules from notice and comment, *see id*. § 553(b), the Guidance does not fall within any of those exemptions. Rather, it is a "substantive" rule that FDA was required to—but did not—issue pursuant to § 553's notice and comment provisions.

Notice-and-comment requirements form a critical pillar of the APA. The "important purposes of this … procedure cannot be overstated." *N.C. Growers' Ass'n*, 702 F.3d at 763. "The agency benefits from the experience and input of comments by the public, which help 'ensure informed agency decisionmaking.'" *Id.* Moreover, this requirement "helps ensure 'that the agency maintains a flexible and open-minded attitude towards its own rules.'" *Id.*; *see N.J. Dep't of Envtl. Prot. v. EPA*, 626 F.2d 1038, 1045 (D.C. Cir. 1980).

In hastily accomplishing a substantial change in regulatory policy through the Guidance, FDA defied those requirements. To start, the Guidance is a substantive rule. As the Supreme Court made clear, "a characteristic inherent in the concept of a 'substantive rule,'" as well as "an

important touchstone for distinguishing those rules" from the exceptions to notice and comment set forth in § 553, is that the rule affects "'rights and obligations.'" *Chrysler Corp. v. Brown*, 441 U.S. 281, 302 (1979) (quoting *Morton v. Ruiz*, 415 U.S. 199, 232 (1974)). A rule therefore constitutes a "substantive" (or "legislative") rule subject to notice-and-comment requirements if it either (1) "is binding, and creates rights or obligations," or (2) "constrains the agency's discretion." *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1320 (D.C. Cir. 1988).

The Guidance is substantive under both criteria: (1) it "creates rights" by categorically exempting newly deemed tobacco products from statutorily required premarket review—thereby authorizing those products to be marketed for several years without a marketing order from FDA; and (2) it "constrains [FDA's] discretion" to engage in premarket review or bring enforcement actions against manufacturers that market newly deemed products without seeking or obtaining premarket authorization under the Act. The Guidance is thus plainly binding in all relevant senses; indeed, the Guidance would be internally incoherent if manufacturers were unable to rely on the stated compliance deadlines and FDA were left to decide whether to enforce the Act's requirements of premarket review on a case-by-case basis.

It is therefore not surprising that FDA and regulated entities have treated the Guidance's compliance deadlines as categorical and controlling. In such circumstances, the Guidance "is for all practical purposes 'binding.'" *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1021 (D.C. Cir. 2000). As FDA made clear with respect to the Deeming Rule's "compliance policy," it "expect[s] that manufacturers of … newly deemed, new tobacco products will continue to market their products without FDA authorization for [the] time periods" set by the agency. AR11,918. And the final RIA states without qualification that "FDA does not intend to initiate enforcement action for failure to have premarket authorization during the respective compliance periods."

AR30,040. E-cigarette and cigar manufacturers have thus predictably treated the Guidance as "a major change in policy" permitting products to continue being marketed for years that would "have been banned," including "99% of vaping products on the market today."[6]

FDA's contrary position—expressed through a boilerplate disclaimer that the Guidance is not "binding" (GAR422)—blinks reality. "It is well-established that an agency may not escape the [APA's] notice and comment requirements ... by labeling a major substantive legal [change] mere [guidance]." *Appalachian Power*, 208 F.3d at 1024. As the Fourth Circuit has explained, it is not how the Guidance "denominates itself" that matters, but its "actual function and effect." *Associated Dry Goods Corp. v. EEOC*, 720 F.2d 804, 809 (4th Cir. 1983). The Guidance permits newly deemed tobacco products on the market as of the effective date of the Deeming Rule to be marketed for years absent FDA authorization—and potentially indefinitely. Those significant changes to the regulatory regime—regardless of FDA's "'characterization'" of the Guidance, *Jerri's Ceramic Arts, Inc. v. Consumer Prod. Safety Comm'n*, 874 F.2d 205, 207 (4th Cir. 1989)—required FDA to proceed by notice-and-comment rulemaking.

Nor does it change the substantive nature of the Guidance that FDA purported to set its "compliance dates" as "a matter of [its] enforcement discretion." GAR425. A significant suspension of a statutory or regulatory mandate requires notice-and-comment rulemaking. Deadlines for regulatory compliance form "an essential part of any rule"; as a result, "material alterations" in those dates are necessarily "subject to the rulemaking provisions of the APA."

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[6] American Vaping Ass'n, *Major Changes to FDA Vaping Regulations Announced* (July 28, 2017); *see also, e.g.*, Vapor Tech. Ass'n, *VTA Response to FDA Announcement on Altering Policies to Embrace Science-Based Regulation* (July 28, 2017) (stating, without qualification, that FDA "granted a four-year extension of the deadline" for PMTAs for e-cigarettes); International Premium Cigar & Pipe Retailers Ass'n, *IPCPR and CRA Release on Today's FDA Announcement* (July 28, 2017) (applauding FDA for providing "clarity" and for "revising the pre-market application deadline to August 8, 2021").

NRDC v. EPA, 683 F.2d 752, 762 (3d Cir. 1982). In striking down extensions of compliance deadlines issued without notice and comment, courts have repeatedly held that "[t]he suspension or delayed implementation" of regulatory obligations "constitutes substantive rulemaking." *Envtl. Def. Fund, Inc. v. EPA*, 716 F.2d 915, 920 (D.C. Cir. 1983); *see, e.g.*, *NRDC v. NHTSA*, No. 17-2780, 2018 WL 3189321, at *12 (2d Cir. June 29, 2018); *NRDC v. Abraham*, 355 F.3d 179, 205 (2d Cir. 2004); *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 580 (D.C. Cir. 1981) (per curiam).

In *Environmental Defense Fund, Inc. v. Gorsuch*, 713 F.2d 802 (D.C. Cir. 1983)—a case involving a similar statute requiring EPA to hold regulated entities to standards through the issuance of facilities permits—the D.C. Circuit flatly rejected an argument analogous to FDA's here that the agency's temporary deferral of the permit process was "a 'general policy' statement" rather than substantive rulemaking subject to notice and comment. Just like EPA's permit process, FDA's premarket review ensures that marketing a given tobacco product "would be appropriate for the protection of the public health." 21 U.S.C. § 387j(c)(2). In "substance," the Guidance is therefore no different from the deferral decision invalidated in *Gorsuch*: It "exempt[s] … a whole class [of newly deemed tobacco products] from prescribed obligations required by law for the protection of the public." 713 F.2d at 817; *see also Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002); *Cmty. Nutrition Inst. v. Young*, 818 F.2d 943, 946-947 (D.C. Cir. 1987); *Alaska v. DOT*, 868 F.2d 441, 447 (D.C. Cir. 1989).

While FDA likewise claimed that its 2016 compliance policy was exempt from notice and comment, it announced that policy after soliciting and responding to extensive public input on the "anticipated compliance policy" "laid out … in the NPRM." AR11,885; *see* AR11,917-11,923. By contrast, the Guidance upends that policy—itself the result of notice-and-comment

rulemaking—without exposing FDA's about-face "to the [same] test of prior examination and comment." *Nat'l Motor Freight Traffic Ass'n v. United States*, 268 F. Supp. 90, 96 (D.D.C 1967) (three-judge court), *aff'd*, 393 U.S. 18 (1968).[7]

Because the Guidance is a substantive rule, FDA was required to adhere to the APA's rulemaking procedures or to incorporate into the Guidance a "finding [of good cause] and a brief statement of reasons" for the lack of notice and comment. 5 U.S.C. § 553(b)(3)(B). FDA did neither, and that defect cannot be cured after the fact. *See N.C. Growers' Ass'n*, 702 F.3d at 766. Nor would there have been a basis for a "good cause" finding. That exception is construed "narrowly"; "[t]here is a high bar to invoke [it]"; and the reviewing court must closely scrutinize the agency's "proffered reason[s]." *Id*. at 767; *accord NRDC v. NHTSA*, 2018 WL 3189321, at *13; *Council of S. Mountains*, 653 F.2d at 580. Nothing prevented FDA from proposing and seeking input on the Guidance in May 2017—when it first issued a delay of compliance deadlines—if not before. FDA's decision to issue a years-long blanket exemption from premarket review thus cannot plausibly be justified on the ground that "notice and public procedure [were] impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(3)(B); *see N.C. Growers' Ass'n*, 702 F.3d at 767 ("The good cause exception applies only in 'emergency situations[.]'"); *Nat'l Nutritional Foods Ass'n v. Kennedy*, 572 F.2d 377, 384-385 (2d Cir. 1978) (Friendly, J.) (explaining legislative history).[8]

[7] The cases relied on by FDA in the Deeming Rule (AR11,918) do not support a different result. The guidance in those cases explained that FDA remained free to exercise its enforcement discretion—the opposite of the safe harbor created here. *Cf. Prof'ls & Patients for Customized Care v. Shalala*, 56 F.3d 592, 597 (5th Cir. 1995) (guidance listed "nine factors" FDA would consider in making "individualized determinations"); *Takhar v. Kessler*, 76 F.3d 995, 1002 (9th Cir. 1996) (guidance described "instances" of illegal conduct likely to trigger enforcement).

[8] Even were the Guidance exempt from § 553, FDA was required by the FD&C Act and its own "good guidance practice" regulation to ensure "prior public participation" unless "not feasible or

III. THE GUIDANCE IS ARBITRARY AND CAPRICIOUS

Finally, the Guidance must be vacated because it is not the product of reasoned decisionmaking. Agency action is arbitrary and capricious when the agency has "relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem," or "offered an explanation for its decision that runs counter to the evidence before the agency." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). "The importance of reasoned decisionmaking … cannot be overemphasized," *Portland Cement Ass'n v. EPA*, 665 F.3d 177, 188 (D.C. Cir. 2011), and an agency breaches that duty when it fails to "cogently explain why it has exercised its discretion in a given manner," 463 U.S. at 48-49. The Guidance fails that standard several times over.

First, FDA did not merely fail to articulate a *reasonable* explanation for the Guidance; it failed to provide *any* explanation. It is "'a fundamental requirement of administrative law … that an agency set forth its reasons for decision; an agency's failure to do so constitutes arbitrary and capricious agency action.'" *Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014). As the Fourth Circuit has held, "a reviewing court may look only to … contemporaneous justifications in reviewing the agency action." *Dow AgroSciences LLC v. Nat'l Marine Fisheries Serv.*, 707 F.3d 462, 467-468 (4th Cir. 2013). The Tobacco Control Act codifies a similar requirement. *See* 21 U.S.C. § 387*l*(e).

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appropriate." 21 U.S.C. § 371(h)(1)(C)(i); 21 C.F.R. § 10.115. FDA's conclusory assertion that participation was "not feasible or appropriate" (82 Fed. Reg. 37,459, 37,460 (Aug. 10, 2017)) is inadequate. Its assertion that it "need[ed] to communicate the extensions in a timely manner" (*id.*) makes little sense because FDA could have sought public comment when it first announced delayed implementation of the Deeming Rule in May 2017, 82 Fed. Reg. 22,338, 22,340 (May 15, 2017), if not before. Any time constraints were thus of the agency's own making, and no basis to disregard FDA's rules. FDA's failure to comply with its own rules compels vacatur. *See Nat'l Envtl. Dev. Ass'n's Clean Air Project v. EPA*, 752 F.3d 999, 1009 (D.C. Cir. 2014); *Yee Dai Shek v. INS*, 541 F.2d 1067, 1069 (4th Cir. 1976).

The Guidance breaches those foundational requirements, as it offers no "contemporaneous justification" for why FDA fundamentally altered the rights and obligations of tobacco product manufacturers and categorically suspended premarket review. Indeed, the "administrative record" produced in this case to support the Guidance contains no data that would undergird FDA's decision, no reasoned analysis by FDA of the advantages and disadvantage of the Guidance that would meaningfully explain or justify it, and no contemporaneous record of how it was made. *See* GAR1-GAR433. Rather, the record is little more than a collection of correspondence sent to FDA about the Deeming Rule. The "administrative record [thus] does nothing to back-up" or justify the Guidance. *Am. Rivers v. FERC*, No. 16-1195, 2018 WL 3320870, at *16 (D.C. Cir. July 6, 2018).

Second, where, as here, an agency changes its existing policy, it must at least "display awareness that it is changing position" and "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Moreover, when a "new policy rests upon factual findings that contradict those which underlay its prior policy," it is incumbent upon an agency to explain the change. *Id.*; *see id.* at 516.

FDA flunked those tests as well. In adopting the initial compliance policy (with far shorter "compliance deadlines"), FDA purported "to balance the public health concerns raised in the comments, allow [FDA] to more efficiently manage the flow of incoming applications, and encourage high-quality premarket submissions from applicants." AR11,918. Significantly, FDA found that much shorter compliance deadlines were "sufficient to allow manufacturers of previously unregulated tobacco products to submit applications." AR11,920; *see also* AR11,901 (manufacturers had been "on notice for more than 4 years," since 2011, of FDA intent to regulate new tobacco products). "Based on currently available scientific evidence," FDA explained, the

policy "strikes an appropriate balance among … often competing considerations." AR11,919.

The Guidance cites no changed circumstances, no new evidence, and no additional considerations that would justify FDA's about-face or recalibration of that balance. Nor does the administrative record fill that void. That, too, compels vacatur. "'An agency's view … may change …. But an agency changing its course must supply a reasoned analysis.'" *Healthy Teen Network v. Azar*, No. CCB-18-468, 2018 WL 1942171, at *10 (D. Md. Apr. 25, 2018) (quoting *State Farm*, 463 U.S. at 57). Here, FDA offered no reasoned analysis of its sweeping changes.

Before issuing the Guidance, FDA did allude in a press release to a handful of potential explanations—including a need to encourage product "innovations," to give FDA time to develop product standards, and to "provide manufacturers additional time" to submit applications. GAR412. But even were FDA to rely on a press release as a reasoned, contemporaneous explanation for the Guidance, those cursory explanations fall short. FDA's "*ipse dixit*" about a vague and undefined need for "innovation" is insufficient. *Bus. Roundtable v. SEC*, 647 F.3d 1144, 1155 (D.C. Cir. 2011).[9] Moreover, nothing in the statute or principles of reasoned decisionmaking supports the bizarre notion that FDA may suspend statutory premarket review requirements while it exercises a separate statutory authority to issue product standards, especially given that such review would necessarily elicit critical information from manufacturers about deemed products that would inform development of those standards.

Finally, FDA's claim that industry needs "additional time" to comply is unfounded, particularly in the face of FDA's prior factual findings regarding the time needed to prepare

[9] If FDA is somehow suggesting that premarket review discourages "innovation" (a proposition that is utterly unsupported by the record), it could not possibly follow that the Guidance encourages innovation, given that only products already on the market as of August 8, 2016 are exempt from premarket review; newer products, apparently, receive no such immunity. The Guidance thus privileges existing products over newly developed products.

applications. *See, e.g.*, AR11,909 ("compliance period … takes into account the time for firms to generate and submit the information for a PMTA"); AR11,920 (similar); AR12,012 (similar); *see also* AR11,920 (rejecting 5-year "compliance period" for PMTAs). "An agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past." *Fox*, 556 U.S. at 537 (Kennedy, J., concurring).

Third, FDA failed to provide a reasoned explanation for other changes to its compliance policy. FDA had initially proposed a single compliance period for all products and types of applications as well as an indefinite exemption period while FDA reviews applications. But after receiving comments, FDA did what it is required to do under the APA: It considered the weight of the evidence and promulgated a rule that differed from its proposal on these points, adopting staggered compliance periods based on application type and rejecting an indefinite exemption period during application review. *See* AR11,918-11,923. In adopting the opposite policies now, FDA hinted at no recognition that it had—just two years prior—rejected this same regime, much less did it identify "good reasons for the new policy." *Fox*, 556 U.S. at 515.

Finally, FDA failed to account for the detrimental effects of its decision on public health, including on the health and well-being of youth. "[R]easonable regulation ordinarily requires paying attention to the advantages *and* the disadvantages of agency decisions." *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015). An agency thus must "face the trade-off[s]" caused by its decisions and explain why "the trade-off" it selected "was worth it." *Competitive Enter. Inst. v. NHTSA*, 956 F.2d 321, 323-324 (D.C. Cir. 1992).

Here, there is no doubt that FDA was aware—or should have been—of the serious consequences that would result from the Guidance's blanket approval of the unlawful marketing of classes of new tobacco products for years without premarket review. In promulgating the

Rule, FDA found that newly deemed products "are widely available," AR11,890, and that there had been a "dramatic rise in youth and young adult use of tobacco products." AR11,892. FDA also found that premarket review was necessary to "prevent more harmful or addictive products from reaching the market." AR11,892. Indeed, FDA characterized "the public health benefits that will accrue from the premarket review" as "*substantial*," explaining that "review is especially critical given the changing nature of the [e-cigarettes] and industry and the increasing interest in these products *from youth and young adults*." AR11,911 (emphases added).

Despite these findings, and in the face of the obvious dangers of permitting new products to remain on the market with no assessment by FDA of health consequences, the Guidance fails to acknowledge, much less account for, the serious costs to public health of permitting new products to remain on the market with no FDA review. The increasing popularity of flavored cigars among youth and the rapidly developing crisis of e-cigarette use by young people—shown most dramatically by the nationwide spread of concealable and highly addictive products that are not even recognizable as tobacco products by parents and teachers[10]—tragically illustrate the profound public-health consequences of FDA's failure of reasoned decisionmaking in suspending premarket review of whole classes of new tobacco products.

CONCLUSION

The Court should grant summary judgment to Plaintiffs, vacate the Guidance, and enter an order awarding appropriate equitable relief.

[10] *See, e.g.*, Kate Zernike, *"I Can't Stop": Schools Struggle with Vaping Explosion*, N.Y. Times (Apr. 2, 2018); Lynh Bui, *Juuling: If You Don't Know What It Is, Ask Your Kids*, Wash. Post (May 10, 2018); Jia Tolentino, *The Promise of Vaping and the Rise of JUUL*, New Yorker (May 14, 2018); *see generally Amoco Oil Co. v. EPA*, 501 F.2d 722, 729 n.10 (D.C. Cir. 1974) ("[B]y the time judicial review is secured events may have progressed sufficiently to indicate the truth or falsity of agency predictions. We do not think a court need blind itself to such events[.]").

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Respectfully submitted,

/s/ Kelly P. Dunbar

Kelly P. Dunbar (D. Md. Bar. No. 20338)
Lynn Eisenberg (D. Md. Bar. No. 20333)
Kevin M. Lamb (D. Md. Bar. No. 20344)
Alex Hemmer (D. Md. admission pending)
WILMER CUTLER PICKERING HALE
AND DORR LLP
1875 Pennsylvania Avenue NW
Washington, D.C. 20006
kelly.dunbar@wilmerhale.com
lynn.eisenberg@wilmerhale.com
kevin.lamb@wilmerhale.com
alex.hemmer@wilmerhale.com
(202) 663-6000

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

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

Counsel for Plaintiffs