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 OPPOSITION TO DEFENDANTS' MOTION TO DISMISS AND CROSS-MOTION FOR SUMMARY JUDGMENT AND IN FURTHER SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

FDA's opposition confirms that the Guidance's categorical suspension of premarket review requirements for almost 25,000 e-cigarette and cigar products exceeds the agency's statutory authority. FDA acknowledges that Congress expressly crafted "a statutory grace period" under the Tobacco Control Act, but one limited in scope. Defs.' Opp./Cross-MSJ Br. 1 (Dkt. 36-1) ("Opp."). It recognizes that Congress included "no statutory grace period" for later-deemed products. *Id.* Yet, the agency claims that it has "inherent discretion"—unrestrained by judicial review—to "extend a similar grace period" to thousands of tobacco products, exempting them from statutory requirements for years to come. *Id.* at 4. Were FDA correct, that boundless view of "enforcement discretion" could justify the suspension of premarket review for decades, and, more generally, would arrogate to agencies *carte blanche* to annul or modify unambiguous statutory requirements. But FDA is incorrect. FDA's position conflicts not only with the text, structure, and purposes of the Act, but with case law establishing agencies' duty faithfully to administer, rather than deliberately to countermand, congressional enactments.

Nor does FDA provide any persuasive defense of its clear-cut violation of its procedural obligations under the APA or its multiple, overlapping failures of reasoned decisionmaking. Congress structured the Act to combat tobacco use and nicotine addiction, especially among the Nation's youth. But by suspending key statutory obligations for as many as 25,000 new tobacco products, the Guidance—without the benefit of notice and comment—has thrown gasoline on the fire of an accelerating public health epidemic with respect to youth use of e-cigarettes and cigars. Nothing in the administrative record provides a reasoned explanation for this seismic shift in regulation; nothing demonstrates that FDA reasonably accounted for the deep and lasting harm to public health caused by the Guidance; and nothing justifies FDA's circumvention of notice and comment. This Court should vacate the Guidance and award appropriate equitable relief.

ARGUMENT

I. PLAINTIFFS' CHALLENGES TO THE GUIDANCE ARE JUSTICIABLE

Eager to avoid judicial review of the merits, FDA fires a volley of threshold objections: standing, nonreviewability, and the lack of final agency action. Each lands wide of the mark.[1]

A. Plaintiffs Have Standing To Challenge The Guidance

Plaintiffs have Article III standing because they have "'(1) suffered an injury in fact, (2) that is fairly traceable to [the Guidance] … and (3) that is likely to be redressed by a favorable judicial decision.'" *Kenny v. Wilson*, 885 F.3d 280, 287 (4th Cir. 2018). Congress passed the Act based on its finding that "[t]he use of tobacco products by the Nation's children is a pediatric disease of considerable proportions" and that, absent effective regulation, the Nation risked "new generations of tobacco-dependent children and adults." Family Smoking Prevention and Tobacco Control Act ("TCA"), Pub. L. No. 111-31, § 2(1), 123 Stat. 1776, 1777 (2009). To that end, 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. As 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.

The Guidance has suspended that statutory process for almost 25,000 products, and in

[1] Because FDA's nonreviewability position overlaps significantly with the merits of Plaintiffs' *ultra vires* claim, Plaintiffs address that argument in Part II.B, below.

doing so, has "impede[d] [Plaintiffs'] efforts" to "carry out [their] mission[s]," *Lane v. Holder*, 703 F.3d 668, 674 (4th Cir. 2012)—directly, concretely, and in an ongoing way. It is enough that a single Plaintiff have standing. *Wilson*, 885 F.3d at 287. Here, all Plaintiffs do.

1. Plaintiffs Have Suffered Concrete Injuries That Are Caused By The Guidance And Would Be Redressed By Its Vacatur

a) Organizational Standing

Six Plaintiffs—the 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 Truth Initiative (collectively, "Organizational Plaintiffs")— have standing because FDA's Guidance "perceptibly impair[s]" their ability to accomplish their missions in at least two ways. *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982); *see Lane*, 703 F.3d at 674.

First, 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. 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. *See, e.g.*, CTFK Decl. ¶¶ 10-17 (Ex. A). Denial of "'access to information'" that leads to the "'inhibition of [an organization's] daily operations'" can constitute injury in fact cognizable under Article III. *PETA v. USDA*, 797 F.3d 1087, 1094 (D.C. Cir. 2015) (quoting *Action All. of Senior Citizens of Greater Phila. v. Heckler*, 789 F.2d 931, 937-938 (D.C. Cir. 1986)).

Contrary to FDA's position, it is not necessary for Plaintiffs to establish that the Tobacco Control Act "'create[s] a legal right to access [that] information.'" Opp. 19. An organizational

plaintiff alleging that it is injured by an agency's failure to release mission-critical information need only show that the information "is essential to the injured organization's activities" and that "the lack of the information will render those activities infeasible." *Competitive Enter. Inst. v. NHTSA*, 901 F.2d 107, 122 (D.C. Cir. 1990); *see also Animal Legal Def. Fund, Inc. v. Espy*, 23 F.3d 496, 501 (D.C. Cir. 1994). That principle was recently reaffirmed in the D.C. Circuit's decision in *PETA*, which found Article III standing on the basis of allegations an agency had failed to take enforcement actions that would lead it to produce "investigatory information" that, in turn, would allow the organization to pursue its mission of "educat[ing] the public," 797 F.3d at 1095—all without asking whether disclosure of such information was required by law.[2]

Nonetheless, if standing doctrine required Plaintiffs to demonstrate a legal entitlement to information, that requirement is satisfied here. One of Congress's express "purpose[s]" in passing the Act was "to require … manufacturers to disclose research which has not been previously made available … relating to the health and dependency effects or safety of tobacco products" to "ensure that consumers are better informed." TCA § 3(6). The Act effectuates that goal in many ways, including through premarket review. It requires manufacturers to disclose to FDA, as part of premarket review, information about the health effects of new products. *See,*

[2] The Supreme Court's statement in *FEC v. Akins*, 524 U.S. 11, 21 (1998), that a plaintiff may *also* obtain Article III standing by showing an "inability to obtain information … that, on [their] view of the law, the statute requires" be made public—much like the Fourth Circuit's reiteration of that principle, *see Dreher v. Experian Info. Sols., Inc.*, 856 F.3d 337, 345 (4th Cir. 2017)—is not to the contrary. *Akins* set out an *alternative* path by which plaintiffs may establish injury in fact, predicated solely on the deprivation of information that a statute or regulation requires be made public with no additional showing of harm. *See Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1549 (2016) (describing *Akins* as case in which "plaintiff … need not allege any *additional* harm beyond" deprivation of information); *Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016) (same); *Kean for Cong. Comm. v. FEC*, 398 F. Supp. 2d 26, 36 (D.D.C. 2005) (same). Here, Organizational Plaintiffs have demonstrated concrete injuries flowing from the absence of information, and need not rely on this alternative standing showing.

e.g., 21 U.S.C. § 387j(a)(4), (b)(1). And the Act requires the agency to summarize and make public those data in a variety of formats—requiring, for example, FDA to issue "detailed information" about the "adverse health effects" of products for which SE reports are approved, *id.* § 387j(a)(4)(B), and directing it to issue "orders" adjudicating PMTA applications, *id.* § 387j(c)(1).[3] Consistent with those mandates, FDA in fact releases to the public orders and detailed summaries of FDA's analysis of approved premarket applications for new tobacco products. *See* CTFK Decl., Att. 1 (67-page summary of FDA's decision to approve Swedish Match "snus" product, including a detailed analysis of its health effects).

Thus, in suspending premarket review for nearly 25,000 tobacco products, the Guidance has denied and will continue to deny Organizational Plaintiffs access to important scientific and health information. *See, e.g.*, ACS CAN Decl. ¶¶ 10-13 (Ex. B); AHA Decl. ¶¶ 7-8 (Ex. C); ALA Decl. ¶ 16 (Ex. D); CTFK Decl. ¶¶ 10-17. These organizations (i) have in the past relied on information released through premarket review to help advance their missions and (ii) would do so today were FDA performing its statutory responsibilities. *See, e.g.*, AHA Decl. ¶ 6 (AHA "could and would use [premarket review] information"); ALA Decl. ¶ 16 (similar); CTFK Decl. ¶¶ 10-14 (detailing use of order in proposing product standard); Truth Decl. ¶ 9 (Ex. E) (detailing use of order in educating public). They are correspondingly "impair[ed]" in their ability to do so by the Guidance. *Havens Realty*, 455 U.S. at 379; *PETA*, 797 F.3d at 1094-1095. Furthermore,

[3] FDA's passing suggestion (Opp. 20 n.11) that such orders could be kept secret from the public flies in the face of foundational administrative-law principles against which Congress enacted the Act, *see* 5 U.S.C. § 552(a)(2) ("orders" must be made available for "public inspection"); it conflicts with Congress's reservation of only limited non-disclosure protections in connection with premarket review, *see* 21 U.S.C. § 387f(c); and it violates FDA's own regulations requiring that "all [FDA] records shall be made available for public disclosure" absent specific exemption, 21 C.F.R. § 20.20(b); *see Action All.*, 789 F.2d at 937-938 (finding informational injury in case where plaintiffs alleged violation of regulations).

this injury is not hypothetical: The Guidance's constraint on the flow of information *currently* impairs Plaintiffs' ability to carry out their missions—whether in educating or counseling the public or seeking redress from FDA—and will continue to do so for years. *See, e.g.*, AAP Decl. ¶¶ 45-51 (Ex. F) (describing AAP programs adversely affected by absence of premarket review); AHA Decl. ¶¶ 8-14 (similar); ALA Decl. ¶¶ 5-15 (similar); CTFK Decl. ¶¶ 15-16 (similar); Truth Decl. ¶¶ 5-14 (similar).

This case is thus on all fours with the D.C. Circuit's decision in *PETA*, 797 F.3d 1087. There, PETA sued to compel USDA to exercise its authority under the Animal Welfare Act ("AWA") with respect to birds. PETA argued that it had standing because the agency's failure to act meant that "USDA was not creating bird-related inspection reports that PETA could use to raise public awareness." *Id.* at 1091. The D.C. Circuit agreed, explaining that "USDA's allegedly unlawful failure to apply the AWA's general animal welfare regulations to birds," by denying PETA access to "bird-related AWA information," had "'perceptibly impaired [PETA's] ability' both to bring AWA violations to the attention of the agency charged with preventing avian cruelty and continue to educate the public." *Id.* at 1095. Because PETA had expended resources in response, the court concluded that its "injuries fit comfortably within … organizational-standing jurisprudence." *Id.* at 1097. All of that is true here: FDA's failure to implement the Act faithfully deprives Organizational Plaintiffs of access to information they would use to educate and counsel the public regarding tobacco use and to seek regulatory redress. And because they have "expended resources to counter these injuries," they have "established Article III organizational standing." *Id.* at 1095.

Second, separate and apart from informational injury, the Guidance interferes with Organizational 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. FDA itself has found that new products "have proliferated in the absence of FDA regulation"; that "consumers have highly imperfect information for choosing among products"; and that "acutely toxic products may be offered for sale." AR30,038. This burden falls most heavily on Organizational Plaintiffs, whose missions center on educating the public about the dangers of such products. *See* ACS CAN Decl. ¶ 15; AHA Decl. ¶¶ 15-17. And it has required Plaintiffs to expend more resources carrying out those missions than they otherwise would have expended—requiring some to divert such resources away from other important programs.

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.

These resource-related injuries easily satisfy Article III. An organization "suffer[s] an injury in fact when a defendant's actions impede its efforts to carry out its mission"—and such an impediment can take the form of a "drain on [the organization's] resources." *Lane*, 703 F.3d at 674-675; *see also Havens Realty*, 455 U.S. at 378-379; *Centro de la Comunidad Hispana de*

Locust Valley v. Town of Oyster Bay, 868 F.3d 104, 111 (2d Cir. 2017) (resource diversion "has been repeatedly held to be independently sufficient to confer organizational standing"). The Guidance here has "frustrated [P]laintiff[s'] mission" to educate the public about the risks of new tobacco products, *Equal Rights Center v. Equity Residential*, 483 F. Supp. 2d 482, 486-487 (D. Md. 2007), and created "new obstacles" that "unquestionably make it more difficult for [them] to accomplish their primary mission" of combatting tobacco use, *League of Women Voters of United States v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016).

b) Associational Standing

AAP independently has associational standing (as does its Maryland chapter) because (1) its pediatrician "'members would otherwise have standing to sue"; (2) "the interests it seeks to protect are germane to [AAP's] purpose"; and (3) nothing "requires the participation of individual members.'" *Lane*, 703 F.3d at 674 n.4. The second and third standards are easily met here: FDA's suspension of premarket review is "germane" to AAP's purpose of ensuring the health of American children, *see* AAP Decl. ¶ 5, and AAP's members are not needed to participate in this lawsuit.

AAP's members also have "standing to sue in their own right," *Hunt v. Washington State Apple Advertising Commission*, 432 U.S. 333, 343 (1977), and AAP thus has standing to sue on their behalf. It is well-established that interference with the practice of one's profession is injury in fact. *See Planned Parenthood of Idaho, Inc. v. Wasden*, 376 F.3d 908, 917 (9th Cir. 2004) (physician's "interests, both financial and professional, in practicing medicine" are protected by Article III); *Pennsylvania Psychiatric Soc. v. Green Spring Health Servs., Inc.*, 280 F.3d 278, 289 (3d Cir. 2002) (standing where defendants' alleged conduct "undermined [psychiatrists'] ability to provide quality health care"). FDA's decision not to implement premarket review for nearly 25,000 new tobacco products interferes with AAP members' practice of medicine.

First, by depriving pediatricians of health information that would otherwise be available and impeding AAP's ability to provide evidence-based recommendations for treating e-cigarette and cigar use, the Guidance undercuts pediatricians' ability effectively to counsel and treat patients. AAP member Dr. Levy attests that her practice has been made substantially more difficult by the proliferation of new tobacco products—notably e-cigarettes—and by FDA's failure faithfully to administer the Act. As Dr. Levy attests, "[n]early every child [she] treat[s] or assess[es] uses some form of e-cigarette product," Levy Decl. ¶ 8 (Ex. G), requiring her to conduct substantial additional research into new products on the market, "just to be able to perform her duties as a medical professional," *id.* ¶ 15. The information vacuum created by the Guidance means that Dr. Levy and others are reduced to searching publicly for data that is often unavailable. *See id.* ¶ 14; *see also* Camenga Decl. ¶ 12 (Ex. H) (same for AAP member Dr. Camenga). The lack of publicly available data about these tobacco products—data that would be available in the decision summaries released by FDA on approval of a new tobacco product, *see* CTFK Decl., Att. 1—has also interfered with AAP members' ability to conduct research on substance abuse and prevention. Camenga Decl. ¶¶ 19-21; *see* Levy Decl. ¶¶ 18-19.

Second, the Guidance harms AAP members by increasing the volume and complexity of patient needs they must confront. The number of patients who present respiratory ailments and symptoms of nicotine addiction, as well as comorbid addiction to multiple substances, has increased alongside the rise of e-cigarettes. Levy Decl. ¶ 7; Winickoff Decl. ¶¶ 6-7 (Ex. I). AAP member Dr. Winickoff explains that the rise of unapproved tobacco products—especially e-cigarettes—now requires him to spend "as much as a third of a visit" counseling patients on tobacco use—time that "either takes the place of time [he] can counsel [his] patients on other important health issues, such as exercise or STD protection, or lengthens [his] sessions so that

[he] can see fewer patients—with a corresponding effect on both [his] patients' health and [his] practice's income." *Id.* ¶ 10; *see also id.* ¶ 5 (proliferation of e-cigarettes has harmed patients and his "practice's income and expenses"); Levy Decl. ¶ 19 (similar with respect to research).

c) Individual Standing

Finally, Plaintiffs Dr. Brasch, Dr. Fishman, Dr. Goldstein, Dr. Hirsch, and Dr. Myles (collectively, "Pediatrician Plaintiffs") have standing. As explained above, interference with one's profession is a cognizable injury, and FDA's decision not to carry out premarket review has inhibited or undermined the Pediatrician Plaintiffs' practice in two ways.

First, the Guidance interferes with their ability to counsel and treat their patients by limiting information available to them about the myriad new tobacco products on the market. An increasing number of their patients use e-cigarettes and other new tobacco products. *See* Brasch Decl. ¶ 3 (Ex. J); Fishman Decl. ¶¶ 5-8 (Ex. K); Hirsch Decl. ¶¶ 5-7 (Ex. L); Myles Decl. ¶ 3 (Ex. M). But Pediatrician Plaintiffs lack the evidence-based empirical data and practical clinical aids they need to counsel patients effectively. *See* Brasch Decl. ¶¶ 4-5; Fishman Decl. ¶ 11; Hirsch Decl. ¶ 8; Myles Decl. ¶¶ 5-6. For example, many of Dr. Brasch's teenage patients tell her that they use "low-percentage nicotine" vaping liquid. Brasch Decl. ¶ 6. But because such manufacturers will not have to submit premarket review applications until 2022, there are no evidence-based resources that Dr. Brasch can consult about the actual content of such products, "limiting [her] ability to carry out [her] responsibility to [her patients] as their physician." *Id.*

Second, the Guidance increases the complexity of patient needs confronting Pediatrician Plaintiffs. Use of newly deemed tobacco products has soared in the last two to three years. *See* Brasch Decl. ¶ 3; Fishman Decl. ¶¶ 5-8; Hirsch Decl. ¶¶ 5-7. Today, Dr. Fishman attests, as many as one third of her adolescent patients reporting using or trying e-cigarettes. Fishman Decl. ¶ 8. That dramatic rise directly affects Pediatrician Plaintiffs' medical practices. As Dr.

Fishman explains, when she learns a patient is using e-cigarettes, she "need[s] to spend some of [her] limited time counseling them," which in turn "reduces the amount of time [she] can spend on other issues," including "health and safety issues such as diet or sexual activity." *Id.* ¶ 9. The number of unregulated and unapproved products on the market—directly attributable to FDA's suspension of premarket review—thus "significantly impedes [Dr. Fishman's] ability to assist [her] patients and improve their health outcomes." *Id.* ¶ 16; *see* Brasch Decl. ¶ 6; Hirsch Decl. ¶ 9; *see also* Brasch Decl. ¶ 7 (similar for plaintiff Dr. Goldstein). By making it more difficult for Pediatrician Plaintiffs to treat their patients, the Guidance gives rise to Article III standing.

2. FDA's Contrary Arguments Are Unpersuasive

FDA's objections to Plaintiffs' standing lack merit. *First*, FDA leans heavily on *Cigar Ass'n of America v. FDA*, 323 F.R.D. 54 (D.D.C. 2017), arguing that the court there rejected the same standing arguments Plaintiffs make here. *See* Opp. 14-15. Not so. *Cigar Association* was an across-the-board challenge to the Deeming Rule brought by cigar manufacturers that had nothing to do with the Guidance. *See* 323 F.R.D. at 58. By the time the district court addressed a motion to intervene by Organizational Plaintiffs in this case, the manufacturers had winnowed their legal challenges, focusing on a constitutional challenge to cigar warning-label requirements. *Id.* at 57. The question there was thus not whether Organizational Plaintiffs were injured by FDA's failure to perform premarket review, but whether they would be injured by invalidation of warning-label requirements. The district court made this very point, affirmatively citing *PETA* and distinguishing it on the ground that *PETA* involved an agency's allegedly unlawful failure to "collect information" that deprived an organization of "information it needed" to communicate with the public. *Id.* at 61. That was not the case in *Cigar Association*—because FDA's failure to conduct premarket review was not at issue—but, of course, it is here.

Even apart from that key difference, the factual proffers here materially differ in scope

and kind from those in *Cigar Association*. The court there found the declarations wanting because, in its view, they were too speculative as to what might happen "if the [Deeming] Rule is vacated." 323 F.R.D. at 62. Moreover, the declarations had been submitted before the manufacturers had narrowed their claims to focus on warning-label requirements, and the court found the declarations did not specifically tie the asserted harm to those narrow requirements. *Id.* at 63. Those concerns are absent here: The Guidance is now in effect; it has already suspended premarket review for nearly 25,000 tobacco products for years; and, as explained above, the Guidance is presently injuring Plaintiffs. In addition, the court in *Cigar Association* found that AAP had only "vague[ly]" described how pediatricians would be affected by the lack of cigar warning-labels, *id.* at 65, while the declarations here describe specifically and concretely how FDA's suspension of premarket review interferes with pediatricians' medical practices.

Second, FDA argues that Plaintiffs' injuries are "too speculative" because it is unknown whether the Guidance will cause manufacturers to "delay [the] submission of premarket review applications" and "continue to market" products covered by the Guidance. Opp. 16. That is a brazen claim. FDA has never questioned that the Guidance would cause manufacturers to delay applications; indeed, that was its purpose.[4] FDA "expect[ed] that manufacturers … [would] continue to market their products without FDA authorization" if it delayed the premarket review process, AR11,918, and that is the logic behind its assertion that manufacturers need "additional

[4] Publicly available evidence also suggests that the intended delay is precisely what has happened. *See* FDA, *Tobacco Product Marketing Orders* (no PMTA order issued since 2015); FDA, *Cumulative Number of Premarket Tobacco Product Applications (PMTA) Received Since Program Inception* (no "final actions" of any PMTA applications since June 2017). And the hyperbolic claims in the industry *amicus* brief that manufacturers may not be able to meet even the Guidance's deadlines should put to rest conjecture that the industry will hasten to act rather than take advantage of FDA's multi-year delay. *See* Dkt. 37-1 at 9 ("manufacturers will need all of the time granted [by the Guidance] … if not more").

time to develop higher quality, more complete applications." GAR412. FDA's newfound agnosticism as to whether industry will take advantage of the multi-year exemption from regulatory review announced by the Guidance thus cannot be taken seriously.

Third, FDA contends that, if manufacturers do delay the submission of applications, that will not put Plaintiffs "in a worse position than the one in which they have always been." Opp. 17. This confuses the relevant baseline for standing. Plaintiffs "need not show that the [agency action] rendered them worse off than the status quo ante. They may alternatively show that, had the [agency] taken the course of action that they claim the law required, they would have been better off." *Nat'l Envtl. Dev. Assoc.'s Clean Air Project v. EPA*, 752 F.3d 999, 1006 (D.C. Cir. 2014); *see also Animal Legal Def. Fund, Inc. v. Glickman*, 154 F.3d 426, 441 (D.C. Cir. 1998). Here, the question is not whether the Guidance impedes Plaintiffs' ability to carry out their mission relative to the pre-2017 status quo, but whether the Guidance impedes Plaintiffs' ability to do so relative to a world in which the Guidance had never been issued. As explained above, Plaintiffs have readily made that required showing of injury.

Finally, FDA argues Plaintiffs "cannot show" redressability because they do not seek to compel manufacturers to file applications or to force FDA to bring enforcement actions. Opp. 21. But FDA's implication that, were the Guidance vacated, *no* manufacturer of the nearly 25,000 products on the market would file an application is facially absurd. It also contradicts FDA's own statement (in the Deeming Rule litigation) that, even under the original compliance period, between "266 and 332 vaping devices, and between 900 and 1,800 e-liquids, will remain on the market at the end of the compliance period," Final Brief for Appellees 27, *Nicopure Labs, LLC v. FDA*, No. 17-5196 (D.C. Cir. June 5, 2018) (citing AR23,991), a finding that presupposes manufacturers will file applications. In all events, in the fanciful scenario FDA posits—in which

no manufacturer ever filed an application—Plaintiffs' informational injuries might not be redressed, but the many injuries caused by an unregulated marketplace would be.[5]

B. The Guidance Constitutes "Final Agency Action"

"The APA embraces a 'strong presumption in favor of judicial review of administrative action.'" *Doe v. Tenenbaum*, 900 F. Supp. 2d 572, 601 (D. Md. 2012), *rev'd on other grounds*, 749 F.3d 246 (4th Cir. 2014). While the APA limits review to "final agency action," 5 U.S.C. § 704, finality requires only that the action (1) "mark the 'consummation' of the agency's decisionmaking process" and (2) be "one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177-178 (1997). Both conditions of this "'pragmatic and flexible'" finality test, *Rhea Lana, Inc. v. Dep't of Labor*, 824 F.3d 1023, 1027 (D.C. Cir. 2016), are satisfied here.

First, as FDA does not seriously dispute, there is nothing "tentative" about the Guidance. *Bennett*, 520 U.S. at 178. Tentativeness would not allow, as the Guidance purports to do, manufacturers to "continue to market" newly deemed tobacco products for years to come without premarket review. GAR412. FDA points to boilerplate language that the Guidance represents the agency's "current thinking." Opp. 31. But that is true of every agency action. The "possibility" of future revision does not change the fact that the Guidance embodies FDA's "definitive decision" to exempt approximately 25,000 products from premarket review until 2021 or 2022, at the earliest. *U.S. Army Corps of Engineers v. Hawkes Co.*, 136 S. Ct. 1807, 1813-1814 (2016); *see Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022 (D.C. Cir. 2000).

[5] At the very least, Plaintiffs have standing to challenge FDA's failure to comply with the APA's notice-and-comment procedures, given that the agency's failure has "impair[ed]" their "concrete interests" in combatting nicotine addiction. *Pye v. United States*, 269 F.3d 459, 467 (4th Cir. 2001); *see also WildEarth Guardians v. Jewell*, 738 F.3d 298, 306 (D.C. Cir. 2013).

FDA's across-the-board exemption, far from being "a 'moving target,'" thus represents "a 'final and binding determination.'" *Safari Club Int'l v. Jewell*, 842 F.3d 1280, 1289 (D.C. Cir. 2016); *see Real Truth About Abortion, Inc. v. FEC*, 681 F.3d 544, 555 n.4 (4th Cir. 2012).

Second, "[t]he definitive nature of [the compliance deadlines] also gives rise to 'direct and appreciable legal consequences.'" *Hawkes*, 136 S. Ct. at 1814.[6] As explained below, the purpose and effect of the Guidance are to create a legal exemption for manufacturers of nearly 25,000 tobacco products from substantive requirements under the Act. *See infra* pp. 17-22. Absent the Guidance, manufacturers could not lawfully market their products without a marketing order from FDA; under the Guidance, they can do just that. Indeed, absent the Guidance, tobacco manufacturers would have had to submit their premarket applications by this month and FDA would have begun reviewing those applications. The Guidance thus "has direct and appreciable legal consequences." *Bennett*, 520 U.S. at 178.

FDA's contention that the Guidance is nonetheless not final because it says it has no legally binding effect (Opp. 31) is meritless. Such "boilerplate" disclaimers, contained in "all [FDA] guidance documents," do not bar judicial review. *Appalachian Power*, 208 F.3d at 1023. The Supreme Court has "long taken" a flexible and "'pragmatic' approach … to finality." *Hawkes*, 136 S. Ct. at 1815; *see Abbott Labs. v. Gardner*, 387 U.S. 136, 149-151 (1967). What matters is "the effect" of the challenged action—not the agency's label or designation. *Hawkes*, 136 S. Ct. at 1814. In *Hawkes*, as here, the agency represented that the challenged action had

[6] As elsewhere explained, the Guidance is a binding substantive rule, *see* Br. 16-20; *infra* pp. 38-40, which necessarily satisfies *Bennett*'s second prong, *see Ctr. for Auto Safety v. NHTSA*, 452 F.3d 798, 806 (D.C. Cir. 2006). But this Court's review of final agency action is not limited to substantive rules. *Compare* 5 U.S.C. § 551(13) (defining "agency action") *with id.* § 553(b) (exempting certain rules from notice and comment, but not other APA requirements). Even were the Court to determine that notice and comment were not required, that would not preclude the Court from reaching Plaintiffs' other claims.

"no legally binding effect on [its] enforcement decisions." *Id*. at 1817 (Kennedy, J., concurring). But the Court rejected that *ipse dixit* as insufficient to bar judicial review. The dispositive fact here, as in *Hawkes*, is that FDA's bright-line compliance deadlines create a *de facto* "safe harbor"—"a 'legal consequence[]' satisfying the second *Bennett* prong." *Id*. at 1814.

None of the cases FDA cites (Opp. 31-32) is on point. The Guidance does not merely "reiterate[] a previously stated agency policy," *Ctr. for Auto Safety, Inc. v. NHTSA*, 342 F. Supp. 2d 1, 24 (D.D.C. 2004), or set forth an interpretation the agency has not yet "'relied upon,'" *Am. Tort Reform Ass'n v. OSHA*, 738 F.3d 387, 395 (D.C. Cir. 2013). To the contrary, the "clear-cut" compliance deadlines revise existing policy and, for all practical purposes, were treated as "effective immediately upon" FDA's issuance of the Guidance. *Abbott Labs.*, 387 U.S. at 152.

Relying on *Flue-Cured Tobacco Cooperative Stabilization Corp. v. EPA*, 313 F.3d 852, 859 (4th Cir. 2002), FDA argues that finality cannot be premised upon harm to Plaintiffs from "manufacturers postpon[ing]" filing "applications." Opp. 32. That confuses finality with "the separate question" of standing. *Bennett*, 520 U.S. at 177; *supra* pp. 2-14. "The second [*Bennett*] prong does not require that the agency action confer rights or obligations *on the plaintiff*." *Doe*, 900 F. Supp. 2d at 602 (emphasis added); *accord Clean Air Council v. Pruitt*, 862 F.3d 1, 6 (D.C. Cir. 2017) (stay of standard was final agency action subject to challenge by environmental organizations not regulated by stayed action); *Nat'l Ass'n of Home Builders v. U.S. Army Corps of Engineers*, 417 F.3d 1272, 1281 (D.C. Cir. 2005). Accepting FDA's argument would lead to the nonsensical result that agency action can be final for certain challengers but not others. In *Flue-Cured Tobacco*, the Fourth Circuit held that an agency report on the health hazards of secondhand tobacco smoke was nonfinal because it "carrie[d] no 'direct and appreciable legal consequences'" *for anyone*. 313 F.3d at 859. That is not the issue here. The Guidance creates

an exemption from and dates certain for compliance that neither the industry nor FDA is free to ignore. That is binding administrative action. *See Clean Air Council v. Pruitt*, 862 F.3d 1, 6-7 (D.C. Cir. 2017) (stay "suspend[ing] … compliance deadlines" is final agency action).

II. THE GUIDANCE IS *ULTRA VIRES*

A. The Guidance Violates The Tobacco Control Act

On the merits, the Guidance is patently unlawful. The Guidance nullifies the Act's premarket review provisions on an unqualified basis for at least a half-decade—despite the fact that Congress imposed mandatory premarket filing obligations on manufacturers and directed FDA to conduct premarket review, pairing those clear-cut obligations with express exceptions when it saw fit. *See* Br. 9-13. By revising that calibrated statutory scheme to satisfy FDA's own aims, and by allowing potentially dangerous and addictive tobacco products to remain on the market for years without public health review required by Congress, the Guidance constitutes paradigmatic "ultra vires" agency action. *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013).

In response, FDA makes no serious effort to square the Guidance with the premarket review regime Congress actually established in the Act. Instead, it doubles down on its view that the Guidance is an exercise of unreviewable "enforcement discretion." That is manifestly wrong, as Plaintiffs have already explained, Br. 13-16, and explain further below, *see* Part II.B. But the statutory arguments FDA does make are equally unavailing.

FDA claims that it has "inherent discretion" under the Act, Opp. 4—discretion that, FDA believes, gives it *carte blanche* to decide when and under what circumstances to administer the Act's premarket review requirements. Nothing in the statute supports that position, and much condemns it. The "larger scheme" established by Congress in the Act—including text, structure, and purpose—*Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson*, 559 U.S. 280, 289 (2010), evinces Congress's intent that premarket review is a mandatory and essential

feature of the Act. As Plaintiffs have explained, under the Act, manufacturers *must* submit applications containing important information about new products before placing those products on the market, 21 U.S.C. § 387j(a)(2), (c)(1)(A)(i), and FDA *must* issue either "an order that the new product may be introduced" or "an order that [it] may not be introduced" after submission, *id.* § 387j(c)(1)(A). When Congress wanted to create exceptions to those requirements, it did so expressly. *Id.*; 21 U.S.C. §§ 387j(a)(2)(B), 387e(j)(2); *id.* § 387j(g); *see Tennessee Valley Auth. v. Hill*, 437 U.S. 153, 188 (1978) (Congress's creation of express exemptions demonstrates intent that there be no other exemptions).[7] Read together and in light of the purposes of the Act, those interlocking statutory provisions impose synchronized duties on manufacturers *and* FDA—manufacturers must submit applications that FDA must review and act on—that are clearly meant to be accomplished before a new product is marketed to the public. That is why the statutory regime is called "[p]remarket review." 21 U.S.C. § 387j(a)(2).

Congress's statutory findings reinforce this point. Congress found that it is "essential" that manufacturers "demonstrate that [tobacco] products will meet a series of rigorous criteria" "prior to marketing such products." TCA § 2(36). Similarly, Congress determined that "[t]he only way to effectively protect the public health" is to ensure new products are "reviewed in advance of marketing." *Id.* § 2(43). FDA's assertion that it nonetheless retains "inherent discretion" (Opp. 4) to decline to apply premarket review provisions and to permit manufacturers to market potentially dangerous and addictive products, subject to *post*market review years down

[7] FDA does not base its "inherent discretion" theory on *Chevron* deference, nor does it invoke *Chevron* in response to Plaintiffs' statutory arguments. FDA has thus "forfeited any claims to *Chevron* deference." *Neustar, Inc. v. FCC*, 857 F.3d 886, 894 (D.C. Cir. 2017). If FDA means that "inherent discretion" exists outside of the Act, that ignores that an agency's authority derives only from Congress. *See La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986).

the road, stands this statutory scheme on its head.[8]

Attempting to avoid the straightforward implications of statutory text and structure, FDA repeats the refrain that the Guidance supposedly does not affect *FDA's* obligations because, FDA says, the agency will perform premarket review of any applications filed in advance of the "compliance deadlines" and thus the only parties who might plausibly be disregarding the Act are "*manufacturers*, not the FDA." Opp. 27-28. This reasoning falls short for multiple reasons.

First, as explained above and in Plaintiffs' opening brief, the Act demonstrates that Congress intended a mandatory premarket review structure—not a regime in which FDA may pick and choose the circumstances in which manufacturers and FDA must comply with premarket review. Courts do not "interpret federal statutes to negate their own stated purposes." *N.Y. State Dep't of Soc. Servs. v. Dublino*, 413 U.S. 405, 419-420 (1973). But FDA's "inherent discretion" theory would do just that. Under FDA's view of "inherent discretion," FDA could announce, for example, that manufacturers of new tobacco products are no longer required to submit premarket applications for decades, in an effort to relieve FDA of its responsibility to review and act on those applications. It cannot be the law that FDA may evade *its* statutory duties by announcing to the world that regulated parties need not comply with their predicate obligation to file applications. That would unlawfully transform what Congress intended to be a *mandatory*, *pre*market review regime into a largely *volitional*, *post*market review structure

[8] FDA says that it "blinks reality" to describe the Guidance as "'a form of *postmarket* review'" because, it claims, there were 11,000 e-cigarettes on the market when the Deeming Rule took effect and, even under the original compliance policy, those products would have undergone postmarket review. Opp. 35. But the lawfulness (or not) of the Deeming Rule's policy is not at issue. The final agency action challenged here is the Guidance; any prior unlawful acts are no defense. *See Judulang v. Holder*, 565 U.S. 42, 60-61 (2011). FDA suggests that Plaintiffs have waived a legal objection to the Guidance, Opp. 35, but Plaintiffs cannot possibly be faulted for not filing comments objecting to the Guidance because FDA (unlawfully) issued the Guidance without notice and comment, depriving interested parties of just that opportunity.

bearing vanishing resemblance to the statute that Congress enacted.

Second, FDA implausibly asks that the Court turn a blind eye to facts that are obvious: The desired effect of the Guidance's multi-year extension of "compliance deadlines" is that rational manufacturers will not submit applications during that exemption period, and as a result, FDA will not review them. *See, e.g.*, AR11,918 (FDA "expect[s] that manufacturers … will continue to market their products without FDA authorization"). The Guidance thus relieves both manufacturers and FDA of statutory duties. In fact, publicly available information demonstrates that FDA has taken no action on any PMTA applications since issuing the Guidance, *see supra* p. 12 n. 4, and one of FDA's (ill-explained) rationales for the Guidance is that FDA does not have sufficient guidance in place to review such applications, Opp. 44-45. It strains credulity to deny that FDA has effectively shuttered premarket review for whole classes of tobacco products.

Third, even if the Act could be read to sanction the Guidance's circumvention of FDA's statutory duties, the Guidance would still be *ultra vires* because it grants a blanket license to manufacturers to keep new tobacco products on the market absent premarket review, in violation of federal law. *See* Br. 14-15. To its credit, FDA does not hide this purpose. FDA acknowledges that Congress created a *statutory* grace period; it observes that Congress created "no statutory grace period for products later deemed subject to the Act," Opp. 1; and it candidly admits that, through the Guidance, FDA "extend[ed] a similar grace period" to new tobacco products, *id.* at 4. FDA thus admits what is clear: The Guidance is not an exercise of enforcement discretion, but rather a blanket, preemptive authorization of industry non-compliance. It is thus an attempt to "establish with the force of law that []prohibited conduct"—marketing new products absent premarket review—"will not violate" federal law. *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2445 (2014) ("*UARG*"). Whether FDA can relieve

itself of its obligations, it cannot "alter[] the statutory requirements" for *manufacturers*. *Id.* at 2445. "The power of executing the laws … does not include a power to revise clear statutory terms that turn out not to work in practice," *id.* at 2446—yet that is exactly what FDA admits that it is doing in creating an extra-statutory "grace period."

FDA objects that the Guidance does not "create any exceptions to the substantive requirements of the statute," Opp. 34, but that position—which must come as some surprise to manufacturers who presumably believe they are not in outright violation of federal law—is not defensible. FDA acknowledges its exemptive purpose in establishing a "grace period," Opp. 4, designed to "give manufacturers time to come into compliance" with the Act, *id.* at 2, and that mimics the exemption created by Congress. By definition, this is an exception to substantive requirements. Moreover, the agency transparently justified the compliance policy on the ground that tobacco manufacturers will "continue to market their products" absent premarket review, AR11,918, thus sanctioning conduct that Congress deemed illegal.

FDA's preferred description of the Guidance as implementing a "compliance period" (Opp. 2, 6, 7, 8, 9, 11, 19, 27, 30, 35) reflects this understanding. Under the Guidance, manufacturers are *not* out of "compliance" with the Act in marketing new tobacco products without premarket review until August 2021 or 2022. Surely, for example, manufacturers availing themselves of the new grace period are not reporting to investors or other agencies that they are presently engaged in conduct brazenly violative of federal law. Instead, they assuredly view the Guidance as creating a *de facto* exemption—precisely as FDA intended. The Guidance is thus an "alteration of … statutory requirements" that exceeds an agency's authority—and the kind of action FDA "cannot[] defend … as an exercise of … enforcement discretion." *UARG*, 134 S. Ct. at 2445; *see* Zachary S. Price, *Enforcement Discretion and Executive Duty*, 67 Vand.

L. Rev. 671, 704 (2014) ("[E]xecutive officials lack inherent authority either to prospectively license statutory violations or to categorically suspend enforcement of statutes for policy reasons.").

FDA responds that *UARG* is distinguishable, Opp. 34, but the distinction it advances is threadbare. In *UARG*, EPA needed to "go beyond merely exercising its enforcement discretion" by creating an effective exemption from substantive requirements in order to avoid private citizen-suit enforcement. 134 S. Ct. at 2445. True, the Act here does not have a citizen-suit provision, Opp. 34, but that provision was relevant in *UARG* only because it showed that EPA had gone beyond non-enforcement. Here, as described above, there are multiple indicia that the Guidance, as in *UARG*, goes "beyond merely exercising enforcement discretion," and instead creates a prospective license for manufacturers to engage in conduct that Congress affirmatively prohibited. *See supra* pp. 20-22. It is that distinction—between agency non-enforcement and agency approval of unlawful conduct—that underlies *UARG*. *See* 134 S. Ct. at 2446 ("An agency … may change its own conduct, but it cannot change the law.").[9]

B. The Guidance Is Not Unreviewable "Enforcement Discretion"

With no basis in the Act to defend the Guidance, FDA labors mightily to show that this Court is powerless to remedy FDA's defiance of law under 5 U.S.C. § 701(a)(2), which bars judicial review of agency action "committed to agency discretion by law," and by *Heckler v. Chaney*, 470 U.S. 821 (1985), which interpreted that provision to preclude review of agency

[9] Any doubt about the proper interpretation of the Act would be resolved, under the canon of constitutional avoidance, against FDA's claimed authority to dispense with premarket review. *See* Br. 12-13. FDA responds that the Take Care Clause binds only the President, Opp. 35-36, but its own authority contradicts that assertion. *See Printz v. United States*, 521 U.S. 898, 922 (1997) (Clause applies to appointed "officers"). Nor does it matter whether the Clause provides a "cause of action" (Opp. 36) because the APA supplies one, 5 U.S.C. §§ 702, 706(2)(B).

decisions "not to take enforcement action," *id.* at 832. *See* Opp. 21-30. FDA is wrong.[10]

Section 701(a)(2) establishes a "narrow exception" to the APA's general presumption of reviewability, applicable only "in those rare instances where statutes are drawn in such broad terms that in a given case there is no law to apply." *Citizens to Pres. Overton Park, Inc. v. Volpe*, 401 U.S. 402, 410 (1971) (internal quotation marks omitted). "Congress rarely intends to prevent courts from enforcing its directives to federal agencies," *Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1651 (2015), and "each category of non-reviewability must be construed narrowly," *Amador Cty. v. Salazar*, 640 F.3d 373, 379 (D.C. Cir. 2011). Consistent with these principles, FDA's claim of nonreviewability fails for multiple reasons. *See* Br. 13-16.[11]

1. Congress Cabined Any FDA Discretion Under The Act

a. At the threshold, FDA's invocation of "enforcement discretion" is misplaced because the Act confines any discretion FDA would otherwise be presumed to have, for all the reasons explained above and in Plaintiffs' opening brief, *supra* Part II.A; Br. 9-13, 14. The

[10] FDA points to comments made by certain Plaintiffs on the Deeming Rule, *e.g.*, Opp. 2, to suggest that Plaintiffs blessed FDA's exercise of enforcement discretion here. That makes too much out of too little. What many of the Organizational Plaintiffs said is that FDA's proposed compliance approach would "permit deemed products" to be marketed that "would otherwise be illegal." AR145,604. Were FDA to take that step, those Plaintiffs insisted that the agency impose guardrails to help safeguard the public health, *id.*, restrictions FDA did not adopt. The notion that, in making that limited point, those Plaintiffs forever signed off on the legality of any enforcement discretion claim that FDA might conjure up is far-fetched. In any event, FDA identifies no legal import to the comments, and Plaintiffs are aware of none. There is certainly no estoppel or waiver given that Pediatrician Plaintiffs did not sign those comments and cannot now, years later, be barred from objecting to the Guidance as *ultra vires* based on past comments filed by other Plaintiffs addressing a separate agency action.

[11] Section 701(a)(2) is no bar to review of the notice-and-comment claim. "[W]hether an agency action required notice-and-comment rulemaking is a pure question of law," *Abington Mem'l Hosp. v. Burwell*, 216 F. Supp. 3d 110, 130 (D.D.C. 2016)—a question with obvious "law to apply." Nor does § 701(a)(2) preclude review of the arbitrary-and-capricious claim. The Act, Congress's purposes underlying it, as well as the Deeming Rule and its record, provide ample "law to apply." *E.g.*, *Robbins v. Reagan*, 780 F.2d 37, 45 (D.C. Cir. 1985); *Planned Parenthood of Wis., Inc. v. Azar*, No. 18-cv-1035, 2018 WL 3432718, at *5 (D.D.C. July 16, 2018).

gravamen of Plaintiffs' statutory claim is thus that there is "law to apply" that renders the Guidance *ultra vires*—namely, the text, structure, and purposes of the Act. *See Delta Air Lines, Inc. v. Exp.-Imp. Bank of the U.S.*, 718 F.3d 974, 977 (D.C. Cir. 2013).

Indeed, *Chaney* was clear that an agency cannot invoke enforcement discretion as authority to "disregard legislative direction in the statutory scheme that [it] administers," 470 U.S. at 833, and that a "pattern of nonenforcement of clear statutory language" is outside *Chaney*'s presumption, *id.* at 839 (Brennan, J., concurring). That should be the end of the matter here. The text, structure, and purposes of the Act reveal that Congress carefully considered the "[a]pplication" of premarket review to "post-February, 2007 products," and it carved out *one* exception with a defined scope, for products introduced after February 15, 2007 but before March 22, 2011, for which an SE report was filed. 21 U.S.C. §§ 387e(j)(2), 387j(a)(2)(B). Congress also delegated to FDA authority to exempt a *single* category of products—those "intended for investigational use"—from premarket review. *Id.* § 387j(g).

Given those express statutory exceptions carefully paired with mandatory obligations, were FDA to announce that through regulatory fiat it was expanding the exemption period beyond 21 months after June 22, 2009, or extending it beyond products for which a substantial equivalence report had been filed, or that it was enlarging § 387j(g) beyond products for investigational use, courts would not hesitate to set aside that action as *ultra vires*. *E.g.*, *Alabama Power Co. v. Costle*, 636 F.2d 323, 356 (D.C. Cir. 1979) (where agency acknowledged regulation was attempted "'expansion' of [a statutory] exemption," action "f[ell] well beyond the agency's [statutory] authority"); *see also NRDC v. EPA*, 755 F.3d 1010, 1019 (D.C. Cir. 2014) (similar). FDA cannot circumvent that outcome by invoking its "enforcement discretion" to accomplish the same alteration of unambiguous statutory requirements.

FDA's contrary position has no natural stopping point and would set a dangerous precedent for agency evasion of statutory requirements. Take an example: Imagine a statute declaring that imported fruit may be marketed only after agency review for public safety. Imagine the statute created exceptions for only two types of fruit: a one-year grace period (permitting marketing without agency review) for oranges, and a similar grace period of two years for apples. Under FDA's capacious notion of "enforcement discretion," the agency could effectively set a grace period of *three* years for apples, oranges, and *all* fruit—amending the statutory scheme in all but name. Were FDA's view correct, agencies would have virtual blank checks to pick and choose which statutory requirements had the force of law for significant periods. That would be an extraordinary power—one that would subvert the principle that agencies are bound by Congress, not vice versa. *Cf. Alexander v. Sandoval*, 532 U.S. 275, 291 (2001) ("Agencies may play the sorcerer's apprentice but not the sorcerer himself.").

b. In addition, the Guidance is reviewable because FDA has "'consciously and expressly adopted a general policy' that is so extreme as to amount to an abdication of its statutory responsibilities." *Chaney*, 470 U.S. at 833 n.4. The Guidance is unquestionably a "policy"—one adopted "consciously" (i.e., deliberately) and "expressly" (i.e., openly). FDA nonetheless maintains that no "abdication" has occurred because the Guidance is "limited in duration" (Opp. 27). But shuttering a mandatory statutory regime is no less an abdication simply because there is an endpoint, particularly when FDA's theory would allow it to extend that endpoint without apparent limit. And refusing to administer the premarket review regime for nearly 25,000 products for five years or more (longer than a presidential administration) is not "limited" under any natural use of that term. It is equally irrelevant whether the Guidance, per FDA's account, is "part and parcel of a broader regulatory plan" (Opp. 27): A desire to limit

nicotine in cigarettes (a laudable goal) neither justifies nor demands FDA puncturing a wide hole in a mandatory statutory regime for years on end.

FDA turns somersaults attempting to distinguish cases applying statutory abdication (Opp. 28-29), but those efforts fail. In *Adams v. Richardson*, the *en banc* D.C. Circuit held that a challenge to an agency's failure to enforce Title VI restrictions on funding to institutions practicing segregation was reviewable. 480 F.2d 1159 (D.C. Cir. 1973). The court stressed that the case was "not" a challenge to the agency's "decisions with regard to a few school districts," but, as here, a challenge to a "general policy" of nonenforcement. *Id.* at 1162. Although the statute did not specify when and how the agency must enforce the prohibition (as opposed to seeking voluntary compliance), the D.C. Circuit held that "[a] consistent failure" to enforce the statute was a "dereliction of duty reviewable in the courts." *Id.* at 1163. Just so here. Plaintiffs do not challenge FDA's decisions to bring this or that enforcement action, but FDA's across-the-board policy of failing to implement, administer, or enforce premarket review mandates.

FDA also claims that *NAACP v. Secretary of HUD*, 817 F.2d 149 (1st Cir. 1987) (Breyer, J.), is off-point because a statutory provision there embodied Congress's goal that the agency "administer" "programs and activities in a manner affirmatively to further the policies" of the statute. Opp. 28. That is no distinction at all. In enacting the Act, Congress specified in even stronger terms that "[i]t is essential that [FDA] review [tobacco] products sold or distributed" and that "[i]t is essential that manufacturers, prior to marketing such products, be required" to satisfy premarket review. TCA § 2(36). As in *NAACP*, this Court is surely capable of determining whether FDA's announced "pattern [and] practice" of nonenforcement is consistent with the agency's statutory duties and congressional purpose. 817 F.2d at 158-159.

In short, if FDA's refusal faithfully to administer a critical component of the Nation's

tobacco laws for more than 25,000 products for years is not an "abdication of … statutory responsibilities," *Chaney*, 470 U.S. at 833 n.4, it is difficult to understand what would be.[12]

2. *Chaney* Does Not Apply To A Categorical, Policy-Based Non-Enforcement Determination Such As The Guidance

Independently from those rationales, *Chaney* is inapposite because the Guidance is a categorical, policy-based determination—a functionally *legislative* judgment about how the statute ought to work—not a case-by-case enforcement decision—the traditional domain of *executive* authority. *Chaney* itself, and multiple appellate decisions FDA does not address, reflect this fundamental distinction. *See* Br. 15-16.

Chaney involved a challenge brought by capital inmates who believed that use of certain drugs in their executions was unlawful. *See* 470 U.S. at 823-24. Because the inmates had requested a judicial order requiring FDA to "take … enforcement actions" against drug manufacturers, *id.* at 837-38; *see id.* at 823-24, the Supreme Court held that their suit fell within § 701(a)(2) and was unreviewable. But § 701(a)(2) has no bearing "when an agency *does* act," *id.* at 832, because that action "provides a focus for judicial review" and "can be reviewed to determine whether the agency exceeded its statutory powers," *id.*—that is, whether the agency has "disregard[ed] legislative direction in the statutory scheme that [it] administers," *id.* at 833.

[12] None of the grab-bag of cases cited by FDA (Opp. 23-30) is to the contrary. All were decided before *UARG*, which limited agencies' use of "enforcement discretion" to rewrite statutory obligations. None involved a statutory structure like the one here, with mandatory synchronized obligations on industry and the agency and limited statutory exceptions to those mandates. And each concerned either a challenge to a discrete enforcement action, *see Ass'n of Irritated Residents v. EPA*, 494 F.3d 1027, 1029 (D.C. Cir. 2007) (challenge to settlement agreements); *Int'l Ctr. for Tech. Assessment v. Thompson*, 421 F. Supp. 2d 1, 6-8 (D.D.C. 2006) (challenge to agency's decision "not to take any enforcement actions with in connection with" specific product), or are otherwise inapposite, *see Jerome Stevens Pharm., Inc. v. FDA*, 402 F.3d 1249, 1257 (D.C. Cir. 2005) (plaintiff did "not dispute any of the district court's legal conclusions" with respect to statutory regime); *United States v. Sage Pharm., Inc.*, 210 F.3d 475, 480 (5th Cir. 2000) (plaintiff alleged enforcement action was "arbitrary and capricious").

This case is far afield from *Chaney*. As FDA itself concedes, "Plaintiffs do not ask the Court to … compel the FDA to take enforcement action against any manufacturer that fails to [submit applications]." Opp. 21. And, unlike in *Chaney*, Plaintiffs challenge an affirmative decision by FDA to suspend premarket review, a decision expressly set out in the Guidance—a document that, in *Chaney*'s words, "provides a focus for judicial review" and "can be reviewed to determine whether the agency" acted unlawfully. 470 U.S. at 832. Finally, the Guidance is not based on resource constraints, or a determination of which legal violations FDA intends to target—the indicia of enforcement discretion identified in *Chaney*. *See id.* at 831. The Guidance instead reflects programmatic considerations about how the statute ought to operate that are the hallmarks of legislative judgments for Congress. *See* Br. 15-16.

Multiple federal courts of appeals—none of which FDA acknowledges—have drawn these very distinctions from *Chaney*. Those courts have recognized that § 701(a)(2) bars suits seeking to compel agencies to take specific, discrete enforcement actions, but not challenges to an agency's categorical and express policy of nonenforcement. *See OSG Bulk Ships, Inc. v. United States*, 132 F.3d 808, 812 (D.C. Cir. 1998) ("agency's adoption of a general enforcement policy is subject to review"); *Kenney v. Glickman*, 96 F.3d 1118, 1123 (8th Cir. 1996) ("*Chaney* applies to individual, case-by-case determinations of when to enforce existing regulations rather than permanent policies or standards"); *Crowley Caribbean Transp., Inc. v. Pena*, 37 F.3d 671, 676 (D.C. Cir. 1994). This makes good sense: Unlike a "single-shot non-enforcement decision," an agency's global policy of non-enforcement is "[b]y definition … abstracted from the particular combinations of facts the agency would encounter in individual enforcement proceedings." *Crowley*, 37 F.3d at 676-77. Because the Guidance is plainly such a policy, it is beyond the scope of *Chaney*'s presumption of nonreviewability and it is "reviewable for legal

sufficiency" by this Court. *Id.* at 676.

FDA has no good answer. It claims that the Guidance is not "categorical" because it does not suspend other statutory provisions or apply to new products that enter the market after August 2016. Opp. 29. Those are not serious distinctions. The Guidance exempts—on an unqualified, across-the-board basis—as many as 25,000 new tobacco products (including e-cigarettes and cigars) from a central mandate of the Act. That is precisely the type of universal annulment, as opposed to case-by-case decision, to which *Chaney* has no defensible application.

FDA's fallback position that *Chaney*, too, involved a categorical policy does not make sense. As discussed above, *Chaney* involved inmate demands for discrete FDA enforcement actions against identified individuals and entities. *See Chaney v. Heckler*, 718 F.2d 1174, 1177-1178 (D.C. Cir. 1983) (describing citizen petition submitted by inmates), *rev'd*, 470 U.S. 821 (1985). Moreover, the inmates in *Chaney* did not seek review of an express policy of non-enforcement, because FDA had not issued one. Saying that *Chaney* involved a categorical policy would thus erase the line between global nonenforcement policies and "single-shot non-enforcement decisions" that multiple courts have recognized. *Crowley*, 37 F.3d at 676.

3. *Chaney* Does Not Apply Because Affirmative Authorization Of Illegal Industry Conduct Is Not "Enforcement Discretion"

Finally, *Chaney* is independently not controlling because its presumption does not attach to an agency's "affirmative act of approval," *Chaney*, 470 U.S. at 831, or to its determination that "otherwise-prohibited conduct" by regulated entities "will not violate [a statute]." *UARG*, 134 S. Ct. at 2445; Br. 14-15. That is dispositive here. As explained fully above, in design and effect, the Guidance establishes an across-the-board license for manufacturers to market e-cigarettes and cigars without premarket review, thus establishing an agency-created exemption

that goes well beyond the statutory exemption in the Act.

Preemptively permitting regulated entities to engage in unlawful conduct—as the Guidance does—is not "enforcement discretion," no matter how many times FDA invokes that label. Were it otherwise, agencies could shirk all manner of statutory duties and effectively rewrite comprehensive and carefully structured statutory schemes at will. FDA fails to confront the fundamental point that the Guidance "cannot" be "defend[ed] … as an exercise of … enforcement discretion" because it "purports to alter [Tobacco Control Act] requirements" and to pronounce that "otherwise-prohibited conduct" "will not violate the [Act]." *UARG*, 134 S. Ct. at 2445; *cf. Texas v. United States*, 787 F.3d 733, 757 (5th Cir. 2015) ("[d]eclining to prosecute does not convert an act deemed unlawful by Congress into a lawful one").

III. THE GUIDANCE IS ARBITRARY AND CAPRICIOUS

The Guidance must also be vacated as arbitrary and capricious because (i) FDA provided no reasoned, rational justification for abruptly departing from its prior compliance policy and (ii) FDA wholly failed to account for the predictable, and devasting, public health consequences that would follow establishing a multi-year exemption from premarket review regime for nearly 25,000 new tobacco products. *See* Br. 21-25. FDA's contrary arguments are unpersuasive.

A. FDA Failed To Reasonably Justify The Guidance

The APA demands that an "agency must give adequate reasons for its decisions." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016). To satisfy this requirement, "conclusory statements will not do; an 'agency's statement must be one of reasoning.'" *Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014). "[T]o accept an agency's blanket conclusions at face-value" where it has failed to explain "'facts found'" and the "rational connection" between those facts and the agency's decision would "abdicate [the judicial] role." *Sierra Club v. U.S. Dep't of Interior*, No. 18-1082, 2018 WL 3717067, at *24 (4th Cir. Aug. 6,

2018). And while an agency may change course, "it must provide 'a reasoned explanation … for disregarding facts and circumstances that underlay or were engendered by the prior policy.'" *Air All. Houston v. EPA*, No. 17-1155, 2018 WL 4000490, at *12 (D.C. Cir. Aug. 17, 2018).

This case well implicates those principles. In the face of a massive administrative record underlying the Deeming Rule and despite prior findings driving FDA's determinations that a much more limited compliance period would best balance competing objectives, FDA abruptly changed course and effected a substantial change in the regulation of nearly 25,000 new tobacco products. In laboring to explain and justify this change, FDA relies on an agency "press release," and accompanying speech. Opp. 44-45. From those limited materials, FDA's lawyers glean three purported justifications for suspending premarket review: (1) to promote "innovation"; (2) so that FDA may develop "product standards"; and (3) to give industry more time to submit applications (and, relatedly, for FDA to issue new guidance). *Id.* If one of those rationales is arbitrary and capricious, that would demand vacatur. *See Nat'l Fuel Gas Supply Corp. v. FERC*, 468 F.3d 831 (D.C. Cir. 2006). Here, *all* of the justifications fail.

1. FDA's "Innovation" Justification Is Unfounded

FDA's lead justification for the Guidance is a need to promote "innovation." Opp. 10, 11, 45, 48. That rationale is arbitrary and capricious for multiple reasons. *First*, the record is devoid of any reasoned explanation, much less findings, by FDA as to how or why applying premarket review to new tobacco products as Congress intended, particularly under the original compliance policy, would dampen innovation or why innovation outweighs other public health objectives. FDA's "conclusory," vague, and unexplained "statements" regarding innovation are wholly insufficient, *Pistole*, 753 F.3d at 1350, as courts do not "simply accept whatever conclusion an agency proffers merely because the conclusion reflects the agency's judgment," *Tripoli Rocketry Ass'n, Inc. v. ATF*, 437 F.3d 75, 77 (D.C. Cir. 2006).

Second, FDA's failure is particularly glaring given that its innovation claim directly contradicts prior findings. FDA previously explained that the balance struck by the Deeming Rule and the original compliance policy "will not stifle innovation but could, instead, encourage it." AR11,915-16. It further found that premarket review "will incentivize development of tobacco products that pose less risk to human health by limiting market access by riskier competitor products." *Id.*; *see* AR11,952 (similar). FDA made those determinations on the basis of a robust record, informed by comments developed over a multi-year rulemaking. By contrast, the Guidance and the press release—issued without any apparent fact-finding and absent notice and comment—pretend those findings do not exist, defying the cardinal principle that "[a]n agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 537 (2009) (Kennedy, J., concurring); *see Air All. Houston*, 2018 WL 4000490, at *12-13 (similar).

Third, FDA's innovation theory is internally incoherent, and the "unexplained inconsistencies" render the Guidance arbitrary and capricious. *Dist. Hosp. Partners, LP v. Burwell*, 786 F.3d 46, 59 (D.C. Cir. 2015) (collecting authority). The Guidance creates an extended exemption from premarket review for nearly 25,000 products on the market as of August 2016; according to FDA, no exemption exists for any new tobacco product placed on the market after that date. FDA's innovation argument assumes (contrary to its prior conclusions) that premarket review discourages innovation in new, reduced risk products; yet the Guidance applies only to products already on the market and preserves premarket review for products not yet introduced. Accepting FDA's own reasoning, the Guidance thus *creates* massive incentives not to innovate. That unexplained disconnect between the agency's proffered rationale and the Guidance renders FDA's action arbitrary and capricious.

Finally, "innovation" cannot possibly justify the Guidance's application to cigars. FDA speaks of the need to encourage "innovations" in products that "generally do not produce the smoke delivered by combustible tobacco products," Opp. 10, and the Guidance and FDA's comprehensive policy are based on the premise that "combustible forms of tobacco" cause significant "harm." GAR406. Cigars, however, are *combustible*. Thus, by its own terms, FDA's rationale for its multi-year suspension of premarket review could not possibly apply to cigars and other combustible products. Why, then, are cigars given an across-the-board exemption? FDA offers no explanation, and none is apparent, as to how its desire to reduce the use of combustible tobacco justifies *loosening* regulation of combustible tobacco. Nor does the record show any ongoing or potential "innovation" in cigars that could possibly advance the public health objectives of the Act or justify a multi-year exemption for the entire cigar industry.

2. FDA's "Products Standard" Justification Is Unfounded

FDA's position that the Guidance is justified by FDA's desire eventually to develop product standards is similarly arbitrary. *See* Opp. 10, 30, 44, 47. *First*, FDA's authority to develop "product standards" is a separate, *discretionary*, authority (21 U.S.C. § 387g) from FDA's *mandatory* premarket review responsibilities (21 U.S.C. § 387j). That authority is neither dependent upon premarket review, nor does it require that product standards precede premarket view. Neither the Guidance nor the press release explains why it is sensible to delay a mandatory requirement—which Congress viewed as essential to public health protection—for half a decade or more so that the agency may develop discretionary standards addressing things like "'batter[ies]'" and "'liquid nicotine'" for e-cigarettes. Opp. 10 (quoting GAR412). Those standards may be important, but promulgating them does not require rendering premarket review a dead letter. In fact, conducting such review would help inform product standards by allowing FDA to learn about new tobacco products. *See* AR11,909 ("information provided as part of

premarket review … will provide critical information on these [new tobacco] products").

Second, like the innovation justification, FDA's product standards claim is irrationally inconsistent with the design of the Guidance. FDA has set forth no explanation—much less a reasoned one—for its inconsistent determination that the approximately 25,000 new products on the market as of August 2016 should be exempt from premarket review because of a desire to develop product standards, while at the same, products marketed after August 2016 should undergo review, absent those product standards. That "unexplained inconsistenc[y]" is fatal to the Guidance. *District Hosp. Partners*, 786 F.3d at 59.

Third, in promulgating the Deeming Rule, FDA considered and rejected proposals to delay premarket review or other Act authorities until it issued product standards. AR11,911. FDA found that "[it] would not protect the public health to forego implementation [of the TCA] until FDA can issue final product standards and tobacco product manufacturing practice regulations." *Id*. FDA, of course, may change its mind, but it must acknowledge that change and provide a non-conclusory, reasoned explanation for it. It did neither here.

3. FDA's "Additional Time for Industry" Justification Is Unfounded

Finally, in yet another unsupported reversal, FDA claims that the Guidance is "designed to build in time for the FDA 'to issue regulations outlining what information the agency expects to be included in [p]remarket applications,'" Opp. 30, and "give manufacturers time to come into compliance," *id.* at 2. These related rationales are unavailing.

First, FDA issued its first guidance on PMTA applications in September 2011—almost seven years ago. *See* FDA, *Guidance for Industry: Applications for Premarket Review of New Tobacco Products* (Sept. 2011). And when FDA promulgated the Deeming Rule, it issued another guidance document on the same topic, focused on e-cigarettes. *See* AR28,350. In neither the Guidance at issue here nor the press release has FDA provided any reasoned

explanation as to why this prior agency guidance is deficient or incomplete.

Second, FDA's assertion that tobacco manufacturers need "additional time" to come into compliance is wholly unsubstantiated. GAR412. In crafting the original compliance period, FDA time and again rejected industry objections—recycled in the industry *amicus* brief here—that more time was needed. *See* Br. 23-24. To start, FDA found that "manufacturers … ha[d] been on notice for more than 4 years," since 2011, "that these products could and likely would be regulated." AR11,901. Moreover, based on a robust record, FDA explained that the original period "takes into account the time for firms to generate and submit the information for a PMTA," AR11,909; FDA found the original policy (with much shorter deadlines) would give "sufficient time" for "high quality applications," AR11,920; and FDA rejected a 5-year compliance period similar to the Guidance, *id.* In addition, in Deeming Rule litigation, FDA has stated in no uncertain terms that "self-serving predictions," such as those made by industry *amici* here, "that [industry] will be unable to meet the August 2018 compliance date should be rejected." Reply in Support of Defs.' Cross-Mot. for Summ. J. 12, *Nicopure Labs, LLC v. FDA*, No. 16-cv-878 (D.D.C. Sept. 9, 2016), ECF No. 48; *see id.* at 12-13.

In changing course, FDA failed to provide a reasoned explanation as to why what the agency had found before was wrong and did not even attempt to identify any new facts or offer a different reading of prior facts that would justify its abrupt shift in regulation. The D.C. Circuit recently rejected an analogous agency action for very similar reasons, *see Air All. Houston*, 2018 WL 4000490, at *12-13, and this Court should do the same.

B. FDA Failed To Justify The Public Health Consequences Of The Guidance

Independently, the Guidance is arbitrary and capricious because FDA failed to account for the foreseeable and devastating costs to public health that would arise from the Guidance's suspension of premarket review. As demonstrated in Plaintiffs' opening brief and by a legion of

public health organizations as *amici*, the Guidance has enabled and amplified a fast-developing public health crisis with respect to e-cigarettes and cigars, especially among the Nation's youth. *See* Dkt. 34-1. But nothing in the administrative record demonstrates whether or how FDA took account of those serious "disadvantages." *Michigan v. EPA*, 135 S. Ct. 2699, 2707 (2015).

FDA asserts that it "considered the potential public health effects" of the Guidance, Opp. 48, but it points to nothing other than a sentence in a speech to support that assertion—no internal qualitative or quantitative analysis; no memoranda weighing advantages and disadvantages; and no factual findings. Based on that speech, FDA claims that the Guidance's health benefits flow from "delaying the immediate market exit of innovative, potentially less harmful tobacco products." *Id.* (citing GAR405-410). That explanation—the apparent sum-total of FDA's weighing of health effects—is inadequate. To begin with, it could not possibly justify suspending premarket review for cigars until 2021 because, as FDA found in the Deeming Rule—and has consistently asserted in litigation defending that Rule, *see* Defs.' Cross-Mot. for Partial Summ. J. 9-11, *Cigar Ass'n of America v. FDA*, No. 16-cv-1460 (D.D.C. Oct. 24, 2017), ECF No. 74—all cigars present health risks because they involve combustion. Equally significant, FDA assumes that manufacturers lacked sufficient time under the Deeming Rule's compliance policy to file applications, a position that directly contradicts FDA's prior findings and its litigation positions, as explained above. Finally, FDA's fear of "market exit" irrationally ignores the other side of the public health ledger—namely, the "substantial" public health benefits that premarket review would entail that FDA itself previously described. AR11,911.

Nothing in the Guidance or the administrative record demonstrates whether and how FDA "face[d] the trade-off[s]" between industry conjecture about market exit, on the one hand, and the concrete benefits of premarket review, on the other. *Competitive Enter. Inst. v. NHTSA*,

956 F.2d 321, 323-324 (D.C. Cir. 1992). FDA's failure to account for these public health consequences is especially indefensible given Congress's repeated findings about the public interest in preventing new generations of the Nation's youth from becoming addicted to nicotine. *E.g.*, TCA §§ 2(1), 2(15), 2(20), 2(21), 2(24), 3(2). Youth tobacco usage was thus an "important aspect of the problem" FDA was obligated to consider and account for before issuing the Guidance. *United Solid Waste Activities Group v. EPA*, No. 15-1219, 2018 WL 4000476, at *9 (D.C. Cir. Aug. 21, 2018) (per curiam). But in its rush to suspend premarket review, FDA wholly failed to account for those devastating public health consequences.

IV. THE GUIDANCE WAS PROMULGATED WITHOUT REQUIRED NOTICE AND COMMENT

Finally, even if FDA had unfettered authority to recalibrate the Act in the manner accomplished by the Guidance (it does not), that type of substantive, significant agency action must comply with APA's notice-and-comment requirements. Likewise, in issuing the Guidance, FDA sharply departed from the Deeming Rule's compliance policy—which itself was a product of notice-and-comment rulemaking—without providing for meaningful public input. Br. 16-20. FDA's deliberate failure to "expose" the Guidance "'to the test of prior examination and comment,'" *National Helium Corp. v. Federal Energy Admin.*, 569 F.2d 1137, 1146 (Temp. Emer. Ct. App. 1977), resulted in agency action that, substantively, is ill-advised, arbitrary and capricious, and has already had disastrous consequences for public health, as explained in Part III, above. But FDA's failure to abide by APA notice-and-comment requirements—a procedural question this Court reviews with no deference to the agency's views, *Chocolate Mfrs. Ass'n of U.S. v. Block*, 755 F.2d 1098, 1103 (4th Cir. 1985)—itself requires vacatur of the Guidance.

In response, FDA has one argument. FDA claims that the Guidance is a "statement of policy" exempt from notice and comment. Opp. 37. This "claim of exemption from APA rulemaking requirements"—which courts "'narrowly construe[] and only reluctantly

countenance[]'"—cannot withstand scrutiny. *Envtl. Def. Fund, Inc. v. Gorsuch*, 713 F.2d 802, 816 (D.C. Cir. 1983). Judicial scrutiny is particularly "exacting" where, as here, FDA seeks "to 'undo'" the prior compliance policy it promulgated in the Deeming Rule "'without giving all parties an opportunity to comment on the wisdom of repeal.'" *Id*. at 816-817.

To qualify as an exempt policy statement, the Guidance would have to (1) operate only prospectively to inform future agency decisionmaking—while having no "present effect"—and (2) "genuinely leave[] the agency and its decision-makers free to exercise discretion." *Am. Bus Ass'n v. United States*, 627 F.2d 525, 529 (D.C. Cir. 1980). The Guidance does neither: First, like the challenged pronouncement in *American Bus*, the Guidance took effect upon publication "without further action by" FDA, and as a result, "restrictions previously imposed … have been lifted." *Id*. at 531. The Guidance thus "does not … operate only prospectively," but "is 'finally determinative'" of the immediately applicable deadlines for regulatory compliance. *Id*. Second, the Guidance does not "'contemplate that" FDA officials "will exercise an informed discretion in the various cases that arise.'" *Id.* at 530. Leaving case-by-case discretion to agency officials would in fact negate the Guidance's purpose—which is to draw a clear line permitting non-compliant activity before the deadline, but not after. Here, as in *American Bus*, because the statutory obligations of premarket review are themselves "legally enforceable," FDA cannot avoid notice-and-comment rulemaking by "us[ing] a policy statement to release" the industry from complying with those obligations. *Id*. at 533.

FDA's contrary argument depends almost entirely on unjustified formalism. But courts "look … at the actual function and effect of the rule," not the agency's labels or its recitation of disclaimers. *Associated Dry Goods Corp. v. EEOC*, 720 F.2d 804, 809 (4th Cir. 1983); *see* Br. 18. As to practical effect, FDA does not deny that the Guidance accomplishes a multi-year delay

of statutory and regulatory compliance, and the agency admits that "[s]uspending a *rule's* effective date" would require notice and comment because it "alters the underlying legal norm." Opp. 41. Yet the Guidance does the same thing in effect, if not name, by delaying so-called "compliance dates" for statutory premarket review, GAR425, establishing an atextual statutory exemption, as explained above, *see supra* pp. 20-22. Moreover, FDA identifies no meaningful distinction between delaying the effective date of a rule—which it agrees is substantive regulation—and delaying the compliance date for a statutory provision—which it insists is not.

FDA's related assertion that the Guidance is "neither categorical, nor an exemption" (Opp. 39) is also unconvincing, again for reasons already explained. *See supra* p. 29. By its terms, the Guidance "applies to all categories of newly regulated products that were on the market on August 8, 2016," GAR424, without qualification. That is explicitly categorical. And the Guidance "exten[ds]," "revises," and "supersed[es]" the previously extended compliance periods in the Deeming Rule, GAR424-425—during which the agency, in its own words, "expect[s] that manufacturers … will continue to market their products without FDA authorization," AR11,918. That is nothing if not an exemption.

None of the cases FDA cites (Opp. 39-40) involved agency actions of this type. To the contrary, in each, "the agency [was] 'genuinely le[ft] … free to exercise discretion.'" *Clarian Health W., LLC v. Hargan*, 878 F.3d 346, 357-358 (D.C. Cir. 2017) (instructions described "criteria" for "enforcement priorities," but agency "expressly retained discretion to deviate"); *Prof'ls & Patients for Customized Care v. Shalala*, 56 F.3d 592, 598 (5th Cir. 1995) ("none of the nine factors listed … establish 'fixed criteria to control the agency's decisions'"); *Brock v. Cathedral Bluffs Shale Oil Co.*, 796 F.2d 533, 538 (D.C. Cir. 1986) (agency "retained [its] discretion"); *Int'l Union, UAW v. Brock*, 783 F.2d 237, 251 n.18 (D.C. Cir. 1986) (memorandum

simply advised on "enforcement priorities"); *Ctr. for Auto Safety*, 342 F. Supp. 2d at 18 (agency was left with "case-by-case basis" discretion).[13]

In contrast, the Guidance—while purporting to set "compliance date[s] … as a matter of enforcement discretion," GAR425—does not suggest that FDA will continue to enforce premarket review on a case-by-case basis. Quite the opposite: The Guidance functions as an on-off switch that "release[s]" manufacturers from compliance in the interim. *Am. Bus*, 627 F.2d at 533. As Plaintiffs have explained, and FDA does not rebut, such a years-long deferral and wholesale revision of the compliance policy in the Deeming Rule is indistinguishable from revisions to "effective dates" long held to be substantive. *See* Br. 18-19. In both cases, setting and altering those dates operates with "the rigor of a rule, not the pliancy of a policy." *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1320-1321 (D.C. Cir. 1988).

CONCLUSION

The Court should vacate the Guidance and award appropriate equitable relief.[14]

[13] FDA's cited cases involving rescission of DACA are similarly inapposite. Those cases relied in part on the fact that DACA itself was announced without notice and comment in concluding that its rescission was exempt from notice and comment. *See NAACP v. Trump*, 298 F. Supp. 3d 209, 237 (D.D.C. 2018); *Casa De Maryland v. DHS*, 284 F. Supp. 3d 758, 772 (D. Md. 2018). But the Guidance repeals a compliance policy that FDA concedes (Opp. 42) was the result of notice and comment alongside the Deeming Rule.

[14] Industry *amici* assert vacatur will prompt "*en masse*" market exit. Dkt. 37-1 at 3. Although vacatur is the baseline APA remedy, this Court may "tailor its remedy to the occasion," *NAACP*, 817 F.2d at 160-161, and Plaintiffs expressly seek equitable relief. Plaintiffs thus respectfully suggest that, if the Court determines that the Guidance is unlawful, it may invite remedial briefing, asking FDA within 14 days of the Court's decision to submit a proposed remedy, with corresponding time for Plaintiffs to brief whether that remedy sufficiently redresses the legal violations found by the Court and Plaintiffs' injuries.

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