No. 23-1038

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, PETITIONER

v.

WAGES AND WHITE LION INVESTMENTS, L.L.C., DBA TRITON DISTRIBUTION, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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In the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or Act), Pub. L. No. 111-31, Div. A, 123 Stat. 1776, Congress directed the Food and Drug Administration (FDA) to authorize a new tobacco product only if an applicant could show that the marketing of its product would be appropriate for the protection of the public health. Applying that standard, FDA denied respondents' applications for authorization to market e-liquids with flavors such as cotton candy, pink lemonade, and milk and cookies because such flavored products pose a serious risk of attracting youth to the use of tobacco without sufficient offsetting benefits for adults. Seven other courts of appeals have upheld similar denial orders, each time unanimously.

In the decision below, however, the en banc Fifth Circuit held that FDA's denial of respondents' applica-

tions was arbitrary and capricious. The Fifth Circuit offered five rationales for its decision, but respondents abandoned one of them before this Court granted the petition for a writ of certiorari. Respondents now retreat from the remaining four rationales, significantly rewriting some of them and defending another only in a footnote. Many of respondents' amici jettison the Fifth Circuit's rationales altogether, instead offering their own alternative grounds for setting aside FDA's orders. All of that just confirms that the Fifth Circuit's outlier decision is wrong. This Court should reverse.

A. FDA Properly Evaluated Applications For Authorization To Market Flavored E-Liquids

In its most significant ruling, the Fifth Circuit held, contrary to the decisions of seven other courts of appeals, that FDA unfairly surprised manufacturers of flavored e-cigarettes during the application process. See Gov't Br. 17. Respondents offer no meritorious defense of that aberrational holding.

1. At the outset, respondents apply the wrong legal test in analyzing their unfair-surprise claims. An agency acts arbitrarily if it announces one standard, and then applies a different standard, without explaining the change and considering serious reliance interests engendered by its previous policy. See Gov't Br. 18. To make that sort of claim, respondents need to show that the agency "affirmatively misdirected" them. *Prohibition Juice Co.* v. *FDA*, 45 F.4th 8, 21 (D.C. Cir. 2022). It is not enough for them to show that the agency did not forecast how it would evaluate their applications or that they had a reasonable, if mistaken, interpretation of the agency's guidance about the process.

In framing their argument, respondents instead contend that FDA was required to "communicate with 'as-

certainable certainty'" the standard that applicants would need to meet in order to obtain authorization. Br. 28 (citation omitted). But an agency generally has no affirmative obligation to issue guidance in the first place. See Gov't Br. 25-28. Nor was the Fifth Circuit correct in concluding that an agency is bound by a private party's purportedly reasonable misreading of its guidance. See *id.* at 28-31.

To support their demand for greater pre-application certainty, respondents invoke principles of due process and fair notice. Of course, "[e]lementary notions of fairness" require the government to provide a person with "fair notice" of "the conduct that will subject him to *punishment*." *BMW of North America, Inc.* v. *Gore*, 517 U.S. 559, 574 (1996) (emphasis added). This Court has thus held that the Due Process Clause prohibits the enforcement of "a criminal law so vague that it fails to give ordinary people fair notice of the conduct it punishes." *Johnson* v. *United States*, 576 U.S. 591, 595 (2015). And in the cases that respondents cite (Br. 28-29, 34), courts of appeals have extended "this 'no punishment without notice' rule" to "the civil administrative context," requiring agencies to provide fair notice before imposing civil penalties. *General Electric Co.* v. *EPA*, 53 F.3d 1324, 1327, 1329 (D.C. Cir. 1995); see *ExxonMobil Pipeline Co.* v. *Department of Transportation*, 867 F.3d 564, 568 (5th Cir. 2017) ("civil administrative penalties"); *Satellite Broadcasting Co.* v. *FCC*, 824 F.2d 1, 3 (D.C. Cir. 1987) ("sanction"); *Radio Athens, Inc., (WATH)* v. *FCC*, 401 F.2d 398, 404 (D.C. Cir. 1968) ("sanction").

But in this case, the government did not seek to punish respondents for violating the law. It simply found that they were not entitled to a benefit for which they

had applied: permission to sell an otherwise unlawful product.

Respondents cite (Br. 35) a case in which the D.C. Circuit required an agency to provide fair notice before dismissing an application as a "sanction" for violating a procedural rule. *Satellite Broadcasting*, 824 F.2d at 3. But FDA did not dismiss respondents' applications to penalize them for procedural violations. Rather, FDA found that respondents were not entitled to the benefit they sought because they had failed to show that their products would be appropriate for the protection of the public health. Respondents cite no case (apart from the decision below) requiring an agency to provide such detailed notice before evaluating an application for a benefit.

Nor do the courts have the power to impose such a requirement. The reviewing court's role is to ensure that agencies comply with the requirements prescribed by Congress—not to enforce its "own notions of proper procedures." *Vermont Yankee Nuclear Power Corp.* v. *NRDC, Inc.*, 435 U.S. 519, 525 (1978). And a court may not abridge an agency's discretion to develop regulatory principles through "case-by-case evolution" rather than through "a general rule" issued in advance. *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 293 (1974) (citation omitted).

Respondents' contrary approach would prove especially unworkable in the context of the Tobacco Control Act. The Act requires manufacturers to obtain authorization before marketing *new* tobacco products. See 21 U.S.C. 387j(a)(1). In evaluating new products, FDA will inevitably encounter new issues. It would make little sense to require an agency to announce ahead of time how it will resolve issues that it has not yet confronted.

See *Bell Aerospace*, 416 U.S. at 293 ("[P]roblems may arise in a case which the administrative agency could not reasonably foresee, problems which must be solved despite the absence of a relevant general rule.") (citation omitted).

Separately, respondents emphasize (Br. 42-45) the principle that an agency may change its policy only if it considers serious reliance interests engendered by its previous policy. But that principle applies only when an agency actually changes its policy. Respondents, like the Fifth Circuit, assert (Br. 43-44) that an agency must also consider a private party's reliance on a purportedly "reasonable" interpretation of the agency's guidance, regardless of whether that interpretation turns out to be "'correct' or 'incorrect.'" But respondents cite no statutory provision or decision of this Court imposing such a requirement.

Respondents' approach, again, would be particularly unworkable in the context of the Tobacco Control Act. Manufacturers have applied to FDA for authorization to market millions of new tobacco products. See Pet. App. 129a. Different applicants may interpret the Act, the regulations, and the guidance in different ways. Respondents' theory would seemingly require the agency to follow a bespoke review process for each applicant, tailored to that particular applicant's purportedly "reasonable" reading of the relevant requirements and guidance. Resp. Br. 43.

2. Regardless of how the legal test is framed, respondents' claim of unfair surprise fails for a more basic reason: They did not lack notice of the relevant considerations. In this Court, respondents primarily contend (Br. 27) that FDA unfairly surprised manufacturers of flavored e-liquids by requiring them to submit evidence

"comparing [their] flavored products to tobacco-flavored products." In fact, respondents stake almost their entire case on that premise. See, *e.g.*, *id.* at 29 ("[FDA] made no public suggestion of any need to compare flavored and tobacco-flavored [e-liquids]."); *id.* at 30 ("FDA made no mention of any requirement * * * to compare one [e-cigarette] product against another."); *id.* at 36 ("[FDA] *never* told applicants that they needed to compare their flavored products to tobacco-flavored products.").

Although respondents emphasized the same theory below (*e.g.*, C.A. Resp. Br. 39), the Fifth Circuit did not rely on it. And the five other courts of appeals to consider that contention have correctly rejected it. See *Liquid Labs LLC* v. *FDA*, 52 F.4th 533, 542-543 (3d Cir. 2022); *Avail Vapor, LLC* v. *FDA*, 55 F.4th 409, 419 (4th Cir. 2022), cert. denied, 144 S. Ct. 277 (2023); *Lotus Vaping Technologies* v. *FDA*, 73 F.4th 657, 670-672 (9th Cir. 2023), petition for cert. pending, No. 23-871 (filed Feb. 9, 2024); *Electric Clouds, Inc.* v. *FDA*, 94 F.4th 950, 958-960 (10th Cir. 2024); *Prohibition Juice*, 45 F.4th at 23-24 (D.C. Cir.).

The most serious problem with respondents' theory is that the statute itself unambiguously requires FDA to make comparative judgments. See, *e.g.*, *Electric Clouds*, 94 F.4th at 958-959. The Act directs FDA, in evaluating whether a new product would be appropriate for the protection of the public health, to consider "the *increased or decreased* likelihood that existing users of tobacco products will stop using such products" and "the *increased or decreased* likelihood that those who do not use tobacco products will start using such products." 21 U.S.C. 387j(c)(4) (emphases added). Those factors are "inherently comparative." *Lotus Vaping*, 73

F.4th at 669. The only way to gauge whether a new product "increases" or "decreases" the likelihood of particular benefits or risks is to compare that product to other products. "[N]othing can 'increase' or 'decrease' in a vacuum." *Avail Vapor*, 55 F.4th at 428 (citation omitted).

If that were not enough, the Act specifically requires the manufacturer to submit, as part of its application, information about "whether [its] tobacco product presents *less risk than other tobacco products*." 21 U.S.C. 387j(b)(1)(A) (emphasis added). The Act then directs FDA to consider "the information submitted" as part of the application—including such information comparing the applicant's product to other products—when reaching its decision. 21 U.S.C. 387j(c)(2).

Thus, the Act alone provided respondents with ample notice. But FDA's 2019 Guidance also reminded applicants to submit comparative evidence. In a section titled "Comparison Products," the guidance encouraged applicants to "compare" their products to other products and to justify their chosen "comparators," explaining that "comparative" data is "an important part" of FDA's analysis. J.A. 30. Other parts of the guidance likewise discussed the importance of submitting comparative evidence. See, *e.g.*, J.A. 51 ("relative health risks of the new tobacco product * * * compared to other tobacco products"); J.A. 53 ("assessment of whether the product will have a positive impact on the health of the population * * * as compared to other tobacco products"); J.A. 58 ("comparison to other e-liquids"); J.A. 101 ("comparative assessments").

Respondents insist (Br. 27, 31 n.25, 36) that the Act and FDA's guidance left applicants "free to select a comparator product of their choosing"; that applicants

need not show that "flavored products" work better than "tobacco-flavored products"; and that applicants may instead obtain authorization to sell fruit-, candy-, and dessert-flavored e-liquids simply by showing that e-liquids are less harmful than "combustible cigarette[s]." But that is an implausible interpretation of the Act and the guidance. The application process is not a game that tests an applicant's skill at drawing comparisons to just any other product. The point of the Act's comparative-evidence requirement is instead to enable FDA to assess a product's marginal "risks and benefits" relative to the range of potential alternatives—and thus to determine whether the product is "appropriate for the protection of the public health." 21 U.S.C. 387j(c)(4).

Here, FDA found that fruit-, candy-, and dessert-flavored e-liquids pose a higher risk of attracting youth than do tobacco-flavored e-liquids. See Pet. App. 183a-197a, 237a-251a, 291a-305a. It explained that the "majority of youth who use [e-cigarette products] report using a flavored [e-cigarette product]"; that youth are "more likely to use flavored [products]" than adults; that youth users "consistently select flavors as a top reason" when asked why they use e-cigarettes; and that "flavoring" makes tobacco products "more palatable for novice youth and young adults." *Id.* at 187a-190a, 241a-244a, 295a-298a. Because flavors thus pose an added risk to public health, FDA sensibly looked for evidence that they provide an "added benefit" that could "outweigh" that risk. *Id.* at 168a, 228a, 280a. But FDA "did not find such evidence" in respondents' applications. *Id.* at 168a, 228a, 263a.

Respondents insist (Br. 36) that FDA never specifically told applicants that "they needed to compare their flavored products to tobacco-flavored products." Even

if that were true, it would not establish unfair surprise. FDA's 2019 Guidance was directed to e-cigarette and e-liquid applicants in general, not to makers of flavored e-liquids in particular. See J.A. 19. It should hardly come as a surprise that guidance addressed to a general audience would speak in general terms.

In any event, respondents' characterization is incorrect. In a section of the 2019 Guidance captioned "Flavors," FDA flagged its concerns about the "impact of flavors" on "appeal to youth and young adults"; stated that it was "important for [applications] for flavored products to examine the impact of the flavoring"; and encouraged applicants to "examin[e] adult appeal of such flavors." J.A. 87-88. The 2019 Guidance, in short, notified applicants of the need to compare "e-liquids with and without flavoring." *Electric Clouds*, 94 F.4th at 960.

Indeed, respondents' own applications reflected a recognition of their need to compare the risks and benefits of products with and without flavors. Respondents asserted that "flavors are crucial to getting adult smokers to make the switch and stay away from combustible cigarettes"; that certain survey participants "started out using tobacco or menthol flavors but now always or almost always use other flavors"; and that "[t]his change in flavor preference * * * has powerful implications" for "the role of flavors." J.A. 319, 321. Respondents thus *attempted* to show the very thing that they claim was an undisclosed requirement: that flavors provide added benefits relative to other types of products. Accordingly, any assertion of unfair surprise is "far off base." *Prohibition Juice*, 45 F.4th at 23. And FDA's conclusion that respondents had failed to provide enough evidence to back up their comparative claims,

see Pet. App. 168a, 228a, 263a, is also unsurprising—especially when respondents' own review of the scientific literature found that "no conclusions can be made about the association of e-cigarette flavors and smoking cessation," J.A. 476.

3. As noted above, the Fifth Circuit did not rely on the theory that FDA surprised applicants by applying the Act's comparative-evidence requirement. See p. 6, *supra*. The court instead reasoned that FDA surprised applicants by requiring particular types of studies. See Pet. App. 36a. Respondents briefly raise that argument as well, but their contentions lack merit.

Respondents repeat (Br. 37) the Fifth Circuit's claim that FDA unexpectedly "required applicants to submit a randomized controlled trial or longitudinal cohort study." That claim conflicts with the plain text of FDA's denial orders, which stated: "This evidence *could* have been provided using a randomized controlled trial and/or longitudinal cohort study[.] * * * Alternatively, FDA *would consider other evidence*[.] * * * We did not find such evidence in your [application]." Pet. App. 167a-168a (emphases added); see *id.* at 227a-228a; *id.* at 263a-264a. Respondents object (Br. 37 n.28) that "any 'other evidence' must still be of comparative efficacy," but that just repeats their meritless comparative-evidence theory.

Seeking to overcome the text of the denial orders, respondents cite (Br. 23) the scientific-review form that FDA used when assessing applications. But that form stated: "This review determines whether the subject [applications] contain evidence from a randomized controlled trial, longitudinal cohort study, *and/or other evidence* regarding the impact of the new [product]." J.A. 617 (emphasis added). Respondents emphasize (Br. 23)

that the form contained boxes, for "Criterion A" and "Criterion B," titled "Randomized Controlled Trial" and "Longitudinal Cohort Study," but those two boxes were immediately followed by another box, for "Criterion C," titled "Other evidence in the [application(s)] related to potential benefit to adults." J.A. 617, 619-620 (emphases omitted). Thus, the form that FDA used to identify applicants' evidence showed—as the denial orders themselves did—FDA's willingness to "look[] beyond randomized trials and longitudinal studies." *Prohibition Juice*, 45 F.4th at 22; see *Electric Clouds*, 94 F.4th at 961. Moreover, since the title for Criterion C expressly addressed the "potential benefit to adults," J.A. 20, respondents err in asserting (Br. 39 n.30) that the "scientific review forms" made "no reference" to respondents' need to substantiate their applications' claims that "flavors are crucial to getting adult smokers to * * * stay away from combustible cigarettes."

Respondents next cite (Br. 18-19) an internal FDA memorandum, issued on July 9, 2021, which proposed treating the lack of a randomized trial or longitudinal study as a "fatal flaw" in an application. J.A. 243; see J.A. 241-244. They also cite (Br. 19-20) another internal FDA memorandum, issued on August 17, 2021, which identified standards for FDA to apply in evaluating applications. See. J.A. 245-280. But the July memorandum was "superseded" by the August memorandum, and "there's no evidence that the FDA ever applied" it when evaluating applications. *Electric Clouds*, 94 F.4th at 960. The August memorandum itself was then "rescind[ed]" only a few days after it was issued. J.A. 282. FDA had "reconsidered the process" for evaluating applications, decided that "it will not consider or rely on" the August memorandum in that process, and deter-

mined that the memorandum was therefore "no longer needed." *Ibid.* The Fifth Circuit thus did not rely on either of the two internal documents, and other courts have uniformly rejected arguments based on them. See *Electric Clouds*, 94 F.4th at 960-961; *Magellan Technology, Inc.* v. *FDA*, 70 F.4th 622, 630 (2d Cir. 2023), petition for cert. pending, No. 23-799 (filed Jan. 22, 2024); *Avail Vapor*, 55 F.4th at 424; *Liquid Labs*, 52 F.4th at 540 n.7; *Prohibition Juice*, 45 F.4th at 22.

That consensus is correct. Agencies "should be judged by what they decided, not for matters they considered before making up their minds." *National Security Archive* v. *CIA*, 752 F.3d 460, 462 (D.C. Cir. 2014) (Kavanaugh, J.) (citation omitted). A contrary approach would inhibit candor during "internal discussions"; would promote "gridlock" by identifying "a point where agency deliberations become frozen in time"; and would deprive agencies of "the value of ongoing dialogue," hampering their ability to change course even if they conclude that previously considered approaches would raise legal concerns that might be avoided under alternative approaches. *Avail Vapor*, 55 F.4th at 424. Here, FDA ultimately agreed to consider other types of evidence, not just randomized trials or longitudinal studies. FDA's denial orders nowhere stated that the agency treated the absence of such trials or studies as a "fatal flaw." Whether FDA had once contemplated a different approach, before it decided respondents' applications, is immaterial.

Respondents invite (Br. 18-20, 23, 29) this Court to infer that, although FDA stated that it was not relying on the July and August memoranda, it surreptitiously did so anyway. That argument conflicts with the "presumption of regularity" that courts owe to executive

agencies, which form part of a coordinate branch of the federal government. *United States* v. *Chemical Foundation, Inc.*, 272 U.S. 1, 14 (1926). While an agency must "'disclose the basis'" of its action, a court must generally accept "an agency's stated reasons for acting." *Department of Commerce* v. *New York*, 588 U.S. 752, 780-781 (2019) (citation omitted). "[F]urther judicial inquiry into 'executive motivation' represents 'a substantial intrusion' into the workings of another branch of Government and should normally be avoided." *Id.* at 781 (citation omitted). A court may look behind an agency's stated reasons only in extraordinary cases involving a "strong showing of bad faith." *Ibid.* (citation omitted). Respondents have not seriously tried to make such a showing here.

Regardless, FDA's internal documents do not "reveal a secret plan" to "nix any application" that lacks a randomized trial or longitudinal study. *Electric Clouds*, 94 F.4th at 961. Although the July memorandum referred to the absence of such evidence as a "fatal flaw," the same sentence said that "any application lacking this evidence will *likely* receive a marketing denial order"—not that it *definitely* will. J.A. 243 (emphasis added). The August memorandum, meanwhile, stated that randomized trials and longitudinal studies are "the strongest types of evidence," but it also said that FDA "would also consider evidence from another study design" if it "reliably and robustly" demonstrates the product's benefits. J.A. 247 & n.ix.

Respondents also contend (Br. 47-49) that FDA should have promulgated the August memorandum through notice-and-comment rulemaking. That theory is not properly before this Court, irrelevant to the outcome of this case, and wrong. The question presented

asks (Pet. I) whether FDA's "denial orders" were "arbitrary and capricious," not whether the August memorandum was procedurally faulty. Nor did the Fifth Circuit pass upon respondents' theory. Further, because FDA rescinded the August memorandum and did not rely on it when denying respondents' applications, any procedural challenge to the memorandum is moot and immaterial to the resolution of this case. In all events, the notice-and-comment theory rests on the erroneous premise that the memorandum imposed a categorical "requirement" to submit a "longitudinal" study. Resp. Br. 47. As explained above, the August memorandum did no such thing; it was almost immediately rescinded; and FDA's denial orders reflected no such requirement.

4. Respondents' remaining arguments about unfair surprise lack merit. Respondents contend (Br. 29, 41) that FDA assured applicants that they would not need to submit "long-term clinical studies," yet turned around and faulted respondents for failing to provide evidence of their products' effects "over time." Our opening brief explained (at 22-23) why that argument is wrong: It overlooks the difference between "long-term" studies (which the 2019 Guidance defined to mean studies conducted over six months or longer) and evidence about a product's effects "over time" (which could include evidence that spans less than six months). See *Liquid Labs*, 52 F.4th at 541 n.10. FDA did not require long-term studies, but it did recommend that applicants submit evidence about "the trends by which users consume the product *over time*." J.A. 53 (emphasis added). Respondents ignore those points.

Respondents also object (Br. 40) that FDA did not invite them to amend their applications and submit new evidence. If FDA had changed the rules after the ap-

plications had been filed, it would indeed have been appropriate for the agency to notify applicants and to give them an opportunity for amendment. But, as explained above, FDA did not change its regulatory approach. Rather, the "final determinations were consistent with the 2019 Guidance"—and with the Tobacco Control Act itself. *Prohibition Juice*, 45 F.4th at 21. Even so, as FDA's denial orders make clear, respondents remain free "to submit new applications for these products." Pet. App. 167a.

In sum, FDA did not unfairly surprise respondents. FDA's denial of their applications instead reflected a "straightforward application" of the criteria set out in the Act and in FDA's guidance. *Prohibition Juice*, 45 F.4th at 24.

B. FDA's Decision Not To Evaluate Respondents' Marketing Plans Was Harmless

The Fifth Circuit also erred in its refusal to apply the harmless-error rule to the agency's decision not to evaluate respondents' marketing plans. See Pet. App. 60a. Respondents offer no good defense of that holding, which contradicts the decisions of six other courts of appeals. See Gov't Br. 31-32.

1. Congress has expressly instructed courts to take "due account" of "the rule of prejudicial error." 5 U.S.C. 706. Yet the Fifth Circuit held that "errors are only harmless where the agency would be *required* to take the same action no matter what" and that the "harmless-error rule simply does not apply to * * * discretionary administrative decisions." Pet. App. 59a-60a.

As our opening brief explained (at 39-40), that holding conflicts with this Court's cases, which have found errors harmless even when no statute required the agency to take the action at issue. See *Little Sisters of*

the Poor Saints Peter & Paul Home v. *Pennsylvania*, 591 U.S. 657, 684-685 (2020); *Department of Commerce*, 588 U.S. at 780. Respondents deny (Br. 55) that those cases involved discretionary action, but they plainly did. See *Little Sisters*, 591 U.S. at 680 (deciding the case on the premise that the agency was not "compelled" to take the action at issue); *Department of Commerce*, 588 U.S. at 771 (explaining that the statutory provisions "le[ft] much to the Secretary's discretion"). Respondents also argue (Br. 55) that, because those decisions held in the alternative that agencies had not erred in the first place, the Court's discussions of harmlessness were dicta. But when a court resolves a case on two alternative grounds, "the ruling on neither is *obiter*, but each is the judgment of the court, and of equal validity with the other." *United States* v. *Title Insurance & Trust Co.*, 265 U.S. 472, 486 (1924) (citation omitted).

Respondents attempt (Br. 52) to ground the Fifth Circuit's approach in the ordinary remand rule, which generally requires a court that detects an error in agency action to "remand to the agency for additional investigation or explanation." *Calcutt* v. *FDIC*, 598 U.S. 623, 629 (2023) (per curiam) (citation omitted). But that rule simply recognizes that, where an issue "has been delegated to an agency," the reviewing court "is not generally empowered to conduct a *de novo* inquiry into the matter." *Ibid.* (citation omitted). If an order's validity depends on a "policy or judgment which the agency alone is authorized to make and which it has not made, a judicial judgment cannot be made to do service for an administrative judgment." *SEC* v. *Chenery Corp.*, 318 U.S. 80, 88 (1943). "[A]n appellate court cannot intrude upon the domain which Congress has exclusively entrusted to an administrative agency," and that is so

"[f]or purposes of affirming no less than reversing [the agency's] orders." *Ibid.*

Here, harmless-error analysis would not require the reviewing court to "conduct a *de novo* inquiry" into the efficacy of respondents' proposed sales and marketing restrictions. *Calcutt*, 598 U.S. at 629 (citation omitted). Instead, the court need only recognize that *FDA itself* has already found that such restrictions are "not sufficient to address this issue." J.A. 220. The remand rule is inapposite in such a case. As Judge Friendly explained, the rule exists to ensure that a "reviewing court [does] not affirm an agency on a principle the agency might not embrace"—not to prolong proceedings "while court and agency engage in a nigh endless game of battledore and shuttlecock." *Erie-Lackawanna R.R. Co.* v. *United States*, 279 F. Supp. 316, 354-355 (S.D.N.Y. 1967) (three-judge court), aff'd with modifications, 389 U.S. 486 (1968).

Respondents also invoke (Br. 50 n.34, 57) the principle that a court may not uphold agency action based on a post hoc rationalization, but that principle does not support the Fifth Circuit's decision either. Respondents are correct that, in deciding whether an agency erred in the first place, a court is "limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record." *Department of Commerce*, 588 U.S. at 780. But a court is not so limited in deciding whether an error was harmless. The whole point of the harmless-error rule is that, even when an agency's contemporaneous justification of its action was defective, something else could show that the error made no difference to the outcome that the agency would reach if the matter were remanded for reconsideration.

2. This Court should reverse the Fifth Circuit's holding that the harmless-error rule "simply does not apply," Pet. App. 60a, and remand the case so that the Fifth Circuit can apply that rule. The Court need not address respondents' fact-bound arguments (Br. 53-58) that FDA's decision not to evaluate their marketing plans prejudiced them. At any rate, those arguments are incorrect.

As an initial matter, respondents mischaracterize (Br. 54) our position as requiring a court to accept an agency's "bald assertion that non-record, undisclosed evidence shows an agency error was harmless." We have advanced no such theory. Our harmlessness argument relies instead on FDA's 2020 Guidance, in which the agency explained that "focusing on how the product was sold would not be sufficient to address youth use of these products." Gov't Br. 34 (quoting J.A. 215). It also relies on publicly available orders confirming that, in other cases, FDA has found various types of marketing restrictions to be insufficient. See *id.* at 34-35. In suggesting otherwise, respondents attack a strawman.

Respondents contend (Br. 56) that their marketing restrictions differ from the restrictions addressed in the 2020 Guidance. But that contention rests (*ibid.*) on the flawed premise that the guidance addressed only some types of e-cigarette devices. In fact, the guidance made clear that, as a general matter, marketing restrictions are "not sufficient to address this issue, given the most recent data that youth use of [e-cigarette] products continues to increase." J.A. 220-221.

Finally, respondents contend (Br. 57) that, when FDA granted another manufacturer, NJOY, authorization to market menthol-flavored e-cigarette products in June 2024, it acknowledged the efficacy of NJOY's pro-

posed marketing restrictions. That is incorrect. FDA has recognized that marketing restrictions may be *necessary* to mitigate risks to youth, but it has repeatedly found that such restrictions are "not *sufficient*." J.A. 220 (emphasis added). Consistent with that approach, when FDA granted NJOY's application, it repeated that marketing restrictions, on their own, do not "sufficiently" "mitigate the substantial risk to youth from flavored [e-cigarette products]." FDA, *Technical Project Lead (TPL) Review of PMTAs* 6 (June 21, 2024), https://www.fda.gov/media/179501/download. But the agency first concluded that NJOY had provided sufficient evidence of its flavored products' benefits relative to tobacco-flavored e-cigarettes (*i.e.*, evidence of their superior ability to help adult smokers switch from combustible cigarettes), which outweighed their risk to youth. *Id.* at 9, 45. Only then did FDA observe that marketing restrictions "may help further limit youth exposure to the new products * * * and the potential for youth initiation." *Id.* at 9.

C. The Remaining Arguments For Setting Aside FDA's Denial Orders Lack Merit

1. The Fifth Circuit concluded—again contrary to the decisions of six other courts of appeals—that FDA's 2020 Guidance distinguished between different types of e-cigarette devices and that FDA then changed its position without explanation when denying respondents' applications. See Pet. App. 46a; Gov't Br. 42-44. Respondents repeat (Br. 45-47) the same argument, but their analysis suffers from the same flaws as the Fifth Circuit's.

To begin, respondents overstate (Br. 45) what FDA said in the 2020 Guidance. FDA did not suggest in that guidance that the marketing of flavored e-liquids would

be appropriate for the protection of the public health so long as the e-liquids were used with the right type of device. To the contrary, the guidance explained that FDA was "concerned about the extraordinary popularity of flavored [e-cigarette] products with youth," that "flavors increase youth appeal," and that "[e]vidence continues to accumulate * * * that youth are particularly attracted to flavored [e-cigarette] products." J.A. 151-152. In distinguishing among such products, FDA merely stated that, because certain flavored products—*i.e.*, "cartridge-based" products—were especially "popular with young people" at that time, the agency would prioritize enforcement against those types of products. J.A. 156; see J.A. 145.

FDA's views regarding device types had evolved by the time it resolved respondents' applications. But FDA acknowledged and explained that change. When it denied respondents' applications, it acknowledged that its 2020 Guidance had prioritized enforcement against the types of devices that "were most appealing to youth at the time." Pet. App. 192a, 246a, 300a. But FDA "subsequently observed a substantial rise" in the use of other types of devices. *Ibid.* "This trend," the agency reasoned, "illustrates that the removal of one flavored product option prompted youth to migrate to another [device] type that offered the desired flavor options, underscoring the fundamental role of flavor in driving appeal." *Id.* at 192a, 246a-247a, 300a. FDA thus did not act arbitrarily; it responded to, and explained its response to, new evidence.

Respondents contest (Br. 46) FDA's weighing of the new evidence, arguing that "device features" rather than "flavors" "drove youth usage." But the Tobacco Control Act vests the authority to evaluate applications

in FDA, not the courts. The arbitrary-and-capricious standard requires courts to ensure that the agency acted within the zone of reasonableness, not to reweigh the evidence for themselves. See *Department of Commerce*, 588 U.S. at 777. In this case, FDA concluded that "the role of flavor is consistent" across "different device types," Pet. App. 191a, 245a, 299a, and it detailed the evidence supporting that conclusion, see *id.* at 191a-192a, 245a-246a, 299a-300a. Because FDA's decision was reasonable and reasonably explained, a court has no basis for setting it aside.

2. The Fifth Circuit also stated that FDA had improperly imposed a "categorical ban" on all flavored e-cigarettes. Pet. App. 47a n.5. Respondents allude to that conclusion in a footnote. See Br. 49 n.33. But we have already explained why it is wrong. FDA's denial orders do not mention any such ban, and the agency has since authorized the marketing of some flavored products. See Gov't Br. 44-47. Respondents do not address those points.

3. The Fifth Circuit separately concluded that FDA had arbitrarily distinguished between menthol-flavored products and other flavored products. See Pet. App. 24a-25a. Respondents disavowed that argument below, see C.A. Doc. 362, at 6 (Feb. 20, 2024), and they do not discuss it here.

4. Apparently dissatisfied with the Fifth Circuit's five grounds for setting aside FDA's orders, respondents' amici offer a surfeit of alternative theories. They argue, among other things, that FDA has misinterpreted the Tobacco Control Act, see Vapor Technology Ass'n Amicus Br. 11-20; that it has violated the major-questions doctrine, see Thirteen Members of Congress Amicus Br. 5-13; and that the Act is void for vagueness,

see Taxpayers Protection Alliance Amicus Br. 6-14. Those arguments were not passed upon below, are outside the scope of the question presented, and have not been briefed by the parties. They are not properly before this Court. See, *e.g.*, *Atlantic Marine Construction Co.* v. *U.S. District Court*, 571 U.S. 49, 61 (2013) (declining to consider an issue raised only by an amicus).

Some amici criticize (RJRV Amicus Br. 2-20) FDA's handling of e-cigarette applications generally. But this is a judicial-review proceeding concerning FDA's denial of particular applications, not a freewheeling inquiry into the application process in general. Amici's contentions lack merit in any event. For example, those amici say (*id.* at 5) that one district court "took a dim view of FDA's conduct" in extending the application deadlines. In fact, that court commended "FDA's laudable efforts," while criticizing e-cigarette manufacturers for taking "dilatory measure[s]." *American Academy of Pediatrics* v. *FDA*, 399 F. Supp. 3d 479, 481, 485 (D. Md. 2019). Amici also contend (RJRV Amicus Br. 10-11) that FDA faced "political pressure" from the "White House" to address youth vaping in 2019-2020. But there is nothing wrong with that; "[a]gency policymaking is not a 'rarefied technocratic process, unaffected by political considerations or the presence of Presidential power.'" *Department of Commerce*, 588 U.S. at 781 (citation omitted).

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In the Tobacco Control Act, Congress gave FDA "the daunting task of ensuring that another generation of Americans does not become addicted to nicotine and tobacco products." *Avail Vapor*, 55 F.4th at 428. It left FDA with flexibility in performing that task, allowing

FDA to determine whether the marketing of a new tobacco product is appropriate for the protection of the public health. FDA found that respondents' e-liquids—which, again, come in flavors such as cotton candy, pink lemonade, and milk and cookies—pose a serious risk of attracting youth to e-cigarettes, yet do not offer sufficient offsetting benefits for adults. That common-sense determination was not arbitrary and capricious.

This Court should reverse the judgment of the court of appeals.

Respectfully submitted.

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