No. 22-1112

In the Supreme Court of the United States

AVAIL VAPOR, LLC, ET AL., PETITIONERS

v.

FOOD AND DRUG ADMINISTRATION

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the Food and Drug Administration's denial of petitioners' applications for authorization to market flavored e-cigarette products was arbitrary and capricious.

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-37a) is reported at 55 F.4th 409.

JURISDICTION

The judgment of the court of appeals was entered on December 12, 2022. On March 3, 2023, the Chief Justice extended the time within which to file a petition for a writ of certiorari to and including May 11, 2023, and the petition was filed on that date. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Family Smoking Prevention and Tobacco Control Act (Act), Pub. L. No. 111-31, Div. A, 123 Stat. 1776, requires a manufacturer to obtain premarket authorization from the Food and Drug Administration (FDA) before introducing any "new tobacco product"

into interstate commerce. 21 U.S.C. 387j(a)(2)(A). The Act defines a new tobacco product as a tobacco product that was not on the market as of February 15, 2007. See 21 U.S.C. 387j(a)(1).

FDA may grant marketing authorization only if the manufacturer shows, among other things, that the product would be "appropriate for the protection of the public health." 21 U.S.C. 387j(c)(2)(A). In applying that standard, FDA must consider both the "likelihood that existing users of tobacco products will stop using such products" and the "likelihood that those who do not use tobacco products will start." 21 U.S.C. 387j(c)(4)(A) and (B). In other words, FDA must weigh a new product's potential to help existing adult smokers completely switch to less dangerous alternatives, or significantly reduce the amount they smoke, against the risk that the product will entice new users (generally young people) to begin using tobacco products. Pet. App. 5a, 18a.

This case involves e-cigarettes—that is, devices that aerosolize nicotine-laced "e-liquid[s]" that users then inhale. Pet. App. 7a. In 2016, FDA promulgated a rule announcing that it would regulate e-cigarettes and e-liquids in accordance with the Act. See *Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products*, 81 Fed. Reg. 28,974, 29,028-29,044 (May 10, 2016). E-cigarettes and e-liquids generally qualify as new tobacco products because they were not on the market as of February 15, 2007. Pet. App. 5a.

This Office has been informed by FDA that, since 2016, FDA has acted on most applications to market e-

cigarettes and e-liquids. On the one hand, FDA has authorized manufacturers to market certain tobacco-flavored e-cigarette products. See, *e.g.*, FDA, *Technical Project Lead (TPL) Review of PMTAs* (Oct. 12, 2021), https://go.usa.gov/xef5N. FDA has found that existing adult smokers are likely to completely switch from conventional cigarettes to those tobacco-flavored e-cigarette products, or significantly reduce the amount they smoke, but that young people have less interest in such products. See *id.* at 17. On the other hand, FDA has denied many applications for authorization to market e-cigarette products flavored to taste like candy, fruit, and desserts. See, *e.g.*, Gov't Opp. to Stay Appl. at 3, *Breeze Smoke, LLC* v. *FDA*, 142 S. Ct. 638 (2021) (No. 21A176). It has explained that such products pose a serious, well-documented risk of attracting young people to the use of tobacco products. *Ibid.* Although it is possible that a manufacturer could show that a particular flavored e-cigarette product produces benefits for adult smokers that outweigh the risks to young people, FDA has denied marketing authorization to manufacturers who have failed to make that showing. *Ibid.*

2. Petitioners make and sell flavored e-liquids. Pet. App. 12a. In September 2020, petitioners applied to FDA for authorization to market dozens of e-liquids in flavors such as "Golden Dawn," which tastes like a "crunchy, savory waffle cone," and "Aphrodite X," a "blend of perfectly ripened strawberries bursting with natural flavor, a touch of juicy melon to add contrast, and just a hint of pillowy marshmallow to balance out the tartness of the strawberry." *Ibid.* (citations and quotation marks omitted).

FDA denied petitioners' applications. Pet. App. 38a-43a, 55a-107a, 108a-130a. FDA explained that the

literature demonstrated that flavored e-cigarettes present a "well-established" risk of "increasing the appeal of tobacco products to youth." *Id.* at 68a-69a. On the other side of the ledger, FDA found that "the evidence regarding the role of flavors in promoting switching among adult smokers is far from conclusive," noting that "the literature does not establish that flavors differentially promote switching amongst [e-cigarette] users in general." *Id.* at 80a. FDA also found that the record did not contain sufficient "product-specific evidence" enabling it to compare the effects of petitioners' products on adult smokers' use of tobacco with the effects of an appropriate "tobacco-flavored" e-cigarette product. *Id.* at 80a-81a; see *id.* at 85a-89a. FDA accordingly found insufficient evidence to demonstrate that petitioners' products "will provide a benefit to adult users that would be adequate to outweigh the risks to youth." *Id.* at 39a-40a; see *id.* at 88a. Petitioners proposed a marketing plan that would purportedly address those risks by limiting youth access to their products, but FDA declined to consider the plan, noting that it was "not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use" e-cigarettes. *Id.* at 79a n.xix.

After petitioners sought further review within the agency, FDA affirmed its original decision to deny the applications. Pet. App. 15a, 28a-30a, 109a-130a. In doing so, FDA concluded that various studies on which petitioners relied provided no reliable evidence that petitioners' products will produce sufficient benefits for existing adult smokers to outweigh the risk of harm to youth. *Id.* at 114a-117a.

3. The Fourth Circuit denied petitioners' petition for review. Pet. App. 1a-37a.

As relevant here, the court of appeals rejected petitioners' contention that "FDA pulled a 'surprise switcheroo' on regulated parties by requiring certain types of evidence that FDA had previously represented were unnecessary"—"namely comparative efficacy evidence presented through randomized controlled trials or longitudinal cohort studies." Pet. App. 22a-23a (citation omitted). The court observed that FDA guidance had made clear that FDA "required 'valid scientific evidence' under which the FDA could evaluate the health risks of the new [e-cigarette] products," and that "nonclinical studies alone are generally not sufficient." *Id.* at 25a (brackets and citation omitted). The court acknowledged that FDA had stated that, "in general, FDA does not expect that applicants will need to conduct long-term studies to support an application." *Id.* at 24a (citation omitted). But the court noted that FDA "made quite clear that it was interested in receiving information about long-term *impact*, even if that information did not necessarily come from a long-term *study*." *Id.* at 26a. Noting that petitioners had failed to present "*any*" "product-specific evidence demonstrating * * * an extra benefit to current smokers over that of other lower-risk products," the court determined that FDA had acted reasonably in denying petitioners' applications. *Id.* at 22a.

The court of appeals also rejected petitioners' argument that FDA acted arbitrarily and capriciously in not considering their marketing plan. Pet. App. 30a-34a. The court explained that FDA had determined that petitioners could not show that their products satisfied the applicable statutory standard, and that "no marketing plan could rectify that baseline infirmity." *Id.* at 31a. The court also held in the alternative that, even if the

agency erred by failing to consider the marketing plan, that error was harmless, because petitioners failed to propose any marketing restrictions beyond those that FDA had "previously determined were not working." *Id.* at 32a; see *id.* at 31a-34a.

ARGUMENT

Petitioners contend (Pet. 20-37) that FDA acted arbitrarily and capriciously by changing evidentiary requirements for marketing authorization without providing fair notice and by failing to consider petitioners' marketing plan. The court of appeals correctly rejected those contentions, and its decision does not conflict with any decision of this Court or of any other court of appeals. This Court recently denied review in another case that raised similar issues. See *Gripum, LLC* v. *FDA*, 2023 WL 3440578 (May 15, 2023) (No. 22-708). The same course is appropriate here.

1. The court of appeals correctly rejected petitioners' contention (Pet. 22-30) that FDA changed the applicable evidentiary standard without notice, and that decision does not warrant further review. The court acknowledged the "bedrock principle of administrative law that 'agencies should provide regulated parties fair warning of the conduct a regulation prohibits or requires.'" Pet. App. 23a-24a (brackets and citation omitted). The court determined, however, that FDA "did not traduce these principles here." *Id.* at 24a. It explained that "FDA told manufacturers about the type and quality of evidence required to be included with their" applications, and that petitioners simply "failed to include this evidence." *Ibid.*

In particular, the court of appeals correctly rejected petitioners' argument (Pet. 22-26) that FDA failed to provide fair notice that applicants were required to

produce evidence comparing their tobacco products with other tobacco products. The Act expressly requires applicants to supply information about whether their product "presents less risk than other tobacco products." 21 U.S.C. 387j(b)(1)(A). And agency guidance expressly recommended that an applicant "compare the health risks of its product to both products within the same category and subcategory, as well as products in different categories as appropriate." Pet. App. 25a (citation and emphasis omitted). The court correctly determined that the statute and the agency guidance together provided ample notice of the need to submit comparative evidence. *Id.* at 25a-26a, 35a-37a.

The court of appeals also correctly rejected the argument (Pet. 26-30) that FDA changed the governing standard by requiring evidence of the long-term effects of tobacco products. FDA stated in a guidance document issued in 2019 that, "in general, FDA does not expect that applicants will need to conduct long-term studies to support an application." Ctr. for Tobacco Prods., FDA, U.S. Dep't of Health & Human Servs., *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems: Guidance for Industry* 13 (June 2019), https://www.regulations.gov/document/FDA-2015-D-2496-0050. But that "general" expectation was never an absolute guarantee. To the contrary, FDA explained that the necessity for new studies in any particular case would depend on whether "an established body of evidence * * * can be adequately bridged to [the] product." *Id.* at 46. And as the court correctly summarized, "[t]he agency made quite clear that it was interested in receiving information about long-term *impact*, even if that information did not necessarily come from a long-term *study*." Pet. App.

26a. Petitioners, however, failed to provide such information. *Id.* at 24a.

2. The court of appeals also correctly rejected petitioners' contention (Pet. 33-35) that FDA acted arbitrarily and capriciously by not considering their marketing plans when evaluating their applications. As the court observed, FDA had previously assessed potential marketing plans and had found that "youth access restrictions and run-of-the-mill marketing plans were inadequate in the fight against the youth vaping epidemic." Pet. App. 32a. Indeed, agency guidance had specifically stated that "youth have continued to access [e-cigarette] products * * * even after voluntary actions by some manufacturers," and that "focusing on *how* the product was sold would not appropriately address youth use." *Ibid.* (citation omitted). In light of that experience, FDA reasonably concluded that it was unnecessary to consider the details of petitioners' marketing plan in evaluating petitioners' application. *Id.* at 78a n.xix; see *NLRB* v. *Seven-Up Bottling Co.*, 344 U.S. 344, 346 (1953) (agency may "draw on enlightenment gained from experience").

The court of appeals likewise correctly determined that, even if FDA erred in not considering the marketing plan, that error was harmless. Pet. App. 31a-34a; see 5 U.S.C. 706 ("[D]ue account shall be taken of the rule of prejudicial error."). Given FDA's earlier determination that "run-of-the-mill marketing plans were inadequate," consideration of petitioners' marketing plan could have changed the agency's analysis only if it presented "novel access restrictions beyond those that the FDA previously determined were not working." Pet. App. 32a. Petitioners, however, proposed no such new restrictions. "Instead, [petitioners'] plan focused solely

on age verification and avoiding marketing that would make its products attractive to youth"—precisely the types of measures that FDA had previously found insufficient. *Ibid.* As a result, "even if FDA had reviewed [petitioners'] marketing plan, it still would have issued a marketing denial order on petitioners' products." *Id.* at 33a.

Because the court of appeals rejected petitioners' argument both on the ground that the agency did not err and on the ground that any error was harmless, petitioners must prevail on both issues in order to obtain reversal. See *United States* v. *Title Ins. & Trust Co.*, 265 U.S. 472, 486 (1924) ("[W]here there are two grounds, upon either of which an appellate court may rest its decision, and it adopts both, 'the ruling on neither is *obiter*, but each is the judgment of the court and of equal validity with the other.'") (citations omitted). Petitioners, however, do not discuss (let alone offer a meaningful argument against) the court of appeals' harmless-error analysis. See Pet. 30-32. Their failure to address that alternative holding makes this case a poor vehicle for reviewing petitioners' contention.

3. Contrary to petitioners' suggestion (Pet. 32-33), the court of appeals' decision does not conflict with the decision of any other court of appeals. Other courts of appeals, like the court in this case, have rejected the contention that FDA has improperly switched standards in evaluating applications for authorization to market e-cigarettes. See *Magellan Tech., Inc.* v. *United States FDA*, No. 21-2426, 2023 WL 4035722, at *5 (2d Cir. June 16, 2023) ("FDA never changed its position"); *Liquid Labs LLC* v. *United States FDA*, 52 F.4th 533, 540 (3d Cir. 2022) ("We join our sister circuit courts who have rejected these 'surprise switcheroo' arguments.")

(citation omitted); *Gripum, LLC* v. *United States FDA*, 47 F.4th 553, 559 (7th Cir. 2022) ("[L]ike our sister circuits, we conclude that the FDA's e-cigarette guidance materials have consistently reflected that product-specific long-term data are required only if existing studies are inadequately related to the proposed product."), cert. denied, No. 22-708, 2023 WL 3440578 (May 15, 2023); *Lotus Vaping Techs., LLC* v. *U.S. FDA*, No. 21-71321, 2023 WL 4384447, at *11 (9th Cir. July 7, 2023) ("Petitioners thus contend that the FDA unfairly surprised them[.] * * * We, like the D.C. Circuit, find this argument to be 'far off base.'") (citation omitted); *Prohibition Juice Co.* v. *United States FDA*, 45 F.4th 8, 21 (D.C. Cir. 2022) ("The FDA nowhere guaranteed that unspecified other forms of evidence [apart from long-term studies] would necessarily be sufficient—only that they might be, so the FDA would consider them."); see also *Breeze Smoke, LLC* v. *United States FDA*, 18 F.4th 499, 506-507 (6th Cir.) (rejecting a similar argument at the stay stage), application for stay denied, 142 S. Ct. 638 (2021).

Similarly, other courts of appeals have assumed without deciding that FDA has erred by failing to consider marketing plans, but have found any such error to be harmless. See *Magellan*, 2023 WL 4035722, at *6 (2d Cir.) ("Even assuming that the FDA's decision not to evaluate [the] marketing plan * * * was error, any such error was harmless."); *Liquid Labs*, 52 F.4th at 544 (3d Cir.) ("[E]ven assuming the FDA erred in declining to review [the] marketing plans, the error was harmless."); *Lotus Vaping*, 2023 WL 4384447, at *13 (9th Cir.) ("We assume, without deciding, that the FDA erred in ignoring Petitioner's marketing plans, but we conclude that any error was harmless."); *Prohibition*

Juice, 45 F.4th at 25 (D.C. Cir.) ("We accordingly assume without deciding that the FDA erred in not individually reviewing the manufacturers' marketing plans[.] * * * The manufacturers' inability to identify how the FDA's denial orders could have come out differently if only it had known the contents of their plans defeats their request.").

Petitioners err in suggesting (Pet. 21, 32-34) that the decision below conflicts with a decision of the Fifth Circuit. To be sure, a motions panel of the Fifth Circuit initially granted a stay of a marketing denial order based in part on the arguments that FDA had improperly changed the evidentiary standard for e-cigarette marketing applications and had failed to consider the applicants' marketing plans. See *Wages & White Lion Invs., L.L.C.* v. *United States FDA*, 16 F.4th 1130, 1136-1139 (2021). But a merits panel of the Fifth Circuit later determined that the agency had not improperly changed its evidentiary standard, that it had properly declined to consider the marketing plans, and that any error in failing to consider the plans was in any event harmless. See *Wages & White Lion Invs., L.L.C.* v. *FDA*, 41 F.4th 427, 439-440 (2022). The Fifth Circuit has since granted rehearing en banc in that case and vacated the panel opinion, see *Wages & White Lion Invs., L.L.C.* v. *FDA*, 58 F.4th 233 (2023) (per curiam), and the en banc court has not issued its decision. The absence of any circuit conflict regarding the questions presented confirms that the questions do not warrant this Court's review at this time.*

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* A motions panel of the Fifth Circuit has also granted a stay in a different case based in part on the argument that FDA had improperly changed its evidentiary standard and had not properly

Petitioners also err in suggesting (Pet. 33-34) that the court of appeals' analysis of the pertinence of petitioners' marketing plan conflicts with a decision of the Eleventh Circuit. In the decision on which petitioners rely, the Eleventh Circuit found that FDA had committed prejudicial error by failing to consider "novel" marketing plans that "included measures not specifically mentioned" in the agency's prior guidance and that the agency had not already found insufficient. See *Bidi Vapor LLC* v. *U.S. FDA*, 47 F.4th 1191, 1205-1206 (2022). Petitioners, in contrast, have not proposed any "novel access restrictions beyond those that the FDA previously determined were not working." Pet. App. 32a.

Petitioners assert (Pet. 35) that FDA's decision threatens to deprive smokers of an important means of switching away from conventional cigarettes. But as discussed above, the Act requires FDA, in evaluating an application for marketing authorization, to weigh a new product's potential to help existing adult smokers completely switch to less dangerous alternatives or significantly reduce the amount they smoke against the risk that the product will entice new users (generally young people) to begin using tobacco. See p. 2, *supra*. FDA determined that petitioners failed to show that the

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considered proposed marketing plans. See 23-60037 C.A. Doc. 121-1, at 6-9 (Mar. 23, 2023). FDA has filed a petition for rehearing en banc of that order, which remains pending. See 23-60037 C.A. Doc. 145 (Apr. 7, 2023). The motions panel's provisional decision in any event does not represent the Fifth Circuit's definitive resolution of the issues and, accordingly, does not establish a circuit conflict. See *Firefighters' Retirement Sys.* v. *Citco Grp. Ltd.*, 796 F.3d 520, 524 n.2 (5th Cir. 2015) ("The motions panel [decision] does not bind the oral argument panel."), cert. denied, 577 U.S. 1102 (2016); *Northshore Dev., Inc.* v. *Lee*, 835 F.2d 580, 583 (5th Cir. 1988) ("[A] motions panel decision is not binding precedent.").

benefits of their products outweighed the risks. See pp. 3-4, *supra*. Petitioners' disagreement with FDA's expert judgment does not warrant further review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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