No. 22-708

In the Supreme Court of the United States

GRIPUM, LLC, PETITIONER

v.

FOOD AND DRUG ADMINISTRATION

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

BRIEF FOR RESPONDENT IN OPPOSITION

SAMUEL R. BAGENSTOS
General Counsel
Department of Health and Human Services
MARK RAZA
Chief Counsel
WENDY S. VICENTE
Deputy Chief Counsel for Litigation
MARCI B. NORTON
Senior Counsel
Food and Drug Administration

ELIZABETH B. PRELOGAR
Solicitor General
Counsel of Record
BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
ALISA B. KLEIN
LINDSEY POWELL
KATE TALMOR
Attorneys

Department of Justice
Washington, D.C. 20530-0001
SupremeCtBriefs@usdoj.gov
(202) 514-2217

QUESTION PRESENTED

Whether the Food and Drug Administration acted reasonably in denying petitioner's application for authorization to market flavored e-cigarettes.

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-15a) is reported at 47 F.4th 553.

JURISDICTION

The judgment of the court of appeals was entered on August 29, 2022. On December 1, 2022, Justice Barrett extended the time within which to file a petition for a writ of certiorari to and including January 26, 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). 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 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). 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). In other words, FDA must weigh a new product's potential to help existing smokers (generally adults) switch to less dangerous alternatives against the risk that the product will entice new users (generally young people) to begin using tobacco. Pet. App. 3a-4a.

This case concerns FDA's application of that standard to e-cigarettes—that is, devices that aerosolize nicotine-laced "e-liquids" that users then inhale. Pet. App. 2a. E-cigarettes and e-liquids generally qualify as new tobacco products because they were not on the market as of February 15, 2007. See *id.* at 2a-3a. 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).

Since then, FDA has acted on a number of 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 particularly interested in switching from conventional cigarettes to those tobacco-flavored e-cigarette products, but that young people have little interest in such products. See *id.* at 17. On the other hand, FDA has denied certain applications for authorization to market e-cigarette products flavored to taste like candy, fruit, and desserts. See, *e.g.*, Gov't Opp. at 3, *Breeze Smoke, LLC* v. *FDA*, No. 21A176 (Dec. 6, 2021). 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 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. Petitioner makes and sells flavored e-liquids. Pet. App. 6a. In September 2020, petitioner applied to FDA for authorization to market hundreds of flavored products carrying "colorful and evocative names such as 'Peanut Butter Milk Pie,' 'Bad Monkey Giovanni,' and 'Sunshine Vape Dragon Berry Balls.'" *Ibid.*

FDA denied the application. Pet. App. 16a-20a. FDA found that flavored e-cigarettes present a "well-established" risk of "increasing the appeal of tobacco products to youth." *Id.* at 30a. 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." *Id.* at 38a. FDA accordingly determined that petitioner's evidence was

"insufficient to demonstrate that these products would provide an added benefit that is adequate to outweigh the risks to youth." *Id.* at 18a.

3. The Seventh Circuit denied petitioner's petition for review. Pet. App. 1a-15a.

The court of appeals first rejected petitioner's argument that "the agency failed to announce ascertainable standards prior to its adjudication of the application." Pet. App. 9a. The court explained that the statute itself sets forth the applicable standard, under which FDA must weigh the "likelihood that existing users of tobacco products will stop" against the "likelihood that those who do not use tobacco products will start." *Id.* at 10a (quoting 21 U.S.C. 387j(c)(4)). The court explained that the agency "properly applied the comparative standard mandated by the statute" and that petitioner "simply failed to meet it." *Id.* at 12a.

The court of appeals also rejected petitioner's contention that "the agency quietly shifted the evidentiary standard after inviting reliance on an earlier, easier-to-meet standard." Pet. App. 9a. Specifically, petitioner had argued that the agency had "changed course" by faulting petitioner for its failure to provide "product-specific clinical studies" as part of its application. *Id.* at 12a. But the court explained that FDA had not "changed course" and that "FDA's e-cigarette guidance materials have consistently reflected that product-specific long-term data are required" where "existing studies are inadequately related to the proposed product." *Ibid.*

Finally, the court of appeals rejected petitioner's contention that "the agency failed to conduct a careful, individualized review of its evidence and instead relied on a general presumption that e-liquids increase youth

tobacco use." Pet. App. 13a. The court observed that, under the Act, petitioner bore the burden of showing that its new tobacco products were appropriate for the protection of public health. *Id.* at 14a. The court explained that petitioner had failed to fulfill its burden. *Ibid.* Specifically, petitioner "failed to provide evidence specific to its products," and although "it did include studies of other products, those studies did not even compare tobacco-flavored e-cigarette products * * * to flavored products resembling those [petitioner] wants to offer." *Ibid.*

ARGUMENT

Petitioner argues for the first time (Pet. 17-22) that FDA should not receive judicial deference in this case because it allegedly has a conflict of interest. But that contention was not pressed or passed upon below, does not have any bearing on the outcome of this case, and in any event lacks merit. Petitioner also renews its contentions (Pet. 22-30) that FDA improperly changed evidentiary standards and that it applied overbroad presumptions rather than evaluating the evidence in this case on its own terms. But the court of appeals correctly rejected those arguments, and its decision does not conflict with any decision of this Court or any other court of appeals. The petition for a writ of certiorari should be denied.

1. Petitioner first argues (Pet. 17) that FDA should receive no "deference" because it had "a budgetary stake in its regulatory decisions." But petitioner did not raise that issue in the court of appeals, and the court accordingly did not consider it. See Pet. App. 9a (summarizing the "three theories" raised by petitioner, none of which concerns deference); Pet. C.A. Br. 45 (discussing deference but raising no argument that FDA had a

conflict of interest). This Court is a "court of review, not of first view," *Cutter* v. *Wilkinson*, 544 U.S. 709, 718 n.7 (2005), and its ordinary practice precludes certiorari on a question that "was not pressed or passed upon below," *United States* v. *Williams*, 504 U.S. 36, 41 (1992) (citation omitted). Petitioner identifies no sound reason for the Court to depart from that practice here.

This case, moreover, does not implicate the issue that petitioner seeks to raise. Petitioner argues (Pet. 15-16) that an agency should not receive deference under *Chevron U.S.A., Inc.* v. *Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), or *Auer* v. *Robbins*, 519 U.S. 452 (1997), when it suffers from a purported conflict of interest. But *Chevron* addresses the deference owed to an agency's interpretation of a statute, and *Auer* concerns the deference owed to an agency's interpretation of its own regulations. This case does not involve an issue of statutory or regulatory interpretation; it instead turns on whether FDA acted arbitrarily and capriciously in denying petitioner's application. See Pet. App. 9a. The court of appeals accordingly did not apply either *Chevron* or *Auer* deference in the decision below, and petitioner's contentions regarding the appropriate level of deference are beside the point.

Petitioner's assertion of a conflict of interest is in all events misplaced. Petitioner suggests (Pet. 17-22) that, because FDA is funded in part through fees levied on cigarettes but not on e-cigarettes, FDA has an incentive to promote the market for cigarettes by denying applications to market e-cigarettes. But contrary to that suggestion, the total amount of user fees paid to FDA does not depend on the volume of cigarette sales. Rather, the total amount of the fees is fixed by statute; only the shares paid by each category of manufacturers

varies with sales volume. See 21 U.S.C. 387s(b)(1) ("The total amount of user fees authorized to be assessed and collected * * * for a fiscal year is the following."). As a result, FDA's denial of applications to market e-cigarettes does not affect the total amount of the fees it receives.

2. Petitioner also argues (Pet. 22-25) that FDA improperly shifted the evidentiary standards applicable to marketing applications. Specifically, it contends (Pet. 23) that FDA initially "reassured the industry that it did not expect long term studies," but then arbitrarily faulted petitioner for failing to produce such studies as part of its application.

The court of appeals correctly rejected petitioner's argument. See Pet. App. 12a-13a. FDA stated in a guidance document issued in 2019 that, "in general, [it] 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 and 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. Thus, as the court correctly summarized, "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." Pet. App. 12a.

FDA followed that approach here. It explained that petitioner "could" have satisfied its statutory burden either by identifying existing evidence that "reliably and robustly" reflected the effects of petitioner's products, or by conducting a new "study" regarding those products. Pet. App. 17a-18a. Because petitioner failed to provide either type of evidence, FDA found the information in petitioner's application "insufficient to demonstrate that these products would provide an added benefit that is adequate to outweigh the risks to youth." *Id.* at 18a.

Other courts of appeals have likewise rejected the contention that FDA has improperly switched standards in evaluating applications for authorization to market e-cigarettes. See *Liquid Labs LLC* v. *FDA*, 52 F.4th 533, 540 (3d Cir. 2022) ("We join our sister circuit courts who have rejected these 'surprise switcheroo' arguments.") (citation omitted); *Avail Vapor, LLC* v. *FDA*, 55 F.4th 409, 422 (4th Cir. 2022) ("FDA neither changed the standard nor the types of evidence required."); *Prohibition Juice Co.* v. *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. *U.S. FDA*, 18 F.4th 499 (6th Cir.) (rejecting a similar argument at the stay stage), application for stay denied, 142 S. Ct. 638 (2021).

Petitioner errs in suggesting (Pet. 24-25) that the decision below conflicts with a decision of the Fifth Circuit. Although a motions panel of the Fifth Circuit initially granted a stay based in part on the argument that FDA had improperly changed its evidentiary standards for evaluating e-cigarette marketing applications, see

Wages & White Lion Investments, L.L.C. v. *FDA*, 16 F.4th 1130, 1138-1139 (2021), the merits panel later rejected that argument, see *Wages & White Lion Investments, L.L.C.* v. *FDA*, 41 F.4th 427, 439 (2022). The Fifth Circuit has since granted en banc rehearing in that case, see *Wages & White Lion Investments, L.L.C.* v. *FDA*, 58 F.4th 233 (2023), but the en banc court has not issued its decision. The absence of any circuit conflict regarding the question presented confirms that the question does not warrant this Court's review at this time.*

3. Petitioner finally argues (Pet. 25-30) that FDA improperly disregarded petitioner's evidence and applied an "overbroad and flawed presumption" that all flavored e-liquids fail to satisfy the statutory standard of appropriateness to protect public health. The court of appeals correctly rejected that contention as well. See Pet. App. 13a-15a.

As the court of appeals observed, petitioner's argument rests "on a questionable reading of both the

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* Since the filing of the petition for a writ of certiorari, a motions panel of the Fifth Circuit has granted a stay in a different case based in part on the argument that the FDA had improperly changed its evidentiary standards. See 23-60037 C.A. Doc. 121-1, at 6-9 (Mar. 23, 2023). But that provisional decision does not represent the Fifth Circuit's definitive resolution of that issue and, accordingly, does not establish a circuit conflict. See *Firefighters' Retirement System* v. *Citco Group Ltd.*, 796 F.3d 520, 524 n.2 (5th Cir. 2015) ("The motions panel's [decision] does not bind the oral argument panel."); *Northshore Development, Inc.* v. *Lee*, 835 F.2d 580, 583 (5th Cir. 1988) ("[A] motions panel decision is not binding precedent."). As noted in the text, the Fifth Circuit has granted rehearing en banc in *Wages & White Lion Investments*, which underscores that the stay ruling in *R.J. Reynolds Vapor Co.* does not represent a definitive resolution of the issue in the Fifth Circuit.

agency's marketing denial order and the statutory burden." Pet. App. 14a. FDA did not refer to, let alone apply, any supposed general presumption that flavored e-liquids inevitably fail the statutory standard. FDA instead recognized that, under the Act, the applicant bears the burden of showing that the product is appropriate to protect public health. See *id.* at 17a; see also 21 U.S.C. 387j(c)(2). FDA simply concluded that petitioner had failed to produce the evidence needed to satisfy that burden. See Pet. App. 18a (finding petitioner's evidence "insufficient to demonstrate that these products would provide an added benefit that is adequate to outweigh the risks to youth"). FDA's order thus reflects an individualized review of petitioner's evidence, not the application of an overbroad presumption.

Contrary to petitioner's suggestion (Pet. 16, 28-29), the decision below does not conflict with the Eleventh Circuit's decision in *Bidi Vapor LLC* v. *FDA*, 47 F.4th 1191 (2022). In that case, the Eleventh Circuit held that FDA had erred by failing to consider an applicant's argument that its proposed restrictions on marketing and sales could decrease risk to youth sufficiently to tip the balance in favor of granting the application. See *id.* at 1203-1208. In this case, in contrast, petitioner has not argued that FDA's approach to such restrictions was in error. The issue in *Bidi Vapor* thus is not presented here.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

ELIZABETH B. PRELOGAR
Solicitor General
BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
ALISA B. KLEIN
LINDSEY POWELL
KATE TALMOR
Attorneys

SAMUEL R. BAGENSTOS
General Counsel
Department of Health and Human Services
MARK RAZA
Chief Counsel
WENDY S. VICENTE
Deputy Chief Counsel for Litigation
MARCI B. NORTON
Senior Counsel
Food and Drug Administration

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