No. 23-871

In the Supreme Court of the United States

LOTUS VAPING TECHNOLOGIES, LLC, PETITIONER

v.

FOOD AND DRUG ADMINISTRATION

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

BRIEF FOR THE RESPONDENT

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QUESTION PRESENTED

The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, Div. A, 123 Stat. 1776, requires a person to obtain authorization from the Food and Drug Administration (FDA) before introducing a new tobacco product into interstate commerce. The agency may grant such authorization only if the applicant shows, among other things, that the marketing of the product would be "appropriate for the protection of the public health." 21 U.S.C. 387j(c)(2)(A). In this case, the agency denied petitioner's applications for authorization to market new e-cigarette products because petitioner had failed to show that marketing the products would be appropriate for the protection of the public health. The question presented is:

Whether FDA's denial order was arbitrary and capricious.

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1-46) is reported at 73 F.4th 657.

JURISDICTION

The judgment of the court of appeals was entered on July 7, 2023. A petition for rehearing was denied on September 14, 2023 (Pet. App. 47). On December 5, 2023, Justice Kagan extended the time within which to file a petition for a writ of certiorari to and including February 11, 2024. The petition was filed on February 9, 2024. 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 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 using such products." 21 U.S.C. 387j(c)(4). In the present context, that standard requires the agency to weigh (1) the likelihood that the new product will help existing smokers (generally adults) completely switch to less dangerous alternatives, or significantly reduce the amount they smoke, against (2) the risk that the new product will entice new users (generally youth) to begin using tobacco products.

This case concerns FDA's application of those provisions to e-cigarettes—that is, devices that aerosolize nicotine-laced "e-liquids" that users then inhale. See Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Services, *E-Cigarette, or Vaping, Products Visual Dictionary* 7. 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. See *Avail Vapor, LLC* v. *FDA*, 55 F.4th 409, 414 (4th Cir. 2022), cert. denied, 144 S. Ct. 277 (2023).

2. Petitioner manufactures e-liquids. See Pet. App. 17. In September 2020, it applied for authorization to market e-liquids with flavors such as "Exotics Cherry Bomb," "Lotus Originals Pineapple," and "Teleos Pure Strawberry." *Id.* at 55.

FDA denied petitioner's applications. See Pet. App. 21. 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 70. On the other side of the balance, the agency determined that "the evidence regarding the role of flavors in promoting switching among adult smokers is far from conclusive" and that "the literature does not establish that flavors differentially promote switching amongst [e-cigarette] users in general." *Id.* at 81-82. The agency accordingly found insufficient evidence to demonstrate that petitioner's products "will provide a benefit to adult users that would be adequate to outweigh the risks to youth." *Id.* at 50-51. Petitioner proposed a marketing plan that would purportedly address those risks by limiting youth access to its 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 80 n.xix.

3. The Ninth Circuit denied the petition for review. See Pet. App. 1-46.

As relevant here, the court of appeals rejected petitioner's claim that FDA had unfairly surprised applicants by changing the standards governing their applications. See Pet. App. 28-35. The court explained that FDA "did not introduce a new evidentiary standard; rather, it consistently required evidence that evaluated the impacts of flavored versus non-flavored products on initiation and cessation." *Id.* at 32. The court added that "FDA acted in conformity with its previous guidance and reasonably rejected [the] applications because [petitioner's] proffered evidence was not sufficiently reliable and robust." *Id.* at 33.

The court of appeals also rejected petitioner's challenge to FDA's decision not to evaluate its marketing plan. See Pet. App. 35-40. The court "assume[d], without deciding," that FDA erred by failing to consider the plan, but held that "any error was harmless." *Id.* at 36. The court emphasized that petitioner had failed to show that its proposed measures were "materially different from those the FDA ha[d] already said are insufficient." *Id.* at 37.

Finally, the court of appeals rejected petitioner's contention that "FDA failed to meaningfully consider the distinction" among different types of e-cigarette devices. Pet. App. 31 n.14. The agency had acknowledged that "there is variability in the popularity of device types among youth, suggesting there may be differential appeal of certain product styles." *Ibid.* (citation omitted). But the court determined that the agency had not acted arbitrarily and capriciously in recognizing that "the role of flavor is consistent" "across these different device types." *Ibid.* (citation omitted).

DISCUSSION

Petitioner renews its contentions (Pet. 17-29) that FDA unfairly surprised e-cigarette companies by changing the standards governing their applications and that FDA committed prejudicial error by declining to evaluate its marketing plan. As petitioner observes (Pet. 17-19), the Ninth Circuit's decision rejecting those claims conflicts with the en banc Fifth Circuit's decision accepting similar claims in *Wages & White Lion Investments, L.L.C.* v. *FDA*, 90 F.4th 357 (2024), petition for cert. pending, No. 23-1038 (filed Mar. 19, 2024).

The government has filed a petition for a writ of certiorari in *Wages & White Lion*. See Pet., *Wages & White Lion*, *supra* (No. 23-1038). As that petition explains, the Fifth Circuit relied on multiple rationales in setting aside FDA's denial orders as arbitrary and capricious, and its decision created multiple circuit conflicts. See *id.* at 10-12, 22-23. In the decision below, however, the Ninth Circuit addressed only three of those legal theories: the claim that FDA unfairly surprised applicants with respect to the manner in which it would review applications to authorize the marketing of e-cigarette products, see Pet. App. 28-35; the claim that FDA had committed prejudicial error by declining to evaluate petitioner's marketing plan, see *id.* at 35-40; and the claim that FDA had improperly failed to distinguish among different types of e-cigarette devices, see *id.* at 31 n.14. The petition for a writ of certiorari in this case focuses on only two of those three issues. See Pet. 20-26 (unfair surprise); Pet. 26-27 (marketing plan).*

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* The Ninth Circuit separately rejected petitioner's claim that FDA exceeded its statutory authority "by requiring applicants to demonstrate that their flavored products better promote smoking cessation than comparable tobacco-flavored products." Pet. App.

Wages & White Lion is thus the only vehicle for deciding the full range of legal issues raised, and resolving the full set of circuit conflicts created, by the Fifth Circuit's decision. Conversely, because the legal issues presented in this case form only a subset of the legal issues presented in *Wages & White Lion*, there would be no need to grant plenary review in this case as well. Granting review in multiple cases would needlessly result in duplicative briefing. This Court should therefore grant certiorari in *Wages & White Lion* and should hold the petition for a writ of certiorari in this case pending the resolution of *Wages & White Lion*.

24; see *id.* at 24-27. But that issue is not the subject of a circuit conflict, and petitioner does not seek review on it. See Pet. 22 (assuming that the Ninth Circuit correctly interpreted the Act but challenging FDA's actions as arbitrary and capricious).

CONCLUSION

This Court should hold the petition for a writ of certiorari in this case pending the disposition of the petition in *FDA* v. *Wages & White Lion Investments, L.L.C.*, No. 23-1038 (filed Mar. 19, 2024), and should then dispose of the petition in this case as appropriate.

Respectfully submitted.

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