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

PETITION FOR A WRIT OF CERTIORARI

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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 respondents' applications for authorization to market new e-cigarette products because they had failed to show that marketing the products would be appropriate for the protection of the public health. The Fifth Circuit set aside FDA's denial orders as arbitrary and capricious, relying on legal theories that have been rejected by other courts of appeals that have reviewed materially similar FDA denial orders. The question presented is:

Whether the court of appeals erred in setting aside FDA's denial orders as arbitrary and capricious.

PARTIES TO THE PROCEEDING

Petitioner (respondent below) is the Food and Drug Administration. Respondents (petitioners below) are Wages and White Lion Investments, L.L.C., dba Triton Distribution, and Vapetasia, L.L.C.

RELATED PROCEEDINGS

United States Court of Appeals (5th Cir.):

Wages & White Lion Investments, L.L.C. v. *FDA*, No. 21-60766 (Jan. 3, 2024)

Wages & White Lion Investments, L.L.C. v. *FDA*, No. 21-60800 (Jan. 3, 2024)

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PETITION FOR A WRIT OF CERTIORARI

The Solicitor General, on behalf of the Food and Drug Administration, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Fifth Circuit in this case.

OPINIONS BELOW

The opinion of the en banc court of appeals (Pet. App. 1a-98a) is reported at 90 F.4th 357. The opinion of the merits panel of the court of appeals (Pet. App. 99a-143a) is reported at 41 F.4th 427. The opinion of the motions panel of the court of appeals (Pet. App. 144a-165a) is reported at 16 F.4th 1130. The Food and Drug Administration's marketing denial orders and technical project lead reviews (Pet. App. 166a-330a) are unreported.

JURISDICTION

The judgment of the en banc court of appeals was entered on January 3, 2024. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent statutory provisions are reproduced in the appendix. Pet. App. 338a-352a.

STATEMENT

A. Legal Background

1. In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or Act), Pub. L. No. 111-31, Div. A, 123 Stat. 1776. In that Act, Congress found that the "use of tobacco products by the Nation's children is a pediatric disease of considerable proportions." § 2(1), 123 Stat. 1777. "Virtually all new users of tobacco products are under the minimum legal age to purchase such products," and an "overwhelming majority" of tobacco users "become addicted to the nicotine in those products before reaching the age of 18." § 2(4) and (31), 123 Stat. 1777, 1779. Cutting minors' use of tobacco in half, Congress further found, would prevent more than three million premature deaths and would save approximately $75 billion in healthcare costs. § 2(14), 123 Stat. 1777.

Congress determined that "past efforts" had "failed adequately to curb tobacco use by adolescents." Tobacco Control Act § 2(6), 123 Stat. 1777. Tobacco companies continued to regard "young people" as "an important and often crucial segment of the tobacco market," § 2(24), 123 Stat. 1778, and had "dramatically increased their advertising and promotional spending in ways that encourage[d] youth to start smoking," § 2(48), 123 Stat. 1781. Congress accordingly established a new

regulatory framework through which the Food and Drug Administration (FDA) could "address issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco." § 3(2), 123 Stat. 1781.

To that end, the Act imposes special restrictions on "new tobacco product[s]"—that is, tobacco products that were not commercially marketed in the United States as of February 15, 2007. 21 U.S.C. 387j(a)(1)(A). A manufacturer may introduce a new tobacco product into interstate commerce only if it obtains authorization from the Secretary of Health and Human Services. See 21 U.S.C. 387j(a)(2)(A). The Secretary exercises that authority through FDA. See 21 U.S.C. 393(d)(2).

An applicant for marketing authorization must show, among other things, that the marketing of the new 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 "the risks and benefits to the population as a whole." 21 U.S.C. 387j(c)(4). Specifically, it 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)(A) and (B). 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.

The agency must apply those standards based on "the information submitted" by the applicant and "other

information" before it. 21 U.S.C. 387j(c)(2). The agency's decision must, "when appropriate," rest on "well-controlled investigations." 21 U.S.C. 387j(c)(5)(A). But the agency may rely on "valid scientific evidence" apart from well-controlled investigations if such evidence "exists" and "is sufficient to evaluate the tobacco product." 21 U.S.C. 387j(c)(5)(B).

An unsuccessful applicant may seek judicial review in a court of appeals within 30 days of FDA's order denying the application. See 21 U.S.C. 387*l*(a)(1)(B). The court must review the agency's order in accordance with the judicial-review provisions of the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq.* See 21 U.S.C. 387*l*(b).

2. This case concerns FDA's application of those provisions to electronic nicotine delivery systems, which are commonly known as e-cigarettes or vapes. See Centers for Disease Control and Prevention, U.S. Dep't of Health and Human Services, *E-Cigarette, or Vaping, Products Visual Dictionary* (*CDC Dictionary*) 3. An e-cigarette is a battery-powered device that heats an "e-liquid" containing nicotine and other substances, converting the e-liquid into an aerosol (a suspension of small airborne droplets) that the user inhales. See *id.* at 7. Some e-cigarettes come prefilled with e-liquids, while others can be filled and refilled with e-liquids that are packaged and sold separately. See *id.* at 6, 8-13.

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; Final Rule, 81 Fed. Reg. 28,974, 29,028-29,044 (May 10, 2016). E-cigarettes and e-liquids generally qualify as "new tobacco product[s]" because they were not on the market as of February 15, 2007. See, *e.g.*, C.A. App. A426.

Since 2016, FDA has received applications for authorization to market millions of new tobacco products. See Pet. App. 129a. The applicants range in scale from large multinational corporations to small independent companies. See FDA, *Tobacco Products Marketing Orders* (Mar. 7, 2024). FDA has acted on most of those applications. See FDA, *FDA Makes Determinations On More Than 99% of the 26 Million Tobacco Products For Which Applications Were Submitted* (Mar. 15, 2023).

FDA has granted applications for authorization to market certain tobacco-flavored e-cigarette products. See FDA, *Premarket Tobacco Product Marketing Granted Orders* (Feb. 22, 2024). It has found that those products can benefit "established cigarette smokers," who have expressed interest in using the products "as a way to reduce or stop smoking" and who have identified tobacco flavor more often than other flavors as their "flavor of interest." FDA, *Technical Project Lead (TPL) Review of PMTAs* 32 (May 12, 2022). At the same time, it has found that those products pose a relatively low risk of enticing new users because "interest in tobacco flavor is low among youth." *Id.* at 27.

By contrast, FDA has denied the applications for authorization to market more than a million products with other flavors, including products flavored to taste like candy, fruit, and desserts. See Pet. App. 51a. FDA has explained that such products pose a serious, well-documented risk of attracting young people to the use

of tobacco. See *id.* at 304a-305a. Although it is possible that an applicant could show that the benefits of a particular flavored product outweigh its harms, FDA has denied authorization to applicants that have failed to make that showing. See *id.* at 305a.[1]

B. Facts

1. Respondent Triton Distribution makes e-liquids for its own brands and for brands owned by respondent Vapetasia LLC. See Resp. C.A. Br. 12. In September 2020, respondents filed applications for marketing authorization. See C.A. App. A354, A414. Triton sought authorization for e-liquids in flavors such as "Jimmy The Juice Man Peachy Strawberry," "Signature Series Mom's Pistachio," and "Suicide Bunny Mother's Milk and Cookies." *Id.* at A24, A33, A37. Vapetasia sought authorization for e-liquids in flavors such as "Blackberry Lemonade," "Iced Pineapple Express," and "Killer Kustard Blueberry." *Id.* at A109, A113. Respondents have described (C.A. Br. 14) their applications as "nearly identical." We describe and cite Vapetasia's submissions below, but the discussion applies to both respondents' submissions.

Respondents acknowledged in their applications that "a number of surveys" had indicated that "minors are increasingly using flavored [e-cigarettes]." C.A. App. A433. But they asserted that those flavors "appeal to adults as well." *Ibid.* According to respondents, a "growing body of scientific evidence" showed that "flavors are crucial to getting adult smokers to make the

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[1] Although tobacco is a flavor for e-cigarettes, we use the shorthand term "flavored product" to refer to products with flavors other than tobacco.

switch and stay away from combustible cigarettes." *Ibid.*

In an effort to substantiate that claim, respondents and other e-liquid companies had funded what they described as a "comprehensive review of the scientific literature." C.A. App. A424. The review, respondents argued, had offered "important insight into the impact" of flavored e-liquids. *Id.* at A436. Respondents ultimately conceded, however, that "there is not enough evidence from well-designed studies to determine whether e-cigarette flavors aid in smoking cessation." *Id.* at A472. They acknowledged, for example, that "observational cohort studies had mixed results" and that "cross-sectional studies that addressed flavor did not do so in a manner t[hat] directly answer[ed] this secondary research question." *Ibid.* And although respondents discussed evidence that e-cigarettes in general "can aid in smoking cessation," they accepted that "no conclusion can be made about the association of e-cigarette *flavors* and smoking cessation as there have not been enough studies investigating this research question." *Ibid.* (emphasis added).

2. FDA denied respondents' applications in September 2021. See Pet. App. 166a-176a, 226a-230a, 278a-284a. The agency relied on substantially the same reasoning in denying both respondents' applications. We describe and cite the order denying authorization for Vapetasia's e-liquids.

FDA denied marketing authorization because it found insufficient evidence that the benefits provided by the flavored e-cigarette products outweighed the risks they posed. See Pet. App. 279a. To begin with the benefits, the agency explained that tobacco-flavored e-cigarettes offer the same type of benefit that respond-

ents claimed for their products, but without "the same degree of risk of youth uptake." *Id.* at 289a. More specifically, the agency "reviewed these applications for any acceptably strong evidence that the flavored products have an added benefit relative to that of tobacco-flavored [e-cigarettes]." *Id.* at 290a. It found that "the literature does not establish that flavors differentially promote switching amongst [e-cigarette] users in general." *Id.* at 310a. And it determined that respondents had failed to fill that gap with "reliable and robust evidence" showing that their flavored e-liquids provided benefits beyond those provided by tobacco-flavored products. *Id.* at 288a.

On the other side of the balance, FDA found a "known and substantial risk to youth." Pet. App. 310a. It observed that, in 2020, approximately 19.6% of high-school students and 4.7% of middle-school students used e-cigarettes. See *id.* at 295a. E-cigarettes were thus "the most widely used tobacco product among youth by far." *Ibid.* Studies had found that, when asked why they used e-cigarettes, "youth users consistently select[ed] flavors as a top reason." *Id.* at 297a. According to one study, "93.2% of youth and 83.7% of young adult [e-cigarette] users reported that their first [e-cigarette] was flavored," and 71% reported that they used e-cigarettes "'because they c[a]me in flavors [they] like[d].'" *Ibid.* The agency explained that flavoring makes e-cigarettes "more palatable for novice youth and young adults, which can lead to initiation, more frequent and repeated use, and eventually established regular use." *Id.* at 298a.

FDA also found "variability in the popularity of device types among youth," but "consisten[cy]" in "the role of flavor." Pet. App. 299a. A 2020 study showed

that 76% of youth users of refillable e-cigarettes and 87% of youth users of non-refillable e-cigarettes preferred flavored cigarettes. *Ibid.* And when the agency prioritized enforcement against the cartridge-based flavored e-cigarettes that were popular with youth in 2020, youth migrated to disposable flavored e-cigarettes. See *id.* at 300a. That trend, in which "the removal of one flavored product option prompted youth to migrate to another [product] type that offered the desired flavor options," confirmed "the fundamental role of flavor in driving appeal." *Ibid.*

FDA declined to evaluate respondents' marketing plans, in which respondents proposed mitigating the risk to youth by restricting the manner in which their products would be marketed. See Pet. App. 308a n.xix.[2] The agency had previously found that the marketing and access restrictions proposed by many companies—such as age-verification technology for online sales, enhanced monitoring of retailer compliance with sales restrictions, and limits on the quantity that can be bought in a single transaction—had proven insufficient to prevent youth from using e-cigarettes at increasing rates. See C.A. App. A190-A191. In denying respondents' applications, the agency recognized that it is "theoretically possible that significant mitigation efforts could adequately reduce youth access and appeal such that the risk of youth initiation would be reduced." Pet. App. 308a n.xix. But the agency explained that it was "not aware of access restrictions that, to date, have been suc-

[2] At oral argument in the court of appeals, counsel for FDA stated that FDA had examined summaries of petitioners' marketing plans. See Pet. App. 24a. But the court of appeals rejected that contention as inconsistent with the administrative record, see *ibid.*, and we do not seek further review of that aspect of its decision.

cessful in sufficiently decreasing the ability of youth to obtain and use" e-cigarettes. *Ibid.*

Based on all those findings, FDA determined that respondents had failed to show that the marketing of their new products would be appropriate for the protection of the public health. See Pet. App. 279a. The agency therefore denied the applications for marketing authorization. See *ibid.*

C. Proceedings Below

1. Respondents sought judicial review in the Fifth Circuit. See Pet. App. 144a. A motions panel granted their motion for a stay pending disposition of the petitions for review. See *id.* at 144a-165a.

2. A merits panel denied the petitions for review. See Pet. App. 99a-143a. As relevant here, it rejected respondents' argument that the agency acted arbitrarily and capriciously in denying marketing authorization. See *id.* at 110a-125a. In particular, the panel rejected respondents' claim that the agency had unfairly surprised them by announcing one set of evidentiary standards in a guidance document issued in 2019, but then applying a different set of evidentiary standards in rejecting the applications. *Id.* at 116a; see *id.* at 116a-120a. The panel also rejected respondents' claim that the agency had erred by declining to evaluate their marketing plans, and it found that any such error was in all events harmless. See *id.* at 120a-125a.

Judge Jones dissented. See Pet. App. 126a-143a. In her view, the agency had improperly "chang[ed] its evaluation rules" midstream and had erroneously "ignor[ed] individualized consideration of [respondents'] plan for marketing restrictions." *Id.* at 143a.

3. The Fifth Circuit granted respondents' petition for rehearing en banc. See Pet. App. 331a-332a. By a

vote of 10-6, the en banc court granted the petitions for review, set aside the agency's orders denying marketing authorization, and remanded the matters to the agency. See *id.* at 1a-98a. The court acknowledged that its decision conflicted with the decisions of other courts of appeals. See *id.* at 51a.

In its most significant ruling, the en banc court determined that FDA had unfairly surprised respondents regarding the types of evidence that applicants would need to submit in order to obtain marketing authorization from the agency. See Pet. App. 26a-51a. In the court's view, the agency had initially told applicants that they were not required to submit long-term studies to support their applications, but then "turned around and denied [respondents'] applications" because of the failure to submit such studies. *Id.* at 32a.

The en banc court also determined that the agency had erred by declining to evaluate respondents' marketing plans. See Pet. App. 21a-26a. The court rejected the agency's argument that the error was harmless, reasoning that the "harmless-error rule simply does not apply" to the "discretionary administrative decisions" at issue here. *Id.* at 60a; see *id.* at 57a-61a.

The en banc court briefly identified three further grounds for holding the agency's orders unlawful. First, the court concluded that the agency had earlier perceived a "material distinction" between different types of e-cigarette devices, but had later abandoned that position without adequate explanation. Pet. App. 46a. Second, the court stated in a footnote that the agency had improperly adopted a "categorical ban" or "de facto ban" on all flavored e-cigarette products. *Id.* at 47a n.5. Finally, the court concluded that FDA had approved menthol-flavored e-cigarette products, yet ar-

bitrarily refused to approve the flavored e-cigarette products at issue here. *Id.* at 24a.[3]

Judge Haynes, joined by four other judges, issued a dissenting opinion in which she rejected the en banc court's rationales for holding that the agency had acted arbitrarily and capriciously. See Pet. App. 62a-93a. Judge Graves issued a dissenting opinion in which he expressed agreement with "most" of Judge Haynes's analysis. See *id.* at 94a-98a.

REASONS FOR GRANTING THE PETITION

In the Tobacco Control Act, Congress sought to ensure that the marketing of new tobacco products does not result "in new generations of tobacco-dependent children and adults." § 2(1), 123 Stat. 1777. It therefore prohibited the marketing of new tobacco products without authorization from FDA, and it required the agency to deny authorization unless the applicant shows, among other things, that the marketing of the new product would be "appropriate for the protection of the public health." 21 U.S.C. 387j(c)(2)(A). Applying that standard, FDA has denied a large number of applications for authorization to market flavored e-cigarette products. In many of those cases, as in this case, the agency has reasoned that the applicants have failed to show that the products' benefits for adult smokers outweigh the risks they pose to youth.

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[3] After the en banc court issued its decision, respondents filed a motion in which they acknowledged that the last of those rationales was erroneous. See C.A. Doc. 362, at 6 (Feb. 20, 2024). They conceded that, "to date, FDA has *not* approved any [applications] for menthol-flavored [e-cigarette] products," and they asked the court to modify its opinion to correct the mistake. *Ibid.* (emphasis added). The court later denied that motion. See Pet. App. 331a-333a.

Manufacturers of flavored e-cigarette products have repeatedly challenged FDA's denial orders as arbitrary and capricious, often relying on the same legal theories that respondents have invoked here. Seven courts of appeals have rejected those arbitrary-and-capricious challenges as meritless. See *Magellan Tech., Inc.* v. *FDA*, 70 F.4th 622, 629-630 (2d Cir. 2023), petition for cert. pending, No. 23-799 (filed Jan. 22, 2024); *Liquid Labs LLC* v. *FDA*, 52 F.4th 533, 539-545 (3d Cir. 2022); *Avail Vapor, LLC* v. *FDA*, 55 F.4th 409, 419-427 (4th Cir. 2022), cert. denied, 144 S. Ct. 277 (2023); *Gripum, LLC* v. *FDA*, 47 F.4th 553, 558-561 (7th Cir. 2022), cert. denied, 143 S. Ct. 2458 (2023); *Lotus Vaping Techs., LLC* v. *FDA*, 73 F.4th 657, 668-673 (9th Cir. 2023), petition for cert. pending, No. 23-871 (filed Feb. 9, 2024); *Electric Clouds, Inc.* v. *FDA*, No. 21-9577, 2024 WL 795952, at *2-*13 (10th Cir. Feb. 27, 2024); *Prohibition Juice Co.* v. *FDA*, 45 F.4th 8, 20-26 (D.C. Cir. 2022); see also *Breeze Smoke, LLC* v. *FDA*, 18 F.4th 499, 503-507 (6th Cir.) (rejecting challenge at the stay stage), stay denied, 142 S. Ct. 638 (2021).

The Fifth Circuit, however, accepted respondents' contentions and set aside FDA's denial orders as arbitrary and capricious. That decision reflects both a misreading of FDA's guidance documents and a misapplication of fundamental principles of administrative law. As the Fifth Circuit acknowledged, the decision conflicts with the decisions of other courts of appeals. The decision also has far-reaching consequences for public health and threatens to undermine the Tobacco Control Act's central objective of "ensuring that another generation of Americans does not become addicted to nicotine and tobacco products." *Avail Vapor*, 55 F.4th at 428.

This Court should grant the petition for a writ of certiorari and reverse the Fifth Circuit's judgment.

A. The Decision Below Is Wrong

The APA directs a reviewing court to hold unlawful and set aside agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. 706(2)(A). "Judicial review under that standard is deferential, and a court may not substitute its own policy judgment for that of an agency." *FCC* v. *Prometheus Radio Project*, 592 U.S. 414, 423 (2021). The Fifth Circuit failed to heed those principles in holding that FDA acted arbitrarily and capriciously when denying respondents' applications for authorization to market their new e-liquids. See Pet. App. 2a-4a.

1. In its most significant ruling, the Fifth Circuit concluded that FDA had unfairly surprised manufacturers of e-cigarette products. Pet. App. 51a. In the court's view, the agency had announced one set of evidentiary standards for e-cigarette products in a guidance document issued in 2019, but had applied a different set of standards in evaluating the applications filed by respondents and other e-cigarette companies. *Id.* at 31a-32a; see C.A. App. A284-A338. That asserted change, the court concluded, denied respondents fair notice, see Pet. App. 26a-41a; violated the requirement that an agency acknowledge and explain a change in its position, see *id.* at 41a-48a; and failed to account for respondents' reliance interests, see *id.* at 48a-51a.

That ruling is incorrect. As seven courts of appeals have held, the agency has evaluated applications for authorization to market e-cigarette products in accordance with the standards set forth in the statute and the 2019 guidance. See *Magellan*, 70 F.4th at 629-630 (2d

Cir.); *Liquid Labs*, 52 F.4th at 540 (3d Cir.); *Avail Vapor*, 55 F.4th at 422 (4th Cir.); *Gripum*, 47 F.4th at 559-560 (7th Cir.); *Lotus Vaping*, 73 F.4th at 670-671 (9th Cir.); *Electric Clouds*, 2024 WL 795952, at *8 (10th Cir.); *Prohibition Juice*, 45 F.4th at 21 (D.C. Cir.); see also *Breeze Smoke*, 18 F.4th at 506-507 (6th Cir.) (rejecting an unfair-surprise argument at the stay stage).

a. To begin, the Fifth Circuit erred in concluding that the agency had told applicants in 2019 that they could obtain authorization without conducting long-term studies about the effects of their products, only to deny respondents' applications because of the failure to conduct such studies. See Pet. App. 34a, 45a-46a. The Act requires an applicant to show that the marketing of its product would be appropriate for the protection of public health by submitting either "well-controlled investigations" or other "valid scientific evidence" that the agency finds "sufficient to evaluate the tobacco product." 21 U.S.C. 387j(c)(5)(A) and (B). The 2019 guidance tracked the statute, reiterating the statutory requirement that a manufacturer provide either "well-controlled investigations" or other "'valid scientific evidence.'" C.A. App. A298. FDA acknowledged that, "[g]iven the relatively new entrance of [e-cigarettes] on the U.S. market," "limited data may exist from scientific studies and analyses." *Ibid.* The agency added that, although it did not "in general" "expect that applicants will need to conduct long-term studies to support an application," applicants would still need to provide other forms of "valid scientific information" showing that marketing their new tobacco products would be appropriate for the protection of public health. *Id.* at A299. And it warned that, where such alternative forms of ev-

idence were lacking, "new * * * studies may be necessary." *Id.* at A332.

The agency adhered to those evidentiary standards in denying respondents' applications. Respondents claimed that the presence of flavors in e-cigarettes can help "adult smokers to make the switch and stay away from [conventional] cigarettes." C.A. App. A433. But respondents did not support that claim with "well-controlled investigations," 21 U.S.C. 387j(c)(5)(A); to the contrary, they conceded that "there is not enough evidence from well-designed studies to determine whether e-cigarette flavors aid in smoking cessation," C.A. App. A472. Nor did respondents support their claim with other forms of "valid scientific evidence," 21 U.S.C. 387j(c)(5)(B); rather, respondents submitted a review of the literature, but the agency found that "the literature does not establish that flavors differentially promote switching amongst [e-cigarette] users in general," Pet. App. 310a. The agency therefore properly denied respondents' applications because they had not submitted evidence that satisfied either of the statutory bases for granting marketing authorization.

b. Relatedly, the Fifth Circuit erred in suggesting that the agency unfairly surprised respondents by distinguishing between flavored and what it called "unflavored" (*i.e.*, tobacco-flavored) e-liquids and by failing to infer the benefits of flavored products from studies about "unflavored" products. Pet. App. 39a (emphasis omitted); see *id.* at 31a-33a, 50a. In fact, the 2019 guidance dedicated an entire section to the significance of flavors. See C.A. App. A327-A328. The agency explained in the guidance that it "considers the appeal and use of [e-cigarette] product flavors important in ascertaining the health risks of these products." *Id.* at A328.

"Because of the potential impact of flavors on * * * appeal to youth and young adults," the agency stated that applicants should submit "scientific reviews of flavors" in support of their applications. *Id.* at A327. The agency also "recommend[ed] examining adult appeal of such flavors in their decisions to * * * cease use of more harmful products." *Id.* at A328.

c. The Fifth Circuit likewise erred in concluding that FDA unfairly surprised respondents by requiring evidence concerning the effects of their products "over time." Pet. App. 36a. The 2019 guidance stated that applications "should include" an assessment of "the trends by which users consume the product over time." C.A. App. A310; see *id.* at A324-A325 ("Evaluation of product use patterns should consider * * * the trends by which users consume the product over time.").

d. The Fifth Circuit stated that, even if the agency's guidance "could be reasonably read" as the agency and other courts of appeals have read them, the guidance "certainly could be read in good faith the way [respondents] read them." Pet. App. 49a-50a. But this Court has never suggested that an agency, when considering an application, is bound by the applicant's good-faith misreading of agency guidance regarding what the application should contain. In any event, for the reasons discussed above, the Act and the 2019 guidance clearly set forth the type of evidence that respondents were required to submit; respondents simply failed to submit such evidence.

2. The Fifth Circuit also determined that FDA acted arbitrarily and capriciously by declining to evaluate respondents' marketing plans, see Pet. App. 21a-26a, and that FDA's omission did not constitute harmless error, see *id.* at 57a-61a. We do not seek further review of the

Fifth Circuit's finding of error, but the Court should review and reverse the Fifth Circuit's holding that the error was not harmless. As six other courts of appeals have recognized, FDA's failure to consider an applicant's marketing plan is harmless where (as here) the applicant has failed to show any material difference between the measures proposed in its plan and others that FDA has previously reviewed and deemed insufficient. See *Magellan*, 70 F.4th at 630-631 (2d Cir.); *Liquid Labs*, 52 F.4th at 544 (3d Cir.); *Avail Vapor*, 55 F.4th at 425-426 (4th Cir.); *Lotus Vaping*, 73 F.4th at 661 (9th Cir.); *Electric Clouds*, 2024 WL 795952, at *13 (10th Cir.); *Prohibition Juice*, 45 F.4th at 24-25 (D.C. Cir.).

The APA provides that "due account shall be taken of the rule of prejudicial error." 5 U.S.C. 706. "[T]he burden of showing that an error is harmful normally falls upon the party attacking the agency's determination." *Shinseki* v. *Sanders*, 556 U.S. 396, 409 (2009).

Respondents have failed to show that FDA's decision not to evaluate their marketing plans caused them any harm. In 2020, FDA concluded that marketing and access restrictions—such as requiring customers to verify their ages at points of sale—did not adequately limit youth access to e-cigarette products. See, *e.g.*, C.A. App. A225-A227. Neither respondents nor the Fifth Circuit has suggested that respondents' proposed marketing and access restrictions materially differed from the restrictions that the agency had already found inadequate. Because respondents cannot show that "the FDA's denial orders could have come out differently if only it had known the contents of their plans," they have failed to establish that any error was prejudicial. *Prohibition Juice*, 45 F.4th at 25; see *id.* at 27 (Katsas, J., concurring).

Contrary to the Fifth Circuit's suggestion, this Court's decision in *Calcutt* v. *FDIC*, 598 U.S. 623 (2023) (per curiam), does not justify a refusal to apply the APA's harmless-error rule. See Pet. App. 58a-59a. In *Calcutt*, the Court explained that a reviewing court may not affirm a faulty agency action by "conduct[ing] a *de novo* inquiry into the matter being reviewed * * * and reach[ing] its own conclusions based on such an inquiry." 598 U.S. at 629 (citation omitted). In this case, however, applying the harmless-error rule would not require a court to conduct a "*de novo* inquiry" into the efficacy of marketing and access restrictions or to reach "its own conclusions" about the adequacy of respondents' marketing plans. *Ibid.* (citation omitted). Rather, a court need only recognize that respondents have failed to show that the measures they proposed differ from those that *the agency* has already deemed inadequate.

The Fifth Circuit's reliance on the Eleventh Circuit's decision in *Bidi Vapor LLC* v. *FDA*, 47 F.4th 1191 (2022), was likewise misplaced. See Pet. App. 56a. In *Bidi Vapor*, the Eleventh Circuit held that the agency committed prejudicial error by declining to evaluate "novel" marketing restrictions that it had not previously rejected. 47 F.4th at 1206. Here, respondents do not claim to have proposed new restrictions that go beyond the restrictions that the agency has already found inadequate.

3. Although the bulk of the Fifth Circuit's opinion concerned the unfair-surprise and marketing-plan issues discussed above, the court made at least three further errors in its analysis.

a. The Fifth Circuit concluded that FDA in 2020 had recognized a "material distinction" between different types of e-cigarette devices, but had then arbitrarily

"changed its position" in denying respondents' applications. Pet. App. 46a. That reasoning is wrong, and six courts of appeals have rejected similar arguments. See *Liquid Labs*, 52 F.4th at 544-545 (3d Cir.); *Avail Vapor*, 55 F.4th at 427 (4th Cir.); *Gripum*, 47 F.4th at 560 (7th Cir.); *Lotus Vaping*, 73 F.4th at 671 n.14 (9th Cir.); *Electric Clouds*, 2024 WL 795952, at *11-*12 (10th Cir.); *Prohibition Juice*, 45 F.4th at 26 (D.C. Cir.).

In 2020, the agency announced that it would "prioritize enforcement" against "cartridge-based" flavored e-cigarettes because those devices were "popular with young people" at that time. C.A. App. A186, A199; see *CDC Dictionary* 9 (describing cartridge-based devices). In denying respondents' applications, FDA observed that, after it adopted that policy, it saw a "substantial rise" in the use of disposable flavored e-cigarettes among youth users. Pet. App. 310a. The agency cited that trend, in which "the removal of one flavored product option prompted youth to migrate to another [product] type that offered the desired flavor options," as evidence of "the fundamental role of flavor in driving appeal." *Ibid.* As that summary shows, the agency did not arbitrarily change its position; rather, it simply recognized the "variability in the popularity of device types among youth" over time. *Id.* at 299a.

b. The Fifth Circuit also asserted that the agency had improperly adopted a "categorical ban" or "de facto ban" on flavored e-cigarettes—a step that, in the court's view, required notice-and-comment rulemaking. Pet. App. 47a n.5. That, too, is wrong. See *Gripum*, 47 F.4th at 560 (7th Cir.) (rejecting the argument that "the agency failed to conduct a careful, individualized review of [the] evidence and instead relied on a general presumption").

FDA has never adopted a categorical ban on flavored e-cigarette products. Rather, it has recognized that, because such products pose a "known and substantial risk to youth," applicants bear a particularly high burden of proving "a potential for benefit to adult smokers that could justify the risk." Pet. App. 314a. And FDA has denied applications for such products after finding that manufacturers have failed to carry that burden. The Fifth Circuit noted that the agency has denied applications for "over one million" flavored e-cigarette products, *id.* at 51a, but that analysis ignores that a single manufacturer might seek authorization to market thousands of products having different flavors but presenting essentially common issues, relying on largely the same evidence for each product. See, *e.g.*, News Release, FDA, *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence They Appropriately Protect Public Health* 1 (Aug. 26, 2021) ("55,000 flavored [e-cigarette] products from three applicants"). And different manufacturers have often relied on substantially similar evidence. See, *e.g.*, C.A. App. A424 (explaining that Triton participated "in a Coalition with other, similarly situated e-liquid companies" to fund the gathering of data). The agency's actions thus reflect the consistent application of the Act, not the adoption of a "de facto ban." Pet. App. 47a n.5.

c. Finally, the Fifth Circuit reasoned that FDA has "approved menthol-flavored e-cigarette products" but has failed to explain why it treated those products differently from respondents' flavored products. Pet. App. 24a. As respondents have conceded, that ruling is incorrect. See C.A. Doc. 362, at 6 (Feb. 20, 2024). "[T]o date, FDA has *not* approved any [applications] for menthol-

flavored [e-cigarette] products." *Ibid.* The Fifth Circuit denied respondent's motion to correct that error in its opinion, citing FDA's decision in 2019 to authorize the marketing of the menthol-flavored "IQOS heat-not-burn cigarette product." Pet. App. 332a; see *id.* at 331a-334a. But that device—which heats "tobacco-filled sticks wrapped in paper" rather than e-liquids—is not an e-cigarette, and no party has ever suggested otherwise. News Release, FDA, *FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway* (Apr. 30, 2019).

B. The Decision Below Warrants This Court's Review

1. The Fifth Circuit's decision warrants this Court's review because it conflicts with decisions of other courts of appeals in a number of respects. The legal theories accepted by the Fifth Circuit in the decision below have been rejected by every other court of appeals to consider them. In particular:

- Seven courts of appeals (the Second, Third, Fourth, Seventh, Ninth, Tenth, and D.C. Circuits) have rejected the claim that FDA has unfairly surprised e-cigarette companies by changing the evidentiary standards governing their applications. See pp. 14-15, *supra*. Another court of appeals (the Sixth Circuit) has rejected that claim at the stay stage. See p. 15, *supra*.
- Six courts of appeals (the Second, Third, Fourth, Ninth, Tenth, and D.C. Circuits) have determined that the agency's failure to consider an e-cigarette company's marketing plan is harmless where the company fails to identify a material difference between its proposal and others that the agency has reviewed and deemed inadequate. See p. 18, *supra*.

- Six courts of appeals (the Third, Fourth, Seventh, Ninth, Tenth, and D.C. Circuits) have rejected the claim that FDA has arbitrarily ignored distinctions between different types of e-cigarette devices. See pp. 19-20, *supra*.
- One court of appeals (the Seventh Circuit) has rejected the contention that the agency has failed to accord individualized consideration to applications for authorization to market flavored e-cigarette products. See p. 20, *supra*.

The Fifth Circuit's en banc decision and Judge Haynes's dissent both observed that the Fifth Circuit's decision conflicted with the decisions of other courts of appeals. See Pet. App. 51a; *id.* at 66a (Haynes, J., dissenting).

The Tenth Circuit's later decision in *Electric Clouds* further entrenched the circuit conflicts. In that decision, the Tenth Circuit considered and expressly rejected the Fifth Circuit's reasons for holding that FDA acted arbitrarily in evaluating applications for flavored e-cigarette products. See *Electric Clouds*, 2024 WL 795952, at *3 n.1, *5 n.4, *9 n.9 (rejecting the Fifth Circuit's reasons for holding that FDA had unfairly surprised regulated parties); *id.* at *14 (rejecting the Fifth Circuit's reasons for declining to apply the harmless-error rule to FDA's failure to evaluate marketing plans).

Before the Fifth Circuit issued the decision below, this Court denied two petitions for writs of certiorari raising similar legal issues to those presented here. See *Avail Vapor, LLC* v. *FDA*, 144 S. Ct. 277 (2023) (No. 22-1112); *Gripum, LLC* v. *FDA*, 143 S. Ct. 2458 (2023) (No. 22-708). But the government opposed those petitions on the ground that no circuit conflict existed at that time. See Br. in Opp. at 11, *Avail Vapor*, *supra* (No. 22-1112)

("The absence of any circuit conflict regarding the questions presented confirms that the questions do not warrant this Court's review at this time."); Br. in Opp. at 9, *Gripum*, *supra* (No. 22-708) (same). Because such a conflict exists now, the Court should grant this petition for a writ of certiorari.

2. Certiorari is also warranted because the legal issues raised by this case frequently recur. Since 2016, FDA has received applications for authorization to market millions of new tobacco products. See Pet. App. 129a. And as the Fifth Circuit noted, the agency has denied applications for authorization to market "over one million" flavored e-cigarette products. *Id.* at 51a. As the 7-1 circuit conflict discussed above suggests, applicants have repeatedly challenged those denials on substantially the same grounds that respondents have raised here—most importantly, on the ground that the agency has unfairly surprised them by changing its standards for evaluating their applications.

We acknowledge that one of the legal issues raised by this case—whether FDA committed prejudicial error by declining to evaluate respondents' marketing plans—is, while the subject of a circuit conflict, of diminishing prospective importance. FDA informs this Office that it began routinely reviewing marketing plans in 2022. Even so, the issue warrants this Court's review. Petitions for review challenging pre-2022 denial orders in which the agency declined to evaluate marketing plans continue to work their way through the federal courts. More broadly, the Fifth Circuit's erroneous constriction of the harmless-error rule—to a scope that the court described as "quite narrow," Pet. App. 57a—could affect judicial review of agency actions apart from those directly at issue here.

3. The practical consequences of the Fifth Circuit's decision underscore the need for this Court's review. Congress found that the "use of tobacco products by the Nation's children is a pediatric disease of considerable proportions." Tobacco Control Act § 2(1), 123 Stat. 1777. Today, e-cigarettes contribute to that disease to a greater extent than any other tobacco product. FDA has found that e-cigarettes "are now the most commonly used type of tobacco product among youth," Pet. App. 295a, and that flavored e-cigarettes pose a serious risk of enticing young users, see *id.* at 295a-299a. The Fifth Circuit's invalidation of FDA's denial orders in this case undermines the agency's efforts to fight that problem, frustrating the Act's goal of ensuring that marketing of new tobacco products does not result in "new generations of tobacco-dependent children and adults." Tobacco Control Act § 2(1), 123 Stat. 1777.

Magnifying the practical consequences of the decision below, the Fifth Circuit has effectively nullified the Tobacco Control Act's limits on venue. See 21 U.S.C. 387*l*(a)(1). The Act allows an adversely affected person to obtain judicial review in the D.C. Circuit, the circuit where it resides, or the circuit where it has its principal place of business. See *ibid.* But the Fifth Circuit has held that a manufacturer based outside the circuit may nonetheless seek judicial review within the circuit, so long as its petition for review is joined by a seller of the manufacturer's products (such as a gas station or convenience store) located within the circuit. See *R.J. Reynolds Vapor Co.* v. *FDA*, 65 F.4th 182, 188 & n.5 (2023). Predictably, out-of-circuit entities have begun flocking to the Fifth Circuit, thus evading unfavorable precedent in the D.C. Circuit or in their own circuits. See, *e.g., Corr-Williams Co.* v. *FDA*, No. 24-60068 (5th

Cir.) (filed Feb. 8, 2024) (manufacturer based in North Carolina); *Shenzhen Youme Information Tech. Co.* v. *FDA*, No. 24-60060 (5th Cir.) (filed Feb. 1, 2024) (manufacturer based in China); *Shenzhen IVPS Tech. Co.* v. *FDA*, No. 24-60032 (5th Cir.) (filed Jan. 19, 2024) (manufacturer based in China). As a result, the practical effects of the decision below are not limited to the Fifth Circuit; rather, they extend nationwide.

4. Two other pending petitions for writs of certiorari present questions concerning the lawfulness of FDA's evaluation of applications for authorization to market flavored e-cigarette products: *Magellan Technology, Inc.* v. *FDA*, No. 23-799 (filed Jan. 22, 2024), which arises from the Second Circuit, and *Lotus Vaping Technologies, LLC* v. *FDA*, No. 23-871 (filed Feb. 9, 2024), which arises from the Ninth Circuit. The same counsel of record who represents respondents in this case also represents the e-cigarette companies in *Magellan* and *Lotus Vaping*.

Of the three cases, this case is the best vehicle for considering the lawfulness of FDA's actions. The Fifth Circuit relied on multiple rationales in holding that FDA had acted arbitrarily and capriciously in denying respondents' applications. But only some of those rationales are at issue in *Magellan* and *Lotus Vaping*. See Pet. at i-ii, *Magellan*, *supra* (No. 23-799); Pet. at i-ii, *Lotus Vaping*, *supra* (No. 23-871). The Second Circuit did not address the claim that FDA arbitrarily ignored distinctions between different types of e-cigarette devices, and neither the Second nor the Ninth Circuit addressed claims that the agency improperly adopted a categorical ban on flavored e-cigarette products or that it arbitrarily distinguished between menthol and other flavors.

This case is thus the only vehicle for addressing the full range of legal issues raised by the decision below.

If this Court grants this petition for a writ of certiorari, it should hold the petitions in *Magellan* and *Lotus Vaping* pending the resolution of this case. Because the legal issues presented in *Magellan* and *Lotus Vaping* are subsets of the legal issues presented here, there would be no need to grant plenary review in those cases as well. And granting review in multiple cases would needlessly result in duplicative briefing.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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