No. 23-1038

In the Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION, PETITIONER

v.

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

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

BRIEF FOR THE PETITIONER

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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 question presented is:

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

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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 court of appeals was entered on January 3, 2024. The petition for a writ of certiorari was filed on March 19, 2024, and granted on July 2, 2024. The jurisdiction of this Court rests on 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

Pertinent statutory provisions are reproduced in the appendix. App., *infra*, 1a-16a.

STATEMENT

A. The Tobacco Control Act

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 the 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. It further found that "[v]irtually 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; that cutting minors' use of tobacco in half would prevent more than three million premature deaths and save around $75 billion in healthcare costs, § 2(14), 123 Stat. 1777; that "past efforts" had not adequately "curb[ed] tobacco use by adolescents," § 2(6), 123 Stat. 1777; and that tobacco companies continued to regard "young people" as a "crucial segment of the tobacco market" and had "dramatically increased their advertising and promotional spending in ways that encourage[d] youth to start smoking," § 2(24) and (48), 123 Stat. 1778, 1781.

The Act accordingly established a new regulatory framework to address "issues of particular concern to public health officials, especially the use of tobacco by young people and dependence on tobacco," and to respond to "the public health crisis created by actions of the tobacco industry." §§ 2(29), 3(2), 123 Stat. 1778, 1781. The statute empowers the Secretary of Health and Hu-

man Services, acting through the Food and Drug Administration (FDA), to implement that framework. See 21 U.S.C. 393(d)(2). The Act automatically applies to some tobacco products, such as cigarettes, but other products become subject to it only once FDA issues a rule that "deems" the product "to be subject to" the Act. 21 U.S.C. 387a(b).

As relevant here, the Act restricts "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 manufacturer may introduce a new tobacco product into interstate commerce only with authorization from FDA. See 21 U.S.C. 387j(a)(2)(A).

An applicant for such authorization must show 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," "taking into account" 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 FDA 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.

FDA must apply that test based on "the information submitted" by the applicant and "any other information" before it. 21 U.S.C. 387j(c)(2). Its decision must, "when appropriate," rest on "well-controlled investiga-

tions." 21 U.S.C. 387j(c)(5)(A). But FDA may rely on "valid scientific evidence" apart from well-controlled investigations if such evidence "exists" and "is sufficient to evaluate" the product. 21 U.S.C. 387j(c)(5)(B). This case involves the "valid scientific evidence" prong of that standard. *Ibid.*

An unsuccessful applicant may file a petition for 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 order under 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); 5 U.S.C. 706(2)(A) (providing for review of whether agency action is "arbitrary" or "capricious").

B. E-cigarettes

This case concerns FDA's application of the Tobacco Control Act to electronic nicotine delivery systems, which are commonly known as e-cigarettes or vapes. See U.S. Public Health Service, U.S. Dep't of Health and Human Services, *E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General* 3 (2016) (*Surgeon General's Report*). An e-cigarette is a battery-powered device that heats a nicotine solution, or "e-liquid," converting the solution into an aerosol (a suspension of small airborne droplets) that the user then inhales. See *id.* at 11. Some e-cigarettes come prefilled with e-liquids, while others can be filled or refilled with e-liquids that are packaged and sold separately. See *ibid.* E-cigarettes were developed in China in 2003 and began appearing in the United States in the mid-2000s. See *id.* at 10.

Although the long-term effects of e-cigarettes are not fully understood, the available evidence shows that they pose health risks. See Pet. App. 301a-304a. Nico-

tine is a highly addictive drug that can harm the developing adolescent brain. See *id.* at 301a-302a. Studies have found that e-cigarette use may be associated with diseases such as asthma, chronic bronchitis, emphysema, and chronic obstructive pulmonary disease. See *id.* at 303a-304a. And e-cigarette users may progress to conventional tobacco products, which can endanger human health even more. See *id.* at 302a-303a.

Despite those risks, e-cigarettes initially escaped regulatory oversight because Congress did not list them among the products to which the Act automatically applied. See 21 U.S.C. 387a(b). E-cigarettes sales rose rapidly in the 2010s after the Act's passage, and their use among high-school students surpassed that of conventional cigarettes by 2015. *Surgeon General's Report* 10.

In 2016, FDA closed the regulatory gap by issuing a rule deeming e-cigarettes and e-liquids to be subject to the Act. See 81 Fed. Reg. 28,974, 29,028-29,044 (May 10, 2016). Because e-cigarettes and e-liquids had generally not been on the market as of February 15, 2007, they qualified as new tobacco products under the Act, and FDA's deeming rule meant that they could lawfully be marketed only with agency authorization. See J.A. 10-11. But FDA announced that it would generally refrain from initiating enforcement actions during an initial period while manufacturers prepared, and the agency reviewed, applications for authorization. See 81 Fed. Reg. at 29,004-29,008. In 2019, FDA also issued guidance explaining how it would apply the statutory standards in evaluating applications and detailing the type of information applicants should submit. See J.A. 1-109.

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 firms. See FDA, *Tobacco Products Marketing Orders* (Aug. 6, 2024). FDA has acted on most of those applications. See *Combatting the Youth Vaping Epidemic by Enhancing Enforcement Against Illegal E-Cigarettes: Hearing Before the S. Comm. on the Judiciary*, 118th Cong., 2d Sess. 5 (2024) (statement of Brian A. King, Director, Center for Tobacco Products, FDA).

FDA has authorized the marketing of fewer than three dozen e-cigarette products, most of them tobacco flavored. See FDA, *E-Cigarettes Authorized by the FDA* (July 2024), https://digitalmedia.hhs.gov/tobacco/hosted/E-Cigarettes-Authorized-FDA-JULY2024.pdf. It has found that those products can benefit "established cigarette smokers," who could switch to them "as a way to reduce or stop smoking" and have identified tobacco more often than other flavors as their "flavor of interest." FDA, *Technical Project Lead (TPL) Review of PMTAs* 32 (May 12, 2022), https://www.fda.gov/media/165236/download. 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 applications for authorization to market more than a million e-cigarette products with non-tobacco flavors, including candy, fruit, various desserts, and menthol. See Pet. App. 51a. FDA has explained that flavored products pose a serious, well-documented risk of attracting youth to the use of tobacco. See *id.* at 304a-305a.[1]

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

The agency has, however, continued to evaluate each new application on its merits, recognizing that the benefits of a particular flavored product might outweigh its risks. See Pet. App. 305a. For example, FDA recently authorized the marketing of four menthol-flavored e-cigarette products because the manufacturer had provided sufficient evidence that the products' benefits outweighed their risks. See News Release, FDA, *FDA Authorizes Marketing of Four Menthol-Flavored E-Cigarette Products After Extensive Scientific Review* (June 21, 2024).

C. Respondents' Applications

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 applied to FDA for authorization to market flavored e-liquids. See J.A. 283-376, 377-476. Respondents describe Triton's and Vapetasia's applications as "nearly identical." Resp. C.A. Br. 14.

Respondents' e-liquids are flavored to taste like fruit, candy, and desserts. The fruit flavors include "Pink Lemonade," "Rainbow Road," "Chewy Clouds Sour Grape," and "Jimmy The Juice Man Peachy Strawberry." J.A. 492, 519, 606, 608. The candy flavors include "Cloud Science Alpha," which tastes "[s]imilar to cotton candy," and "Cloud Science Epsilon," which "delivers the memorable taste of your favorite little rainbow fruit candies." J.A. 502, 504; Vape Shop, *Alpha – Cloud Science E-Juice (120 Ml)*, https://perma.cc/7PZR-EEFS; Vape Shop, *Epsilon – Cloud Science E-Juice (120 Ml)*, https://perma.cc/CY75-6AVD. Respondents' dessert flavors include "Crème Brulee," "Killer Kustard," "Strawberry Parfait," and "Suicide Bunny Mother's Milk and Cookies." J.A. 518, 546, 593, 612.

Respondents' applications acknowledged "a number of surveys" showing that "minors are increasingly using flavored [e-cigarettes]." J.A. 319, 409. But they asserted that 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 switch and stay away from combustible cigarettes." *Ibid.*

In an effort to substantiate that claim, respondents and other e-liquid companies funded what they described as a "comprehensive review of the scientific literature." J.A. 303. The literature, respondents said, provided "important insight into the impact of [flavored e-liquids] on public health." J.A. 325, 375. But the "State of the Science" review itself actually concluded that "there is not enough evidence from well-designed studies to determine whether e-cigarette flavors aid in smoking cessation." J.A. 475. It 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.* Although the review discussed evidence that e-cigarettes in general "can aid in smoking cessation," its final sentence cautioned that "no conclusions can be made about the association of e-cigarettes flavors and smoking cessation as there have not been enough studies investigating this research question." J.A. 476.

D. FDA's Orders

FDA denied respondents' applications in September 2021. See Pet. App. 166a-176a, 226a-230a, 278a-284a. It relied on substantially the same reasoning in denying both respondents' applications.

FDA explained that flavored e-cigarette products pose a "known and substantial risk to youth." Pet. App. 200a, 254a, 308a. It observed that 19% of high-school students and 4.7% of middle-school students used e-cigarettes in 2020—making e-cigarettes "the most widely used tobacco product among youth by far." *Id.* at 187a, 241a, 295a. When asked why they used e-cigarettes, youth users consistently identified flavor as "a top reason." *Id.* at 189a, 243a, 297a. In one study, 93% of youth e-cigarette users reported that their first e-cigarette was flavored, and 71% reported using e-cigarettes "because they come in flavors I like." *Ibid.* (citation omitted). FDA thus determined 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 190a, 244a, 298a.

Reinforcing that assessment, FDA found "variability in the popularity of [e-cigarette] device types among youth," but "consisten[cy]" in "the role of flavor." Pet. App. 191a, 245a, 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 e-liquids. See *ibid.* After FDA prioritized enforcement against certain refillable flavored e-cigarettes that were popular with youth, they migrated to disposable flavored e-cigarettes. See *id.* at 192a, 246a, 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.*

Because flavored e-cigarettes posed "known risks to youth," FDA demanded "robust and reliable evidence" of "the magnitude of the potential benefit to adult smok-

ers." Pet. App. 167a, 227a, 263a. But FDA "did not find such evidence" in respondents' applications. *Id.* at 168a, 228a, 263a. It noted that tobacco-flavored e-cigarettes offer the type of benefit that respondents claimed for their products, but without "the same degree of risk of youth uptake." *Id.* at 181a, 235a, 289a. And it found that "the literature does not establish that flavors differentially promote switching amongst [e-cigarette] users in general." *Id.* at 202a, 256a, 310a.

"[F]or the sake of efficiency," FDA declined to evaluate respondents' marketing plans, which proposed mitigating the risk to youth by restricting the manner in which their products would be marketed and sold. See Pet. App. 201a n.xix, 255a n.xix, 309a n.xix. FDA had previously found that the kinds of 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 proved to be insufficient to prevent youth from using e-cigarettes at increasing rates. See J.A. 215-228. In denying respondents' applications, FDA recognized that it is "theoretically possible that significant mitigation efforts could adequately reduce youth access and appeal such that the risk for youth initiation would be reduced." Pet. App. 200a n.xix, 254a n.xix, 308a n.xix. But FDA explained 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. *Ibid.*

Based on all those findings, FDA determined that respondents had failed to show that the marketing of their products would be appropriate for the protection of the

public health, and it denied their applications. See Pet. App. 166a-167a, 226a-227a, 279a.

E. Fifth Circuit Proceedings

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

2. A merits panel denied respondents' petitions for review, rejecting their arguments that FDA had acted arbitrarily and capriciously in denying their applications. See Pet. App. 99a-143a. Judge Jones dissented, taking the position that FDA committed multiple errors in evaluating the applications. See *id.* at 126a-143a.

3. The court of appeals granted respondents' petition for rehearing en banc. See Pet. App. 334a-335a. By a vote of 10-6, the en banc court granted the petitions for review, set aside FDA's denial orders, and remanded the matter to the agency. See *id.* at 1a-98a.

In its most significant holding, the en banc court concluded that FDA had improperly subjected respondents to a "surprise switcheroo." Pet. App. 51a. In the court's view, the agency initially told applicants that they were not required to submit certain types of studies to support their applications, but then "turned around and denied [respondents'] applications" because of their failure to submit such studies. *Id.* at 32a.

The en banc court also held that FDA had erred by declining to evaluate respondents' marketing plans after its previous guidance had called such plans critical to an application. See Pet. App. 21a-26a. The court refused to countenance, as a "*post hoc* justification," the suggestion that "FDA did in fact look at 'summaries' of [respondent's] marketing plans." *Id.* at 24a (brackets and citation omitted). And the court rejected the agen-

cy's argument that the decision not to evaluate the plans after calling for their submission 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 FDA's orders unlawful. First, the court concluded that FDA 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 authorized menthol-flavored e-cigarette products yet arbitrarily refused to authorize the flavored e-cigarette products at issue here. See *id.* at 24a.

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 agreed with most of Judge Haynes's analysis. See *id.* at 94a-98a.

4. Respondents filed a motion conceding that the en banc court had erred in concluding that FDA arbitrarily distinguished between menthol and other e-cigarette flavors. See C.A. Doc. 362, at 6 (Feb. 20, 2024). They asked the court to correct its opinion, but the court denied their motion. See Pet. App. 331a-333a.

SUMMARY OF ARGUMENT

Seven courts of appeals have unanimously rejected arbitrary-and-capricious challenges to FDA's orders

denying authorization to market flavored e-cigarettes. The Fifth Circuit's contrary decision is incorrect.

A. To begin, the Fifth Circuit erred in holding that FDA unlawfully departed from previously announced evidentiary standards when evaluating respondents' applications for flavored e-cigarette products. The Tobacco Control Act requires applicants to support their claims with "valid scientific evidence," 21 U.S.C. 387j(c)(5)(B), and FDA's guidance explained that such evidence could include either new studies or other forms of evidence. FDA denied respondents' applications because they failed to support their claims with sufficient evidence in any form. FDA's evaluation of respondents' applications thus accorded with the standards announced in its earlier guidance.

The Fifth Circuit's contrary decision rested on a misreading of the record. For instance, the court concluded that FDA's denial orders departed from its guidance by requiring "randomized controlled trials and longitudinal cohort studies." Pet. App. 35a. In fact, FDA stated: "This evidence *could* have been provided using a randomized controlled trial and/or longitudinal cohort study[.] * * * Alternatively, FDA *would consider other evidence*[.] * * * We did not find such evidence in your [application]." *Id.* at 167a-168a, 227a-228a, 280a (emphases added).

The Fifth Circuit's decision reflected serious errors of administrative law as well. The court required FDA to notify applicants in advance how it planned to evaluate flavored e-cigarette products. But the court's notice requirement went far beyond anything demanded by the APA and disregarded agencies' well-established discretion to develop regulatory standards through case-by-case adjudication. Compounding that error, the court

deferred to respondents' incorrect but purportedly reasonable interpretations of agency guidance. That unfounded approach violates the courts' obligation to "determine the meaning or applicability of the terms of an agency action." 5 U.S.C. 706.

B. The Fifth Circuit held that FDA also erred by declining to evaluate respondents' proposals to mitigate their products' risks by restricting how those products are marketed and sold. Even assuming there was any such error, it was harmless. FDA has repeatedly considered similar proposals and found that such restrictions "would not be sufficient to address youth use of these products." J.A. 215. When, as here, an applicant's marketing plan replicates only measures that FDA has considered and rejected, FDA's decision not to evaluate that plan makes no difference to the result.

The Fifth Circuit invoked the principle that a court may not uphold defective agency action based on the court's own de novo inquiry. But applying harmless-error analysis here would not require a court to conduct a de novo inquiry into the efficacy of marketing and sales restrictions. A court need only recognize that FDA itself has found such proposals inadequate to address the risks of flavored e-cigarettes.

C. The Fifth Circuit's remaining objections to FDA's analysis also lack merit. First, the court concluded that FDA in 2020 recognized a material distinction between different types of e-cigarette devices, but then arbitrarily changed its view in denying respondents' applications. That is incorrect. In 2020, FDA decided to prioritize enforcement against certain flavored e-cigarettes that were popular with youth at that time (cartridge-based devices). But after adopting that enforcement priority, FDA saw a substantial rise in youth

use of a different type of flavored e-cigarette (disposable devices). FDA inferred that "the removal of one flavored product option prompted youth to migrate to another [product] type that offered the desired flavor options," which underscored "the fundamental role of flavor in driving appeal." Pet. App. 192a, 246a, 300a. Accordingly, FDA did not arbitrarily change positions; it reacted reasonably to new information.

Second, the Fifth Circuit concluded that FDA had imposed a categorical ban on flavored e-cigarettes. But FDA's denial orders make no reference to any such ban, showing instead that FDA considered each application on an individual basis. And while the petition for a writ of certiorari in this case was pending, FDA granted applications for authorization to market four flavored e-cigarette products—a step it could not have taken if it had subjected such products to a categorical ban.

Finally, the Fifth Circuit concluded that FDA had acted arbitrarily by authorizing other manufacturers' menthol-flavored e-cigarette products, but refusing to authorize respondents' flavored e-cigarette products. As respondents have conceded, that conclusion was wrong. At the time of the court's decision, FDA had not actually authorized any menthol-flavored e-cigarette products. And although FDA has since authorized four such products, it did so only after evaluating them under the same framework that it has applied to other flavored e-cigarettes.

ARGUMENT

The APA's arbitrary-and-capricious standard requires agency action to be "reasonable and reasonably explained." *FCC* v. *Prometheus Radio Project*, 592 U.S. 414, 423 (2021). In applying that "deferential" standard, "a court may not substitute its own policy judgment for

that of the agency." *Ibid.* The court's role is instead limited to ensuring that the agency "acted within a zone of reasonableness" and "reasonably explained the decision." *Ibid.*

Deferential review is fully appropriate here. In the Tobacco Control Act, Congress recognized FDA, not federal courts, as "the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products." § 3(1), 123 Stat. 1781. Congress directed FDA to judge whether authorizing a new product would be "appropriate for the protection of the public health," 21 U.S.C. 387j(c)(2)(A), and the word "appropriate" leaves FDA with significant "flexibility," *Loper Bright Enterprises* v. *Raimondo*, 144 S. Ct. 2244, 2263 (2024) (citation omitted). Congress also directed FDA to weigh a new product's "risks and benefits," 21 U.S.C. 387j(c)(4), and a court that second-guesses an agency's "weighing of risks and benefits" has "improperly substituted its judgment for that of the agency," *Department of Commerce* v. *New York*, 588 U.S. 752, 775, 777 (2019). Congress, finally, required FDA to assess "scientific evidence," 21 U.S.C. 387j(c)(5)(B)—a task that falls within the agency's, but outside the courts', expertise.

The FDA orders here easily satisfy the deferential arbitrary-and-capricious standard. The Fifth Circuit did not suggest, and could not have plausibly suggested, that FDA's bottom-line result, denying respondents' applications, fell outside the "zone of reasonableness." *Prometheus*, 592 U.S. at 423. Respondents' products—which come in flavors such as "Rainbow Road," "Suicide Bunny Mother's Milk and Cookies," and "Jimmy The Juice Man Peachy Strawberry," see p. 7, *supra*—"seem designed to have appeal for kids." Pet. App. 64a

(Haynes, J., dissenting) (citation omitted). FDA reasonably determined that those flavored products posed serious risks to youth, that respondents had failed to prove a sufficient offsetting benefit for adults and, accordingly, that authorizing the products would not be appropriate for the protection of the public health.

The Fifth Circuit instead held that FDA's orders were not "reasonably explained." *Prometheus*, 592 U.S. at 423. The court identified five purported flaws in FDA's reasoning, but each of the court's rationales lacks merit. Four of them have been rejected by every other court of appeals to consider the issue, and the fifth has been disavowed by respondents themselves. This Court should reverse.

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

The Fifth Circuit held that FDA unfairly surprised manufacturers of flavored e-liquids by announcing one evidentiary standard in its regulatory guidance, but then applying a different standard when evaluating their applications for marketing authorization. See Pet. App. 26a-51a. As seven other courts of appeals have unanimously determined, FDA did no such thing. See *Magellan Technology, 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, 540 (3d Cir. 2022); *Avail Vapor, LLC* v. *FDA*, 55 F.4th 409, 422 (4th Cir. 2022), cert. denied, 144 S. Ct. 277 (2023); *Gripum LLC* v. *FDA*, 47 F.4th 553, 559-560 (7th Cir. 2022), cert. denied, 143 S. Ct. 2458 (2023); *Lotus Vaping Technologies, LLC* v. *FDA*, 73 F.4th 657, 670-671 (9th Cir. 2023), petition for cert. pending, No. 23-871 (filed Feb. 9, 2024); *Electric Clouds, Inc.* v. *FDA*,

94 F.4th 950, 955 (10th Cir. 2024); *Prohibition Juice Co.* v. *FDA*, 45 F.4th 8, 21 (D.C. Cir. 2022).

1. FDA evaluated applications for flavored e-liquids in accordance with its regulatory guidance

The APA requires an agency that changes its policy to provide a "reasoned explanation for its action." *FCC* v. *Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). The agency must "display awareness that it is changing position," "show that there are good reasons for the new policy," and account for "serious reliance interests" engendered by its old policy. *Ibid.* (emphasis omitted).

Under those principles, it would have been unlawful for FDA to announce one evidentiary standard in its regulatory guidance, but apply a different standard when evaluating applications, without explaining the change. But as every other court of appeals to consider the issue has held, FDA did not change its policy. Rather, FDA evaluated applications for flavored e-liquids in accordance with the Act and the agency's regulatory guidance.

a. Under the Act, an applicant bears the burden of "showing" that authorizing the marketing of its new tobacco product would be "appropriate for the protection of the public health." 21 U.S.C. 387j(c)(2)(A). In deciding whether the applicant has made that showing, FDA must, as relevant here, rely on "valid scientific evidence" that is "sufficient to evaluate the tobacco product." 21 U.S.C. 387j(c)(5)(B).

In 2019, FDA issued a document (2019 Guidance) that provided applicants with non-binding guidance about the Tobacco Control Act's provisions, including the valid-scientific-evidence standard. See J.A. 1-109. Most of that document concerned e-cigarettes generally, rather than flavored products in particular.

The 2019 Guidance discussed "the types of information an applicant should include" in order to meet the Act's valid-scientific-evidence standard. J.A. 97. "Ideally," FDA explained, an application "will include studies conducted using the new tobacco product." J.A. 104. And in some instances, "studies may be necessary." J.A. 98. Yet, FDA explained, "in some cases, it may be possible to support a marketing order" "without conducting new * * * studies." *Ibid.* In particular, "if there is an established body of evidence regarding the health impact" of a product, such as data from "published literature," then that "may be sufficient to support" an application. *Ibid.* But FDA warned that "literature reviews" "are considered a less robust form of support," and it urged applicants who relied on them to provide "additional information" "to strengthen the likelihood" of receiving authorization. J.A. 100, 102.

b. FDA's denials of respondents' applications were consistent with its guidance. Respondents claimed that the presence of flavors in e-cigarettes can help "adult smokers to make the switch and stay away from [conventional] cigarettes." J.A. 319. Triton did not conduct studies to support that claim. See Pet. App. 113a n.9. Vapetasia did conduct a study, but FDA rejected it because of methodological flaws. See *id.* at 112a-113a, 317a. The en banc court did not mention that study, and it is not at issue here.

Respondents instead sought to substantiate their claims about the benefits of flavors by invoking a "comprehensive review of the scientific literature," J.A. 303, 392—*i.e.*, a type of evidence that FDA had warned was "considered a less robust form of support," J.A. 100. But respondents' own literature review recognized that "there is not enough evidence from well-designed stud-

ies [that have already been published] to determine whether e-cigarette flavors aid in smoking cessation." J.A. 475. Respondents' review therefore found that "no conclusions can be made about the association of e-cigarettes flavors and smoking cessation." J.A. 476.

FDA considered respondents' literature review, but found it inadequate to support respondents' applications. See Pet. App. 201a-202a, 255a-256a, 309a-310a. FDA explained that, while the extant literature amply demonstrated the *risks* of flavored e-cigarettes, it contained insufficient evidence of their *benefits*. See *ibid.* In FDA's words: "[T]he evidence regarding the role of flavors in promoting switching among adult smokers is far from conclusive. In fact, the findings are quite mixed and as a result the literature does not establish that flavors differentially promote switching amongst [e-cigarette] users in general." *Id.* at 202a, 256a, 310a (footnote omitted).

FDA, in short, did not automatically deny marketing authorization simply because respondents had failed to conduct new studies. Nor did FDA reject respondents' literature review simply because it was a literature review. FDA instead considered the review and found that it did not support respondents' scientific claims. That approach was fully consistent with FDA's 2019 Guidance—and with the APA.

2. The Fifth Circuit's analysis reflected a misreading of the record

The Fifth Circuit nonetheless concluded that FDA's denials of respondents' applications departed from FDA's earlier guidance in multiple respects. On each point, the court misread the guidance, the denial orders, or both. Other courts of appeals have uniformly rejected similar misinterpretations in other cases.

a. The Fifth Circuit first claimed that FDA, without prior warning, required manufacturers of flavored e-liquids to submit a "randomized controlled trial" and a "longitudinal cohort study" showing their products' effects. Pet. App. 32a; see *id.* at 35a ("FDA imposed two requirements—randomized controlled trials and longitudinal cohort studies."). A randomized controlled trial is a study in which participants are randomly divided into separate groups, one that receives the product being tested and one that does not. See *id.* at 181a n.iv. A longitudinal cohort study is a study in which a group of participants is observed over a period of time. See *id.* at 181a n.v.

As Judge Haynes noted in dissent, "even a cursory read" of FDA's denial orders refutes the claim that the agency *required* either type of study from respondents. Pet. App. 82a. The orders stated that, given the "known risks" of flavored e-liquids, "robust and reliable evidence [wa]s needed regarding the magnitude of the potential benefit to adult smokers." *Id.* at 167a, 227a, 279a. "This evidence *could* have been provided using a randomized controlled trial and/or longitudinal cohort study[.]" *Id.* at 167a, 227a, 279a-280a (emphasis added). "Alternatively," the agency "would consider other evidence" that "reliably and robustly evaluated the impact" of the flavored product; but FDA "did not find such evidence" in respondents' applications. *Id.* at 167a-168a, 227a-228a, 280a. FDA thus required neither randomized controlled trials nor longitudinal cohort studies. Instead, it reasonably concluded that respondents had failed to submit *any* "robust and reliable evidence" to support their claims. *Ibid.*; see *Magellan*, 70 F.4th at 630; *Liquid Labs*, 52 F.4th at 540-541; *Avail Vapor*, 55 F.4th at 422; *Lotus Vaping*, 73 F.4th at 672-

673; *Electric Clouds*, 94 F.4th at 961; *Prohibition Juice*, 45 F.4th at 21-22.

b. The Fifth Circuit emphasized the 2019 Guidance's statement that, "in general, FDA does not expect that applicants will need to conduct long-term studies to support an application." J.A. 28; see Pet. App. 7a, 32a-35a. The court concluded that FDA departed from that guidance by demanding evidence that showed the benefits of flavored e-liquids to adult smokers "over time." Pet. App. 168a, 228a, 280a; see *id.* at 36a-37a. That, too, is incorrect.

As an initial matter, the Fifth Circuit "conflate[d] 'long-term' studies with studies examining behavior 'over time.'" *Liquid Labs*, 52 F.4th at 541 n.10. The 2019 Guidance defined the term "long-term studies" to mean "studies that are conducted over six months or longer." J.A. 29. But a study that measures behavior "over time" can be "shorter than six months." *Liquid Labs*, 52 F.4th at 541 n.10. And the 2019 Guidance specifically encouraged applicants to submit evidence about "the trends by which users consume the product over time," without suggesting that such evidence was limited to long-term studies, as opposed to, for instance, "surveys." J.A. 53, 82-83.

In addition, although FDA told applicants that they likely would not need to conduct long-term *studies*, it encouraged them to submit evidence of their products' "long-term health *impacts*." J.A. 29 (emphasis added). "[I]nstead of conducting [new] clinical studies that span months or years," FDA explained, "applicants could demonstrate possible long-term health impact" by "extrapolating from short-term studies" or by citing "existing longer duration studies in the public literature" and explaining why the evidence in those existing studies is

"applicable to the new tobacco product." J.A. 29. FDA's denial orders were consistent with that guidance: FDA faulted respondents for failing to submit "robust and reliable evidence" of their products' effects, but it never insisted that such evidence take the form of new studies or specific kinds of studies. Pet. App. 167a, 227a, 279a; see *Liquid Labs*, 52 F.4th at 541-542; *Avail Vapor*, 55 F.4th at 422-423; *Gripum*, 47 F.4th at 559-560; *Lotus Vaping*, 73 F.4th at 672; *Electric Clouds*, 94 F.4th at 955-958; *Prohibition Juice*, 45 F.4th at 22.

c. The Fifth Circuit also concluded that FDA deviated from its previous guidance on "bridging"—that is, inferring the effects of one product from studies about other products. See Pet. App. 39a-40a. In the court's view, FDA unfairly surprised applicants by refusing to infer the benefits of "flavored product[s]" from studies about "unflavored products" (*i.e.*, products with no flavor other than tobacco). *Id.* at 39a (emphasis omitted). Once more, the court erred.

The 2019 Guidance explained that, while an application would "[i]deally" include "studies conducted using the new tobacco product," "bridging of data from one product to another may be feasible" in some cases. J.A. 104. But FDA emphasized that such extrapolation is permissible only if the new product is "similar" to the studied product and only if the applicant adequately explains "why the data used are applicable to [the] new tobacco product." J.A. 81, 105. For example, FDA suggested that an applicant who seeks to market e-liquids with the same flavor but with different nicotine concentrations need not conduct "unique studies for each nicotine concentration"; instead, a study for one level "may be bridged to other concentrations," so long as the ap-

plicant provides an adequate "justification" for that extrapolation. J.A. 105.

The 2019 Guidance also made clear that FDA regarded flavored products as materially different from, rather than similar to, unflavored products. See J.A. 87-88. In a section titled "Flavors," the guidance recognized "the attractiveness of flavors to youth and young adults," described flavors as an "important" aspect of the analysis, and recommended that applications for flavored products examine the "impact of the flavoring" and the "adult appeal of such flavors." J.A. 88.

FDA acted consistently with that guidance in denying respondents' applications. FDA recognized that an applicant could "bridg[e] from studies based on comparable products." Pet. App. 199a, 253a, 307a. For example, an applicant could draw inferences about "one of [its] flavors" from a study about "other flavors * * * in the same flavor category (e.g., 'fruit')." *Id.* at 205a, 259a-260a, 313a. But respondents sought to go much further and to "draw inferences about *flavored* products" from previously published "scientific studies involving *unflavored* products." *Id.* at 17a. FDA reasonably rejected that leap, explaining that respondents' evidence did not sufficiently support their claims regarding "the impact of the new flavored [products]." *Id.* at 168a, 209a, 280a.

FDA's decision also accorded with common sense. Respondents' applications claimed that flavors have unique benefits—specifically, that "flavors are crucial to getting adult smokers to make the switch and stay away from combustible cigarettes." J.A. 319, 409. But the Fifth Circuit did not explain how one could logically infer unique benefits of flavors from studies about unflavored products.

d. Finally, the Fifth Circuit concluded that FDA deviated from a presentation made by an agency official at a public meeting in October 2018 and later posted on the agency's website. See Pet. App. 6a, 31-32a. But the presentation included a disclaimer stating: "This is not a formal dissemination of information by FDA and does not represent Agency position or policy." Iilun Murphy, Dir., Div. of Individual Health Sci., Office of Sci., Ctr. for Tobacco Prods., FDA, *Premarket Tobacco Product Application Content Overview* 1 (Oct. 23, 2018), https://perma.cc/BV8D-HR7H. Given that the presentation "d[id] not represent Agency position or policy," *ibid.*, any departure could not have been a "change in [FDA's] position," Pet. App. 45a.

Regardless, FDA did not contradict the presentation in denying respondents' applications. The Fifth Circuit emphasized the presentation's assurance that "[n]o specific studies are required." Pet. App. 45a (citation omitted). But as discussed above, FDA did not require specific studies. It instead considered the other evidence that respondents submitted—mainly, respondents' literature review—and found that it did not support their scientific claims. See pp. 19-20, *supra*.

3. The Fifth Circuit's analysis also reflected serious errors of administrative law

The Fifth Circuit also went far beyond holding that an agency that departs from its previous guidance must explain the departure. The court concluded that FDA had an affirmative obligation to issue specific guidance that gave applicants "fair notice" of how it would evaluate flavored products, Pet. App. 26a, and that an applicant's "good faith" reading of an agency's guidance is controlling even if that reading is wrong, *id.* at 48a. Neither conclusion is sound.

a. The Fifth Circuit reasoned that FDA had a duty to issue guidance giving e-cigarette manufacturers "fair notice" of precisely how it planned to evaluate flavored products and exactly what type of evidence would suffice to obtain authorization. Pet. App. 26a; see *id.* at 26a-41a. The court required FDA to "specify the * * * scientific goal line" in advance, *id.* at 37a, and it faulted FDA for failing to inform respondents ahead of time that "literature reviews involving non-flavored products" would be insufficient to establish "the public health benefits of flavored e-cigarettes," *id.* at 40a n.4 (emphasis omitted).

The Fifth Circuit's advance-notice requirement has no basis in the Tobacco Control Act. The Act provides that the Secretary "shall issue regulations or guidance" on "the scientific evidence required" for authorization of a different category of products—namely, "modified risk tobacco products." 21 U.S.C. 387k(*l*)(1). But it does not require such guidance with respect to "new tobacco product[s]," the class of products at issue in this case. 21 U.S.C. 387j(a)(1). "That is significant because Congress generally acts intentionally when it uses particular language in one section of a statute but omits it in another." *DHS* v. *MacLean*, 574 U.S. 383, 391 (2015).

Nor does the Fifth Circuit's requirement have any basis in the APA. The APA *allows* agencies to issue interpretative rules, which "advise the public of the agency's construction of the statutes and rules which it administers," and general statements of policy, which "advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Chrysler Corp.* v. *Brown*, 441 U.S. 281, 302 n.31 (1979) (citations omitted); see 5 U.S.C. 553(b)(4)(A). But no provision of the APA *requires* agencies to do so.

The Fifth Circuit's requirement contradicts two hornbook principles of administrative law. First, the APA sets forth "the maximum procedural requirements which Congress was willing to have the courts impose upon agencies." *Vermont Yankee Nuclear Power Corp.* v. *NRDC, Inc.*, 435 U.S. 519, 524 (1978). A court may not impose additional procedures beyond those specified in the statutory text, as the Fifth Circuit did here. See *ibid.* Second, an agency may choose to proceed through adjudication rather than rulemaking—*i.e.*, to develop a regulatory standard through "case-by-case evolution" rather announcing a general standard "prospectively." *SEC* v. *Chenery Corp.*, 332 U.S. 194, 202-203 (1947) (*Chenery II*); see *NLRB* v. *Bell Aerospace Co.*, 416 U.S. 267, 290-295 (1974). By requiring FDA to announce the "scientific goal line" in advance, Pet. App. 37a, the court disregarded FDA's discretion to develop evidentiary standards "by individual order" rather than "by general rule," *Chenery II*, 332 U.S. at 202-203.

The Fifth Circuit traced its fair-notice requirement to the Due Process Clause. See Pet. App. 27a-28a. As the Fifth Circuit noted, this Court has read the Clause to require fair notice in criminal laws, see *Johnson* v. *United States*, 576 U.S. 591, 595 (2015), and the D.C. Circuit has invoked due-process principles in requiring fair notice before agencies impose civil sanctions, see *General Electric Co.* v. *EPA*, 53 F.3d 1324, 1328-1334 (1995). But the Due Process Clause applies when the government seeks to deprive a private party of life, liberty, or property. It does not apply when a private party approaches the government to seek a benefit to which it lacks an established entitlement—here, authorization to sell otherwise unlawful products based on an agency's determination that granting authorization

would be appropriate for the protection of the public health. See *American Manufacturers Mutual Insurance Co.* v. *Sullivan*, 526 U.S. 40, 60-61 (1999). Even in the criminal context, the Due Process Clause requires only an "ascertainable standard of guilt." *United States* v. *L. Cohen Grocery Co.*, 255 U.S. 81, 89 (1921). The Clause does not require "meticulous specificity" of the sort that the Fifth Circuit demanded from FDA here. *Grayned* v. *City of Rockford*, 408 U.S. 104, 110 (1972) (citation omitted); see, *e.g.*, Pet. App. 40a n.4 (faulting FDA for failing to specify in advance that "literature reviews involving *non-flavored* products" do not establish "the public health benefits of *flavored* e-cigarettes"). And FDA's guidance in fact gave applicants fair notice of the types of information they should submit to satisfy the Act's "valid scientific evidence" standard. See pp. 18-20, *supra*.

b. When considering "the good faith reliance doctrine," the Fifth Circuit concluded that a private party is entitled to rely on its own interpretation of agency guidance, even if that interpretation is wrong, so long as that interpretation is reasonable. See Pet. App. 49a-51a. "[F]or FDA to prevail," the court stated, "not only must its understanding of the [guidance] be reasonable, but the manufacturers' understanding of those rules also must be *unreasonable*." *Id.* at 51a. The court concluded that FDA did not meet that standard: Even if its guidance "could be reasonably read" to support FDA's position, the guidance "certainly could be read in good faith the way" respondents read it. *Id.* at 49a-50a.

The Fifth Circuit's version of good-faith reliance cannot be squared with the APA, which requires courts to "decide all relevant questions of law" and to "determine the meaning or applicability of the terms of an

agency action." 5 U.S.C. 706. As this Court recently held, the APA requires reviewing courts to "determine the best reading" of the law "by applying their own judgment." *Loper Bright*, 144 S. Ct. at 2261, 2266. That holding forecloses any contention that courts should accord controlling effect to a private party's purportedly reasonable but incorrect reading of a guidance document (which is "an agency action," 5 U.S.C. 706). To be sure, the Court held long ago that courts must defer to *an agency*'s reasonable reading of an ambiguous regulation, see *Bowles* v. *Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945), and it held more recently that *stare decisis* required adherence to that precedent, see *Kisor* v. *Wilkie*, 588 U.S. 558, 586 (2019). But it has never held that a court may canonize *a private party*'s reasonable but incorrect interpretation of agency guidance.

The Fifth Circuit's approach also contradicts the "general rule" that "a mistake of law is no defense." *Cheek* v. *United States*, 498 U.S. 192, 199 (1991). When Congress means to depart from that rule, it usually says so. For example, some statutes ask whether a person has acted "willfully," a standard that, in some contexts, excuses "a good-faith misunderstanding of the law." *Id.* at 200-201. Similarly, some statutes specifically protect persons who act in reasonable or good-faith reliance on regulations or agency guidance. See, *e.g.*, 15 U.S.C. 57b–4(b); 29 U.S.C. 259(a); 52 U.S.C. 30111(e). But the Fifth Circuit cited no provision of the Tobacco Control Act that requires FDA to authorize a new product when an applicant has relied on an incorrect, but purportedly reasonable, interpretation of the agency's guidance.

Moreover, agency guidance ordinarily lacks the force and effect of law. See *Perez* v. *Mortgage Bankers Ass'n*, 575 U.S. 92, 97 (2015). The 2019 Guidance warned read-

ers that it "does not establish any rights for any person and is not binding on FDA or the public." J.A. 5. Every page of the guidance included the boldface header "Contains Nonbinding Recommendations." *Ibid.*; C.A. App. A288-A338. Yet under the Fifth Circuit's approach, FDA effectively *is* bound—not just by the guidance, but by private parties' *mis*interpretations of it. Nothing in the APA authorized the court to transform the legal effect of the 2019 Guidance in that way.

The Fifth Circuit's approach is not only unsound in principle, but unwise in practice. While agencies generally have no legal obligation to issue guidance, such guidance can furnish private parties with useful advice about how the agency interprets the law and how it plans to exercise its discretion. See *Chrysler*, 441 U.S. at 302 n.31. But because of "the limits of human language and foresight," any guidance document will contain ambiguities. *Loper Bright*, 144 S. Ct. at 2257. By automatically resolving all such ambiguities against the agency, the Fifth Circuit's approach discourages agencies from providing guidance in the first place—an outcome that, in the long run, harms rather than helps regulated parties.

The Fifth Circuit invoked this Court's decisions in *Fox* and *Christopher* v. *SmithKline Beecham Corp.*, 567 U.S. 142 (2012), but neither case supports its holding. See Pet. App. 48a. In *Fox*, this Court stated that an agency that changes its policy must consider "serious reliance interests" engendered by its previous policy. 556 U.S. at 515. That statement refers to reliance on the agency's actual policy, not reliance on a purportedly reasonable misinterpretation of the agency's policy. See *ibid.* And FDA has not changed its actual policy here. See pp. 18-20, *supra*. In *Christopher*, the Court

declined to defer to an agency's interpretation of an ambiguous regulation when that interpretation would "impose potentially massive liability" for "conduct that occurred well before that interpretation was announced." 567 U.S. at 155-156. The Court warned against imposing "new liability" for "past actions which were taken in good-faith reliance on agency pronouncements." *Id.* at 157 (brackets and citation omitted). But this case does not involve deference to an agency's interpretation of a regulation or retroactive imposition of liability.

c. In sum, Congress did not require FDA to spell out in advance how it planned to evaluate applications for authorization to market flavored e-cigarette products. Nor did Congress create a safe harbor for regulated parties' good-faith misinterpretations of FDA guidance. The APA *did* require FDA to explain any departure from its guidance, but as seven other courts of appeals have unanimously held, no such departure occurred.

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

The Fifth Circuit separately held that FDA erred by declining to evaluate respondents' marketing plans—*i.e.*, their proposals to mitigate the risks that their products posed to youth by restricting the marketing and sale of those products—after providing guidance that "marketing plans were 'critical' to the success of e-cigarette applications." Pet. App. 22a-23a. The court rejected FDA's argument that any error was harmless. See *id.* at 57a-61a. We have not sought review of the Fifth Circuit's threshold finding of error. But as six other courts of appeals have determined, FDA's decision not to evaluate a marketing plan is harmless where, as here, the applicant fails to show any material difference between the measures proposed in its plan and

others that FDA has reviewed and rejected. See *Magellan*, 70 F.4th at 630-631; *Liquid Labs*, 52 F.4th at 544; *Avail Vapor*, 55 F.4th at 425-426; *Lotus Vaping*, 73 F.4th at 661; *Electric Clouds*, 94 F.4th at 966-969; *Prohibition Juice*, 45 F.4th at 24-25.

1. FDA has repeatedly found marketing restrictions to be insufficient to address the risks of e-cigarettes

a. In the Tobacco Control Act, Congress expressed concern about how tobacco companies had been marketing their products. It found that "[t]obacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents." § 2(5), 123 Stat. 1777. It also found that "[r]estrictions on advertising are necessary to prevent unrestricted tobacco advertising from undermining legislation prohibiting access to young people." § 2(26), 123 Stat. 1778.

At the same time, Congress determined that marketing restrictions, on their own, had proved insufficient to address youth smoking. It found that "past efforts to restrict advertising and marketing of tobacco products" had "failed adequately to curb tobacco use by adolescents." Tobacco Control Act § 2(6), 123 Stat. 1777. And it found that those "[p]ast efforts" had "not been successful" in preventing the "increased use of such products by youth." § 2(15), 123 Stat. 1777-1778.

b. FDA's approach to the marketing of e-cigarettes follows from those congressional findings. FDA has made clear that the inclusion of marketing and sales restrictions may be necessary for obtaining authorization. In the 2019 Guidance, for example, FDA "recommend[ed] sharing your marketing plan." J.A. 83. FDA also stated in a proposed rule that "[t]he applicant's marketing plans will help FDA determine whether permitting the new tobacco product would be [appropriate for the pro-

tection of the public health] because they will provide input that is critical to FDA's determination." 84 Fed. Reg. 50,566, 50,581 (Sept. 25, 2019).

But in a guidance document issued in 2020 (2020 Guidance), FDA explained that marketing and sales restrictions had proved insufficient to address e-cigarette use among youth. In the 2020 Guidance, FDA reported that it had been "vigorously enforc[ing]" requirements that e-cigarette sellers verify buyers' ages. J.A. 220. FDA had also been considering "how the product was sold" in deciding how to focus "enforcement priorities for flavored [e-cigarette] products." J.A. 215. And FDA discussed various measures that manufacturers had proposed or voluntarily implemented, such as establishing "mystery shopper programs" to monitor retailers' compliance with age-verification rules, imposing "contractual penalties" upon retailers who sell e-cigarettes to youth, using "age-verification technology" to restrict access to manufacturers' websites, and limiting "the quantity of [e-cigarette] products that a customer may purchase within a given period of time." J.A. 138.

Despite those efforts to enforce age-verification requirements, there was a "surge in youth use of [e-cigarette] products." J.A. 147. The "alarming data" on "youth use of [e-cigarette] products," FDA concluded, "show[ed] that the FDA's enforcement efforts to date did not adequately address this problem." J.A. 218. "The reality [wa]s that youth" had been able to maintain "continued access to [e-cigarette] products in the face of legal prohibitions and even after voluntary actions by some manufacturers." J.A. 166.

Thus, even though FDA's earlier draft guidance had proposed focusing on how e-cigarette products were sold, when finalizing the 2020 Guidance, "after consid-

ering the comments [submitted in response to the draft], the public health threats, and new evidence, FDA determined that focusing on how the product was sold would not be sufficient to address youth use of these products." J.A. 215. The 2020 Guidance reiterated that conclusion several times. See J.A. 166 ("[F]ocusing on how the product was sold would not appropriately address youth use."); J.A. 215 ("[F]ocusing on how the product was sold would not be sufficient."); J.A. 220-221 ("[A]ge verification alone is not sufficient to address this issue, given the most recent data that youth use of [e-cigarette] products continues to increase.").

FDA has issued multiple orders echoing its 2020 Guidance. To take just one example, consider FDA's decision in another case that is pending before this Court, *Logic Technology Development LLC* v. *FDA*, petition for cert. pending, No. 23-1125 (filed Apr. 15, 2024). See Pet. App. at 71a-227a, *Logic Technology*, *supra* (No. 23-1125) (*Logic* Pet. App.). In that decision, which was issued after the denial orders in this case, FDA discussed potential "[r]estrictions on advertising and promotion," such as "avoiding use of cartoons" and "not advertising on billboards located within 500 feet of any elementary or secondary schools." *Id.* at 137a-138a. FDA explained that, "[b]ecause these restrictions are intended to curb youth appeal but do not directly prevent youth use, they do not in themselves provide enough assurance of a sufficient reduction in youth use to mitigate the substantial risk that flavored [e-cigarette products] pose to youth." *Id.* at 139a. FDA therefore concluded that, "for flavored [e-cigarettes], these promotion and advertising restrictions do not reduce the risk of youth initiation and use to a material enough degree that FDA could find that a product is [appropriate for the protec-

tion of public health] in the absence of robust evidence of countervailing benefit to adults." *Ibid.*

In the same decision, FDA also discussed potential "[r]estrictions on sales access," such as "requiring age- and identity-verification prior to selling products" and "penalizing retailers and distributors for underage sales." *Logic* Pet. App. at 139a-140a. FDA found that "these restrictions do not by themselves mitigate the high risk to youth posed by flavored [e-cigarettes] to a degree material enough to establish that a product is [appropriate for the protection of public health] in the absence of robust and reliable evidence of benefit to adults." *Id.* at 140a. "This is because youth have been able to obtain products, including flavored [products], despite sales restrictions." *Ibid.*

2. FDA's decision not to evaluate a marketing plan is harmless if the plan replicates measures that the agency has considered and rejected

In this case, FDA's orders stated that it was not evaluating the marketing plans submitted with respondents' applications. FDA explained as follows:

> [T]o date, none of the [e-cigarette applications] that FDA has evaluated have proposed advertising and promotion restrictions that would decrease appeal to youth to a degree significant enough to address and counter-balance the substantial concerns, and supporting evidence, discussed above regarding youth use. Similarly, we are not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use [e-cigarettes]. Accordingly, for the sake of efficiency, the evaluation of the marketing plans in applications will not occur at this stage of review, and

> we have not evaluated any marketing plans submitted with these applications.

Pet. App. 200a-201a n.xix; *id.* at 255a n.xix; *id.* at 308a-309a n.xix.

When seeking certiorari, we excluded any challenge to the Fifth Circuit's holding that FDA erred by declining to evaluate respondents' marketing plans. See Pet. 17-18. FDA no longer declines to evaluate the marketing plans included in applications. See Pet. 24 (noting that FDA had informed this Office that it began routinely reviewing applicants' marketing plans in 2022). Although FDA has repeatedly found various marketing and sales restrictions to be insufficient to decrease youth use of e-cigarettes, a particular application might propose new measures that FDA had not previously considered, thus making it possible to approve the application.

But even assuming that the Fifth Circuit's finding of error in this regard was correct, respondents' own marketing plans did not include any novel restrictions. The plans instead replicated measures that FDA has considered and found insufficient. Thus, any error in declining to evaluate those measures anew in respondents' case was harmless, as six other courts of appeals have held in materially similar cases.

a. The Tobacco Control Act directs courts to review FDA orders "in accordance with" the judicial-review provisions of the APA. 21 U.S.C. 387*l*(b). The APA, in turn, states that "due account shall be taken of the rule of prejudicial error." 5 U.S.C. 706. That APA provision codifies "the 'harmless error' rule applied by the courts in the review of lower court decisions as well as of administrative bodies, namely, that errors which have no substantial bearing on the ultimate rights of the parties

will be disregarded." U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* 110 (1947). "[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).

The D.C. Circuit's decision in *Prohibition Juice* illustrates the proper application of the harmless-error rule. In *Prohibition Juice*, as here, FDA rejected applications for authorization to market flavored e-liquids without evaluating the applicant's marketing plans. See 45 F.4th at 16-17. The court noted "serious arguments" that FDA erred by "assum[ing] the contents of plans without reading them." *Id.* at 25. But the court determined that the applicants had failed to prove prejudice. "The measures they highlight[ed] in their marketing plans [we]re not materially different from those the FDA had previously found insufficient." *Ibid.* For example, their plans "to require customers' self-verification of age at the point of sale" "track[ed] measures the FDA in its 2020 guidance deemed inadequate to prevent or otherwise materially limit youth access." *Ibid.* The applicants thus could not "identify how the FDA's denial orders could have come out differently if only it had known the contents of their plans." *Ibid.*; see *id.* at 27 (Katsas, J., concurring).

Other courts of appeals, apart from the Fifth Circuit, have followed the same approach as the D.C. Circuit. The Second, Third, Fourth, Ninth, and Tenth Circuits have all determined that FDA's decision not to consider a marketing plan is harmless where the applicant fails to identify a material difference between its proposed restrictions and the restrictions FDA has already found insufficient. See *Magellan*, 70 F.4th at 630-631; *Liquid*

Labs, 52 F.4th at 543-544; *Avail Vapor*, 55 F.4th at 425-427; *Lotus Vaping*, 73 F.4th at 673-675; *Electric Clouds*, 94 F.4th at 966-969. The Eleventh Circuit reached a consistent result when it found that FDA's decision not to consider a particular marketing plan was prejudicial error because, in the court's view, that plan contained "novel marketing and sales-access restrictions" that FDA had not previously assessed. *Bidi Vapor LLC* v. *FDA*, 47 F.4th 1191, 1206 (2022).

b. Because this Court is "a court of review, not of first view," *Cutter* v. *Wilkinson*, 544 U.S. 709, 718 n.7 (2005), it need not analyze respondents' marketing plans in the first instance. The Court need only identify the correct harmless-error rule and remand the case, allowing the Fifth Circuit to determine whether respondents have met their burden of showing prejudice.

In any event, as the original Fifth Circuit panel held, respondents have not met that burden. See Pet. App. 124a-125a. "[N]othing in [respondents'] briefing to [the Fifth Circuit] indicate[d] that their marketing plan was in fact unique." *Id.* at 124a. Respondents' marketing plans instead "called for their products to be sold only in age-gated vape and specialty tobacco shops and through age-gated online sales." *Ibid.* "But FDA has already explained that such attempts do *not* work." *Ibid.* As FDA stated in the 2020 Guidance, "age verification alone is not sufficient to address this issue." J.A. 220.

3. The Fifth Circuit's analysis is incorrect

The Fifth Circuit did not suggest that respondents' marketing plans included any novel measures that FDA had not previously encountered and found insufficient. The court nonetheless rejected FDA's argument that its decision not to evaluate respondents' plans was

harmless. See Pet. App. 57a-61a. The court's reasons for that holding lack merit.

a. The Fifth Circuit reasoned that, "[i]n administrative law, the harmless error rule is quite narrow." Pet. App. 57a. The court believed that "APA errors are only harmless where the agency would be *required* to take the same action no matter what. In all other cases, an agency cannot avoid remand." *Id.* at 59a.

That is incorrect. By directing courts to apply "'the rule of prejudicial error,'" the APA incorporated "the same kind of 'harmless-error' rule that courts ordinarily apply in civil cases," *Sanders*, 556 U.S. at 406, not some uniquely "narrow" harmless-error rule applicable only "[i]n administrative law," Pet. App. 57a. In civil litigation —and, for that matter, in criminal litigation—the harmless-error rule requires a court to ask whether "the judgment would have been the same" without the error. *Waters-Pierce Oil Co.* v. *Texas*, 212 U.S. 86, 106 (1909); see *Neder* v. *United States*, 527 U.S. 1, 19 (1999) ("whether the jury verdict would have been the same absent the error").

The harmless-error rule in administrative law works the same way. In that context, as elsewhere, a court must ask whether the agency "would have reached the same conclusions" without the error. *Ohio* v. *EPA*, 144 S. Ct. 2040, 2057 (2024); see *Sanders*, 556 U.S. at 411 (explaining that harmless-error analysis involves "an estimation of the likelihood that the result would have been different"). A court need not ask whether the agency was "*required* to take the same action no matter what." Pet. App. 59a. This Court has found agency error to be harmless even when no statute required the agency to take the action at issue. See *Little Sisters of the Poor Saints Peter & Paul Home* v. *Pennsylvania*,

591 U.S. 657, 684-685 (2020) (finding an alleged procedural error in a rule's issuance to be harmless even though no statute required the rule); *Department of Commerce*, 588 U.S. at 780 (finding an alleged procedural error in the decision to include a citizenship question in the Census to be harmless even though no statute required the question's inclusion).

b. The Fifth Circuit reasoned that applying the harmless-error rule here would contravene a principle of administrative law known as the remand rule. See Pet. App. 57a-59a. That, too, is mistaken.

Under the remand rule, a court that determines that an agency "has not considered all relevant factors" generally must "remand to the agency for additional investigation or explanation." *Calcutt* v. *FDIC*, 598 U.S. 623, 628-629 (2023) (per curiam) (citation omitted). A court may not accept "counsel's *post hoc* rationalizations." *Burlington Truck Lines, Inc.* v. *United States*, 371 U.S. 156, 168 (1962). Nor may a court "conduct a *de novo* inquiry into the matter being reviewed" and "reach its own conclusions based on such an inquiry." *Calcutt*, 598 U.S. at 629 (citation omitted).

The remand rule reflects the principle that Congress has entrusted the power to make policy judgments to "the agency alone"—not to the agency's lawyers or to courts. *SEC* v. *Chenery Corp.*, 318 U.S. 80, 88 (1943) (*Chenery I*). A court thus may not substitute "counsel's discretion for that of the [agency]." *Burlington*, 371 U.S. at 169. Nor can "a judicial judgment" "be made to do service for an administrative judgment." *Chenery I*, 318 U.S. at 88.

The remand rule is consistent with harmless-error analysis. Harmless-error analysis requires "awareness of what body (jury, lower court, administrative agency)

has the authority to reach th[e] result." *Sanders*, 556 U.S. at 411. A court need not remand when it can determine, without "an improper judicial invasion of the administrative province," that the agency would not have reached a different result "but for the error." Henry J. Friendly, Chenery *Revisited: Reflections on Reversal and Remand of Administrative Orders*, 1969 Duke L.J. 199, 211.

Conducting harmless-error analysis in this case would fully comport with the remand rule. Applying the harmless-error rule here would not require accepting "counsel's *post hoc* rationalizations." *Burlington*, 371 U.S. at 168. Nor would it require a court to "conduct a *de novo* inquiry" into the benefits and drawbacks of marketing and sales restrictions or "reach its own conclusions based on such an inquiry." *Calcutt*, 598 U.S. at 629 (citation omitted). Rather, a court need only recognize that *FDA itself* has repeatedly found, in guidance and in other orders, that conventional marketing and sales restrictions are insufficient to address e-cigarette use among youth.

A remand would be appropriate if respondents' marketing plan contained novel restrictions that FDA had not previously assessed. In that scenario, a court could not properly conduct its own inquiry into the efficacy of the proposed restrictions and declare the agency's error harmless based on that inquiry. But where a proposed plan replicates restrictions that FDA has already considered and found insufficient, FDA's decision not to evaluate the plan's specific restrictions is harmless. See *Electric Clouds*, 94 F.4th at 968 ("[The remand rule] doesn't apply here because we're basing harmlessness on the FDA's existing approach to marketing restrictions, not a reason that we've detected on our own.").

More generally, the remand rule does not require courts to "convert judicial review of agency action into a ping-pong game." *Morgan Stanley Capital Group Inc.* v. *Public Utility District No. 1*, 554 U.S. 527, 545 (2008) (citation omitted). A court need not remand a matter to an agency when there is no "uncertainty as to the outcome" of the proceedings on remand. *Calcutt*, 598 U.S. at 630 (citation omitted). No such uncertainty exists here, given FDA's repeated determinations that the types of measures proposed in respondents' plans would be insufficient to address youth e-cigarette use. "To remand would be an idle and useless formality." *Morgan Stanley*, 554 U.S. at 545 (citation omitted).

c. The Fifth Circuit's remaining rationales are simply inconsistent with Congress's decision to codify a harmless-error rule in the APA. See 5 U.S.C. 706. The Fifth Circuit declared that a court "cannot forgive procedural violations simply because the court thinks they did not matter" or "look past the error on the supposition that the error would not affect the agency's decisionmaking." Pet. App. 58a. But that is precisely what the harmless-error rule requires: the disregarding of errors that "did not matter" and "would not affect the agency's decisionmaking." *Ibid.*

C. The Fifth Circuit's Remaining Objections To FDA's Analysis Lack Merit

The Fifth Circuit briefly identified three additional reasons to set aside FDA's orders. None is sound.

1. FDA reasonably explained its determination that the role of flavor is consistent across different types of e-cigarette devices

The Fifth Circuit concluded that FDA's 2020 Guidance recognized a "material distinction" between differ-

ent types of e-cigarette devices, but that FDA "changed its position" without explanation in denying respondents' applications. Pet. App. 46a. That theory is wrong, and six courts of appeals have properly rejected similar arguments. See *Liquid Labs*, 52 F.4th at 544-545; *Avail Vapor*, 55 F.4th at 427; *Gripum*, 47 F.4th at 560; *Lotus Vaping*, 73 F.4th at 671 n.14; *Electric Clouds*, 94 F.4th at 964-965; *Prohibition Juice*, 45 F.4th at 26.

a. In the 2020 Guidance, FDA explained that it planned to prioritize enforcement against "[f]lavored, cartridge-based [e-cigarettes]." J.A. 145. A cartridge-based e-cigarette is a type of device that holds e-liquid in a "small, enclosed unit," known as a "cartridge" or "pod." J.A. 143; see Pet. App. 14a (reproducing image of cartridge-based e-cigarettes).

FDA's prioritization of cartridge-based devices rested on data showing that "youth overwhelmingly prefer[red] cartridge-based [e-cigarette] products." J.A. 155. FDA observed that such products' "relatively small size" makes them "easy to conceal" and able to be "used discreetly." J.A. 156, 163. It also noted that such products have "intuitive and convenient features"; "there are no settings to change and very little assembly is required." J.A. 156-157. FDA explained that it would focus its limited enforcement resources on addressing the unlawful marketing of the types of flavored products that were most widely used by youth at that time. See J.A. 145-146.

b. The evidence on youth preferences for different types of devices evolved by the time FDA denied respondents' applications. Although FDA continued to recognize "variability in the popularity of device types among youth," it stated that, "across these different de-

vice types, the role of flavor is consistent." Pet. App. 191a, 246a, 299a.

In denying respondents' applications, FDA acknowledged that its 2020 Guidance had prioritized cartridge-based flavored e-cigarettes, "which were most appealing to youth at the time." Pet. App. 192a, 246a, 300a. But it explained that "the preference for device types and popularity of certain styles is likely fluid," and that the "marketplace" had "shift[ed]" after the issuance of the 2020 Guidance. *Ibid.* After FDA prioritized enforcement against cartridge-based flavored e-cigarettes, it observed "a ten-fold increase" in the use of "disposable flavored [e-cigarettes]." *Ibid.* That trend showed that "the removal of one flavored product option prompted youth to migrate to another [device] type that offered the desired flavor options, underscoring the fundamental role of flavor in driving appeal." *Id.* at 192a, 246a-247a, 300a. FDA, in short, did not arbitrarily change its position without explanation; it reasonably reacted (and explained its reaction) to new information.

2. FDA properly accorded individualized consideration to respondents' applications

The Fifth Circuit also stated that FDA had arbitrarily imposed an "across-the-board ban on *all* flavored products." Pet. App. 47a; see *id.* at 47a n.5 ("categorical ban"; "de facto ban on flavored e-cigarettes"). But FDA did no such thing. FDA's decision in this case, like its decisions on other applications for authorization to market flavored products, reflected "a careful, individualized review" of the evidence. *Gripum*, 47 F.4th at 560.

The Fifth Circuit did not (and could not plausibly) suggest that FDA's orders, on their face, imposed a categorical ban on flavored e-cigarettes. The orders explained why FDA determined, after reviewing the evi-

dence, that respondents had failed to prove that authorizing their flavored products would be appropriate for the protection of the public health. FDA evaluated the risks of flavored e-cigarettes, discussing the ways in which e-cigarettes can harm health, see Pet. App. 193a-196a, 247a-250a, 301a-304a, and the attractiveness of flavored products to youth, see *id.* at 187a-192a, 240a-247a, 295a-300a. It reasoned that, "as the known risks increase, so too does the burden of demonstrating a substantial enough benefit." *Id.* at 197a, 251a, 305a. "In order for marketing of a new flavored [e-cigarette] product to be found [appropriate for the protection of the public health], an applicant would have to show that the significant risk to youth could be overcome by likely benefits substantial enough such that the net impact to public health would be positive[.]" *Ibid.* FDA then reviewed the evidence that respondents submitted and found it "insufficient to demonstrate that these products would provide an added benefit that is adequate to outweigh the risks to youth." *Id.* at 168a, 228a, 280a. That individualized analysis belies any suggestion that FDA imposed an "across-the-board ban." *Id.* at 47a.

The Fifth Circuit effectively dismissed FDA's stated rationale as pretextual, concluding that, although FDA "pretended otherwise," it imposed a "de facto ban on flavored e-cigarettes." Pet. App. 47a & n.5. As a general rule, however, a court must accept an agency's "stated reasons for acting." *Department of Commerce*, 588 U.S. at 781. A court may question those stated reasons only upon a "strong showing of bad faith or improper behavior." *Ibid.* (citation omitted). No such showing has been made here.

The Fifth Circuit emphasized that FDA has denied applications for "over one million" flavored e-cigarette

products. Pet. App. 51a; see *id.* at 2a. But that statistic does not come close to showing that FDA has covertly adopted a "categorical ban" on flavored e-cigarettes. *Id.* at 47a n.5. To start, the "one million" figure conveys a misleading impression. A single applicant might seek authorization to market tens of thousands of products that come in different flavors, sizes, or varieties, yet rely on largely the same evidence for each product. In one news release, for example, FDA announced that it had denied "applications for about 55,000 flavored [e-cigarette] products" from just "three applicants." FDA, News Release, *FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing to Provide Evidence That They Appropriately Protect Public Health* 1 (Aug. 26, 2021).

Applications for different flavored products can also raise common issues. Many different applicants have sought authorization for products that have similar types of flavors (*e.g.*, fruit, dessert, or candy flavors) and that accordingly pose similar risks to youth. See, *e.g.*, *Magellan*, 70 F.4th at 625 ("fruit and dessert flavors"); *Liquid Labs*, 52 F.4th at 537 ("Berry Au Lait"); *Avail Vapor*, 55 F.4th at 417 ("fruit- and dessert-flavored"); *Gripum*, 47 F.4th at 555 ("candy, fruit, or baked goods"); *Lotus Vaping*, 73 F.4th at 665 ("cinnamon candy"); *Electric Clouds*, 94 F.4th at 955 ("Ice Cream Dream" and "Candy Man") (emphasis omitted); *Prohibition Juice*, 45 F.4th at 15 ("Blueberry Dream Cake" and "Sugar Rush Peach Ring Candy"). And different applicants have often provided similar evidence of their products' purported benefits. Here, for example, respondents participated "in a Coalition with other, similarly situated e-liquid companies" to fund the gathering of data. J.A. 303; see J.A. 401. FDA's actions re-

flect the consistent application of the Act, not the adoption of a "de facto ban." Pet. App. 47a n.5.

In all events, while the petition for a writ of certiorari was pending, FDA granted a different manufacturer, NJOY, authorization to market four menthol-flavored e-cigarette products. See p. 7, *supra*. As in this case, FDA explained that, because such flavored products posed a "known and substantial risk to youth," the applicant was required to submit "sufficiently reliable and robust evidence" of the products' benefits. FDA, *Technical Project Lead (TPL) Review of PMTAs* 35, 39 (June 21, 2024) (NJOY Review), https://www.fda.gov/media/179501/download. But FDA found that NJOY, unlike respondents here, had met that burden. See *id.* at 41-45. For example, NJOY had submitted data from a longitudinal study showing that its menthol-flavored products worked better than tobacco-flavored products at promoting "complete switching" from conventional cigarettes among adults. *Id.* at 40-41. FDA's decision to authorize those products refutes the conclusion that it has imposed an "across-the-board ban on *all* flavored products." Pet. App. 47a.

3. FDA has accorded consistent treatment to menthol and other flavors

Finally, the Fifth Circuit asserted that "FDA ha[d] approved menthol-flavored e-cigarette products notwithstanding its ban on 'flavored' products." Pet. App. 24a. The court stated that FDA arbitrarily failed "to explain why * * * it approved menthol products" and asked "how [FDA] could rationally approve menthol products while denying [respondents'] flavored products." *Id.* at 25a.

That rationale was so clearly wrong that respondents filed a motion asking the Fifth Circuit to modify its

opinion. See C.A. Doc. 362, at 6. As respondents explained, "FDA ha[d] *not* approved any [applications] for menthol-flavored [e-cigarette] products" as of the time of the en banc court's decision. See *ibid.*

Instead of correcting its mistake, the Fifth Circuit doubled down. The court denied respondents' motion, stating that, "[i]n April 2019, FDA authorized the marketing of a menthol-flavored IQOS heat-not-burn cigarette product." Pet. App. 332a (citation omitted). But that product is not an e-cigarette at all. Instead of heating an e-liquid, as e-cigarettes do, it heats "tobacco-filled sticks wrapped in paper." FDA, News Release, *FDA permits sale of IQOS Tobacco Heating System through premarket tobacco product application pathway* 1 (Apr. 30, 2019). And "[a]vailable data" indicated that "few non-tobacco users," "including youth," "would be likely to choose to start using" that product, *id.* at 2, which simulates the experience of smoking conventional cigarettes more closely than e-cigarettes do. The court said that it had "used the term 'e-cigarette products' as a catch-all term to refer to a wide array of products," Pet. App. 332a, but its choice of terminology does not change the reality that the menthol-flavored products that it mentioned differed meaningfully from the flavored e-cigarettes at issue here.

As discussed above, after the Fifth Circuit issued its decision, FDA did authorize four menthol-flavored e-cigarette products. See p. 7, *supra*. But FDA explained that its "approach to the [appropriate for the protection of the public health] analysis for menthol-flavored" e-cigarette products is "the same as for other non-tobacco-flavored" products. NJOY Review 36. FDA simply found that, in that particular instance, the applicant had provided sufficient evidence that its products'

benefits outweighed their risks. See *id.* at 45. It stated that "[y]outh use of menthol [products] is greater than tobacco flavor, but lower than other flavors such as candy, desserts, and sweets." *Id.* at 30. In denying respondents' applications, moreover, FDA explained that "the effectiveness of a product in promoting switching among smokers arises from a combination of its product features," including flavor as well as "nicotine concentration," "sensory and subjective experience (taste, throat hit, nicotine delivery)," and "how the device itself looks and feels." Pet. App. 258a-259a. FDA's subsequent authorization of four of NJOY's menthol-flavored products therefore does not show that other manufacturers' flavored products satisfy the statutory standard.

In sum, the Fifth Circuit's analysis is replete with factual and legal errors. As every other court of appeals to consider materially identical challenges has held, FDA has acted reasonably in denying applications for authorization to market flavored e-cigarettes.

CONCLUSION

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

Respectfully submitted.

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APPENDIX

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APPENDIX

1. 5 U.S.C. 706 provides:

Scope of review

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

2. 21 U.S.C. 387j provides:

Application for review of certain tobacco products

(a) In general

(1) New tobacco product defined

For purposes of this section the term "new tobacco product" means—

(A) any tobacco product (including those products in test markets) that was not commercially marketed in the United States as of February 15, 2007; or

(B) any modification (including a change in design, any component, any part, or any constituent, including a smoke constituent, or in the content, delivery or form of nicotine, or any other additive or ingredient) of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007.

(2) Premarket review required

(A) New products

An order under subsection (c)(1)(A)(i) for a new tobacco product is required unless—

(i) the manufacturer has submitted a report under section 387e(j) of this title; and

the Secretary has issued an order that the tobacco product—

(I) is substantially equivalent to a tobacco product commercially marketed (other than for test marketing) in the United States as of February 15, 2007; and

(II) is in compliance with the requirements of this chapter; or

(ii) the tobacco product is exempt from the requirements of section 387e(j) of this title pursuant to a regulation issued under section 387e(j)(3) of this title.

(B) Application to certain post-February 15, 2007, products

Subparagraph (A) shall not apply to a tobacco product—

(i) that was first introduced or delivered for introduction into interstate commerce for commercial distribution in the United States after February 15, 2007, and prior to the date that is 21 months after June 22, 2009; and

(ii) for which a report was submitted under section 387e(j) of this title within such 21-month period,

except that subparagraph (A) shall apply to the tobacco product if the Secretary issues an order that the tobacco product is not substantially equivalent.

(3) Substantially equivalent defined

(A) In general

In this section and section 387e(j) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to the tobacco product being compared to the predicate tobacco product, that the Secretary by order has found that the tobacco product—

(i) has the same characteristics as the predicate tobacco product; or

(ii) has different characteristics and the information submitted contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that it is not appropriate to regulate the product under this section because the product does not raise different questions of public health.

(B) Characteristics

In subparagraph (A), the term "characteristics" means the materials, ingredients, design, composition, heating source, or other features of a tobacco product.

(C) Limitation

A tobacco product may not be found to be substantially equivalent to a predicate tobacco product that has been removed from the market at the initiative of the Secretary or that has been determined by a judicial order to be misbranded or adulterated.

(4) Health information

(A) Summary

As part of a submission under section 387e(j) of this title respecting a tobacco product, the person required to file a premarket notification under such section shall provide an adequate summary of any health information related to the tobacco product or state that such information will be made available upon request by any person.

(B) Required information

Any summary under subparagraph (A) respecting a tobacco product shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such tobacco product is substantially equivalent to another tobacco product.

(b) Application

(1) Contents

An application under this section shall contain—

(A) full reports of all information, published or known to, or which should reasonably be known to, the applicant, concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products;

(B) a full statement of the components, ingredients, additives, and properties, and of the

principle or principles of operation, of such tobacco product;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such tobacco product;

(D) an identifying reference to any tobacco product standard under section 387g of this title which would be applicable to any aspect of such tobacco product, and either adequate information to show that such aspect of such tobacco product fully meets such tobacco product standard or adequate information to justify any deviation from such standard;

(E) such samples of such tobacco product and of components thereof as the Secretary may reasonably require;

(F) specimens of the labeling proposed to be used for such tobacco product; and

(G) such other information relevant to the subject matter of the application as the Secretary may require.

(2) Referral to Tobacco Products Scientific Advisory Committee

Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may, on the Secretary's own initiative; or

(B) may, upon the request of an applicant,

refer such application to the Tobacco Products Scientific Advisory Committee for reference and for sub-

mission (within such period as the Secretary may establish) of a report and recommendation respecting the application, together with all underlying data and the reasons or basis for the recommendation.

(c) Action on application

(1) Deadline

(A) In general

As promptly as possible, but in no event later than 180 days after the receipt of an application under subsection (b), the Secretary, after considering the report and recommendation submitted under subsection (b)(2), shall—

(i) issue an order that the new product may be introduced or delivered for introduction into interstate commerce if the Secretary finds that none of the grounds specified in paragraph (2) of this subsection applies; or

(ii) issue an order that the new product may not be introduced or delivered for introduction into interstate commerce if the Secretary finds (and sets forth the basis for such finding as part of or accompanying such denial) that 1 or more grounds for denial specified in paragraph (2) of this subsection apply.

(B) Restrictions on sale and distribution

An order under subparagraph (A)(i) may require that the sale and distribution of the tobacco product be restricted but only to the extent that the sale and distribution of a tobacco product may be restricted under a regulation under section 387f(d) of this title.

(2) Denial of application

The Secretary shall deny an application submitted under subsection (b) if, upon the basis of the information submitted to the Secretary as part of the application and any other information before the Secretary with respect to such tobacco product, the Secretary finds that—

(A) there is a lack of a showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health;

(B) the methods used in, or the facilities or controls used for, the manufacture, processing, or packing of such tobacco product do not conform to the requirements of section 387f(e) of this title;

(C) based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular; or

(D) such tobacco product is not shown to conform in all respects to a tobacco product standard in effect under section 387g of this title, and there is a lack of adequate information to justify the deviation from such standard.

(3) Denial information

Any denial of an application shall, insofar as the Secretary determines to be practicable, be accompanied by a statement informing the applicant of the measures required to remove such application from deniable form (which measures may include further research by the applicant in accordance with 1 or more protocols prescribed by the Secretary).

(4) Basis for finding

For purposes of this section, the finding as to whether the marketing of a tobacco product for which an application has been submitted is appropriate for the protection of the public health shall be determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product, and taking into account—

(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and

(B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.

(5) Basis for action

(A) Investigations

For purposes of paragraph (2)(A), whether permitting a tobacco product to be marketed would be appropriate for the protection of the public health shall, when appropriate, be determined on the basis of well-controlled investigations, which may include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product.

(B) Other evidence

If the Secretary determines that there exists valid scientific evidence (other than evidence derived from investigations described in subparagraph (A)) which is sufficient to evaluate the tobacco product, the Secretary may authorize that

the determination for purposes of paragraph (2)(A) be made on the basis of such evidence.

(d) Withdrawal and temporary suspension

(1) In general

The Secretary shall, upon obtaining, where appropriate, advice on scientific matters from the Tobacco Products Scientific Advisory Committee, and after due notice and opportunity for informal hearing for a tobacco product for which an order was issued under subsection (c)(1)(A)(i), issue an order withdrawing the order if the Secretary finds—

(A) that the continued marketing of such tobacco product no longer is appropriate for the protection of the public health;

(B) that the application contained or was accompanied by an untrue statement of a material fact;

(C) that the applicant—

(i) has failed to establish a system for maintaining records, or has repeatedly or deliberately failed to maintain records or to make reports, required by an applicable regulation under section 387i of this title;

(ii) has refused to permit access to, or copying or verification of, such records as required by section 374 of this title; or

(iii) has not complied with the requirements of section 387e of this title;

(D) on the basis of new information before the Secretary with respect to such tobacco prod-

uct, evaluated together with the evidence before the Secretary when the application was reviewed, that the methods used in, or the facilities and controls used for, the manufacture, processing, packing, or installation of such tobacco product do not conform with the requirements of section 387f(e) of this title and were not brought into conformity with such requirements within a reasonable time after receipt of written notice from the Secretary of nonconformity;

(E) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when the application was reviewed, that the labeling of such tobacco product, based on a fair evaluation of all material facts, is false or misleading in any particular and was not corrected within a reasonable time after receipt of written notice from the Secretary of such fact; or

(F) on the basis of new information before the Secretary, evaluated together with the evidence before the Secretary when such order was issued, that such tobacco product is not shown to conform in all respects to a tobacco product standard which is in effect under section 387g of this title, compliance with which was a condition to the issuance of an order relating to the application, and that there is a lack of adequate information to justify the deviation from such standard.

(2) Appeal

The holder of an application subject to an order issued under paragraph (1) withdrawing an order issued pursuant to subsection (c)(1)(A)(i) may, by petition filed on or before the 30th day after the date upon which such holder receives notice of such withdrawal, obtain review thereof in accordance with section 387*l* of this title.

(3) Temporary suspension

If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a tobacco product under an order would cause serious, adverse health consequences or death, that is greater than ordinarily caused by tobacco products on the market, the Secretary shall by order temporarily suspend the authority of the manufacturer to market the product. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

(e) Service of order

An order issued by the Secretary under this section shall be served—

(1) in person by any officer or employee of the department designated by the Secretary; or

(2) by mailing the order by registered mail or certified mail addressed to the applicant at the applicant's last known address in the records of the Secretary.

(f) Records

(1) Additional information

In the case of any tobacco product for which an order issued pursuant to subsection (c)(1)(A)(i) for an application filed under subsection (b) is in effect, the applicant shall establish and maintain such records, and make such reports to the Secretary, as the Secretary may by regulation, or by order with respect to such application, prescribe on the basis of a finding that such records and reports are necessary in order to enable the Secretary to determine, or facilitate a determination of, whether there is or may be grounds for withdrawing or temporarily suspending such order.

(2) Access to records

Each person required under this section to maintain records, and each person in charge of custody thereof, shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records.

(g) Investigational tobacco product exemption for investigational use

The Secretary may exempt tobacco products intended for investigational use from the provisions of this subchapter under such conditions as the Secretary may by regulation prescribe.

3. 21 U.S.C. 387*l* provides:

Judicial review

(a) Right to review

(1) In general

Not later than 30 days after—

(A) the promulgation of a regulation under section 387g of this title establishing, amending, or revoking a tobacco product standard; or

(B) a denial of an application under section 387j(c) of this title,

any person adversely affected by such regulation or denial may file a petition for judicial review of such regulation or denial with the United States Court of Appeals for the District of Columbia or for the circuit in which such person resides or has their principal place of business.

(2) Requirements

(A) Copy of petition

A copy of the petition filed under paragraph (1) shall be transmitted by the clerk of the court involved to the Secretary.

(B) Record of proceedings

On receipt of a petition under subparagraph (A), the Secretary shall file in the court in which such petition was filed—

(i) the record of the proceedings on which the regulation or order was based; and

(ii) a statement of the reasons for the issuance of such a regulation or order.

(C) Definition of record

In this section, the term "record" means—

(i) all notices and other matter published in the Federal Register with respect to the regulation or order reviewed;

(ii) all information submitted to the Secretary with respect to such regulation or order;

(iii) proceedings of any panel or advisory committee with respect to such regulation or order;

(iv) any hearing held with respect to such regulation or order; and

(v) any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

(b) Standard of review

Upon the filing of the petition under subsection (a) for judicial review of a regulation or order, the court shall have jurisdiction to review the regulation or order in accordance with chapter 7 of title 5 and to grant appropriate relief, including interim relief, as provided for in such chapter. A regulation or denial described in subsection (a) shall be reviewed in accordance with section 706(2)(A) of title 5.

(c) Finality of judgment

The judgment of the court affirming or setting aside, in whole or in part, any regulation or order shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28.

(d) Other remedies

The remedies provided for in this section shall be in addition to, and not in lieu of, any other remedies provided by law.

(e) Regulations and orders must recite basis in record

To facilitate judicial review, a regulation or order issued under section 387f, 387g, 387h, 387i, 387j, or 387p of this title shall contain a statement of the reasons for the issuance of such regulation or order in the record of the proceedings held in connection with its issuance.