Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

FOOD AND DRUG ADMINISTRATION *v.* WAGES AND WHITE LION INVESTMENTS, L. L. C., DBA TRITON DISTRIBUTION, ET AL.

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

No. 23–1038. Argued December 2, 2024—Decided April 2, 2025

This case concerns whether the Food and Drug Administration (FDA) lawfully denied respondents authorization to market certain electronic nicotine delivery system products—known as electronic cigarettes, e-cigarettes, or vapes. These products have rapidly gained popularity during the past 20 years, offering existing smokers a potentially safer alternative to traditional combustible cigarettes. But e-cigarettes carry their own health risks, and the panoply of available flavors—which include not only traditional cigarette flavors (like tobacco and menthol) but also fruit, candy, and dessert flavors—appeals to non-smokers, particularly younger Americans.

The FDA has long had the responsibility to determine whether manufacturers may market new drugs, but it was the passage of the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA) that first gave the FDA broad jurisdiction to regulate tobacco products. Although the Act barred the FDA from banning all regulated tobacco products outright, see 21 U. S. C. §387g(d)(3), it prohibited a manufacturer from marketing any "new tobacco product" without FDA authorization, see §387j(a)(2)(A). One pathway to authorization of a "new tobacco product" is the submission of a premarket tobacco product application. See §387j(c)(1)(A)(i). The TCA *requires* the FDA to deny such an application unless an applicant shows that its product "would be appropriate for the protection of the public health." §387j(c)(2)(A). To determine this, the FDA must consider, among other things, "the risks and benefits to the population as a whole" and "tak[e] into account" the likelihood that users of existing tobacco products will stop

using those products and that non-users will start using them. §387j(c)(4).

In 2016, in response to the surging youth demand for flavored products, the FDA deemed e-cigarettes "tobacco products." Given that most e-cigarette products were not marketed in the United States before February 15, 2007, the vast majority of these products qualified as "new tobacco product" under the TCA. Most manufacturers of e-cigarette products would thus need to comply with the TCA's premarket-authorization regime to sell their products. This made the continued sale of most e-cigarette products illegal absent authorization. So to give these manufacturers adequate time to submit premarket tobacco product applications, the FDA delayed enforcement for two to three years. See 81 Fed. Reg. 28977–28978. This permitted e-cigarette products to remain on the market while manufacturers filed their applications. A Federal District Court ultimately imposed a deadline of September 9, 2020, for applications.

In the lead up to the application deadline, the FDA issued numerous forms of guidance concerning premarket tobacco product applications that orbited around four central themes: (1) the types of scientific evidence that would be required; (2) the importance of cross-product comparisons and investigations; (3) the FDA's enforcement priorities with respect to device type; and (4) manufacturers' marketing plans, which were described as "specific restrictions on sale and distribution" meant to deter new smokers from taking up e-cigarette products. In 2019, the FDA proposed a rule related to the submission of premarket tobacco product applications, and the proposed rule distilled the four topics discussed in the predecisional guidance. See 84 Fed. Reg. 50566, 50580, 50581, 50585, 50603.

Respondents submitted applications seeking approval to market and sell flavored e-liquids for open-system e-cigarettes. The FDA denied respondents' applications, concluding they had not provided sufficient scientific evidence to demonstrate that the marketing of their products would be appropriate for the protection of public health. Specifically, the FDA held respondents had not provided evidence from a randomized controlled trial, longitudinal cohort study, or other "robust and reliable" evidence that their dessert-, candy-, and fruit-flavored products had benefits over tobacco-flavored products. Despite previously describing marketing plans as "critical," the FDA decided "for the sake of efficiency" not to evaluate respondents' marketing plans. To each denial order, the FDA appended a "Technical Project Lead (TPL) Review." See App. to Pet. for Cert. 177a, 285a. These lengthy documents, which canvass the scientific literature on youth e-cigarette use, reflect the FDA's evolving understanding of how flavor, regardless of e-cigarette device type, drives youth smoking initiation and nicotine addiction.

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Respondents petitioned for judicial review of the FDA's denial orders under the Administrative Procedure Act (APA). See §387*l*(b) (citing 5 U. S. C. §706(2)(A)). The Fifth Circuit, sitting en banc, granted respondents' petitions for review and remanded to the FDA. The en banc majority held that the FDA had acted arbitrarily and capriciously by applying application standards different from those articulated in its predecisional guidance documents regarding scientific evidence, cross-flavor comparisons, and device type. The court expressed particular concern about the FDA's failure to review marketing plans it previously deemed critical. It also rejected the FDA's argument that any errors were harmless.

Held:

1. As a preliminary matter, the Court declines to reach and thus expresses no view on respondents' argument that the FDA erred in evaluating respondents' applications under standards developed in adjudication rather than standards promulgated in notice-and-comment rulemaking. This complicated question sweeps beyond the question presented and lacks adequate briefing. P. 19.

2. The Fifth Circuit's conclusion that the FDA acted arbitrarily and capriciously in its adjudication of manufacturers' premarket tobacco product applications is vacated because the FDA's denial orders were sufficiently consistent with its predecisional guidance—as to scientific evidence, comparative efficacy, and device type—and thus did not run afoul of the change-in-position doctrine. Pp. 20–41.

(a) The Court analyzes the Fifth Circuit's conclusion that the FDA acted arbitrarily and capriciously under the change-in-position doctrine, which provides that "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change," "'display awareness that [they are] changing position,'" and consider "'serious reliance interests.'" *Encino Motorcars, LLC* v. *Navarro*, 579 U. S. 211, 221–222 (quoting *FCC* v. *Fox Television Stations, Inc.*, 556 U. S. 502, 515). This doctrine asks two questions: first, whether an agency changed existing policy, and second, whether the agency displayed awareness of the change and offered good reasons for the new policy. Pp. 20–25.

(b) The FDA's denial orders were sufficiently consistent with its predecisional guidance regarding scientific evidence. The TCA states that either "well-controlled investigations" or other "valid scientific evidence" if found "sufficient" may support a finding that a new tobacco product is "appropriate for the protection of the public health." §387j(c)(5)(A)–(B). The TCA thus left the FDA broad discretion to decide what sort of scientific evidence an applicant was required to submit. Across its various guidance documents, the FDA's main point was that manufacturers who failed to submit evidence based on "well-con-

trolled investigations" would need to provide rigorous scientific evidence that the sale of their particular products would be appropriate for the protection of the public health. The applicants did not submit randomized controlled trials or longitudinal cohort studies, so the fate of their applications turned on whether they submitted "other evidence" that met the FDA's standard of scientific rigor and relevance to their product. The FDA rejected respondents' applications because that test was not met. As evidence of a change in position, respondents point to the FDA's July 9, 2021, internal memorandum, which stated that the failure to submit evidence from a randomized controlled trial or longitudinal cohort study would constitute a "fatal flaw" that would "likely" result in denial of an application. But the FDA issued a superseding memorandum, which recognized that "other evidence" may demonstrate a product is "appropriate for the protection of the public health," and the FDA represents that it did not rely on the July 9, 2021, internal memorandum when adjudicating applications—a representation afforded a presumption of regularity. Pp. 25–32.

(c) The FDA's comparative-efficacy requirement was not inconsistent with its predecisional guidance. The TCA expressly contemplates comparisons of different tobacco products, and the FDA's guidance elaborated on the types of comparisons that would be helpful. The FDA's 2019 guidance recommended that a manufacturer "compare the health risks of its product to both products within the same category and subcategory, as well as products in different categories as appropriate," and its 2020 enforcement guidance telegraphed the FDA's view that dessert-, candy-, and fruit-flavored products were more likely than tobacco- and menthol-flavored products to appeal to the young. Thus, when the FDA denied respondents' applications for failing to demonstrate the benefit of their flavored products over tobacco-flavored products, it was following a natural consequence of its predecisional guidance. Pp. 32–37.

(d) The FDA's treatment of device type did not violate the change-in-position doctrine. The FDA's 2020 guidance did not establish a "safe harbor" for non-cartridge-based products. Although the 2020 guidance emphasized the FDA would prioritize enforcement against cartridge-based products, it stated the FDA would also prioritize enforcement against manufacturers "whose [products'] marketing is likely to promote use by . . . minors." That latter category seemingly covers respondents' products. Even if the FDA had changed its position in this respect, it offered "good reasons," namely, evidence showing that youth demand had moved from flavored *cartridge-based* products to flavored *disposable* products. *Fox Television,* 556 U. S., at 515. From that evidence, the FDA drew the reasonable inference that youth were most strongly drawn by flavor rather than device type. Pp. 37–41.

3. The Fifth Circuit relied on an overly broad reading of *Calcutt* v.

FDIC, 598 U. S. 623 (*per curiam*), to reject the FDA's claim of harmless error regarding the agency's change of position on marketing plans.

The FDA does not contest that despite assuring manufacturers that marketing plans would be "critical" to their applications, the FDA ultimately did not consider respondents' marketing plans. The FDA argued below that any error in this respect was harmless error because it issued denial orders to other manufacturers after reviewing marketing plans that were materially indistinguishable from respondents'. The Fifth Circuit rejected the FDA's harmless-error argument, relying on this Court's decision in *Calcutt* for the proposition 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." 90 F. 4th 357, 390.

The Court agrees with the FDA that the Fifth Circuit read *Calcutt* too broadly. That said, the proper standard presents a difficult problem, requiring reconciliation of the so-called remand rule developed in *SEC* v. *Chenery Corp.*, 318 U. S. 80, 88, 93–95, with the APA's instruction that reviewing courts must take "'due account'" of "'the rule of prejudicial error'" that "ordinarily appl[ies] in civil cases," *Shinseki* v. *Sanders*, 556 U. S. 396, 406 (quoting 5 U. S. C. §706). The most natural interpretation of the APA's language is that reviewing courts should adapt the "rule of prejudicial error" applicable in ordinary civil litigation (also known as the harmless-error rule) to the administrative-law context, which, of course, includes the remand rule. In *Calcutt*, after reciting the remand rule in strong terms, the Court acknowledged that a "remand may be unwarranted . . . [w]here the agency 'was *required*' to take a particular action." 598 U. S., at 630 (quoting *Morgan Stanley Capital Group Inc.* v. *Public Util. Dist. No. 1 of Snohomish Cty.*, 554 U. S. 527, 544). Although the Fifth Circuit interpreted *Calcutt*'s discussion to mean that there is only one exception to the remand rule, it has long been accepted that a remand may not be necessary when an agency's decision is supported by a plethora of factual findings, only one of which is unsound, because a remand would be pointless. See, *e.g., Massachusetts Trustees of Eastern Gas & Fuel Associates* v. *United States*, 377 U. S. 235, 248. The existence of this exception is sufficient to show that the Fifth Circuit's reading of *Calcutt* went too far. That said, the FDA's reading of *Sanders* may also be excessive. The FDA has not asked the Court to decide the harmless-error question at this juncture, and the Court vacates and remands so the Fifth Circuit can decide the question afresh without relying on its overly expansive reading of *Calcutt*. Pp. 41–46.

90 F. 4th 357, vacated and remanded.

ALITO, J., delivered the opinion for a unanimous Court. SOTOMAYOR, J., filed a concurring opinion.

SUPREME COURT OF THE UNITED STATES

No. 23–1038

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

[April 2, 2025]

JUSTICE ALITO delivered the opinion of the Court.

This case concerns the efforts of the Food and Drug Administration (FDA) to regulate the sale of "e-cigarettes," a product that rapidly gained popularity during the past 20 years. The governing federal law, the Family Smoking Prevention and Tobacco Control Act of 2009 (TCA), restricts the sale of all "tobacco products" that were not commercially marketed in the United States before February 15, 2007. Unless otherwise authorized, a manufacturer may not introduce such a product to the market until the FDA determines that it is "appropriate for the protection of the public health." 21 U. S. C. §387j(c)(2)(A). In this case, we consider whether the FDA lawfully denied authorization to market certain flavored e-cigarette products.

I

One of the FDA's longstanding responsibilities, dating back nearly a century, is to determine whether manufacturers may market new drugs. For much of that history, the FDA lacked jurisdiction to regulate tobacco products. By the time Congress conferred that authority in 2009, a new

product was ascendant on the market: the e-cigarette. This product offers existing smokers a potentially safer alternative to traditional combustible cigarettes. But e-cigarettes carry their own health risks, and they come in a dizzying array of flavors, many of which, such as dessert, candy, and fruit flavors, are particularly appealing to the young. The surging youth demand for flavored products—and the prospect of a new generation of smokers—caught the FDA on its back foot. In 2016, the agency declared that manufacturers of e-cigarette products would need to obtain the same marketing authorization that is required for other "tobacco products." The FDA's regulatory efforts culminated in the 2021 denial of over a million applications for flavored e-cigarette products. The dispute before us arises from that mass denial.

A

The Pure Food and Drug Act of 1906 was Congress's first foray into the comprehensive regulation of food and drugs. The Act prohibited the interstate transportation of "any article of food or drugs which is adulterated or misbranded." Ch. 3915, §2, 34 Stat. 768. That Act also vested important responsibility in the precursor to the FDA, the Bureau of Chemistry in the U. S. Department of Agriculture. §4, *id.*, at 769. But early in its tenure, the Bureau disclaimed any authority to regulate tobacco products "labeled in such a manner as to indicate their use for" nonmedicinal purposes like "smoking or chewing or as snuff." Dept. of Agriculture, Bureau of Chemistry, 13 Service and Regulatory Announcements 24 (Apr. 1914) (Feb. 1914 Announcements ¶13, Opinion of Chief of Bureau C. Alsberg). Congress later renamed the Bureau of Chemistry, first as the Food, Drug and Insecticide Administration and then as the FDA, the name by which we know it today. A Historical Guide to the U. S. Government 249 (G. Kurian ed. 1998).

In 1938, Congress enacted the Federal Food, Drug, and

Cosmetic Act (FDCA), which vastly expanded the FDA's regulatory authority over "drugs and devices." 52 Stat. 1049. One of the FDCA's major innovations was the establishment of a system for premarket authorization under which manufacturers are prohibited from marketing "any new drug" in interstate commerce without the FDA's approval. §§505(a)–(b), (d), *id.*, at 1052; Historical Guide, at 251. To receive such authorization, manufacturers must prove to the FDA that their new products are safe for use. And if the FDA has "insufficient information" to make that determination, it must "issue an order refusing" marketing authorization. §505(d), 52 Stat. 1052.

By the middle of the 20th century, nearly one in two Americans regularly smoked. See R. Rabin, A Sociolegal History of the Tobacco Tort Litigation, 44 Stan. L. Rev. 853, 855 (1992). Toward the latter half of the century, however, the public became increasingly aware of the "great" "potential hazard" of tobacco, Dept. of Health, Education, and Welfare, Surgeon General's Advisory Committee, Smoking and Health 25 (1964), and the addictive properties of nicotine, see L. Goitein, G. Chernack, G. Liu, & M. Davis, Developments in Policy: The FDA's Tobacco Regulations, 15 Yale L. & Pol'y Rev. 399, 402 (1996).

The FDCA was enacted long before public awareness of the dangers of smoking became widespread, and neither its text nor its legislative history provided any indication that tobacco products fell within the FDA's jurisdiction. See A. Boeckman, An Exercise in Administrative Creativity: The FDA's Assertion of Jurisdiction Over Tobacco, 45 Cath. U. L. Rev. 991, 1015 (1996). Thus, during the first 60 years after the FDCA's enactment, the FDA (like the Chemistry Bureau) repeatedly stated that it "lacked authority under the FDCA to regulate tobacco absent claims of therapeutic benefit by the manufacturer." *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U. S. 120, 144 (2000); see R. Kluger, Ashes to Ashes: America's Hundred-Year Cigarette War,

the Public Health, and the Unabashed Triumph of Philip Morris 757–759 (1997) (Kluger).

Tobacco regulation was largely left to Congress, which enacted various statutes between 1965 and the turn of the century to address the harms of tobacco use, including the imposition of warning requirements (15 U. S. C. §§1331, 1333, 4402(a)(1) (2000 ed.)); restrictions on the advertisement of certain tobacco products (15 U. S. C. §§1335, 4402(a)(2), (f) (2000 ed.)); requirements that the Secretary of Health and Human Services report on scientific findings about, among other things, "the addictive property of tobacco" (42 U. S. C. §290aa–2(b)(2) (1994 ed.)); and age restrictions on the sale or distribution of tobacco products (42 U. S. C. §300x–26(a)(1) (2000 ed.)). See *Brown & Williamson Tobacco Corp.*, 529 U. S., at 137–139, 143–144. At no point during that period did Congress grant the FDA jurisdiction to regulate tobacco or tobacco products under the FDCA. And when the FDA tried via regulation to assert such jurisdiction in 1996, see 61 Fed. Reg. 44619–45318 (1996), this Court rejected that effort as beyond the FDA's statutory authority, see *Brown & Williamson Tobacco Corp.*, 529 U. S., at 126.

Against that backdrop, Congress enacted the Family Smoking Prevention and Tobacco Control Act of 2009, 123 Stat. 1776. The TCA vests the Secretary of Health and Human Services, acting through the FDA, with the authority that this Court previously found lacking: namely, the power to regulate the manufacturing, marketing, sale, and distribution of tobacco products. See §901, *id.*, at 1786. The TCA explicitly granted the FDA regulatory authority over "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco." 21 U. S. C. §387a(b). It also granted authority to regulate "any other tobacco products" that the FDA "by regulation deems" to meet the definition of a tobacco product. *Ibid.*

The TCA's reach was broad. While the Act barred the

FDA from banning all regulated tobacco products outright or requiring manufacturers to reduce nicotine yields to zero, see §387g(d)(3), it prohibited a manufacturer from marketing any "new tobacco product" without FDA authorization, see §387j(a)(2)(A). A "new tobacco product" is one that was not marketed in the United States before February 15, 2007, and the TCA subjected such products to a premarket authorization process. See §§387j(a)(1)(A), (a)(2).

One pathway to authorization of the sale of a new tobacco product is the submission of a premarket tobacco product application.[1] §387j(c)(1)(A)(i). These applications require, among other things, information about a product's components and additives, the method by which it is manufactured, any proposed labeling, and an assessment of its health risks. See §387j(b)(1). There are many reasons why the FDA may deny marketing authorization to a "new tobacco product," but of main importance here, the agency *must* deny an application unless it is shown that the product "would be appropriate for the protection of the public health." §387j(c)(2)(A).

To determine whether a product meets this standard, the FDA must consider "the risks and benefits to the population as a whole" and "tak[e] into account" the "increased or decreased likelihood" of two outcomes: first, that the new product will induce users of existing tobacco products such as conventional cigarettes to stop using those products and,

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[1]The TCA establishes a handful of other authorization pathways for new tobacco products. For example, manufacturers may ask the FDA to make a determination that a new tobacco product is substantially equivalent to a product commercially marketed as of February 15, 2007. See 21 U. S. C. §§387j(a)(2)–(3). And a showing of substantial equivalence may be unnecessary for new tobacco products that make only minor modifications to products commercially marketed as of February 15, 2007. See §387e(j)(3)(A). Moreover, manufacturers may seek authorization for "modified risk tobacco products," that is, products used "to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products." §§387k(b)(1), (g)(1).

second, that "those who do not use tobacco products will start using" them. §387j(c)(4). The FDA's determination regarding the likely effects of a new product must, "when appropriate," be based on "well-controlled investigations" or other "valid scientific evidence" that is "sufficient to evaluate the tobacco product." §387j(c)(5).

The FDA must act "[a]s promptly as possible" on a premarket tobacco product application and "in no event later than 180 days after the receipt of an application." §387j(c)(1)(A). If the FDA denies an application for premarket authorization, "any person adversely affected" by the denial has 30 days to seek judicial review in a court of appeals. §387*l*(a)(1). The reviewing courts must in turn apply the provisions of the Administrative Procedure Act (APA). §387*l*(b) (citing 5 U. S. C. §706(2)(A)).

B

At the end of the 20th century, tobacco manufacturers tried without much luck to market safer alternatives to traditional cigarettes, such as "smokeless" cigarettes. See Kluger 599–604; Dept. of Health & Human Servs., E-Cigarette Use Among Youth and Young Adults: A Report of the Surgeon General 9 (2016) (2016 Surgeon General's Report). But in 2007 a new product hit the American market: electronic nicotine delivery systems, which are popularly known as electronic cigarettes, e-cigarettes, or vapes. See *id.*, at 10; K. Lichtenberg, E-Cigarettes: Current Evidence and Policy, 114 Mo. Med. 335 (2017). Practically overnight, e-cigarettes became ubiquitous. Sales for e-cigarette products "surged exponentially" after 2010, 2016 Surgeon General's Report 152, and according to one estimate, 11.2 million American adults used e-cigarettes by 2016, see O. Obisesan et al., Trends in E-Cigarette Use in Adults in the United States, 2016–2018, 180 JAMA Internal Med. 1394 (2020).

The impetus for the invention of e-cigarettes was the desire to create a product that would reduce the health risks of smoking. A traditional combustible cigarette contains shredded tobacco wrapped in paper, and when lit, the tobacco "catches fire" and "produces smoke, which contains nicotine" and "tar"—a "complex chemical mixture of more than 7,000 compounds that cause a wide range of diseases." Brief for Global Action To End Smoking, Inc., as *Amicus Curiae* 14 (internal quotation marks omitted). In contrast, an e-cigarette contains a battery, a heating element or atomizer, a liquid nicotine reservoir, and a mouthpiece. See 2016 Surgeon General's Report 11. When an e-cigarette user inhales through the device's mouthpiece, the heating coil engages, and the liquid (called e-liquid or e-juice) turns into a nicotine-infused vapor. See *ibid.* Unlike a traditional cigarette, an e-cigarette does not release tar or other "by-products of combustion," but it does "emit potentially toxic substances," including "fine particulate matter," "metals," and, of course, nicotine. Brief for Global Action To End Smoking, Inc., as *Amicus Curiae* 15–16 (internal quotation marks omitted).

E-cigarettes typically come in either a "closed" or "open" system. See 2016 Surgeon General's Report 151–152. Closed-system e-cigarettes contain a set amount of e-liquid that is determined by the manufacturer. Some closed-system products are designed to be discarded after the e-liquid supply runs out, while others can be reused by inserting a cartridge or pod that contains e-liquid. By contrast, an open-system e-cigarette contains a "tank" that users can manually refill with the desired amount of e-liquid. Users of open-system products may mix their own e-liquids and adjust the amount of e-liquid in the tank.

There is fierce public debate about the potential benefits and harms of e-cigarettes. On one hand, many view e-cigarettes as a harm-reduction tool. They enable current smokers who are addicted to nicotine to reduce exposure to

some of the more harmful byproducts of traditional combustible cigarettes. See *id.*, at 10–11; National Academies of Sciences, Engineering, and Medicine, Committee on the Review of the Health Effects of Electronic Nicotine Delivery Systems, Public Health Consequences of E-Cigarettes 18 (2018). On the other hand, e-cigarettes, as noted, pose their own health risks, and there is concern that the use of e-cigarettes by non-smokers—and especially young non-smokers—may eventually lead them to smoke conventional cigarettes. See *id.*, at 532–535.

Early on, evidence began to mount that young Americans are particularly drawn to e-cigarette products. By the mid-2010s, approximately 2.4 million high-school students and 620,000 middle-school students reported using an e-cigarette at least once in the last 30 days. 2016 Surgeon General's Report 5, 10. And a more recent estimate suggests that approximately 3.6 million American middle- and high-school students used an e-cigarette within a 30-day period. See Congressional Research Service, H. Sheikh & V. Green, FDA Regulation of Tobacco Products 1 (2021).

One particular feature of e-cigarette products appears to drive this youth demand: the panoply of e-liquid flavors. One nearly decade-old estimate found that there were 7,700 unique e-liquid flavors, including not only flavors that were familiar to cigarette smokers (tobacco and menthol) but also fruit, candy, and dessert flavors that were appealing to non-smokers. See 2016 Surgeon General's Report 11. The kaleidoscope of flavor options adds to the allure of e-cigarettes and has thus contributed to the booming demand for such products among young Americans. See *ibid.*

Because the popularity of e-cigarettes is a relatively recent phenomenon, these products initially escaped the FDA's regulatory reach. But in 2016, the FDA issued a rule deeming e-cigarettes and e-liquids to be "tobacco products." 81 Fed. Reg. 29028 (2016). Since most e-cigarette products were "not commercially marketed in the United States as of

February 15, 2007," the deeming rule retroactively rendered such products "new tobacco products" subject to the TCA's premarket-authorization regime. 21 U. S. C. §387j(a)(1)(A). And because those products had not received premarket authorization, the effect of the rule was to make their continued sale illegal. Companies that proceeded to sell their products without such authorization would be subject to stiff penalties. See §§331(a), 333(a)(1), and (f)(9).

To give these manufacturers adequate time to apply for "premarket" authorization, the FDA delayed enforcement for two to three years. See 81 Fed. Reg. 28977–28978. This permitted e-cigarette products to remain on the market while manufacturers filed their applications. Initially, applications were due by August 8, 2018. See *Vapor Tech. Assn.* v. *FDA*, 977 F. 3d 496, 498 (CA6 2020) (citing 81 Fed. Reg. 29010–29011). The FDA later tried via guidance to extend the compliance deadline through 2022, but a Federal District Court ultimately imposed a deadline of September 9, 2020, adding to the time crunch for compliance. See *American Academy of Pediatrics* v. *FDA*, 399 F. Supp. 3d 479, 487 (Md. 2019) (imposing a May 12, 2020, deadline); Order in *American Academy of Pediatrics* v. *FDA*, No. 18–cv–883 (D Md., Apr. 22, 2020), ECF Doc. 182, p. 1 (extending the deadline to September 9, 2020, due to the COVID–19 pandemic); see also *Vapor Tech. Assn.*, 977 F. 3d, at 498–500 (detailing the shifting compliance deadline).

C

At the center of this case are the FDA's actions leading up to its adjudication of manufacturers' premarket tobacco product applications. The agency proposed a rule outlining application requirements, issued guidance to assist e-cigarette manufacturers, and crafted internal memoranda discussing how applications were to be reviewed. These voluminous and discursive documents paint a picture of an

agency that was feeling its way toward a final stance and was unable or unwilling to say in clear and specific terms precisely what applicants would have to provide. Pervading these documents are four overarching topics that animate the dispute before us.

1

The first topic was the types of scientific evidence needed to show that an e-cigarette product is "appropriate for the protection of the public health." §387j(c)(2)(A). Recall that the TCA states that "well-controlled investigations" may support such a showing "when appropriate," §387j(c)(5)(A), as can "other 'valid scientific evidence' if found sufficient to evaluate the tobacco product," App. 28 (quoting §387j(c)(5)(B)). At an October 23, 2018, public meeting, an FDA official opined that "[i]n most situations," the FDA would expect "some analytical testing specific to [a manufacturer's] product." FDA/Center for Tobacco Products, Tobacco Product Application Review, A Public Meeting October 22–23, 2018—Day 2, Sess. 7, Part 2, at 2:12:35–2:12:43, https://www.fda.gov/tobacco-products/ctp-newsroom/tobacco-product-application-review-public-meeting#Video2 (2018 Presentation Video). But the FDA also assured manufacturers that no "specific studies," "[y]outh behavioral data," or "new nonclinical or clinical studies" would be required. FDA, Premarket Tobacco Product Application Content Overview 18, 26 (Oct. 23, 2018), https://www.fda.gov/media/117507/download (2018 Presentation). The FDA said much the same thing in a lengthy 2019 guidance document, noting that the "relatively new entrance" of e-cigarette products meant that "limited data may exist from scientific studies and analyses." App. 28. So, according to this document, the FDA would not require "long-term studies," and manufacturers could instead rely on various alternatives, like observational studies, literature reviews, or evidence bridging their new tobacco product to "a studied

tobacco product." *Id.*, at 28, 99–105.

After manufacturers submitted millions of applications for flavored e-cigarette products, the FDA "develop[ed] a new plan to effectively manage" the scientific evidence underlying the onslaught of applications. *Id.*, at 242. In a July 9, 2021, internal memorandum, the FDA took a far less capacious view of the scientific evidence it would consider. Specifically, the FDA said that it would consider it a "fatal flaw" if an application lacked scientific evidence about a product based on either a randomized controlled trial or a longitudinal cohort study. *Id.*, at 243. A "fatal flaw" would lead to a manufacturer's "likely receiv[ing] a marketing denial order" for that product. *Ibid.*

Over a month later on August 17, 2021, the FDA issued another internal memorandum that differed in some respects from the July memorandum. It stated that, in addition to randomized controlled trials and longitudinal cohort studies, the FDA "would also consider evidence from another study design, provided that it could reliably and robustly assess behavior change" and "compar[e] users of flavored products with those of tobacco-flavored products." *Id.*, at 247, n. ix. Then, on August 25, 2021, just before denying respondents' applications, the FDA rescinded the August 17, 2021, memorandum and stated it would "not consider or rely" on it when evaluating premarket tobacco product applications. *Id.*, at 282.

2

The second topic was the need for manufacturers to compare their proposed products to other products. The TCA requires premarket tobacco product applications to provide "full reports of all information . . . concerning investigations which have been made to show" that a new product "presents less risk than other tobacco products." 21 U. S. C. §387j(b)(1)(A). Elaborating on that standard at a presenta-

tion on October 23, 2018, an FDA official encouraged applicants to provide comparisons between their products and a "representative sample of tobacco products on the market." 2018 Presentation 11. And a 2019 guidance document similarly recommended comparisons of "the health risks of [a manufacturer's] product to both products within the same category and subcategory, as well as products in different categories as appropriate." App. 30. The 2019 guidance also gave manufacturers discretion to choose comparator products as long as the FDA could "understand [an] applicant's rationale and justification for [the] comparators chosen." *Ibid.* Later that year at a public meeting, an FDA official offered the same general advice that a successful premarket tobacco product application "may include comparisons to other tobacco products in the same category or in other categories or subcategories." FDA/CTP, Deemed Tobacco Product Applications, Video Presentation of Premarket Tobacco Product Applications (PMTAs) Review Process and Resources (Oct. 28, 2019), at 31:10–31:16, https://collaboration.fda.gov/ptf21jryjxyk/?OWASP_CSRFTOKEN=7a8d148ac776ca8f3aec38aff7dee12ea4988c1caed05010cded06ab7496714f.

3

In a lengthy April 2020 guidance document,[2] the FDA elaborated on a third theme: its enforcement priorities based on device type. The agency said it would "prioritize enforcement of flavored, cartridge-based" e-cigarette products "other than tobacco- and menthol-flavored products." App. 160. It claimed that "youth overwhelmingly prefer

[2]The Fifth Circuit suggested that the FDA's 2020 guidance does not apply here because respondents manufacture "bottles of flavored nicotine *liquids*," not e-cigarette products themselves. 90 F. 4th 357, 369 (2024) (en banc). But the 2020 guidance concerned the FDA's enforcement priorities with respect to "[e]lectronic nicotine delivery systems" or "ENDS," and, as the guidance document explains, "[e]-liquids are a type of ENDS product." App. 143 (emphasis deleted).

cartridge-based" products, which are "easy to conceal, can be used discreetly, may have a high nicotine content, and are manufactured on a large scale." *Id.*, at 163. And the document asserted that certain flavors, such as candy and fruit flavors, "are a strong driver for youth use." *Id.*, at 164; see also *id.*, at 190 (discussing the increased use of "fruit- and candy-flavored" products). Although the FDA suggested that its focus on flavored, cartridge-based products "should have minimal impact on small manufacturers (*e.g.*, vape shops) that primarily sell non-cartridge-based" products, it noted that it would also prioritize enforcement against "[a]ll other [e-cigarette] products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access," as well as "[a]ny [e-cigarette] product that is targeted to minors or whose marketing is likely to promote use of [e-cigarettes] by minors." *Id.*, at 160–161.

4

The final theme cutting across these documents is the FDA's unflinching advice that manufacturers should submit "marketing plans" as part of their applications. "Marketing plans" broadly refer to a manufacturer's "specific restrictions on sale and distribution" that could, for example, "decreas[e] the likelihood that those who do not use tobacco products will start using tobacco products." *Id.*, at 27. In its 2019 guidance, the FDA urged manufacturers to "shar[e]" their "marketing plan[s] to enable FDA to better understand the potential consumer demographic" of their products. *Id.*, at 83. The 2020 enforcement guidance hit the same note, suggesting the FDA "intend[ed] to consider" marketing plans and that such plans would be relevant to the agency's enforcement "prioritization." *Id.*, at 167, 169. The FDA even offered examples of what marketing restrictions manufacturers might consider, including screening retailers, age-verification technology, mystery-shopper

programs, controls over distributors, and quantity limits. *Id.*, at 167–169, 223. It also cautioned that, based on its experience, "focusing on how the product was sold" and "age verification" "would not be sufficient to address youth use." *Id.*, at 215, 220–221.

D

In 2019, the FDA proposed a rule setting out the requirements for premarket tobacco product applications. See 84 Fed. Reg. 50566 (2019). That proposed rule, in significant part, crystallized the four themes discussed above. It offered specifics on the "types of [scientific] investigations" that applications "would be required to contain." *Id.*, at 50603; see, *e.g.*, *ibid.* (listing "[c]ross sectional and longitudinal surveys," "epidemiologic studies," and "analytic studies" like "randomized controlled clinical trials, cohort studies, and case control studies"); *id.*, at 50599 (proposing "health risk investigations" besides new clinical studies). The proposed rule also required certain cross-product comparisons. See *id.*, at 50603 (requiring that applicants "submit investigations that have been made to show whether the tobacco product has the same or different potential health risks . . . than other tobacco products"). And it underscored the importance of device type with respect to product testing. See *id.*, at 50585 (proposing requirements for constituent testing specific to open-system products). In addition, the proposed rule obligated manufacturers to submit marketing plans, which were described as "provid[ing] input that is critical" to the agency's review. *Id.*, at 50580, 50581.

Notice-and-comment rulemaking takes time, and with a court-imposed deadline fast approaching, the FDA proceeded to adjudicate the first major wave of premarket tobacco product applications in August and September 2021 without a final rule and the standards it included. It was not until October 5, 2021, that the FDA adopted the final

rule. See 86 Fed. Reg. 55300 (2021).

1

Respondents Wages and White Lion Investments, LLC, doing business as Triton Distribution, and Vapetasia, LLC, manufacture flavored e-liquids for open-system e-cigarettes. Their e-liquid flavor offerings include "Killer Kustard Blueberry," "Rainbow Road," "Iced Blackberry Lemonade," "Pineapple Express," "Suicide Bunny Mother's Milk and Cookies," and "Blueberry Parfait." See App 396, 546, 587, 593, 605, 608.

Respondents submitted premarket tobacco product applications on September 9, 2020, the final court-ordered deadline. As the FDA recommended in its guidance, their applications included marketing plans, which touted respondents' use of third-party age-verification technology, quantity limits, and requirements for retailers to develop compliance checks. See *id.*, at 431–436, 441. To show the safety of their products, respondents "pool[ed] resources" with "other, similarly situated e-liquid companies" to "fund the development of certain, required non-product specific data," including what they characterized as a "comprehensive review of the scientific literature." *Id.*, at 311. One of the respondents, Vapetasia, also submitted the results of a cross-sectional survey of current and former adult e-cigarette smokers. See App. to Pet. for Cert. 280a.

The FDA received applications from more than 500 companies in total, covering more than 6.5 million e-cigarette products. See FDA Denies Marketing Applications for About 55,000 Flavored E-Cigarette Products for Failing To Provide Evidence They Appropriately Protect Public Health (Aug. 26, 2021), https://fda.gov/news-events/press-announcements/fda-denies-marketing-applications-about-55000-flavored-e-cigarette-products-failing-provide-evidence. Almost a year after the court-ordered deadline, the FDA ad-

judicated its first slate of premarket tobacco product applications and issued marketing denial orders to three manufacturers whose applications covered 55,000 flavored e-cigarette products. See *ibid.* The FDA concluded that the manufacturers failed to provide "sufficient product-specific scientific evidence to demonstrate enough of a benefit to adult smokers that would overcome the risk posed to youth." *Ibid.* Such "scientific evidence," the agency said, "would likely be in the form of a randomized controlled trial or longitudinal cohort study," but the FDA promised that it remained open to "other types of evidence" that are "sufficiently robust and reliable." *Ibid.*

Shortly thereafter, the FDA denied respondents' applications. See App. to Pet. for Cert. 166a, 278a. It concluded that respondents had not provided sufficient scientific evidence to demonstrate that the marketing of their products would be appropriate for the protection of public health. See *id.*, at 166a–167a. Specifically, the FDA held respondents had not provided evidence from a randomized controlled trial, longitudinal cohort study, or another "reliabl[e] and robus[t]" method showing that their dessert-, candy-, and fruit-flavored products had benefits "over an appropriate comparator tobacco-flavored" product. *Id.*, at 167a. With such evidence lacking, the FDA deemed respondents' products "misbranded" and "adulterated" under the FDCA. *Id.*, at 168a.

To each denial order, the FDA appended a "Technical Project Lead (TPL) Review." See *id.*, at 177a, 285a. These lengthy documents have several noteworthy features. To start, they offer a window into the FDA's evolving understanding of how flavor, regardless of e-cigarette device type, drives youth smoking initiation and nicotine addiction. The reviews canvass the scientific literature on youth e-cigarette use and explain that this literature had led the agency to conclude that flavors make e-cigarette smoking "more pal-

atable for novice youth and young adults" and may "increase nicotine exposure by potentially influencing the rate of nicotine absorption." *Id.*, at 190a, 298a. What is more, the FDA stated, young people are drawn to particular flavors, and the FDA anticipated that its crackdown on one type of e-cigarette device would lead youth to flock to a different type of device to continue using a desired flavor. See *id.*, at 192a, 300a.

Despite the FDA's prior representations about the importance of marketing plans, the reviews stated that, "for the sake of efficiency," the FDA had decided not to evaluate respondents' marketing plans. *Id.*, at 200a–201a, n. xix, 308a–309a, n. xix. The FDA acknowledged that it "is theoretically possible that significant mitigation efforts" could decrease the appeal of flavored e-cigarettes to a sufficient degree to counterbalance the documented risks of such products, but it found that none of the marketing plans the FDA had seen had managed to do that. *Ibid.*

The FDA estimates that in its first wave of marketing orders, it issued denials to 320 applicants, who sought approval for approximately 1.2 million products. See Tr. of Oral Arg. 33.

2

Respondents petitioned for review in the Fifth Circuit. A motions panel initially granted a stay of their marketing denial orders pending review, see 16 F. 4th 1130, 1134 (2021), but a divided merits panel ultimately denied the petitions, see 41 F. 4th 427, 430 (2022).

The court then reheard the case en banc, granted respondents' petitions for review, and remanded to the FDA. The en banc majority held that the FDA had acted arbitrarily and capriciously in denying respondents' applications. In its view, the FDA performed a surprise switch from the requirements articulated in the various predecisional docu-

ments. 90 F. 4th 357, 362 (2024). The court pointed to several main examples of this phenomenon, including the FDA's positions on scientific evidence, cross-flavor comparisons, and device type. See, *e.g.*, *id.*, at 376, 377, 384. The court expressed particular concern that the FDA pulled the rug out from under manufacturers by "not even read[ing] the marketing plans it previously said were critical." *Id.*, at 372. Although the FDA's attorneys represented that the agency had reviewed "'summar[ies]'" of respondents' marketing plans, the court deemed that representation an illicit *post hoc* rationalization. *Id.*, at 373.

In a footnote, the en banc majority also suggested that the FDA had violated a provision of the TCA's notice-and-comment requirements, see 21 U. S. C. §§387g(c)–(d), by imposing a "de facto ban on flavored e-cigarettes" through mass adjudicatory denials, 90 F. 4th, at 384, n. 5.

Having found that the FDA had erred in these ways, the court rejected the FDA's suggestion that any errors were harmless. Relying heavily on our decision in *Calcutt* v. *FDIC*, 598 U. S. 623 (2023) (*per curiam*), the court suggested that "APA errors are only harmless where the agency would be *required* to take the same action no matter what. In all other cases," the court concluded, "an agency cannot avoid remand." 90 F. 4th, at 390. And, in a brief alternative analysis, the court found that each of the FDA's errors "plainly affected the procedure used" and was prejudicial. *Ibid.* (internal quotation marks omitted).

Judge Haynes, joined by four other judges, dissented. See *id.*, at 390. Judge Graves joined the dissent in part. See *id.*, at 405.

The en banc Fifth Circuit's decision conflicted with those of other Circuits, and we granted the FDA's petition for a writ of certiorari. 603 U. S. ___ (2024). We now vacate and remand.

II

The question we agreed to decide is whether the FDA acted arbitrarily and capriciously in denying respondents' applications for premarket approval of their tobacco products. See Pet. for Cert. I. But before tackling that question, we briefly address as a preliminary matter an argument that is touched on in respondents' brief: namely, that either the APA or the TCA required the FDA to use notice-and-comment rulemaking to set out the requirements that must be met in a premarket tobacco product application.

Unless Congress has specified otherwise, agencies are generally free to develop regulatory standards "either by general [legislative] rule or by individual order" in an adjudication. *SEC* v. *Chenery Corp.*, 332 U. S. 194, 202–203 (1947) (*Chenery II*). Of course, if a statute requires rulemaking, the affected agency must comply. *Ibid.* And that is what respondents claim in passing here. Respondents' defense of the decision below is based almost entirely on 5 U. S. C. §706(2)(A) and related case law. But their brief also suggests that the FDA's decision to issue denials based on standards developed in adjudication violated other provisions of the APA and TCA that, they claim, required notice-and-comment rulemaking. See Brief for Respondents 47–49, and n. 33. This echoes an argument the Court of Appeals made in a short footnote. See 90 F. 4th, at 384, n. 5 (citing 21 U. S. C. §§387g(a)(1)(A), (a)(2), (c)–(d)).

We did not grant certiorari on that question, and without adequate briefing, it would not be prudent to decide it here. See *Anza* v. *Ideal Steel Supply Corp.*, 547 U. S. 451, 461 (2006). Accordingly, we do not reach that question and express no view on its merits.[3]

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[3] Respondents' *amici* offer numerous alternative grounds for affirmance. Three of these arguments are based on the Constitution: (1) that the TCA unconstitutionally delegated lawmaking power to the FDA with respect to, among other things, the necessary contents of a premarket tobacco product application, see Brief for Taxpayers Protection Alliance

III

We now turn to the Court of Appeals' holding that the FDA acted arbitrarily and capriciously. That decision was multifaceted, but its analysis boils down to a central concern: it faulted the FDA for allegedly changing the requirements for premarket tobacco product applications between the time of its guidance and the denials of respondents' applications.

The feature of our current case law on arbitrary-and-capricious review that addresses that issue is our change-in-position doctrine. Under that doctrine, we must ask whether the FDA changed course and, if it did, whether it offered satisfactory reasons for the change. Analysis of the FDA's position prior to the denials at issue requires a close reading of nuanced statements in a body of guidance documents that evidence the agency's evolving assessment of the relevant issues. Affected parties may have come away with the impression that the agency would apply a less demanding standard of proof than is evident in the denial orders the FDA ultimately issued, but in the end, we cannot

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as *Amicus Curiae* 7–8; (2) that the relevant provisions of the TCA are unconstitutionally vague, see *id.*, at 6–8; and (3) that respondents were denied due process, see Brief for Washington Legal Foundation as *Amicus Curiae* 8–11; Brief for Thirteen Members of Congress et al. as *Amici Curiae* 13–16. Some *amici* also argue that the FDA violated our "major questions" doctrine. See, *e.g.*, Brief for Vaping Industry Stakeholders as *Amici Curiae* 30–34; Brief for Thirteen Members of Congress et al. as *Amici Curiae* 6–13.

Although these issues have a bearing on what appears to have been the Court of Appeals' animating concern—*i.e.*, that the FDA did not give respondents and other applicants fair and accurate notice regarding what it would insist that an application contain—these arguments fall outside the scope of the question presented, were not passed on below, and were not pressed in respondents' brief. We therefore decline to reach them. See, *e.g.*, *Atlantic Marine Constr. Co.* v. *United States Dist. Court for Western Dist. of Tex.*, 571 U. S. 49, 61 (2013). And our opinion should not be read to suggest any view on their merits.

say that the FDA improperly changed its position with respect to scientific evidence, comparative efficacy, or device type. With respect to the FDA's guidance on marketing plans, we clarify the appropriate legal standard governing claims of harmless error, and we remand to the Fifth Circuit to apply that standard in the first instance.

A

We begin with our change-in-position doctrine. The APA requires a reviewing court to "hold unlawful and set aside agency action" found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U. S. C. §706(2)(A). Our well-worn arbitrary-and-capricious standard ensures that an administrative agency "examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Assn. of United States, Inc.* v. *State Farm Mut. Automobile Ins. Co.*, 463 U. S. 29, 43 (1983) (internal quotation marks omitted). The scope of this review "is narrow," and reviewing courts must exercise appropriate deference to agency decisionmaking and not substitute their own judgment for that of the agency. *Ibid.*

Our case law identifies numerous ways in which an agency may act arbitrarily and capriciously. The Fifth Circuit concluded that the FDA overstepped this standard in four such ways. In its view, the FDA (1) "invent[ed] *post hoc* justifications" for its failure to consider applicants' marketing plans; (2) failed to give "fair notice" of the evidentiary and comparative requirements that would be imposed at the application stage; (3) changed its position regarding scientific evidence and device type; and (4) faulted respondent "for relying in good faith on [its] previous" guidance. 90 F. 4th, at 371–386.

All four of these principles orbit around the same basic concern: an agency should not mislead regulated entities.

The essence of respondents' argument is that the FDA told them in guidance documents that it would do one thing and then turned around and did something different when it reviewed their applications.

The change-in-position doctrine is administrative law's answer to that problem. Under that doctrine, "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change," "'display awareness that [they are] changing position,'" and consider "'serious reliance interests.'" *Encino Motorcars, LLC* v. *Navarro*, 579 U. S. 211, 221–222 (2016) (quoting *FCC* v. *Fox Television Stations, Inc.*, 556 U. S. 502, 515 (2009)). For reasons we explain, the change-in-position doctrine provides the governing framework here.

Respondents appear to recognize as much, although they suggest at times that the applicable requirements are not just part of arbitrary-and-capricious review but are rooted in part on the constitutional right to due process. See Brief for Respondents 28–29, 35, 44. In substance, however, there is little difference in the standard they ask us to apply.[4] They do not rely on four distinct administrative-law principles; rather, their arguments before this Court rest primarily on the FDA's supposed change in position regarding application requirements. See *id.*, at 29–42, 45–47; Tr. of Oral Arg. 88. To the extent respondents raise a free-standing "fair notice" argument, see *id.*, at 90, the exact contours of that contention are somewhat unclear. By asking us to affirm the decision below, respondents do not now

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[4] At one point, however, respondents seem to suggest that the FDA violated their due-process rights simply because it failed to provide clear notice before it denied their applications and thus effectively put them out of business. See Brief for Respondents 44. But the freestanding due-process question to which the respondents fleetingly refer lies outside the question on which we granted review and is not well developed in their brief. We therefore decline to decide it. See *Anza* v. *Ideal Steel Supply Corp.*, 547 U. S. 451, 461 (2006).

suggest that under the TCA the FDA "had an affirmative obligation to issue specific guidance" as to how it would evaluate flavored products. Brief for Respondents 33 (internal quotation marks omitted). Instead, respondents merely support the Fifth Circuit's conclusion that when an agency issues guidance, it cannot "change the requirements set forth therein without consideration of applicants' reasonable reliance interests, proper notice to applicants, and a reasonable opportunity for applicants to conform to the changed requirements." *Ibid.* It is unclear what, if any, daylight exists between that conception of "fair notice" and our change-in-position doctrine. See, *e.g.*, *Encino Motorcars*, 579 U. S., at 221–222 ("In explaining its changed position, an agency must also be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account. . . . [A] reasoned explanation is needed for disregarding facts and circumstances that underlay or were engendered by the prior policy" (internal quotation marks omitted)).

B

The change-in-position doctrine asks two questions. The first is whether an agency changed existing policy.[5] And we

[5] The parties assume that the change-in-position doctrine applies when an agency abandons a position it first articulated in a nonbinding guidance document. We have traditionally applied the change-in-position doctrine when an agency shifts from a position expressed in a more formal setting. See, *e.g.*, *FCC* v. *Fox Television Stations, Inc.*, 556 U. S. 502, 517 (2009). True, we have on at least one occasion applied the doctrine when an agency altered a position first stated in a policy statement. See *Department of Homeland Security* v. *Regents of Univ. of Cal.*, 591 U. S. 1, 30 (2020). But as we explained in that case, the policy statement instituted "a standardized review process" that "effectively" resembled adjudication. *Id.*, at 18. Given neither party has pressed this argument here, we assume, without deciding, that the change-in-position doctrine applies to an agency's divergence from a position articulated in nonbinding guidance documents.

have suggested that this occurs when an agency acts "inconsistent[ly]" with an "earlier position," *id.*, at 224, performs "a reversal of [its] former views as to the proper course," *State Farm*, 463 U. S., at 41, or "disavow[s]" prior "inconsistent" agency action as "no longer good law," *Fox Television*, 556 U. S., at 517 (internal quotation marks omitted). For example, we have held that an agency changed its position when it rescinded a prior regulation, see *State Farm*, 463 U. S., at 41–42, "expand[ed] the scope of its enforcement activity," *Fox Television*, 556 U. S., at 517, and "abandon[ed a] decades-old practice" applied in enforcement actions, *Encino Motorcars*, 579 U. S., at 218.

Once a change in agency position is identified, the doctrine poses a second question: Did the agency "display awareness that it *is* changing position" and offer "good reasons for the new policy"? *Fox Television*, 556 U. S., at 515. At this second step, the agency does not need to show "that the reasons for the new policy are *better* than the reasons for the old one." *Ibid.* Nor must it "provide a more detailed justification than what would suffice for a new policy created on a blank slate." *Ibid.* But the agency must "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Encino Motorcars*, 579 U. S., at 221–222 (quoting *Fox Television*, 556 U. S., at 515).

Echoing the Fifth Circuit, respondents claim that the FDA violated the change-in-position doctrine with respect to the four principal themes discussed above. See *supra*, at 9–14. First, according to respondents, the FDA, after initially telling applicants that no specific kinds of scientific evidence were required, turned around and rejected all applications lacking evidence from a randomized controlled trial or longitudinal cohort study. See Brief for Respondents 37, 40–42. Second, respondents claim, the FDA told applicants they had discretion to choose appropriate comparator products, but it ultimately denied applications on

the ground that they failed to make specific comparisons between dessert-, candy-, and fruit-flavored products, on the one hand, and tobacco-flavored products on the other. See *id.*, at 27–36. Third, respondents claim that the FDA abandoned earlier guidance about the importance of device type and instead denied authorization to all dessert-, candy-, and fruit-flavored e-cigarette products regardless of device type. See *id.*, at 45–47. And fourth, according to respondents, the FDA went back on its word by failing even to consider their marketing plans. See *id.*, at 49–50.

As to the first three issues, we conclude that the FDA's denial orders were sufficiently consistent with its predecisional guidance and thus did not run afoul of the change-in-position doctrine. As to the failure to consider marketing plans, the FDA does not seek review of the Fifth Circuit's finding of error. See Brief for Petitioner 31. Rather, it asks us to clarify the harmless-error rule and remand for application of the proper standard. See *id.*, at 38. We agree with the FDA that that is the appropriate course of action.

1

We first address the FDA's position on scientific evidence. In respondents' view, the FDA initially stated that manufacturers would not need to provide specific kinds of studies like randomized controlled trials or longitudinal cohort studies but then treated such evidence as essential.

a

Respondents express frustration about the lack of clear prior notice regarding the type of scientific evidence that was essential for approval of an application, but we cannot agree with their argument that the FDA went back on any commitments made in the guidance it provided before ruling on respondents' applications.

Both the TCA itself and the FDA's guidance left the

agency broad discretion to decide what sort of scientific evidence an applicant was required to submit. The TCA itself imposes only basic requirements on this matter. It says that the agency's determination of what "would be appropriate for the protection of the public health" must be made based on either "well-controlled investigations, which *may* include 1 or more clinical investigations by experts qualified by training and experience to evaluate the tobacco product," 21 U. S. C. §387j(c)(5)(A) (emphasis added), or—and this is the point that is critical here—other "valid scientific evidence" that "is sufficient to evaluate the tobacco product," §387j(c)(5)(B). The TCA leaves it to the FDA to decide what constitutes a "well-controlled investigatio[n]" or other "valid scientific evidence" that is "sufficient."

Before ruling on respondents' and other manufacturers' applications, the FDA addressed the issue of scientific evidence in a series of lengthy documents and oral presentations by agency officials, but it is hard to find in all this verbiage any specific commitments about exactly what sorts of scientific evidence an applicant would have to provide. As we will detail below when we discuss the particulars of respondents' applications, the FDA commented on the strength of various types of evidence and how particular types of evidence would likely be evaluated, but at no point did it lay down any clear test.

For example, during an October 23, 2018, public meeting, an agency official said that *"[i]n most situations* it is *likely* that at least some [new] analytical testing specific to the product *would be* conducted to support an" application. 2018 Presentation Video, at 2:12:35–2:12:44 (emphasis added). The official then offered examples such as "randomized controlled clinical trials"; "alternatives" like "pharmacokinetic," "pharmacodynamic," "biomarker," "topography," or "focus group studies"; published peer-reviewed literature; and literature reviews more generally. *Id.*, at 2:13:07–2:14:44. But the official never stated that any particular

type of study was necessary. On the contrary, the FDA acknowledged that it was open to evidence besides "new nonclinical or clinical studies." 2018 Presentation 26. And the FDA promised that it would consider evidence "bridging" new tobacco products to already marketed products whose safety was backed by "existing clinical, nonclinical, or product information." *Id.*, at 18, 27. None of this amounted to anything like a hard-and-fast commitment as to the minimum evidence the agency would require for marketing authorization.[6]

A June 2019 guidance document was similarly noncommittal. After reiterating the statutory requirement of "well-controlled investigations," the document recognized that the "relatively new entrance" of e-cigarettes "on the U.S. market" meant that "limited data may exist from scientific studies and analyses." App. 28 (citing 21 U. S. C. §387j(c)(5)(A)). As a result, the document stated, the FDA would consider "other 'valid scientific evidence' if found sufficient." App. 28. But it cautioned that "[n]onclinical studies alone are generally not sufficient." *Ibid.*

The guidance document went on to give examples of "other evidence" that might suffice, but in doing so, it cautioned about the need for scientific rigor. For example, while stating that applicants could cite "data from the published literature or government-sponsored databases," it warned that such data must be "adequately bridged to your product" with "a scientific rationale." *Id.*, at 98. The document told manufacturers that they could also cite "[p]ublished literature reviews (including meta-analysis),"

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[6] It is true that the FDA's accompanying slideshow represented that "[n]o specific studies" would be required for a premarket tobacco product application. 2018 Presentation 26. But in light of what the TCA itself demanded (*i.e.*, "well-controlled investigations" or other "sufficient" "scientific evidence") and the FDA official's numerous examples throughout the presentation, the obvious import of the "[n]o specific studies" statement was that many different types of studies could potentially suffice.

but that such evidence is "considered a less robust form of support." *Id.*, at 100. And applicants were advised that they could "conduc[t] independent analyses of published studies," but that "if critical study details are not submitted, the studies may not be useful in FDA's review." *Id.*, at 102.

A fair summary of the main point made in all this guidance is that (a) it was not essential for manufacturers to submit evidence based on "well-controlled investigations," such as randomized controlled trials or longitudinal cohort studies, but (b) if they did not do so, they would have to provide rigorous scientific evidence that the sale of their particular products would be appropriate for the protection of the public health. In this case, the applicants did not submit randomized controlled trials or longitudinal cohort studies, so the fate of their applications turned on whether they submitted "other evidence" that met the FDA's standard of scientific rigor and relevance to their product. The FDA rejected respondents' applications because it concluded that its "other evidence" test was not met, and the explanation in its denial orders echoed statements made at various points in its earlier guidance.

Both respondents relied on a "comprehensive review of the scientific literature." *Id.*, at 303, 392. But respondents had notice from the 2019 guidance that the FDA considered literature reviews "a less robust form of support." *Id.*, at 100. The 2019 guidance also instructed that applicants submitting literature reviews should, among other things, "[i]nclude comparative assessments of the health risks associated with use of [a manufacturer's] new tobacco product compared to the risks associated with quitting tobacco product use, using other tobacco products, and never using tobacco products." *Id.*, at 101. Respondents' literature review did the opposite. It concluded that "there is not enough evidence . . . to determine whether e-cigarette flavors aid in smoking cessation." *Id.*, at 475.

One of the respondents, Vapetasia, submitted results from a cross-sectional survey finding that "82.99% of survey respondents indicated that e-cigarettes helped them quit smoking combustible tobacco." 41 F. 4th, at 436. But the FDA concluded the survey was not adequately tied to Vapetasia's flavored products. App. to Pet. for Cert. 280a. That requirement echoed the 2019 guidance's advice that manufacturers submitting evidence from "new nonclinical . . . studies" should "explain why [a] study is relevant to use for the [manufacturer's] product (e.g., the similarities between the product, product use, or product market)." App. 98–99.

Based on the FDA's largely noncommittal guidance on scientific evidence and its specific reasons for rejecting respondents' applications, we cannot say that the agency deviated "from a prior policy *sub silentio* or simply disregard[ed]" what it had previously said. *Fox Television*, 556 U. S., at 515. In line with the agency's prior guidance, each denial order was based on the applicant's failure to provide either evidence from well-controlled investigations, such as "a randomized controlled trial and/or longitudinal cohort study," see App. to Pet. for Cert. 167a, or other evidence that was found to be "reliabl[e] and robus[t]," *id.*, at 167a–168a. No change in position occurred in this respect.

b

Contrary to respondents' contention, this conclusion is not undermined by the FDA's scientific-review form, which contained checkboxes to indicate whether an applicant submitted a randomized controlled study (Criterion A), a longitudinal cohort study (Criterion B), or other evidence "related to potential benefit to adults" (Criterion C). App. 615–638; see Brief for Respondents 32. Criterion C appears to defeat respondents' argument, but they contend that the FDA made it clear that this criterion demanded a study of the effect of flavored products on adult smokers "'"over

time"'" and that this requirement duplicated Criterion B, which looked for a "longitudinal cohort study." *Id.*, at 37.

This argument fails because a "longitudinal cohort study" and evidence of a product's effects "over time" are not the same thing. The term "longitudinal study" is typically used to describe a particular kind of long-term study, namely, one that "employ[s] continuous or repeated measures to follow particular individuals over prolonged periods of time—often years or decades." E. Caruana, M. Roman, J. Hernández-Sánchez, & P. Solli, Longitudinal Studies, 7 J. Thoracic Disease E537 (2015). Not every study that considers a product's effects "over time" falls within this understanding.[7]

c

Based on the FDA's internal memoranda from the summer of 2021, respondents argue that the agency secretly enforced a new requirement that manufacturers must submit evidence from either a randomized control trial or longitudinal cohort study. See Brief for Respondents 31–32. Recall that the FDA's July 9, 2021, memorandum stated that the failure to submit such evidence would constitute a "fatal flaw" that would "likely" result in denial of an application. App. 243. Even though this statement, like most of what the FDA said in its guidance, was not categorical, it certainly suggested a much harder stance than was implied by

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[7] In a related argument, respondents argue that the FDA "repeatedly represented that it did not expect long-term clinical studies" in predecisional guidance but later required such studies. Brief for Respondents 41. But a "long-term study" and evidence "over time" are not the same thing. As the 2019 guidance explained, the FDA describes "long-term studies" as "those studies that are conducted over six months or longer." App. 29. Nothing in the denial orders suggested that the FDA imposed a rigid requirement that evidence come from such studies. And the 2019 guidance also underscored the FDA's expectation that applicants present evidence about the "possible long-term health impact" of their new tobacco products. *Ibid.*

the FDA's public statements, which told applicants that "other evidence" might be capable of proving a new tobacco product's appropriateness for the protection of public health.

Respondents suggest that the FDA surreptitiously applied the "fatal flaw" memorandum, and as evidence, they note that until well after their applications were denied, the FDA rejected all applications for flavored products. But agencies are entitled to a presumption of regularity, *Citizens to Preserve Overton Park, Inc.* v. *Volpe*, 401 U. S. 402, 415 (1971), and the record offers enough support for us to conclude that the FDA never enforced a rigid "fatal flaw" standard.

To start, a later internal memorandum dated August 17, 2021, appeared to contradict the "fatal flaw" memorandum. The new memorandum represented that the FDA "would also consider evidence from another study design" besides randomized controlled trials and longitudinal cohort studies, "provided that it could reliably and robustly assess behavior change" and "compar[e] users of" dessert-, candy-, and fruit-flavored "products with those of tobacco-flavored products." App. 247, n. ix. The FDA also acknowledged that "indirect evidence or bridged data from the literature might still be appropriate for many new products" too. *Id.*, at 266. Even though the FDA predicted these "other types of evidence" would "not likely be sufficiently robust or direct," the August 17, 2021, memorandum is unambiguous that the FDA would nevertheless consider such evidence. *Id.*, at 267.

This memo might be viewed as dooming any argument based on the earlier "fatal flaw" memorandum, but on August 25, 2021, the FDA rescinded the August 17, 2021, memorandum and represented that it would "not consider or rely on [it] as a supporting document." *Id.*, at 282.

Rescission of the August 17 memorandum raises the question whether that action effectively reinstated the July

9, 2021, "fatal flaw" memorandum or was a pretext to mask the FDA's adherence to secret criteria. But the FDA represents that these internal memoranda played no role in its review of applications, see Reply Brief 11–12, and for us to peel back the curtain on that representation would have required respondents to make a "strong showing of bad faith or improper behavior," *Overton Park*, 401 U. S., at 420; see also *Department of Commerce* v. *New York*, 588 U. S. 752, 781 (2019) ("[J]udicial inquiry into 'executive motivation' represents 'a substantial intrusion' into the workings of another branch of Government and should normally be avoided" (quoting *Arlington Heights* v. *Metropolitan Housing Development Corp.*, 429 U. S. 252, 268, n. 18 (1977))). Respondents have not surmounted the high standard that must be met to warrant such a "substantial intrusion" into the Executive's functioning. *Id.*, at 268, n. 18 (internal quotation marks omitted).

We thus conclude that respondents failed to show that the FDA changed its position with respect to the scientific evidence supporting premarket tobacco product applications.

2

Next, we turn to the FDA's comparative-efficacy requirement, which called on manufacturers to compare the health effects of their dessert-, candy-, and fruit-flavored products to those of tobacco-flavored products. On respondents' reading of the record, the FDA initially gave applicants broad discretion to select appropriate comparators for their products, but it later categorically rejected applications that failed to show that "*flavored* e-cigarettes promote more switching than *unflavored*" or tobacco-flavored e-cigarettes. 90 F. 4th, at 376—377; accord, Brief for Respondents 29–33.

a

The record does not suggest that the FDA contradicted its predecisional guidance by requiring certain cross-flavor comparisons. To start, the TCA expressly contemplates comparisons of different tobacco products. It requires an applicant to provide "full reports of all information . . . concerning investigations which have been made to show . . . whether [its] tobacco product *presents less risk than other tobacco products*." 21 U. S. C. §387j(b)(1)(A) (emphasis added). Moreover, the FDA's determination that a new tobacco product is "appropriate for the protection of the public health" is an inherently comparative judgment. The FDA must account for the "increased or decreased likelihood that existing users of tobacco products will stop using such products" and the "increased or decreased likelihood that those who do not use tobacco products will start using such products." §387j(c)(4). This balancing test calls out for various types of comparisons, including comparisons between new tobacco products and those that are already available, as well as between different types of new tobacco products that may attract new smokers.

Through its predecisional guidance, the FDA elaborated on the types of comparisons that would be helpful. Echoing the TCA, the June 2019 guidance document recommended that a manufacturer "compare the health risks of its product to both products within the same category and subcategory, as well as products in different categories as appropriate." App. 30. The FDA went on to explain what it means for manufacturers to make comparisons to "similar, marketed tobacco products in the same category." *Id.*, at 58. "For example," it advised, "if your [application] is for an e-liquid, we recommend a comparison to other e-liquids with similar nicotine content, flavors, and other ingredients, used in the same manner and under similar conditions." *Ibid.* The plain implication of this statement is that the FDA might consider whether an application for a flavored

product included a comparison with other products in the flavored category.

Other parts of the 2019 guidance also underlined the FDA's concern about "the potential impact of flavors on product toxicity and appeal to youth and young adults." *Id.*, at 87. The FDA noted that it "considers the appeal and use of [e-cigarette] product flavors important in ascertaining the health risks of these products" and thus recommended "scientific reviews of flavors." *Id.*, at 87–88. Specifically, it called on manufacturers to "examine the impact of flavoring on consumer perception . . . especially given the attractiveness of flavors to youth and young adults." *Id.*, at 88.

Further, in its 2020 enforcement guidance, the FDA telegraphed its view that dessert-, candy-, and fruit-flavored e-cigarette products are more likely than tobacco- and menthol-flavored products to appeal to the young. The FDA noted its intent to "prioritize enforcement of flavored" e-cigarette products "other than tobacco- and menthol-flavored products," *id.*, at 160, and observed that "youth use of mint- and fruit-flavored [e-cigarette] products is higher than that of menthol- and tobacco-flavored [e-cigarette] products." *Id.*, at 163. The FDA also relied on data that flavors like tobacco and menthol "were preferred more by adults than youth."[8] *Id.*, at 162.

When it reviewed respondents' applications, the FDA did not contradict any previously announced position with respect to the comparative effects of differently flavored products. As respondents' marketing denial orders stated, their applications were unsuccessful because they failed to "demonstrat[e] the benefit of" their dessert-, candy-, and

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[8] An initial draft of the 2020 guidance exempted from enforcement priority mint-flavored products, treating them similarly to tobacco- and menthol-flavored products. But in the revised 2020 guidance that we discuss here, the FDA no longer exempted mint-flavored products based on new evidence that youth are also drawn to mint flavors. See App. 162–164.

fruit-flavored e-cigarette "products over an appropriate comparator tobacco-flavored" e-cigarette product. App. to Pet. for Cert. 167a. Admittedly, the FDA has not pointed us to any portion of its predecisional guidance that said in so many words that manufacturers must draw that precise comparison. And, in fact, the 2019 guidance gave manufacturers some discretion in choosing appropriate comparators as long as the "FDA [could] understand [an] applicant's rationale and justification for comparators chosen." App. 30. But the FDA's comparative-efficacy standard was a natural consequence of its predecisional guidance, which highlighted, among other things, (1) the need for robust cross-product comparisons (including on the dimension of flavor) and (2) the FDA's heightened concern with dessert-, candy-, and fruit- flavored products compared to tobacco- and menthol-flavored products. Such a predictable outgrowth from previous guidance is not an "[u]nexplained inconsistency" amounting to a "change" under the change-in-position doctrine. *National Cable & Telecommunications Assn.* v. *Brand X Internet Services*, 545 U. S. 967, 981 (2005); cf. *Long Island Care at Home, Ltd.* v. *Coke*, 551 U. S. 158, 174 (2007) ("The Courts of Appeals have generally interpreted this to mean that the final rule the agency adopts must be a logical outgrowth of the rule proposed" (internal quotation marks omitted)).

b

Respondents contend that the FDA "said nothing about comparing" dessert-, candy-, and fruit-flavored "products to tobacco-flavored products," Brief for Respondents 27, and even suggested manufacturers could "freely select" comparators as long as they provided adequate "justification or rationale" for their comparator choice, *id.*, at 30–31.

As we noted, respondents are correct that the FDA did not provide this precise instruction in its predecisional guidance. But, as an FDA official noted at the 2018 public

presentation, manufacturers were encouraged throughout the application process to think hard about "what is or are the most appropriate comparators" to their products. 2018 Presentation Video, at 1:57:37–1:57:42. And the agency's subsequent guidance emphasized the importance of cross-product comparators and the FDA's specific worry that dessert-, candy-, and fruit-flavored products would appeal to youth more than tobacco- and menthol-flavored products. The FDA is thus better understood as having extended, not reversed, its previous guidance. See *supra*, at 34–35.

Quite tellingly, respondents appear to have received the FDA's message on this front. Their applications are replete with statements attempting (albeit unsuccessfully) to draw comparisons between dessert-, candy-, and fruit-flavored and tobacco-flavored products—the same sort of comparisons for which the FDA allegedly provided no notice. See, *e.g.*, App. 320 ("Another recent survey of more than 69,000 adult vapers found that just 16% identified tobacco, menthol, or mint as flavors they used most often; the vast majority preferred fruit and sweet flavors"); *ibid.* ("'Fruity' flavor was the number one flavor preference by 49.98% of all respondents. Only about 3% of all respondents stated that they preferred no flavor"); *id.*, at 321 (noting that a third of surveyed smokers "stated that they started out using tobacco or menthol flavors but now always or almost always use other flavors"). All that is to say, respondents' applications are themselves strong evidence that regulated entities had adequate notice of the sort of comparative analysis the FDA anticipated.

Furthermore, even assuming the predecisional guidance did not perfectly predict the comparative-efficacy standard ultimately applied to applications, the FDA was not required to issue such guidance in the first place. Respondents do not argue that the TCA imposed an affirmative obligation on the FDA to spell out in detail how it expected

applicants to compare a new tobacco product to other tobacco products. See Brief for Respondents 33. Rather, as we have explained, the FDA had discretion to work out the meaning of the TCA's comparative standard when evaluating premarket tobacco product applications. See 21 U. S. C. §§387j(b)(1)(A), (c)(4). A contrary rule would be in tension with *Chenery II*'s teaching that, absent a statutory prohibition, agencies may generally develop regulatory standards through either adjudication or rulemaking. 332 U. S., at 202–203.

3

Finally, we turn to the issue of device type. In respondents' view, the FDA's 2020 guidance saw a material distinction between cartridge-based and other flavored products, but when it came to ruling on applications, the FDA effectively imposed a flat ban on *all* flavored products. Brief for Respondents 45–47.

a

We cannot agree with respondents that the denial orders' treatment of device type was "inconsistent" with any "earlier position." *Encino Motorcars*, 579 U. S., at 224. The 2020 guidance explained how the FDA "intend[ed] to prioritize [its] enforcement resources." App. 129. Specifically, the agency planned to target three types of e-cigarette products: (1) "[f]lavored, cartridge-based" products; (2) "[a]ll other [e-cigarette] products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access"; and (3) "[a]ny [e-cigarette] products targeted to, or whose marketing is likely to promote use by, minors." *Id.*, at 145. Admittedly, on any reading of this guidance document, the FDA's central concern was the first category because data suggested "youth are more likely to use certain flavored, cartridge-based [e-cigarette] products." *Id.*, at 147.

But nothing in the 2020 guidance suggested the FDA would decline to take enforcement action against other products that might be appealing to the young. In fact, the FDA's enumeration of the second and third enforcement priorities, which are not limited to flavored cartridge-based products, supports the contrary conclusion. So when the FDA ultimately denied authorization to respondents' flavored (though non-cartridge) products, it did not reverse course. Rather, it followed through on the 2020 guidance's warning that the agency would *also* prioritize enforcement against manufacturers "whose [products'] marketing is likely to promote use by . . . minors." *Id.*, at 145. Indeed, the FDA's marketing denial orders stated that respondents' applications were "insufficient to demonstrate that the[ir] products would provide an added benefit that is adequate to outweigh the risks to youth." App. to Pet. for Cert. 168a. That is a consistent application of the 2020 guidance's enforcement framework or, at the very least, an application that did not "revers[e the FDA's] former views as to the proper course." *State Farm*, 463 U. S., at 41.

This case is unlike *Fox Television*, in which we held that an agency changed position by "expanding the scope of its enforcement activity." 556 U. S., at 517. That case concerned the Federal Communications Commission's (FCC) enforcement of the federal indecency ban against the use of offensive words on broadcast television. Initially, the FCC distinguished between literal and nonliteral uses of offensive words and determined that fleeting uses of nonliteral offensive words were not actionably indecent. See *id.*, at 508. But then, in a subsequent adjudication, the FCC eliminated that safe harbor for nonliteral expletives and explained that even a single use of an offensive word was actionably indecent. See *ibid.* We deemed that shift in enforcement policy "a change" for purposes of the change-in-position doctrine. See *id.*, at 517.

Here, in contrast, the FDA's 2020 guidance did not establish "a safe harbor" for non-cartridge-based products. *Id.*, at 518. True, the 2020 guidance unmistakably emphasized cartridge-based products, but it said nothing to suggest dessert-, candy-, and fruit-flavored products for open-system e-cigarettes would escape regulatory scrutiny. And further distinguishing *Fox Television*, the FDA's actions here did not "br[eak] new ground." *Id.*, at 517. Indeed, there was no new ground to break because respondents' denial orders were part of the FDA's first major exercise of its new authority over tobacco products under the TCA. In other words, the FDA could not "expan[d] the scope of" previously nonexistent "enforcement activity." *Ibid.*

Even if the FDA had changed its position, it offered "good reasons" for looking beyond cartridge-based e-cigarette products, *id.*, at 515, namely, that there was evidence from national surveillance data that youth demand had moved from flavored *cartridge-based* products to flavored *disposable* products, App. to Pet. for Cert. 191a–192a. From this, the FDA drew the conclusion that "across these different device types, the role of flavor is consistent." *Id.*, at 191a. If one type of flavored product were removed from the market, the FDA concluded, youth would "migrate to another" type of flavored product. *Id.*, at 192a. So the FDA decided to focus on the "role of flavors . . . across tobacco product categories." *Id.*, at 191a. The FDA made this "conscious change of course" because it "*believe[d]* it to be better," and the agency gave "good reasons" for the change. *Fox Television*, 556 U. S., at 515.

Respondents cannot claim that the FDA's revised enforcement priorities upset a "legitimate reliance" interest. *Smiley* v. *Citibank (South Dakota), N. A.*, 517 U. S. 735, 742 (1996). At most, the 2020 guidance may have led respondents to *believe* that the FDA was more likely to authorize their open-system products than other manufacturers' cartridge-based products. But such a belief about how an

agency is likely to exercise its enforcement discretion is not a "serious reliance interes[t]." *Fox Television*, 556 U. S., at 515. Our prior change-in-position cases have set a much higher bar, requiring, for example, "decades of industry reliance on [an agency's] prior policy." *Encino Motorcars*, 579 U. S., at 222. Here, in contrast, respondents could not have built up decades of reliance because they were part of the very first wave of marketing denials under the FDA's newly minted jurisdiction over tobacco products.

We thus hold that the FDA's treatment of device type, even if it evolved over time, did not violate the change-in-position doctrine.

b

Respondents take issue with the FDA's explanation that it changed enforcement priorities based on evidence that youth demand shifted from cartridge-based products to disposable products. In respondents' view, that evidence had nothing to do with products such as theirs that are intended for open-system e-cigarette products. See Brief for Respondents 45–46. And respondents cite evidence from a study finding that between 2020 and 2021 high-school-student demand for devices compatible with flavored bottled e-liquids actually decreased. See *id.*, at 46, and n. 32 (citing E. Park-Lee et al., Centers for Disease Control and Prevention, *Notes From the Field*: E-Cigarette Use Among Middle and High School Students—National Youth Tobacco Survey, United States, 2021, 70 Morbidity and Mortality Weekly Rep. 1387, 1387–1388 (2021)).

This counterargument is not persuasive. Even though the FDA did not cite evidence that was specifically about increasing youth demand for open-system e-cigarette products, the FDA drew a reasonable inference based on the data before it: namely, that the rapid shift in youth demand from flavored cartridge-based products to flavored disposable products strongly suggested that youth were most

strongly drawn by flavor rather than device type. We see no reason why the FDA could not extrapolate from that data and conclude that young people would be drawn to flavored products for open-system e-cigarettes. Regardless, we are not positioned in this arbitrary-and-capricious challenge to consider respondents' evidence from a study that postdates the filing of their applications and is, in any event, outside "the administrative record already in existence." *Camp* v. *Pitts*, 411 U. S. 138, 142 (1973) (*per curiam*). Nor is respondents' evidence of sufficient heft to call into question whether the FDA's "factual determinations" about the powerful effect of flavor is supported by "substantial evidence" in the "existing administrative record." *Biestek* v. *Berryhill*, 587 U. S. 97, 102 (2019).

C

That brings us to the FDA's guidance concerning marketing plans. Recall that the FDA does not contest the Fifth Circuit's finding that it changed position regarding the submission of marketing plans, but it argues that this error was harmless. This question presents a difficult problem. It requires us to reconcile the so-called remand rule developed in *SEC* v. *Chenery Corp.*, 318 U. S. 80, 88, 93–95 (1943) *(Chenery I)*, and *Chenery II*, 332 U. S., at 196–197, with the APA's instruction that reviewing courts must take "'due account'" of "'the rule of prejudicial error'" that "ordinarily appl[ies] in civil cases," *Shinseki* v. *Sanders*, 556 U. S. 396, 406 (2009) (quoting 5 U. S. C. §706).

1

In *Chenery I*, the Court announced the now-bedrock principle that an agency action cannot stand "unless the grounds upon which the agency acted in exercising its powers were those upon which its action can be sustained." 318 U. S., at 95. There, we rejected the Securities and Exchange Commission's belated request to affirm its action on

an alternative ground raised for the first time in litigation. *Id.*, at 92–94. We reasoned that when Congress vests an agency with authority to make "a determination of policy or judgment" and the agency fails to exercise that authority, "a judicial judgment cannot be made to do service for an administrative judgment." *Id.*, at 88. Upholding agency action on an alternative ground not considered by the agency, the Court reasoned, would "intrude upon the domain which Congress . . . exclusively entrusted to an administrative agency." *Ibid.* We reaffirmed this principle in *Chenery II*, see 332 U. S., at 196–197, and a necessary implication of that principle is that the better course when an agency error is identified is for the reviewing court, "except in rare circumstances," "to remand to the agency for additional investigation or explanation," *Florida Power & Light Co.* v. *Lorion*, 470 U. S. 729, 744 (1985). That implication of *Chenery* is colloquially referred to as the "remand rule." See *INS* v. *Orlando Ventura*, 537 U. S. 12, 18 (2002) (*per curiam*) (internal quotation marks omitted).

Three years after *Chenery I* was handed down, Congress enacted the APA. Ch. 324, 60 Stat. 237. At that time, Rule 61 of the Federal Rules of Civil Procedure instructed courts not to disturb a judgment or order unless refusal to do so would be "inconsistent with substantial justice." Fed. Rule Civ. Proc. 61 (1939). The APA picked up on this principle and required courts reviewing agency action to take "due account . . . of the rule of prejudicial error." §706. Taking "due account" of a rule is not literally the same as applying that rule lock, stock, and barrel. The most natural interpretation of the APA's language is thus that reviewing courts should adapt the "rule of prejudicial error" applicable in ordinary civil litigation (also known as the harmless-error rule) to the administrative-law context, which, of course, includes the remand rule.

The FDA's failure to consider marketing plans and its chosen arguments in litigation have set the remand rule and the APA's harmless-error principle in tension. Despite assuring manufacturers in predecisional guidance that their marketing plans would be "critical," the FDA refused to consider respondents' marketing plans when it reviewed their premarket tobacco product applications. 84 Fed. Reg. 50581. Based on its experience, the FDA opined that marketing and access restrictions on flavored e-cigarette products are, as a practical matter, categorically insufficient to sustain an otherwise inadequate application. See App. to Pet. for Cert. 200a, n. xix. The Fifth Circuit held that this about-face was arbitrary and capricious, see 90 F. 4th, at 372–373, and the FDA has "not sought review of the Fifth Circuit's threshold finding of error," Brief for Petitioner 31. Instead, it expands upon an argument it raised before the Fifth Circuit, see En Banc Brief for Respondent in No. 21–60766, p. 29, and contends that its failure to consider marketing plans was harmless error because, subsequent to denying respondents' applications, it issued denial orders to other manufacturers after reviewing marketing plans that were materially indistinguishable from respondents'. See Brief for Petitioner 34–36. That is proof, the FDA says, that reviewing respondents' marketing plans would not have made a difference.

The Fifth Circuit rejected the FDA's harmless-error argument based on our most recent decision invoking the remand rule, *Calcutt* v. *FDIC*, 598 U. S. 623 (2023) (*per curiam*). See 90 F. 4th, at 389–390. In *Calcutt*, after reciting the remand rule in strong terms, we acknowledged that a "remand may be unwarranted . . . [w]here the agency 'was *required*' to take a particular action." 598 U. S., at 630 (quoting *Morgan Stanley Capital Group Inc.* v. *Public Util. Dist. No. 1 of Snohomish Cty.*, 554 U. S. 527, 544 (2008)). The Fifth Circuit interpreted *Calcutt*'s discussion to mean

that there is only one exception to the remand rule. See 90 F. 4th, at 390 ("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"). That is certainly a plausible interpretation of *Calcutt*, but it would imply a need to remand for all but the narrowest category of agency errors, minimizing the role of harmless-error review.

The FDA disagrees with this broad reading of *Calcutt* and cites, among other authorities, our decision in *Sanders*. In that case, we opined that the APA incorporates "the same kind of 'harmless-error' rule that courts ordinarily apply in civil cases." 556 U. S., at 406. That principle, taken to its logical extreme, could permit a reviewing court to sustain a flawed agency decision whenever it finds that the agency would have reached the same result absent the initial error. Understood in that way, harmless error might swallow the remand rule.

There is thus obviously tension between *Calcutt* and *Sanders*, and neither decision sought to harmonize the remand and harmless-error rules. *Calcutt* made no reference to the APA's prejudicial-error provision, and *Sanders* did not discuss the remand rule or even cite *Chenery*.

Commentators have long puzzled over this tension and proposed ways to bridge the divide. See H. Friendly, *Chenery* Revisited: Reflections on Reversal and Remand of Administrative Orders, 1969 Duke L. J. 199, 222–225 (Friendly); N. Bagley, Remedial Restraint in Administrative Law, 117 Colum. L. Rev. 253, 302–307 (2017) (Bagley); C. Walker, Against Remedial Restraint in Administrative Law, 117 Colum. L. Rev. Online 106, 115–120 (2017). And the courts of appeals have apparently developed their own practices to reconcile the remand and harmless-error rules. See Bagley 302, n. 328 (citing cases). We will not attempt to provide a complete answer to this vexing problem here.

For now, we agree with the FDA that the Fifth Circuit

read *Calcutt* too broadly. It has long been accepted, for example, that a remand may not be necessary when an agency's decision is supported by a plethora of factual findings, only one of which is unsound. When it is clear that the agency's error "had no bearing on the procedure used or the substance of [the] decision reached," a remand would be pointless. *Massachusetts Trustees of Eastern Gas & Fuel Associates* v. *United States*, 377 U. S. 235, 248 (1964); see Friendly 210–211 ("*Massachusetts Trustees* v. *United States* . . . might be regarded as a true indentation of *Chenery*, [but] it is an altogether sound one").[9] We do not suggest that this exception and the one recognized in *Calcutt* exhaust the universe of exceptions to the remand rule. But the existence of this exception is sufficient to show that the Fifth Circuit's reading of *Calcutt* went too far.

That said, the FDA's reading of *Sanders* may also be excessive. In an article that the FDA quotes with approval, see Brief for Petitioner 41, Judge Friendly accurately captured the core of the remand rule when he wrote, "[w]here the agency has rested decision on an unsustainable reason, the court should generally reverse and remand even though it discerns a possibility, *even a strong one*, that by another course of reasoning the agency might come to the same result," Friendly 222 (emphasis added). There is an important distinction, if only a subtle one, between this formulation and the FDA's argument that a party attacking

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[9] Despite its holding that *Calcutt* is the sole exception to the remand rule, the Court of Appeals appears to have issued a brief alternative holding at the very end of its opinion. In that short discussion, the court cited Circuit precedent echoing the rule of *Massachusetts Trustees*. See 90 F. 4th, at 390 (citing *United States* v. *Johnson*, 632 F. 3d 912, 930 (CA5 2011)). But the Court of Appeals applied *Massachusetts Trustees* at a high level of generality, and absent any analysis applying *Massachusetts Trustees* to the FDA's failure to consider respondents' marketing plans specifically, we are unable to affirm the decision on that alternative basis.

an agency decision must prove that an error had a "substantial bearing" on the decision. Brief for Petitioner 36–37. And the FDA has not identified any prior case in which we have held that the application of an erroneous understanding of the governing law was harmless because a subsequent agency decision shows that the agency would have reached the same result if it had applied the correct understanding of the law.

The FDA has not asked us to decide the harmless-error question at this juncture. True, in its petition for certiorari, it requested that we "review and *reverse* the Fifth Circuit's holding that the error was not harmless." Pet. for Cert. 18 (emphasis added). But the FDA unmistakably abandoned that full-throated request after we granted certiorari. In its opening brief, the FDA asked that we "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." Brief for Petitioner 38. It reiterated that position in its reply. See Reply Brief 18. And at argument, when asked, the FDA was upfront that it seeks vacatur and remand so the Fifth Circuit can decide the question afresh without relying on its overly expansive reading of *Calcutt*. Tr. of Oral Arg. 55–56. We follow that course.

* * *

For these reasons, we vacate the judgment of the United States Court of Appeals for the Fifth Circuit and remand the case for further proceedings consistent with this opinion.

It is so ordered.

SUPREME COURT OF THE UNITED STATES

No. 23–1038

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

[April 2, 2025]

JUSTICE SOTOMAYOR, concurring.

I join the Court's opinion, as it rightly rejects the contention that the FDA acted arbitrarily and capriciously in denying respondents' applications for premarket approval of their tobacco products. I write separately, however, to clarify one point.

I do not believe the FDA, in the lead up to denying respondents' applications, "was feeling its way toward a final stance and was unable or unwilling to say in clear and specific terms precisely what applicants would have to provide." *Ante*, at 10. Instead, the record shows the agency reasonably gave manufacturers some flexibility as to the forms of evidence that would suffice for premarket approval of their products, while hewing to (and never suggesting it would stray from) its statutory duty to approve only those products that would be "appropriate for the protection of the public health." 21 U. S. C. §387j(c)(2)(A). In light of the statutory text and the well-documented and serious risks flavored e-cigarette products pose to youth, it should have come as no surprise that applicants would need to submit rigorous scientific evidence showing that the benefits of their products would outweigh those risks. See §387j(c)(4).