UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

August Term 2022

Argued: February 6, 2023
Decided: June 16, 2023

No. 21-2426

MAGELLAN TECHNOLOGY, INC.,

Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

On Petition for Review of a Final Marketing Denial Order
by the Food and Drug Administration

Before: JACOBS, PÉREZ, and MERRIAM, *Circuit Judges*.

Petitioner Magellan Technology, Inc. ("Magellan"), the distributor of various electronic nicotine delivery systems ("ENDS") products, petitions for review of a marketing denial order issued by Respondent, the United States Food and Drug Administration (the "FDA"). In September 2021, the FDA denied Magellan's premarket tobacco application, concluding that the application lacked

sufficient evidence to demonstrate that the marketing of Magellan's flavored ENDS products was appropriate for the protection of the public health. Because we conclude that the FDA's denial of Magellan's application did not violate the Administrative Procedure Act and was well within the FDA's statutory authority under the Family Smoking Prevention and Tobacco Control Act, we deny Magellan's petition.

ERIC N. HEYER (Joseph A. Smith, Jessica Tierney, *on the brief*), Thompson Hine LLP, Washington, D.C., *for Petitioner Magellan Technology, Inc.*

DAVID H. HIXSON, Trial Attorney, Consumer Protection Branch (Brian M. Boynton, Principal Deputy Assistant Attorney General, Civil Division, Arun G. Rao, Deputy Assistant Attorney General, Civil Division, Gustav W. Eyler, Director, Consumer Protection Branch, Hilary K. Perkins, Assistant Director, Consumer Protection Branch, *on the brief*), U.S. Department of Justice, Washington, D.C. (Samuel R. Bagenstos, General Counsel, U.S. Department of Health and Human Services, Wendy S. Vicente, Acting Deputy Chief Counsel for Litigation, U.S. Food and Drug Administration, William D. Thanhauser, Associate Chief Counsel, Office of the Chief Counsel, U.S. Food and Drug Administration, Silver Spring, MD, *of counsel*), *for Respondent United States Food and Drug Administration.*

J. Gregory Troutman, Troutman Law Office, PLLC, Louisville, KY, *for Amici Curiae 38 National and State Electronic Nicotine Delivery*

System Product Advocacy Associations, in support of Petitioner.

Mary G. Bielaska, Zanicorn Legal PLLC, New York, NY, *for Amici Curiae Dr. David B. Abrams, Clive D. Bates, and Professor David T. Sweanor, in support of Petitioner.*

Shawn Naunton, Zuckerman Spaeder LLP, New York, NY, *for Amici Curiae Medical and Public Health Groups, in support of Respondent.*

MYRNA PÉREZ, *Circuit Judge*:

This case concerns the United States Food and Drug Administration's (the "FDA") efforts to regulate electronic nicotine delivery systems ("ENDS") products, more commonly known as e-cigarettes. ENDS are a relatively new type of tobacco product that deliver aerosolized liquid containing nicotine derived from tobacco ("e-liquids") when a user inhales. They have rapidly become popular—especially among young people, who have overwhelmingly adopted flavored ENDS products as their tobacco products of choice.

Magellan Technology, Inc. ("Magellan") distributes ENDS products, including replaceable cartridges,[1] also known as "pods." Magellan's pods contain e-liquids at four different nicotine strengths in fruit and dessert flavors—"Mango," "Pretzel Graham," and "Blue Razz"—as well as tobacco and menthol flavors. The FDA differentiates between e-liquids in fruit and dessert flavors ("flavored ENDS products" or "flavored pods") and e-liquids in tobacco and menthol flavors. *See* Joint App'x at 84.

Magellan sought authorization from the FDA to market its ENDS products under the Family Smoking Prevention and Tobacco Control Act (the "TCA"), Pub. L. No. 111-31, 123 Stat. 1776 (2009). The FDA denied Magellan's premarket tobacco application ("PMTA") with respect to its flavored pods, finding insufficient evidence showing that marketing the pods would be appropriate for the protection of the public health, a finding that requires denial of a PMTA under the TCA. *See* 21 U.S.C. § 387j(c)(2)(A). Magellan now petitions for review. It argues that the FDA's denial of its PMTA was arbitrary and capricious because (1) the FDA departed from its stated standard of review without providing notice to

[1] A cartridge is a "small, enclosed unit . . . designed to fit within or operate as part of an electronic nicotine delivery system" that "holds liquid that is to be aerosolized through product use." Joint App'x at 83.

or considering the reliance interests of applicants; and (2) despite previously emphasizing the potential importance of marketing plans to its PMTA assessment, the FDA failed to consider Magellan's. Magellan also argues that the FDA exceeded its statutory authority by requiring applicants to demonstrate that their flavored ENDS products are more effective than tobacco-flavored products at promoting cessation or switching from combustible cigarettes to ENDS products. For the reasons stated herein, we uphold the FDA's decision and deny Magellan's petition.

I. Background

A. Statutory Framework

In enacting the TCA in 2009, Congress found that the use of tobacco products was "the foremost preventable cause of premature death in America" and, in particular, that youth use "is a pediatric disease of considerable proportions." TCA §§ 2(1), (13), 123 Stat. at 1777. To combat the public's use of and dependence on tobacco, the TCA "provide[s] authority to the Food and Drug Administration to regulate tobacco products under the Federal Food, Drug, and Cosmetic Act . . . , by recognizing it as the primary Federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products." *Id.* § 3(1), 123 Stat. at 1781.

The TCA requires the FDA's premarket review of "new tobacco products" (defined in 21 U.S.C. § 387j(a)(1) as, inter alia, tobacco products not commercially marketed in the United States as of February 15, 2007).[2] *Id.* § 387j(a)(2). Accordingly, unless an exemption applies, a manufacturer must submit a PMTA and obtain premarket authorization from the FDA to introduce a new tobacco product into interstate commerce. *Id.* §§ 387j(a)(1)–(2), (c)(1)(A)(i). As relevant here, to obtain FDA approval, an applicant must show that allowing its tobacco product to be marketed would be "appropriate for the public health" ("Appropriate"). *Id.* § 387j(c)(2)(A).

In determining whether the marketing of a tobacco product is Appropriate, the FDA considers the "risks and benefits to the population as a whole, including users and nonusers of the tobacco product." *Id*. § 387j(c)(4). The FDA must take into account "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." *Id*. §§ 387j(c)(4)(A)–(B). Thus, the FDA must weigh the potential

[2] The TCA "grandfathered tobacco products on the market as of February 15, 2007, excusing them from the premarket authorization requirement." *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 13 (D.C. Cir. 2022) (citing 21 U.S.C. § 387j(a)(1)).

benefits of the new tobacco product in promoting smoking cessation against the risks of the product contributing to smoking initiation. *See Avail Vapor, LLC v. FDA*, 55 F.4th 409, 414 (4th Cir. 2022). The FDA bases this finding on "well-controlled investigations" or other "exist[ing] valid scientific evidence . . . which is sufficient to evaluate the tobacco product." 21 U.S.C. §§ 387j(c)(5)(A)–(B).

B. Regulatory Framework

The TCA also empowers the FDA to deem "tobacco products" as being subject to the TCA's requirements. *Id.* § 387a(b). In 2016, the FDA issued a rule deeming all tobacco products to be subject to the requirements of the Federal Food, Drug, and Cosmetic Act, as modified by the TCA. *See* Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products, 81 Fed. Reg. 28,974, 28,975 (May 10, 2016) (codified at 21 C.F.R. §§ 1100, 1140, 1143).

The "Deeming Rule" applied to tobacco products, including ENDS products, which were brought to market after Congress passed the TCA. The practical effect of the Deeming Rule was that ENDS products already on the market could no longer be sold legally without the FDA's approval, as they were

now subject to the TCA's premarket authorization requirement. *See* Joint App'x at 78. Instead of requiring ENDS applicants to recall their newly deemed tobacco products, however, the FDA permitted them to continue marketing their products pending review. The deadline for submission of PMTAs for all deemed tobacco products was September 9, 2020.

C. The FDA's Pre-Deadline Preparation

In anticipation of the application deadline, the FDA published several nonbinding guidance documents aimed at helping ENDS applicants prepare their PMTAs. Relevant here, the FDA issued one such document in June 2019 (the "June 2019 Guidance"), which was intended to "assist applicants in submitting an ENDS PMTA that could support a showing that the marketing of a new tobacco product would be [Appropriate]." Joint App'x at 211. To that end, the FDA explained that, as part of its consideration, it would review the "health risks associated with changes in tobacco product use behavior (e.g., initiation, switching, dual use, cessation)" and recommended that applicants compare their products with other products in relevant categories. *Id.* at 212–13.

The June 2019 Guidance also outlined what could be considered sufficient scientific evidence demonstrating that an ENDS product was Appropriate. The FDA acknowledged that "[g]iven the relatively new entrance of ENDS on the U.S.

market, . . . limited data may exist from scientific studies and analyses." *Id.* at 211. As a result, the FDA would not limit its review to "well-controlled investigations," such as clinical randomized control trials ("RCTs") and longitudinal cohort studies but would consider other valid scientific evidence as well. *Id.* The FDA cautioned, however, that "[n]onclinical studies alone are generally not sufficient to support a determination that permitting the marketing of a tobacco product would be [Appropriate]." *Id.*

The FDA also issued internal guidance (that was promptly superseded) detailing how it intended to manage the PMTA review process. Central to Magellan's claims is the FDA's July 2021 internal memorandum (the "July 2021 Memorandum"). The July 2021 Memorandum laid out the FDA's plan "to take final action on as many [non-tobacco flavored ENDS product] applications as possible by September 10, 2021." *Id.* at 46. Specifically, it stated that the FDA would engage in a preliminary "fatal flaw review" of the non-tobacco-flavored ENDS PMTAs not yet in the substantive scientific review phase. The FDA would review these submissions for "fatal flaw[s]," which it identified as the absence of an RCT or a longitudinal cohort study. *Id.* at 46–47. "[A]ny application lacking this evidence w[ould] likely receive a marketing denial order . . . ." *Id.* at 47.

The July 2021 Memorandum was superseded by another internal memorandum (the "August 2021 Memorandum"). *Id*. at 58–59. The August 2021 Memorandum stated that, in addition to RCTs and longitudinal cohort studies, the FDA would also consider evidence from other study types, provided that those studies "could reliably and robustly assess behavior change (product switching or cigarette reduction) over time, comparing users of flavored products with those of tobacco-flavored products." *Id.* at 59 n.ix.

D. Procedural History

Magellan submitted a PMTA for various ENDS products, including its flavored pods ("Mango," "Pretzel Graham," and "Blue Razz"), on September 8, 2020, which was after the FDA issued the June 2019 Guidance, but before it internally circulated the July 2021 Memorandum.

To demonstrate that its ENDS products were Appropriate, Magellan submitted four nonclinical studies: (1) a focus group of only two dozen subjects, in which participants were asked about their perceptions of and intentions for ENDS products generally, and about the packaging and marketing of Magellan's specific products; (2) a two-week online diary study that examined the behavior of only twenty users of Magellan ENDS products, of whom eighteen completed the study; (3) a "human factors stud[y]" involving only fifteen participants that

aimed to measure consumer comprehension of product labeling and instructions for Magellan's products; and (4) an online cross-sectional perception and intent survey of 400 current smokers and 1,002 nonsmokers.

Notably, none of Magellan's studies robustly "evaluat[ed] the effects of the ENDS on users, including effects on initiation, switching behavior, cessation, and dual use; and on nonusers' initiation of the product," as the June 2019 Guidance recommended. Joint App'x at 237. Three of Magellan's four studies included no more than two dozen participants. The diary study—the only study that documented actual ENDS usage—was completed by just eighteen participants over a two-week period. Although it reflected some participants' intent to use ENDS products to quit smoking combustible cigarettes, it did not measure the actual effectiveness of Magellan's products at promoting cessation. The focus group study and online survey similarly focused on participants' intent with respect to ENDS products rather than outcomes.

As part of its PMTA, Magellan also submitted a marketing plan outlining its strategy to restrict youth access to its products and to limit youth exposure to

its marketing, as well as a systematic literature review that summarized scientific data about the use of ENDS products.

On September 8, 2021, the FDA issued a Marketing Denial Order (an "MDO") to Magellan for its flavored pods.[3] The FDA concluded that Magellan's PMTAs "lack[ed] sufficient evidence demonstrating that [its] flavored ENDS will provide a benefit to adult users that would be adequate to outweigh the risks to youth." *Id.* at 7. Specifically, the FDA determined that Magellan had not shown the comparative efficacy of its flavored ENDS products over tobacco-flavored ENDS products in helping smokers completely switch to ENDS products or stop smoking altogether.

Because the FDA found Magellan's evidence to be "insufficient," it did not proceed "to assess other aspects of the[] application[]." *Id.* at 8. After the FDA issued the MDO, Magellan timely petitioned this Court for review.

II. Standard of Review

The TCA incorporates by reference the standard of review established by the Administrative Procedure Act (the "APA"). *See* 21 U.S.C. § 387l(b) (citing 5 U.S.C. § 706(2)(A)). Under the APA, we must "hold unlawful and set aside

[3] As of the date of Magellan's opening brief, the FDA had not issued marketing decisions for Magellan's tobacco- and menthol-flavored pods.

agency action, findings, and conclusions found to be . . . arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Agency action is "arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

"Under the arbitrary-and-capricious standard, judicial review of agency action is necessarily narrow. A reviewing court may not itself weigh the evidence or substitute its judgment for that of the agency." *Islander E. Pipeline Co. v. McCarthy*, 525 F.3d 141, 150 (2d Cir. 2008) (citations omitted); *see also FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021) ("A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision.").

Judicial review of agency action incorporates the APA's prejudicial error rule. *See* 5 U.S.C. § 706. Under the prejudicial error rule, a court will not disturb

an agency's decision if it determines that the outcome of the agency action would be the same absent agency error. *See Nat'l Ass'n of Home Builders v. Defs. of Wildlife*, 551 U.S. 644, 659–60 (2007) ("'In administrative law, as in federal civil and criminal litigation, there is a harmless error rule.'" (quoting *PDK Lab'ys Inc. v. U.S. Drug Enf't Admin.*, 362 F.3d 786, 799 (D.C. Cir. 2004))); *see also Green Island Power Auth. v. FERC*, 577 F.3d 148, 165 (2d Cir. 2009) ("[W]e will not disturb [agency action] if we can determine that the outcome . . . w[ould] be the same absent [agency] error."). "[T]he burden of showing that an error is harmful normally falls upon the party attacking the agency's determination." *Shinseki v. Sanders*, 556 U.S. 396, 409 (2009).

III. Discussion

A. Magellan's Challenge to the FDA's Standard of Review

Contrary to Magellan's claims, the FDA did not apply a new standard of review in evaluating Magellan's PMTA. Therefore the FDA was not obligated to notify Magellan or consider its reliance interests, as it would be if the FDA had applied a new standard of review.

When an agency changes course, it must provide notice, *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("An agency may not . . . depart from a prior policy *sub silentio* or simply disregard rules that are still on the

books."), and consider the reliance interests of the governed parties, *Dep't of Homeland Sec. v. Regents of Univ. of Cal.*, 140 S. Ct. 1891, 1913 (2020) (where an agency policy has engendered a reliance interest among the governed, the agency must be "cognizant" of that fact and take potential reliance interests "into account" (quotation marks omitted)).

But here the record shows that the FDA never changed its position: that it might accept evidence other than long-term studies to demonstrate that an ENDS product was Appropriate *if* that evidence had sufficient scientific underpinnings. Consistent with its position, the FDA considered Magellan's weak scientific evidence and found it insufficient to support an Appropriate finding.

In support of its argument, Magellan points to a statement in the June 2019 Guidance that the FDA did not "expect that applicants will need to conduct long-term studies to support an application"; but this out-of-context fragment does very little to help Magellan. Joint App'x at 212. There is no dispute that the June 2019 Guidance contemplated that evidence besides long-term studies *might* be sufficient, but it did not guarantee that other scientific evidence *would be* sufficient. *See Prohibition Juice Co. v. FDA*, 45 F.4th 8, 21 (D.C. Cir. 2022) ("The FDA did not reverse course. . . . The text of the FDA's 2019 Guidance makes that clear."). The

June 2019 Guidance consistently used conditional language when describing acceptable evidence (as set out in the margin[4]). It also cautioned that "[n]onclinical studies alone are generally not sufficient to support a determination that permitting the marketing of a tobacco product would be [Appropriate]." Joint App'x at 211.

According to Magellan, the July 2021 Memorandum heightened the standard of review by saying that the FDA would conduct a "fatal flaw" analysis for the absence of an RCT or longitudinal cohort study. However, the July 2021 Memorandum was circulated internally and superseded before Magellan received its MDO. *See Avail Vapor*, 55 F.4th at 424 (reasoning that "internal documents [are] unlikely to create reliance interests" and the July 2021 Memorandum was "rescinded . . . or superseded" by the time the FDA issued its MDO).

[4] Specifically, the June 2019 Guidance states:

- Other evidence might be acceptable if "it is valid scientific evidence sufficient to demonstrate that the marketing of a product would be [Appropriate]." Joint App'x at 211.
- "[I]n some cases, it may be possible to support a marketing order for an ENDS product without conducting new nonclinical or clinical studies." *Id.* at 245.
- "In cases where a product has not yet been sufficiently reviewed, new nonclinical and clinical studies may be necessary to support a marketing order." *Id.*
- "[P]ublished literature reviews . . . or reports may be acceptable to support a PMTA, but are considered a less robust form of support . . . ." *Id.* at 246.

Nor does the record support Magellan's contention that the FDA surreptitiously applied the July 2021 Memorandum's "fatal flaw" analysis to Magellan's PMTA notwithstanding that the July 2021 Memorandum was superseded shortly after its internal circulation. Instead, the record shows that the FDA considered Magellan's evidence and found it insufficient. Specifically, the FDA's Technical Project Lead ("TPL"), a document Magellan received with the MDO, identified deficiencies in the evidence Magellan submitted, which led the FDA to conclude that Magellan's evidence was "not adequate" to support an Appropriate finding. Joint App'x at 38. This analysis would have been unnecessary had the FDA engaged in a fatal flaw review because the FDA could have denied the application solely on the grounds that it lacked an RCT or longitudinal cohort study.

Given that the FDA did not impose a new evidentiary standard on Magellan, the FDA did not need to provide notice or consider its reliance interests. We therefore conclude that the FDA did not act arbitrarily or capriciously. *See Prohibition Juice*, 45 F.4th at 20–21; *see also Avail Vapor*, 55 F.4th at 422; *Liquid Labs LLC v. FDA*, 52 F.4th 533, 539–42 (3d Cir. 2022); *Gripum, LLC v. FDA*, 47 F.4th 553,

559–60 (7th Cir. 2022), *cert. denied*, No. 22-708, 2023 WL 3440578, at *1 (U.S. May 15, 2023).

B. Magellan's Challenge to the FDA's Failure to Consider Its Marketing Plan

Even assuming that the FDA's decision not to evaluate Magellan's marketing plan as part of its PMTA review was error, any such error was harmless because it did not affect the outcome of the FDA's review.[5]

As previously stated, agency action is arbitrary and capricious when the agency "entirely failed to consider an important aspect of the problem," *State Farm*, 463 U.S. at 43, or when the decision did not include "a consideration of the relevant factors," *id.* (quotation marks omitted). In Magellan's TPL, the FDA noted that evidence regarding risk to youth "would . . . be evaluated to determine that the totality of the evidence supports a marketing authorization" and that such an assessment would "include[] evaluating the appropriateness of the proposed marketing plan." Joint App'x at 35. However, in the same document, the FDA stated that "for the sake of efficiency," it had "not evaluated any marketing plan[]

[5] Magellan also argues that the FDA's failure to consider its other evidence—its four studies and literature review—was arbitrary and capricious. But as discussed above, the FDA did consider this evidence and concluded that it was "not sufficiently strong to support the benefit to adult smokers of using these flavored ENDS because it does not evaluate product switching or cigarette reduction based on flavor type to enable comparisons between tobacco and other flavors." Joint App'x at 38.

submitted with the[] application[]." *Id.* at 35 n.xix. Given that the FDA itself identified the marketing plan as a relevant factor to its determination of whether Magellan's flavored pods would be marketed, it was likely error that the FDA did not review the marketing plan. *See Green Island Power Auth.*, 577 F.3d at 158.

The potential error, however, did not affect the outcome of the FDA's review of Magellan's PMTA because there is no indication that the marketing plan would have made up for the PMTA's other defects. *See Shinseki*, 556 U.S. at 406; *see also Green Island Power Auth.*, 577 F.3d at 165. According to Magellan, the focus of its marketing plan was to "limit[] youth access and exposure" to ENDS products and marketing material principally through the implementation of various age verification provisions. Pet'r's Br. at 37–38. But the FDA had previously stated that similar age verification strategies "would not be sufficient to address youth use of [ENDS] products." Joint App'x at 118. Magellan does not explain how its marketing strategies differ from the similar measures the FDA had uniformly rejected or why conditions had changed such that the measures would now be effective. Thus, Magellan has not shown that the FDA would have reached a different result had it reviewed Magellan's marketing plan. *See Bechtel v. Admin. Rev. Bd., U.S. Dep't of Lab.*, 710 F.3d 443, 449 (2d Cir. 2013) (finding legal error

immaterial where petitioner's failure to establish a needed element was a sufficient reason to rule against his claim); *see also Prohibition Juice*, 45 F.4th at 25 ("Where a petitioner had ample opportunity yet failed to show that an agency error harmed it, vacatur and remand to give the agency an opportunity to fix the error is unwarranted."); *Liquid Labs*, 52 F.4th at 543 ("The FDA's decision to decline to review [petitioner's] marketing plan does not change the result because there is no indication the plan would have made up for the deficiencies the FDA identified in [petitioner's] applications."). Accordingly, any error was harmless.

C. Magellan's Challenges to the FDA's Statutory Authority

The FDA was well within its statutory authority to impose on applicants a comparative efficacy requirement—the requirement that applicants demonstrate their flavored ENDS products are more effective than tobacco-flavored products at promoting cessation or switching from combustible cigarettes to ENDS products.

The TCA expressly contemplates a comparative analysis among tobacco products in the context of evaluating whether the products are Appropriate. The TCA states that PMTAs must include "full reports of all information . . . concerning investigations which have been made to show the health risks of such tobacco product and *whether such tobacco product presents less risk than other tobacco products*."

21 U.S.C. § 387j(b)(1)(A) (emphasis added). The TCA also requires that the FDA deny PMTAs where "there is a lack of a showing that permitting such tobacco product to be marketed would be [Appropriate]." *Id.* § 387j(c)(2)(A).

Because the TCA instructs the FDA to consider this type of comparative evidence, we conclude that the FDA was well within its authority to require applicants to submit it. *See Prohibition Juice*, 45 F.4th at 19 ("[T]he [TCA] not only allows but expressly instructs the FDA to consider evidence regarding just the comparison that the manufacturers say the FDA lacks statutory authority to make."); *Avail Vapor*, 55 F.4th at 427 ("The TCA explicitly contemplates that FDA must embark on a comparative inquiry before allowing any marketing of a new tobacco product."). Finally, we also reject the argument that the comparative efficacy requirement would lead to irrational results.[6]

[6] First, Magellan contends that by requiring applicants to demonstrate their flavored ENDS products are more effective than tobacco-flavored products at promoting cessation or switching from combustible cigarettes to ENDS products, the FDA more rigorously regulates flavored ENDS products, and this is irrational. But this is not irrational. The FDA found that flavored ENDS products pose a much greater risk of youth uptake than tobacco and menthol-flavored ENDS products do. Given the greater risk, it is appropriate that flavored ENDS products are subject to higher standards than their tobacco and menthol-flavored counterparts. Second, Magellan argues that the comparative efficacy requirement leads to flavored ENDS products being regulated more rigorously than nicotine replacement therapy drugs and modified risk tobacco products. This is demonstrably false. These more heavily regulated tobacco products are subject to entirely distinct statutory provisions, which renders the evidentiary standards different and Magellan's contrast inapposite. At bottom, we need not consider these arguments at all because the TCA expressly empowers the FDA to perform the comparative analysis with which Magellan takes issue.

* * *

For the foregoing reasons, we **DENY** Magellan's petition for review.[7]

[7] In denying Magellan's petition for review, we join the majority of our sister circuits who have considered these issues. *See Avail Vapor*, 55 F.4th at 428; *Liquid Labs*, 52 F.4th at 545; *Gripum,* 47 F.4th at 561; *Prohibition Juice*, 45 F.4th at 26.