No. 21-60766 consolidated with No. 21-60800

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

WAGES AND WHITE LION INVESTMENTS, L.L.C., doing business as TRITON DISTRIBUTION,

Petitioner,

v.

FOOD & DRUG ADMINISTRATION,

Respondent.

On Petition for Review of a Final Marketing Denial Order of the U.S. Food and Drug Administration

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OPPOSITION TO PETITION FOR REHEARING EN BANC

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INTRODUCTION

Petitioners challenged orders of the U.S. Food and Drug Administration (FDA) denying their applications for authorization to market certain "e-cigarette" products in flavors that are particularly popular among youth. The panel upheld FDA's marketing denial orders because the evidence supported FDA's determination that the risks that petitioners' products pose to youth outweigh the potential benefit for adults seeking to stop or significantly reduce smoking combustible cigarettes. FDA reasonably concluded that petitioners failed to show that the marketing of their products would be appropriate for the protection of the public health, which is the showing required by the governing statute.

The panel decision is correct and consistent with decisions recently issued by the D.C. Circuit and Seventh Circuit. *Prohibition Juice Co. v. FDA*, 45 F.4th 8 (D.C. Cir. 2022); *Gripum, LLC v. FDA*, 47 F.4th 553 (7th Cir. 2022). There is no disagreement among the circuits as to the central issues presented by FDA's marketing denial orders. Although there is some disagreement with respect to a narrow question—whether FDA was required to consider applicants' plans to reduce youth use through measures such as online age-verification and advertising restrictions—the

only court to find error in FDA's approach expressly distinguished this case because FDA had reviewed a summary of the marketing plans at issue. *See Bidi Vapor LLC v. FDA*, -- F.4th --, No. 21-13340, 2022 WL 3594073, at *10 (11th Cir. Aug. 23, 2022).

Furthermore, as in *Prohibition Juice*, "petitioners here made no serious argument that the FDA's failure to consider their marketing plans was prejudicial, as required for them to obtain relief under the [Administrative Procedure Act (APA)]." *Prohibition Juice*, 45 F.4th at 27 (Katsas, J., concurring). In guidance issued in 2020, FDA comprehensively reviewed marketing and sales access restrictions and found them insufficient to prevent youth access to flavored e-cigarettes. *See* Panel Op. 23-24; FDA, *Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry* (2020) (2020 Guidance).[1] Petitioners' assertion that their marketing plans contained "novel features," Pet. 7, is meritless and also forfeited by their failure to make that argument before the panel. Whereas certain e-cigarette companies "are developing novel

[1] https://go.usa.gov/xeG3C.

technologies" such as "facial recognition software to unlock their products," *Prohibition Juice*, 45 F.4th at 16, the marketing and sales access restrictions that petitioners describe, *see* Pet. 7, "are not materially different from those the FDA had previously found insufficient to stem the surge in youth e-cigarette use," *Prohibition Juice*, 45 F.4th at 25.

Petitioners' reliance on the stay order entered in this case is misplaced. The merits panel was not bound by that preliminary ruling, which entered a stay pending plenary review. *Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130 (5th Cir. 2021). Moreover, after the motions panel granted that stay, a motions panel of the Sixth Circuit denied another manufacturer's analogous stay motion. *Breeze Smoke, LLC v. FDA*, 18 F.4th 499 (6th Cir. 2021). That manufacturer then filed a stay application with Circuit Justice Kavanaugh, urging that a stay was warranted for the reasons set out by the motions panel in this case. Justice Kavanaugh referred the stay application to the full Court which, after considering FDA's response, denied the application without recorded dissent. *Breeze Smoke, LLC v. FDA*, 142 S. Ct. 638 (2021).

Petitioners do not identify any issue warranting consideration by the full Court, and their petition should be denied.

BACKGROUND

The Family Smoking Prevention and Tobacco Control Act (TCA or Act) makes it unlawful for a manufacturer to market a new tobacco product without FDA authorization. 21 U.S.C. § 387j(a)(1)-(2). The Act requires FDA to deny an application to market a new tobacco product unless FDA finds that marketing the product would be "appropriate for the protection of the public health," taking into account the impact on both nonusers and existing users of tobacco products. *Id.* § 387j(c)(2), (4). Because virtually all new users of tobacco products are youth, *see* TCA, Pub. L. No. 111-31, § 2(4), 123 Stat. 1776, 1777 (2009), FDA weighs (among other things) the risk that a new tobacco product will promote youth initiation and use against the product's potential for helping adults who smoke combustible cigarettes switch to a less dangerous alternative.

The new tobacco products at issue here are e-cigarette products. E-cigarettes deliver nicotine, which is "among the most addictive substances used by humans," "by vaporizing a liquid that includes other chemicals and flavorings." *Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). In September 2021, FDA denied petitioners' applications to market e-cigarette liquids in flavors such as sour grape, pink lemonade,

peachy strawberry, milk & cookies, and pound cake. Panel Op. 6-7. In finding insufficient evidence that the marketing of these products would be appropriate for the protection of the public health, *see* A96-97; A148-49, FDA cited the extensive and well-documented evidence that flavors encourage youth to begin experimenting with e-cigarettes and promote more frequent and sustained use, *see* A88-89; A140-41. In a 2016-2017 study, "93.2% of youth and 83.7% of young adult [e-cigarette] users reported that their first [e-cigarette] was flavored," and 71% said they used e-cigarettes "because they come in flavors I like." A88-89; A140-41. Similarly, in 2020, 84.7% of high school e-cigarette users and 73.9% of middle school users reported using a flavored product. A88; A140. The majority of middle and high school users (over 70%) reported using fruit flavored e-cigarettes, while others used flavors including "candy, dessert, or other sweets." A88; A140.

The risks that flavored e-cigarettes pose for youth greatly exceed the risks of tobacco-flavored e-cigarettes, which are far less popular with youth, A85, A88-89; A137, A140-41, and for which FDA has in some cases granted marketing authorization, *see infra* p.14. FDA found that the evidence did not show that petitioners' flavored products would provide a

countervailing benefit by helping adults reduce or cease their use of combustible cigarettes as compared to tobacco-flavored products. Petitioners' own literature review acknowledged that "there is not enough evidence from well-designed studies to determine whether e-cigarette flavors aid in smoking cessation." A472. FDA also looked at the cross-sectional survey results and other data submitted by petitioners and found that they did not provide robust and reliable evidence of a benefit to adult smokers. *See* A94; A146; *see also* A124-25. Accordingly, FDA denied petitioners' applications for authorization to market their flavored e-cigarette products.

ARGUMENT

The Petition Does Not Present Any Issue Warranting En Banc Review.

A. The Only Issue As To Which There Is Disagreement Among The Circuits Is Not Directly Presented Here And, In Any Event, Does Not Warrant Rehearing En Banc.

The panel correctly upheld FDA's orders denying petitioners' applications for authorization to market e-cigarettes in flavors that particularly appeal to children. There is no disagreement among the circuits as to the central issues presented by FDA's marketing denial orders. Extensive evidence discussed by FDA shows that flavoring is the

principal driver of the epidemic of youth e-cigarette use. *See, e.g.*, *Prohibition Juice Co. v. FDA*, 45 F.4th 8, 11, 13 (D.C. Cir. 2022) (describing such evidence). FDA accordingly requires applicants seeking to market flavored e-cigarettes to demonstrate that their products provide a countervailing public-health benefit that exceeds the benefit offered by tobacco-flavored products, which do not present the same risk of youth use. *See id*. at 13. Here, and in similar cases, FDA found that the applicants failed to make that showing. Indeed, petitioners' own literature review conceded that "there is not enough evidence from well-designed studies to determine whether e-cigarette flavors aid in smoking cessation." A472.

The only issue as to which there is disagreement among the circuits is whether FDA was required to consider the particulars of applicants' marketing plans, and whether any error in failing to do so was harmless in light of FDA's conclusion in its 2020 guidance that marketing and sales access restrictions are insufficient to prevent youth from obtaining and using e-cigarettes. In the subsequent determinations made here and in similar cases, FDA acknowledged that it was "theoretically possible that significant mitigation efforts could adequately reduce youth access and appeal such that the risk for youth initiation would be reduced," but FDA

explained that it was not reviewing applicants' marketing plans because it was "not aware of access restrictions that, to date, have been successful in sufficiently decreasing the ability of youth to obtain and use" flavored e-cigarettes. A93 n.xix; A145 n.xix. Similarly, FDA noted that it had not identified "advertising and promotion restrictions that would decrease appeal to youth to a degree significant enough to address and counter-balance the substantial concerns, and supporting evidence, discussed above regarding youth use." A93 n.xix; A145 n.xix.

The panel held that FDA did not err in taking this approach and, alternatively, that any error was harmless given the findings made in the 2020 guidance. *See* Panel Op. 23-24. The D.C. Circuit assumed (without deciding) that FDA erred in not reviewing the marketing plans but agreed that any error was harmless. *See Prohibition Juice*, 45 F.4th at 24-25; *see also id.* at 27 (Katsas, J., concurring in the harmless-error ruling). While the Eleventh Circuit disagreed as to whether FDA needed to review the marketing plans, it expressly distinguished this case on the grounds that FDA had reviewed a summary of petitioners' plans. *Bidi Vapor LLC v. FDA*, -- F.4th --, No. 21-13340, 2022 WL 3594073, at *10 (11th Cir. Aug. 23, 2022); *see also* A378 (summary describing petitioners' plans to limit

advertising on social media, radio, and television and to use age-verification technologies in connection with online sales). Accordingly, this case does not implicate the shallow disagreement among the circuits over the need for FDA to review marketing plans.[2]

Furthermore, as in *Prohibition Juice*, "petitioners here made no serious argument that the FDA's failure to consider their marketing plans was prejudicial, as required for them to obtain relief under the APA." *Prohibition Juice*, 45 F.4th at 27 (Katsas, J., concurring). Petitioners implicitly acknowledge that the access restrictions proposed in their marketing plans—such as "online sales restricted to adults verified through independent, third-party age verification and sales quantity limits," Pet. 7—are not materially different from the restrictions addressed in the 2020 guidance. The 2020 guidance explained that, in 2019, youth e-cigarette use hit the highest levels ever recorded, despite manufacturer safeguards such as age-verification technology for online sales, enhanced monitoring of retailer compliance with age-verification and sales restrictions, contractual

[2] The petitioner in *Gripum* did not object to FDA's failure to consider its marketing plan, and the court did not reach that question. *See Gripum, LLC v. FDA*, 47 F.4th 553, 558 n.1 (7th Cir. 2022).

penalties for retailers that failed to comply with such requirements, and limits on the quantity of e-cigarettes that a customer could purchase within a particular time period. *See* 2020 Guidance 6-8. As the panel explained, FDA concluded in the 2020 guidance that such restrictions are insufficient to prevent underage use:

> FDA has been focusing enforcement efforts on age verification as a strategy to address youth use of tobacco products, and FDA continues to enforce age restrictions. However, FDA believes that age verification alone is not sufficient to address this issue, given the most recent data that youth use of [e-cigarette] products continues to increase. FDA determined that focusing on how the product was sold would not be sufficient to address youth use of these products given the many sources of products available for youth access. The reality is that youth have continued access to [e-cigarette] products in the face of legal prohibitions and even after voluntary actions by some manufacturers.

Panel Op. 23 (quoting 2020 Guidance 44).

Whereas certain e-cigarette companies "are developing novel technologies" such as "facial recognition software to unlock their products," *Prohibition Juice*, 45 F.4th at 16, petitioners conceded in their panel briefing that their marketing plans made no such technological proposals. *See* Reply Br. 21 n.6 (indicating that petitioners proposed to sell

bottled e-liquids that can be used with any open-system device, regardless of whether it has a locking mechanism).

In their rehearing petition, petitioners nonetheless assert that their marketing plans contained "novel features, such as not using influencers and limiting social media posts to product imagery only without human models." Pet. 7. That argument is both forfeited and meritless. Petitioners' panel briefs did not even mention these features of their marketing plans, much less claim they were novel. Br. 13, 32; Reply Br. 18-25. The panel thus explained that "nothing in Petitioners' briefing to this court indicates that their marketing plan was in fact unique." Panel Op. 23.

There is in any event nothing novel about proposals to limit the way tobacco products are advertised and promoted. Congress itself found that "efforts to restrict advertising and marketing of tobacco products have failed adequately to curb tobacco use by adolescents." Panel Op. 20 (quoting TCA § 2(6), 123 Stat. at 1777). And the 2020 guidance explained that youth use had surged despite FDA's crackdown on manufacturers that advertised e-liquids resembling kid-friendly products or relied on online posts by social media influencers on the companies' behalf. *See* 2020 Guidance 6-8. The marketing plans at issue here thus were "not materially

different from those the FDA had previously found insufficient to stem the surge in youth e-cigarette use." *Prohibition Juice*, 45 F.4th at 25.

The contrary view of the majority in *Bidi Vapor* is based on a different assessment of the facts, not a different view of the law. As petitioners note, *Bidi Vapor* "recit[ed] an identical formulation of the test" for harmless error as the panel in this case. Pet. 9. Applying that standard, the dissenting judge in *Bidi Vapor* agreed with the panel majority here. *Bidi Vapor*, 2022 WL 3594073, at *12, 15-19 (Rosenbaum, J., dissenting). The difference in views distills to a factual dispute as to whether FDA's consideration of the marketing plans would inform its view of the "likelihood that those who do not use tobacco products will start using such products." Pet. 5 (quoting *Bidi Vapor*, 2022 WL 3594073, at *7). The panel in this case, like the D.C. Circuit in *Prohibition Juice*, correctly concluded that further consideration of the marketing plans would not have any bearing on FDA's assessment of the risk of youth use. Panel Op. 23; *Prohibition Juice*, 45 F.4th at 24-25.

Petitioners emphasize that an error is not harmless in situations "[w]here the agency's failure 'plainly affected the procedure used.'" Pet. 8 (quoting *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 215 (5th Cir. 1979)). But

review of the marketing plans would not implicate a different procedure. This case is readily distinguishable from *Steel Corp.*, in which this Court declined to "assume that there was no prejudice" when the agency's error as to the need for notice-and-comment procedures deprived interested parties of the opportunity to submit comments before the rule was promulgated. *Steel Corp.*, 595 F.2d at 215. Here, the only thing that petitioners claim the agency would need to do differently on remand is to consider the details of the marketing plans. And because "[t]he measures [petitioners] highlight in their marketing plans are not materially different from those the FDA had previously found insufficient to stem the surge in youth e-cigarette use," such further consideration would have no effect on the outcome of these proceedings. *Prohibition Juice*, 45 F.4th at 25.

B. Petitioners' Legal Arguments Rest On Their Misunderstanding Of The Record.

Although petitioners purport to raise various issues of law in support of rehearing, their arguments rest on a misunderstanding of the record.

1. Petitioners assert that reliance on the 2020 guidance is a "*post hoc* rationalization." Pet. 6. But the 2020 guidance predates the marketing denial orders at issue here; thus, the conclusions that FDA reached in the

2020 guidance properly informed FDA's subsequent determinations and were appropriately considered by the panel.

Similarly, petitioners are wrong to characterize FDA's approach to the marketing plans as a failure to consider an "important aspect of the problem." *Michigan v. EPA*, 576 U.S. 743, 752 (2015). As discussed above, FDA considered the marketing plans' relevance in light of its prior experience with marketing restrictions. Petitioners miss the point when they note that FDA has described marketing restrictions as a "critical" element of an application to market a new tobacco product. Pet. 10 (quoting A93 n.xix, A145 n.xix.). FDA has made clear that such restrictions are a necessary, but not sufficient, part of an application. Thus, when FDA has granted authorization to market tobacco-flavored e-cigarette products (which are relatively unpopular with youth), it has required the manufacturers to have measures in place to restrict youth access. *See* FDA, *Technical Project Lead Review for Applications Submitted By R.J. Reynolds Vapor Company* 4, 18-20 (Oct. 12, 2021).[3] But for flavored products like petitioners'—which are especially popular among youth—FDA has

[3] https://go.usa.gov/xef5N.

determined that known marketing and access restrictions are insufficient to overcome youth demand for such products or the ability of youth to obtain access despite such restrictions.[4]

2. Petitioners are likewise mistaken to assert that FDA's review of their evidence marked a departure from guidance that FDA provided in 2019. In denying petitioners' applications, FDA explained that petitioners' own literature review found that "there is not enough evidence from well-designed studies to determine whether e-cigarette flavors aid in smoking cessation." A472. FDA further concluded (among other things) that petitioners' cross-sectional survey data did not suffice to demonstrate that their flavored products would provide a benefit for adult smokers of combustible cigarettes that is sufficient to outweigh the serious risks for youth. FDA explained that "[u]ptake and transition to [e-cigarette] use is a

[4] Petitioners' observation that the 2020 guidance focused on cartridge-type devices, *see* Pet. 6, is immaterial because the evidence shows that youth migrated to other device types after FDA increased enforcement against cartridge-based devices. *See* Panel Op. 15-16 (holding that FDA reasonably concluded that "what truly impacts youth smokers is flavor preference, not device preference"); *Prohibition Juice*, 45 F.4th at 26 (upholding FDA's conclusion that "youth preferences for different device types are 'fluid'" and that the migration of youth to different device types "'underscores the fundamental role of flavor in driving appeal'").

behavioral pattern that requires assessment at more than one time point." A94; A146. A single data collection, like petitioners' surveys, "does not enable reliable evaluation of behavior change over time" and therefore does not provide a sufficiently robust measure of the products' potential benefits to outweigh their well-documented risks. A94; A146; *see* A124-25. FDA thus determined that petitioners had not carried their burden of showing that the marketing of their products would be appropriate for the protection of the public health. A96-97; A148-49.

FDA's evaluation of petitioners' evidence was consistent with the agency's prior guidance and the Act's requirements. Petitioners contend that FDA denied their applications based on the absence of long-term studies of a type that FDA's 2019 guidance stated would not be required. *See* Pet. 13-14. But that position mischaracterizes both the 2019 guidance and the agency's denial orders. As the panel concluded, Panel Op. 16-18, and as the Seventh Circuit recently explained, the 2019 guidance "indicated only that '[FDA] *might* accept evidence other than long-term studies, if that evidence had sufficient scientific underpinnings.'" *Gripum, LLC v. FDA*, 47 F.4th 553, 560 (7th Cir. 2022) (quoting *Breeze Smoke, LLC v. FDA*, 18 F.4th 499, 506 (6th Cir. 2021)). FDA "nowhere guarantee[d] that unspecified

other forms of evidence would necessarily be sufficient—only that they might be." *Id.* (quoting *Prohibition Juice*, 45 F.4th at 21).

Contrary to petitioners' contention, the panel did not apply a novel "'conditional language' exception" to the rule that agencies must provide fair notice of what is required. Pet. 13 (capitalization omitted). Rather, the panel engaged in a close reading of the 2019 guidance and determined that it provided fair notice of the standard that FDA applied to petitioners' applications. *See* Panel Op. 18-19. Consistent with that guidance, FDA considered whether petitioners' other forms of evidence sufficed to make the statutorily required showing. Panel Op. 19 (finding FDA's review of petitioner's evidence "entirely consistent with FDA's prior statements").

As the panel correctly observed, "[t]he fact that Petitioners presented other scientific evidence does not make that scientific evidence valid." Panel Op. 19. The "agency's finding that the evidence was insufficiently rigorous" in a given case "does not reflect a changed standard, but the manufacturers' failure to meet the standard the agency consistently applied." *Prohibition Juice*, 45 F.4th at 21. FDA considered the evidence that petitioners submitted and reasonably concluded that "there were strong reasons to doubt" the results. Panel Op. 13. Contrary to petitioners'

contention, Pet. 12-13, the panel's review of this evidence and its conclusion that FDA "did not act arbitrarily in concluding that Vapetasia's survey 'is not sufficient to show a benefit to adult smokers'" is not a *post hoc* rationalization but simply a determination that the agency's conclusion was reasonable. Panel Op. 13.

As the foregoing shows, the contrary conclusion reached by the motions panel and the dissent in this case results not from a different view of the applicable legal standard but from a different view of the record. *See* Panel Op. 18. The panel's view of these questions accords with the view of the majority of the courts to consider them, and any disagreement as to the record does not raise a question of exceptional importance or otherwise meet the standard for en banc review.

CONCLUSION

For the foregoing reasons, the petition for rehearing en banc should be denied.

Respectfully submitted,

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September 2022

CERTIFICATE OF SERVICE

I hereby certify that on September 30, 2022, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

/s/ Lindsey Powell
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CERTIFICATE OF COMPLIANCE WITH
FEDERAL RULE OF APPELLATE PROCEDURE 32(a)

I hereby certify that this brief complies with the requirements of Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Book Antiqua, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Rule 35(b)(2)(A) because it contains 3,589 words, excluding the parts of the brief exempted under Rule 32(f), according to the count of Microsoft Word.

/s/ Lindsey Powell
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