No. 24-474

IN THE

Supreme Court of the United States

FOOD AND DRUG ADMINISTRATION,

Petitioner,

v.

SWT GLOBAL SUPPLY, INC., *et al.*,

Respondents.

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

BRIEF IN OPPOSITION

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CORPORATE DISCLOSURE STATEMENT

There are no parent corporations of Respondents nor any publicly held companies that own 10% or more of the stock of any Respondent.

TABLE OF CONTENTS

TABLE OF CITED AUTHORITIES

Page

Cases

Page

Other Authorities

STATEMENT OF THE CASE

1. The Court is familiar with the regulatory background at issue in this matter, given its review of *Food and Drug Administration v. Wages and White Lion Investments, L.L.C., dba Triton Distribution*, No. 23-1038, which was argued on December 2, 2024. Respondents will not repeat the general background here but will highlight certain material factual and legal distinctions from the record in *Wages*.

Respondents are Texas and Mississippi based companies that manufacture e-liquids used in open-tank systems. *SWT Global Supply, Inc., et al. v. Food & Drug Admin.*, No. 21-60762 (5th Cir. 2024), App. 4a. Respondents all spent substantial time and money preparing premarket tobacco applications (PMTAs), relying on the guidance Petitioner had promulgated, and filed their PMTAs with FDA before the September 2020 deadline. App. 4a. Respondents' applications were all denied in marketing denial orders (MDOs) issued shortly after the FDA's August 26, 2021 press release announcing a new substantive standard of scientific review. See App. 4a.

As in *Wages*, the MDOs claim that each PMTA "lacks sufficient evidence demonstrating that your flavored [ENDS] will provide a benefit to adult users that would be adequate to outweigh the risks to youth." *See, e.g.*, A128, A131 (SWT Global Supply, Inc.); A556 (Cloud House); A1333 (Vaporized); A1354 (SV Packaging); Supp. App. 2a (Paradigm). The MDOs demand:

> robust and reliable evidence . . . regarding the magnitude of the potential benefit to

> adult smokers. This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of your flavored [ENDS] *over an appropriate comparator tobacco-flavored ENDS*. Alternatively, FDA would consider other evidence but only if it reliably and robustly evaluated the impact of the new flavored *vs. Tobacco-flavored products* on adult smokers' switching or cigarette reduction over time.

A128, A131 (SWT Global Supply, Inc.); A556 (Cloud House); A1333 (Vaporized); A1354 (SV Packaging); Supp. App. 2a (Paradigm). (emphasis added).

The MDOs add that, because "key evidence demonstrating APPH [appropriate for the protection of public health] is absent," "scientific review did not proceed to assess other aspects of your application." *E.g.*, A129, A132; A557.

2. Respondents each petitioned for review in the Court of Appeals for the Fifth Circuit and their petitions were consolidated. In November 2021, Respondents moved for a stay pending review of their petitions by the Circuit Court. Given that the Fifth Circuit had recently entered a stay on behalf of petitioners in *Wages & White Lion Investments L.L.C. v. Food and Drug Administration*, 16 F.4th 1130 (5th Cir. 2021), the FDA did not oppose the request. On November 29, 2021, a motions panel granted the stay request without providing any independent analysis. After the parties completed merits briefing, the

Circuit held the matter in abeyance pending the decision in *Wages*. App. 5a.

Merits briefing had been completed with the filing of Respondents' Reply Brief in April 2022. But on August 10, 2022, Filter Magazine published an online article describing an internal FDA memorandum dated August 2020 (immediately prior to the September 2020 PMTA filing deadline) discussing FDA's planned review process for ENDS applications. *See Respondents' Motion to Supplement the Administrative Record and for Leave to File Supplemental Briefs* at 3 (filed Aug. 29, 2022). Filter Magazine reported that it had obtained this memorandum in response to a Freedom of Information Act request. *Id.* Because this memorandum had not been included in the administrative record filed by the FDA, Respondents moved in the Circuit Court to supplement the record. *Id.* Respondents argued that a proper administrative record "'is not limited to documents relevant only to the merits of the agency's decision' but also 'includes documents and materials relevant to the process of making the agency's decision.'" *Id.* at 5 (quoting *Oak Grove Techs., LLC v. United States*, 156 Fed. Cl. 594, 600 (2021) (quoting, in turn, U.S. Dep't of Justice, Env't and Nat. Res. Div., Guidance to Federal Agencies on Compiling the Administrative Record 1 (Jan. 1999)), *aff'd*, 116 F.4th 1364 (Fed. Cir. 2024)). Respondents emphasized that the relevance of a memorandum describing the process for review of PMTAs is particularly particularly acute "where, as here, the regulated entities argue that the agency changed the substantive standard of evidence without providing fair notice." *Id.* FDA opposed the motion to supplement, arguing that an internal memorandum describing FDA's plan for review of PMTAs—issued less than a month

before the filing deadline for such applications—"is not part of the administrative records for the decisions under review." *Resp. to Mtn. to Supplement Admin. Record* at 1 (filed Sept. 2, 2022).

3. Respondents' motion to supplement the administrative record was never decided. After the en banc Court of Appeals granted relief for the industry petitioners in *Wages*, 90 F.4th 357 (5th Cir.) (en banc), cert. granted, 144 S. Ct. 2714 (2024), the merits panel below granted Respondents' petitions in an unpublished, per curiam decision entered on July 31, 2024. As FDA here correctly points out, Pet. at 4, the panel decided Respondents' petitions "in light of the en banc decision in *Wages*," App. 2a, and stated that "[t]here is no basis to distinguish this case from *Wages*," App. 6a. Respondent's MDOs were set aside and their premarket applications remanded to FDA for further proceedings. App. 6a. The motion to supplement the record was denied as moot in a separate order entered on the same date as the decision.

It is certainly true that *Wages* provided a sufficient rule of decision to control the outcome here in Respondents' favor, as Respondents do raise (at least two of) the same arguments advanced by petitioners in *Wages*, and it was therefore unnecessary for the panel to venture beyond the facts and analysis stated by the en banc court. However, the record here also provides certain additional relevant facts and points of legal emphasis that support a decision for Respondents that were not present or not fully considered by the en banc court in *Wages*.

4. Respondents argue that FDA imposed an evidentiary standard that was never articulated to the regulated public before the application deadline. It is a

basic principle of administrative law that an agency cannot sanction an individual for violating the agency's rules unless the individual had fair notice of those rules. *See FCC v. Fox Television Stations, Inc.*, 566 U.S. 502, 515 (2009); *SNR Wireless License Co., LLC v. Fed. Commc'ns Comm'n*, 868 F.3d 1021, 1043 (D.C. Cir. 2017). The standard that was actually applied differs from the standard provided in the FDA's guidance and other public statements in at least *two* material ways. Respondents' 5th Cir. Br. at 14-20, 28-30. First, despite its attempts to marginalize the "fatal flaw" memorandum (FDA Br. at 46), the FDA effectively treated the lack of particular *types* of long-term studies (randomized control trials or longitudinal cohort studies) as a fatal flaw. The record reflects that FDA's review of any "other evidence" in Petitioners' PMTAs was cursory, if it was undertaken at all, and FDA's attempts to identify deficiencies in such evidence for the first time before the Court is impermissible because the Agency is limited to the rationale expressed in the denial orders. Second, even if the Agency *had* given sufficient attention to other evidence, its "scientific review" was still arbitrary and illegal because the substantive standard applied—requiring applicants to show a comparison "to the applicant's tobacco-flavored products"—is a retroactive invention that was articulated to applicants for the first time *in their denial orders*. *See* Respondents' 5th Cir. Br. at 28-30; Reply at 6-11.

Respondents each learned, upon receipt of their MDOs, the actual substantive standard FDA applied to determine whether a product is "appropriate for the protection of the public health." FDA's technical review for each of Respondents' PMTAs describes the "Scope of Review" as follows:

> The reviews evaluated whether the subject PMTAs contain evidence from a randomized controlled trial, longitudinal cohort study, and/or other evidence regarding the impact of the new products on switching or cigarette reduction that could potentially demonstrate the added benefit to adult users of their flavored ENDS *over an appropriate comparator tobacco-flavored ENDS*.

A158, A183 (Technical review, SWT Global) (emphasis added); *see also* SVPackaging-FDA-1-000134 (same); Paradigm-Distribution-FDA 1-000046 (same); Vaporized-FDA1-000686 (same); Cloud House-FDA-1-001208 (same). The FDA's verbatim, two-sentence conclusion as to each Petitioner (found at the same pages just cited) unequivocally applies this hyper-specific standard, faulting the applicant for a lack of a "randomized controlled trial and/or longitudinal cohort study" or "other evidence" of a "benefit to adult users of their flavored ENDS *over an appropriate comparator tobacco-flavored ENDS*[.]"

To Petitioners' knowledge, this standard was first articulated in the FDA's *internal* "fatal flaw" memo, which was written ten months after the application deadline. A296-97 ("FDA has determined this evaluation requires evidence that can demonstrate whether an applicant's new non-tobacco flavored product(s) will provide an incremental benefit to adult smokers relative to the applicant's tobacco-flavored product(s)."). While FDA now claims that the lack of a randomized controlled trial or longitudinal cohort study was not a fatal flaw, FDA has not denied that—whatever evidence was to be considered—the question the Agency expected applicants to answer was the one stated

for the first time in that memo, requiring a comparison with a tobacco-flavored e-liquid.[1] Nor could the Agency deny that this was the standard applied, given, as shown above, its recitation in the technical reviews and the denial orders. FDA's Brief below confirms that Respondents' applications were denied for purported failure to meet this standard. *See*, *e.g.*, FDA 5th Cir. Br. at 52 n.14 (explaining that Petitioners' evidence was not worthy of consideration because it did not address "an added benefit over a comparable tobacco-flavored product").

Respondents emphasized below that this policy requiring comparison to a tobacco-flavored ENDS as a prerequisite to proceed any further in scientific review was a new standard that directly contradicted the FDA's earlier published guidance. In its brief, FDA points to the June 2019 Guidance as providing the parameters for applications. FDA 5th Cir. Br. at 56 (claiming that the denials were "consistent with FDA's nonbinding 2019 Guidance and other agency statements regarding the Act's evidentiary requirements"); *Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems—Guidance for Industry* (June 2019), A241-95. In fact, Respondents argued, the June 2019 Guidance definitively repudiates the FDA's current demand for a specific comparison to a *tobacco*-flavored e-liquid, focused

1. As Respondents have argued, FDA's claim that the "fatal flaw" policy and memorandum was rescinded is belied, in material respects, by the record. While it is true that the Agency inserted a perfunctory reference to consideration of "other evidence" in its description of the scope of its technical review, to the extent the FDA examined "other evidence," it was still solely to determine whether the PMTA included evidence *of the comparison with a tobacco-flavored ENDS product*.

on comparative efficacy. The 2019 Guidance includes a section on "Comparison Products." *See* 2019 Guidance at A256-57. The Guidance clearly contemplates a range of potential valid comparators, affirmatively left to the discretion of the applicant. *Id.* Far from announcing the very specific comparison declared after the fact, the Guidance simply stated that "FDA recommends the product's health risks be compared to those health risks presented by other e-liquids used in a similar manner." A257. FDA said that "if your PMTA is for an e-liquid, we recommend a comparison to other e-liquids with similar nicotine content, *flavors, and other ingredients*." A270. Comparing flavors to other flavors was *specifically recommended* because "there may be significant differences in the health risk of flavors[.]" A284.

5. Respondents also argued below that their MDOs were arbitrary and capricious because, in refusing to even read their marketing restriction plans, FDA ignored a material factor relevant to the decision. And unlike the applicants in *Wages*, Respondents here all proposed marketing plans that went far beyond merely "age-gating" of store and website entry. Respondents' 5th Cir. Br. at 42. As one example, Respondent SWT Global Supply, Inc. cites, among other things, the same "Trace/Verify" system that the Eleventh Circuit identified in *Bidi Vapor LLC v. U.S. Food and Drug Administration*, 47 F.4th 1191, 1205 (11th Cir. 2022), as an illustrative example of a proposed marketing measure that the FDA has not previously evaluated and rejected—not with regard to disposables or cartridge-based ENDs and certainly not with respect to open-tank e-liquids that are less appealing to youth in the first place. Respondents' 5th Cir. Br. at 42. All Respondents here went beyond mere "age-gating," *see*

id., and therefore beyond the measures proposed by the manufacturers in *Wages*.

ARGUMENT

A. Certiorari should be denied outright because alternate grounds support affirmance.

Respondents acknowledge that, if all else were equal, the same grounds that support review of *Wages* would support review here. However, these cases are not identical. Material distinctions between Respondents' marketing plans and those proposed in *Wages* provide an independent basis for affirmance of the Fifth Circuit's judgment for Respondents. The FDA has waived any challenge to this basis for the judgment below because it has not addressed Respondents' marketing plans in its petition.

It is undisputed that FDA refused to review Respondents' marketing plans before issuing their MDOs. E.g., A155 n. xix. The Fifth Circuit held that this was error justifying vacatur of the MDOs in *Wages*, 90 F.4th at 371-73. FDA's petition for certiorari in *Wages* "excluded any challenge to the Fifth Circuit's holding that FDA erred by declining to evaluate respondents' marketing plans." *Wages*, No. 23-1038, FDA Merits Br. at 36. FDA's only argument in *Wages* is that its refusal to review the marketing plans was harmless because the marketing plans there "did not include any novel restrictions." *Id.* The applicants in *Wages* explained that their products were "sold only in age-gated vape and specialty tobacco shops and through age-gated online sales." *Id.* at 38; *Wages*, 90 F.4th at 369-70. FDA's petition for certiorari here simply

relies upon its petition in *Wages* without addressing the particulars of Respondents' marketing restrictions and other affirmative actions intended to prevent youth access to their products, at least one of which has been expressly identified by the Eleventh Circuit as the kind of novel measure not yet evaluated by FDA. *Bidi Vapor LLC*, 47 F.4th at 1205.

Respondents all proposed more robust measures to prevent youth access to their products than at issue in *Wages*, and FDA has not addressed these measures in its petition, which, instead, relies entirely on its petition and arguments in *Wages*. FDA's refusal to review Respondents' marketing plans therefore provides an independent basis for affirmance which FDA's petition does not even argue was harmless.

B. If review is not denied outright, the petition should be held pending decision in *Wages*.

If review is not denied outright, Respondents agree with FDA that the Court should hold this petition pending decision in *Wages*. In the event that the en banc Fifth Circuit decision in *Wages* is affirmed, then there will be no reason to disturb the judgment for Respondents. On the other hand, if this Court reverses or remands the *Wages* matter, it could then dispose of the petition here appropriately, which would most likely be to grant certiorari and remand for reconsideration by the Court of Appeals in light of the *Wages* disposition.

In the latter instance—i.e., if the Court reverses judgment in *Wages*—then remanding Respondents' cases here for reconsideration by the Fifth Circuit in the first

instance would be in keeping with this Court's normal practice. The two matters are not on all fours, and the Court of Appeals should pass first upon any factual or legal distinctions in light of the opinion in *Wages*.

Aside from the material distinctions in the marketing plans as discussed above, several differences in these matters may justify different treatment. With regard to the issue of lack of fair notice to Respondents, the manufacturers here emphasize not just the FDA's change to require certain *types* of studies (long-term randomized controlled trials or longitudinal cohort studies), but also, and primarily, focus upon FDA's narrowing of the potential comparator products that would warrant further scientific review of an application by the Agency. While *Wages* raised this latter point in its briefing in this Court, Respondents focused more intently on it throughout their case. The FDA's own 2019 Guidance document expressly advised applicants to choose comparator products that consumers view as interchangeable, and, for e-liquids, products that have a similar flavor profile to the product(s) in review. At oral argument, counsel for the manufacturers in *Wages* focused primarily on the former (change of study *type*) without emphasizing the equally-important change in potential comparator products.

Additionally, Respondents' motion to supplement the record in the Fifth Circuit—which was not denied on its merits but merely as moot, given the disposition in *Wages*—might prove important following a remand in *Wages*. The internal memorandum omitted from the record below describes the FDA's plan for reviewing PMTAs yet does not refer to any requirement that any PMTA for a flavored product will be stifled in scientific

review unless it used a tobacco-flavored comparator. *See* Mtn. to Supplement at 8. The import, if any, of the proffered supplemental material should be addressed in the first instance by the Court of Appeals, should *Wages* be remanded.

CONCLUSION

Certiorari should be denied. Alternatively, the Court should hold the petition to be disposed of after resolution of *Wages*.

Respectfully submitted,

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