IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

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

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
by the United States Food and Drug Administration

PETITIONERS' PETITION FOR PANEL REHEARING

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CERTIFICATE OF INTERESTED PERSONS

Nos. 21-60766 and 21-60800

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made so that the judges of this Court may evaluate possible disqualification or recusal.

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INTRODUCTION

Petitioners' request for panel rehearing is premised on two independent bases: (1) the majority opinion's factually erroneous assertion that "FDA does not now—and has not ever—*required* studies of smoking cessation," that underpinned the majority's conclusion that FDA had not engaged in a "surprise switcheroo," Slip Op. at 16 (citing *Wages & White Lion Invs., LLC v. FDA*, 16 F.4th 1130, 1138 (5th Cir. 2021) (granting stay)); and (2) Petitioners' recent discovery that FDA withheld a material internal memorandum adverse to FDA's litigation position when it certified the administrative record, rendering the administrative record incomplete.

Because consideration of either of these errors should cause the panel majority to reconsider its opinion, Petitioners respectfully move for rehearing.

BACKGROUND

When FDA certified the administrative record and associated index in this case on October 28, 2022, the agency failed to include an internal memorandum dated August 19, 2020 (the "2020 Review Memorandum"), with a subject line of "Bundling and Bracketing Approach for Review of ENDS Open E-Liquid PMTAs."[1] A member of the press obtained the Memorandum from FDA through a

[1] An electronic copy of the 2020 Review Memorandum is available at tinyurl.com/msf9sjek. Petitioners have not appended a copy of the 2020 Review Memorandum to this petition because of guidance from the Clerk's Office that such appendices are not permitted for petitions for rehearing.

Freedom of Information Act request only after the Court published its opinion on July 18, 2022. The 2020 Review Memorandum became public knowledge through an online article in *Filter Magazine* that was published on August 10, 2022.[2]

The August 2020 Review Memorandum, which is dated only three weeks before the September 9, 2020 deadline for Petitioners and other applicants to file premarket tobacco applications ("PMTAs") for their electronic nicotine delivery system ("ENDS") products, describes a holistic review approach for PMTAs for bottled e-liquids, like Petitioners', with "characterizing flavors" other than tobacco. The Memorandum directs reviewers in the Center for Tobacco Products' Division of Population Health Science and Division of Individual Health Science to "review the entire PMTA in order to reach conclusions for any portion of the submitted products." 2020 Review Memorandum, *supra* n.1, at 2. The Memorandum states that the purpose of the "bundling and bracketing" approach set forth therein is to "increase the likelihood that FDA issues a greater number of marketing orders" for such flavored e-liquid products. *Id*. at 4. Significantly, the 2020 Review Memorandum makes no reference whatsoever to requiring randomized controlled trials, longitudinal cohort studies, or "other evidence" comparing flavored bottled e-

[2] *See* Alex Norcia, Filter Magazine, *The FDA's Early Plan to Expedite Open-System Vape Marketing Applications* (Aug. 10, 2022), https://filtermag.org/fda-open-vape-plan/.

liquids to tobacco-flavored bottled e-liquids in terms of their ability to promote cessation of use of combustible cigarettes.

Nevertheless, on July 9, 2021, ten months after Petitioners' PMTAs were due, FDA developed an internal memorandum describing a new "standard for evidence" that its reviewers would apply to applications for such flavored bottled e-liquids. A155. This standard required either a randomized controlled trial or a longitudinal cohort study to determine whether the applicant's new non-tobacco-flavored products "will provide an incremental benefit to adult smokers relative to the applicant's tobacco-flavored product(s)." *Id*. While FDA purported to rescind a subsequent internal memorandum dated August 17, 2021, that explained the reasons for this approach, A167, A182, large portions of that memorandum were incorporated word-for-word into the Technical Project Lead ("TPL") reports FDA prepared regarding Petitioners' applications, A83, A135.

In its internal review forms utilized to review Petitioners' applications, FDA described the scope of its review as follows:

> This review determines whether the subject PMTAs contain evidence from a randomized controlled trial, longitudinal cohort study, and/or other evidence regarding the impact of the new ENDS on switching or cigarette reduction that could potentially demonstrate the benefit of their flavored ENDS over an appropriate comparator tobacco-flavored ENDS.

A70, A77, A130, A133. In its TPL reports, FDA emphasized that the PMTAs "did not contain evidence from a randomized controlled trial or longitudinal cohort study

examining the benefit to adult users of their flavored ENDS over an appropriate comparator tobacco-flavored ENDS in terms of switching from or reducing cigarettes." A96, A148. The marketing denial orders ("MDOs") likewise faulted the PMTAs for failing to include randomized controlled trials, longitudinal cohort studies, or "other evidence [that] reliably and robustly evaluated the impact of the new flavored vs. Tobacco-flavored products on adult smokers' switching or cigarette reduction over time." A57, A66, A124.

Petitioners claim FDA violated the Administrative Procedure Act by imposing after the submission deadline and without notice the agency's new standard requiring evidence of marginally greater reductions in cigarette use by users of the subject flavored ENDS products versus tobacco-flavored ENDS products. In addressing this argument, the majority opinion concludes that "FDA does not now—and has not ever—*required* studies of smoking cessation." Slip Op. at 16. Rather, the majority opinion concludes, such studies have always been, and continue to be, only optional: "FDA has always suggested and continues to suggest that such studies *might* be useful, in particular where, as here, the evidence presented in an application is otherwise weak." *Id*.

As Judge Jones noted in dissent:

> This is surprising, because petitioners were only advised in the TPLs underlying their MDOs—when it was too late—that such studies are "most likely" to provide reliable and robust evidence to satisfy the APPH standard. And only then were they advised that studies "over time" should have been included. From October 2018 through the September 2020 PMTA deadline,

> and until August 2021, the FDA continually repeated that such studies were neither necessary nor expected. . . .
>
> If this meandering administrative course is not an "administrative switcheroo," it is hard to know what is. . . .

Id. at 36.

ARGUMENT

I. The Majority Opinion Misapprehends FDA's New Requirement of Comparative Evidence of Smoking Cessation Promotion for Flavored versus Tobacco-Flavored ENDS Products

Prior to the PMTA submission deadline, FDA repeatedly told manufacturers that long-term studies were not required. A299, 84 Fed. Reg. 50566, 50619. As emphasized by the motion panel in its stay decision, *Wages*, 16 F.4th at 1138, Petitioners took FDA at its word and relied on its statements in preparing their applications. But then FDA changed its mind and denied Petitioners' applications for not including these very studies.

The majority opinion found no problem with this, stating "FDA does not now—and has not ever—*required* studies of smoking cessation." Slip Op. at 16. But this assertion is flatly contradicted by the administrative record. That FDA required such studies is apparent from the face of the review forms themselves, the TPL reports, and the MDOs.[3]

As noted above, the review forms state as follows:

[3] Lest there be any semantic confusion, throughout this case, Petitioners (like FDA) have consistently used the term "smoking" to refer exclusively to the use of combustible cigarettes. ENDS products are not "smoked" (because, after all, using them involves no combustion or smoke, but rather the inhalation of aerosol, or "vapor"), but rather "vaped."

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

A70, A77, A130, A133 (emphasis added). They explicitly pose the following question referencing "smoking cessation" to determine whether the required evidence is present: "Do outcomes include users' ENDS and smoking behavior to assess switching and/or cigarette reduction (e.g., measures of cigarettes per day, smoking cessation, ENDS use)?" *Id*.

The TPL reports contain virtually identical language. A85-86, A96. And the MDOs justify the denials by referencing the applications' lack of randomized controlled trials, longitudinal cohort studies, or "other evidence [that] reliably and robustly evaluated the impact of the new flavored vs. Tobacco-flavored products on adult smokers' switching or cigarette reduction over time." A57, A66, A124. Regardless of whether these longitudinal studies are described as measuring "switching," "substitution," "reduction," or "cessation," all these terms describe the same phenomenon—cigarette users smoking fewer cigarettes that they previously did before taking up ENDS products.

While the majority opinion cites from the TPL reports the line that "other types of evidence could be adequate[] and will be evaluated on a case-by-case basis," Slip Op. at 18, the opinion ignores footnote vi at the end of that sentence, which makes clear that such "other types of evidence" must be of cigarette reduction or switching to ENDS over time,

comparing users of flavored ENDS products with those of tobacco-flavored ENDS products:

> For example, we would consider evidence from another study design if it 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.

A137 n.vi.[4]

The majority opinion's erroneous conclusion that FDA does not "require" comparative studies measuring how many fewer cigarettes study subjects consume over time after starting use of either flavored or tobacco-flavored ENDS products underpins the majority's conclusion that FDA did not engage in a "surprise switcheroo" when it implemented its new "standard for evidence." A155. Because the majority opinion erroneously concluded that such studies not only had always been optional, but continued

[4] The remainder of the same footnote also underscores that the requirement to conduct such studies over time (that is, on a longitudinal basis) is new and was only imposed by FDA *after* it began reviewing PMTAs that were required to be submitted by September 9, 2020:

> . . . . In ***our review of PMTAs for flavored ENDS so far, we have learned*** that, in the absence of strong evidence generated by directly observing the behavioral impacts of using a flavored product vs. a tobacco-flavored product over time, we are unable to reach a conclusion that the benefit outweighs the clear risks to youth.

A137 n.vi (emphasis added); *accord* Slip Op. at 36 (Jones, J., dissenting); *Wages*, 16 F.4th at 1140-41.

to be, it erroneously found no change in FDA's policy. Slip Op. at 16-18.[5] Accordingly, rehearing is appropriate. As Judge Jones correctly concluded, FDA disregarded "principles of fair notice and consideration of reliance interests," Slip Op. at 38, when it reversed policies on the studies it required without notice, explanation, or consideration of Petitioners' reliance interests.

II. FDA's Improper Failure to Include the 2020 Review Memorandum in the Administrative Record Caused the Court to Issue its Opinion on an Incomplete Record

Rehearing is also justified on a separate, independent ground. Because the administrative record certified by FDA in this case was incomplete and omitted the 2020 Review Memorandum adverse to FDA's position, the Court should vacate its opinion and judgment, order the 2020 Review Memorandum included in the administrative record, and, if the Court deems appropriate, order supplemental briefing regarding the 2020 Review Memorandum's relevance to the issues before the Court.[6]

The Administrative Procedure Act ("APA") requires judicial review of agency action to be based on "the whole record." 5 U.S.C. § 706. For this petition

[5] Indeed, the majority opinion engages in an exercise in circular logic, suggesting that because FDA repeatedly stated that it expected the appropriate showing could be made with evidence other than long-term studies and no long-term study requirement previously existed, it does not now, either. Slip Op. at 17-18.

[6] Petitioners expect that the points they would raise in such supplemental briefing would be largely duplicative of those set forth herein.

for review of a marketing denial order issued under 21 U.S.C. § 387j(c)(2), the "record" includes information "relevant to such . . . order." 21 U.S.C. § 387*l*(a)(2)(C). The "whole record" includes not only the "evidence supporting" an agency's ultimate determination, but also material that "fairly detracts" from that position. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 487-88 (1951). "If the record is not complete, then the requirement that the agency decision be supported by 'the record' becomes almost meaningless." *Portland Audubon Soc'y v. Endangered Species Comm.*, 984 F.2d 1534, 1548 (9th Cir. 1993).

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.'" *Oak Grove Techs., LLC v. United States*, 156 Fed. Cl. 594, 600 (2021) (quoting U.S. Dep't of Justice, Env't and Nat. Res. Div., Guidance to Federal Agencies on Compiling the Administrative Record 1 (Jan. 1999)).

Supplementation with materials a petitioner believes should have been properly included in the administrative record is appropriate: "1) if the agency deliberately or negligently excluded documents that may have been adverse to its decision, 2) if background information was needed in order to determine whether the agency considered all of the relevant factors, or 3) if the agency failed to explain administrative action so as to frustrate judicial review." *City of Dania Beach v. FAA*,

628 F.3d 581, 590 (D.C. Cir. 2010) (internal quotation marks and citations omitted). Each of those three bases for supplementing the administrative record applies here.

The August 2020 Review Memorandum is both highly relevant to Petitioners' challenge and adverse to FDA's position. Unlike the subsequent approach outlined in FDA's later "fatal flaw" memorandum dated July 9, 2021, A155, the memorandum dated August 17, 2021, A167, FDA's review forms, A70, A77, A130, A133, or the Technical Project Lead reports, A96, A148, the approach described in the August 2020 Review Memorandum makes no reference whatsoever to requiring randomized controlled trials, longitudinal cohort studies, or "other evidence" comparing flavored e-liquids to tobacco-flavored e-liquids in terms of their ability to promote cessation of use of combustible cigarettes. The Memorandum's silence in this regard speaks volumes about FDA's subsequent change in policy and to the evidentiary standard.[7]

The omission of the August 2020 Review Memorandum from the administrative record also hides FDA's actual initial approach of reviewing and considering PMTAs in their entirety when weighing risks and benefits – an approach

[7] That the substantive evidentiary standard for flavored e-liquids changed after the submission deadline is highlighted by the fact that, prior to September 9, 2020, FDA never specified or suggested a single test or study for flavored ENDS that it did not also recommend for tobacco-flavored ENDS. FDA did not apply its "comparative efficacy" review standard to Petitioners' tobacco-flavored e-liquids and their applications for those products, like applications for hundreds of other tobacco-flavored ENDS products, remain pending.

consistent with the statements in the 2019 Guidance, A298, and Proposed and Final PMTA Rule, 84 Fed. Reg. 50566, 50581; 86 Fed. Reg. 55300, 55320, 55385, suggesting that FDA would evaluate the entirety of the application prior to determining whether the product was appropriate for the protection of public health.

Such a comprehensive review, if conducted, would have differed materially from the later-adopted "standard for evidence," A155, focusing exclusively on a showing of greater efficacy at promoting smoking cessation than tobacco-flavored ENDS products before the remainder of the application—including harmful and potentially harmful constituent data, applicable literature, consumer surveys, and marketing and access-restriction plans—would be considered. Inclusion of the 2020 Review Memorandum in the administrative record is necessary because it confirms that FDA's original review process was consistent with that which the agency had conveyed to applicants leading up to the PMTA submission deadline and differed substantially from the policy FDA ultimately employed in its blanket issuing of MDOs for flavored ENDS products. The Memorandum thus further confirms that FDA failed to account for Petitioners' reliance interests when it modified both the review process and the substantive standard of evidence it would consider in July and August 2021.

Because the August 2020 Review Memorandum was relevant to both FDA's switch to a circumscribed review process that ignored entire facets of PMTAs for

flavored products ten months after applications were due *and* to FDA's after-the-fact adoption of a different substantive evidentiary standard for flavored e-liquids, FDA's exclusion of the Memorandum from the administrative record was improper and frustrates judicial review.

CONCLUSION

For the foregoing reasons, the Court should grant Petitioners' request for panel rehearing, order the 2020 Review Memorandum included in the administrative record,[8] and issue a new opinion and judgment granting Petitioners' petition for review, setting aside the MDOs, and remanding the matters to FDA.

Respectfully submitted,

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[8] If the Court deems it appropriate, it should also order supplemental briefing by both parties regarding the 2020 Review Memorandum's relevance to the issues before the Court.

CERTIFICATE OF SERVICE

I hereby certify that on September 1, 2022, a true and correct copy of the foregoing Petitioners' Petition for Panel Rehearing was filed with the Clerk's Office for the United States Court of Appeals for the Fifth Circuit using the CM/ECF system and served via electronic mail via the Court's ECM/ECF system. Participants in this case are registered ECM/ECF users, and service will be effected via the ECM/ECF system.

/s/ Eric N. Heyer
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CERTIFICATE OF COMPLIANCE

I hereby certify that Petitioners' Petition for Panel Rehearing complies with the type-volume requirement set forth in Federal Rule of Appellate Procedure 40(b)(1). The word count feature found in Microsoft Word reports that the Petition contains 2,727 words, excluding the items exempted by Federal Rule of Appellate Procedure 32(f).

The Petitioners' Petition complies with the typeface and typestyle requirements of Federal Rule of Appellate Procedure 32 because this document has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman, size 14 font.

/s/ Eric N. Heyer
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