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5th Circuit Issues Blistering Critique of FDA's Handling of PMTAs for E-Cigarettes

Article By:

Azim Chowdhury

Eric P. Gotting

Neelam Gill

In a long-anticipated decision, the U.S. Court of Appeals for the Fifth Circuit ruled against FDA on January 3, 2024, criticizing the Agency for its handling of Wages and White Lion Investments, LLC, d/b/a Triton Distribution and Vapetasia LLC ("Vapetasia") (collectively, "Triton") premarket tobacco product applications ("PMTAs") for its non-tobacco flavored, open-system e-liquid products. This decision comes following an *en banc* rehearing of the case, after the original Fifth Circuit three-judge panel denied Triton's appeal in 2022.

By way of background, Triton submitted comprehensive PMTAs for a variety of non-tobacco flavored open-system e-liquid products ahead of the September 9, 2020 court-ordered deadline. The PMTAs contained information, including detailed marketing plans, based on FDA's guidance documents, proposed PMTA rule, and FDA public meetings, among other things. But in the Fall of 2021, Triton's PMTAs, along with thousands of applications covering millions of non-tobacco flavored products, were denied by FDA for not including "robust and reliable" evidence in the form of a randomized controlled trial and/or longitudinal cohort study demonstrating the benefit of the non-tobacco flavored ENDS products over an appropriate comparator tobacco-flavored ENDS product. The PMTAs were automatically denied for this so-called "fatal flaw."

Triton immediately petitioned the Fifth Circuit to review its marketing denial order ("MDO") and sought a stay of the denial. In October 2021, a three-judge panel had unanimously granted the stay, finding that the MDO was likely "arbitrary and capricious" under the Administrative Procedure Act ("APA"). The Court held that FDA must consider reasonable reliance interests of regulated entities and must acknowledge changing long-held policy. The FDA-issued MDO, according to the Court, did not justify the abrupt change in policy (stating that the Agency repeatedly moved the regulatory goalposts and pulled a "surprise switcheroo"). The Court also found that FDA was "arbitrary and capricious" in not considering youth access and marketing restrictions.

In July 2022, however, a separate merits panel surprised many by upholding the MDO, reasoning that FDA had not engendered "reliance interests" because it never said applicants could rely solely on literature reviews and surveys. Further, the Court pointed out that FDA used conditional language in its guidance and PMTA rule, stating that clinical/long-term studies *may* not be required, and that the MDO said FDA may consider "other" evidence. The Court also found that the Agency's failure to review youth access and marketing restrictions was lawful, relying on 2020 FDA guidance which stated such restrictions were not effective, despite no actual evidence of underage use of any of Triton's products. Triton then appealed that decision for *en banc* consideration.

Now, after a panel of all active Fifth Circuit judges reheard the case, the Court has reversed the 2022 ruling by a vote of 10-6. The decision concluded that FDA changed the evidentiary standards and wholly ignored the Companies' marketing plans, which were previously characterized by the Agency as "critical." In doing so, the Court found FDA's denials of petitioners' PMTAs to be arbitrary and capricious. Specifically, Judge Oldham, writing for the majority, noted that FDA did not give manufacturers fair notice of the rules; the Agency did not acknowledge or explain its change in position; the Agency ignored reasonable and serious reliance interests that manufacturers had in the pre-MDO guidance; and the Agency tried to cover up its mistakes with *post hoc* justifications at oral argument.

It is perhaps possible that FDA did its part to give the regulated community clear guidance and that one million out of one million not only got it wrong but got it *unreasonably* wrong. But administrative law does not turn on such infinitesimal possibilities.

Accordingly, the Court has set aside Triton's MDO and remanded it back to FDA for further review. The Fifth Circuit's decision results in an even more pronounced circuit split, as five circuits had previously ruled in favor of FDA on separate MDO challenge, while the Eleventh Circuit held last year that FDA acted in violation of the APA, reasoning that FDA's refusal to consider what the Agency had previously characterized as "critical" marketing plans constituted an arbitrary and capricious failure to consider "an important aspect of the problem." *Bidi Vapor LLC v. FDA,* 47 F.4th 1191, 1203 (11th Cir. 2022).

Acknowledging that five circuits have sided with FDA, while the Eleventh Circuit and now the Fifth have found the Agency acted arbitrarily and capriciously, the Court nevertheless cautioned that "law is not a nose-counting exercise." In addressing FDA's main arguments (i.e., use of conditional language in guidance and other materials, and arguments concerning harmless error because the Agency would still likely deny Triton's PMTAs upon remand), the Court found that FDA nevertheless changed its position based on that qualified language, and that the harmless-error rule does not apply to discretionary administrative decisions such as the fact-specific, case-by-case PMTA reviews.

This case is highly significant for FDA and the entire regulated vaping industry. After all, a more pronounced circuit split over the FDA's handling of vaping product applications furthers the possibility of a Supreme Court review. This is coupled with the fact that, in this momentous decision, the Fifth Circuit characterizes FDA's denial of *all* PMTAs for non-tobacco flavored ENDS products as a *de facto* flavor ban that circumvents the required notice-and-comment rulemaking process:

Never in this long, winding, and byzantine regulatory process of meetings, PowerPoint decks, proposed rules, comment periods, guidance documents, and enforcement priorities did FDA *ever* say that it was contemplating an ***across-the-board ban on flavored products***.

This decision will undoubtedly impact the industry and the future regulation and marketing of nicotine ENDS products in the U.S.

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