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SCOTUS
TERM IN REVIEW

April 2, 2025

Supreme Court Unanimously Holds that FDA's Denial of Applications to Market Flavored E-Cigarette Products Was Not Arbitrary and Capricious

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Today, the Supreme Court held 9-0 in *FDA v. Wages & White Lion Investments, LLC* that the Food & Drug Administration ("FDA") did not act arbitrarily or capriciously in denying applications for authorization to market flavored liquids for e-cigarette products.

Under the Family Smoking Prevention and Tobacco Control Act, the FDA must deny an application for marketing new tobacco products—which includes e-cigarettes—unless the marketer shows that marketing the product "would be appropriate for the protection of the public health." In applying that standard, the FDA considers "the risks and benefits to the population as a whole," including both the possibility that people who currently use existing tobacco products will stop and the risk that people who do not use tobacco products will start to use them. The FDA's decision must be based on "well-controlled investigations" or other "valid scientific evidence."

In this case, the FDA denied several companies' applications because of the "known and substantial risk to youth" from flavored e-cigarette products and a lack of scientific evidence that flavored e-liquids would provide a benefit to adult smokers. The Fifth Circuit, sitting en banc, vacated those denials, holding that the FDA acted arbitrarily and capriciously because it changed the requirements laid out in predecisional documents; in other words, the FDA had given marketers guidance to follow but then made its decision based on new, different requirements. The Fifth Circuit also suggested that the FDA had violated the Tobacco Control Act's notice-and-comment requirements by imposing a "de facto ban on flavored e-cigarettes" through its denials of the applications (rather than through rulemaking).

In an opinion by Justice Alito, the Court unanimously reversed the Fifth Circuit's decision. The Court first declined to reach the notice-and-comment issue because it did not grant certiorari on that question. The Court then held that the FDA's denials were not arbitrary and capricious because the agency did not improperly change its position with respect to three topics: the type of scientific evidence required, comparative-efficacy (i.e., a comparison of the health effects of flavored products to unflavored or tobacco-flavored products), and the type of device (i.e., cartridge-based and non-cartridge-based products). Justice Alito analyzed the FDA's position on each topic, as reflected in guidance documents, presentations, and meetings, and concluded the agency did not change its position, "even if it evolved over time."

On the fourth and final topic, the Fifth Circuit had held that the FDA improperly changed its position on the significance of marketing plans—which the marketers had submitted and then FDA refused to consider—and that this required remand to the agency because the FDA would not have been required to take the same action (denying the applications) absent the error. The FDA argued remand was improper because any error was harmless. The Court held the Fifth Circuit applied the wrong legal standard and remanded for the Fifth Circuit to determine, in the first instance, whether the marketers met their burden of showing that FDA's error was prejudicial.

The Court's ruling resolves a split between the Fifth Circuit and seven other circuits, which sided with FDA in reviewing denials of similar applications for flavored e-cigarette products. But the Court declined to make any broad rulings about the scope of the FDA's authority or agency powers. The Court limited its decision to the specific facts of the FDA's position on each topic the companies raised on appeal, and did not reach broader questions, such as whether the FDA violated notice-and-comment requirements by effectively denying all flavored e-cigarette products.

The decision marks a rare victory for administrative agencies before the Supreme Court. The unanimous judgment in favor of the FDA suggests that while a majority of the Court is skeptical of efforts by administrative agencies to exercise their authority in novel ways, the Court as a whole is likely to remain deferential to the expertise and judgment of agencies on matters that fall within their purview. Companies contemplating judicial challenges to administrative orders should keep in mind that even while federal courts have increasingly scrutinized agency actions, challenges to agencies' exercise of their judgment remain difficult.

Weil's SCOTUS Term in Review is published by the Appeals and Strategic Counseling practice of Weil, Gotshal & Manges LLP, 767 Fifth Avenue, New York, NY 10153, +1 212 310 8000, www.weil.com.

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