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FDA's Latest Loss in E-Cigarette Case Shows Path to High Court

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Documents

Opinion

Docket

- Fifth Circuit advances split on premarket tobacco applications
- Supreme Court has yet to hear e-cigarette case this term

An en banc Fifth Circuit decision rebuking the FDA's denial of two e-cigarette product applications could usher in a chance for the US Supreme Court to hear a case this term on how the agency regulates vaping products.

The high court has yet to agree to review a case involving vaping device manufacturers litigating the Food and Drug Administration's denial of some premarket flavored electronic cigarette product applications, but the ruling from a conservative federal court could change that.

The US Court of Appeals for the Fifth Circuit said last week the FDA acted arbitrarily and capriciously when it rejected the premarket flavored liquid for e-cigarettes applications of Wages and White Lion Investments LLC, doing business as Triton Distribution, and Vapetasia LLC, for FDA approval to sell their products.

The Fifth Circuit's 10-6 decision advances an already-existing circuit split, following an earlier Eleventh Circuit ruling siding with industry objections to the FDA's rejection of applications. Several other circuit courts have agreed with the FDA on similar challenges that it was reasonable to issue the marketing denial order.

"The split is greater now than it was a few days ago," said Cliff Douglas, president and CEO of the Foundation for a Smoke-Free World, a nonprofit organization advocating for global health and ending smoking.

"It would be sort of the tipping point if it comes to pass," Douglas said, in regard to the Supreme Court adding the case to its docket.

The question remains whether the agency plans to seek Supreme Court review, or if the high court will take a case from a pending writ of certiorari on a similar matter. The Supreme Court this term already declined to review *Avail Vapor, LLC v. FDA*, a case in which the Fourth Circuit sided with the FDA in denying Avail's application and determining the manufacturer hadn't shown that its products had benefits for adults that offset the risk to youth.

The split is a "strong indicator that it's going to be on a fast track to the Supreme Court," said Jim McCarthy, a spokesperson for the American Vapor Manufacturers, a national trade organization representing the independent vapor industry.

"FDA is skating on super thin ice," McCarthy said.

The FDA declined to comment.

Deepening The Split

The FDA in 2016 determined that e-cigarettes were subject to its regulation under the Tobacco Control Act like traditional tobacco products. The agency allowed companies until September 2020 to submit applications for FDA approval, even if they were already on the market.

The FDA at the time received nearly 7 million applications by the deadline, but rejected more than 1 million of them, which prompted legal battles that are ongoing.

The Fifth Circuit majority rejected the FDA's argument that it never guaranteed any submission would be granted, and that the agency "sent manufacturers of flavored e-cigarette products on a wild goose chase," telling them what would be needed to approve their products, and then denying all applications.

The court also recognized the circuit split, raising the question on whether their "sister circuits have spotted a defect in petitioners' arguments" that they may have missed. "With deepest respect for our colleagues who have seen this case the other way, we think not," wrote Judge Andrew S. Oldham for the majority.

Judge Catharina Haynes's dissent, though, said the agency's decision was reasonable and the Supreme Court denying certiorari for two cases where other circuits considered similar facts and denied the petition for review is "telling." Haynes pointed to to *Gripum, LLC v. FDA*, and *Avail Vapor, LLC v. FDA*.

Haynes wrote the dissent joins the opinions of the Second, Third, Fourth, Seventh, and D.C. Circuits that the agency's finding that the "evidence was insufficiently rigorous does not reflect a changed standard, but the manufacturers' failure to meet the standard the agency consistently applied."

"The agency did not act arbitrarily or capriciously by concluding that Petitioners' evidence fell short of that standard," Haynes said.

A case in the Tenth Circuit regarding application for e-cigarettes also remains.

Unclear Situation

The case, and the Fifth Circuit's decision, showcases that the agency's communication has been "confusing and unclear," not only with regard to what it is requiring of applicants for premarket tobacco authorization, but also to the public about the health impacts of these products, Douglas said.

"The situation there is kind of a morass. That's been underscored by the various sort of concerns raised by this court," he said.

The American Lung Association, the American Cancer Society, and Campaign for Tobacco-Free Kids—all of whom filed an amicus brief on behalf of FDA—say the FDA was doing its job when it issued a marketing denial order and urged the court to uphold the FDA's order.

Mary Rouvelas, legal counsel for the American Cancer Society, said although they were disappointed in the majority opinion, there's a "stronger possibility" the Supreme Court could take the case prompting a different response to the agency's actions.

The FDA acknowledges that "e-cigarettes may help adults who smoke to transition completely away from, or significantly reduce their use of, more harmful cigarettes," but "no e-cigarette product has been approved by FDA as a smoking cessation device."

As of October 2023, the FDA has only approved 23 e-cigarette products, which are all tobacco flavored.

The FDA has 60 days to respond from when the decision was issued on Jan. 3.

Michael Bloomberg has campaigned and given money in support of a ban on flavored e-cigarettes and tobacco. Bloomberg Law is operated by entities controlled by Michael Bloomberg.

The case is Wages & White Lion Invs. LLC v. FDA, 5th Cir., No. 21-60766, 21-60800, en banc 1/3/24.

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