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By [Lizzy Lawrence](#)

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FDA Reporter

The Supreme Court heard a case on Monday regarding the Food and Drug Administration’s decision to block several flavored vaping products from the market. The court’s decision next year could change the way the agency regulates tobacco and other products under its purview.

The FDA was sued by two e-cigarette manufacturers after the agency denied their marketing applications in 2021. The manufacturers, Triton Distribution and Vapetasia, argued that the FDA unfairly changed its standards in the middle of the application process by adding a requirement for long-term studies. The FDA, meanwhile, maintains that it was right to deny the companies based on a lack of evidence of public health benefit.

The 5th U.S. Circuit Court of Appeals ruled against the FDA in January, taking issue with the agency saying it is not bound to statements made in its guidance documents. If the Supreme Court upholds this decision, the FDA may release fewer guidance documents in areas beyond tobacco regulation. Guidance documents give companies insight into the agency’s broader thinking on various regulatory issues.

Most vapes sold in the United States are technically illegal, having never received the FDA’s stamp of approval. The agency has authorized only [34 e-cigarette products](#) to date, and has [struggled to punish the thousands more](#) remaining on the market. Some public health experts believe the agency should approve more flavored vapes in order to [help adults quit smoking](#). Others, fearful of the risks flavored vapes [pose to kids](#), want the agency to crack down on these companies.

Cliff Douglas, the CEO of Global Action to End Smoking, called the agency’s current approach a “de facto ban” on vapes that could wean more adults off of cigarettes. He hopes the court will side in favor of the manufacturers.

“The court could find that in fact the FDA should apply a more broad, flexible approach to allowing such products to be authorized,” Douglas said.

His organization is currently reliant on 2023 funding from cigarette and vape maker Philip Morris International, but is looking for new funders that aren’t associated with tobacco or non-medicinal nicotine products.

During Monday’s arguments, several justices seemed inclined to side with the FDA. The three liberal justices — Ketanji Brown Jackson, Elena Kagan, and Sonia Sotomayor— all appeared skeptical of the vaping companies’ argument that the FDA unlawfully changed its standards for demonstrating the products are a healthier alternative to cigarettes.

“I guess I’m not really seeing what the surprise is here or what the change is here,” Kagan said. “Everybody basically knows that flavors are particularly dangerous in terms of kids starting the use of smoking products.”

Jackson noted that prior to the companies’ submissions, the FDA already emphasized the need for evidence showing the benefit of an e-cigarette’s flavor to adult smokers outweighs the risk to youth. The argument, she said, relies on the court agreeing with the companies’ interpretation that the FDA said something new.

Justice Amy Coney Barrett, a Trump appointee, echoed this point as well, asking the companies' lawyer Eric Heyer: "So your position is that the switch is clear and that's all we have to decide for you to win?"

Another conservative justice, Brett Kavanaugh, seemed skeptical of the companies' argument. He said he struggled to figure out the "legal error," and noted that the companies can reapply for FDA approval no matter the outcome of the case.

Heyer replied that his clients will have to shut down if they lose the case, as they can't afford to wait the years it may take for the FDA to come to another decision.

"If these [marketing denial orders] are not vacated and remanded back to the agency, they're closing their doors and they're done," Heyer said. "This was their one shot."

Other conservative justices seemed more sympathetic to the vaping companies, with Clarence Thomas describing the FDA's standards as a "moving target" and Neil Gorsuch wondering if the agency had given the companies enough notice.

President-elect Trump [posted on X](#) in September that he "saved" flavored vaping in 2019, and said he intends to do it again. Robert F. Kennedy Jr., Trump's nominee for health secretary, has promised to shake up FDA regulation in order to fight chronic disease — but has said little on tobacco and nicotine products. Heyer suggested his clients might have a better shot at approval under a Trump FDA. He also referenced the Supreme Court's [reversal of the Chevron doctrine](#) this summer, which limits the FDA and other agencies' ability to interpret vague statutory language.

This article has been updated to clarify the funding of Global Action to End Smoking.

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Lizzy Lawrence leads STAT's coverage of the Food and Drug Administration. She was previously a medical devices reporter.

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