

FDA v. White Lion Investments, LLC.

Civics is all around us. The United States Supreme Court is the highest court in the land. Through its power of judicial review, its decisions have a lasting impact on "We the People".

So what is the Court hearing this session and how might the justices rule? Let's help each other expand our civic literacy.

The Case of E-Cigarettes

The Facts of FDA v. White Lion Investments LLC.:

E-cigarettes have become the most commonly used tobacco product among youths in the United States. With flavors ranging from cotton candy to fruit and chocolate, it's easy to see the appeal to the nation's young people. However, these flavored vapes and e-cigarettes still contain nicotine, which is highly addictive and contributes to stunted brain development and various diseases, including cancer, heart disease, and respiratory illnesses.



The Food and Drug Administration (FDA) has regulated the manufacturing, marketing, and distribution of tobacco products since the passage of the Family Smoking Prevention and Tobacco Control Act in 2009. A large part of this effort is to ensure that customers are aware of the harmful effects of tobacco use. According to the Act, tobacco manufacturers must obtain authorization from the FDA before introducing products to the market. The marketing must be "appropriate for the protection of public health." The FDA must take into consideration whether the marketing will propel more individuals to begin using tobacco products or if it will discourage them from using them.

The respondents, Vapetasia and Triton Distribution, applied for permission to market the flavored liquids in their e-cigarettes. These included flavors like "Rainbow Road" and "Jimmy the Juice Man Peachy Strawberry." The FDA rejected both applications on the basis that flavored liquids in tobacco products would make more young people likely to use the products, leading to an increase in tobacco use by those who do not regularly use it, and would not offer any benefits to those who are already tobacco users. The respondents claim they were unfairly surprised by the denial, citing that it could encourage consumers to switch to e-cigarettes, which would lead to lessened exposure to toxic chemicals than traditional smoking. The respondents also claimed that waiting, sometimes for three to four years, for the FDA to authorize their applications makes it difficult for the company to survive.



The U.S. Court of Appeals for the 5th Circuit ruled in favor of Vapetasia & Triton Distribution, citing that the FDA had pulled a "regulatory switcheroo." The companies initially followed the FDA's set of requirements, but were denied authorization due to a new set of requirements.

On December 2, 2024, the U.S. Supreme Court Justices were asked to address one question:

 Was the Food and Drug Administration's order denying respondents' applications for authorization to market new e-cigarette products arbitrary and capricious, in violation of the Administrative Procedure Act?

On April 2, 2025, the Justices vacated and remanded the case, 9-0, in an opinion offered by Justice Alito with Justice Sotomayor filing a concurring opinion. The Court unanimously rejected the lower court's ruling and ruled in favor of the FDA, stating that the FDA's rejection was neither arbitrary nor capricious under the Administrative Procedure Act. Alito explained that federal agencies may change their positions as long as they "provide a reasoned explanation for the change, display awareness that they are changing position, and consider serious reliance interests."

Supreme Court Precedent Used in this Case:

- SEC v. Chenery Corp. (1943): This case established that courts must evaluate regulatory decisions based on the standards used by the agency at the time.
- Calcutt v. FDIC (2023): This case reinforced the principle that courts should assess regulatory decisions using the same standards
 originally applied by the agency.
- Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc. (1984): This case set the standard for judicial review of administrative
 agency interpretations of statutes that they administer.
- Motor Vehicle Manufacturers Association v. State Farm Mutual Automobile Insurance Co. (1983): This case provided guidelines for determining whether an agency's action is arbitrary and capricious.
- FDA v. Brown & Williamson Tobacco Corp. (2000): This case involved the FDA's authority to regulate tobacco products and was significant in shaping the legal landscape for tobacco regulation.
- Citizens to Preserve Overton Park v. Volpe (1971): This case established the standard for judicial review of administrative actions under the Administrative Procedure Act.
- Heckler v. Chaney (1985): This case discussed the limits of judicial review of agency decisions not to take enforcement actions.

<u>To Think and To Do</u>: Does this ruling have a greater impact beyond tobacco companies? Do you think the justices' rationale could be applicable to food and drug companies? Explain your answer.

To Learn More: Brief for the Petitioners, Food & Drug Administration Brief for the Respondents, Wages & White Lion Investments, L.L.C., Triton Distribution, et al.



