



Breeze Smoke LLC v. FDA (6th Cir.)

Topics Covered: Tobacco and Electronic Nicotine Delivery Systems

Issue

The issue in this case is whether the Food and Drug Administration (“FDA”) acted lawfully when it denied marketing approval for electronic nicotine delivery systems (“ENDS”)—colloquially called “electronic cigarettes” or “e-cigarettes”—featuring non-tobacco flavors.

AMA Interest

The AMA encourages the FDA to prohibit the use of all flavoring agents in tobacco products, which includes electronic nicotine delivery systems as well as combustible cigarettes, cigars, and smokeless tobacco.

Case Summary

In 2009, Congress enacted the Family Smoking Prevention and Tobacco Control Act (“TCA”) to regulate tobacco products. See Pub. L. No. 111-31, 123 Stat. 1776 (2009). In part, the TCA prohibits manufacturers from selling any “new tobacco product” without prior written authorization from the FDA. See 21 U.S.C. § 387j(a).

In 2016, the FDA deemed ENDS a “new tobacco product” under the TCA, thus requiring authorization. See 81 Fed. Reg. 28,973 (May 10, 2016) (“Deeming Rule”). In determining if an e-cigarette is appropriate for authorization, the FDA must weigh two competing factors: (1) the likelihood that the product will help existing users stop using tobacco products versus (2) the likelihood that the product will lead non-tobacco users, including youth, to begin using tobacco products. See 21 U.S.C. § 387j(c)(4).

The FDA delayed immediate enforcement of the Deeming Rule and, instead, created a series of staggered deadlines for review. This allowed ENDS manufacturers to sell their products for several years while the FDA reviewed applications from more than 500 companies covering more than 6.5 million products.

In August 2021, five years after promulgation of the Deeming Rule, the FDA began issuing marketing denial orders (“MDOs”) banning further marketing and sale of selected ENDS products. The FDA found that any benefit to current smokers would be insufficient to overcome the public health threat posed by the anticipated use of such products by new (primarily youth) smokers. The FDA has been issuing MDOs on a rolling basis since August 2021.

On October 4, 2021, Breeze Smoke petitioned the Sixth Circuit Court of Appeals to review the FDA’s MDO with respect to its ENDS products. The TCA permits the manufacturer to file directly in the court of appeals, rather than with a federal district court. See 21 U.S.C. § 387l. Breeze Smoke contends that the FDA acted outside of the scope of the TCA when it denied further marketing and sale of the Breeze Smoke products.

AMA Involvement

The Litigation Center and the Ohio State Medical Association (“OSMA”) joined an *amicus* brief in the Sixth Circuit Court of Appeals discussing the harm caused by flavored ENDS products, especially on young people.

Sixth Circuit Court of Appeals Brief