Bidi Vapor LLC v. FDA (11th 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 staggard 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 September 29, 2021, Bidi Vapor petitioned the Eleventh Circuit 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. Bidi Vapor contends that the FDA acted outside of the scope of the TCA when it denied further marketing and sale of the Bidi Vapor products.

AMA Involvement

The Litigation Center and the Medical Association of Georgia ("MAG") joined an *amicus* brief in the Eleventh Circuit, which highlighted the harm caused by flavored ENDS products, especially to young people.

Eleventh Circuit Court of Appeals Brief