PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 21-2077

AVAIL VAPOR, LLC; BLACKSHIP TECHNOLOGIES DEVELOPMENT, LLC; BLACKBRIAR REGULATORY SERVICES, LLC,

Petitioners,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION,

Respondent.

AMERICAN VAPING ASSOCIATION, INC.; AMERICAN VAPOR MANUFACTURERS ASSOCIATION, INC.; CONSUMER ADVOCATES FOR SMOKE-FREE ALTERNATIVES ASSOCIATION, INC.; SMOKE-FREE ALTERNATIVES TRADE ASSOCIATION, INC.; UNITED VAPERS ALLIANCE, INC.; ARIZONA SMOKE FREE BUSINESS ALLIANCE, INC.; BREATHE EASY ALLIANCE OF ALABAMA; CONNECTICUT CHAPTER OF SMOKE FREE ALTERNATIVES TRADE ASSOCIATION; FLORIDA SMOKE FREE ASSOCIATION, INC.; GEORGIA SMOKE FREE ASSOCIATION, INC.; HAWAII CHAPTER OF SMOKE FREE ALTERNATIVES TRADE ASSOCIATION; KANSAS SMOKE FREE ASSOCIATION; KENTUCKY VAPING RETAILERS ASSOCIATION, INC., d/b/a Kentucky Smoke Free Association; INDIANA SMOKE FREE ALLIANCE, INC.; IOWANS FOR ALTERNATIVES TO SMOKE AND TOBACCO, INC.; IOWA VAPE ASSOCIATION, INC.; LOUISIANA VAPE ASSOCIATION, INC.; MARYLAND VAPOR ALLIANCE; MICHIGAN VAPE SHOP OWNERS, INC.; MIDWEST VAPE COALITION, INC.; MINNESOTA SMOKE FREE ALLIANCE; MISSOURI SMOKE FREE, INC.; MONTANA SMOKE FREE ASSOCIATION, INC.; NEBRASKA VAPE VENDORS ASSOCIATION, INC.;

NEVADA VAPING ASSOCIATION, INC.; NEW MEXICO SMOKE FREE ALLIANCE, INC.; NEW YORK STATE VAPOR ASSOCIATION, INC.; NORTH CAROLINA VAPING COUNCIL, INC.; OHIO VAPOR TRADE ASSOCIATION, INC.; ROCKY MOUNTAIN SMOKE FREE ASSOCIATION, INC.; RHODE ISLAND CHAPTER OF SMOKE FREE ALTERNATIVES TRADE ASSOCIATION; SMOKE FREE ALTERNATIVES COALITION OF ILLINOIS, INC.; SOUTH CAROLINA VAPOR ASSOCIATION, INC.; TEXAS CHAPTER OF SMOKE FREE ALTERNATIVES TRADE ASSOCIATION; TENNESSEE SMOKE FREE ASSOCIATION, INC.; VIRGINIA SMOKE FREE ASSOCIATION, INC.; WASHINGTON SMOKE FREE ASSOCIATION, INC.; WEST VIRGINIA SMOKE FREE ASSOCIATION, INC.; DR. DAVID B. ABRAMS; CLIVE D. BATES; PROFESSOR DAVID T. SWEANOR, J.D.,

Amici Supporting Petitioners,

MEDICAL AND PUBLIC HEALTH GROUPS,

Amici Supporting Respondent.

On Petition for Review of an Order of the Food & Drug Administration. (PM0001233)

Argued: October 25, 2022 Decided: December 12, 2022

Before WILKINSON and DIAZ, Circuit Judges, and MOTZ, Senior Circuit Judge.

Petition denied by published opinion. Judge Wilkinson wrote the opinion, in which Judge Diaz and Senior Judge Motz joined.

ARGUED: Eric Nathan Heyer, THOMPSON HINE LLP, Washington, D.C., for Petitioners. Antonia Marie Konkoly, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Respondent. **ON BRIEF:** Joseph A. Smith, Jessica Tierney, THOMPSON HINE LLP, Washington, D.C., for Petitioners. Brian M. Boynton, Principal Deputy Assistant Attorney General, Eric B. Beckenhauer, Assistant Branch Director, Cormac A. Early, Federal Programs Branch, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C.; Daniel J. Barry, Acting General Counsel, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, Washington, D.C.; Wendy S. Vicente, Acting Deputy Chief Counsel for Litigation, Seth I. Heller, Associate Chief Counsel, Office of the Chief Counsel, UNITED STATES FOOD AND DRUG

ADMINISTRATION, Washington, D.C., for Respondent. J. Gregory Troutman, TROUTMAN LAW OFFICE, PLLC, Louisville, Kentucky, for Amici 38 National and State Electronic Nicotine Delivery System Product Advocacy Associations. Mary G. Bielaska, ZANICORN LEGAL PLLC, New York, New York, for Amici Dr. David B. Abrams, Clive D. Bates, and Professor David T. Sweanor, J.D. William B. Schultz, Andrew N. Goldfarb, ZUCKERMAN SPAEDER LLP, Washington, D.C.; Dennis A. Henigan, Connor Fuchs, CAMPAIGN FOR TOBACCO-FREE KIDS, Washington, D.C., for Amici Medical and Public Health Groups.

WILKINSON, Circuit Judge:

The Family Smoking Prevention and Tobacco Control Act requires manufacturers of new tobacco products to obtain authorization from the United States Food & Drug Administration (FDA) prior to marketing their products. *See* Pub. L. 111-31, § 910, 123 Stat. 1776, 1807–12 (2009) (codified at 21 U.S.C. § 387j(a)). In reviewing a manufacturer's Premarket Tobacco Product Application, FDA must determine that the marketing of the product is "appropriate for the protection of the public health." § 910(c)(4), 123 Stat. at 1810. The agency denied Avail Vapor LLC's application for its flavored electronic cigarettes, chiefly on the grounds that its products posed a serious risk to youth without enough offsetting benefits to adults. We now uphold that decision and deny Avail's petition for review.

I.

A.

Congress enacted the Tobacco Control Act (TCA) in 2009. It found that "[t]he use of tobacco products by the Nation's children" was "a pediatric disease of considerable proportions that result[ed] in new generations of tobacco-dependent children and adults." § 2(1), 123 Stat. at 1777. Further, "[v]irtually all new users of tobacco products are under the minimum legal age to purchase such products," and "[t]obacco advertising and marketing contribute significantly to the use of nicotine-containing tobacco products by adolescents." §§ 2(4), 2(5), 123 Stat. at 1777. Congress's previous attempts to curb adolescent tobacco use had failed, and thus the TCA sought "to address comprehensively the public health and societal problems caused by the use of tobacco products." § 2(7), 123

Stat. at 1777. Congress entrusted the FDA with this important task, finding that it "possesses the scientific expertise needed to implement effectively all provisions of the [TCA]." § 2(45), 123 Stat. at 1781.

The TCA authorizes the FDA to regulate tobacco products including "cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco," as well as "any other tobacco products that the [FDA] by regulation deems to be subject" to the TCA. § 901(b), 123 Stat. at 1786. Relevant here, the TCA requires manufacturers of "new tobacco products" to submit Premarket Tobacco Product Applications (PMTAs) and receive authorization from the FDA prior to releasing their products on the market. *See* § 910(a)(2)(A), 123 Stat. at 1807. A "new tobacco product" is any tobacco product that was not "commercially marketed in the United States as of February 15, 2007." § 910(a)(1)(A), 123 Stat. at 1807.

The FDA must deny a PMTA if it finds that "there is a lack of showing that permitting such tobacco product to be marketed would be appropriate for the protection of the public health." § 910(c)(2)(A), 123 Stat. at 1809. Whether a product is "appropriate for the protection of the public health" is "determined with respect to the risks and benefits to the population as a whole, including users and nonusers of the tobacco product." § 910(c)(4), 123 Stat. at 1810. As part of this inquiry, the TCA explicitly requires the FDA to consider "the increased or decreased likelihood that existing users of tobacco products will stop using such products" and "the increased or decreased likelihood that those who do not use tobacco products will start using such products." § 910(c)(4)(A)–(B), 123 Stat.

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