United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 29, 2019 Decided July 7, 2020

No. 18-5195

CIGAR ASSOCIATION OF AMERICA, ET AL.,
APPELLANTS

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:16-cv-01460)

Michael J. Edney argued the cause for appellants. With him on the briefs were *Mark S. Raffman* and *Andrew Kim*.

Mark Brnovich, Attorney General, Office of the Attorney General for the State of Arizona, and *Keith Miller*, Senior Litigation Counsel, were on the brief for *amicus curiae* State of Arizona in support of appellants.

Lindsey Powell, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Jessie K. Liu*, U.S. Attorney, *Mark B. Stern*, *Alisa B. Klein*, and *Tyce R. Walters*, Attorneys, U.S. Department of Justice, and *Robert P. Charrow*, General Counsel, U.S. Department of Health and Human Services.

Nandan M. Joshi, *Allison M. Zieve*, and *Scott L. Nelson* were on the brief for *amicus curiae* Public Citizen in support of appellees.

Mark Greenwold and *Andrew N. Goldfarb* were on the brief for *amici curiae* Public Health Groups in support of appellees.

Rachel Bloomekatz was on the brief for *amicus curiae* Public Health Law Center in support of appellees.

Justin M. Pearson and *Paul M. Sherman* were on the brief for *amicus curiae* J. Scott Armstrong in support of neither party.

Before: GARLAND and KATSAS, *Circuit Judges*, and RANDOLPH, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge* KATSAS.

KATSAS, *Circuit Judge*: The Tobacco Control Act permits the Food and Drug Administration to regulate tobacco products for the public health, but only after considering whether the regulation would likely increase or decrease the number of smokers. Under this authority, the FDA promulgated regulations requiring extensive health warnings on packaging and in advertising for cigars and pipe tobacco. The FDA concluded that these warnings would help communicate the health risks of smoking, but it failed to consider how the warnings would likely affect the number of smokers. We hold that this failure violated the Tobacco Control Act and the Administrative Procedure Act.

I

A

The Family Smoking Prevention and Tobacco Control Act, Pub. L. No. 111-31, 123 Stat. 1776 (2009) (Tobacco Control Act), amended the Federal Food, Drug, and Cosmetic Act (FDCA) to establish a comprehensive regulatory scheme for tobacco products. As amended, the FDCA regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. 21 U.S.C. § 387a(b). The FDCA also now extends to "any other tobacco products" that the Secretary of Health and Human Services "by regulation deems to be subject to" the FDCA. *Id.* The FDCA further provides that the Secretary may by regulation restrict the sale or distribution of any tobacco product if he "determines that such regulation would be appropriate for the protection of the public health." *Id.* § 387f(d)(1). In making that determination, the Secretary must consider the likelihood that the regulation will increase or decrease the number of tobacco users in the overall population. *See id.* The FDA administers the Tobacco Control Act for the Secretary. *See id.* § 387a(e); Office of the Commissioner Reorganization, 74 Fed. Reg. 41,713, 41,732 (Aug. 18, 2009).

Under this authority, the FDA promulgated a regulation deeming the FDCA to cover all tobacco products. Deeming Tobacco Products to Be Subject to the FDCA, 81 Fed. Reg. 28,973 (May 10, 2016) (Deeming Rule). The Deeming Rule subjects newly regulated tobacco products, including cigars and pipe tobacco, to requirements akin to those previously imposed by statute on cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. *Id.* at 28,976. To that end, it requires extensive health warnings on packages and in advertisements for cigars and pipe tobacco.

The Deeming Rule makes it unlawful to manufacture or sell any cigar product without one of six rotating warning statements. 21 C.F.R. § 1143.5(a)(1). Collectively, the warnings inform prospective and current smokers that cigars cause various diseases, create pregnancy risks, are addictive, and are not a safe alternative to cigarettes. *Id.* The warnings must be printed on at least thirty percent of the two "principal display panels" of each cigar package, with contrasting white-on-black or black-on-white ink. *See id.* § 1143.5(a)(2). For cigars sold individually, the warnings must appear on an 8.5 x 11-inch sign posted within three inches of the cash register. *Id.* § 1143.5(a)(3). For both kinds of warnings, the regulation specifies the necessary font, font size, capitalization, punctuation, and centering. *Id.* § 1143.5(a)(2)(ii)–(v), (a)(3)(ii)–(iv). The same warnings also must cover at least twenty percent of cigar advertisements. *Id.* § 1143.5(b). Manufacturers must submit to the FDA a "proposed warning plan" at least twelve months before selling or advertising any cigar product. *Id.* § 1143.5(c).

For pipe tobacco, packages and advertisements must bear a warning that the product contains nicotine, an addictive chemical. 21 C.F.R. § 1143.3(a)(1). The warning must follow the same formatting requirements as the warnings for cigars. *Id.* § 1143.3(a) (packaging); § 1143.3(b) (advertising).

In promulgating these requirements, the FDA stated that "[t]he warning statements required by this final rule will help consumers better understand and appreciate the risks and characteristics of tobacco products." Deeming Rule, 81 Fed. Reg. at 28,981. At the same time, the FDA acknowledged that "[r]eliable evidence on the impacts of warning labels … on users of cigars, pipe tobacco, waterpipe tobacco, and [electronic nicotine delivery systems] does not, to our knowledge, exist." Deeming Tobacco Products to Be Subject

to the FDCA, Final Regulatory Impact Analysis, ECF Doc. 81-2 at 62 (May 2016).

B

Three cigar and pipe tobacco industry associations challenged various provisions of the Deeming Rule in the district court. As relevant here, the plaintiffs argued that the warning requirements for cigars and pipe tobacco violate the Tobacco Control Act and the Administrative Procedure Act because the FDA did not adequately consider how the warnings would affect smoking. The plaintiffs also argued that the warning requirements violate the First Amendment.

The district court rejected these challenges to the warning requirements. On these claims, the court denied the plaintiffs' motion for summary judgment, granted the FDA's cross-motion for summary judgment, and denied as moot the plaintiffs' motion for a preliminary injunction. *Cigar Ass'n of Am. v. FDA*, 315 F. Supp. 3d 143, 159–74 (D.D.C. 2018). The court then entered final judgment on the claims under Federal Rule of Civil Procedure 54(b). J.A. 330. Finally, the court stayed enforcement of the warning requirements during this appeal. *Cigar Ass'n of Am. v. FDA*, 317 F. Supp. 3d 555 (D.D.C. 2018).

II

Our analysis begins, and ends, with the plaintiffs' statutory claims. Those claims arise under the Administrative Procedure Act, which provides for judicial review of any "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. The APA instructs a reviewing court to set aside agency action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *Id.* § 706(2)(A). When a district court reviews agency action

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