IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit

FILED
June 25, 2020

Lyle W. Cayce
Clerk

No. 19-60921

BIG TIME VAPES, INCORPORATED;
UNITED STATES VAPING ASSOCIATION, INCORPORATED,

Plaintiffs–Appellants,

versus

FOOD & DRUG ADMINISTRATION;
STEPHEN M. HAHN, Commissioner of Food and Drugs;
ALEX M. AZAR, II, Secretary,
U.S. Department of Health and Human Services, in his official capacity,

Defendants–Appellees.

Appeal from the United States District Court
for the Southern District of Mississippi

No. 19-60921

Before SMITH, HIGGINSON, and ENGELHARDT, Circuit Judges.

JERRY E. SMITH, Circuit Judge:

The Family Smoking Prevention and Tobacco Control Act[1] establishes a thorough framework for regulating tobacco products. Four such products—cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco—are automatically subject to the Act. But in section 901 of the TCA, Congress authorized the Secretary of Health and Human Services ("the Secretary") to determine which other products should be governed by the TCA's regulatory scheme. Big Time Vapes, Incorporated, and the United States Vaping Association sued the Food and Drug Administration ("FDA"), its Commissioner, and the Secretary, asserting that Congress's delegation to the Secretary was unconstitutional. The district court dismissed, and we affirm.

I.

The facts are not disputed. This appeal turns on a purely legal question: Whether section 901's delegation to the Secretary violates the nondelegation doctrine.

A.

In 2009, Congress enacted the TCA, thereby amending the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, *et seq*. Congress sought to empower the FDA to regulate tobacco products,[2] whose use Congress found to be "the foremost preventable cause of premature death in America." TCA § 2(13), 123 Stat. at 1777. "Because past efforts to restrict advertising and marketing of

[1] Pub. L. No. 111–31, 123 Stat. 1776 (2009) (codified at 21 U.S.C. § 387, *et seq*.) ("TCA" or "the Act").

[2] In so acting, Congress legislatively abrogated the result of the watershed decision in *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 126 (2000), which held that the FDA lacked the authority to regulate tobacco as a "drug."

tobacco products ha[d] failed adequately to curb tobacco use by adolescents, comprehensive restrictions on the sale, promotion, and distribution of such products [we]re needed." *Id.* § 2(6). Accordingly, Congress gave the FDA broad authority to address "the public health and societal problems caused by the use of tobacco products." *Id.* § 2(7).

To advance its public-health purpose, Congress established a detailed framework for regulating tobacco. But that statutory scheme did not apply—at least not immediately—to all forms of tobacco. Instead, Congress automatically applied the TCA "to all cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco."[3] Section 901 provided that the TCA also would apply "to any other tobacco products[4] that the Secretary [of Health and Human Services][5] by regulation deems to be subject to [the Act]." *Id.* § 387a(b).

The TCA imposes several requirements on "tobacco product manufacturers."[6] They must submit to the FDA truthful information about their products, including: (1) "all ingredients, [*i.e.*,] tobacco, substances, compounds, and additives"; (2) "[a] description of the content, delivery, and form of nicotine in each tobacco product"; and (3) certain information, including manufacturer-developed documents, related to the "health, toxicological, behavioral, or physiologic effects of current or future tobacco products" and their component parts.

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[3] TCA § 901, 123 Stat. at 1786 (codified at 21 U.S.C. § 387a(b)). Each of those terms is statutorily defined. *See* 21 U.S.C. § 387(3)–(4), (15), (18).

[4] Congress defined "tobacco product" as "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)." 21 U.S.C. § 321(rr)(1).

[5] The Secretary delegated that power to the FDA Commissioner, who delegated it to several deputy and associate commissioners. *See* FDA Staff Manual Guide 1410.21(1)(G)(1).

[6] That term "means any person, including any repacker or relabeler, who—(A) manufactures, fabricates, assembles, processes, or labels a tobacco product; or (B) imports a finished tobacco product for sale or distribution in the United States." 21 U.S.C. § 387(20).

Id. § 387d(a). Manufacturers must file annual registration statements listing all tobacco products they make, *id.* § 387e(i)(1), and those lists must be updated biannually to reflect current offerings, *id.* § 387e(i)(3).

The TCA likewise prohibits manufacturers from introducing any "new tobacco product" without premarket authorization. *Id.* § 387j(a). A tobacco product is considered "new" if it "was not commercially marketed in the United States as of February 15, 2007."[7] A manufacturer can obtain premarket authorization through two primary channels: (1) by tendering a "premarket tobacco application" ("PMTA") demonstrating that the product "would be appropriate for the protection of the public health," *id.* § 387j(a)(2), (c)(2)(A); or (2) by submitting a "report" showing that the product "is substantially equivalent to a tobacco product commercially marketed" before February 2007, *id.* § 387j(a)(2)(A)(i).[8] The PMTA process is onerous, requiring manufacturers to gather significant amounts of information.[9]

Finally, the FDA can impose additional rules by regulation, such as minimum-age restrictions, mandatory health warnings, method-of-sale limits, and advertising constraints. *See id.* § 387f(d). Failing to comply with the TCA's

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[7] *Id.* § 387j(a)(1)(A). The definition also encompasses "any modification . . . of a tobacco product where the modified product was commercially marketed in the United States after February 15, 2007." *Id.* § 387j(a)(1)(B).

[8] Under certain circumstances not relevant here, manufacturers can also request an exemption from the "substantial equivalence" requirements. *See id.* § 387j(a)(2)(A)(ii); *see also id.* § 387e(j) (outlining the parameters for products exempt).

[9] PMTAs must include: (1) report(s) "concerning investigations which have been made to show the health risks of such tobacco product and whether such tobacco product presents less risk than other tobacco products"; (2) a full statement of the product's ingredients, components, and principles of operation; (3) a description of how the product is manufactured and prepared for sale; (4) references to any applicable statutory standards and information showing how those standards are met; (5) product samples; and (6) examples of the proposed labeling for the product. *Id.* § 387j(b)(1). According to the plaintiffs, curating the necessary data to submit a PMTA can cost anywhere from about $180,000 to more than $2 million.

or the FDA's regulations has serious consequences. A non-compliant manufacturer's product may be designated as "adulterated" or "misbranded," *see id.* §§ 387b, 387c, which could result in, among other things, civil penalties, *see id.* § 333(f)(8)–(9), or seizure of the offending product, *see id.* § 334.

B.

In May 2016, the FDA promulgated a rule that "deem[ed] all products meeting the statutory definition of 'tobacco product,' except accessories of the newly deemed tobacco products, to be subject to FDA's tobacco product authorities under [the TCA]."[10] That swept into the TCA's ambit several popular tobacco products, including Electronic Nicotine Delivery Systems ("ENDS").[11] The FDA maintained that regulating ENDS would benefit public health, because (1) those products had the potential to effect public harm, and (2) regulation would permit the FDA to "learn more about that potential." Deeming Rule, 81 Fed. Reg. at 28,983. That was especially true given that long-term studies hadn't yet been conducted to determine whether ENDS products were harmful or beneficial to public health. *Id.* at 28,984.

As a result of the FDA's rule, ENDS and e-liquid producers were "subject

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[10] Deeming Tobacco Products to Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products ("Deeming Rule"), 81 Fed. Reg. 28,974, 28,976 (May 10, 2016).

[11] ENDS include "e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, and electronic pipes." *Id.* Those devices work by heating and aerosolizing a liquid mixture—called an "e-liquid"—that includes various levels of nicotine and sometimes flavoring. *See Nicopure Labs, LLC v. FDA*, 944 F.3d 267, 270 (D.C. Cir. 2019). After the liquid is aerosolized, it is then inhaled as vapor. *See id.* Not all e-liquids contain nicotine, but "[d]ata suggest that experienced ENDS users are able to achieve clinically significant nicotine levels and levels similar to those generated by traditional cigarettes." Deeming Rule, 81 Fed. Reg. at 29,031. Some e-liquids can also contain chemicals that are known to pose health risks including diacetyl and acetyl propionyl, formaldehyde, and various other aldehydes. *Id.* at 29,029–31.

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