United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
July 30, 2024
Lyle W. Cayce
Clerk

No. 21-60762

SWT Global Supply, Incorporated,

Petitioner,

versus

Food & Drug Administration,

Respondent,

consolidated with

No. 21-60777

Cloud House, L.L.C.,

Petitioner,

versus

Food & Drug Administration,

Respondent,

consolidated with

No. 21-60778

PARADIGM DISTRIBUTION,

Petitioner,

versus

FOOD & DRUG ADMINISTRATION,

Respondent,

CONSOLIDATED WITH

No. 21-60779

VAPORIZED, INCORPORATED,

Petitioner,

versus

FOOD & DRUG ADMINISTRATION,

Respondent,

CONSOLIDATED WITH

No. 21-60801

SV PACKAGING, L.L.C.,

Petitioner,

versus

FOOD & DRUG ADMINISTRATION,

Respondent.

Petition from the Food & Drug Administration
Agency Nos. PM0003792, PM0003640,
PM0000968, PM0001094, PM0001168,
PM0001191, PM0003578

Before WIENER, ELROD, and WILSON, *Circuit Judges*.

PER CURIAM:[*]

Petitioners seek to set aside marketing denial orders (MDOs) issued by the Food & Drug Administration (FDA) for their e-cigarette products. In light of this court's en banc decision in *Wages & White Lion Invs., L.L.C. v. FDA*, 90 F.4th 357 (5th Cir. 2024) (en banc), *cert. granted*, --- U.S. ----, 2024 WL 3259693 (July 2, 2024) (No. 23-1038), we grant the petitions for review, set aside the MDOs, and remand these matters to the FDA.

I.

In 2016, FDA labeled e-cigarettes and their component parts as "new tobacco products" subject to regulation under the Family Smoking Prevention and Tobacco Control Act, 21 U.S.C. §§ 387–387v. *See Wages*, 90 F.4th at 363.[1] As part of those regulations, e-cigarette manufacturers had to submit premarket tobacco applications (PMTAs) for FDA approval before selling their products. *Id.* (citing 81 Fed. Reg. 28,977 (May 10, 2016)). The deadline to submit PMTAs was September 9, 2020. *Id.* at 363 n.2.

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[*] This opinion is not designated for publication. *See* 5TH CIR. R. 47.5.

[1] *Wages* provided a full review of FDA's rule-making process at issue in this case. *See* 90 F.4th at 363–69. We provide only a short synopsis here.

From 2018 to 2020, FDA provided a "dizzying" array of detailed instructions explaining the requirements for PMTAs. *See id.* at 363–68. But "[n]ever in this long, winding, and byzantine regulatory process of meetings, PowerPoint decks, proposed rules, comment periods, guidance documents, and enforcement priorities did FDA *ever* say that it was contemplating an across-the-board ban on flavored products." *Id.* at 368. "Nor did FDA ever give fair notice that *flavored* product manufacturers had to submit robust scientific studies on *flavored* e-cigarette products." *Id.* at 368–69.

Petitioners are Texas and Mississippi companies that, like the petitioners in *Wages*, manufacture flavored nicotine-containing e-liquids used in open tank systems.[2] Petitioners submitted PMTAs for their products before the September 2020 deadline. They submitted various documents, including "Youth Access Prevention Plans," "Marketing Plans," and survey data from their customers. In accordance with FDA guidance, Petitioners explained how they would limit their marketing carefully to target adult consumers and only sell their products in age-restricted vape and tobacco-specialty shops or age-restricted online stores. Some of the petitioners joined trade associations to ensure they were complying with FDA guidelines for their PMTAs. But based on FDA's guidance, Petitioners did not conduct or otherwise proffer long-term clinical studies for their products.

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[2] Open tank e-cigarette products are different than cartridge-based products. Cartridge-based e-cigarettes are inconspicuous and easier to use, and more susceptible to abuse by youth. *See Wages*, 90 F.4th at 367–68. In contrast, open tank systems are "less innocuous in appearance" and "more complicated" to use, making them less attractive to underage vapers. *See id.* at 367. In January 2020, FDA issued an enforcement guidance document stating that it would "prioritize enforcement resources against flavored, cartridge-based [e-cigarette] products." *Id.* at 366 (internal quotations omitted). Because Petitioners bottle only product for open tank systems, "it is common ground that FDA's 2020 Enforcement Guidance did not apply to [P]etitioners or their liquids." *Id.* at 369.

"On August 26, 2021, FDA issued a press release to announce the *en masse* denial of 55,000 flavored e-cigarette applications." *Wages*, 90 F.4th at 370. "In that press release, FDA announced for the first time that, for flavored e-cigarette applications, the agency *would* require" long-term clinical studies. *Id.* Less than a month later, FDA issued an MDO to each Petitioner stating that their products had been denied. Specifically, FDA stated:

> All of your PMTAs lack sufficient evidence demonstrating that your flavored [e-cigarette products] will provide a benefit to adult users that would be adequate to outweigh the risks to youth . . . . This evidence could have been provided using a randomized controlled trial and/or longitudinal cohort study that demonstrated the benefit of your flavored [e-cigarette] products over an appropriate comparator tobacco-flavored [e-cigarette product].

In making this determination, FDA did not consider the thousands of other documents provided by Petitioners.

On October 1, 2021, Petitioners filed their petitions for review, seeking to vacate or modify the MDOs. Petitioners then filed a motion to stay their respective MDOs pending review in our court, which a motions panel granted. After the parties completed their briefing, the court placed this case in abeyance pending the decision in *Wages*. Once the mandate issued in *Wages*, the court removed this case from abeyance in April 2024.

II.

As in *Wages*, Petitioners argue that "FDA pulled a surprise switcheroo" by denying their PMTAs for lack of long-term studies after providing years of guidance that no such studies were necessary. In *Wages*, the en banc court agreed and concluded that FDA's denials of the *Wages* petitioners' PMTAs were arbitrary and capricious. 90 F.4th at 388.

Specifically, the court determined that (1) FDA did not give e-cigarette manufacturers fair notice of the rule requiring long-term studies for PMTAs; (2) FDA did not acknowledge or adequately explain its change in position; and (3) FDA ignored reasonable and serious reliance interests that manufacturers had in the pre-MDO guidance. *See id.* at 374–88.[3]

There is no basis to distinguish this case from *Wages*. As there, Petitioners in this case manufacture flavored nicotine-containing e-liquids. Petitioners spent substantial time and resources preparing their PMTAs based on FDA guidance that they would not need to submit long-term clinical studies. Nevertheless, FDA rejected their PMTAs using the same boilerplate language it used for the *Wages* petitioners' denials, as well as those of thousands of other e-cigarette manufacturers. Accordingly, for the reasons amply explained by the en banc court in *Wages*, we hold that FDA acted unlawfully here as well by denying Petitioners' PMTAs based on the absence of long-term clinical studies.

III.

For the foregoing reasons, the petitions for review are GRANTED, FDA's marketing denial orders are SET ASIDE, and these cases are REMANDED to FDA for further proceedings.

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[3] The court also determined that FDA tried to cover up its mistakes with *post hoc* justifications at oral argument. *Wages*, 90 F.4th at 388. That reasoning does not apply in this case because no oral arguments were held.