HB1069 #2

United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
January 3, 2024
Lyle W. Cayce
Clerk

No. 21-60766

WAGES AND WHITE LION INVESTMENTS, L.L.C., *doing business as* TRITON DISTRIBUTION,

Petitioner,

versus

FOOD & DRUG ADMINISTRATION,

Respondent,

CONSOLIDATED WITH

No. 21-60800

WAGES AND WHITE LION INVESTMENTS, L.L.C., *doing business as* TRITON DISTRIBUTION; VAPETASIA, L.L.C.,

Petitioners,

versus

FOOD & DRUG ADMINISTRATION,

Respondent.

Appeal from the Food & Drug Administration
Agency Nos. 21 USC 3871, PM0003531

Before RICHMAN, *Chief Judge*, and JONES, SMITH, STEWART, ELROD, SOUTHWICK, HAYNES, GRAVES, HIGGINSON, WILLETT, HO, DUNCAN, ENGELHARDT, OLDHAM, WILSON, and DOUGLAS, *Circuit Judges*.*

ANDREW S. OLDHAM, *Circuit Judge*, joined by RICHMAN, *Chief Judge*, and JONES, SMITH, ELROD, WILLETT, HO, DUNCAN, ENGELHARDT, and WILSON, *Circuit Judges*:

Over several years, the Food and Drug Administration ("FDA") sent manufacturers of flavored e-cigarette products on a wild goose chase.

First, the agency gave manufacturers detailed instructions for what information federal regulators needed to approve e-cigarette products. Just as importantly, FDA gave manufacturers specific instructions on what regulators did *not* need. The agency said manufacturers' marketing plans would be "critical" to the success of their applications. And the agency promulgated hundreds of pages of guidance documents, hosted public meetings, and posted formal presentations to its website—all with the (false) promise that a flavored-product manufacturer *could*, at least in theory, satisfy FDA's instructions. The regulated manufacturers dutifully spent untold millions conforming their behavior and their applications to FDA's say-so.

Then, months after receiving hundreds of thousands of applications predicated on its instructions, FDA turned around, pretended it never gave anyone any instructions about anything, imposed new testing requirements without any notice, and denied all one million flavored e-cigarette

* JUDGE RAMIREZ joined the court after this case was submitted and did not participate in the decision.

applications for failing to predict the agency's *volte face*. Worse, after telling manufacturers that their marketing plans were "critical" to their applications, FDA candidly admitted that it did not read a single word of the one million plans. Then FDA denied that its voluminous guidance documents and years-long instructional processes meant anything. Why? Because, the agency said, it always reserved the implied power to ignore every instruction it ever gave and to require the very studies it said could be omitted, along with the secret power to not even read the marketing plans it previously said were "critical." It was the regulatory equivalent of Romeo sending Mercutio on a wild goose chase—and then admitting there never was a goose while denying he even suggested the chase. *Cf.* WILLIAM SHAKESPEARE, ROMEO AND JULIET act 2, sc. 4.

FDA justifies its behavior with two principal arguments. First, FDA argues that its years' worth of regulatory guidance was not worth the paper it was printed on because it was hedged with cautious qualifiers and never *guaranteed* that any particular submission would be granted. Second, and most disturbingly, FDA argues that its capriciousness should be forgiven as harmless because the agency promises to deny petitioners' applications even if we remand to make the agency follow the law.

Today we reject both propositions. As the Supreme Court recently reminded us: "If men must turn square corners when they deal with the government, it cannot be too much to expect the government to turn square corners when it deals with them." *Niz-Chavez v. Garland*, 593 U.S. 155, 172 (2021). No principle is more important when considering how the unelected administrators of the Fourth Branch of Government treat the American people. And FDA's regulatory switcheroos in this case bear no resemblance to square corners. As for the agency's harmless-error argument, the Supreme Court recently, unanimously, and summarily rejected it. *Calcutt v. FDIC*, 598 U.S. 623 (2023) (per curiam). We do the same here with the expectation that

public health benefit. And FDA could not reject a PMTA for it after scoring only half of its test.

In any event, even if the "and" in § 387j(c)(4)(A) could or should be read as "or," that is *still* not enough to save the FDA. As noted, the Eleventh Circuit held the agency repeatedly represented that the marketing plans were "critical" and "necessary" to a successful application. *Bidi Vapor*, 47 F.4th at 1203–04. The agency cannot now claim they were in fact always meaningless.

* * *

In sum, FDA's denials of petitioners' PMTAs were arbitrary and capricious. The agency did not give manufacturers fair notice of the rules; the agency did not acknowledge or explain its change in position; the agency ignored reasonable and serious reliance interests that manufacturers had in the pre-MDO guidance; and the agency tried to cover up its mistakes with *post hoc* justifications at oral argument. The contrary views expressed by some of our sister circuits do not address our principal concerns with FDA's decisionmaking. We therefore hold the agency acted unlawfully.

III.

Finally, FDA argues that even if it arbitrarily and capriciously denied petitioners' applications, that error was harmless. FDA reasons that there is nothing special about petitioners' applications, so the agency will deny them on remand even if we send the case back and order FDA to conform its decisionmaking to the APA. FDA EB Br. 27–28.

FDA misunderstands how harmless error review works under the APA. We (A) explain the harmless error rule and then (B) hold it provides no help to the agency.

with the entirety of the Eleventh Circuit's analysis and its application of a harmless error rule identical to *Johnson*'s. *See Bidi Vapor*, 47 F.4th at 1205–08.

* * *

The petitions for review are GRANTED, FDA's marketing denial orders are SET ASIDE, and the matters are REMANDED to FDA.