No. 99-1034

In the Supreme Court of the United States

CENTURY CLINIC, INC. AND KATRINA TANG,
PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the definition of clear and convincing evidence adopted by the Food and Drug Administration (FDA) Hearing Officer rendered his decision arbitrary or capricious.

2. Whether the FDA Hearing Officer's reliance on a tape recording in finding that petitioners violated a consent decree rendered his decision arbitrary or capricious.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-4a) is unpublished but the decision is noted at 189 F.3d 475 (Table). The decision of the district court (Pet. App. 5a-8a) is unreported. The report and recommendation of the magistrate judge (Pet. App. 9a-28a) is unreported.

JURISDICTION

The judgment of the court of appeals was entered on July 22, 1999. A petition for rehearing was denied on September 14, 1999 (Pet. App. 58a). The petition for a writ of certiorari was filed on December 13, 1999. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Before 1993, petitioners used an unapproved medical device (an ohmmeter) to diagnose whether patients had various diseases, such as Chernobyl radiation, Nevada underground radiation, formaldehyde poisoning, Bubonic plague, malnourishment, and exposure to hepatitis. Pet. App. 10a-11a. After diagnosis, petitioners would recommend that their patients undergo expensive tests and treatments for those diseases. *Id.* at 11a.

In March 1993, the United States filed suit against petitioners alleging that their use of the medical device violated the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*. The United States and petitioners simultaneously entered into a consent decree that was approved by the district court. Pet. App. 73a-81a. The decree enjoined petitioners from using certain medical devices unless there was in effect an approved application for premarket approval pursuant to 21 U.S.C. 360e, or an approved application for an investigational device exemption (IDE), pursuant to 21 U.S.C. 360j(g). Pet. App. 74a-75a. The decree further provided that petitioners shall pay the United States $200,000 per violation of the decree. *Id.* at 78a-79a.

Under the decree, the Food and Drug Administration (FDA) has authority to make an initial determination whether the decree has been violated. If FDA notifies petitioners of a violation, petitioners are permitted to challenge that determination within the FDA. Pet. App. 79a. If FDA affirms its initial decision, petitioner may challenge the decision in district court under the "arbitrary and capricious review standard of 5 U.S.C. § 706(2)(A)." *Ibid.* That review must be based on the

record that was before FDA at the time of its decision. *Id.* at 79a-80a.

The provision in the decree enjoining petitioners from using certain medical devices without approval from the FDA tracks requirements in the FDCA. Under the FDCA, a medical device generally may not be introduced into interstate commerce without premarket approval by the FDA. 21 U.S.C. 360e. The FDCA contains an exemption from that requirement for devices used for investigative purposes. 21 U.S.C. 360j(g) (1994 & Supp. IV 1998). Under the exemption, investigators are required to proceed in strict accordance with FDA regulations and any conditions imposed by FDA. 21 C.F.R. 812.100, 812.110. If a device is used in a manner that does not conform to FDA's regulations or the conditions imposed by FDA, the device is considered adulterated under the FDCA. 21 U.S.C. 351(f)(1)(B) and (i).

2. After entry of the decree between the United States and petitioners, Biosource Inc., which is not a party to this action, filed an application to conduct an investigative study of the LISTEN System device—one of the devices that petitioners had been enjoined from using absent FDA approval. Pet. App. 12a. FDA approved the Biosource application on the condition that the device would be used solely to collect data to determine whether the device could detect *diabetes*. *Ibid.* That study was to be done by comparing data from the LISTEN System with data from a fasting blood test that measured glucose levels. *Id.* at 12a-13a. Petitioners obtained two LISTEN System devices from Biosource for the alleged purpose of participating as clinical investigators in the study. *Id.* at 13a.

After an investigation, FDA determined that petitioners were using the two LISTEN System de-

vices for unapproved purposes. Pet. App. 13a. In particular, the evidence demonstrated that petitioners were using the two devices to diagnose serious medical diseases, and to recommend further expensive testing for those diseases. The evidence also demonstrated that petitioners were not collecting the data necessary for the Biosource study. *Id.* at 13a-14a. Some of the evidence came from a tape recording made by an undercover investigator who posed as a patient. *Id.* at 39a-45a. Based on all the evidence, the FDA found that petitioners had committed two violations of the consent decree and imposed the $400,000 fine specified by the decree. *Id.* at 29a.

An FDA Hearing Officer affirmed the FDA's initial decision. Pet. App. 29a-57a. The district court upheld the Hearing Officer's decision, ruling that it was "not arbitrary, capricious, contrary to law, or unsupported by substantial evidence." *Id.* at 5a-8a.

The court of appeals affirmed. Pet. App. 1a-4a. The court found that there was "substantial evidence," including evidence from the tape recording of the undercover investigator, that petitioners "used the LISTEN System for diagnostic purposes beyond what the diabetes study authorized." *Id.* at 3a.

ARGUMENT

1. Petitioners contend (Pet. 9-16) that the Hearing Officer in this case erred in holding that the clear and convincing evidence standard is satisfied by proof that the facts alleged are "highly probable." Petitioners, however, did not challenge the FDA Hearing Officer's decision in the court of appeals on that ground. Nor did the court of appeals address that issue. Because petitioners failed to raise the issue below, and the court of appeals did not address it, that question is not properly

presented here. See *Delta Air Lines, Inc.* v. *August*, 450 U.S. 346, 362 (1981).

In any event, petitioners' challenge to the Hearing Officer's definition of clear and convincing evidence is without merit. Petitioners entered into a consent decree that gives the FDA authority to determine whether there is a violation of the decree subject only to review under the arbitrary or capricious standard. Pet. App. 79a. Nothing in the decree requires the FDA to apply a particular definition of clear and convincing evidence. Indeed, nothing in the decree requires the FDA to apply a clear and convincing evidence standard rather than a preponderance of the evidence standard. As petitioners concede (Pet. 12), the Hearing Officer defined clear and convincing evidence in the same way that this Court defined clear and convincing evidence in *Colorado* v. *New Mexico*, 467 U.S. 310, 316 (1984). The Hearing Officer's definition of clear and convincing evidence therefore did not render its decision either arbitrary or capricious. *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (arbitrary and capricious standard limits judicial review to determining whether the agency has "examin[ed] the relevant data," and articulated "a satisfactory explanation for its action including a rational connection between the facts found and the choices made") (internal quotation marks omitted).

Cruzan v. *Director, Missouri Department of Health*, 497 U.S. 261 (1990), relied upon by petitioners, does not call into question the Hearing Officer's decision. In that case, the Court held that the Due Process Clause does not prohibit States from requiring clear and convincing evidence that a patient desires to terminate life-sustaining medical treatment. *Id.* at 284. The Court recited in a footnote two definitions of clear and

convincing evidence that States had applied in that context. *Id.* at 285 n.11. The Court did not suggest, however, that States are required to apply those particular definitions in the context of deciding a patient's desire for life-sustaining treatment, much less that those definitions must be applied in a federal or any other context. Nor did that decision suggest that it would be arbitrary or capricious for an administrative agency to use the *Colorado* clear and convincing evidence standard in enforcing a consent decree like the one at issue here. Petitioners' reliance on *Cruzan* is therefore misplaced.

For similar reasons, the asserted conflict in the circuits identified by petitioners (Pet. 12-14) does not provide any basis for review in this case. Because petitioners did not raise the issue below and the court of appeals did not address it, the decision below does not conflict with any of the decisions cited by petitioners. Moreover, the cases cited by petitioners cut across a spectrum of state law and federal law contexts. Within the broad limits of the Due Process Clause, however, States are free to define clear and convincing evidence in any manner they choose. *Addington* v. *Texas*, 441 U.S. 418, 432-433 (1979). Different federal law issues may call for somewhat different formulations of what constitutes clear and convincing evidence. And different formulations may be used to convey the same basic standard. See *United States* v. *Dixon*, 185 F.3d 393, 404 (5th Cir. 1999) (holding that two of the formulations identified by petitioners state the same basic standard). For those reasons, the cases cited by petitioners do not necessarily reveal any conflict in the circuits warranting this Court's review. Whatever the extent of the conflict, however, none of the cases cited by petitioners suggests that it would be arbitrary or

capricious for an administrative agency to apply the *Colorado* definition of clear and convincing evidence in the context of enforcing a consent decree like the one at issue here. The cases cited by petitioners are therefore inapposite here.

2. Petitioners also contend (Pet. 16-23) that the Hearing Officer erred in relying on a tape recording as the exclusive basis for finding a violation of the decree, when portions of the recording were garbled, inaudible, and silent, and when the agent who made the recording was not subjected to cross-examination. That fact-bound contention is without merit and does not merit review.

Initially, petitioners' assertion that the tape recording was the exclusive basis for the Hearing Officer's finding of a violation is incorrect. The Hearing Officer also relied on petitioners' admission that they failed to collect any of the data necessary to determine whether the LISTEN System device could detect diabetes. Pet. App. 38a, 53a. That evidence was sufficient by itself to establish a violation of the decree.

In any event, petitioners' challenge to the Hearing Officer's reliance on the recording is without merit. As the Hearing Officer explained, while the recording was incomplete, it "unmistakably establishe[d] that Dr. Tang tested [the investigator] for a multitude of diseases and abnormalities with the device." Pet. App. 53a; see *id* at 39a-45a. The Hearing Officer's reliance on the recording therefore was not arbitrary or capricious.

Petitioners' complaint that they did not have an opportunity to cross-examine the undercover investigator who made the recording is similarly without merit. The consent decree that petitioners voluntarily signed established a procedure under which the FDA would provide notice to petitioners of a violation, and peti-

tioners would then have an opportunity "to submit *written* materials on their behalf, and to make an oral presentation." Pet. App. 79a (emphasis added). The Hearing Officer did not act arbitrarily or capriciously in adhering to that procedure.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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