CIBA CORP. *v.* WEINBERGER, SECRETARY OF HEALTH, EDUCATION, AND WELFARE, ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 72–528. Argued April 17, 1973—Decided June 18, 1973

Petitioner manufactures a drug called Ritonic Capsules, for which it filed a new drug application (NDA) that became effective in 1959, on the basis of the drug's safety. After the enactment of the 1962 amendments to the Federal Food. Drug, and Cosmetic Act, the Food and Drug Administration (FDA) withdrew approval of the NDA on the ground that there was no substantial evidence that the drug was *effective* as claimed, under § 505 of the Act. Petitioner sought review of the withdrawal order in the Court of Appeals for the Second Circuit, as provided in § 505 (h), and that court affirmed the order. Prior to the issuance of the withdrawal order, petitioner sought declaratory and injunctive relief in the District Court in New Jersey, which granted the Government's motion to dismiss the complaint for lack of jurisdiction. The Court of Appeals for the Third Circuit affirmed, holding that FDA was authorized to decide the jurisdictional question as an incident of its power to approve or withdraw approval for NDA's, that its decision was reviewable on direct appeal by a court of appeals, and since the Court of Appeals for the Second Circuit had ruled against petitioner on that appeal, the jurisdictional issue could not be relitigated in a separate suit for a declaratory judgment. *Held:*

1. FDA has jurisdiction in an administrative proceeding to determine whether a drug product is a "new drug" within the meaning of § 201 (p) of the Act. *Weinberger* v. *Bentex Pharmaceuticals, Inc., post,* p. 645. Pp. 643–644.

2. While the Act provides FDA with sanctions, such as civil injunction proceedings, criminal penalties, and *in rem* seizure and condemnation, to enforce the prohibition against sale in commerce of any article in violation of § 505, the Act does not create a dual system, one administrative and the other judicial. P. 644.

3. Where petitioner had an opportunity to litigate the "new drug" issue before FDA and to raise the issue on appeal to

a court of appeals, it may not relitigate the issue in another proceeding. P. 644.

463 F. 2d 225, affirmed.

DOUGLAS, J., delivered the opinion of the Court, in which all Members joined, except BRENNAN, J., who took no part in the consideration or decision of the case, and STEWART, J., who took no part in the decision of the case.

Clyde A. Szuch argued the cause and filed a brief for petitioner.

Deputy Solicitor General Friedman argued the cause for respondents. On the briefs were *Solicitor General Griswold, Assistant Attorney General Kauper, Andrew L. Frey, Howard E. Shapiro, George Edelstein,* and *Peter Barton Hutt.**

MR. JUSTICE DOUGLAS delivered the opinion of the Court.

Petitioner manufactures a drug called Ritonic Capsules† for which it filed a new drug application (NDA) that became effective in 1959. Under the Act then in force, an NDA for a "new drug" required the manufacturer to submit to the Food and Drug Administration (FDA) adequate proof of the drug's safety. This

*Briefs of *amici curiae* urging reversal were filed by *Lloyd N. Cutler, Daniel Marcus,* and *William T. Lake* for Pharmaceutical Manufacturers Assn., and by *Thomas D. Finney, Jr., Thomas Richard Spradlin,* and *Daniel F. O'Keefe, Jr.,* for the Proprietary Assn.

Bruce J. Terris, Joseph Onek, and *Peter H. Schuck* filed a brief for American Public Health Assn. et al. as *amici curiae* urging affirmance.

†It is a prescription drug recommended "for patients who are losing their drive, alertness, vitality and zest for living because of the natural degenerative changes of advancing years"; and for patients who are "debilitated or depressed by chronic illness, overwork, etc., as well as those recuperating from illness or surgery."

particular NDA became effective on the basis of the drug's safety. As we have noted in the companion cases, the 1962 amendments to the Federal Food, Drug, and Cosmetic Act of 1938, 52 Stat. 1040, as amended, 76 Stat. 780, directed FDA to withdraw approval for NDA's which became effective prior to that time if, after notice and opportunity for hearing, it found a lack of "substantial evidence" that the drug involved was *effective* as claimed in its labeling. And, as we have noted, "substantial evidence" as used in the Act, §§ 505 (d) and 505 (e)(3), 21 U. S. C. §§ 355 (d) and 355 (e)(3), means "adequate and well-controlled investigations" from which experts may conclude that the drug will have the claimed effect.

A panel of the National Academy of Sciences-National Research Council (NAS–NRC) reviewed the claims made for Ritonic Capsules and found it "ineffective" for each of the claims. FDA concluded there was a lack of substantial evidence of its efficacy and gave notice of its intent to withdraw the NDA, offering petitioner an opportunity to submit the required kind of data bearing on the efficacy of the drug and stating that withdrawal of approval of the NDA would cause the Ritonic Capsules to be a "new drug" for which no NDA was in effect, thereby making future sales unlawful.

Petitioner responded, submitting data on the issue of efficacy and maintained that Ritonic Capsules was not a "new drug" for purposes of the Act as amended. FDA concluded that petitioner's evidence was insufficient to establish effectiveness and gave notice of a hearing on the withdrawal of the NDA. Petitioner responded, contested FDA's authority to proceed further, and claimed that the product was not a "new drug" under the 1962 Act. It reserved the right to establish its position in the administrative proceedings, in judicial proceedings, or in both. Petitioner filed no more data to support its

position; and accordingly FDA withdrew approval of the NDA on the ground that there was no substantial evidence that the drug was effective as claimed. Petitioner sought review of the withdrawal order in the Court of Appeals for the Second Circuit, as provided in § 505 (h), 21 U. S. C. § 355 (h). The Court of Appeals affirmed the withdrawal order. *CIBA-Geigy Corp.* v. *Richardson,* 446 F. 2d 466.

Meanwhile, and prior to the issuance of the withdrawal order, petitioner brought suit in the District Court for the District of New Jersey seeking declaratory and injunctive relief. After hearing, the District Court granted the Government's motion to dismiss the complaint for lack of jurisdiction. On appeal, the Court of Appeals for the Third Circuit affirmed, 463 F. 2d 225, holding that FDA was authorized to decide the jurisdictional question as an incident of its power to approve or withdraw approval for NDA's, that its decision on that issue was reviewable on direct appeal by a court of appeals, and since the Court of Appeals for the Second Circuit had ruled against petitioner on that appeal, the jurisdictional question could not be relitigated in a separate suit for a declaratory judgment. We affirm the Court of Appeals.

We have stated in *Weinberger* v. *Bentex Pharmaceuticals, Inc., post,* p. 645, our reasons for concluding that FDA has jurisdiction in an administrative proceeding to determine whether a drug product is a "new drug" within the meaning of § 201 (p) of the Act, 21 U. S. C. § 321 (p). A decision that FDA lacks authority to determine in its own proceedings the coverage of the Act it administers, subject of course to judicial review, would seriously impair FDA's ability to discharge the responsibilities placed on it by Congress. As we said in *Weinberger* v. *Hynson, Westcott & Dunning, Inc., ante,* p. 609, and the *Bentex* case, *supra,* the definition of "new drug" as used in § 201 (p)(1) in-

volves a determination of technical and scientific questions by experts. The agency is therefore appropriately the arm of Government to make the threshold determination of the issue of coverage. Cf. *Oklahoma Press Publishing Co.* v. *Walling,* 327 U. S. 186, 210–211, n 47.

It is, of course, true that the Act gives FDA a second line of defense—civil injunction proceedings, criminal penalties, and *in rem* seizure and condemnation. See §§ 302 (a), 303, 304, 21 U. S. C. §§ 332 (a), 333, 334. Those are sanctions to enforce the prohibition of the Act against the sale in commerce of any article in violation of § 505. But the Act does not create a dual system of control—one administrative, and the other judicial. Cases may arise where there has been no formal administrative determination of the "new drug" issue, it being first tendered to a district court. Even then, however, the district court might well stay its hand, awaiting an appropriate administrative determination of the threshold question. See the *Bentex* case, *supra.* Where there is, however, an administrative determination, whether it be explicit or implicit in the withdrawal of an NDA, the tactic of "reserving" the threshold question (the jurisdictional issue) for later judicial determination is not tolerable. There is judicial review of FDA's ruling. But petitioner, having an opportunity to litigate the "new drug" issue before FDA and to raise the issue on appeal to a court of appeals, may not relitigate the issue in another proceeding. *Yakus* v. *United States,* 321 U. S. 414, 444–446.

Affirmed.

MR. JUSTICE BRENNAN took no part in the consideration or decision of this case. MR. JUSTICE STEWART took no part in the decision of this case.