The Burger Court Opinion Writing Database

Weinberger v. Bentex Pharmaceuticals, Inc.

412 U.S. 645 (1973)

Paul J. Wahlbeck, George Washington University
James F. Spriggs, II, Washington University
Forrest Maltzman, George Washington University

To: The Chief Justice
Mr. Justice Brennan
Mr. Justice Stewart
Mr. Justice White
Mr. Justice Marshall
Mr. Justice Blackmun
Mr. Justice Powell
Mr. Justice Rehnquist

1st DRAFT

From: Douglas, J.

Circulated: 5-10-73

Recirculated: _____

SUPREME COURT OF THE UNITED STATES

No. 72-555

Caspar W. Weinberger, Secretary of Health, Education, and Welfare, et al., Petitioners, v. Bentex Pharmaceuticals, Inc., et al.

On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit.

[May —, 1973]

MR. JUSTICE DOUGLAS delivered the opinoin of the Court.

In this case Bentex and some 20 other firms that market drugs containing pentylenetetrazol filed this suit for a declaratory judgment that their drugs containing pentylenetetrazol are generally recognized as safe and efficient and not "new drugs" within the meaning of § 201 (p)(1), and also that they are exempted by the grandfather clause. § 107 (c)(4).

Three separate NAS–NRC panels reviewed the evidence concerning these drugs and each concluded that the drug was "ineffective" for the indicated use. The Commissioner concluded there was a lack of substantial evidence that these drugs were effective for their intended uses and gave notice announcing his intention to initiate proceedings to withdraw approval of the NDAs (34 Fed. Reg. 13673) because of the failure to submit any "adequate and well-controlled studies" (§ 505 (d)) bearing on the efficacy of the drugs in question. Only one NDA holder submitted further evidence which the Commissioner held did not satisfy the statutory standard. He

Changes throughout

To: The Chief Justice
Mr. Justice Brennan
Mr. Justice Stewart
Mr. Justice White
Mr. Justice Marshall
Mr. Justice Blackmun
Mr. Justice Powell
Mr. Justice Rehnquist

From: Douglas, J.

Circulated: _____

Recirculated: 6-12

2nd DRAFT

SUPREME COURT OF THE UNITED STATES

No. 72-555

Caspar W. Weinberger, Secretary of Health, Education, and Welfare, et al., Petitioners, *v.* Bentex Pharmaceuticals, Inc., et al.

On Writ of Certiorari to the United States Court of Appeals for the Fourth Circuit.

[June —, 1973]

MR. JUSTICE DOUGLAS delivered the opinion of the Court.

In this case Bentex and some 20 other firms that market drugs containing pentylenetetrazol filed this suit for a declaratory judgment that their drugs containing pentylenetetrazol are generally recognized as safe and effective and thus not "new drugs" within the meaning of § 201 (p)(1) of the Federal Food, Drug, and Cosmetic Act of 1938 as amended, 21 U. S. C. § 321 (p)(1). They also sought exemption from the new effectiveness requirements by reason of § 107 (c)(4) of the 1962 amendments to the Act, known as the "grandfather" clause.

As part of FDA's Drug Efficacy Study Implementation program, three separate NAS–NRC panels reviewed the evidence concerning these drugs, and each concluded that the drug was "ineffective" for the indicated use. The Commissioner concluded there was a lack of substantial evidence that these drugs were effective for their intended uses and gave notice announcing his intention to initiate proceedings to withdraw approval of the NDAs. FDA had taken the position that withdrawal of approval of an