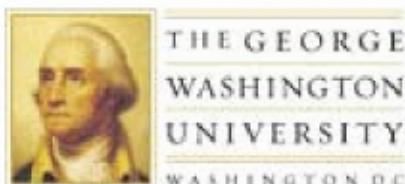


The Burger Court Opinion Writing Database

Weinberger v. Bentex Pharmaceuticals, Inc.
412 U.S. 645 (1973)

Paul J. Wahlbeck, George Washington University
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Forrest Maltzman, George Washington University



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1st DRAFT

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

SUPREME COURT OF THE UNITED STATES

From: Douglas, J.

No. 72-555

Circulated: 5-10-2

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

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

[May —, 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 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

2nd DRAFT

SUPREME COURT OF THE UNITED STATES

No. 72-555

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: 4-12

666
3/4/4-14
5/2/8
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Caspar W. Weinberger, Secretary
of Health, Education, and
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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