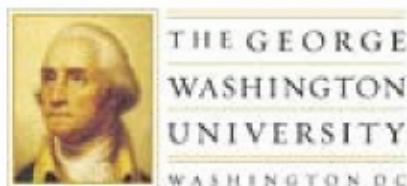


The Burger Court Opinion Writing Database

CIBA Corp. v. Weinberger
412 U.S. 640 (1973)

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



S.D.C.

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

SUPREME COURT OF THE UNITED STATES

From: DOUGLAS, J.

No. 72-528

Circulated: 5-10-73

CIBA Corporation, Petitioner,
 v.
 Caspar W. Weinberger, Secretary
 of Health, Education, and
 Welfare, et al.

On Writ Recirculated:
 to the United States
 Court of Appeals for
 the Third Circuit.

[May —, 1973]

MR. JUSTICE DOUGLAS delivered the opinion of the Court.

Petitioner manufactures a drug called ritonic capsules* for which it filed an NDA that became effective in 1959. Under the Act then in force an NDA for a "new drug" required the manufacturer to submit to FDA adequate proof of the drug's safety. This particular NDA became effective on the basis of the drug's safety. As we have noted in the companion cases the 1962 Act directed FDA to withdraw approval for NDAs which became effective prior to that time if after notice and opportunity for hearing it is found that there is "substantial evidence" that the drug involved is *ineffective* as claimed in its labeling. And as we have noted, "substantial evidence" as used in the Act, § 505 (d) and § 505 (e)(3), means "adequate and well-controlled investigations" from which experts may conclude that the drug will have the claimed effect.

A panel of NAS-NRC reviewed the claims made for ritonic capsules and found it "ineffective" for each of the

*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, over-work, etc., as well as those recuperating from illness or surgery."

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2nd DRAFT

C
SUPREME COURT OF THE UNITED STATES

No. 72-528

From: Douglas, J.

CIBA Corporation, Petitioner,
v.
Caspar W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.

Circulated: _____
On Writ of Certiorari
to the United States
Court of Appeals for
the Third Circuit.
Recirculated: 6-12

[June —, 1973]

MR. JUSTICE DOUGLAS delivered the opinion of the Court.

Petitioner manufactures a drug called Ritonic Capsules* for which it filed an NDA that became effective in 1959. Under the Act then in force an NDA for a "new drug" required the manufacturer to submit to FDA adequate proof of the drug's safety. This 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 directed FDA to withdraw approval for NDAs which became effective prior to that time if after notice and opportunity for hearing, it is found that there is a lack of "substantial evidence" that the drug involved is *effective* as claimed in its labeling. And as we have noted, "substantial evidence" as used in the Act, § 505 (d) and § 505 (e)(3), means "adequate and well-controlled investigations" from which experts may conclude that the drug will have the claimed effect.

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*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, over-work, etc., as well as those recuperating from illness or surgery."

Supreme Court of the United States
Washington, D. C. 20543

CHAMBERS OF
JUSTICE HARRY A. BLACKMUN

June 11, 1973

Re: No. 72-528 - Ciba Corp. v. Weinberger
No. 72-555 - Weinberger v. Bentex Pharmaceuticals
No. 72-666 - USV Pharmaceutical Corp. v. Weinberger

Dear Bill:

Please join me in the respective opinions you have
prepared for these cases.

Sincerely,

H.A.B.

Mr. Justice Douglas

cc: The Conference

Supreme Court of the United States

Washington, D. C. 20543

CHAMBERS OF
JUSTICE HARRY A. BLACKMUN

June 11, 1973

Re: No. 72-528 - Ciba Corp. v. Weinberger
No. 72-555 Weinberger v. Bentex Pharmaceuticals ✓
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Dear Bill:

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Sincerely,

H.A.B.

Mr. Justice Douglas

cc: The Conference

Dear Bill:

In No. 72-555, page 3, last paragraph, first line, is the date "May 1922." Do I correctly suspect that this is a typographical error? I would not bother you with this inquiry except that the date is so obviously disjointed and affects the meaning of the sentence in which it appears.

H.A.B.