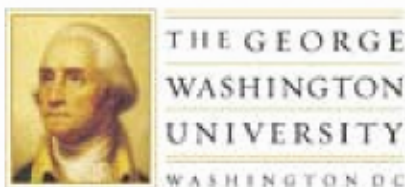


The Burger Court Opinion Writing Database

Weinberger v. Hynson, Wescott & Dunning, Inc.

412 U.S. 609 (1973)

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



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



CHAMBERS OF
THE CHIEF JUSTICE

May 22, 1973

PERSONAL

72-394

Re: Drug Cases

Dear Lewis:

Re your memorandum to Justice Douglas and the Conference dated May 16: this case has never been voted on in Conference. Bill Douglas was requested to prepare a memo analyzing the cases to afford a background for voting. Thus, there is no occasion yet to deal with a possible dissent.

Regards,

Mr. Justice Powell

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

CHAMBERS OF
THE CHIEF JUSTICE

May 30, 1973

Re: No. 72-394 - Weinberger v. Hynson, Westcott & Dunning
No. 72-414 - Hynson, Westcott & Dunning v. Weinberger
No. 72-528 - CIBA v. Weinberger
No. 72-555 - Weinberger v. Bentex Pharmaceuticals
No. 72-666 - USV Pharmaceuticals v. Weinberger

Dear Bill:

I am close to agreeing with you on all these cases except
that in No. 72-394, Weinberger v. Hynson, et al. I tend to agree
with Byron and Lewis on the hearing point.

I will await other reactions before I am fully at rest.

Regards,

WRB

Mr. Justice Douglas

Copies to the Conference

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

CHAMBERS OF
THE CHIEF JUSTICE

June 15, 1973

Re: No. 72-394) - Weinberger v. Hynson
No. 72-414) - Hynson v. Weinberger

No. 72-528 - CIBA v. Weinberger
No. 72-555 - Weinberger v. Bentex
No. 72-666 - USV v. Weinberger

Dear Bill:

Please join me.

Regards,



Mr. Justice Douglas

Copies to the Conference

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

CHAMBERS OF
JUSTICE WILLIAM O. DOUGLAS

May 8, 1973

MEMORANDUM TO THE CONFERENCE:

The FDA Cases

Nos. 394 and 72-414 are the main cases in the series. The problem of the summary administrative procedure which looked troublesome turns out to be picayune.

W D C
W. O. D.

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

2nd DRAFT

SUPREME COURT OF THE UNITED STATES

Nos. 72-394 AND 72-414

From: Douglas, J.

Circulated: 5-10-73

Recirculated: _____

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.,
Petitioners,

72-394

v.

Hynson, Westcott and Dunning,
Incorporated.

Hynson, Westcott and Dunning,
Incorporated, Petitioner,

72-414

v.

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.

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

[May --, 1973]

MR. JUSTICE DOUGLAS delivered the opinion of the
Court.

These cases, together with *Weinberger v. Bentex Pharmaceuticals, Inc.*, post, at —, *Ciba Corp. v. Weinberger*, post, at —, and *USV Pharmaceutical Corp. v. Weinberger*, post, at —, all here on certiorari, raise a series of questions under the 1962 Amendments¹ to the Federal Food, Drug, and Cosmetic Act of 1938. 52 Stat. 1040. The 1938 Act established a system of premarketing clearance for drugs. That Act prohibits the introduction into commerce of any "new drug" unless an application (NDA) filed with the Food and Drug Administration

¹ This is called the Harris-Kefauver Act, 76 Stat. 780, amending 21 U. S. C. § 301 et seq.

6.12

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

3rd DRAFT

From: Douglas, J.

SUPREME COURT OF THE UNITED STATES

Nos. 72-394 AND 72-414

Recirculated: 5/30/72

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.,
Petitioners.

72-394

Hynson, Westcott and Dunning,
Incorporated.

Hynson, Westcott and Dunning,
Incorporated, Petitioner

72-414

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.

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

[May -- 1973]

MR. JUSTICE DOUGLAS delivered the opinion of the
Court

These cases, together with *Weinberger v. Bentez Pharmaceuticals, Inc.*, post, at —, *Ciba Corp. v. Weinberger*, post, at —, and *USV Pharmaceutical Corp. v. Weinberger*, post, at —, all here on certiorari, raise a series of questions under the 1962 Amendments¹ to the Federal Food, Drug, and Cosmetic Act of 1938. 52 Stat. 1040. The 1938 Act established a system of premarketing clearance for drugs. That Act prohibits the introduction into commerce of any "new drug" unless an application (NDA) filed with the Food and Drug Administration

¹ This is called the Harris-Kefauver Act, 76 Stat. 780, amending 21 U. S. C. § 301 et seq.

10-11, 12, 18, 19, 21, 24
sty. 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

4th DRAFT

From: Douglas, J.

SUPREME COURT OF THE UNITED STATES

Circulated: _____

Recirculated: 6/6/7

Nos. 72-394 AND 72-414

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.,
Petitioners,

72-394 v.

Hynson, Westcott and Dunning,
Incorporated.

Hynson, Westcott and Dunning,
Incorporated, Petitioner.

72-414 v.

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.

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

[May —, 1973]

MR. JUSTICE DOUGLAS delivered the opinion of the
Court.

These cases, together with *Weinberger v. Bentex Pharmaceuticals, Inc.*, post, at —, *Ciba Corp. v. Weinberger*, post, at —, and *USV Pharmaceutical Corp. v. Weinberger*, post, at —, all here on certiorari, raise a series of questions under the 1962 amendments¹ to the Federal Food, Drug, and Cosmetic Act of 1938. 52 Stat. 1040. The 1938 Act, which established a system of premarketing clearance for drugs, prohibited the introduction into commerce of any "new drug" unless an application (NDA) filed with the Food and Drug Administration

¹ This is called the Harris-Kefauver Act, 76 Stat. 780, amending 21 U. S. C. § 301 et seq.

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

CHAMBERS OF
JUSTICE WILLIAM O. DOUGLAS

June 7, 1973




72-394

Dear Lewis:

I have your further memo on
the FDA cases.

If there is anything further
I can do in 394 to ease your problem, I'd
be happy to try.


William O. Douglas

Mr. Justice Powell

9 — file
Changes
throughout

5th DRAFT

SUPREME COURT OF THE UNITED STATES

Nos. 72-394 AND 72-414

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: 6-13

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.,
Petitioners,

72-394 v.

Hynson, Westcott and Dunning,
Incorporated.

Hynson, Westcott and Dunning,
Incorporated, Petitioner,

72-414 v.

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.

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

[June —, 1973]

MR. JUSTICE DOUGLAS delivered the opinion of the Court.

These cases, together with *Weinberger v. Bentex Pharmaceuticals, Inc.*, post, at —, *CIBA Corp. v. Weinberger*, post, at —, and *USV Pharmaceutical Corp. v. Weinberger*, post, at —, all here on certiorari, raise a series of questions under the 1962 amendments¹ to the Federal Food, Drug, and Cosmetic Act of 1938. 52 Stat. 1040. The 1938 Act, which established a system of premarketing clearance for drugs, prohibited the introduction into commerce of any “new drug” unless a new drug application (NDA) filed with the Food and Drug Administration

¹ Drug Amendments of 1962 (Harris-Kefauver Act), 76 Stat. 780, amending 21 U. S. C. § 301 et seq.

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

CHAMBERS OF
JUSTICE WM. J. BRENNAN, JR.

April 10, 1973

MEMORANDUM TO THE CONFERENCE

RE: No. 72-394 Richardson v. Hynson, Wescott, etc.
No. 72-414 Hynson, Wescott, etc. v. Richardson
No. 72-528 CIBA Corporation v. Richardson
No. 72-555 Richardson v. Bentex Pharmaceuticals
No. 72-666 USV Pharmaceutical v. Richardson

When I picked up the briefs in the above cases preparing for the arguments next week, I discovered for the first time that petitioner in No. 72-528 CIBA Corporation v. Richardson is represented by my old firm Pitney, Hardin and Kipp, and that the argument for petitioner is being made by Clyde Szuch, a partner of that firm and my law clerk in the 1956 Term which was my first Term. I have not yet participated in any case since coming here in which my former firm represented a party. I recommended Clyde Szuch for employment by the firm after he finished his clerkship with me and think that, although it is now 25 years since I resigned from the firm, this series of cases would be particularly inappropriate for me to depart from the practice. Since the issue presented by that case is common to all of the cases, I shall not participate in the consideration or decision of any of the cases.

W. J. B. Jr.

WB
WJ

9
Supreme Court of the United States
Washington, D. C. 20543

CHAMBERS OF
JUSTICE WM. J. BRENNAN, JR.

May 10, 1973

RE: The FDA Cases

Dear Bill:

Will you please note at the foot of each of your
opinions in these cases that "Mr. Justice Brennan took
no part in the consideration or decision of these cases."

Sincerely,



Mr. Justice Douglas

cc: The Conference

7

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

CHAMBERS OF
JUSTICE POTTER STEWART

May 11, 1973

Re: FDA Cases

Dear Bill,

Please add at the foot of your opinion
in numbers 72-394 and 72-414 the following:

Mr. Justice Stewart took
no part in the decision of
these cases.

In each of the other opinions, please add at the foot
thereof:

Mr. Justice Stewart took no
part in the decision of this
case.

Sincerely yours,

P.S.
/

Mr. Justice Douglas

Copies to the Conference

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7

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

CHAMBERS OF
JUSTICE BYRON R. WHITE

May 22, 1973

Dear Bill:

I join your opinions in Nos. 72-414, 72-666, 72-528 and 72-555.

I cannot agree with you on the hearing issue in No. 72-394 and will shortly file a brief dissent to this effect. It is not my point that the administrative summary judgment procedure is unacceptable or that the regulations providing for the submission of evidence creating a substantial issue of fact were invalid. The Court of Appeals in this case did not question them; indeed it agreed with Ciba-Geigy Corp. v. Richardson, 446 F. 2d 466, that the Commissioner was authorized to require the submission of sufficient materials to make out a prima facie case and to create a genuine issue of fact. The Court of Appeals, on the basis of the record before it, simply disagreed with the FDA that the company's submitted evidence was insufficient. I would not overturn that judgment but would affirm it essentially for the reasons stated by the Court of Appeals.

Sincerely,



Mr. Justice Douglas

Copies to Conference

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

1st DRAFT

From: White, J.

SUPREME COURT OF THE UNITED STATES

Circulated: 5-25-73

Recirculated: _____

No. 72-394

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.,
Petitioners,
v.
Hynson, Westcott and Dunning,
Incorporated.

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

[June —, 1973]

Memorandum of MR. JUSTICE WHITE.

Section 505 (e) of the Federal Food, Drug, and Cos-
metic Act as amended, 21 U. S. C. § 355 (e) provides:

"The Secretary shall, after due notice and op-
portunity for hearing to the applicant, withdraw
approval of an application with respect to any drug
under this section if the Secretary finds . . . (3) on
the basis of new information before him with re-
spect to such drug, evaluated together with the evi-
dence available to him when the application was
approved, that there is a lack of substantial evidence
that the drug will have the effect it purports or is
represented to have under the conditions of use
prescribed, recommended, or suggested in the label-
ing thereof. . . ."

Elsewhere in the Act, the term "substantial evidence"
is defined as:

"evidence consisting of adequate and well-controlled
investigations, including clinical investigations, by
experts qualified by scientific training and experience

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3

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

CHAMBERS OF
JUSTICE BYRON R. WHITE

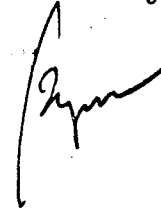
June 5, 1973

Re: Nos. 72-394 & 72-414 - Weinberger v.
Hynson, Westcott and Dunning, Inc.

Dear Bill:

I join Part II of your opinion. As for Part I, I shall not file my May 25 memorandum as an opinion; but if Lewis is writing I should like to see what he has in mind before coming to rest.

Sincerely,



Mr. Justice Douglas

Copies to Conference

M

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

CHAMBERS OF
JUSTICE BYRON R. WHITE

June 12, 1973

Re: Nos. 72-394 & 72-414 - Weinberger v.
Hynson, Westcott & Dunning, Inc.

Dear Bill:

I now join your opinion in these cases.

Sincerely,

Byron

Mr. Justice Douglas

Copies to Conference

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

CHAMBERS OF
JUSTICE THURGOOD MARSHALL

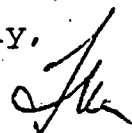
June 6, 1973

Re: The Drug Cases
Nos. 72-394, 72-414, 72-528, 72-555, 72-666

Dear Bill:

With your recirculation today
in Nos. 72-394 and 72-414, I am glad to
join each of your opinions in these cases.

Sincerely,



T.M.

Mr. Justice Douglas

cc: Conference

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

CHAMBERS OF
JUSTICE HARRY A. BLACKMUN

June 11, 1973

Re: No. 72-394 - Weinberger v. Hynson, Westcott
& Dunning, Inc.
No. 72-414 - Hynson, Westcott & Dunning, Inc.
v. Weinberger

Dear Bill:

Subject to any further writing that might be forthcoming, I am glad to join your proposed opinion for these cases.

Sincerely,

H. A. B.

Mr. Justice Douglas

cc: The Conference

3
Supreme Court of the United States
Washington, D. C. 20543

CHAMBERS OF
JUSTICE LEWIS F. POWELL, JR.

May 16, 1973

Drug Cases - No. 72-394, 72-528, 72-555, 72-414 and 72-666

Dear Bill:

First, may I express my admiration for the speed in which you were able to write and circulate opinions in these complex cases.

I have made a first review of your opinions and think I will join you in all except one. This is not a formal "join" note at this time, but merely an indication of my present thinking.

I also wanted to advise you and the Conference that I remain unconvinced that the Fourth Circuit was wrong on the hearing issue in 72-394 (Weinberger v. Hynson, etc.), and would like to see a dissenting opinion affirming CA 4 on this issue.

Sincerely,

Lewis

Mr. Justice Douglas

cc: The Conference

lfp/gg

9

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

CHAMBERS OF
JUSTICE LEWIS F. POWELL, JR.

June 5, 1973

No. 72-394, 72-414, 72-528, 72-555, 72-666

Dear Bill:

I will join Part II of your opinion, and concur in the result in Part I (on the hearing issue).

Your opinion does affirm the Court of Appeals' holding that there was sufficient evidence for a hearing. But the opinion also broadly approves the validity of the regulations (p. 9). I doubt whether it is necessary to reach this question in the case before us. I am considering writing a brief opinion to this effect, especially as I have considerable doubt as to the validity of the regulations in so far as they may go beyond the legislative definition of substantial evidence.

Sincerely,

Lewis

Mr. Justice Douglas

CC: The Conference

lfp/gg

3
Supreme Court of the United States
Washington, D. C. 20543

CHAMBERS OF
JUSTICE LEWIS F. POWELL, JR.

June 6, 1973

No. 72-394 Weinberger v. Hynson
No. 72-414 Hynson v. Weinberger
No. 72-528 CIBA v. Weinberger
No. 72-555 Weinberger v. Bentex
No. 72-666 USV v. Weinberger

Dear Bill:

In my note yesterday, the caption included all five of the drug cases. The text of my note related only to your opinion in 72-394 and 72-414.

In order to clarify the confusion I write to reaffirm my indicated position in my note of May 16, and therefore to join your opinion in No. 72-528, 72-555 and 72-666.

As to your opinion in 72-394 and 72-414, I will join Part II thereof and concur in the result in Part I (the hearing issue).

For the reason indicated in my earlier note yesterday, I expect to write something on the hearing issue.

Sincerely,

Lewis

Mr. Justice Douglas

cc: The Conference

lfp/gg

No. 72-394 Weinberger v. Hynson, Wescott
and Dunning, Incorporated
No. 72-414 Hynson, Wescott and Dunning,
Incorporated v. Weinberger

MR. JUSTICE POWELL, concurring in part, and con-
curring in the result in part.

I concur in Part II of the Court's opinion, which disposes
of the issues raised by Hynson, Wescott and Dunning, Incorporated,
in its cross-petition (No. 72-414). As to Part I, which addresses
issues raised in the petition filed by the Commissioner of FDA
(No. 72-394), I concur only in the result and state briefly the
limited sense in which I accept the Court's conclusion.

Insofar as the Court today sustains the holding below that
Hynson's submission to FDA raised "a genuine and substantial
issue of fact" requiring a hearing on the ultimate issue of efficacy,
21 C. F. R. 130.14(b) (1970), I am in accord. Hynson's presentation
in support of the efficacy of Lutrexin clearly justified a hearing as
to whether the drug was supported by "adequate and well controlled
investigations," 21 U. S. C. 355(d), even as that term is defined
in the Commissioner's regulations. 21 C. F. R. 130.12(a)(5)(1970).
For this reason I concur in the result reached in this case. I

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Printed
1st DRAFT

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

SUPREME COURT OF THE UNITED STATES

Nos. 72-394 AND 72-414

From: Powell, J.

Circulated: _____

Re-circulated: JUN 13 1973

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.,
Petitioners,
72-394 v.
Hynson, Westcott and Dunning,
Incorporated.
Hynson, Westcott and Dunning,
Incorporated, Petitioner,
72-414 v.
Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.

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

[June —, 1973]

MR. JUSTICE POWELL, concurring in part, and concurring in the result in part.

I concur in Part II of the Court's opinion, which disposes of the issues raised by Hynson, Westcott and Dunning, Incorporated, in its cross-petition (No. 72-414). As to Part I, which addresses issues raised in the petition filed by the Commissioner of FDA (No. 72-394), I concur only in the result and state briefly the limited sense in which I accept the Court's conclusion.

Insofar as the Court today sustains the holding below that Hynson's submission to FDA raised "a genuine and substantial issue of fact" requiring a hearing on the ultimate issue of efficacy, 21 CFR § 130.14 (b) (1970), I am in accord. Hynson's presentation in support of the efficacy of Lutrexin clearly justified a hearing as to whether the drug was supported by "adequate and well

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1 — P 2

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

2nd DRAFT

SUPREME COURT OF THE UNITED STATES

From: Powell, J.

Nos. 72-394 AND 72-414

Circulated: _____

Recirculated: **JUN 15 1973**

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.,
Petitioners,

72-394 v.

Hynson, Westcott and Dunning,
Incorporated.

Hynson, Westcott and Dunning,
Incorporated, Petitioner,

72-414 v.

Casper W. Weinberger, Secretary
of Health, Education, and
Welfare, et al.

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

[June —, 1973]

MR. JUSTICE POWELL, concurring in part, and concurring in the result in part.

18-111
I concur in Part II of the Court's opinion, which disposes of the issues raised by Hynson, Westcott and Dunning, Incorporated, in its cross-petition (No. 72-414). As to Part I, which addresses issues raised in the petition filed by the Commissioner of FDA (No. 72-394), I concur only in the result and state briefly the limited sense in which I accept the Court's conclusion.

Insofar as the Court today sustains the holding below that Hynson's submission to FDA raised "a genuine and substantial issue of fact" requiring a hearing on the ultimate issue of efficacy, 21 CFR § 130.14 (b) (1970), I am in accord. Hynson's presentation in support of the efficacy of Lutrexin clearly justified a hearing as to whether the drug was supported by "adequate and well

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

CHAMBERS OF
JUSTICE WILLIAM H. REHNQUIST

May 29, 1973

Re: No. 72-394 - Weinberger v. Hynson, et al.

Dear Byron:

Please join me.

Sincerely,

WHR

Mr. Justice White

Copies to the Conference

5-1111

3
file
Supreme Court of the United States
Washington, D. C. 20543

CHAMBERS OF
JUSTICE WILLIAM H. REHNQUIST

June 12, 1973

Re: No. 72-394 - Weinberger v. Hynson
No. 72-414 - Hynson v. Weinberger
No. 72-528 - CIBA v. Weinberger
No. 72-555 - Weinberger v. Bentex
No. 72-666 - USV v. Weinberger

Dear Bill:

Please join me in your opinions for the Court in these
cases.

Sincerely,
WHR

Mr. Justice Douglas

Copies to the Conference