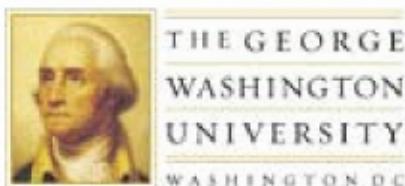


The Burger Court Opinion Writing Database

USV Pharmaceutical Corp. v. Weinberger
412 U.S. 655 (1973)

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



1
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

No. 72-666 seems to me to present
the most difficult legal question,
though the result reached is necessary
lest the Act be turned on its ear.

W. O. D. *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

1st DRAFT

SUPREME COURT OF THE UNITED STATES

No. 72-666

Circulated: 5-10-73

USV Pharmaceutical Corpora-
 tion, Petitioner,
 v.
 Caspar W. Weinberger, Secretary
 of Health, Education, and
 Welfare, 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.

Petitioner sells a line of drugs containing citrus bioflavonoid as a principal active ingredient which is an extract from fruit skins. The drugs are sold in capsules, syrup, and tablets. In the 1950s NDAs were issued for six of them; two, however, were sold without any NDA. In 1961 FDA advised petitioner that two of the products, when distributed under the existing labels, were not new drugs. These drugs were recommended for a wide variety of ailments from bleeding to hypertension to ulcerative colitis. After the 1962 Act these products, together with a large number of other bioflavonoid products, were examined by FDA for drug effectiveness. NAS-NRC panels examined them. One panel on Metabolic Disorders concluded that the "use of these materials as hemostatic agents for capillary fragility is felt to be unjustifiable and not proved." A panel on Hematologic Disorders found there was no proof that these products were efficacious for any medical use. FDA gave notice of its conclusion and notice of a hearing on the withdrawal of NDAs for drugs containing these compounds.

3, 10, 11
and stylistic changes

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.

No. 72-666

Circulated:

Recirculated:

5-25-73

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

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.

Petitioner sells a line of drugs containing citrus bioflavonoid as a principal active ingredient which is an extract from fruit skins. The drugs are sold in capsules, syrup, and tablets. In the 1950s NDAs were filed and became effective for seven of them; two, however, were sold without any NDA. In 1961 FDA advised petitioner that two of the products, when distributed under the existing labels, were not new drugs. These drugs were recommended for a wide variety of ailments from bleeding to hypertension to ulcerative colitis. After the 1962 Act these products, together with a large number of other bioflavonoid products, were examined by FDA for drug effectiveness. NAS-NRC panels reviewed them. One panel on Metabolic Disorders concluded that the "use of these materials as hemostatic agents for capillary fragility is felt to be unjustifiable and not proved." A panel on Hematologic Disorders found there was no proof that these products were efficacious for any medical use.

Based upon the NAS-NRC reports and its own evaluation, FDA gave notice of opportunity for hearing on its

7 11

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.

Circulated:

Recirculated: 6-14

SUPREME COURT OF THE UNITED STATES

No. 72-666

USV Pharmaceutical Corpora-
tion, Petitioner,

v.

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

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.

Petitioner sells a line of drugs containing citrus bioflavonoid as a principal active ingredient which is an extract from fruit skins. The drugs are sold in capsules, syrup, and tablets. In the 1950s NDAs were filed and became effective for seven of them; two, however, were sold without any NDA. In 1961 FDA advised petitioner that two of the products, when distributed under the existing labels, were not new drugs. These drugs were recommended for a wide variety of ailments from bleeding to hypertension to ulcerative colitis. After the 1962 amendments these products, together with a large number of other bioflavonoid products, were examined by FDA for drug effectiveness. NAS-NRC panels reviewed them. One panel on Metabolic Disorders concluded that the "use of these materials as hemostatic agents for capillary fragility is felt to be unjustifiable and not proved." A panel on Hematologic Disorders found there was no proof that these products were efficacious for any medical use.

Based upon the NAS-NRC reports and its own evaluation, FDA gave notice of opportunity for hearing on its