ORIGINAL

In the

Supreme Court of the United States

UNITED STATES OF AMERICA, ET AL.,	)	
	)	
Petitioner,	)	
	)	
v.	)	No. 78-605
	)	
GLEN L. RUTHERFORD, ET AL.,	)	
	)	
Respondent.	)	

Washington, D. C.
April 25, 1979

Pages 1 thru 42

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Friday, April 25, 1979
Washington, D.C.

The above-entitled matter came on for argument at 1:21 o'clock, p.m.

BEFORE:

WARREN E. BURGER, Chief Justice of the United States
WILLIAM BRENNAN, Associate Justice
POTTER STEWART, Associate Justice
BYRON R. WHITE, Associate Justice
THURGOOD MARSHALL, Associate Justice
HARRY A. BLACKMUN, Associate Justice
LEWIS F. POWELL, JR., Associate Justice
WILLIAM H. REHNQUIST, Associate Justice
JOHN PAUL STEVENS, Associate Justice

APPEARANCES:

WADE H. McCREE, JR., ESQ., Solicitor General of the United States, Department of Justice, Washington, D.C. 20530; on behalf of petitioners.

KENNETH RAY COE, ESQ., Looney, Nichols, Johnson & Hayes, 219 Couch Drive, Oklahoma City, Oklahoma 73102; on behalf of respondents.

C O N T E N T S

P R O C E E D I N G S

CHIEF JUSTICE BURGER: We will hear arguments next in 78-605, United States against Rutherford.

Mr. Solicitor General.

ORAL ARGUMENT OF WADE H. McCREE, JR., ESQ.,

ON BEHALF OF THE PETITIONERS

GENERAL McCREE: Mr. Chief Justice, and may it please the Court:

This case concerns a drug or group of drugs variously referred to in the record as Laetrile, with a capital "L," laetrile with a lower case "l," amygdalin, and Vitamin B-17.

Part of the problem with this case is the difficulty of distinguishing just which drug is referred to in a particular context.

Generically, this drug or group of drugs comprise a compound known as a cyanogenetic glucoside. I understand a glucoside to be one of a group of organic compounds found in the kernels and seeds of most fruit that hydrolize or break down to yield glucose, which is a sugar; and in the case of a cyanogenic glucoside, hydrogen cyanide, as well, which of course, is a poison.

Amygdalin is the name of a cyanogenic glucoside that is frequently used interchangeably with Laetrile, either with a capital "l" or a small case "l."

One other definition might be useful. One of the

chemical definitions of laetrile--or proper definitions of laetrile--that has been--was made in the administrative record as laevo, l-a-e-v-o, laevo-mandelonitrile-beta-glucoside.

I say all of that to suggest the origin of the name, laetrile. L-a-e-v-o is the first part, which means "left," as I understand it from the Latin. And mandelonitrile is the chemical. And if we take "l-a-e" from "laevo," and the "t-r-i-l-e" from "mandelonitrile," we have laetrile.

And this is the drug with which we are concerned today. The left business, the "laevo," is in contrast to "dextro" which would be a right rotation. And it refers to the way these two drugs show up in polarized light.

The proponents of this drug laetrile contend that it is a cancer cure, and in some instances, a cancer preventive.

The processes change from time to time, but in short it appears to be the following: It is the theory of the proponents that laetrile releases hydrocyanic acid, which is a poison, and it does so in the presence of an enzyme that allegedly occurs in greater concentration in malignant cells than it does in normal cells. And therefore the malignant cells are destroyed by the action of this chemical.

The case comes before us as a consequence of a curious proceeding. The Federal Food, Drug and Cosmetic Act

prohibits the introduction of any new drug as defined in the statute into interstate commerce unless a new drug application, a NDA, supported by appropriate evidence of the drug's safety and effectiveness, has been approved by the Commissioner of the Food and Drug Administration, who is the Secretary of Health, Education, and Welfare's designate; or unless the drug is exempted from the approval requirements by one of the act's two grandfather provisions: One in 1938 and the other in 1962, both of which are still operative.

Because Laetrile had not been established as being entitled to grandfather status, or as having met the statutory requirements for approval as a new drug, the Food and Drug Administration brought a series of civil and criminal proceedings to prevent the introduction of laetrile under various names into interstate commerce.

In March, 1975, respondents brought a suit in the United States District Court for the Western District of Oklahoma to enjoin the government from interfering with the sale and distribution to patients suffering from cancer of a substance known as B-17, laetrile and amygdalin.

The District--

QUESTION: What was the status of the respondents? What conferred upon them standing to bring this suit?

GENERAL McCREE: That's a question for which I haven't a good answer, if the Court please. The government

has raised the question of the jurisdiction of the court and their standing. But it was decided adversely to the government. And in its present posture, we suggest that on a remand, there probably was jurisdiction.

But at this stage, I cannot answer, Mr. Justice Stewart.

QUESTION: Are these--do the respondents allege in their complaint that they want to use it, or members of their family want to use it?

GENERAL McCREE: They wish to use it.

QUESTION: They're not producers or sellers of it, are they?

GENERAL McCREE: They're not producers. They allege that they were patients suffering from cancer, and that they were terminally ill cancer patients. And they were later certified as a class consisting of terminally ill cancer patients.

And they wish access to the drug for their therapy to be administered to them by their physicians.

The District Court issued a preliminary injunction forbidding the government from preventing the purchase and interstate movement of laetrile for respondent Rutherford and the other members of the class who could show by affidavit that they were terminally ill with cancer.

On appeal by the government, the Tenth Circuit

upheld the granting of the injunction, but instructed the District Court to remand the case to the Commission for the development of an administrative record adequate under the Administrative Procedures Act, addressing the issues, first, whether laetrile is a new drug within the meaning of the Act; and second, if so, whether it is exempt from the premarketing requirements because of either the 1938 or the 1962 grandfather clause.

Upon remand, the Commissioner initiated administrative proceedings through a Federal Register announcement seeking public comment.

In the proceedings, which included two days of oral presentation, produced more than 400 submissions and more than 5,000 pages of testimony, at the conclusion of which the Commissioner concluded, first, that laetrile was a broad generic term for a group of related compounds, and that in its various forms, it is a new drug within the meaning of the Food and Drug Act; and that it was definitely toxic when taken orally; that it had not been adequately tested for safety; that it was not generally recognized among experts as safe for use in man; and the distribution prior to meeting the pre-marketing approval of the FDA, would be unlawful, unless it qualified for exempt status under either grandfather provision.

He concluded that it was not exempt under the 1938

exemption, grandfather exemption; or the 1962, because the drug with which he was concerned had not been used commercially under the same or similar label for therapeutic purposes before either the 1938 time or the 1962 time, which would have permitted it to continue in commerce.

He concluded that the distribution of laetrile in interstate commerce is in violation of the Food, Drug and Cosmetic Act, and subject to regulatory action.

QUESTION: Mr. Solicitor General, what evidence did the District Court have before it as the basis for finding that this was non-toxic?

GENERAL McCREE: If the Court please, the District Court, when it initially granted the injunction, had no evidence before it except--

QUESTION: But he did make a finding that it was non-toxic, did he not?

That's my impression from the summary of your argument or part of your brief.

GENERAL McCREE: Well, the matter went back to the District Court from the Administrative hearing; and do I understand you're inquiring about the second time the District Court looked at it or the first time?

QUESTION: Well, I wasn't clear from what I read whether it was the second time or the first time.

At any time, what evidence did the District Court

have of this drug--this material--being non-toxic?

GENERAL McCREE: It's my understanding that the District Court did not take evidence in this matter but relied on the administrative record that was made.

QUESTION: But he did make a finding that it was non-toxic?

GENERAL McCREE: He made a finding when he reviewed this administrative record that I've just related, which is the next step in the proceeding.

What the District Court did was to sustain the Commissioner's conclusion that laetrile was a new drug. He agreed that it was not exempt under the 1938 grandfather clause. But he concluded that it was exempt under the 1962 grandfather clause; and in doing so, we contend improperly reviewed the evidence that was before the Commissioner, and that was--that was properly within the jurisdiction of the Commissioner to make findings.

And then he did a curious thing which we contend also was in error. He held that the Food and Drug Administration had offended the constitutional right to privacy by denying the right to use a non-toxic substance inconnection with one's own personal health, despite his finding--the Commissioner's finding that laetrile has a known toxicity when taken orally and that the testing is insufficient to determine its toxicity in any form.

QUESTION: Well, isn't there an additional curiosity about the District Court's constitutional holding in that he had already found that it was covered by the grandfather clause in '62 so he didn't have to reach that question?

GENERAL McCREE: Mr. Justice Rehnquist, we agree that it was quite unnecessary for the District Court to make that finding. But the District Court did this nevertheless.

The government appealed it again to the Tenth Circuit. And the Tenth Circuit, without addressing the grandfather ground, or the constitutional ground on which the District Court relied, held as a matter of law that the safety and effectiveness terms used in the statute have no reasonable applications to terminally ill cancer patients, and that the Food and Drug Administrator had erroneously applied the Act to these persons.

Nevertheless, it modified the District Court's injunctions to limit the use to intravenous injections, administered by a licensed medical practitioner, and only to a person certified by a licensed medical practitioner to be terminally ill of cancer in some form.

And he directed the Food and Drug Administration to promulgate regulations within this limitation as if the drug was found by the Commission to be safe and effective for the terminally ill cancer patients.

And the matter is before this Court on a writ of certiorari.

We submit that the following questions are presented:

First, whether the safety and effectiveness requirements of the Federal Food, Drug and Cosmetic Act apply to drugs intended for use by the terminally ill; which is the issue on which the Court of Appeals decided the matter;

We submit further that if the Court decides that question as we think it should, it would want to consider the two grounds found by the District Court for enjoining the interstate distribution of the drug; and therefore it would consider whether the judgment of the Court of Appeals barring application of the Act to interstate distribution of the drug for intravenous administration to terminally ill patients is sustainable on the grounds that laetrile is exempt because of the pre-marketing--from the pre-marketing requirements because of the 1962 grandfather clause; and finally,

Whether the judgment of the Court of Appeals was sustainable on the ground that the prohibition of the interstate distribution violates a constitutional right to privacy.

I'd like to address the first question now, if I may.

QUESTION: Those last two are really questions for your opposition to propose.

GENERAL McCREE: Indeed they are.

QUESTION: And they have, I take it.

GENERAL McCREE: And he's entitled to urge the Court to sustain the judgment on those alternative grounds.

QUESTION: And he has presented them?

GENERAL McCREE: And he has presented them, yes, sir.

The--we submit that the Court of Appeals has misconstrued the statute in holding that the safety and effective requirements of the Act do not apply to terminally ill persons.

In the first place, the Act makes no such exception. There is no language in the Act that says it does not apply to terminally ill persons.

And the legislative history does not support this exception that's contended for. The Food and Drug Administration has consistently administered the Act without recognizing such exception, and the Congress has indicated its acquescence in the administration--the way the Act has been administered, because on at least two occasions, it has amended the Act without changing the construction that the Commission placed on the statute.

We further submit that there's no reliable means of identifying the class except in retrospect. The administrative record teaches that cancer is a disease about

which very little is known; that it frequently goes into spontaneous remission for reasons not understood; and that a person designated as terminally ill may surprise his physician by outliving the prognosis that he makes at the time the designation is indicated.

We also suggest that a drug can be unsafe for a dying person, contrary to the decision of the Court of Appeals, if it poses a risk of shortening the life of the terminally ill person, or if it poses the risk of aggravating the symptoms experienced by the so-called terminally ill person.

QUESTION: I suppose you could add to that, if it had any tendency or risk of hastening death?

GENERAL McCREE: And of course if it was toxic, if it hastened death, it would be a fortiori that it would be unsafe for the terminally ill patient.

We also suggest that the drug is ineffective as well as unsafe if it does not produce the effects of prolonged life or the surcease from pain that is claimed for it. And if it's ineffective, then we say that the Court of Appeals was erroneous in its determination.

We also submit that the terminally ill have the same right to be protected from ineffective drugs just as other people have, and that the Tenth Circuit, by substituting its judgment for that of the Agency charged by Congress with the responsibility of keeping unsafe drugs out of the marketplace

was in error and that this Court should reverse its judgment.

The grandfather's clause, if I may pass to that and anticipate the argument that's in my brother's brief, we submit--and perhaps my brother will answer this--that there's no claim that laetrile was marketed commercially before 1962. And of course to be within the grandfather's clause, the person contending the exemption must show commercial marketing.

We submit that there was not, and we submit that the administrative record is very clear about that.

The Commissioner also found that the composition of different substances referred to as laetrile before and after 1962 varied as to their formulations so that no one could state with certainty just what substance had been grandfathered.

And of course there would be another reason for the grandfather's clause not to apply.

We also submit that the record supports the Commissioner's conclusion that the drug was not generally recognized as safe as required by Section 201(p). He found specifically that there was a hazard of cyanide poisoning. And the record shows that when ingested orally the drug has a very definite toxic effect, and that there was insufficient testing of its consequences when taken by injections, parenterally.

QUESTION: General McCree, in your view who has the burden of proof on the grandfather clause issue?

GENERAL McCREE: I would think the person who

asserted the exemption would have the burden of proof.

QUESTION: Are there any cases that so hold?

GENERAL McCREE: I can't think of a case that specifically addresses that question. But normally a person claiming an exemption from a general rule, in the ordinary theory of the allocation of the burden, would have to sustain it.

This case is curious in another respect: It's not the typical food and drug case. And so the matter of burden, who bears the burden, takes on an interesting aspect.

Here we have patients contending that they have a right to use a drug. And it's not the typical case of the manufacturer of a drug seeking a clearance for it when he would understand what he had to show.

We think contrary to the finding of the District Court that the Commissioner was extremely fair in the hearing that he conducted, because he invited persons who were sponsors of the drug, who were not themselves cancer patients, to present evidence, and he considered their evidence in arriving at his conclusion.

We suggest that there's another reason why the grandfather's clause does not apply, because the only labelling of the drug before 1962 was for investigational use only and not for commercial use; it was labelled to instruct physicians who were conducting experiments in its use, and

as such it did not qualify for the grandfather's clause.

Finally, we say that the District Court employed an improper standard of review by overturning the Commissioner's finding of fact.

There was evidence to support everyone of the Commissioner's findings. We submit that it was his right to do this, and that the District Court improperly invaded the province of the adminsitrative agency in making these findings.

Finally, we would address the constitutional issue. In the first place we say that the asserted right of privacy which would give a terminal patient the right to use this drug is premised upon something that is not so.

It is premised on the unwarranted belief that laetrile has been shown to be non-toxic. And we submit that the record shows clearly that it is toxic. And if it is, the entire premise for this determination is destroyed, and the conclusion should fall.

QUESTION: Is that just true if taken orally?

GENERAL McCREE: It is certainly true if taken orally, and there is no adequate investigation of its consequences when taken by injection.

QUESTION: So you can't say then that it's not toxic?

GENERAL McCREE: You can't say that it's not toxic.

QUESTION: Well, you can't say that it is, either.

GENERAL McCREE: That is correct.

QUESTION: And the Tenth Circuit's order--

GENERAL McCREE: But the--the conclusion--

QUESTION: --the Tenth Circuit's order is limited to intravenous--?

GENERAL McCREE: It is so limited, and we suggest two things from that: First, the limitation that was gratuitous indicates that the Court of Appeals recognized the toxicity when taken orally; but we also suggest that it is his premise that a person has a constitutional right to use a non-toxic drug. And it would appear then that if there is no evidence of toxicity or not, that his conclusion fails, particularly when the drug is shown to be toxic in one form, and it is clear that one of its components is a deadly poison, and no one knows whether it is released in the--when taken parenterally, when injected instead of ingested.

We also suggest that this Court in discussing the right of privacy, has not extended it beyond protecting the individual interest and making independent decisions in matters relating to marriage, procreation, family relationships and bearing and education.

In Whalen v. Roe this Court, at 429 U.S., page 600, in footnote 26, said expressly that the right of privacy did not extend to the drugs that were involved there that were

subject to potential abuse.

We also suggest that the Court has made it clear that even in these protected areas the right of a person not to be regulated might be restricted in the interests of protecting the health of the person concerned.

We point to the abortion cases, the case that involved the saline amniocentesis method of abortion, where the Court said that this wasn't--the prohibition there wasn't to protect the health of the woman, but it was for a different purpose and improper purpose.

And here the concern, if for the health, would not be prohibited.

Also we suggest that historically the exercise of the police power to protect people from harmful drugs or improperly labelled drugs is--far antedates the constitution. When the constitution was adopted, this was a common practice. In fact, we show in our appendix that it began in 1266. I guess that's 200 years after the Norman Conquest. And continuously in Anglo-American history, public health has been protected.

I see my time is nearly expired, and I would like to reserve any remaining time I might have for rebuttal.

MR. CHIEF JUSTICE BURGER: Very well.

QUESTION: Mr. Solicitor General, may I ask you one question?

I read in the press that marijuana is very helpful in relieving pain in cancer patients. Has the FDA ever addressed that question as it arises with respect to marijuana?

GENERAL McCREE: I'm not aware that a new drug application has been filed with the FDA for that.

QUESTION: I've been told it's used for that purpose?

GENERAL McCREE: I have heard that too. And I think I have read, too, that experimental use has been authorized. And I think I read recently that someone who is authorized to use it experimentally had been arrested, I think in one of the New England States, for possessing marijuana that he said was furnished him or authorized by the Food and Drug Administration.

I'm not aware of any litigation.

QUESTION: Has any State passed a right-to-die statute?

GENERAL McCREE: I'm not aware of any right today.

QUESTION: A number of such statutes have been introduced in state legislatures.

GENERAL McCREE: I am aware of that, but I am not aware that any State has done this.

We point out in our reply brief that the only State that has addressed this question of a right of privacy

challenge to self medication is California, and in People V. Privatera, which was just decided March 15th, 1979. California found under both the Federal and the State constitution no constitutionally protected right to take a particular drug.

QUESTION: For medication.

GENERAL McCREE: If I have a moment, I would like to reserve it.

MR. CHIEF JUSTICE BURGER: Mr. Coe.

ORAL ARGUMENT OF KENNETH RAY COE, ESQ.,

ON BEHALF OF THE RESPONDENTS

MR. COE: Mr. Chief Justice, and may it please the Court:

I think initially it is incumbent upon me to discuss with you briefly the limitations that are imposed inherently in this case by the lower courts' rulings.

This case applies only to a class of terminally ill cancer patients, which are represented in this case by Mr. Glen Rutherford. It applies only to the application of the substance known as laetrile. It applies only to the intravenous application of that particular substance. And it applies to application of that substance only under the care of a super--excuse me, of a supervising doctor.

This case has nothing at all--no content other than that, what I've just discussed.

Now the reason I mention that is because it has been asserted in the government's brief, to a large extent, that this case bodes very ill for the Food and Drug Administration. And I just do not believe that is the case. And I do not believe it's the case when you consider what has happened.

Initially this case was brought in the United States District Court for the Western District of Oklahoma by several cancer patients who were desirous of using laetrile, were in the terminal state, and almost immediately died.

Mr. Rutherford was brought in as a replacement or supplemental plaintiff. And at that point in time we moved the court for a temporary injunction so that he wouldn't suffer the same fate as the original plaintiffs.

The District Court granted the injunction just as to Mr. Rutherford, which decision was, of course, appealed to the Tenth Circuit Court of Appeals.

That Circuit made a determination that, in fact, Mr. Rutherford was entitled to the temporary injunction, but that it did not appear to that court that the Food and Drug Administration had a sufficient record upon which to base its new drug determination.

So the case was remanded back to the District Court and a hearing was held before that District Court. At that point in time, Judge Bohannon asked the attorneys for the Food and Drug Administration what administrative record had

been compiled to determine that laetrile was a new drug or that it was not grandfathered by provisions of the '62 amendments or the '38 amendments.

The government attorney stipulated in court at that time--it's a matter of record--that they had no record exclusive of one affidavit which had been prepared by a Food and Drug Administration medical doctor.

Judge Bohanon then remanded the case to the Food and Drug Administration, so that a proper administrative record could be compiled on which he could base some decision and the Tenth Circuit could base some decision as to authenticity of the Administrator's findings.

The Food and Drug Administration then held this rulemaking proceeding. And we've contended throughout this litigation that the rulemaking proceeding that the FDA conducted was not proper under the circumstances.

QUESTION: How did this case get to the District Court, Mr. Coe? It--was it originally an application for administrative review?

MR. COE: No, Your Honor, it was a complaint filed in the United States District Court for the Western District of Oklahoma on behalf of terminally ill cancer patients alleging that the Food and Drug Administration by virtue of a determination that laetrile was a new drug had effectively prohibited their use of the drug and there is

authority for that; I believe that's Weinberger v. Hynson, Westcott & Dunning; that after the Food and Drug Administration has made its initial determination, that a District Court may then review.

QUESTION: So it was an application for administrative review under the--

MR. COE: Yes, Your Honor, I guess you'd have to call it that.

QUESTION: But it went forward just on the administrative record?

MR. COE: Your Honor, it's been backwards and forwards.

QUESTION: Yes, but I mean, has it finally got to--finally, before Judge Bohanon, it--he proceeded on the administrative record.

MR. COE: Yes, Your Honor.

QUESTION: No new evidence?

MR. COE: No new evidence was heard.

The administrative record that was compiled, which was ordered by the Tenth Circuit Court of Appeals, was ordered to comply with the Administrative Procedures Act, Section 554(c). Within that subsection it requires that cross-examination be allowed to the proponents and to the other side in the case.

Now, the Food and Drug Administration selected the most informal proceeding of the variety of proceedings it could

possibly hold, and in fact, allowed witnesses to testify without the administration of an oath, or without the opportunity of cross-examination to determine the veracity of any of those witnesses.

Now, that was so even though an objection was made to the Hearing Examiner at the time to that particular type of proceeding.

The--

QUESTION: You say the Administrative Procedure Act prohibits that?

MR. COE: I'm sorry, I missed that?

QUESTION: You say that the Administrative Procedure Act prohibits that?

MR. COE: No, the Tenth Circuit Court of Appeals required that the FDA conduct proceedings pursuant to 554(c) of the Administrative Procedure Act.

QUESTION: So that you say that 554(c) prohibited the sort of proceedings conducted by the Food and Drug Administration?

MR. COE: Actually, sir, that refers to 556, which grants the right of cross-examination.

QUESTION: So indirectly you say it's--what the FDA did here is prohibited by the Administrative Procedure Act?

MR. COE: By that, and as it was espoused by the

Tenth Circuit Court of Appeals.

QUESTION: Well, you know, I presume the Tenth Circuit has the right to construe the statute, but not to impose its own requirements.

MR. COE: The FDA also has proceedings in which, generally speaking, when a court sends a case to it for review. And generally speaking, those requirements are for a more formal type of hearing. That's in addition to the reqirements of the Tenth Circuit.

That was not met in this case. Now, the argument--

QUESTION: Is that part of the APA? Is that part of the Administrative--

MR. COE: No, it's part of the regulations for the Food and Drug Act, I believe it's Section 1060 or 1080 of their procedures. That's cited in our brief.

At any rate, the FDA did hold its proceedings, and the Commissioner did issue findings, just as the Solicitor General advised the Court.

This was then appealed to the District Court for the Western District of Oklahoma. Judge Bohanon examined the entire administrative record, and based on his review of that record, made a determination that the entire proceedings were arbitrary, capricious, and abused discretion, and not in accordance with law.

He based that upon several things. First he made a

determination that the Food and Drug Administration, by virtue of a notice filed in the Federal Register, espoused the same continuing view toward laetrile as it had been espousing for many years since the 1950s; the same entrenched position.

QUESTION: Well, what's the matter with that?

QUESTION: It just could be correct.

QUESTION: I mean, they're not just judges. They're--they presumably have some right to decide what positions to take on things.

MR. COE: Your Honor, I think that is exactly the point the judge was making. The FDA has made its decision, has made its decision back in 1950 before it had any administrative record whatsoever; and continues to make the same.

He used that particular item to show that there was a lack of in-depth fact finding in the administrative proceedings.

QUESTION: They simply weren't open even to persuasion by new evidence?

MR. COE: I believe that's the point the court was trying to make, Your Honor.

The court decided, as I've just previously said, that the Food and Drug Administration Commissioners' decision should be set aside.

That was set aside. It was set aside on two bases. First of all, it was set aside on the basis that

laetrile is subject to an exemption by virtue of the 1962 grandfather provisions of the Act. He also made a determination that it was not--that it should be set aside based on the fact that it would be a violation of the right to privacy guaranteed by the Ninth Amendment of the Constitution.

QUESTION: What was the evidence on its use before 1962?

MR. COE: Your Honor, there was substantial evidence on use prior to 1962. The evidence of use prior to 1962--

QUESTION: Commercial use. Commercial use, that's the requirement, isn't it?

MR. COE: The requirement is commercial use prior to 1962, Your Honor.

The court cited in, I believe it's footnote 22, affidavits by Chauncey Leake and several other individuals as to commercial use prior to 1962.

QUESTION: Well, you needn't stop to find it now.

MR. COE: At any rate, Your Honor, the District Court found that it was used prior to 1962 and it was used commercially.

The District Court found that the labelling was the same, for all practical purposes, as it was before that date. The District Court found that it was not--thatit was safe, and that it was non-toxic.

Now, without going into great detail on each and

every one of those, because the District Court's opinion sets it out in great detail, and I've briefed it in my brief and the government has briefed it in theirs.

The case law establishes that if there is a difference of opinion among experts, for instance, such as to safety--and this applies across the board, I believe, to the 1962 grandfather exemption--that is a fact question to be determined by the trier of fact.

In this case, Judge Bohanon was sitting as both the trier of law and the trier of fact.

QUESTION: What facts did he have before him?

MR. COE: The facts he had before him were the facts-

QUESTION: Was the administrative record, that's all.

MR. COE: That's all he had.

QUESTION: Well, when you say facts, don't you mean testimony?

MR. COE: Your HOnor, in this case I do mean testimony and--

QUESTION: Well, what case is it that says that he looks at the administrative record, throws out the finding of the administrative body, and replaces it with his own?

Isn't that what was done here?

MR. COE: Your Honor, there is--

QUESTION: Isn't that what was done here?

MR. COE: I'm sorry, Your Honor?

QUESTION: Isn't that what was done here?

MR. COE: Thathe threw out the findings and superimposed his own?

QUESTION: Yes?

MR. COE: Yes, Your HOnor, that's exactly what he did.

QUESTION: And authority for that?

MR. COE: The authority for that is the cases which I've cited under that particular proposition in my brief.

First of all, Your Honor, if I may address the fact that--

QUESTION: Well, where did he get the fact that the law didn't apply to terminally ill people? Where did he find that in the record?

MR. COE: Well, Your Honor, he didn't find anything in the record. In the record, that the law did not apply to terminally ill patients, because that would have been a legal conclusion on his part.

QUESTION: Well, where did he find it?

Where did he find it?

MR. COE: He determined--well, as a matter of fact, I think it was the Tenth Circuit that actually made that determination as such. The Tenth Circuit--

QUESTION: Where did the Tenth Circuit find it?

MR. COE: I think they found that--

QUESTION: You think? You don't know, do you?

MR. COE: Your Honor, I know it in my own mind.

QUESTION: Go ahead and think.

MR. COE: All right. I think, Your Honor, that the Tenth Circuit found that the Act did not apply to terminally ill cancer patients, because it would be ridiculous to apply the term "efficacy" to a terminally ill cancer patient?

QUESTION: Why? Aren't there pain-relieving properties in some drugs that could be used on terminally ill patients?

MR. COE: Your Honor, many of the drugs that are used on terminally ill cancer patients do in fact have pa n killing effects, and generally speaking, that's--

QUESTION: And isn't that the function of this agency, this regulatory body, to see that any--any pain relieving drugs are safe and meet all the other standards?

MR. COE: It is the duty of the Food and Drug Administration to fulfill its Congressional mandate. And it is our position before the Court that the Congressional mandate, which added "efficacy" in particular to the Food and Drug A ct which came out after the thalidomide tragedies, does not have application to terminally ill cancer patients.

And the reasoning behind that is very simply that if in fact there were an effective cancer remedy, then you

wouldn't have terminal cancer patients. They'd be terminal from some other cause entirely.

And as long asyou do not have an effective cancer remedy, that to require that of laetrile is an absurd result from the Act.

QUESTION: Well, what about theChief Justice's question that even a terminally ill patient may need relief from symptomatic conditions;nnot a cure, perhaps not even a remission; relief from pain?

MR. COE: I certainly do not disagree with that. I have no problem with that whatsoever--

QUESTION: You think the Tenth Circuit would exempt that and say, go down and buy a few grains of morphine if you feel it would relieve the pain?

MR. COE: The tTenth Circuit ruled strictly relative to laetrile in the intravenous form. I do not know what the Court would do with some other kinds.

QUESTION: What's your position on that?

MR. COE: My position, as it always has been, is that we have terminal cancer patients desiring to use laetrile. This case has brought that particular issue before the Court. And my position is thatthey should be allowed to use it.

QUESTION: And the Food and Drug Act doesn't apply to terminal patients?

MR. COE: It does not apply to terminally ill cancer

patients desiring to use laetrile under their physician's care.

QUESTION: Where in the world do you get that thing? The statute doesn't say it.

MR. COE: Your Honor, the statute--

QUESTION: The regulations--

MR. COE: Well, I certainly agree with that.

QUESTION: Well, did anybody say it before the court in this case?

MR. COE: No.

QUESTION: So it's brand new?

QUESTION: And you'd say the same thing about heroin or cocaine?

MR. COE: It is my--no, I do not have a heroin or cocaine case, Your Honor, so I would not discuss that at all. I do understand--

QUESTION: No, but you are saying it about oral--about laetrile taken orally?

MR. COE: No, we're just discussing the intravenous form.

QUESTION: No, but I thought my brother Rehnquist asked you about--wouldn't you take the same position with respect to laetrile taken orally?

MR. COE: I would take the same position.

QUESTION: Yes. Well, yet the court didn't decide

that, did it?

MR. COE: The Tenth Circuit did not decide that.

QUESTION: So that--but you would take the position with respect to the oral ingestion of laetrile, but not heroin, even though it's a terminally ill cancer patient who wants it?

MR. COE: It is my understanding, totally outside of anything I know from this case, that in England heroin and some other opiates are being used for terminally ill cancer patients. And the reason it's being used is because they're terminal; there's nothing that can be done to help them, and it will take them off some of the really mind-deadening drugs.

So, to that extent--

QUESTION: Could I suggest you stay with the microphones when you answer questions.

MR. COE: I'm sorry, Your Honor.

I would like to address if I may next the constitutional aspects in this particular case. The lower court, the District Court, found that to deny the use of laetrile to terminally ill cancer patients violated their right to privacy.

The Tenth Circuit Court of Appeals did not rule on this issue, and as the Court has been informed, neither did it rule on the issue of the grandfather clause.

As to the constitutional issue, the argument, the decision of the District Court was made that this Court's decision in Roe v. Wade and likewise in Doe v. Bolton, both abortion cases, justified the extension of a right to privacy to a health care context.

Now, as we've briefed, it is the position of the respondents that the intent and spirit of both Doe v. Bolton and Roe v. Wade established that they are in a health care context. For instance, the health of the mother in Roe v. Wade is mentioned over and over again, and in Doe v. Bolton, Justice Douglas, of course, Mr. Justice Douglas in his concurring opinion enumerated the right to care for one's own health as a fundamental right.

It is our position that if in fact the right to health care, to make a determination as to the care of one's own body under medical supervision is a fundamental right in fact, then the petitioner--well, the respondents in this case, the palintiffs below--have a right to use laetrile under the court's orders, and within the court's limitations, as they had previously been enunciated.

Now, in order to overcome this, the Food and Drug Administration must establish a compelling State interest. And in this case, that compelling State interest has been enunciated as more of a desire to maintain a system than to reach the merits of the issue.

QUESTION: Mr. Coe, you seem to concede that the constitutional right would not exist without the doctor's supervision?

Or do you? Is it only a constitutional right to take this drug in a particular way if a doctor supervises it?

MR. COE: Your Honor, I have only argued within that context, because that is within the context of the lower court's decision, and outside of that, I don't think--

QUESTION: But if you acknowledge that the State can impose regulatory control for the safety even of the terminally ill cancer patient, by saying the doctor has to supervise it, why would not the constitution also give the State the power to say, w ell, certain kinds of drugs, heroin, marijuana, whatever it might be, laetrile, cannot be used for these people?

What's the difference between a flat rule against a particular kind of drug and a condition that the doctor approves of, in terms of constitutional terms?

MR. COE: I think it's somewhat analogous to the decision in Roe v. Wade, in which this Court made a determination that during the first trimester of pregnancy, because of the facts and circumstances adduced, that there was no justification for a compelling State interest, and that therefore, an abortion may be had without any interst of the State at all.

And then, after that particular point in time, the compelling State interest came into play. And I think in this case, it's the same thing.

In this case, if you have a patient who is not terminal, who has not been diagnosed as such by his doctor, and to be led away from possibly useful orthodox therapy to laetrile--

QUESTION: Well, I was assuming for the purpose of my question that they had all been diagnosed as terminally ill by the doctor.

But then the question is, why do they need doctor's supervision to take the drug any more than they need--why is that anymore acceptable than an FDA approval of the particular drug to be taken.

MR. COE: Your Honor, that was the decision rendered by the Tenth Circuit that they had to have medical care. I personally, and the patients in this case, are of the opinion that they should be subject to medical care, because they're in a very bad condition and they need continuing supervision.

Now, as to what actual legal effect that has as to the constitutional argument--

QUESTION: Whatif they lived in a--what if Oklahoma had a State rule that said that a doctor would be guilty of malpractice if he prescribes laetrile which has not been approved by the FDA?

Would that--I suppose that rule would be unconstitutional in your view?

MR. COE: Yes, Your HOnor. As a matter of fact, Oklahoma is one of the 19 States that I believe now has legalized the use of laetrile.

The decision of the District Court, in relation to the constitutional issue, has been pretty well explained up to this point.

Basically, it is the right to privacy, as enunciated in Roe v. Wade, Doe v. Bolton, the fact that there is no compelling State interest when the case is considered in the terms of terminal cancer patients who have been declared by their doctors to have passed that stage where they're going through death's door.

In their application, in their instance, there is no possible application of a compelling State interest that could havean effect.

As to people who have not been designated as terminal cancer patients, as to those who might have some other help, then the compelling state interest might come in, and there is no problem in this particular case in rendering a decision to that effect.

I'd like to address the decision by the Tenth Circuit Court of Appeals before I finish, if it please the Court.

QUESTION: Mr. Coe, at this point, you've always

spoken of the doctor. Do you mean by that a medical physician? Would it cover a chiropractor, an osteopath, a naturopath?

MR. COE: As a matter of fact, Your Honor, the District Court, in one of its previous orders in which it instituted the affidavit system, which is a system in which the individual to obtain laetrile has to have an affidavit from his doctor to demonstrate that he is in fact a member of the class.

Judge Bohanon limited it to medical doctors, M.D.s, and I do not--

QUESTION: What is your position on that?

MR. COE: Thatis my position, Your Honor.

The Tenth Circuit's ruling, which was made to a certain extent, or completely, without any authority in support, of it, made a determination that laetrile should be used by terminal cancer patients, and could be, for the reason that the term safe and effective did not have any meaning to terminal cancer patients.

As to effective, as I've already said, I certainly agree. There is no efficacious treatment for cancer.

QUESTION: Is the act contrary?

MR. COE: I'm sorry, Your Honor.

QUESTION: Is there support in the Act for that?

MR. COE: That it does not apply?

QUESTION: Yes.

MR. COE: There is no support in the Act itself. The Act is flat out, adds terms, requirements for safety and effeicacy. The Administrator, the Commissioner of Food and Drugs has had to apply the Act, and therefore has added an administrative gloss to it.

But there is nothing in either the Act nor the administrative gloss which gives an exemption for terminally ill cancer patients, with the exception of common sense. And I believe that's what the Tenth Circuit was using when it made its decision.

QUESTION: You didn't--this wasn't your position in the Tenth Circuit?

MR. COE: It was not.

The Tenth Circuit opinion found the "safe" and "effective" did not have meaning for terminal cancer patients. Terminal, it is submitted to this Court, does not have meaning--or efficacious does not have meaning for terminal cancer patients.

The term "safety" for terminal cancer patients can, in effect, have no more meaning than non-toxic. And I think the record amply demonstrates that laetrile is non-toxic. I think it demonstrates it's non-toxic both as to liquid and to tablets, but based on the Tenth Circuit's opinion, the argument is made at this time that it is non-toxic

as to the liquid form.only.

The record is replete with that. The judges--the lower courts' decision is replete with that.

If there are no questions, I have no--

QUESTION: I take it the Solicitor General heartily disagrees with that statement.

QUESTION: Mr. Coe, I have one other question.

Your constitutional argument, you make the same argument--would it apply equally to one who is not a terminally ill cancer patient?

MR. COE: No.

QUESTION: I wonder why.

MR. COE: The reason I say it would not, Your Honor, is because in this particular instance the State has a legitimate interest in controlling--

QUESTION: But if it's non-toxic.

MR. COE: Pardon?

QUESTION: But if it's non-toxic, I don't know it wouldn't apply equally.

MR. COE: I do not disagree, nor does this case disagree, nor does the lower courts' opinions, disagree with the Act--with the Food and Drug Act or the intent of it as to safety and efficacy.

The disagreement is that those two terms have been very rigidly strictured by the Food and Drug Administration

to not allow what should be a very obvious exclusion or an exception from the Act.

In this case, we do not object to the fact that it is limited. The plaintiff's class is composed of terminally ill cancer patients, and that's all the case is before the Court.

QUESTION: Of course if it is under the 1962 grandfather clause, then it's permissible for use by anybody?

MR. COE: That's correct, Your Honor.

MR. CHIEF JUSTICE BURGER: Mr. Solicitor General, do you have anything further.

REBUTTAL ARGUMENT OF WADE H. McCREE, JR., ESQ.,

ON BEHALF OF THE PETITIONERS

GENERAL McCREE: I'd just add this, Mr. Chief Justice:

In response to Mr. Justice Blackmun's question--and I was unable to give him the citation; in fact, I told him I wasn't aware of it. On page 163A of our petition for certiorari we state that the Court in Bentex Ulcerine held 469 Fed. 2nd, at 878, that a party seeking to show that a drug comes within the grandfather exemption, quote, must prove every essential fact necessary for invocation of the exception.

And with--

QUESTION: On the question--I need some help. On

the--limiting it to terminally ill, why wouldn't that--I'm not espousing this, but couldn't an equity court, as this court was, just draw on its ability to provide remedy?

GENERAL McCREE: I think it could, but this is a constitutional determination that it made.

QUESTION: Yeah, that's what worries me.

GENERAL McCREE: It worries me, too.

QUESTION: Okay.

GENERAL McCREE: If it please the Court, the government submits its case on its brief.

MR. CHIEF JUSTICE BURGER: Thank you, gentlemen.

The case is submitted.

[Whereupon, at 2:16 o'clock, p.m., the case was submitted.]