Supreme Court of the United States

OCTOBER TERM - 1968

In the Matter of:

UNITED STATES OF AMERICA,

Petitioner,

vs.

AN ARTICLE OF DRUG

BACTO-UNIDISK

Respondent.

Docket No. 343

Place Washington, D. C.

Date January 23, 1969

ALDERSON REPORTING COMPANY, INC.

300 Seventh Street, S. W.

Washington, D. C.

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vs.	:	No. 343
AN ARTICLE OF DRUG BACTO-UNIDISK Respondent.	:	

Washington, D.C.
January 23, 1969

The above-entitled matter came on for argument at 1:51 p.m.

BEFORE:

EARL WARREN, Chief Justice
HUGO L. BLACK, Associate Justice
WILLIAM O. DOUGLAS, Associate Justice
JOHN M. HARLAN, Associate Justice
WILLIAM J. BRENNAN, JR., Associate Justice
POTTER STEWART, Associate Justice
BYRON R. WHITE, Associate Justice
ABE FORTAS, Associate Justice
THURGOOD MARSHALL, Associate Justice.

APPEARANCES:

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P R O C E E D I N G S

MR. CHIEF JUSTICE: No. 343, United States versus an article of drug.

Mr. Wallace?

ARGUMENT OF LAWRENCE G. WALLACE, ESQ.

ON BEHALF OF PETITIONER

MR. WALLACE: Mr. Chief Justice, may it please the court, this case is here on a write of certiorari to the United States Court of Appeals for the Sixth Circuit and it an in rem seizure proceeding brought by the government against an interstate shipment of five cases of antibiotic sensitivity discs bearing the trade name Bacto-Unidisk.

Counsel have asked the clerk to distribute a sample of the seized article to each member of the court.

The government's libel alleged that the shipment violated Section 502L of the Federal Food, Drug and Cosmetic Act in that the Bacto-Unidisk was a drug within the meaning of the Act, was composed in part of the specified antibiotics and was neither certified, nor exempted from certification, pursuant to Section 507 of the Act.

And the amended answer by the claimant Difco Laboratories, the manufacturer of the Bacto-Unidisk, admits that the article is composed in part of the specified antibiotics, and as neither been certified nor exempted from certification.

The claimant's denial that the shipment violated the Act was based solely on the contention that the antibiotic certification requirements of the statute are inapplicable because the Bacto-Unidisk is not a drug within the meaning of the statute and the only issue in this case therefore, is whether sensitivity testing discs, such as the Bacto-Unidisk are drugs within the definition in Section 201G of the Act, which appears on page 2 of our brief.

This issue arises because Section 507 of the Act imposes the batch testing certification requirement only on antibiotic drugs and these are defined in Section 507 by reference to the general term "drug", which in turn is defined for purposes of the entire Act in Section 201G.

Q Where is that 507?

A 507 appears on page 3 of our brief. That is the batch testing requirement for antibiotic drugs. And in the middle of page 4 the definition of antibiotic drugs is in terms of "drug" and that brings into play the general definition of "drug" in the statute as a whole.

Q As I see 507 it talks about batches of drugs.

A That refers to production batches.

Q The certification of batches of drugs.

A That is correct. Each production batch has to be certified by taking a sample from that production batch and testing it to see that it has the proper characteristics

of identity and strength and potency, et cetera, to assure its safety and efficacy of use and that has to be done before that production batch of an antibiotic drug can be disseminated for use.

Now, the manner in which the Bacto-Unidisk and similar products are used in the course of antibiotic therapy is described in the Opinion and Findings of the District Court and in the printed enclosure which claimant includes in each carton of Bacto-Unidisk, which appears in the record, and to which I shall refer later.

The discs are used in a screening test which in the words of the District Court, "serves as a guide to a medical doctor in his determination of the choice of antibiotics he prescribes for a patient."

This is accomplished by first drawing from the patient a specimen of affected body fluid which contains the infecting microorganisms that is causing his illness. Typically, this specimen is then taken to the hospital of other clinical laboratory and placed upon a culture medium in a small glass dish, a so-called Petri dish, where it is incubated for a period of hours to assure that mature colonies of principal infecting organisms can be isolated from the specimen for use in the sensitivity test.

This so-called isolate of the infecting microorganisms is then applied upon a second culture medium in another Petri

dish and the dry paper sensitivity discs, each of which has been impregnated with a certain quantity of a particular antibiotic, are placed upon the surface of this freshly innoculated culture.

During the ensuing incubation period of six to 18 hours, the antibiotics disseminate outward forming circular zones around each of the small impregnated discs.

Q Can these be bought by a layman? Do they have to be bought on prescription? Are they sold to doctors or what?

A I don't know the answer to that. They cannot be bought until after they have been certified. They cannot be marketed to anyone and as a practical matter, they are used only in clinical laboratories.

Q Yes, your position is that they have to be certified and the other is that they don't.

A Well, that is correct.

Q I want to know whether I can go into a drug store and get one of these and perform one of these tests on myself. It has a bearing, I should think, on your argument.

A Of course to my knowledge, they are not now being disseminated and this would be a prescription drug,if our position is correct,that they are a drug within the meaning of the Act. Of course, if they are not a drug, that would make a difference in answering that question.

Q But they are manufactured and sold for use by

clinical laboratories, not by individuals.

A That is correct. They are not intended --

Q That is what the product is, isn't that correct?

A The product is intended for this testing use in laboratories and not to be ingested by individuals in any way.

As I say, in the tests the antibiotics disseminate outward, forming circular zones around each of these small impregnated discs and then if the infecting organism is sensitive to the antibiotic on a particular disc, its growth will be inhibited in the zone around that disc leaving a clear circle, a so-called zone of inhibition, on the medium in the dish surrounding that particular disc.

But in the zones around discs containing an antibiotic to which the microorganism is resistant, the isolate will grow leaving little or no clear area.

From the presence or absence of these zones of inhibition around the various discs the microbiologist advises the physician which of the antibiotics appear to be effective and which appear to be ineffective against the infecting microorganism.

This report is then used by the physician as a guide in selecting an antibiotic for treatment of his patient's infection and these discs are quite widely used, as records show. There is testimony that the volume of disc sensitivity

testings is approximately 5,000 per month in one Chicago hospital.

Q The antibiotics are in the --

A They are impregnated on each of the small circular discs.

Q Not by the doctor, but in --

A In the manufacturer's laboratory in the manufacture of them. The disc as you have it is already impregnated with various antibiotics labelled around the edge and with one sulpha.

Q Are those antibiotics that are produced by the manufacturer? This is subject to the testing in the batches of drugs in 507?

A Not unless the discs are drugs and the use in the disc is a drug. Otherwise, there would be no batch testing whatsoever of these antibiotics required under the statute. Unless they happen to be comingled with antibiotic powders that are going to be disseminated for use directly on patients, in which case, they would have been tested in that form, but the batch testing requirement does require testing of each form of the antibiotic as it is prepared for use, because of the peculiar scientific problem of changing the antibiotic from one form to another.

It is clear then that this discs contain antibiotic substances, which in the words of the statute are "chemical

substances which are produced by a microorganism and which have the capacity to inhibit or destroy other microorganisms."

And it is equally clear that the use of the sensitivity discs in medical practice is dependent upon the purported capacity of the antibiotics impregnated on the discs to function as antibiotics, to actually inhibit or destroy the growth of microorganisms.

In this respect, the discs differ from medical books or the Petri dishes in the laboratory or other articles that may also be used as a guide to therapy.

Now for more than 20 years, Congress has recognized in Section 507 of the Act and its successive amendments, that because of the particular scientific properties of these biologically produced antibiotic drugs, special quality control procedures must be required to assure their scientific reliability, or in the words of the statute, "to insure their safety and efficacy of use."

Section 507 therefore, requires that before it is disseminated each production batch of antibiotic drugs must be tested and certified pursuant to regulations promulgated by the Secretary of Health, Education and Welfare, to assure that the drugs have such characteristics as identity, strength, quality and curity as to insure their safety and efficacy in use.

At first, antibiotics intended only for laboratory

use in sensitivity testing were exempted by regulations and the batch testing requirements and that exemption applied to commercial sensitivity discs, such as the Bacto-Unidisk, which came into use in 1950, as the number of antibiotics began to proliferate.

The exemption of sensitivity discs from the certification requirement was terminated in a rule making proceeding in 1960, in which regulations were adopted to require their batch certification. This is discussed in our brief.

The order adopting the regulations recited that following numerous complaints by the medical profession, hospitals, and laboratory technicians, the Food and Drug Administration made an extensive survey of the conditions surrounding the production and marketing of discs and found them unreliable in their statements of potency, with resultant impairment of their safety and efficacy.

It was therefore deemed in the words of the author, "vital to the protection of the public health to adopt the regulations requiring their batch certification."

The question in this case then is whether the Secretary correctly interpreted the statute as authorizing the application of the batch testing requirement to antibiotic sensitivity discs, which brings us back to the interplay of definitions in the statute.

The District Court was of the view that a literal

reading of the Act's definition of "drug", on page two of our brief, and particularly the language in sub-part B of the definition, "Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease...", the District Court was of the view that this language clearly has application to the sensitivity discs, but, despite this, and despite the fact that drugs are contained in the article, again in the words of the District Court, the District Court decided that the Act should not be interpreted as including sensitivity discs as drugs, because no part of this article is administered to man or other animals either internally or externally and its sole function is to provide medical doctors with information for use by them as guidelines.

The Court of Appeals affirmed the holding that sensitivity discs are not drugs within the meaning of the statute, expressing the viewsthat the discs only aid the physician to determine what antibiotics to use for the cure, mitigation or treatment of the patient's disease.

And, in the words of the court, that it was not the legislative intent to apply the phrase, "intended for use in the cure, mitigation, treatment..." et cetera, in such an indirect manner.

Neither court cited any legislative history in support of this interpretation of the statutory definition.

We believe first that it is clear on this record

and in the District Court finding that batch testing of antibiotic sensitivity discs serves the Congressional purpose expressed in Section 507 of assuring the safety and efficacy of antibiotic therapy.

The role of the discs in therapy is adequately described in the claimant's own printed enclosure packaged in the cartons of Bacto-Unidisk, which is reproduced in our appendix on page 182. We can look at the first paragraph there. It says that "Bacto-sensitivity discs and Bacto-Unidisks" -- only the latter are involved here -- "are standardized paper discs containing known amounts of the more commonly employed antibiotics," et cetera. "They are recommended as a rapid practical, clinically accurate and inexpensive means of determining the relevant sensitivity of microorganisms to these therapeutic agents. Bacto-sensitivity discs are especially valuable in selecting the drug effective against chronic or persistent infections refractory to primary therapy."

The testimony in the case explained the test is medically important because there are various strains of the same general group or type of infecting organisms, such as staphylococcus, and there are differences among these strains in their sensitivity and resistances to various antibiotics.

The claimant argues that it is somehow significant that treatment with an antibiotic frequently is begun

before the results of the test are known, but that does not disprove the discs play an important role in antibiotic therapy. The testimony unequivocably shows, consistently with the claimant's printed representation, that as a result of tests with the discs the treatment is sometimes switched from antibiotic to another and this is particularly true in the critical situations in which a patient is not responding to the primary therapy. We collected those references on page 23 of our brief.

Another factual consideration that is important to this point in my argument also is indicated in the claimant's printed enclosure in the Bacto-Unidisk, this time on page 185 of the appendix, the little chart in the middle of that page shows that a difference in the concentration or potency of the antibiotic on the discs can make a difference as to whether a zone of inhibition will appear at all in the tests and not merely a difference in the size of the zone.

Because of this, discrepancies in disc potencies can cause misleading test results and leave physician to precribe the wrong antibiotic for his patient. This was explained at the trial in the testimony of Dr. Joseph Truant, Chief of the Bacteriology Section of the laboratory in Henry Ford Hospital in Detroit on page 83 of your printed appendix.

After complaining of the discrepancies his hospital

had found in discs, prior to the certification requirement, Dr. Truant explained in the last two paragraphs on page 83, "There is a possibility of having too low a potency in that disc, too low a concentration, in which case the organism would tend to be reported out as being a resistant one, or being more resistant, than if the true potency were in the disc.

"And on the other hand, you might have too high a potency, which means that you would report a sensitive organism, which in fact might not be in that very sensitive category.

"So it might be an error in either direction, which would give us false readings and we would be giving misinformation to the clinician and he in turn, obviously, being unaware of the situation as we would be would not treat the patient properly.

"Therefore, we feel that we can't take this chance of using discs that are not certified. It to us is a real hazard."

Additional testimony to the same effect is summarized on page 27 of our brief. The point is that the whole legislative purpose reflected in the batch testing requirement of Section 507 and brought out in the legislative history reviewed in our brief, the purpose of trying to assure the patient will get the therapeutic benefit intended when physicians prescribe antibiotic drugs for them, can be defeated, regardless of how pure and potent the pills, capsules

and injections administered to the patient may be if because of faulty discs the wrong antibiotics are administered.

We believe that a proper respect for the Congressional judgment requires that the issue of interpreting statutory definitions in this case be approached with this background in mind. When this consideration is combined with the general principle that the Food, Drug and Cosmetic Act is broadly construed in accord with its purpose to protect the public health, we think it is clear first, that the use of the discs shown in this record is a use in the treatment of disease within the meaning of the statutory definition of the drug.

The claimant argues that the use of the disc in the course of the patient's treatment is too indirect a use to be considered a use in the treatment of disease within the statutory definition.

But this would mean that the discs are neither drugs nor devices within the meaning of the Act, since the definition of "device" uses precisely the same statutory language and since the Act's protection against adulteration or misbranding apply only to drugs and devices, the result would be that the publi would be utterly unprotected against any kind of mislabeling or adulteration of the discs. There would be no statutory recourse for example, even if the discs were being marketed with every antibiotic on them falsely labeled.

Nothing in statutory language or in the legislative history requires such an absurd result, which would so seriously endanger the public health.

The more substantial interpretative question presented by this case in our view is the problem of distinguishing the statutory definitions of drug and device, on pages 2 and 3 of our brief. Their terms insofar as pertinent here are almost identical and yet, the two definitions are expressly mutually exclusive.

The District Court recognized this problem and undertook to solve it by limiting the statutory term "drug" to what it believed to be the common medical usage of the word drug outside the statute, as articles administered to man or other animals, either internally or externally.

We believe that this is where the District Court went wrong because this is inadequate as an approach to the interpretation of this complex technical regulatory scheme for the protection of the public health in which the Congress has provided its own definition of the term "drug" for the purposes of the Act.

It is a statutory term of art to be interpreted in a manner to effectuate the objectives of the statute.

In our view, Securities and Exchange Commission against Ralston-Purina Company, in Vol. 346 U.S., is the exemplary opinion of this court which alluminates the proper

approach to interpreting such a provision of a regulatory statute, so as to accomplish the congressional purpose.

There in interpreting the statutory exemption from registration for a private offering of stock, this court held that because it was the congressional purpose to exempt transactions as to which there was no practical need for the statute's application, the interpretation of the exemption should turn on whether the particular class of persons affected needs the protection of the Act.

Applying this standard, the court held that the company's offering of Treasury stock to its key employees was a public offering subject to the provisions of the Securities Act, because in the words of the court, "employees had not been shown to be able to fend for themselves."

The same basic approach was recently taken by the Court of Appeals for the Second Circuit in distinguishing between the definition of drug and device in the statute before us, in the case of AMP Inc. against Gardner, which is cited in our brief and in which this court denied certiorari in No. 86, this term.

The court there looked to the practical consequences in terms of the Act's differences in the requirements imposed upon drugs and devices to determine whether the particular article there at issue should be classified as one or the other. And the practical consequences of that difference

in classification are restricted to a very few provisions of the statute, in fact, at the beginning, when the definitions first came into the statute, there was no difference in the regulation of drugs and devices at all.

In our own case, the only significance of the classification of the discs as either drugs or devices, is that if they are classified as drugs the batch testing requirement for antibiotic drugs will apply. And otherwise, they will not.

The scientific qualities of antibiotics which led Congress to require batch testing are the same whether the antibiotic is used for a pill, a hypodermic injection or as a test to determine what pill or injection to administer.

And, as I have said, the record shows that the medical need for assurance as to quality and potency exists whether the antibiotic is used on a disc or in a pill or injection.

It is therefore manifest that the Secretary correctly interpreted the Act to reflect the legislative purpose in concluding that the discs are drugs under Section 201G, subject to the batch testing requirements of Section 507.

And accordingly we ask the contrary judgement of the Court of Appeals be reversed.

If I may, I will save any remaining time for rebuttal.

MR. CHIEF JUSTICE: Mr. Williams.

ARGUMENT OF EDWARD BROWN WILLIAMS

ON BEHALF OF RESPONDENT

MR. WILLIAMS: Mr. Chief Justice, may it please the court.

The chief effort of the government in its brief in this matter and in its argument has been to create the impression that all or most antibiotic therapy in the United States is based on the sensitivity disc test of which we are talking here today. And, that unless this procedure, this testing procedure, is controlled by the government through certification of these discs, that the public health will be endangered, the patient's life will be in jeopardy.

I shall come back to that. We shall show you can establish very simply that on the basis of the literature cited by the government itself and on the basis of the testimony at the trial and the Judge's findings in the District Court, that these efforts of the government simply do not hold water. They won't stand up.

Q What do you mean? That there is no danger?

A I mean that there is no danger and I mean that the extent of basing of antibiotic therapy upon the disc test is far more limited than the government would have us believe.

In fact, I might say right here since the question has arisen, that in our brief, page 18, we refer to the figures of the Medical Market Guide, which show that in 1967 77 percent

of the antibiotics sold in that year were purchased on prescription or by physicians.

Now, it is obvious that only about 23 percent went to hospitals, which as the government concedes are the place where the tests are made in the hospital laboratories.

As Dr. Keefer, a witness at the trial, said, "I would say from the total number of infections that doctors see and treat, the sensitivity test is not used routinely."

There is a good reason. That is, that the initial therapy, the wide-spectrum antibiotic, which the doctor starts before the test is ever begun -- it takes 24 to 36 hours for the test -- is ordinarily successful because of the doctor's experience and the information he is able to draw from other sources.

It is after the fact that he looks at the test and as Dr. Keefer stated and the court found: "The test is used to confirm his judgment."

Now, I should like to make a few remarks, if I may, about some of the statements made by my friend here.

There was a trial in the District Court, which lasted, I believe, about three days. There were quite a number of distinguished witnesses. They knew what they were talking about, at least most of them did. The findings were made. They have been almost ignored by the government in this case. They are not clearly erroneous. There is no question about

that and there has been no contention that they are clearly erroneous.

Q Do they have to be?

A I think they have to be in order to be reversed. I think that is clear from your decision.

Q Well the findings yes, but is--

A I am talking about the findings.

Q Is this all a factual question?

A No, sir, it isn't at all a factual question.

Now, on the question of the application of Section 507, the batch testing provision of the Act, this doesn't look like the sort of thing which lends itself to description as a part of a batch. To me, --

Q As a part of what?

A As a part of a batch, which is to be tested by the government. The term batch to me, Mr. Chief Justice, certainly means something with some homogeneity to it. And here, we have an entirely different sort of an article. Here are eight different antibiotic substances --

Q The government says each of those eight came from a "batch".

A Yes, sir. They came from a batch which was manufactured by a company which manufactures antibiotics which are tested by the government under Section 507.

Q They have already been tested?

A They have been check tested I doubt not because I can't conceive of a company who manufactures antibiotics and sells them for medicine, manufacturing separate antibiotics for use on these discs. That just wouldn't be good business.

Q If the only market for the manufacturer of the antibiotics were the maker of this Unidisk, then as I understand it, 507 would not require batch testing.

A If the only market --

Q That is a complicated question. I understand that the maker of this product here in issue is not the manufacturer of the various antibiotics --

A That is correct.

Q -- but gets them from somewhere else, some other manufacturer.

Now, if this were the only customer of that manufacturer, then there would be no batch testing required of that manufacturer under 507, is that right?

A The government would require it because they consider this a drug.

Q No, no, as I understand it they consider this a drug.

A Yes, sir. But they would also consider the antibiotic going into it a drug, because it would be a component of a drug under the statute. That would be the government's attitude as I understand it.

Q You started to say in answer to another question, whether or not these had already been batch tested before they were sold to the maker of the Unidisk. And you said, well, you thought maybe or maybe not, because probably the manufacturer would not have differentiated his various antibiotics depending upon to whom he was going to sell them.

A I can't conceive that he would. I think they are check tested by the Food and Drug Administration.

Q Can you tell me precisely what this thing does?

A I can try, Your Honor. There are in the sensitivity testing procedures, which --

Q Sensitivity to a drug.

A Yes, sir. In this testing procedure which is entirely a laboratory operation, never comes anywhere near the patient, there are involved this device here, which is called a sensitivity disc, which has antibiotic substances on it, a Petri plate upon which is deposited agar, which is streaked with an isolate from the patient. On top of the agar, with the isolate in it, is placed this disc. Around the disc, if the organism from the patient is sensitive to a particular antibiotic in contact with it, there will be a zone of inhibition.

If it is not sensitive to it, there will be no zone.

Q If it is put over the body?

A Sir?

Q Where do you say this is put?

A It is put on an agar plate. A glass or china plate in the laboratory.

Q What does it contact with reference to the human being?

A It doesn't. The only thing it contacts is an isolate which is taken from, shall we say, urine, or sputum --

Q That is taken from --

A The human being, that is right. You are taking some excretion from the body.

Q You are taking excretion from the body. Probably it has some kind of infection. The infection takes what? A bacterial form?

A If an antibiotic is used, it will only affect bacteria.

Q So they take the fluid, whatever it is, and put it in the dish. Whatever you call it. They isolate from it whatever the particular infection is.

A The first step is the isolation. That takes some 18 hours.

Q And then you put this thing in the dish itself. Don't you?

A You streak the agar on the plate with the isolate.

Q Don't streak me. They take this thing, don't

they? And they put it in some kind of a dish. Is that right?

A I am not sure you have the order right.

Q That is what I want to get straight.

A The agar goes on the dish. The isolate from the patient goes on the agar --

Q What is the agar?

A It is a growing medium. The bacteria in the isolate.

Q Right. These little pegs on this thing are already impregnated with various kinds of antibiotics, is that right?

A Right.

Q And there is some kind of attraction to the particular antibiotic which would be effective against this particular infection, whatever it may be, is that right?

A If the infectious strain is sensitive to the antibiotic --

Q Sensitive meaning the antibiotic might clear it up?

A Might clear it up, right. You don't know that it would, because this is an in vitro test and when it is transferred to the body it may act entirely different.

Q This is then to tell whom? The laboratory technician or the doctor? This is the kind of antibiotic, it would appear, that might be effective against this

infection in this patient's body. Is that right?

A That is what the laboratory technician may tell the doctor. He may say that since there is a showing of sensitivity in vitro that you might try this because it may be effective.

Q And it may or may not work. The point is this disc is out of the case after it has performed that function, is that it?

A That is correct.

Q And as I understand it from what Mr. Wallace suggested, the antibiotics used to impregnate these little things on this disc, are not taken from batches which have been certified. Is that correct?

A I would assume that they are from batches which have been tested by the Food and Drug Administration.

Q I thought Mr. Wallace told us that is one of the problems.

A He did say that. I would assume differently.

Q What does the record show?

A There is nothing in the record on that.

Q What does the government want to test? The antibiotic?

A They want to test the disc.

Q They don't want to test just the batches of antibiotics used to impregnate these discs, they want to

take the completed discs and test them?

A That is correct.

Q And that I take it -- I think that is what Mr. Wallace said -- that except and whatever it is that impregnates these discs, has gone through the certification procedures, you can't be sure that the role this disc is supposed to perform can be properly performed. Is that it?

A That is the position.

Q And at that time might have a deleterious effect and consequence upon the patient who may be treated by a result, because it is not impregnated with certified batches, might come up with the wrong answer or no answer.

A That is the position of the government.

Q But do they claim there is something else that needs testing besides the antibiotics that are used to impregnate these discs? Is there something that happens to the antibiotics because of contact with the disc which means that the discs themselves, the impregnated discs, have to be tested? Or would they be satisfied with testing the antibiotics used to impregnate them?

A The government thinks the discs themselves should be tested because they have found that the public health in their mind will be endangered if they are not tested.

We have seen no evidence whatsoever of it. And let me point this out now. In the six years since this litigation

began in 1962, I believe, or 1961, nobody has come up with a single instance of an erroneous result from a test due to a faulty disc. And in the 12 years --

Q Have they been in circulation?

A Yes, sir.

Q Ever since the litigation started?

A Other discs which are being certified.

Q This is a different question.

A I know, but if you will permit me, sir --

Q All right.

A In the 12 years previous to certification, in those years, nobody came up with a single case of an erroneous interpretation of a sensitivity test due to a faulty disc.

Now Dr. Truant, as my friend said, at the hearing, at the trial, stated that he felt there was a danger to public health involved. He said two or three times, he was asked on cross examination if he had had one single instance to which he could point to show that the public health was involved. He could not point to any.

Q Are we supposed to second-guess the agency on this kind of a judgment? Whether public health is endangered? Do you really suggest that we make that judgment?

A This is not a finding made by the agency which is binding on the court. I am not asking any second guessing. I am asking that the evidence be looked at. It shows that

there is no such public health problem and furthermore, the law is such that there is no basis, in my opinion, for holding this article to be anything other than a drug, unless possibly it were regarded as a device, because the definition involved reads in terms of treatment of substances intended for use in the treatment or diagnosis of disease.

Now it is quite obvious that treatment means treatment of a patient and nobody can maintain that --

Q What about diagnosis?

A Well, diagnosis was practically abandoned by the government in the lower court as a ground for exposition. They come back to it in the upper court.

But, Dr. Keefer made it quite clear, and he was, perhaps I should say, the most distinguished witness at the trial, he made it quite clear that there cannot be a diagnosis of an infection without identification of the organism. Obviously, the test does not identify the organism.

Q Has the agency at any time made any findings with respect to why these discs qualify either under the treatment or diagnosis?

A They made a legal conclusion in the proceeding which has been referred to, in the course of which the regulations were adopted, they made a legal conclusion that the discs were drugs.

Q They didn't say whether it was because of

treatment or diagnosis?

A I don't recall that they did.

Q Did they pass --

A They have dealt in terms of diagnosis. Excuse me.

Q Did they pass at all whether the disc was a device?

A So far as I know that was not considered by the agency. It didn't appear in the public proceeding.

Q There has been no ruling on that.

A No, sir, as far as I know.

Q I take it though the government all but concedes that the disc is also covered by the definition of device.

Q The government doesn't even mention device as I read this dispute.

A I think the government's point was that the language of the device section and 201H in the statute, the language of the drug section 201G, are quite similar, except that 201G excludes devices from the definition of drugs.

Q Is sulfadiazine a drug? Are antibiotics drugs?

A Yes.

Q Well, in a device you wouldn't have batch testing.

A No, you wouldn't have batch testing, but you

could have control as we point out in our brief.

Q This branding possibly?

A Yes. We have pointed out in our brief the control --

Q That issue of device is not here. I don't find it in the government's contentions. Or have I misread the brief?

A It isn't before the court in my opinion, sir.

Q The court below didn't pass on it.

A The court below said that if it was anything it was probably a device because the only difference between a device and a drug is that a device is an apparatus or an instrument or a contrivance.

Q But the agency didn't rule whether it was or was not a device.

A No, they ruled it was a drug, thereby excluding it from the definition of device.

Q Mr. Williams, suppose this disc were made so that it could be applied to the human body for therapeutic purposes. Exactly the same disc was to be applied to the human body for therapeutic purposes. Would there be any doubt that it was a drug?

A No, sir, there would be no doubt.

Q Suppose it were to be applied to the human body for a diagnostic purpose. That is to say, what the purpose

let us say of finding out what sort of microorganism is causing the difficulty. Is there any doubt that that would be a drug?

A If it were applied to the human body for diagnostic purpose? No, sir.

Q So that the question here comes down to this, as I understand it: This disc is applied not to the human body, but is applied to a smear taken from the agar plate, from a substance derived from the human body and it is done in the laboratory and the question is: Does that distinction remove it from a category of a drug?

A Yes, sir. I should like to stress, Mr. Justice, that treatment of a patient is the test of whether this is used in treatment.

First, there is no treatment of a patient by this device.

Secondly, it cannot be used in diagnosis because it does not identify the organism. That is perfectly clear. You can't diagnose unless you know what the organism is.

Q In a sense it is used in treatment in the sense that it is used for the purpose of determining the antibiotic to be used in treatment. In that sense it is arguable, I suppose, it is used in treatment even though it is one step removed.

A It is used in a sense to determine the antibiotic used in treatment under certain circumstances.

Q May I ask you this, sir, if you happen to know. There are various substances, things and what not, that are used in the laboratory for the purpose diagnostic purposes, to determine what the microorganism is. Are those classified as drugs?

A No, sir. There are several hundred, maybe thousands, or laboratory tools of this nature which are used in the industry and a clinical laboratory which have never been classified as drugs and if this is classified as a drug I can see no alternative to classifying all of these other hundreds and thousands of articles.

Q How about something like this, if there is such a thing. Suppose in the laboratory there is used for purposes of application to human tissue a tubercular batch or whatnot. Would that be classified as a drug?

What I am saying is that I am sure that if injected into the person in the treatment of one form of tuberculosis or another, it would be classified as a drug. That is the fact that the substance is used solely in the laboratory. Remove it from that classification.

A I believe so under this statute, Mr. Justice.

Q You don't know of any cases?

A I do not happen to know of a case, but the line to be drawn here is whether or not it is used in the treatment of diagnosis of a disease.

Q I asked you a few moments ago if antibiotics were drugs and you said yes.

A Yes, sir.

Q You said sulfadiazine was a drug. As I understand it, antibiotics are put on each one of these spokes and sulfadiazine. Why aren't they drugs when they are put on there the same as if they hadn't been put on there?

A I will tell you why, sir. They are not drugs because under the statute it is well established, there is no doubt whatsoever, that an article is not a drug unless it is intended for use in the treatment or diagnosis or prevention or cure of disease.

Q Well, that drug is, isn't it?

A This is not.

Q I am not talking about this disc, I am talking about the drugs that are put on it.

A If this drug were used to wash a window, it certainly would --

Q It would still be a drug, wouldn't it?

A No, sir, not under this statute.

Q It wouldn't be a drug?

A Not under this statute. It might be a drug in some sense, but not under this statute.

Q This is used in diagnostic purposes?

A No, sir, it is not, because it does not identify

the organism and without identification of the organism there cannot be diagnosis.

Q Is it the government's theory that when you do this it does not give you a correct answer and you may give a man this drug on the false assumption that he is not sensitive to it.

A That is their contention and I obviously don't have time to go into my argument, but it is quite clear from the literature and from the trial that there are so many built-in protections against the sort of thing the government apparently fears, that this is simply not going to occur. The physician does not rely principally upon this test even if his initial therapy has not been successful.

Q Whether it is a little or much, I wouldn't want him to rely on it at all. What they say is the case.

A In my opinion, it isn't the case.

Q It was the opinion of Dr. Truant, wasn't it?

A Yes, and I asked Dr. Truant for some kind of specifics on that point and he could give me none.

Q Should we wait until they know someone who has died from the use of this before they pass a valid judgment for the government?

A After 16 years, Mr. Chief Justice, I should think something would have occurred if it were going to.

Q Well, maybe you would think so, but the

government through its research might think differently and should we hazard the health of the public by saying this isn't necessary.

A The government through its research has come up with nothing. That is demonstrable, that is demonstrated in our brief, it was demonstrated at the trial and it will appear from the literature provided by the government itself.

Q Do you say that this disc is not a device either?

A I say that if it is anything it is a device.

Q Does it have to be one or the other, either a drug or a device?

A No, sir.

Q Do you say it is neither?

A I say it is realistically under the statute it is neither, but if it is anything, it comes more nearly being an apparatus or an instrument than it does --

Q To be a device under the statute it has to be used for the diagnosis or treatment of a disease just like the drug.

A That is correct. And if it were used for that it would be more likely to be a drug.

Q You say it isn't used for that, so it can't be either.

A That is my position, yes.

I would like to conclude by saying that the literature

cited by the government, which is in the record entirely, was never even mentioned at the trial, shows clearly that if a laboratory, as all good laboratories do, sets up the proper standards of zone sizes for the various antibiotics, that that laboratory and any other which does that will have no problem with the zone sizes which seem to trouble the government.

That is very clear from many of the articles cited by the government itself. That is true, regardless of whether they are certified and it might be added that even under the government's certification regulations the claimed potency, that is, the potency claimed on the label of the disc may vary from 67 to 150 percent in the device itself, or the sensitivity disc itself.

In other words, you can be from 67 to 150 percent off and still get these discs certified. In fact, as between the lowest and the highest discs being tested by the government, you can go as far as 250 percent off.

Now, that kind of system is hardly conducive to the kind of allying of fear, which the government wants here.

I see my time is up.

MR. CHIEF JUSTICE: Very well.

You have a minute or two, Mr. Wallace.

REBUTTAL ARGUMENT OF LAWRENCE G. WALLACE

ON BEHALF OF PETITIONER

MR. WALLACE: I want to clarify that our position is that under the statute it would be entirely fortuitous if this disc if not a drug, whether or not the powders put on the disc were batch tested, the statute would not require that they be batch tested, but our position goes beyond that and we say that regardless of whether those powders are batch tested the disc itself needs to be batch tested to assure that the proper potency and the proper amount of the powder is impregnated on each of these discs and that it will diffuse properly for the task and that the labeling is correct on the disc.

That would not be accomplished by batch testing of the powders themselves.

Q Let me get this clear, now. I gather the government does not claim that whatever was used to impregnate these discs was not batch tested and indeed, they may well all have been batch tested.

A That may be.

Q But the government feels nevertheless these should be given other tests. Is that right?

A The discs themselves should be subjected to the batch testing requirement. That is correct.

The paper on which these antibiotics are contained is merely that, a container, the paper plays no part in the test. It is just a convenient way of getting these

antibiotics into the culture that has been drawn from the patient.

And I think it should be properly looked at that way. We believe that it is correct to interpret this statute functually, so as to afford the public the protections of the statute that are scientifically pertinent to the characteristics of the article at issue and to the medical use for which it is intended.

Dr. Truant himself, while he could not recall a specific example, did recall the number of instances of false results that had been brought to his attention by individuals in the infectious disease department. But in addition, there is no challenge made to the record that was developed in the rule making proceedings in which the Food and Drug Administration determined on the basis of complaints from laboratories that the disc had proved unreliable and that there was a medical scientific need for batch testing.

MR. CHIEF JUSTICE: We will recess.

(Whereupon, at 2:55 p.m., the argument in the above entitled matter was concluded.)