STATE OF OHIO,)
) SS: Terrence O'Donnell, J.
COUNTY OF CUYAHOGA.)

IN THE COURT OF COMMON PLEAS

Doc. 296

ANTHONY P. DiMARCO, SR., et al.,

Plaintiffs,

vs. Case No. 93882

LEONARD H. BERNSTEIN, M.D.,

Defendant.

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Deposition of PHILLIP IRWIN LERNER, M.D., a witness herein, taken by the Plaintiffs as if upon cross-examination before Marguerite A. Sancly, RPR/CM and Notary Public within and for the State of Ohio, at Mt. Sinai Medical Center of Cleveland, One Mt. Sinai Drive, Cleveland, Ohio, on Monday, the 15th day of September, 1986, commencing at 3:30 p.m., pursuant to notice and agreement of counsel.

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APPEARANCES:

Joseph L. Cotiecnia, Esq.,

On Behalf of the Plaintiffs.

Jacobson, Maynard, Tuschman & Kalur Co., L.P.A,
by: William D. Bonezzi, Esq.,
and
Dale L. Kwarciany, Esq.,

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STIPULATIONS

It is stipulated by and between counsel for the respective parties that this deposition may be taken in stenotypy by Marguerite A. Sandly; that her stenotype notes may be subsequently transcribed in the absence of the witness; and that all requirements of the Ohio Rules of Civil Procedure with regard to notice of time and place of taking this deposition are waived.

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PHILLIP IRWIN LERNER, M.D,

a witness herein, called by the Plaintiffs for the purpose of cross-examination as provided by the Ohio Rules of Civil Procedure, being by me first duly sworn, as hereinafter certified, deposes and says as follows:

CROSS-EXAMINATION

BY MR. COTICCHIA:

Q. Please state your full name.

A. Phillip Irwin Lerner.

Q. How do you spell your last name?

A. L-e-r-n-e-r.

Q. What is your home address?

A. 2567 Edgerton, E-d-g-e-r-t-o-n, Road, University Heights.

Q. What is your occupation or profession?

A. Physician.

Q. Are you employed?

A. Yes.

Q. Who is your employer?

A. Mt. Sinai Medical Center.

Q. Do you specialize in any area of medicine?

A. infectious diseases.

Q. What is the specialty of infectious diseases?

A. The diagnosis and treatment of infections.

Q. Will you relate to us your educational background.

A. It's very extensive and it's contained in my curriculum vitae, which should save us a little time.

MR. KWARCIANY: A copy of which I have already furnished you, Mr. Coticchia.

MR. COTICCHIA: You did?

MR. KWARCIANY: Yes.

MR. COTICCHIA: I have a curriculum vitae of a Philip Hanus. I don't think I got one --

Oh, here it is. All right. I'm sorry.

Q. (BY MR. COTICCHIA) Essentially, I'll quickly go over this, you received a Bachelor of Science from Western Reserve in 1954, correct?

A. Correct.

Q. You received your medical degree from Western Reserve in 1958; is that correct?

A. Correct.

Q. You served your internship and residency at Beth Israel, Boston, Massachusetts?

A. And at Tufts New England Medical Center.

Q. First, it was in '58, '59?

A. The first two years of the four-year program were at Beth Israel, and the last two were at the Tufts New England Medical Center.

Q. Are you Board certified?

A. No.

Q. Do you currently teach in any medical school?

A. Yes. At Reserve.

Q. What subjects do you teach?

A. Infectious diseases.

Q. I'm going over a list of papers that have been published and papers in preparation. Is this a current list?

A. I have no idea when I supplied it to you. Let me check.

There are probably one or two pages that have been published since, but this is essentially up-to-date.

Q. Items No. 53, 54 and 55 essentially discuss respiratory infections; is that correct?

A. Those particular ones are forms of respiratory infections, yes.

Q. How is it that you came about being contacted by Mr. Kwarciany?

A. You'd have to ask Mr. Kwarciany.

Q. Do you know him?

A. I don't believe we have had anything that we have worked on before this case.

Q. Do you know anyone from the offices of Jacobson, Maynard, Tuschman & Kalur?

MR. BONEZZI: Objection.

A. Yes. Yes, I do.

Q. Who do you know from those offices?

A. I know Bob Maynard, I've met Aaron Jacobson. I knew Cyril McIlhargie when he worked there.

Q. Have *you* **ever** had occasion to testify as a medical expert in any medical malpractice case on behalf of any of the attorneys that you just mentioned?

MR. BONEZZI: At arbitration, trial?

MR. COTICCHIA: At any matter, deposition, medical reports, testimony.

MR. BONEZZI: **Objection.**

A. Yes.

Q. Are you insured by way of **professional** liability **insurance?**

A. Yes.

Q. Is your insurance carrier PIE?

A. Yes.

Q. Have you ever sat on any review committees composed of insureds of PIE in regard to medical malpractice claims?

A. I am not sure I understand that.

Q. Independent of this case, have you been asked to review other cases involving medical malpractice?

A. By who?

Q. By any of these attorneys.

MR. BONEZZI: Objection.

Q. (BY MR. COTICCHIA) Do you understand the question?

A. Yes. I have been involved in cases with them before. This is --

Q. All right. Would this be on behalf of the doctor who was being sued?

A. I review cases for both sides.

Q. For plaintiffs, in other words, patients as well as for doctors?

A. Yes.

Q. Have you given testimony on behalf of a patient in a lawsuit against a doctor or a hospital?

A. Yes.

Q. When is the last time you did this, if you recall?

A. Deposition?

Q. Yes. Or trial.

A. It was a couple weeks ago.

Q. Was that in Cuyahoga County?

A. Yes.

Q. Do you remember the name of the case?

A. I could look it up. I just don't recall the names at the moment.

Q. Do you recall the name of the attorney who represented the patient?

A. No, I'd have to look it up.

MR. COTICCHIA: Would you mark this Lerner Deposition --

A. Wait a minute. I do remember. Edwin Kennedy.

Q. Okay. Thank you.

MR. COTICCHIA: Would you mark this Plaintiff's Lerner Deposition Exhibit No. 1.

(Plaintiff's Lerner Deposition Exhibit No. 1 was marked for identification.)

MR. COTICCHIA: Now, Mr. Bonezzi,

you wanted to say something?

MR. BONEZZI: It need not be said.

MR. COTICCHIA: Then I'd request that you keep your comments on the record.

MR. BONEZZI: I tried to put it on the record, Mr. Coticchia, but you stopped me.

MR. COTICCHIA: That's because the Court Reporter was marking an exhibit. Would you care to repeat what you were saying before?

MR. BONEZZI: No, I don't care.

MR. COTICCHIA: Then I'd renew my request.

MR. BONEZZI: Keep on going, would you please, with the deposition.

MR. COTICCHIA: I think I know how to handle my own deposition.

MR. BONEZZI: I am wondering.

MR. COTICCHIA: Do you want to get involved in an argument on the record?

MR. BONEZZI: Let's go. You heard my statement.

MR. COTICCHIA: Any --

MR. BONEZZI: If you want to argue, go ahead and do it with somebody else.

MR. COTICCHIA: For the record, counsel for the defendant made a comment while the Court Reporter was marking an exhibit and now he refuses to repeat the comment.

MR. BONEZZI: That is correct.

Q. (BY MR. COTICCHIA) Dr. Lerner, you testified a moment ago that you have testified in medical malpractice cases for both plaintiffs and defendants. Can you give me a percentage of the cases in which you've testified for plaintiffs and a percentage of cases you have testified for defendants?

A. I do not keep track of that.

Q. How often in the last 12 months have you testified in either type of, or either side of a malpractice case?

A. I do not have that in my head. It would be something that would have to be looked up.

Q. Would it be more than once a month?

MR. BONEZZI: Once a month for what?

MR. COTICCHIA: Providing testimony or reviewing medical records in regard to malpractice cases.

MR. BONEZZI: On behalf of

plaintiffs or defendants?

MR. COTICCHIA: Either.

A. I would say that I review approximately two dozen cases a year, and the breakdown I just don't keep track of it.

Q. Out of the two dozen cases per year, how often would you give testimony?

A. Half of them end up getting depositions given, approximately.

Q. Okay. I call your attention to what's been marked Plaintiff's Exhibit No. 1. It's dated July 7th. It was sent to Mr. Kwarciany. Is that your signature at the end of the letter?

A. Yes.

Q. Is this also a copy of it, what's been marked Exhibit 1?

A. Yes.

Q. Would you please tell me what materials you reviewed prior to this letter in regard to DiMarco versus Bernstein?

A. They're listed in the letter that Mr. Kwarciany sent to me on June 10th, 1986. I don't have that letter with me.

Q. Well, what materials --

A. That lists all the materials he sent me.

At the moment, it was the record -- as far as I know, it was the record of the hospitalization in question and I think it was Dr. Bernstein's deposition. Was it more than that?

MR. KWARCIANY: For the record, Mr. Coticchia, I've already provided you with the answer to that question. Namely, I provided Dr. Lerner with the following: one, the patient's complete medical, hospital records; two, Dr. Bernstein's hospital records; three, Dr. Bernstein's deposition; four, the report of Dr. Stephen Schreibman, the ENT specialist; five, the expert report of Peter Proctor; and six, the package insert and manufacturer's literature concerning Tobramycin.

Q. (BY MR. COTICCHIA) Did you review any other depositions since you wrote this letter, or any other materials?

A. I don't believe so.

Q. Did you review a letter prepared by Dr. Porter?

A. Porter?

Q. Yes.

A. I don't believe so,

Q. Did you review the deposition of

r Porter?

A. That name doesn't ring a bell.

Q. Did you review the deposition of Dr. Proctor?

A. I don't know if I reviewed his deposition or his letter, whatever was sent to me on July 10th, on June 10th.

Q. We know you reviewed his letter, there was a subsequent deposition by Mr. Kwarciany.

A. I didn't review that.

Q. Did you review a letter prepared by Dr. Katz, dated October 2nd, 1985?

A. If it was not included in the packet sent to me on June 10th, I did not review it.

MR. COTICCHIA: I don't remember when you read off that list, was that --

MR KWARCIANY: I did not provide him with Dr. Katz' letter.

Q. (BY MR. COTICCHIA) I'd like to go to the third page of your report, Dr. Lerner, the beginning of the last sentence. I quote, "Despite no objective evidence of infection and/or sepsis, it was mandatory that Dr. Bernstein cover this patient with an extended course of a broad-spectrum prophylactic antibiotic since the patient's

bleeding continued and required repeated bladder irrigation to remove clots," et cetera, "representing a major and continuing avenue for sepsis," close quote.

Isn't it correct that prior to the administration of Kefzol, Dr. Bernstein had administered Kefzol and Keflex to Mr. DiMarco?

A. That's correct.

Q. Are these not broad-spectrum antibiotics?

A. Not as broad as aminoglycosides.

Q. Not as broad, but are they broad-spectrum antibiotics?

A. Some people do consider them broad-spectrum, I do not.

Q. You've mentioned that the bladder irrigation represented a major avenue for sepsis. Is there anything in the record to support this statement?

A. Support what statement?

Q. That the bladder irrigation was a major avenue for sepsis in regard to Mr. DiMarco.

MR. BONEZZI: Objection.

A. I don't understand your question. The statement is a statement.

Q. How do you know that?

A. How do I know what?

Q. That it's a major avenue for sepsis.

A. I have been practicing in infectious diseases for 25 years. This man had an appreciably invaded prostatic bed of tissue that was raw and friable and a major risk in light of the fact that his bladder was constantly being irrigated to keep it free from blood clots. That is a major avenue of sepsis.

Q. All right. I understand what you're saying.

How do you determine whether, in fact, at the time that the bladder irrigations were being performed that sepsis was present?

A. I didn't say that it was present.

Q. I didn't say that you said it. I am saying, if Dr. Bernstein wanted to determine, in fact, that sepsis was present, how would he have determined this?

MR. BONEZZI: Objection. You may answer if you can.

A. Dr. Bernstein initiated this therapy at the time the patient developed some alarming new symptoms. He developed a serious bleeding problem several days after the surgical procedure, herald

by the patient's complaints of feeling shaky and very cold.

Dr. Bernstein obtained a urine culture and did not wait for the results of the culture, but initiated this therapy. Despite the fact that the urine culture didn't grow anything, he continued to administer this antibiotic because of the fact that the bleeding was continuing, the irrigations were continuing and the same risk eventuated. It would have been foolhardy and totally inappropriate not to cover this man with an appropriate broad-spectrum antibiotic during this maneuver.

Q. Is it unusual following prostate surgery for a patient like Dr. DiMarco to pass blood in his urine?

MR. BONEZZI: Mr. DiMarco.

Q. I mean Mr. DiMarco.

A. Blood in the urine post transurethral resection is not uncommon. What was a little bit uncommon in this case was the bleeding worsened X number of

the part of the patient.

A. He was complaining of feeling cold, very cold, and was shaky, suggesting that he was either about to develop a toxic reaction or a high fever or something of that nature.

Q. Isn't it a fact, based on the records, that there was no high fever?

MR. BONEZZI: Objection.

A. I'd have to look at that at this point to see.

Q. Is there anything in the record?

A. I'd have to see what his temperature was on that particular day. I don't recall that point at the moment.

What was the date of the surgery?

MR. KWARCIANY: 9-2.

A. 9-2, okay. There are a minimum number of temperatures recorded on, at least on this graphic sheet. On the 5th there's one at 8 p.m., a temperature recorded. On the 6th there's an 8 o'clock in the morning temperature, and then 8 p.m. is the only other one taken, and that is elevated at 99 plus. And likewise, a 99 plus temperature recorded on the 7th at 8 p.m., but because there is a minimum number of recordings, the fact that there is no recorded temperature at that point doesn't

eliminate the fact that a septic and potentially serious febrile condition was of concern.

Q. Isn't a spiked fever a symptom of sepsis?

A. It can.

Q. Post-surgically?

A. It can be one of the signs, unless the temperatures are taken at frequent enough intervals Particularly in a situation such as this where a urinary tract infection or sepsis is possible. These temperatures go up and go down very, very quickly. And if you are not taking readings at frequent enough intervals, they can be missed.

Q. Was Mr. DiMarco's temperature taken at frequent enough intervals?

A. I would have to look at the specific pages. The graph, as recorded by the secretary, doesn't indicate, say, Q four hours, or every four hour temperatures, so I would have to look that up.

If you would care to take the time, I can look it up.

Q. I would like to move on. We can go back to it. What I'm getting at is if, as you stated, irrigating the bladder was an avenue for sepsis, wouldn't a blood culture or blood serum culture be necessary prior to the administration of Nebcin?

MR. BONEZZI: Objection.

A. Drawing a blood culture is only one way to make that estimation. If the doctor wanted to know what organism he had to deal with, then a urine culture would be the most appropriate test to obtain. The presence or absence of a positive blood culture by itself does not rule in or rule out sepsis. There are many instances where patients are septic and have negative blood cultures, particularly when they have been on antibiotics, such as Mr. DiMarco.

Q. Is it your testimony that it wasn't necessary for a blood culture under these circumstances?

MR. BONEZZI: Objection.

A. What I am saying is that it was not critical that a blood culture be obtained. The most important culture to obtain in this setting would be a urine culture. The blood culture is over and above the urine culture.

Q. You're saying it wasn't critical. My question is, are you saying it was not necessary?

MR. BONEZZI: Objection.

A. I'm saying in the context of the most important culture to obtain, it was less important

than the urine culture.

Q. That still doesn't answer my question, Dr. Berner.

Was it necessary or not to do a blood culture along with a urine culture prior to the administration of Nebcin?

A. Was it absolutely necessary, no. It wasn't absolutely necessary.

Q. And that's in light of the type of patient and symptoms that Mr. DiMarco was manifesting?

A. Correct.

Q. Was there anything significant in his history that would have influenced the use or the elimination of Nebcin as a broad-spectrum antibiotic?

A. I am not sure I understand that. Is there any contraindications to using it in this patient?

Q. Yes.

A. No.

Q. Are you familiar with his history?

A. I know he had a stapedectomy in the past.

Q. Does this have any influence on whether or not a doctor determines with a patient like,

with a patient like Mr. DiMarco the use of Nebcin?

A. No. It has no bearing on it.

Q. So the fact that we have a patient with impaired hearing through a stapedectomy, and I believe there was a wire in his ear, this does not increase the risk of ototoxicity?

A. All I know from the charts that I reviewed is that he had a stapedectomy. Now, a simple stapedectomy, this interferes with bony conduction in the hearing cycle and not with nerve conduction. These drugs are, when they are toxic, are toxic to the nervous structure of the auditory apparatus and not to the bony structure.

Q. Do you know if he had a simple stapedectomy?

A. I have no way of knowing. I didn't review any details of that particular event.

Q. Do you think that Dr. Bernstein should know this before he administers Nebcin?

MR. BONEZZI: Objection.

A. Should know that he had a stapedectomy?

Q. Yes, and whether it was complicated or uncomplicated?

MR. BONEZZI: Objection.

A. Not necessarily.

Q. That is not necessary information for him to have --

A. No.

Q. -- prior to the administration of Nebcin?

A. No. The critical thing was to get this patient under cover of an affective broad-spectrum antibiotic because of the potential risk for sepsis, which is more, which is potentially life threatening and a much greater concern than any problems with ototoxicity at the point in time that he initiated the therapy.

Q. Well, I want you to assume, at least for this question, that the stapedectomy was complicated. Wouldn't there have been a safer choice with less risk that Dr. Bernstein could have used to avoid the ototoxicity rather than Nebcin?

MR. BONEZZI: Objection.

A. I would be willing to hear your suggestions. I don't know of any safer choice antibiotic that would guarantee that you were covering the resistant bacteria that might have been involved in this situation. The man had been in the hospital for several days with a catheter in his bladder, on antibiotics, and the risk of a resistant organism getting into his system is the

single most important consideration. It takes precedence over everything else.

You have to save the patient's life before you worry about the subtleties or possible side affects of drugs.

Q. On page three, your last sentence, do you not state, "Despite no objective evidence of infection and/or sepsis," unquote.

Did I quote that correctly?

A. Yes.

Q. Now, I assume then when you make a statement that there is a life-threatening condition, there's nothing in the record to support that?

MR. BONEZZI: Objection.

A. To repeat, I would repeat what I said before. At the time that the antibiotic was initiated, it was appropriate to do so and to select this antibiotic. The fact that the cultures subsequent did not establish or direct Dr. Bernstein to a specific infection do not negate the fact that the condition that led him to initiate the therapy continued on. Namely, the persistant bleeding, the presence of clots and the requirement for repeated irrigation of the bladder.

It would have been stupid to stop the antibiotic that he had started to cover this man for the possibility of an infection, but he may well have aborted the serious septic complication by his very early administration of an antibiotic to stop it and wait and see if he got into trouble again. At that point in time it was more than prudent. It was absolutely commendable to continue the antibiotic while the condition that exposed this man, the sepsis, continued on.

Q. You are basing that on the presence of sepsis, despite your statement that there was no objective evidence of sepsis; is that correct?

MR. BONEZZI: Objection.

A. I am saying that as clearly as I can, that Dr. Bernstein initiated therapy with the aminoglycoside because he was appropriately concerned that his patient might become septic. The fact that you are disappointed that he did not become septic is your problem. The patient should be grateful because Dr. Bernstein treated him in exactly the ideal fashion and did not let him become septic.

Q. What was the purpose of the use of Kefzol and Keflex?

A. That is the appropriate initial prophylactic antibiotic used in transurethral resections in this community. Also to minimize the risk of infection. However, the organisms covered by Kefzol and Keflex are primarily the more sensitive bacteria that initially take advantage of a situation like this.

Once you've gone through what Mr. DiMarco went through, which is several days of antibiotics, irrigation and bleeding, at that point in time the sensitive organisms, which are covered by the cephalosporins, Kefzol and Keflex, are no longer the only organisms you have to worry about. You have to worry about organisms such as Pseudomonas, P-s-e-u-d-o-m-o-n-a-s, Serratia, S-e-r-r-a-t-i-a, Enterobacter, E-n-t-e-r-o-b-a-c-t-e-r, Acetobacter, A-c-e-t-o-b-a-c-t-e-r, Citrobacter, C-i-t-r-o-b-a-c-t-e-r, and I can go on and on.

These are resistant organisms found in a hospital setting that are extremely serious. And the only antibiotic that is uniformally affective against the vast majority of these organisms are aminoglycosides, of which Nebcin is a representative.

Q. And I think your report to Mr. Kwarciany says that this particular aminoglycoside, Nebcin,

does have a risk of ototoxicity?

A. All aminoglycosides do.

Q. In regard to the various bacteria that you've discussed, could not these be detected through a blood culture?

A. If they were present in the blood, they might grow.

Q. Were they present in the urine culture?

A. The urine culture submitted at the time the aminoglycosides were initiated did not grow any organism.

Q. How about prior to the initiation of the aminoglycosides?

A. I would have to check those urine cultures. I don't recall. As far as I know, he did not have any positive cultures.

Q. What I am getting at, wouldn't taking a blood culture prior to the use of Nebcin have aided Dr. Bernstein in determining the antibiotic without necessarily using Nebcin?

A. Not necessarily. It might have given him an opportunity to recognize an organism in a patient who was about to become septic. But as I stated before, a person can be septic with a negative blood culture,

Q. Well, I think you used the term, it was used as a prophylactic or to cover the danger or the possibility of sepsis; is that correct?

A. It was initiated at a time when the patient was complaining of symptoms and signs that were suggestive of the possibility of an early sepsis.

The fact that the urine culture obtained at that time did not grow an organism does not rule out or negate that original impression. There could have been enough antibiotic on board from the Keflex to suppress or delay the growth of the organism in the urine culture. It could have been one of these bacteria that I mentioned to you and it could have been suppressed, but not eradicated, depending on how the specimen was handled and held by the laboratory at Marymount, how many hours it remained in the lab, whether it was discarded after 12 hours or 36 hours, none of which is known to me.

These are possible reasons for the urine culture to have been reported at no growth. It doesn't mean there wasn't an organism in there. They reported no growth. I don't know what their cut-off point is fox organisms. They may have had 10 to 30,000 per LM and in their lab they may call

that a negative culture. Other labs report 10 to 30,000 and will identify the organism, depending on the procedure in a given lab.

So the fact that they reported a negative culture has to be taken into account on how they handle their cultures, how they handled this particular culture.

Q. What I am interested in, you mentioned the signs and symptoms of possible early sepsis, what are they or what were they here in this case with Mr. DiMarco?

A. He had absolutely nothing objective. He had a very important subjective complaint.

Q. What was that?

A. He felt cold and shaky. And that can be the very earliest sign of endotoxin shock. The gram-negative bacteria that are involved in these types of infections, and there are many, they are almost all in the gram-negative category, have in their cell walls a substance called endotoxin. This is a poison which causes many things to happen when it is released into the blood stream. The major circumstance is shock and kidney shut down and then a whole variety of other tissue events. The optimal time and the only time to alter the

course of urinary induced endotoxin shock is before the patient goes into shock.

All studies in the past 30 or 40 years of endotoxin shock point to the fact that the only time we influence the mortality of this disease is before the patient has gone into shock and renal shut down. And the earliest sign when it is present is hypotension, but even that may not be necessarily present at the time the patient first begins to complain. Something that should not be occurring at that point in time, a small amount of endotoxin could well have accounted for the complaints that the patient gave at that point in time.

And at that point in time it was mandatory that aggressive treatment be undertaken, aggressive and appropriate treatment be undertaken. You can't afford to be wrong, because if you give the wrong antibiotic, the patient can be dead before the results come back from the lab the next day.

Q. All right. In light of the use and in light of the risk of Nebcin, and particularly your comment about aggressive treatment, don't *you* think that the peak and trough blood serum levels were

1 necessary?
2 A. Absolutely not.
3 Q. What is the basis for your opinion?
4 A. The monitoring of aminoglycoside therapy
5 is directed at minimizing toxicity. You cannot
6 prevent toxicity from occurring because these drugs
7 are toxic to certain cells in the body. The serum
8 levels reflect only serum levels. The kidney and
9 the ear are targets of excess concentration by
1 these drugs. The most rigorously controlled
1 studies demonstrate that the peak and trough levels
12 are related primarily to efficacy and avoidance of
13 toxicity in a short course such as Mr. DiMarco
14 received.
15 In a patient who is under the age of 60,
16 who has no renal disease as evidenced, no kidney
17 excretory problem as evidenced by his serum
18 creatinine, it has been shown conclusively that the
19 excretion of the aminoglycoside is reflected by the
20 level of the serum creatinine in the body and that
21 monitoring the serum creatinine in a patient who is
22 receiving a short course, that is less than ten
23 days of antibiotic therapy, is appropriate. And
24 that is the standard in this community.
25 If you are giving the drug to someone who

is over 65 years of age, has changing renal function or an abnormal creatinine level to begin with, then it is mandatory to monitor serum levels for toxicity purposes only. And in that instance the primary level that should be monitored is a trough level, not the peak.

Q. You keep mentioning renal or kidney toxicity. In fact, what we're concerned with in Mr. DiMarco's case is the ototoxicity risk, aren't we?

A. That is the manifestation of toxicity here. But the fact of the matter is that the patient must be able to excrete the aminoglycoside that has accumulated in his kidney and in the specific target cells in the auditory apparatus once you stop giving him the drug, because that is the circumstance that will determine toxicity or not.

If the patient's renal function has been impaired by the drug at the time you stop the medication, then even though you've stopped the medication there will be continuing damage to these susceptible target cells, because the drug cannot be excreted from the body. So that the primary and most important aspect of monitoring this therapy is

to monitor the kidney's ability to excrete the drug

Q. I want to back up a little bit. In regard to the history for the stapedectomy that Mr. DiMarco underwent, don't you recall that a small -- a tiny wire was left in the middle ear?

A. I did not review any records relative to the stapedectomy. All I have is the statement in this chart that he had had a prior stapedectomy.

Q. Did you review the nurse clinician's notes that were prepared for Dr. Bernstein which is part of the record?

A. If it's in the hospital record, I may or may not have looked at it. I don't recall.

Q. Would you be concerned if the stapedectomy was co plicated because this tiny wire that was left in his ear had moved or shifted a fraction to the point where the hearing aid was no longer effective?

MR. BONEZZI: Objection.

A. I don't know how I'm qualified to comment on something that I haven't reviewed.

Q. If you were Dr. Bernstein, wouldn't yow want to know that before you administered Nebcin?

MR. BONEZZI: Objection.

A. I would want to know what the status of

the patient's hearing was at the time I administered the drug, and I would want to know what the status of his kidney function was at the time I administered the drug. And unless the patient said something to suggest that there was a hearing problem over and above problems related to the necessity to perform a stapedectomy, I would not be concerned.

A hearing aid improves hearing only in patients who have a bony conduction problem. It does not alter or influence the hearing of a patient who has a nerve associated problem as far as the hearing is concerned. So whether the shift of the wire had taken place or not, it would not be relevant to the administration of this drug.

If the patient mentioned things that suggested he might have a nerve problem in relationship to hearing, that's a different story.

Q. In regard to the nerve problem or the vestibular damage, I understand that this comes about through some damage to the eighth nerve; is that correct?

A. A portion of the eighth nerve.

Q. There is a -- I am now referring to Dr. Hanus' letter. Did you review the appendix

attached to a letter by Dr. Manus, M-a-n-u-s, in regard to clinical consideration of ototoxicity?

A. I don't believe I did.

Q. I'm going to quote from this reference. "The following recommendations should prove useful in preventing or eliminating ototoxicity due to aminoglycosides: Reduce or discontinue aminoglycosides if the patient develops evidence of renal or eighth nerve dysfunction." Do you agree with that statement?

A. No, I don't agree with that statement, because that statement is self-contradictory.

Q. Did you read Mr. DiMarco's deposition?

A. I don't recall. I don't think so.

Q. Are there tests that can be administered to a patient like Mr. DiMarco to determine whether there is eighth nerve dysfunction while undergoing the administration of Nebcin?

MR. BONEZZI: Objection.

A. There are tests.

Q. (BY MR. COTICCHIA) Were there any done in his case?

MR. BONEZZI: Objection.

A. No, there were not.

Q. In light of the risk of ototoxicity,

don't you think they should have been done?

MR. BONEZZI: Objection.

A. Absolutely not. It's not the standard in the community.

Q. Do you agree with the statement that it is necessary to assess auditory and vestibular function, clinical or laboratory, before, during and following therapy especially in high-risk patients?

MR. BONEZZI: If you're reading from something, why don't you show to him what you are reading so that he can go along with you.

MR. COTICCHIA: There's a copy of it in your records. It's attached --

MR. BONEZZI: We were looking for it. We don't have it.

MR. COTICCHIA: Well, it's the only one I have right now and I am quoting verbatim.

MR. BONEZZI: Could you read that back, please.

(Notary read back as requested.)

A. I would agree to a certain degree in high-risk patients. I do not agree with the first part of the statement. It is impractical and it is

simply not the standard of practice.

Q. Is there a risk of ototoxicity in the use of Kefzol and Keflex?

A. No.

Q. Don't most, if not all, broad-spectrum antibiotics cause the white blood cell count to go down?

A. You mean go down to abnormally low levels?

Q. No. When it would be above normal.

A. You mean to return to normal?

Q. Yes.

A. That's a question that's not really a question. Because an appropriate antibiotic, if I can rephrase it -- any antibiotic that is appropriate to the infection being treated can cause the white blood count to return to normal if the infection subsides.

Q. Again, in relation to the white blood count, wouldn't taking a blood culture prior to the use of Nebcin have aided Dr. Bernstein in determining whether or not to use a high-risk ototoxic drug like Nebcin?

MR. BONEZZI: Objection.

A. If the blood culture had been positive, it would have reenforced his selection, If it were

negative -- by itself a negative blood culture could not have changed the basic problem that was present in this situation, which was the continuing risk of the introduction of infection because of the bleeding and irrigation.

Q. (BY MR. COTICCHIA) On page three, Dr. Lerner, the first paragraph, let's see, eight lines down, I quote your statement, "Critically ill patients frequently undergo base line auditory testing before" --

A. I believe it says "cannot undergo."

Q. I'm sorry. I'm sorry. "Critically ill patients frequently cannot undergo base line auditory testing before receiving aminoglycosides." In Mr. DiMarco's case, could he have undergone auditory testing?

A. I wouldn't have waited for auditory testing in this patient.

Q. Why would a doctor or why would you make a statement like that; why are you interested in auditory testing?

MR. BONEZZI: Objection.

A. The statement is made in the context of an explanation to Mr. Kwarciany, which explains -- I obviously intended it for you as well -- which is

part of a three-page orientation to the pharmacology and toxicity and clinical realities of the use of aminoglycosides. I do not begin to discuss the case itself until the bottom of the third page.

The statement which you have just read is a statement that I made in the course of outlining the complex question that we're talking about. And the statement was made in relationship to my describing the incidence of ototoxicity as reported in the literature and the problems in investigating this in patients in the hospital who are ill and in need of immediate therapy. And that's why the statement was made. It was not made in relationsnip specifically to Mr. DiMarco's case. And I will not answer any questions that are attempts to take things out of the context of which I phrase them.

Q. In regard to Mr. DiMarco, we know before his hospital admission that he has an auditory problem?

A. You know that. I do not know that. I know that he's had a stapedectomy and he wears a hearing aid.

Q. You don't consider that an auditory

problem?

A. I don't know the extent of the problem.

Q. Wouldn't you want to know that if you're Dr. Bernstein?

MR. BONEZZI: Objection.

A. The only thing I would want to know is whether or not the man had a contraindication to the use of aminoglycosides.

Q. Therefore, you would like to know whether or not there is a pre-existing auditory problem?

A. I would like to know if there is a pre-existing contraindication to the use of aminoglycosides. There are auditory problems related to the bony conduction apparatus of the ear, which would not in any way be a contraindication to the use of aminoglycosides.

Q. Is discussing the risk of ototoxicity damage to the labyrinths a standard of care prior to administering Nebcin to Mr. DiMarco?

MR. BONEZZI: Objection.

A. Do you mean should one ask a patient if they have any labyrinthine disease before you administer aminoglycosides?

Q. No. That's not my question.

MR. COTICCHIA: Would you repeat

the question, please.

(Notary read back as requested.)

MR. BONEZZI: Objection.

A. It's not a question. You're asking me is something a standard of care and then you are asking me about Mr. DiMarco.

Q. You've discussed at length in the first couple of pages the tendency of kidney damage or damage to the labyrinths, or the vestibular damage, as you call them, in the use of aminoglycosides, correct?

A. Correct.

Q. Don't you think that prior to the use of Nebcin Dr. Bernstein should have discussed this risk with Mr. DiMarco?

MR. BONEZZI: Objection. We're talking about a urologist and we're talking about an individual who practices in infectious diseases, and what you are attempting to do is to go ahead and ask this witness to set the standard of care in another discipline. I object to the form of the question.

Q. (BY MR. COTICCHIA) Are you qualified to answer that question, Dr. Lerner?

A. I am qualified to tell you what the

standard of care is for the administration of aminoglycosides in critical situations.

Q. Will you please tell me.

A. The single overwhelming major consideration is whether or not the patient is going to be able to excrete the dose of aminoglycoside that you give them.

If a patient has the normal creatinine, the normal renal function, you can initiate therapy and monitor the kidney function. As I stated before, the critical nature of sepsis and heading it off before it gets out of control takes precedence over everything else.

There are no toxicities associated with the use of short courses of aminoglycosides. So that one can always initiate an aminoglycoside under any situation, the dose being chosen, based on the patient's ability to excrete the drug. Even in 90 year old people whose kidneys are functioning at 10 percent of normal, if sepsis is your concern, you begin treating with an aminoglycoside. You load the patient up with one dose and you give a second dose, and even if that patient is not making any urine, you initiate your therapy and you modify your dose according to what supervenes after that

point: how much drug the patient is able to get rid of on his own; what the serum levels show you; since the patient has abnormal renal function, what the kidney output is. You monitor the dose according to the subsequent course of events.

And that's exactly what was done in this case. The drug was initiated in a very appropriate dose, the minimally effective dose appropriate for urinary tract infections, and it was monitored by frequent determinations of the serum creatinine to assure that the patient could excrete the drug when it was stopped.

Q. Number one, let's talk about two things, the risk and the warning, and then your comment about monitoring the serum levels. Isn't there a warning in the Physicians' Desk Reference about ototoxicity in the use of aminoglycosides?

A. There certainly is.

Q. Shouldn't this have been discussed with Mr. DiMarco by Dr. Bernstein?

MR. BONEZZI: Objection.

A. Absolutely not necessary.

Q. Secondly, you commented about monitoring through serum levels, but I think we both agree that there were no blood serum monitoring, was

there?

A. I gave an example in which, an extreme example, in which even an elderly patient who had abnormal or deplenished kidney function would be a candidate for the initiation of aminoglycoside therapy in a life-threatening situation. I gave you an example in which it would be not only appropriate, but it would be necessary to monitor the serum levels of the drug.

Q. Let's go to page four, the last paragraph.

A. I'm sorry. What page?

Q. Page four, the last paragraph of your report.

A. Okay.

Q. You made some comments about Dr. Proctor's report. I'd say in six or eight lines down you start a sentence right on the margin, "Furthermore, he fails to comment on the most unusual occurrence in this particular case of apparently total vestibular destruction." Did I quote that correctly, Dr. Lerner?

A. Correct.

Q. Would you please, for your own reference, take a copy of Dr. Proctor's letter of February 26th, 1985.

Do you have a copy?

A. Yes, I do.

Q. Under the heading "Case Discussion," would you read the first sentence, please.

MR. BONEZZI: I'm going to object. It speaks for itself. You have a copy of it and so does Dr. Lerner. What is it that you want to know from that first sentence?

Q. (BY MR. COTICCHIA) Would you read the first sentence.

MR. BONEZZI: No. I am not going to have him read it. He has got it in front of him, you have got it in front of you. There is no necessity to read something that is obvious to the both of you. That document speaks for itself as does yours.

Q. (BY MR. COTICCHIA) Doesn't the first sentence state, "This case involves two separate questions. First, was Tobramycin administration responsible for the loss of vestibular function"?

A. Now, what are you asking me? is that what the sentence says?

Q. Isn't that what the sentence says?

A. Yes, that's what it says,

MR. BONEZZI: Objection.

A. It's a question. It's not a sentence.

Q. Well, doesn't he, in fact, comment upon the vestibular destruction?

A. No. That's not what my sentence says.

Q. Well, will you tell me the difference between vestibular destruction and/or loss of vestibular function?

A. He is not commenting on it, he's asking. He makes a statement in the paragraph above that, "Subsequent work-up by an ENT specialist showed complete absence of vestibular function. That's not a comment on his part. He is simply restating, and then he is asking a question. He is not commenting on what I am asking him to comment on, which is why did this man who received such a short course of an appropriate dose of an aminoglycoside develop such a complete vestibular dysfunction. I don't see where he's discussing it.

Q. Okay. That answers my question.

How much do you charge for your testimony as a medical expert witness?

A. Between 150 and $200 an hour.

Q. Well, what do you determine as 150 and what determines $200?

A. It depends on how much I an

inconvenienced.

Q. I hope we haven't inconvenienced you too much.

MR. COTICCHIA: I don't have any more questions. I'm going to order a transcript of this and it doesn't matter or not whether you care to waive signature.

MR. BONEZZI: He doesn't.

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(Deposition concluded at 4:40 p.m.)

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I have read the foregoing transcript from page 1 to page 46 and note the following corrections:

PAGE:	LINE:	CORRECTION:	REASON:

PHILLIP IRWIN LERNER, M.D.

Subscribed and sworn to before me this day of , 1566.

Notary Public

My Commission Expires:

THE STATE OF OHIO,)
) SS: CERTIFICATE
COUNTY OF CUYAHOGA.)

I, Marguerite A. Sanaly, RPR/CM and Notary Public within and for the State of Ohio, duly commissioned and qualified, do hereby certify that PHILLIP IRWIN LERNER, M.D. was by me, before the giving of his deposition, first duly sworn to testify the truth, the whole truth, and nothing but the truth; that the deposition as above set forth was reduced to writing by me by means of Stenotype and was subsequently transcribed into typewriting by means of computer-aided transcription under my direction; that said deposition was taken at the time and place aforesaid by agreement of counsel; and that I am not a relative or attorney of either party or otherwise interested in the event of this action.

IN WITNESS WHEREOF, I hereunto set my hand and seal of office at Cleveland, Ohio, this 25th day of September, 1986.

Marguerite A. Sanaly, RPR/CM and Notary
Public within and for the State of Ohio
540 Terminal Tower
Cleveland, Ohio 44113

My Commission Expires: October 30, 1989.