IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

Case No.: 280713

STEVEN MAKSIM, et al.,

Plaintiffs,

vs.

JOSEPH JAMHOUR, M.D., et al.,

Defendants.

DEPOSITION OF MICHAEL RADETSKY, M.D.
October 10, 1996
8:30 a.m.
1901 University Blvd., NE
Albuquerque, New Mexico 87102

PURSUANT TO THE OHIO RULES OF CIVIL PROCEDURE this deposition was:

TAKEN BY: MR. HOWARD D. MISHKIND
ATTORNEY FOR THE PLAINTIFFS

APPEARANCES

For the Plaintiffs:

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BY: MR. HOWARD D. MISHKIND (Telephonically)

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Also Present:

Goffe & Associates Videography
BY: Mr. Roy Matthews

I N D E X

MICHAEL RADETSKY, M.D.

after having been first duly sworn under oath, was questioned and testified as follows:

EXAMINATION

BY MR. MISHKIND:

(Exhibits 1 and 2 marked)

Q. Again, this is Howard Mishkind. Before I begin my questioning, we just agreed that as you stated, this is a discovery deposition of your expert witness that we have agreed to do the deposition.

Everyone knows that you are in Albuquerque and the rest of us are in Cleveland; that there is a court reporter from New Mexico and a videographer from New Mexico; and that essentially, the deposition and any formalities are being waived in connection with the conducting of this discovery deposition.

MR. BONEZZI: Yes.

Q. (By Mr. Mishkind) Okay. Would you please state your name?

A. Michael S. Radetsky.

Q. Dr. Radetsky, as you know from talking to Mr. Bonezzi, my name is Howard Mishkind. I am going to be asking you a series of questions this

morning concerning your participation as an expert witness on behalf of certain defendants in this lawsuit.

Have you had your deposition taken before, sir?

A. Yes.

Q. So that you are somewhat familiar with the process, but to any extent my questions are confusing, especially in light of the fact that we are doing it over the phone, would you please stop me before answering and tell me that you don't understand, and I will rephrase it or have the court reporter read back the question to you?

A. That would be fine, sir.

Q. Thank you. To begin with, and to try to simplify matters a bit, I had the court reporter, before the deposition began, mark your curriculum vitae as an exhibit.

Do you have that in front of you, sir?

A. Yes.

Q. Would you identify on the record what the exhibit number is, sir?

A. Exhibit Number 2.

Q. A copy of the CV that I have back here in Cleveland has 12 pages. Does that have the same

number?

A. No, this is an updated CV with 14 pages.

Q. The one that I have ends with three abstracts, the last abstract being an October 1985 publication, abstract 760.

Could you tell me, if you can, when this particular CV would have been prepared and perhaps what additions might be on the one that you have in front of you that I don't have?

A. Sure. I prepared this one yesterday, so it's as recent as I could make it. And assuming that your CV does place me here in Albuquerque at the Lovelace Health System, the major differences then would be the addition of certain honors which have occurred since the last CV and publications which have occurred between the last CV and the preparation of this one.

Q. Tell me what honors and what publications need to be added to what I have to bring it up to what you have in front of you.

A. Okay. Well, perhaps, then, you could help me by telling me the last listing in any particular category, and, then, I can tell you what additionally needs to be added on. Would that be all right with you?

Q. The honors and awards.

A. If you go to page 2, does your copy of the curriculum vitae include a journal editorship?

Q. Yes, it does.

A. Under "journal reviewer," I am a reviewer for six journals, and I don't know how many you have there.

Q. I have four journals ending with Pediatrics.

A. Right. I am a reviewer for the Journal of Pediatrics and Pediatric Emergency Care in addition to the four you have.

Q. Okay.

A. Let's see, Board certification, I wanted to double-check there, I am Board certified in pediatrics, Board certified in pediatric critical care, 1987, but recertified 1995. I am finally Board certified in pediatric and infectious diseases, 1995.

Q. And the copy I have, you were Board eligible, but had not been Board certified at the time. Can you explain to me what, how it is that you went from being Board eligible to now becoming Board certified in pediatric infectious disease?

A. Yes, in the end of 1994, the first examination in pediatric infectious disease was set by the American Boar of Pediatrics, and I took that first examination, was passed through the examination, became Board certified.

Prior to that, there had been no Board certification, so the board eligibility is the most that anyone could claim.

Q. And I take it, Doctor, that you were successful in becoming Board certified in your first attempt?

A. Yes, sir.

Q. Okay. All right. Under the "honors and awards," page 8, the last honor and award, Clinical Teacher of the Year, Department of Pediatrics, University of California School of Medicine, are there any updates with that?

A. What year was that?

Q. 1993.

A. Yes, there have been three more. In 1994, I was the Inaugural Recipient at the William and David Gelfand Lectureship, Children's Hospital in Denver, 1995; I was invited to give the Alpha Omega Alpha Lectureship in Tucson at the University of Arizona; and this year, I was

selected in Best Doctors of America, Central Region.

Q. Any other visiting professorships? The last one I have is 1993 at Children's Hospital.

A. Yes. That's the last one of those.

And, then, publications, I have 22 journal publications -- excuse me, 21, the 22nd has been submitted but not yet accepted.

Q. The copy that I have, Doctor, ends with the fifteenth, Pediatric and Neonatal Infections. Rather than having you read the additions, can you just tell me whether any of those articles between 15 and the current number have any relevance to the issues that you believe you have been asked to provide opinions on?

A. Yes, they do.

Q. How many?

A. I would say two.

Q. What's the subject of those articles?

A. The first is a commentary on the interaction between antimicrobial therapy and outcome in serious bacterial infections, and the second is the laboratory evaluation for newborn sepsis.

Q. And the date of publication, journal, and

all that information is contained on the CV that you have there?

A. That's correct.

Q. Okay.

A. Book chapters, I now have 13 book chapters.

Q. I had nine ending with Streptococcal Infections. Between 9 and your current number, do any of those relate to the subject of this lawsuit?

A. Well, the thirteenth, which is in a second edition of Pediatric Critical Care, yet to be released, involves the use of antimicrobials in infectious diseases in a pediatric intensive care unit.

As such, it would include E. coli sepsis and the treatment of meningitis in children, and with respect to that, would have a bearing on this case.

Q. And you believe that the articles that are contained in the CV that I have, as well as the additions that you have just talked about, that they support the opinions that you maintain in this case?

A. Well, they form the foundation for the

opinions.

Q. Okay. Fair enough.

A. But, obviously, not exclusively.

Q. I understand that. I am not suggesting that they are exclusive, but, certainly, what you have written is consistent with the opinions that you have expressed in your report and I presume that you will talk to me about during this deposition and at trial?

A. That's correct.

Q. Thank you. In terms of antimicrobial therapy, is there a difference in terms of the outcome when one is administering antibiotics or antimicrobial therapy to a child that is septic as opposed to a child that has already developed meningitis?

A. I'm sorry, sir, I don't understand the question.

Q. The outcome, in terms of the morbidity and the mortality, is there a lower morbidity and mortality where antimicrobial treatment is started while the child is septic, but yet has not advanced to a state of meningitis?

A. Again, I don't quite understand the question the way you have linked sepsis and

meningitis as a temporal linkage, I don't understand that.

Q. There certainly can be a temporal relationship between sepsis and the end stage process of meningitis, correct?

A. No, I wouldn't say that as a general rule.

Q. A child that is septic in the neonatal period can, on occasion, if that sepsis is not treated, develop meningitis, correct?

MR. BONEZZI: Howard, restate that, you just blipped out in the middle of your question.

Q. (By Mr. Mishkind) No problem. If a child, an infant, has sepsis, is septic, I should say, if the child is septic and there is not any treatment for that child in terms of antimicrobial therapy, some of those children will develop meningitis, correct?

A. If I could just restate what I think your question is.

Q. Go right ahead, if it's easier.

A. Are you asking me that if a child is septicemic but is inexplicably left untreated for that condition, could a percentage of those

children develop subsequent meningitis?

Is that the question?

Q. Well put. Yes, it is, Doctor.

A. Yes.

Q. Now, that doesn't automatically mean that a child that is septic or has septicemia will automatically develop meningitis if that child is not treated. A certain statistical percentage will, correct?

A. Let me try to answer it this way so I can be accurate. In those children who are septicemic but do not have meningitis, if inappropriately they are left untreated, a percentage of them may develop meningitis in the course of their illness.

Q. In a child that is septicemic, is it important to administer antimicrobial therapy so as to minimize the likelihood of neurological complications including meningitis?

MR. BONEZZI: Objection. Go ahead and answer if you can.

THE WITNESS: Let me try to answer it this way. In a child who is septicemic, it's important as part of the total treatment package to administer antimicrobials.

Q. (By Mr. Mishkind) Tell me, why is it

important to do that in a child that is septicemic?

A. The main reason, Mr. Mishkind, is that untreated septicemia, particularly in the newborn period, may be fatal. Now, it's a complex question, and I will tell you why it's a complex question -- let me put it this way, it's a complex answer. Maybe it's a simple question, but a complex answer.

The reason is that most infectious diseases, and this would include septicemia, have at least two time courses. In one of them, the disease, itself, is very explosive, malignant, and there is an inexorable downhill course which is really unmodified by any therapy currently available.

Under those circumstances, the timing of antimicrobials, although given in all good faith, would not prevent an inevitable demise or severe damage, and that severe damage can be damage to any of the organs of the body, as well as damage to limbs and that sort of thing.

There is another kind of presentation in which a child, again, is septicemic, meaning recognizably ill with bacteremia in which

antimicrobials, when given, will reduce the chances of an inexorable decline if given in conjunction with other supportive care, but the main reason for doing so is not to prevent meningitis, since in almost all, but not all, but in almost all, cases of meningitis, the onset of the symptoms of septicemia and the symptoms attributable to the meningitis are congruent.

Q. With regard to the latter type of evolution, is it, then, from your experience and in the medical literature still efficacious in terms of reducing the degree of morbidity associated with meningitis to administer the antimicrobial therapy?

A. Could you restate it one more time? I am not quite sure, again.

Q. No problem. I understand that there are two courses, one that we might call a fulminant course, I think was what you had described first, correct?

A. All right, I am with you.

Q. Would that have been the type, would the fulminant type of meningitis have been what you had indicated as one of the two types of septicemia where meningitis develops very quickly?

A. No. I'm sorry, sir, I see where the confusion is. Your prior question only had to do with septicemia, and so my answer only had to do with septicemia.

I didn't, I wasn't making commentary on the different forms of meningitis as they present, but to the different forms of septicemia as they might present and the influence of antimicrobials vis a vis the septicemia and subsequent meningitis.

Q. Okay. And I think we are talking about the same thing, but in any event, let me just simplify it to be as clear as I possibly can.

I think you told me that even if a child is recognized to have bacteremia and to be ill and is started on antibiotics, that child may still go on to develop meningitis, correct?

A. No, that's not exactly what I said.

Q. Okay. Tell me what you said, then. I will call it wrong with my statement.

A. What I said was that with septicemia, there are two easily discernible forms, one is an explosive disease, fulminant is a pretty descriptive word for that, in which the disease has an inexorable course uninfluenced by therapy.

That course actually rarely causes meningitis, primarily because the patient dies before meningitis can occur.

The most vivid exposition of that particular form is fulminant meningococcemia, which, of course, is not the subject matter of this lawsuit here, but there is an example in which the disease is so explosive that meningitis doesn't even develop and the person dies or is severely maimed.

But there is another form in which the individual is ill with bacteremia. Theoretically, theoretically, it is possible, if meningitis is not present, to treat the septicemia and prevent the meningitis.

In reality, however, by the time a patient is septicemic, meaning bacteremia with illness, with severe clinical illness, if they are going to develop the meningitis, they will have done so already, so that in reality, prevention of meningitis as a complication of septicemia is rarely an issue.

The use of the antimicrobials along with supportive therapy is to try to terminate the disease, not to prevent the meningitis, per se.

Q. And what benefit is there in terminating the disease as early on in the course of the illness and the bacteremia?

A. Well, there eventually can be end organ damage as a result of septicemia if the disease, itself, is not lethal. So the idea is to prevent specific damage to organs of the body by the treatment of the disease.

I must say, in all fairness, the use of antimicrobials in that treatment package probably has the least influence on it because of the fact that antimicrobials take hours to days to actually begin to influence the course of a disease.

But, of course, it's an important part of the package, because without antimicrobials, many of these diseases were universally fatal.

Q. How would you describe the damage suffered by Steven Maksym in connection with his meningitis?

MR. BONEZZI: At what point?

Q. (By Mr. Mishkind) At the point in time that the diagnosis of meningitis was first made.

A. I'm sorry, you asked me how do I describe the damage caused by the meningitis at the time the diagnosis was made?

Q. You know, let me withdraw that question. He was obviously worked up for meningitis and had a shunt put in while he was at Metro, and, then, was discharged the middle of September from Metro, and basically, I just want, based upon the course that this boy followed during this hospitalization at Metro, was this a significant case of meningitis in terms of the impact on the boy's brain, and if so, why?

Do you understand my question?

A. Now I do, yes, sir.

Q. Okay.

A. This was a tragic case of meningitis based on the amount of injury that the child has sustained.

Q. Can you tell me why he sustained as much injury in this case?

A. I think I can, yes.

Q. Okay. Please.

A. The reason that he sustained such severe injury in this case is that E. coli meningitis is an aggressive, destructive disease, and in the best of circumstances, of which I believe this is one, it causes severe brain injury in the majority of cases.

Q. When do you believe that Steven first became ill and had bacteremia?

A. I can't tell specifically, sir, but, you know, to the hour, because of the fact that there is no good contemporaneous chronology of how the child was in the hours to days immediately preceding his admission, but based on what is known about E. coli infection in newborns, the knowledge that that disease is a rapidly explosive and aggressive disease, the onset of the septicemia was within a short period of time prior to the admission, and that the coincident presence of the meningitis with the septicemia is common in E. coli meningitis, I don't believe the child was ill for a long period of time, I believe he was ill for a short period of time and became deathly ill very rapidly, which is the hallmark of E. coli septicemia of the newborn.

Q. When you say that you believe that he was ill for a short period of time, can you give me an approximation as to what you mean by "a short period of time"?

A. A short period of time is a day before he is admitted to the hospital or less.

Q. Now, you know from the records that I

presume you have reviewed relative to the Deaconess emergency room visit, and his condition on admission at Metro, you know how ill he was at that point, correct?

A. Yes, I do.

Q. Can you, based upon the seriousness or the severity of his illness at that point, can you tell me to a probability when Steven probably became ill and bacteremic?

A. The day before the admission. I rely on the history that was obtained at the time of the admission to hospital, which said, basically, that the child the previous afternoon and evening was having respiratory problems, and I believe that was the demarcating event for the onset of serious illness, so I am talking about the child is seen at the Deaconess emergency department on the 21st of August and the respiratory difficulties occurred that afternoon.

Q. So if the testimony in this case from one or more experts, based upon their review of the facts, were to be that Steven was ill and bacteremic dating back to a period of time prior to his discharge from Deaconess, you would take issue with that position, correct?

A. That's not my opinion, sir.
Q. You would disagree with that opinion?
A. Yes.
Q. Correct?
A. That's correct.
Q. All right. If Ste en had been kept at Deaconess, hypothetically, there had been reason for him to have been kept in the hospital rather than discharged on August 17th, and a workup hypothetically had been justified for sepsis, what would that workup have consisted of?
MR. BONEZZI: Objection. Go ahead and answer.
THE WITNESS: In 1989, a workup for suspected sepsis in a newborn consisted of two kinds of tests, one group of tests were almost universal, and the other group of tests were, what's the correct word, the other group of tests were optional, depending on the clinical setting.
The group of tests that were universal consisted of a blood culture, the most universally performed test, as well as a complete blood count and differential.
The more optional tests had to do with a spinal tap, which even in 1989 was not done

universally if, in the opinion of the physician, the child did not display clinical evidence of meningitis, and a urine culture which was usually not done if the child were ill early in his life, in the first day or two after birth, but usually was done if the child were older than that, but that varied from place to place and from person to person, so I would say that in answer to your question, and I say this generically because you have not given me enough of a hypothetical to answer any more than that, but the child would have received a blood culture, a complete blood count and a differential, depending on the clinical circumstances, the child may have received a spinal tap and urine may have been obtained for culture.

Q. (By Mr. Mishkind) All right. We will use the universal approach back in 1989 and include the spinal tap and the universal test, at least for purposes of our discussion.

In 1989, how long would it have normally taken to have obtained the results back from that type of workup for sepsis?

A. Again, I am not answering specifically, but only as a general microbiological question.

In a child who is bacteremic, let's say with E. coli, the blood culture, if it is going to be positive at all, is positive approximately 90 percent of the time by 48 hours of incubation and 100 percent of the time by 72 hours of incubation.

Q. In a patient hypothetically that there are enough indications to warrant a septic workup as we have just described, pending the outcome of the blood culture, was there a standard of care in terms of what treatment, if any, is to be provided to that child?

A. The answer is that there were a range of options, depending on the reasons for the workup.

Q. Okay. Tell me what those options were, Doctor.

A. Sure. If a blood culture, for example, is being obtained in a well child who may have some soft risk factors for neonatal sepsis but is not sick, the child may not receive any therapy at all, pending the results of the blood culture, because, in the mind of the practitioner, the risks of there truly being sepsis are low.

On the other hand, if the child had a historical setting of risk, prematurity, for example, mother severely ill prior to birth,

prolonged rupture of the fetal membranes are examples of historical risk factors, or if the child was symptomatically ill in a way that raised the level of concern in the mind of the clinician, then the choice usually is to begin presumptive antimicrobial therapy, and there are a number of different choices as to what those would be while one is awaiting the results of the laboratory tests which I have just enumerated.

Q. Hypothetically, if the child is full term and otherwise healthy at birth, but hypothetically has evidence of jaundice during the first day of life, has feeding difficulty, with regurgitation, difficulty feeding and is noted to be lethargic during the first day of life and has a 6.5 bili followed by a 10.2 bili, and there is hypothetically concern on the doctor's part sufficient enough to warrant a septic workup, in that hypothetical patient, would the standard of care have required antimicrobial therapy, or would it have been optional?

MR. BONEZZI: Objection. Go ahead and answer.

THE **WITNESS:** Of the litany that you just gave me, the only physical finding that is of

concern is the lethargy. The hyperbilirubinemia, or clinical jaundice, in the first day of life arise from 6 milligrams to 10 milligrams per deciliter in 24 hours.

Feeding difficulties do not raise the risk of neonatal sepsis, but lethargy certainly does, and, of course, lethargy is a very potent word that has no universal meaning, so I will answer your question in the following way: If, in the mind of the clinician, the lethargy being described in your hypothetical was an indication of an abnormally depressed child, then the diagnosis would have been clinical septicemia or clinical serious illness, of which septicemia was one possibility, and antimicrobials, then, would have been required.

Q. (By Mr. Mishkind) So in the hypothetical that I gave, if we exclude lethargy and we just have a child who, during the first 24 hours of life, has observable jaundice, who has an elevation in bili from 5.6 to 10.2, who has reported bouts of poor feeding, and if we add, Doctor, during that 48 or 48-hour to 56-hour confinement has, on the last day of the confinement, a temperature of 37.8 or 37.9, and

the child is reported by the parent not to cry briskly, would that symptom complex that I have just described, without evidence of lethargy, be sufficient enough, number one, to do a septic workup, and number two, to start antimicrobial therapy pending the septic workup?

MR. BONEZZI: Objection to your question, Howard, you are asking a hypothetical question, and you are also, at the same time, attempting to go ahead and put into that question what you believe to be the facts relative to this case, so it's not truly a hypothetical question.

Now, if you want him to answer that question purely hypothetical with no meaning or impact on this case, that's fine, but otherwise, some of the facts that you have included in your hypothetical are erroneous, especially based upon these records.

Go ahead and answer, Doctor.

Q. (By Mr. Mishkind) Let me just indicate, Doctor, obviously, there are different interpretations of different statements, as you well know, and I am asking him to assume hypothetically these facts that may or may not be in evidence at trial and may or may not be -- I am

entitled to put a question to your expert in a hypothetical fashion based upon facts that I believe will be in evidence.

They may or may not be, we have different interpretations in terms of what went on, I am asking him, based upon those facts in that hypothetical that may or may not be Steven Maksym, tell me whether a septic workup was indicated, and if so, what kind of therapy, if any, would have been provided pending the outcome.

MR. BONEZZI: I understand that, Howard, you have every right to go ahead and ask questions as you deem fit regarding this expert's opinion, all I am suggesting to you is that there is a difference, and the most important thing that each of us have to contend with is fairness and the truth.

Go ahead and answer, Doctor.

THE WITNESS: Again, with regards to the litany that you gave me, Mr. Mishkind, with the exception of fever, all the other items that you are talking about are seen routinely in newborn babies and would not trigger a sepsis evaluation, anyway.

Now, the temperature level you gave me

was 37.8 or 9. In the records of this case, the maximum temperature on one occasion was 37.6, so I am taking the things that you are asking me to be those of a hypothetical child, not this child, and in answering that, what I can say to you is that fever in a newborn, if persistent, not just a single temperature reading, but in two separate temperature readings, separated by at least an hour or two, persistent fever above some threshold, and there is no universally agreed-upon threshold, would usually trigger an evaluation in which sepsis was a possibility, but the jaundice that we described, feeding intolerance that you mentioned, a perception on the part of the family that the child is not crying in a way that they like, if, on the physician's side, the examination showed to that physician a child who fell within the expected behaviors of a well newborn, then a sepsis evaluation would not be mandatory, and, certainly, antimicrobial therapy would not be indicated.

Q. (By Mr. Mishkind) Is it important for that physician to do a clinical examination of that patient in response to the concern that the family may be having concerning their child to

determine whether or not the child is, in fact, as ill as the parents believe he is?

A. No. It's not incumbent that the physician do a personal examination of the child if information from the nursing staff, which is trustworthy, can be obtained to have the same information on which to make a working decision.

In other words, if the child is known to the physician, if the parents are concerned, if the nursing staff is in agreement with the physician's impression based on when the physician last saw the patient and nothing new has intervened, then the physician does not need to rush in and to do a physical examination under those circumstances, and a period of waiting and reevaluation, even by the nursing staff, is perfectly appropriate.

Q. Doctor, is it incumbent upon the nursing staff to accurately communicate to the attending pediatrician any changes in the child's status that they observe or that they assess or any concerns expressed by the family that would relate to feeding difficulties, level of responsiveness in terms of crying and things of that nature, is it incumbent upon the nurses to communicate that

information to the attending doctor?

MR. MARKWORTH: Objection.

THE WITNESS: Is it important for nurses to communicate clinically meaningful changes in the child? The answer is yes. I have not finished, I'm sorry, sir.

Q. (By Mr. Mishkind) All right. Go ahead, Doctor, I didn't mean to cut you off.

A. It is important for the nursing staff to convey concerns expressed to them on the part of the parents to the doctor in due time. I mean, many of those are not necessarily communications, but they should be communicated, so the answer in those two situations is yes to both.

Q. Would it be, in your professional opinion, below the standard of care for the nursing staff in the newborn period not to communicate in due course to the attending doctor by phone, assuming that the attending doctor isn't actually in to see the patient himself, the concerns that the family has and any changes in the child's clinical status?

MR. BONEZZI: Objection.

MR. MARKWORTH: Object.

THE WITNESS: Well, as I said, I

have already said that it's important for the nurses to communicate those two items to the physician in due course.

The clinically meaningful changes in the child's health condition should be communicated at the time that those changes are observed if, in fact, they are alarming or worrisome to the nurse.

With respect to the parents' apprehension, questions, worries, if the nurse feels that the child is doing well, then it's really a question of counseling to the family regarding newborns and to their newborn, in particular, some of which is done by the nurses, some would subsequently be done by the physician, and the communication of their concerns from the nurse to the physician should take place in due time, but it's not an emergency communication.

Q. (By Mr. Mishkind) Again, if the nurse has reason to be concerned about the child's condition, would you agree that if that information that the nurse assesses of the child is not communicated to the attending doctor that isn't actually there to see it himself, that that would not be in keeping with accepted standards of

care?

MR. BONEZZI: Objection.

MR. MARKWORTH: Objection.

THE WITNESS: Well, again, sir, it depends what the concern is.

Q. (By Mr. Mishkind) Right. I understand that, but we are talking about if there was a legitimate concern and that if information is not conveyed to the pediatrician, you would agree that the nurse would not be complying with her requirement to meet the standard of care, right?

MR. MARKWORTH: Objection.

Q. (By Mr. Mishkind) Doctor, do you understand?

A. Well, I understand, I just want to be able to distinguish different levels of concern.

Q. I understand that, again, we are talking about if there is enough information, we are talking hypothetically, enough clinical information that the nurse observes and she, based upon her experience, has reason to be concerned about that condition of a child, if, hypothetically, she doesn't then convey that information back to the doctor, would you agree with me that that would not be acceptable care, it

would be substandard care on the part of the nurse?

MR. BONEZZI: Objection. Go ahead and answer.

THE WITNESS: If the concern is one about an alarming picture emerging about the child's health, that should be communicated. Failure to do so would be failure to be practicing their professional responsibilities adequately.

Q. (By Mr. Mishkind) Okay. Thank you. Doctor, I jumped way ahead of myself. I want to back up for a moment and ask you some questions about your background, and, then, I will leap back into the heart of this matter momentarily.

Going back to your CV, on page 9 of 9, the first organization listed is the American Society for Law and Medicine, is that the first one on yours as well?

A. No. The first one on mine is the Infectious Disease Society of America.

Q. Are you still a member of the American Society for Law and Medicine?

A. Yes, although they have changed their name to the American Society for Law, Medicine and Ethics, but I still am a -- I belong to the

organization in order to get their publications, and I still do that, yes, sir.

Q. Are you active with that organization?

A. No, I am not.

Q. Have you ever been active with that organization?

A. No.

Q. Do you have, Doctor, any particular interest or specialty in the area of galactosemia?

A. I do not have a specialty interest in galactosemia.

Q. Do you consider yourself to be an expert in the area of galactosemia or metabolic disorders?

A. An expert, no, over and above what a practicing pediatrician knows.

Q. Have you ever written anything or presented any lectures or speeches to medical groups or medical students on the issues surrounding the diagnosis and treatment of galactosemia?

A. The answer is yes, as it applies to galactosemia being a risk factor for neonatal sepsis and infectious E. coli sepsis.

Q. Is that outlined at all on your CV?

A. No, my CV does not contain lectures or teaching modules.

Q. Do you maintain any type of a list of teaching presentations that would outline presentations relating to galactosemia and sepsis?

A. No.

Q. Can you tell me when the last time it was that you would have given a presentation that touched on galactosemia in that setting?

A. Well, I always mention it when I am giving lectures about newborn bacterial disease, but it's mentioned in a very brief phrase, just as a point of information, for people who may not know about the connection between those two entities.

The last time of which I gave a more extended presentation about that was probably the mid-80s.

Q. Even though you aren't an expert in the area of galactosemia, you do have an exposure to it, as you have indicated, in your practice as a pediatric infectious disease physician, correct?

A. Well, I have exposure to the issue, but the numbers of cases of children with galactosemia who develop E. coli sepsis is quite small.

Q. Can you agree that galactosemia in a newborn infant is considered to be a medical emergency?

A. It is a medical urgency.

Q. You differ with my use of the term "emergency"?

A. Sure, I mean, you know, words mean different things to different people.

I interpret an "emergency" as something which requires swift and rapid emergency reactions: Heart attacks, people bleeding from orifices, diseases which will kill or maim within minutes to hours are true emergencies.

Urgencies are medical conditions which require accelerated investigation and intervention, but the time course is one which is not minutes to hours, but, rather, is one of days, perhaps as long as weeks.

Q. Is it your testimony that in a neonate where there is a suspicion of galactosemia that confirmatory testing, either to rule out or to confirm the existence of galactosemia, is not a medical emergency?

MR. BONEZZI: Objection. That's not what he said. Go ahead and answer, Doctor.

THE WITNESS: I will try and reanswer it, sir, so that I know that you are understanding me. It does not require cardiopulmonary resuscitation or admission to an intensive care unit or any of those other emergency things.

If the child is suspected of having galactosemia, two things are done, and they are done with some rapidity: One is to put the child on a galactose-free diet pending resolution of the diet, and the second is to do the confirmatory test, but you understand the confirmatory test is you get the result in some days.

Even so, obviously, it's not an emergency of the sort that, in my business, we consider to be emergencies which require you to drop everything and start running. I just don't want to be hampered by your definition of "emergency," so I have tried to give you a flavor of what my definition is.

Q. (By Mr. Mishkind) If there is a suspicion of galactosemia and that information is indicated verbally from a lab, would you agree that the parents of that child should be notified immediately?

And "immediately," I will define within 24 hours, so that the child is, at that point in time, put on a galactose-free diet?

A. I think that's good policy, yes.

Q. And thereafter, the issue of ruling out or confirming the existence of galactosemia need not be done on an emergent basis, but should be done within a period of time thereafter?

A. Yes, sir, one might use the word "expeditious1y."

Q. Okay. And, again, just so that I have an idea, once verbal notification of abnormal or suspicious galactosemia is communicated, what is your opinion, back in 1989, as to the time period that the retesting to confirm or rule out galactosemia should expeditiously be done within?

A. I think most places that I had worked, prior to and including 1989, ask that the child be brought in within the next week to ten days for retesting.

Q. And during the pendency of that, the child is placed on a totally restricted diet with no galactose or lactose?

A. That's correct.

Q. Okay. Why is that that the child must

immediately be placed on a restricted diet once verbal concern about abnormal galactosemia results is known?

A. I am not an expert in galactosemia, as I have already stated, but there is sufficient concern that the injury which results from the presence of galactosemia occurs early in the child's life who is on a diet containing galactose, so that restricting the entry of galactose into the system is hoped to be a way of restricting the scope of the injury caused by the defect.

Q. Okay. Can we agree that it would be below the standard of care, and, in fact, in your opinion, back in 89, would be below the standard of care for a pediatrician's office that is notified by phone of abnormal galactosemia results not to immediately -- and, again, I will define @@immediately@@ as within 24 hours -- notify the parents of the abnormal results and the need to place the child on a restricted diet?

A. Yes, I believe good policy was that you try to get ahold of the parents, I mean, you make an attempt to get ahold of the parents within a day or two as you have already suggested. I think

that was good policy, certainly.

Q. And, certainly, if one did not make that attempt once receiving verbal notification of the abnormal results, would you agree that that would be below the standard of care?

A. Yes.

Q. Do you have any evidence from your review in this case that any attempt was made by the pediatrician's office within a day or two to reach the Maksym family following the verbal notification that Steven had an abnormal or suspicious galactosemia result?

A. I believe the notification to the office was around the 25th.

MR. BONEZZI: 24th.

THE WITNESS: 24th of the month, and my information is that the phone call occurred in the first week of September, so that there was a delay of greater than a week between those two events.

Q. (By Mr. Mishkind) And, certainly, you would agree with me that that would be substandard in terms of notification to the family of a need to place the child on a galactose or lactose-restricted diet pending the retesting of

the child?

A. Yes.

Q. Okay. Doctor, I didn't ask you much about your practice because I'm going to use your CV and other information, but can you just tell me how you divide your professional time?

A. Sure. 50 to 60 percent of my professional time is spent in patient care; the Lovelace Health System is the largest HMO in New Mexico. In our group of 19 practitioners, 13 pediatricians and six midlevel practitioners, we care for approximately 60 to 65,000 children.

I have office hours where I see patients in a regular office/clinic setting approximately five half days a week. I work in the nursery and on the ward similar to the other physicians, because we have no residents or interns in our hospital.

I consult on all cases of severe infections or severe illness, in general, in the hospital, and that comprises approximately 60 percent of my work time.

The remaining 40 percent is spent in administrative work, of which there seems to be a never-ending amount. I teach and attend

periodically at the University of New Mexico Health Science Center, and I have some scholarly pursuits which fill up the rest of my time.

Q. Amongst your clinical practice, do you have any portion that you would consider to be a general pediatric practice?

A. Yes, the majority of it is a general pediatric practice.

Q. So you are seeing well patients as well as sick patients?

A. That's correct.

Q. What percentage of your clinical practice would you say is dedicated to seeing patients that have some type of infectious disease process?

A. Well, you know, the average pediatrician who is seeing sick children is dealing with infections between 50 and 80 percent of the time.'

Q. Are you seeing sick children with infections at a greater percentage because of your position and your training?

A. Yes, I am, the additional infectious disease work that I do is consulting infectious disease work so that the illnesses consequently would be illnesses of a more severe nature, trickier nature, or one which has failed therapy

previously.

Q. Do you have an office outside of the hospital?

A. No.

Q. You see private patients at the hospital as well as hospital patients?

A. I see ambulatory clinic patients in my office in the hospital, and I do my hospital work on the ward in the nursery within the same physical plant.

Q. And do you have, basically, a private clinical practice as well?

Is that what you define as your ambulatory practice?

A. My practice is the practice that I share with my 18 other colleagues, in which 70 percent of our patients are a prepaid managed care group, and 30 percent we see on a fee-for-service or Medicaid basis.

Q. You are currently, as I understand it, working as an expert witness for Mr. Bonezzi on another case; is that correct?

A. Yes.

Q. What is the subject matter of that case?

A. Hypothyroidism.

Q. Do you have any special expertise in the area of hypothyroidism?

A. The answer is no, over and above what is part of my general pediatric knowledge.

Q. And in that case, is it your opinion that -- strike that.

Are you appearing as an expert on behalf of Dr. Caro?

Q. And is it your opinion in that case that Dr. Caro complied with the standard of care?

A. Yes.

Q. You have been deposed in that case, correct?

A. No.

MR. BONEZZI: No.

Q. (By Mr. Mishkind) To your knowledge, is your deposition scheduled?

A. I do not know.

MR. BONEZZI: No.

Q. (By Mr. Mishkind) Are you scheduled to --

MR. BONEZZI: He is not scheduled, Howard.

MR. MISHKIND: I'm sorry, Bill?

MR. BONEZZI: He is not scheduled.

MR. MISHKIND: You faded off on me that time.

MR. BONEZZI: He is not scheduled.

MR. BONEZZI: The trial is not set, all of this will occur, anyway, subsequent to this case.

Q. (By Mr. Mishkind) Doctor, is that your understanding?

MR. BONEZZI: It certainly is. That's what I told him.

Q. (By Mr. Mishkind) Doctor, is that your understanding?

MR. BONEZZI: Tell him yes.

Q. (By Mr. Mishkind) That you are not scheduled to testify in deposition or at trial?

A. Yes.

Q. Okay. Are you working as an expert witness for Mr. Bonezzi on any other cases besides the Maksym and the Burns vs. Caro case?

A. No.

Q. Have you ever worked with Mr. Bonezzi before either of these two cases?

A. I have been retained by Mr. Bonezzi in other cases prior to those two, yes.

Q. How many?

A. Just one.

Q. I'm sorry?

A. Just one.

Q. What was the subject matter of that case?

A. I believe that was a child who had meningitis who had a prior illness, fever-producing illness, with meningitis as a final diagnosis.

Q. And were you giving opinions as to the standard of care relative to a pediatrician?

A. I don't honestly recall. I certainly was giving an opinion with regards to the causative link between the actions of the treating physician and the outcome.

Q. And was it your opinion that the doctor's care did not cause the outcome?

A. I believe so, sir, but the case is not fresh in my mind and I don't want to be held to anything I might say today.

Q. Have you worked on any cases for any of the other attorneys in the Jacobson & Maynard law firm?

A. Yes.

Q. How many other cases?

A. I believe I have been involved in only one other case from another one of their offices.

Q. What's the name of the lawyer that you are working for?

A. I honestly can't remember at this moment, I'm sorry.

Q. Have you given deposition testimony or testified at trial as an expert on behalf of any of the attorneys at Jacobson & Maynard?

A. No.

Q. Have you ever served as an expert witness

in any Ohio cases other than the Dayton case and this case?

A. Yes.

Q. How many other cases in Ohio?

A. Well, again, I don't have a complete memory, I do remember being involved in at least one case from Cincinnati.

Q. What was the subject matter, Doctor?

A. It was a child who was infected with the meningococcus who had a severe illness.

Q. Were you appearing on behalf of the doctor or the patient in that case?

A. The physician in this case.

Q. Was your deposition taken in that case?

A. Yes, it was.

Q. Do you recall offhand the name of any of the parties or any of the lawyers?

A. No.

Q. Any other Ohio cases that you have served as an expert witness on?

A. I can't recall any more at this time, sir.

Q. How many medical malpractice cases do you review on average during a calendar year?

A. Well, it's quite variable. I have been

reviewing cases since 1982, and I believe during those 14 years, I have probably reviewed between 100 and 125 total cases.

Q. So is it fair to say that somewhere in the range of eight to twelve cases a year?

A. I think that would be a numerical average, yes, but as I say, it's irregular.

Q. Okay. Currently, how many cases are you serving as an expert witness on --

A. I don't know.

Q. -- besides the two cases that we just talked about for Mr. Bonezzi?

A. I don't know.

Q. Are you expected to give deposition testimony or to testify at trial in any cases other than the Maksym case?

A. There is a case from St. Louis which is set for trial at the end of this month, but it has been put off sequentially for about three years, so 1 don't have complete faith that it will actually happen at this time, either.

Q. Your deposition was taken in that case?

A. Yes, it was.

Q. What's the name of that case?

A. McCormick vs. Roden, R-o-d-e-n.

Q. What's the name of the attorney that you are working for in that case?

A. Mr. Edward Crites, C-r-i-t-e-s.

Q. And he is in St. Louis?

A. That's correct.

Q. Have you testified previously at trial in a medical malpractice case?

A. Yes.

Q. How many times, Doctor?

A. I would say now maybe 16 times, more or less.

Q. And of the 100 to 125 cases that you have reviewed over the 14 years, in how many cases have you given deposition testimony?

A. Half of them.

Q. So it would be fair to say that you have been deposed 50 to 60, 65 times?

A. I think that's the order of magnitude, yes.

Q. What percentage of your work in terms of review of cases has been for the plaintiff versus the defendant?

A. I believe about 15 percent have been for plaintiffs and the remainder for defendants.

Q. Have you ever testified at trial on

behalf of a plaintiff?

A. Yes.

Q. How many times of the 16 times that you testified at trial?

A. One time.

Q. And of the 50 to 60 or so depositions, how many of those have been for the plaintiff?

A. I believe 15 percent, a proportional number.

Q. Doctor, in some of the writings that you have generated over the years, have you expressed any attitude toward malpractice litigation?

A. I don't quite understand that question, sir.

Q. Have you indicated a concern about the specter of malpractice litigation and the impact that it has on a pediatrician in the daily clinical setting?

A. I am sure I have in some setting.

Q. And, in fact, in your writings, Doctor, have you indicated that malpractice litigation imperils individual initiative?

A. It sounds like a phrase I might have used.

Q. And is that your feeling as of 1996?

A. I don't know if I would use such a strong word as "imperils" now in 1996 as I must have used at some time, but I think that the underlying concern that the specter of liability in today's world interferes, to some degree, with judicious and enlightened medical practice is still a concern of mine.

Q. Okay. Have you ever been named as a defendant in any medical malpractice cases?

A. Yes.

Q. Tell me, if you would, how many times you have been named as a defendant.

A. Twice.

Q. Was your deposition taken in either of those cases?

A. I believe it was taken in one of the cases, but it's been sometime now.

Q. Was that in Denver?

A. If it was taken, if it were taken -- and I am not entirely sure that it has been -- it would have been in Denver, yes.

Q. Do you recall the name of the patient in that case?

A. Yes, I do.

Q. Tell me, please.

A. Wendy Holland.
Q. Spell the last name, please.
A. H-o-l-l-a-n-d.
Q. Did that case have anything to do with meningitis?
A. No.
Q. Did it have anything to do with septicemia?
A. No.
Q. What was the subject of that claim against you?
A. Wendy was a 7-year-old girl who went into renal failure. She was admitted by me to the hospital in my third year of pediatric residency and transferred to the intensive care unit, during which time she had a cardiac arrest.
Q. Did either of the cases that you have been named as defendant ever go to trial?
A. No.
Q. What do you charge, Doctor, for medical/legal review of records?
A. $350 an hour.
Q. And what is your charge to be today for the deposition?
MR. BONEZZI: Million dollars an

hour.

THE WITNESS: For you, Mr. Mishkind, $400 an hour.

Q. (By Mr. Mishkind) I'm sorry, how much?

A. 400.

Q. And what do you normally charge for deposition testimony?

MR. BONEZZI: I had suggested to him maybe $50 an hour except for you, Howard.

MR. MISHKIND: Flattery and courtesy will get you everywhere, Bill.

MR. BONEZZI: Thank you.

Q. (By Mr. Mishkind) Doctor, is that your normal charge of $400 an hour?

A. Yes, it is, sir.

Q. And for purposes of your trial testimony in Cleveland in this case, what will you be charging?

A. For the time that I am testifying in court, $450 an hour.

Q. Tell me the reason that in-court testimony is more than deposition testimony per hour.

A. Well, there are two reasons, in my mind: One is that it is a much more important moment,

and, therefore, extracts, I think, the greatest amount of concentration and patience on my part.

Q. Any other reason?

A. No.

Q. Okay. Now, in your letter, which, I believe, is Exhibit 1, if I am correct in what the court reporter assigned to your March 18, 1996 letter, there is a reference to having received a letter from Mr. Bonezzi on January 23, 1996; do you see that?

A. Yes.

Q. Do you have that letter in front of you?

A. I believe I do. Let me pull it out from my file. I have it, sir.

Q. Apparently, that letter itemizes certain information that was provided to you, correct?

A. Yes, it does.

Q. All right.

MR. MISHKIND: Bill, do you have any problem with that letter being marked as an exhibit?

MR. BONEZZI: Yes, but I'm going to let him do it.

(Exhibit 3 marked)

Q. (By Mr. Mishkind) Would you please tell

me what material was provided to you prior to your preparing the March 18th, 96 report?

A. Well, I took the liberty of bringing everything that has been supplied to me for this deposition. Would you like me just to go through the pile of things that I have or read from the letter?

Q. I'd like to know what it was that you had before preparing the report and what additional information, if any, you received since preparing this report, so if you would do that, I would appreciate it.

A. Okay. Well, in preparing the report, 1 had the Deaconess Hospital records from 8/15 onward, including the emergency department record; I had the MetroHealth Medical Center records, 8/21/89 through 9/16/89, which included, primarily, the first five days of admission; I have the physician office records from a number of different physicians, including Dr. Jamhour; Dr. Skrinska, S-k-r-i-n-s-k-a; Dr. White; Dr. Thompson; Dr. Caravella; Dr. Grisoni; Dr. Corwin; Dr. Kerr, K-e-r-r; and from the Cleveland Clinic Foundation, I had the plaintiff's expert reports, which were packaged but included reports from Dr.

Gold; Dr. Rehmus, R-e-h-m-u-s; Dr. Hand; Dr. Jay, J-a-y; Dr. Levy, L-e-v-y; and I had deposition transcripts from Joanne Maksym; Dr. Joseph Jamhour; Dr. Murty, M-u-r-t-y, Vuppala, V-u-p-p-a-l-a; and that's the package that I was initially sent by Mr. Bonezzi.

Q. And was that the information, then, that was the predicate for your preparing this March 18, 1996 report?

A. Yes, sir.

Q. And by the way, do you still maintain the opinions that you expressed in that March 18, 1996 report?

A. Yes, I maintain the opinions, although you'll notice on page 4 when I comment on the telephone contact between the doctor's office and the mother on 9/16/89, I said that it was sufficient, and I am quoting, "was sufficient to discharge the obligation of these doctors to follow up on the abnormal newborn screening test," but you understand that as I have already stated, the duration of time between the contact to the office and that telephone call I thought was excessive.

Q. And you have already told me previously

that that excessive period of time, in your professional opinion, violates the standard of care?

A. That's correct.

Q. Okay. With that modification to your report, do you stand behind everything else that you have stated in the report?

A. Yes.

Q. Have you arrived at any new or additional opinions beyond those expressed in the report, Doctor?

A. No.

Q. Now, you told me what information was sent to you by Mr. Bonezzi prior to your preparing the March 18, 96 report. Have you received anything since then?

A. Yes, I have.

Q. Could you tell me what you received?

A. Sure. These consist of depositions. There is a deposition of Dr. Skrinska; deposition of Nurse Strong; deposition of Dr. Levy; deposition of Violet Khoury, K-h-o-u-r-y, and I don't know if I am pronouncing it correctly; Dr. -- a deposition of Dr. Jerome Klein, K-l-e-i-n; deposition of Dr. Buist, B-u-i-s-t.

Again, I apologize not knowing how the pronunciation went. And I received expert opinion letters from Dr. Klein and Dr. Buist as well.

Q. Did that cover all of the information that you have been provided in this case?

A. Let me just double-check, sir, I believe it does. No, I have one more thing here, it's a -- no, I'm sorry, I have already covered these items in my prior list, yes, that's all of the items that I received.

Q. You have never been provided or reviewed any of the depositions of the nurses from Deaconess; is that correct?

A. The only nurse is Nurse Strong. No, the answer is yes, that's correct.

Q. Okay. The information that you have just described to me that came to you after March 18, 96, was any of that information given to you just today?

A. No, I received no information just today. By the way, there is one more item, and I don't know if I separately mentioned it, I did receive a copy of the Guidelines for Ohio Newborn Screening, effective December 2, 1991.

Q. Okay. And do you have that with you

right now?

A. Yes.

Q. Okay. If you would, hand that to the court reporter, and I'd like, too, for her to mark that as Exhibit 4.

(Exhibit 4 marked)

Q. (By Mr. Mishkind) Exhibit 4 is the guidelines from the state of Ohio?

MR. BONEZZI: 1991, they don't have any impact on this case.

Q. (By Mr. Mishkind) Okay. Did you review that before the preparation of your report, or is that since the report?

A. No, I received that prior to my making my report, I believe I did. I can double-check the correspondence.

Q. Okay. In fact, if you would just give me a moment, I will double-check the correspondence.

Q. Okay.

A. Mr. Bonezzi said he sent me this subsequent to my initial review.

Q. Does that document, Exhibit 4, have any particular relevance or significance as it relates to your opinions in this case?

A. No.

Q. Do you hold any opinions concerning whether the state of Ohio, in particular, the Ohio Department of Health, was negligent in any respect in this case?

A. Well, I personally have concerns about how the arrangement for the notification procedures on the part of the Ohio Department of Health at that time was conducted.

Q. And those concerns, are they sufficient enough for you to say that the state of Ohio, in your professional opinion, the Ohio Department of Health, I should say, did not comply with accepted standards of practice?

A. I don't think I am in a position, in all honesty, to comment on accepted standards of practice, not being either employed by or trained in general public health of this sort, but as a practicing physician, I have grave misgivings about the conduct of the notification procedure and the division of responsibility that was present in 1989 on the part of the Department of Public Health in the state of Ohio.

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

A. I do not have a deposition from Mr. Porter.

Q. Is it fair to say that you do not know directly what information was conveyed by Mr. Porter according to his testimony in this case?

A. Again, I didn't read a deposition, I have no way of knowing.

Q. What are the concerns or the misgivings that you have concerning the Ohio Department of Health in this specific case?

A. My misgivings are the following: That it is not sufficient, I don't believe, as a matter of public safety, from a pediatrician's point of view, for the Department of Public Health to discharge their responsibility towards a patient who may have a serious metabolic illness on to the "physician of record" who was caring for the child at the time that the test was generated.

I believe that a state department of public health has an individual responsibility to that child and needs to have procedures by which the safety of that child is insured, independent of the actions of the physician of record.

Q. What is your understanding as to procedures that were in effect in 1989 in the state of Ohio?

A. My understanding is that once a telephone

call had been generated by the Department of Public Health to the office of the physician of record, that no matter who answered the phone and no matter what they did with that particular information, the obligation of the health department had been discharged and that there was no follow-up procedure to see that the child's true medical condition had been clarified or that therapy for that condition, whatever it might be, had been instituted.

Q. What's the source for that opinion, Doctor?

A. Well, as I said, I am not trained in public health, nor am I or have ever been employed by a state department of public health.

Q. You misunderstood me. What is the source for your statement as to what you believe to have been the procedure in 1989 in the state of Ohio as you have just described?

A. Well, two: One has to do with the way things were, in fact, conducted, and no evidence that, in fact, the state department of public health made any efforts to follow up on this particular child over the course of years, really; and secondly, has to do with these guidelines that

I received, which were effective 1991, which did not include a follow-up procedure that was adequate, from my point of view, anyway.

Q. Have you ever been provided with any written guidelines that would have been in effect in 1989?

A. No.

Q. Would you agree that -- strike that.

Are there any other criticisms or concerns that you have, as you understand the procedures to have been in effect in 1989, as it relates to the state of Ohio's responsibility?

A. No.

Q. Would you agree that irrespective of the state of Ohio's responsibility, a pediatrician's office that receives a telephone call with that kind of information on a metabolic condition, that there has to be a system in effect at the pediatrician's office so that that information conveyed to the pediatrician, in this case, the pediatrician that had ordered the galactosemia test?

A. No, I don't necessarily think that the pediatrician individually needs to be notified for a couple of reasons. One is the pediatrician

oftentimes does not order any kind of testing at all.

The testing is mandated by the state and is part of the normal newborn procedure, but the name of that pediatrician of record is included on the test as it is ordered.

Secondly, the pediatrician may no longer be the treating pediatrician of the child, and third, the step which is required which is to notify the parents of the result and have them contact their care provider can be accomplished by any trained person in the office, and it doesn't need to be the pediatrician, for example, the office nurse could do it, or the laboratory technician in the office could do it, or someone else who is trained to know the gravity of the situation, so it doesn't need to be communicated, necessarily, to the pediatrician, as long as it's a trained individual who takes responsibility for the notification.

Q. And would you agree that if that individual that receives that information is not trained to understand the gravity of the information, then the procedure in effect at that pediatrician's office would be below the standard

of care?

A. Well, I am not an attorney, but it seems to me there has to be two components: One is that the person was not trained, and secondly, they didn't do the right thing; in other words, they didn't act according to the expeditious notification that you and I have already talked about.

Q. I am putting aside the expeditious notification, and 1 am asking you separately, if the individual that receives the information hasn't been provided with the training by the pediatrician to know the gravity of the situation, would you agree that that would be a separate and distinct violation of the standard of care for the pediatrician's office?

A. Well, I am sorry, sir, you are sort of using legal language about separate and distinct. I mean, if the person didn't know the gravity of the situation, and in not knowing the gravity of the situation, acted with inappropriate lassitude, then, of course, that would not be appropriate for such an important issue.

Q. Do you see any evidence, Doctor, in this case, from your review of Violet's deposition that

she understood the gravity of the metabolic condition of galactosemia?

A. I honestly don't recall, sir, whether there was a lot of questioning regarding the deponent's knowledge base about galactosemia.

Q. She should have had a knowledge based on galactosemia in order to understand the gravity of that situation, the need to communicate it immediately to the parents, correct?

MR. BONEZZI: Objection.

THE WITNESS: **No**, not necessarily, she should have had some matrix within which she acted regarding the reporting of laboratory tests; for example, if all laboratory tests received by her were immediately reported to a physician or the nurse of the office or directly to the parent, she wouldn't necessarily need to know the gravity of the situation regarding galactosemia, because she would be acting with alacrity, no matter what the laboratory test was.

But if failure to act expeditiously was based on failure to know what the consequences of inaction were, then there is a link between the ignorance of the issues and the slowness of the reaction time.

Q. (By Mr. Mishkind) You mentioned earlier, Doctor, that you reviewed reports from Dr. Jamhour as part of the set of information that you received from Mr. Bonezzi prior to reporting your report, what reports do you have from Dr. --

MR. BONEZZI: Dr. Who?

MR. MISHKIND: Dr. Jamhour.

MR. BONEZZI: Are you talking about Dr. Jamhour's office?

MR. MISHKIND: Yes.

MR. BONEZZI: He didn't say that.

MR. MISHKIND: I may have misunderstood you, Doctor, I thought you said after MetroHealth Medical Center that you received records, and I thought it was Dr. Jamhour.

MR. BONEZZI: No.

THE WITNESS: I may have misstated myself. I said I received office records in the case of Dr. Jamhour which consisted of the ones that 1 named. If I said office records from Dr. Jamhour, I misstated myself. I don't have any office records.

Q. (By Mr. Mishkind) Okay. Have you ever seen a picture of Steven?

A. No.

Q. Do you know Dr. Gold?
A. Not personally, but I know who he is.
Q. Do you know him -- do you have any knowledge as to his reputation?
A. Well, I have some general knowledge, but as I said, I don't know him personally.
Q. Could you tell me what your general knowledge is of his reputation?
A. I believe that he is an honored member of the pediatric infectious disease community and certainly holds a responsible position at the Hospital for Sick Children in Toronto.
Q. And what about Dr. Levy, do you know him, either personally or by reputation?
A. The only knowledge I have of Dr. Levy has to do with his authorship of the 1977 article linking galactosemia and E. coli sepsis.
Q. What about the other plaintiff's expert, Dr. Ivan Hand?
A. I don't know Dr. Hand.
Q. And Dr. Rehmus, Dr. James Rehmus?
A. I don't know that doctor.
Q. What about Dr. Susan Jay?
A. Excuse me?
Q. Dr. Susan Jay?

A. No, I'm sorry, I don't know Dr. Jay.

Q. Did you do any medical research prior to preparing your report, Doctor?

A. I did review Dr. Levy's article, 1977. Other than that, part of my ongoing professional responsibilities include being up to date on issues that are relevant to this case, and, therefore, I did not do specific research on the case.

Q. Does your file contain any medical literature?

A. My files --

MR. BONEZZI: No.

THE WITNESS: Oh, I'm sorry, this little file that I brought with me?

Q. (By Mr. Mishkind) Yes.

A. No, it doesn't. It just contains correspondence.

Q. How many pieces of correspondence do you have there from Mr. Bonezzi?

A. Well, we have the January 23rd, 1996 cover letter that's already been marked as an exhibit. In addition to that, I have three correspondences.

Q. Are they essentially cover letters

enclosing documents?

A. That's correct, except for the last one, which is a notification of the time and date of the deposition.

a. Do any of the three correspondences that have not been marked contain any statements as to the facts as Mr. Bonezzi sees them in the case?

MR. BONEZZI: First of all, I don't see the facts in any way other than what is written; and secondly, I would not be so foolish, Howard, as to go ahead and put in my beliefs and opinions into any letter that would ultimately be reviewed by you.

MR. MISHKIND: And I appreciate that. Having said that, I just want to make sure that you didn't slip.

MR. BONEZZI: Not this time, nor will I ever.

MR. MISHKIND: Well, we will keep you on your toes.

MR. BONEZZI: I should not have said that.

MR. MISHKIND: We will quote you on that.

MR. BONEZZI: I'm afraid you might.

Q. (By Mr. Mishkind) Suffice it to say, Doctor, the correspondence you have is just cover letters and referencing the deposition?

A. I think I can say that these letters are admirably bland.

Q. Okay. Having reviewed Dr. Levy's report and after having reviewed Dr. Levy's deposition as it relates to the impact of the delay in diagnosis of galactosemia and it being a factor in causing Steven's brain damage with mental retardation, are you in a position, based upon your experience, to take issue with or to indicate concurrence with Dr. Levy's opinions?

MR. BONEZZI: Objection. Go ahead and answer.

THE WITNESS: As already stated, sir, I am not an expert in galactosemia; however, I can, in all honesty, disagree with Dr. Levy in the characterization that the child's current condition is the result of the galactosemia.

Q. (By Mr. Mishkind) And in what respect do you disagree with Dr. Levy on that point?

A. Well, Dr. Levy says, both in his opinion letter and in his deposition, that following the notification by the state health department to the

office of Dr. Jamhour, that a confirmation and treatment of galactosemia, at that point, would have prevented the substantial brain damage and the mental retardation that the child has now been saddled with.

My disagreement is that the meningitis that the child experienced was an aggressive and malignant infection which caused the brain damage that is evident today, and that at the time of the notification of the 24th, the child was already three days into the E. coli meningitis, and the child was not receiving any galactose then, anyway, so that even confirmation of the diagnosis of a galactosemia done at that time would not have altered the outcome.

Q. Your opinion is that the meningitis caused Steven's current disabilities?

A. That's correct.

Q. Are you ruling out the prolonged period of time that Steven went without a diagnosis and without a totally restricted diet as being a factor in any of his damages?

A. Well, to use your phrase, "to a reasonable degree of medical probability," I believe his injuries are due to the meningitis.

The fact that galactosemia, my understanding is, causes the brain injury relatively early in the course of the disease and the fact that the child actually did not have galactose in his diet for months to a year, is my understanding, to me, undercuts the importance of galactosemia in causing the brain damage.

Q. All right. Let me ask you a couple questions about that assumption. Number one, let's assume that the child had a totally restricted galactose and lactose-free diet for the period that you are talking about, and we are now in 1996, with much, if not all, of the damage caused by meningitis.

Is it your opinion that the presence of galactosemia, even with a restricted diet during the first year, is not contributory in terms of causing some of Steven's IQ deficits, language deficits and other neurological deficits?

A. That's my opinion.

Q. Is it your opinion, then, had the meningitis been avoided, prevented with early treatment of the sepsis and some luck on the part of that antimicrobial therapy, the effect of meningitis prevented, that Steven today would, to

a reasonable degree of probability, be a normal healthy child?

A. No, that's not my opinion.

Q. Okay. Why is it not?

A. Because of the fact that whatever degree of injury was caused by the galactosemia -- it's two reasons, I'm sorry, one is had the child had a miraculously benign course with the E. coli meningitis, undoubtedly, his dietary picture would have been changed over the first year and it would not have been what we see.

Secondly --

Q. Why do you say that? Let me just interrupt.

A. What?

Q. Why do you say that?

A. Well, remember, much of the basis for his dietary difficulties had to do with his severity of his incapacity and the treatment for that severe incapacity. If he had been a normal child, a week out from his meningitis, he would have been treated as a normal child.

Secondly, whatever impairment might be due to the untreated galactosemia in a normal child had already been subsumed by the damage

caused by the meningitis, and, therefore, I hold the opinion that the damage caused by the meningitis was so severe and global that it coopted or included within it any possible damage that might have occurred due to the galactosemia, but without the meningitis, some possibility of damage due to the galactosemia would be present in an otherwise normal child.

Q. And, again, in an otherwise normal child where meningitis did not ensue, but that child had galactosemia, what is your opinion as to the impact that that would have had or would have on Steven in that hypothetical situation, would he be normal today or would he have disabilities?

A. I believe that if Steven had never had the meningitis but had only had untreated galactosemia for four years, he, in all likelihood, would have sustained some neurological impairment.

Q. Can you quantify how much neurological impairment he would have sustained had he gone for four years with untreated galactosemia?

A. No.

Q. Can you differentiate how much neurological damage he would have sustained had a

timely diagnosis of galactosemia been made and appropriate dietary intervention provided, in the face of a child that did not sustain meningitis?

A. It's very hard to know that, because I would need to know something more of the dietary history prior to the notification of the diagnosis and the child's condition at the time of the notification of the diagnosis.

Q. Let me give you more facts to help you with that, okay? If the diagnosis was made within the first 7 to 14 days of life and no meningitis existed and dietary intervention -- appropriate dietary intervention was started immediately upon notification, and we now move out to current day, do you have an opinion as to whether or not Steven would have any deficits associated with being a galactosemic who had dietary -- appropriate dietary intervention started within seven to 14 days?

MR. BONEZZI: Objection, I am assuming that your question does not take into account the amount of galactose diet into his system during that period of time, am I correct, Howard?

MR. MISHKIND: I am not sure I

understood your objection.

MR. BONEZZI: Well, you are asking him what damage would have been caused or no damage caused in that period of time, but inherent in your question must be another question; that is, how much galactose did he take in during that period of time.

MR. MISHKIND: Well, I suppose you could put it that way, but I want to know whether this doctor, who may or may not have an opinion as to a reasonable probability, if a child who doesn't have meningitis, but has classic galactosemia that is detected within the first 7 to 14 days of life, and is, at that point, then, placed on a totally restricted diet, whether or not that child, at 7 years of age, would have still sustained some neurological deficits associated with the underlying condition, galactosemia.

MR. BONEZZI: I am still going to object, Howard. The notification from the state of Ohio came after that 7-day period of time but before the 14, and I am not quite sure what you mean by "classic galactosemia," but go ahead and answer if you can, Doctor.

THE WITNESS: Well, again, I'm not going to put myself out as an expert on galactosemia, my understanding is that in a child who is taking in a full diet of a lactose-containing formula, who is diagnosed with galactosemia based on screening somewhere at 10 or 14 days of life, and, then, taken off his regular formula and put on a lactose-free formula and galactose-free formula, that there still was the possibility of brain damage in that child's future, but I understand that there are enough variables in that situation which include, among others, the amount of the exposure to galactose and the susceptibility to galactose levels on the part of the child, that it's very hard to quantify, so all I can do is answer and say yes, there is the possibility of neurological injury, but it would be dependent on other factors, some of which Dr. Bonezzi has already mentioned -- excuse me, Mr. Bonezzi.

Q. (By Mr. Mishkind) He has been elevated to a doctor?

A. These days, it is not a compliment, but it is a mark of a compliment.

MR. BONEZZI: Why don't we take a

break right at this moment.

(Recess taken)

Q. (By Mr. Mishkind) Doctor, what is your understanding as to the dietary history for Steven during the first year of his life?

A. Well, my understanding is that he was on a lactose/galactose-free diet for the first year.

Q. Is it your understanding that he was on a totally restricted or lactose and galactose-free diet?

A. Yes, for the first year of life.

Q. All right. And if, in fact, he was not on a totally restricted galactose and lactose-free diet but did have some exposure to lactose or galactose in portions of his diet, what impact, if any, would that have on his condition of galactosemia?

A. Well, I believe it's very dependent on the volume of material that he was taking in. If it was a minor component of his diet occurring only infrequently, it probably has no impact at all.

Q. Would you defer to a metabolic specialist in terms of opining the significance of exposure to some galactose or lactose in the diet and the

impact that that has on the child's brain?

A. I would not defer to a metabolic specialist in the issue of whether the child's brain injury was caused by the meningitis or caused by the galactosemia. I would defer to a metobolic specialist in terms of the risks that might be involved in quantity exposure to galactose or to lactose.

Q. All right. So that if we did not have meningitis as the overwhelming feature, as you see it in this case, the impact, if any, that exposure to galactose and lactose had to Steven's brain during the first year, that's something that you would defer to a metabolic specialist on?

A. That's correct.

Q. And, certainly, after the first year of life, the same would apply in terms of exposure to a nonrestricted diet, the impact that that would have on Steven's brain and his functioning today, you would defer to a metabolic specialist on that as well?

A. That's correct.

Q. Okay. Doctor, have you or do you currently make your name available to any services?

A. None voluntarily.

Q. Is your name made available to any services involuntarily?

A. Not to my knowledge.

Q. Are the parents of a child that has jaundice advised at the time of discharge of that newborn baby of a significance of bilirubin levels and increasing jaundice?

A. I don't quite understand the question, I'm sorry.

Q. In a newborn period, if the child has jaundice, and at the time of discharge, they show truncal and facial jaundice, is it important for the parents to be advised relative to the significance of jaundice and what to look for?

A. Again, I don't quite understand the drift of the question because it's such a general question.

Q. What should parents be told at the time of discharge, if a decision is made to discharge their newborn baby and that newborn baby has jaundice, what should they be told about the jaundice?

A. Oh, that's easier.

Q. Okay.

A. Before anything is told to the parents, there are certain items that have to be decided upon by the physician or the physician's agent regarding the jaundice. The first has to do with the fact of the child's general condition, is this a well child or a sick child.

Children who are sick are treated differently with or without jaundice, but children who are sick with jaundice would have a more expanded investigation of the cause of the jaundice than children who are well with jaundice.

Secondly, the child's risk factors involving newborn jaundice, for example, is the child premature or not; was the child afflicted with intrauterine problems of one sort or another or not; did the child have evidence of a very concentrated blood volume, or what's called polycythemia or not; does the child have bruising or not; whether the mother's blood type influences this and whether there are any familial illnesses which have declared themselves in the newborn period by jaundice.

So you try to get a feeling whether this is likely to be nonserious physiologic jaundice or

whether it's likely to be jaundice due to a more serious condition and a feeling for the likelihood that the level of the bilirubin would rise quickly and high or would not rise quickly and high.

Armed with that information, if the child is a full-term child who is not clinically ill to the practitioner, who does not come from a history in which serious cause of jaundice is likely and whose mother does not have O blood type, the following information should be provided, which is your child is yellow, this is normal in children, as long as your child is acting well and eating well, all will be well, and that's what we say.

If, on the other hand, the child becomes ill in any way, then you should contact us. And that's normally said, of course, with all children who are discharged. No specific attention to the jaundice should usually be made, and the reason is that parents are not capable of judging the level of the bilirubin based on physical findings, simple as that.

Q. Would you agree that it's important that the parents be verbally educated that if the child becomes ill, that contact with the pediatrician or with the hospital be made?

A. Well, the answer is yes, but, you know, there is a generic admonition when the child leaves the hospital which is given to them, usually more than once, which is, if you have any problems with your baby, give a call to your doctor.

And that kind of admonition is almost universal, but one does not hone in on specific possibilities and give any more detailed instruction than that.

Q. The rise in bilirubin, in this case, from 6.5 to 10.2 during the time period that was involved, was that rise during that period of time for a full-term, otherwise healthy baby, concerning to you?

A. No.

Q. Would you have instructed the parents to have a repeat bili?

A. No.

Q. Why?

A. The reason is that this was a well child whose mother had A positive blood type and was full term, and under those conditions, levels of bilirubin of the sort that you mention are not only not alarming, but rarely reach a level which

is of any concern at all.

Q. If Steven had clinical signs with abdominal distension, had a temperature the morning of the discharge at 37.8 or 37.9, and it had episodes throughout the newborn period of regurgitation and poor feeding, and had the jaundice levels that we have talked about, would that have changed in any respect the home-going instructions that you have given?

MR. BONEZZI: Howard, at what time in the morning do you believe the temperature was 37.8 or 37.9, for purposes of your question?

Q. (By Mr. Mishkind) According to the records, it would be 3:00 a.m., in the morning, and if I am wrong to assume that to be a fact, it will be borne out in the records.

If there was a temperature elevation of 37.8 or 37.9 with the facts that I have just given you, would that have changed the discharge instructions that you have just described for me?

A. Well, as I said, the definition of fever in a newborn is a sustained temperature above some threshold. No one is entirely sure what the threshold is.

Q. What threshold do you use, Doctor?

A. Well, I will use all the time of a sustained temperature of 38 degrees and above. Between 37.5 and 38, depends to a certain degree on the child's prematurity, whether the child is being artificially heated, either in an isolette or under an open warmer, the degree of bundling, child's general condition.

Normal children will have rectal temperatures or actually any type of temperatures of 37.8, normal children will do that, so 37.9 is kind of an in-between, a gray zone, but, again, it has to be a sustained fever. A single elevated temperature level does not constitute a fever.

Q. And in order to have a sustained level, if you had 37.9, when would you, to determine whether that's a sustained temperature, when would you next take the temperature?

A. Oh, commonly, it's done an hour or a couple of hours later.

Q. And that's in order to give you an idea as to whether or not this is an isolated event or something more significant, correct?

A. Correct. In a way, it's to let you know whether this is, in fact, a fever, if one defines 37.9 as a fever, or an isolated elevation in

temperature not due to conditions which produce fevers.

Q. Over what period of time would you have to have a sustained temperature of 37.8 or 37.9 and above in order for you to feel that this is a fever, as opposed to an isolated temperature elevation?

A. Again, you are asking me, and for me, a temperature of 38 in a full-term child is the threshold level.

Q. Let me rephrase that. What level should there at least be a concern about temperature elevation in the newborn period, what sustained period of time must there be at or above that level for there to be some concern?

A. Well, as I just said, independent of what you're going to define as a threshold, then a sustained -- a recorded temperature above the threshold, whatever that might be, on successive measurements, taken at least an hour apart, would convince me that that temperature is persistent, and, then, if I define that temperature as being evidence of a fever, then the child would have a fever.

Q. And would you wait for five or six hours

to take the next temperature, or would you take it serially at hour intervals after you saw that 37.9?

A. It kind of depends on what the level is; in other words, an in-betweener, like 37.9, an in-betweener, 37.9, you could -- in a well child, see, it all comes back to is the child sick or well. In a well child, he would be measured in four hours, that would be fine.

Q. And, again, if the child has feeding difficulty, poor feeding, regurgitation of food and has the temperature elevation, would you check that temperature again at four to six hours, or would you check the temperature on a more regular basis?

A. Feeding problems and some degree of abdominal distension are not independent signs of newborn sepsis and wouldn't alter the approach.

Q. The instructions that you would give to parents that had a child with feeding problems and signs of, clinical signs, consistent with abdominal distension that had that one temperature elevation of 37.9 with no evidence of sustained temperature, would the instructions to that parent or parents that's taking the child home, and that

child happens to have jaundice, would the instructions be any different than what you have previously given to me?

A. Well, they wouldn't have changed with regard to the interaction over the jaundice issue. They would change over the interaction of feeding difficulties.

Feeding difficulties are extremely common in newborns and we counsel families all the time about feeding your baby and burping your baby and an adequate amount of intake, what constitutes too much spitting up, and other feeding issues that are a normal part of infancy.

Q. What significance, in terms of the health and well-being of a child, are those feeding instructions where the child has had feeding difficulties during the neonatal period?

A. I'm sorry, could you say that one more time, sir?

Q. What's the significance of the feeding instructions that you would give to the parents, or why would you give those feeding instructions to the parents of a child who had demonstrated feeding difficulties during the newborn period in the hospital?

A. Well, feeding your child is the main event. It's the main interaction you have with a neonate like this, and, therefore, it is the main area of education for a family.

Feeding difficulties are potentially, I don't want to use the -- I want to use the correct word, are potentially frustrating to the family and may deny a child adequate intake in the early days of life, and, therefore, they have to be dealt with directly for the sake of both the parents and the child.

That's why you are counseling them on feeding difficulties. You're not counseling them on feeding difficulties with the idea that the feeding difficulties are a harbinger of a more serious illness.

Q. But, certainly, you, as the clinician, have an appreciation or a sensitivity to the fact that feeding difficulties can be a harbinger of particularly serious complications?

MR. BONEZZI: Objection. Go ahead and answer.

Q. (By Mr. Mishkind) Right?

MR. BONEZZI: Objection. Go ahead and answer.

THE WITNESS: No, isolated feeding difficulties are never a harbinger of serious illness.

Q. (By Mr. Mishkind) I am talking about sustained feeding difficulties.

A. No. But as an isolated issue, it's never an indication of serious problems with the child. In conjunction with other findings, it forms a clinical constellation, but as an isolated finding, it is not the harbinger of serious illness.

Q. What other symptoms in that constellation would you need with feeding difficulties for you, as a clinician, to be concerned about?

A. Oh, gee, there is an awfully long list, feeding difficulties, along with respiratory problems, along with cyanosis, along with severe diarrhea, along with rashes, along with children who are not active who don't have good tone who have seizures, I mean, you can kind of go on and on and on. Feeding difficulties, in and of themselves, are almost universal in childhood.

Q. Is it acceptable to provide the parents of a newborn infant with written materials explaining the issue of jaundice and feeding

issues such that that would supplement or replace a verbal discharge instruction along the lines that you have described?

A. Well, you know, the discharge instructions that I described are extremely general, and I think it's a source of commendation to distribute written materials to the family to be read at their leisure.

Q. But can we agree that that information that's given to be read at least sure doesn't substitute for adequate verbal discharge instructions, as general as they may be?

A. I think they serve two different purposes, the information that's given out oftentimes reinforces what might have been said, but oftentimes also gives more detail.

The discharge instructions that I mentioned are really not instructions, they are just general admonitions that are always said to families by way of leaving the hospital, and, in and of themselves, do not constitute unique information not usually possessed by the family.

Most families know that if their child is ill, they should contact somebody. Most families know that if the child is not feeding well and

this keeps going on and on, they should contact somebody.

Most families know that if the child is not responding well in their eyes, they should contact somebody, and that's the only kind of admonition that is generally given to the family at all, anyway.

Q. If a child is jaundiced at the time of discharge and that jaundice continues, and the child is having feeding difficulties and the feeding difficulties continue after discharge, and that child is lethargic and the lethargy continues after discharge, are those three continuing symptoms hypothetically concerning matters that should need to be brought to a doctor's attention?

A. Well, of the three, jaundice is not an issue that needs to be brought to a doctor's attention since visible jaundice in newborns is, some degree of visible jaundice is almost universal. And it independently is not an important issue in an otherwise healthy child.

Feeding difficulties are universal, and in and of themselves, do not constitute a marker for severe illness. It is only lethargy which falls outside the norm, but as you and I have

already discussed, that's a word for which there is no common definition.

If, by "lethargy," one is really talking about a child who looks and acts sick, that should be communicated to the physician.

Q. And should the parents be advised if their child looks and acts sick when they are taking the child home from the hospital that a physician or a hospital should be contacted?

A. Well, I think it's part of, it's almost part of the social interaction of discharging someone from the hospital --

Q. I am not talking --

A. Let me finish my answer, if I could. It's such a common notion on the part of parents that it doesn't even need to be said.

Q. So is it your testimony that the doctor or nurse that's providing discharge instructions need not make that verbal discharge instruction or information about the child, if the child does not appear or seems to be acting -- not appear to be acting well or appears ill, you don't feel that they have an obligation to tell the parents that are taking the newborn home to immediately contact the pediatrician or the hospital?

A. What I am saying is this, let me see if I can say it in a different way.

Q. Well, Doctor, can you answer the question the way it's presented to you?

A. No, I can't.

Q. Okay. Well, go ahead and rephrase it.

A. What I am saying is that the admonition to call us if your child gets ill is a redundancy, because everybody knows that already, and, therefore, does not constitute obligatory information that must be imparted from health care personnel to the parents of newborns.

Failure to communicate that does not constitute a breach of practice, but failure to communicate something like that, call us if there are any problems, you know our number, call our doctor if you have any questions, if something is bothering you, give a phone call, something of that sort is so universally said that I would be somewhat surprised if something like that weren't said in this particular case.

Q. All right. Universally stated as it may be, surprised as you may be, if it wasn't said in this case, hypothetically, if it wasn't said, would that be unacceptable practice on the part of

a doctor or a nurse in a hospital discharging a newborn baby?

A. No, it would not be unacceptable.

Q. What level do you believe Steven's bilirubin was at on subsequent days after discharge before arriving at MetroHealth Medical Center?

A. Well, hang on for a second. I believe that the bilirubin level on the days between the discharge on the 17th and the time of the first remeasurements on the 22nd were all less than the remeasurement level of 17 milligrams per deciliter on the 22nd.

Q. Based on the level on the 22nd, what is your opinion as to whether Steven's jaundice was, in fact, physiological as opposed to pathological?

A. I believe his jaundice at the time of the original hospitalization surrounding his birth was all physiologic. I believe that the bilirubin present at the time of his admission to the hospital and subsequently was a mixture of physiologic and secondary jaundice, the jaundice being secondary to the E. coli sepsis.

Q. Do you normally see physiological jaundice for, clinical evidence of physiological

jaundice within the first 24 hours of life?

A. It's common.

Q. It is common?

A. It's common.

Q. Okay. What's your understanding, in this case, as to whether there was evidence of physiological -- I'm sorry, evidence of jaundice during the first 24 hours of Steven's life?

A. My understanding is that the mother claims the child was born jaundiced. My understanding from the nursing notes and the physician notes that the child was not jaundiced on the 15th.

Q. Your understanding is the mom's testimony was that the child was born jaundiced?

A. That's what I said.

Q. Okay. Have you seen any of the written material that Deaconess claims to have provided to the Maksym family?

A. No.

Q. In looking at the hospital records from Deaconess, can you tell me how many progress notes the pediatricians wrote?

A. I don't believe there were any progress notes written except for the discharge summary by

Dr. Vuppala, and that was on the 17th.

Q. Do you know, was that discharge summary written before or after Steven was already out of the hospital?

A. I don't know.

Q. Do you have the records in front of you?

A. Yes.

Q. Do you see a note written on August 17th in the progress notes?

A. There is a progress note written on the 17th.

Q. Do you know who wrote that progress note?

A. I am trying to decipher the signature, it looks like a Dr. Jamhour's signature, but I don't know for sure.

Q. Do you know what that says?

A. Well, as best I could read it, it says the following, "Mother has been told about cord care and the," and I can't read the next two words, "to," and I can't read the next word, "of the pediatrician of," and I can't read the next two words, "for follow-up and advised to call if any problem after going home."

MR. BONEZZI: It's "pediatrician of their choice."

THE WITNESS: Pediatrician of their choice, Mr. Bonezzi says.

Q. (By Mr. Mishkind) Again, Doctor, I don't want to repeat areas that we have already talked about, but if Steven did have poor feeding and was lethargic, and, in fact, was regurgitating or throwing up his feedings during his hospitalization, would you agree that these type of symptoms, if they are either brought to the nurses' attention or observed by the nurses, should have been recorded in Steven's records?

A. I think they should be recorded in Steven's records if they fall outside of the norm.

Q. Okay. And would you agree further that if those conditions, in terms of poor feeding, lethargy, and actually throwing up feedings, were symptoms that were brought to the nurses' attention or observed by the nurses, that not only should they be recorded in the records if they are outside of the norms, but they should also be brought to the physician's attention?

A. Yes, along the lines that we discussed previously.

Q. And what would constitute feeding problems and levels of lethargy that would be

outside of the realm of norms?

A. Well, you are asking a very good question, but somewhat difficult to explain, because the normal range is one, broad; and two, is usually defined by one's individual experience in taking care of newborns.

Babies spit up all the time. Babies don't take to the bottle or the breast well all the time. Babies will reject a nipple all the time. Parents are frustrated all the time.

And, therefore, it has to be one which is so persistent, resulting in such poor oral intake, that there is a concern about either hydration or nutrition on the part of the observer that would lift that general expected condition to the level that it would be outside of a normal range.

Q. In reviewing the material in this case, have you ever been advised as to the existence of a pediatrician by the name of Dr. Amigo?

A. I have never been advised that such a pediatrician or such a physician has ever been found.

Q. Do you have any reason to believe that Violet Khoury, who claims to have talked to Mrs. Maksym on September 6th, 1989, either

misunderstood the information provided to her by Mrs. Maksym, or, perhaps, didn't actually talk to Mrs. Maksym on September 16th, 1989?

MR. BONEZZI: Objection.

THE WITNESS: Well, I believe that she talked to Mrs. Maksym, both because of the memory of the event that she had and the note that she wrote, on top of the laboratory slip, but I accept as possible that a misunderstanding of a doctor's name might have occurred, and, therefore, a Dr. Amigo might have been stated to have been some other doctor, but just not well understood.

Q. (By Mr. Mishkind) Recognizing the criticism that you have in terms of conveying the information not on the 24th, or when it was received, and waiting until the 6th when the written report came up, do you have an opinion as to whether it was acceptable for Violet to have made a telephone call to the mother and to have done nothing further by way of follow-up for that child in terms of making sure that the baby was retested after that date?

MR. BONEZZI: Objection.

THE WITNESS: I have an opinion.

Q. (By Mr. Mishkind) And what is your

opinion?

A. It's my opinion that a notification of the parent, if the child is not in your own practice, understanding that notification of the parent that an abnormal test has resulted and they should contact their doctor for retesting, is sufficient on the part of an office when dealing with a child which is no longer under their care.

Q. Is there any obligation to contact the physician or the hospital if you have reason to know that that child had just recently been admitted to the hospital with sepsis?

MR. BONEZZI: Objection.

THE WITNESS: Again, I don't think that that changes my answer.

Q. (By Mr. Mishkind) It's your opinion, then, it was acceptable and reasonable for Violet's employers, Drs. Jamhour and Vuppala, to have retained the retest kit from the state of Ohio and to have taken no further action to follow up with the Maksyms or with any doctor treating Steven?

A. I think it was acceptable.

Q. What would you have done, Doctor?

MR. BONEZZI: Objection as to what

he would do. It has nothing to do with this case, Howard.

Q. (By Mr. Mishkind) Okay. Doctor, please, go ahead.

MR. BONEZZI: Just hang on, Doctor, 1 am not sure I'm going to let you answer that, because it has nothing to do with this case, what he would do.

MR. MISHKIND: I am entitled to ask the doctor.

MR. BONEZZI: No, Howard, you're not.

MR. MISHKIND: Wait, let me finish, please, I have -- I can ask, and you know darn well I can ask, an expert witness what he would have done; whether or not ultimately, I am entitled to ask him that at trial is not a basis for you to prevent me from asking this doctor what he would have done under the circumstances.

MR. BONEZZI: Howard, you are absolutely in error. This is a 2-B-4 deposition. You are entitled to ask this physician what his opinions are and the basis for those opinions, and that's it.

You're not entitled to ask him what he

would have done under the same or similar circumstances.

Q. (By Mr. Mishkind) Doctor, and you --

MR. BONEZZI: And I am not going to let him answer it, Howard.

MR. MISHKIND: What's that?

MR. BONEZZI: I'm not going to let him answer it.

Q. (By Mr. Mishkind) Doctor, do you consider yourself to be a reasonable and prudent practitioner?

A. I hope I am, yes, sir.

Q. And given the facts that I have just described, what would you have done under the same circumstances in terms of follow up with the family if, in fact, you had reason to know that the child was admitted to the hospital with sepsis, if, in fact, after that telephone conversation, you had no further contact from the family?

MR. BONEZZI: He is not going to answer the question. He has already provided you the answer.

MR. MISHKIND: Excuse me?

MR. BONEZZI: He is not going to

give you an answer. He has already provided his answer, Howard.

MR. MISHKIND: I'm sorry?

MR. BONEZZI: He has already provided his answer relative to what his opinions are and the basis for his opinions, and I'm not going to let him answer what he would have done. It has nothing to do with this case.

MR. MISHKIND: I would ask the court reporter with regard to these last couple minutes if that could be sent up to me ahead of time of the transcript for purposes of a motion to the Court, because I am absolutely 100 percent entitled to ask that question, and I just absolutely resent the fact that you are not permitting him to answer that question.

But be that as it may, I'm not going to --

MR. BONEZZI: Howard, your attitude of resentment has nothing to do with this deposition.

MR. MISHKIND: I know it has nothing to do with it, but I am entitled to ask him.

MR. BONEZZI: You're not. Would you do me a favor, ask your questions, would you

please, I have been sitting here for the last two hours and 40 minutes listening to you now. Would you please continue on.

I have got to check out of this place. I have only got this room for another 20 minutes.

MR. MISHKIND: That's not my problem.

MR. BONEZZI: Yes, it is. You keep on going on and on and on and on, and it is your problem. Let's go.

MR. MISHKIND: No, it is not.

MR. BONEZZI: Come on, Howard. Don't argue with me.

MR. MISHKIND: I will ask the next question. Are you done?

MR. BONEZZI: Not with you, I am not. Go ahead and ask.

Q. (By Mr. Mishkind) Would you agree that elevated bilirubin levels in a neonate can be a sign of infection?

MR. BONEZZI: At what time?

Q. (By Mr. Mishkind) During the newborn period, during the first 48 hours?

A. I don't believe that they are a sign of infection, but they are seen in infections, but

along with almost every other condition. I don't believe isolated elevated bilirubins are a sign of infection.

Q. What is your opinion in this case when the infection first invaded the meninges?

MR. BONEZZI: Are you asking him when the bacteria crossed the blood-brain barrier?

MR. MISHKIND: My question is pretty clear.

MR. BONEZZI: No, it isn't.

Q. (By Mr. Mishkind) When was there first an invasion of the meninges, in your professional opinion, in this case?

MR. BONEZZI: You have to cross the blood-brain barrier before you get to that, Howard. I would have thought you would have known that. Go ahead and answer that, Doctor.

Q. (By Mr. Mishkind) Go ahead, Doctor.

A. Well, again, in these particular conditions, the onset of clinical meningitis and the onset of clinical septicemia usually coincide, and that occurred, I believe, on the afternoon of the 21st, as I have already stated, when the child started having indications that he was severely

ill, according to the record.

Q. Does the fact that Steven had galactosemia and was otherwise healthy at birth, in a full-term baby, does that have any impact, in your professional opinion, on his ability to fight the infection that he had in his body, as opposed to a premature infant that had galactosemia?

A. I didn't quite get that, sir, I'm sorry.

Q. Okay. The fact that he was healthy and full term and had galactosemia, do you think that his ability to fight the infection in his body, that he was better able to handle the sepsis than if he had been a premature, unhealthy infant?

A. I will try and answer it as best I can. It's still not an entirely clear question to me, but galactosemia puts him at higher risk for developing the infection and in a poorer position to independently resist the infection.

An independent risk factor for disease and severity of disease is prematurity, but I don't know that I can compare the degree of risk that a premature child is in with the degree of risk that a term galactosemic child is in, in any honest way.

Q. Steven had bilateral congenital ptosis,

correct?

A. I understand that to be the case.

Q. Do you have any explanation in this case for why physical examinations, during the newborn period, did not discover the congenital bilateral ptosis?

A. It's not always discernible in the a newborn period.

Q. Do you know, in this particular case, why it wasn't discovered?

A. What I am saying is, as a general proposition, congenital ptosis is not always discernible in the newborn period, and since the eyes were, in fact, looked at here, based on the documentation provided, it must not have been discernible in this child's newborn period.

Q. Do you rule out as a factor that the physical examination done was inadequate, or is that also a possibility for why the congenital bilateral ptosis was not discovered?

A. I don't think that's a meaningful possibility. Congenital ptosis is not always discernible in the newborn period, and, therefore, is commonly missed. And I say "missed" not because it should have been found, but missed

because it doesn't display itself in a recognizable way.

Q. Doctor, do you know for a fact whether Dr. Jamhour did examine Steven on August 16th, 1989 from the hospital records, themselves?

A. Well, the record, itself, does not have a dated examination, but it does have two examinations by Dr. Jamhour, but neither one of them has a date that I can read it.

Q. From reviewing Dr. Jamhour's deposition, what is your understanding as to whether or not Dr. Jamhour wrote a progress note on August 16, 1989?

A. I don't believe he wrote a progress note on August 16th, according to his deposition.

Q. Do you agree that Dr. Jamhour had an obligation to write a progress note on August 16th, 1989?

A. No, I don't agree with that.

Q. Why?

A. Because it's not an obligation.

Q. Simply if he did the examination, he doesn't need to to write a progress note with regard to his findings?

A. First of all, there are two questions

locked into one. He did perform two examinations, he was present on the 15th and the 16th, the nursing notes show that.

And, so, the inference is, and, then, the deposition testimony seems to support that, that the examination, one of those reported examinations was done on the 16th, and, in fact, that is documentation of his interaction and involvement with the child's care and is adequate documentation of that, but there is a second question which is does a physician need to write a progress note every day on every patient, and the answer is no.

Q. Are there any circumstances, Doctor, that repeat bilirubin levels are ordered upon discharge on a jaundiced child within, say, a 24- to 48-hour period after discharge?

A. I got the second half of the question, sir, I just missed the opening phrase.

Q. No problem. Are there circumstances where parents of a child are instructed to return the child within 24 to 48 hours, one to two days after discharge, to repeat a test on bilirubin levels on their jaundiced child?

A. Yes.

Q. And under what circumstances would the child be sent home but yet be told to come back 24 to 48 hours later for a repeat bili test?

A. The circumstances are that the child has a, runs a reasonable risk of having very elevated levels of bilirubin based on risk factors; under those conditions, a retest sometime after discharge is advisable.

Q. What type of levels would you need to see in the newborn period to have warranted a one- to two-day follow up?

A. It's not primarily based on the level at the time of discharge, although it may be, but also based on the risk that the level seen at discharge may still be going up at a fairly rapid rate, with a likelihood of high peak, so I think there are two components here, one is the level that you are at when you are discharged, and the second is the likelihood that that level is going to shoot still higher.

Q. And what kind of dynamics would you need with regard to the levels at the time of discharge in order to warrant a one- to two-day repeat bili?

A. I don't understand what you mean by "dynamics.

Q. Well, you said that it isn't necessarily the level. Are there levels, in and of themselves, that would cause you, as a pediatrician, to say "You can go home, Mom and Dad, with your baby, but baby does need to be retested tomorrow or the day after because of his jaundice and the level of jaundice that we have here"?

A. Yes, there are such levels.

Q. And what levels would you need to see for that kind of mandate to take place?

A. Well, it depends on how old the child is, obviously, but, for example, in a child who is two to three days old, most people would ask the child to come back if the level was greater than, say, 15 milligrams per deciliter at the time of that discharge.

Q. Below that and absent any signs of illness in the child, a level between 10.2 and below 15 would require a 24- to 48-hour follow-up?

A. Only -- that's true except in the cases in which the child has another condition which is likely to keep the bilirubin level going up.

Q. Have you read over Dr. Skrinska's deposition?

A. Yes.

Q. Do you have any criticisms with regard to Dr. Skrinska's care?

A. No.

Q. In your report at page 4, you indicate that "The failure," this is in the third paragraph, "The failure to follow up on this suspicion, especially in light of the well-known association between galactosemia and E. coli septicemia first described in 1977, is inexplicable in my opinion." Do you see that?

A. Yes, I do.

Q. Do you still hold that opinion?

A. Yes.

Q. And why was it a failure to follow up on the suspicion of galactosemia?

A. Well, it was a failure because it wasn't done by the MetroHealth team taking care of the child.

Q. And was that failure, in your professional opinion, a violation of the standard of care?

A. Yes.

Q. Towards the end of your report, Doctor, you indicate, "The combined failures of the family

to follow through on this information and of the MetroHealth Medical Center staff to pursue their suspicions of a metabolic disorder are both regrettable."

Do you still hold that opinion?

A. Yes.

Q. What specifically, what specific failures do you believe are chargeable, if you will, to the family in this case?

A. The family was notified by the doctor's office by that telephone call that the child had an abnormal laboratory test and did not communicate that to the treating personnel at MetroHealth or to any subsequent doctor, and that was regrettable.

Q. Are there any other failures of the family in this case that you believe to be positive of the problems to Steven?

A. I honestly don't think so. You know, based on the admission information, the child was not sick for a very long period of time prior to becoming deathly ill; according to the mother's deposition, the child was sick for quite a long time, and that is her memory, and I accept the fact that she has a memory of that sort, and if

that had been true that the child was ill on the day of discharge and the day after discharge and the next day and the next day, the fact that the child was not brought to see any health care provider is certainly worrisome with regards to the parents' ability to follow up on illnesses and their child, but I honestly believe the child became suddenly ill and was brought in on death's door, was resuscitated but sustained severe damage.

Q. If the child was as ill as mom testifies to, that you have derived from reading her deposition, could Steven have been discharged from Deaconess Hospital on August 17th?

A. Well, the part I was referring to was the statements that the mother made that the child just laid around 24 hours a day for the two to three days prior to admission to hospital on the 21st and was, quote, I don't know if you used the word, "lethargic," but the implication that the child was inappropriately ill, very sick during two to three days, that's the part that I was referring to.

Q. And if you --

A. Excuse me. If I can just finish my

answer.

Q. I'm sorry. Go right ahead, Doctor.

A. Sure. The Deaconess Hospital records, I think, are quite clear that the mother's enumeration of concerns regarding her child did not constitute a seriously ill condition, but we don't have any unopposed observations or records for the time period between the discharge, on the one hand, and the readmission, on the other hand, so all we know about that time is what's included in the admission notes and what her memory is, and that's the area that I am focused upon.

Q. Okay. Again, if her memory and the statements as to what she recalls being Steven's condition, both during the hospitalization and continuing thereafter, are accurate, and I understand your position with regard to the veracity or the accuracy of that information, but if, in fact, Steven was as ill as she describes him to have been in the hospital, should he have been discharged on August 17th, 1989?

A. No.

Q. What should have been done if, in fact, he was as sick as mom describes him to have been?

A. Well, if he were as sick as the

implications of the mother's memory seem to suggest, then the child should have been reevaluated by his treating physician. What should have been done in that case would have been the fruit of the reevaluation.

Q. Would a septic workup have been part of the clinical judgment process that that doctor would have had to have considered?

A. Yes.

Q. And if the decision was made to do a septic workup, would the child have been discharged or kept in the hospital?

A. I believe kept in the hospital.

Q. Since you commented in your report about the persuasiveness and the veracity of certain testimony, when you look at Mrs. Maksym's testimony and what's in the records, as a pediatrician, how credible or believable, in your mind, is it that a parent would be contacted by a pediatrician's office and told about an abnormal newborn test and the need to redo the test and that parent then fails to advise any doctor of the abnormal newborn test and the nature of the telephone call?

MR. BONEZZI: Also, in the face of

the fact that her infant is already admitted to another institution during the time of the phone call. Go ahead and answer.

Q. (By Mr. Mishkind) Right.

A. Yes, I think it's very possible.

Q. Have you ever had a parent fail to follow up on a newborn's screening?

MR. BONEZZI: Objection.

THE WITNESS: Well, given the systems of notification with which I have been associated, all children with newborn screening tests have been followed up upon.

Q. (By Mr. Mishkind) Doctor, hypothetically, if Steven had been seen one to two days --

MR. BONEZZI: We didn't hear a thing you said after "discharge."

Q. (By Mr. Mishkind) I am asking him, hypothetically, if Steven had been seen by a pediatrician 24 to 48 hours after August 17th, and a thorough physical examination had been done at that point, based upon what you know to be Steven's condition in the emergency room at Deaconess Hospital on August 21st and his condition upon transfer to Metro, do you have an

opinion as to what a thorough physical examination would have discovered?

A. I have an opinion.

Q. And what is your opinion?

A. It would have discovered a child with jaundice who did not have signs of serious illness.

Q. Would that examination have disclosed any clinically apparent evidence of lethargy?

A. I don't believe so. The examination, however, might have picked up a big liver. The child did have an enlarged liver at the time of the admission on the 21st; depending on how close to the 21st the examination was conducted in your hypothetical, the child could have had hepatomegaly at the time of the examination, but I can't know for sure.

Q. If hepatomegaly was picked up in the physical examination during the 24 to 48 hours post hospitalization, what, if anything, would a reasonable clinician have done with regard to the child at that point?

MR. BONEZZI: Objection.

THE WITNESS: Well, I think that an evaluation would have probably been instituted.

This is assuming there are no other physical findings to help out with the hepatomegaly. An evaluation would have been instituted, they probably would have taken between, oh, three days to a week to complete, which probably would have involved testing for metabolic disease, a liver ultrasound would have been performed.

I think those would probably be the two most important tests that would have been done, but it would not have been done as a medical emergency, or even that much of an urgency, but would have been done, I am sure, as early as possible.

It just, these are things that just aren't done very quickly.

Q. (By Mr. Mishkind) Would the child have been placed on any kind of antimicrobial therapy?

A. Not unless the child was clinically ill or toxic, no.

Q. What would you have needed to have seen along with the hepatomegaly and continued jaundice, outward manifestation of jaundice, in order to justify institution of antimicrobial therapy?

A. Well, really of infectious causes in an

otherwise child of an enlarged liver and jaundice, congenital viral disease is really the major cause, and so the child would have been cultured, but probably would have been cultured for viruses like the CMV Virus; with regards to bacterial infections, the child would not have been cultured unless the child displayed other more compelling features of neonatal sepsis, the very sick-looking child that we have already described.

Q. If blood cultures had been drawn on August 17 on Steven, knowing, again, what you know as to his condition on August 21st at Deaconess ER, and, then, upon admission, do you have an opinion as to the likelihood of the blood cultures being positive?

A. I have an opinion.

Q. What's your opinion?

A. They would have been sterile.

Q. When do you believe the earliest blood culture would have been positive?

A. Well, I believe they would have been positive on the 21st. Whether they would have been positive on the 20th, I think is a much more difficult area to speculate upon. I do not believe they would have been positive on the 19th,

18th or the 17th.

Q. Doctor, have you been asked between now and the time of trial to review any additional information in connection with this case?

A. No, other than new information which might be generated over the course of time, other depositions, for example.

Q. Do you know in Dr. Gold's opinion he has summarized six conclusions with regard to medical care?

A. I am getting his opinion out now, sir.

MR. BONEZZI: Howard, how much longer do you have? You told me 30 minutes ago 30 minutes ago.

MR. MISHKIND: I have five minutes.

THE WITNESS: Part two of his opinion letter?

Q. (By Mr. Mishkind) Yes.

A. Okay. I have his opinion in front of me.

Q. Let me ask it to you this way, and I will see if this can speed things along, can you tell me whether there are specific aspects of his opinions by paragraph that you take issue with?

A. Well --

MR. BONEZZI: Objection.

THE WITNESS: I mean, this is going to take awhile, because each of these opinions starts off with a sentence, but there is more than one opinion included in each of those paragraphs. Do you want me to just start going through it?

Q. (By Mr. Mishkind) Well, I'm not going to have you do this at this particular point. I am just wondering whether you had made any notations or you recall specifically something that stands out in your mind, from reviewing Dr. Gold's report, what you take issue with in terms of disagreeing with his conclusions.

A. Well, you know, conclusion number one, for example, is very dependent on the nursing staff seeing a child who was extremely ill or lethargic, to use Dr. Gold's words, and, then, a number of different consequences of that observation follow.

It's my opinion that the child was not clinically unwell, and, therefore, never required prolonged hospitalization, thereby voiding most of the conclusions of part one.

Q. Let me ask you this, in part one, you agree at least with Dr. Gold that if the child had remained in the hospital for further observation

that the child's increasing lethargy and poor feeding noted by the mother soon after discharge would have become apparent?

A. Will, I think I have already tried to explain, sir, that I don't believe that the child was severely ill on the day after discharge or even the day after that; that I trust the history as given at the time of admission, that the child really became ill the day before, but I know the mother does have this other memory, and, obviously, if the mother were correct and the child were in the hospital during the period that the mother's memory was that the child was severely ill and lethargic, then those events would have occurred in the hospital, but I already think I have testified to my reading of the child's evolution of illness.

Does that answer your question?

Q. It does, yes, thank you. You would agree, would you not, that if Violet did not make that telephone call to Mrs. Maksym and conveyed information about the newborn screening test and the need to be retested that that would be a violation of the standard of care as well?

MR. BONEZZI: Objection.

THE WITNESS: Yes.

Q. (By Mr. Mishkind) And not only for the call to be made, but, certainly, that individual needs to convey enough information to express the importance to the mom about retesting that child for this newborn potential abnormality?

MR. BONEZZI: Objection. He has already testified to this. Go ahead.

THE WITNESS: Yes.

Q. (By Mr. Mishkind) All right, Doctor. I'm not going to have you go through the report line by line, but aside from commenting, perhaps, on the expert's reports, have we covered the opinions that you hold in connection with your review in this case?

A. I think exhaustively so, sir.

Q. Okay. And to the extent that you arrive at any new opinions or change any opinion before you take the stand, would you please be kind enough to advise Mr. Bonezzi so that he can impart that to me ahead of time?

A. I will be faithful.

MR. MISHKIND: Okay. I have no further questions, thank you for your time.

MR. MARKWORTH: No questions.

MR. GOLDWASSER: No questions.

MR. BONEZZI: Howard, do you want to ask him about signature?

MR. MISHKIND: I presume you want to have the doctor read the deposition. I'm not going to take the time. He can have more than the normal seven days to read the transcript, I do want the original ordered, and as to what you all want to do, you can instruct the court reporter accordingly.

(The deposition was concluded at 11:45 a.m.)

STEVEN MAKSYM, et al. vs. JOSEPH JAMHOUR, M.D., et al.

DEPONENT SIGNATURE/CORRECTION PAGE

If there are any typographical errors to your deposition, indicate them below.

PAGE LINE

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Any other changes to your deposition are to be listed below with a statement as to the reason for such change.

PAGE	LINE	CORRECTION	REASON FOR CHANGE

I, MICHAEL RADETSKY, M.D., **do hereby certify** that I have read the foregoing pages of my **testimony as transcribed, and that the same is a** true and correct transcript of the testimony given by me in this deposition, except for the changes made.

_____

MICHAEL RADETSKY, M.D.

IN THE COURT OF COMMON PLEAS
CUYAHOGA COUNTY, OHIO

Case No.: 280713

STEVEN MAKSYM, et al.,

Plaintiffs,

vs.

JOSEPH JAMHOUR, M.D., et al.,

Defendants.

CERTIFICATE OF COMPLETION OF DEPOSITION

I, Denise Kopan, CCR #124 DO HEREBY CERTIFY that on October 10, 1996 the deposition of MICHAEL RADETSRY, M.D. was taken before me at the request of, and sealed original thereof retained by:

MR. HOWARD D. MISHKIND
Attorney for Plaintiffs
1660 West Second Street, Suite 660
Cleveland, Ohio 44113

I FURTHER CERTIFY that copies of this certificate have been mailed or delivered to the following counsel and parties not represented by counsel appearing at the taking of the deposition,

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I FURTHER CERTIFY that examination of this transcript and signature of the witness was required by the witness and all parties present.

I FURTHER CERTIFY that the recoverable cost of the deposition to MR. HOWARD D. MISHKIND is $ 522.53

I FURTHER CERTIFY that I did administer the oath to the witness herein prior to the taking of this deposition; that I did thereafter report in stenographic shorthand the questions and answers set forth herein, and the foregoing is a true and correct transcript of the proceeding had upon the taking of this deposition to the best of my ability.

I FURTHER CERTIFY that I am neither employed by nor related to any of the parties or attorneys in this case, and that I have no interest whatsoever in the final disposition of this case in any court.

Denise Kopan

Denise Kopan, CCR #124
Certified Court Reporter
License Expires: 12/31/96

MICHAEL RADETSKY MD CM Pediatrics—Critical Care—Infectious Disease

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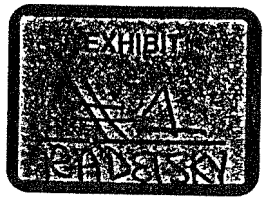

March 18,1996

Re: Maksym v Jamhour et al

Dear Mr. Bonezzi:

I have reviewed all of the materials which you have sent to me in the aforementioned case and which are itemized in your letter of January 23, 1996. In addition, I have also reviewed the deposition testimony of Violet Khoury taken on November 15, 1995. In accordance with your request, I now send to you my analysis and opinion regarding the care given to Steven Maksym.

Steven Maksym was a term infant born at 1:15 am on 8/15/89 by spontaneous vaginal delivery. There were no recorded complications of the preceding pregnancy or labor. The membranes were ruptured 45 minutes prior to birth. The baby was vigorous and had Apgar scores of 9 at one minute and 9 at five minutes of age. He weighed 8 lbs. 4 oz (3741 grams). The mother states in her deposition that Steven was jaundiced at the time of birth, that he was vomiting in the hospital "soon after I had him," that he was crying "and he just lays there for me," that his cry was "squeaky," and that she conveyed this information to Dr. Jamhour and the nursing staff. The contemporaneous medical records do not confirm these memories. His initial physical examination performed by Dr. Jamhour was recorded as normal. The nursing note at the time describe him as being "active" with a "lusty" cry. He was circumcised on his day of birth without complication. On the next day the record reveals once again an "active" baby with a "lusty" cry, whose temperature and vital signs were normal. He was voiding well and had 4-5 stools. **A** bilirubin determination was ordered and was 6.5 mg/dl. On 8/17/89 the baby was again described as "active" with a "lusty" cry. No abnormalities in feeding, behavior, or physical examination were recorded in the neonatal nursing notes. However, there is a notation in one of the notes of an obstetrical nurse included in the mother's hospital record to the effect that the infant was "lethargic" at some point during the first day of life. **A** repeat bilirubin level was 10.2 mg/dl. Dr. Vuppala arranged for the baby's discharge by telephone. He also claims that he talked to the mother by telephone on the day of discharge and gave her advice concerning cord care and further reasons to call **a** pediatrician, a memory which is disputed by the mother. The baby was discharged from hospital.

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Subsequent to this discharge, neither Dr. Vuppala or Dr. Jamhour saw the baby. Mrs. Maksym made it clear in her deposition that once she left the hospital she did not consider either Dr. Vuppala or Dr. Jarnhour to be her son's doctor, and if she had any need for medical advice she would not have called either of them. Instead, she sought all of her further care from Dr. Skrinska, her pediatrician of choice. She claims to have contacted Dr. Skrinska's office two days after discharge to discuss feeding difficulties. Finally, on 8/21/89 the baby was brought to the Emergency Department of Deaconess Hospital because of grunting and respiratory distress. The child appeared significantly ill, and he was transported by ambulance to Cuyahoga County Hospital (MetroHealth Medical Center) for further evaluation and management. The Emergency Department notes from Deaconess characterized the baby as having "spit up" feeds since going home. The admission note to Metro recorded that for the "last several days at home child has been sleeping 24 hours per day." In any event, the child was severely ill on 8/21/89 with *E. coli* septicemia and meningitis, clinical septic shock with disseminated intravascular coagulopathy and renal failure.. He also had hepatomegaly, abnormal liver function tests, moderate hyperbilirubinemia, and hypoglycemia. Some metabolic disorder was part of the original differential diagnosis. Conventional antimicrobial therapy was initiated with ampicillin and gentamicin and the child was given critical care support in the intensive care unit.

In 1993 the original abnormal galactosemia screening test was rediscovered, and the diagnosis of galactosemia was confirmed by appropriate testing. The child's diet was changed accordingly.

The mother's states that Steven's current condition is that he is unable to speak, he has left sided muscle paralysis, he has trouble walking, and that he is delayed in development by one to one and one-half years.

According to the deposition testimony of Violet Khoury, the receptionist at the office of Drs. Vuppala and Jamhour, contact was made with Mrs. Maksym during the time the baby was at Metro. This contact was a result of a telephone call from the Ohio Department of Health that the initial metabolic screening test (PKU test) on Steven had been abnormal. that it would need to be repeated, and that a new PKU kit would be sent out. Ms. Khoury contacted Mrs. Maksym on September 6, 1989, and informed her that the blood test had been abnormal and that she had the testing kit in the office for the repeat test required by the Ohio Health Department. Ms. Khoury was told that another doctor, Dr. Amigo, was taking care of Steven and also would take care of the blood test, and that she, Mrs. Maksym, would let Dr. Amigo know. On the next day, Ms. Khoury had telephone contact with the laboratory at Deaconess and notified them that contact with Mrs. Maksym had been made and that the baby was now under the care of

Dr. Amigo. As an exhibit to her deposition, Ms. Khoury includes a copy of the laboratory notation of this conversation (exhibit 2).

It is my opinion that the care rendered to Steven Maksym by Dr. Vuppala, Dr. Jamhour and the staff of the Deaconess Hospital met the applicable standards of care. The physician and nursing notes written contemporaneously with the events clearly describe a normal newborn infant at a number of point observations. In this context, the mother's personal memories, although honestly held, are not persuasive, and the one notation by the obstetrical nurse of "lethargy" is inconsistent with the multiple observations made by trained neonatal staff. Therefore, I do not find that this baby displayed findings which should have raised undue worry in the minds of physicians or staff. The newborn jaundice experienced by the baby was a routine occurrence and the level of bilirubin appropriately was measured on two occasions. However, in this term infant whose mother's blood type was **A+,** bilirubin levels of 6.5 at 24 hours of age and 10.2 at 48 hours of age would not warrant further concern at that time. Certainly it was not a contraindication for discharge home at 48 hours of age, and I found no need for a repeat bilirubin level to be formally scheduled at the time of discharge. In this regard, a single examination of a child by a physician during a 48 hour hospital stay of a normal newborn is a common practice, so that the discharge and parent conference performed by Dr. Vuppala by telephone was perfectly acceptable. **As** the records and depositions make clear, the medical care of the baby following discharge from hospital was in the hands of another physician. The baby's subsequent deterioration and severe infection was tragic. However, I could find no evidence that the baby was infected at the time of his original hospitalization at Deaconess Hospital, nor could I identify any risk factors which could reasonably have predicted these events which were to occur following his discharge home. The care of Steven Maksym while at Deaconess Hospital was acceptable in every way.

It is also my opinion that the telephone contact between Violet Khoury, the experienced receptionist at the office of Drs. Vuppala and Jamhour, and Mrs. Maksym was sufficient to discharge the obligation of the doctors to follow up on the Ohio Newborn Screening test. Following the notification by Mr. Leonard Porter of the Ohio Public Health Laboratory and acting on behalf of the office, Ms. Khoury did in fact notify the parent of the baby that the screening test was abnormal or suspicious and needed to be repeated, and she was told that the baby was under the care of another physician who would perform further testing. The veracity of her memory of this conversation with Mrs. Maksym is supported by the notation made by the laboratory technician on 9/7/89 (exhibit 2, deposition of Violet Khoury).

Although the medical staff at MetroHealth Medical Center did provide acceptable hospital care for *E. coli* septicemia and meningitis, I do agree with the expert opinion of Dr. Ronald Gold expressed in his letter of October 23, 1995 to Mr. Howard Mishkind that:

"The differential diagnosis of a one-week old infant who presents with a history of poor feeding, vomiting, lethargy and jaundice and on examination was found to have jaundice, hepatomegaly, abnormal liver function, metabolic acidosis, and severe hypoglycemia must include galactosemia. The fact that he also had *E. coli* sepsis and meningitis should have strengthened the consideration of a diagnosis of galactosemia. I such a situation, it was mandatory to screen urgently this particular infant for galactosemia."

Some metabolic disorder as the cause for the baby's illness was originally considered at the time of the hospital admission. The failure to follow up on this suspicion, especially in light of the well known association between galactosemia and *E. coli* septicemia first described in 1977, is inexplicable in my opinion.

In summary, then, I find that the care given Steven Maksym by Dr. Jamhour, Dr. Vuppala, and the Deaconess Hospital staff met the all applicable standards of care. I find no indication that the child was ill or worrisome enough to warrant a delay in home discharge. The newborn jaundice experienced during the first two days of life in hospital was a routine newborn problem and was managed acceptably. Follow up with the baby's primary pediatrician was acceptable discharge planning. There was no reason for the hospital doctors themselves to schedule additional patient contact or laboratory testing following discharge home. The child's subsequent medical problems could not have been anticipated or prevented during his hospital stay. I also find that the personal telephone contact between the doctors' office and the baby's mother on 9/6/89 was sufficient to discharge the obligation of these doctors to follow up on the abnormal newborn screening test. The combined failures of the family to follow through on this information and of the MetroHealth Medical Center staff to pursue their suspicions of a metabolic disorder are both regrettable.

Sincerely yours,

Michael Radetsky MD CM
Chairman, Department of Pediatrics
Lovelace Medical Center
Clinical Professor of Pediatrics
University of New Mexico School of Medicine

CURRICULUM VITAE

NAME:

MICHAEL S RADETSKY MD CM

DATE'AND PLACE OF BIRTH:

November 19,1945
Denver, Colorado
USA

PROFESSIONAL ADDRESS:

Department of Pediatrics
Lovelace Medical Center
5400 Gibson Boulevard SE
Albuquerque, NM 87108
Telephone (505) 262-3542

CURRENT POSITION

Chairman, Department of Pediatrics
Consultant, Pediatric Infectious Disease
Consultant, Pediatric Critical Care
Lovelace Health System
Albuquerque, New Mexico

Attending Physician
Pediatric Intensive Care Unit
Consultant, Pediatric Infectious Disease
University of New Mexico Health Science Center

Clinical Professor of Pediatrics
University of New Mexico School of Medicine
Albuquerque, New Mexico

Fellow, Center for Public Policy and Contemporary Issues
University of Denver
Denver, Colorado

JOURNAL EDITOR

Editor
Section on Pediatric and Neonatal Infections
Current Opinion in Infectious Diseases
1993-1996

JOURNAL REVIEWER

Pediatric Infectious Disease Journal

American Journal of Diseases of Children

Journal of the American Medical Association

Pediatrics

Journal of Pediatrics

Pediatric Emergency Care

UNDERGRADUATE EDUCATION:

Harvard College - A.B. cum laude, 1967

POSTGRADUATE ACTIVITIES

Harvard Law School - 1967-1968
(Courses passed. Leave of Absence)

United States Peace Corps, Malariologist
Thailand - 1968-1969

Alternative National Service (Conscientious Objection) - Boston Floating Hospital for Children/Tufts New England Medical Center - 1970-71

PREMEDICAL EDUCATION

University of Colorado
Boulder, CO - 1972-1973

MEDICAL EDUCATION:

McGill University - Montreal, Quebec
Canada - M.D.C.M. (Honors), 1973-1977

ROTATING INTERNSHIP:

San Francisco General Hospital, 1977-1978

PEDIATRIC INTERNSHIP:

University of Colorado School of Medicine
Denver, Colorado, 1978-1979

RESIDENCY IN PEDIATRICS:

University of Colorado School of Medicine
Denver, Colorado, 1979-1981

FELLOWSHIP TRAINING IN PEDIATRIC INFECTIOUS DISEASES

University of Colorado School of
Medicine/The Children's Hospital
Denver, Colorado, 1980-1982

PRIOR POSITION:

1991-1993

Director, Pediatric Critical Care Services
Consultant, Pediatric Infectious Disease
Kaiser Pemanente
Sacramento, CA

Attending Pediatric Intensivist
University of California Medical Center
Sacramento California

Pediatric Intensivist
Sutter Memorial Hospital
Sacramento California

Consultant, Pediatric Infectious Diseases
University of California Medical Center
Sacramento California

Clinical Professor of Pediatrics
University of California School of Medicine

Davis, California

PRIOR POSITION:
1989-1991

Assistant Director of Pediatrics
Director, Pediatric Critical Care Services
Consultant, Pediatric Infectious Disease
Denver General Hospital

Attending Physician
Ambulatory Pediatric Clinic
Denver General Hospital

Attending Physician
Intensive Care Unit
The Children's Hospital of Denver

Visiting Professor in Pediatrics
Fitzsimmons Army Medical Center
Denver, Colorado

Associate Professor of Pediatrics
University of Colorado School of Medicine
Denver, Colorado

Lecturer in Ethics
Graduate School of Public Affairs
University of Colorado, Denver
Denver, Colorado

Lecturer in Medicine and Social Policy
University of Denver
Denver, Colorado

PRIOR POSITION:
1987-1989

Director of Pediatric Critical Care Services
Tucson Medical Center
Tucson, AZ

Attending Physician
Pediatric Intensive Care Unit

University Medical Center
Tucson, AZ

Consultant in Pediatric Infectious Disease
Tucson Medical Center, and
University Medical Center
Tucson, AZ

Clinical Associate Professor of Pediatrics
University of Arizona School of Medicine
Tucson, AZ

PRIOR POSITION:

1982-1987

Associate Director
Infectious Disease Service
The Children's Hospital
Denver, Colorado

Attending Physician
Intensive Care Unit
The Children's Hospital of Denver

Assistant Professor of Pediatrics
University of Colorado School of Medicine
Denver, Colorado

Visiting Lecturer in Medical Ethics
and Social Policy
Department of Public Affairs
University of Denver
Denver, Colorado

Lecturer in Ethics
Graduate School of Public Affairs
University of Colorado, Denver
Denver, Colorado

PRIVATE PEDIATRIC PRACTICE

Children's Medical Center
1575 Vine Street

Denver CO
(Occasional and part–time coverage 1981-1987)

PROFESSIONAL LICENSURE:

State of New Mexico

State of Colorado

State of California (inactive)

State of Arizona (lapsed)

Medical Council of Canada

BOARD CERTIFICATION:

American Board of Pediatrics - 1983

Pediatric Critical Care
American Board of Pediatrics - 1987
Recertification - 1995

Pediatric Infectious Disease
American Board of Pediatrics - 1995

NATIONAL FACULTY:

Pediatric Advanced Life Support
American Heart Association

HONORS AND AWARDS:

Gold Medal Winner, Thames Cup
Henley Royal Regatta, England - 1966

Haines' Memorial Award for Excellence in Athletics - Harvard College - 1967

Alexander Stewart Prize for Medical School Excellence, McGill Medical School, 1977.

Surgery Prize, McGill University, 1977.

Kaiser-Permanente Clinical Teaching Award Finalist, University of Colorado School of Medicine, 1983.

Kaiser-Permanente Clinical Teaching Award Finalist, University of Colorado School of Medicine, 1984.

Kaiser-Permanente Clinical Teaching Award Finalist, University of Colorado School of Medicine, 1985.

The Gary Way Award for Outstanding Teaching
Department of Pediatrics
The Children's Hospital
University of Colorado
School of Medicine, 1985.

Kaiser-Permanente Teaching Award
Finalist in the Basic Sciences
University of Colorado School of Medicine, 1986.

Commencement Speaker
University of Colorado School of Medicine
Hooding and Oath Ceremony, 1986.

Pediatric Housestaff Special Award
Department of Pediatrics
University of Colorado School of Medicine, 1987

Dean's List for Excellence in Teaching in the Clinical Sciences Award
University of Arizona College of Medicine, Tucson, AZ, 1988

Finalist, Clinical Teaching Award

University of Arizona College of Medicine,
Tucson, AZ 1989

Commencement Speaker
University of Colorado School of Medicine
Hooding and Oath Ceremony, 1989

Attending Physician of the Year
Family Practice Residency Program
University of Arizona College of Medicine,
1989

Pediatric Residents' Teaching Award
University of Arizona College of Medicine,
1989

The Gary Way Award for Outstanding
Teaching
Department of Pediatrics
The Children's Hospital
University of Colorado School of Medicine,
1990.

Honorary Faculty Membership
Alpha Omega Alpha Honor Medical Society
University of Colorado School of Medicine
1991

Joseph W. St. Geme Jr. MD Award for
Exceptional Ability in Promoting the Overall
Mission of the School of Medicine
University of Colorado School of Medicine
1991

Excellence in Teaching Award
Medical Student Council
University of Colorado School of Medicine
1992

Clinical Teacher of the Year
Department of Pediatrics
University of California School of Medicine - Davis, 1992

Clinical Teacher of the Year
Department of Pediatrics
University of California School of Medicine - Davis, 1993

Inaugural Recipient
William and Daniel Gelfand Lectureship
The Children's Hospital/University of Colorado
1994

Alpha Omega Alpha Annual Lectureship
University of Arizona School of Medicine
1995

Selected
The Best Doctors in America: Central Region
1996-1997

VISITING PROFESSORSHIPS:

Hospital for Sick Children, Great Ormond Street, London, England
1982

Hospital for Sick Children, Great Ormond Street, London, England
1985

Duke University School of Medicine, Durham, NC
1987

Hospital for Sick Children, Great Ormond Street, London, England
1989

University of Florida School of Medicine,
Jacksonville, Florida
1990

Akron Children's Hospital, Akron, Ohio
1990

Cincinnati Children's Hospital, Cincinnati, Ohio
1991

University of Minnesota School of Medicine
1991

"Aglaia Kyriakou" Children's Hospital
Athens, Greece (invited only)
1991

Tripler Army Medical Center
Honolulu, Hawaii
1991

Children's Hospital
Omaha, Nebraska
1993

PROFESSIONAL ORGANIZATIONS

Infectious Disease Society of America

Pediatric Infectious Disease Society

American Society for Law, Medicine and Ethics

PUBLICATIONS:

Journals

rit in medicine. N Engl J Med 298:114

2) **Radetsky MS,** Istre GR, Johansen TL, Parmelee SW, Lauer **BA,** Wiesenthal AM, Glode MP. Multiply resistant pneumococcus causing meningitis: its epidemiology within a day-care centre. Lancet 2:771-773, 1981.

3) **Radetsky MS. A** diagnostic approach to Epstein-Barr virus infections. Pediatr Infect Dis 1:425-429, 1982.

4) **Radetsky MS**. Personal view: the hero in medicine. Brit Med J 287:493, 1983.

5) **Radetsky M,** Todd JK. Criteria for the evaluation of new diagnostic tests. Pediatr Infect Dis 3:461-466, 1984.

6) **Radetsky MS**. The clinical evaluation of the febrile infant. Primary Care; 11:395-405, 1984.

7) **Radetsky M,** Wheeler RC, Roe MH, Todd JK. Comparative evaluation of kits for rapid diagnosis of group **A** streptococcal disease. Pediatr Infect Dis, 4:274-281, 1985.

8) Radetsky M. The rise of the academic clinician. **Am** J Dis Child 139:861, 1985.

9) **Radetsky M.** Sudden intimacies. JAMA 254:1361,1985; reprinted in: Dan BB, Young RK (eds). **A** Piece of My Mind, 1988; New York: **AA** Knopf.

10) **Radetsky** M. Laboratory evaluation of acute diarrhea. Pediatr Infect Dis, 5:230-238, 1986.

11) **Radetsky** M, Wheeler RC, Roe MH, Todd JK. Microtiter broth dilution method for yeast susceptibility testing with validation by clinical outcome. J Clin Microbiol, 24:600-606, 1986.

12) **Radetsky M,** Soloman JA, Todd JK. Identification of streptococcal pharyngitis in the office laboratory: reassessment of new technology. Pediatr Inf Dis, 6: 556-563, 1987.

13) **Radetsky M.** Duration of treatment in bacterial meningitis: a historical

inquiry. Pediatr Infect Dis J 1990; 9: 2-9.

14) **Radetsky M.** Duration of Symptoms and Outcome in Bacterial Meningitis: An Analysis of Causation and the Implications of a Delay in Diagnosis. Pediatr Infect Dis J 1992;11: 694-8.

15) **Radetsky M.** Pediatric and neonatal infections: Editorial overview. Curr Opinion Infect Dis 1993;6:545-6.

16) **Radetsky M.** Infectious disease emergencies. Curr Opinion Pediatr 1994; 6: 310-6.

17) **Radetsky M.** The timing of antimicrobial therapy and outcome in serious bacterial infections. Curr Opinion Infect Dis 1994;7:341-4.

18) **Radetsky M.** The laboratory evaluation of newborn sepsis. Curr Opinion Infect Dis 1995;8:191-9.

19) **Radetsky M.** Use of antimicrobials for the prevention of recurrent urinary infection in children. Dialogues in Pediatric Urology 1995;18:7-8.

20) **Radetsky M.** Decision–making in febrile infants. Curr Opinion Infect Dis 1996;9:171-5.

21) **Radetsky M.** The discovery of penicillin. Pediatr Infect Dis J 1996 1966;15:811-8.

22) **Radetsky M.** Faith and renewal in changing times (submitted for publication)

Book Chapters

1) **Radetsky M. A** clinical approach to the diagnosis of streptococcal pharyngitis. In: Barkin RM (ed.) The Ernergently Ill Child, Rockville MD, Aspen Publishers, 1987.

2) **Radetsky M.** The Nature and History of Medical Ethics. In: Nussbaurn E. (ed.) Pediatric Intensive Care, 2nd ed., 1989, Mt. Sisco NY, Futura Publishing. Reviewed in: Arch Dis Child 1990;65:816.

3) **Radetsky M.** The Doctrine of Informed Consent. In: Nussbaum E. (ed.) Pediatric Intensive Care, 2nd ed., 1989, Mt. Sisco NY, Futura Publishing. Reviewed in: Arch Dis Child 1990;65:816.

4) **Radetsky M.** Decisions to Limit, Diminish, or Withdraw Therapy. In: Nussbaum E. (ed.) Pediatric Intensive Care, 2nd ed., 1989, Mt. Sisco NY, Futura Publishing. Reviewed in: Arch Dis Child 1990;65:816.

5) **Radetsky M.** The Definition and Determination of Death. In: Nussbaum E. (ed.) Pediatric Intensive Care, 2nd ed., 1989, Mt. Sisco NY, Futura Publishing. Reviewed in: Arch Dis Child 1990;65:816.

6) **Radetsky M.** Enterobacteriaceae. In: Patrick C (ed.) Infections in Immunocompromised Infants and Children, 1992, New York, Churchill Livingston.

7) **Radetsky M.** The Use of Antimicrobials and a Synopsis of Infectious Disease in the Pediatric Intensive Care Unit. In: Fuhrman BP, Zimmerman JJ. (eds.) Pediatric Critical Care, 1992, St. Louis, Mosby Year Book

8) **Radetsky M.** Exanthematous Viral Infections. In: McAnarney ER, Kreipe RE, Orr DP, Comerci GD (eds.) Textbook of Adolescent Medicine, 1992, Philadelphia, W.B. Saunders.

9) **Radetsky M.** Streptococcal Infections. In: Burg FD, Ingelfinger JR, Wald ER (eds.) Current Pediatric Therapy 14, 1993, Philadelphia, W.B. Saunders.

10) **Radetsky** M. Streptococcal Infections. In: Burg FD, Ingelfinger JR, Wald ER (eds.) Current Pediatric Therapy 15, 1995; Philadelphia, WB Saunders.

11) **Radetsky** M. Staphylococcal Infections. In: Burg FD, Ingelfinger JR, Wald ER (eds.) Current Pediatric Therapy 15, 1995; Philadelphia, WB Saunders..

12) **Radetsky** M, **Overturf GD.** Epstein-Barr Infections in Adolescents and Young Adults. In: Overturf GD, Jacobs RF (eds.). Adolescent Medicine: Viral Infections of the Adolescent, 1995, Philadelphia, Hanley and Belfus.

13) **Radetsky M.** The Use of Antimicrobials and a Synopsis of Infectious

Disease in the Pediatric Intensive Care Unit. In: Fuhrman BP, Zimmerman JJ. (eds.) Pediatric Critical Care, 2nd ed., St. Louis, Mosby Year Book (in press)

D) Abstracts

1) **Radetsky MS,** Glode MP, Istre GR, Lauer BA, Wiesenthal AM. Emergence of multiply resistant pneumococcus. Presented at the 21st Interscience Conference on Antimicrobial Agents and Chemotherapy. Chicago, November 1981.

2) Todd JK, Parmelee SW, **Radetsky M.** Antimicrobial combination interactions with Streptococcus pneumoniae and Haemophilus influenzae. Presented at the 22nd Interscience Conference on Antimicrobial Agents and Chemotherapy. Miami, October 1982. Abstract 222.

3) Wheeler RC, **Radetsky MS,** Roe MH, Todd JK. Comparison of two candida antigen detection systems for identifying patients with disseminated candidiasis. Presented at the 25th Interscience Conference on Antimicrobial Agents and Chemotherapy. Minneapolis, October 1985. Abstract 760.

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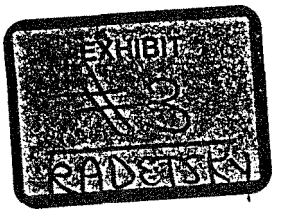


PERSONAL & CONFIDENTIAL

January 23, 1996

Michael S. Radetsky, M.D.
1217 Rockrose Road, NE
Albuquerque, New Mexico 87122

Re: Steven Maksym, A Minor - DOB 8/15/89
Drs. Joseph A. Jamhour and Murty S. Vuppala
Maksym, etc. vs. Jamhour, et al.

Dear Dr. Radetsky:

First of all, I wish to express my appreciation for your willingness to review the enclosed materials on behalf of Drs. Jamhour and Vuppala, the on-call Pediatricians who cared for Steven Maksym immediately after his birth on 8/15/89 (no attending pediatrician having been designated by the parents).

This case is interesting from a legal standpoint, as well as from a medical standpoint. When the suit involving Steven was originally filed by his parents, Joanne and Kenneth Maksym, it was alleged that Drs. Jamhour and Vuppala "were . . . negligent by not appropriately working Steven Maksym up for neonatal sepsis . . . As a direct and proximate result of the . . . negligence of the Defendants, Steven Maksym's neonatal sepsis was permitted to develop into spinal meningitis which resulted in significant brain injury and permanent physical disability to Steven Maksym . . ."

During the course of the discovery process which ensued, it was discovered that Steven's PKU test conducted during his delivery confinement had been reported as questionable, and a second test should have been conducted at that time (copy of Ohio's Department of Health's Guidelines for Ohio Newborn Screening enclosed). Subsequent testing wasn't commenced until October of 1993 (approximately four+ years after his birth), and in January of 1994 a diagnosis of galactosemia was confirmed.

The original lawsuit filed in this matter was dismissed in December of 1993. When refiled in December of 1994, the lawsuit included allegations of negligence regarding the handling of the

PKU results by both Drs. Jamhour and Vuppala, and MetroHealth Medical Center (questionable blood work at Metro),

I will now provide you with a brief summary of Steven's medical history:

Steven was born at Deaconess Hospital on 8/15/89 following an uncomplicated delivery. APGARS at birth were 9[1] and 9[5]. His hospitalization was unremarkable, and he was discharged home on 8/17/89. Of note were the bilirubins drawn on 8/16/89 and 8/17/89, which were 6.5 and 10.2, respectively.

Steven was then seen in the Deaconess Hospital ER on 8/21/89. At that time, his respirations were 24-48/minute and shallow. He was lethargic and was noted to be in respiratory distress. The decision was made to transfer him to MetroHealth Medical Center.

Steven was admitted to MetroHealth through the ER on 8/21/89. He was noted to be dehydrated and lethargic. His lower extremities were mottled with purpura. Lab studies revealed a bilirubin of 24 and an Hct of 69. Blood cultures were positive for *E. coli*. He was started on Ampicillin and Cefotaxime. Due to his critical condition upon presentation to MetroHealth, an LP was not performed as part of the initial workup. The LP performed 6 days later on 8/26/89 showed cerebral edema and patchy hypodensities, ventricular dilatation and cortical atrophy. A VP shunt was performed on 9/6/89. He was also treated for DIC, septic shock, and renal failure during this hospitalization. He was discharged home on 9/16/89.

When this case was originally filed, Plaintiffs' then pediatric infectious disease expert (no written report was ever submitted) would have allegedly claimed, among other things, that Steven was jaundiced and septic at the time he was discharged from Deaconess Hospital, which he then would have apparently correlated with the *E. coli* [meningitis ?] which was ultimately detected at MetroHealth Medical Center.

As indicated, Steven's medical history was further complicated after the diagnosis of galactosemia was confirmed in January of 1994, after testing which was commenced and ordered in October of 1993 by Steven's then Pediatrician, Dr. Edward C. White. It would appear that he began treating Steven in April of 1993. Prior to April of 1993, Steven's Pediatrician was Dr. Algirdas J. Skrinska, who appears to have commenced treating this infant in October of 1989, shortly after Steven's discharge from MetroHealth Medical Center.

I have enclosed copies of the following for your perusal:

1. Deaconess Hospital

   a. 08/15/89 Birth Admission

2. Deaconess / MetroHealth Medical Center

   a. Deaconess 08/21/89 ER; and
   b. MetroHealth 08/21/89 ER and Admission. (1st five days of admission)

3. Other/Office Records

   A. Galactosemia Screening
   B. Algirdas J. Skrinska, M.D.
   C. Edward C. White, M.D.
   D. George H. Thompson, M.D.
   E. Louis P. Caravella, M.D.
   F. Enrique Grisoni, M.D.
   G. Robert G. Corwin, M.D.
   H. Cleveland Clinic Foundation
      - Bruce T. Cohen, M.D.
      - Alan R. Gurd, M.D.
   I. Douglas S. Kerr, M.D.

4. Plaintiffs' Expert Witnesses' Reports

   1. Ronald Gold, M.D. Paediatrics/ID

      (You will note on Pages 2 and 4 of Dr. Gold's report that he refers to a pediatrician who was contacted by Mrs. Maksym on 8/20/89 and 8/21/89. In Mrs. Maksym's deposition transcript, this pediatrician is identified as Dr. Skrinska, not Drs. Jamhour or Vuppala.)

   2. Ivan L. Hand, M.D. Neonatology
   3. James H. Rehmus, M.D. Pediatrics
   4. M. Susan Jay, M.D. Pediatrics
   5. Harvey L. Levy, M.D. Medicine/Genetics.

5. Deposition Transcripts

   1. Joanne Maksym, Plaintiff
   2. Joseph A. Jamhour, Defendant
   3. Murty S. Vuppala, Defendant

This is a very difficult case, because there seems to be evidence of an *E. coli* meningitis superimposed on a galactosemic abnormality. When you conduct your analysis of the enclosed material, I would like you to focus on the following questions:

1. Was Steven inappropriately discharged from Deaconess Hospital, i.e., was his bilirubin high enough to have warranted continued hospitalization?

2. Is the high bilirubin count linked to the subsequent diagnosis of ***E. Coli*** meningitis at MetroHealth?

3. Is there a link between galactosemia and *E.* ***coli*** meningitis?

and

4. To which disease process, i.e., possible ***E.*** *coli* meningitis or galactosemia, can or should Steven's current disabilities be attributed?

Additionally, can you suggest a geneticist to whom I could refer this case? The geneticist I contacted in Cleveland will not, I **am** afraid, have the time to provide an in depth analysis, e.g., he is currently in South Africa!

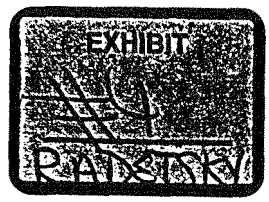
Lastly, as Maureen advised you, my reports in this case are due by March 22, **1996**. If there is anything further you would like to review, please do not hesitate to contact me or Maureen.

I look forward to your assessment of the enclosed materials. Please call me at your earliest convenience to discuss this case in more detail.

Kindest regards,

William D. Bonezzi

WDB/mmk
Enclosures
(UPS Overnight Delivery)



GUIDELINES **FOR OHIO** NEWBORN SCREENING
CHAPTER 119. SECTION 3701.501
EFFECTIVE DECEMBER 2, 1991

INTRODUCTION

Newborn screening for phenylketonuria (PKU) began in Ohio in 1962; for galactosemia and homocystinuria in 1972; congenital hypothyroidism in 1977; sickle cell and other hemoglobinopathies in 1990. In Ohio the cumulative incidence of the disorders is 1 in 13,540 for PKU, 1 in 209,514 for homocystinuria; I in 49,151 for galactosemia, **1** in 8,940 for congenital hypothyroidism; and I in **3,200** for sickle cell disease. Newborn screening is a preventive public health program for early identification of rare disorders that can lead to death, disability **or** mental retardation. The success of the Ohio Newborn Screening program depends on coordination of responsibility **for** collection of specimens, analysis by the laboratory, follow-up of affected individuals, and effective treatment.

I. OBTAINING A **BLOOD** SPECIMEN **FOR** NEWBORN SCREENING

RULE: For births which occur in a hospital/licensed maternity center, a blood specimen is collected from each newborn child prior to discharge from the newborn nursery. The specimen is collected using blood collection kits obtained from the Ohio Department of Health and is sent to the Bureau of Public Health Laboratories for testing not later than two working days after it is collected.

EXCEPTIONS For a premature or otherwise ill newborn who remains in the hospital of birth, or who is transferred to another hospital, the blood specimen shall be collected no later than when the child reaches seven days of age.

For births which occur outside a hospital/licensed maternity center, the attending physician or nurse-midwife is responsible for collection of a blood specimen from each newborn child between the age of **48** hours and seven days. If there is no physician or midwife in attendance, the Iocal registrar of vital statistics notifies the Health Commissioner of the district in which the birth occurred. The Health Commissioner is then responsible for ensuring collection of a specimen within seven days of the time of notification of the birth.

INTERPRETATION The child is enrolled in the Ohio Newborn Screening Program. The specimen is tested for PHENYLKETONURIA, HOMOCYSTINURIA, GALACTOSEMIA, HYPOTHYROIDISM, AND SICKLE CELL AND OTHER HEMOGLOBINOPATHIES. This specimen provides a valid test for galactosemia and sickle cell and other hemoglobinopathies, regardless of age of the child at time of collection.

A second specimen may be necessary under the following conditions:

A. **THE** SPECIMEN **IS** UNSATISFACTORY BECAUSE

1. Not enough blood on filter card (none, poor saturation, circles incompletely filled).
2. Too much blood on filter card (layered, clotted).
3. Card is contaminated (water, ink, other).
4. Specimen is more than 10 days old.

Within seven days after receiving notice that the specimen is inadequate or unsatisfactory, the child's attending physician at the hospital of birth shall collect a repeat specimen. This specimen is sent to the Bureau of Public Health Laboratories and should be marked First Specimen. It is tested for all disorders listed above.

If the attending physician (usually the child's primary care physician[a]) cannot be identified, the second test shall be ordered by the person[b] who submitted the specimen or, if that person cannot be located, by the chief of the medical staff[c] of the hospital of birth or a hospital employee designated by the chief[d].

Each person listed ([a, b, c, d]) should document, in the infant's medical chart, efforts to obtain the repeat specimen and should submit documentation to the chief of the Bureau of Public Health Laboratories of efforts made to secure the repeat.

If after ten working days the persons listed have been unable to locate the newborn child, the Health Commissioner[e] of the health district in which the mother, legal guardian, or legal custodian resides shall be notified. The Health Commissioner shall make a reasonable effort to locate the child and to obtain a repeat specimen. If all these efforts fail, the Chief of the Bureau of Public Health Laboratories should be notified. The Chief may then record that the child could not be located and the file is closed.

B. THE CHILD IS **LESS** THAN **48** HOURS OF AGE AT DISCHARGE

Metabolite accumulation may be insufficient to detect phenylketonuria and homocystinuria in specimens collected earlier than **48** hours. Specimens collected when the child is less than **24** hours old may not provide a valid test for congenital hypothyroidism. The child's attending physician at the hospital of birth shall make a reasonable effort to ensure that a second specimen is collected when the child **is** at least **48** hours but less than **14** days **of** age. This should be marked Second Specimen. THE SECOND SPECIMEN IS TESTED ONLY FOR PHENYLKETONURIA AND HOMOCYSTINURIA.

STATEMENT ON TRANSFUSIONS/DIALYSIS Transfusions add foreign red blood cells to the infant's circulation altering the level of enzymes in the blood, leading to false positive and false negative screening results. The assays affected by transfused red blood cells are those **for** galactosemia and hemoglobinopathies. Dialysis and plasma exchange transfusions may reduce the concentration of circulating metabolites and hormones, resulting in false negative screening test for phenylketonuria and congenital hypothyroidism. IT **IS** RECOMMENDED THAT THE SCREENING §AMPLE BE OBTAINED PRIOR TO TRANSFUSION **OR** DIALYSIS.

11. HOW TO COLLECT **BLOOD** SPECIMENS FOR NEWBORN SCREENTNG

GLOVES **ARE** WORN **FOR** ALL PROCEDURES INVOLVING CONTACT WITH **BLOOD.**

Blood is collected from the infant's heel. It is helpful if the foot is warmed first; holding the infant with feet hanging down will also help to increase blood flow. The heel is cleaned with isopropyl alcohol (70%) (rubbing alcohol), wiped dry with sterile gauze and allowed to dry completely. The heel is punctured on the lateral edge with a sterile lancet or automated lancet device to a depth of 2.0 to **2.4** mm. The center portion of the heel should not be used to avoid damage to the heel bone. Toes and fingers should never be used.

The first drop of blood should be wiped off; it contains tissue fluids which may dilute the sample. The filter paper is then touched gently against a large drop of blood that soaks through to fill completely the preprinted circle on the filter paper. The heel should not touch the filter paper directly nor be pressed against it. The process is continued until all circles are filled. BLOOD SHOULD BE APPLIED **TO** ONE SIDE ONLY; SUCCESSIVE APPLICATIONS RISK LAYERING WHICH MAY CAUSE THE SPECIMEN TO BE REJECTED. After blood **is** collected the foot should be elevated above the body and a sterile gauze or cotton used to apply pressure until bleeding stops. (See also Appendix, p 19).

The blood specimen should be allowed to air dry **2** to 6 hours at room temperature, away from direct sunlight, avoiding damp or humid areas. After drying the specimen may be placed in an envelope for transport to the Bureau of Public Health Laboratories. Specimens to be sent in batches they should be stored on edge with dried blood spots alternated (rotated 180^{o} from adjacent card). Specimens must be sent to the laboratory no more than two working days after collection.

III. REPORTING AND FOLLOW-UP **OF** SUSPICIOUS OR ABNORMAL RESULTS

RULE: If, upon initial testing of a specimen, the Bureau of Public Health Laboratories determines that a test result is suspicious or abnormal to a clinically significant degree, the following procedures apply:

A. The Director of Health communicates the results to the attending physician (usually the child's primary care physician) or, if that person cannot be identified, to the person who submitted the specimen or, if that person cannot be located, to the chief of the medical staff of the hospital of birth or a hospital employee designated by the chief. Abnormal results, as outlined in Table 1, are communicated by telephone and/or mail, and recommendation for follow-up is made depending on the condition and the degree of abnormality. A written report is sent to the hospital and the physician on all specimens. Test results, both normal and abnormal should be placed in the infant's hospital record.

B. The person notified under III. A. by the Director of the abnormal or suspicious results shall communicate the results to the child's parent, legal guardian, or legal custodian and shall obtain and submit a second blood specimen for testing as outlined in Table 1. If none of the persons listed in 111. A. can be located, the Health Commissioner shall be notified. The procedure described in I.A. for an unsatisfactory specimen may be followed.

When the abnormal or suspicious results are for phenylketonuria, galactosemia, homocystinuria, or hypothyroidism, the second specimen must be submitted within ten days of notification of result on initial specimen. If result of the second test is also abnormal or suspicious, after reporting results to parents, legal guardian, or legal custodian, the physician shall refer the child for specific diagnostic testing, follow-up and management by a physician approved as a provider for the Bureau for Children with Medical Handicaps.

When abnormal or suspicious results are **for** sickle cell or other hemoglobinopathy, the second specimen is obtained before the child reaches one month of age and the child **is** referred to an Ohio Sickle Cell Center, to a physician approved as a provider for the Bureau for Children with Medical Handicaps, or to a physician certified as a pediatric hematologist.

Each hospital should designate a staff person to coordinate screening and to function as liaison with community physicians, Bureau of Public Health Laboratories, and the Bureau of Early Intervention at the Ohio Department of Health.

IV. RESPONSIBILITY

HOSPITAL/ ATTENDING **PHYSICIAN**

Obtain a supply of Blood Collection Kits.

Notify parents that blood will be collected from their baby for newborn screening and provide printed information describing the newborn genetic/endocrine/metabolic screening program (Why Must My Newborn be Screened? Ohio Department of Health, Division of Maternal and Child Health, **1992;** to order, see Appendix, p **32).**

Assign an employee to obtain the blood specimen after completing the information on the Blood Collection Kit. All copies must be legible. Complete information **is** essential if results are to be returned to the proper individuals and the infant located if repeat specimens are needed.

Collect a blood specimen from every infant before discharge or by age **7** days if infant remains in the hospital.

Dry specimen carefully; send to Bureau of Public Health Laboratories, P. **O.** Box **2568,** Columbus, OH **43216-2568** as soon **as** possible, but no later than two working days after collection. EXTRA POSTAGE **MAY** BE REQUIRED ON SPECIMEN **ENVELOPES.**

Document in infant's medical record that specimen was obtained unless parents refuse screening on religious grounds. Obtain signed Religious Objection Statement for refusal. (See Appendix, p **21).**

Inform parents of infants who are discharged from the hospital prior to **48** hours of age that the child must be tested again after **48** hours of age but no later than **2** weeks of age. It **is** recommended that **a** form be signed by the parent stating they understand the tests for **PKU** and homocystinuria may be invalid under **48** hours (congenital hypothyroidism may also be invalid if infant **is** under **24** hours of age at discharge), and that they are responsible for obtaining a second routine screen no later than when the child **is 14** days of age.

Obtain a repeat specimen if notified by the laboratory that the initial specimen was unsatisfactory. (See **I.** A.)

Following notification of an abnormal or suspicious result on initial screening, obtain a repeat specimen or a specimen for confirmatory testing. (See Table 1)

If the infant cannot be located for repeat testing after ten working days, notify the Health Commissioner of the health district in which the mother resides.

Place reports in the infant's medical record; transmit copy to infant's physician or public health clinic.

LABORATORY (see Flow Chart, Appendix p **23)**

Provide instructions for collecting, handling and transporting specimens.

Record receipt of specimens.

Notify hospital/submitter of unsatisfactory specimen; request repeat.

Carry out tests using standard testing methods. Repeat test on specimen showing abnormal or suspicious result as indicated in Table 1.

Complete each test within eight working days after receipt of specimen.

Report in writing normal/negative results to hospital/submitter of specimen. (See E.(1)a of RULES, Appendix, p 17).

Report abnormal/suspicious result to appropriate person by telephone.

Recommend procedure for follow-up as indicated below and in Table 1:

PKU: Seek immediate evaluation of babies having phenylalanine > 6 mg/dL.

Homocystinuria: Seek immediate evaluation if clinical symptoms are evident in babies having methionine > 2 mg/dL.

Galactosemia: For suspicious or positive test indicating lack of galactose-1-phosphate uridyl transferase activity, call immediately to see if child is well. If child is not well, immediately seek further evaluation.

Congenital hypothyroidism: Seek immediate endocrine consultation for babies having T4 ≤ 5; TSH > 30.

Report abnormal results in writing for child's medical record.

Inform Bureau of Early Intervention of abnormal or suspicious results.

If a child cannot be located by hospital, attending physician or primary care physician, the chief of the medical staff of the hospital, or the Health Commissioner of the health district in which the mother, legal guardian, or legal custodian resides, the Chief of the Bureau of Public Health Laboratories, when so notified, records the failure to locate the child and closes the file.

Keep records for a minimum of twenty-one years.

PRIMARY CARE PHYSICIAN

Notify parent, legal guardian or legal custodian of abnormal or suspicious results.

Obtain second-blood specimen for confirmatory testing:

as soon as possible, but no later than 10 days after notification for PKU, homocystinuria, galactosemia or congenital hypothyroidism;

within one month for sickle cell or other hemoglobinopathy.

Respond immediately to the following:

PKU: Seek immediate evaluation of babies having phenylalanine > 6 mg/dL.

Homocystinuria: Seek immediate evaluation if clinical symptoms are evident in babies having methionine > 2 mg/dL.

Galactosemia: For suspicious or positive test indicating lack of galactose-1-phosphate uridyl transferase activity, call immediately to see if child is well. If child is not well, immediately seek further evaluation.

Congenital Hypothyroidism: Seek immediate endocrine consultation for babies having T4 ≤ 5; TSH > 30.

If results of second test are positive, notify parent, legal guardian, or legal custodian of positive test and

Refer the child for more specific diagnostic testing, follow-up and management. (See Consultants, pp **33 - 38).**

Transmit results of the second test to the Bureau of Public Health Laboratories.

If the child cannot be located after ten working days, notify the Health Commissioner of the health district in which the mother, legal guardian, or legal custodian resides.

Respond to request by Bureau of Early Intervention **for** information **on** diagnosis, treatment, and referral.

HEALTH COMMISSIONERS (See appendix, p **32)**

The local registrar of vital statistics, when notified of a birth with no physician or nurse-midwife in attendance, notifies the Health Commissioner of the health district in which the birth occurred. The Health Commissioner then shall cause a blood specimen to be collected within seven days of being notified of the birth.

When requested by the hospital of birth/attending physician, attempt to locate infants who require repeat testing because of unsatisfactory specimens **or** because of abnormal or suspicious result on screening of initial specimen. (See Public Health Standards **for** Local Health Departments, Appendix p 24).

If the child cannot be located within thirty days after receiving the request, notify the Chief of the Bureau of Public Health Laboratories of the failure to obtain the repeat specimen.

BUREAU **OF** EARLY INTERVENTION

Receive reports of abnormal screening results from the Bureau of Public Health Laboratories.

Within ten working days of receiving notice of abnormal results send by regular mail a follow-up letter to physician of record requesting information on diagnosis, treatment, and referral. (See Letters, Appendix pp 25, 26)

FOR HEMOGLOBINOPATHIES Send a copy of abnormal screening results to the Sickle Cell Center in the health district in which the mother, legal guardian or legal custodian resides.

For the following abnormal results:

PKU: Phenylalanine = **4** - 6 mg/dL; repeat screening test requested.
Homocystinuria: Methionine = **2** mg/dL; repeat screening test requested.
Congenital Hypothyroidism: **T4** $\leq$ 5, TSH normal; quantitative measurement of **T4, TSH** requested.
Hemoglobinopathy: Sickle cell or other clinically significant hemoglobin pattern; confirming test requested.

If no response is received after **30** days, send a second letter to same physician, requesting same information,

ceived after **45** days, call physician of record requesting information.

abnormal results

ine ≥ 6 mg/dL: quantitative measurement of serum phenylalanine re-
clinical evaluation requested.
Methionine > 2 mg/dL: quantitative measurement of serum methionine
ate clinical evaluation requested.
nsferase activity not detected: quantitative measurement of transferase
immediate clinical evaluation requested.
yroidism: Low T4 with high TSH: quantitative measurement of **T4,**
mediate endocrine consultation requested.

eceived after IO working days, call physician of record requesting in-

formation describing the newborn genetic, endocrine and metabolic
ppendix, p **32** to order).

assistance to health providers on follow-up protocols of Newborn

ution statewide of metabolic formulas to clients with phenylketonuria

BY NEWBORN SCREENING LABORATORY

ylketonuria is based on a bacteriat inhibition assay in which the growth
bited by B-2-thienylalanine. Phenylalanine, if present in dried blood
s, stimulates the growth of bacteria around the spot. Normal values,
stimulate excess growth. Confirmation of **PKU** is by quantitative
plasma phenylalanine by amino acid analyzer or fluorometry. (Guthrie,
henylketonuria. J Amer Med Assoc **178:** ***863,*** 1961).

ocystinuria is similarly based on a bacterial inhibition assay in which
hibition of the methionine antagonist, methionine sulfoxime. Normal
not stimulate excess growth. Confirmation is by quantitative measure-
homocystine in freshly collected plasma; on storage homocystine is
roteins. (Guthrie. R. J., Screening for inborn errors of metabolism in
ltiple test program. Birth **De€**Orig Art Ser **4: 92, 1968).**

ctosemia is based on a simple fluorescence spot test for erythrocyte
dyl transferase activity in dried blood spots. The specimen is incubated
e, uridinediphosphoglucose and nicotine adenine dinucleotide phos-
nsferase is present the normal enzyme cascade for converting galactose
ucing NADP. The fluorescence of reduced NADPH under ultraviolet
nsferase activity. Reduced activity (< 25% of normal) may not be dis-
y in the screening test. The enzyme is easily inactivated if stored under
Activity can be restored using a sulfhydryl-protective agent. Confir-
measurement of galactose-1-phosphate uridyl transferase activity and
concentration in hemolysates of red blood cells. Variants and
nguished from classical galactosemia by starch-gel electrophoresis of

. and Baluda M. C., A simple spot screening test for galactosemia. J 966. Berry. H. K., and Croft. C. C., Personal Communication: 1979; of galactose-1-phosphate uridyltransferase activity in dry blood spots.).

for congenital hypothyroidism is based on measurement of thyroxine y in dried blood spots. Specimens with low values for T4 are routinely nts of thyroid stimulating hormone (TSH). Positive tests in preliminary 'ed by further tests of thyroid function for confirmation. If hormone er diagnostic studies, such as a thyroid scan and bone age x-ray, may be ype and severity of the hypothyroidism. (Dussault. J. H.. and Laberge, ine (T4) par methode radioimmunologique dans l'eluat de sang siche: stage de l'hypothyroidie neonatale. Union Med Can 102:2062, 1973).

noglobinopathies is performed by isoelectric focusing of a hemolysate blood specimen. Bands of hemoglobin are identified by their migration eld. Aging of specimens interferes with identification of certain s may cause false negative results. Confirmation of all abnormal results obin electrophoresis or high pressure liquid chromatography. (Koepke, id Schmidt. R. M., Identification of human hemoglobins by use of Clin Chem 21: 1953, 1975. Black, J., An isoelectric focusing method ariants in newborn blood samples including the B-thalassemias. 1-689, 1988)

JMMARY OF SPECIFIC DIAGNOSTIC TESTS

CU (> 6 mg/dL by GIA), confirmed by quantitative measurement of asma. Rule out biopterin defect, variant forms of PKU.

omocystinuria (methionine > 2 mg/dL), confirmed by quantitative ine in serum/plasma, homocystine in serum/plasma, homocystine, ulfide present in urine.

alactosemia (transferase activity not detected). Quantitative measure- e in red blood cells; quantitative measurement of galactose-1-phosphate d galactitol in urine (unless infant already on galactose/lactose free

pothyroidism (T4 ≤ 5; TSH > 30). Quantitative measurement of T4,

ickle cell or other hemoglobin of clinical significance. Hemoglobins ocusing with quantitative densitometry, HPLC separation.

TABLE 1

FOR REQUESTING REPEAT/CONFIRMATORY **TESTS**

normal Result	Recommended Follow-Up
nylalanine = 4–6 mg/dL[a]	Repeat screening test
nylalanine ≥ 6 mg/dL[a]	Quantitative measurement of serum phenylalanine[#]
nsferase activity[a]	Quantitative measurement of,
t detected	transferase enzyme[#]
thionine = 2 mg/dL[a]	Repeat screening test
thionine > 2 mg/dL[a]	Quantitative measurement of serum methionine#
<5; TSH > 30[a]	Quantitative measurement of T4, TSH[#]
kle cell disease[a]	Confirming test[#]; referral
kle cell trait, her hemoglobinopath .clinical significance'	Confirming test[#]; referral

3

OULD NOT be sent to the Bureau of Public Health Laboratories, but to a e reference laboratory must be CLIA approved and must report results abnormal pediatric values. Results of testing by the reference laboratory person who submitted the sample AND to the Chief of the Bureau of s.

TABLE 2

RETATIONS OF ABNORMAL SCREENING RESULTS

	Possible Causes
	Phenylketonuria Hyperphenylalaninemia Variant PKU Biopterin synthetase deficiency Dihydropteridine reductase deficiency
ed or **absent**	Classical galactosemia Variant form (Duarte) Compound heterozygote Glucose-6-phosphate dehydrogenase deficiency
	Homocystinuria Liver disease High protein intake
elevated	Improper sample collection (layering) Rarely: galactosemia
	Primary hypothyroidism Prematurity Pituitary abnormalities Thyroid binding globulin (TBG) deficiency
	Sickle cell disease (SS) Other clinically significant hemoglobinopathy Hemoglobin variant

VI. HOW TO OBTAIP BLOOD COLLECTION KITS (Appendix, pp 27, 28)

HOSPITALS, PRIVATE PHYSICIANS, PRIVATE CLINICS, COLLECTING NEWBORN BLOOD SPECIMENS PURCHASE BLOOD COLLECTION KITS FOR A FEE. THESE ARE ORDERED DIRECTLY FROM THE ADDRESS BELOW. DAMAGED KITS OR **KITS** WITH INFORMATION ERRORS WILL BE REPLACED FREE OF CHARGE. WRITE "VOID/DAMAGED" ACROSS THE KIT AND SUBMIT TO THE SAME ADDRESS.

Heather Ridewood
Ohio Department of Health - Accounting
P.O.Box **118**
Columbus, OH **43266-0118**
614-644-7602

PUBLIC HEALTH DEPARTMENTS AND PUBLIC HEALTH AGENCIES ARE SUPPLIED KITS FREE OF CHARGE BY THE OHIO DEPARTMENT OF HEALTH. REQUESTS SHOULD BE SENT T O

Bureau of Early Intervention - Newborn Screening Program
Ohio Department of Health
P.O.Box **118**
Columbus, OH **43266-0118**
614-644-8389

ONCE THE INITIAL TEST IS OBTAINED, BLOOD COLLECTION KITS USED TO COLLECT REPEAT SPECIMENS WILL BE REPLACED FREE OF CHARGE. THIS INCLUDES KITS USED TO COLLECT A SECOND SCREENING SPECIMEN. THE INFORMATION BELOW MUST BE SUBMITTED TO THE OHIO DEPARTMENT OF HEALTH LABORATORY IN ORDER TO OBTAIN A REPLACEMENT KIT.

Child's name
Date **of** Birth
Mother's name
Date of follow-up test and test kit number

REQUESTS FOR REPLACEMENT KITS SHOULD BE SENT TO:

Kathy Tucker
Public Health Laboratories
Ohio Department of Health
P. **O.** Box **2568**
Columbus, OH **43216-2568**
614-466-2278

VII. DISORDERS COVERED BY THE **OHIO** NEWBORN **SCREENING PROGRAM**

PHENYLKETONURIA

The biochemical defect in classical phenylketonuria (PKU) is a deficiency of the liver enzyme, phenylalanine hydroxylase, which catalyzes the conversion of phenylalanine **to** yield tyrosine. The system is complex, requiring besides phenylalanine hydroxylase, a cofactor, tetrahydrobiopterin, and another enzyme, dihydropteridine reductase. Defects occur **in** any component of the system. Phenylalanine accumulates in blood and other body fluids and abnormal metabolites of phenylalanine are excreted **in** urine. Screening **of** newborns for elevated blood phenylalanine uncovers variant forms of PKU in addition to the classical form.

Few clinical signs arouse suspicion of PKU in infants. There may be vomiting and feeding difficulties. The baby is usually physically normal and progresses normally for the first months of life, but developmental milestones may be delayed. Treatment of infants with blood phenylalanine concentrations above 20 mg/dl should begin treatment as soon as possible after confirmation of the diagnosis. **A** low-phenylalanine formula is substituted for the infants regular formula. Care must be taken to ensure that the diet contains enough phenylalanine, usually provided by small amounts of milk, to meet the needs for this essential amino acid without exceeding the limited capacity to utilize it.

Untreated PKU causes severe mental retardation. Before newborn screening approximately 1% of patients in institutions for mentally retarded had PKU. Infants are now detected early in life and treatment begun before onset of brain damage. Children with PKU who are maintained on a low-phenylalanine diet from infancy have normal intellectual development. Current studies suggest that subjects with classical PKU may need to continue the diet indefinitely to avoid behavioral and mental disturbances.

The harmful effects of PKU are not limited to those who inherit the disease directly. In pregnant women it can cause fetal complications, including intrauterine growth retardation, microcephaly, mental retardation, and a high incidence of heart defects.

Low phenylalanine formulas are provided at no cost to residents of Ohio identified with PKU so long as they are receiving treatment by a metabolic management team. (See Appendix: Metabolic Formula Program Policy, p **29;** Metabolic Service Teams, p **30;** Maternal PKU, pp 31, **39).**

GALACTOSEMIA

Classic galactosemia is an inherited defect of carbohydrate metabolism in which galactose cannot be converted to glucose because of a missing or defective enzyme, galactose-1-phosphate uridyl transferase. Patients with classical galactosemia usually have less than 1% of normal transferase activity and require immediate treatment with galactose-free diet. Genetic variants and heterozygotes, both with reduced activity of the transferase enzyme, may be detected in the screening process. The Duarte variant has 50% of normal activity. Compound heterozygotes of the Duarte/Classical forms have 25% of normal activity. These are usually asymptomatic; some infants may require dietary treatment if galactose-1-phosphate accumulates in red cells.

The disease has severe consequences for affected infants who are on milk diets, since galactose is a component of the milk sugar, lactose. The galactosemic infant may appear normal at birth but symptoms appear within a few days of life. Jaundice and hepatomegaly are often early

signs of disease, leading to cirrhosis. There may be cataracts, hypoglycemia, feeding difficulties, coagulation problems, and decreased immunity. Without treatment infants often die of Escherichia coli sepsis. Those who survive the liver disease and hemorrhagic episodes have cataracts and are physically and mentally retarded.

Neither the screening test nor the quantitative test for the transferase enzyme is reliable in infants who receive transfusions before testing. Accumulation of galactose-1-phosphate is not affected by transfusion, but galactosemic neonates are frequently too ill to ingest milk before the specimen is collected. Clinicians must exercise a high degree of suspicion for sick infants who exhibit symptoms of galactosemia.

Most symptoms disappear when infants are fed a galactose-free diet - no milk or milk products, galactose-containing substances, or medications that contain lactose as fillers. If treatment begins by 1 month, the cataracts diminish, liver abnormalities disappear and growth resumes.

It is probably wise to continue galactose restriction throughout life. Liver toxicity may not recur, but cataracts form when galactose concentration rises in body fluids. Treatment has not been entirely successful in achieving optimum intellectual development. The majority of galactosemic women have experienced ovarian dysfunction.

HOMOCYSTINURIA

Homocystinuria results from a deficiency of cystathionine synthetase, which normally converts methionine to cystine. Homocystine and its precursor, methionine, accumulate in blood and urine. Infants have no clinical symptoms, but they appear later, involving the connective tissues, central nervous system and cardiovascular system. Lens ectopia is typical, and it may cause glaucoma, myopia, retinal detachment and cataract. The skeletal system consistently shows genu valgum with frequent chest, vertebral and foot deformities. Major motor seizures are often present. The lethal complication is in the cardiovascular system where multiple arterial and venous thromboses occur as a result of enhanced platelet stickiness. Mental retardation is a common but inconstant finding, and probably results from vascular occlusive disease.

Approximately 50% of homocystinuric patients respond to treatment with pharmacologic doses of pyridoxine, the cofactor needed to activate cystathionine synthetase. Pyridoxine-resistant patients are placed on a low-methionine diet, supplemented with cystine. Patients may need lifelong treatment to reduce risk of thromboses. Pregnancy in a woman with homocystinuria carries no risk to the fetus, although there is a high rate of fetal loss and pregnant women are at risk for thromboembolism.

Low methionine formulas are provided at no cost to residents of Ohio identified with homocystinuria. These clients must be receiving receiving treatment by a metabolic management team. (See Appendix, Metabolic Formula Program Policy, p 29).

CONGENITAL HYPOTHYROIDISM

Neonatal hypothyroidism is a collection of defects affecting thyroid function. If undetected it can cause mental and physical retardation. There are no overt clinical signs or symptoms during the neonatal period. As the infant matures the lack of thyroid hormones results in decreased stature, coarse facial features and mental retardation. Other symptoms may include hypotonia, prolonged neonatal jaundice, enlarged posterior fontanelle,. high incidence of respiratory distress, umbilical hernia, macroglossia, hoarse cry, feeding problems, mottled, dry skin, constipation, lethargy.

Primary hypothyroidism is the most common cause of neonatal hypothyroidism. Thyroxine (T_4) is decreased and is unable to exert feedback control to the pituitary gland, resulting in an increase of thyrotropin (TSH). Secondary and tertiary hypothyroidism are due to defects in the pituitary gland and hypothalamus.

Primary hypothyroidism is caused by a variety of developmental and genetic defects, including thyroid aplasia, hypoplasia and ectopic thyroid, dyshormonogenesis, endemic goiter, and maternal goitrogen. Treatment consists of placing the infant on L-thyroxine supplements as early as possible; delay in instituting effective therapy results in poor prognosis. Therapy is lifelong.

Premature infants may have low blood T_4 levels with normal TSH values. These infants need observation to ensure that T_4 levels rise to normal ranges as the infant matures. Specimens collected on the first day of life may not reveal affected infants because of normal physiological changes occurring in both T_4 and TSH.

HEMOGLOBINOPATHIES

One in 600 newborn African Americans is homozygous for the sickle cell gene and therefore has sickle cell anemia. Infants and young children with sickle cell anemia are remarkably susceptible to pneumococcal infections which are often fatal. The purpose of newborn screening is to detect at birth those infants needing penicillin prophylaxis. The standard of care consists of initiating by four months of age prophylaxis with oral penicillin administered twice daily for the first five years of life. Prophylaxis dramatically reduces the rate of these infections, lowering the mortality rate. Close supervision is necessary to assure that lapses in administration of penicillin do not occur. Affected children are anemic, have repeated episodes of pain, and a number of other complications including transient episodes of bone marrow aplasia and splenic sequestration of a large proportion of the circulating red blood cell mass. If primary care is not given by a specialist, hematologic back up is desirable.

Newborn screening also detects other clinically significant hemoglobinopathies, most notably sickle cell-hemoglobin C disease and sickle cell-beta-thalassemia. Sickle cell trait, the simple heterozygous state, while not clinically significant, signals the possibility that this family may be at risk of having children affected with sickle cell anemia in subsequent pregnancies. Genetic counseling may allow at-risk families to realize their reproductive options.