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State of Ohio, )
County of Cuyahoga. ) SS:

IN THE COURT OF COMMON PLEAS

MATTHEW CHASE WAGONER, etc., et al.,
Plaintiff,
vs.
MARK R. EVANS, M.D., et al.,
Defendants.

Case No. 497179
Carolyn B. Friedland

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THE DEPOSITION OF LAWRENCE D. LILIEN, M.D.
THURSDAY, APRIL 8, 2004

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The deposition of LAWRENCE D. LILIEN, M.D., called by the Plaintiffs for examination pursuant to the Ohio Rules of Civil Procedure, taken before me, the undersigned, Charles A. Cady, Registered Merit Reporter and Notary Public within and for the State of Ohio, taken at the offices of Cady Reporting Services, Inc., 55 Public Square, Suite 1225, Cleveland, Ohio, commencing at 11:10 a.m., the day and date above set forth.

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APPEARANCES:

On behalf of the Plaintiffs:
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On behalf of the Defendant Parma Community General Hospital:

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On behalf of the Defendant Lawrence D. Lilien, M.D.:
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ALSO PRESENT:
Scott W. Kolodny, M.D.
Becker & Mishkind Co., LPA

LAWRENCE D. LILIEN, M.D.
of lawful age, called by the Plaintiff for examination pursuant to the Ohio Rules of Civil Procedure, having been first duly sworn, as hereinafter certified, was examined and testified as follows:

EXAMINATION OF LAWRENCE D. LILIEN, M.D.

BY MR. BECKER:

Q Good morning, Doctor. Would you tell me your full name, please, and spell your last name.

A Lawrence Douglas Lilien. L-i-l-i-e-n.

Q What is your current business address?

A I think it's 300 Claridon Avenue in Phoenix. That's the main office for our group.

Q And what is the name of your current professional group?

A They call it NAL, which is Neonatal Associates Limited. NAL.

Q Is that a hospital-based neonatology group?

A Pretty much. We cover pretty much all the hospitals in Phoenix, in the Scottsdale area. So we move between different hospitals. We don't have, like, outpatient practice.

of Pediatrics?

A A member? No.

Q Did you ever receive the American Academy of Pediatric publications?

A Receive them? I don't know if I receive them, but I see them, usually. I don't know if they're mailed. I don't know if they're mailed to me.

Q How do you become aware of the American Academy of Pediatrics publications?

A I see them in the office. I mean, I don't know. They're all over the place. Some of them do get mailed to me even though I'm not a member, because I am on the mailing list, apparently.

Q Well, were you ever a member?

A I don't think so. I don't think so. The dues were high. I don't think I ever joined.

Q Do you subscribe to the journal entitled Journal of Pediatrics?

A I get it on line, basically.

Q And how long have you been obtaining that on line in terms of years?

A On line, maybe three years.

the publication, the book?

A I was getting, I think, Journal of Pediatrics, not Pediatrics. The other ones I get at the library.

Q Okay. And in 1999 were you receiving or

subscribing to the Journal of Pediatrics?
A I don't remember. I mean, I get those at the library primarily now. In other words, I don't get three journals, five journals. I get abstracts that come to me through the Internet and I review those. It's a much more efficient way of doing it.
And then I get the articles I like either on line or from the library.
Q Going back to the publications from the American Academy of Pediatrics, have you found them useful and helpful in the past?
A Yes.
Q And have you found the Journal of Pediatrics reliable and helpful?
A Pretty much all -- yes. Pretty much all journals are pretty reliable and helpful.
Q Doctor, were you aware that in early 1999, the American Academy of Pediatrics issued a policy statement regarding surfactant replacement

therapy for respiratory distress syndrome?
A You mean the one in March?
Q Yes.
A Yeah.

A I would assume so, yes.
Q And as a result of seeing that, did you take any steps at Fairview General Hospital to develop a protocol or policy consistent with the recommendations of the American Academy of Pediatrics?
A I think we did make an effort to make a protocol at that time.
Q Okay. And did you participate in the creation of a policy or protocol?
A Assuming one was made, and I'm pretty sure one was, I would have to sign off on it.
MR. BECKER: And, John, that policy has been requested by me. You're aware of that.
MR. BULLOCH: I don't know that I'm specifically aware of that, Mike, but I'll go back and see if we have that policy.
Just for the record, too, I'd like to make a point that the American Academy of Pediatrics

was a recommendation, not an absolute guideline or a standard that they promulgated. It was a recommendation.
But I will go back -- to answer your question, I'll go back and see if there is such a policy at Fairview.
MR. BECKER: If you look at the correspondence between our offices, you will see that I think there was a formal request for production of documents, as well as a letter from me to a young gentleman in the office that was taking over this case for either Chris or George -- and his name escapes me right now. But it was represented to me that there was no policy, so I'm somewhat surprised by that.
Q Doctor, do you recall the substance of the

policy?
A No. A lot of the policies -- as I remember, we had a whole pile of them -- were removed and replaced with textbooks. So a lot of the policies which I've asked for from here to go back to get them from Fairview, because I want them now, I can't get them.
A lot of them were changed over because of some new JCAHO guidelines at that time saying

that we have to use textbooks instead of writing our own guidelines. Our guidelines are used as a teaching model for our nurses, primarily, and to constantly allow us to review techniques and procedures that we're doing.
MR. BULLOCH: The bottom line is you have my -- I'll go back and see if we can find that policy. It's possible that -- Bob Austria, I think, is the person who was working with you --
MR. BECKER: Yes. That's his name.
MR. BULLOCH: -- didn't know the right question to ask.
I'll go back and see if there's a historical document that existed at about the time and get it to you if there is one. I don't know if there is one.
Q Doctor, what I'm interested in, sir, is, were there any guidelines, protocol, outlines, care pathways, algorithms, that you had assisted in the creation of that would assist other pediatricians relative to when to administer a surfactant to a child suffering from respiratory distress syndrome?

A No. The pediatricians were administering surfactants. But, again, when that guideline came out, I think we made an effort to make such a guideline. Does it exist? I don't know. I think it probably does. Do I know where it is? I don't know.
Q All right. But here's my question, Doctor. I'm interested in whether or not that guideline, if you recall, was it directed to nurses or was it directed to the neonatologists and pediatricians?
A If it does exist, it would be directed primarily to nurses.

today.
As you know, this is a question-and-answer session under oath. It's important that you understand the question that I pose. If you don't understand the question or if it's inartfully phrased, I want you to stop me and tell me so. And I'd be pleased to attempt to rephrase or restate the question.
Fair enough?

A Fair enough.
Q However, unless you indicate otherwise to me, I'm going to assume that you have fully

understood the question that I have posed and you have given me your best and most complete answer today.

Fair enough?

A Fair enough.

Q What have you reviewed in preparation for today's deposition?

A The medical records of Matthew Wagoner and the x-rays from Parma, as well as the x-rays from Fairview, as well as the MRI scan from Fairview. And that's primarily it.

Q When you say "medical records," can you be specific for the record?

A I have --

Q You have Parma records as well as Fairview records of Matthew?

A I don't have Parma records. I have Fairview records.

Q So you have not reviewed Parma records?

A No. Except there may be pieces of it referred to in our records, but not specifically Parma

And this is just Matthew's chart.

Q From Fairview?

A From Fairview.

Q So you have looked at films from Parma, films from Fairview, the child's chart from Fairview.

Anything else?

A And the MRI scan from Fairview.

Q Of his brain?

A Of his brain.

Q Okay. Have you done any research in preparation for today's deposition?

A Research? I pretty much know most of the literature historically. Have I gone over some more of it?

Q Yes.

A Basically, I've gone over the stuff I went over before, yes.

Q That's what I'm interested in, Doctor.

In anticipation or preparation of today's deposition, what articles, what textbooks, what did you look at?

A I think the guidelines I went over, because there's about 18 references, I think, in there pertaining to surfactant. I went over some of those.

A There are about 18 references.

There's a slight delay on this.

I went over those references.

I also tried to review the literature on infants that are large who get surfactants and could not find any studies to date, at least until -- pertaining to surfactant on babies over 1700, 1750 grams.

And I also reviewed some other literature not showing any evilness about or any signs saying surfactant improves CNS function in follow-up, which are basically in those 18 or 19 articles in the guidelines.

Q When you say "guidelines," can you be more specific exactly what you're referring to?

A Those are the March ones. I think it's March of '99. The last page has a whole bunch of references. I think 18 of them pertain to surfactant usage in premature babies.

Q So the literature that you looked at would be the articles cited at the end of the guidelines?

A Primarily.

A I think there was another reference of term babies, babies over 36 weeks, over two kilos, that was published in 1998. And I'm not sure. I think the author was Lotze. L-o-t-z-e. And that pertained, basically, to using a surfactant on those type of babies.

But those babies were babies that had pulmonary hypertension, pneumonia, and meconium aspiration. And as I remember, the conclusion was less ECMO but no difference in air traps or anything else.

Q Other than the one article by Lotze that you have cited -- and do you remember which journal that was published in? Did you tell me?

A I think it's the Journal of Peds.

Q Other than that article, any other articles outside of the articles listed and attached to the guidelines?

A I think that's it.

Q Okay. Doctor, do you have any criticism of the care rendered to Matthew Wagoner while Matthew was still at Parma General Hospital?

MR. TORGERSON: Objection for the record.

Please answer.

A I did not review those charts, so it's pretty hard for me to criticize it.

Q If Matthew, Doctor, would have been transferred to your facility, Fairview General Hospital, two, four, even six hours earlier, would any of your subsequent treatment have been different?

MR. TORGERSON: Objection.

Please answer.

A May I --

MR. BULLOCH: You can go ahead and answer. He's just making an objection for the record.

A It may have.

Q Please elaborate as to how it may have.

MR. TORGERSON: Just a continuing objection.

Go ahead, Doctor.

A Again, this is based on fragmentary knowledge of the chart, of their record. There are two blood gases I'm aware of. One was like a 7.25 pH, a CO2, I think, was 40. Then when I put the arterial line in, there's another gas that was an improving base deficit, meaning the child was improving in terms of blood gas. And the question is whether or not an earlier blood gas would have been worse. I don't know.

And if it were the case, maybe fluids would have been indicated earlier. I would have

given antibiotics earlier, but I don't think that would have made any difference. It would not have made any difference.

So I guess the main maybes would be maybe I would have done a gas earlier. This is a maybe. I don't know what the child was really doing before I got there, from my records. At least not in great detail. And maybe that gas would have shown a significant metabolic acidosis, and maybe I would have done something at that time. Those are all the maybes.

And maybe I would have put the kid on antibiotics earlier, but that would not have made any difference.

46 Q If there would have been earlier evidence of metabolic acidosis, would you have likely intubated earlier?

A Probably not. It depends upon how severe it is. It depends upon how much oxygen the baby was on and what he looked like.

If he was perfusing well, if his FiO2 requirement was only 30 or 35 percent O2, it's

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hard to perceive that I would have intubated him.

47 Q Let me try this again, Doctor, because I want to make sure that we've covered it, because this is an important issue to everyone sitting at this table. I want to make sure that we've covered this thoroughly.

Had this child been transferred to Fairview two hours, four hours, and even up to six hours earlier, is there a chance -- a chance -- that this child's intubation and the administration of surfactant would have occurred earlier than when it ultimately did occur?

MR. TORGERSON: Objection.

You may answer.

A I don't think so.

48 Q Now, you responded yourself, personally responded, to the call from Parma for this child?

A Yes, yes.

49 Q Was there the creation of a run sheet, a separate document, for your run over to Parma to pick up this child?

A I'm not understanding you.

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the run from the neo team from Fairview going over to Parma?

A There was a document created by the nurse and the ambulance who went over to Parma. I went over separately to get there faster. I drove over there by myself, met our run team, which appeared, I'm guessing, maybe 20, 30 minutes after I got there.

So when I got there I started to work on the baby, between the UAC, getting some gases, and then our run team got there 20, 30 minutes later. It allowed us -- it allowed me to get there quicker. If I went with the run team, I would get there a half an hour later.

The document that was created is my

admission note, which was written while I was at Parma, some of it. And the run team, as you say, was the nursing note, the transport note, that's included in the chart.

51 Q. You have already mentioned one of the things you did once you arrived is you created a line through the umbilicus of this child?

A. Yes.

And I should say, Doctor, at any time during the balance of this deposition, you are more than free to look at any charts, records before responding. It's not a memory contest.

A. I think the main thing was put that line in, get another -- a repeat gas, because they had previously got a capillary gas. And I think the blood culture they were not able to obtain, and they started antibiotics just before I got there. There was a white count that was drawing differential.

I think the main thing is that line, doing a gas, and then speaking to the parents.

53 Q. And Matthew was ultimately transported back to Fairview, and I assume that you went back in your own vehicle?

A. I went back in my own vehicle, most likely. And I probably followed the transport van back, but I don't know for sure if I followed them or whether or not I literally left and went home from Parma.

54 Q. Were you the physician or neonatologist that was in charge of Matthew's care from the time he arrived at Fairview up until the time his second pneumothorax was diagnosed?

A. Yes.

55 Q. And when you weren't at the hospital but were at home at night or during the early morning hours, were you regularly contacted regarding Matthew's condition?

A. Yes.

56 Q. Would you explain kind of the interplay or how it works between the house pediatrician, the neonatal nurses, and you, the interplay when you're not in house?

A. There was a house physician in house around the clock. And I would say their main job was to stabilize any sick baby and take care of emergencies, because obviously, we could not be there instantaneously.

So whenever we weren't there, we would sign out to the one that was on call, let them know what infant may give them grief or difficulties. And then if there are problems, emergencies, they take care of them. If it could wait, they would defer to us the following morning or they'd have the nurse call.

Pretty much anything that happened that was at all slightly unusual with the infant, they would call the house physician, but they would also let us know as well. And so we would decide based on what happened whether or not we

would be coming in for that event.
Maybe further questions may help.
57 Q Were they supposed to contact you before they contacted the house physician?
A No. They would do both or they would do the house physician right away. Because the house physician was literally sleeping down the hall. And if there was, like, an air trap or a pneumothorax, they obviously would call them right away, not us.
So if they diagnose by transillumination, they're going to call the house physician to fix it because I can't fix it on the phone.
58 Q When you say "they," you mean the nurses?
A The nurse practitioner, the nurses, yes.
59 Q Well, could the pediatric house officers make their own independent decisions on your patients without checking with you?
A They could make some decisions, but if it was a, quote, "large decision," they would not.
In other words, if you're talking about a little glucose, do I give a push of sugar, they would do that. If you're talking about holding

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a feeding, they would do that. They would use their judgment and so would our nurses.
If the house physician did something -- this didn't happen that often -- that the nurses felt uncomfortable about, they would let the house physician know and they would go call us. They would let them know they were calling us. They would not go around them without them being made aware.
The same thing. If I did something to the baby that was sick, I would try to let them know as well that I was doing something so they could keep up with what's happening with the infant.
60 Q When you say "they," you're referring to the nurses and the pediatric house officer?
A Well, the nurse would know because I'd be speaking with her --
61 Q Yes.
A -- so that would be the house physician.
In other words, if I decided to make a respirator change that I think was important for the house physician to know, I would either call them or I would tell the nurse or ask the nurse, "Will you please let the house physician know I made a change in the ventilator?" because they

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have to know as well because they're there all the time. They're there all the time.
62 Q If the pediatric house officer sensed a need to administer surfactant therapy, could they do that on their own?
A They would not do that on their own, especially in '99. I don't know what they do now at Fairview, but in '99 they would not do that on their own because that would not be like an emergency, like a three-second decision, in '99.
63 Q You obviously recommended the transfer of Matthew from Parma to Fairview after your arrival, correct?

A Actually, before my arrival.
Q Okay. And what was the basis of that decision?
A Probably with that much O2 he was on, I spoke with Dr. Evans. And my general pattern would be if the child is requiring more than 40 percent and looked like he's not going to get better, get him out.
I also spoke to him and I was most likely the one that asked to do the white count, do a blood culture, start him on antibiotics. That was initiated with phone calls with me. I should say most likely.

And the gas was probably my initiation as well.
Q But the reason for the transfer was that this child would receive better or more specialized care in the NICU?
A I'm going to change -- I think the reason for the transfer is the concern that a baby was requiring 40, 50 percent oxygen, is going to get worse and need a ventilator, and they're not equipped to provide a ventilator or CPAP or give surfactant.
Q What was your working diagnosis when you had an opportunity to assess Matthew at Parma?
A Respiratory distress of some sort. Could be a wet lung, could be hyaline membrane disease in a large baby. It could be infection. I don't think I had any evidence of this infant being shocky before because you could also have shock lung.
In other words, I think he was perfusing well, as best as I could tell, previously, before I got there. But I would say respiratory distress from some etiology, either infectious, hyaline membrane disease, pulmonary distension, all things I would be thinking about in Matthew.
Q You mentioned respiratory distress syndrome. Would you give me a definition of that, please.
A Usually when we say that, we'll say surfactant deficiency. And I probably would want to also say it's surfactant deficiency from being premature, because you can get surfactant deficiency from meconium aspiration; you can get surfactant deficiency maybe from sepsis; you can get surfactant deficiency from shock lung.
But when I say respiratory distress syndrome, I would mean surfactant deficiency, probably because the infant is premature. And even though we expect most babies over 34 weeks to have surfactant, there are some of them who do not.
I think that answers it.
Q With surfactant deficiency it means in real lay terms that they have nonelastic, or stiff, lungs?
A No. I would say it's a lack of a chemical called surfactant or a phospholipid that allows those lungs to collapse. So you have to give

positive pressure to expand them or give surfactant that will help decrease the surface tension and allow them to remain open. In a sense I guess it's lungs that are stiff.

Q Now, you mentioned, did you say, hyaline membrane disease?

A That's the same as respiratory distress syndrome.

Q Okay. At Parma did you review the chest film taken at Parma?

A Yes, yes.

Q And I know that you have reviewed that chest film recently.

A Yes.

Q Okay. Tell me your interpretation of that chest film at Parma, taken at Parma.

A It was an unusual projection because the ribs are horizontal, so it's hard to assess lung volume. But the lung volume on that projection looked like it was low, and there was haze bilaterally. Heart size, as best as one can tell, was normal. Visualized bones and gas pattern were also normal.

Q Did that chest film assist you in making a working diagnosis?

A It tells me the child could have fluid in the membrane disease or respiratory distress syndrome. It tells me the child could have an infection. It tells me the child could also have hypoplastic lungs.

It didn't narrow it down. It did rule out some other things. It ruled out an obvious pneumothorax.

There's one more thing on that x-ray too. There was a hypolucent area in the right-middle lobe lung areas as well, which was unusual. But it ruled out, like, diaphragmatic hernia. It didn't assist tremendously except for the rule-outs.

Q Tell me again what the unusual finding was on that film.

A It wasn't reported by the radiologist, but there's a hypolucent area in the right-lower lung field which is a hyperinflated area, most likely, of lung. It tells me that the aeration is not homogeneous.

Q Consistent with RDS?

A It's not part of RDS specifically.

Q Would it be inconsistent with RDS?

A No. In other words, it's another finding. The child has homogeneous lung fields that are not well ventilated on that projection. Again, it's another -- the projection -- or the child's lungs are not that well ventilated.

In addition to that, there was an area of lung that was hyperinflated, and that could be a blowout mechanism from secretions that are causing that little piece of lung to hyperinflate, to overexpand.

Q Was RDS the most likely diagnosis at the time

you left Parma?
A I'm not -- he had respiratory distress. I wouldn't necessarily say it was respiratory distress syndrome. The baby was five pounds and 35 weeks' gestation. I would say he has a breathing problem, and it could be immature lung, it could be sepsis. This child had a very high band-to-neutrophil ratio.
The mother, I think, was put on antibiotics, so it could be an infection as well. The platelet count, I think, was 131,000. This goes also with infection. So if -- I'd be worried about infection, immature hyaline disease, or respiratory distress syndrome.
It could also be fluid in the lung from a rapid delivery process. It could also be

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hypoplastic lung, smaller lung volume, smaller lungs than the infant should have. There are a lot of other diagnoses.
I wouldn't say it was just respiratory distress syndrome. I was concerned about a whole bunch of things.
78 Q I understand that. But at the top of your list of differentials was RDS?
A It was one of the diagnoses along with sepsis, infection. Those would be the two biggest ones, but --
79 Q Did you ever -- excuse me, Doctor.
A In a 35-weeker I have to worry about hypoplastic lungs as well.
80 Q Would you give me the definition of hypoplastic lungs, then, and distinguish that from RDS?
A Hypoplastic lungs is a smaller lung weight. And if you look at the number of alveoli in cross-sectional assessment of the lung, there will be fewer alveoli. If you look at terminal bronchioles and how close they are to the surface of the lung, there will be fewer radii from the terminal bronchiolus to the surface of the lung. In other words, there are less air sacs.

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There may be less branches as well in a lot of babies that are 35, 36 weeks who don't behave very well on respirators, who besides maybe having hyaline membrane disease, or respiratory distress syndrome, probably have a component of this hypoplastic lung. And that's why a lot of them have a rough go.
81 Q Do you have an opinion in terms of probability as to whether this child ever really ever had hypoplastic lungs?
A There's no way, unless I have an autopsy, really, of diagnosing that. I think after he's intubated, his lung expansion was rather good. It was about nine rib expansion. And that would lead me to think he really doesn't have hypoplastic lungs.
82 Q Did you ever make a diagnosis of RDS in this child?
A I think he probably did have RDS. I mean, I can't do a diagnosis in terms of measuring

phosphoglycerol or other surfactants in his lung. But the way he behaved, I think he behaved like an immature lung.

He may have also had sepsis. He may have also had a viral infection. But I think he definitely had a component of respiratory distress syndrome.

83 Q Did you ever rule out sepsis while he was at Fairview?

A It's hard -- we ruled out sepsis in terms of bacterial disease. But viruses, there are lots of indicators that he may have had a virus early on, in fact.

84 Q So you ruled out sepsis, bacterial sepsis, and you said that the child had some evidence of a virus?

A We ruled out as best we could. We didn't have a blood culture before. We had an endotracheal tube culture at the time of intubation. We had white counts that had high band-to-neutrophil ratios. We treated the child, I think, with antibiotics probably about for seven days.

Do I think he had a bacterial infection? I don't think so. But it was hard to rule it out. We didn't have blood cultures. Viral infections are things that are very difficult to rule out.

But we know that in the first -- when he was intubated and we did a gram stain of the secretions, there were lots of mononuclear cells, and when he was reintubated about a week later, lots of mononuclear cells in the endotracheal tube secretions.

Also about a week later, when he was reintubated, the white count had lots of mononuclear cells. Also a week later on the spinal tap that was done, lots of mononuclear cells. They are suggestive of a viral infection.

The only one that we really cared about was the one we could treat, and that was herpes. So that's why we cultured for herpes in the spinal fluid, nasopharyngeal culture, and stool culture. None of those drew out herpes.

But there's a lot of information and new stuff coming out in the literature now that says a lot of these babies that behave unusually and end up with CNS problems probably have viral infections.

And the way they made that assessment is by looking at the placenta, by doing some fancy PCR testing, which was not available for us, nor would we be able to do it in '99. In other words, a lot of this infant's clinical course may have been compatible with some sort of chronic viral problem.

85 Q And what do you think that chronic viral problem -- what type of virus was it?

A Don't know. The literature that came out actually recently -- now, this is from March of

this year -- Coxsackie is a big virus that they find, Picornavirus, polyoma virus, and herpes were the four, I think, that they report seeing in evidence in the placenta on infants who behave unusually. And you can't explain why they have CNS problems later on.

And in their study --

86 Q Well -- excuse me. Let me know when you're done.

MR. BULLOCH: Let him finish.

A There's a lag.

In their study I think 46 percent of the babies they looked at the placentas, they found evidence of viral infections.

87 Q When this virus is a mechanism or the means of brain injury, how does it appear radiographically, if you know?

A I'm not in a position to specifically know.

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damaged today?

A I would have to review all his records later on. And I don't know what kind of brain damage he has, so it's hard to make that assessment.

But assuming he has brain damage -- and, again, it depends if it's motor or mental and what kind of motor deficiency it is. There's too many variables. But to me, if he has a brain problem, a viral infection or some sort of fetal inflammatory syndrome would be a possibility.

There also could be a metabolic subcomponent, but, again, we could not find it. We were concerned about the way he behaved on day seven and eight. It did not fit his clinical course.

89 Q Doctor, it sounds to me like at the moment you don't have an opinion in terms of probability as to the etiology of this child's brain damage, correct?

A I do not see -- I don't see -- I'm trying not to avoid your question. On the medical records that I have, I can see nothing horrendous that we did after we got him until he left that would account for brain damage.

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I do see evidence of a viral infection, as best one could assess. And if I had to guess, if he does have a brain problem, I would say most likely viral would be what I would say. There are -- there are other possibilities, like genetic and metabolic, but I would bet more for viral infection based on my records.

90 Q I hear you. But I want to know if you hold that opinion to a reasonable degree of medical probability that the cause of this child's brain injury today is viral rather than anything else.

MR. BULLOCH: Mike, I'm just wondering. Are you asking him if his opinion is, is the cause of Matthew's problem viral as opposed to these pneumothoraxes?

91 Q Okay. We'll start there.

Do you have an opinion as to which of the two entities, viral versus respiratory distress

syndrome and the bilateral pneumothorax that this child sustained, which of the two is more likely for the cause of this child's brain injury?

A Again, not knowing his brain injury, it's hard to tell. But viral would be higher on my list because the pneumos that he had were taken care of very quickly.

And as best I can tell from our records, blood pressures were stable, pulse is good. Gases before and after showed no evidence of metabolic acidosis. He had good urine output after the event, no BUN creatinine abnormalities. His question mark inappropriate ADH that occurred, occurred like six, seven days later, and that would not be attributed to an event, meaning the pneumothoraxes.

In other words, everything that happened around the pneumos and immediately after does not fit for any CNS damage. And also, neurologically he behaved -- he was irritable when we first picked him up. He did not change dramatically after those pneumos. His CNS status remained the same.

It's really hard to perceive those pneumos adding anything or contributing to his CNS problem.

92 Q You mentioned an ADH something. I didn't hear what you said.

A He probably had inappropriate ADH that occurred around September 1. In other words, his sodiums went down. And we responded to it by adding more sodium, restricting fluid, and putting him on the radiant warmer.

At that time he was getting a little bit puffy; he was less active as Accuchecks were elevated; his white counts were viral looking. His endotracheal tube, when we intubated him again around that time, had mononuclear cells. That all fit for maybe a viral-induced inappropriate ADH.

It would not fit for something that happened six, seven days earlier. Too far removed.

93 Q Going back to my question, as you sit here today, Doctor, do you have an opinion in terms of reasonable medical probability as to the etiology of this child's brain damage? If you don't have an opinion, that's fine, we can move on.

MR. BECKER: And what I need to know is -- and I'm sure John will do this -- if subsequently you look at records and you develop an opinion, then, John, you have to let me -- timely let me know.

A Assuming the child has brain damage, and I assume that's why we're here, I'd be betting for a viral syndrome.

94 Q When you say "betting," are you saying more likely than not?

A More likely than not, that would be the etiology. And then as subpossibilities -- again, this is without seeing the child now -- metabolic and genetic.
But I have lots of evidence, I think, for a viral syndrome of some type.

95 Q Doctor, I want you to assume that the head studies in this child reflect an ischemic injury.
Is an ischemic injury more consistent as to etiology RDS or viral?
MR. GOLDWASSER: Objection.
MR. BULLOCH: I'm going to object as well. I don't quite understand your question.
But go ahead.
MR. BECKER: John, if the doctor doesn't understand the question, he'll let me know.

96 Q I'm giving you a hypothetical, Doctor. And then I asked you a question.

A I'll try to answer it as best I can, and if I don't, you'll fire back a new question. If he had periventricular leukomalacia, that's associated with three things.

97 Q I didn't say -- excuse me, I did not say PVL.

A You said --
MR. BULLOCH: Let him finish.

A You said evidence of ischemia. You'll see where I'm going, I think.
There are three reasons why you get PVL, assuming he had that. Let's pretend he did.

98 Q Wait a minute. That's not my question.

A It's going to be your question, I think.
Ischemic injury to a brain causes, can cause, PVL. Does that help? If you have a baby who's shocky, especially a premature baby, one of the parts of the brain that does not get enough blood flow is around the ventricles. PVL, periventricle damage.
But there are two other etiologies for it as well besides ischemia or decreased blood flow to the brain. One is overventilating a baby. If you put a small baby on a respirator and overventilate them and drive their CO2s down, you can get the same damage.
And the other one is this fetal inflammatory syndrome, viral infections. People are beginning to see that a lot of that PVL, that damage around the ventricles that looks like it could be ischemic, that could be related to overventilating. Could also be from viral infections.

99 Q You said you looked at the MRI at Fairview --

A Definitely.

100 Q -- on this child's brain. Any abnormalities?

A There is something that I was concerned about, and that was around the ventricles there was some whiter areas that I wasn't sure whether or not that was early PVL or whether or not that was some just early maturation process.

Q What was the reason that you ordered a head study?
A He wasn't behaving normally. He was very -- he was floppier. This event that started happening around day six or seven when he got edematous and high Accucheck and he wasn't behaving right, we couldn't explain it. He was puffy and less active.
I also had some ultrasounds done much earlier on. Some of them I thought maybe the area around the ventricle was whiter than what

it should be, and that's really hard to call.
So based on that, based on his behavior, based on the fact we had a neurologist look at the child as well who recommended it, that's why we did it.
Q What was the date of your first ultrasound?
A I'll have to check.
Q And what was the reason that you performed it?
A Without even checking, one thing I would assume is a baby, early 35-weeker on a respirator, I would do an ultrasound on. It probably was done around day six or seven. It looks like it was done on day eight.
Wait.
Yes, day eight, on 8-31, which is typically when we do it on your premature babies that are sick on ventilators. At that time it said, "Normal ventricle size, no intracranial hemorrhage, normal anatomy." So at that time it looked friendly, normal.
Q Okay. You say that you typically do it on preemies. But why do you typically do it on preemies at that age of life?
A They have a higher chance of having hemorrhages. If a premature baby hemorrhages, half of them do

it on day one, 45 percent do it on day two and three, and about 5 percent do it from day three to day seven. So if you do a screening ultrasound on day seven, you should pick up most preemie hemorrhages.
Q Okay.
A We do it on day seven, others do it on day three and day 10.
Q What was your understanding of this child's gestational age at the time that you arrived at Fairview?
A I thought -- let me look at the chart. I thought he was about 35 weeks. Yes, I thought he was about 35 weeks, and that's based on exam, physical exam, not neurologic exam. Yes.
Q Going back to our discussion on head studies -- and I'm not talking about PVL, I'm talking about just the plain old ischemic pattern of brain injury. I'm not talking about PVL.
You appreciate that PVL when it appears is like scallops around the ventricles when it's truly PVL, a scalloplike appearance?
A It looks honeycombedlike sometimes. There's cystic PVL and there's noncystic, but most of the stuff that we see is cystic PVL, small holes

around the ventricles. Sometimes they're small and they're sometimes multiples and sometimes they're large and not as many, and it occurs right around the ventricular area.

Q All right. Assume that this child had brain injury, assume it's true that there is evidence of an ischemic brain injury. In other words, the origin is ischemic in nature -- assuming those two to be true, is it more likely than not that this child's brain injury is from RDS rather than from any type of viral infection?

MR. BULLOCH: Objection.

MR. GOLDWASSER: Objection.

A I'm not sure I understand it. Most of the time when we see events from shocky episodes or, as you say, from ischemic episodes, if it happens now, you won't see the PVL typically from our scans until a month. So if we have a baby who, say, at two weeks has evidence of PVL, that means he had an ischemic episode two weeks earlier in utero, or it's related to infection.

I don't know if that answers the question.

Q It doesn't. What I'm going to ask you to do, Doctor, is --

MR. BECKER: Chuck, I'm going to ask you if you could go back and reread that question to him, please.

(The record was read.)

MR. BULLOCH: Objection.

Go ahead and answer.

A I don't understand the question.

Assuming there's an ischemic injury -- well, if it's ischemic, then it wouldn't be from infections. Infection is a different mechanism. It has to do with something called cytokines that are released by the infection that stick to that part of the brain, we think, and causes necrosis or damage or cytolysis.

Q So it's your opinion that --

A I don't understand the question.

What you're maybe saying is if the infant had some terrible --

MR. BULLOCH: Well, Doctor, wait a minute. Don't guess at what he's asking you. Make him ask you a different question. If you don't understand the question, you don't understand it.

A I don't understand the medical question, the question.

Radiographically, if there's evidence that there was an ischemic injury to this child's brain, radiographically is that more consistent with RDS than something of viral origin?

MR. BULLOCH: Objection.

MR. GOLDWASSER: Objection.

A Radiographically you cannot tell if it's ischemic or viral infection. They -- they'll look the same. They'll look the same, pretty much.

Q Would you defer that issue to a

neuroradiologist?
A It depends if he's good. There are also neuroradiologists that are not good.
113 Q Was Matthew stable by the time he was transported back to Fairview?
A Yes.
114 Q Within the first few hours after Matthew had arrived at Fairview, what was your working diagnosis?
A We mentioned this. Respiratory distress syndrome, rule out sepsis. That was our main diagnosis; that was the working diagnosis.

severe?
A I would say he's mild to moderate. In the chart I wrote "moderate" sometimes, and I wrote "mild." So I would say mild to moderate would fit. It was definitely not severe.
116 Q And how does one distinguish mild, moderate, or severe RDS?
A Somewhat by how much oxygen the child is requiring and what kind of settings he's requiring, and on the x-ray findings.
After he was intubated, he had good expansion, and this haziness of his lungs, or reticular granulation, was mild to moderate. So we assessed him based on the x-ray and how he's behaving as a large baby with mild to moderate hyaline membrane disease, or respiratory distress syndrome.
117 Q Is there any correlation between what you see radiographically and the clinical severity of RDS?
A Sometimes there is. In large babies it's sometimes not a very good assessment. Sometimes the x-ray findings in large babies don't look as severe as the infant turns out to be. Like an atypical respiratory distress syndrome on large

babies.
118 Q You treat the patient; you don't treat the x-ray, right?
A Sometimes we treat the x-ray today. Not so much in '99. In other words, there are babies that we would sometimes give surfactant to today based on an x-ray, even though their findings are not all that severe.
But back then I would say we treat the baby, not the x-ray, how he's behaving.
You have to remember another thing too. This is a 35-weeker, five-pound baby. We had no double-blind studies back then on use of surfactant in those babies. There is no evidence for us to base -- science on for us to give this infant Survanta. We'd be going outside of the studies in 1999.
119 Q Well, was there anything published in 1999 that said that you don't give babies of either this gestational age or this birth weight surfactant?
A Are you saying don't do it?
120 Q Yeah, don't do it.
A There are -- there is -- there are recommendations of when to use it, and they do

not include babies that are five pounds,

35 weeks.

Q. Well, do the --

A. It's not a benign process. We were worried in '99 a lot about pulmonary hemorrhage. So you did not willy-nilly just give surfactant to a baby who has a breathing problem back then because we were worried about complications from it, especially in babies that we perceived as being stable.

And there were no studies to support our using it. And that is a little bit scary for a person in a Level 3 community hospital.

Q. What's the rate of complication of hemorrhage from surfactant? What was the known rate of complication of administration --

A. Of small babies?

Q. -- of surfactants to a 35-weeker? What was the rate of complication of hemorrhage?

A. We wouldn't know that because there were no studies that pertained to babies that are 35 weeks. If you ask me the percentage of babies between 600 grams and 1750 grams, then I would say it's 1 percent.

A. We don't know. We don't know. I don't know and I don't think anyone else does.

Q. The gases that you drew at Parma, the FiO2 was 51 percent, the pH 7.29, CO2 was 46, and the PaO2 was 72.

Was that relatively reassuring, that gas?

A. Reassuring? I mean, he was perceived by me at that time as being stable.

Q. Okay.

A. Then I could take him back in a hood, gently, and follow him when I get back to Fairview. It's also probably -- I mean, those are the worst gases that we ever saw. They weren't that bad. The gases at Fairview always were above 7.30.

But seeing that the original gas was 7.25 with a CO2 of 40, and then another gas that we did thereafter at Parma was 7.29 and a CO2 of 46 with a PO2 of 72, that made me happier that this child was stable and maybe even getting better.

Q. You chose not to intubate Matthew at Parma. Why did you make that decision?

A. Again, this is back in '99. We generally used more than 60 percent as a cutoff for trying either nasal CPAP or intubating in our hospital

in 1999.

Q. Did you use a ratio of P, small a, O2 versus P, large A, O2 to make a determination of when to intubate?

A. I think you're talking about AO2 differences.

Q. Right.

A. No. Basically we look at how much O2 we need.

Q. I didn't hear you.

A. We basically use -- another index you can do as well to follow babies on ventilators is an oxygenation index. But generally, in terms of

intubating, we used how much O2 you needed, and we kept the infants' sats above 90 at that time.

In other words, how much oxygen does he need to keep his right-hand pulse oximeter saturation above 90? And if that were over 60 percent, or we thought it was going to be happening pretty soon, we'd go ahead and intubate or try nasal CPA, depending on how fast the infant was progressing.

He went from 35 at Parma to 51. He sat at our place, at Fairview, when he was admitted, around 50, 55 percent, then he started going up to 60 percent pretty quickly, and across that number. And that's why I think Dr. Saxena

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intubated. We had an understanding that when he crossed 60 percent, tube him.

131 Q And that was what you expected at Fairview of your pediatric house doctor, intubate once his oxygen demands exceeded 60 percent to maintain a pulse ox of greater than 90 percent?

A Yes.

132 Q When one has a respiratory distress syndrome, is there a normal course? Does it come on initially slow, and then after day two or three it gets much worse? Is there a regular or anticipated course of RDS?

A If it's purely respiratory distress syndrome, most of those infants historically, the way we did it in '99, would get worse and peak out at about 72 hours. And at 72 hours they start getting better.

There were infants who will require 50 percent oxygen who we thought were respiratory distress syndrome who just stayed at 50 percent oxygen and never went up and just got better over several days, and those infants may not be pure respiratory distress syndrome.

So when Matthew was picked up, he was retracting, he was grunting, he was on

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50 percent oxygen. His pulse oxes were reading good. His gases were improving in terms of metabolic acidosis, and there was a chance he was going to sneak by and not need a ventilator. And that would have been ideal.

But once he started crossing 60 percent, we figured he was only going to get worse and worse, and that's why we intubated him.

In other words, there are babies like Matthew, when we saw them at 50 percent, who may not have needed to be intubated. They could have sat at 50 percent, especially if there's an element of pulmonary hypertension, especially if there's a chance that they have a bacterial infection, or even a viral infection. He could have leveled off and not required intubation.

133 Q Apparently the first gas drawn at Fairview shows his FiO2 at 66 percent?

A Let me see. If the nursing flow sheets where all the gases are listed, because -- on the initial --

MR. BULLOCH: Mike, do you

want to point where you're getting that?
A Yes, I want to look.
The nursing notes when he got admitted

have different O2s. The gas was not done maybe
the minute he walked through the door.
Let me show you. Here. This is on
page 84. I think it's -- the times on mine are
cut off, but on page 48, the one that has a
circle in it --
134 Q Yes.
A -- it's a nursing note. It says 1940. I think
it says 1940. I see a 9:40. Heart rate of 138;
color, pink; FiO2, 60, or .60; pulse oximeter,
98. Then there's another time which I don't see
right underneath that with a heart rate of 134.
Are you on the same page? I don't know.
Are you? I can hold it up. It's not going to
help you.
Then the FiO2 is 57 percent.
Then at, I think, 1955 it says 58 percent.
Then at 1956 it says 64 percent. It was
bouncing around, and somewhere between 57 and 64
percent.
When the gas was done, you may have been
correct. If it said 60-some or 66 percent, that
was probably done a little bit later.

military time, 8 p.m., showing the FiO2 at 66
percent.
Assuming that's true --
A Right.
137 Q -- why wasn't this child intubated at that time?
A You don't intubate them -- you don't intubate
him the minute he crosses 60. Do you follow?
It's not like he goes to 62, you intubate him,
because they bounce around. When you think he's
going to cross it and you're sure about it, then
we would intubate.
It's not like at 61 percent the tube goes
in his throat. It happens sometime thereafter,
and it happened fairly quickly thereafter.
I think a better way of saying it is, when
it's consistently above 60 percent, not like
instantaneously, because you see how he bounces
around. You have to look at the trend. But
when it's felt he was staying above 60 percent,
that's when he was intubated.
138 Q Is it likely that you were contacted prior to
the intubation?
A I'm very, very certain that I spoke to
Dr. Saxena and I gave him instructions that if

he required more than 60 percent, intubate him.
Once he was intubated, the nurses would have
called me or Dr. Saxena would have called me.
139 Q You have already given me a sense of what your
answer is. But let's ask you specifically at
that point.
At the time of intubation why didn't you
administer surfactant therapy?
A You're right. I anticipated it.
Lots of reasons. One is on the initial

x-ray from Parma he had that hyperlucent area, and that means not homogeneous lung disease. And in '99 we were scared to administer surfactant to babies that had big cysts or who had nonhomogeneous lung disease, especially if the infant was considered as being stable.

I also considered the infant relatively stable. He was intubated at eight hours of age. His x-ray following intubation was mild to moderate hyaline membrane, but was very well expanded, and we figured that it wasn't that severe of hyaline membrane.

And the other reason would be -- really is that in 1999 there were no double-blind, controlled studies using Survanta in babies other than about 600 grams to 1350 or 1750 grams. There were no studies on Survanta on babies that were this big.

And for us to give it means we had to have a really good reason to do it, because we were going outside of controlled studies. And we didn't like to do that, especially in a community hospital.

You could do that more easily if you're in a research hospital.

140 Q. Are you saying, Doctor, that in 1999 in this country, the standard of care was not to administer surfactant therapy in moderate RDS after a child has been intubated?

A. To babies that are 35 weeks and five pounds, correct, I am saying that.

141 Q. And can you point me to any literature that suggests that there should be a cutoff by babies' age or weight relative to the administration of surfactant?

MR. BULLOCH: Objection. I think he has answered that.

Go ahead.

A. If the studies are between 600 grams and 1350, primarily, and there were a few outliers up to 1750 grams, and those infants were probably around 23 weeks to -- or 24 weeks maybe to around 32 weeks, and that's where all the studies were done, and you want to use that surfactant on infants outside those studies and something bad happens, like a pulmonary hemorrhage, what would you do to me then?

Would you come after me saying I'm using it outside of the studies and I shouldn't have been using it because I had this terrible side effect? I bet you would.

142 Q. I'll bet you think that too.

Doctor, why did you ultimately give surfactant?

A. The infant was sicker at that time and was not as stable. Initially he was stable and we felt that he would hold his own until 72 hours and start getting better. Once he blew pneumos, or blew pneumos and required higher pressures in ventilator settings and higher tidal pressures, we figured we'd try it. But it didn't help, but

we tried it.

Q. Doctor, did you go to the mom at any time prior to when you ultimately made the decision to administer surfactant? Did you go to the mom and say, "Look. Your child may need surfactant therapy, but because of his age, because of his weight, he" -- "it could be real dangerous. And it's a tough call, but it may help his lungs. He's having problems here"?

Did you do that, Doctor?

A. It may have been --

Q. Yes or no, Doctor. Did you do that?

A. At that moment, no.

Q. Did you ever go to the mom and say, "I'm withholding surfactant therapy for some medical reasons"? Did you ever tell the mom that?

A. That may have been told to her on the following morning when we spoke to her again. Because I spoke to her when we picked up the baby.

And then when the following morning occurred and we reviewed everything again and thought about it and we spoke to the mother, there's a very high chance I said, "This is not a child we'd give surfactant to. If he was much smaller, we would consider it. We would be doing it, but not in a baby who is this large."

There's a very high chance that was told to the mother the following morning.

specifically saying that to the mom?

A. No.

Q. Did you ever chart that, the reason you're withholding surfactant therapy is because of your concern of this child's weight and age is beyond the studies --

A. No.

Q. -- or that you were concerned about a complication? Did you ever chart that such is the reason you were withholding surfactant therapy?

A. No. No.

Q. The gases done after intubation reflect the FiO2 as 80 percent, the pH 7.36, the CO2 is 37, and the PaO2, 61.

What do you draw from those numbers postintubation?

A. That the child has no significant metabolic acidosis and that he has an adequate PO2.

Q. In your mind, Doctor, at any time at Fairview, did his respiratory distress syndrome become severe?

A. Again, whether or not his respiratory distress syndrome or respiratory distress syndrome with some added component, his breathing problem,

became more severe after he blew a pneumo, required chest tubes, required higher pressures to inflate him, keep his PO2 or saturation adequate, that's why we gave the surfactant at that time.

As I mentioned before, there are studies on large -- at least a study on large babies

getting surfactant for things like meconium aspiration, pneumonia, pulmonary hypertension. And those studies indicate that you only decrease the incidence of ECMO.

And those studies say giving it late, meaning not right at birth or at six hours of age, is maybe a good thing to try on infants because you can perhaps prevent the need for ECMO, which is partial lung bypass, and that the side effects from doing it, other than the occasional pulmonary hemorrhage, are fairly benign. And there were no change in pneumothoraxes after you gave it. In other words, there was no improvement in terms of air traps after you give it.

So it probably was a fairly okay thing to try on a large baby like this who had some sort of breathing problem in terms of safety. But we

wouldn't do it on everybody. We would do it on infants that were sicker, and this infant was perceived at that time to be sicker.

MR. BECKER: Chuck, would you read the last couple things he said.

(The record was read.)

151 Q The blood gases at 6 a.m. on the 25th reflected a FiO2 of 85 percent, pH 7.40, CO2 of 33, and a PAO2 of 33.

What is the significance of those numbers? This is 6 a.m. on the 25th.

A Yes. The infant, some of the infants, when you intubate get dramatically better and open up and go down. You don't know that until many hours.

So many hours passed and he's basically similar. He's the same, you know, 80 percent, 75 percent, 85 percent. So we considered him stable at that time. Blood pressures were stable. He was not -- and the pressures on the ventilator were relatively the same. So we considered him stable at that point.

labs are reported?

A I will tell you why. Because they see a PO2 of -- can you give me the gas? Because I think that's wrong. But this says a PO2 of 33.

There are a few reasons. That gas may have been a capillary gas too. It may not have been an arterial gas.

Because the infant had a sodium that was a little bit low, and we frequently, when you pull out blood from a line, would get a low sodium because it's diluted. And we would sometimes do a capillary gas at that time.

Let's see what it's labeled. Let's see. It doesn't say what it is, but it's very possible that was a capillary gas so we could check the infant's sodium. Because when you do a heel stick, you get the blood right from the heel; there's no dilution. And it's very possible that's why it was done.

More important than that PO2 being 33 is the pH and PCO2, because for the PCO2s we were using saturation, the continuous pulse oximeter

reading. So what I would like to know is what was the infant's pulse oximeter at 6:00 in the morning that the nursing notes show. That's more important than that one, again, because it may be a capillary sample.

And the other reason is you have a saturation that you're monitoring continuously that you're determining how much O2 he needs, not the blood gas. The blood gas is primarily for pH and PCO2. And at 6:00 in the morning it looks like his sat was reading 92.

154 Q Well, what is more indicative of a true PO2, gases or pulse ox?

A We go by the continuous number, primarily the pulse ox. And actually, I lied. It was 94. The sat was 94. And previously it was ranging, anywhere from like 1:00 or from midnight -- from midnight down to, let's say, 6:00, the pulse oxes range from 98 to 94, and there are several 94s. There's also a 94 at 3:00 in the morning.

We determined how much oxygen to give him on the ventilator by the pulse ox primarily, because that's sustained and that's being done all the time, not intermittently. The main reason for those --

PCO2.

156 Q Would it be concerning to you that if there was a trend apparent where there was -- the FiO2 requirement was trending higher, and if PO2 was trending lower, would that be concerning to you?

A It would be concerning to me.

157 Q Why?

A If the FiO2 is going higher and the sats are going lower?

158 Q Yes.

A It means he's getting worse, or it may mean that he has a pneumothorax.

159 Q Would that cause a patient, in your mind, to be more unstable if after he was ventilated, he was showing a worsening O2 by gases?

A By gases?

160 Q Yes.

A It was one gas. I think the next one was probably okay. I mean, it's one gas. We're looking at the whole baby. I think at noon he has a PO2 of 64 and nothing was done differently on the ventilator at that time. It does go up and down. Plus, that gas may have been a capillary gas for the reason I mentioned to you before.

We were checking the electrolytes again at that time, and wanted to make sure we did not get a diluted from the UAC, from the arterial line.

161 Q Going back to the administration of surfactant in a 35-weeker. You feel, Doctor, that there was not an established, recognized indication for the administration of surfactant to a 35-weeker with RDS who is assisted with

mechanical ventilation?
A Who weighs five pounds, one ounce in 1999, correct.
162 Q Does surfactant improve oxygenation and improve ventilation in premature infants with RDS?
A Yes.
163 Q And that's true whether you're talking about a three-pounder, a four-pounder, or a five-pounder?
A Are you asking me what I believe? In 1999 we had no studies to tell us that. But do I think it does? Today I definitely do. Back then I think it did as well.
164 Q Does surfactant reduce the rate of pneumothoraces and pulmonary interstitial emphysema in premature infants with RDS?

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A In babies between 600 grams and about 1750, which is the data that we had in 1999, that is correct. In babies that are more than 1750, we had no data to suggest that, using Survanta. And we also have no data to date that says it improves CNS status.
165 Q I understand that it's necessary for the child to be intubated to administer surfactant.
A Correct.
166 Q How many doses are needed of surfactant for it to become effective, and what time period in terms of hours does there need to be between each dose?
A It depends on which surfactant you're giving. If you're giving a natural surfactant, like this was Survanta, which has protein, I think, B and C in there, it's a natural surfactant, you see the improvement usually within 15 or 20 minutes.
And you have to be wary of that because you have to start lowering the respirator settings. If you use something like Exosurf, which most people don't use anymore, it takes quite a while before you see the effect.
The dosing depends on what you're using. If you use Exosurf, you maybe only give one dose

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and not get near the second dose. If you use Survanta, some people give it every six hours, some people give it every 12 hours. Some people in '99 gave one dose and saw how the infant behaved and then dosed accordingly. It is very variable, especially in 1999.
167 Q Looking retrospectively, Doctor, do you think it's likely that had there been earlier administration of surfactant that it could have possibly prevented the development of his bilateral pneumothoraces?
A Thoraxes?
168 Q Yes.
A Pneumothoraxes?
169 Q Yes.
A He had a hyperlucent area on his x-ray at Parma, which means that he had an area of his lung that was hyperinflated. That may have -- that may have predisposed him to developing pneumothoraxes. In other words, it may have

just have been hyaline membrane on a ventilator.
On the other hand, he was a premature baby on a ventilator and they have higher chances of getting air traps. If I gave him surfactant, it may have cut down the incidence of pneumothoraxes. But --

Q That's all I asked you.
A But it was not the standard of care in '99.
Also, in this particular baby, when we gave it, it did not make him better. So had I given it earlier, I don't know if it would have made him better anyway.

Q How many doses did you give him?
A One dose. But --

Q Did you ever give him a second -- excuse me.
A No. We gave him one dose.

Q You gave him one dose. And it's your opinion it didn't make him any better?
A It did not make him any better.

Q Was it recognized in the field of neonatology in August of 1999 that moderate to severe RDS, if severe enough to cause pneumothorax or bilateral pneumothoraxes, could lead to ischemic brain injury?
A If you have a pneumothorax that is severe and you ignore it, yeah, it can cause brain damage. It can cause decreased cardiac output. But if you pick up when it's not severe and you pick it up quickly, it shouldn't.
And that's probably why in the studies they give surfactants to babies. One group gets it, one group doesn't. They have not been able to show any difference in brain problems subsequently.
The studies to date don't show any improvement in brain function on babies who do get surfactant versus those who don't. They do show less air traps, they do show less death in the smaller babies.

Q I didn't hear the end of that.
A They do show less death in the smaller babies. In the larger babies, like the 14-, 1,500-grammers, there is no difference in mortality. In all babies there's no difference in brain problems in the babies who get it. That's today's data as well.

Q All right. Let's see if we can agree on this: that it was full-blown in the field of neonatology in 1999 that pneumothoraxes, or thoraces, if unaddressed or untreated, can cause ischemic brain injury --
MR. BULLOCH: Objection.

Q -- in a neonate.
A It was known probably in 1875, I guess. I mean, if you don't treat them and if they're severe.
There are pneumothoraxes that we sometimes don't drain with chest tubes if they're mild and not causing any cardiac compromise.
If you have a child on a ventilator like Matthew and the sats are dropping and it

transilluminates by our high-power light and you're concerned that that pneumo is obviously causing his ability to oxygenate, you're going to drain it.

If you did not drain it and then the blood pressure starts going down, the heart rate starts going down, I would have concern about whether or not we caused any damage. If we did not drain it and he developed a metabolic acidosis, that could be a sign that he's not giving enough oxygen to his body and that also could affect brain.

We didn't have that with Matthew. We had stable blood pressures, good blood gases and good urine output and same neurological findings after the event.

178 Q It seems to me that you are saying that one needs acidosis, evidence of acidosis, to know whether or not the pneumothoraces could be responsible for an ischemic brain injury.

Is that what you're saying?

A It's one of many things, because if you don't give adequate oxygen to your body, your body starts making acids. So having no metabolic acidosis, it's really hard to understand how he had a period of lack of oxygen delivery.

And when you have lack of oxygen delivery and develop an acidosis, it's not like it goes away in three minutes, it hangs around there for a while.

179 Q Okay. Let me ask you this: Do you appreciate that with an ischemic process you will less likely have an acidotic situation as compared to a hypoxic situation in a newborn?

A No. I mean, it's all degree. When you're ischemic it means you don't have enough blood flow delivering stuff to your body. That stuff is oxygen and glucose. So if you're ischemic, that tells me you're not pumping enough blood to the body, that means you're not delivering oxygen. They go hand in hand.

To have ischemia without delivering -- to have an ischemic part of your body and you're delivering perfectly normal oxygen doesn't compute, doesn't fit. If you're ischemic, you're not delivering enough blood. Blood carries oxygen.

180 Q In the general concept of an asphyxiated newborn, when you're talking about the child was hypoxic in utero, you would expect to see evidence of acidosis at birth, correct?

A Correct.

181 Q However, if there was a sudden ischemic process to the newborn, you wouldn't necessarily see acidosis?

MR. BULLOCH: Objection. I'm not sure, when did this happen? When did this --

THE WITNESS: I think it's a hypothetical.

MR. BULLOCH: Okay. Go ahead

if you can answer.
THE WITNESS: I don't know if I can.
MR. BULLOCH: Then don't answer it. Ask him to ask you another question.
A Ischemia means lack of blood flow. If you don't have blood flow, you don't have glucose, you don't have oxygen going there. You're also not carrying away some of the evil metabolites.

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It's not healthy to a cell.
And if you're ischemic, usually you'll be developing cellular and eventually systematic acidosis.
182 Q Is it safe for me to assume that prior to Matthew Wagoner, you had never administered surfactant to a 35-weeker?
A No. I probably did. I probably did.
183 Q Do you think it's likely that you administered surfactant to a neonate that weighed five pounds prior to Matthew Wagoner?
A It depends upon how severe the infant was. I can't -- I don't have all my records here.
The odds are very high that with the number of babies that we saw that I probably administered surfactant to babies with meconium staining, pulmonary hypertension, or pneumonia. These are all babies, and probably large babies similar to Matthew, that were having a breathing problem.
But I would not be giving it to them unless it was real severe. I'd give them a trial to see how well they behaved on conventional respirators and conventional settings.

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you have ever administered surfactant for RDS to?
MR. BULLOCH: Objection.
Doctor, I'm going to ask you not to answer that unless you have a good idea. I don't want you to guess.
A It's not a guess, I mean. We have babies that are meconium, meconium hypertension, that may have been 41, 42 weeks' gestation, and we could have very possibly given surfactant to that type of baby. But we would not do it right off the bat; we would try to do conventional ventilation before.
185 Q At the time that you administered surfactant to this child, did you tell the family that it's unproven whether or not it's going to work and there may be some harmful effects?
MR. BULLOCH: Asked and answered.
A At the time that it was done, I did not -- I'm sure I did not, because it was late at night and it was happening rather quickly.
The following morning I would have reviewed with the mother what happened, and the

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father, because I spoke with them pretty much every day.

Q Can you estimate for me how long Matthew had this right pneumothorax prior to the placement of the chest tube?
A I can give you a guess.
Q What's your best estimate?
A Let me find the page. I don't want to be repeating things.
I know at 1740 there was a drop of sat, they transilluminated at that time and everything was negative.
However, when you look at the saturations after 1740, yes, at 1700, 1800 -- this is on the 25th? Following morning, yeah -- you see that his FiO2 went up to a hundred percent. Sats are okay. The respirator settings are all the same, pulse, blood pressure is okay.
So he could have had a small pneumo at that time, but it wasn't affecting cardiac because -- because his pulse is picking up and his blood pressure is good.
He may have had the beginning of it at that point but, obviously, it didn't cause a problem until about 1845, when his sats went

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down to 70 and they tried to bag him. And he came up, actually, with bagging, which means higher pressure. But at that time the transillumination was positive and it was negative. So I assume it was getting bigger.
So the answer to your question is, sometime around 1700, 1800, he may have had the early signs of it, maybe, but it wasn't bothersome until 1800, because that's when he was transillumination positive.
Q And that was on the right side?
A On the right side.
Q And does it reflect whether or not they bothered to do transillumination on the left side?
A They would have done both sides. It was routine. They did it -- at 1740 it says "bilateral" -- "transilluminate bilateral. Right positive. Left negative." They would have done both.
Again, they checked it later. Again, they were doing it pretty much continuously, because, again, it transilluminated positive around 2225.
And because of that, even though he was relatively stable and the sats are okay, they put a chest tube on the left side. They were

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waiting for it, because they also knew there was a pneumomediastinum on the x-ray that was done after the first chest tube.
Q Would you repeat that, please? They were waiting for what?
A When the first chest tube was put in, they -- before it was put in they diagnosed with transillumination. They did not get an x-ray, because it takes too long and the baby had sats that were low and you wanted to fix that. So they put the chest tube in, sats came up, they got an x-ray.
When the x-ray was obtained, the right

pneumo was pretty much gone or wasn't there. There was a pneumomediastinum, and there was no obvious pneumothorax on the left.

But with a substantial pneumomediastinum you have to worry about new air traps developing, just like the pneumothorax on the right. You have to worry about other pneumos. So they kept transilluminating.

And the next one they picked up before he had symptoms, just because he transilluminated positive on the left. That's why the second chest tube was put in.

Then there was a follow-up x-ray which showed both pneumos are pretty much okay, but there's a persistent pneumomediastinum.

191 Q Wasn't there a radiology report describing bilateral pneumothorax?

A There was. And I'm not so sure he's correct or she's correct.

192 Q Okay. You take issue with --

A There may have been -- you know, when you have a pneumomediastinum that large, it's sometimes hard to distinguish as a pneumothorax or a pneumomediastinum because they overlap. The black area overlaps.

193 Q Assuming that that was true, that there was bilateral pneumothorax at the time of this chest film on the 25th at roughly 7:26 p.m., this child's left pneumothorax went unaddressed for roughly four hours; is that correct?

A I think your -- I'm confused now. Basically --

194 Q I'm asking you to assume, Doctor --

A The question --

195 Q Listen to me. I'm asking you to assume that the radiology report is accurate and it reflects bilateral pneumothorax done on 8-25 at 7:26 p.m.

A It did not go unaddressed. They were constantly monitoring his blood pressure, his gases, his saturation, and they're transilluminating him.

So if transillumination is negative and the saturations are okay and the blood pressure is okay, you're not necessarily going to put a chest tube in. It's either a very small pneumo or a nonexistent pneumo. But you worry about it.

So the minute you get something that allows you to put a chest tube in, like transillumination positive, then you put it in.

196 Q Explain to me what the setup was at Fairview in '99 relative to a chest film on a neonate. Who took it, who read it, and how was that communicated to you if this was other than during working hours?

A We rely mostly on the nurse -- on the house physician and ourselves to read those x-rays. The reason for that is radiology, although it may have been available all the time, would not necessarily read them instantaneously, and we had to see those x-rays.

Neonatologists and the house physicians who put chest tubes in are more familiar with

tube position and chest tube position and
getting their questions answered by looking at the films themselves. When those x-rays are taken they are brought up for us to review. We reviewed them.

Then they are sent out and the radiologist was like quality control and would review them, and if there was something abnormal would frequently give us a call. But we relied on us looking at them, neonatologists and the house physician.

Q Right. But --

A I wouldn't want to wait -- I wouldn't want to wait for the official reading. It could take an hour or two hours.

Q Okay. I hear you. I just want to get this clarified.

Was there, then, a radiologist in house during off hours in '99?

A I don't know. The way we could tell is by looking at the report and see when he read it.

Q Okay. And did you have the capability by way of this technology to have the film sent to your home so you could visualize it, have the image?

A No.

MR. GOLDWASSER: Off the record.

(Discussion held off the record.)

(Thereupon, Mr. Goldwasser and Mr. Torgerson left the deposition.)

BY MR. BECKER:

Q When surfactant was ultimately administered to Matthew, did he in fact have any adverse reactions?

A He may have blown another pneumo after it. Well, he did blow a pneumo after it, actually. It got worse. Now it's transilluminated positive where it wasn't transilluminated positive prior. So I don't think he liked it.

MR. BULLOCH: Did he answer the question?

A I answered. I'm just looking for --

Q Any other complications?

A Well, I'm going to look for the actual flow sheet here. After he got it he required higher pressures, higher FiO2. But let me look on the next page. I've got to find it.

Yes, he required higher FiO2 and higher pressures, and it wasn't until -- actually, higher pressures. He did not like it. Did it make him worse? I don't know. It may have.

And that sometimes happens with some of the infants.

Q Doctor, I want to talk a little bit about medical negligence claims against you alleging medical negligence.

Any of them involve or allege --

MR. BECKER: And, John, you have a continuing objection to this.

Q -- inappropriate management of RDS?

A I don't think I have --

MR. BULLOCH: Just show a continuing objection.
But go ahead and answer.
A I don't think -- I don't have any cases against me.
205 16 Q In the past, ever?
A In the past?
206 18 Q Ever.
A I was only sued once and that had nothing to do with this. It was 20-some years ago.
207 21 Q So the answer to my question would be no?
A No.
208 23 Q Okay. Have you ever acted as an expert in a medical-legal case?
A Yes.

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expert, did it involve the subject matter of RDS, surfactant therapy, anything along those lines?
A I don't think so. I don't think so.
210 6 Q What was the reason you left Fairview General Hospital?
MR. BULLOCH: Objection.
A Hospital politics.
211 10 Q Please be more specific.
MR. BULLOCH: Well, I'm going to instruct him to not answer anything that might be the subject of any type of agreement that you entered into -- and I don't know that you did -- or anything that would be protected by attorney-client privilege.
MR. BECKER: Well, John, I have an absolute right to inquire as to why he left his institution, where he had been at for a number of years, and moved to Arizona. I have an absolute right to inquire into that. If you're going to direct him not to answer, then we're going to go to the court for it.
MR. BULLOCH: I'm not instructing him not to answer. I'm instructing

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him not to answer anything that might be subject to attorney-client privilege. And I guess that's it.
A I think the best way to answer that is the Cleveland Clinic acquired Fairview Hospital and they had certain aims of what they wished me to do which I had no desires to do. Some of which was closing down our unit, basically, in terms of sending babies out to the main mother ship and basically put down the unit that we worked hard, nursing and I worked hard, to build. And there were constraints that were being put on me which were not agreeable.
MR. BECKER: Off the record.
(Off the record.)
BY MR. BECKER:
212 17 Q Just a couple more questions for you, Doctor. In general, relative to your concern about adverse reactions with the administration of surfactant, are you more concerned in smaller, more premature babies than in larger, more mature babies?

A I can't say that because we don't have those great studies about big babies and little babies and side effects.

A I would assume they're similar, but I don't know.

Q And speaking about double-blind studies, have there ever been double-blind studies relative to surfactant administration?

A Yes. Lots of them.

Q Okay.

A At least -- there's lots of them.

Q And you're saying there's never been a double-blind study of children this large or of this birth weight or this gestational age?

MR. BULLOCH: Objection. I think he has answered this.

But go ahead.

A Using Survanta and other natural surfactants, correct.

MR. BULLOCH: Except, just to clarify --

A For --

MR. BULLOCH: He didn't ask that.

Q Why do you think they have not done double-blind studies with babies this large?

A It may be a factor of numbers, and it's the same reason why we give, like, steroids to mothers. We use it between 24 and 34 weeks' gestation in utero. That's where the larger number of those infants lie, and that's where they've shown good effect, and that's where most of the hyaline membrane is.

It's really hard to get pure hyaline membrane disease, 35-weekers, five-pounders, get a lot of them in one study. You'd have to have a humongous study to do that. That may be the reason.

But the other reason is most hyaline membrane is in smaller babies.

MR. BECKER: That's it, Doctor. Thank you for your time.

MR. BULLOCH: We will not waive signature. I'd like to have the doctor take a look at this transcript before he is given an opportunity to sign it.

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

I, Charles A. Cady, a Notary Public within and for the State of Ohio, duly commissioned and qualified, do hereby certify that the within-named witness, Lawrence D. Lilien, M.D., was first duly sworn to testify the truth, the whole truth, and nothing but the truth in the

cause aforesaid; that the testimony then given by him was by me reduced to stenotypy in the presence of said witness, afterwards transcribed on a computer/printer, and that the foregoing is a true and correct transcript of the testimony so given by him, as aforesaid.

I do further certify that this deposition was taken at the time and place in the foregoing caption specified. I do further certify that I am not a relative, counsel, or attorney of either party, or otherwise interested in the event of this action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Cleveland, Ohio, on this day of April, 2004.

Charles A. Cady, Notary Public
within and for the State of Ohio
My Commission expires November 3, 2004.

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THE STATE OF )
) SS:
COUNTY OF )

Before me, a Notary Public in and for said state and county, personally appeared the above-named Lawrence D. Lilien, M.D., who acknowledged that he did sign the foregoing transcript and that the same is a true and correct transcript of the testimony so given.

IN TESTIMONY WHEREOF, I have hereunto affixed my name and official seal at this day of , 2004.

LAWRENCE LILIEN

Notary Public

My Commission expires: