IN THE COURT OF COMMON PLEAS

CUYAHOGA COUNTY, OHIO

MATTHEW CHASE WAGONER, ETC., ET AL

V.

MARK R. EVAN, M.D., ET AL

DEPOSITION OF ROBERT A. DARNALL, M.D., taken at Wilder, Vermont, on July 27, 2006.

APPEARANCES:

Michael F. Becker, Esquire
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134 Middle Avenue
Elyria, Ohio, 44035-5623, on behalf of the Plaintiff, Matthew Chase Wagoner, et al.

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INDEX

EXHIBITS

ROBERT A. DARNALL, M.D., DULYSWORN?

DIRECT EXAMINATION

BY MR. BECKER:

Q Good morning, Doctor.

A Good morning.

Q Would you state your full name for me, please, and spell your last name?

A Robert A. Darnall. D A R N A L L.

Q Doctor, what did you bring with you today by way of your file?

A Let's see. I brought my correspondence with Mr. Bulloch. I brought expert letters for the Plaintiff from Marcus Hermansen, Jonathan Cronin, Raymond Redline, Daniel Adler and Barry Pressman; and then letters for the defense from Carlos Sivit, Dr. Nelson, Janice Lage, or Laga, I'm not sure, Lage, how she pronounces her name. Ricardo Rodriguez, Harlan Giles, Robert Clancy, Mike Jacobstein, and my own. And I have depositions from Jonathan Cronin, Daniel Adler and Marcus Hermansen. I also have the reports for Fairview Hospital and the three x-rays taken at Fairview.

Q Do you have both volumes of Dr. Hermansen's

discovery deposition?
A Yes, sir.
Q And have you read them?
A Yes.
Q You didn't mention anything about your notes on this case. Did you generate any notes as a result of your review?
A I have a spreadsheet that I put together that just outlines the things happened during the course at Fairview and between the time of about 4 o'clock on the 25th to 8 o'clock on the morning of the 26th.

MR. BECKER: Cynthia, what I'd like to do is mark the correspondence with Mr. Bulloch as well as the spreadsheet as Plaintiff's Exhibit --

MR. BULLOCH: Exhibit 2. You want to do all the correspondence as one and the spreadsheet as 2?

MR. BECKER: Right. Correspondence is 1 A and 1 B, 1 C, whatever.

MR. BULLOCH: I assume you trust me to do this, Mike? I'll try not to screw it up.

Q Doctor, you did not bring your copy of your vitae

with you by chance?

A No, I did not.

MR. BULLOCH: Mike, I think I've got a copy of it that was just produced that he just gave us. Let me check. Yes. I've got one.

Q Okay. Why don't we mark that as 3. Number 3.

MR. BULLOCH: Well, you know what, Mike? I'll let him use this, but I don't want to mark it because I might have some stray marks on it. I will be happy to mark one or send the court reporter a blank one, but I believe I've got some marks on his CV that would be attorney work product. I can share that with him if you'd like. If you don't want me then we can skip that.

Q All right. Well, Doctor, if need be -- we'll not mark it then. And I may ask you a few questions off the vitae shortly but are we ready? Are all the other exhibits marked now?

MR. BULLOCH: Yes, sir. The Exhibit 1 is 1 A through 1 G in no particular order. They might not be chronological. Exhibit 2 is the spreadsheet that he has referred to and -- Dr. Darnall has referred to.

Q Doctor, the spreadsheet that -- are we back on the record?

COURT REPORTER: Yes.

Q Doctor, the spreadsheet, would you pull that up for me, please? And how is that marked?

A Exhibit 2.

Q Is that typed or is that handwritten?

A That's an Excel spreadsheet.

Q All right. I'm not the best in technology so I don't know what that means. What's an Excel --

A It's a computer spreadsheet that's been printed.

Q Doctor, have you been deposed before?

A Yes.

Q How many times have you been deposed?

A I think three times.

Q Just to review the ground rules with you, this is a question and answer session under oath. It's important you understand the question that I ask you. If the question is inartfully phrased or doesn't make any sense, I want you to stop me, tell me so and I'd be pleased to restate or rephrase the question. Fair enough?

A Fair.

Q However, unless you indicate otherwise to me, I'm going to assume that you fully understood the question that has been posed and you are giving me your best and complete answer today, fair enough?
A That's fair.
Q I don't know how I'm coming through there, but I can hear you very well. The only problem I'm detecting on this video conference is for some reason I'm getting somewhat of an echo occasionally. I'm not sure if that's before or after I ask the question. So if we could each give each other an extra second or two after we speak, I think that might resolve that problem.

MR. BULLOCH: I think it's more on your end because we're hearing the doctor's response on your end coming back to us. We're not getting the echo. The technician on this side said your monitor might be too loud on your side. There is a delay, however.

Q We're going to press forward and if it gets too bothersome to me, I'll get some help here. Let's talk about your medical legal experience, Doctor, first of all. How long have you been reviewing

medical legal cases?

A Oh, boy. I suspect a few cases that I've reviewed I've done since I started at the University of Virginia in 1979.

Q I'm getting the sense that in your lifetime you've not reviewed more than five or ten cases, is that fair?

A That's probably true. Maybe at the upper end of that.

Q Well, have you ever testified in Federal Court?

A In Federal Court?

Q Yes.

A I don't know. I testified in court one time as an expert witness.

Q Where was that at?

A That was in Virginia. I believe it was just after I had moved to New Hampshire so that would have been 1990, something like that.

Q Were you an expert for a physician or medical provider or for the plaintiff?

A No, I was an expert for the plaintiff.

Q And what was the subject matter?

A I don't recall. I honestly don't remember what it

was about.

Q Do you remember the name of the attorney in Virginia that hired you?

A No.

Q Do you remember anything about the case? The name of the case?

A Only that I went to Virginia, and I was on the witness stand for a little while. I don't recall anything about the case.

Q So you've testified once in a courtroom, and this might be your third deposition?

A No. I've done -- oh, yes. Third or fourth. I don't keep track of those things, Mr. Becker.

Q Okay. So you might review a case -- you've been practicing about 25 or 30 years?

A That's right.

Q And have you -- you might review a case once every couple of years?

A That's fair.

Q Do you know how it was that Mr. Bulloch happened to or his law firm happened to contact you in this case?

A I have no idea. How did you?

MR. BULLOCH: You can't ask me questions.

Q Doctor, I appreciate that you have a subspecialty interest in SIDS and sleep apnea, correct?

A That's part of my interest. Yes.

Q Okay. Any other subspecialty interest that you can share with me?

A Well, the interest in apnea of prematurity and SIDS is part of a broader interest in respiratory control disorders. Those are just a couple of them.

Q On the topic of -- have you written on anything that -- please feel free to look at your vitae and feel free to look at your spreadsheet or medical records at any time before answering my questions. This is not a memory contest.

Have you written on anything that would be potentially relevant to this subject matter of this case?

MR. BULLOCH: Did you say relevant?

Q Yes, sir.

MR. BULLOCH: Okay. Thank you.

A I guess it depends what you mean by relevance. I haven't written any papers about clinical,

clinical case reports or things like that. I have done -- I guess the closest thing, I've done animal studies looking at the effects of hypoxia on cerebral blood flow in animals, on their breathing, blood pressure, heart rate changes. These are physiologic studies.

Q Can you identify -- can you identify those for me on your vitae?

A All right. This is going to take a couple seconds.

Q You know what, Doctor? To move this along, if you could just simply check, at the end of this deposition checkmark those that you feel are relevant, and then hand that on your vitae to John and John can send me the checkmarked pages of your vitae and feel free to white out your work product, John.

MR. BULLOCH: Fair enough, Mike.

Q Fair enough?

A Yes. But I think they're pretty obvious in the titles as well. But okay.

Q Well, Doctor, I quickly got a -- jumped through some hoops to get a chapter that you wrote on

breathing disorders in the newborn infant thinking that I would see something about respiratory distress syndrome and surfactant and was surprised to see that it's mostly about sleep apnea so you fooled me by the titles of that.

A Which chapter was that?

Q It's Chapter 10 of the Workbook in Practical Neonatology?

A Is that the one that hasn't come out yet? Is that the previous edition or the new edition?

Q Correct.

A I haven't even seen the new edition. How did you get that?

The point of the chapter is on respiratory control. Okay? Respiratory control has to do with how your brain controls your breathing. So things like apnea, and upper airway problems, things like that, are considered respiratory control problems.

RDS surfactant is a, yes, it's a respiratory problem, but it's not a respiratory control problem.

Q Okay.

A All right?
Q Just so, you know, I did not obtain a copy of your most recent new edition. I was looking at the 2001.
A I see. Okay.
Q Doctor, you grew up in San Mateo, California, I noticed on your vitae, and to me -- you're going to have to bear with me and let me finish my questions.
A Sorry.
Q That's pretty close to Palo Alto. Is that true or not?
A That's true. I was born in San Mateo and that's right up the street from Palo Alto.
Q And I appreciate and respect that you went to your school in -- I have a brother that lives in Palo Alto. That's the only reason I know that, but I appreciate that you grew up there, you went to school there, you went to med school there, you did your -- other than one year in Cleveland you did your training, your residency, I think even your fellowship there, and once you finished your training I think you did about one year in

Stanford and then you left for Virginia. Correct?
A Not exactly.
Q Okay. Correct me.
A I was -- I did my undergraduate work at Stanford. I went to Medical School at UCLA. I did my internship at Case Western in Cleveland. I went to the Indian Health Service for two years in Arizona, and then I went back to Stanford, finished my pediatric residency, did my neonatology fellowship at Stanford and that all ended in 1979. Then I moved to Virginia.
Q And my question is why did you leave Stanford and go to Virginia?
A Because that's where the job was. Academic jobs are not exactly plentiful so you try to pick the few that are available and the University of Virginia had a very good program. Dr. Catwinkle who was the Chief there was also a fellow when I was an intern in Cleveland so I knew him quite well and he's the one that actually developed nasal Cpap that's being used all over at this time. And I liked the town and I think it was a good place to have kids so that's why I took that

job.

Q And why did you leave Virginia to go to New Hampshire?

A That was a mid-career kind of move. I had gotten to the point where I was doing research in Virginia and the people that I had been working with had over the years had been leaving, and so I was sort of on my own. I collaborated with people in pharmacology there. We also had a new chairman and as you know things are often turbulent when departments change leadership, and I just thought it was best at that point to seek another place to go, and I looked at a bunch of things. You know, I wasn't sure I wanted to continue doing research at that time. I looked at a couple of Chief jobs.

And then the job at Dartmouth came along and it was a great opportunity because it allowed me to pursue my research interests with a group of very internationally known investigators as well as continue my clinical practice in neonatology.

Q I understand that you spent a lot of your professional time in research, correct?

A Well, I've spent -- up until about eight years ago

I was a full-time, had a full-time clinical commitment, and by clinical I mean combinations of patient care, teaching, and research, but I didn't have any grant funding that paid my salary and as of eight years ago I've started to be able to get some grant support for my salary so I've been able to cut a little bit on my attending time in the intensive care unit. Right now I spend about, I have about a half time commitment to actually being in the nursery, and the other half is involved in my research and which my research is, of course, clinically relevant.

Q So you spend 50 percent of your professional time in the clinical practice of medicine?

A It depends how you define that. I guess that's fair. I mean you'd have to compare it to someone who wasn't doing any research so I spend half the time that they do in the nursery.

Q I didn't hear the end of that answer.

A Comparing what I do to someone who doesn't have grant support and is just doing the research that they can given their free time, I spend half the time that they do actually attending in the

nursery.

Q I know that you know Marcus Hermansen?

A Yes. I know Marcus.

Q And do you respect him as a clinician?

A Yes.

Q Have you ever found yourself on the opposite sides of a medical legal case, you and Marcus, prior to this case?

A No.

Q Do you know whether or not any other neonatologists have reviewed this case on behalf of Mr. Bulloch and felt that they couldn't support his defense?

MR. BULLOCH: Objection, but you can answer, Doctor.

A I don't know of any other than the ones that I have letters from. There's one other neonatologist. Dr. Rodriguez.

Q Do you know Dr. Rodriguez?

A No.

Q Just so I can learn something about SIDS in a few minutes, what has your research told you as to the etiology of SIDS?

A Well, our research is based on some very important findings by Hannah Kinney who's a neuropathologist in Boston that about 50 percent of babies who died of SIDS have abnormalities in the brainstem, and these abnormalities mostly involve certain neurotransmitters and most importantly serotonin. So these babies have abnormal binding of serotonin receptors in the brainstem.

So I'm involved in a very large program project that involves investigators at Dartmouth, Harvard, Yale and Columbia, investigating the hypothesis that serotonin in the brainstem plays a role in Sudden Infant Death Syndrome. We use animal models to try to recreate the abnormality so we go in and we turn off the serotonergic neurons, we destroy them, we activate them, whatever, and then we look at the animal's responses to things like hypoxia, hypercapnia, too much CO2, we look at their responses to airway stimulation, we look at their body temperature changes and their response to cooling and heating and we look at their sleep. And what we found is that abnormalities in this system in animal models

have reduced the response to hypercapnia, reduced the response to hypoxia, prolonged the apnea that occurs with laryngeal stimulation, disrupts sleep, and interferes with thermoregulation. These are all issues that are important in the etiology of Sudden Infant Death Syndrome. Does that tell you enough? Or too much?

Q Tells me enough. So, well, I just wanted to get a basic understanding. So what the research has told you is that there might be a broken wire or one part of the brain's not sending the right message for breathing purposes. That's very, that's probably a horribly gross simplification but is that --

A It's not just breathing. It's many, many autonomic functions. Thermoregulation, sleep, all those sorts of things, but more importantly is the translational aspect of this. That by knowing these things, we can devise tests that we can go out and test babies to see what they're susceptible, whether they're candidates, are at high risk for dying and ultimately perhaps perfect either pharmacologic agents or other things that

could protect these babies.

So that's our ultimate goal. But you have to do the basic physiology before you can go to that next step, and actually there are, we're involved in plans now to carry that forward into the translational area within the next five years.

Q Moving to the topic of neonatal apnea, or cessation of breathing, what are the basic etiologies that you discovered for neonatal apnea?

A Well, my research by animal research has really been mostly with SIDS and hypoxia. I've written a recent paper with John Catwinkle, oh, within the last five or six, maybe it's longer than that, can't remember, that has to do with just the management of babies who have apnea of prematurity. How long they should be kept in the hospital before going home, for example, and that sort of thing. The etiology is complicated and perhaps one of the most important experts on this is right in Cleveland, Dr. Richard Martin, who is at Babies Hospital who has written extensively on this subject, but it has to do with immaturity of the brainstem which involves connections between

neurons. It involves myelination which is the covering of axons which speed up the transmission, that basically causes preterm babies to not breathe regularly. A normal pattern for a preterm baby is interrupted breathing so you have breathing and apnea, breathing and apnea; when that apnea becomes too long then it can produce decreases in heart rate and periods of low oxygenation

Q Jumping back to your medical legal work, Doctor, whether acting as a defense witness or a plaintiff's witness, have you ever given previous testimony or merely written a report on the topics of management of RDS, surfactant therapy or brain injury secondary to hypoxia or ischemia?

A I have not written any papers on in that subject, but I take care of hundreds of babies, I have hundreds of babies with all of those kinds of characteristics that I take care of every day.

Q You didn't understand or I didn't make myself clear. Relative to your medical legal review cases?

A Oh. Oh. Okay. Have I written about? I don't

understand. Have I written about the medical legal aspects of --

Q No. No. In the medical legal cases that you have reviewed?

A Okay.

Q Was the subject matter in any of them regardless of what side you were on having to do with either RDS or surfactant replacement therapy or how a child sustains brain injury from either hypoxia or ischemia or combination?

A Yes. I have reviewed cases that had to do with perinatal hypoxic ischemic injury. I don't recall whether it was related, my role was related directly to linking that with long-term neurodevelopmental outcome or not, but certainly some of the cases that I reviewed were involved in hypoxic ischemic injury in newborns.

Q Okay. And do you have any means of going back to your office and identifying those cases either by attorneys or case captions?

A I don't keep any records of these. Once I'm done, I throw them away.

Q Do you have Volpe's Fourth Edition of Neurology in

your office?
A I don't think I have his latest edition, but I have access to it.
Q Doctor, would you agree that physicians unfortunately occasionally do commit medical malpractice?
A I suspect that that's true.
Q I trust you would concede that you can have a bad outcome due to medical negligence?
A That's possible.
Q I trust you would agree that a neonatologist can exercise bad judgment and that bad judgment can lead to a bad outcome that might be tantamount to medical negligence?
A I'm sure that's possible.
Q We can agree, Doctor, that there are deaths and brain injuries in newborns that are caused by bad medical care by neonatologists?
A Anything is possible, Mr. Becker.
Q Under those circumstances, that would constitute medical negligence?
A I guess if you could show cause and negligence perhaps.

Q You would agree, Doctor, that a bad outcome due to medical negligence, the patient or his representative should be fairly and fully compensated as a result of a doctor's negligence?
A I don't have an answer to that. I don't know what the answer to that is. I don't have an opinion.
Q I didn't hear your answer.
A I don't have an opinion on that.
Q You don't feel that doctors should be held financially accountable for his or her actions if it causes harm to a child?
A That's our current --
Q And is negligent --
A That appears to be our current legal system. I think there ought to be adequate peer review, and I think there ought to be adequate -- I don't know whether punishment is the right word, but adequate results of having knowingly or being negligent. You know, whether this is a financial issue, that's what we do in this country. I don't have any idea of whether that's right or wrong.
Q You don't have a feeling about it one way or the other?

A No.
Q How we do that in this country?
A Well, I think it -- well, I don't know how to answer that question. I guess in a very, very, very few cases where something like this happens, it's a sad situation, and I feel badly for parents and for the children. I don't know that financial compensation is necessarily the best way to deal with this. But I don't -- that's not my area of interest. And I don't think about it very much.
Q Why do you say there are very, very few cases?
A I think there are very few where you can actually say for a surety that something somebody did in the neonatal period is actually responsible for any specific outcome.
Q Is that your understanding as to what's necessary to show causation in a case, that there has to be surety?
A I think, well, my understanding is there has to be, it has to be more likely than not that some event or series of events led to the cause of some outcome.
Q Do you appreciate that's different than certainty

or a surety?

A I assume a surety means a hundred percent. Is that what you mean?

Q Yes.

A Yes.

Q Doctor, let's talk about surfactant now. What role does that play in a newborn's lungs?

A Surfactant is a surface active agent. It actually acts to reduce surface tension in the lung which prevents the lung from collapsing at the end of a breath. It also is important in making sure that water doesn't get into the lungs. So the two things that surfactant does that is very important is keeping the lungs from collapsing at the end of a breath in a dynamic way and keeping water out of the lung.

Q Can we agree, Doctor, that the development of surfactant replacement therapy either via synthetic or natural surfactant substitute has been one of the biggest advances in the field of neonatology in the last 25 years?

A Yes. That coupled with the use of antenatal steroids have been very important in the small

preterm baby.

Q Can we agree, Doctor, that moving on to surfactant replacement therapy, that such works immediately on the newborn and can be effective within seconds if not minutes?

A It really depends on what kind of babies you're talking about. Are you talking about babies who are very small, less than 1500 grams, who have RDS who are treated with surfactant? In those babies specifically it can act quickly, but it also doesn't act in some percentage, it's not effective in certain percentages as well.

Q Right. And I guess that percentage is about 25 percent, is that accurate?

A I don't recall 25, 30 percent sounds but again, you have to limit this to a certain kind of baby. Okay? The evidence that we have is only in babies less than 1500 grams.

Q What evidence?

A The studies, I'm trying to answer your question in that how fast a surfactant works. I think that was the question you asked.

Q Right.

A And in babies who are less than 1500 grams that have been studied, surfactant can act very quickly, but in 25 to 30 percent of the cases there's no effect.

Q Okay. And let's deal with babies that are bigger than 1500 grams. How quickly do you see based on, forget about studies, I want your clinical experience about how quickly in large babies; 2,000 grams, 2300 grams, how quickly have you seen surfactant work once it's administered?

A Well, surfactant is rarely used in those babies. And when it is used in those babies, if, you know, if it works, the effects can start as early as seconds to several minutes to an hour before you see effects. That's in my own experience. Now, this has not been studied in any controlled way.

Q When you say rarely used in those babies, you say that because bigger babies don't get, don't have the frequency of RDS as smaller babies; is that what you mean?

A That's correct.

Q But you've given surfactant therapy to 2000 or 2300 gram babies in the past who have RDS,

correct?

A Yes. I have.

Q In general, Doctor, can we agree that when surfactant therapy is effective that it reduces the course and the severity of RDS?

A Again, my own experience, do you want to focus on the big babies or do you want to talk about the babies where there are controlled studies looking at this?

Q Well, you can answer it any way you want to. My question should include big babies so if there's an exception, you let me know.

A All right. In babies where we have studies in small babies and again all those randomized control studies have been in babies less than 1500 grams, the general consensus is that surfactant is beneficial, that it reduces mortality, that it changes the course of RDS to a perhaps milder course over the short-term.

On the other hand, it has no effect on chronic lung disease, it has no effect on neurodevelopmental outcome. It has no effect on any long-term outcome. Okay? In big babies we

don't have any studies comparing surfactant versus no surfactant in babies who the clinicians thought had RDS. And the problem with that is that big babies have respiratory distress from all kind of other etiologies. And in fact, the other things are much more common than hyaline membrane disease, and these are meconium aspiration, clear fluid aspiration, retained fetal lung fluid, pneumonia. So in those babies who are given surfactant if they are given surfactant the results can be highly variable. And so that you can get some babies that respond, you can get other babies that don't respond at all, and you think they have hyaline membrane disease and you give them the surfactant and they don't do anything. So my experience in the bigger babies is that they're much more complicated and each individual case is an individual judgment and the surfactant doesn't work anywhere near as frequently as it's does in the small babies.

Q Okay. But let's assume that we're dealing with a baby that has RDS, 34, 35 week; assuming that that happens, then what is your answer?

A Well, the problem is you at the time you decide or don't decide to give surfactant you never know for sure whether they have RDS. In the first 24 hours the x-ray doesn't tell you, the clinical signs and symptoms are similar for many of these things, particularly pneumonia. And so you're always thinking, you start antibiotics, you say gee, should I give surfactant, should I not give surfactant. If you decide to give surfactant you usually only find out later whether in retrospect, whether you thought this baby really had RDS. And much of the time they don't. They have something else.

Q All right. Well, let me just jump right ahead, fast forward, Doctor, to your question, do you feel more likely than not that Matthew Wagoner had RDS? More likely than not?

A I think he more likely than not from the course and from everything else I can't rule out pneumonia. But I think probably more likely than not he had RDS.

Q Okay.

A But I want to clarify that and say at the time if

I were taking care of him I wouldn't know that. At the time I would have to make a decision about surfactant or not. I mean I've only gleaned that from looking at the whole course and the whole record.

Q Right.

A Which isn't available when you're taking care of the baby.

Q Right. But if there was a working diagnosis of RDS, then you treat RDS, correct?

A Well, you may have several various things in your differential diagnosis including RDS. Okay? There may not be one working diagnosis. You may think gee, I don't know. This baby may have a pneumonia, he may have clear liquid aspiration, he may have RDS. The first question is how should we treat any of those forms of respiratory distress. Some of these babies we don't intubate. Some of these babies we treat with just oxygen alone. Some of them we nasal Cpap and they won't get surfactant. Some of them get intubated, and some of those get surfactant, and so if I think it's hyaline membrane disease, if you, in the rare

situation, if you knew that up front, yes, I probably would elect to give surfactant but the fact is that often you don't know, and so you have to weigh the risks and benefits of using the treatment.

Q Well, again, fast forwarding, it's not that Dr. Lillien was unsure of the diagnosis. He deferred surfactant, he deferred surfactant based on the size of this child and allegedly because in his mind the child was stable. Correct?

MR. BULLOCH: Objection. I don't think that's what's the evidence or Dr. Lillien stated, but go ahead and you can try to answer that.

A I don't know he what he was thinking. I know that he wrote, I remember seeing in the record that he deferred it because he thought the baby was large and was stable as you said. But I think -- you have to remember that there's no evidence surfactant is beneficial in babies of 35 weeks' gestation. Okay? You have to also remember that there are risks to giving this. Dr. Lillien was exercising his judgment as a clinician.

Now, having said that, many neonatologists

might have elected to give surfactant. But it doesn't mean that it was inappropriate not to give surfactant.

Q All right. We're going to get to your opinions in a moment. I just want to make sure that, going back, going back I think my question and this is not your fault, this is my fault because we kind of got far afield here. Going back to my question a few minutes ago, I think I was asking you in a baby. Let's talk about a 2300 gram baby who has RDS and receives surfactant timely, can we agree that generally alters the course and severity in general of RDS?

A I'm not sure what you mean by in general. In probably -- if you're saying that there's a 30 percent failure rate of surfactant in the other percentage there probably, there will be some improvement in the course of RDS, that's correct. So when it works, when it works. Yes.

Q And when you say improvement, you mean that it shortens the length of NICU stay and it shortens the -- reduces the ventilation requirements, it shortens the -- reduces the severity of the

respiratory difficulties during the NICU stay in general? Is that true?

A Some of those things are true. Some of them aren't true. There are effects on pulmonary mechanics so in other words it doesn't require as much mechanical ventilation. That's true. Usually reduce, the main thing it does is reduces the amount of oxygen that you're giving the baby. Okay? It does not affect the incidence of chronic lung disease, nor do I believe that it affects the length of stay in the nursery. Babies have complications, and this is based again on the smaller babies. We don't have any data on babies 34, 35 weeks' gestation. We have data on the very small babies and in those babies there's no effect on long-term outcome. And I would refer you to the American Academy statement from 1999 in that regard. So yes, it has immediate improvement in pulmonary mechanics, it requires less pressure on the ventilator, for example, less oxygen, and they may come off their ventilator sooner. But there's very few effects on long-term outcomes.

Q Well, you referred me just a minute ago to the

American Academy of Pediatrics statement of 1999?

A Yes.

Q Can you be more specific?

A Do you have it with you? I don't have it.

Q I have a number --

A I don't have --

Q But --

A The American Academy of Pediatrics puts out statements every once in a while of consensus statements, okay? This was a consensus statement about the use of surfactant. And in that statement, as I recall, the best of my ability to recall it, they talked about the fact that surfactant had beneficial acute effects on ventilation and hours on ventilators and things like that in surfactant-deficient babies. Okay? And I believe it also said that there was no effect on things such as chronic lung disease or neurodevelopmental outcome. I don't remember the other details for sure.

Q Doctor, it appears to me that you're not familiar with any literature written before 1990 that have done studies on surfactant in 30 to 36 weekers; is

that true?

A I don't know of any randomized controlled studies that compare no surfactant to surfactant in 34 to 36, 37 weeks' babies. That's correct.

Q Okay. Can we agree that surfactant therapy in the newborn changes the course of the respiratory distress syndrome including the duration of the ventilatory support?

A I believe you asked me that already, but again, it only -- the data we have only applies to the small preterm baby less than 1500 grams.

Q Can we agree that surfactant is now conclusively shown to reduce mortality, in several aspects morbidity in babies with RDS?

A That's what the early studies show. However, you need to be aware, and I'd like to say a couple things if I can. You need to be aware that in 2006 some of our smallest babies at good centers are not given surfactant, and these babies are not even ventilated. They're treated with nasal Cpap and not given surfactant and even those studies show a decrease in morbidity, good neonatologists at good academic centers where there's published

data have shown improved outcomes in babies who have not received surfactant even as little as 26 weeks' gestation.

Q Those morbidities that you spoke about include deficits in oxygenation, incidence of pulmonary air leaks and duration of, I've already talked about that. So including the deficits, the morbidities -- let's start over.

The morbidities include deficits in oxygenation and incidence of pulmonary air leaks that are reduced, correct?

A Well, we didn't talk about air leaks. You didn't mention that before. There is evidence in the smaller babies that a reduced number of air leaks in those babies. Again, there's no evidence in big babies that that's the case.

Q And it's your position that there's no evidence that surfactant replacements increases the likelihood of survival without bronchopulmonary dysplasia which is chronic lung disease, correct?

A The statement of the Academy talks about chronic lung disease specifically, yes. And in fact, in this day and age, 2006, the incidence of chronic

lung disease is actually higher than it was in 1999 with a lot of use of surfactant in very small babies.

Q Have you ever withheld surfactant to a 35 weeker that you presumptively have diagnosed to have RDS solely due to the weight or size of the newborn?

A I can't recall, like I said, I don't know of any cases where I've said yes, this baby has RDS. So I've certainly given surfactant to those babies. Yes. But as I said before, the diagnosis is up for grabs in the first 24 hours, and you can't say for a surety that the baby has hyaline membrane disease. If I think that's a most likely cause, yes, I would probably give surfactant.

Q What's the largest baby either by weight or gestational age, maturity wise, that you've ever administered surfactant to?

A There's some recent evidence that have meconium aspiration syndrome might be buffered by surfactant so I've given surfactant to some big babies who have had meconium aspiration syndrome who have been at term.

Q Did it improve --

A My experience, I haven't seen any effects of the surfactant on those babies. But you know, there's a lot of research going on for the use of surfactant in things other than hyaline membrane disease in term babies. Okay? So people are experimenting with that at this point.

Q Let's talk a little bit about pneumothorax and its impact on the newborn. Can you explain to me, first of all, what pneumothorax or air leaks are and then what are the potential deleterious effects on the newborn?

A Air leaks or pneumothorax is just one type of air leak that you can get in a baby. It's a very common complication of babies who have respiratory distress, with or without mechanical ventilation, with or without nasal Cpap. It occurs without doing anything. What happens is when there's an air leak, the air tracks inward along the perivascular bundle to the mediastinum which is the center area of the chest and then depending on the resistance there it gets out into the pleural space and you end up with a pneumothorax, okay? I don't know if that's too much of an answer for

you.

Q Let's go to the second part of my question. What are the potential deleterious effects on the pneumothorax on a newborn?

A As you might imagine there are all grades and severities of pneumothorax. You can have a small, in fact a certain percentage of 30 full-time babies who have nothing done to them have pneumothorax, I think about 5 percent. In these cases they're quite small. Doesn't require any treatment. In babies who are on mechanical ventilation, often the pneumothoraces are larger, and when they get, particularly when they're under tension. In other words, when they're under tension and putting pressure on the cardiac system in the midline you can see things like decrease in oxygenation, you can see increase in CO2, sometimes you can see decreases in blood pressure, and if those things aren't promptly treated and the pneumothorax is very large, then those things can have severe consequences.

Q What is the effect of a pneumothorax on venous return?

A That really depends on how much pressure there is on the cardiac system. There is some decrease in venous return, but that's going to be variable. It can be a little bit of decrease or a lot of decrease depending on the amount of gas and the pressure in the chest.

Q What are the dangers of decrease in venous return?

A Well, that results in decreased cardiac output which is generally reflected in a decrease in blood pressure.

Q What is the impact, potential impact of pneumothorax, whether a unilateral or bilateral pneumothorax on cerebral blood flow?

A I don't know of any studies -- there probably are, but I don't know of any that actually measured cerebral blood flow. My guess would be that it depends on the severity. If there's any change in cardiac output it's going to have some effect on cerebral blood flow. But you also have to remember that when you get a pneumothorax, your oxygenation decreases and the primary effect of low oxygen on cerebral blood flow is an increase in cerebral blood flow. So, in other words, it

causes those vessels to dilate so that you get more flow to the brain. You have to balance that against the decrease in venous return. And there's no way to measure those things in a clinical situation obviously. But it would only be problematic when it was very severe and prolonged.

Q Do you remember back in the presurfactant era where you were taking care of children with RDS where you had a sense or a feeling that the child was likely going to have neurological abnormalities at the time of discharge?

A Okay. So what kind of babies are you talking about here?

Q I'm talking about babies in the presurfactant era before the '90s, in the '80s, when you didn't have surfactant, and you were taking care of babies with RDS and you had concern while taking care of them either because of their clinical condition or the imaging that may go on to develop neural abnormalities, whether developmentally delayed or cerebral palsy?

A I'm having difficulty answering this because there

are so many different types of babies you might be talking about. In the presurfactant era, and I wouldn't even label it the presurfactant era. In the early '80s as is now the case, there are babies who are very premature who have imaging results that suggest that there was a greater risk for cerebral palsy. And of course the most common one is periventricular leukomalacia and that can occur in preterm babies with or without having required lots of mechanical ventilation, with or without pneumothoraces, with or without chronic lung disease. So yes, in answer to your question there are preterm babies that have imaging evidence that they might have problems. There are some if they stay in the nursery long enough is they also have neurological symptoms that you can pick up on. Decreased sucking and inability to feed and things like that.

Q Decreased tone?

A So yes, and I guess, yes. I don't know what, but we see that today even in the surfactant era. I mean, I don't link this to the surfactant era, before or after. We see it now, we saw it then.

Q But relative to managing babies, whether they are 1500 grams or 2500 grams, with RDS, can you say whether or not you see less incidence of or circumstances where you have less of a concern for neurodevelopmental outcome?
A No.
Q And since the '90s --
A No. No. Actually, in fact, there are more babies who have potential problems with this than before because we're taking care of smaller and smaller babies who are more prone to have those kinds of problems.
Q You are saving babies that ten or 15 years ago would have expired?
A That's correct. And I think the data would show that there's no change in the incidence of cerebral palsy, for example, or neurodevelopmental outcome, 1980s to 1990s or 2000s.
Q Can you cite me to any data?
A I've looked at papers. I can't cite a specific one. No.
Q Are you aware of any articles written that suggest that antenatal steroids and postnatal surfactant

when used appear to improve survival and neurodevelopmental outcome in preterm babies who require prolonged ventilation?

A It sounds like you're referring to a title of a paper in that statement which I don't, haven't seen. But I don't know of any data that would show -- I mean the combined use of antenatal steroids and surfactant there's no question reduces mortality, okay?

Q And you're not aware --

A But I don't know. I think the data looking at long-term neurodevelopmental outcome is not consistent. There's no good evidence that in 2006 the incidence of babies who have bad neurodevelopmental outcomes is any difference than it was back in the '80s and the reason is not, you can't, it's confounded by the fact that we're taking care of smaller and smaller babies. So you have to correct these data for gestational age. And there are probably, well, that's, I mean you have to do it by gestational age if you want to look at that.

Q And I respect that, but what you're saying,

Doctor, is you're not aware of an article written in 2001 standing for the proposition that improved survival -- you are or not?

A I don't know -- no. I don't know whether I've reviewed that article along with several others. But in my review, the results were inconsistent. In other words, there were some that says there was improvement, some that said there wasn't. My interpretation of that is we don't know, and we can't say for any degree of a surety that it has improved.

Q Can we agree that in the presurfactant era pneumothoraces were much more common?

A In the smaller babies. In the small group of babies that have been studied. Yes, that's probably true. And in my own experience with small babies, yes.

Q By your limitation in that answer, are you saying that that doesn't apply to larger babies?

A I don't think we have any evidence to show whether it does or not because there are so few of them and so few of them are treated in this way, and I don't know of any babies in my own practice that

have had a pneumothorax at 35 weeks that's gone on to develop neurodevelopmental problems. I don't know of any data in the big babies.

Q When you say data, so that we're communicating, you mean what?

A I mean published.

Q Controlled, published what?

A I mean there are all kinds of studies. There are controlled, randomized trials, respective reviews, there's case reports or case controlled studies. There have been a fair number of studies comparing, you know, what happened presurfactant and postsurfactant, and those are the studies I'm referring to that haven't been consistent in showing any differences in long-term outcome. And I'm sorry I can't quote them, but I certainly can get them for you if you want.

Q Okay. Well, would you give them to Mr. Bulloch and then he can send them to me?

A Sure.

MR. BULLOCH: Except, Mike, I'm not going to ask this doctor to do research for you. I mean you're quite capable of finding the same articles

that he is. He's testified that he is not aware of any such studies showing any improvement in neurodevelopmental and he's aware of studies that.

MR. BECKER: John, I'm not hearing you.

MR. BULLOCH: I threw a piece of paper over the mike. I apologize. What I said was I am not going to ask this Doctor to do research that you're perfectly capable of doing. He says that he's not aware ever any studies that show any proof of long-term neurodevelopmental improvement in these babies and he's aware of conflicting studies. I mean that's what he's testified to and that's all he's going to do for you.

Q Well, except when he volunteers to give me studies which he's just done so I'm taking him up on this and just --

A Maybe I shouldn't have.

Q That will teach you to volunteer, Doctor, so if you would send them to Mr. Bulloch and Mr. Bulloch and I can fight about this. But would you do that, sir?

A Whatever. Okay.

MR. BULLOCH: He'll do as I instruct him to.

Q Can we agree, Doctor, that pneumothoraces can cause hypoxemia as well as ischemia in newborns' brains?
A Severe untreated pneumothoraces, yes.
Q And that can be a source or a cause of brain injury whether it's cerebral palsy or developmental delay?
A A single event, I don't know of any data that shows that a single pneumothorax in this age baby leads to cerebral palsy or neurodevelopmental delays.
Q What are the risk factors for RDS?
A The risk factors for RDS. You mean like prematurity?
Q Prematurity is one?
A Prematurity is the main one. You mean by RDS, do you mean hyaline membrane disease or just respiratory distress? Which --
Q Correct.
A Prematurity is the major one. Babies of diabetic mothers have more incidence of RDS at 34 weeks where you don't usually see it.
Q Doctor, if I've used that term RDS wrong I

apologize. I assumed it was synonymous with hyaline membrane disease; it is not?

A It doesn't have to be, but if you're using it that way, that's fine. I'll hear it that way. Okay?

Q Okay. Have you heard of, relative to risk factors for RDS, of a "wimpy white boy syndrome." Have you heard of that before?

A Yes, I have.

Q Tell us about that. What does that mean?

A I don't know how that's relevant to anything, but it seems, it is rumored and talked about frequently in the nursery that babies who are white and male do worse than females and particularly black females with respect to their outcomes and degree of respiratory distress. It's a term that's loosely thrown around, has no scientific validity, other than saying that the risk of hyaline membrane diseased is increased in males. That's what it comes from. And the experience that in black population, there seems to be lots of small preterm babies who don't have severe respiratory distress. It's not a term that I use myself, but I've certainly heard it.

Q Is surfactant therapy considered to be more effective or less effective as the gestational age of the newborn increases?

A I am not aware of anything showing that it's more or less effective. There is a -- we use it a lot more in the smaller babies so that it seems to be more effective in smaller babies, but I don't know that there's a relationship between gestational age at birth and whether surfactant works or how well it works. I don't know of anything along those lines.

Q Is the use or administration of surfactant after a subjective pneumothorax somewhat controversial?

A At this point in time it is. Yes. In fact some people advocate and some people don't, and I don't know that that question has been settled.

Q Why is it, what are the down sides or what is the impact of giving surfactant after the baby has a pneumothorax?

A You know, I don't know any detail. I have not reviewed this literature. So I don't really know what the proposed mechanism is. I think there was some -- I would be really way out on a limb here

so I'm not going to say anything. I really, I don't know what the mechanism is. If you have underlying surfactant deficiency and you have a pneumothorax, there certainly could be some benefit of giving surfactant. But again, I guess I've talked informally with people about this who have told me that, you know, there's studies on both sides of the fence here.

Q Doctor, do you have a policy at your institution for the surfactant replacement therapy?

A A written policy saying that we under what circumstances we give it? Is that what you mean?

Q Yes. And who can give it. What type of medical caregiver can give it.

A We do not have a written policy on who gets it. That's up to the judgment of the care team. In our unit, the respiratory therapists and the nurses give it under our supervision which is very common in a tertiary center where you've got lots and lots of deliveries and we're giving it every day.

Q Going back to my question though, is there a written policy?

A In fact -- on who gives it? I'm unaware of any written policy. Sometimes our nurse practitioners, sometimes nurses do, the respiratory therapists do it. You know, we've got five or six people standing around the bedside when this happens. So who actually does it doesn't really matter.

Q Okay. Are you aware whether or not the American Association of Pediatrics as well as the JCAH requires a policy, a written policy for the administration of medication?

A Medication in general?

Q In the NICU?

A I'm sorry. Did you mean the an American Academy of Pediatrics?

Q Yes.

MR. BULLOCH: You were talking over each other. Could you repose the question, Mike? I'm sorry. What I said is it seems like you two were talking over each other because of the delay. And I am not sure if the question was heard or not. Could you reask the question, please?

Q Well, I guess I was curious if he's aware that the

American Academy of Pediatrics as well as JCAH requires, strongly recommends or urges that there be a written policy specifically for surfactant replacement therapy?

A If there's a requirement I'm sure there's a policy. I don't -- from a clinical point of view it's not something that's relevant to our practice. A hospital has to have a policy, I'm sure, about how it's stored and how it's mixed and how it's given, but in terms of which babies you give it to and actually the personnel involved, I'm not aware of any, but there may be. I'm just telling you what we do.

Q Is surfactant, administered correctly and properly, considered a safe drug?

A Safety is always relative. There are risks involved, and there are benefits. And you weigh the risks and benefits any time you give a medication. It's relatively safe. Yes.

Q Are you aware whether or not there was ever at Fairview General Hospital in 1999 a constitutionally approved surfactant therapy protocol?

A I don't know why I would know that one way or the other.

MR. BULLOCH: Especially when you don't know if you have one in your own institution, correct?

Q Are you aware of any literature that stands for the proposition that withholding surfactant therapy from larger infants with RDS who are receiving ventilation because they're thought to have a good prognosis without surfactant is not justified?

A Can you repeat that, please? There were a lot of negatives, double negatives in there.

Q Yes. Are you aware of any literature that stands for the proposition that withholding surfactant therapy for larger infants with RDS who are receiving ventilation because they are thought to have a good prognosis without surfactant is not justified?

A That's a long one. If you're asking whether there's any data showing that it's not justified to give surfactant to a large baby who has RDS and is on mechanical ventilation, I know of none. If that's what's you're asking. I don't know of any

literature saying that it's not. Is that right? Not justified? I don't know. I don't understand your question.

MR. BULLOCH: Too many double negatives.

Q Are you aware of any literature that stands for the proposition that surfactant therapy should be, essentially stands for the proposition that surfactant therapy should not be withheld from larger infants?

A No. I'm not aware of that and I don't know. It's not -- it's not an universally held practice or feeling among neonatologists that I know about.

Q You recognize the New England Journal of Medicine is one of the most prestigious journals? Particularly somebody from New Hampshire?

A It is, but I don't have a subscription to it.

MR. BULLOCH: Mike.

Q I bet it's in your library at the hospital.

A Yes.

MR. BULLOCH: Is that like the Cleveland Clinic Quarterly should be in every Cleveland Hospital as well because it's such a prestigious organization?

Q Are you aware of any literature, Doctor, that stands for the proposition that surfactant therapy results in a marked decrease in pneumothorax and other air leaks?

A As I stated earlier, I believe, there are lots of studies in babies less than 1500 grams showing a reduction of air leaks in babies who get surfactant who have RDS. Not just the articles in the New England Journal of Medicine.

Q Can you tell me, Doctor, what the average course is by way of a NICU stay for a 35 weeker with RDS?

MR. BULLOCH: Objection.

A The average course of a 35 weeker with RDS. There are so few of those that these babies can have a highly variable course. There is no such average course. Some of them resolve this very quickly and don't require any mechanical ventilation at all. Some of them are treated with nasal Cpap, some of them are treated with mechanical ventilation, some of them are treated with surfactant. There are some of them that end up having chronic lung disease, there are some of them that end up having prolonged stays because of

other issues. It's highly variable, but the number of babies that we see that have a clearcut diagnosis of RDS at 35 weeks is very small so I can only speak from my own experience. There's no average. I can't -- a lot of it depends on how fast they get better after their initial course. So if they get better within a couple of days, then their course is going to be short. If they end up staying on a ventilator for two weeks, then they probably will end up staying a long time. It's a long answer for a short question. I'm sorry.

Q Can we agree, Doctor, that surfactants synthesis is a dynamic process that depends on such factors as pH, temperature, perfusion, and may be compromised by cold, stress, hypoxemia, hypovolemia?

A I'm sure any of those things can have effects on surfactant, and it's not just synthesis. We're talking about surfactant synthesis, we're talking about getting the surfactant out into the pleural space or into the interface, we're talking about repackaging it, reabsorbing it, the whole process

can be affected by any of those things.
Q And that's whether you're talking about the natural surfactant that's in the baby or you're talking about replacement surfactant therapy, correct?
A Well, replacement therapy, replacement surfactant is not human surfactant in most cases. I think in the case of this case it's bovine surfactant. And actually, surfactant given exogenously does get repackaged and taken back into the system and get recirculated in the newborn, not in the adult. But yes. All these, all metabolic processes can be affected by all the things you mentioned.
Q And that's before the baby receives replacement surfactant therapy or that principle can apply even after a baby receives surfactant replacement therapy?
A I'm really talking as a physiologist here in saying that all metabolic processes are affected by temperature, and levels of oxygenation and so forth. From a clinical perspective, it's not apparent that there's any -- it's not something we consider to be something that has any relevant to

clinical practice.

Q I guess in real basic terms, Doctor, I'm interested in whether artificial surfactant or animal surfactant, whether its effectiveness can be impaired by concurrent hypoxemia.

A I don't -- I guess again from a physiologic point of view I might guess that it might, but I don't know of any situations where that comes up clinically that it's ever discussed. I can't remember ever discussing that one on rounds. I suspect that may be some effects but --

Q Would you agree that exposure to high inspired oxygen concentration, the effects of barotrauma from assisted ventilation go to further damage the alveolar epithelial lining resulting in reduced surfactant synthesis?

MR. BULLOCH: Mike, I'm going to object because he's already told you that, you know, theoretically that can happen but none of this is clinically relevant or apparent. But go ahead, Doctor. You can answer it if you can.

A I think the question was whether high oxygen levels in barotrauma can change the synthesis of

surfactant? Is that what you --

Q Yes.

A I don't know the answer to that. I don't know of any data. That doesn't mean it can't happen. I just don't know the answer.

Q Is there a clinical use now of multi-dose surfactant compared to a single dose?

A This has always been controversial. And again in the smaller babies, we will often give a second dose of surfactant six to eight hours after the first one if things aren't improving the way we think they should. Frankly, I've never seen a second dose do much. In larger babies, who are given surfactant, they are most likely not to get a second dose.

Q Doctor, air leaks have been attributable to barotrauma caused by high levels of peak inspiratory pressure, correct?

A Mechanical ventilation per se is one of the factors that can predispose to a pneumothorax and obviously higher pressures are at more risk than lower pressures, but it's only one of the factors.

Q What are the other risk factors for pneumothorax

besides an elevated pressure?

A I think babies who have, I mean just having RDS puts you at risk for pneumothorax or having other pulmonary diseases that cause some, how should I say it, inhomogeneity of alveolar gas filling. So that anything that puts, any situation where you have some alveoli that are open and some are closed increases your risk for pneumothorax. The baby factors clinically that we see are babies who are on nasal Cpap or get mechanically ventilated have a higher incidence of pneumothoraces. These are the two major risk factors. The big factors.

Q Surfactant replacement therapy in part will help reduce the high levels of peak inspiratory pressure, correct?

A When it is effective. You usually see a decrease in peak inspiratory pressure and levels of oxygen needed. However, having said that, it can also increase your risk of pneumothorax. And the reason for that is that if you give surfactant and it is effective and it rapidly increases compliance of the lungs or decreases stiffness, you can actually get more pressure transmitted to

the chest and increase the risk of pneumothorax so giving surfactant can cause a pneumothorax. Or high pressure, high ventilative pressures can contribute to it. How long you're ventilated, that makes a difference.

Q Doctor, I guess I want to get a sense as to what is more effective, what has a greater risk of causing pneumothorax? High inspiratory pressure or giving surfactant?

A I suspect that the high pressures on the ventilator are a major predisposing factor because I don't think there's any question about that. But it is one of the risks of surfactant if it's given and it acts very quickly and then those ventilator pressures are transmitted to the chest. That's a risk, okay? I've seen it happen. I saw it happen last week in our nursery in a baby that was 34 weeks' gestation.

Q Doctor, do you recognize that newborns who sustain significant hypoxia can sustain brain damage without having an asphyxial insult?

A Can you explain what you mean by hypoxia?

Q Reduced oxygen concentration.

A Where?
Q In the blood.
A No. The answer to your question, no. If that's what your definition of hypoxia is. What you're talking about is hypoxemia, okay? Hypoxemia has to do with how much oxygen is in the blood. When people talk about hypoxia they're talking about tissue hypoxia, okay? Tissue oxygen starvation. They're two very different things.
Q All right. Let's --
MR. BULLOCH: Let him finish. Please.
A If the question is whether tissue starvation of oxygen can lead, when it's prolonged and severe can that lead to later neurological deficit the answer is yes. If you're talking about brief periods of hypoxemia where there are dips in the P02 or the saturation for a short period of time, no. The answer is no. Because it's not, doesn't tell you anything about what the tissues are doing.
Q Well, what will tell you what the tissues are doing? Is there a certain test or laboratory analysis that will tell you what the tissue is

doing?

A Unfortunately, no. And what commonly is used is if the tissues are not receiving enough oxygen, and if the ability to extract more oxygen is exceeded, which is in a data patient, then the tissues start to change in that metabolism so they produce lactic acid and lactic acid can then be washed into the bloodstream and what you see is an acidosis, a metabolic acidosis. That's one side of tissue starvation. Off in the sequence of events that where you have oxygen, tissue oxygen starvation you also have decreases in cardiac output because the heart is also having oxygen starvation so you see decrease in cardiac output, you see decrease in blood pressure, which then leads to decreased perfusion, decreased cerebral blood flow and that can predispose to brain injury.

Q Without lactic acidosis?

A You generally have, well, there is lactic acidosis. Whether you see it in the blood or not, okay, is dependent on how well those tissues are perfused. So if you have oxygen starvation, your

tissues produce lactic acid. If there's a decrease in blood flow to those tissues because the cardiac output is down or the blood pressure is low, the acid stays in the tissues and it doesn't go out in the bloodstream so you don't see it. It's only after the baby recovers or that they're resuscitated that you often see the acid in the bloodstream and it's kind of paradoxical so you say here's a sick baby, doesn't have an acidosis, but resuscitate him and now we see the acidosis. However, that occurs rarely. In those case when there's adequate perfusion and this happens before there's decrease in cardiac output you do see a metabolic acidosis that you can measure in the blood.

Q Doctor, I guess what I'm getting at is do you appreciate that through hypoxia/hypoxemia or ischemia you can cause, Volpe says you can cause brain damage without an asphyxial pattern; do you acknowledge that?

A What do you mean by axphyxial pattern, what do you mean by that?

Q Well, when you have multi-system organ failure,

when you have evidence of lactic acidosis?

A Okay. Are you referring to hypoxic ischemic encephalopathy, is that what you're --

Q Yes. Yes. That's what we're here talking about.

A In full-time babies or in big babies it would be very, very, very rare not to have any signs or clinical signs. If you had some event or series of events that led to severe tissue hypoxia including brain hypoxia now, not talking about brief drops in blood oxygen levels, it would be more likely than not to see some clinical neurological signs of that. And there's no real difference in something that might occur 24 hours after birth and what might occur in the birth process. Big babies who have asphyxial injury develop neurological signs very soon after birth. And those are the babies where you can say maybe there's an increased chance of cerebral palsy. I don't agree that you can have just primary hypoxia without any, in this type, in this kind of baby, that you can have enough tissue hypoxia that would cause a long-term outcome problem that wouldn't cause some symptoms in the nursery.

Q When you mean symptoms, you mean signs of asphyxia?
A Neurological symptoms. Yes. Poor feeding, brainstem, sometimes brainstem symptoms, problems with tone and posture. Seizures, those sorts of things.
Q What is the significance of a child in the newborn nursery with RDS that suddenly becomes extremely dusky or cyanotic?
A Happens all the time.
Q What does it mean? I didn't ask you how often it happens. I asked you what's the significance.
A What it means is that the hemoglobin is desaturated and the color of hemoglobin is red when it's saturated and dark blue when it's not saturated and so the baby has a bluish color discoloration. It means that for that moment in time the saturation is low. So we're talking about the amount of oxygen in the blood at this point.
Q Can you help me appreciate looking at the distinction and the clinical importance to you as a clinician comparing PAO2 and oxygen saturations?

A So what's the question? How they relate to one another?

Q How they relate to one another and how does it, you as a clinician figure out what's really going on? One of those is poor important. What do you rely on more?

A Do you want a short answer or long answer.

Q I'll take a long answer.

A Do I have a blackboard? There's clearly a relationship, there's an equilibrium between the amount of oxygen that's on hemoglobin or the saturation and the amount of dissolved oxygen which is reflected in the PO2. The amount of oxygen carried in the dissolved state is very, very small. Most oxygen is carried on hemoglobin. So the important thing here is oxygen content. So it's how much oxygen the blood is carrying. That's going to depend on the amount of hemoglobin and on the saturation, and depending on the hemoglobin and the saturation there will be an equilibrium with PO2. So, for example, and these things, the oxygen content will be affected by how saturated the hemoglobin is, how much hemoglobin

there is, and what type of hemoglobin you have.

In the fetus and in the newborn infant, probably up to 2 or 3, 4 weeks of age, a good deal, 85 percent of the hemoglobin is what we call fetal hemoglobin. Fetal hemoglobin hangs on to oxygen more tightly. And therefore, shifts the dissociation between saturation and PO2 to the left. So, for any given saturation there's a lower PO2 than there would be in an adult. So simply stated, today in 2006, in our nursery, we rarely get blood gases. We do blood gases only to check PCO2 and pH because we primarily use saturation to guide us in terms of how much oxygen is being delivered.

So in general, you know, you kind of use both of them. You use your saturations to give a general idea and you use your blood gases mainly for pH and for PCO2 to see how well you're ventilating.

Q Okay, Doctor.

MR. BECKER: John, do you have a plane to catch?

MR. BULLOCH: I've got plenty of time, Mike.

My plane is not until -- I've got to drive back to Manchester, but my plane leaves at 2 o'clock. So I'm good.

Q Doctor, let's go to your report. The report I have, Doctor, is dated December 22nd, 2005. Is that correct?

A Yes.

Q Is that the only report you wrote in this case?

A That's correct.

Q The exhibits of correspondence from Mr. Bullock's office, are they merely letters about, are they -- first of all, is the correspondence from him to you or from you to him?

A They're all from him to me.

Q And it's more of a please find enclosed kind of thing; medical records or depositions and stuff like that?

A Pretty much.

MR. BULLOCH: There's one letter, Mike, where I'm asking him, giving him dates for trial and dates that we anticipate calling him at trial.

Q Going to the second page of your report, Doctor, you talk about the clinical condition of this

child when he essentially was leaving Palmer and headed to Fairview, do you see that? At the top of the page?

A At the top? Is that the first paragraph?

Q Yes.

MR. BULLOCH: Look back at the prior page, but I think you're actually talking about his condition at Fairview.

A Where it says infant was transported to Fairview by Dr. Lillien. Is that the paragraph? That's at the bottom of the first page?

Q Yes. First of all, let me start over, Doctor. And I didn't ask you this and I should have. You don't know Dr. Lillien, do you?

A No. I don't.

Q Going to the child, did you actually look at the chest films?

A I looked at the chest films that were done at Fairview. I did not see the chest film that was done at Palmer. There was one, I think.

Q Do you have any disagreement with the official interpretation, that is the Fairview General Hospital radiologist interpretation of those chest

films?

A Could you refresh my memory as to what they were? I don't recall. I looked at them. I could tell you what I thought they looked like.

Q Well, I want you to look at the official interpretation and tell me if you disagree.

A Which one are you talking about? The first one?

Q First, second and third. All of them.

A The first one he describes a hazy ground glass appearance, maybe see with RDS but other consideration would be other things and he talks about infection. And he's got something about catheter placement. Yes. The first x-ray which I'm looking at I certainly would agree with that. It's generalized. It's hazy. Endotracheal tube is in good position, he's got some generalized ground glass appearance. Yes. I wouldn't disagree with that. I would just add that I think that it would be very difficult to distinguish RDS at this point on that film from other things like pneumonia which was mentioned by the radiologist or possibly a clear fluid aspiration as well is another thing we see commonly.

The second film was very difficult to interpret because it was very overpenetrated. So what I see is a chest tube in good position, I see a pneumomediastinum mainly there and this says there's evidence of pneumothorax bilaterally and I don't agree with that. Certainly on the right side there's a very clearcut pneumomediastinum with maybe a little residual air up at the top which is common after putting a tube in. And the other side, the film is so dark that that area, the area on the left side is probably pneumomediastinum and I can't, but there is a situation where I would probably go over this film with a pediatric radiologist and we put our heads together and try to see what that was. I think it's uninterpretable because of the poor quality of the film.

The last one is -- if the second one was overpenetrated, this is underpenetrated. So looks very white. And again, I don't see any, I see mostly pneumomediastinum and maybe some residual air on both sides, but the tubes are in very good position and there's clearly been, I don't know

what, obviously I don't know what the film would have looked like at the point of the second pneumothorax because we don't have a film at that point, but it looks like most of the air is gone, and so this guy says there's residual pneumothorax most pronounced medially in the right. Now that's a pneumomediastinum on that side in my opinion. It's less pronounced on the earlier study. Hazing of lung fields so the lungs are intact so I agree with some of it but I think that he's misinterpreting on the right side there's clearly a pneumomediastinum there, and that's not a pneumothorax.

Q Doctor, can we agree that when the child was admitted to Fairview his neuro exams were normal?

A As far as the record shows they were.

Q And can we agree, Doctor, that by day nine or ten of life, he started to demonstrate some abnormal neuro signs?

A That was the time which he showed signs and symptoms that all of us would interpret as being infection or sepsis. He was treated promptly for that. Part of that was decreased activity and

then I believe at the time he was discharged, he was described as having some hypotonia at that time. So there was some other event that occurred around day nine or ten that is unrelated to his respiratory course.

Q Well, what was the other event?

A I don't know. Nobody seems to know what the cause of it was, but the initial things were certainly consistent with sepsis. There was hyperglycemia, hyponatremia. Baby had decreased activity. He had been just extubated and so his respiratory stuff was resolved at that point. He had some mild respiratory distress associated with this which is also common with sepsis. He was intubated again at low settings if I recall. And then they did a thorough workup looking for meningitis, they did LPs, they were worried about herpes. They treated him with acyclovir and antibiotics. There could have been a viral thing. I don't think anybody has a good explanation for this, although it's certainly consistent with an infectious process

Q You don't have an opinion in terms of probability

what happened during day eight or nine or ten?

MR. BULLOCH: Other than what he just stated?

A I just stated what I thought happened. That's as good as I can do.

Q Are we talking possibilities here, is that your opinion?

A I think it's -- in my opinion, it's most likely that was an infectious process.

Q Well, the neuro signs that he showed on day 8, what do you attribute that to?

A Which neural signs were those on day 8?

Q Decreased tone?

A He showed decreased activity. Didn't say increased tone. I don't believe that term is used until later but I may be wrong about that. Tone and activity are often used interchangeably and sometimes it's difficult unless you have a neurologist actually do an exam on the baby do you get a good idea of what's happening. But babies who are septic can have decreased tone as well as decreased activity.

Q You're saying that no matter what happened to this child between the time that he had good neuro

signs at admission and bad neuro signs at the time of discharge, it's unrelated to his respiratory management, correct?

A Yes.

MR. BULLOCH: Objection to the term "bad neuro signs." I don't think that's been established yet, Mike.

A If you're talking about the decreased activity and decreased tone, I don't think there's any relationship between the respiratory course and those things that were part of that infectious event.

Q Okay. And explain the bases for that opinion.

A Well, I guess there's a couple of things you would look at. You would look at timing. You would look at when this all, when this second of whatever you want to call it, when this second episode occurred which I think was infectious, he had all but resolved his respiratory problems. So I don't think the events are related.

Q Well, you say, Doctor, that there wasn't any evidence of severe respiratory compromise here to permit hypoxia to be a cause of this child's brain

injury. What do you mean, what would you need to see by way of severe respiratory compromise? How bad are the oxygen sats or PAO2s?

A As I stated before, you can't use just saturations and PO2s to predict tissue hypoxia. And in this case, there were brief periods of hypoxemia as evidenced by some PO2s that were in the 30s. And then I think the lowest sat recorded on their ICU record was 84 and in the nurse's notes they talk about the sats being in the 60s and 70s around the time of the pneumothorax. But these were brief, they were transient, they were not sustained. I don't know exactly how low you have to go and how long, but I suspect if the sats were very low, in the 20s and 30s, and that lasted for an hour or something, I mean I'm guessing, I don't know. But you have to have enough to have, to result in enough decreased oxygen delivery that those tissues could not extract enough oxygen, that mechanism would have to fail, then we have to have tissue oxygenation. There was no sign of a metabolic acidosis during this period of time. There was no sign of a decrease in blood pressure

during this time. There was no sign of anything that normally could be construed as contributing to a neurological deficit. Absolutely nothing. The pneumothorax --

MR. BULLOCH: Mike, you're interrupting him again.

A You have to remember that the pneumothorax is only not good when it produces tissue hypoxia and changes in blood flow and in this case, there was no evidence for that in the record.

Q And that evidence you're talking about, you mention blood pressure, you've mentioned what else besides blood pressure?

A Well, I mean --

Q Besides the PO2.

A The nurses at Fairview did an excellent job of recording all of the things that were going on. These are some of the best records I've ever seen, and they basically outline everything that happens to this baby, and I think that if you follow heart rate and blood pressure and you follow the blood gases and the metabolic component of those blood gases and you follow the saturations, what you see

is some brief dips in saturation and PO2 with no changes in PCO2, no changes in acid base, no changes in blood pressure. They were not sustained. And those are not related to later neurological or brain injury, those kinds of events. These kinds of events happen all the time in the nursery. Every preterm that has apnea has these things happen 8 to 12 times a day. Same degree of hypoxia, same degree, and these babies do not get cerebral palsy.

Q Doctor, did you note any inconsistency between the nurses' charting and the laboratory values of the laboratory findings on or about the doctor's notes?

A Not really. I'm referring to my spreadsheet now which basically is just an extraction from the record so I can look at it without going back through the record. Everything, no. I didn't see any discrepancy there.

Q Doctor, what is a normal ammonia level?

A It depends on, it depends on the lab. And I don't know what, I mean I think this baby has two of them and I think the 34 I think that I remember

was a normal value for that lab.

Q Is a 67 a venous abnormal?

A If it were sustained and repeatable I would worry about it, but that's why they repeated it because they didn't think it was an accurate number.

Q Do you know whether or not an elevated ammonia level is considered a sign of encephalopathy?

A Actually I would worry more about a metabolic disease which can masquerade as cerebral palsy. Things like lactic acidosis or changes in ammonia levels can all be early signs of a genetic disorder.

Q What is a normal MAP, mean arterial pressure, that you want in a newborn?

A It depends on the size and age and frankly, I have written reviews on blood pressure measurement in babies so I'm very familiar with the topic, but it's a big range and babies that are this age, the lower limit of normal is probably around 30, I would say, mean pressure, and I would worry about blood pressures less than 30 for prolonged periods of time.

Q All right. Doctor, let's go back to the standard

of care. Assuming hypothetically that Doctor -- and we're about wrapping down because I have to leave shortly anyways -- but going back to Dr. Lillien, if in fact he made the presumptive diagnosis of RDS, we have a child that's not intubated and requiring increasing pressures, to support good oxygenation, are you saying, Doctor, if that you would have had that presumptive diagnosis you would have given surfactant, correct?

A Dr. Lillien did give surfactant. It was the timing. It was the timing of the surfactant. But the timing of not giving it initially as he did is not outside the standard of care.

Q Okay. But let's start with what, we can agree fairly, Doctor, you would have given surfactant before this child demonstrated pneumothoraces more likely than not? You?

MR. BULLOCH: Are you referring, Mike, to Matthew Wagoner? Would he have given Matthew Wagoner surfactant in 1999. Is that the question?

Q Yes. That's the question.

A That's difficult to answer because I wasn't there

and I don't know. I might have treated this baby with nasal Cpap in 1999.

Q I thought you told us earlier, Doctor, that when you have, when you have in fact RDS you give surfactant. When you have a presumptive diagnosis of RDS you give surfactant to a baby that's intubated?

A No. I'm talking about using nasal Cpap without intubating him. I might have treated this baby with nasal Cpap but not intubated him in 1999 in which case I wouldn't have given him surfactant.

I can't say exactly what I would have done, but one of the common things that's done now and we do it all the time is you start a baby on nasal Cpap, and you see if that can be tolerated and if it's tolerated, and I must say some of those babies develop pneumothoraces when that happens, and then if you end up intubating them it may be 24 hours later. And if you intubate them at that point, yes, we usually would give surfactant if they failed nasal Cpap. And that's probably what I'd -- so I can't tell you that I would have intubated him right then and given him surfactant.

I probably would have tried some other method of support first, and I might have gotten into the some trouble with pneumothoraces either way. It's a common complication, with and without. If I got to the point where I was going to intubate him, I probably would have given surfactant. But that doesn't mean that it was wrong not to because there clearly is no standard of care in this age baby.

Q And when you say there's no standard of care in this age baby, you mean what? There's no studies?

A No. I mean that there's no absolute consensus about whether a baby like Matthew would have been intubated, not been intubated, given surfactant, not given surfactant because of what I stated earlier, and that is that you can rarely be sure that the baby has hyaline membrane disease when you have to make the decision to intubate this baby.

Q Ms. Court Reporter, could I have his last answer read back, please?

REQUESTED PORTION READ BACK BY REPORTER

Q I'm sorry, Ms. Court Reporter. You faded out on

me.

REQUESTED PORTION READ BACK BY REPORTER

Q But, Doctor, my hypothetical is and we didn't even have to look at the hypothetical. The facts of this case are Lillien had presumptive diagnosis of RDS, this baby was already intubated. Are you saying that there's no consensus with a presumptive diagnosis and an intubated baby as to whether or not to give surfactant?

A Not in a 35 week baby in 1999. No.

Q That's all I have.

MR. BULLOCH: Doctor, you have the right to read the deposition transcript.

Q Wait a minute. Wait a minute. Hold on.

MR. BULLOCH: Too late. Too late.

Q Hold on a minute, Doctor. I just want to confirm you don't have an opinion as to the etiology of this child's brain injury?

A No. I think it's -- all I can say is it's much more complicated than just some presumed previous event. The type of cerebral palsy is consistent with metabolic disease with previous injury. I am not a neurologist.

Q So you would defer on that issue?
A I would defer to a pediatric neurologist, that's correct.
MR. BULLOCH: You down now, Mike?
MR. BECKER: Yes. John, just so the record is clear he doesn't have an opinion as to the probability as to the etiology so I don't get surprised at trial?
MR. BULLOCH: I think he's quite clearly told you that he does not believe the etiology has anything to do with any event in the first few days of Matthew's hospitalization. I think the question you asked him --
MR. BECKER: But as to his opinion as to what the actual etiology is he does not have an opinion in terms of probability? That's all I need to know.
MR. BULLOCH: Maybe like Bachmann he doesn't know what caused it. He knows what did not cause it and that's --
MR. BECKER: John, I suggest to you that you read Bachmann's deposition again.
MR. BULLOCH: I have, Mike. I suggest you

read it again.

The bottom line is the Doctor has told you repeatedly he does not believe that the cause of Matthew's CP has anything to do with -- with respiratory.

MR. BECKER: I want to know if he, you know, I want to know if he has an opinion in terms of probability at trial as to what the true etiology of this child's injuries are. He's made it clear to me that he feels it's not what the Plaintiffs say. That's clear to me.

MR. BULLOCH: Okay.

MR. BECKER: I want to know if he has an opinion, John, in terms of probabilities as to the etiology. If he doesn't, fine. We're done.

MR. BULLOCH: And I think that he has answered you that he does not have an opinion of what caused Matthew's CP. He only has an opinion of what did not cause it, Matthew's CP.

BY MR. BECKER:

Q I need to hear that from you, not from your attorney.

A I think I said it. I don't have an opinion as to

what caused this. I am convinced that this wasn't his respiratory issues in the nursery that caused it.

MR. BULLOCH: Okay. Doctor, you have the right to read the transcript in this deposition and make corrections. I suggest that you do that.

MR. BECKER: Doctor, let me thank you they for making the trip over to this video conference. That was very nice to of you to do that.

MR. BULLOCH: He's a very nice guy.

DEPOSITION ENDED

I have carefully read the foregoing deposition, and the answers made by me are true.

_____
ROBERT A. DARNALL, M.D.

STATE OF _____

_____, SS.

At_____on the _____ day of _____ A.D. 2006, personally appeared the above-named ROBERT A. DARNALL, M.D. and made oath that the foregoing answers subscribed by him are true.

Before me,

_____
Notary Public

C E R T I F I C A T E

I, Cynthia Foster, RDR, Stenographic Reporter and Notary Public, hereby certify that on the 27th day of July, A.D. 2006, there appeared before me ROBERT A. DARNALL, M.D. as a witness in the matter of MATTHEW CHASE WAGONER, ETC., ET AL V. MARK R. EVANS, M.D., ET AL, now pending in the Court of Common Pleas, Cuyahoga County, Ohio;

That said deposition was then taken at the time and place aforesaid;

That the said witness was duly sworn;

That the foregoing testimony was taken by me in Shorthand and thereafter reduced to typewriting by me, and the foregoing pages 3 through 90, inclusive, comprise a full, true and correct transcription of my verbatim stenographic notes of the deposition of said witness.

Dated at West Lebanon, New Hampshire, this 1st day of August, 2006.

_____

Cynthia Foster, RDR