STATE OF OHIO)
) SS:
COUNTY OF CUYAHOGA)

IN THE COURT OF COMMON PLEASE

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MATTHEW CHASE WAGONER, etc., :
et al., :
Plaintiffs, :
vs. : Case No. 497179
MARK R. EVANS, M.D., et al., : Carolyn B.
Defendants. : Friedland

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DEPOSITION OF JONATHAN H. CRONIN, M.D., a witness called on behalf of the Defendant, Lawrence D. Lilien, M.D., taken pursuant to the applicable provisions of the Ohio Rules of Civil Procedure, before Valerie R. Johnston, Registered Professional Reporter and Notary Public in and for the Commonwealth of Massachusetts, at the Offices of O'Brien & Levine Court Reporting Services, at 195 State Street, 5th Floor, Boston, Massachusetts, on Monday, June 19, 2006, commencing at 3:10 p.m.

A P P E A R A N C E S:

Becker & Mishkind Co., L.P.A.
(by Michael F. Becker, Esq.)
Becker Haynes Building
134 Middle Avenue
Elyria, Ohio 44035,
on behalf of the Plaintiffs.
Tel: (440) 323-7070

Moscarino & Treu, LLP
(by John T. Bulloch, Esq.
and George Moscarino, Esq.)
The Hanna Building
1422 Euclid Avenue, Suite 630
Cleveland, Ohio 44115,
on behalf of the Defendant,
Lawrence D. Lilien, M.D.
Tel: (216) 621-1000

I N D E X

E X H I B I T S

P R O C E E D I N G S

JONATHAN H. CRONIN, M.D.,
having been satisfactorily identified by the production of Massachusetts Driver's License No. 031420705, and duly sworn by the Notary Public, was examined and testified as follows:

DIRECT EXAMINATION

BY MR. BULLOCH:

Q. Dr. Cronin, my name is John Bulloch. I know we met before the deposition began, but for the record, I represent Fairview Hospital in this matter.

Have you had your deposition ever taken before?

A. I have.

Q. Okay. We'll get to that in a minute.

You were kind enough to share with me your file that you have in this case, and it looks like it comprises the records from Parma Community Hospital, Fairview Hospital, Dr. Ahmed's (phonetic) prenatal records, some records from Dr. Evans and some records from the free clinic; is that correct?

A. That's correct.
Q. And then you also have a couple of letters from counsel. Have you removed anything from this file?
MR. BECKER: I have.
MR. BULLOCH: Do you mind telling me what you removed and when?
MR. BECKER: Sure. I removed some e-mail correspondence between Scott Kolodny of my office -- formerly my office and to the doctor.
MR. BULLOCH: For the record, we believe we have the right to see those. So just make a record of that in the transcript, please.
BY MR. BULLOCH:
Q. You also have a report from a Dr. Rodriguez, Carlo Rodriguez, from University Hospital in Cleveland.
A. Correct.
Q. Do you know Dr. Rodriguez, by any chance?
A. No, I don't.
Q. Okay. And you have a couple of bills in here.
(Mr. Moscarino entered the conference

room.)

MR. BECKER: This is George Moscarino.

THE WITNESS: Hi. How are you?

MR. MOSCARINO: Good to meet you. Sorry I'm a little late here.

BY MR. BULLOCH:

Q. Doctor, are these all the bills that you've generated to date in this matter?

A. That's correct.

Q. So you spent an hour writing a report and two and three-quarter hours reviewing the case; is that correct?

A. That's correct.

Q. Have you ever seen any other -- other records from this case?

A. No.

Q. Any other subsequent care records or anything?

A. No, other than what I have here. This is the entire file (indicating).

Q. Have you ever talked to counsel for the Plaintiff about any of the other Plaintiffs or the other expert witness reports that have been generated in this case?

A. About their findings?
Q. Yes.
A. Once.
Q. Do you recall the -- the scope of that conversation? I mean, was it the Plaintiffs' experts that you were reviewing?
A. I didn't review. It was -- it was a discussion between -- it was a phone discussion between me and the Plaintiffs' counsel.
Q. Was that with Mr. Becker?
A. That's correct.
Q. Okay. Was that pretty recent?
A. Yes.
Q. And was it predominantly a discussion about defense experts or about Plaintiffs' experts?
A. Plaintiffs' experts.
Q. Did you have any other conversations about any other reports that have been generated in this case by any of the defense experts?
A. No, I have not.
Q. And then you have a -- it looks like two pages of handwritten notes, correct?
A. Correct.

Q. I assume these were notes that you took as you were reviewing Matthew Wagner's records.

A. That's correct.

Q. You had Dr. Lilien's deposition transcript as well, correct?

A. That's correct.

Q. Have you seen any of the other deposition transcripts that have been generated in this case?

A. I have not.

Q. Have you had any discussion with Plaintiffs' counsel about any of the testimony that's been offered by any of the other witnesses in this case?

A. I have not.

MR. BULLOCH: Go ahead and mark that as Exhibit 1, please.

(Document marked as Exhibit 1 for identification)

BY MR. BULLOCH:

Q. Doctor, I'm going to hand back to you your two pages of notes, which we've marked Exhibit No. 1. I'll probably ask you to read portions of these into the record, and I don't

believe I asked you this, but did you review any of the x-ray films that were generated?

A. I've never seen an x-ray film.

Q. Okay. So, obviously, you've looked at reports from the radiologist, correct?

A. That's correct.

MR. BULLOCH: Okay. Mark this Exhibit 2, please.

(Document marked as Exhibit 2 for identification)

BY MR. BULLOCH:

Q. Doctor, I'll hand you what's been marked as Exhibit 2, which is a copy of your CV that was provided to us by Plaintiffs' counsel, which is -- which would be 23 pages long, correct?

A. (Witness reviews document) No. This is not my CV. I have things from Barry Pressman.

Q. I am sorry. Something got stapled together.

A. This is not my CV (indicating).

Q. All right. We got some -- how these got put together -- I'm sorry, Doctor. I'll correct that.

MR. BULLOCH: Off the record.

(Discussion off the record)
MR. BULLOCH: Back on the record.
BY MR. BULLOCH:
Q. I apologize for the mix-up.
You now have in front of you what's your CV dated as of March 20th, 2006?
MR. BECKER: Is this a copy?
MR. BULLOCH: Yeah.
A. (Witness reviews document) Yes.
Q. Do you have a more current CV, sir?
A. Yes, I do.
Q. You don't happen to have one with you, do you, by any chance?
A. Yes, I do (indicating).
Q. Terrific. Is this the only copy that you have (indicating)?
A. Yes.
MR. BULLOCH: All right. Can we mark that as Exhibit 3.
(Document marked as Exhibit 3 for identification)
BY MR. BULLOCH:
Q. The CV that you handed me we've marked as Exhibit 3 has a new date of June 6th, 2006.

This is your most current CV?

A. Correct.

Q. Are there any additions or deletions to this CV that you would add at this time?

A. Not significant ones that I recall.

Q. Okay. And, since you have the March 20th, 2006, CV in front of you, could you tell me what is different on what we marked as Exhibit 2 and what's marked as Exhibit 3.

A. (Witness reviews documents) There may be a small change in -- in a hospital affiliation that I have, but it's essentially the same. I just keep my CV up to -- up to date --

Q. Okay.

A. -- but there's no -- there's no significant change between the two.

Q. All right. And, as far as hospital affiliation, you mean hospitals that you're currently practicing in?

A. Correct.

Q. Are there any new articles or book chapters or abstracts or reviews or anything of that nature that you've added to this CV?

A. No, not since the one in March.

Q. Okay. I'll hand you back your current CV, and I'll work off the old one. Fair enough?

A. Okay.

Q. You tell me if I'm making any errors in any assumptions or if there's been any changes that I might not have.

I understand that you have -- you are dual boarded, correct?

A. That's correct.

Q. Pediatrics was a sub-board in neonatal and perinatal medicine?

A. That's correct.

Q. Is the latter board held by most neonatologists?

A. That's correct.

Q. Is it also the same board that's held by perinatologists, or are they basically the same thing?

A. No. That's a different board.

Q. Okay. So the neonatal perinatal medicine board is actually for neonatologists?

A. That's correct.

Q. Okay. Have you had that board recertified? Have you ever been recertified in

that board?

A. I have not, because it has not been required.

Q. Okay. You're kind of grandfathered --

A. Grandfathered.

Q. -- in for life?

A. Correct.

Q. Okay. I understand from your prior CV that we had, which is roughly two and a half months old, that you were -- are an assistant professor in pediatrics.

A. That's correct.

Q. And that's with Harvard Medical School?

A. That's correct.

Q. Is that a clinical position, Doctor?

A. I don't understand.

Q. Well, let me explain. We see a lot of people that have professorships or have academic appointments, and what they're really doing is mentoring people, second and third-year law school -- in your case, NICU. You're trying to teach them medicine clinically as opposed to didactic, where there's a lot of lectures and classroom type instruction. Is yours more the

former or the latter?

A. It's a combination of both.

Q. Okay. So you actively give lectures at Harvard Medical School?

A. Not at Harvard Medical School. I give didactic lectures to people at Massachusetts General Hospital, trainees, and I also do bedside teaching with the residents when I'm rounding.

Q. And the latter is more what I mean by clinical professorship.

Now, the lectures that you give at Mass. General, are those to residents, or is that more nursing staff or --

A. Residents -- pediatric residents, pediatric clinical care fellows, neonatology fellows, nursing staff and an occasional medical student.

Q. Okay. I also noticed in your -- your CV you had a lot of ECMO.

A. Correct.

Q. Is that predominantly what you give lectures in?

A. It's one of the things that I talk a lot about.

Q. Good.

You're an assistant professor. The next step would be -- associate professor is the next step up?

A. Correct.

Q. And then a full professorship, correct?

A. Correct.

Q. All right. You also listed in your current hospital appointments pediatrics at Mass. General --

A. Correct.

Q. -- and a neonatologist at the Brigham, correct?

A. Correct.

Q. Okay. I guess, I'm a little bit confused. Are you -- are you -- are -- why don't you tell me what you practice in terms of both locations.

A. These are hospital titles, and Massachusetts General Hospital does not have a hospital title for being a neonatologist. They just have hospital title for, I think it's, junior pediatrician --

Q. All right.

A. -- and then pediatrician.
Q. Okay.
A. Whereas at the Brigham, because they only have a neonatal intensive care unit -- they don't have a pediatric department over at the Brigham -- you're either a junior neonatologist or a neonatologist.
Q. I see.
A. These are just sort of all hospital titles.
Q. Okay. And correct me if I'm wrong; is most of your clinical responsibilities in NICUs?
A. Neonatal intensive care units and step-down units, Level 2 nurseries.
Q. Okay. You don't have an active pediatric practice where you're giving kids MMR shots or things of that nature?
A. That is correct.
Q. You're not treating kids with inflammation of tympanic membrane or things of that nature?
A. That is correct. I do not.
Q. Is it fair to say that a hundred percent

of your clinical time is spent in the NICU?

A. Or Level 2 nursery, yes.

Q. Or Level 2 nursery. Thank you.

Let me ask you about that. What percentage of your time would you estimate you're in a Level 2 nursery as opposed to a Level 3 nursery?

A. My Level 3 nursery time -- let me rephrase that.

Of my clinical time, the vast majority of that is neonatal intensive care units, and the -- the minority is in Level 2s.

Q. Okay. Can you -- and I'm not --

A. I can quantify that.

Q. I am not going to hold you to these numbers, but yeah. Can you quantify that for me a little further.

A. This academic year and those in the recent past, I've done approximately 12 weeks a year in the neonatal intensive care unit being on service, and I've done --

Q. And that's a Level 3 nursery?

A. Correct.

Q. I don't mean to interrupt you.

So that's roughly 25 percent of your time in Level 3?

A. Correct.

Q. Okay.

A. And approximately three to four weeks a year in a Level 2 nursery.

Q. Okay. Either you have got a great vacation planned, or my -- my math is really failing me. What do you do the rest of the time?

A. I do 40 to 50 nights a year of night call.

Q. Okay. And what does that entail?

A. That entails being the senior neonatologist in-house at night, nights, holidays and weekends --

Q. Okay.

A. -- covering the NICU, covering the Level 2, backing up the -- the labor and delivery, being the senior person in the house.

Q. Okay. And, as senior person in the house, that's -- what did you say -- 40 or 50 nights a year?

A. Correct.

Q. Okay. Do you also get summoned to

the -- to the pediatric wards?

A. No, I do not.

Q. Okay.

A. That is not my responsibility.

Q. Okay. What do you do the rest of your time professionally?

A. A lot of administration time, being the acting chief of the unit. Before that, I was the associate chief of the unit, and I try to write a chapter in a textbook every several years.

Q. And I noticed that, and I planned to get to that in a moment, but you -- well, let me go to this.

You -- there were -- there were a number of things that I wanted to talk to you about just to get a better understanding of what your practice is all about.

You stated that or your CV lists MGPO Management Education Program for Specialist Leaders.

A. Correct.

Q. I assume MGPO is Mass. General Physician Organization.

A. That is correct.

Q. And that's essentially a group of doctors in private practice, correct?
A. Not really, no.
Q. Okay. Why don't -- why don't you tell me what it is, Doctor.
A. There are two corporate entities. Number one is Massachusetts General Hospital, and they have they have their own corporate board of trustees. Very closely affiliated is the Massachusetts General Physicians Organization. That is the organization that employs all of the physicians that work at Mass. General Hospital and -- but it is a -- but it is --
Q. A wholly-owned subsidiary of the hospital?
A. Not of -- not of the hospital. It's a -- it's a separate corporation and has separate board --
Q. Okay.
A. -- but, of course, they work very closely together --
Q. Okay.
A. -- but they are distinct, separate entities.

Q. Okay. And then you're under contract through the -- through the MGPO?
A. That is correct.
Q. And then the MGPO, I assume, contracts with Mass. General to provide physicians in --
A. That is correct.
Q. -- every specialty.
A. That's correct.
Q. Now, there's Management Education Program for Specialist Leaders. I mean, that's a mouthful, but I assume that you're being groomed or you were in that program being groomed for some type of administrative position; is that fair?
A. Back in 1997, there was an opportunity to, you know, get some education about, you know, management education, sort of a mini-B school, if you will, and it was something that I was interested in, so I took it. It was a week-long course that I took.
Q. A mini M.B.A. program?
A. Correct.
Q. Okay. Now, you also list -- and I want to get this right for the record, so I apologize for reading, but MGPO Physician Practice Leaders,

and what -- what was that all about? I think that went from 2002.

A. From 2002 to 2003, the MGPO Physician Practice Leaders Forum. That was a monthly meeting of people who -- some of whom had gone through the management education program, but I had selected myself, if you will, something that I'm interested in -- in furthering my career through medical management, and the following year the MGPO Physician Leadership Development series just sort of followed hand-in-hand, and this was a -- again, this is an attempt by the MGPO to take physicians who are interested in becoming more administrative leaders in the organization.

Q. Okay. What's your role with the MGPO currently?

A. I'm a physician within the group.

Q. Sure.

A. And, number two, I'm an elective member of the MGPO Executive Committee.

Q. Okay. And what's your role in the executive committee?

A. I go to meetings twice a month and represent subspecialists' interests.

Q. Okay. And I assume to represent subspecialists interests you're doing some -- you just don't go to these meetings and represent your subspecialists' interests, correct?

A. That's correct. I represent -- I'm one of two, I believe, sub -- subspecialist -- elected subspecialist representatives, and my job is to represent the outlook of MGPO subspecialists.

Q. All subspecialists?

A. Yes.

Q. Wow.

And do you have to meet with the various subspecialists from time to time to get a feel of what their interests are? I mean, you're going to represent them in front of the executive committee. How do you go about obtaining the data or the information you need to -- to represent their interests?

A. Well, there are three -- it's a three-year term, and there are three -- three of us who are subspecialists who represent the subspecialist members.

I -- I know a lot about pediatrics; I know a lot about obstetrics and, certainly, a

certain degree of anesthesia. So people who I -- who come along sort of in my practice, and there are two others, who are usually medicine and surgical types, who span out and -- and get the opinions of others.

It's not -- it's not a formal I sit down with all the subspecialists --

Q. Okay.

A. -- or anything like that.

Q. What percentage of your time do you think you're involved in just that aspect of being on the executive committee?

A. 5 percent.

Q. 5 percent?

A. It's small.

Q. All right. You -- you've got numerous committee assignments on your CV, too, correct?

A. Correct.

Q. And, just for the record, could you tell me what those currently are. I guess -- well, you tell me where you start, but on my older version of this, I guess, I would start at chairman of Emerson Hospital Perinatal Committee.

A. Starting in 19 -- that's correct. I've

done that since 1997.

Q. That's current?

A. Yeah. That is correct.

Q. Okay. Go on. Can you tell me the rest of the committees that you're -- the major committee assignments, as you put it, that you're currently involved in.

A. Sure.

Q. You know what; I am sorry. I'm going to ask you to back up. I misread this.

There's major committee assignments on the national and regional level as well, correct?

A. Correct.

Q. Are you still on both of those?

A. Yes, I am.

Q. What is the Technical Advisory Group on Neonatal Intensive Care?

A. It's an ad hoc group put together by the Department of Public Health and the Commonwealth of Massachusetts that's called every now and then when people of DPH have technical advisory questions about neonatal intensive care unit.

Q. So this is a formal committee that sits down from time to time?

A. It's an ad hoc group. It's met about four times in the last 10 years.

Q. Okay. Is there any administrative work that you're doing for that particular advisory group?

A. No.

Q. What percentage of your time do you think is involved in this particular group?

A. Minuscule.

Q. Okay. Fair enough.

The AAP Neonatal Resuscitation Program, what's that all about, sir?

A. That's a -- the education work group. It's, again, a very small amount of work, which usually has to do with e-mail questions and putting together teaching materials for the AAP, Neonatal Resuscitation Program.

Q. The AAP being the American Academy of Pediatrics?

A. That's correct.

Q. This is a national program, obviously.

A. International.

Q. International.

Can you give me a percentage that you

spend on national and regional matters?

A. It's -- it's small. I mean, one to 2 percent.

Q. Okay. And then, as I said -- I'm sorry I skipped those very important assignments, but you were starting with the chairman of Emerson Hospital Perinatal Committee.

A. Right. Emerson Hospital is a Level 2 nursery, which is affiliated with Partners Health Care, which is a conglomerate here in Boston.

Q. I'm familiar with that.

A. And I'm the -- I'm the medical director of the Level 1 and Level 2 nurseries at Emerson, and as part of those responsibilities, I'm chairman of the perinatal committee, which is a committee that's mandated by the Department of Public Health. Every hospital perinatal service has to have that, and I'm also chairman of the Emerson Hospital Neonatal Care Review Committee where we go over certain cases that meet certain criteria. It's a peer review committee.

Q. By peer review committee, I assume that meets monthly at least.

A. Correct. Yes.

Q. Okay. What about the other two committees that you mentioned; how often do they meet?

A. The other two?

Q. I thought you said there were two. I only see one, but I thought you mentioned two.

A. There's the perinatal committee and then the neonatal peer review committee at Emerson Hospital.

Q. Are those the only two committees you served on at Emerson currently?

A. That's correct, yes.

Q. Okay. And you're a chairman, so you, obviously, have some role in putting together agendas and --

A. I do that with the nurse manager, correct.

Q. Maybe, this is an easier way to break that down. About what percentage of your time do you think is involved in the administrative responsibilities just at Emerson?

A. 3 percent.

Q. Okay.

A. I hope you don't think this is all going

to add up to a hundred.

Q. No, I don't, but I expect it to be very close. I'm kidding.

Then you have Mass. -- Mass. General Hospital Fetal Maternal Task Force. Is that the next thing that you're currently still serving on?

A. Yes, although that committee has been dormant for -- for about six months to a year and may come back. Unclear. I do not chair that.

Q. Okay.

A. I'm just a member of it.

Q. We talked about the MGPO --

A. Correct.

Q. -- Executive Committee, correct?

A. That's correct.

Q. Okay. Did we talk about the MGPO Physician Practice Advisory Council?

A. No. That's -- the Physician Practice Advisory Council was a -- on Page 1, after the physician MGPO Physician Leadership Development series ended -- that was a year-long process -- they formed with the same group of us the Physician Practice Advisory Council. So we are a group that meets on a monthly basis to basically

advise the leadership of the MGPO on issues regarding physician practice.

Q. Okay. And what percentage of your time would you estimate you spend in that practice --

A. We --

Q. -- advisory council?

A. We meet once a month. Again, it's small. It's two to 3 percent.

Q. Okay. And then the MGPO Continuity of Care Task Force, are you still active in that, sir?

A. I am. That hasn't been -- I'm not the chairman of it. I'm a member of it, and it hasn't really gone anywhere in recent time.

Q. Okay. And did we talk about the Mass. General Hospital General Executive Committee. This is different, isn't it?

A. This is different. I --

Q. This is the general executive committee of the entire hospital?

A. That's correct.

Q. Mass. General?

A. That is correct.

Q. And what's your role in that?

A. It meets twice a month. I go to both of those meetings as representing the MGPO.

Q. And what percentage of your time do you think you spend in that role preparing for going to meetings and so forth?

A. Again, it's, probably, 3 percent. It meets twice a month.

Q. Okay. You have certain departmental responsibilities as well, and the first one I'm showing is -- well, let me back up before I ask you that.

Are there any other hospital-wide committees that you're currently serving on that we haven't already talked about?

A. No.

Q. Okay. The departmental, would you cover those for me, sir. The first one that I have is Mass. General Newborn Services Collaborative Practice --

A. Collaborative Practice Committee. That's a monthly meeting -- interdisciplinary meeting for all of us who are involved in the care of neonates. We meet once a month.

Q. Okay.

A. The Vincent Memorial Obstetrics --

Q. Before you go on to that, how much time of your time do you think you spend on this?

A. It's -- we meet -- we meet once a month, and there may or may not be some work to do that, but we meet once a month.

Q. Two or 3 percent?

A. It's small. Obviously, it might be less, because two to 3 percent might be when I'm meeting twice a month.

Q. Okay. How long do all of these meetings usually last?

A. Well, it depends. The GEC meetings, General Executive Council, are two-hour meetings. MGPO meetings are usually two-hour meetings. This one here is a one-hour meeting.

Q. Okay. I understand you have certain committees that you just basically get ready for and go to and others that you do a substantial amount of work --

A. Correct.

Q. -- to prepare for?

A. Correct.

Q. Okay. Then you started telling me about

the Vincent --

A. Memorial Obstetrics Division Work Group. That's another interdisciplinary meeting chaired by obstetrics and perinatology, and I represent neonatology in that group.

Q. The same amount of time spent on that, 2 to 3 percent?

A. It's two hours, and it's twice a month.

Q. So, maybe, that's a little more?

A. Right.

Q. What would you estimate that at, 5 percent?

A. Yeah. Four to 5 percent.

Q. Okay. And then you have membership and professional societies. Are you involved in -- I understand what membership entails, but somebody of your level, are you also involved in any type of administrative capacity with any of these organizations?

A. No, I'm not.

Q. Doctor, maybe, I should have asked you this before, but -- wait a minute.

Out of all of the administrative responsibilities that you have, if you'd sit down

and compare the number of days that you're in the NICU, the number of days that you're on-call, can you kind of convert that to hours? And then the number of hours you're involved in an administrative capacity, what percentage of total professional time would you estimate is involved in some type of administrative capacity?

A. Probably, around 40 percent.

Q. And that's the best estimate you can give me today?

A. Uh-huh.

MR. BECKER: Can we take a two-minute break.

MR. BULLOCH: Sure.

(Recess)

BY MR. BULLOCH:

Q. Doctor, you've been deposed before how many times?

A. Less than a dozen.

Q. Okay. Well, you probably know the ground rules, but just to remind you. I mean, you're doing a great job, and you're verbalizing your answers, but for the court reporter's benefit, she can't really record nods of the head.

We're all guilty of that.

A. Okay.

Q. This is not the normal way we have conversations, and as she said, if you could just wait until I finish my question, I'll try like hell to not interrupt your answers. I'm probably worse at this than you are, so...

All right. Doctor, you -- you told me about your activity in Level 2 and Level 3 nurseries, and was that -- the percentage that you spent in Level 2 versus Level 3 nurseries today, was that also true in 1999?

A. Yes.

Q. Was that about the same percentage?

Okay. What's the difference between a Level 2 and Level 3 nursery?

A. Well, within the Commonwealth of Massachusetts, Level 2 nurseries are defined by the ability to provide continuous positive airway pressure, nasal CPAP, as their highest mode of respiratory care, and only some nurseries can do that. It's a very highly regulated, complex process in Massachusetts.

Q. Is that true only in Massachusetts?

Because we all have level -- I've seen Level 2 and Level 3 nurseries through the country. Is that individually state licensed and regulated?

A. In general, yes. There are some states where you can do mechanical ventilation, if you're a Level 2 nursery. It's -- it can get very complicated, but in Massachusetts, what a nursery can do and how it's graded Level 3, Level 2A. Level 2B is highly regulated by the Department of -- the Department of Public Health.

Q. Okay. These organizations that you're involved in, do any of -- have they promulgated directives or -- or guidelines to what they believe should be a Level 2 versus a Level 3 nursery?

A. A couple of years ago the American Academy of Pediatrics came out with a policy statement, for lack of a better word, trying to make a little method to the madness on a national level.

Q. Did that have any impact?

A. In Massachusetts, it has. I can't speak for other states.

Q. Well, in -- and I'm not asking you to

from your perspective or anything, but just for -- obviously, I'm sure you go to a lot of seminars, and you, probably, talk at a lot of seminars, and I'm sure you're in contact with other physicians that are neonatologists. Do you find a big difference between Level 2 and three nurseries in Massachusetts as opposed to most other states?

A. As it relates to community hospitals, it -- it can be, yes.

Q. Okay. Would you agree with me that Level 3 is kind of the gold standard? I mean, I assume there's not a Level 4, correct?

A. Actually, there is a Level 4 --

Q. Oh.

A. -- a Level 4 category in the new AAP guidelines.

Q. Okay. But not in Massachusetts?

A. That is correct.

Q. So I assume you would agree with me Level 3, at least in Massachusetts, is kind of the golden standard, correct?

A. That's correct.

Q. Now, when you're a neonatologist in a NICU, are you -- are you essentially the attending

physician?

A. That's correct.

Q. And what's the role of consultants that come into the NICU -- consultants -- for example, a pediatric neurologist? Can you explain that for me, what their role is as opposed to your role as a neonatologist.

A. Well, in the NICU at Massachusetts General Hospital, where I've worked for 12 years, all of the patients are admitted under my name, and I am the attending neonatologist.

Q. You're the captain of the ship?

A. Correct.

Q. Okay.

A. And I will ask for a consultant -- I will request a consultation on a certain subspecialist to help me care for a certain patient.

Q. Okay. So, when you call in a subspecialist, it's for that specific purpose, correct?

A. Yes.

Q. For example, if you call in an orthopaedic surgeon, it's to evaluate a child for

some orthopaedic condition, correct?

A. Correct.

Q. When you call in a cardiologist, it's for some cardiac manifestation, correct?

A. Correct.

Q. Now, when you call in a pediatric neurologist, it's for a neurologic deficit; fair enough?

A. Neurologic --

Q. Deficit or neurological condition.

A. -- issue.

Q. Symptom. Issue. Thank you.

Okay. So, obviously, you're in the NICU all of the time you're working clinically as opposed to a pediatric neurologist who might have office hours and be doing other things, correct?

A. Yes.

Q. So, when I'm talking to you, I'm talking to the guy that should know the most about what goes on in a NICU; is that fair enough?

A. Yes.

Q. Okay. The way -- and I think you answered this, but in -- in Massachusetts, at least, who determines if a NICU is a Level 2 or a

Level 3; is that the state?

A. Yes.

Q. Okay. And the primary determinant is whether or not you can give oxygen under pressure?

A. It's much more complicated than that.

Q. Okay.

A. We have department -- we have perinatal regulations that are promulgated by the Department of Public Health. They are around 300 or 400 pages long.

Q. Okay.

A. And, within those pages, they delineate exactly what you need to have to be a Level 1, a Level 2 or a Level 3 as it pertains to staffing, equipment, consultants, the whole ball of wax.

Q. Okay. In your mind, the major determinant -- and tell me if this isn't fair, but I'm just trying to get -- in your mind, the major determinant is the ability to give oxygen under positive pressure?

A. Nasal -- it's just -- it's not that simple, because in Massachusetts, we have 2A nurseries, which can't give nasal CPAP --

Q. Okay.

A. -- but 2B nurseries can give nasal CPAP.
Q. Can they also -- can Level 2 nurseries in Massachusetts also vent a baby?
A. No, they -- no, they cannot.
Q. Okay. Only a Level 3 nursery can vent -- put a baby on a ventilator?
A. That is correct.
Q. Okay. And a Level 2 nursery that had a baby that needed a ventilator would transfer that patient or should transfer the patient to a Level 3 nursery; fair enough?
A. That is correct.
Q. You don't give surfactant, unless you're on a ventilator, correct?
A. Unless you have an endotracheal tube in place.
Q. Would you have an endotracheal tube in place and not be on a vent?
A. You might be on a -- a bag, an anesthesia bag.
Q. Okay. In your experience, do Level 2 nurseries in Massachusetts frequently or infrequently administer surfactant to babies?
A. For babies that are to be transferred

frequently.

Q. So they might start it, the surfactant, and then transfer the baby; is that what you're saying?

A. That is correct.

Q. But that would be not under ventilation; that would be with a bag?

A. Depending upon -- correct, depending upon whether the particular Level 2 hospital had a ventilator.

Q. Okay. Well, wait a minute, though. Didn't you tell me that a Level 2 can't put a baby on a vent?

A. We're getting into semantics here in Massachusetts between Level 2A nurseries and Level 2B nurseries.

Q. Okay.

A. The Level 2A nurseries that I work at do not have infant ventilators. If there is a baby born who they feel needs surfactant, the child will be intubated, and then surfactant will be given by either the person who is there or the transport team when they arrive --

Q. Okay.

A. -- and then the baby will be transported.

Q. Or, I suspect, sometimes they might wait until the baby is actually transported and then administer the surfactant at the Level 3 nursery, correct?

A. That happens very infrequently today.

Q. Okay. At least the first dose?

A. That happens very infrequently today. Transport teams in Massachusetts all give surfactant on transport.

Q. Okay. And, again, they would not be giving multiple doses on transport, would they?

A. No. Just the first dose.

Q. Just the first dose. Okay.

Do you give it the same way when you're using -- when you're giving it with a vent? Do you have to position the baby so many different ways --

A. Yes.

Q. -- to enter the tube?

A. There's a protocol that we follow, yes.

Q. Okay. Is there a difference in the level of skill of a neonatologist working in a

Level 2 versus Level 3 nursery, in your mind?

A. I feel that neonatologists who primarily work in Level 3 NICUs are -- are more skilled at dealing with those types of issues as opposed to a level -- as opposed to a neonatologist who works in a Level 2 nursery and occasionally goes to work in a Level 3 NICU.

Q. They're seeing sicker babies, essentially, in a Level 3 nursery?

A. Correct.

Q. They might have a little bit more training; they might be a little more competent -- I am sorry. I interrupted you. You nodded your head yes, correct?

A. I think there's -- let me leave it at this: I think there's a difference between neonatologists who work primarily in -- in NICUs and deal with acute issues in newborns as opposed to the neonatologists who work primarily in Level 2s and then episodically go into NICUs for, perhaps, a little refresher.

Q. Tell me briefly what goes on in a Level 3 nursery. I mean, there's a lot of monitors, obviously; there's a lot of staff, correct?

A. Correct.

Q. The monitors, what are you -- what are you monitoring these babies for when you have a -- in a Level 3 nursery hooked up to all of these machines? What exactly are you typically monitoring on a neonate?

A. The basic monitor, we're monitoring their heart rate, their respiratory rate, their blood pressure and their oxygen saturation.

Q. Okay. And these monitors -- let's move back to 1999. These monitors, I assume, have certain levels that are preset, and once the level goes outside of that preset normal limit, then I assume it alarms, correct?

A. That's correct.

Q. The reason I ask you this is I've been in a NICU before, and there's a lot of alarms going off all the time, correct?

A. Correct.

Q. But there's a lot of nurses, too, isn't there, in most NICUs?

A. Correct.

Q. Is there a certain staffing requirement for NICUs that you're aware of?

A. The patient/nurse ratio is determined by the nursing staff, depending upon the acuity of the patient.

Q. Okay. A child with RDS, respiratory distress syndrome, is that typically one-on-one, or is the nurse covering two patients?

A. If the -- if the patient is -- I'm talking a little bit about my -- you know, this is more of a nursing expertise, but what I've observed through the years is that, if you had a -- a baby who is severely ill with hyaline membrane disease, it's one-to-one, but most often these days it's -- it's two patients to one nurse.

Q. Okay. And I assume the nurse is watching patients that are next to each other, so she can watch both monitors? And, again, in your experience.

A. It depends upon -- it depends upon the nursing staff and --

Q. Okay.

A. -- how they work that. I don't get involved in that part.

Q. I understand, but certainly, you've been in NICUs long enough, and you've got leadership

positions in NICUs, that you, certainly, feel qualified to say what the nurses seem to be doing with your patients, correct?

A. True. Yes.

Q. Okay. I assume the nurse is making fine adjustments based on some orders that have been provided by the doctors or standing orders of certain things happening to the baby.

A. Correct.

Q. For example, if the oxygen saturation goes up, the nurse might have the authority to increase the rate of nasal oxygen flowing into the baby's or into the bassinet?

A. She would -- she would be given an order to increase the amount of fractional inspired oxygen that the patient is receiving.

Q. Okay. If the baby's blood pressure would drop, I would assume they have the ability to increase the rate of IV, for example.

A. Not increase their rate of an IV, but might be able to increase the amount of a certain cardiac drug to monitor blood pressure, to support blood pressure.

Q. And, certainly, the nurse would be

informing you of changes in the patient's condition as well, correct?

A. That is correct. Maybe, me, the fellow, the resident team that is taking care of that.

Q. Doctor, are you familiar with Dr. Robert Darnall of Dartmouth?

A. I know the name.

Q. How do you know the name?

A. I may have met him -- I know some of the names of some of the people in the New England neonatal groups. I believe I may have met him at a conference on Cape Cod once.

Q. So you know him as a neonatologist?

A. I believe so, yes.

Q. He's at Dartmouth?

A. I believe so.

Q. I assume you -- even though you're Mass. General, you feel Dartmouth is a fine facility, a wonderful hospital?

A. I don't have any firsthand experience with Dartmouth, other than football.

MR. BULLOCH: Okay. Off the record.

(Discussion off the record)

MR. BULLOCH: Back on the record.

BY MR. BULLOCH:

Q. Do you know Dr. Darnall as having a subspecialty in pulmonary diseases of the neonate?

A. I didn't know that.

Q. Okay. I assume you respect Dr. Darnall.

A. I don't really know him.

Q. Okay. Fair enough.

Do you know a Dr. Marcus Hermansen?

MR. BECKER: Hermansen.

Q. Hermansen.

MR. BULLOCH: Thank you.

A. I know the name.

Q. How do you know his name?

A. His name? Primarily I've seen it on an Internet chat board that has to do with neonatal intensive care units.

Q. Is that a -- is that a neonatal chat site that you frequently participate in?

A. I don't usually participate in it. It's a message board as opposed to a chat room, and I sometimes scan through some of the postings that have been put out there, and I've seen his name, because I know he is in New Hampshire.

Q. Do you respect Dr. Hermansen?

A. I don't know Dr. Hermansen personally or clinically.

Q. Okay. Doctor, I wanted to go to your list on your CV of your articles and on somewhat on your presentations. There are a substantial number of presentations that you've made over the years, but I guess, the easiest way to ask this is, which of these numerous publications or presentations do you believe are directly related to the facts at issue in this case as you understand the facts at issue?

A. (Witness reviews document) Well, specifically you would have to go towards my bibliography, and I -- I have written, you know, numerous chapters on dealing with the respiratory problems of infants.

Q. And, as we've talked before, a lot on articles on extracorporal membrane oxygenation or ECMO?

A. In my presentations, yes. I'm sorry. I jumped ahead to my bibliography.

Q. Okay. Your bibliography lists three journal articles; is that correct?

A. Correct.

Q. Has there been any additional ones since the one that would have been published in 1991 on my CV?

A. No.

Q. Okay. And then book chapters, you've contributed to 10 textbooks, correct?

A. Correct.

Q. Is there any -- let me back up.

Is there any specific article that you published in peer review literature that's relevant to the -- you know, directly relevant to the facts at issue in this case?

A. In my review, where I wrote about high frequency ventilator therapy for newborns, you know, again, we did discuss pulmonary disease.

Q. Sure. And -- and that high frequently ventilator therapy, is it another ECMO -- primarily centered towards ECMO, or no?

A. No. It's a different type of technology.

Q. Okay. Can you explain the difference to me as a lay person. I didn't know there was a difference.

A. Between?

Q. ECMO and high frequency ventilator therapy.

A. Oh. Well, high frequency ventilator is a -- it's a special kind of ventilator that breathes at very, very high rates, about 600 to 900 breaths per minute. It's very small breaths at very, very high rates, and that's what the machine does.

Q. Okay. Is that high pressure or low pressure?

A. It's usually low pressure --

Q. Okay.

A. -- but very high rates.

Q. Okay.

A. So high frequency ventilator therapy. ECMO is extracorporal membrane oxygenation. That's something totally different, which is taking the blood out of a baby or an infant who's in hypoxemic respiratory failure, taking the blood out, oxygenating it with a certain type of technology and then putting it back into the baby.

Q. Right. So that's the equivalent of a renal dialysis machine would be to the kidneys, correct?

A. Yes.
Q. It does sort of function --
A. I think of it more as cardiopulmonary bypass.
Q. Okay. All right. The book chapters that you edited or authored, which of those do you believe are related directly to the facts at issue in this case?
A. Well, in neonatal emergencies, I had discussed, you know, certain respiratory issues that patients can get before they're -- before they're transported, which -- you know, I mean, transient tachypnea in the newborn as respiratory disease. Obviously, there's Chapter No. 7 there, hyaline membrane disease, and then No. 8, meconium aspiration. You know, these are all relatively common respiratory diseases of infants.
Q. And the one most on point in this case would be No. 7, the article that you edit -- the chapter that you authored in Saunders, correct, on hyaline membrane disease?
A. That's correct.
Q. Okay. Any abstracts, Doctor, that you feel directly are related?

A. Not specifically.

Q. Okay. So -- and, just for the record -- and I understand this -- the only -- the only publication that you've authored that's directly on point that relates to hyaline membrane disease would be the chapter in Saunders, correct?

A. Correct.

Q. Okay. Any publications or presentations related to the use of surfactants?

A. Not specifically, no, although surfactant is, obviously, mentioned in this chapter.

Q. Doctor, we -- you talked a little bit about -- let me back -- strike that.

Just looking at your CV as a whole, is it fair to say that you have a special interest in ECMO and neonatal resuscitation?

A. As well as a few other things, but yes.

Q. And what would those few other things be?

A. High frequency ventilation --

Q. Okay.

A. -- ECMO, neonatal resuscitation and pulmonary -- persistent pulmonary hypertension of

the newborn.

Q. Okay. You mentioned briefly the difference between ventilators and CPAP when you were talking about ad nauseam to you, I'm sure, the difference between Level 2 and Level 3 nurseries, but specifically as to ventilators and CPAP, is there a difference in the rate of pneumothoraxes that occur or likely will occur with ventilators as opposed to CPAP?

A. I don't know of any recent data, but air leaks would be -- air leaks are more common with mechanical ventilation than it is with CPAP.

Q. Than with CPAP?

A. Yes.

Q. I had that backwards. I always heard that CPAPs have higher air rate.

A. I don't believe so.

Q. Now, you would be the guy that would know, not me, so I'll take your word for it.

What exactly happens in a pneumothorax?

A. It's a collection of extrapleural air causing the lung to collapse.

Q. Essentially what happens, I assume, is some of the alveoli rip, actually tear.

A. That's what is felt to be responsible. So air escapes from the alveolus out into the extrapleural or sort of the extrapulmonary space, the space between the lung and chest wall.

Q. What are some of the causes of pneumothoraxes?

A. The most common cause is too much pressure from -- it's iatrogenic. It's too much pressure from ventilator pressure. I can be caused, probably -- it's been associated, although I can't tell you definitely cause and effect, but it's more common in kids who have an infection.

Sometimes you can have a baby who's just -- there's a weakness in the area. It's probably a congenital defect, and it just happens. Sometimes it's seen in babies who had meconium aspiration as well, and it's probably more of a -- sort of a ball valve where air goes into the alveolus, and the alveolus gets bigger and bigger, and because there's obstruction to gas flow, it can't escape, and finally, it just rips, and you get a pneumothorax.

Q. What happens in an infection; does it actually weaken the wall?

A. That's the theory behind it, yes.
Q. And does that occur in bacterial as well as viral infections?
A. I believe so, yes.
Q. Okay. Now, you -- you implied that pneumothoraxes occur with ventilation, correct?
A. Correct.
Q. I mean, it's a known -- let me ask it this way, perhaps: It's a -- it's a known risk of ventilation that you can have a pneumothorax; is that correct?
A. That's correct.
Q. And, when you put a child on a ventilator, are you watching for the occurrence of a pneumothorax?
A. You're, certainly, aware that that's a possibility, yes.
Q. You would -- would your nurses know to watch for signs and symptoms of a pneumothorax on a child that was on a ventilator?
A. Yes.
Q. Do pneumothoraxes just occur naturally? I mean, I've heard of these occurring in adults --
A. Yes.

Q. -- that aren't on ventilators? So can they happen in neonates, just develop a pneumothorax?

A. Yes.

Q. And that would be partially, because of a congenital abnormality that a child may have?

A. That would be the thought.

Q. But, certainly, you don't believe that, because a child has a pneumothorax, that a doctor did anything wrong, do you?

A. Not necessarily, no.

Q. Just because a child has a pneumothorax, you don't believe that a doctor necessarily violated a standard of care, correct?

A. Yeah. With taking care of a child on a ventilator, that's correct.

Q. And that's, because it's a known risk of a ventilator --

A. That's correct.

Q. -- a pneumothorax?

What's the treatment for a pneumothorax, Doctor?

A. Removal of that air, that gas, which is between the chest wall and the lung.

Q. And you do that with a chest tube essentially; is that correct?

A. You can do a thoracentesis, or you can do a thoracostomy, too.

Q. Can you explain the difference between the two.

A. What most people will do is they will put a needle -- it's -- thoracentesis is putting needle into the chest withdrawing that air and then taking the needle out, with the hope that the pneumothorax does not reaccumulate. That's what most people will do as the -- as the first thing to do, and then should the pneumothorax reaccumulate, then put in the chest tube.

Q. Okay. Now, if a child is on a ventilator where there's a likelihood, I assume, because you have, probably, torn something -- the child has, probably, torn something, would the first step in a child that develops a pneumothorax would be to put in a chest tube?

A. For most people, yes.

Q. Okay. And, certainly, if you thought the pneumothorax was caused by an infection, for example, you'd treat the underlying infection as

well, correct?

A. Absolutely.

Q. Okay. I assume that, if you've got to have a pneumothorax, the right place to have it would be at Mass. General in a Level 3 nursery, right?

A. Sure.

Q. And that's, because you have nurses there that are watching for these to occur, correct?

A. Correct.

Q. You have house officers that are aware of the possibility, and they're watching for it?

A. Correct.

Q. I assume you have ways to test to see if there was a pneumothorax.

A. Correct.

Q. You have children on monitors, so that you know if the oxygen sats are dropping or Po2s are going down, correct?

A. Correct.

Q. What happens to the child physically -- maybe, that's a bad question. Appearance-wise what happens to a child that experiences a

pneumothorax?

A. Well, it depends upon the severity of the pneumothorax. If you have a severe one, it can cause tension, meaning if it's on the right side, it can push the mediastinal contents, which is the heart, esophagus and the trachea, over to the left side, and you can have oxygen desaturation. You usually have a instability of blood pressure, and the child can also, from a blood gas point of view, not only become hypoxemic, but also become hypercarbic and have a high Co2.

Q. Okay. Does that all that happen when you have cardiac manifestation of the pneumothorax?

A. It can happen with or without, depending upon whether the pneumothorax is large enough to cause tension or not.

Q. Okay. So, if you have a pneumothorax that's not displacing the heart towards the mediastinum, then you're not going to get those effects, correct?

A. Usually not. It's a spectrum of severity.

Q. What's the difference between pneumothorax and pneumomediastinum?

A. Pneumothorax is air in the pleural space, and pneumomediastinum is air in the surrounding the mediastinal structures, but outside of the pleural covering, which covers the lung.

Q. Do you treat a pneumomediastinum?

A. Rarely, but I've had to if it's severe enough, yeah.

Q. Why don't -- why don't you treat it? Is it, because it doesn't cause any harm to the child?

A. It would be asymptomatic.

Q. All right. When the child -- when you're called over to a crib, or better term, bassinet -- is that a better term?

A. Isolate.

Q. Thank you.

When you're up in your NICU and you're called over to an isolate, the nurses and doctors think this child has a pneumothorax, what does a child look like physically? What's the child doing? Not so much about what you're seeing with

translumination or what you're seeing with the Po2s, but what physically does the child look like?

A. Potentially cyanosis.

Q. Okay. Is -- is that -- is that life-threatening, the cyanosis?

A. It can be, yes.

Q. It's more a symptom of what's occurring?

A. Correct. It's a manifestation of the pneumothorax and the pressure of the gas in the extrapleural space having an effect on gas exchange and also potentially blood pressure.

Q. Does this matter if it's a central cyanosis as appear -- as opposed to his fingers are blue?

A. We're talking central cyanosis, not acrocyanosis.

Q. Now, I've heard the term bantered around about duskiness. What is dusky or duskiness, and how is that different from cyanosis, if you can tell me that?

A. Duskiness is not a precise medical term.

Q. Is it pink?

A. Yes. I think that would be fair.

Q. I assume you've seen children that have been cyanotic from pneumothoraxes, correct?
A. Yes.
Q. And, when you treat those children, have they responded well?
A. Most have.
Q. Okay. And the treatment is usually, again, the thoracentesis or the chest tube, depending if they are on vent or not?
A. Depending on the severity and the circumstances, that's correct.
Q. The children that have had bad outcomes that you've seen or have the central cyanosis, what else have they demonstrated as far as your observation of the child? Does that question make any sense?
MR. BECKER: I was going to object, because I didn't understand the question.
A. Not really.
Q. All right. Let me try again, and not being a doctor, certainly, not being a neonatologist, but when you've had children that have had severe central cyanosis, I assume their Po2 levels are very low; is that correct?

A. Correct. Yes.
Q. Their pulse ox. becomes very low?
A. Correct.
Q. Their blood pressure falls?
A. It can. It depends upon the situation that you're talking about.
Q. Okay.
A. What's -- what's causing the central cyanosis?
Q. Okay. Well, again, we're talking about a child that's had a pneumothorax, correct?
A. All right. I wanted to make sure that was clear.
Q. Let me reask it, so it's clear.
A child that has central cyanosis with a pneumothorax, you would expect their Po2 level to be low, correct?
A. Correct.
Q. How low?
A. It depends on the severity of how -- of how big the pneumothorax is and the severity of the -- of the effects that that is causing --
Q. All right.
A. -- as it relates to blood pressure.

Q. Fair enough.

So there's really no easy measure; you can't tell me, because they're cyanotic, their Po2 level should be X, for instance?

A. If they are cyanotic, I know their Po2 is, certainly, below 85 and, probably, below 80 percent.

Q. Okay. Pulse ox.? Typically happens with pulse ox. to get central cyanosis?

A. It would be -- it would be low, because the pulse oximeter measures your oxygen saturation.

Q. Okay. So are we are talking the same thing --

A. Correct.

Q. -- the pulse ox. reading be would be the same as a Po2?

A. Correct. One is invasive; one is not invasive, but in essence, we are talking about the same thing.

Q. Okay. Would you expect to see acidosis in a child like that?

A. Potentially, yes.

Q. Okay. All right. Well, we'll come back

to that. Let's move on to something else.

The -- the normal effect of a pneumothorax -- again, I am talking about child on a ventilator. The normal effect of a pneumothorax that's treated with chest tubes is a child gets better, I presume; is that fair?

A. Correct.

Q. The child doesn't go on to have any long-term problems?

A. If it's addressed quickly and appropriately and if the degree of hypoxemia is not prolonged, yes, I would expect that.

Q. And how long -- because I've heard that before, too. Prolonged hypoxemia, to have any kind of neurological damage, what are you -- what are you talking about as far as -- can you give me some measure of time and -- and oxygen levels?

A. It's hard, because you're extrapolating a lot from adult data, but obviously, common sense would tell you the lower the oxygen level, the shorter time it's going to take to cause cellular damage.

Q. Okay. Are your neonatal resuscitation activities -- is that primarily with problem

deliveries?

A. Correct. High-risk deliveries.

Q. Okay. And, when you talk about your activities in neonatal resuscitation, you're referring only to that delivery after or resuscitation after delivery?

A. The program is specifically geared towards neonatal resuscitation in the delivery room.

Q. Are you ever called to one of the emergencies rooms or the OR rooms to resuscitate a child?

A. To the -- to an emergency room, occasionally, when a woman who would be -- would be rolling into the emergency room and about to deliver, I could be called for that.

We have had deliveries of very sick moms in operating rooms, and we've -- we've been there to provide support for infants.

Q. Okay.

A. These are moms who are usually in operating room with --

Q. Bursts of --

A. -- you know, cancer or something like

that, and they have to take the baby, and so we will be there for that, but primarily it's in the labor and delivery suite.

Q. Okay. Now, the ER resuscitations that you've done, have those ever involved near drownings --

A. No.

Q. -- or carbon monoxide poisonings or anything of that nature?

A. No.

Q. Okay. And have you ever had to resuscitate a child that wasn't on a vent, but might have been in your unit for infection or something of that nature?

A. Sure.

Q. What kind of circumstances?

A. Any baby who's in a neonatal intensive care unit, whether they're there for a reason and whether they're on a ventilator or not, are at risk of having untoward cardiovascular events requiring resuscitation.

Q. Okay. Have you ever been involved in a case where a child has an infection and being transported to your hospital and has to be

intubated en route and has to receive presser agents en route? Have you ever had occasion for that to occur?

A. Not recently, but, yes, in my training.

Q. What were the circumstances, do you recall?

A. Not -- not really. I mean, I -- this was back in the '80s. The goal is to avoid those types of situations.

Q. At all cost?

A. Yeah, pretty much. That's why, when you have a baby that's in a community hospital and they have some type of respiratory distress, depending upon the severity of the distress and the work of breathing, it's common for transport teams to intubate those children -- those babies, so you have sort of complete control of their airway, and you also have lines in them, so that you can give them fluid. You can give them medicine for their blood pressure should you need to do that.

You want to do as little as possible in the back of an ambulance during a transport, because it's not ideal. So you try to anticipate

problems that you might run into during the transport and do things in the referring hospital to avoid those things before you get into the ambulance.

Q. Sure. An hour or two-hour drive to a tertiary facility is not the best place to be taking care of a baby?

A. Correct.

Q. If you had a baby that was under a year old and was in a community hospital, suspected infection, required ventilation, intubation, on the way to a tertiary facility that was an hour away, needed IV boluses, needed presser support, what would your concerns be for that child when you finally received him at the tertiary facility?

A. When I see the baby coming through the door and they put them on -- you know, on our warming table, I'm initially concerned about their vital signs, temperature, pulse, respiratory, blood pressure, pulse ox. Those are my initial concerns.

Q. Okay. A baby that needed presser agents, would you be concerned about brain damage in a child?

A. Potentially, yes.

Q. Would you be more concerned about that child that I just described or one that experiences a pneumothorax in a Level 3 nursery?

A. I would be concerned about both of them as having some kind of untoward neurodevelopmental outcome.

Q. Okay. Which would be more likely to have a neurodevelopmental outcome?

A. It depends on the severity of the illness of either one.

Q. Okay. And, again, just for the record, you never reviewed any of Matthew Wagoner's records past the time that he was treated in Cleveland, Ohio, correct?

A. That's correct.

Q. Have you ever treated -- and this is a silly question, I realize, but I'm going to -- I need to ask it. Have you ever treated babies with congenital cardiac conditions?

A. Yes, I have.

Q. Tell me what usually happens with those children as far as Po2 levels and -- and central cyanosis and blood pressure.

A. Well, it depends upon the type of congenital heart disease that they have, number one, and when they're born, we usually know about these prenatally, because of the use of ultrasound that the baby was born vaginal birth or cesarean section, and depending upon what the baby has, they may come down to the NICU, or if they are quite well, they may go to observation Level 2 nursery, and any baby that's admitted we'll, you know, monitor their vital signs right away, temperature, pulse, respiratory.

We know that, if it's a cyanotic lesion, that we will fully expect to have oxygen saturations usually in the 80s, and the cardiologists are very happy with that, and then we'll call a pediatric cardiologist and get an echocardiogram to, if you will, definitively make the diagnosis of what they stopped prenatally, and then we will go from there after we have all of the information.

Q. Do these children frequently have -- maintain low oxygen saturations for an extended period of time?

A. They can maintain -- depending upon

their situation, they may have oxygen saturations in the 80s.

Q. For a prolonged period of time?

A. Yes. Sometimes cardiologists are very happy with that type of situation.

Q. Do those children frequently or rarely suffer any kind of neurological damage?

A. There have been some long-term neurodevelopmental tests done. I think Jane Newberger at Children's Hospital has done a lot of that, looking at long-term neurodevelopmental outcome of infants with congenital heart disease, but a lot of that has to do with babies that have been repaired and been on pumps, you know, been on a cardiobypass pump for their operation or not and hypothermia and different issues --

Q. And possibly clots?

A. Right. Correct.

Q. I guess, I'm asking from your experience, when you've had children who had congenital heart disease and extended periods of low pulse oximetry readings, have you personally seen cases where the child has significant neurodevelopmental --

A. I don't follow them. I mean, I take care of sort of the preoperative infants, and hopefully, if they do go to the operating room, postoperatively they usually will go to the pediatric ICU.

Q. Okay. Children on ventilators are more likely to develop pneumonia, I presume.

A. They are, certainly, at risk for that than a child who is not on, yes.

Q. And a lot of times, when you have a baby and you're not sure what the mother's GPS condition was or something like that, you start antibiotics early just to cover potential infections?

A. Yes.

Q. Okay. What are the signs of a viral infection?

A. In a baby?

Q. Yeah.

A. One of the --

Q. Viral pneumonia.

A. One of the classics is usually they can have a fever, and then with pneumonia, they can go into respiratory distress, grunting, flaring,

retracting, abnormal breath sounds, increased work with breathing.

Q. Their x-rays -- what happens with their x-rays?

A. Their x-rays --

Q. Chest x-rays.

A. Yeah. Their chest x-rays can have -- usually there's an interstitial pattern to the -- to the chest x-ray, which gives you -- may give you some idea that it could be a viral illness as opposed to others, but that's a soft call.

Q. So a lot of similarities between RDS and pneumonia in these tiny babies as far as signs and symptoms?

A. As far as the clinical signs of respiratory distress, yes.

Q. Would you put any significance on if you -- if you cultured an ET tube and found a lot of white cells and a lot of mononuclear cells or secretions from ET?

A. I need more -- in how old a baby? How long have they been intubated?

Q. Okay. Let's say a neonate, intubated for five to seven days.

A. Okay.

Q. And you found -- if you suspected a viral infection and you found mononuclear cells in the ET secretions, what significance would you put on those?

A. Were there lots of secretions?

Q. I don't know to, tell you the truth, Doctor.

A. Because it would be very unusual for -- to have a baby who's intubated for five to seven days and then have a mononuclear infiltrate in the tracheal aspirate, that's unusual.

Q. What's it a sign of?

A. I would -- it could be a pneumonia of some type, a viral pneumonia.

Q. Okay. All right. Doctor, I wanted to talk to you a little bit about your testimony history. I'm curious; how many cases do you review on a monthly basis or an annual basis for a lawyer?

A. Probably, six to eight cases a year.

Q. And how long have you been reviewing that number of cases?

A. Since about 1992.

Q. Has the number of cases you've reviewed since 1992 changed dramatically from year to year, or has it been basically six to eight cases a year?

A. On average.

Q. For the past 14 years?

A. It's about the same.

Q. So you've reviewed over a hundred cases, probably --

A. Probably.

Q. -- in your career? Okay.

A. Yes.

Q. Do you know what percentage has been on behalf of the Plaintiff as opposed to on behalf -- behalf of the Defendant?

A. The exact percentage I don't know, but I assume it's around 50/50.

Q. We already talked -- you spent three and three-quarter hours reviewing all of the records and all of the materials that you have in this case?

A. Correct.

Q. And about an hour generating your report?

A. Correct.
Q. And about how many depositions do you sit for a year?
A. How about total?
Q. That's fine, too, Doctor.
A. Probably, around -- less than a dozen.
Q. Have you appeared at trial?
A. Yes, I have.
Q. And how many times have you appeared at trial?
A. Three to four times.
Q. Were those all in the Massachusetts area, or were they --
A. No. One was in Georgia; one was in Philadelphia, and one was in Middlesex County right here next to Boston.
Q. Of the -- I am sorry. Were you done? Were any of those in federal court?
A. No.
Q. Okay. Now, about half of your reviews are on behalf of the defendant. Do you maintain any records, by the way, of who you've done work for -- medical/legal work for?
A. Not really, no.

Q. Well, can you tell me the names of any of the defense counsels that you've consulted with over the past year, the three to four defense counsels that you've, probably, consulted with?

A. Not as I sit here, no.

Q. Would you have records of those in your office?

A. Right.

Q. Would you mind providing a list of the attorneys you have worked with in the past couple of years to -- to Mr. Becker, and he will provide it to us?

A. Okay.

Q. Thank you.

When you -- what do you charge for reviewing cases?

A. 350 an hour.

Q. And for depositions?

A. The same.

Q. And what about trial?

A. The same.

Q. Do you charge for a full day when you go to trial or a half day, or do you have any policy on that?

A. Yeah. It -- it's happened so infrequently I usually just talk with the attorney and just come to something which is reasonable and what everybody does.

Q. Okay. Do you have any idea what percentage of your income derives from medical/legal work?

A. Less than 10 percent.

Q. And about how much time do you spend a year in medical/legal work -- well, let me -- let me rephrase that. Let's go back to these percentages.

What percentage of your time do you spend serving as a legal/medical consultant?

A. Probably, about 5 percent.

Q. Have you ever served as an expert on behalf of the Becker Mishkind law firm in Cleveland or Elyria, Ohio?

A. No.

Q. Ever serve as an expert for Howard Mishkind in Ohio?

A. No.

Q. David Kulwicki in Ohio?

A. No.

Q. Larry Peskind?
A. No.
Q. John Barnett?
A. I don't think so.
Q. And not Mr. Becker in the past --
A. I am sorry?
Q. And not for Mr. Becker either?
A. No.
Q. Have you ever been a defendant in a lawsuit?
A. Yes.
Q. How many times?
A. Once.
Q. Can you tell me just basically what the circumstances of that lawsuit was.
A. I'm one of three neonatologists and a pediatric ophthalmologist that is being sued here in Suffolk County in Boston for events treating a premature -- 25 week premature infant who developed retinopathy in prematurity.
Q. Surprised, huh, that the child developed retinopathy?
A. It's an expected outcome of that gestational (inaudible).

Q. Doctor, this might be a real silly question, but I assume that you agree with me that, just because the doctor gets sued doesn't mean that the doctor did anything wrong, correct?

A. Correct.

Q. Just because the doctor gets sued doesn't mean that the doctor was negligent, correct?

A. Correct.

Q. Just because the child has a bad outcome doesn't mean that the doctor is negligent either, does it?

A. Correct.

Q. In this case, just because the child has cerebral palsy doesn't necessarily mean that the physician was negligent either, correct?

A. Correct.

Q. Let's talk a little bit about cerebral palsy, and I just want to explore your understanding of cerebral palsy, but I assume you would agree with me that the vast majority of cases of cerebral palsy were not caused by physician negligence; is that fair?

A. Correct. Yes.

Q. There are many different causes of cerebral palsy, correct?
A. Yes.
Q. For example, genetic abnormalities --
A. Yes.
Q. -- is a cause?
There could be metabolic causes, correct?
A. Yes.
Q. And some metabolic masqueraders of cerebral palsy, correct?
A. Define metabolic masquerader. I don't know that term.
Q. For example, pyruvate dehydrogenation deficiency can be a masquerader, a metabolic masquerader. It's not true cerebral palsy, but it looks a lot like cerebral policy, correct? Maybe, you want to call it cerebral palsy, and that's fine.
A. You're talking about the ultimate neurodevelopmental outcome of a patient with pyruvate dehydrogenation deficiency?
Q. Yes.
A. You can have a patient that has some

type of abnormal neurodevelopmental outcome that can be sort of led back to that metabolic reason being the deficiency.

Q. Okay. But you would call that --

A. Etiologic --

Q. -- metabolic etiology? You would call that a metabolically caused cerebral palsy, correct?

A. That's correct.

Q. Okay. So we have the same terminology going.

Certainly, certain autoimmune defects can cause cerebral palsy?

A. Yes.

Q. Some coagulopathies can cause cerebral palsy? For example, we talked earlier about a mom that might be throwing some clots into the fetal circulation, and that can cause the type of ischemic injury that would cause a cerebral palsy, correct?

A. Okay. Yes.

Q. And, of course, the baby can have some coagulopathies that, in essence, does the same thing, correct?

A. Correct.
Q. Can trauma cause cerebral palsy?
A. Yes.
Q. And, certainly -- I think you'll agree with me on this -- the big cause of cerebral palsy is just prematurity, isn't it?
A. One of them, yes. That's right.
Q. Okay. Maternal abruption can cause cerebral palsy?
A. Yes.
Q. What about uteroplacental insufficiency; can that cause cerebral palsy?
A. Yes.
Q. Do you have any idea what percentage of all causes of cerebral palsy is caused by a hypoxic ischemic event?
A. I don't know the exact number. I -- I know it's small.
Q. What would you guess, with my pension for asking you percentages?
A. 5 percent. Five to 8 percent.
Q. And I've heard 6 percent cited by many authors. You wouldn't disagree with 6 percent, I assume, correct?

A. No.

Q. And what percentage of those cases of CP caused by hypoxic ischemic events occur in utero or while the child is being delivered?

A. The -- the -- I don't know the exact number, but I believe that the preponderance of that would be in utero.

Q. Okay. The vast majority would be in utero?

A. Yeah.

Q. Do most babies who suffer a hypoxic event end up with cerebral palsy?

A. It depends upon the etiology.

Q. What do you mean by that, Doctor?

A. What's the -- you said what's the etiology of the hypoxia?

Q. Okay. Fair enough.

Can you tell me that if there's -- just in general.

A. Not really.

Q. Then we can get into more detail.

A. I would need to get into more detail.

Q. Okay.

A. I don't like to totally generalize.

Q. All right. We'll get to that.

What is uteroplacental insufficiency? I know I'm a little bit outside of your area of expertise, but what do you understand uteroplacental insufficiency to be?

A. Well, insufficiency of the uterus and placenta to provide enough oxygen for the developing fetus.

Q. And does the injury to the baby usually result in later stages of the pregnancy in utero placental deficiencies?

A. It depends when it's -- it depends on when the uteroplacental insufficiency began.

Q. Okay. If it begins early enough, I assume the baby will probably self-abort, though, correct?

A. That would be one extreme situation; that's correct.

Q. Or die in utero?

A. Correct.

Q. It would be stillborn?

A. Correct.

Q. Okay. If a placenta is small for the size of the baby, is that what is occurring in

unteroplacental insufficiency?

A. I don't understand that.

Q. If the placenta is too small to support the baby, is that what we mean by the uteroplacental insufficiency?

A. Not necessarily, just -- not necessarily.

Q. Is that part of it?

A. It can be, depending upon the situation you're dealing with.

Q. And an abruption would be an example of insufficiency, correct?

A. Severe.

Q. Severe. Okay.

But you can have partial abruptions, too, correct?

A. That's correct.

Q. What are some of the causes of your understanding of a spastic cerebral palsy?

A. Hypoxic -- I mean, usually it's the end result -- again, in my realm, usually it can be seen as the end result of some type of hypoxic ischemic encephalopathy.

Q. And what about athetoid cerebral palsy?

A. That's a cerebral palsy usually caused by hypoxic ischemia to the basil ganglia.

Q. Is there any -- are there any articles or textbooks that you could refer me to for that last contention, that -- that an athetoid cerebral palsy is caused by a hypoxic ischemic event?

A. Volpe's textbook of "Neurology in the Newborn" would be an excellent resource.

Q. So, if you have a mixed spastic athetoid cerebral palsy, in your mind, that would, probably, be caused by an anoxic ischemic event or could be caused?

A. Could be caused, yes.

Q. Could it be caused by other things?

A. Yes.

Q. What other things?

A. Clots, trauma, hemorrhage.

Q. A lot of Matthew's subsequent treating doctors in North Carolina, including some doctors at the University of North Carolina, diagnosed Matthew as being -- suffering from a mixed spastic athetoid cerebral palsy. Would you have any reason to disagree with that diagnosis?

A. None whatsoever.

Q. What about postnatal cerebral palsy; what are the common causes of a postnatal cerebral palsy?

A. Can you define postnatal cerebral palsy.

Q. Yes.

A. I've never heard that term.

MR. BECKER: You mean in the newborn period?

MR. BULLOCH: Yeah.

MR. BECKER: Neonatal period.

He is talking potentially hypoxic ischemic insult, I think.

MR. BULLOCH: Well, thanks, Mike. I'm not sure that's what I was referring to, but...

BY MR. BULLOCH:

Q. A child that isn't born with cerebral palsy, so postpartum in the neonatal period that goes on to develop cerebral palsy, what are some of the causes of the cerebral palsy in a child?

A. If you're talking about, say, the happy, healthy, full-term baby in the full-term nursery who then goes home with mom and dad and then develops cerebral palsy down the road, most of the -- as I understand, most of the etiologies of

that are just unknown, but as we were saying earlier, there could be genetic causes; there could be metabolic causes, but most of those are unknown without some type of antecedent event that would make you think that that may be responsible for what has been seen down the road.

Q. Now, I think I asked you this: You were not aware of any case where you've treated a child with a pneumothorax that the doctors eventually postulated that the child's pneumothorax was the cause of the child's cerebral palsy; is that correct?

A. It's hard for me to answer that, because I personally do not follow kids long term.

Q. I understand.

A. But I have, certainly, taken care of children who have had pneumothorax -- pneumothoraxes who at the time of discharge we, certainly, had concern about their neurologic development, because at the time of their discharge, they had an abnormal neurologic exam.

Q. Okay. And, in all of those children, did you feel that the abnormal neurological exam was directly related to the pneumothoraxes?

A. You know, there had been cases like that, yes. These are -- these are very sick infants.

Q. Have these cases been reported in the medical literature?

A. No. This was all primarily during the 1980s in the pre-surfactant era.

Q. Okay. Are you familiar with any reports of pneumothoraxes being linked to cerebral palsy?

A. I'm not aware of any paper making that exact connection, no.

Q. Okay.

MR. BECKER: Could we just take a one-minute break --

MR. BULLOCH: Sure.

MR. BECKER: -- so I can make a call.

(Recess)

BY MR. BULLOCH:

Q. Doctor, before we took a little break, I -- I just wanted to make sure I understood what you were saying. You said that, while you believe there have been cases of cerebral palsy induced by pneumothoraxes --

MR. BECKER: He says -- he said

developmental delay.

MR. BULLOCH: I am sorry?

MR. BECKER: He said developmental delay, as I recall. Neurodevelopmental delay was his testimony.

MR. BULLOCH: You're correct. Okay. Let me correct that.

BY MR. BULLOCH:

Q. You said you believe there have been neurodevelopmental delays associated with pneumothoraxes.

MR. BECKER: He said it was the pre-surfactant area.

MR. BULLOCH: Mike, come on.

MR. BECKER: We are going to be here all night.

MR. BULLOCH: Well, we might be.

BY MR. BULLOCH:

A. In the pre-surfactant era, when pneumothoraxes were much more common than they are today in the post-surfactant area, it is not uncommon to have infants, premature and infants, who develop pneumothoraxes that end up with some type of neurodevelopmental delay.

Q. Okay. Thank you.

Do you recall seeing any cases or reading any articles where that was documented?

A. I experienced it firsthand.

Q. Okay. And did any of those children, as far as you know, develop cerebral palsy?

A. I believe they did, but I did not follow them long term.

Q. And are you familiar with any articles in the professional literature that makes that association?

A. As I sit here right now, no.

Q. Okay. Would you have articles like that in any kind of file in your possession?

A. I would say no, since I pretty much use the Internet now.

Q. Okay. Does -- does the occurrence of serious or frequent infections in a child have any significance in trying to determine the etiology of the child's cerebral palsy?

A. I'm sorry. I don't -- I don't understand the question.

Q. All right. If -- if you have a specific child that has cerebral palsy --

A. When you say, "child," how old? I need to be -- I need the specifics of the age. Since I'm a neonatologist, I primarily deal with newborn infants. When you say, "child," I don't know whether you're meaning a baby or someone three or four years old.

Q. Well, true. You told me you don't do pediatric work.

A. Correct.

Q. The age you stop with most children would be a year or less?

A. Much less than a year.

Q. Okay. All right. Strike that.

Doctor, your report is dated -- did we mark his report? Let's mark the report.

(Document marked as Exhibit 4 for identification)

BY MR. BULLOCH:

Q. Doctor, I'm handing you what's been marked as Exhibit 4. Is that a copy of your report?

A. (Witness reviews document) That's correct.

Q. And this report was dated August 20th,

2004, correct?

A. Correct.

Q. Am I correct to assume that this report contains all of your opinions that you hold in this case?

A. Correct.

Q. And I think we've already talked about it. The -- the materials that you listed, did you review it in formulating your opinions that are listed in your report, correct?

A. Correct.

Q. You've reviewed nothing else in formulating these opinions, correct?

A. Correct.

Q. Would it be important to you to know any of the child's subsequent course before you rendered an opinion on what caused Matthew's cerebral palsy? Do you understand the question?

A. Yes and no, but I -- I think I need to ask him a question in order to answer it.

Q. Well, let me try to ask you another question.

A. All right.

Q. If certain things had happened in

Matthew's life since you left of the care of Fairview Hospital where your records end, and those events might be explanatory to the cause of Matthew's CP, do you feel it would be necessary to review those subsequent records?

A. Depending upon the question that I was asked to answer. I was asked to review this case specifically as it related to the administration or the lack thereof of exogenous surfactant therapy.

Q. And you had no depositions, besides Dr. Lilien's, correct?

A. That is correct.

Q. And I believe you told me that you haven't had any discussion about depositions that have been taken subsequent to Dr. Lilien's deposition, correct?

A. That's correct.

Q. Did you read Dr. Evangelista's deposition?

A. I don't believe so.

Q. Do you know who Dr. Evangelista --

A. Oh, deposition. No. Everything I have is right here.

Q. Dr. Evangelista is the doctor that responded to Matthew's pneumothorax at Fairview Hospital, and she described very quickly -- responding very quickly, correcting pneumothoraxes with chest tubes. Would that be important in your determination of whether or not Dr. Lilien breached the standard of care?

MR. BECKER: What Dr. Evangelista did after the pneumothorax?

MR. BULLOCH: Yes.

Q. I take it no.

A. Well, in -- I don't understand what the question is.

Q. All right. Well, let me back up.

I guess, your opinion is just basically that you believe Dr. Lilien breached the standard of care by not administering surfactant, correct?

A. I believe that the standard of care was breached, because Matthew was not treated in -- in a timely fashion with exogenous surfactant therapy.

Q. Okay. But you told me earlier, I believe, that the treatment for a pneumothorax is the insertion of a chest tube, correct?

A. Correct.

Q. So is your testimony just the fact that Matthew developed pneumothoraxes, because he did not get surfactant in a timely manner?

A. This is -- let me make this clear. Okay.

Q. Okay.

A. I think the paragraph that I wrote for my opinion essentially states it very clearly, that Matthew Wagner was a premature infant at 35 weeks. He was at risk of having respiratory distress syndrome or surfactant deficiency. I do believe, according to all the information that I have and in reviewing the charts, that that was the etiology of his pulmonary disease.

Because of that, he went into respiratory failure as evidenced by grunting, flaring, contracting, increased work of breathing, requiring supplemental oxygen. His case deteriorated to the point where he needed ventricular intubation.

All of that was fine. After he was endotracheal intubated for what, I believe, his respiratory distress was secondary to surfactant

deficiency or respiratory distress syndrome, he did not receive any exogenous surfactant therapy at that time. Because he did not receive that therapy, which I believe breached the standard of care, he required increasing amounts of FIO2. He required increasing peak inspiratory pressure on the ventilators, which, unfortunately, resulted in him having pneumothorax and episodes of hypoxemia, as evidenced by some oxygen levels of 33, which are in the laboratory data. So I'm a little bit -- so that's my answer.

It's a premature infant, white male, lots of risk factors, hyaline membrane disease, respiratory distress syndrome, who was endotracheal intubated, because of increased work of breathing and then never received surfactant therapy until much later after he had developed pneumothorax.

Q. Okay. And you're not offering any testimony on what -- on any neurodevelopmental disorders Matthew sustained, correct?

A. I was not asked to do that.

Q. You're not linking any of these events to Matthew's neurological outcome, correct?

A. That is correct.
Q. Okay.
A. Although I will say it, because I can say it from years -- my years of experience and also a lot of years in the pre-surfactant era, that it was not uncommon for babies at that time who had surfactant deficiency or hyaline membrane disease to develop pneumothoraxes and then develop some type of neurodevelopmental delay down the road. That was not uncommon.
Q. But, again, you have no evidence of that in the literature, that pneumothoraxes caused the neurodevelopmental disorder, correct?
A. The pneumothorax causes -- causes in this case hypoxemia, low oxygen levels, and that can be an etiology for cerebral palsy.
Q. But there's a lot of etiologies. We've already discussed that, Doctor --
A. That's correct.
Q. -- in all fairness, correct?
A. That is correct.
Q. We discussed there's a multitude of things that can cause cerebral palsy, correct?
A. That's correct.

Q. And only about 6 percent of all cerebral palsies are caused by a hypoxic ischemic event, correct?

A. Correct. We agreed upon that earlier.

Q. So can we agree, just because a child develops a pneumothorax, doesn't mean that's the cause of the CP?

A. Correct.

Q. You talked just now about some risk factors that Matthew exhibited for developing hyaline membrane disease, and I believe what you said was the fact that he was a male, white male and 35 to 36 weeks gestation, right?

A. Correct.

Q. But aren't there a lot of causes for maternal -- for hyaline membrane disease that Matthew did not exhibit? For example, maternal diabetes, isn't that a risk factor for developing hyaline membrane disease?

A. Yes, it is.

Q. Delivery by C section, isn't that a risk factor for developing hyaline membrane disease?

A. No, it is not.

Q. It's not.

A. I've never heard that.

Q. Doctor, you list in your CV Saunders Manual Pediatric Practice, Edition 2, a chapter on hyaline membrane disease, correct?

A. Yes.

Q. You wrote that entire chapter of that text?

A. Yes.

Q. Under epidemiology -- and I will share this with you in a moment -- it says, "Other risk factors for development of hyaline membrane disease include delivery by cesarean section." Do you see that?

A. (Witness reviews document) Yes.

MR. BECKER: You're showing him his chapter.

MR. BULLOCH: Yes, I am showing him his chapter.

A. Uh-huh. Yeah. I do -- I do see that, and there are other risk factors in there much, much less, but cesarean section in and of itself is not a high risk factor.

Q. All right. But it's a risk factor? Okay. You'd agree with me?

A. Fine.

Q. All right. Is perinatal depression also a risk factor for development of hyaline membrane disease?

A. It's a risk factor for shock of lung, which could inactivate surfactant, which I wouldn't necessarily call hyaline membrane disease, which is more of a developmental issue.

Q. Well, wait a minute. Isn't hyaline membrane disease an absence of surfactant?

A. Yes, it is. Yes.

Q. So, no matter what causes the absence of surfactant, if it's absent, then you have hyaline membrane disease, correct?

A. Whether you're getting into absence of surfactant versus inactivation of surfactant -- again, are we talking about a premature infant?

Q. I'm reading from your textbook, Doctor.

A. Right.

Q. And it's there. So I assume you agree with me that one of the risk factors for developing hyaline membrane disease are perinatal depression, correct?

A. Sure. It's shocked lung, in essence,

yeah.

Q. Okay. Another risk factor for developing hyaline membrane disease that you listed was second born of twins, correct?

A. That's correct.

Q. And another risk factor was a positive family history, correct?

A. Correct.

Q. Now, out of all of the risk factors that we have listed, Matthew did not have maternal -- mom did not have maternal diabetes, correct?

A. That's correct.

Q. Matthew was not delivered by C section, correct?

A. Correct.

Q. Matthew did not have perinatal depression, correct --

A. Correct.

Q. -- that we know?

A. Correct.

Q. He, certainly, wasn't the second-born of twins, correct?

A. Correct.

Q. There's no positive family history noted

in Matthew's prenatal record, correct?

A. Correct.

Q. So Matthew had a lot -- according to your own textbook, very few risk factors out of the total number of risk factors that exist out of the hyaline membrane disease?

A. He had two of the most important ones that are on the list.

Q. What are the most important ones?

A. Premature caucasian male.

Q. Let's talk about that.

Doctor, you wrote that hyaline membrane disease is primarily a disorder of premature infants less than 35 weeks gestational age, correct?

A. It's primarily, not exclusively, correct.

Q. I understand.

A. Uh-huh.

Q. Matthew was 35 to 36 weeks, according to your report, correct?

A. Correct, according to the records.

Q. And then you go on in this article -- you said, "In infants less than 35 weeks

gestational age, the incidence is 10 to 15 percent," correct?

A. Correct.

Q. "In infants less than 28 weeks, the incidence is 70 percent," correct?

A. If that's what it says. I don't have it in front of me, but I believe you. Okay.

Q. Yeah.

A. I don't recall that chapter verbatim, as I sit here.

Q. Doctor, I understand. Please, you're free to look at this any time.

A. Okay.

Q. I don't have a copy, so I apologize.

A. All right.

Q. You said that the incidence in full-term infants is about 1 percent, correct?

A. Correct.

Q. Now, would you agree with me that Matthew is near term at 36 weeks?

A. Yes, I would.

Q. So I assume that his incidence of developing hyaline membrane disease is close to 1 percent, correct?

MR. BECKER: Is what?

Q. Close to 1 percent.

A. The latest data out there indicates one to 2 percent in term babies and in near-term babies, perhaps, two to 4 percent of hyaline membrane disease.

Q. Okay. So the incidence has gone up since you wrote this in 2002; is that what you're saying?

A. Again, I don't have that in front of me, but that's the way -- I'm just -- I'm just telling you what the latest data is.

Q. Doctor, please. I am not trying to be argumentative.

A. Okay.

Q. I'm trying to understand this. I'm not a doctor. I'm just trying to understand this.

What was it in 1999? What was the believed incidence in 1999?

A. The -- the important part -- there two generalized important parts. Number one, as the gestational age increases, your incidence of hyaline membrane disease increases. That's number one.

Q. Okay.

A. Number two, what we teach is that the incidence of hyaline membrane disease in terms infants is not zero, and that's something a lot of people don't appreciate. So we talk about a one to 2 percent incidence, and in babies that are a little bit less mature than near-term infants, 35 to 36 and six-sevenths, we talk about an incidence about two to 4 percent.

Q. Okay.

A. Again, lower than term babies. Obviously -- excuse me -- higher than term babies, but lower than smaller babies.

Q. Do you know what the thought was about the risk of developing hyaline membrane disease based on gestational age in 1999 as we sit here today?

A. Essentially the same.

Q. Okay. The same as what you wrote in 2002?

A. Essentially the same as what I -- what I just stated.

Q. Well, I'm confused, because you were talking about what you wrote in 19 -- or 2002 --

A. Uh-huh.
Q. -- and what's currently being written, which is different than what you wrote?
A. It's not significantly --
Q. Okay.
A. It's not significantly different.
Q. All right. But you agree with me it's different?
A. Fine.
Q. And would you agree with me, in 1999, what we, probably, suspected on incident was closer to what you wrote in 2002 than what's currently being written today?
A. No. I just don't think that there's a significant change. Hyaline membrane disease in near-term infants was not as -- there's a better appreciation of that now, because there happen to be more near-term babies being born.
Q. All right. And then you said there were two risk factors that Matthew had. His other was male sex?
A. Correct.
Q. Okay. So just so I understand, the only risk factors that you can point to that Matthew

had in developing hyaline membrane disease was his gestational age and the fact that he was a male, correct?

MR. BECKER: White male.

Q. Well --

A. White male, which increases his risk as opposed to -- you can show that to me. I'm just going on my working knowledge --

Q. Okay.

A. -- of what I use every day.

Q. Doctor, please, I am not trying to be argumentative.

A. Okay.

Q. But it doesn't say white male anywhere here, does it?

A. I believe it says, "male sex," right here (indicating).

Q. Male sex, not white male.

A. Okay.

MR. BECKER: He said that in his report, John.

THE WITNESS: Caucasian -- I said, "caucasian male."

MR. BULLOCH: I'm asking him for where

it is in his literature.

MR. BECKER: All right. All right.

BY MR. BULLOCH:

Q. All right. The vast majority of 35 to 36-week-old baby boys don't develop hyaline membrane disease, do they?

A. Correct.

Q. So, when you have a 35 to 36-week-old baby boy developing hyaline membrane disease, it's somewhat of a surprise?

A. Not to me, no.

Q. Well --

A. To most neonatologists, no. It's a potential expected outcome.

Q. But, certainly, fairly rare?

A. I wouldn't call it rare. I would call it more uncommon --

Q. Okay.

A. -- but it's, certainly, not rare.

Q. 1 percent?

A. Well, we're talking the two to 4 percent.

Q. Okay. Now, we talked briefly about the symptoms of hyaline membrane disease as being

tachypnea, correct?

A. Tachypnea.

Q. Tachypnea.

A. Uh-huh.

Q. Nasal flaring?

A. Uh-huh.

Q. Chest wall retractions?

A. Uh-huh.

Q. Grunting and cyanosis, right?

A. Yes.

Q. There are other conditions that you've written about that have the identical presentation, correct?

A. Correct.

Q. What are some of those?

A. Retained amniotic fluid, pneumonia, meconium aspiration.

Q. There's also something called transient --

A. Transient tachypnea in a newborn. That's the same as retained amniotic fluid.

Q. Also, known as Type 2 respiratory distress syndrome?

A. That's a term that hasn't been used in

many years, but yes.

Q. Okay. All of these other conditions, meconium aspiration, pneumonia, are they treated with surfactant?

A. At the present time, meconium aspiration is usually treated with surfactant. If you think a child has meconium, that's a little controversial. Some people do, and some people don't.

Q. It's, certainly, not standard of care to treat?

A. To treat meconium, I would say it's not, yes.

Q. All right. But there were four or five different conditions that we talked about that mimic respiratory distress syndrome --

A. With their --

Q. -- in 1999?

A. I could just say that mimic their clinical presentation, yes.

Q. Okay. Now, in 1999, were any of those treated with surfactant, except for -- besides, rather, respiratory distress syndrome?

A. Yes. Meconium aspiration syndrome was.

Q. In 1999?
A. Yes.
Q. Okay. If you have this transient tachypnea of a newborn, how long does it take for this condition to resolve?
A. It's very variable. It could be a couple of hours to 24, hours which would be the outside --
Q. Okay.
A. -- but usually it's within, you know, two to three to four hours.
Q. Okay. Can it take several days to resolve?
A. I would say no. I would be very reluctant to call a clinical course that far out with transient tachypnea of the newborn.
Q. Okay. The reason why I ask that question, Doctor -- I don't mean to be argumentative -- you read there what you wrote about --
A. Uh-huh.
Q. -- that particular disease under treatment.
A. (Witness reviews document) Hours to

several days, yeah.

Q. Okay.

A. That's what -- that has been stated in several of these papers. It's not something that I clinically feel is necessary.

Q. Okay. But that's what you wrote?

A. Yeah.

Q. It can take several days to resolve?

A. Yeah.

Q. And you talk about the treatment here, and -- and you don't use surfactants for transient --

A. TTN.

Q. Thank you.

A. That is correct; we do not use surfactant for treatment of TTN.

Q. Okay. So, if a doctor is not sure he's got TTN as opposed to RDS, is the doctor entitled to withhold surfactants for several days until he decides what it is?

A. It's the job of the doctor to make a diagnosis.

Q. But you just told me that the --

A. We hadn't talked --

Q. -- clinical findings and the radiographic findings are the same?

A. No. I -- I didn't say anything about radiographic findings.

Q. All right. How are the radiographic findings different?

A. Between?

Q. Between TTN and respiratory distress syndrome.

A. Okay. In respiratory distress syndrome, you usually have a bilateral ground glass appearance, and it's distinctly different from transient tachypnea, which shows more of an interstitial pattern, which has dilated lymphatics, particularly in the lower lobes.

Q. So the entire diagnose -- diagnosis of TTN and differential diagnosis for TTN as opposed to RDS is made on radiographic findings?

A. Many times, that's correct.

Q. You said that these radiographic findings are usually found, but not always found?

A. That's correct, as most things in medicine.

Q. Okay. Can you have TTN and have ground

glass appearance in the lung?

A. I'm sure you can.

Q. Okay.

A. You have to determine what -- which is the predominant pathologic process going on.

Q. Okay. And what about pneumonia; is -- is there any difference in the presentation of pneumonia than RDS?

A. Well, are you talking about clinical presentation or radiographic?

Q. Let's talk first about clinical.

A. Clinical presentation, they can be completely the same, grunting, flaring, retracting, tachypnea.

Q. Okay.

A. But radiographically you can usually -- sometimes you cannot tell the difference at all between bacterial pneumonia and respiratory distress syndrome, and sometimes you can, but radiographically they can be -- they can look exactly the same.

Q. So it can be real difficult to tell the difference between pneumonia and respiratory distress syndrome?

A. It can be, yes, as you're sitting there with a brand new baby that's several hours old, yes, and that's the reason why we treat with antibiotics.

Q. If you had a 2,300 gram baby, what's more common, hyaline membrane disease or pneumonia?

A. Statistically, probably, pneumonia.

Q. Okay. And you don't give surfactant for pneumonia, correct?

A. For pneumonia?

Q. Yes.

A. I do, but it's not -- again, some people do, and some people don't.

Q. It's, certainly, not the standard of care?

A. It does -- it's not at a standard of care level; that is correct.

Q. It's, probably, a little more cutting edge would you say?

A. I don't know if I would say that.

Q. Can you point me towards any articles where surfactant use in -- this is, certainly, an off-label use of surfactant, right?

A. Yes.
Q. Can you --
A. There have been one or two articles -- I can't cite you chapter and verse as I sit here --
Q. Okay.
A. -- that have suggested -- have suggested the fact that treating babies with pneumonia with exogenous surfactant can be beneficial.
Q. Are those pretty recent articles?
A. Not very recent, no. I would say late '90s.
Q. Doctor, how does surfactant work?
A. Surfactant works by decreasing the forces of the alveolus wall to prevent it from collapsing down. It decreases surface tension.
Q. So surfactant is basically a surface-acting agent?
A. Right.
Q. Much like soap would be on a -- on water with grease on top, correct?
A. Correct.
Q. So this is really more of a mechanical process as opposed to a drug activity that requires absorption and distribution or partial

metabolism or anything of that nature, correct?

A. Well, not completely. There are some surfactants that actually need to get into the cell and then get packaged, and then they are excreted out of the cell in order to form its effect. So that's not completely true.

Q. Okay. Is that the exosurf type of surfactant?

A. Very good. That's correct.

Q. It's not true of the naturally-occurring surfactants, correct?

A. That's correct. Much more so.

Q. Okay. So the naturally-occurring surfactants act fairly rapidly, I presume, correct?

A. That's correct.

Q. Can you tell me, then, why Matthew developed a second pneumothorax?

A. I suspect that he developed a -- well, I suspect he developed a second pneumothorax, because of the pressures being delivered with the ventilator to support his lung disease.

The use of surfactant after an established pneumothorax is relatively

controversial. Some people do it, and some people don't.

Some feel it's not worth doing, because any surfactant you put in might leak out in the pleural space, and then you would suck it out by your chest tube. There are other people who believe there may be some benefit to it.

Q. Okay.

A. But I believe he got a -- his second pneumothorax again, because of, you know, the high pressures that he was requiring on the ventilator.

Q. Well, typically, when you give surfactant, the pressures can come down, correct?

A. If you give it in a timely fashion; that's correct.

Q. Now, when do you believe this second pneumothorax started?

A. Just going by the chart, it happened at 8/25 and eleven p.m. at about 23 -- at about 34 hours of age, according to my notes.

Q. Well, the first pneumothorax, according to your notes, occurred at what time?

A. 8/25 at 7:05 p.m., approximately 30 hours of life.

Q. 7:05 p.m.?
A. Correct.
Q. And the surfactant was given when?
A. That's unclear to me, because the surfactant was ordered -- this is where the notes sort of get very fuzzy, because I'm relying on the notes that the doctors wrote are not completely very intelligible, and there was nothing helpful in the discharge summary.
Q. Okay.
A. There was Survanta ordered on 8/26 on 8:15. That was the first time I ever saw it ordered, but there was -- I had a question here -- and you can see that on my notes -- that, after the first pneumothorax, question whether they actually gave surfactant at that time after the first pneumothorax.
Q. All right. Do you have any reason to believe they did not give the surfactant?
A. You know, I don't -- I just don't know, to tell you the honest truth.
Q. Okay.
A. I just extract what I can out of this, and I did not read any depositions, which

sometimes fill in the holes.

Q. All right. And -- and when do you believe the second pneumothorax occurred?

A. Well, according to the notes here, it was 8/25 at eleven p.m., so approximately four hours after the first pneumothorax.

Q. Do you believe that second pneumothorax was developing prior to this time, or did it just occur at eleven p.m.?

A. I would say the latter.

Q. It just occurred --

A. Pneumothoraxes just happen. They don't necessarily evolve per se.

Q. So, assuming that the surfactant was given at 8:15 p.m. and the second pneumothorax occurred almost three hours later, that should have been more than enough time for the surfactant to exhibit its effects, correct?

A. Right, and that's possibly why he got a pneumothorax.

Q. I -- I don't -- I don't understand. Can you explain what you mean by that.

A. Because the -- the child was being treated with a lot of pressure, has had a

pneumothorax. Then what can happen -- and, again, this is why the administration of surfactant with a -- with a pneumothorax present is controversial, because when you have a pneumothorax, that can sometimes, you know, overexpand some parts of the lung and collapse other parts of the lung, and sometimes, when you add a dose of surfactant with a -- with a -- with an ongoing pneumothorax, you may cause another one, because you may -- the pressure that's being delivered to the areas that are already expanded, then you're improving their compliance even more, and then you may cause a pneumothorax like giving surfactant.

Q. All right. But you don't believe that Dr. Lilien decision to actually give the surfactant at 8:15 itself breached the standard of care; what you believe Dr. Lilien breached the standard of care was failing not to give it before seven o'clock?

A. Much earlier on, actually, right after intubation.

Q. Okay. You have no criticism of Dr. Lilien giving the drug at 8:15, correct, assuming he gave it?

A. Well, the -- I mean, again, the criticism comes back that, if you -- that what the natural progression would be, the child is in respiratory distress; you intubate them; you document the placement of the endotracheal tube radiographically, and then you go ahead and give a dose of surfactant within, you know, a half hour of -- of intubation, and that's -- that's the common standard of care treatment of this therapy, and with that you would never -- you would have avoided all of these higher pressures that they got into later on, which I think was the reason why the child developed the pneumothorax.

Q. Okay. And I think I understand what you're saying, but your real criticism is Dr. Lilien should have given this surfactant sometime before seven o'clock?

A. Yeah, shortly after intubation.

Q. Okay. Certainly, the second dose or the dose of -- of surfactant that they gave Matthew was -- was not effective in preventing the pneumothorax, correct? We know that.

A. Correct.

Q. We know that Matthew's respiratory

problems gradually resolved, correct?

A. Correct.

Q. Are you, therefore, limiting the time of Matthew's damage to the specific time period? Do you know what I mean?

A. No.

Q. Well, is there a certain period of time after which -- well, I think you've answered it. Your only criticism is Dr. Lilien is he didn't give the drug shortly after intubation, correct?

A. Correct.

Q. Okay. We can skip that.

Doctor, one of the other things that I read that you wrote in Saunders was that the widespread use of prenatal maternal steroids has markedly decreased the incidence of hyaline membrane disease, correct?

A. Correct.

Q. There are two ways that you can prevent or significantly reduce your risk of hyaline membrane disease, which is keep the baby in utero, correct --

A. Correct.

Q. -- or give the mom maternal steroids,

correct?

A. Correct.

Q. Do you have any criticisms of the obstetrician for failing to extend this pregnancy?

A. I'm sorry. Repeat that question.

Q. Do you have any criticism of the obstetrician for failing to extend this pregnancy to use tocolytics and -- and keep Matthew in utero?

A. I'll answer the question just with the understanding I am not an expert in obstetrics --

Q. Okay.

A. -- but I can say that it is almost unheard of for obstetricians to stop labor with tocolytics at 35 weeks.

Q. Okay. Now, when you give steroids to mom, there's not a lot of risk to the mom or the fetus, correct?

A. There's little risk.

Q. Little risk. Sodium retention in the mom?

A. Potentially.

Q. I mean, we're not talking about any kind life-threatening risks here by giving a couple of

doses of prednisone, are you?
A. Or dexamethasone or betamethasone. Usually not.
Q. Pretty significant benefit, correct, in a -- in a premature infant?
A. Potentially, correct.
Q. Do you have any criticisms of the obstetrician's failure to not prescribe steroids?
A. Again, I will answer this just under the proviso that I'm not an obstetric expert, but it's almost unheard of to give mothers prenatal glucocorticoid therapy at 35 weeks.
Q. Why?
A. Because their incidence of the disease, hyaline membrane disease, is so small.
Q. Okay. So you don't run the small risk of giving the mom sodium retention, because the benefit is so small, correct?
A. Correct, because the --
Q. Okay.
A. -- incidence of the disease at that gestational age is so low.
Q. Doctor, that's kind of what you do when you prescribe the medication, isn't it? I mean,

when you are prescribing medication, you kind of weigh the benefits versus the risks, correct?

A. Correct.

Q. And that's part of exercising your professional judgment as a physician, right? You decide whether a patient needs a certain medication, correct?

A. Correct.

Q. If you have a drug that has a potential for causing a severe adverse reaction, but it has no known benefits in a certain population, what would you do? Would you give the drug to that population?

A. Probably not.

Q. What are the risks of exogenous surfactants?

A. In general?

Q. Yeah.

A. If it's administered incorrectly, you get some sort of apnea, bradycardia, hypoxemia. It's -- it's very low. If it's administered correctly and properly, it's a very safe drug, actually.

Q. Okay. Is there some reason -- I have

read this, and I don't really understand it. Perhaps, you can explain it to me, but is there some reason that large babies, when you give surfactant, it tends to plug -- they have a higher incidence of plugging the ET tube?

A. I've never heard of that, because bigger babies have bigger endotracheal tubes.

Q. Okay. So, if I provided literature to you that said that's a potential risk of surfactant, you wouldn't necessarily agree with it, at least not in your experience?

A. In my 15 years of experience, I've never had a large -- I've never had an endotracheal tube in a large baby be plugged by surfactant.

Q. All right. And, when you give surfactant, some of the risks you said are bradycardia?

A. Yes.

Q. What causes the bradycardia?

A. Usually stimulation of the vagus nerve, which is one of the nerves that kind of innervates the airways, and you also have manipulation a little bit of the endotracheal tube.

Q. Okay. So the bradycardia that's caused

is actually a mechanical effect of the administration of the drug, correct?

A. Correct.

Q. And can you get oxygen desaturations when you administer surfactants?

A. Yes, you can.

Q. Isn't that why one of the precautions and warnings is that you don't give this in community hospitals; you give it in facilities that are equipped to handle these type of emergencies?

A. Well, as the policy states, you, certainly, need to be facile with the ability to administer surfactant, absolutely.

Q. And the policy you refer to is the AAP policy, correct?

A. That's correct, and most institutions that -- that administer surfactant usually have some type of policy.

Q. Okay. Who usually gives the -- who actually administers the drug in your institution? Do you give it?

A. No. I used to years ago, but for many years it's now a combination of respiratory

therapy and nursing.

Q. Okay. So the policy that AAP came up with, is that primarily to give guidelines to people that were not neonatologists in administering the drug?

A. You would have to ask them.

Q. Okay. Fair enough.

We talked about this briefly. There were -- there were naturally occurring surfactants in '99, and there was one synthetic surfactant, correct?

A. Exosurf, correct.

Q. E-x-o-s-u-r-f.

And I think you've already touched upon this. There are specific benefits with using the naturally-occurring surfactants, correct?

A. Correct.

Q. It works better than naturally occurring -- better than the synthetic?

A. In general, felt to work much more quickly, and the improved lung compliance that people saw, everyone seemed to -- it was better -- more quickly and better than Exosurf.

Q. Okay. Part of the reason for that is

Exosurf doesn't contain the surface-acting proteins, correct?

A. Correct.

Q. Were there -- and I believe you touched upon this, too. There were more risks with Exosurf than there was with the naturally occurring?

A. Not -- risks for Exosurf?

Q. Yes.

A. Not that I recall.

Q. Okay. Did your hospital put Exosurf on the formula, or did you have naturally occurring, do you recall?

A. I've been in Massachusetts General Hospital since 1994, and we've never -- I believe we've never had Exosurf on the formula.

Q. But --

A. But I do have -- but I do have experience with it in a previous position earlier on.

Q. And I assume that's, because you -- well, I don't want you to speculate why that was.

Can you refer me to a single study -- a single controlled study prior to 1999 where

exogenous surfactant was used in newborn babies that were as large as Matthew was at 2,305 grams?

A. No, because I don't believe those studies were done.

Q. And, in fact, even today there's no controlled studies on larger babies with the use of surfactant, is there?

A. I think that's correct.

Q. All controlled studies that have been done on surfactants has been on younger and smaller babies; is that correct?

A. On smaller babies with decreased gestational age, and the main reason for that is, because that's where the incidence of the disease is greater.

Q. Okay. And you cannot cite me to a single article, I assume, where surfactants have been shown to have a positive impact on neurodevelopment?

MR. BECKER: On what?

MR. BULLOCH: Neurodevelopment.

A. Not chapter and verse. What you would have to do in that sense, again, is -- is look at outcomes of infants in the pre-surfactant era

versus post-surfactant era.

Q. Or look at hospitals that don't get surfactant. Is that possible?

A. I would hope there aren't many of those per se. You know, again, if the hospital gives -- at least the transport team is giving it.

Q. Are you aware of what Columbia Hospital's -- Columbia University's hospitals are studying currently in CPAP and not giving surfactant?

A. They -- I'm aware of their CPAP experience for years.

Q. Okay. And, when they use CPAP, they do not give surfactant; is that correct?

A. I suspect not since -- if -- I -- I don't know. You know, it depends whether -- some places -- I know of one study over in England -- not England -- Scandinavia where they intubated a child. They gave surfactant. Then they extubated the child right away and put them on CPAP and studied those infants.

So, when you're talking about Columbia, I just don't know anything about what you're talking about.

Q. Would you ever intubate a child just to give the child surfactant?

A. I don't practice that way, but I know people that do.

Q. Okay. But would you?

A. Not at -- not at the present time at Mass. General.

Q. All right. And, again, let me represent to you that there are ongoing studies at Columbia, and the -- there is a -- essentially the way they treat children with RDS is to put them on CPAP and not administer surfactant. Okay. Let me represent that to you.

Are all of those doctors breaching the standard of care by failing to give surfactant to their child?

A. I really can't comment on that, because I don't know anything about what you're talking about, and I don't know any of the -- of the specifics.

Q. All right. Are you familiar with the Vermont Oxford network?

A. Yes, I am.

Q. Is that a respected entity?

A. Yes, it is.

Q. Do you know anything about the Vermont Oxford database on RDS children?

A. Not specifically, since we just joined Vermont Oxford about four months ago.

Q. Okay. Let me represent to you that the database includes 3,505 infants between 1,400 and 1,500 grams. Not all of those children were given surfactant. Okay.

A. Uh-huh.

Q. I'm representing that. Do you believe that the physicians that participated in that study made a -- you know, breached the standard of care when they decided to withhold surfactant?

A. Again, you're asking me things that I -- I cannot make a comment based on just what you say. I think that's very unfair.

Q. All right. Fair enough.

Do you ever consult the manufacturers' dosing charts that come with surfactants on how to give the drug?

A. I've read them.

Q. Okay. I assume you've consulted the PDR on -- on the use of surfactants at some point in

time?

A. Not the PDR, but I mean, I have, certainly, read product information.

Q. All right. The product information, essentially the drug product monograph that appears in the PDR, correct?

A. Okay.

Q. If you open the package of Survanta, S-u-r-v-a-n-t-a, what you're going to find in there is basically the same thing that appears in the PDR, correct?

A. Correct.

Q. Is there anything in there about giving surfactant to a baby larger than 2,000 grams?

A. I don't recall, since I haven't read it recently.

Q. If I represent to you that there is not. Is then giving this drug to babies the size of Matthew an off-label use?

A. I guess, by -- by the letter of the law, yes.

Q. Okay. Does that require some form of informed consent from your patients?

A. In neonatology, we've given a lot of

medicines that way.
Q. Off label?
A. Off label, yes.
Q. And, I guess, what you're saying from that is you don't bother getting the parents' informed consent, correct?
A. In giving surfactant?
Q. Yes.
A. That is correct.
Q. So, if you gave surfactant to a child that weighed 2,300 grams, you wouldn't get the parents' consent to do that, correct?
A. No, we would not.
Q. Doctor, I guess, I'm just a little confused. How -- how do you believe that Dr. Lilien breached the standard of care when he failed to give Matthew surfactant when there were no studies in 1999 giving surfactant to children Matthew's size? It was an off-label use, and there are entities that have not given surfactant. How -- how did he breach the standard of care?
A. I think he breached the standard of care, because the diagnosis of this infant, in my opinion, was surfactant deficiency, and it's been

the standard of care everywhere I know, when you make the diagnosis of surfactant deficiency or hyaline membrane disease or respiratory distress syndrome in an infant clinically and radiographically who requires endotracheal intubation, then to treat that child with exogenous surfactant.

Q. Okay. Maybe, we've got a problem with semantics here. In your mind, what is the standard of care?

A. The standard of care is that, when you make the diagnosis of surfactant deficiency, hyaline membrane disease or respiratory distress syndrome, you treat that disease with exogenous surfactant.

Q. I'm sorry. The question was vague. In general, what was the standard of care?

MR. BECKER: He wants know what the term means to you.

Q. What does the term, standard of care, mean to you?

A. I know every state has a different standard of care.

Q. I don't care what the state says,

Doctor. I want to know what Dr. Cronin thinks. When you use the term, breached the standard of care, what does that mean to you?

A. I think that a physician -- you know, I mean, we can get into the semantics, due diligence of, you know, providing care.

Q. Okay.

A. This was -- the treatment -- the use of exogenous surfactant to treat surfactant deficiency, I believe -- the nonuse of that, I believe, breached the standard of care --

Q. Okay.

A. -- in the treatment of this infant, a white male, premature infant, who had no risk factors for infection and chest x-ray consistent with that diagnosis.

Q. I hate to get off the subject, but was there no risk of infection known to Dr. Lilien in this patient?

A. The only risk factor, to me, is prematurity.

Q. So there was a risk factor?

A. There was a risk factor, yes. Sure.

Q. And are you aware of the fact that Margo

Wagoner underwent an artificial ruptured membrane?

A. I am aware of that, yes.

Q. Doesn't that carry a higher risk of fetal infection as well?

A. It does, but it would be very small.

Q. Let's get back to this issue of standard of care.

How -- how is a standard of care created? Again, I'm just talking about congenital. I'm not talking about Matthew Wagoner. I'm talking about, in your mind, how is the standard of care developed?

A. Well, this is -- you know, a standard of care that's put out in 1999 by the American Academy of Pediatrics, you know, to treat surfactant replacement for children whom you've diagnosed with respiratory distress syndrome, I mean...

Q. Well, how was the standard of care created? Is it one -- does one article create a standard of care?

A. Policy statements from -- from organizations have -- in essence, do that.

Q. Okay. Does it say anywhere in here that

the standard of care is to give children above 2,000 grams --

A. There's no weight determination in that -- in that statement.

Q. A lot references, correct (indicating)?

A. (Witness reviews document) Yup. Right. Yes, but I'm saying the policy itself.

Q. Okay. Do any of these articles -- let me back up.

Do these articles support conclusions that are reached here? Would you assume that's the case?

A. Yes.

Q. So the support of this policy is found in these articles, correct?

A. Correct.

Q. Can you show me any of these articles that administer surfactant that are listed here to a child larger than 1,750 grams?

A. No. There probably isn't, because again, we go back to why do they do that? Why have they picked smaller babies? It's, because the incidence of the disease is greater in smaller babies, and in order to make, you know, the study

come through, that's where they pick -- where you have the greatest incidence of the disease.

Q. Well, certainly, they could have been all inclusive when they designed their study, though, correct?

A. They could have been, yes.

Q. And they weren't for what reason, or you don't know?

A. Well, usually the answer is they want to finish a, you know, randomized control study within a reasonable amount of time. So, in order to -- you know, meaning a couple of years rather than looking at something that happened much less frequently, the study is going to take longer, or you have to get more study centers in order to get the number of patients.

Q. But, Doctor, what you're sitting here telling me is there's no difference in giving it to a large baby as opposed to giving it to a small baby. So why didn't those studies just be all inclusive, including children that have RDS?

A. Talk to the people who did the studies.

Q. Is it fair to say that a standard of care is created by a series of well-controlled

studies?

MR. BECKER: Objection.

You can answer.

A. It certainly goes into developing a standard of care.

Q. And it's not one person that announces, This is a new standard of care, that develops a standard of care, correct?

A. No. Usually it's a -- it's a group, as there is in this situation, and in neonatology, the committee on fetus and newborn is a group of people that does set standards.

Q. But, again, Doctor, we've talked about the purpose of this policy. You told me the purpose of the policy was really to give directions on how the drug is administered, correct, not to whom it was administered? Can you point out anywhere in that article where it says to whom that drug is to be administered?

A. No.

Q. Does it really talk about how you give the drug? I've read it a hundred times, and I'm sure you have, too.

A. Well, you've, probably, read it more

than I have.

Q. All right. Your report specifically states that Dr. Lilien breached the standard of care, because in 1999, it was common practice to treat premature infants with respiratory distress syndrome who required greater than 30 percent FIO2 and a ventilator mean pressure greater than 8 centimeters of water surfactant. Did I read that correctly?

A. Correct. Yes.

Q. And, again, can you point to one single article where it says that, if you have a child that requires greater than 30 percent FIO2 and a ventilator pressure of 8 centimeters water, you give them surfactant, no matter what size the child is?

A. Well, those were very common criteria used in these studies of development of this therapy. That's where those numbers come from, the Survanta articles -- back in the late '80s as well as the Survanta articles.

Q. Well, the admission criteria were basically if the child was on ventilator, correct?

A. Well, they also need other specifics,

not just on the vent or off the vent.

Q. What are those studies?

A. The more important ones that I can think of off the top of my head. There were -- because for years people ask, what are the determinants of a baby who has -- a premature baby with hyaline membrane disease is intubated. What are the criteria for exogenous surfactant therapy?

Q. Again, off-label use?

A. It can be.

Q. Well, let me ask you this: Does the manufacturer say that this is the criteria for giving surfactant?

A. I have not read that, so I can't -- I can't comment on that.

These -- these numbers come from the studies, and they're also clinical parameters that we've used for many, many years.

Q. That's what I'm interested in. Are these clinical parameters that were used at Harvard?

A. Massachusetts General Hospital.

Q. Okay. So these were the standards that, in your many years of experience, were used at

Mass. General to give a child surfactant?

A. Correct.

Q. Do you know if that was the same standard that was employed in Cleveland, Ohio?

A. I do not.

Q. Do you know if that was the same standard employed in any other hospital in the country?

A. I do not, because I have not seen the criteria.

Q. Do you know if there was anything written that said this is the criteria nationally, that this is the standard when you have -- or are we talking more about what happened at Mass. General?

A. Well, these criteria that we use at Mass. General are from the national studies. If I have a child on 21 percent oxygen, I usually don't treat that child with exogenous surfactant.

Q. Okay. You said that these came from the more important studies that you recall. Do you recall the authors of any of those studies?

A. I -- I don't -- I don't recall. They're from the late '80s, early '90s.

Q. Okay. So, if I generally go back and look at the literature written in the early -- or late '80s and early '90s on surfactant therapy, you believe that's what I'll find in the majority of the study?

A. Yes, I do.

Q. Okay.

A. We didn't make these numbers up out of the blue.

Q. I'm sure you didn't, Doctor, but you know as well as I know that sometimes the numbers aren't out there, and some hospitals of the caliber of Mass. General will say, This is what makes sense to us, correct?

A. Correct.

Q. There are occasions when numbers are not pulled out of the blue, because I think that's not a correct characterization, but certainly, there are times when prestigious institutions like Mass. General says, There's no criteria out there. This is what we're going to use, correct?

A. Correct, based on the best data that we have --

Q. Sure.

A. -- available.
Q. Sure.
MR. BULLOCH: Take a couple-minute break, if we could.
(Recess)
BY MR. BULLOCH:
Q. Doctor, I just wanted to clean up one thing.
We said something about off-label use. Another term for off-label use is use of an approved drug in a nonapproved manner, correct?
A. Correct.
Q. Not approved by who, the FDA?
A. I assume.
Q. Okay. Doctor, if -- I want to talk about Matthew for a moment, and -- and the rest of my questions today, unless I tell you otherwise, will be related to Matthew and specifically about a child who develops two pneumothoraxes and, as a result, Plaintiffs' claim developed cerebral palsy. Okay.
A. Yes.
Q. And specifically a spastic athetoid type of cerebral palsy. Have you ever heard of a child

developing spastic athetoid cerebral palsy as a result of a pneumothorax?

A. I don't recall.

Q. Okay. If -- if a child had a hypoxic ischemic event severe enough during a pneumothorax to cause cerebral palsy, what would you expect to see to happen to the child by way of kidney function?

A. Again, it depends on -- we're getting into -- you're not talking about Matthew. That's why I'm -- I'm confused. You said you were talking about Matthew. Now you're talking about generalities.

Q. Why do you think I am not talking about Matthew?

MR. BECKER: Because you said, "if a child." How's that?

Q. All right. Let me back up, then.

If Matthew, in fact, developed cerebral palsy as a result of the -- of the two pneumothoraxes, what would you expect to see to happen to his liver function or his kidney function?

A. Maybe something; maybe nothing.

Usually -- usually nothing, because it would be below his -- his kidney function was fine --

Q. Okay.

A. -- other than he did develop an aortic lot, which was, probably, secondary to an umbilical line.

Q. Okay. And that has nothing to do with an ischemic event is what you're saying; that has to do with the line that was --

A. Correct.

Q. So, in Matthew's case, there was no hit on his kidney function, correct?

A. That's correct.

Q. What happened to his liver function?

A. His liver function was essentially within normal limits.

Q. So, essentially, as a result of this hypoxic ischemic event sufficient to cause cerebral palsy in Matthew, there was no hit to his liver function, correct?

A. That's correct.

Q. What about his bone marrow; what happened to his bone marrow?

A. I'm not aware of anything happening to

his bone marrow.

Q. And you're correct; nothing happened to his bone marrow. There was no thrombocytopenia that you recall, correct?

A. No. That's correct.

Q. So, as a result of this hypoxic ischemic event sufficient to cause cerebral palsy, there was no hit to his bone marrow, correct?

A. That's correct, that I'm aware of, yes.

Q. Okay. If a child has -- well, let me keep it with Matthew. Did Matthew have coma? Did he go into coma?

A. No, he did not.

Q. Did he have seizures?

A. No, he did not.

Q. Did he have any EEG changes?

A. He had an EEG on 9/8, which was read as normal.

Q. So, again, answer my question: As a result of this hypoxic ischemic event sufficient to cause cerebral palsy in this little boy, he had no EEG changes?

A. Correct.

Q. Okay. Did Matthew experience any

changes to his head images as --

A. According to the records, well, yes.

Q. What was that change?

A. Well, he had two ultrasounds, which were normal on the 31st, and then -- the 31st of August and then the 9th of September.

Q. Okay. So, as a result of this hypoxic ischemic event sufficient to cause cerebral palsy in Matthew, he had no changes in his head ultrasounds, correct?

A. That is correct.

Q. Okay. What about CTs or any other head imaging?

A. Well, there was an MRI done on the 9th of -- excuse me -- the 8th of September, day of life 16, where they had MRI where they were questioning the finding of early periventricular leukomalacia.

Q. Okay. So can we say -- did Matthew ever show any signs in his head of edema?

A. Not on ultrasound. You're talking cerebral edema?

Q. Yes.

A. Not on ultrasound and not as stated on

MRI report.

Q. So, as a result of this hypoxic ischemic event sufficient to cause cerebral palsy in Matthew, there was no cerebral edema that you saw, correct?

A. That is correct.

Q. So is it fair to say that, as a result of this hypoxic ischemic event, the only thing that you saw in the medical record as sequelae was possible periventricular leukomalacia?

A. Correct. In the radiology report, yes.

Q. You saw nothing else consistent with a hypoxic ischemic event in the sequelae, correct?

A. I'm sorry. Say that again.

Q. Strike that. You already answered it, Doctor. I'm wasting your time.

Are you aware of the fact that Dr. David Bachman, who was the head of pediatric neurology at Ohio State University, became Matthew's subsequent treating pediatric neurologist in North Carolina?

A. I have -- am I aware of that?

Q. Yeah.

A. No, not at all.

Q. Okay. Let me represent to you that that is, in fact, the case, and we have medical records of Dr. Bachman, and in fact, we took Dr. Bachman's deposition.

Dr. Bachman testified that he had two board certified neuroradiologists take a look at the Fairview films, the MRI and the ultrasounds, and that both of these neuroradiologists decided there was no PVL. Now, I'm not asking you to accept that it's true.

A. Okay.

Q. That's what's been represented.

A. All right.

Q. Now, all that we have from Fairview is the possibility for early PVL, correct?

A. That's what's in the record.

Q. Dr. Bachman testified, in fact, what one of these neuroradiologists said, actually -- this possible PVL was actually early myelinization, which is a normal finding, correct?

A. It can be, yes.

Q. All right. I want you to assume for the moment that these two neuroradiologists are correct, that there's no abnormality in Matthew's

MRI that was performed at Fairview Hospital. In that occasion, you can't point to anything in the sequelae -- Matthew's sequelae that is consistent with a hypoxic ischemic event sufficient to cause cerebral palsy, correct?

A. That's correct, not in the information I've reviewed.

Q. Okay. Now, tell me, Doctor, patients that have had hypoxic ischemic events in the neonatal period sufficient not only to cause brain damage, but sufficient to cause cerebral palsy, and not only cerebral palsy, a spastic athetoid cerebral palsy that is affecting even the basil ganglia, would you expect to see some sequelae after the hypoxic event in the form of liver function, kidney function, bone marrow, testings, seizures, EEG changes or imaging?

A. All I can really tell you is that, is it possible? It certainly is. Even in Volpe's book, it depends, you know, where the blood flow goes and where the blood flow doesn't go, and when you have patients with hypoxic ischemic cephelopathy, 50 percent of them only have a brain injury. Then I think there's another 25 percent who had brain

and kidney, and then there's another 25 percent who had other -- other indications.

Q. What does your experience tell you? Should you have seen some sequelae from this hypoxic event?

A. Well, again, you're leaping a little bit ahead of where I am. I'm going -- I'm going on the data that was presented to me in the chart.

Q. I understand.

A. And I'm just going -- yeah. Okay. He had MRI, and he had question of early PVL, and I look at this, and I go, gee, could these two pneumothoraxes and not -- you know, not meeting what I think the standard of care in treating this child appropriately with exogenous surfactant, two pneumothoraxes, a lot of hypoxemia, I'm sure some blood pressure problems -- can that cause brain damage? Well, yeah, it can.

Q. Well, knowing what you know about Matthew, knowing that there was no PVL, there was no sequelae, there was absolutely nothing abnormal on the -- on the head imaging films, is it likely that Matthew's CP was caused by --

MR. BECKER: Objection. He's answered

the question, John. Now, you know, if he answers it strongly, then you're not going to like his answer.

MR. BULLOCH: So we might be here for a couple more hours.

MR. BECKER: That's right. So be careful of what you're asking him.

BY MR. BULLOCH:

Q. Doctor, I'm asking you, would you expect to see something on this child if he had a hypoxic ischemic event?

MR. BECKER: Objection. Asked and answered.

Q. Well, you can answer again.

MR. BULLOCH: Let me finish my question first, Mike, please.

Q. But, if a child had a hypoxic ischemic event sufficient to cause cerebral palsy, would you expect to see something similar, even including when you said some only have brain, but wouldn't you expect to see something on the imaging or some other sequelae?

A. Yes, you would expect to see something on MRI image.

Q. More likely than not?
A. Yeah, more likely than not.
Q. Doctor, you -- you mentioned to me that you saw some depressions in, I think, pulse oximetry or Po2 in the chart. Can you point specifically to those events?
A. I do have to -- are we going to be here a lot longer, because I'm supposed to be somewhere?
Q. No. I promise we'll get you out of here.
A. If you go to Fairview laboratory and then go to blood gasses --
Q. Maybe, I can circumvent this for you. Are you talking about the points in time when there were some panic levels reported?
A. Yeah. Okay. I see what you're saying when you call them panic levels, but sure.
Q. Those aren't a panic level for a neonate, though, are they?
A. A Po2 of 33, absolutely.
Q. Okay. You would consider that a panic level?
A. Absolutely.

Q. Okay.

A. Anything under -- you know, I don't know -- this is a hospital thing of what can cause a panic. A normal Pao2 for a baby is at the lowest 50. It should be in the sort of 50 to 70 range or, certainly, above 50.

Q. Anything above 50 is normal?

A. Right. That's correct. I mean, you know, we've had 33s and 45s and 32, and I mean, you don't have to go through this, but there are multiple episodes of hypoxemia that I'm concerned about.

Q. And those aren't prolonged periods, right? I mean, they're -- they're low, and then they're up; they're low, they're up, correct?

A. Well, you know, I don't have any -- you know, when you look at the flow sheets on the nurses here, the pulse ox. is always reading absolutely fine all the time, and I -- I wonder about some of that when -- when you have what these, what you call, panic levels.

Q. Okay.

A. But the child did take hits, and these are documented hits.

Q. Now, are -- is it possible to get Po2 levels that aren't accurate?

A. Of course, it is.

Q. And you get those sometimes with arteriole sticks, I understand.

A. I'm talking about the arteriole Po2s --

Q. Okay.

A. -- not the capillary sticks, which happen a little bit later on.

Q. Okay. And you can get erroneous results with arteriole sticks, too, can't you?

A. Yes, you can, but you can get erroneous results with any laboratory tests.

Q. Doctor, I think I am done. I'll get you out of here. I apologize for being so lengthy.

A. Okay.

Q. I appreciate your cooperation and not getting too angry at me in front of my boss. Thanks.

(Discussion off the record)

BY MR. BULLOCH:

Q. We did mark your notes --

A. Right.

Q. -- as an exhibit, and I would ask that

you give those to the court reporter. She'll copy all of the exhibits and then send them back to you.

Let me see those notes real quick, Doctor. I did tell you I might have you read them.

I think I can read these pretty well. I used to be a pharmacist, so your writing really isn't that bad. Okay.

A. All right.

(Whereupon the deposition concluded at 6:20 p.m.)

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PLEASE ATTACH TO THE DEPOSITION OF JONATHAN H. CRONIN, M.D.

CASE: Matthew Chase Wagoner, et al. vs. Mark R. Evans, M.D., et al.

DATE TAKEN: Monday, June 19, 2006

ERRATA SHEET

Please refer to Page 166 for errata sheet instructions and distribution instructions.

PAGE	LINE	CHANGE	REASON

I have read the foregoing transcript of my deposition and except for any corrections or changes noted above, I hereby subscribe to the transcript as an accurate record of the statements made by me.

Executed this ___ day of _____, 2006.

_____.

JONATHAN H. CRONIN, M.D.

COMMONWEALTH OF MASSACHUSETTS)
SUFFOLK, SS.)

I, Valerie Rae Johnston, Shorthand Reporter and Notary Public in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the 19th day of June 2006, at 3:10 p.m., the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of his knowledge touching and concerning the matters in controversy in the cause; that he was thereupon examined upon his oath, and his examination reduced to typewriting under my direction; and that the deposition is a true record of the testimony given by the witness.

I further certify that I am neither attorney or counsel for, nor related to or employed by, any attorney or counsel employed by the parties hereto or financially interested in the action.

In witness whereof, I have hereunto set my hand and affixed my notarial seal this _____ day of June 2006.

_____

Notary Public

My commission expires: 8/05/2008