IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

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| LEROY CARHART, M.D., WILLIAM G. FITZHUGH, M.D., WILLIAM H. KNORR, M.D., and JILL L. VIBHAKAR, M.D., on behalf of themselves and the patients they serve,<br><br>Plaintiffs,<br><br>vs.<br><br>JOHN ASHCROFT, in his official capacity as Attorney General of the United States, and his employees, agents and successors in office,<br><br>Defendant. | 4:03CV3385<br>April 7, 2004<br>9:00 a.m.<br>Lincoln, Nebraska |

VOLUME VII,
TRANSCRIPT OF TRIAL PROCEEDINGS,
BEFORE THE HONORABLE RICHARD G. KOPF,
UNITED STATES DISTRICT JUDGE

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

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| COURT REPORTER: | DAVID C. FRANCIS, RMR<br>Official Ct. Reporter (Ret)<br>6300 Briar Rosa Drive<br>Lincoln, Nebraska 68516 |

Proceedings recorded by manual stenograph, transcript produced with computer.

(Wednesday, April 7, 2004, at 9:00 a.m.)

THE COURT: Good morning.

MR. COPPOLINO: Good morning, Your Honor.

THE COURT: Counsel, you may proceed.

MR. COPPOLINO: Your Honor, the defendant calls Dr. Curtis Cook.

DR. CURTIS COOK, DEFENDANT'S WITNESS, SWORN

THE COURT: You may inquire.

DIRECT EXAMINATION

BY MR. COPPOLINO:

Q. Thank you, Your Honor. Good morning. Good morning, Dr. Cook. Would you tell the Court, please, who you are, where you're from, and what you do for a living?

A. My name is Dr. Curtis Cook. I'm a maternal fetal specialist from Grand Rapids, Michigan.

Q. Dr. Cook, I put in front of you on the witness stand a copy of Defendant's Exhibit 527. Would you please take a look at that. Could you identify that document for the Court?

A. This is a document of my curriculum vitae that I believe was most recently updated in January of this year.

Q. And did you create this document, Dr. Cook?

A. I did.

Q. And does it accurately reflect your education, work experience, publications, the organizations that you are a

member of?

A. It does.

MR. COPPOLINO: Your Honor, the Government moves to admit into evidence Defendant's Exhibit 527.

MS. SMITH: No objection.

THE COURT: Received.

BY MR. COPPOLINO:

Q. Dr. Cook, what is your area of medical specialty?

A. I'm a maternal fetal medicine specialist, board certified in maternal fetal medicine. I'm also a obstetrician gynecologist, and board certified in obstetrics and gynecology. In general, you would describe my position as taking care of women with complicated pregnancies.

Q. You anticipated my next question. Could you tell the Court, if there is anything more to say, what is a maternal fetal specialist?

A. Maternal fetal medicine specialist is someone who has done an additional length of training, beyond their obstetrics and gynecology residency, to learn to care for complicated pregnancies that may include complications that are medical complications for the fetus or medical complications for the mother.

Q. Is that also referred to as a perinatologist?

A. Yes. There are different terms that are utilized. Perinatology, meaning around the time of birth. High risk

obstetrics, but generally the official term we use is maternal fetal medicine specialist.

Q. Doctor, where do you practice medicine?

A. In Grand Rapids, Michigan, and some other locations in west Michigan.

Q. Are you licensed to practice in Michigan?

A. I am.

Q. Who are you employed by?

A. I'm employed by Spectrum Health, which is a large health care organization predominantly in western Michigan.

Q. Are you associated with a medical school?

A. I am. I have an academic appointment with the Michigan State College of Human Medicine.

Q. And what is your -- if there is a title or position that you hold in connection with Michigan State?

A. I'm Associate Clinical Professor in the Department of Obstetrics and Gynecology.

Q. So is it correct to say, that in addition to your clinical duties at Spectrum Health, do you teach medical students and residents?

A. That's correct.

Q. Where did you go to medical school, Doctor?

A. I graduated from Indiana University, School of Medicine.

Q. What year did you graduate?

A. 1989.

Q. And where did you do your residency?
A. I did my residency at what was then called Butterworth Hospital, and is subsequently now part of Spectrum Health.
Q. Could you just explain briefly how a medical student goes on to be an OB/GYN?
A. After successful completion of your medical school training, you then enter a four-year residency program in obstetrics and gynecology. And then in the situation of maternal medicine, there is an additional training period called your fellowship training period in complicated pregnancies, which is currently a three-year training commitment.
Q. And where did you do your residency, Doctor?
A. I did my residency at Butterworth Hospital in Grand Rapids.
Q. At that time, were you working on OB/GYN matters?
A. At that time, I was training in obstetrics and gynecology, yes.
Q. Your fellowship, Doctor, where was that?
A. My fellowship training in maternal fetal medicine was at the University of Louisville in Kentucky.
Q. Did there come a time after the completion of your fellowship training that you returned to Grand Rapids and Butterworth Hospital?
A. I did return in Grand Rapids in 1995, where I have

subsequently practiced maternal fetal medicine.
Q. What course of instruction did you go through to become a maternal fetal medical specialist?
A. Well, there is a series of both clinical and didactic experiences that are required, but for myself, it was a six-year training program; four years of obstetrics and gynecology, and two years of maternal fetal medicine. Subsequent to my training, they have increased the commitment of training to seven years, with four years of the residency and three years of a fellowship.
Q. And just to be a little bit more specific, in your fellowship on maternal fetal medicine, what kinds of things are you exposed to, in order to prepare you to become a board certified maternal fetal medicine specialist?
A. We are expected to have a experience and expertise in a wide variety of both medical and surgical complications for both the mother an her unborn child or children, which would include ultrasound capability, would include managing surgical complications that may arise for either the fetus or the mother. Doing certain intrauterine surgical procedures on a fetus, things of that nature.
Q. Doctor, what positions do you currently hold in Spectrum Health, and could you tell us what they entail?
A. Currently, I'm the Associate Director for Maternal Fetal Medicine at Spectrum Health, which means I have certain

administrative responsibilities, as well as responsibilities in the area of helping form clinical protocols and certain quality assurance oversight issues. Things of that nature. I also have a teaching appointment in our residency program, which I previously helped administrate, but I don't administrate the residency program currently. So we have a lot of responsibilities of teaching and supervising the training of medical students and residents, generally in the area of complicated pregnancy, but I also have responsibilities in other areas of obstetrics and gynecology as well.

Q. Now, you said you were an Associate Clinical Professor at Michigan State. Could you tell us what your duties are in that connection?

A. My primary responsibilities with my Michigan State appointment is the teaching and training of their medical students, when they rotate on obstetrics and gynecology rotations, as part of their third year of their clinical medical school training. And then, occasionally, students doing further elective rotations during their fourth year. Those rotations typically focus more on just complicated pregnancies.

Q. Could you just describe to the Court what you teach when you're working with the medical students at Michigan State?

A. It's a variety of clinical and medical management. I'm

sorry. Surgical and medical management in the field of clinical obstetrics and sometimes gynecology as well. We teach them surgical techniques, indications for surgery, management of complications of surgery, and in the same sort of things in the medical realm, all in relation to generally obstetrics but also some gynecology.

Q. What settings do you teach the medical students in at Michigan State?

A. They participate in our didactic lectures. They participate in our on-the-floor clinical management teaching or teaching of clinical management of patients. They participate in our operating rooms where we also are doing clinical teaching. They also come over to our office where they experience some of the ambulatory medical management and surgical management of complicated pregnancies.

Q. Could you describe what you teach medical students, with reference to the various trimesters of pregnancy?

A. Well, there are multiple issues that we teach, that we have to touch on during the course of their education. Everything from fetal development issues to maternal physiologic changes of pregnancy. We also have to deal with the management of complications in all three trimesters, and those complications can include delivery in all three trimesters, or management of complications of deliveries in all three trimesters.

Q. If you could, I would like to you describe in a little more detail, in your clinical practice, what you do, the kind of cases you handle?

A. Well, currently, my clinical practice is virtually all made up of patients that are referred to our office from other physicians that have been caring for the patient. Most often family practitioners and obstetrician gynecologists, but we also see pregnant women from a variety of specialists with a variety of surgical and medical complications with the mother. Some of those are preexisting medical complications, such as chronic medical illness like diabetes, hypertension, malignancy, things of that nature. We see women that develop complications during the course of their pregnancy, such as early labor, early braking of the water, and then we see pregnancies that are complicated because of fetal concerns like suspected abnormalities of the fetus, multiple gestation, things of that nature. So we have a very large volume referral practice where we then either do a one-time consultation, an ongoing consultation, or total management of the care of that pregnancy from that point forward.

Q. You mentioned, I believe, diabetes, and malignancy and hypertension. What other types much specific maternal health conditions do you typically see in pregnant women that you treat?

A. Again, it's a very large volume practice covering a very large referral area. So we see pretty much the entire gamut of medical and surgical complications that include hypertension, preeclampsia, renal disease, cardiovascular problems, other vascular problems. You name it, we pretty much see it.

Q. Okay. Do you deliver babies in your practice, Doctor?

A. We do.

Q. Okay. But is it fair to say that you are delivering babies in the context of high risk pregnancies?

A. Most of the deliveries we are doing are in the context of high risk pregnancies, but we also take rotational call where we also supervise normal low risk pregnancies as well as gynecologic procedures.

Q. Actually, how many babies do you deliver a year?

A. I deliver something on the order of 100 to 200 babies a year typically.

Q. Would you estimate approximately how many babies have you delivered in the course of your career?

A. Several thousand.

Q. Do you also perform medical procedures on living fetuses?

A. I do.

Q. Would you describe what those are and the circumstances in which you do that to the Court?

A. Again, there are a variety of procedures that we perform on the fetus as part of being a maternal fetal medicine specialist. They may include procedures that are sampling procedures, where we are taking material from a fetus, maybe fluid or tissue from various body cavities; from the chest, the abdomen. We may be putting shunts into a fetus, in order to bypass an obstruction. We may be doing transfusions into the baby for certain anemia situations. We sometimes treat the baby directly with certain types of medications to facilitate our ability to do other surgical procedures. So there is a number of different biopsies, samplings, training, treatments that we do.

Q. Are any of those procedures that you perform on living fetuses life saving procedures for the fetus?

A. Many of them are, yes.

Q. Which ones are those?

A. Most specifically, when we are transfusing a fetus that has severe anemia, without those transfusions the fetus would not be able to survive the pregnancy.

Q. Do you also treat women for complications of abortion?

A. We do.

Q. Would you describe for the Court what types of complications you treat, for women that have had abortions?

A. If we see a patient in the immediate period of time after an attempted abortion, it's typically a treatment

regarding some sort of inadvertent perforation, or laceration, or incomplete termination where there is retained fetal parts. If we are treating a longer term or delayed complication of a prior termination of pregnancy, that usually entails issues related to cervical weakness or cervical incompetence or premature labor.

Q. Doctor, does your practice involve the termination of pregnancy before term?

A. Sometimes it does.

Q. And, first of all, let me just ask, what's the most common method of pregnancy termination, prior to term that you utilize?

A. In our practice, because of the nature of the patients that we see and the gestational age, at which they are referred, it's predominantly through the method of medical induction.

Q. Why is that?

A. Well, for a number of reasons. One is many of the indications are babies with certain types of lethal fetal abnormalities. They are typically diagnosed by mid trimester ultrasound, and don't come to our attention until generally later than 16 to 18, and often, later than 20 weeks gestation. In addition, if it is a suspected fetal abnormality, we frequently want to have a complete fetus for pathologic evaluation after delivery. Also, many of the

patients that we see also have underlying maternal medical complications that mandate that we try to deliver them in as controlled a situation as possible, using as normal a process as possible for the delivery.

Q. Okay. Now, Doctor, in addition to medical induction have you had occasion to perform abortion by other methods?

A. There have been some rare instances where we have been involved in other types of procedures including surgical evacuation of the uterus in the second trimester.

Q. And why did you describe it as rare instances that you were performing surgical evacuation?

A. Because, again, most of the ones we see are later gestational ages, or we feel that the preferable way to deliver them is by medical induction. There are a few instances where we have been involved in surgical delivery of a second trimester fetus, because at that time, that would be the optimal route for delivery.

Q. Have you had occasion to have to terminate a pregnancy on a fetus that is living?

A. I have been involved in cases where we have had to complete the pregnancy on a still, at that time, living fetus, prior to viability.

Q. And could you describe to the Court the different circumstances in which you might proceed, in which you have to terminate a pregnancy both pre and post-viability. Let's

start with post-viability. How do you proceed when you have to terminate a pregnancy post-viability, prior to the actual due date?

A. In the post-viability situation, which usually means 23 weeks and beyond, we never need to do anything that would destroy or harm the fetus. We just need to end the pregnancy or separate the fetus from the mother. So most often, that is done by medical induction of labor, where our goal is to try to get an optimal outcome for both the mother and the baby.

Q. Now, in the pre-viability circumstance, how does that typically proceed when it's necessary to end the pregnancy before the time in which the fetus is likely to be viable outside the womb?

A. In the pre-viable situation, 22 weeks or less, it's less common that we need to end the pregnancy, but it still occurs. In that situation, again, all that is required is separating the fetus from the mother. So we do the best we can to accomplish that in as safe a way as possible for the mother, which usually would be medical induction of labor in that situation.

Q. You used the term viability in the last few minutes. We all have a sense of what that means after a week-and-a-half, but perhaps you could give us your view of what the term viability means?

A. Well, viability usually refers to the fetus's ability to survive as a neonate, separate from the mother, while still availing itself of all the current medical technology that is available, and because the medical technology has continued to improve in the area of neonatal medicine, the line of viability continues to be pushed back. But at this point in time, currently 23 weeks gestation or about 400 grams is considered the lower limit of viability with survival rates nationally of about 30 to 40% at that gestational age.

Q. Is it ever possible for a fetus to survive earlier than 23 weeks?

A. There have been people that have discussed survival of fetuses potentially even at 22 weeks, but most of that data is somewhat suspect, because of the inherent error in dating pregnancies at that point and because of the weights of the fetuses at that gestational age. So it more likely represents a misdated pregnancy than a true 22-week fetus. Although technology continues to improve, and we may be seeing survival at gestational age in the not so distant future.

Q. What did you mean when you said something like the inherent error in viability dating. Did I quote that correctly?

A. I think the inherent dating of gestational age.

Q. What were you referring to, I believe, when you said with respect to the potential accuracy of dating this that gestational age?

A. Prior to the error of routine, early ultrasound evaluation of pregnancies, the best way to date a neonate was by looking for certain features of the neonate after delivery, as well as looking at the neonate's weight. And that was not found to be as accurate because of the individual variation that occurs in any given population. It was not found to be as accurate as early ultrasound would be. So in the era of routine ultrasound dating, we now rely on that predominantly for our gestational age dating, but there is an error range with ultrasound as well. In the first trimester, it may be plus or minus a week gestation. In the second trimester, it may be plus or minus up to two weeks gestation. And in the third trimester, it may be plus or minus even three weeks gestation.

Q. What's the gestational age of pregnancies that you are typically involved with?

A. Well, we do get involved in gestational ages across the board. For instance, if a mother has a preexisting known medical complication such as diabetes, we may be involved from the very beginning of their pregnancy, or even before they get pregnant, in order to try to optimize their outcome. But if it's predominantly a referral for suspected

fetal abnormality, typically we see those patients in the late second trimester initially.

Q. And what weeks would you describe as the late second trimester?

A. Generally 20 weeks and beyond.

Q. And just so that we are clear, because we are going to be talking about weeks throughout your testimony, are you dating it based on so-called last menstrual period dating?

A. Yes. Generally in the area of clinical management of pregnancies, it's pretty universally utilized as last menstrual period initiating the initial dating of the pregnancy. So we'll talk in menstrual weeks for gestational age. If we are talking about other types of issues, like the effects of certain types of radiographs or medications on a pregnancy, then we usually will talk in embryonic weeks which is dating the pregnancy from fertilization forward. So menstrual dating will actually add two weeks prior to fertilization in general. But by convention, clinically, when we talk about weeks gestation, we are referring to menstrual weeks with 40 weeks being a full pregnancy.

Q. I believe you testified earlier that you receive referrals from other OB/GYNs to deal with complicated pregnancies; is that correct?

A. That is correct.

Q. And just explain why that is the case. Why are cases

being referred to you that a regular OB/GYN is not handling?
A. Well, they recognize the additional training and expertise that we have in the management of complicated pregnancies. And they are availing themselves of that resource. At times, it involves just a single meeting with the patient and a single recommendation. At other times, it's ongoing co-management of a pregnancy. And in other instances, they are asking us to take over total care of the pregnancy because of the level of complication involved.
Q. Now, Doctor, your practice does not involve the performance of abortions for elective reasons; is that correct?
A. That is correct.
Q. Does your practice and your specialty, nonetheless, require that you have expertise in safe and effective methods of terminating a pregnancy?
A. Yes. It is necessary, because of the medical complications we see in both the mother and the fetus, to have expertise in emptying the uterus in all three trimesters of pregnancy.
Q. And is it also the case -- we may have established this already, but let me just make it clear on the record. Is it also the case that there are occasions when you may have to end the pregnancy when you know that the fetus is likely to die from prematurity?

A. That is the case at times, because of the complications that the mother is experiencing with the pregnancy.

Q. And is understanding how to end a pregnancy prematurely part of what it takes to be a maternal fetal specialist?

A. That is a correct statement.

THE COURT: Mr. Coppolino, at some point, I'll want to know if the doctor has, in the past or presently, performs D & Es.

MR. COPPOLINO: Coming right to that, Your Honor. I knew you were going to want to know that.

THE COURT: It's a matter of intuition. Go ahead.

MR. COPPOLINO: Thank you, Your Honor.

BY MR. COPPOLINO:

Q. Now, you mention that you primarily perform induction terminations; is that correct, Doctor?

A. That is correct.

Q. Could you just provide the Court a range of gestational weeks in which you are performing induction terminations?

A. Generally, if we are emptying the uterus beyond 16 to 18 weeks gestation, we are using medical induction as our predominant form of emptying the uterus.

Q. So to say after?

A. 16 to 18 weeks.

Q. What methods of abortion are you familiar with, based on your clinical experience or your study?

A. I'm familiar with suction, aspiration or curettage procedures. I'm familiar with other mid trimester surgical evacuation procedures such as D & E. I'm familiar with medical induction of labor, predominantly through the use of Prostaglandins. And I'm also familiar with the use of other surgical techniques such as hysterotomy.

Q. Let's just briefly go through those. Could you just give us your description and understanding of what the suction curettage method is, when it applies and what kind of a method that is?

A. The suction curettage method is typically a vacuum aspiration method, usually reserved for the first trimester of pregnancy, meaning the fetuses that are 12 weeks gestation or less. And it involves minimal dilation of the cervix with the passing of a cannula, whereby you are then applying a vacuum suction in order to evacuate the intrauterine contents. There may be a follow-up sharp curettage done with an instrument following this procedure as well.

Q. And have you had occasion to perform that procedure?

A. I have.

Q. And in what circumstances?

A. Typically, in the situation of a pregnancy that's termed a missed abortion, which means a spontaneous loss of a fetus or a spontaneous miscarriage, where they have not passed the

tissue on their own.
Q. Now, you mentioned the D & E method abortion. First of all, what does D & E stand for?
A. Stands for dilation and evacuation.
Q. Have you ever performed a D & E abortion?
A. I have.
Q. First of all, can you describe that procedure as you understand it?
A. Typically, it's a procedure that requires more cervical dilation, in order to remove the fetus, which typically is dismembered in the process of that procedure. And following the procedure, the dismembered parts are them assimilated and accounted for to assure there has been completion of the procedure.
Q. Why don't we just go to the judge's question. Have you ever performed -- tell us what your experience is in performing D & Es, both in the circumstances of a living fetus or a fetus that is not living?
A. First, my experience is not a large number of cases predominantly, because of the timing at which patients are referred to me and the nature of the patient that is referred to me, but there have been some rare instances where the clinical situation would necessitate a surgical evacuation. And I have been involved in some of those cases. I have also been involved in some cases where I'm

providing ultrasound support or guidance for another practitioner who is doing the procedure, typically because there has been a failure of another procedure.

Q. If you can estimate it, Doctor, have you ever performed a D & E on a living fetus?

A. To my knowledge, I have not directly been the one performing the procedure on a fetus that is living at the time of D & E. I have either assisted or participated in cases where the baby was recently living but not living at the time of the procedure. And there are some cases where I may providing ultrasound guidance where we are not exactly sure when the fetus had a loss of the heart rate.

Q. And, again, why don't you typically perform D & Es on living fetuses?

A. Well, mostly because it's not my treatment of choice, because of the other clinical circumstances that are going on at that time. But if the case arose where we felt that it was in the mother's best health interest to end the pregnancy, and we could not do it safely as in the manner of a labor induction, then I have experience doing the D & E technique and would do that, if the clinical situation necessitated that, in order to preserve the health of the mother.

Q. All right. Now, have you had occasion to utilize the D & E technique to empty the uterus on a fetus that's already

dead?
A. I have.
Q. And could you describe to the Court your experiences of the numbers of times you have had occasion to do that, either in a year, or per year, or over the course of your career?
A. Again, that's not very commonly needed procedure in our practice, so I might do it one time a year or less. But there have been some clinical situations that are relatively unique to our practice where that has been the method that we have felt has been the most effective method for emptying the uterus.
Q. Getting back to the process of the D & E, could you just describe a little more specifically how fetal parts are grasped and removed during the course of a D & E?
A. In years prior to ultrasound guidance, it was done in a more blind fashion by first having some period of time of cervical preparation or dilation, in order to allow passing of instruments which are typically large grasping-type instruments, where they try to grasp whatever portion of the fetus they can get ahold of. And they try to drag it down through the cervix, while at the same time, trying to disarticulate those portions of the fetus so they can deliver the fetus through a smaller opening.
Q. And did I hear you correctly to say the operator

employees some sort of traction in removing the fetal part in a D & E?

A. That is correct.

Q. And traction against specifically what?

A. Typically, against the cervix.

Q. And I hope this is a clear question, but what is the result of a D & E, in terms of the state of the fetus, at the conclusion of the procedure?

A. Well, typically the fetus is delivered in portions that are disarticulated or nonintact. And following the end of the procedure, there should be confirmation that all of the fetal parts are present, including the thorax and all four extremities. But most importantly, the after coming head, which can sometimes be the most difficult part of the procedure.

Q. Doctor, could you describe for the Court what the nature of fetal tissue is like in prior to 20 weeks?

A. Well, prior to 20 weeks, the general nature of the tissue is much more fragile than we observe, for instance, at 24 weeks and beyond. The skin is much more easily disrupted, the fetus bruises much more easily, inadvertent disarticulations or trauma can occur much more easily.

Q. Can you explain to the Court how it is that you know what the nature of fetal tissue is both before and after 20 weeks, since you don't perform D & Es on all that many

occasions?

A. Well, there are many experiences that we have with the fetus across the gestational age time frame or spectrum. We frequently deliver babies at that gestational age where we have been unsuccessful in holding off the pregnancy, so we frequently have, or hold, or are in direct contact with fetuses of that gestational age and all the gestational ages thereafter.

Q. What are some of those procedures that you're performing on a living fetus that gives you an idea of what fetal tissue is like prior to 20 weeks?

A. Well, these include both in utero and ex utero procedures. Ex utero, it's mostly the issue related to delivery of the fetus. In utero, it would be the various different medical and surgical procedures that we are doing which include biopsies, transfusions, aspirations, things of that nature.

Q. We may have covered this in some of your answers before, but I would like to just ask it as a separate question and give you an opportunity to explain it separately. You have, through the years, performed quite a few less D & Es in your career than medical induction; is that correct?

A. This is correct.

Q. And, again, why is that? Why is it that you've performed predominantly medical induction procedures in your

type of practice?
A. Well, there are a variety of different reasons. One is just the gestational age at which most patients present to us with the issues specifically of a lethal fetal abnormality or significant fetal abnormality. Those we frequently see in our office are 20 weeks and beyond, where a D & E is a much more complicated procedure and potentially a much riskier procedure. In addition, it is preferable for babies with suspected abnormalities to have a completely intact, including an intact central nervous system, to be able to evaluate that fetus for pathologic studies, because it would have implications potentially for other family members or other pregnancies for that same patient. In addition, many of the patients that we see are devastated by the unexpected outcomes of the fetuses, and want to be able to have whatever period of time they can with their baby, which would include generally being able to hold a baby that's is intact as and normal appearing as possible.
Q. Doctor, is there something about the maternal health conditions that you deal with that you believe that medical induction is the more appropriate procedure in the cases that you're dealing with?
A. Well, some of the reasons that we have to end pregnancies early on are because of maternal medical complications, rather than just fetal abnormalities. In the

setting of maternal medical complications, we want to try to utilize as natural and as physiologic a process as possible to complete the pregnancy, which would mean a monitored labor induction. We have also improved significantly in our ability to safely monitor and support a woman through a labor and delivery process, even with significant underlying medical conditions.

Q. Why is it -- you have used the word monitored a couple of times in your answer. Why is it important to be able to monitor a woman's health condition during the procedure?

A. Well, for some of these women, their underlying disease may include major cardiovascular concerns or central nervous system concerns, or other health concerns that may involve the use of more sophisticated, either invasive or noninvasive monitoring to demonstrate that they are doing well during the process. The surgical options are generally less physiologic, more invasive and potentially more complicated for the mother.

Q. Now, even though it is the case that you perform primarily induction terminations in your practice, do you, nonetheless, need to understand how surgical methods are performed in your practice?

A. We do, because there are some situations where the surgical method may be the preferred method. Also, we oftentimes are asked to get involved in complications of

surgical terminations, and so we need to be familiar with how they are done.

Q. Um-hm. In your practice, if it was necessary to terminate a pregnancy pre-viability, would you say there would be some circumstances in which the D & E procedure would be an option?

A. Yes, there may be some situations where D & E is the preferred route.

Q. And what might those situations be?

A. Well, one situation I had encountered myself involved a patient that had had an abdominal cerclage placed, which is a stitch around the cervix placed after performing a laparotomy, or an abdominal incision, because she had had multiple failed attempts at a vaginal cerclage with other pregnancies, who subsequently had a fetal loss and now has a stitch that is constricting the amount of dilation that her cervix can achieve. And our only option, at that point, would be either a D & E procedure on, at that time, a nonliving fetus, or a repeat laparotomy and hysterotomy. And in that situation, for instance, after discussion with the patient, it was felt that D & E would be the preferred method for emptying her uterus while avoiding another major abdominal surgery for the mother.

Q. Doctor, is there a period in gestation when the D & E procedure might be an option for treating the kinds of women

that you're treating?
A. I'm sorry. Could I have you repeat the question?
Q. Is there a period in gestation where it may be the case that the D & E procedure is an appropriate procedure, in your view, for terminating a pregnancy?
A. Yes. I believe that D & E can be done safely and may be an appropriate procedure for emptying a uterus in the earlier mid trimester, up to 20 weeks gestation, if the medical situation warrants it. Meaning that the mother's condition or the fetal condition is such that emptying of the uterus is necessary.
Q. Do you ever have occasion to refer women to physicians that perform D & Es?
A. I do.
Q. And in what circumstances do you do that?
A. In our office, if we diagnosis a fetus with a nonlethal fetal abnormality, we do not perform those terminations of pregnancy through our office, and so we will refer them out to another office, another university or a local facility, if the patient, indeed, wants to proceed with termination of pregnancy.
Q. Now, a moment ago, I asked you to give me an estimate of the number of D & Es you typically perform. I would like to ask you if you can give me a estimate of the typical inductions you perform in a given year?

A. In that -- in the pre-viable or less than 23 week gestational age, that may come up only once or twice a month. In the gestational age beyond 23 weeks, it may come up as frequently as once a week that we feel the need to induce the pregnancy or complete the pregnancy early, in order to facilitate the recovery of the mother, or because we think the fetus is not thriving in utero and needs to be delivered.

Q. Would you describe for the Court the medical induction procedure for second trimester terminations?

A. The medical induction procedure for second trimester terminations of pregnancy utilizes predominantly Prostaglandins in either an intravaginal, oral, rectal or even intramuscular route. There may be some cervical preparation that's done prior to instigating that medical induction, and that cervical preparation may include the placement of cervical dilators, prior to initiating the induction.

Q. And, again, we may have covered this, but in inductions that you perform prior to viability, there are occasions when those are performed on a living fetus?

A. That is correct.

Q. And in those circumstances, the living fetus dies?

A. At some point in the processor, or else the fetus may be born with signs of life but is not able to survive

ultimately, just because of the early gestational age.
Q. Doctor, do you also treat women -- I believe you said you also treat women for complications of abortion, is that correct?
A. That is correct.
Q. Why is that a part of your practice?
A. Well, we are generally recognized as experts in the management of complicated pregnancies. And if somebody experiences an unexpected complication during a pregnancy, then we'll be asked to get involved. That may include everything from a scheduled nonobstetric surgery for a patient, such as an appendectomy or a cholecystectomy, where they are removing the gallbladder, but it can also include people that have attempted a termination of pregnancy and then experienced a complication; most commonly perforation, bleeding or infection, where we then are asked to get involved because of our expertise in management of those types of patients.
Q. Okay. I believe you just mentioned perforation, bleeding, and infection. Are there other types of complications of abortion that you've treated or are those the general categories?
A. Those are the general categories. Sometimes it's retained fetal parts, but those patients usually have other co-existing problems such as bleeding, infection or

perforation.

Q. Doctor, does your experience in treating abortion complications -- what does that tell you about the safety of different abortion methods?

A. Well, most of the patients that we see with complications of surgical evacuation of the uterus are those that are done at the later second trimester gestational ages or those in which there was an under estimate of the gestational age, and there may not have been adequate cervical dilation or the operator may not have appreciated the size of the fetus. But most of the ones that we see are complications of surgical management of mid trimester pregnancies.

Q. Now, Doctor, have you heard of a procedure called either intact D & E or D & X?

A. I have.

Q. What is your understanding of that procedure? Let's use the term D & X for now. What's your understanding of a D & X procedure?

A. My understanding of that procedure is that it was a procedure designed as a method of surgical evacuation of the uterus in the late second trimester and beyond, generally 20 weeks gestation and beyond that, was designed to try to facilitate delivery of a larger fetus with a larger after coming head, while trying to maintain the intactness of the

remainder of the fetus below the neck.

Q. And how did you come to hear of that particular procedure?

A. I believe I first became aware of it when it was proposed through the U.S. Congress as a procedure that would be worthy of being evaluated and potentially banned, if, indeed, it turned out to have some of the potential risk or concerns that subsequently have come to light.

Q. So I'm clear, Doctor, has that procedure that you just described a moment ago, the D & X procedure, has that sometimes been referred to as partial-birth abortion?

A. It has.

Q. What do you understand the term partial-birth abortion to refer to?

A. I understand it to refer to the procedure basically described by Dr. Haskell as a D & X procedure. Dr. McMahon, as an intact D & E procedure, and others as the intact D & X procedure, the hallmark of which is overt dilation of the cervix, potentially internal podalic version or turning a fetus to a breech position, grasping the fetus, pulling it down through the dilated cervix to the level of the after coming head, such that all the fetus is delivered but the head. And then doing some sort of destructive and decompression procedure on the fetal head to allow passage of the remainder of the baby.

Q. Doctor, based on your understanding of the D & E procedure that we talked about earlier, and the procedure you just described, D & X or partial-birth abortion, do you understand that the D & X procedure refers to a procedure that is distinct from D & E?

A. I do understand it to be distinct.

Q. All right. And how is it distinct?

A. Well, it's distinct at a variety of levels. It's performed at a much later gestational age than most D & Es are performed. It's performed on a larger fetus than most D & Es are performed. It involves much more cervical dilation or distension than atypical D & E would involve. It involves more intrauterine manipulation of the fetus, and it also involves a decompression procedure of the fetal head that is unique in its form of aspirating out the brain contents.

Q. In your response, I believe you indicated that the procedure was utilized at later gestational ages. Do you have an opinion as to whether the D & X procedure, partial-birth abortion procedure, was designed for use at greater gestational ages?

A. Yes.

MS. SMITH: Excuse me, Your Honor. Foundation.

THE COURT: What foundation is lacking? What foundation is lacking?

MS. SMITH: I'm sorry. I'm sorry, Your Honor. The foundation for how he knows why the procedure was designed to do what.

THE COURT: That will be overruled. Go ahead.

THE WITNESS: My initial understanding of this procedure was from reading the presentation that Dr. Haskell gave at, I believe, a National Abortion Federation seminar for management of late second trimester terminations of pregnancy, where he was describing a technique that he utilized between 20 and 26 weeks gestation for emptying a uterus, that he distinguished as an innovative new procedure distinct from the classical D & E procedure. Subsequent to his presentation, there was communication between himself and Dr. McMahon, from California, who had been doing the similar, if not the same, procedure under the term intact D & E, but also under the same circumstances generally later in gestation starting predominantly in the late second trimester.

BY MR. COPPOLINO:

Q. I want you to take a look at some exhibits in the notebook.

MR. COPPOLINO: Your Honor, I want to approach the witness.

THE COURT: You may.

BY MR. COPPOLINO:

Q. Dr. Cook, what exhibit are you looking at there in your notebook?
A. I'm looking --
Q. Could you give us the exhibit number first, please?
A. I'm looking at an exhibit that's numbered Defendant's Exhibit 580.
Q. Okay. Could you identify that document, please?
A. This is a document from a National Abortion Federation seminar from the fall of 1992, held in Dallas, Texas.
Q. What is the title of this document?
A. It's entitled Second Trimester Abortion from Every Angle, and it's part of their fall risk management seminar.
Q. And if you would look at the second page of the exhibit, what is the title of the document listed on the table of contents that Dr. Haskell prepared?
A. Dr. Haskell's presentation is the Second Trimester D & X, 20 Weeks and Beyond.
Q. Have you seen this document before?
A. I have.
Q. When did it first come to your attention?
A. I believe when I was asked to provide expert testimony for a Congressional hearing regarding the potential banning of this procedure.
Q. Did you summarize for the Court the instances in which you testified before Congress, concerning this procedure?

A. I believe I testified twice in front of Congress. Once for a special joint hearing of both the House and Senate Judiciary Committees regarding some recent information that had come to light regarding previously inaccurately disseminated or inaccurate disseminated information regarding medical aspects of the procedure. I believe that was in 1995, or I'm sorry, 1997. And then I was asked most recently, I believe, in March of 2003, to address just a House Subcommittee, which I believe may have been the Subcommittee on the Constitution for the House Judiciary Committee, regarding some further fact finding regarding specific medical concerns with this procedure.

Q. How did you come to be asked to testify before Congress on the partial-birth abortion procedure?

A. As I can best recollect, there was a period of time where one of the concerns for the procedure was whether or not anesthesia that was administered was the agent that actually caused the death of the fetus, and that statement which was medically incorrect and later admitted by practitioners of the procedure as being incorrect. Caused a great deal of concern to people such as myself who do nonobstetric surgery or procedures on pregnant women at all points in pregnancy, and were concerned that there was a misconception that anesthesia was going to cause a risk to the unborn fetus. So at that time, the current President of

the Society of Obstetrical Anesthesia contacted me and asked if I would be willing to answer some questions that were being put to him about other clinical aspects of this procedure that he did not feel he had the expertise to comment on. And he asked if I would assist in that manner that led to my involvement at various different state levels and eventually at a federal level testifying on this issue.

Q. All right.

MS. SMITH: Your Honor, I have an objection to testimony about the subject matter of fetal anesthesia and whether or whether anesthesia during the abortion causes the death of the fetus.

THE COURT: I only understood this as background. The question was how did you get involved and this was background.

MS. SMITH: If it's not being offered for the truth, then I would withdraw my objection, not the truth but the background.

THE COURT: I didn't understand it to be offered for that burden of proof, and I certainly won't consider it for that purpose. Go ahead.

MS. SMITH: Thank you, Your Honor.

BY MR. COPPOLINO:

Q. Dr. Cook, on your CV, it indicates that you're a member of several organizations, and I would like to just briefly

identify those. You're a member of the American Medical Association?

A. That is correct.

Q. A member of the American College of Obstetricians and Gynecologists?

A. Correct.

Q. A member of the Association of Professors of Gynecology and Obstetrics?

A. Correct.

Q. A member of the Society of Maternal Fetal Medicine; is that correct?

A. That is correct.

Q. A member of the Christian Medical and Dental Society; is that correct?

A. That is correct.

Q. Are you also a member of an organization called -- what is -- I believe it's here somewhere, but an organization called the Association of Pro-life OB/GYNs?

A. Yes, I'm involved with that group as well.

Q. Now, have you heard of an organization called FACT, Physicians Ad Hoc Coalition for Truth?

A. I have.

Q. Were you involved with that organization in some way?

A. I was.

Q. Tell the judge what that group was and what it did and

how it operated?
A. Well, that group was a number of predominantly academic physicians with expertise in the management of complicated pregnancies, although other areas related to complicated pregnancies, or neonates, or young infants, who came together because of our concern at that time about the medical misinformation that was being put forward regarding this procedure. So we wanted to come together and put out some factual and supported documents for educational purposes regarding specifics of this procedure and this procedure alone. It was not our purpose to address any other abortion procedures or any other matters related to anything in the whole realm of discussion about fetuses and fetal rights or anything else along those lines. It was a very narrow scope and focus, which essentially has served its purpose, at this point.
Q. Is this FACT organization an existing or political lobbying organization?
A. It is not. It was just an organization for trying to put out accurate medical information regarding this procedure and this procedure alone. Doesn't really have an active function at this time.
Q. Does it even have an office?
A. No, it never had an office really.
Q. Now, you testified, you said you testified before

Congress. You testified live before Congress on two occasions?

A. I did.

Q. All right. And at the time of your Congressional testimony, what assertions regarding -- were being made regarding the maternal health need for the partial-birth abortion procedure that you were responding to?

A. Well, there were a variety of evolutions of the medical -- what I refer to as medical misinformation regarding this procedure. Initially, there was not even an acknowledgment the procedure was ever done. Then there was the assertion that it was done in a very rare instance, maybe a couple of hundred times a year. Then there was the assertion that the anesthesia was involved in causing the loss of the baby. Then there was the assertion that these rarely performed procedures were only done on moms with severe medical conditions or babies with severe fetal anomalies. Those were some of the initial assertions that we felt the need to correct, and essentially did that, by bringing together a group of experts in this area. And I think at its peak, there were something on the order of 400 specialists in dealing with complicated pregnancies at some level that were involved in this group.

Q. Now, getting back to Dr. Haskell's paper, Exhibit 580, you reviewed this document prior to your Congressional

testimony?
A. I did.
Q. And did you review this document, in preparing your expert opinion in this case?
A. I'm not certain that I reviewed it just prior to my expert opinion in this case, just because I was very familiar with the document over the years.
Q. Take a look at the first sentence on page 127. It says under the introduction the surgical method described in this paper differs from classic D & E in that it does not rely on dismemberment to remove the fetus. Doctor, do you agree with that sentence?
A. I do.
Q. The second sentence or the second paragraph indicates that the author has coined the term dilation and extraction, or D & X, to distinguish it from dismemberment type D & Es. And you understand that the procedure Dr. Haskell describes in his paper is a D & X?
A. I do.
Q. Take a look on page 128, next page. The third segment down. There is a sentence which reads -- well, actually second sentence. Classic D & E is accomplished by dismembering the fetus inside the uterus with instruments and removing the pieces through an adequately dilated cervix. Do you agree with that sentence?

A. I do.
Q. The next sentence says, however, most surgeons find dismemberment at 20 weeks and beyond to be difficult, due to tough necessary of the fetal the issues at this stage of the development. Do you see that sentence?
A. I do.
Q. Do you agree with that sentence?
A. I do agree with that sentence.
Q. Why is that sentence correct?
A. Well, because it's true that it is more difficult to disarticulate or dismember a fetus beyond 20 weeks, unless the fetus has not been living for some period of time, and there is some autolysis or degeneration that is occurring or there has been some pretreatment of the fetus to make it easier to dismember or disarticulate.
Q. Further down, under the caption patient selection, there is the first sentence which indicates the author routinely performs this procedure on all patients 20 through 24 weeks, LMP, with certain exceptions. The author performs the procedure on selected patients 25 through 26 weeks, LMP. Do you see those sentences, Doctor?
A. I do see those sentences.
Q. And do you have an understanding that the D & X procedure is an abortion procedure designed to be used late in the second trimester after 20 weeks?

A. Yes, late in the second trimester and into the early third trimester.

Q. And why do you have that understanding?

A. Well, that what was described by both Dr. Haskell and Dr. McMahon, both of whom have gone on the record with their experiences with this procedure.

Q. If you take a look at the next page of the Exhibit 580, this is -- there is a page number at the top, 129, I believe. Is there a page number at the top of 129.

A. There is a page number at the top of my copy?

Q. The first page describes the dilation and extraction procedures taking place over three days, and in a nutshell, can be described as follows. Why don't you read the list of elements of the procedure, for the record, Doctor?

A. The first element says dilation. The second element in bold type with capital letters says more dilation. The third element says real time ultrasound visualization. The fourth element says version, which means turning the baby parenthetically as needed, or as I read, if required. The next element is intact extraction. The next element is fetal skull decompression. And the next element is removal followed by clean up and then finally recovery.

Q. Doctor, is it your understanding that these are the elements of the D & X procedure as described by Dr. Haskell?

A. That is my understanding.

Q. And when you testified before Congress, were you addressing this particular abortion procedure?
A. I was addressing this procedure and the procedure as described by Dr. McMahon.
Q. Okay. And you have an understanding that these steps described by Dr. Haskell were the general steps in a D & X procedure?
A. That is correct.
Q. Do you understand there might be some variation in the precise procedures used in a D & X or partial-birth abortion?
A. Yes, there may be some variation, specifically, in how the cervix is dilated, how much the cervix is dilated, and also in how the skull is decompressed.
Q. To your understanding, does the D & X or partial-birth abortion necessarily involve an instrumental conversion of the fetus to the breech position?
A. It doesn't necessarily involve it, if the fetus is already presenting in a breech presentation.
Q. To your understanding, does the D & X procedure or partial-birth abortion procedure, necessarily involve puncturing the head of the fetus with a sharp object in order to collapse the skull?
A. It doesn't necessarily involve that. It does involve some method of decompressing the skull, which could include

external compression or could include internal evacuation.

Q. Doctor, you were asked by the Government to offer opinion testimony in connection with the partial-birth abortion procedure; is that correct?

A. That is correct.

Q. I would just like you to -- I would like you to identify the topics of your opinion and ask you to briefly state what your opinion is, and then we are going to discuss your opinions in further detail. And the first question I have is do you ever an opinion as to whether the partial-birth abortion procedure is ever medically necessary to promote the health interests of mothers facing the kind of complicated high risk pregnancies that you deal with. Do you have an opinion on that?

THE COURT: Now, pardon me, Mr. Coppolino. I don't mean to be picky with you, but are you specifically limiting that opinion to the high risk pregnancies that this doctor deals with? I understood you to do so.

MR. COPPOLINO: Let me rephrase it perhaps a little more broadly. I think we are going towards the same end, Your Honor.

THE COURT: I'm not trying to be cute with you. If you intended that, fine. If you intended it more broadly --

MR. COPPOLINO: I'll state it more broadly. It may well be a distinction without a difference, because I think

he deals with every particular high risk pregnancy but we'll establish that.

BY MR. COPPOLINO:

Q. Do you have an opinion as to whether the partial-birth abortion procedure is ever medically necessary to deal with the health interests of mothers facing high risk pregnancies?

A. I do have an opinion on that matter.

Q. What is your opinion?

A. My opinion is that it is never medically necessary, in order to safely evacuate a uterus, and it is my opinion that it is not even necessarily the preferred method. That it may entail unforeseen and unnecessary risk both immediately and in the future, and I feel that this is the situation, whether we are dealing with a healthy mother and a healthy fetus, or a sick mother and/or a sick fetus.

Q. And do you have an opinion, Doctor, as to whether the partial-birth abortion procedure presents risks to the woman undergoing it as compared to other methods of termination of pregnancy?

A. Yes. I believe that the various elements as described by practitioners of this procedure include elements that I would say have an unacceptable either immediate or potential later risk associated with them.

Q. All right. Let's take those one at a time, Doctor. Why

are you of the view that partial-birth abortion is never medically necessary to care for women with complicated pregnancies?

A. Well, it's my opinion that is the situation, because this procedure doesn't add anything to existing medical options that are already safely and readily available for the mother for ending her pregnancy or evacuating her uterus. In addition, they involve some elements that I think have potential increased risks that are not necessary, and I also don't see that in any way facilitates our ability to empty a uterus, in that it is still a multiple-day procedure, in less than an optimally monitored situation. And I think it's an in humane way to deliver a fetus.

Q. How long have you been providing care to women with complicated pregnancies, Doctor?

A. Well, I started taking care of obstetrical-type patients in the late 80s, and started seeing complicated pregnancies from that first day. But I have been treating more exclusively complicated pregnancies since 1993.

Q. Have you ever experienced the clinical situation in which the partial-birth abortion procedure has ever been, in your view, required or necessary?

A. I have not.

Q. Now, but you testified earlier that it is sometimes necessary to terminate a pregnancy for maternal health

reasons; is that correct?
A. That is correct.
Q. First of all, is that common?
A. It is not very common, even in our practice where we see only complicated pregnancies.
Q. Why isn't it common?
A. Well, because, most times, mother's can be adequately supported through their pregnancy or we can at least get them to the point where the fetus has the chance for survival, and then we can help her to deliver or separate herself from her fetus so that her recovery process can be initiated, and the fetus can still have a reasonable chance for survival.
Q. What conditions have you seen or treated in a pregnant woman that you determined were prior to the pregnancy be terminated -- prior to -- let's just leave it there, that you require the pregnancy be terminated?
A. Well, most commonly, they would be situations that are unique to the pregnancy such as an infection or heavy bleeding with the pregnancy. Or they may be elements of an exacerbation or worsening of an underlying preexisting medical condition such as hypertension, heart disease, diabetes, or other unique elements of pregnancy such as severe pre-eclampsia or some of its variants such as HELLP Syndrome and things of that nature.

Q. Would you explain why it may be necessary to terminate a pregnancy prematurely because of these conditions?
A. Most of those conditions are either unique to pregnancy or exacerbated by the pregnancy. So in order to facilitate the mother's recovery from that situation, we need to work toward ending the pregnancy or delivering the fetus. It doesn't require that we destroy the fetus. It just requires that the fetus and the mother are separated from one another, and that the placenta is delivered, in order to facilitate the recovery process for the mother.
Q. Now, when you need to terminate a pregnancy for one of these maternal health conditions, do you proceed differently depending on whether the fetus is pre or post-viable?
A. We do. If it is a fetus that is beyond the period of time where we think the baby has a reasonable chance for survival, then we will be doing more continual fetal monitoring, and we will attempt to deliver in a manner that is both safe for the mother and least traumatic for the fetus. If it's a situation where the fetus has a lethal fetal anomaly or is pre-viable, we may not be continually monitoring the fetus, and we may not be considering as much the fetal contributions to the delivery method or route as much as we would consider the maternal implications of those methods.
Q. Okay. So specifically for a fetus that you've

determined has a chance to survive outside the mother, how do you approach a pregnancy termination in that circumstance?

A. Well, it is always our preference to try to deliver vaginally by utilizing, again, a normal laboring process because it's most physiologic and generally best tolerated by the mother. And so that's how we would generally proceed. In some situations where we need to deliver prematurely, the fetus may be also experiencing complications such as a situation of pre-eclampsia where the baby may not be growing adequately or getting adequate nutrition; where the baby may not tolerate a vaginal delivery. In that situation, we would then do an operative delivery such as a cesarean delivery in order to facilitate maternal recovery and to allow the least traumatic method of delivery of the fetus.

Q. And how do you proceed differently for a fetus that you've determined has no chance of survival outside the mother?

A. Well, then we are less concerned about the fetal tolerance of labor in the vaginal delivery process specifically. So we would put a greater emphasis on trying to deliver vaginally, if there aren't fetal concerns involved.

Q. Doctor, could you explain how you evaluate a maternal

health condition during pregnancy in order to determine whether and when the pregnancy should end?

A. Well, that's obviously a complicated assessment that includes a variety of physical exam and history collection. It involves certain laboratory tests and radiographic studies. It generally involves a consultation of some of our other subspecialty colleagues, such as the neonatal physicians or potentially other subspecialists such as cardiologists, oncologists, people of that nature.

Q. And this might be too general a question, but let's give it a shot. When does something move from being merely a health problem that the woman is facing during pregnancy to something that you consider to be potentially more serious that could actually cause serious damage to her health or may even jeopardize her life?

A. Yes. That is a good question. Generally, the situation that we would recommend that the pregnancy needs to be delivered would be a situation where we feel the fetus is either attained a gestational age where survival is very likely and the fetus would do well, and we won't accept any level of abnormality in the pregnancy. Or in the earlier gestational ages, if we recommend early delivery, it's because we feel we can no longer control the underlying medical or surgical condition with the treatment modalities that are available to us at that time.

Q. Is it the case, Doctor, that if the mother was -- if the fetus was close to viability but not yet there, if you had an -- if you were able to, consistent with her health, would you try to stabilize her condition or treat her condition in order to buy time to get the fetus past viability?

A. We would, mostly at the behest of the mothers who are willing to do almost anything they can to facilitate the safe delivery of their fetus. We would never put a mother in jeopardy to enhance a good fetal outcome, but it is commonly the case where we can support a mother through some critical weeks of the pregnancy, in order to get a good outcome for both the mother and the fetus, because both of them are our patients.

Q. Now, in dealing with a situation where you have a pregnant woman with a serious medical condition, and you're facing the need to possibly terminate the pregnancy early, I would like you to give the Court a sentence of how often do you have to do this prior to viability, versus how often are you able to get the mother past viability and deliver both -- and deliver the baby successfully?

A. Well, it has become much easier in the last few years for us to be able to attain a level of viability, because the viability line keeps shifting backwards. And even during the course of my career, there has been a marked improvement in survival at 23, 24, and 25, and 26 weeks

gestation. So it's easier for us to reach that level. In addition, our medical technology has grown to the point where we can support very complicated pregnancies for longer periods of time than we could in the past. Complications such as underlying malignancy, cardiovascular disease, what have you. So it's not very often that we truly have to deliver a baby pre-viability because of severity of a mother's condition. It does come up on a regular basis in our practice because of the kind of patients we deal with, but it doesn't come up as frequently as it used to.

Q. Um-hm. When a pregnancy has to be ended prematurely, because of a maternal health condition of the kind that you treat, is it ever necessary to take a destructive act against the fetus directly, in order to protect the health interests of the mother?

A. No, all that is required for recovery of the mother is for separation of the fetus and placenta from her system so that she can start the recovery process. There is nothing inherent in the destruction of the fetus that starts to facilitate that process.

Q. But I take it you also want to utilize the safest method of termination possible in the circumstance where you have to terminate the fetus pre-viability?

A. Yes, in the world of maternal fetal medicine, we, of course, have both as patients, both the mother and the

fetus. And our goal is always to have an optimal outcome for both. In the rare situation where we feel we cannot optimize the fetal outcome, we would never jeopardize maternal health for that reason, and her health concerns would always be the predominant concern at that point. So we would then proceed to deliver her in the method that we think is safest and most well tolerated by her, but frequently, we can achieve it -- a goal where we can do a delivery process that is optimal for both the mother and the fetus.

Q. In your opinion, Doctor, would there ever be a medical need to use the partial-birth abortion or D & X procedure to terminate a pregnancy, specifically because of a particular type of maternal health condition that the woman has during a pregnancy?

A. I know of no such condition, and we have been discussing this same issue for many years, and I have never heard anyone propose a condition, I think, that would warrant that situation.

Q. I'm going to give you -- I'm going to talk about some specific maternal health conditions, Doctor. You mentioned, I believe, a condition called pre-eclampsia, and if you didn't, could you at least tell us what is pre-eclampsia?

A. Pre-eclampsia is a medical condition unique to human pregnancy, generally starting after 20 weeks gestation or

actually, by definition, starting after 20 weeks gestation that usually involves high blood pressure or hypertension in the mother, as well as proteinuria or protein in her urine, and may involve other clinical signs such as edema or as welling as well.

Q. Doctor, could pre-eclampsia ever evolve to a point that it could be an indication to terminate a pregnancy?

A. That is correct.

Q. Could that ever occur, prior to the point at which the fetus is viable?

A. Yes, this is true.

Q. Okay. And in your opinion, would the partial-birth abortion D & X procedure ever be necessary to terminate a pregnancy because of a severe threatening pre-eclampsia condition?

A. It would not.

Q. And why not?

A. Because there are other better options available that, again, are readily accessible to most practitioners that would allow a safer completion of the delivery process, while still maintaining the option for the best outcome for the fetus.

Q. How would you proceed to deal -- to terminate a pregnancy for a woman suffering from pre-eclampsia to such an extent you felt the pregnancy had to be terminated before

viability?
A. Well, in the situation that you're speaking of, it would be for pregnancies between 20 and 23 weeks gestation. And most commonly, what we would do, because you are so near the point of viability or peri-viable, we would do our best to support the mother during those critical weeks while administering certain medications to her that would improve the outcome for the fetus, and do our best to try to get her to the point of viability, and then proceed with either a vaginal delivery or cesarean delivery, based upon the clinical scenario. If it's a situation where the mother is rapidly deteriorating and we are not able to control the situation, and she's still less than 23 weeks, we generally would then proceed with a medical induction of labor with careful monitoring of the mother's health status.
Q. At your opinion, in that stage of gestation you just described for this condition between 20 and 23 weeks, and for this condition, pre-eclampsia, would a surgical termination of the pregnancy be indicated?
A. No. I would be very concerned about that. One of the Hallmarks of pre-eclampsia is something that has a long-term, but it's a microangiopathic process which means it's an abnormality of the vascular system which predisposes, as part of that, to low platelets or a problem with adequate clotting of blood. Also a propensity to

having more bleeding, and there are other things that happen in pre-eclampsia that make a woman less tolerable of bleeding complications specifically. So I would be very concerned about doing a surgical evacuation of a uterus in the setting of severe pre-eclampsia in that 20 to 23-week range.

Q. All right, Doctor. I think you may have mentioned in your expert report another condition called renal disease. Could you tell us what types of -- what a renal disease is in the context of complicated pregnancy?

A. Well, renal disease refers to disease of the kidney, which may either be the primary disease focus or it may be a secondary manifestation of another underlying disease process such as diabetes or hypertension. But if we have the situation where the woman has a deteriorating renal condition that we feel is secondary to the pregnancy, then we are in the same sort of situation we described with pre-eclampsia, trying first to achieve viability and maximize the good fetal outcome. And in the situation where that is not possible, and her health status is rapidly deteriorating despite our best efforts, then we would recommend trying to proceed with a physiologic a process as possible, which would be a medical induction of labor.

Q. So is it correct to say, Doctor, a renal condition could deteriorate to the point where it might be an indication for

termination of pregnancy, prior to fetal viability?
A. Yes, that would be the case.
Q. In that case, Doctor, in your opinion, would the partial-birth abortion D & X procedure ever be necessary to terminate a pregnancy, specifically because of the nature of the renal disease?
A. It would not.
Q. Why not?
A. Again, because there are other safer and readily available options that are present. In addition, a woman that has an underlying severe renal condition is also not a woman who can tolerate significant blood loss, loss of fluid, need for fluid replacement, and other situations that would be I think just too high a risk to proceed with a surgical evacuation in the late second trimester.
Q. All right, Doctor. Now, another category of potential complications in a pregnancy is cardiac disease as listed in your report. I want to ask you about that. What types of cardiac diseases would so complicate a pregnancy that there would be a need to terminate the pregnancy, prior to the due date?
A. Well, we see women with a large number of cardiac conditions, mostly because the other areas of medical management have improved so much. And so we see many more children born with congenital heart disease, repaired or

nonrepaired. They are now surviving to child bearing ages. We see women having children later in age than before. So we see women that are pregnant after having prior myocardial infarctions or heart attacks. We see women with certain types of heart rhythm problems that could not be controlled in years past that are now controlled, and they can achieve not only a child bearing age, but a health status that would allow pregnancy. So we see a number of cardiac conditions, but the number that would actually necessitate an early delivery pre-viability is relatively small; includes predominantly those people that have significant pulmonary hypertension or shunting of blood in the opposite direction of its usual shunting, so that they are having deoxygenation problems or problems delivering adequate oxygen to their issues. There are also other conditions such as the condition of the dilation of the aorta as part of something called Marfan's Syndrome. That if it reaches a certain critical level, dilation is at risk for aortic dissection or disruption, which would be life threatening to the mother. These are all some specific conditions that may warrant early termination of pregnancy.

Q. And let me just run through those. The pulmonary condition, would that -- could that be an indication for terminating the pregnancy prior to viability?

A. Yes, it could be.

Q. And the shunting of the blood condition that you described, could that also be a condition for terminating the pregnancy prior to viability?

A. Yes.

Q. Marfan's Syndrome, could that be a indication for terminating the pregnancy prior to viability?

A. If it involved significant aortic dilation.

Q. Let's take them one at a time again. Well, let me just -- I'm going to ask you a single question and ask you to address those three conditions. In your opinion, would the partial-birth abortion or D & X procedure ever be medically necessary to terminate a pregnancy for those three cardiac conditions you just mentioned, the pulmonary condition, the shunting condition, and the Marfan's Syndrome?

A. No, I don't believe it is ever medically necessary in any of those conditions, nor do I believe it's even the preferable way to go or even and equivalent option. I'm concerned about doing, again, a surgical procedure late in the second trimester where the risk for perforation, bleeding, infection, and other complications that would not be well tolerated by a mother with those sort of conditions would be just unacceptable to me. In addition, we also want to carefully manage and monitor even things as simple as her pain sensation and her release of certain types of endogenous, or within her own system, hormone stress

responses that may further complicate her underlying cardiac conditions. So we want to proceed in a method that is as physiologic as normal, as controlled and as gentle a process as possible, specifically in the area of complicated cardiovascular disease.

Q. Is it the case, however, Doctor, that an induction procedure could impose some physiological stress on a woman undergoing it?

A. Absolutely. We generally have these patients meet with our anesthesia colleagues prior to proceeding with these procedures, and there are specific steps that we take using issues such as epidural anesthesia, careful cardiovascular monitoring, careful evaluation of input and output in the form of fluids for the patient, all to maintain as normal as physiologic and as gentle a process as possible, and that can be done much better in a controlled, monitored medical induction, you know, procedure.

Q. Why wouldn't a surgical termination of that abortion for pulmonary heart condition, or shunting condition, or the Marfan's Syndrome be a procedure that would be less stressful on the woman and, therefore, potentially more favorable given her heart condition?

A. Well, the gestational ages at which we are discussing in this later second trimester are much more difficult procedures to do a surgical evacuation on; do involve

greater risk for, again, bleeding, perforation, infection and other things that would not be well tolerated by a mother with these underlying conditions. In addition, there are some really practical issues related to having a woman who is awake and alert, yet is receiving adequate pain control, in a patient with an underlying cardiac condition. Meaning by that that they want her to be able to report to us if she's having chest pain, shortness of breath, other symptoms that need to be addressed. Things you can't do if a patient is intubated and not communicating with you.

Q. What is peripartum cardiomyopathy?

A. It refers to a condition that seems to be exacerbated if not caused alone by the pregnancy, the hallmark of which is a dilated heart with less than adequate contractility or function. So a woman goes into a heart failure type of situation most commonly diagnosed in the immediate post-partum period, meaning after delivery.

Q. I see. So is that a condition that typically implicates the need to terminate a pregnancy prior to term?

A. It could. It oftentimes doesn't present itself until after delivery. Although, there are underlying cardiomyopathies caused by other situations such as hypertension, and illicit drug use, and things of that nature, which could potentially indicate the need for an early termination of pregnancy, if it was a preexisting

condition.
Q. And if that indication arose where there was a need to terminate the pregnancy prior to viability for cardiomyopathy condition, in your opinion, would partial-birth abortion D & X procedure ever be necessary to do that?
A. Again, the optimal method would be utilizing something that would have a lower risk for complication, a greater ability for monitoring and assessment, and something that would utilize a variation on a normal physiologic process.
Q. And in that circumstance, for the cardiomyopathy condition, you would, again, proceed by medical induction?
A. I would.
Q. Doctor, what is help syndrome, H-E-L-L-P. Is that the correct acronym?
A. That is correct.
Q. Would you tell Court what that is?
A. It's an acronym for a clinical spectrum that basically is a variant of severe pre-eclampsia, the hallmark of which is hemolysis or destruction of red blood cells, and then elevated liver enzymes and low platelets.
Q. Is it a potentially serious health condition for a pregnant woman?
A. It is a potentially life threatening condition, although reversible by the process of continuing to complete her

delivery.
Q. Have you treated a pregnant woman with this condition?
A. Many times.
Q. By the way, the other conditions we have talked about, the cardiac conditions, the renal conditions, have you treated women with the conditions you have discussed this morning?
A. I have treated women with all those conditions.
Q. Severe pre-eclampsia as well?
A. Yes, that's a very common referral to our practice.
Q. All right. Now, could HELLP Syndrome -- I believe you said it could be an indication for termination of pregnancy prior to viability?
A. This is correct.
Q. In your opinion, would the partial-birth abortion D & X procedure ever be necessary to terminate a pregnancy with this condition?
A. It would not.
Q. And why not?
A. Again, for very similar reasons to the other situations we discussed. That there are safer readily available options. There are better options, I think, in order to maintain a normal, you know, variant of a physiologic process. Specifically with HELLP Syndrome, the platelet counts are quite low and the risk for bleeding complications

is quite high. So anything that we think would potentially increase the risk for a bleeding complication, perforation, hemorrhage, what have you, would be something we would want to avoid at all costs.

Q. Doctor, what about a patient with leukemia? Have you ever -- first of all, have you ever treated a pregnant woman who had leukemia?

A. I have treated pregnant women with active lymphoma during pregnancy, and I have treated women who had leukemia in the past, but I'm not sure I have taken care of a woman who had active leukemia during her pregnancy.

Q. Would leukemia potentially be an indication for early termination of pregnancy?

A. Very rarely, but potentially, if there is a new diagnosis of leukemia, leukemia is treated most commonly by a combination of certain therapeutic agents, some of which can be modified and still given during the course of the pregnancy. Some of which would not be well tolerated during the pregnancy. So in a rare instance where they feel the best treatment is something that the fetus would not tolerate and they feel the need to institute therapy immediately, then it could arise. But I would think that that would be, you know, a very rare situation.

Q. I should have asked you for the uninitiated -- What is leukemia.

A. Leukemia is a malignancy of the blood system, specifically the white blood system, where there is an over production of abnormal or malignant white blood cells. The treatment of which is predominantly in the form of medical management or chemotherapy, often times with a combination of chemotherapeutic agents.

Q. In those circumstances where it might be an indication for early termination of a pregnancy, because of the need to provide the woman the medication necessary to treat that condition, in your opinion, would the partial-birth abortion D & X procedure ever be medically necessary to terminate that pregnancy?

A. It would not.

Q. And why not?

A. Again, for some of the same reasons; other safer alternatives available. It -- also leukemia can have, as part of its manifestation, a replacement of other blood products lines, specifically platelets. So they can have also very low platelets. And in addition, their blood counts can be depressed significantly, if they are receiving chemotherapy. So those are reasons that we would also want to avoid specifically anything that we think would increase the risk for hemorrhage, bleeding and perforation.

Q. Those are reasons you would want to avoid surgical termination?

A. This is correct.
Q. Okay. What is it about the surgical process that would exacerbate those conditions?
A. Again, in these peri-viable periods of time 20 to 23 weeks, the D & E is a much more complicated procedure, and larger fetus, more need for manipulation, more potential for perforation, bleeding and hemorrhage.
Q. Doctor, what is sepsis?
A. Sepsis is a clinical state in which there is an infection that has involved the body systemically that is moved from a local infection to being a more global or systemic infection.
Q. Could a women have an infection of her uterus that would be so severe in her pregnancy that an early termination, prior to viability, would be indicated?
A. Yes.
Q. Have you ever seen or treated such a condition?
A. I have.
Q. All right. In those instances where a woman has a severely infected uterus early in her pregnancy, would a partial-birth abortion procedure ever be necessary, in your opinion, to terminate that pregnancy?
A. It would not be.
Q. Is there anything specific about the infection condition that you would think a surgical termination, in particular,

would be contraindicated?

A. Yes. In the situation where we are looking at a severe infection, we oftentimes are trying to intervene before infection continues or migrates or extends beyond the uterus and its contents. So if we have a severe infection limited to the uterus, and it is not responding to our therapies, we would like to try to empty the uterus of that infection as part of the treatment, before it gets to the point where there is a systemic infection that is truly life threatening for the mother. One of the concerns about a surgical method is that it would potentially increase the risk for seeding or allowing extension of infection into the general maternal vascular system, because of the instrumentation involved, and the risk, again, for bleeding and perforation. So we would not like that contained infection to have access either to her intraabdominal area, peritoneal cavity or to her vascular system.

Q. Is that one of the reasons why you would proceed by medical induction to terminate a pregnancy of a woman who had severe sepsis?

A. Yes. In addition, the body usually responds to a localized infection by trying to expel the uterine contents on their own. So, generally, those people are very easy to get delivered, often times with very minimal assistance, medically.

Q. What about other types of cancer? Let's just say breast cancer. Have you ever treated a woman who is pregnant and has breast cancer?

A. Yes, I have.

Q. Might it be necessary to terminate a pregnancy of a woman who has breast cancer, prior to her due date?

A. Yes. That is possible. I have treated several women faced with that decision where they were diagnosed in the first trimester, some of which opted to end their pregnancy and start their therapies, some of which opted to continue their pregnancy with a modified therapy or delayed therapy.

Q. What specifically might be the indication for a termination of a pregnancy for a woman who has breast cancer. Is it the medication that she needs?

A. Generally, it's the medication. The pregnancy process, in and of itself, doesn't necessarily, to our knowledge, exacerbate the malignancy, or change the long-term course of the malignancy, but it does limit some of our treatment options. Whether it's radiation therapy or chemotherapy.

Q. In your opinion, Doctor, in those instances in which it may be necessary to terminate a pregnancy because of the treatment needed for breast cancer, would a partial-birth abortion or D & X procedure ever be necessary, specifically because of the breast cancer and the need to treat it with medication?

A. No, I do not believe it would ever be necessary.
Q. And that is because?
A. Well, many of the same reasons women with malignancies of any sort do have, as part of their disease process, commonly severe anemia, and may also have very low platelets and other conditions that, again, would not allow a woman to tolerate a surgical procedure, particularly a riskier surgical procedure, meaning that done at later gestational ages.
Q. I would like to ask you about at least one more, Doctor, and that is have you ever treated a woman who was pregnant that has had a prior scar on her uterus?
A. Many times.
Q. And what's the cause of that? In your experience, what has been the cause of the experience where a woman has a scar on her uterus?
A. A vast majority of the time is because after prior cesarean delivery, a hysterotomy, although we see patients who have this surgical incisions on their uterus, such as removing a uterine fibroid; a procedure called myomectomy.
Q. Have you ever faced a situation where it was necessary to terminate a pregnancy early, a prematurely, let's say -- pre or post-viability, where a woman has had a scar on her uterus?
A. Yes, I have.

Q. Okay. Now taking it post-viability, how would you proceed?
A. Generally, we would proceed in the same fashion. We would, if there was no scar on the uterus, with the exception that we may choose to use more cervical preparation before the medical induction, and we would probably avoid certain specific types of Prostaglandins in that situation.
Q. Would a prior scar on the uterus ever be a contraindication for a medical induction?
A. No, not an absolute contraindication.
Q. Would it ever be a relative contraindication for induction, a prior scar on the uterus?
A. It could be, depending on what the situation is. Specifically, if a patient has had a known prior uterine rupture or more extensive involvement in the scar on the uterus.
Q. Does a prior scar on the uterus increase the risk for uterine rupture, during a medical induction?
A. Well, a prior scar on the uterus increases your risk for uterine rupture, whether you're in spontaneous labor or whether you're having a medical induction.
Q. And how do you manage that risk when you're performing a pregnancy termination, either pre or post-viability?
A. Well, generally if they have had one prior low

transverse cesarean section incision, which is the vast majority of incisions, their risk for uterine rupture is about half a percent or one out of 200. So we believe that amount of risk is an acceptable risk, in a situation where we were carefully monitoring the mother and had the capability to proceed to other surgical procedures, if necessary, if she does experience a complication.

Q. Would it be safer, in the case of a woman having a prior uterine scar, to perform a surgical termination in order to end the pregnancy?

A. One of the difficulties of having a prior scarred uterus is that you have inherent weakness in the integrity of the uterine wall, which would mean you would be prone for uterine perforation, which is known risk of surgical evacuation of the uterus. So I don't believe necessarily that a surgical procedure allows you to avoid the risk of uterine perforation or uterine rupture.

Q. Prior to fetal viability, if a woman had a scar on her uterus, would there be any point at which you believe a D & E termination would be an acceptable alternative?

A. I think it would be in a situation where you have made a reasonable attempt to try to induce labor with standard Prostaglandins, and in lieu of maybe using excessively higher doses or other types of Prostaglandins, you may elect to do a surgical evacuation in a controlled setting.

MR. COPPOLINO: Your Honor, this would be a good breaking point, if you would like to take your morning break.

THE COURT: That will be fine. Give me a sense of how much longer you'll be with the doctor.

MR. COPPOLINO: I'm certainly going to try to finish my direct examination by the lunch break, Your Honor.

THE COURT: The only reason that I ask, I have a very long telephone conference that I have scheduled for over the noon hour that I cannot reschedule, so we'll break promptly at noon. And I don't want to -- just keep that in mind. So if you come to a good breaking point either in your direct or in the cross, feel free to tell me, because I'm not going to go beyond noon today.

MR. COPPOLINO: Fine, Your Honor. If I'm not done at noon, I expect I would not have much into the afternoon session. And this is our only witness today, so I anticipate that would be sufficient time to finish the witness.

THE COURT: I'm not asking you to vamp, but just tell me when we get close to noon, if we are at a good breaking point, and we'll do that then, so I don't interfere with your examination. We'll stand in recess. Doctor, you may stand down, sir.

(Recess from 10:47 to 11:08 a.m.; all parties present).

THE COURT: Doctor, if you would retake the witness stand, please.

(Dr. Cook resumed the witness stand)

THE COURT: You may proceed.

BY MR. COPPOLINO:

Q. Thank you, Your Honor. Dr. Cook, before the break, we had been discussing a number of specific maternal physical health conditions that could arise during a pregnancy, and I'm not going to ask you about anymore specific ones, you may be happy to hear, but I do want to just ask you a couple of wrap-up questions. First, can you think of any maternal physical health complication for which a partial-birth abortion or D & X procedure would be a medically necessary procedure, prior to fetal viability?

A. Again, I have been involved in this process and these discussions for a number of years and many scenarios have been presented to me, and I have considered many scenarios, and I have yet to come across a single case where I see it's necessary medically or otherwise to do a partial-birth abortion. In order to effectively and efficiently deliver the mother or separate the mother from her fetus. So I'm not aware of any clinical separation that warrants this procedure.

Q. In particular, Doctor, if the maternal health condition was deteriorating rapidly, and you had an emergency where

you had to end that pregnancy as quick as possible, would the partial-birth abortion D & X procedure be appropriate in that circumstance?

A. It would not.

Q. Why not?

A. Again, because of the other available options, both medical and surgical, that have been available for a long period of time, can be done safely. Patients have ready access to those procedures. So that, and the fact that I think this procedure has other unacceptable risks involved.

Q. What about the time that would be involved in treating a woman with an emergent condition? Would you have the time, even if you considered the partial birth abortion procedure to be a relatively safe option, to do it?

A. Well, I have commented in the past that one of the, in my opinion, unreported aspects of the partial birth abortion procedure is that it involves, you know, at least two days of cervical preparation, prior to doing the procedure, in order to achieve the amount of overt dilation that you need for the cervix, in order to complete that particular procedure. So if you are in a time-limited situation, then you would not be able to utilize this procedure.

Q. Now, Doctor, we reviewed a number of situations regarding serious maternal health problems in pregnancy, and whether the D & X partial-birth abortion procedure would

ever be necessary to treat them. If you had a situation where a baby was pre-viable, where the maternal situation -- maternal health situation was deteriorate to go the point you felt it might jeopardize her life, and you felt the D & E procedure was the most appropriate option to terminate the pregnancy, would you have any moral or ethical objection to performing the D & E procedure in that circumstance?

A. Well, we, oftentimes, have to make difficult decisions in the world of maternal fetal medicine, as we are constantly trying to achieve and optimal outcome for both the mother and her child. In the situation where there may be a conflict of interest, we would always choose the mother's's interest over the unborn child, meaning we wouldn't sacrifice a mother, in order to try to continue a pregnancy. So there could be a scenario that would arise in the early or mid second trimester where we feel the condition had deteriorated to the point we can no longer treat the mother effectively. And if she is in danger, then I would not have an objection or any sort of hesitation to proceed in any manner I felt was necessary, in order to deliver her baby and allow her to recover. And if that included D & E on a baby that was still living at that time, then that would be what we would have to do, after, again, careful consideration, consultation with other physicians, consultation with the family.

Q. Doctor, you've testified this morning that you also treat patients, pregnant women with fetal anomalies; is that correct?

A. That's correct.

Q. At the time you testified before Congress concerning the Partial-Birth Abortion Act, did you hear any justification for that procedure on the grounds that it would be necessary to terminate a pregnancy that involved a fetal anomaly?

A. Well, throughout my experiences in this legislation over the years, I have been presented with many potential scenarios that have been proposed as clinical situations that would mandate this procedure. Some of those have been maternal conditions like we have just discussed. Some are fetal conditions, various types of fetal abnormalities that have been proposed as a justification for this procedure. So at various times throughout the years, I have addressed each and every one of those, and have not found a single fetal condition, just like I haven't found a single maternal condition, that mandates the use of this procedure.

Q. What types of fetal anomalies do you encounter in your practice?

A. Again, we see a wide variety and range of fetal abnormalities involving virtually every organ system the baby has. We see a lot that involve the central nervous system. We see abdominal wall defects, spine defects, heart

defects. We see inborn errors of metabolism or metabolic diseases. We see infectious problems. We see malignancies or neoplasms in fetuses. Pretty much you name it, we see it.

Q. Do pregnancies involving a fetal abnormality threaten the health of the mother?

A. Generally, a fetus that has an abnormality doesn't pose any additional risk to the mother over and beyond that which a nonmalformed fetus would pose; meaning that no greater risk than just normal risk inherent in a continued pregnancy. There are some rare instances where moms can start to develop complications like high blood pressure, in response to certain types of fetal conditions, but generally the fetus doesn't threaten a mother, just because it has a malformation.

Q. Is it necessary to destroy an anomalous fetus, in order to advance maternal physical health interests?

A. No. Again, the only thing that's necessary is that you separate the fetus from the mother. If there is the rare situation where a fetal abnormality is exacerbating the pregnancy, let's say in the area of high blood pressure complications, then you don't need to destroy the fetus. You just need to separate the fetus and the placenta from the mother, just like in the pre-eclampsia cases we discussed before.

Q. Is it your experience, Doctor, in your practice, that many women choose to terminate a pregnancy where the fetus has an abnormality of some kind?

A. Yes. Whenever we see baby that have suspected abnormality, depending upon the type of abnormality and our confidence in the diagnosis, then the patient is always given the option of whether or not she wants to continue the pregnancy or terminate the pregnancy. If she opts to terminate the pregnancy for a nonlethal fetal abnormality, then she's referred to another location. If it's a lethal fetal anomaly, then generally one of the physicians in our office will assist her in that delivery.

Q. In your experience, are pregnancies involving fetal anomalies, are these typically wanted pregnancies?

A. Yes, virtually all of them are strongly desired pregnancies by the mothers and fathers.

Q. When the choice is made to terminate the pregnancy for a lethal fetal abnormality, do you provide care to the women in completing that procedure?

A. I do. I provide them support afterwards. I see them before. I help manage any complications of the procedure and, again, our goal is to try to complete the delivery in a manner that is not only humane for the fetus, but also is as gentle and physiologic as possible for the mother. And we also try to allow the parents to have time with their child,

since their time is going to be very limited, and that includes being able to hold their hopefully intact baby, even the malformation notwithstanding.

THE COURT: Mr. Coppolino, just for your background I understood the doctor does not, himself, perform these procedures in the case of a fetal --

MR. COPPOLINO: Anomaly, Your Honor.

THE COURT: In the case of a lethal fetal anomaly, he'll have one of his partners do it, and he may supervise the care, but another person will do it. If I misunderstand that, I think it would be helpful to clarify it.

BY MR. COPPOLINO:

Q. Dr. Cook?

A. Yes. My general practice is if the situation of the pregnancy is complicated solely by a lethal fetal anomaly with no maternal medical complications related to that, then one of my partners will do the actual delivery process, and I will do the before and aftercare or management of complications. If it's a lethal fetal condition where it is causing some sort of deterioration of maternal condition, then I will do the delivery.

Q. Why do you divide, why do you divide matters that way?

A. Well, generally, what I do is try to assist in getting the best outcome I can for both the mother and the fetus. And if the fetus isn't acutely threatening the mother and I

have partners that are comfortable doing that procedure, then I let them do that procedure.

Q. Doctor, where a decision has been made to terminate the pregnancy for a fetal anomaly, in your opinion, is it ever medically necessary to utilize the partial birth abortion D & X procedure because of the specific nature of the anomaly?

A. No, that's not the case. Again, multiple various types of fetal conditions have been proposed that people have suggested would be treated best or potentially only by the procedure partial-birth abortion. And I haven't found that to be the case in any of the proposed cases.

Q. Can you think of one fetal anomaly for which termination of the pregnancy by the D & X procedure would be required?

A. I cannot.

Q. Can you think of any fetal anomaly for which termination of a D & X procedure would be the most appropriate option, because of the nature of the fetal anomaly?

A. In the case of hydrocephaly, I would like to address that.

Q. Can you tell the Court what hydrocephaly is?

A. Hydrocephaly refers to the distention of the ventricular system in the baby's brain, which is the fluid filled canal system within the central nervous system of a fetus. And if that canal system gets overly distended, secondary to either a blockage or an over production of cerebral spinal fluid,

then that leads to a condition called hydrocephaly. Which, in its most extreme form, can lead to actual macrocephaly, or a large fetal head.

Q. In that case, what can be done to safely deliver the woman?

A. Well, most cases of hydrocephalus don't have macrocephaly associated with it. They have large distended ventricles but not a large fetal head. In that situation, you would proceed, as you would in any other, induction of labor. But if it's a situation where they have macrocephaly, then what we would do is an intrauterine procedure similar to a procedure they would do ex utero, meaning wheeled decompress the ventricular system by placing a needle aseptically, surgically into the distended ventricular system, and aspirating off some of that fluid just like they do in the neonatal period, in order to make the head size small enough to be able to allow vaginal delivery. Now, there are some situations where if a patient declines that procedure, then we would proceed with a cesarean delivery.

Q. In this particular condition of hydrocephaly, would there typically be a desire or need to have fetal brain material, in order to conduct pathologic testing?

A. Yes. Many of the abnormalities that we see do involve the central nervous system, and they do have recurrence

risk, and they can be difficult to distinguish by just an anti needle ultrasound. So pathology is sort of a big tool we would utilize in those situations. So having an intact central nervous system would be critical, if the concern was for the central nervous system. If the concern was that the baby had abnormal chromosomes or something of that nature, when the intactness of the central nervous system is less critical.

Q. And would the partial-birth abortion procedure be suitable for pathology testing for anomalies for which brain tissue would be for pathology?

A. No. I can't even see how they would be able to interpret that tissue, if, indeed, the primary problem is in the central nervous system.

Q. If an intact fetus is deemed necessary or desirable for pathological testing, is there a safe alternative to partial-birth abortion D & X procedure?

A. Yes. It would be either an induction of labor or potential cesarean delivery.

Q. I would like you to look at Defendant's Exhibit 608, and let me assist you in finding that. Doctor, have you seen this document before?

A. I have.

Q. Did you review this document in connection with preparing your expert report in this indicates?

A. I did.
Q. What do you understand this document to be?
A. I understand it to be, again, a presentation made at a National Abortion Federation Conference in New Orleans, in April of '95, by Dr. McMahon.
Q. Could you turn to page Bates stamped at the bottom, CH 0000513, where it says fetal indications at the top?
A. Unfortunately, my copy is photocopied such that I can't really read it.
MR. COPPOLINO: Your Honor, if it please the Court, could I give the witness a better copy?
THE COURT: Sure. Of course. And if you would like to stand next to him, if you only have one copy, that's fine.
MR. COPPOLINO: Thank you, Your Honor.
THE COURT: At that PE thing, there should be a microphone there too, Mr. Coppolino.
MR. COPPOLINO: Thank you, and I'll speak extra loudly too, Your Honor
BY MR. COPPOLINO:
Q. Dr. Cook, this may be a better copy. Why don't you take a look at the page I had indicated to you.
A. Yes. I can read this more easily.
Q. What do you understand this list to be?
A. It appears to be a list that Dr. McMahon submitted

detailing some of the specific -- what he termed fetal indications for his partial-birth abortion procedure, which I believe he calls intact D & E.

Q. Did you review this list in connection with preparing the expert report you submitted in this case?

A. I did.

Q. And are you familiar with the fetal indications listed on these pages?

A. I am. There are, I believe, more than one page of fetal indications.

Q. And does this list purport to describe abnormalities of the fetus?

A. It does.

Q. And, by the way, did you review this list, prior to your testimony before Congress?

A. I did.

Q. And do you recognize the medical terms listed here for the fetal indications?

A. I do.

Q. Could you describe what some of the indications are on this list, Doctor, specifically with reference to the severity of the procedures?

A. Just for clarification, you mean the severity of the underlying conditions?

Q. Yes. Could you describe some of the indications on that

list in connection with whether they are, in your views, indications, severe indications of fetal anomalies?

A. I think I understand now. The initial portion of the list includes multiple chromosomal issues, some of which are considered quite minor chromosome abnormalities. Some of which are more severe in nature. Particularly things like translocations and sex chromosome abnormalities are conditions where babies would survive to adulthood with normal mental functioning and a normal productive life. Then there are other types of indications and specific types of abnormalities in a fetus that we would consider to be fairly routine and minor conditions such as hydronephrosis, which as mild dilation of the kidneys that, oftentimes, is a transient intrauterine phenomenon. Frequently responds or resolves spontaneously after delivery. Then there are some other conditions that would, likewise, be considered variations on normal or minor defects at most.

Q. Did Dr. McMahon's list include some easily correctable conditions such as cleft lip?

A. Yes, there are some conditions that are easily amenable to surgical repair such as cleft lip. Some that are not surgically repaired, but just followed serially with different types of tests like ASD or VSD, which is a small hole between the chambers of the heart, which frequently are not even repaired but just followed serially with echo and

repaired as needed.
Q. And is it your opinion that some of the other fetal indications listed of little clinical significant such as a two-vessel cord?
A. Yes, a two-vessel cord specifically is a normal finding that occurs in about 1% of the general population. If there are not other associated anomalies with it, then it's considered a benign finding.
Q. What about asymmetric fetal growth. Did you mention that?
A. I mentioned that possibly in my expert report, but I didn't mention it here now, but that also is a condition that we frequently observe which would be an indication -- if it became severe for delivery, but by no means is it an indication for termination of the pregnancy in any sort of destructive way for the fetus, because they have normal catch-up growth, almost universally, after they deliver.
Q. What about or normal cord insertion?
A. Abnormal cord insertion, again, is a very vague term, but that's a common problem that we see in our office as well. No long-term significance for the fetus. As a neonate, can potentially compromise the ability for the fetus to thrive inside the uterus in the form of getting adequate nutrition and growth. So we would follow that pregnancy closely. At the point which we thought the baby

was not thriving, then we would work toward delivery. Again, they have very good recovery and catch-up growth ex utero, outside the uterus.

Q. What about placental cysts? Is that on the list as well?

A. I don't see it here immediately. I have seen it before on the list. I just don't see it right now. But I see placental insufficiency. It's a long list. But placental cyst, in an of itself, is a benign finding seen frequently. Doesn't threaten maternal health. Doesn't have long-term implications for the fetus. Another one I see now, which I think I have mentioned before, which makes up a very large number of his indications are polyhydramnios or increased amniotic fluid volumes. Again, no risk necessarily to the fetus, if no other underlying abnormalities are seen. And, again, just a common finding in pregnancy.

Q. Thank you, Doctor. Doctor, I would like to talk about the safety issue surrounding the partial birth abortion D & X procedure. Are you of the view that -- what is your view with respect to simply the safety of the partial birth abortion procedure, in and of itself, as a method of terminating pregnancy?

A. Well, whenever we talk about using surgical methods late in the second trimester, early third trimester, that always concerns me, because those are known to be riskier

procedures, greater risk for bleeding, infection, perforation. But specifically with this procedure, there are elements that I'm very concerned about. I'm concerned about the marked over distension of the cervix which is much greater than is used in other procedures. I'm concerned not only about immediate issues like, you know, discomfort for the patient and unsupervised monitoring of the patient during her two-day pre-procedure induction, but I'm also concerned about what implications that may have for her later ability to continue to maintain a pregnancy to a point of viability with subsequent pregnancies. I'm concerned about other specific elements of the procedure like the concept of turning a baby in the uterus, which also increases the risk for maternal injury, and generally is abandoned in the practice of modern obstetrics. I'm concerned about the method in which a baby's life is taken, when it's virtually completely delivered then has its, you know, brains sucked out of its head.

Q. To your knowledge, have there been any studies evaluating the medical safety of the partial-birth abortion D & X procedure? Are you aware of any?

A. I'm not aware of any studies that are comparison studies that are published to date looking at specifically safety issues, either in the short-term or the long term.

Q. Now, I just showed you this morning the papers by Dr.

Haskell and Dr. McMahon. Why aren't they studies that support the safety of the D & X procedure?

A. There is not any sort of comparison group that's presented, so it's lacking sort of a basic element of medical research, which is a control group to be able to compare with so that you know that the outcomes that they are describing are comparable to the outcomes that you would have with other options for procedures of that same gestational age. They also, I don't believe, either of them include any sort of long-term follow up on their patients.

Q. But, Doctor, aren't these reviews of the cases that they have performed using this procedure? Isn't that typical as to how we began to learn about the safety of certain procedures?

A. Well, there is generally a process of sharing medical information that starts with maybe an isolated case report and then --

MS. SMITH: Your Honor, I'm sorry. I'm going to object to this line of questioning this witness has never been disclosed as an expert on the development of surgical techniques. We have heard Dr. Mazariegos on that. He did not express that in his deposition. Specifically limited his opinions to those expressed in his expert report.

THE COURT: Well, that will be overruled. You may answer, Doctor. Go ahead.

MS. SMITH: Thank you, Your Honor.

THE COURT: Incidentally, I appreciate that other places have different precepts about civility. Here it is never necessary to thank me for over ruling your objection, and it really isn't necessary, if I sustain your objection.

MS. SMITH: Okay.

THE COURT: But in any event, go ahead, Mr. Coppolino.

BY MR. COPPOLINO:

Q. Doctor, do you still have my question in mind?

A. As I understood the question, it had to do generally with how we share medical information, and can you share it without having a control group or comparison group, and medical evidence does initially start out with sharing clinical experience, case reports or maybe small case series. But to be able to draw any significant inferences, especially from a new proposed procedure, particularly if there is any concerns or danger involved in the procedure, then it's going to, by necessity, require that it either is instigated with some sort of oversight or some sort of independent body evaluating the safety of doing this, or have, at least, the very least, some sort of comparison group. Hopefully a historically concurrent comparison group to see if there is an implication that it may be a better way to go. And then maybe, at that point, put the

significant resources that are required to perform an actual clinical trial. But, at least, there should be an effort to try to show a comparison group to be able to justify instituting a new type of therapy, particularly if there is potential risk for the new therapy.

Q. Now, but, Doctor, you would agree that Doctors Haskell and McMahon, in those two reports, reported on their own cases and reported largely that they had no complications with those cases; is that correct?

A. Yes. They were reporting, as I understood it, their immediate short-term complications. And, again, there is a concern for longer term implications as well. I don't recall either of them offered those up.

Q. Well, assuming what they are saying is true for the moment, and they are reporting no short-term complications, why isn't that good evidence that the Court could rely on as to the safety of the D & X or intact D & E procedures, as they called them?

A. Well, introducing a new procedure involves several elements. You can introduce a new procedure because you think it's safer than existing procedures. You can introduce it because you think it's more efficacious or efficient in accomplishing what you want it to do with maybe similar risk. Or you may say it's something that involves less cost financial cost or less time. So there are

multiple things a new procedure potentially could bring to the table. But if you are going to introduce a new proceed irrelevant, again, one with potential risk, and introduce it on the face that it has relatively low complications associated with it, I think the onus is on you to show that those complications, even if low, are lower than other existing techniques, or offer some real benefit over other existing techniques. And I don't see where this procedure offers any additional benefits.

Q. In your opinion, should there be some form of independent review of the cases of those who assert that their procedures are safe?

A. Well, generally to maintain the integrity of the data, it should have some independent oversight, either in the form of peer review or a supervisory committee for human subjects and human studies.

Q. Doctor, you, yourself, conduct studies and publish studies; is that correct, in the field of internal fetal medicine?

A. That's correct.

Q. What kinds of research tools do you utilize?

A. Well, we first try to ask a question that we think needs to be answered. We look at -- in my world, I do predominantly clinical research, at this point in time. We try to look at a question that doesn't seem to have clarity

in the existing literature, and say is there something we can do to either clarify this issue or improve on this issue? And then once we ask what we think is a good question, we try to see if we can answer that question from existing data that is already available, and that may be in the form of a case controlled study, a retrospective case controlled study. And then once we have asked the question that we think there is some credence to pursuing it and a prospective manner, then we go through the somewhat arduous process of setting up a clinical trial, and that includes writing out a specific proposal, in my institution, for our institutional review board to approve. And, in fact, we have one that was being considered last night at our institutional review board that I'm a part of. And if they approve it, then we go through the process of instigating it, and there is continued ongoing oversite, including a requirement to submit interim data and continue to report back to the oversight committee, so that they can maintain all the things that they feel need to be maintained on the subject's study including anonymity, including privacy issues, including safety issues. So there is a whole host of things they review for us. So it can be a complicated process if done the right way.

Q. You would agree, Doctor, a review of the doctor's individual cases would be one way of ascertaining the safety

of a procedure?
A. Yes. It would be the lowest level of evaluation, but it's a starting point.
Q. Is there some reason you can think of why peer review of case studies of physicians who perform in procedure partial-birth abortion D & X procedure is not possible?
A. I don't know of any reason why it shouldn't be possible. Peer review is done all the time, in a number of matters, whether institutional specific or related to insurance and reimbursement issues, or liability issues. So I don't know of a reason why there can't be independent review of people's experiences with this procedure.
Q. Would you agree, Doctor, that in trying to compare the relative safety of new procedures, if it's believed that their complication rates are going to be close, you would need a large number of cases to review?
A. Well, that's a phenomena of statistical analysis. Whenever you are trying to show the distinction of two populations that have a great deal of overlap, meaning they don't differ by very much, you're going to need a large number of subjects to be able to show that those two populations are, indeed, distinct populations. If the populations are already inherently quite distinct, then you don't need as many subjects to be able to demonstrate that.
Q. Is there any reason you can think of where, if you

wanted to do a retrospective review of cases involving D & X, intact D & E partial-birth abortion procedure, there would be an insufficient number of cases to review?

A. I'm sorry. Could you repeat the question?

Q. If we were going to do a retrospective case review of this procedure and have it peer reviewed, I'm referring to the D & X, intact D & E procedure, is there any reason to believe there would be an insufficient number of cases to review?

THE COURT: The more specific you get about doing these studies, to the extent that the doctor was not designated in that area, the more likely that I am to sustain an objection. Can you tell me, Mr. Coppolino, was the doctor designated at this level of specificity?

MR. COPPOLINO: Well, I believe that subject is well within the scope of his expert report, and if you would like, I will put the expert report in front of him and we can go through what he said about how you go about studying.

THE COURT: If you would just show it to me, that might be helpful.

MR. COPPOLINO: May I approach, Your Honor?

THE COURT: Sure. Just give me a sense of the page.

MR. COPPOLINO: Your Honor, I'm specifically referring to page 12, caption B, which begins to talk about

relative safely issues which is the subject I have now turned to.

THE COURT: All right. Give me just a moment to read it.

MR. COPPOLINO: Sure. I would just call the Court's attention to the remainder of page 12 up through the first paragraph on page 13.

THE COURT: As a general matter, as I indicated earlier, I don't have a problem with the doctor giving us his experience about running clinical trials. However, you're now into an area which I perceive to be different and not disclosed in his report, but I want to give you an opportunity to tell me why I'm wrong.

MR. COPPOLINO: Okay. I'm not going to belabor this particular issue. All I would simply say is that Dr. Cook, opines his report with respect to the lack of studies for this procedure, and whether in the form of nonconcurrent cohort study or a clinical trial. He then says advances in surgical techniques fall under the direct supervision of institutional review boards under controlled settings with published and shared data within the medical community. Those procedures deemed more efficacious, less complicated or less expensive become incorporated into modern surgical innovation. So Dr. Cook's report discusses the lack of study for this particular procedure and the means of

studying medical procedures. So I felt that's well within the scope of his report.

THE COURT: Well, I appreciate that, and I think I have let you talk about that. What I'm a little -- feel a little awkward having you now talk about is the doctor, at the level of specifies, -- the spending question was and we can have the robbery read it back if you like, but I think my recollection is accurate. Is simply whether or not there is enough of a population to do the study. And that is a very specific question that is different, that requires far more awareness about both D & E and D & X procedures that this witness, at least, at this point, has disclosed no expertise on. And certainly that wasn't discussed in his expert report. And so that is where I have the problem.

MR. COPPOLINO: You know, Your Honor, I'm happy to move past that question. The question was solely seeking to elicit his understanding as to the number of cases that have been done in the past on this, but it's really not worth getting hung up over. As long as you understand, I was just asking him in his understanding of how many times this procedure has been performed, based on published data or some other understanding, does he think there would be a sufficient number of cases to study.

THE COURT: Right. And I think your earlier physician from Pittsburgh and the other physician from

University of Michigan were well qualified to talk about that.

MR. COPPOLINO: Let's just leave the point, Your Honor.

THE COURT: But I don't think this witness is, and I don't think his expert report adequately made counsel aware that you were going here, so I take it --

MR. COPPOLINO: That's fine. I will withdraw the question.

THE COURT: Thank you. Go ahead

BY MR. COPPOLINO:

Q. And I don't -- I have just a couple more on these lines and I don't think they run a foul, but if they do, we'll hear of it I'm sure. Doctor, if you assume that the D & X intact D & E procedure is considered to be an innovative procedure, at some point, are innovative practices in medicine subjected to some study?

A. Yes. In this country, particularly those things that may have any sort of perceived or associated risk, are not incorporated within the general medical regimen without being subject to some sort of study first.

Q. Now, judging from Dr. Haskell's paper, he gave this paper in 1992. Are you aware of a single published peer reviewed study of the D & X procedure since that time?

A. I'm not.

Q. Are you familiar with the medical literature in the field of obstetrics and gynecology and maternal fetal medicine?
A. In a general sense, I am, yes.
Q. Do you tend to read journals involving issues of obstetrics, gynecology and maternal fetal medicine?
A. I do on a regular basis, yes.
Q. Do you read articles in those journals that concern the procedures for pregnancy termination?
A. I do review those articles, but my focus isn't on those articles generally when I'm reading the literature.
Q. Based on your review of those journals, would you agree there are many, many articles on abortion practices and techniques, journals involving obstetrics and gynecology and maternal fetal medicine?
A. Yes. There has been recently a large number of publications looking specifically at variations on medical induction; specifically on how to improve medical inductions of termination.
Q. Doctor, do you believe that intuition is a sufficient basis to judge the safety of the partial-birth abortion, the D & X procedure?
A. Well, I think that if you are going to incorporate any sort of surgical medical procedure, that you should be basing that upon more than just intuition.

Q. Now, the plaintiffs, and others who have testified in favor of this procedure, assert that the procedure appears to be safe because it, involves among other things, fewer instrument passes. It also involves not having to remove sharp fetal fragments. And, for that reason, may present less risk of uterine perforation and cervical laceration. Do you think that assessment of those possible benefits is sufficient for the Court to judge that the procedure is safe?

A. No, I consider that insufficient evidence. It is very common in the field of medicine, particularly in the field of obstetrics, where things that may appear to have a potential benefit on the surface, when actually placed to the test of some sort of study or trial, prove to be just the opposite and potentially harmful. And there are many examples in obstetrics and gynecology specifically, and I can talk about those.

MS. SMITH: Your Honor, I think we are back into the --

THE COURT: This is general enough, that will be overruled. Go ahead

BY MR. COPPOLINO:

Q. Did you finish your answer, Doctor?

A. I didn't go into the specifics, but anything from people that had DES exposure in the past, thinking it would help

them with miscarriages, was published in a noncontrolled fashion. Was heavily incorporated into this country and later found to be a cause of many complications including vaginal cancer and genital tract abnormalities. And it wasn't until it was studied in a clinical trial that people recognized the danger of that technique, and it was subsequently abandoned, after having been used for many years. And there were other examples even within obstetrics and gynecology.

Q. Doctor, do you, yourself, agree that the intact D & E or D & X procedure might appear to present some advantages such as the need for fewer instrument passes?

A. Well, on the surface, an intact D & E procedure or D & X procedure may appear to offer some benefits when compared to a traditional D & E procedure, as far as the amount of instrumentation involved. But I don't generally think that's an accurate comparison, since generally D & Es are being done at earlier gestational ages, and the partial-birth procedures are being done at later gestational ages, where I believe the more accurate comparison is with induction techniques.

Q. Now, at the outset of this discussion of this topic, you have identified some specific concerns with the procedure and I want to just address a few of those. First of all, just -- I believe you indicated that one concern you had

with this procedure was the potential long-term complications it might have on cervical incompetence; is that correct?

A. Cervical incompetence and pre-term delivery.

Q. Would you explain what your concern is with the procedure in connection with cervical incompetence and pre-term deliver?

A. Well, there is an increasing body of evidence that supports that people that have had a prior termination of pregnancy are at increased risk for subsequent pre-term deliveries and potentially low birth weight infants. And those studies are done predominantly on people that have procedures done in the first trimester, where there is very little manipulation necessary for the cervix, in the form of dilation. So some data would suggest the risks are higher when you're doing mid term procedures, or mid trimester procedures. I believe that is related to the amount of manipulation necessary in the amount of dilation to the cervix. So if you take that to an even a greater extreme where there is a massive over dilation of the cervix, then I have an even greater concern about the potential integrity of the cervix, and the ability to maintain a pregnancy to term in the future.

Q. What is your understanding of the process of dilation for the D & X procedure that causes you to have these

concerns about potential long-term complications?
A. Well, obviously when you deliver a child, you achieve, you know, full dilation of the cervix which is, you know, 10 centimeters in general. But it occurs as a result of a normal physiologic process. Uterine contractions then lead to cervical dilation and change. When you're talking about doing it in a short time frame and doing it with mechanical distension of the cervix, there is greater risk for disrupting the normal integrity of what we call the matrix, cellular matrix or the collagenous cellular matrix of the cervix, which is at a cellular and physiologic level, what makes up the normal architecture of the cervix.
Q. Doctor, do you understand the dilation process for the D & X procedure, particularly as practiced today, can be a gradual process over a couple of days involving natural osmotic dilators, how can that potentially threaten -- how can that potentially lead to a long-term complication involving pre-term birth or cervical incompetence?
A. Again, it's the manner of focusing on the cervix rather than using uterine activity and uterine contractions to lead to cervical change. The normal process, and the way it's designed, is for the uterine contractions to lead to gradual and physiologic dilation of the cervix. If you are just trying to force open the cervix alone, whether using dilators that are osmotic or instrument dilators, it's using

a decidedly nonphysiologic process to try to force open the cervix.

Q. What is potentially dangerous about multiple insertions of laminaria in the cervix for long-term complications from this procedure?

A. Well, any time you're placing things into the cervix, you increase the risk for infectious complication. The more things you place into the cervix, the greater the risk. But my primary concern long term is for this, again, achieving a greater level of cervical forced cervical dilation for -- that is necessary for this procedure.

Q. And would you include the use of laminaria among what you just described as forced cervical dilation?

A. I would.

Q. And why?

A. Because it's not changing the cervix by the method of using the typical physiologic process of uterine contractions, but by using dilators that absorb fluid and grow to two, three, four times their size, in order to force dilation of the cervix.

Q. Are you familiar with the drug Misoprostol, also known as Cytotec?

A. I am.

Q. Do you use it in your own practice?

A. Yes, it's probably the mainstay of therapy for medical

induction of pregnancy in our practice.
Q. Would you agree that Cytotec is improved the process of preparing the cervix for termination of pregnancy?
A. Well, we use Misoprostol predominantly to cause uterine contractions and expel the uterus, when we are trying to deliver a pregnancy early. There have been people talking about using Misoprostol in a cervical preparatory fashion for mid trimester terminations as well. In our practice and in many practices, we use Misoprostol for term pre-induction cervical ripening or for pre-term induction. We aren't currently using Misoprostol for mid trimester preparation, prior to a surgical procedure.
Q. Is Misoprostol considered a dilating agent?
A. No, it's a Prostaglandin whose role is to cause uterine contractions and uterine activity.
Q. Does that process assist in preparing the cervix for a surgical abortion procedure?
A. It can. Again, by utilizing the typical variation on the physiologic process of uterine contractions leading to gradual cervical change.
Q. If dilation is achieved, in part, through the use of Misoprostol, would that alleviate, to some extent, the concerns that might exist with respect to potential long term cervical incompetence leading to pre-term birth?
A. On the surface, it would in my mind, because I'm

concerned, again, about the nature in which you're achieving the cervical dilation. Again, when you deliver a child normally, you're going to achieve full dilation of the cervix. So I'm not always concerned about just how dilated it is, but how you got to that point. So if you get to that point using the normal physiology or the variation of normal physiology, and you use contractions, whether those contractions are caused by Prostaglandins or Pitocin, I'm less concerned about that. But if it's just a mechanical forcing open of the cervix without using uterine activity, then that makes me very concerned about the potential lack of integrity of that cervix for subsequent pregnancies.

Q. And, would you agree -- would your concern with respect to the mechanical forcing open of the cervix apply specifically where a mechanical dilator was used?

A. It would apply any time you're using a process to try to dilate the cervix where you are focusing only on the cervix and not utilizing uterine activity. Misoprostol utilizes uterine activity to cause cervical change.

Q. In considering the risk of generous dilation that's used in the D & X procedure, do you need to consider also the gestational age at which the procedure is being performed?

A. Yes. The further in gestation, the greater the amount of cervical dilation that's necessary.

Q. Is dilation a four to five centimeters after 20 weeks

potentially worse than two-and-a-half centimeters between 18 to 20 weeks?

A. Yes. The more dilation you have to achieve, if you achieve it through a nonphysiologic process, the more I'm concerned.

Q. Have you seen any peer reviewed data concerning the effects of slow generous dilation over two days using osmotic dilators?

A. No.

Q. Have you seen any peer reviewed scientific data comparing or analyzing the use of Misoprostol to achieve a slow generous dilation over a one or two-day period?

A. I believe there has been case reports or case series proposing that, but no comparative studies that I'm aware of.

Q. Is there any existing data you could call the Court's attention to on the effect of abortion that might indicate a potential long-term problem with the D & X procedure?

A. Well, again, there is an increasing body of evidence that shows that people that have had induced abortions have a higher risk for pre-term delivery and possibly low birth weight with subsequent pregnancies. And those studies are still done predominantly on people that had first trimester terminations. So I guess my concern would be even greater with those that are having later gestational age

terminations.

MR. COPPOLINO: Ready to break, Your Honor.

THE COURT: The doctor's answer, and I appreciate that the terms are used may be used differently. I did not understand the last answer to apply specifically to abortions accomplished by the induction method, although the word induced was used in the doctor's answer. I understood his answer to be broader than induction abortions.

MR. COPPOLINO: Yes, Your Honor. Perhaps I can clarify that when we return. The term induced, I think, is referring to various methods of abortion, but we can clarify that when we return.

THE COURT: All right. We'll stand in recess until 1:30. Doctor, you may step down, sir.

THE WITNESS: Thank you.

(Recess from 11:59 to 1:30 p.m.; all parties present).

THE COURT: Doctor, if you will come forward, please, and take a seat in the witness stand.

(Dr. Cook resumed the witness stand).

THE COURT: Counsel, you may inquire.

BY MR. COPPOLINO:

Q. Thank you, Your Honor. Dr. Cook, before the break, I was asking you some questions about potential long-term consequences of the D & X procedure, and I want to just go over some of that very briefly. Is there any existing data

on the effect of abortion that believe might indicate a problem with the intact D & E procedure or D & X procedure in terms of long-term consequences?

A. Well, I think I mentioned before, there is an increasing body of evidence regarding the potential risk of induced abortion. And, again, when I use that term, I'm distinguishing it from spontaneous abortion or miscarriage. So abortions that are caused by care providers, there is an increasing body of evidence that that subset of patients is at increased risk with subsequent pregnancies for both pre-term delivery, mostly secondary to cervical incompetence issues, and also potentially at risk for low birth weight infants. The existing data has looked predominantly at the earlier terminations of pregnancy where there is less cervical manipulation. And so my concern is, and there is data to suggest this, that the later procedures, where there is even a greater amount of cervical manipulation, would lead to potentially even a greater concern, specifically for pre-term labor, specifically pre-term labor related to cervical weakness issues.

Q. When you use the term induced abortion, that's including all methods of abortion that are provided by the physician; is that correct?

A. Correct.

Q. All right. And how does that data that exists

concerning potential complications of abortion relate to your concerns with respect to the D & X procedure?

A. Well, one of the hallmarks or distinguishing features of the D & X procedure is this, again, super distension or over distension of the cervix beyond that which is usually done for typical second trimester procedures like D & E, and certainly beyond that done for first trimester procedures like suction curettage. So if the concerning data is with the issue of pre-term delivery, and that data exists even for people that have first trimester abortions, then I'm concerned the risk would be even greater with those that had later abortions, specifically by a technique that would involve marked or over distension of the cervix.

Q. Doctor, turning to another safety concern. To the extent that the D & X partial-birth abortion procedure involves an internal podalic version of the fetus to the breech position, do you have an opinion as to the safety of that procedure?

A. I do. It is concerning, whenever you talk about trying to turn an infant within the womb, that you can increase the risk for maternal trauma in doing that, and it's generally not part of current obstetrical practice to still utilize that technique. That was an older technique used years ago for different situations and has been sort of resurrected for this particular procedure. But I think there are

inherent risks associated with it that have been recognized by obstetricians that practice other methods of abortion and other methods of just delivering of infants, and, I believe, even practitioners of this particular procedure -- there has been some concern about doing internal podalic version.

Q. Doctor, would the risks of the internal podalic version be less in mid second trimester or mid trimester as opposed to at term, in delivering a baby at term?

A. I'm not certain that the risk changes that much, based upon the gestational age, because it's the concept of being within the uterus in a somewhat blind fashion and manipulating a fetus within that closed environment that is the risk.

Q. And what is the risk of that procedure?

A. Well, perforation of the uterus, trauma to the uterus, and then all the things that go along with that, including risks of bleeding and infection.

Q. With respect to the issue of uterine perforation, would the use of ultrasound offer some protection against perforation in performing a D & E, in which the fetus is dismembered?

A. Well, certainly I think ultrasound is always advantageous whenever we are doing any procedure within the uterus, because you're working with a window into the womb so-to-speak. You're not doing your procedure as blindly, so

you can identify specifically in D & E where the head may be or certain extremity may be, and you don't have to be grasping around within the uterus blindly with your forceps. You can go right to the area you're trying to target.

Q. What would be your opinion of performing a D & E or a D & X without the use of ultrasound?

A. Well, I think it would be not practicing contemporary obstetrics. It's a tool that is part of our routine armamentarium and should be utilized in any procedures where you are doing intrauterine manipulations. We use it for therapies targeted at the fetus. I even use it where we have a situation where there may be a retained placental tissue after a medical induction, abortion or procedure, and the baby has been expelled but the placenta remains. If we have to do D & C or dilatation and curettage, we do that under ultrasound guidance to reduce our risk of perforations or other complication.

Q. For those who would assert they performed D & E or D & X procedures safely without ultrasound, because of the experience that they have gained, would you say that they are practicing a safe procedure?

A. Well, you certainly can accomplish it without the benefit of ultrasound, and it was done that way for years when ultrasound was not available. And experience is helpful in that regard, but I would say that you're not

availing yourself of all the resources that are available, and you're not performing it as safely as you could be performing it in this day and age.

Q. Doctor, do you have an opinion as to whether the safety of the D & X procedure should be evaluated by reliance on data demonstrating the safety of the D & E procedure?

A. Well, I do have concerns about that that I believe I mentioned that it is difficult to compare a traditional D & E procedure, most of which are still done at earlier gestational ages than most of the D & X procedures. I think it's difficult to compare those two from a risk assessment standpoint, because we know the risks are tied greatly to gestational age. The higher gestational age, the greater the risk. I think, again, the more accurate comparison is what truly happens as it is proposed now medical induction as proposed D & X procedure beyond 20 weeks of gestation.

Q. Do you have an opinion as to whether the safety of the D & X procedure, as compared to induction procedures, medical induction procedures, should be evaluated by reliance on data comparing the D & E procedure to prior methods of induction?

A. Well, that's problematic as well. You always want to be comparing groups that are comparable and are contemporary. And the problem with looking at data that is several decades old, utilizing old induction techniques, specifically

installation techniques, and comparing that to D & E or even worse by extrapolation D & X, would be really a stretch. It's just not an accurate comparison. You need to compare contemporary induction methods with Prostaglandins administered orally, vaginally, intramuscularly. Compare that group with what would be a more appropriate comparison group, the D & X procedure as it's been described and performed.

Q. What is your understanding of the statistics that existed -- that exist, based on prior studies, as to the relative safety of the D & E procedure with prior methods of installation induction?

A. Well, again, data now several decades old would demonstrate that D & E is considered generally a less complicated procedure than installation techniques of induction, up until about 16, or maybe 16 to 18 weeks gestation. After that, they are comparable risk.

Q. Doctor, do you believe that current methods of induction, termination in the second trimester, have improved over the installation methods of induction that have been previously used?

A. I do. This is an area of active research and development. Instead of, again, using installation of saline, hypertonic saline or Prostaglandins, we now administer new and different types of Prostaglandins by

different routes, constantly studying different formulations and strengths and intervals of administration to figure out which group will be delivering in the most expeditious and safest manner.

Q. Could you provide the Court a little bit more detail with respect to how modern Prostaglandins have improved the safety and the speed of induction terminations?

A. Well, in the last several years, Misoprostol or Cytotec has played a larger role, and they have continued to look at which strengths same to be most effective, and which intervals of administration seem to be most effective, and can now, you know, get medical inductions down to pretty reliable 12 hour, on average, interval of time or less. And do it in a manner that minimizes risk for both maternal complications and still allows, if it's appropriate, adequate outcome for the fetus.

Q. What is your response to the assertion that medical inductions are a more painful and physiologically stressful procedure than a surgical termination such as D & E?

A. Well, I think surgery is decidedly nonphysiologic as opposed to labor. So a labor induction is a much more physiologic process or utilizes a natural process more than surgery would. But it also is a more controlled and monitored situation, as opposed to the D & X procedure, meaning that patients are constantly monitored for pain

control, analgesia is constantly available to them in various forms, including patient controlled IV anesthesia or epidural, as opposed to having a handful of Motrin or Ibuprofen, going to a hotel room somewhere for a couple of days while the cramping and contracting is taking place.

Q. So would you summarize, then, your views as to why you favor medical induction terminations after 20 weeks over surgical abortion terminations?

A. Well, I think there is many potential advantages, particularly in the type of patients that we care for. I have mentioned already but, again, this taking advantage of a normal physiologic process, having a situation that you can more adequately monitor, not just for patient analgesia or pain relief concerns, but for maternal stability concerns, particularly if there is underlying medical disease, particularly cardiovascular disease, or uterine scar or what-have-you. And then also, the ability to have an intact fetus, you know, for pathologic evaluation.

Q. Doctor, I put on the desk there what's been marked as Defendant's Exhibit 545. Is that correct, is that the right number?

A. Yes, I have it.

Q. And it's Exhibit 545 is an article by Dr. Amy Autry and others entitled a Comparison of Medical Induction and Dilation and Evacuation for Second Trimester Abortion. Are

you familiar with this article, Dr. Cook?
A. I'm familiar with it.
Q. And you've read it before?
A. I have.
Q. Do you understand that this article concludes that the D & E method of second trimester abortion poses fewer complications than the medical induction method of abortion in the second trimester?
A. Yes, that is the conclusion they state.
Q. Do you agree with that conclusion?
A. I do not.
Q. Why don't you agree with it?
A. Well, it's not supported, at least, by the data that they present. They do present some data that is very small number of patients, and they define complications in a manner that I think is somewhat misleading, and then make the conclusion that they made, that that method is a safer method; that D & E is a safer method than the other methods they compared with.
Q. What is misleading about the manner in which they have defined complications, in your view, or for the medical induction procedure?
A. Well, the reason I find it misleading is it's pretty consistently demonstrated in multiple people's experiences, published or personal experiences, that with a medical

induction of pregnancy as it is done now, there will be about a 10% incidence of a placenta that doesn't pass in a reasonable time frame spontaneously, after the baby has already been expelled, which then would necessitate the need for a D & C. And I think to consider that a complication, plus they sort of double dip when they talk about retained fetal products, and the need for D & C are listed as two separate complications, which I assume there is overlap there. So I don't know that I consider that a complication. The complications that I would consider of concern include things that they did look at hemorrhage requiring transfusion. Laceration of the cervix requiring repair. Hospital admission. If you look at those type of complications, there was no difference between the two groups.

Q. You agree that in this article, 77% of the complications associated with medical induction were to extract a retained placenta?

A. Correct.

Q. How long do you typically wait after a medical induction -- if the placenta has not passed, how long do you typically wait for it to pass naturally?

A. I usually will wait up to an hour or two, as long as the patient is stable without evidence of bleeding or infection.

Q. Do you believe that's consistent with normal care

provided by physicians after a medical induction?
A. Yes, I believe that that is pretty consistent. I honestly don't recall in this article if they defined what length of time they waited before they proceeded with a D & C, if necessary.
Q. Or whether they defined a time before they characterized something as a retained placenta?
A. Correct. I don't recall that being discussed.
Q. Now, you wouldn't wait two hours, I take it, Doctor, if the woman was bleeding at the time, would you?
A. No. If the mother was not considered stable, then we would proceed sooner.
Q. And if the retained placenta was creating an emergent situation, would you regard that as a complication of the medical induction?
A. Yes, if she was having bleeding significant enough to cause us to intervene for that, then I would consider that a complication.
Q. How do you remove a retained placenta after a medical induction?
A. We do it in the form of introducing forcep or a sharp curette, and I do it under ultrasound guidance.
Q. How would that be any different from the manner in which a retained placenta is removed during a D & E abortion?
A. It would be no different.

Q. Do you feel that the inclusion of retained placenta, as a complication in this study, has somehow skewed or biased the results of this study?

A. I do. I think by starting up front and defining that one of your complications is going to be retained placenta, where you know that that is a normal result of a medical induction, and you know that you're going to be instrumenting in removing it in the other scenario, so that it shouldn't ever occur in the one group, then I think you have a preset bias against one type procedure or the other. That's why I would rather see the focus on complications be on things that are of greater significance, where it's not an expected outcome with either arm. Things like organ damage, readmission to the hospital, cervical laceration, hemorrhage requiring transfusion. All of those four categories were looked at and they did not differ between the two groups, but, again, it's a very small study.

MR. COPPOLINO: May I have one moment, Your Honor?

THE COURT: Certainly.

MR. COPPOLINO: Your Honor, no further questions at this time.

THE COURT: Counsel, you may inquire.

CROSS-EXAMINATION

BY MS. SMITH:

Q. Doctor, Priscilla Smith for the plaintiffs. I have been

told I'm a fast talker, so I'm going to try to slow down.

A. I'll try to listen fast.

Q. Okay.

THE COURT: Incidentally, I'll remind you again, don't listen to my court reporter.

MS. SMITH: Speed is a good thing in some people's minds.

THE COURT: That's right. He'll take it.

BY MS. SMITH:

Q. Doctor, you have never done a first trimester abortion on a live fetus; is that right?

A. I have not.

Q. And you've performed between three and five D & Es; is that right?

A. That is correct, that I have actually performed myself.

Q. And none of them involved extraction of a fetus that was living; is that right?

A. None of them involved an extraction of fetus that was living at the time the procedure was done.

Q. Thank you. And you've supervised under 20 D & Es; is that right?

A. That's correct, supervised or participated in, to some extent.

Q. But not performed?

A. Correct.

Q. And it was only a small number of those 20 cases that you have supervised or participated in that the fetus was living at the beginning of the procedure; is that right?
A. That is correct.
Q. Maybe one or two, five?
A. Probably a third. Less than half.
Q. So less than ten. And some of those D & Es might have been 16 to 18 weeks at the latest, but it's unusual in your practice to do a D & E after 16 weeks; isn't that right?
A. Not exactly. My experiences where I have been a participant or performing the procedure have included cases that went up to 20 weeks but usually were at the earlier gestational ages.
Q. So it's unusual to go beyond 16?
A. It's not common.
Q. Thank you. And no one in your current office performs D & Es, but they did in your previous practice in Louisville; is that right?
A. I don't recall my current partners doing a D & E recently, but I do recall that being a larger part of our practice when I was in Kentucky.
Q. Thank you. By the way, Doctor, you testified that you will do a termination on a woman who has a lethal -- carrying a fetus with a lethal anomaly, only if she also has a medical condition where her health is deteriorating; is

that right?
A. That's correct.
Q. Can you give me some examples where you have performed an early termination of pregnancy for a lethal fetal anomaly when the health condition was deteriorating? What type of health conditions were those?
A. One that comes immediately to mind when a baby has nonimmune high drops. For want of a better term, is sort of like congenital heart -- I'm sorry. Congestive heart failure for the fetus. And there is lots of conditions that can cause that. Then that can induce what we call a mirror syndrome, where the mother gets a subsequent pre-eclampsia-type picture, as a result of that.
Q. Um-hm?
A. So that's an example of where a mother's health could be threatened by a continuation of nonimmune high drops, which generally has about a 90% mortality for fetuses.
Q. Anything else you can think of?
A. Well, that's the one that came most immediately to mind.
Q. And you can't think of any others right now?
A. Well, no. There are other situations. There are certain types of fetal anomalies that will lead to increased amniotic fluid volume in polyhydramnios, which can start to impair maternal efforts at breathing and normal respiration. Situations like that, that could be an example? Not trying

to get you to list them all, just -- I suppose I could think of some others.

Q. Okay. Please do.

A. Well, there are a number of fetal conditions that, in theory, could start to cause maternal complications. Another would be in a situation of a partial molar gestation which is usually a triploidy type of genetic situation which typically is a nonsurvival situation for a fetus that can also lead to maternal hypertensive disease, and also significant risk for bleeding. There is also a subset that can cause malignant degeneration and risk concerns for the mother for that as well. Do you want more?

Q. Yes. I would love them.

A. We have a patient in our practice right now with conjoined twins, one of which is no longer living. And the other one that is, who -- if you have conjoined twins that are in later gestational ages and they are conjoined in an area where there is not much hope for being able to separate them, meaning conjoined, for instance, at the chest where they have to share a single heart, that that situation can also lead to a difficulty in trying to deliver that baby vaginally. So it would necessitate an abdominal delivery. If we knew that diagnosis early on, sometimes they could still be delivered vaginally at earlier gestational ages. I'm sure I could come up with others.

Q. Thank you, Doctor. That's great. Doctor, you have never inserted laminaria, prior to doing a surgical abortion where the fetus was living; is that right?

A. I'm not sure that is right. We do do laminaria placement, especially before we had Misoprostol as our major induction technique. We used to put laminaria in routinely on patients that were going to have terminations of pregnancy, whether by induction or by surgical technique.

MS. SMITH: May I approach, Your Honor?

THE COURT: Yes.

BY MS. SMITH:

Q. Doctor, I have just handed you a copy of your deposition. It's in a mini-transcript form. I don't know if you have seen this before but if you could turn to page two 15, line 2 and tell me when you find it.

A. I have found it.

Q. The question there was, okay, and I'm sorry, Doctor, you probably have answered this already, but have you ever inserted laminaria prior to doing a surgical procedure to terminate the pregnancy where the fetus was living at the beginning of the abortion? Answer: No, because I don't generally use D & E as my first line of treatment. And in the scenarios where I had to use D & E, the cervix already had some level of dilation. Was that your testimony at your deposition, Doctor?

A. Yes, it was.
Q. And is that a true statement?
A. It is.
Q. Thank you.
A. I believe, as I understood your question, it was do we every place laminaria before during terminations on living fetuses. And I said that prior to using Misoprostol, that was a way that we commonly did it. We put laminaria in first, then we would proceed, whether it be medical or termination. We used to place a lot more laminaria in years passed than we do currently.
Q. Even for your D & Es; is that right? You're talking about for medical induction?
A. I'm talking now more for medical induction because those are the ones we do predominantly. But if we had a patient that D & E was the necessary procedure we felt, we would definitely do a preparation before doing a D & E, and that would include laminaria or some sort of cervical dilator placement.
Q. Okay. Thank you, Doctor.
A. You're welcome.
Q. You have no personal experience with Misoprostol for surgical abortion; is that right?
A. I use Misoprostol almost daily in my practice, but we use it for cervical ripening, for term inductions. And we

use it as our method of inducing to empty the uterus in the mid trimester or the third trimester. Using Misoprostol as a cervical ripening agent prior to D & E would be a reasonable option, but, again, as I have stated before, D & E is not something that is generally preferable nor required in the type patients I care for.

Q. So you have no personal experience with Misoprostol for surgical abortion?

A. I have a lot of experience with Misoprostol but not in that specific area you're discussing.

Q. Thank you. Doctor, it's your opinion when you insert the same amount of laminaria in two different women, the laminaria will lead to a very predictable amount of dilation; is that right?

A. I'm not sure very was part of my prior testimony, but generally, it does lead to predictable amount of dilation.

Q. For example, Doctor, if you had two women at the same gestational age, one was 16 years old, never had a child. The other was 30 years old, had three vaginal deliveries, you believe the same amount of laminaria would lead to the same amount of dilation in those two women, don't you?

A. Well, those two women are different women, as you are sort of suggesting, but the difference is in how many laminaria can be placed, not where they end up. So each laminaria has a prescribed, by the manufacturer, maximal

size that it will attain. They have to maintain certain standards in order to be produced as a product. So they have predictable amounts of dilation they cause, but you certainly can put more in in a patient who is multiparous and had children before.

Q. I think as you said in your deposition, the two women might start out at a different point, but they would end up at the same place?

A. If you place the same number of laminaria for both women.

Q. There is no circumstance where they would dilate more than the laminaria, for example?

A. That's not what I'm saying at all. If you are talking about what they respond to as far as laminaria placement, it is predictable. If you are talking about how they would respond to other stimuli like uterine activity and things of that nature, that does vary from patient to patient.

Q. I'm just talking about placement of laminaria, Doctor.

A. I have answered your question.

Q. Thank you. In your opinion, Doctor, in a D & E, the physician would take steps to limit the amount of dilation, in order to provide traction to assist in dismemberment; isn't that right?

A. No. I believe my statement is not necessarily that they would take steps to limit it -- that they would not see the

need to dilate beyond that which is necessary to deliver a fetus. It would not make any sense to dilate more than is necessary to deliver a fetus, particularly a smaller fetus, with a smaller BPD at earlier gestational ages.

Q. Doctor, I have just handed you a copy of your expert report, your final version, and if you could look on page eight?

A. I'm on page eight.

Q. Doctor, at the end of the middle paragraph, you state the physician planning to perform a D & E would take steps to limit the amount of dilation of the cervical os in order to provide some traction to assess in the dismemberment process. Isn't that right?

A. That's right. I guess in your world, the term maybe is that it wasn't as artfully phrased as it could have been. My point is that there would be no reason in dilating more than is necessary. So in that sense, they limit the amount of dilation necessary, and the cervix is used as a point of traction to assist in dismemberment, but the point of limiting it isn't solely for the purpose of assisting the process. It's to limit the amount of invasiveness required for the procedure.

Q. And so the steps that you are referring to there that they take to limit the dilation is really not to take anymore steps to achieve greater dilation; is that right?

A. Right. It would be to do as minimally invasive a procedure as possible.
Q. And, in your opinion, the physician has control over the amount of dilation; isn't that right?
A. Well, you have control over how many laminaria you place.
Q. But you said previously, Doctor, that if you place the same amount of laminaria in two different women, even one who is multi -- I'm going to say the word incorrectly.
A. Multiparous.
Q. Multiparous. And one who is nulliparous, you would end up at the same place?
A. I'm not sure I understand the question.
Q. I'll withdraw it, Your Honor. Doctor, in your practice, you have never treated a woman who has had a -- what you call a partial-birth abortion; isn't that right?
A. To my knowledge, I have not treated a woman that's had a partial-birth abortion. I was going to say, I have been asked to review medical cases of women that have had the procedure done, as part of my expert testimony for Congress.
Q. I see. But you didn't rely on those in forming your opinion in this case, did you, Doctor? At least you didn't disclose those us to, did you?
A. Well, I didn't recognize that that was something that I was to disclose. When you're involved for the number of

years that I have been, it's hard to separate out where your knowledge has come from over those years. But as part of my official record which I believe was disclosed, my Congressional testimony, it's included in there that I reviewed clinical scenarios of several women that made their records available that had this procedure done. To comment specifically on the medical necessity of the procedure, the need for it with their particular fetal and maternal conditions, and the potential safety concerns of the procedure.

Q. And Doctor, you perform only a handful of inductions each year; isn't that right?

A. That is not correct, but would need clarification. Induction meaning induction of labor, induction of abortion.

Q. I'm sorry, I mean induction abortions.

A. Induction abortions. I'm not sure how many a handful is, but we frequently, probably on a weekly basis, need to end a pregnancy because of a maternal medical condition. Now, most of those situations are in situations beyond 23 weeks, where we are trying to get an optimal fetal outcome, as well as an optimal maternal outcome. I did four of those cases this weekend.

Q. Doctor, will you look at your deposition on page 258, please. And go to line 21. Tell me when you get there.

A. I'm there.

Q. Okay. Okay. Is the question. Now, is it still the case that in your practice, you do approximately three or fewer induction abortions per year where the fetus is alive at the beginning of the induction? Mr. Coppolino objects. The witness: I'm not sure it's that small, but it's not a large number. I just did one this weekend, but it probably comes up once every few months.

MR. COPPOLINO: Excuse me, Your Honor, objection. Did you say 58?

MS. SMITH: 258.

MR. COPPOLINO: Thank you, Your Honor.

THE COURT: That's fine. Hold on just a minute. Let's make sure the lawyers -- have you got the page? Tell me, Mr. Coppolino when --

MR. COPPOLINO: I am. Thank you, Your Honor.

THE COURT: Go ahead.

BY MS. SMITH:

Q. Is that what your testimony was at your deposition?

A. Yes, but it does require clarification.

Q. Okay.

A. In this line of questioning, I understood the questioning that they were giving me here, since we were referring to fetuses at 18 weeks, and doing D & Es, was that they were referring to pre-viable medical inductions of abortion, meaning those less than 23 weeks. That is a

scenario that comes up in a fewer number where we do maybe a couple of month. And when I refer to I had done one that weekend, it was a scenario of someone who had severe pre-eclampsia at 22 weeks, and we needed to do that. But when you asked the question previously, I understood it as a medical induction to terminate or end a pregnancy, meaning to deliver her prematurely. That is a scenario that comes up much more frequently, something on the order of weekly.

Q. I'm sorry if my question wasn't clear, Doctor. I was asking about induction abortions. Thank you.

A. Induction abortions pre-viable?

Q. Pre-viability. That's correct?

A. That was not my initial understanding. I'm sorry.

Q. As opposed to early terminations of pregnancy post-viability; right?

A. Correct.

Q. We are on the same page.

A. Correct.

Q. Doctor, you have not written any articles about abortion other than partial-birth abortion; is that right?

A. That is correct. I write articles, but that is not the area I generally write about, with the exception of partial-birth abortion.

Q. Okay. And you've not participated in any clinical studies or research about abortion, including partial-birth

abortion; isn't that right?
A. Well, I don't have ongoing research right now, currently in the area of abortion. I do do research and am still doing research on issues related to cervical incompetence, pre-term labor, and premature rupture of membranes, which are some of the areas of concern regarding this procedure.
Q. In relationship to abortion or just those subjects by themselves?
A. Just -- at this point, just those subjects by themselves, but, certainly, a number of those patients have had abortion procedures and they do make up a known risk factor for those out comes.
Q. Doctor, I understand --
THE COURT: Doctor, I tell you what. You need, as best you can, to answer counsel's questions directly or she'll need to begin to be more aggressive, in control. I understand your point, but try to answer the questions directly and to the extent you can, don't volunteer. Thank you.
MS. SMITH: Thank you, Your Honor.
BY MS. SMITH:
Q. Doctor, I understand that you do do some peer review of articles, but you have never peer reviewed an abortion article; is that correct?
A. It is correct that I do peer review, and it is correct

that I have not done a peer review for an abortion article.
Q. Thank you, Doctor. Doctor, the basis for your statement in your expert report that the delivery of an intact fetus prior to 20 weeks gestation, at the time of an intended D & E, is highly unlikely given the fragile nature of the fetal tissue at this gestational age is your experience; is that right?
A. Could I have you repeat the question?
Q. Yes. I'm sorry. I know it's a complicated question. There is a quote in your expert report. Let's start there. You say the delivery --
A. Could I just have you direct me to where the page is.
Q. Definitely. That would have been a useful reference point for you. I actually have your deposition cite where you talk about it is what I have.
A. Should I look at this?
Q. Yeah. On page 76.
A. Where in the deposition now? I'm sorry.
Q. In the deposition, yes.
A. Not the expert report. Okay.
Q. At line 15, it talks about, okay. It talks about your expert report on page six, so we can refer back. And I'm sorry to do this to you, Doctor.
A. Now, back to the expert report?
Q. Yes. At the bottom of page six. Now I don't see it

there. Well, let's come back to that, Doctor. Page seven at the top, the second full sentence, Doctor. The delivery of an intact fetus, prior to 20 weeks gestation, at the time of an intended D & E, is highly unlikely given the fragile nature of the fetal tissue at this gestational age. That's what you wrote; is that correct, Doctor?

A. That is correct.

Q. And that statement is based on your experience performing abortions on demised fetuses; is that right?

A. Well, that's based upon the sum total of my experiences with fetuses of that gestational age that we discussed earlier, because we do do procedures on fetuses of this gestational age that are not necessarily D & E procedures.

Q. Thank you, Doctor. Doctor, I would like to talk a little bit about your opinion that so-called partial-birth abortion is never medically necessary. Your definition of medically necessary is, and I'll quote, necessary to preserve the life of the mother or to improve upon her medical condition over and above any other readily available and commonly used alternatives. Is that right?

A. Could I ask where you are quoting from?

Q. Sure. In the deposition at page one 21.

A. I only ask, because sometimes if I see the context, it will help clarify the question for me.

Q. Line two. Let's try line 10. What do you mean by the

term medically necessary, as you use it in this expert report? Answer: I mean necessary to preserve the life of the mother or to improve upon her medical condition over and above any other readily available and commonly used alternatives. Is that right?

A. That is correct.

Q. And expanding on that, you said that medically necessary means something that quote, adds to the medical armamentarium. That's on page one 22, line six to nine?

A. Okay.

Q. Is that right, Doctor? Do you agree with that?

A. Yes.

Q. So, Doctor, if there were a range of options that were equivalent in risk and equivalent in cost or complexity, then they would all be equally available as an option and you would be hard pressed to justify adding a new alternative; is that right?

A. That would be correct, and that would represent redundancy.

Q. You anticipated my next question. A procedure -- but it's also your opinion, isn't it, Doctor, that a procedure can be medically necessary, even if it is medically redundant, as long as it improves a particular calamity or pathology at a particular time; isn't that right?

A. I believe I had testified that it could be medically

appropriate, but medically necessary means that you don't have other safe or equivalent alternatives available to you.

Q. Doctor, can you look at page 123 on your deposition starting at line five. Question: Are you there, Doctor?

A. I'm there, thank you.

Q. Question: Let's leave aside partial-birth abortion for one minute. If you had another medical situation where there were a range of different treatment options and all of the options were equivalent in terms of risk, cost and complexity, would you say that any single one of those options was a medically necessary option? Mr. Coppolino: Objection: The witness: Well, they are all on their surface medically necessary, if they serve a purpose. They may be medically redundant, but they are medically necessary if they improve a particular, you know, calamity or pathology at that particular time. Do you agree with that statement, Doctor?

A. Yes. I think for clarification, I would say, and I think this came up in the deposition, it would be like having multiple options of a particular antibiotic available to treat an infection. And most hospitals will select one antibiotic on their formulary, since it would be redundant to have multiple options that are all the same. So any one that is the only one available may be medically necessary or medically appropriate. But if you have multiple options

available, you don't necessarily need to have a fourth a fifth or a sixth.

Q. But you also believe, don't you, Doctor, that it's rare that all options are equivalent, because you need to consider things like allergies, cost, availability, patient preference and other considerations; isn't that right?

A. That is true. Again, for clarification, this is a normal process we deal with in the hospital where the hospital has determined -- in the area of antibiotics we are speaking of, the pharmacy and therapeutics committee has determined they, indeed, are equivalent in all of these areas and oftentimes restrict which ones are available to us and which ones aren't.

Q. You also believe, Doctor, don't you, that it's common to review all alternative options and the risks and benefits associated with each of those alternatives, and in cooperation with the patient, to choose the best treatment plan; isn't that right?

A. Well, that is true if the alternative options are available and the risk and benefits are truly known.

Q. Thank you. And you also agree that reasonable physicians can disagree about whether a particular treatment is medically necessary; isn't that right?

A. I think they can disagree about which treatment is the optimal treatment.

Q. Well, do you think they can disagree about whether a particular treatment is medically necessary?
A. I guess I don't understand the question. There are frequently differences of opinions about what is the best approach to take with a particular patient. And that's why patients sometimes seek second opinions.
Q. Doctor, can you look at the deposition on page 126 at line 22? The question is, and can physicians disagree about whether a particular treatment is medically necessary? Answer: Physicians can disagree about the necessity for any medical or surgical procedure. Question: Can reasonable physicians disagree? Mr. Coppolino: Objection: Witness: I believe that reasonable and unreasonable physicians can disagree, but that's why patients sometimes seek second opinions. That was your testimony; is that right, Doctor?
A. Yes. I thought that's what I just said but, yes, it's my testimony.
Q. And you agree with that?
A. I do agree with that.
Q. Doctor, you do not believe that there is a significant body of medical opinion that believes that D & E, not D & X, D & E is sometimes the best option in the second trimester between 16 and 20 weeks; don't you?
A. I'm not sure I have ever said that.
Q. Okay. Doctor, let's look at the deposition at page 137.

MS. SMITH: Your Honor, would you like a copy of the deposition transcript?

THE COURT: Not unless you're going to get in real detail or there is a fight about whether you're being unfair.

MS. SMITH: Okay.

THE COURT: I presume Mr. Coppolino, in that circumstance, would provide me with a copy. Go ahead.

MS. SMITH: I do have one here if Your Honor would like one.

BY MS. SMITH:

Q. Doctor, page 137, line eight. Question: In your opinion, is there a significant body of medical opinion that believes that D & E is sometimes the best option in the second trimester between 16 and 20 weeks? Mr. Coppolino: Objection: The witness: The only data that I know that has been most frequently cited about D & E as an option in the mid trimester has been safety data that now is approaching 20 to 30 years of age. Comparing it to techniques that have been used historically in the past, we now have new options and new techniques that I believe are better. Ms. Gartner: Question: Are you referring to new techniques for D & E or new techniques for induction? Answer: New techniques for emptying the uterus but predominantly induction. Question: But, Dr. Cook, in your opinion, is there a -- leaving aside

the data for a minute. Answer: It's a hard thing to leave aside but I will. Question: Is there -- thinking just about medical opinion in this country, whatever it's based on, is there a significant body of medical opinion that believes that a D & E is sometimes the best option for a second trimester termination? Mr. Coppolino: Objection. I'm sure that there are individuals who believe -- individuals that believe that D & E may be the best option for mid trimester termination of pregnancy. Mrs. Gartner: Okay. Answer: In particular scenarios. Question: Do you believe there is a significant body of medical opinion that believes that D & E is the best option for most women terminating their pregnancy in the second trimester? Mr. Coppolino: Objection. The witness: I do not. Was that your testimony, Doctor?

A. Yes, but, again, I feel the need to clarify it, now that you put it in that context. If you ask me the question is there exist tinge data that people have used looking at the safety of D & E compared to contemporary methods of induction of labor using contemporary agents, I would say there is no such body of evidence, and that's what I was referring to when I said there is not a large body of evidence supporting that.

Q. But that's not what you were asked, Doctor, was it? You were asked whether there was a significant body of medical

opinion. And you were asked to leave aside the data; isn't that right?

A. I did not understand that to be the question. I understood the question being that as it was presented before, that the data has shown this to be true. And I said, no, the data is not contemporary and does not show that to be true. And then when asked to put aside the data, I said it's difficult to do. I'm not sure what you want me to answer.

Q. So, in other words, you don't agree with that statement. Is that what you're saying, Doctor?

A. I would standby the testimony in my deposition. So if you are asking me do I agree with what I attested to in my deposition, the answer is yes.

Q. But, Doctor, in your deposition, you answered the question is there a significant body of medical opinion that D & E is sometimes the safest, and you said, no. And now you're telling me that you misunderstood the question. So I'm just trying to clarify. Did you misunderstand the question, which is one thing, or do you stand by your testimony that there is not a significant body of medical opinion that D & E is sometimes the safest between 16 and 20 weeks of pregnancy?

A. Could I have just a little leeway, Your Honor, to try to explain myself here?

THE COURT: Sure. And, Doctor, I'm going to have her ask a question to you again. She appreciates that you do not agree upon the reliance of the old numbers. What she wants to know is regardless of people who may rely upon those old numbers, are there -- I think what she wants to know, are there doc now, although they may be as misinformed because they are relying on old data, are there docs now who hold competing views on this subject. I think that's what she's asking, because she doesn't want to argue with you or question you now on the old data versus new data. Now, Counsel, put the question to the doctor again.

BY MS. SMITH:

Q. Thank you, Your Honor. The only clarification I would make is that I'm not asking about whether there are just random individuals out there. What I am asking is, is there a significant body of medical opinion that believes that D & E is sometimes the safest for a particular woman between 16 and 20 weeks of pregnancy?

A. I stand by my original statement. When I hear the question significant body of medical opinion, to me that means an informed body of medical opinion and medical opinion that's derived from data. And so when I hear that question, a significant body of medical opinion, to me, that means an informed and accurate opinion. If you ask me are there people that just have that feeling or that sense or

that predisposition or bias, then, yes. There certainly are physicians that believe that. But do I believe that they are making an informed and contemporary data driven evidence-based medicine decision; I do not.

Q. So, Doctor, let me ask you this question. Is there a significant body of medical opinion that holds that induction abortion is sometimes the safest for a particular woman between 16 and 20 weeks of pregnancy, using your definition of significant body of medical opinion?

A. Again, there is data lacking comparing contemporary induction methods versus other methods at that gestational age.

Q. So you would say no?

A. I would say no.

Q. Thank you. Doctor, if you had a woman at 16 weeks who needed to end her pregnancy, and she had a prior scarred uterus, your preferred course would be to do a labor induction using Prostaglandins; is that right?

A. Well, there are many things that come into our decision in that situation, but what I testified to before, most commonly, it's a single scar, low transverse uterine segment. If that's the scenario, yes, I would recommend a medical induction avoiding the use of Prostaglandin E1 or Misoprostol; using Prostaglandins that have been demonstrated as save to use in that specific clinical

scenario.
Q. Okay. Thank you. But you do believe that there are some women for whom a labor induction mid trimester abortion would be absolutely contraindicated because the physiological process of labor is contraindicated, right?
A. I don't know that I made the comment that it would be absolutely contraindicated. There are relative contraindications for certain maternal conditions which could include certain types of previous trauma to a uterus.
Q. Well, Doctor, before we go to the deposition, let me just ask you about two specific examples how about a woman carrying conjoined twins. Is that an absolute contraindication to labor induction abortion?
A. It's not an absolute contraindication, depending upon the gestational age at which you are doing the procedure. It is difficult to do, and is a relative contraindication, when you're talking about doing it late in pregnancy or late in the mid trimester.
Q. And by late in the mid trimester, you mean at what gestational age?
A. Well, I'm always talking about 20 weeks and beyond, because that's how the procedure was designed. And the intact D & E, D & X partial-birth abortion was specifically designed for 20 weeks and beyond. So I'm pretty much always talking about that gestational age.

Q. So, right now, that's what you're talking about with conjoined twins at 20 weeks or beyond, that is one situation where labor induction abortion would be absolutely contraindicated, but not at earlier gestational ages; is that right?

A. Again, I'm not certain about the absolute contraindication. It may be relatively contraindicated. As I alluded to before, I have a conjoined twin pregnancy in my practice right now. One of which has a single child that is no longer living, and the other child is still living. We are intending on trying to do a vaginal delivery for that patient.

Q. What about a woman with an unstable intracranial hemorrhage. Is that an absolute contraindication to labor induction abortion or just a relative contraindication?

A. I would say a relative contraindication.

Q. Doctor, can you go to page 176 of the deposition? Line four.

A. I'm there.

Q. Question: Are there women for whom you would not induce a mid trimester abortion because the process of going through labor is absolutely contraindicated for her? And by that, I mean I'm distinguishing it from the particular chemical agent, but just that the physiologic process of going through labor is absolutely contraindicated. Are

there women for whom you would say that's the case? Mr. Coppolino: Objection. The witness: Yes. That may be the case. Ms. Gartner: Can you give me examples of those situations? Answer: Well, those would be very rare situations. One might be the situation of conjoined twins, another might be a situation of a woman with an unstable intracranial hemorrhage, but there are very few contraindications to labor. And then you go on to discuss some conditions that are not contraindications and some conditions that are relative contraindications. Was that your testimony, Doctor?

A. Yes. I chose the words very carefully, and when I say one might in the situation of conjoined twins and another might be the situation of a woman with an unstable intracranial hemorrhage, I mean there are some situations of conjoined twins and some situations of intracranial hemorrhage where we may choose not to labor the patients. There are other situations of conjoined twins and intracranial hemorrhage where we might allow them to labor. It is an individually determined situation based upon that patient's situation.

Q. So there are some patients with that condition where it would be an absolute contraindication, and there are some patients for whom it's only a relative contraindication. Is that what you're saying, just so I understand?

A. What I'm saying is it's a relative contraindication meaning you have to evaluate each patient individually and decide what you think is the best option. When I say absolute contraindication, an absolute contraindication would be in a situation like a placenta previa, where you can't deliver the baby without excessive bleeding. If I have a patient with an intracranial hemorrhage and she is laboring and about to deliver her baby, I'm not going to stop and do cesarean section just before the baby comes out.

Q. I'm not talking about a situation where a woman comes in in labor, Doctor. I'm talking about a situation where you would induce a labor induction abortion. My question was, if you had a woman with than unstable intracranial hemorrhage, would you induce a labor induction abortion on her.

A. Well, the question was, do you believe -- it says a term of labor is absolutely contraindicated. I don't know if that meant a trial of labor. That was the question put to me in the deposition.

Q. And that's when you said it was absolutely contraindicated, right?

A. That's when I said that this is a situation where it might be contraindicated.

Q. Okay. Doctor, you don't believe that labor induction is absolutely contraindicated in a woman with an inadequate

pelvis that was secondary to some type of trauma, do you?
A. I do not believe it's an absolute contraindication. It may be a relative contraindication. Again, it requires evaluation of individual patients.
Q. Hock. Doctor, let's move on to another situation. Doctor, in a patient who is 22 weeks pregnant, she has unstable bleeding in her brain and a vaginal hemorrhage that cannot be stabilized, and where you decide ultimately you have to empty the uterus. You believe that the optimal way to do that would be to try to deliver the fetus vaginally, i.e., by induction or by facilitation of a natural delivery process that might occur; isn't that right?
A. Are you referring to a particular statement I made somewhere.
Q. Well, yes, Doctor, I am. On page 178.
THE COURT: Doctor, just so you know, I won't let the lawyers -- they have to ask you the question in the way counsel is doing because it's improper for them to go to a deposition and wave it around in the beginning of the question, because it implies that there is something that you have said that is inconsistent. So the lawyers have to put the question to you, irrespective of whether they know you made a similar -- they think you made a similar statement. So counsel is not being cute with you. It's just the way the rules require her to approach it. Go

ahead, counsel.

THE WITNESS: Could I ask a clarify question, Your Honor?

THE COURT: Sure.

THE WITNESS: Is it appropriate for me to ask, when she asks a question that has been put to me in some form before, to try to understand the context in which the question was put to me?

THE COURT: Sure. Within reason, as long as you really are trying to clarify and, sure. If you want to ask her, did I make that statement before or something like that so that you can be -- she can cue you in, that's fine. I just want you to know that the process is not designed to be tricky but respectful. So if you want some clarification, if it's a true clarification, you ask it, and counsel should give to you.

THE WITNESS: I had a specific reason why I asked that, because generally if you are talking about a patient who is having vaginal bleeding and has an unstable maternal condition like bleeding in her brain, then generally the approach we would think is the safest is to go and do an operative procedure to empty her uterus in the most expeditious manner possible, which would be a cesarean delivery or hysterotomy. That's why I was surprised when you said I would deliver her vaginally. So I wanted to know

the context in which I was asked that question.

BY MS. SMITH:

Q. Doctor, that's where I was going. You anticipated where I was going. Because, initially, it may be improper of me to say this, so I won't. But if induction or facilitation of a natural delivery process was the first choice, then the next question was going to be: Your next option would be a hysterotomy, because in your opinion, at 22 weeks, a D & E is very complicated and dangerous procedure; is that right?

A. You're asking me to accept that whole premise. And I agree that hysterotomy was my preferred method, but it's not because I think D & E is inherently a more dangerous method. It's because if a patient is having vaginal bleeding, we don't want to make a bad situation worse by doing more vaginal surgery on her. We want to try to empty the uterus in the most controlled, expeditious manner possible, which would mean emptying it abdominally. Because the scenario, at least always you propose it to me, was the patient unstable also with vaginal bleeding. So it's not because I think D & E is a bad procedure or unsafe on its surface. I think it's not the appropriate procedure for the case you presented.

Q. Okay. So in that case, you would prefer a hysterotomy; is that correct?

A. I believe that would be the best treatment route in the

case you presented.

Q. And actually, Doctor, in your opinion, at 22 weeks a hysterotomy is safer than a D & E; isn't that right?

A. I'm not sure what that is based upon either. What I think I said before, is that when you look at various methods of doing a surgical procedure or emptying a uterus, and you get beyond 18 weeks gestation, all the methods are of similar risk.

Q. Doctor, could you look at page 183? Line 15. And I apologize this is going to be a long colloquy, but I think it's all needed to make sense. Question: Let's say that she has -- she has been diagnosed with breast cancer and she needs to start radiation treatment right away. Answer: Okay. Then I would advise her to wait a few weeks and have Betamethasone or antenatal steroids administered. She could have a viable baby with no impact on her health with her breast cancer question. Question: If she was insistent, she was nervous about letting the breast cancer be untreated for that time period, and she understood your personal view was maybe she should wait, but she was insistent that she felt she couldn't wait, and she wanted your advice about which would be safer for her, D & E or hysterotomy at 22 weeks, what would you advice here. Mr. Coppolino: Objection. The witness: I would advise her to talk to the other medical oncologists to see what their opinion about

the necessity of immediate treatment is. By Ms. Gartner: Question: But if she asked you, would you give her -- if your patient asked you specifically for advice about the safety of two gynecological procedures, D & E or hysterotomy at that gestational age that she was, would you answer her? Answer: I would. But my role is to help take care of the patient. And so she's asking a question that is not the appropriate question. We need to help her ask the appropriate question, and the appropriate question is, does she need to be delivered right now. Question: Okay. And if she said, I understand, Doctor, and I intend -- see, I have an appointment set up with another oncologist. I'm looking into all my options. But I need to be planning. I need to be thinking about it. If I decide I need an abortion, which do you think would be safer for me, D & E or hysterotomy. Answer: Hysterotomy. Was that your testimony, Doctor?

A. It was. Again, I hope you understand I'm answering as I understood this specific case scenario. I did not understand the question to be what is safer at 22 weeks, D & E or hysterotomy. I was understanding the question to be, in this case scenario, what would be the safer procedure. We did cover this ground the that people with breast cancer do more commonly have other problems like anemia, thrombocytopenia, it would make a surgical procedure that is

a less controlled surgical procedure a riskier. A surgical procedure a surgical procedure that is a more controlled procedure like hysterotomy would be the preferred route in this particular patient. But this is not meant to be a comment on the relative safety, or lack thereof D & E and hysterotomy in all case scenarios at 22 weeks.

Q. So, Doctor, it's your opinion a hysterotomy is a more controlled surgical than a D & E; is that right?

A. At that gestational age, for that issue related to bleeding, I believe that it is a more controlled surgical procedure.

Q. Doctor, are you aware of the mortality rates for hysterotomy versus D & E?

A. I'm aware that the hysterotomy and the D & E mortality rates, as I understood them, from the data that has been available that I have reviewed, are similar when you get beyond 20 weeks gestation.

Q. Doctor, can you look at Defendant's Exhibit 577, please?

A. Do I have that exhibit?

THE COURT: Counsel will help you. It's in one of those big books, Doctor.

THE WITNESS: That was number 577.

MS. SMITH: That's correct.

THE WITNESS: Thank you. Small print.

BY MS. SMITH:

Q. I apologize, Doctor. I know it's very hard to read.

THE COURT: You want to put it on the screen, we can magnify it, and Ms. Beran, if you want to help counsel, that would be good.

MS. SMITH: Here is a larger print size.

THE WITNESS: This is the 1985 article from Dr. Corson.

MS. SMITH: Yes.

THE WITNESS: Okay.

THE COURT: Counsel is handing you a larger print version of it apparently.

BY MS. SMITH:

Q. Doctor, this is an article entitled Morbidity and Mortality from Second Trimester Abortions, Grimes and Schultz are the authors. It is a 1985 document. In the first paragraph of the study, the mortality rate - let's see, halfway down in that paragraph, there is a sentence that starts an analysis. Can you read that sentence for me. Do you see that, Doctor?

A. I'm sorry. Could you direct me one more time?

Q. It's in the first paragraph that's italicized.

A. It's in the abstract.

Q. Yes.

A. Um-hm.

Q. In the middle of the abstract, there is a sentence that

says an analysis of abortion mortality. Can you read that for me, please?

A. Yes, down to what level?

Q. Just the sentence itself.

A. An analysis of abortion mortality in the United States from 1972 to 1981, revealed a death to case ratio of 4.9 per 100,000 abortions associated with D & E. 9.6 with installation methods, and over 60 with hysterotomy and hysterectomy.

Q. Thank you, Doctor.

A. Was there a question? I'm sorry. Or was I just supposed to read it.

Q. Is that what the Grimes paper reports, Doctor, the hysterotomy rate is 60 per 100,000, and the D & E rate is 4.9 per 100,000?

A. I'm afraid it's not that simple. They are looking at D & Es across all gestational ages. As I understood what we were discussing, it was the later gestational ages at 20 weeks and beyond. If you look at that data, including Grimes has published and the CDC makes available, the mortality rates become indistinguishable at the later gestational ages. If you look at all D & Es, they'll have a lower mortality rate.

Q. Okay. Doctor. We'll come back to that. Doctor, you testified that it's not -- and this was during your direct,

that it's not accurate to compare D & E to D & X, because D & Es are performed at earlier gestational ages and that induction abortions are performed at later gestational ages. Is that right?

A. That is correct. Well, that's one of the reasons I don't think it's appropriate to compare them.

Q. Okay. Doctor, could you look at Plaintiff's Exhibit 32 and let me help you get that.

A. I think I have it.

Q. Okay. And, Doctor, that's the morbidity and mortality weekly report published by the CDC; is that correct?

A. That is correct.

Q. And that was published on November 28th, 2003?

A. Correct.

Q. And it's entitled Abortion Surveillance: United States, 2000; is that right?

A. Correct.

Q. Have you seen this document, Doctor?

A. I'm not certain that I have.

Q. Okay. Doctor, can you turn to page 32, please, and look at table 18.

A. We are getting.

THE COURT: Is this document in evidence?

MS. SMITH: Not yet, Your Honor. I was going to move it in.

THE COURT: Well, before you question him about it, I suppose we ought to have it in evidence, don't you think?

MS. SMITH: Okay. Your Honor, I would like to move Plaintiff's Exhibit 32 into evidence.

THE COURT: Okay. Is there an objection?

MR. COPPOLINO: I believe there is, Your Honor. I just need to double check my exhibit list.

THE COURT: Do I understand the Government to be objecting to the Government's own publication on hearsay grounds?

MR. COPPOLINO: Probably, we may well be. What's the number. 32. Yes. Hearsay.

THE COURT: Well --

MS. SMITH: I believe that the Government also offered this as an exhibit.

THE COURT: Well, I'm going to overrule the Government's objection to its own publication. It's received.

MS. SMITH: Thank you, Your Honor.

BY MS. SMITH:

Q. Doctor, did you find page 32 and table 18, sir?

A. I got a little confused in the other activity. I apologize, but I do have it now.

Q. Okay. And, Doctor, that's a table entitled Reported Legal Abortions by Known Weeks of Gestation and Type of

Procedure: Selected States, United States 2000; is that right?

A. Yes.

Q. And I believe, Doctor, that you've testified before that when you were talking about later abortions, you're referring to 20 weeks and beyond or around that time period; is that right?

A. Well, yes, that's the time period I chose was that -- was the time period chosen by the practitioners of the procedure we are talking about.

Q. Okay. We'll get to that point later, Doctor, but right now, under type of procedure, the first listing is curettage and in parenthesis, suction or sharp; is that right?

A. Correct.

Q. And if you see the little asterisk on there, if you look down to the bottom, the little cross asterisk says includes dilatation and evacuation. Is that right?

A. Correct.

Q. And then if you go over by weeks of gestation to greater than or equal to 21 weeks?

A. Yes.

Q. The percentage -- do you see the percentage figures there, Doctor?

A. I do.

Q. And it lists 85%, doesn't it, for the curettage

procedures at 21 weeks or greater. Is that right?
A. It does.
Q. And if you add up all the other categories, there is intrauterine saline installation, intrauterine Prostaglandin installation, medical -- which I assume means other types of medical abortions, and even the other category. That adds up to 15.1 percent, doesn't it, Doctor?
A. Well, that would be .1 percent more than a hundred but 15%, yeah.
Q. They must have rounded up or down there. I guess rounded up. So, Doctor, it's true, isn't it, that there are many, many more curettage, meaning D & E procedures, occurring at 21 weeks and greater, than medical induction abortions, isn't that right?
A. I don't agree with that. This is solely reported data, self-reported data, from selected states. I don't believe this represents comprehensively what's happening in this country.
Q. So you think there are maybe -- just look back at the numbers again. They were in order of 7,500 D & E abortions at 21 weeks or greater on here, and maybe a thousand of the others, 1,200 of the others. You think there are another 6,000 medical induction abortions at 21 weeks or greater out there floating around that haven't been reported; is that what you're saying?

A. What I'm say is I don't believe they necessarily inflated the curettage numbers. I think there may be underreporting of the medical termination procedures, because not all of those procedures are listed by providers as terminations, if they are done at a point where the baby has viability, which start at 23 weeks. So I don't think they are reporting those when they are doing medical inductions to deliver a mom at 24 weeks as an abortion procedure.

Q. Right, so my question was, you think they are in order of six, 7,000 unreported installation, rather medical abortions out there not reported?

A. Not installations, but I believe --

Q. Medical abortions?

A. I believe there are tens of thousands of instances of medical induction of labor at 23 weeks and beyond that people are not reporting as an abortion, because they are not doing anything to intentionally destroy the fetus. They are just trying to induce the labor and proceed with having the mother recover from her pregnancy. So I think it's a very misleading statistic, when you're looking at this chart that way.

Q. I see. And that's your intuition, is it, that there are these many, many more procedures being performed?

A. No. We do, in our own hospital, more medical inductions

for 23 weeks and beyond than they have reported for the whole sum total of their United States.

Q. But, Doctor, you're talking about early deliveries; is that right? You're talking about post-viability deliveries. You're not talking about abortions where's the intend is to result in fetal death; is that right?

A. The intent is to separate the fetus from the mother. And if we are talking about how often a medical induction procedure is done, and is it safely done, which is my understanding of what you're asking, it is done by the order of tens of thousands all the time in multiple hospitals around the country and done very safely.

Q. Okay. Doctor, you believe that a partial-birth abortion involves up to ten times the amount of dilation of the cervix than a D & E, is that right?

A. Based upon the submitted testimony of the practitioners of the submitted procedure, yes.

Q. So, Doctor, how would that work if you get -- how many centimeters of dilation do you get in a D & E?

A. Well, generally they would try to achieve something in the order of two or three centimeters, and may try to achieve something more on the order of four to six centimeters or more with the D & X procedure.

Q. But four to six isn't ten times two to three, is it?

A. I was basing that on the number of dilators they place.

They have admitted to placing up to take to 30 dilators. Most practitioners of D & E that I'm aware of may place two, three or four dilators.

Q. So what you meant to say, the dilation involves up to ten times the amount of laminaria; is that right?

A. That is correct.

Q. It's your belief, isn't it, Doctor, that a D & E between 22 and 24 weeks poses significant risks for maternal mortality; is that right?

A. I believe it poses greater risks than those done at the earlier procedures. Earlier gestational ages, I'm sorry.

Q. You believe it poses significant risks, don't you?

A. I do.

Q. Doctor, sometimes when you have performed an induction abortion previously, you have had to perform a D & E; isn't that right?

A. That is correct.

Q. And it's your opinion that in a case where you're performing an induction abortion, and the fetus's head became stuck, and you were forced to perform a D & E to remove the fetus, that a Duhrsen's incision would be a safer procedure in the case of fetal head entrapment than collapsing the fetal skull with forceps; isn't that right?

A. Could I have us just repeat the question one more time? I'm sorry.

Q. It's your opinion, Doctor, that in a case where your performing an a induction abortion, and the fetus's head became stuck, and you were forced to perform a D & E to remove the fetus that a Duhrsen's incision would be a safer procedure, in the case of fetal head entrapment, than would collapsing the fetal skull with forceps?

A. Well, there are several elements there that I don't agree with in your statement and some that I do. When we are doing an induction, and the after coming head becomes trapped, we don't do a D & E procedure. We have multiple options available in order to try to facilitate the remaining portion of the baby to be delivered, meaning the after coming head. And those options include medical treatments of the mother with agents that help relax the uterus, like nitroglycerin is one that be use. One of the other options would be to place after coming forceps on the head. Another option would be to make Duhrsen incisions to create more room for the cervix. Another option would be to do some sort of crushing procedure on the baby's head or some sort of suctioning or evacuation of the fetal brain contents. Those are all options available. Then if you ask me what I believe are the best options, I believe the best options would be the first three. Medical relaxation of the cervix, forceps for after coming head, or Duhrsen incisions. Did that answer your question?

Q. So if the medical relaxation of the cervix didn't work and the forceps didn't work, you would do a Duhrsen's incision; is that correct?
A. That's correct.
Q. You explain to the Court what a Duhrsen's incision is?
A. A Duhrsen's incision is taking a scissor and making a one to two centimeter cut on the cervix. We usually do it either at 12:00 o'clock, or we'll do it at like 4 or 7:00 o'clock, in order to try to avoid the major blood vessels on the cervix. And then if need be, do a surgical or suturing of that area of after the delivery.
Q. So, for example, if this cup is the cervix, you would make incisions like that? Is that right? Around the top?
A. You would make one incision and see if that -- and that frequently is fluff to release the after coming head. And then sometimes we don't even need to repair it, because when a woman delivers, she frequently has cervical lacerations as well, in a normal situations. What we do is if it looks like it's bleeding, we tend to repair it. If it looks like it's not bleeding, we tend not to put suture in it just to reduce the risk for adhesion formation and other manipulation.
Q. Doctor, just to clarify, did you say that the compression would be tried before the Duhrsen's incision or after?

A. In my opinion, it would be a latter choice. It would be a less favorable choice.

Q. Okay. And, Doctor, do you believe a Duhrsen's incision is more gentle than dilation using osmotic dilators?

A. I do believe that that is the case. It's a single incision that's done in a portion of the cervix with immediate repair.

Q. Doctor, is it part of the natural physiologic process?

A. It is observed frequently as part of the natural physiologic process of labor. We frequently see cervical lacerations in that area.

Q. So it's your contention that a Duhrsen's incision is part of a natural physiological process, because sometimes the cervix tears during delivery?

A. That's exactly what I'm saying.

Q. Okay.

A. In the same location.

Q. So, Doctor, is it your contention that a procedure that causes injury to the cervix 100% of the time, meaning one, two or three, one to two-centimeter long incisions through the cervix, with the resulting scarring that would occur because of stitching, is less likely to cause cervical incompetence than slow dilation using osmotic dilators over a period of one to two days?

A. Well, I'm not sure how to answer that. I don't agree

with all of your adjectives. But, yes, I do believe a single surgical incision on the cervix, which is observed as a natural process of delivering a child's head in other situations is a procedure that can be done safely and can be repaired easily and result in good outcomes. It's a very much more complex issue, when you talk about disrupting the integrity of the intactness of the cervix by dilating it forcibly over a period of time. That zone of injury goes to the entire cervix, not just to the area we are making an incision. By correlation, I'm also operating frequently in the past couple of weeks, it seems like, on patients that have cervical cells that are abnormal in their cervix. And during the course of the pregnancy, we are actually removing the lower portion of their cervix. And they seem to do quite well with those pregnancies and subsequent pregnancies. And there are publications looking at people that had prior conizations where they are actual removing a significant lower portion of the cervix, and they still have successful pregnancy outcomes.

Q. So you don't believe a Duhrsen's incision violates the integrity of the cervix?

A. Not to the degree that I believe it does when you're putting multiple laminaria into the entire length of the cervical canal.

Q. Okay. Doctor, moving on, you believe that at about 18

weeks, D & Es become more complicated and require more expertise than you have, is that correct?

A. Well, I believe that they become more complicated in a gradation type fashion, as you get to increasing gestational ages. The further a long you are, the more complicated they are. That means that generally, those are procedures that you would want to have done by people that have the greatest experience at those gestational ages. I do not have personal grade experience at doing D & E procedures at later gestational ages.

Q. And, Doctor, you believe that induction -- I think you testified to this this morning. You believe that induction becomes a safer method than D & E, once you get beyond 20 weeks and certainly beyond 24 weeks; is that right?

A. Well, I believe that the relative benefit of D & E starts to fade away, as you get to the later gestational ages.

Q. And you believe that induction is safer at that point; is that right, after 20 weeks?

A. Induction using modern techniques and modern agents, I do believe, yes.

Q. Are there any randomized controlled trials establishes that induction is safer than D & E past 20 weeks?

A. I'm not aware of any using modern day induction techniques.

Q. And, Doctor, you believe that some of the danger of D & E at these later gestational ages is the difficulty of disarticulating the fetus; is that right?
A. No. There are multiple things that make it more complicated at later gestational ages. A larger more distended uterus, a larger fetus, greater calcification of the fetus. More difficulty disarticulating the fetus, as you mentioned. More cervical dilation than is necessary. There is a number of reasons why it becomes more complicated later on.
Q. Doctor, you believe at the same gestational age, just focusing on the extraction portion of the second trimester surgical procedures, leaving aside the dilation portion, you think D & E and intact D & E are a comparable risk, don't you?
A. I think that the same gestational ages, they are probably of comparable risk. If you are looking only at the issue of extraction. But if you are looking at different gestational ages, it's always going to be riskier at the later gestational ages.
Q. My question was just about the same gestational ages and just about extraction, Doctor. So you would agree with that; is that right?
A. Yeah, I'm sorry. I didn't hear you say the same gestational ages.

Q. Yes. I did.
A. Yes.
Q. Doctor, you have also testified that certain aspects of an intact procedure may be safer than a nonintact procedure such as fewer instrumental passes. The fact that it would be easier to extract the fetus with more dilation and that there would be a shorter time of extraction; is that right?
A. What I believe I testified to in the past would be that an intact D & E or D & X procedure may be a preferable procedure at the same gestational age than a D & E, if you are able to have less need for instrumentation inside the uterus. I don't know that that is always the case in that situation, but anything that can reduce the amount of instrumentation necessary would be a preferable way to deliver. I believe the least number of instrumentation necessary would be medical induction, which is why I think that's the optimal way to deliver.
Q. I didn't ask you about medical induction, Doctor. I was asking you just about D & E and D & X. If you would just answer my questions, okay.
A. Sorry.
Q. Doctor, you have testified that it would be nicer, I'm talking about surgical abortions now. It would be nicer to have a more dilated cervix to work with. A more intact baby with less need for intrauterine disarticulation and

manipulation; is that right?
A. The same answer as before. The less in intrauterine manipulation necessary, the better the procedure, as far as risk would go.
Q. Your main concern with the intact procedure in terms of safety to the woman is with the amount of cervical dilation. You have expressed that on a number of occasions, I think; is that right, Doctor?
A. Again, I'm sorry. We are kind of going back and forth could you repeat that question again?
Q. Yes. Your main concern with the intact procedure is with the amount of cervical dilation; is that right?
A. That is one of my concerns, but it's not the only concern.
Q. Okay. I thought it was your main concern. I understood you also were concerned about the internal podalic version as well?
A. Well, it is my main concern for long-term complications. My main concern for short-term complications is amount of manipulation, internal podalic version, and the things that I have been talking about this last few minutes. You understand I have concerns about the short-term and long-term.
Q. I understand, Doctor. Thank you. Doctor, your basis for saying that partial-birth abortion or intact D & X, or

however you would like to refer to it, is less safe than D & Es is extrapolation, isn't it? You're extrapolating from other data?

A. Well, I'm basing it upon the best data that we have available, which would be the data provided by the practitioners of the procedure. And part of that data is driven by the gestational age at which they are performing the procedure. And then part of it is based upon existing data using similar techniques, meaning internal podalic version and things of that nature. So, yes, some of the risks have to be drawn out or elucidated from other existing data that uses similar techniques or addresses similar gestational ages.

Q. So let's take those things twice. I think you said later gestational ages that the procedure is performed, the so-called partial-birth abortion is performed at later gestational ages. So you could extrapolate from that and see that it would be more dangerous than procedures performed at earlier gestational ages, right? So, Doctor, assuming that you were performing an intact D & E at 22 weeks, and a D & E at 22 weeks, they are at the same gestational age, wouldn't that affect your calculations?

A. My calculations of what?

Q. Your opinion about the relative safety?

A. Well, it would nullify the concern of different

gestational ages, but it wouldn't nullify the other concerns like more cervical dilation, internal podalic version, internal manipulation.

Q. Okay. Thank you, Doctor. Doctor, I am jumping around a bit and I apologize for that. It was a bit of a late night last night. I'm going to jump to another topic then we'll jump back. And I'm not doing it to try to confuse you. I think I'm confusing myself just as much. But I would like to ask you just a few questions about fetal demise and inducing fetal demise in an abortion procedure. In induction abortions, you have never used Digoxin or KCL to induce fetal demise in performing inductions, because you always considered it unnecessary; isn't that right?

MR. COPPOLINO: Objection. Your Honor, to the extent the scope of the witness's expert report matters, the subject is not within the scope of his expert report or was it within the scope of his direct examination.

MS. SMITH: He testified about it at his deposition, Your Honor.

MR. COPPOLINO: He was asked about it at his deposition but it is not within the scope of either his expert report or with the direct examination this morning.

THE COURT: Let me tell you that when I need a colloquy, I'll tell you. And right now, I don't need one, because I'd like to know what the doctor does and doesn't

do. That area wasn't inquired into, but it will help me understand what he does and doesn't do. If you go very much farther than this area, then counsel's point is well taken. So it's overruled.

MS. SMITH: I have four very limited questions, Your Honor.

THE COURT: Well, we'll see.

MS. SMITH: Okay.

THE COURT: The objection to this one is not good, or at least I don't think it is, so you go ahead.

BY MS. SMITH:

Q. Doctor, the question was, in inductions, you have never used Digoxin or KCL to induce fetal demise in performing inductions, because you always considered it unnecessary; is that right?

A. That is not correct. I have not utilized those techniques but not because I consider them unnecessary ever. They haven't been necessary for my clinical situations, because the people that utilize those techniques utilize it so they can guarantee that there is not a live born baby at time of delivery. And, if possible, I want a live born baby at time of delivery. They also may use it to try to induce a demise to facilitate their ability to disarticulate a fetus, and it is not generally the type of abortion technique that I'm using when I need to deliver a woman. If

I did, indeed, feel that my only option available was a disarticulation procedure, I guess I would consider that as an option.

Q. Doctor, my question was in reference to the induction abortions and just to the abortions you have performed. I'm not asking you to opine about whether it would be useful or not in every situation, but just in the induction procedures that you performed. So I'll ask you again. In the induction procedures that you've performed, you have never used Digoxin or KCL to induce fetal demise, because you always considered it unnecessary in those procedures; is that right?

A. You're correct. It would be unnecessary in those procedures.

Q. You agree, don't you, Doctor, that injecting Digoxin or KCL reduces risk?

MR. COPPOLINO: I'll renew my objection, Your Honor.

THE COURT: That will be overruled. You may answer.

THE WITNESS: Every invasive procedure we do entails risk. We do invasive procedures frequently on fetuses, and we frequently inject them with different medications. Is that the question?

BY MS. SMITH:

Q. Yes, thank you. In your opinion, there are some women for whom injection of Digoxin or KCL would carry additional risks. For example, women with known viral diseases such as hepatitis and HIV; is that right?

A. What I was saying is if there is not a need to do an invasive procedure, an invasive procedure carries some risk, then it would be unnecessary and unwise to do it. And I think I was asked in what scenarios might it be a greater risk than others. And I mentioned some of those scenarios might be in a woman has known HIV, for instance.

Q. Thank you, Doctor. Maybe hepatitis also as another example?

A. As another example, that would be correct.

Q. Thank you. And, Doctor, the risks that you are concerned about, the risk to the woman that you're concerned about from partial-birth abortion, they would not be alleviated if a KCL was given minutes before the evacuation, would they?

A. Not necessarily. If the practitioner of a disarticulation procedure feels that they can do it with less cervical dilation, if they inject the fetus first and we don't have to dilate the cervix as much, that would be preferable.

Q. Doctor, you before you believe viability occurs at 23 completed weeks, LMP; is that right?

A. Yes. Would you define for me how you define 23 completed weeks.
Q. That was my next question to you, Doctor. How do you define 23 completed weeks?
A. It's not my definition, but the medical definition of completed weeks means attaining 23 weeks gestation which means 23 and zero. You are then into the 24th week, by the way that they are officially dated, but in a common misunderstanding of weeks, we tend to call people 23 and two/sevenths, 23 and four/sevenths, which means you are more than 23 weeks, but people still call that 23 weeks. Is that clear?
Q. Yes, I think so. So you believe ha that viability occurs at 23.0 weeks. That's what you mean by 23 completed?
A. Well, it's not my belief but is it the existing published data in our large data set which is a Transatlantic database involving hundreds of countries and tens of thousands of babies. So it's not a belief. It's documented data. The survival at 23 weeks currently is approximately 30 to 40% and that's based predominantly -- what I'm telling you from the Vermont-Oxford database that we participate in, along with literally thousands of other neonatal units.
Q. In your opinion a 30 to 40% survival rate means that's viability?

A. Viability means being able to survive independently of the mother outside of the womb with current technology, so yes. That is viability.

Q. What's the survival rate at 22 weeks, Doctor?

A. It's considered by the Vermont-Oxford database as zero. There are people, as I state stated before, that have claimed they have had a 22-week fetus that has survived, although there has been questions about was it an accurately dated fetus, based partly upon the weight and the appearance of the fetus. But the current data, as we speak now, would say that the survival rate is zero. But this is an area that has a lot of active improvement, and so it would not be unreasonable in a few years from now to say there is 30% survival at 22 weeks. But as it stands now, there is not.

Q. Okay. Thank you, Doctor. Doctor, moving onto the area of cervical incompetence. In your opinion the intact D & E procedure, as you deny fine it, poses increased risks of cervical incompetence over D & Es in which the fetus is not removed intact; is that right?

A. What I have said is that I'm concerned about the potential for that increased risk.

Q. That's right, Doctor. That anticipates my next question, which is you said in your expert report that partial-birth abortion, quote, may very well, unquote, pose risk to future fertility; is that right?

A. That is correct. And that's what I'm still saying.
Q. Okay.
A. There is reasonable evidence to inform that opinion.
Q. And so you don't know for sure, as you're saying, you're theorizing, based on the evidence as you see it?
A. Correct. From making my best medical assessment based on the data available to me.
Q. Now, at your -- withdrawn. Doctor, you have not, to your knowledge, I think we may have covered this already and I apologize if we have. You have not, to your knowledge, cared for any woman with cervical incompetence that has had what you know to have been a quote partial-birth abortion; is that right?
A. That is correct. I have not care for such a patient directly that I know that that's the procedure she had done. I have been asked to review medical records, again, of a person who had this procedure and subsequently had that type of complication.
Q. Doctor, at your deposition, you based your opinion about cervical incompetence on two articles, the Audu article and an article from France by Henriet. H-e-n-r-i-e-t, is that correct?
A. I'm not sure that I stated that the sum total of my concern for cervical incompetence came from those two articles. I think those were just two articles that were

included, amongst other articles, to support some of my expert report.

Q. Well, Doctor, let's look at your deposition at page 226. On line three.

A. Okay. I'm there.

Q. Question: And just to clarify, Doctor, other than these two articles we are going to talk about now the British Journal article and the Audu article, can you recall any other data sets that you've looked at that indicate a connection between mid trimester abortion and cervical incompetence? Answer: Not that I have recently reviewed. So at least at your deposition, Doctor, the only two that you pointed to were Audu and Henriet; is that right?

A. Yes, but it does neat clarification. When she says data sets, I include the article and the supporting bibliography of that article in the data set. So there are other individual articles, referenced, for instance in the French study, that do refer to other supporting evidence.

Q. Thank you, Doctor. And those were the only two articles that you listed in your expert report; isn't that right, Henriet and the Audu? A-u-d-u?

A. I did list other articles.

Q. And cervical incompetence. Those were the only two listed; is that right, Doctor?

A. Those are the only two that addressed issued related to

pre-term delivery, yes.

Q. Doctor, you indicated that the studies on which you based your concerns about cervical incompetence or subsequent -- in subsequent pregnancies looked at first trimester procedures; isn't that right?

A. Not all of them, but the predominance of that data has been from first trimester.

Q. The Audu and Henriet article particularly, is that right?

A. Correct. The Audu article -- I believe I'm confused by the authors. I refer to them as the journals, but the British Medical Journal --

Q. That would be Henriet.

A. Or the British Journal of OB/GYN, that article did reference -- one included data sets from the mid trimester as well.

Q. Doctor. You mean it included it in the study or in the references it cited to?

A. It included it in the references which I included in my response to question data sets.

Q. Okay. Doctor, you believe that the -- let me go on. Let's just go right to the Audu article. If you could look at defendant's Exhibit 544?

THE COURT: Counsel, I'm willing to take a break whenever you tell me.

MS. SMITH: This would be a fine time.

THE COURT: All right.

MS. SMITH: Because this is going to be a rather long -- I think we have got a few articles to go through, so we could stop now.

THE COURT: Give me a sense about the doctor's travel plans. Incidentally, did our fellow yesterday make his airplane?

MR. WARDEN: He did.

MR. COPPOLINO: Yes, the same flight, 6:15 out of Lincoln.

THE COURT: Well, give me a sense, Ms. Smith, about --

MS. SMITH: Well, I am -- I think I am more than halfway through, Your Honor. And I think it will go much faster after we get through the next piece.

THE COURT: Okay. Well, let's -- I'll ask the Government to have whoever they had stand by yesterday to run the doctor out to the -- I suspect he'll be in the hospital tonight, but out to the airport. And we'll try to get him there for his airplane. Let's everybody try to do that. We'll take a break until 3:30. We'll start again promptly at 3:30.

THE WITNESS: Your Honor, would it facilitate things for me to know which articles are going to be

addressed and review those quickly beforehand.

THE WITNESS: That's a good idea, Doctor.

MS. SMITH: We are going to talk about the Audu article which is 544.

THE WITNESS: Okay.

MS. SMITH: Henriet is 49 or 585, I'm sorry. It should be in that same one.

THE WITNESS: Got it.

MS. SMITH: Those are the next two we are going to discuss.

THE COURT: All right. Thank you. We'll stand in recess until 3:30.

(Recess from 3:15 to 3:30 p.m.; all parties present)

THE COURT: Please be seated. Counsel, I will have a couple of questions for the Doctor, two or three, but it won't take very long, but please give me five or ten minutes, maybe, at the end of the day.

MS. SMITH: I actually spent a little bit of my break taking questions out of the cross-examination and shortening it, Your Honor.

THE COURT: That's marvelous.

THE WITNESS: It's much appreciated by all.

BY MS. SMITH:

Q. Doctor, let's talk about the Audu case now. That's a Defendant's Exhibit 544.

A. I have it.
Q. And can you tell me what the title of that article is, please?
A. Diagnostic Features of Cervical Incompetence Amongst Women in Maiduguri.
Q. And, Doctor, Maiduguri is in Nigeria; is that correct?
A. That's my understanding.
Q. And that study was a retrospective chart review; is that right?
A. It was a retrospective study evaluating people with cervical incompetence and looking at risk factors associated with that.
Q. And out of the 141 records reviewed, only seven women had a history of previous induced abortion; is that right? I believe that's in table 2.
A. I don't think that is correct. They had 141 patients total and 113 that had a previous mid trimester abortion; and 48 had two, 50 had three or more.
Q. How many had induced abortions, Doctor?
A. Oh, I'm sorry. This is that same misunderstanding of the terminology. Abortion by the technique of induction. I apologize. I would have to look back at the table again. Where was that you were referring to?
Q. Table 5 or table -- sorry -- table 2, number 5.
A. Yes. I assume when they say induced abortions, they are

talking about by medical induction. Yes. Seven is correct. I'm sorry.

Q. Doctor, do you think it's by medical induction, or do you think it's by -- These were first trimester procedures; don't you think?

A. I would have to look at that specific part of the data. I don't see that it clarifies that. The focus of the article is on people with previous mid trimester abortions and consecutive mid trimester abortions, and 80% had prior mid trimesters and 30% had consecutives, so that's where I focused my reading of the article.

Q. That's not a discussion of induced abortion; is it? That doesn't prove anything about the impact of induced abortions?

A. Abortion by induction, medical induction, is that what you're asking? I'm sorry. I'm just unclear about the question.

Q. I think abortion is defined as a loss of pregnancy in this case; right, as opposed to induced abortion which is how I understood you to use the language previously.

A. I can maybe clarify. When we talk about the term induced abortion, it is in contradistinction to a spontaneous abortion or miscarriage, so induced abortion by any method, when I say induced abortion, this article's focus is on people with mid trimester abortions, and they

looked at those that had them, and those are the numbers that are presented.

Q. Including miscarriages and spontaneous abortions; is that right, Doctor?

A. In the total number.

Q. Yes. Well, in table 2, Doctor, where it says previous consecutive mid trimester abortions, that is referring to miscarriage and spontaneous abortion, isn't it, as opposed to number 5 which is previous induced abortion which, as you pointed out, is an abortion other than a miscarriage; is that right?

A. They don't say spontaneous abortions here in that table.

Q. Do you understand table 2, number 2 and number 1, to include induced abortions as you have defined them?

A. That was my initial understanding.

Q. And number 5 which says previously induced abortion would be what?

A. Initially, I thought that meant by induction, but I may have a misunderstanding of the way they are presenting their data.

Q. Doctor, there is no indication in this article of what means of dilation was used; is there?

A. They do not comment.

Q. In any abortions, whether we talk about the induced abortions or however many there were, there is no indication

of that at all, right?
A. The specific type of procedure done is not commented on. It's the just the gestational age at which it occurred.
Q. Thank you. And Doctor, in the French study, the Henriet study, that's Exhibit 585?
A. I have that one now.
Q. That looked just at first trimester abortions as well; didn't it?
A. That is correct.
Q. And they didn't discuss there what type of dilation was used; did they?
A. They did not.
Q. Now, Doctor, I believe you said earlier in your direct examination that there was no study of the impact of osmotic dilators in second trimester abortions; is that right?
A. I'm not sure I recall that exactly. Was that in response to a particular question.
Q. I don't remember what question it was in response to. Is that your belief that there is no study of the impact of osmotic dilators in second trimester abortions, Doctor?
A. I don't know that there is any study specifically looking at the issue of osmotic dilators. There are studies looking at the issue of having had a procedure or not having had a procedure, having had multiple procedures and having had later procedures.

Q. Doctor, could you look at Defendant's Exhibit 596, please? Do you have the binder there for that, please?
A. I'm working on it. I'm sorry. May be a different one. This is 587.
Q. This is it.
A. Thanks.
Q. Are you there, Doctor?
A. I am here.
Q. Doctor, that's a study by Drs. Kalish, Chasen and others entitled Impact of Mid Trimester Dilation and Evacuation on Subsequent Pregnancy Outcome. Is that right?
A. Correct.
Q. And that article was published in October of 2002; is that right?
A. I'll assume it's correct. I don't see the date right this very minute.
Q. And this study looked at -- Have you seen the study before, Doctor?
A. I don't recall seeing this one, no.
MS. SMITH: Doctor -- Your Honor, rather, I would like to offer Plaintiffs' -- Defendant's Exhibit 596.
MR. COPPOLINO: Objection.
MS. SMITH: And again, Your Honor, I'm offering it for, not for the truth but for evidence of the debate in the medical community.

THE COURT: I'll reserve ruling on that as I have for all of the similar articles.

MS. SMITH: Thank you.

BY MS. SMITH:

Q. Doctor, this study looked at women who had abortions between 14 weeks and 24 weeks LMP; is that right?

A. That is correct.

Q. And the patients in that study all received laminaria over at least 24 hours; isn't that right?

A. I haven't read the article so I'll take your word on it.

Q. And, Doctor, if you look on page 883, I think you can see the laminaria regimen that patients having abortions over 20 weeks or with a BPD of 45 millimeters usually had two sets of laminaria over 48 hours?

A. I'm sorry. Where on 883?

Q. That's on page 883 on the left-hand column right at the top, first couple of sentences.

A. Okay.

Q. And if you look on page 885, Doctor, in the left-hand column there, and actually, Doctor, if you look at the top of that page, you can see that this was published in the American Journal of Obstetrics and Gynecology, volume 187, number 4; is that right?

A. That is correct.

Q. Now, Doctor, in that left-hand column about two-thirds

of the way down, there is a sentence that begins when greater. Could you read that sentence, please?

A. When greater cervical dilation -- is that correct?

Q. Yup.

A. When greater cervical dilation is achieved with laminaria, pre-term delivery in future gestations appears less likely possibly because of a decrease in cervical trauma.

Q. That was the conclusion of this study; is that right?

A. That's an editorial statement made that I don't know is supported by this data. There are a very small number of people included, and just prior to that, they review data that would contradict that.

Q. And this was published in a peer review journal; is that right?

A. That is correct.

Q. Doctor, I just have a few last questions for you, believe it or not. Doctor, you said you're a member of PHACT. That's P-H-A-C-T; is that right?

A. I was one of the members that initially formed it, yes.

Q. So you were one of the founders; is that right?

A. I suppose you could describe it that way.

Q. And that PHACT describes for Physicians Ad Hoc Coalition for the Truth; is that right?

A. That is correct.

Q. I believe you testified that that was a group that was formed specifically to address issues around partial-birth abortion; is that correct?
A. Yes. That's why we chose the term ad hoc, like an ad hock committee, you know, to just a particular point.
Q. Thank you, Doctor. And, Doctor, were there any members of that group who provide D & Es in the second trimester on live fetuses on a regular basis?
A. I believe that there are.
Q. Do you know who?
A. Well, there again were over 400 physicians involved, and I know some of the physicians were physicians that did perform abortion techniques, and I have no reason to suspect they don't do mid trimester abortion techniques as well.
Q. On a regular basis, or are you referring to someone like yourself who performs maybe four or five of them in their career?
A. Well, it was never our prerequisite to be involved that you had to do a certain number or not do a certain number.
Q. Yeah. That wasn't my implication at all. I'm just asking whether there were, whether you know if there were, and you can tell me who they were.
A. Well, the person that first comes to mind would be Dr. Frank Baum who does do terminations of pregnancy who was involved, and I know that there were other individuals that

also do terminations of pregnancy that were involved, but I was never one in possession of an entire list of all the physicians, nor did I communicate with all the physicians. That wasn't really my role.

Q. Thank you, Doctor.

THE COURT: Is this the Frank Baum at Vanderbilt.

THE WITNESS: That is the same one.

THE COURT: Thank you. Go ahead.

BY MS. SMITH:

Q. Doctor, you submitted written testimony, as you I think testified earlier, in favor of the Congressional bans on partial-birth abortion in both 1997 and 2002; is that right?

A. That is correct.

Q. And you were consulted by the staff of certain members of Congress and asked to do that; isn't that right?

A. I was asked by the specific committees to do that.

Q. Thank you. And you suggested that the Act be limited to procedures performed after 20 weeks; isn't that correct?

A. Well, it's part of the discussion regarding this procedure, particularly after the previous Carhart decision, I was asked as were others to give advice on how we could write a better Bill, how we could most narrowly define the procedure, and so I put forward several recommendations, some of which became incorporated, some of which did not.

Q. I didn't ask that, Doctor. I asked you whether or not

you suggested that the Act be limited to procedures performed after 20 weeks. That was my question. Did you or didn't you?

A. I did make that as one of the suggestions. I was trying to put it in context. I'm sorry.

Q. Thank you, Doctor. And that suggestion was not followed; is that right?

A. That is correct. It was not followed.

Q. And, Doctor, you have also testified in support of partial-birth abortions statutes in cases challenging such laws in Michigan, Missouri and Wisconsin; is that right?

A. That is correct.

Q. Any other states, Doctor, that I left out?

A. Well, in Wisconsin I didn't testify, but I think I submitted an affidavit of merit or something. I don't know the correct legal term.

Q. A declaration?

A. Declaration.

Q. Okay?

A. I testified in Missouri, and I testified in Michigan.

Q. Thank you. And, Doctor, you are being compensated for your testimony here today; is that right, $500 a day, I believe it is for actual testimony?

A. Well, I haven't received any compensation, but they assure me I will.

Q. And $250 a day for other work that you do on the case; is that right?

A. That has been my understanding.

Q. And then your travel expenses as well?

A. That's correct.

MS. SMITH: Your Honor, if I could just have a moment.

THE COURT: Sure.

MS. SMITH: Your Honor, I may have neglected to offer the Dr. Grimes article into evidence. Did I, Defendant's Exhibit 577?

THE COURT: Well, the Grimes article, you have also got that listed, too, don't you? Hang on just a minute.

MS. SMITH: And Defendant's Exhibit 545 the Autry article, I think that may have already been moved as a Plaintiff's Exhibit though. I think that was.

THE COURT: 577 is the old Grimes article; right?

MS. SMITH: Yes.

THE COURT: Yeah, and I take it once again, you offered both for the truth, and if not the truth, for understanding the parameters or the so-called debate; right?

MS. SMITH: That's right, Your Honor.

THE COURT: I'll reserve ruling, and there is only a hearsay objection. What was the other one you wanted?

MS. SMITH: I think I already offered 596; is that

right, the Kalish article?

THE COURT: You did, and I reserved ruling on that.

MS. SMITH: Thank you.

THE COURT: Mr. Coppolino.

REDIRECT EXAMINATION

BY MR. COPPOLINO:

Q. Dr. Cook, near the end of Ms. Smith's examination, she noted you testified in some other cases concerning partial-birth abortion act bans enacted by various state legislatures. I believe you testified in a few cases that are listed in your expert report, the case in Michigan, case in Missouri, and you may have submitted affidavits, it appears, in Wisconsin and Alaska. Why did you offer your expertise to those courts in those cases?

A. Well, I was contacted by somebody at the state level regarding my willingness to provide some support of information for the legislation that they were attempting to enact in their particular state, and sometimes I was available and sometimes I was not.

Q. It's fair to say, Doctor, where this issue has come up, you have been willing to provide various federal courts here with your expertise on it; is that correct?

A. That's right, I have always tried to be available when I could.

Q. Is it fair to say as we look back over the four cases

that you've testified in in federal court and twice before Congress, this is an issue that concerns you; is that correct?

A. It's is an area that I'm concerned about.

Q. You mentioned a moment ago that you had made a suggestion to Congressional staff regarding a 20-week gestational line, and you wanted to add some context to your answer. Why don't you add that context now?

A. Well, I was just trying to explain how that particular issue came up. I was asked my opinion about how they could improve the writing of the Bill, and specifically in the area of narrowly focusing on this procedure and this procedure alone, and I made some suggestions including things like anatomic landmarks, and, you know, things regarding intentional or volitional destructive procedures, some things like that excluding things like completing a normal, you know, vaginal delivery, and I also offered a gestational age limit to try to bring some greater narrowness to the definition.

Q. Okay. I would like to just go through a couple of the articles that Ms. Smith asked you about and either clarify or further obscure the record on them. Let's start with Dr. Grimes' article, and you know you may have it there in front of you?

THE COURT: You can have continuing leave, yes.

You're talking about 577, the older Grimes article?

MS. SMITH: Yes, I believe so, Exhibit 577.

THE WITNESS: That's in here . I have it here in the small print version.

BY MR. COPPOLINO:

Q. Okay. Ms. Smith called your attention to a sentence in the abstract at the beginning of the article that discusses the abortion mortality in the United States for various procedures including hysterotomy and hysterectomy. Do you see that sentence?

A. I see it.

Q. And the sentence, the portion of the sentence which specifically refers to hysterotomy also refers to hysterectomy; is that correct?

A. That's correct.

Q. Now, you previously discussed in response to Ms. Smith's question the relative risks of D & E and hysterotomy at greater than 20 weeks. Why do you think that hysterotomy is as safe as D & E after 20 weeks?

A. Well, the thing that's misleading about the Grimes data here is, again, including D & E across the gestational ages, and also, when you lump hysterectomy and hysterotomy together, those are usually uniquely reserved for certain higher risk or inherently risky situations, specifically hysterectomy usually means somebody has already had

significant bleeding or invasive cancer or something else that would already predispose them to more complications, so I think that data is misleading but also not contemporary. If you look at just the performance of a hysterotomy, I believe that those risks in and of themselves are inherently similar to the risk of D & E based upon the increasing complications related with D & E at later gestational ages.

Q. All right. Doctor, now, you were asked a question about the Audu article which is in front of you there. Could you remind me of the exhibit number on that article?

A. It's 544.

Q. Defendant's 544. I just want to -- I want you to turn to the chart, table 2, that Ms. Smith was asking you about, appears to be on page 131 of the article.

A. Okay.

Q. A question arose as to what the induced abortions referred to. Now, let me just go back and clarify. Earlier when I was asking you questions and the phrase induced abortions came up in reference to articles studying long-term complications of abortion, you testified that that phrase in that context included all methods of abortion; is that correct?

A. That's correct.

Q. Now, it's not clear, and Ms. Smith asked you whether in table 2 where it also refers to the term induced abortions,

is that referring to abortions by all methods?
A. That wasn't clear to me in my initial review of the article.
Q. Take the look at the first paragraph under results and read where it says -- you can read where it says as shown in table two. Just read that to yourself down to the end of that paragraph.
A. As shown in table --
Q. Do you want it on the record? You can put it on the record. Go ahead read it out loud.
THE COURT: That's fine.
THE WITNESS: I'm sorry. As shown in table 2, the most common obstetric history was of a mid trimester abortion. This was found in 80.1% of patients. In 98 patients or 69.5%, there is a history of consecutive mid trimester abortions representing 86.7 of those with a history of mid trimester abortion.
BY MR. COPPOLINO:
Q. Do you want to continue to the end of the paragraph?
A. Oh. 68 or 50.7% of patients had pre-term deliveries, 42.6% of which occurred at least three times while 65 or 46% had a cervical cerclage inserted in a previous pregnancy. Says only seven patients submitted to a dilatation and curettage for termination of pregnancy.
Q. Does that shed any light on what the seven abortions

referred to in number 5 on table 2 is referring to?
A. It seems to imply that seven patients had a termination of pregnancy in this situation by the method of dilatation and curettage.
Q. Ms. Smith also asked you some questions about the Kalish and Chasen article, Defendant's Exhibit 596. You had not read that article prior to today; is that correct?
A. That's correct.
Q. You've not read the entire article as yet; is that correct?
A. That's correct.
Q. All right. Would you take a look at page -- well, it's the third page of the exhibit, and I believe it's page 884.
A. The number, one more time, is 596?
Q. Yes. I'm sorry. 596.
A. And I have page 884.
Q. Down at the bottom of the right-hand column, there's a paragraph beginning our study reviewed, and I would like you to read that paragraph which begins our study reviewed.
A. Our study reviewed the medical records of 600 patients who underwent a D & E procedure and revealed 96 subsequent pregnancies at our institution. The patients undergoing D & E were referred from physicians at our institution as well as from physicians affiliated with other hospitals. After the D & E, most patients returned to their referring

obstetrician for future obstetric care. We did not assess subsequent pregnancy outcomes of patients delivered at other institutions. Although these patients were not included in our study, we believe that significant bias as a result would be unlikely.

Q. Wouldn't that affect, that last part that we just read, the fact that they didn't follow up with all of the patients involved, wouldn't that affect any conclusions regarding this study regarding the relationship between D & E and pre-term birth?

A. Well, that was my point about the limitation was that of the 600 patients he reviewed, they only had follow up on 96, and only 77 of them actually delivered, meaning the other ones had miscarriages, ectopics, what-have-you.

Q. Okay. Doctor, small point, but you mentioned to Ms. Smith that you had reviewed some medical records in connection with your testimony before Congress. I believe she suggested that you had not disclosed that in your expert record. Do you have your expert report up there?

A. I do.

THE COURT: Would you help the witness with the documents? He's trying to hold big books and look at a bunch of stuff.

THE WITNESS: I have it now in front of me.

BY MR. COPPOLINO:

Q. And look under where it says item 9, information considered in forming my opinions. In addition to my extensive experience in maternal fetal medicine and the materials I considered prior to my Congressional testimony, I have specifically considered the following materials in forming the opinions stated in this report. Is that sentence in the expert disclosure report that you provided in this case?

A. It is.

Q. All right. Now, you were asked some questions about induced fetal demise and possible risks of that procedure. Do you perform procedures that involve injections of medications into the uterus?

A. I do.

Q. Do you perform other procedures that involved injections into the uterus?

A. I do. We perform needle procedures into the uterus on a regular basis.

Q. Could you discuss the risk of those procedures?

A. In general, when we are putting a needle into the uterus, there is approximately a 1 in 200 to 1 in 500 chance of losing the pregnancy from a complication such as breaking the bag of water, causing an infection, bleeding, contractions, things of that nature. If we are giving medications specifically for transfusing a fetus directly,

then there is approximately a 1% mortality risk associated with that procedure. Fetal mortality risk. I'm sorry.

Q. Would losing a pregnancy through an injection where the intent is to kill the fetus in the first place be a complication of that procedure?

A. If the intent is to kill a fetus, that would not be a complication. There are potential risks for infection and maternal sepsis whenever you're injecting into a woman's abdomen, and -- but I believe the risks are fairly small.

Q. Doctor, for an injection of Digoxin for women with cardiac conditions, you would agree that most women with cardiac conditions would tolerate Digoxin well if it was given to them directly, and in this situation, you're giving Digoxin locally to the fetus, so the amount of maternal exposure would be quite small. Would you agree with that statement?

A. I would agree there are very rare cardiac conditions that would not tolerate Digoxin in pregnancy or any time, but even so, the woman's exposure is minimal.

Q. Doctor, one last question. I would like you to tell the Court, given your limited number -- given the limited number of D & Es that you performed on living fetuses, what assistance can you offer the Court concerning the medical issues raised by the Partial-Birth Abortion Act based on your expertise as a maternal fetal specialist?

MS. SMITH: Your Honor?

THE COURT: Yes.

MS. SMITH: I think that's outside the scope of the cross.

MR. COPPOLINO: It isn't. She asked him about a number of D & Es, Your Honor.

THE COURT: Mr. Coppolino --

MS. SMITH: I didn't object to the leading question.

THE COURT: Well, you have got to lead on redirect anyway.

MS. SMITH: Okay.

THE COURT: And that just sort of as an aside, when I taught trial advocacy, that question on redirect is what you always wanted to ask. It was the throat open to your expert question so he could give you the summary at the end.

MR. COPPOLINO: So you can't blame me then; is that what you're saying?

THE WITNESS: I didn't say I couldn't blame you. All I'm saying is what I taught my students to do, and when the objection came, I taught them how to handle it and --

THE WITNESS: How was that?

THE COURT: Hang on, Doctor. You're going to get a chance to answer this in a minute. I told them to just keep refining it until it got within the scope.

MR. COPPOLINO: Okay. Let me give that a shot.

THE COURT: No, I think the question is fine. Go ahead and answer it.

MR. COPPOLINO: Did you hear my question?

THE WITNESS: Could I have the question repeated one more time?

BY MR. COPPOLINO:

Q. My question is, given the number of D & Es that you have performed on living fetuses, what assistance can you offer the Court concerning the medical issues offered by the Partial-Birth Abortion Ban Act of 2003 based on your expertise as a maternal fetal medical specialist?

A. Well, I think there are many areas that we can be helpful in trying to evaluate this procedure because we do take care of just complicated pregnancies, complicated by maternal conditions and fetal conditions, and we do that as parts of our regular practice. I think we can comment on the medical necessity and availability of other safe alternatives, particularly in unique complications of mothers and fetuses. I think we can comment on what are ways that we would manage complications of other types of techniques and thus have an understanding of what are the risks for complication of some of these other techniques, and because we do perform other techniques, even on a limited basis, we do have firsthand experience with those

procedures.

Finally, I think that we have a very good understanding of the fetus in general because it is one of our patients, so we have an understanding of fetal tissues, fetal responses, fetal discomfort and the size of fetuses and the various challenges that come up at various gestational ages. In the rare situation where we do feel the need to make a choice, then we would always choose the maternal situations, a situation that we would want to optimize. And in those situations, we want to deliver the mother in a manner that is safest for her and in a manner that she would best tolerate, mostly because she has underlying concerns at that time if we are going those kind of procedures, and we would still like to do that with a certain level of respect and concern for the fetus who has also been our patient. We just can't continue to advocate or help that patient at this time.

MR. COPPOLINO: Thank you, Your Honor.

EXAMINATION

THE COURT: Thank you. Doctor, before you leave, and I appreciate you have got an airplane to catch, I have a few questions. I realize that your reading of the McMahon and Haskell articles, among other things, have caused you to focus on 20 weeks and after. However, I have heard evidence in this case in which an earlier gestational age has been

mentioned, and I want to ask you some questions about that briefly, and here is the circumstance.

You have got a woman and a fetus 17 weeks, you want to do a standard, I mean, you typically do a D & E, whatever dilation you typically use for that. You go in to do the D & E, and in a certain number of cases, the fetus delivers in one pass all except for the head which hangs up in the internal cervical os. As a physician, what are your alternatives at that point?

THE WITNESS: Well, I think that was a question that was put to me by plaintiff's counsel, I believe. If you are in that situation and we have encountered that situation, I have encountered that situation before.

THE COURT: Um-hm.

THE WITNESS: We were inducing a pregnancy and everything delivers by the after coming head.

THE COURT: Right.

THE WITNESS: Most often, it's sort of a benign neglect. What I mean by that, if we just let the woman continue to labor over the next several minutes, she generally passes that baby on her own, and that's usually the preferred method because it's the least invasive method. However, I have been in that same situation where the woman is having more bleeding, and we're concerned about the need to proceed more rapidly to delivery, and that's a situation

where we have utilized things like IV nitroglycerin, or less often, forceps. Usually it has been more often IV nitroglycerin. If necessary, a single incision on the cervix. I have never been, myself, in a situation where I have had to do a compression or crushing or aspiration procedure to accomplish that.

THE COURT: So in the case of, and I appreciate that, and I don't want to use value laden terms. If I use a value laden term that you object to, you tell me, but I appreciate that you don't do elective abortions, but in the circumstance where and elective abortion has taken place, is being conducted and we are at that 17th week and the head hangs up at the cervix, do you think it's medically reasonable for the physician performing that procedure to wait to see if the 17-week-old fetus delivers through labor?

THE WITNESS: Well, I guess it would depend upon what length of time you're talking about trying to wait. If I was in the situation, let's say I'm in an offsite clinic, and I have a healthy mother, and we are doing an elective termination for whatever reason, and everything is delivered but the after coming head, my response generally would be to stock something which is very quite simple to stock, like IV nitroglycerin, have my assistant give her 50 micrograms of that initially to see if it loosens the cervix, and if not, do what I can to manipulate the head out of the cervix which

could include a single small incision on the cervix.

THE COURT: And if that doesn't work?

THE WITNESS: If that doesn't work, at that point a fetus is not able to still be alive because it's now been hanging out for some number of minutes with complete occlusion of the cord, so if you felt at that point you had to do some sort of a procedure to let the head come out, then if you had to do a crushing procedure or an aspiration procedure, the fetus wouldn't be alive, and it wouldn't be covered under this Act.

THE COURT: Well, it would be alive, wouldn't it, if for, if one couldn't cut the cord at that point.

THE WITNESS: It's not the cutting of the cord. Again, I have seen many fetuses in this exact situation. They just can't survive in that case because they are still attached by their cord to the placenta, and if all that is out is but the head, there is complete occlusion of the cord, and there is data, for instance, in Rhesus monkey trials where they do complete occlusions of the cord. After five minutes, every fetus has acidosis. After 15 minutes, no fetus survived. You can't completely occlude a cord for more than a few minutes and still have a live fetus.

THE COURT: And by occlusion, you mean the pressure --

THE WITNESS: Compression.

THE COURT: The compression of the cervix on the cord and the skull presumably.

THE WITNESS: Right. When you have been in that situation, the cervix is quite tight around the baby's head, so it's complete compression of the cord. That's why a single incision is sometimes helpful on the cervix.

THE COURT: Right, so at that point, the physician either waits for the fetus to die because of the occlusion that you have described, or if that waiting becomes unacceptable, the physician does the cervical incision that you have spoken about; is that right.

THE WITNESS: Well, I personally would go with the medical treatment first because it involves no invasion like IV nitroglycerin. There are other agents as well.

THE COURT: Okay.

THE WITNESS: And we use that in other areas of obstetrics. If the placenta comes out or the uterus comes out, we have to push it back in or if the shoulders are stuck or whatever, so I would do that first. Then you could do an incision if necessary. To me, the least beneficial option is to do something that involves aspiration or a crushing because it does still expose the cervix to that, you know, the risk of that skull fragments and all those sort of things you would like to avoid if you could, plus I think it doesn't seem to me to be a very humane way, you

know, to treat a fetus notwithstanding it's no longer living.

THE COURT: All right. You recommended to Congress that they limit the reach of this Act to 20 weeks and forward. Was the circumstance that you and I have just discussed among the concerns that you had?

THE WITNESS: It was really, to be quite honest, to just alleviate a large number of discussions and battles over the vagueness argument that I think personally sometimes is made in a somewhat disingenuous fashion to say, oh, this could include miscarriages in the first trimester. I think you could have just put that all to the side by saying, no, this starts at 20 weeks. That was really my purpose in suggesting that you could just alleviate all those discussions about the earlier gestational ages. It wasn't because I felt this procedure needed to be made available for 16, 17 or 18 weekers. I don't believe that it does, but I was merely trying to make the argument simpler.

THE COURT: All right. So from, and I don't mean to, this is not pejorative, but from your point of view, it was tactical.

THE WITNESS: I guess I would consider it expeditious, but yeah, tactical. It was just a purely a semantics sort of issue.

THE COURT: All right. Thank you, Doctor. Doctor,

I'm going to show you a sketch, and the courtroom deputy will put it up on the viewer, and she'll give you a copy and give the lawyers a copy. I want to ask you a question about the sketch. And Colleen, if you can focus that to get it on one page. You may not be able to. Doctor, I have handed you what I have marked as Court's Exhibit 1 which is my two-dimensional sketch of what I have called the relevant pelvic anatomy of a female, and it's not to scale. I want to ask you -- Let me back up and give you the context. For someone who is not medically trained, it is helpful for me to visualize the pelvic anatomy, and I have had a hard time doing that by reference to Gray's Anatomy, other texts, so I have drawn this sketch, and what I want to ask you is whether you think this sketch is generally accurate.

THE WITNESS: I believe that it is a schematic that generally represents the issue, although this idea of scale implies that the size of the uterus is about equivalent to the vaginal canal, and I -- it decidedly is not in pregnancy.

THE COURT: No, I understand that. Just because I'm not a very good artist, I think, and it is not to scale, but generally speaking, for a nonpregnant female, the length of the uterus is around two-and-a-half inches; is that fair?

THE WITNESS: I think that's fair.

THE COURT: And generally speaking, for, and I

realize that there is a variation, but generally speaking for a nonpregnant female, the vagina is typically five inches long for a nonpregnant female?

THE WITNESS: Actually, that doesn't tend to really change pregnancy, notwithstanding the length of the vaginal canal.

THE COURT: Well, okay. So with your comment that this rather crude judge's drawing is not to scale, may I assume that it's generally accurate?

THE WITNESS: Yes. Just my concern, I have to admit is that even looking at this, if it's not actually to scale, it's not in scale relative to two structures within this drawing, is my concern.

THE COURT: All right. Thank you, Doctor. Now, Doctor, I want to hand you another document, and I'll have the courtroom deputy come forward, and she'll give you a copy and give the lawyers a copy, and she'll put the table on the viewer. Doctor, you have now been handed Court's Exhibit 2 which is a table that I have prepared from some information on fetal growth and development, and basically what I'm trying to visualize in my own mind are size and length during fetal growth from 12 weeks to 24 weeks, and the table then represents what I understand typically is the length and weight at 12 weeks, 14 weeks, 16 weeks, 18 weeks, 20 weeks, 22 weeks, and 24 weeks, and I would like to know,

Doctor, whether you think the weight and length as compared to the gestational ages set forth in Court's Exhibit 2 is accurate.

THE WITNESS: I believe generally it is. My difficulty, Your Honor, is that we work in centimeters and grams, so I'm having to sort of convert here, but yes, that does appear to be generally accurate.

THE COURT: All right. And I'm sorry, I should have realized you would have -- I want to give you -- this is fairly important to me just for understanding, so if you have any questions about the conversion, we can get you a calculator. Are you satisfied that you have had enough time?

THE WITNESS: I'm satisfied. I looked at a couple of key weeks like 12, 20 and 24, and they seem to be accurate in my conversions in my head.

THE COURT: All right.

THE WITNESS: If I could just add one thing just to make sure that I'm being clear on this point.

THE COURT: Sure.

THE WITNESS: It is understood, I think, by the Court that, in general, a uterus length would be equal in centimeters to a week's gestation in centimeters, so at 18 weeks, about an 18 centimeter uterus.

THE COURT: Thank you. Lastly, well, the last

exhibit I want to show you is a letter that I think that you have seen before, Dr. Darney's letter to Senator Feinstein of March 12, 2003.

THE WITNESS: Yeah. There was a letter when I was giving Congressional testimony this most recently which was March of '03 sent by Feinstein's office over to the Congressional committee that I was asked to look at and comment on.

THE COURT: Right.

THE WITNESS: I'm assuming that's the same letter.

THE COURT: I think that it is. We'll put it on the screen and give the lawyers a copy and give you a copy. Doctor, is this the letter that you have seen before?

THE WITNESS: I believe that it is.

THE COURT: All right. Dr. Darney represents in this letter that he's the chief of obstetrics and gynecology at San Francisco General Hospital where his department provides about 2,000 abortions yearly to poor women in Northern California. Do you know Dr. Darney?

THE WITNESS: I'm familiar with him and his work, but I don't know him personally.

THE COURT: Do you consider him to be a competent OB/GYN?

THE WITNESS: Well, he's not a maternal fetal medicine specialist, so he doesn't take care of the most

complicated obstetrical cases, but he's a competent obstetrician/gynecologist, so in the letter to which I have referred, Dr. Darney said, although I have not reviewed medical records in order to count the number of times we have employed intact D & E, I will provide examples of cases in which the technique was critical to safe conduct of our surgery. Then the Doctor sets forth in some detail two patients upon which his department or Dr. Darney himself found that the use of the intact D & E was critical to the safe conduct of our surgery.

I would like to ask you to look at those two examples and tell me why it is you think that Dr. Darney's apparent opinion that the technique was critical in those cases was -- is wrong.

THE WITNESS: Well, if I can speak frankly without appearing disrespectful.

THE COURT: Sure.

THE WITNESS: When they first presented this to me, I honestly thought it was laughable and didn't believe these were real cases because I could not imagine somebody managing these pregnancies in this way, so I thought initially maybe it was some sort of hypothetical case, and I can go into the specifics, but in the first case, was a case I kind of mentioned before, if you have a placenta previa, meaning you have a placenta that is presenting ahead of the

baby, and you're having so much bleeding that you're replacing blood products, and you have a patient who is coagularpathic or what-have-you, the last thing I know of any maternal fetal medicine person would do or obstetrician would be to attempt further vaginal procedures on that patient. That patient needs a definitive procedure like yesterday, so we would have proceeded with hysterotomy, removal of the placenta, removal of the fetus, and the reason for that is that you want to be able to correct the situation rapidly. Also, there is at least a 5% risk of a placenta accreta which is the next situation.

THE COURT: Sure.

THE WITNESS: Which would be an even further complication where you require hysterectomy to control bleeding, so to me, it was a very poorly made decision, and when they first presented it to me, I said I could not honestly believe somebody did that to a patient.

THE COURT: Um-hm.

THE WITNESS: So I thought both of these were truly absurd examples.

THE COURT: So you just think they are just plain -- the doctor was plain wrong in doing these procedures?

THE WITNESS: Yes. I guess even more strongly if that's truly how they are managing these kind of

pregnancies, I think that patient has a very significant case that she has been mistreated.

THE COURT: All right. Doctor, this man is the chief of obstetrics and gynecology at a major metropolitan hospital that cares for a lot of women who perform abortions. While I appreciate that you may disagree with his selection of the technique for use in these two cases, can you give me a reason to think that there is just something wrong with the chief of OB/GYN at San Francisco General Hospital?

THE WITNESS: The chief frequently is an administrative position. They are not generally doing the clinical work, so I first question whether or not these are cases he actually did or he heard that someone did, and I would really want to look at the case records to really show that this, indeed, did happen because it really does seem extreme and absurd, and I don't know how else I can say it other than to offer it to other maternal fetal medicine people and have them look at this and say what would you do in this situation. This is considered -- this is the time we would use absolute contraindication to do a vaginal delivery with a placenta previa, and a placenta accreta is a even a more complicated procedure. I just did a cesarean hysterectomy on a patient like this prior to coming here last week. These patients are referred from hours away. By

the nature of the case, this is to be done by a physician such as myself. Dr. Darney, to my knowledge, has never taken care of patients like this and hasn't in some number of years, so I find it a little disingenuous. That's why when I first was given this, I truly found it laughable.

THE COURT: All right. Thank you. One last question on perhaps a lighter note. You were on the McNeil-Lehrer Hour; is that right?

THE WITNESS: I did do that show, yes.

THE COURT: And you debated a physician from Cincinnati, if I recall correctly.

THE WITNESS: That is correct.

THE COURT: How did you end up on that television show?

THE WITNESS: Jim Lehrer is my uncle. No, I'm teasing. It came up because I testified extensively on the issue, and I'm on the record, and I don't know, I think somebody at the News Hour saw me testify at some point and asked if I would be available, but I have done a number of other news programs including NPR and CNN and C-Span and other programs on the same topic, so it's not that unusual.

THE COURT: And who was the physician? Someone was on the other side. What was that doctor's name?

THE WITNESS: Dr. Paula Hilliard who as an adolescent gynecologist who hasn't done obstetrics in

decades, I don't think.

THE COURT: All right. In any event, you and she had a debate at that time, as I understand it.

THE WITNESS: That is correct.

THE COURT: All right. This occurred at about the time the Act that we are here to talk about was passed; is that right.

THE WITNESS: It was done, I believe, the day of the Bill signing.

THE COURT: Yeah. Okay. Thank you very much, Doctor. I found your testimony very helpful. I'm going to let the lawyers follow up first for the Government, then the plaintiff, and then the Government. Go ahead.

REDIRECT EXAMINATION

BY MR. COPPOLINO:

Q. Thank you, Your Honor. Dr. Cook, with respect to Court's Exhibit 2, the measurements?

A. Yes.

Q. My question is simply that would these numbers, to your knowledge, represent an average of length and weight at these particular gestations?

A. That is true. I'm slightly uncomfortable. Again, I've not having tried to convert each measurement, but my initial review looks like that is an accurate reflection.

Q. Would it be fair to say for each of these weeks of

gestation, there might be a slight range in variation as to the lower and higher number?

A. Yes, you can usually give about a 10 to 20% leeway on either direction of the mean.

Q. All right. With respect to the -- I don't have an exhibit number on Dr. Darney's letter. Is that from the Court's record?

THE COURT: It's number 3.

BY MR. COPPOLINO:

Q. With respect to Dr. Darney's letter, Court Exhibit 3, could you just state for the record what placenta previa and placenta accreta are and why as a result of those conditions you were of the view the intact D & E was not proper procedure because of those two types of conditions?

A. Well, you could pretty much consult any basic obstetrics text, and they would say that having the situation of placenta previa would be a contraindication to vaginal delivery, and the part I found laughable was they had a patient who had this history of this placenta previa, and she was already known to have risk factors with a clotting disorder, and they went ahead, despite that, and tried to deliver her vaginally by intentionally causing contractions and cervical change which is why you have bleeding with the placenta previa because you bleed with a previa because the cervix starts to dilate or the lower end segment thins out,

so they intentionally caused a situation that we knew was going to complicate bleeding in a patient with underlying risk factors of a clotting disorder, and then when they decided the heavy bleeding was so great they couldn't keep up, then they did this intact D & X procedure. That's what is laughable. They would never have had to have gone down that road at all nor put that patient in jeopardy had they proceeded with what I think any reasonable maternal fetal medicine person would have done which was a hysterotomy.

Q. Placenta previa a blockage of the vaginal area with the -- vaginal opening by the placenta?

A. It is. It's the placenta presenting in front of the fetus across the cervical opening and preventing delivery of the fetus without extensive bleeding.

Q. Has it detached already from the uterine wall in that condition?

A. No. What happens is, the placenta is a relatively fixed structure, and the cervix and uterus are relatively elastic, so I don't know if I can do this for the court reporters, but as the lowering segment is starting to thin out or the cervix is starting to dilate. It causes a shearing against the relatively static nonelastic placenta. That is what causes the bleeding.

Q. Now, placenta accreta.

A. Placenta accreta is a variation of placenta previa, kind

of like HELLP Syndrome is a variation of severe pre-eclampsia. Placenta accreta includes not only a placenta previa but that case in which the placenta has actually grown into the uterine wall, so that you are unable to separate the placenta without causing great risk for bleeding.

Q. Okay. It's not apparent from the letter, I don't believe, whether Dr. Darney personally performed these procedures; is that correct?

A. I did not believe it clearly stated that he did the procedures.

MR. COPPOLINO: Thank you, Your Honor.

THE COURT: Ms. Smith?

MS. SMITH: I have nothing further, Your Honor except for to offer Defendant's Exhibit 544, the Audu article which I neglected to do previously.

THE COURT: I'll observe ruling on that. Thank you, Doctor. You may step down. May the doctor be excused?

MR. COPPOLINO: Yes, Your Honor.

THE COURT: You're excused, Doctor. Thank you. I'll withhold ruling on 544. All right. It's now 4:30. What does the day hold for us tomorrow?

MR. COPPOLINO: Your Honor, our next witness will be tomorrow morning, Dr. Elizabeth Shadigian.

THE COURT: And the doctor will testify about?

MR. COPPOLINO: Dr. Shadigian is also an OB/GYN from the University of Michigan, and she's going to testify, if I can recall generally, not entirely dissimilar from Dr. Dr. Cook's testimony. She's going to talk about the medical necessity of the procedure, and she's also going to talk about some literature searches she conducted with respect to long-term complications of abortions. Those, I think, are the two general topics. She's also going to talk from her perspective as an OB/GYN who treats women with complications of abortions and complications of pregnancy.

THE COURT: And do you think it will take most of the day?

MR. COPPOLINO: I, you know, I don't. I think it might be just -- I don't really know because I don't know how long the cross is going to be, but I anticipate it will certainly go to the afternoon but perhaps not as long as today's examinations were.

THE COURT: All right. The people, my judicial assistant who does scheduling for me tells me that there are some lawyers who would like to start a trial next Tuesday. Do you think we'll be able to?

MR. COPPOLINO: My expectation and hope is that we will conclude entirely on Friday including providing the plaintiffs an opportunity to have some hours to take a rebuttal case. I, of course, am not sure about that. I

don't know how long they might take on cross-examination of the witness scheduled for that day, but I think we are all hoping that we can complete this on Friday.

THE COURT: Counsel?

MS. SMITH: I certainly have the same hope, Your Honor, but I never would have believed that we would be here until 4:30 today, so that's my only concern about Dr. Lockwood. He's a very important witness.

THE COURT: Sure. I appreciate that. I think that what I'll do then, I have to be in St. Louis on Monday.

MS. SMITH: Okay.

THE COURT: As it turns out, and so -- and you all would prefer to start on Tuesday if we need to. I understand that, so I'll tell -- we'll start our trial on Wednesday, but Tuesday is it. That's as long as I can go.

MS. SMITH: Your Honor, I also am not sure we are going to need much time, if any, for rebuttal. We have Dr. Creinin who is testifying in rebuttal for us in San Francisco, and I haven't made, we still haven't made a final decision to see what's coming in and whether or not there is something else we need to do. So it's possible we might not have rebuttal.

THE COURT: Sure.

MS. SMITH: Live rebuttal.

THE COURT: I understand if it ends up that either

you don't need Tuesday and you can't make that decision until Friday and I have got to lose a day, then I understand that, but just be careful, and we'll start our trial on Wednesday.

MS. SMITH: Thank you, Your Honor.

THE COURT: You're welcome. Is there anything else well should take up?

MR. COPPOLINO: Nothing here, Your Honor.

THE COURT: We'll see you in the morning at 9:00 o'clock. We stand in recess.

(Recess at 4:35 p.m.)

C E R T I F I C A T E

I, David C. Francis, certify that the foregoing is an accurate transcription of the record of proceedings made in the above-entitled matter.

/S/ David C. Francis Date: April 7, 2004

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