IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

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,	)	4:03CV3385
	)	April 8, 2004
	)	9:00 a.m.
	)	Lincoln, Nebraska
Plaintiffs,	)	
vs.	)	
JOHN ASHCROFT, in his official capacity as Attorney General of the United States, and his employees, agents and successors in office,	)	
Defendant.	)	

VOLUME VIII,
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:

FOR THE PLAINTIFFS:

PRISCILLA J. SMITH
JANET CREPPS
NAN E. STRAUSS
Attorneys at Law
Center for Reproductive Rights
120 Wall Street, 14th Flr.
New York, New York 10005

JERRY M. HUG
Attorney at Law
1823 Harney Street, #1004
Omaha, Nebraska 68102

FOR DEFENDANT:	ANTHONY J. COPPOLINO TERRY M. HENRY PREEYA M. NORONHA ANDREW I. WARDEN U.S. Department of Justice Civil Division - Federal Programs Branch P.O. Box 883 Washington, DC 20044
COURT REPORTER:	DAVID C. FRANCIS, RMR Official Ct. Reporter (Ret) 6300 Briar Rosa Drive Lincoln, Nebraska 68516

Proceedings recorded by manual stenograph, transcript produced with computer.

(Thursday, April 8, 2004, at 9:00 a.m.)

THE COURT: Good morning.

MR. COPPOLINO: Good morning, Your Honor.

THE COURT: Counsel, I would like to receive into evidence the exhibits that I spoke about yesterday with Dr. Cook. Court's Exhibit 1, which is my rather crude sketch. Is there any objection to the Court receiving Court's Exhibit 1?

MR. COPPOLINO: No objection.

MS. SMITH: No objection, Your Honor.

THE WITNESS: It's received. The second is Court's Exhibit 2, little table regarding gestational age, length and weight, from 12 weeks to 24 weeks. Is there any objection?

MR. COPPOLINO: No objection.

MS. SMITH: No objection, Your Honor.

THE COURT: Received. And the third is Court's Exhibit number 3 which is in the record or will be in the record, Congressional Record, which is Darney's -- Phillip Darney's letter to Senator Diane Feinstein dated March 12, 2003, and it's somewhat redundant to receive it, but to make the record clear about what I was talking with this particular doctor about, I think it would be helpful. I'm not offering it for the truth of the matter asserted, simply to understand my questions of the doctor.

MR. COPPOLINO: No objection, Your Honor.

MS. SMITH: No objection.

THE COURT: All right. It's received. With regard to Court's Exhibit 3, I want you to know that I intend to ask the Government's OB/GYN witnesses today and tomorrow questions regarding the two scenarios raised by Dr. Darney. All right. Are you ready to proceed?

MR. COPPOLINO: Yes, Your Honor.

THE COURT: You're ready to proceed.

MR. COPPOLINO: Yes.

MR. COPPOLINO: The defendant calls -- Your Honor.

THE COURT: That's all right.

MR. COPPOLINO: The defendant calls Dr. Elizabeth Shadigian.

DR. ELIZABETH SHADIGIAN, DEFENDANT'S WITNESS, SWORN

THE COURT: You may inquire.

DIRECT EXAMINATION

BY MR. COPPOLINO:

Q. Thank you, Your Honor. Good morning, Dr. Shadigian. Would you please tell the Court what you do for a living?

A. I would be glad to. My name is Elizabeth Shadigian, and I'm a practicing physician the State of Michigan. I'm an obstetrician gynecologist, a generalist, and I practice at the University of Michigan as a fulltime faculty member.

Q. Doctor, how long have you been on the faculty of

University of Michigan?

A. I'll be completing my tenth full year this June.

Q. Doctor, I have put on the ledge near you where you're standing, just the first document, please, which is marked as Defendant's Exhibit 529. Do you see that?

A. Yes, I do.

Q. Is this a copy of your CV, Doctor?

A. Yes, it is.

Q. And did you create this document?

A. Yes, I did.

Q. And at the time you prepared it for us, does it accurately reflect your education, work experience and publications?

A. Yes.

MR. COPPOLINO: Your Honor, the Government moves to admit Exhibit 529.

MS. CREPPS: No objection.

THE COURT: Received.

BY MR. COPPOLINO:

Q. Dr. Shadigian, why did you decide to specialize in obstetrics and gynecology?

A. I was very interested in taking care of women throughout their lifetimes, and especially interested in the issues around reproductive health and reproductive choices, and why women choose what they do.

Q. Are you board certified as an OB/GYN?
A. Yes, I am.
Q. How long have you been so certified?
A. Since 1996.
Q. Are you a fellow of the American College of Obstetricians and Gynecologists?
A. Yes, I am.
Q. Since when?
A. 1997.
Q. What does it mean to be a fellow of ACOG?
A. It means I have been accepted by my colleagues at a national level. I have fulfilled all the requirements of board certification, also on recommendations of other fellows to be part of this college.
Q. Are you a member of an organization called -- tell me if I don't get this straight, the American Association of Pro-life Gynecologists, did I say that right?
A. AAPLOG, American Association of Pro-Life Obstetricians and Gynecologists is actually not separate from ACOG. It's actually a special interest group of ACOG, just like there is another special interest group on various other topics in ACOG.
Q. Could you tell the Court what the focus of the organization, the Pro-Life Obstetricians and Gynecologists is? What is that organization interested in?

A. Right. About 900 to 1,000 full fellows of ACOG are physicians who may have performed abortions in the past but do not currently perform abortions, and they say that they don't but the real focus is medical education. It's about understanding women's health issues and obtaining information to give to women.

Q. Let's just back up a little bit more on your personal biography. Where did go to college?

A. I obtained my undergraduate degree, a bachelors of science and chemistry from Purdue, University.

Q. Medical school?

A. The Johns Hopkins School of Medicine.

Q. Graduated what year?

A. I graduated in 1990 from Hopkins.

Q. Could you tell us when and where you did your residency and in what specialty?

A. My specialty was and is obstetrics and gynecology. And I took my training at the Franklin Square Hospital Center in Baltimore, as well as Johns Hopkins.

Q. After your residency, you came to work for the University of Michigan?

A. Yes. I started fulltime as a Clinical Assistant Professor of Obstetrics and Gynecology after my residency.

Q. That was in 1994?

A. Correct.

Q. Could you tell the Court, just briefly summarize what you do on the faculty of the University of Michigan?
A. I'm a fulltime member, and I devote my time in three areas. My biggest area is actually taking care of real women patients. I also do research, and I teach both medical students and residents from other specialties, as well as especially our own OB/GYN specialty.
Q. Let's start with your clinical experience taking care of patients. Could you tell the Court what types of OB/GYN services you provide to your patients?
A. Yes. I'm a generalist, which means basically, I take care of both pregnant women and women who aren't pregnant. And in terms much pregnancy, I do both high risk obstetrics as well as low risk obstetrics. I do have limits though, because I'm a generalist not a maternal fetal medicine specialist. So I take care of women with hypertension, women with diabetes, women with connective tissue disorders, or rheumatological disorders an neurological disorders, and twins, but I don't take care of some kinds of the most sick women. In addition, the low risks pregnancies I take care of is an important part of my practice. I follow women over time, not just in pregnancy, but outside of pregnancy, I perform gynecological surgery on women and also do a lot of well woman care and family planning.
Q. You also deliver babies too; is that correct?

A. Yes, that's included in all that.
Q. All right. Doctor, what kinds of high risk complications would you refer to a maternal fetal specialist?
A. There are some complications that I might have had a little bit of training on as a resident, but because I didn't spend the additional three years necessary to be board certified maternal fetal medicine, I refer most of my patients with complex cardiac disease, patients with severe connective tissue disease, such as lupus, and women who are HIV positive, or have triplet or quad pregnancies are usually referred to the maternal fetal specialists.
Q. Doctor, are there occasions when caring for a pregnant woman, you have had to terminate a pregnancy before the due date?
A. Yes.
Q. Could you tell the Court for what reasons you have had to do that?
A. There are many different medical reasons that necessitate us delivering a baby early, and there is a broad range of them. But just to give a few examples: Pre-eclampsia is a disease which is characterized by high blood pressure, protein in the urine, and general swelling of a woman. That is one of the diseases that could make us have to deliver the baby early to protect the health of the

mom. In addition, we have to deliver women early sometimes if the baby is growth restricted or we are worried the baby is not getting enough blood supply inside. And then there can be other situations that necessitate earlier delivery. For example, for twins, we think babies have better outcomes if they are delivered a little earlier than full term singleton pregnancies.

Q. Doctor, have you ever diagnosed fetal anomalies in pregnant women you have treated?

A. Yes.

Q. How do you do that?

A. We generally perform a second trimester rule out anomalies ultrasound.

Q. Which anomalies have you, in your experience, had occasion to detect in women you have treated?

A. It has been a broad range over 14 years. Some examples are women with babies who have Trisomies such as Trisomy 18, 21 or 13. Turner's Syndrome. There is also other moms who have babies with omphalocele or gastroschisis, which are problems with the gastrointestinal tract of babies. Sometimes the twins I have taken care of have been stuck together and not completely separated. That's called conjoined twins.

Q. Doctor, in the curse of your medical training and practice, have you become familiar with the different

methods of terminating a pregnancy?
A. Yes, I have.
Q. In your current medical practice, which methods of pregnancy termination have you had occasion to utilize?
A. Well, depending on the gestational age of the baby, I have had to use D & Cs, D & Es, and medical induction of labor.
Q. Just so the record is clear, could you just briefly describe what a D & C is for the Court?
A. Right. D & C stands for dilation and curettage, which is the French word to mean to scrape. But generally, a first trimester D & C is anywhere -- the first trimester starts at the woman's last menstrual period, when she gets a positive pregnancy test about five weeks up to 12 weeks of pregnancy. The cervix is dilated, and then using sharp or suction curettage, all the contents of the uterus are removed, including the baby and the placenta and the fluid.
Q. And I believe you mentioned -- did you mention the dilation and evacuation method?
A. Yes the D & E is another method I'm well familiar with.
Q. Would you explain that for the Court briefly?
A. The dilation and evacuation method is generally used in the second trimester of pregnancy where the cervix is dilated over a series of days with laminaria or osmotic dilators. In current use, sometimes we use medicine such as

Misoprostol to dilate the cervix and prepare the cervix. Then the woman is taken back to the operating room, the laminaria are removed, and the amount of dilation may be increased with more dilators in the operating room. Finally traction is placed on the cervix, which straightens it out from the cervix to the uterus. And then a series of instruments are put inside the uterus to facilitate removal of a larger baby.

Q. And how would you describe a medical induction?

A. A medical induction is a way of terminating a pregnancy where we actually put medications, either in the uterus or intravaginally, or in a woman's mouth, to help give her contractions and to start the physiological process of labor.

Q. Doctor, I would like to ask you some questions specifically on your experience in performing abortions and pregnancy terminations. Let's start with D & C. And could you summarize for the Court your experience in performing D & Cs? If it would be easier, you might start with your experience in med school, residency, and then up to the present?

A. Right. To be clear, except in some medically indicated terminations of pregnancy, all the babies that I have taken care of that I have performed abortions on were dead by the time I actually took care of the baby. So in the first

trimester, as a student -- you asked me to start with when I was a student.

Q. D & C, give the Court your experience. You can go back to med school, residency?

A. Right. So as a medical student, at that level, I actually watched the performs of D & Cs on live babies but never participated holding instruments with live babies, but had helped with several of them, probably six or less as a student. In residency, we had a very busy obstetrical program, and I did literally hundreds of D & Cs on babies that had expired. And then I also made it a point to actually be present and see techniques to see if they were different or not for people performing abortions on live babies as well.

Q. And do you continue to perform D & Cs, in your current practice?

A. Yes, I do.

Q. Let's go to dilation and evacuation starting in medical school and up to your residency, and your current practice. Would you describe to the Court your experience in either performing or observing the dilation and evacuation method of abortion?

A. So as a medical student, I probably watched six or less D & Es, just getting an idea and flavor for what happens during them. But during my residency, because it was such a

busy program, I actually helped participate between 30 and 50 D & Es on babies that had died. Or if I decided to be present in the room, I could also observe the techniques on live babies as well, but I didn't participate holding instruments.

Q. Since you have been at the University of Michigan, how many times, on occasion, have you -- how many occasions have you had to perform a D & E procedure on a fetus that had already died?

A. Probably between ten and 20 times.

Q. Is there any change in the procedure of extraction that you utilize in performing a D & E, when the fetus has died?

A. No, we use the same disarticulation, meaning pulling the baby out in pieces. However, on a dead baby, it may be easier to actually pull the baby apart because of the process of death being initiated already.

Q. Up to what gestational age have you observed a D & E on a living fetus?

A. Probably between 20 and 22 weeks.

Q. How many D & Es have you performed with the fetus between 18 and 19 weeks?

A. Probably eight to ten.

Q. Have you terminated a pregnancy where the fetus was alive, where the termination was necessary to treat a maternal health complication?

A. Yes, I have.
Q. And in such cases, what technique have you used?
A. I have used medical induction of labor to take care of women who were very sick, who need to have their pregnancy ended.
Q. So is it correct to say, Doctor, you will terminate a pregnancy on a live woman in order to treat a woman facing a serious health complication?
A. Yes, I will and I have.
Q. As an OB/GYN, do you have an understanding of how to empty the uterus during a pregnancy, if necessary, before the due date?
A. Yes, I do.
Q. When you were in medical school in Baltimore, did you make a special effort to learn about abortion?
A. Abortion and women's health choices around abortion have been a subject that have been very interesting to me for my whole career. So I have paid a special attention to both the techniques and the complications of abortion.
Q. What institutions did you work at in Baltimore that provided abortion services that you were able to learn about abortion?
A. In addition to Johns Hopkins, there was a very large county hospital called Francis Scott Key Medical Center, and they actually did quite a few elective terminations of

pregnancy, both by D & E and by medical induction. In fact, I think had the biggest service in the entire greater Baltimore area. So I had access to those people who were teaching me to actually ask questions, and they helped me understand the procedures very well as a student.

Q. Why did you make a special effort to learn about abortion procedures while you were at, in Baltimore for med school and residency?

A. I just wanted to understand it. I wanted to be able to be very clear with my own patients as I was going into OB/GYN what the risks and techniques were. And I wanted to be good at how to do the procedure, so I could actually explain that to people, so I could provide those services to women.

Q. Is it also the case you were involved in working on teen pregnancy issues while you were in Baltimore?

A. Yes. In my residency program, we had one of the busiest hospitals, Franklin Square Hospital, but we had a very big teen clinic. Baltimore, unfortunately has one the highest teen pregnancy rates in the country. So I had the opportunity to take care of a lot of teenagers.

Q. Now, let's just touch on medical induction again. Could you tell the Court what your experience has been in observing and performing medical inductions? Let's just go with med school and residency for now.

A. In medical school, medical induction of labor was one of the techniques used for elective terminations. So they had a whole ward and area that they did every day, or three days a week, medical inductions of labor for elective reasons. So I got -- I saw probably more of those even than D & Es in medical school. And then in residency, most of my experience on medical inductions were for medical reasons and/or fetal anomalies, but I didn't participate in medical inductions for fetal anomalies but the techniques were the same.

Q. And in your current practice, could you give the Court an indication of the frequency with which you use medical induction to terminate a pregnancy, prior to term?

A. Well, prior to term, there are a lot more indications than prior to viability. So I would say on a weekly basis, there would be people we're inducing for medical reasons that need to get delivered.

Q. And why don't you give the Court an idea of your experience in terminating a pregnancy using the induction method prior to viability?

A. Those particular circumstances are a lot more rare, and thank goodness, women generally get through pregnancy without having such severe complications in the second trimester. But there are such complications and the two, most common ones I take care of are infections in the uterus

called chorioamnionitis, which is an infection of the membranes, the placenta, the baby, the uterus, and it can be any variation therein. So that's one example of why I need to use my medical induction techniques. And the other common medical complication of pregnancy is severe pre-eclampsia that I have the most experience with.

Q. Doctor, would you explain to the Court why it is you need to be familiar with both surgical and medical forms of abortion in your practice?

A. Well, babies that I take care of who have already died inside their moms, I want to be able to provide that service to offer the D & E, just like I do to my first trimester patients. So I generally offer that myself. If I find that's it's beyond my scope of practice and I feel like my surgical skills aren't as good, then I have my maternal fetal medicine colleagues, who are specialists, I can also refer to.

Q. Why is it that you have occasion to perform more inductions than D & Es in your practice?

A. It just so happens the way the system is at the University of Michigan is I actually, when I take call, take care of a greater number of women on call than I would in my own sort of almost private practice. So I have all the transfers of care patients from all around the southern part of Michigan are transferred to University of Michigan. So

we are supervising the residents and all the transfer patients as well. So that's why medical induction is more common for me.

Q. Is there a stage in gestation where medical induction termination of a pregnancy is more common, in your practice?

A. It's most common 16 weeks and greater gestational age, but even more so, 20 weeks and greater.

Q. All right. Doctor, you also have teaching responsibilities at the University of Michigan?

A. Yes, I do.

Q. Could you just describe those responsibilities to the Court, who do you teach, what do you teach and where do you teach?

A. So I teach at the undergraduate, graduate level as well as medical students. So undergraduate teaching, I teach in women's studies. I teach about domestic violence and sexual assault. That's my other area of expertise that I have taught about for many, many years. And in addition to undergraduate students and women's studies in psychology, I also teach a graduate students and nurse midwifery programs in sociology, I have. And then at the medical student level, I teach sort of on three levels. I help run a course could the Interpersonal Violence Course to second-year students. We are just finishing that up this week actually. So that's about 16 contact hours of both didactic lectures

and small groups. And I have done that for ten years. In addition, for the students, I give the third-year students direct hands-on teaching both in my office and the gynecology ORs, labor and delivery, just as they rotate through our department. In addition, I give two didactic lectures every six weeks. One on breast feeding and one on issues around violence against women. And then, finally, I run an elective called Primary Care in Obstetrics and Gynecology, where I take the most senior medical students who are interested in a variety of topics and let them sort of see what it's like to become an attending, and a faculty member, and all the range of what we do. We actually allow them to choose the kinds of experiences they want. And those are the medical students I teach.

Q. Okay. You talk a little faster than even I do.

A. Sorry.

Q. Make sure the reporter is getting it all. That's fine. Now, let's talk about residents. To the extent you haven't covered it, give the Court and idea of how you work with residents?

A. The residents that I teach are mostly obstetrician gynecology residents. We have a four-year program and have at least 20 residents at all different stages. So I supervise them directly in the inpatient care. They don't come to our offices, however. They have their own clinics

at the University. But any of the cases that come from the clinics, I might be asked to help in. And in addition, there are internal medicine seen and pediatrics residents, and they are also asked to rotate with me to get special examinations, and pelvic exams, because of the different work I do in gynecology. And then there are family practice residents who are learning about obstetrics and gynecology too. We supervise them as they rotate on our service.

Q. Do you have occasion, then, in that context, to have residents come with you and have you supervise them in the performance of pregnancy termination?

A. Yes.

Q. Could you describe that to the Court both in terms of the frequency of that and what procedures you're supervising residents on?

A. Whenever a patient from my own practice needs to have any kind of procedure and I'm available to do it, I'll do it myself. In the course of that, we have residents and sometimes medical students who will be participant. So depending on the level of the resident, I will allow them to participate up to the safe level of their learning. But I will be the one supervising everything.

Q. Do you let the residents actually insert instruments, say, in the performs of a D & E on fetal demise?

A. Yes.

Q. But you take over the procedure, if it's necessary, for the safety of the mother?

A. Absolutely.

Q. Could you explain to the Court the process of the extraction during a D & E that you would -- that you would teach the resident, as you're doing the procedure?

A. Yes, I would. Basically, in addition to actually giving them the physical hands on skills, one of the other things we do is we are teaching didactically as we are doing it. So I might ask, well, should we use an ultrasound machine while we do this, because then we can see where the instruments are actually going. So we'll go over and discuss should we use an ultrasound machine in this instance or not. And then before a resident may even perform the procedure such as a D & E, I'll start asking them questions. So what is the first thing you're going to do before you do it? I'm going to put the speculum in if vagina. I'm going to pull out the laminaria. I'm going to check how dilated it is, and then I'm going to decide which kind of instrument for traction I'm going to use. I might quiz them. Do you want to use one that is dull or sharp, and what will reduce the amount of bleeding, and, you know, how hard do you want to pull. So I'll go each step, I'm asking them questions to see if they have been reading to see if they understand the literature. So we'll sort of go through that as we go, and

then I'll ask well what kind of forceps do you want to use today to pull -- to disarticulate. Then we'll go through what our choices are.

Q. About how many times a year will you be working with a resident in performing D & E on fetal demise?

A. Depends on the year because most of those patients are actually from my practice. So it could be zero to two per year.

Q. About how many times a year will you have a resident with you while you're performing a D & C?

A. In almost every D & C I do, but I do so many more of those.

Q. You also supervise residents in the performance of medical induction?

A. That's correct. When a woman needs to have a medical induction, whether they are before viability or after, the residents will be participant fully in the decision making and also the actual putting in the medications and figuring out how often to dose the medications.

Q. Do you also teach about abortion complications?

A. Yes, I do.

Q. Would you describe, first of all to the Court, why you have developed an interest in abortion medical complications?

A. Yes. In the course of taking care of well women,

abortion is a very common procedure. It has been estimated up to 43% of American women will have an elective abortion or a medically necessary abortion by the time they are age 45. So it's just a very common thing that women decide to have. So I want to know how to best take care of those women, if they have had an abortion or they haven't. And sometimes, when we look at individual studies, I can't make heads or tails out of what I should advise women based on one study. So I have been become very involved in something called systematic reviews, where we do a whole literature search on a whole topic. And I have done this on several different topics now, where we look at the world's literature on a certain topic, and then we try to make sense of what we find. Because as an individual physician, it's very difficult to make good value and medical judgments, just based on one or two articles you may know. So I found taking care of women, I couldn't answer these questions by just looking at one or two articles and just looking at guidelines. I wanted to actually get down to the actual articles and read them myself.

Q. What types of abortion complications have you seen and treated in your practice?

A. Well, there are a whole range of them. The most common once are things like infections or lots of blood loss after an abortion procedure. But I have also had occasion to take

care of women who have had scar tissue in their uterus, because of their procedures, and women who have actually had early births the next time after an induced abortion. There is a big range.

Q. Besides your duties as a professor and your clinical practice, have you had time to do research in areas related to your practice?

A. Well, even when I was a resident, I did a research project every year. And that has sort of been my way of approach important things, is that I try to concurrently do research as I find either clinical problems in my practice, or if there is issues around care of women that are important. For example, I just got published in the International Journal of OB/GYN about how to take care of women in pregnancy who have domestic violence issues in looking at homicide data, for example. So that's another area that I look at as well.

Q. Now, I noticed in your CV and from your testimony this morning, that not all of the areas that you research may seem to be directly related to obstetrics such as violence against women. Why don't you explain to the Court how you feel those topics, such always violence against women, sexual assault, do relate to your practice of obstetrics.

A. Just because I take care of general women coming to my office, they just have lots of histories of domestic

violence and sexual assault. And, unfortunately, between a fourth and a third of all women have been sexually assaulted or molested sometime in their life. So I'm going to be doing surgical procedures, for example, on women who have been violated. So if I can understand that that happened, and I can explain to women that they are giving their bodies over to someone like myself and they need to trust me, and they need to be able to feel safe, I can actually explain to women what's going to happen very succinctly, and also help them feel reassured that it's their choice to have this done, and that we will do everything we can to make it feel better for them, even if they have had a traumatic experience.

Q. Doctor, I would like you to, have -- I would like you to tell the Court about your experience in testifying in other judicial proceedings concerning the issue of abortion.

A. I have been asked by several different states to help them in different legislation around informed consent for abortion. In addition, parental consent for abortion, and there have been a couple of other kinds of topics, but those are the two other topics I have been asked to offer opinions on.

Q. Right. And what, just generally, are the issues involving informed consent and parental consent involving abortion that you have testified in, and what has been the

nature of your opinion in those matters?

MS. CREPPS: Your Honor, I'm going to object on relevance grounds at this point.

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

THE WITNESS: I think my varied experience in explaining things to people, I have sort of honed those over the years. So just as I gave the example of trying to really explain procedures on people who have had sexual assault, as part of their history, I make it a very big point to be able to really explain how we do procedures on women and what complications there are in plain language to women, so that they can actually understand it. That's part of my role as a physician and surgeon. But I think because the women I really take care of have such varied experiences, you know, in my office, I have made that a special kind of area that I'm very explicit with them.

BY MR. COPPOLINO:

Q. All right. A little more specifically, what issues, in the cases in which you have testified concerning informed consent, what issues specifically have you testified about and what opinions have you rendered?

A. Right. One other thing that I have done is tried to explain that it's not good enough just to tell people about the short-term complications on abortion consent forms, but

that there are well studied and well documented long-term complications, and women have the right to know what those are too. It may not change their thinking about a procedure in front of them, but they should know what could happen to them later on, and their doctor should know that too.

Q. Doctor, you understand this case concerns a Partial-Birth Abortion Act, Ban Act of 2003, correct?

A. Yes.

Q. What study have you undertaken of that procedure, in connection with your testimony here today?

A. When I was asked to see if I would like to be an expert in this case, I was actually asked about studies on D & X. So I didn't really know if there had been studies done on D & X or not. I hadn't heard of any, but what I did was using the other techniques I had used to look at long term complications of abortion, and homicide, and suicide, and pregnancy; all the same techniques. I went to the library and it said this is the topic. These are the words we need to use, and then performed a systematic review.

Q. If you will just slow down for the reporter.

THE COURT: Trust me, he's ornery enough if he can't take it, he'll tell you. And if he starts getting tired, he'll tell you repeatedly.

BY MR. COPPOLINO:

Q. Doctor, what is your understanding of the term

partial-birth abortion?
A. Partial-birth abortion has been described in many different ways. I generally use interchangeably the partial-birth abortion term, the intact D & E term.
Q. All right. So what's your understanding of -- is it also occasionally referred to as the D & X procedure?
A. And the D & X procedure, dilatation and extraction procedure.
Q. What's your understanding -- let's pick one for today for convenience. Let's pick D & X. What is your understanding of the D & X procedure?
A. As I understand the D & X procedure, there is generally considered four parts to it. One is dilating the cervix over several days to accomplish an adequate amount of dilation. The second part is the instrumental conversion of a fetus from whatever position it's in initially to a breech, and then it's delivering the fetus up into the head, which is called a breech extraction, and then it's the admitting of instruments into the base of the skull of the fetus, and then extracting the contents of the skull to facilitate delivery of the head.
Q. Doctor, in preparing for your expert testimony, you've read the Partial-Birth Abortion Ban Act of 2003?
A. Yes, I have.
Q. Have you also read the report of the U.S. house of

Representatives on the Partial-Birth Abortion Ban Act of 2003?

A. Yes, I have.

Q. Have you read the description of the D & X procedure attributed to Dr. Haskell?

A. Yes, I have.

Q. Have you also read the description of the so-called intact D & X procedure prepared by ACOG?

A. Yes, I have.

Q. Have you also read some of the declarations prepared by a couple of the experts testifying in the three cases that are pending on the partial-birth abortion?

A. Yes, I have.

Q. Do you agree, Doctor, that there are variations in the various procedures referred to as intact D & E, D & X, intact D & X?

A. Yes, there are several variations.

Q. Do you have a view as to whether the procedure could be described as a D & X, if the baby was already in a breech position, instrumental conversion was not required?

A. That would still, in my mind, fulfill the D & X criteria.

Q. Doctor, you have been asked to testify about a couple of topics in this case, I would just like to have you identify those topics, and have you summarize your opinion for the

Court. Do you have an opinion as to whether the D & X procedure is ever medically necessary to properly treat pregnant women suffering from high risk medical complications?

A. I know circumstance in which the D & X is medically necessary to treat women with medical problems.

Q. Do you have an opinion as to whether there is a basis on which to conclude that the D & X procedure offers safety advantages to women over other methods of abortion?

A. Since the D & X has never been studied in a formal way in peer review literature, there is no basis to say the D & X is safer than any other procedure.

Q. And so do you have an opinion as to the relative safety of the D & X procedure, as compared to the induction method of abortion?

A. Well, there is no sound basis on which to conclude the D & X is safer than medical induction.

Q. Okay. I would like to talk first about the medical necessity of partial-birth abortion, your opinion in connection with that. I believe you testified earlier this morning that it is sometimes necessary to terminate a pregnancy for maternal health reasons; is that correct?

A. Yes.

Q. And you may have said this already, but just describe to the Court how common that actually occurs with reference to

both pre and post-viability?

A. Post-viability, there are several times that we need to induce labor, and that's a very common thing that obstetricians/gynecologists learn in their training; how to do that safely for babies at different gestational ages. It's uncommon to find a mom who has such a complication in the second trimester, that it actually necessitates termination of the pregnancy. But the two I take care of most frequently are the chorioamnionitis and the severe pre-eclampsia.

Q. Why don't we, then, just briefly restate for the record what those two conditions are. I want to ask you about your experience terminating pregnancy for those conditions. Let's start with severe pre-eclampsia.

A. Severe pre-eclampsia is a medical condition that is specific to pregnancy. We don't see it outside of pregnancy. Where a woman's liver is affected, where a woman's platelets are affected, and where a woman can get swollen, and have their blood pressure go very high. And in those situations, a woman can start getting so sick that she's at risk of hemorrhaging and dying from the actual medical condition.

Q. Chorioamnionitis?

A. Chorioamnionitis, again, is an infection in the fluid around the baby. The baby itself, and it can extend into

the mother's's uterus, and then into the mother. So that it, in fact, affects both the baby and the mom.

Q. Now, when you are faced with a need to terminate a presentation because of maternal health complication, is that situation approached differently depending on whether the baby is pre or post-viable?

A. In the situation in the late second trimester, we basically don't do anything different. We don't try to make the baby die but we accept that the baby could die as a normal part of this physiological process of terminating the pregnancy.

Q. When the fetus -- when you have judged that the fetus has no chance of survival outside pregnancy, is there any difference in the actual method of induction?

A. We can use higher dose medications that may cause the uterus to have a higher rate of both rupture, and it also may be a quicker process, if we use higher doses of medications.

Q. And, Doctor, you personally have had to terminate a pregnancy on a living fetus you knew was not likely to survive the termination; is that correct?

A. Yes.

Q. How do you evaluate maternal health conditions during a pregnancy to determine whether and when you should end the pregnancy, because of a severe maternal complication?

A. Those are tricky situations to make those sort of hair line decisions. But basically we look at a lot of different medical factors. So it's not enough that a woman would have just premature rupture of membranes, say, as a precursor to the chorioamnionitis. We actually have to find physical signs and symptoms. So the uterus has to be tender, the woman has to have a fever. It's not good enough just, for example, the membranes are ruptured. So we have to see that certain criteria are fulfilled. And in the severe pre-eclampsia, it's not enough just that the blood pressure is high. We can manage blood pressure independent. But when we see the liver being affected, the kidneys being affected, the platelets. When we see other organ systems being affected by the process, then we make the call that it's affecting the mother so much that she's in danger.

Q. In circumstances in which the baby is potentially post-viable, is your approach to try to deliver the baby and then turn the baby over to neonatologists for what they can do?

A. We try to deliver the baby in the safest way to give the baby the most chance of surviving, if the baby is in the viability range.

Q. Now, in all these circumstances in which you have terminated pregnancy prematurely, you have used the medical induction method?

A. Yes.
Q. When a pregnancy has to be ended pre-viability for a maternal health reason, is it ever necessary to take a destructive act directly against the fetus, in order to protect the health interests of the mother?
A. I have never needed to use such an act.
Q. And why not?
A. It's just not necessary.
Q. What is necessary to serve the health interests of the mother, when she needs her pregnancy to end pre-viability?
A. The most important thing is ending the pregnancy, which means delivering the baby and the placenta. Once that's accomplished, then the mom will get well spontaneously.
Q. In your opinion, Doctor, would there ever be a medical need to use the D & X procedure to terminate a pregnancy, specifically, because of a particular type of health condition that the mother is facing in the pregnancy?
A. I can't think of a situation.
Q. Are there, in your opinions, save and effective ways to terminate a pregnancy for maternal health reasons without the D & X procedure?
A. Yes. We have the disarticulation D & E procedure, and we have the medical induction procedure with many different kinds of medicines that have both been well studied.
Q. Would a D & X procedure ever be an appropriate procedure

to terminate a pregnancy in the circumstance in which maternal health is deteriorating rapidly?

A. No, that would be a circumstance that it would not be good, because it takes so many days to treat the cervix a head of time and get the body prepared for the actual procedure itself.

Q. I would like to turn back to the subject of fetal anomalies. You testified you had some involvement with that. What happens when one of your patients is diagnosed with a fetal anomaly?

A. When I get the ultrasound report, many times I almost get it at the same time they are doing it. The radiologist will call me. It's our practice that after the ultrasound, the woman comes up to my office and talks to me or my nurse practitioner. So in those situations, I explain what the anomaly is. I explain if it's a kind of what we call fixable or something that we can treat after the baby is born, or even during the course of the pregnancy. And then tell them what the likely outcome is. In addition to that, I think it's always in one of these situations that it's complicated, I most generally get a consultation from our maternal fetal medicine colleague, so they can give their opinion to the patient. Many times after that, they want to call me back and see me again or go over things again, because I do have a long-term relationship with most of my

patients.
Q. Just to be clear, you diagnosis the anomalies in your patients?
A. Yes.
Q. And how do you do that?
A. Well, I order a second trimester ultrasound, and then I get to explain what it means to the patient. And sometimes I have to order additional tests like a fetal echocardiogram or a second ultrasound a few weeks later, if they couldn't see all the parts.
Q. In cases involving a fetal anomaly, can there be a maternal health problems that's associated with the woman carrying the anomalous fetus that might independently justify terminating the pregnancy?
A. Usually, they are two separate situations. Either mom is sick and has her own issues around being sick, or that the baby has problems, and the fetus is anomalous, but rarely would they be, if at all, connected in any way.
Q. Do you have knowledge of the procedures that may be used to terminate a pregnancy for a fetal anomaly?
A. Yes.
Q. What types of abortions are offered for patients at the University of Michigan for fetal anomalies?
A. Generally, at the University of Michigan, D & Es are offered to women 20 weeks and before. After 20 weeks, they

may be offered, but the general trend is that we are doing almost exclusively medical inductions of labor after 20 weeks.

Q. So what method of pregnancy would you recommend for termination of pregnancy involving a fetal anomaly after 20 weeks?

A. I generally would recommend the medical induction.

Q. And why?

A. Well, there as few reasons. Basically because the safety data is so much better on medical inductions, especially with the newer Prostaglandins. It used to take much longer to induce labors and it was more distasteful for women and even more difficult to manage people over three days. But now, we have Misoprostol and we can actually deliver babies within four to 24 hours with the new medication. So it's safer. And, also, the older studies show that there is a lot less maternal mortality for medical inductions for 21 weeks and later.

Q. Doctor, I believe you testified that you'll treat a patient, maybe you did -- let me just ask it directly. Do you ever continue to treat your patients after they have had a termination for a fetal anomaly?

A. I treat most of my patients afterwards, if they choose to come back. I specifically tell my patients, whether they choose to abort their baby or not, I'm willing to take care

of them later. In fact, I do, in most of their subsequent pregnancies.

Q. I was going to ask. You anticipated my next question. Have you delivered some babies for your patients after terminations they have had?

A. Yes.

Q. And that's also in the case involving fetal anomalies, have you delivered babies for patients after they have had a termination for a fetal anomalies?

A. Yes. Both for fetal anomalies and other reasons.

Q. In your opinion, Doctor, is the D & X procedure ever necessary to terminates a presentation in which there is a fetal anomaly?

A. No.

Q. Why not?

A. It's just not necessary, because we have such other well studied techniques that work very effectively; both the D & E, and the medical induction are very well studied, and we know where the lines are that there are increased risks with one or the other.

Q. In your experience, Doctor, in being involved with pregnancies involving fetal anomalies, is there anything unique about fetal anomalies that would require an intact extraction provided by the D & X procedure?

A. Not that I can think of. Even with anomalies that are

very large -- I mean what's really, what we are really talking about is are there babies where their parts are so big that we actually have to decompress them first to do a good job for mom. And there are only a couple of thoughts I have. One, is if the head is very big with hydrocephaly, there is actually a procedure we can do to draw off the fluid around the baby's head, for the head to get a little bit smaller and make it easier to have the baby come out. And I had my own experience with a set of conjoined twins, which are twins that are connected together, and they were actually connected from the chest all the way down to the abdomen. There were two heads and two sets of shoulders. And we safely at University of Michigan used a medical induction after 20 weeks and the babies didn't have to be destroyed in any way. They just naturally died in the labor process.

Q. In that case of conjoined twins, was there a subsequent pregnancy outcome for the mother?

A. Yes, the mom had a term birth, I believe, about a year-and-a-half later under my care.

Q. Doctor, I would like to turn now to some of the safety issues involving the D & X procedure. You stated an opinion, I believe, that there was no basis to conclude that the D & X procedure is safer than other methods of abortion. Would you tell the Court what the basis of your opinion is

on that?
A. Well, I did do this literature search, looking at both the international and domestic literature to see if there were any studies whatsoever on D & X. And there are no studies that tell us what the correct indication should be for a D & X. We don't know what the short-term complications are. We don't know the long-term complications. And because it hasn't been studied at all, we can't really even compare it to a D & E or to a medical induction of labor.
Q. And in your opinion, Doctor, what does that lack -- what is the significance of this lack of formal study of the D & X procedure tell you?
A. Just tells me, I don't know if it's safe or not. I don't know if it's going to cause women even more problems in the end or less problems. And when something is so unstudied and -- I'm just not willing to, you know, put my patients own reproductive health on the line for something that I know we already have good data on D & E procedures and medical induction procedures.
Q. Doctor, the Court has heard from doctors who perform abortion procedures with a fair degree of frequency, and perform some variation of the D & X procedure. And the Court has heard them testify that it's safe, based on their experience. What is your opinion, with respect to

assertions that the D & X procedure is intuitively safe, based on the experience of practitioners who are performing it?

A. Well, I know those practitioners have their best intellectual judgment in mind. And I know they want to be honest and truthful in what they are saying, but really it's just anecdotal evidence they have that they think it's safe. They don't have any long-term studies or even a comparison of the D & X to another kind of procedure. So I don't question that they really believe that, but really without data, we can believe a lot of things, but medicine is based on evidence. It's based on doing studies. It's based on comparison of what we know to what we don't know. And in the absence of that, those are just anecdotal thoughts or feelings that a physician may have.

Q. Okay.

THE COURT: Can I see the lawyers at the bench here just briefly? I want to ask you a question.

(Side bar)

THE COURT: She's not worried about copyright protection. Can you provide it to your witness?

MR. COPPOLINO: It has been provided, but I have not discussed that issue as to whether or not she should alluded to it because when she wrote her expert report, it became available subsequently, and Ms. Crepps will have that

issue that they had before.

THE COURT: I'm not being critical. I just didn't know.

MR. COPPOLINO: She has reviewed it, but I don't know if I'm going to inquire of that. She hadn't examined it.

THE COURT: I'm not being critical. I just wasn't certain how those things were being handled. I didn't know if she refused to sign it.

THE COURT: No, she's signed it.

THE COURT: Okay. Thank you. That's all I wanted.

(End of side bar)

THE COURT: Pardon me for interrupting, Doctor. I just wanted to ask the lawyers a legal question. And I'm sorry that I interrupted counsel's interrogation. Go ahead, counsel.

BY MR. COPPOLINO:

Q. I would like to then ask you about a couple of specific assertions as to the safety of the procedure, the D & X procedure. For example, it has been asserted the D & X procedure offers a safety advantage because it involves fewer instrument passes and involves the extraction of fewer sharp fetal fragments. What is your view as to whether that is a sufficient basis on which to evaluate the safety of this procedure?

A. Well, that's a very good theory that may describe what might happen. I don't know if that's actually true; if it's actually safer to pull the baby through the cervix. It actually involves more dilation. On the other side, I could say, well, the cervix is more dilated. You're pulling the baby through rather than letting a physiological process happen. So for every example that people can say they think this is safer, because there is less passes, there is another way you can look at it. That it might be less safe, because the cervix is dilated differently or more than in a medical induction.

Q. Do you agree, Doctor, that specifically with respect to sharp fetal fragments, that removing the fetus intact would reduce the risk of laceration or perforation, as a result of sharp bony fragments?

A. It should.

Q. Would you agree that -- that the procedure, as designed, does have fewer instrument passes than a dismemberment D & E procedure?

A. Yes, it does have less passes.

Q. Do those, in your opinion, do those potential benefits of the procedure provide the whole picture as to the safety of the procedure?

A. It doesn't to me, and it doesn't because of both short-term complications and long-term complications. Many

of the people performing the D & X procedure don't actually see the patients back later, so they don't actually know if they had complications outside a certain number of -- a certain number of hours that they may be observing the patient. So it's hard to say what those outcomes would be.

Q. What's your basis for that last assertion as to the follow-up of the abortion practitioners with their patients?

A. Well, there have been several studies. One, I quote specifically which is the Picker study from 1999, and they actually asked women about the quality of their abortion care, because this is such an important issue. And, in fact, it turns out that only about 29% of women actually follow up with their abortion provider afterwards. So it's hard for me to understand how abortion providers, in quotes, know their complications, if they don't even see their patients back later.

Q. I believe you testified you have reviewed Dr. Haskell's 1992 paper, the National Abortion Federation Regarding the D & X Procedure?

A. Yes, I have.

Q. Would you agree that in that paper, Dr. Haskell reported on the results of cases he had undertaken to date using that procedure, and that he had found no complications?

A. That's what he said.

Q. Okay. Isn't that a case review that provides some

evidence of the procedure's safety?
A. Well, the problem I have with Dr. Haskell's report is he said there weren't complications, but he actually never called the patients to find out. He doesn't describe finding out actually about complications. These are just ones that he knows about from his practice.
Q. Let's just assume for a moment that his conclusions with respect to complications are accurate. Isn't it the case that understanding the safety of a procedure starts with case reviews such as the kind Dr. Haskell presented to the National Abortion Federation?
A. Certainly, we do start with case reviews and correlations. We look, at first, to see new procedures by a short case review.
Q. In your opinion, is it sufficient to rely on such self-reported case reviews of physicians who are reporting a procedure and evaluating the safety of the procedure?
A. It's not enough. It's not sufficient.
Q. Why not?
A. Because the person has an invested interest in their, in quotes, new technique they designed themselves. They want to -- they have a feeling and desire that they want it to be safer. And they have no other comparison group that they use to compare the two groups, if there isn't one.
Q. What about if a physician who is performing this

procedure talks and confers and meets with other physicians that he knows perform this procedure, and, collectively, it's their experience that the procedure is safe. I'm referring to the D & X procedure. Isn't that common experience an indication as to the safety of the procedure?

A. Again, these are the very initial steps people should take to discuss in academic settings or national meetings about a new procedure. But it's the very first step in evaluating procedures. After that happens, there is a series of evidence-based studies that need to happen for us to make any conclusions about the general safety or unsafety of a procedure.

Q. Doctor, now this Court has heard some testimony that there are now some medical schools in the United States purportedly starting to teach the D & X procedure. And assuming that's true, wouldn't that be some indication that the procedure has certain potential safety advantages?

A. I don't think it says anything about safety.

Q. Why not?

A. Because it doesn't evaluate safety. Just because I talk to a group of students about a personal experience I have doesn't mean that it's the way it should be done.

Q. Just hold on for one second, Doctor.

A. Um-hm.

Q. I would just like to talk about some of the specific

concerns that you have with the D & X procedure itself, and as sort of a foundation for that, I would like you to just describe what your understanding is of how dilation is typically achieved for the D & X procedure.

A. Dilation is typically achieved over a set of two days where laminaria or osmotic dilators are placed in the cervix. Sometimes the cervix needs to be straightened out before those are placed. Sometimes they can be placed directly. And then overnight, the dilators expand, the cervix dilates more. A woman comes back the next day. They put even more dilators in and let those expand. And then on the following day, a procedure such as the D & E is then -- or D & X is then started.

Q. I may have missed this if you said this and I apologize, but is it your understanding Misoprostol can be used in conjunction with the dilation process?

A. Yes, Misoprostol is now being used by many practitioners in conjunction with laminaria.

Q. In the process of dilation necessary for the performance of a D & X procedure have consequences on a woman's health?

A. Could you restate that question?

Q. Could the process of dilation for the D & X procedure, in your opinion, have any consequences on a woman's health short-term or long-term?

A. Yes. How many dilators are put in. If they are put in

gently or forced into the cervix. Also, we know we can put dilators in the wrong place. Sometimes the cervix may be stenotic or have some scar tissue on there. You can create a false tract, if you are not careful. All the things that actually manipulate a woman's body, such as dilation, can have longer term effects.

Q. Now, in an induction termination, is it the case that the cervix is ultimately dilated to the full size of the fetus coming out? Is that the case?

A. Yes, it is in medical induction.

Q. And is that -- why isn't that as potentially as harmful, in your view, as the consequences of the dilation achieved using the methods utilized in the D & X procedure?

A. Again, the D & X procedure uses those laminaria or osmotic dilators whereas in the medical induction procedure, it's only medications that actually have the woman's body start a physiological process of contraction. So there is no laminaria put in in a medical induction, except in very, very rare circumstances.

Q. Just to summarize for the Court, what are your specific concerns with respect to the dilation procedure utilized in the D & X procedure?

A. The concerns are how many times the woman's cervix is dilated over so many days, and how far it's dilated with the number of laminaria. So no one has ever done a study to

show what the optimum dilation is of the cervix to reduce trauma. And what we are really talking about is how do we safely reduce trauma to a woman's cervix so they don't go on and have problems with their cervix later.

Q. Doctor, is it your position that there has to be a prospective randomized controlled study, in order to evaluate this procedure?

A. There are many different epidemiological studies that could be performed. And they don't all have to be the ones you described. The prospective randomized blinded trial.

Q. What other ways are there for evaluating the safety of this procedure other, than a randomized prospective controlled trial?

A. So there are other studies such as retrospective case controlled studies.

Q. What is a retrospective case controlled study?

A. That's when there is something called a case and a control. A case is whatever you're trying to study. So in this case, it would be a D & X procedure. Then you decide what kind of control group to compare it to. So you could say I'm going to compare the D & X to a medical induction of labor at the same gestational age. I'm going to compare the D & X to a D & E at the same gestational age. It's where we try to control for many, many factors that would be the same in all the groups, but then have one factor different. And

then we can head-to-head look at what the differences are between the groups.

Q. What is your response to the assertion that in trying to compare, say, a D & X to a dismemberment D & E in a study, in a prospective study, it would be difficult to do because it will be -- some women will simply choose not to undergo the dismemberment procedure when there is an intact alternative available?

A. Well, I think we have examples where women know that there may be more risk with one procedure or another, but they are willing to have themselves in a trial. One example would be the term breech trial. We had the experience in the United States where we really didn't know if it was safer to have a baby deliver vaginally who is breech or bottom first, versus shall we do the C section on those patients. So some doctors would say one thing and some doctors would say another. And all we had was retrospected or looking backwards data. Instead, we did this new term breech trial a few years ago looking prospectively. In other words, we said to women, we don't really know what's the safest procedure. We would like you to please be randomized to one of these two groups. Either trying a vaginal birth or going for a C section. And women would do it. I had three of my own patients in my own practice say, yes, I'll put myself into your care, the trial's care. That

we will randomize you then we are going to find out what the data shows. And I'm sure women undergoing the D & E or D & X or medical induction would, with good informed consent, be able to say, you know, Doctor, if you don't know what's safer, I want my care to be part of something bigger than myself, so I can help other women.

Q. And would those same views hold true with an effort to compare D & X to medical induction?

A. Yes.

Q. Do you feel that if there is any question as to whether one procedure is safer than the other, the informed consent process would assist in having women choose one or the other, in order to evaluate the two procedures?

A. Yes. And there are institutional review boards at major medical institutions that actually check those things to make sure they are even, and make sure women really get informed consent, when they are enrolled in prospective trials.

Q. Do you have any doubt that for the women who chose medical induction terminations after 18 or 20 weeks, that they would be undergoing a safe and effective procedure for termination?

A. It would be safe and effective.

Q. I would like to talk to you a little bit now specifically about potential long-term complications of the

D & X procedure. Have you had occasion to study the literature concerning abortion in order to assess its potential long-term complications?

A. Yes, that's one of the papers I have recently published in the last year-and-a-half.

Q. I think I have put it there on the ledge, Doctor. It's Defendant's Exhibit 631. Would you identify Defendant's Exhibit 631 for the Court, Doctor?

A. Yes. This is the review article I referred to, Long-term Physical and Psychological Health Consequences of Induced Abortion Review of the Evidence.

Q. And you are a co-author of this article; is that correct, Doctor?

A. Yes.

Q. You, in fact, participated in this systematic review of the literature?

A. Yes.

Q. And you relied on this article in providing your opinions today?

A. Yes.

Q. And you identified this article in the expert report that you provided to the plaintiffs in this case?

A. Yes, I did.

Q. What does this article address, Doctor?

A. This article looks at seven different possible physical

and psychological health consequences that occur after six weeks after the termination of pregnancy.

Q. How did you go about preparing and writing this article?

A. Well, we did what we call our own research using the computers to look at different databases that contained medical and psychological literature. So we asked with key words what -- basically, what are the articles out there if we do a literature search? So it started with a literature search then we honed it down to different topics.

Q. Did you call this a systematic review of the literature, Doctor?

A. It is a systematic review, because we have inclusion criteria and exclusion criteria.

Q. What are inclusion criteria and exclusion criteria?

A. Inclusion criteria were that we had specific ways of including a study or excluding it. For example, because we wanted to just look at the bigger studies and not look at just anecdotal case reports in such a systematic review, we limited it to having at least 100 subjects and a follow-up of two months or longer after an elective abortion.

Q. What other inclusion exclusion criteria, if you would recall? If you would like to refer to the article --

A. Right. We also looked at publications in English, so we didn't have any foreign publications translated for this particular systematic review. And then we did restrict it

to the med line database as well.
Q. Doctor, what is the -- you may have already touched on this. So we are clear on the record, what is the purpose and the benefit of this kind of a review?
A. Well, again, individual doctors don't have time to do this. This is so we can look at data in an aggregate, meaning we can combine things either by looking at individual articles next to each other, or we can see the limitations of individual articles next to each other.
Q. Now, Doctor, this article, your article here, looked at seven potential complications of abortion; is that correct?
A. Yes.
Q. Could you identify, for the record, what those complications were that you looked at?
A. Yes. We looked at seven complications, three of them showed no effect between.
Q. Let's just identify the complications right now.
A. The seven complications that we looked at are subsequent spontaneous miscarriage, subsequent infertility, and a subsequent ectopic or tubal pregnancy. In addition, we looked at breast cancer, placenta previa, pre-term birth and psychological effects.
Q. Doctor, what are some of the limitations in to trying to determine what the health effects of an abortion are?
A. Some of the limitations would include how do we actually

ascertain if a woman has had an abortion or not. So there may be some records that are hospital based records or data registry from national databases. Other times, women just report if they have had an abortion or not, and that might be one what we call ascertainment by us -- where we find out -- how did we find out if the actual event happened, such as an induced abortion.

Q. With respect to follow-up, is the extent of follow-up a potential limitation in trying to determine the health effects of an abortion?

A. Yes. People move quite a bit both in the United States and abroad. So sometimes, we don't have follow up on a particular woman. The other thing is sometimes when we go back to look, someone might have died from some other kind of reason, or maybe lost a follow up because her name changed or she has other reasons to not be in the area anymore.

Q. Is the adequacy of any reported data or statistics on abortion a potential limitation, on trying to evaluate the health effects of abortion?

A. It is.

Q. Why so?

A. Unless someone is actively looking for long-term complications, it may not be clear that they even correlate with them. That's why the long-term studies are so helpful,

because one can't always know a head of time if, say, a certain cancer might be related to a surgical procedure or if another kind of complication, such as pre-term birth, might be related to something that happened a year or two ago.

Q. I'm going to call your attention to a couple of statements or passages in your article, Doctor. The first one I want to call your attention to is on page 74, just a sentence. You state on the right-hand column, on page 74. That the long-term health consequences of elective abortion have been highly politicized. What do you mean by that?

A. It's just that people who actually are trying to do studies about long-term effects or any short-term effects on induced abortion -- that you always have this -- there is basically a fear on both sides. People -- that their own personal opinions about abortion will somehow in influence what their research shows about abortion. So this is caused -- instead of people on both sides of this argument saying women's health is really important and we are both for healthy women and we need to, you know, make some kind of collaborative effort to study long-term effects, it has been polarized instead.

Q. The very next sentence goes on to state those who would grant a moral status to an embryo or fetus, and thus limit elective abortion, often use adverse health consequences,

adverse health consequence claims as a tool to further their moral agenda. Has that been your experience in researching the issue of abortion?

A. Well, both of the thoughts -- may I actually say, I don't know where you are, so I'm having a hard time following.

Q. Page 74.

A. Right.

Q. Right-hand column.

A. Okay.

Q. Top of the page. Let me just read it all for the record. First there is a sentence which begins, the long-term health consequences of elective abortion have been highly politicized. Those who would grant a moral status to an embryo or fetus and thus limit elective abortion, often use adverse health consequence claims as a tool to further their moral agenda. While those who support no restriction on abortion access are, at times, unwilling to consider that pregnancy interruption could affect future and mental and physical health. That's a statement in your article. Is that right, Doctor?

A. Yes.

Q. Do you hold that opinion?

A. Yes, that. In fact, the research is always being questioned because of all the other political statements

that research can be used for.
Q. Doctor, just so we are clear, was this article that you co-authored, was this article motivated to exaggerate the health consequences of abortion?
A. No.
Q. What was it motivated by?
A. The whole point of this article is to let women know what the long-term possible consequences might be for their health, so that we can actually take care of women better.
Q. If you look a little bit further down on that page, Doctor, page 74, near the very end of the right-hand column where it says women deserve to be fully and accurately informed. Do you see that?
A. Yes.
Q. Could you just, why don't you read it this time for the record. Could you read that last sentence?
A. Sure. Women deserve to be fully and accurately informed about potential health effects of elective abortion, preferably in a health education context separate and distinct from the time frame of actually being faced with making difficult decisions about whether to continue or end a pregnancy.
Q. And does that statement reflect your views and opinions as to the need to inform women about the health consequences of abortion?

A. Yes.
Q. And just so we are clear, why do you think that's an important thing to do?
A. Women need to know, before they are faced with a crisis pregnancy, what would happen if they chose one path or another in their lives. It's not just about what's going to happen to that baby or potential baby. It's about what's going to happen to her possibly for the rest of her life. That she needs to have that information even before there is a crisis pregnancy. This is the kind of stuff that should be taught to teen-age girls. But the other thing is the doctor should understand this, and this is not previously been well understood.
Q. Doctor, which conditions, in your systematic review of the literature on this topic, which conditions did you find there was insufficient evidence of adverse consequences from a prior abortion? In other words, the ones that you showed, there was not sufficient evidence to show that abortion led to an adverse consequence?
A. Right. Three different topics that were researched and several articles were pulled on each of the topics. An induced abortion was not associated in the aggregate with ectopic pregnancy, tubal pregnancy that is, subfertility or difficult time getting pregnant the next time, and subsequent spontaneous miscarriages.

Q. You used the term abortions. What do you mean in the context of your study?

A. The way it's actually done in this study is this was done before first trimester medical inductions, meaning are you 486. So these are mostly all surgical abortions, and because surgical abortion is much more common the first trimester, it focuses on that, but also includes all comer abortion.

Q. Sometimes we talk about the induction method and sometimes we talked about induced abortions. In the context of your article, does induced abortion mean all methods of abortion that were utilized as -- that were utilized in the studies that you studied?

A. Yes, it's elective termination of pregnancy.

Q. Does that include surgical and medical induction?

A. Yes.

Q. Which finding, in your review, do you think is the most relevant to the partial-birth abortion debate?

A. The one finding that is the most striking, in fact, will have the most impact on women, is that about induced abortion in subsequent pre-term birth. So pre-term birth in the next pregnancy.

Q. All right. Now, I just want to do this a couple of times. I realize it's a little tedious, but I would like you to turn to page 75.

MR. COPPOLINO: May I approach the witness, Your Honor?

THE COURT: Sure. If you want to put that on the screen, Mr. Coppolino, that might help.

MR. COPPOLINO: Why don't we try to do that. That way everyone can see it.

THE COURT: Perhaps your assistant could help you or Ms. Beran can: I shamelessly promote this.

THE WITNESS: Thank you.

THE COURT: I appreciate this is not an eye test, so you're going to have to focus in on the sentence that Mr. Coppolino -- or the paragraph he wants to talk about.

MR. COPPOLINO: Thank you, Your Honor. The left side of the page, the first column and just move it up just a little. I'm going to have her read a portion for the record, Your Honor.

THE COURT: Go ahead

BY MR. COPPOLINO:

Q. Doctor, I would like you to read basically the first half of the second, of the left-hand column which begins abortion is a procedure.

A. Certainly.

Q. Down to the word prematurely about halfway down?

A. Right.

Q. You can read it off the text -- you can read it off the

paper. Whatever is easier.

A. Abortion is a procedure most used by women at the outset of their reproductive life. Most women having an induced abortion are under 30 years old. Pre-term birth is common affecting around 10% of deliveries in the western world, and is the leading cause of infant morbidity and mortality. Despite substantial investigative effort, primary preventive measures to lower the rate of pre-term births have proven futile, and rates have been steady or increased over the past two decades. The population based studies we reviewed suggest that induced abortion increases the risk of pre-term birth in subsequent pregnancies. Moreover, these reports suggest that a dose-responsive effect is present with increasing numbers of abortions associated with increasing risk. And that the linkage is most strong with extremely premature deliveries, less than 32 weeks, which is the population of newborns that experiences the bulk of morbidity and mortality that occur from being born prematurely.

Q. Okay. Let's just hold it right there, Doctor. Those statements you just read appeared in the study that you co-authored. Is that correct?

A. Yes.

Q. Those statements reflect -- they reflect the results of the research you undertake in helping to prepare this

article?
A. Yes.
Q. Would you explain to the Court what dose-response effect means?
A. Certainly. That means when you have one time something happens you get one kind of effect. So for this particular example, when women had one abortion, then they had a premature risk that was, say, one-and-a-half times greater. When they had two abortions, then they had two times greater the risk. And when they had three abortions, they may have had five times greater risk. So as you increase the number of abortions, the amount of risk for pre-term birth increases.
Q. All right. Doctor, I would like you to summarize for the Court what you found, as a result of your review of the literature, as to what studies indicated as to the effect of induced abortion on pre-term risk -- on pre-term -- let me just start that one over. I completely bungled that. Would you summarize for the Court what your article summarizes with respect to the connection between induced abortion and pre-term birth and subsequent pregnancies?
A. Yes. Pre-term birth, especially in the most modern of these studies, and the most recent ones, showed an increased risk in pre-term birth with induced abortion; between 1.3 -- meaning 30% higher to double the amount.

Q. Okay. I would like to just approach for a second, Your Honor. Page 70. All right, Doctor. I would like to call your attention to a passage on page 70 of your paper.

A. Yes.

Q. This is on the right-hand column, lower right-hand column under the caption induced abortion and subsequent pre-term birth. A little higher. All right. Doctor, would you read into the record the sentence beginning the portion beginning 12 studies down to the words a dose-response effect?

A. Yes. 12 studies found an association between these two phenomena, which is the pre-term birth and the induced abortion actually. I'll start again. 12 studies found an association between these two phenomena with consistent results in risk ratio elevation of 1.3 to 2.0. Moreover, seven of the 12 identified a, in quotes, dose-response effect, end quote, with risk estimates rising action a woman had more induced abortions. Also notable is the increased risk of very early deliveries at 20 to 30 weeks gestation after induced abortion, first noted by write Campbell and Beazley in 1972. Seven subsequent articles displayed this phenomena of mid pregnancy pre-term birth associated with induced abortion, which is especially relevant because these are the infants with the most risk of morbidity and mortality upon which society expends so many resources. Of

particular note are the three large cohort studies done in the 1990s, 20 to 30 years after legalization. Each shows elevated risk and a dose-response effect.

Q. Doctor, the passages you have just read are from the study that you co-authored here at what's the exhibit number? At exhibit number?

THE COURT: Should be 531 or pardon me. Yes, 631

BY MR. COPPOLINO:

Q. At Exhibit 631. Correct, Doctor?

A. Yes.

Q. And the information you just read in the record summarizes part of the results of your research; is that correct?

A. That is correct.

Q. All right. Now, also in the passage you just read, you omitted footnotes numbers, but the numbers in the parentheticals are the references to numbers contained at the article?

A. Yes. It lets other people look at the exact article and know what we are talking about.

Q. What I would like you to do is now that we have read the passage, if you could summarize, in your own words here in court, what the results of your research were, with respect specifically to the relationship between prior abortion and pre-term birth?

A. The results show that many of the studies looking at induced abortion and pre-term birth do show an elevation in pre-term birth. What that exactly means is women deliver before 37 weeks of pregnancy more often up to a doubling of that effect, when they have had induced abortion, or what we call abortion here.

Q. Yeah. And is this a risk of pre-term birth a risk that is beyond the normal risk of pre-term birth in a pregnancy?

A. Yes. This is when all the other risk factors for pre-term birth have already been looked at and controlled for during these studies.

Q. All right. Now, in your opinion, what does this -- these findings with respect to pre-term birth indicate, with respect to the potential long-term risks of the D & X procedure?

A. The concern is this: The studies we looked at looked mostly at first trimester abortions, and some second trimester, but even with these abortions in these studies, that there is an almost doubling effect of pre-term birth. And now, in the D & X procedure, we are talking a much greater size of the baby, and this baby being pulled through a partially open cervix such that the mechanism for injury which is purported to be both damage to the cervix, as well as possibly infections. That the potential for damage to the cervix is much greater in a D & X procedure than it

would be in a simple first trimester procedure.
Q. Now, Doctor, is it fair to say that your study and the studies that you rely upon don't say that abortion causes pre-term birth; is that right?
A. It does not show that. It says that there might be a correlation between the two.
Q. In your opinion, Doctor, what should women undergoing an abortion be told about the potential long-term complications of the procedure?
MS. CREPPS: Your Honor, I'm going to object on relevance, and I don't feel this was disclosed as within the scope of the opinions the doctor would be offering.
THE COURT: Well, what relevance does this have to anything we are talking about?
MR. COPPOLINO: Your Honor, first of all, this article was disclosed and it was inquired of at her deposition.
THE WITNESS: I'm not talking about the article.
MR. COPPOLINO: Right.
THE COURT: There is no consent issue in this case, it seems to me directly. I think that issues of consent, as the doctor has spoken about, about people need to know risk that sort of thing. And that's why she is particularly interested in risk, and how it's explained in common terms is perfectly appropriate background. But you're getting

much more specific here, and I don't understand the relevance.

MR. COPPOLINO: Well, I'll just briefly explain it. The point -- the question goes to the doctor has offered an opinion on the potential long-term complications of this procedure.

THE COURT: Sure.

MR. COPPOLINO: I think it's relevant for you to understand why she thinks that is important. And her desire to inform her patients about why that is important, I think, is relevant to helping you understand why she thinks it's important. If you are not interested in the answer to the question, Your Honor, I'll just move past it.

THE COURT: And I know you didn't mean it in the sense, but I don't determine relevance on whether I'm interested. As a matter of fact, I find the most interesting questions frequently the most irrelevant. So in any event, we won't get into that rather philosophical debate. I'm going to sustain the objection.

MR. COPPOLINO: That's fine, Your Honor. Your Honor, this would be a good breaking point. I don't have much more to do, but probably we should take a break now, if that's okay with the Court.

THE COURT: Is that agreeable, counsel.

MS. CREPPS: Yes, Your Honor.

THE COURT: All right. We'll take a 15-minute break now. Doctor, you may stand down.

THE WITNESS: Thank you, very much.

(Recess from 10:31 to 10:50 a.m.; all parties present).

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

(Dr. Shadigian resumed the witness stand).

THE COURT: You may proceed.

BY MR. COPPOLINO:

Q. Thank you, Your Honor. Doctor, if you still have your article, I would just like to ask you about one additional sentence in the article. It's on page 75, and we'll forego the technology, Your Honor. It's just one sentence for this one?

THE COURT: Sure.

BY MR. COPPOLINO:

Q. Page 75, left-hand column, last sentence of the middle paragraph. And I'll just read it, Doctor. It says for those women -- are you with me?

A. Yes.

Q. For those women who choose abortion techniques that, in theory, protect the cervix from trauma such as laminaria or pre-abortion cervical ripening should be used. Is that a sentence in your article, Doctor?

A. Yes.

Q. Now, in your opinion, would the use of such techniques reduce or even eliminate the potential long-term risks of pre-term birth from abortion?

A. It may.

Q. And is that something you believe requires further study before we know that?

A. Yes.

Q. Why is that the case?

A. Theoretically, by using laminaria or Misoprostol, these other cervical ripening techniques, we may reduce trauma to the cervix. And that may be the postulated mechanism of why pre-term birth is higher, especially in first trimester abortion where it's not used as often.

Q. Given the stage in gestation when D & X might be performed, and the amount of dilation that's typically utilized, will we know the answer to that question until the issue is studied?

A. That's the whole point is we need to study it to know if the laminaria actually help or not.

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

A. The D & X procedure is really a separate procedure from the D & E, and it cannot be relied upon -- the data on D &

E cannot form the opinion for D & X complication safety rates.

Q. Why, specifically, do you think that's the case?

A. Just like a D & C is considered a separate procedure as a D & E, that they are different complications in the first trimester, there are different complication the D & E procedure, so it is with D & X. It is a different procedure. It may use similar techniques at the beginning of the procedure but it really has a different set of ways of going about delivering the infant.

Q. What is it about some of the differences between the procedures, either with reference to gestational age or amount of dilation, that you feel it cannot be judged based on the safety of the D & E procedure?

A. Without head-to-head studies, we cannot conclude anything about the D & X procedure. Specifically, because it was purportedly initially used for babies at different gestational ages, in fact, greater gestational ages than usually use the procedure D & E was used for, and that the cervix is more dilated to accomplish an intact procedure.

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

A. Again, can I not rely on D & E data versus medical

induction to form an opinion on D & X, because it really is a separate procedure, so can't draw a conclusion of the safety of D & X to medical induction.

Q. In particular, do you think studies that compare D & E to prior methods of induction provide any information that the Court could look to in attempting to evaluate or compare D & X to medical induction?

A. The older methods of medical induction are what we have the most data on, unfortunately. We don't have much data on the Misoprostol, although that is safer in the newer studies. So we can't use old data well, but that's all we have sometimes. So looking at medical induction numbers, we can compare them head-on-head with D & E, when there are such studies, but we can't head on head compare them to D & X.

Q. Even if we were to rely on prior studies comparing prior methods of D & E or -- let me rephrase that. Even if we rely on prior studies comparing D & E to prior methods of induction, what would that tell us with respect to the relative safety of D & E and prior methods of medical induction such as installation saline, installation.

A. We do have some head-to-head steady studies looking at that. One thing people should know that at 21 weeks and greater, that the mortality data, meaning moms dying later, is actually less for medical induction as compared to D & E

at 21 weeks gestation and greater. It's about the same around 20 weeks. But the medical induction and D & E are safe procedures, especially in the 16 to 20-week range.

Q. Doctor, are you familiar with an article recently written by Drs. Autry, et al., entitled A Comparison of Medical Induction and Dilation and Evacuation for Second Trimester Pregnancy. Are you aware of that article?

A. Yes, I am.

Q. If you look at placed on the desk there, Exhibit 545, Defendant's Exhibit 545. I believe that's what it says. Is that what it says at the bottom?

A. Yes.

Q. Do you recognize this article, Doctor?

A. Yes.

Q. Did you have occasion to review this article?

A. Yes.

Q. Did you review it in connection with preparing your expert record in this case?

A. Yes, I did.

Q. I believe you cited this article in the appendix of your expert report?

A. Yes, I did.

Q. Doctor, this article appears to conclude the D & E method of abortion is safer, based on mortality or morbidity statistics than the induction method of abortion; is that

correct?

A. Their conclusion is that D & E is safer for women but I don't think they looked at mortality.

Q. Okay. Let me ask you then, why don't you summarize what this article concludes instead of me, and then I want to ask you questions about what you think about it.

A. This article concluded that dilation evacuation was the safest method of second trimester abortion but that the Misoprostol was safer than other abortion methods.

Q. All right. Now, to what extent do you agree with the conclusions set forth in this article?

A. Well, I had several problems with this article. One is the biggest complication they talk about is retained placenta. Retained placenta is when the baby comes out and the placenta remains inside the woman's uterus after a period of time. They don't actually define what a retained placenta is. They don't say it's two minutes or 20 minutes or two hours. So one of my biggest complaints is they never define how long it is to have, in quotes, a retained placenta. At term, we wait up to 30 minutes for a placenta to come out, but usually in the second trimester, we wait at least two hours. But they never define that here and I don't even know what their criteria is. So the first thing is they don't define what a retained placenta really is. In addition, they don't tell you why women were chosen for

either group. It wasn't randomized. You don't know why some people had a medical induction or underwent a D & E procedure. And it doesn't say if the people writing the article were actually blinded as to who was in what group. Finally, one of the key points is the gestational age was very different between the two groups for medical induction and for the D & E. And I'm going to refer to a table, if that's okay.

Q. Sure?

A. So in the surgical induction or in the surgical group, the gestational age was two weeks less, so around 18-and-a-half weeks, as compared to 20-and-a-half weeks. So that, in and of itself, just having a difference of two weeks in gestational age, may account for the entire difference scene in this article. And they even say this was statistically a different set of populations, but they still draw those conclusions. So I can't really -- because I think this article is so flawed, I can't draw any conclusions to help me because of these problems I have with it.

Q. With respect to the last point you made on the differences in gestational age, what is the significance of that disparity in terms of evaluating the results of this article?

A. We know from prior research that the farther along a

woman goes in the pregnancy, the more complications there is -- there are for terminating a pregnancy. And because in the medical induction group, the women were at least two weeks farther along in the pregnancy than the surgical group, that may, in fact, account for all the complication differences. I don't think it does 100%, because of the retained placenta issue, but it certainly could account for most of the differences. So, in other words, if we had the exact same gestational age in both groups, then in this article, I might be able to draw some kind of conclusion.

Q. With respect to the retained placenta issue, Doctor, you mentioned, I believe, that your practice is to wait about two hours for the placenta to pass after induction termination, if it's not passed immediately?

A. Yes.

Q. And is that the case when there is no emergent circumstances such as maternal bleeding?

A. That's correct.

Q. All right. And would an emergent circumstance such as maternal bleeding constitute a true complication of the induction procedure?

A. Yes. Maternal hemorrhage is a complication.

Q. All right. Now, how common a practice is it to wait up to two hours for the placenta to pass after an induction?

A. Seems to be a fairly common practice, at least for my

colleagues at U of M, University of Michigan.
Q. What is done to remove a retained placenta, when you have to go back in and remove it?
A. Most of the time, we see if the cervix is dilated enough to actually just put our gloved hand up inside the uterus and gently pull away the placenta from the sidewall of the uterus. Sometimes that's already happened a little bit. We just further place our hand between the placenta and the uterus. However, sometimes we have to do a curettage or a scraping of the placenta to come out.
Q. Now, if you -- how different is the procedure for removing a retained placenta after a medical induction from a procedure for removing the placenta in a D & E abortion?
A. It's essentially the same procedure. It's removing the placenta. It's just the timing of when the baby comes out and when the actual placenta comes out that's different.
Q. In the Autry study, the removal of the retained placenta was counted as a complication; is that correct?
A. That is right.
Q. Do you have an opinion as to whether counting the retained placenta as a complication of medical reduction has skewed the comparison between the safety of the two procedures?
A. It has, in this study.
Q. Do you think that her statistical comparison of the

safety of the two procedures is reliable because she's used retained placenta as a complication of medical induction?

A. I think this is part of the flaw of the study that we can't really use that as a true complication.

MR. COPPOLINO: Just one moment, Your Honor.

THE COURT: Sure.

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

THE COURT: Counsel, you may inquire.

CROSS-EXAMINATION

BY MS. CREPPS:

Q. Thank you, Your Honor. Dr. Shadigian, can you tell me who is the chair of your department at the University of Michigan?

A. Yes. His name is Timothy RB Johnson.

Q. You respect Dr. Johnson as a physician; is that correct?

A. Yes, I do.

Q. And you're aware, aren't you, Doctor, that Dr. Johnson is a plaintiff in the New York case challenging the partial-birth abortion ban?

A. Yes, that's what I have been told.

Q. Doctor, you described, in some detail, the literature search that you conducted in formulating your opinions and preparing your expert report in this case?

A. Yes.

Q. And you reviewed, I believe, in the conduct of that literature search between 80 and 150 abstracts, is that correct?

A. That's correct.

Q. And all of the articles that you felt were relevant to your opinions from that search are cited in your expert report; is that correct?

A. I believe they are.

Q. And in your report, you have cited ten journal articles and book chapters; is that right?

A. I think. Yes, that's correct.

Q. And the sources you've cited have come from reputable sources that physicians would, such as yourself, would rely on in doing looking at issues in this field?

A. Yes. They were peer reviewed journals that we looked at.

Q. Doctor, do you believe there is a substantial body of medical opinion that induction is safer than D & E after 20 weeks?

A. Yes.

Q. Do you believe there is a substantial body of medical opinion that D & E is safer than induction after 20 weeks?

A. There are some opinions that D & E is safer, such as the Autry article that I just cited.

Q. But it's your opinion that there is not a substantial

body of medical opinion that believes that D & E is safer than induction after 20 weeks?

A. It depends on what you mean by body of opinion. If you could define that, maybe I could explain.

Q. Well, let me go back a step then. When I asked you if you believed that there was a substantial body of medical opinion that induction is safer after -- safer than D & E after 20 weeks, and you responded yes, what were you referring to?

A. I was referring to the literature search I did and the review of the articles that I did. And so it was my opinion, plus the opinion of others that did review articles, that brought that to light.

Q. All right. So it's your synthesis of the information that's out there that leads you to conclude that there is a substantial body of medical opinion?

A. Yes.

Q. Doctor, do you agree that the safest and most appropriate abortion procedure for a particular woman depends, in part, on the gestational age of the fetus?

A. Yes.

Q. And that the safest and most appropriate abortion procedure depends, in part, on the woman's health?

A. Yes, it may.

Q. And that the safest and most appropriate abortion

procedure for a particular woman depends, in part, on medical contraindications to a particular procedure or part of a procedure for that woman?

A. Yes.

Q. And do you agree that the safest and most appropriate abortion procedure for a particular woman depends, in part, on her history of gynecological surgery?

A. It may, yes.

Q. And that the safest and most appropriate abortion procedure may also depend, in part, on the training, skill and experience of the physician performing the abortion?

A. It may.

Q. You would agree, wouldn't you, Doctor, even if two procedures are statistically similar in terms of risk, the safety for each particular woman depends on her individual circumstances?

A. Yes.

Q. Doctor, just to go back through some of your earlier testimony. You do not perform abortions on live fetuses, except when it's your belief the mother will die, if the pregnancy is not terminated; is that correct?

A. That's correct.

Q. That is luckily a very rare occurrence; is that right?

A. Yes.

Q. And your best estimate is that you have had to terminate

a pregnancy in that circumstance between 20 to 40 times in your career?

A. Yes.

Q. And in every case in which that was necessary where the fetus was alive, you did that by induction and not D & E; is that correct?

A. That is correct. In my practice.

Q. And in your career, you have performed -- well, since you have been at the University of Michigan, approximately 10 to 20 D & E procedures; is that correct?

A. I believe that's so. I never counted them.

Q. Okay. And the latest that you will -- that you've performed a D & E procedure is approximately 20 weeks?

A. I would say 20 weeks in my residency, and probably up to 17 to 18 weeks in my practice at the University of Michigan.

Q. And in your capacity as a supervising physician, you estimate that you supervise residents doing D & Es zero to two times a year; is that right?

A. That's correct.

Q. And, again, these are -- you are supervising is also in cases of fetal demise; is that right?

A. Yes, it would be only in case of fetal demise, because I don't perform any on live babies.

Q. So you wouldn't supervise somebody else doing that?

A. Correct, because I'm considered the practitioner also,

and I would be helping if I did it.
Q. Okay. And you supervise approximately two to five inductions of labor per year, for the purpose of removing a dead fetus; is that right?
A. No, that's not what I said.
Q. Okay. Can we -- in the second trimester, can you estimate how many times a year you would supervise a procedure to remove a dead fetus by labor induction?
A. Probably about two or three times per year.
Q. And you have never discussed, I think we are using the term D & X for your testimony. You have never discussed the D & X abortion procedure with Dr. Johnson; is that correct?
A. If we discussed it at all, it may have been in a teaching situation, not one-on-one with somebody else there.
Q. And you have never discussed the D & X procedure with any physician, any other physician who performs it; is that correct?
A. That is correct.
Q. And you have never induced fetal demise by means of a drug administered to kill the fetus; is that correct?
A. That is correct.
Q. At the University of Michigan, among the physicians who perform abortions on live fetuses, the decision whether or not to induce fetal demise, prior to the procedure, is left to the individuals physicians; is that correct?

A. That is correct.
Q. You do not give formal lectures to medical students at the University of Michigan on the complications of abortion; is that correct?
A. What do you mean by formal lectures.
Q. A scheduled classroom lecture.
A. No.
Q. Doctor, you testified on direct that you are a member of the American Association of Pro-Life Obstetricians and Gynecologists; is that correct?
A. Yes, it is.
Q. In fact, you have served on the executive board and are currently secretary of that group?
A. That's correct.
Q. You've also received an award the Matthew J. Bulfin Award for Research, and Matthew J. Bulfin was the founder of the American Association of Pro-Life Obstetricians and Gynecologists; is that correct?
A. Yes, and he's passed away now.
Q. And you are also -- and that award is based on the best scientific project with respect for life and its origin; is that correct?
A. It was the best -- it's a research award. It's based on literature and research.
Q. But the award is given on the basis of scientific

projects with respect for life and its origin; is that correct?

A. I believe that's the subtitle of the award but I haven't looked at that.

Q. And you're also a member of the Catholic Medical Association and have lectured at meetings of that organization; is that correct?

A. Yes.

Q. And it is the position of the Catholic Medical Association that abortion is an unspeakable crime, and no Catholic physician should cooperate formally or materially in its performance; is that correct?

A. I don't know.

Q. And it's also correct, is it not, Doctor, that many of the presentations listed under extra mural invited presentations on your resume have been at meeting either at the American Association of Pro-Life Obstetricians and Gynecologists or the Catholic Medical Association?

A. I believe I have only lectured the Catholic Medical Association one time, but I would lecture to anyone who would invite me to come to their meeting.

Q. You have also given, as reflected on your resume, presentations to the National Institute of Family and Life Advocates; is that correct?

A. Yes.

Q. And Right to Life of Michigan?
A. Yes.
Q. And the Baptists for Life in Grand Rapids?
A. Yes.
Q. And among some of the writing that's listed on your resume, one is chapter entitled Breaking the Silence, Long-term Physical Complications of Induced Abortion and that appears in a book entitled Back to the Drawing Board, the History of the Pro-Life Movement; is that correct?
A. Yes, it is. It's a summary of the article we just went over.
Q. And in your prior work as an expert in other cases, you have actually only testified in front of a judge on one occasion; is that right?
A. That is correct.
Q. Doctor, in your expert report, I think as you have testified here today, you have stated no comparisons between medical induction of labor for termination of pregnancy and D & X procedure have been done; is that that's correct?
A. To my knowledge, that is correct. Based on the literature.
Q. You also state in your report medical induction is a safer abortion procedure than D & X; is that correct?
A. That sentence may be in there, but it is based upon another set of sentences with it.

Q. Do you agree, Doctor, that medical induction -- is it your opinion that medical induction has been established to be a safer abortion procedure than D & X?

A. I would say it is the study and safer abortion procedure, yes.

Q. And you hold that opinion, even though there are no published peer review medical studies comparing D & X and induction?

A. I believe you're taking the title of a section of my expert report, and that is the title of a section of my expert report. And then I have several paragraphs explaining why I believe that.

Q. Well, Doctor, is that your opinion? Medical induction is a safer abortion procedure than D & X?

A. Because we don't have any safety data on D & X, I would say it is, yes.

Q. And you hold that opinion, even though there are no published peer reviewed medical studies evaluating the D & X procedure?

A. Yes.

Q. You also stated in your expert report, and I believe in your testimony today, that in the absence of any published peer reviewed medical studies, evaluating the indications and complications of the D & X procedure, there is no sound basis for concluding that the D & X procedure offers safety

or clinical advantages over alternative abortion methods. Is that your opinion, Doctor?

A. Yes.

Q. And is it your opinion, Doctor, that the clinical experience of board certified OB/GYNs, who would routinely perform second trimester abortions, is not a sound basis for concluding that D & X offers safety or clinical advantages over other methods of clinical abortions?

A. Correct.

Q. When you were discussing earlier -- I believe it was the Haskell presentation, you indicated one of the problems with this kind of a case report is that the physician has nothing to compare it to. Am I characterizing that correctly?

A. Yes, I said there were no comparison or control groups in such a study.

Q. For a physician practicing abortion, practicing doing abortions in the second trimester on a routine basis who has integrated attempts to remove fetuses intact into his practice, isn't it true that that physician would have a basis of comparison, which would be his earlier practice of removing the fetus through dismemberment with his current practice of attempting to remove the fetus intact?

A. The practitioner that you're describing would have a basis to compare what's at hand in front of them but wouldn't be able to necessarily talk to short or long-term

complications.
Q. Doctor, I believe you testified that, in your opinion, a partial-birth abortion is never medically necessary as a procedure to terminate the pregnancy of a woman, in order to preserve her life or health; is that correct?
A. Yes.
Q. And that one of the reasons supporting your opinion is that the circumstances in which it's necessary to do a termination to preserve a woman's life or health is very rare; is that right?
A. That's part of it, yes.
Q. But the fact that it's rare doesn't change the fact that the woman in that situation should have access to the safest and most appropriate abortion procedure; isn't that right?
A. Yes, if they are well studied, we could see if something is safe and effective.
Q. It's your opinion, Doctor, killing the fetus in these circumstances is never necessary?
A. The baby dying would be a natural secondary result of medical induction abortions, for example. But in an of itself, killing the baby does not offer any health benefits for a woman nor will it change her medical outcome.
Q. And that opinion would apply with equal force to D & E procedures in the same circumstance; isn't that correct?
A. Yes, it would.

Q. In your practice, you would never perform a D & E procedure in that circumstance?
A. On a live baby, I would not. No.
Q. I believe you may have given some examples where you felt that there were reasons why you would want to avoid a surgical procedure for women in certain health situations; is that right?
A. Yes.
Q. And, again, those opinions would apply with equal force to whether the procedure was going to be done by D & E or by D & X, as you understand that procedure; isn't that correct?
A. I would have to go back to the exact paragraph that you're talking about.
Q. All right. We'll just move on then.
A. Okay.
Q. One of the differences, I think that you described in your induction procedures for fetuses that have not obtained viability or fetal -- let me start that over. One of the differences, in the way you perform induction procedures for fetuses that are dead is that you can give higher doses of the medications that you use, because there is no concerns about the fetus; is that right?
A. Yes.
Q. And I believe you testified that this can result in a shorter time for the induction procedure?

A. It may.
Q. Doctor, did I understand your testimony that you do not personally perform amniocentesis your patients?
A. I did as a resident and as an early faculty member, but now there is a whole unit that just does fetal diagnosis, so I don't now.
Q. So you would refer your patients who needed that to that unit?
A. At the University of Michigan, certainly. Yes.
Q. Doctor, when you perform D & C procedures, you use mechanical dilation; is that correct?
A. Yes, I do.
Q. And when you perform vacuum aspiration procedures to remove a dead fetus, you also would use mechanical dilation as needed; is that correct?
A. Yes.
Q. And you have also used laminaria for some of your abortion procedures; is that correct?
A. Yes, I have.
Q. And in some instances, that has included serial laminaria, which by that, I mean more than one insertion of laminaria?
A. That is correct.
Q. And you're also considering for future cases, or maybe at the present time, adding Misoprostol with the laminaria

for the D & E procedures that you use?
A. Yes.
Q. And you think that may hold safety advantages for the dilation process?
A. It may.
Q. The patients who receive laminaria are allowed to leave and return the next day for the procedure; is that correct?
A. Yes.
Q. Doctor, I think you testified that one of your concerns about the D & X procedure is that the dilation process may apply or result in a different or greater force being applied to the cervix than in an induction procedure; is that correct?
A. I don't think I used those words today.
Q. Is that a correct statement, though, that those are your concerns -- let me restate the question. That the dilation process for D & X may result in a greater or different type of force being applied to the cervix than in induction procedures?
A. I think it's not just -- may I clarify?
Q. Yes.
A. Thank you. I think the point that I was trying to make -- it's not just the dilation that's different and greater, but it's actually the nonphysiological process of bringing the baby through the open cervix that is different in a

medical induction versus a D & E, for example, or D & X. I'm sorry, for example.

Q. But you can't quantify the differences there, in order to express your concerns and how they might increase the risks between the procedures; is that right?

A. That's exactly right. And that's why the studies need to be done, so we can understand what those risks may or may not be.

Q. Doctor, I meant to ask you, when you've used laminaria, I believe it was your testimony that in some cases you also would use additional mechanical dilation at the time that the products of conception are removed; is that correct?

A. Sometimes.

Q. So just to be clear, Doctor, for example, there is no way, at this point, for us to compare dilation that is achieved over two days using laminaria with, for example, a four-hour induction using Misoprostol alone; is that correct? In terms of risks to the cervix?

A. There are ways to compare those things.

Q. Based on current studies?

A. I see what you're getting at, so could you restate the question, please.

Q. Sure. It wasn't very artfully asked. At this point, based on what we know now, there would be no way to compare, for example, the effect on the cervix of two days of

laminaria used to dilate the cervix with the use of Misoprostol, which results in expulsion of the fetus in four hours?

A. Exactly. That there are no head-to-head studies looking just at how the cervix is dilated in a serial dilation over several days versus how it's dilated over four hours. That is correct.

Q. Doctor, just a few questions on the review article that you discussed, Defendant's 631. I don't think you'll need to read out of it, but if you would like to have that in front of you, that's fine. That article looked at 24 studies looking at an association between abortion and pre-term birth; is that correct?

A. Yes, it did.

Q. And 12 of those studies, in other words, half of those studies found no association; is that correct?

A. Yes, the older studies showed no association. There happened to be 12 of them, yes.

Q. And even among the more current studies, isn't it correct that not all of them found an association? I believe, if you cut it off at about 1980, the six later studies, four found an association but two did not; is that correct?

A. That's correct. I didn't look at your numbers but I'm going to assume you're right.

Q. And your concern that there may be a correlation -- well, before I get to that question, let me just confirm. You testified that most of these studies are looking at first trimester abortions, or that's the majority of abortions that are considered in those studies; is that correct?

A. Yes, they were probably the majority of the abortions in those studies, that's correct.

Q. And you believe that based on these studies, there may be a correlation between greater dilation in the second trimester and pre-term birth, based on studies showing an association with dilation in the first trimester?

A. Well, my concern is just that really, it's a mixed bag of first and second trimester basically in these studies, and most of them didn't separate those out, unfortunately. But the concern is you don't dilate as much in the first trimester and you actually dilate more in the second trimester. So the concern is, could there be even more pre-term birth with second trimester abortions or later gestational age ones.

Q. But because those studies are looking primarily at first trimester abortions, in which the method of dilation was most likely mechanical dilators, whereas abortions in the second trimester are being done with laminaria or a combination of laminaria and Cytotec, it's purely

hypothetical that there might be a greater risk, based on these studies?

A. Yes. That's the whole point is we don't have studies on whether they use laminaria or not in whatever trimester, but it is one of the concerns. But it is a theoretical concern, rather than one based completely on solid evidence. Correct.

Q. And Doctor, was -- did the studies that you included in the review article include a study by Kalish at all, looking at abortions from 14 to 24 weeks?

A. No, I don't believe it did.

Q. Doctor, it's your opinion, isn't it, that it's impossible during a D & E procedure that most of the fetus can be removed in a single pass?

A. I think I said it would be rare, unlikely.

Q. And that's based on your experience performing D & Es and observing D & Es; is that correct?

A. Yes, and from reading reports, yes.

Q. And you agree that the fetus is more friable as a result of demise and, therefore, disarticulation is more likely or may be more likely with a dead fetus than a live fetus; is that right?

A. Would be more likely or more easily performed.

Q. Well, more easily performed, I guess would be appropriate, based on your prior answer?

A. Yes.
Q. And Doctor, you believe the average time for the surgical removal of the fetus during a D & E procedure under normal circumstances is between 30 minutes and two hours; is that correct?
A. I don't think I said that was the normal range. I think probably the normal average is probably closer to 30 minutes. I think when the question was asked, I was being asked about a full range.
Q. Doctor, let me have you take a look at your deposition and we'll sort that out. May I approach, Your Honor?
THE COURT: Yes.
MR. COPPOLINO: I have got the deposition. Thank you.
THE WITNESS: Thank you.
BY MS. CREPPS:
Q. Doctor, can you turn, please, to page 141 of your deposition?
A. Yes. Just a second.
Q. And I'm looking at line 11, and I'm going to read my question and your response and see if that's your opinion. How long, on average, does a surgical removal of the fetus take? Answer: Again, it depends on the gestational age and other factors, meaning that if the woman has a uterine anomaly, it may take longer or if there is a complication.

However, in the basic usual circumstances, it can take probably between 30 minutes and two hours. That was the response to that question you gave in your deposition; is that correct, Doctor?

A. It is.

Q. Thank you.

A. I think -- may I say something though or not?

THE COURT: Typically, Doctor, the lawyers will. It puts them in an awkward position, because they are supposed to ask the questions and not argue with you, but if you can certainly add anything if you want -- if you think that your answer is unclear, you feel free to do that. But if it regards something else, then I would prefer that you not. So if you think the answer you just gave is unclear and you need to explain it, feel free to do that. If not, wait for somebody to give you a question that will give you an opportunity.

THE WITNESS: Okay. I'll wait.

THE COURT: Okay.

BY MS. CREPPS:

Q. And, Doctor, you acknowledge that it's theoretically possible intact removal of the fetus could result in less sharp bony fragments within the uterus; is that correct?

A. Yes.

Q. Some of the concerns you have indicated about insertion

of laminaria were, I believe, the risk of infection or trauma to the cervix; is that right?

A. Yes.

Q. And those risks are present whenever laminaria are inserted, whether it's a single time or two times or more; isn't that right?

A. Yes .

Q. Doctor, you do not believe there is a substantial body of medical opinion that D & X may be the safest and most appropriate procedure for some women in some circumstances; is that correct?

A. Yes, based on the medical literature.

Q. And you believe there may be a substantial body of personal opinion that D & X may be the safest procedure for some women in some circumstances; is that correct?

A. I believe when I said that, I believe I meant personal/medical anecdotal.

Q. Yes. I would like to have you take a look at Plaintiff's Exhibit 5, which I'm going to come and get the binder for you, and this is one of the ACOG statements of policy.

A. Thank you. I'm there.

Q. You're familiar with this statement of policy; is that correct, Doctor?

A. Yes, I am.

Q. And I believe there is a description of intact dilation and extraction on page two, which you indicated on direct, you had reviewed in formulating your opinions in this case; is that correct?

A. Yes.

Q. And according to the policies, to this policy statement, the intact D & X procedure is one method of terminating a pregnancy after 16 weeks; is that correct? I'm looking at the last sentence on page two.

A. That's what the sentence says, yes.

Q. Now, if you will go to page three, Doctor, and in the right-hand column, I'm going to read the second sentence. An intact D & X, however, may be the best or most appropriate procedure in a particular circumstance to save the life or preserve the health of a woman, and only the doctor in consultation with the patient, based upon the woman's particular circumstances, can make this decision. Do you agree with that statement, Doctor?

A. I'm just reading it again. I'm sorry.

Q. Take your time.

A. I would say that the person who is in front of the woman, her physician at the time, is probably the best person to make the decision, but it has to be based on not just personal experience but on the medical literature too.

Q. Doctor, if a physician who routinely performs D & E

procedures believes that intact removal of the fetus is the safest and most appropriate procedure, is it your opinion that that physician should, nonetheless, not do that procedure?

A. I think the issue is around the belief. What contributes to a belief about something and that's what the whole issue is around this. So it's around that word belief that I have the most hard time with.

Q. So would it be your opinion, Doctor, that physicians should limit the amount of dilation they attempt to achieve in a D & E procedure, in order to avoid the possibility of intact removal of the fetus?

A. Not necessarily.

Q. And it's your opinion, Doctor, that this ACOG statement of policy is simply a compilation of the personal opinions of several physicians who sat on the executive board at the time this statement was issued; isn't that correct?

A. It is correct that it was just approved by the executive board, which is a small number of physicians, but they didn't talk to any of the rest of the body of ACOG about any of these issues.

Q. And so it's your feeling that this is simply a statement of their personal opinions; isn't that correct?

A. It's a statement of their personal/medical, anecdotal opinions, yes.

Q. Doctor, one of the concerns that you've raised about D & X procedure is that the indications for the procedures have not been studied; is that correct?

A. Yes.

Q. By indications, you mean the reason why the procedure would be performed?

A. The reason why that procedure would be performed over other procedures.

Q. And, Doctor, in your report, you cite an article by Epner, et al., entitled late term abortion. Is that correct?

A. Yes.

Q. I would like to have you look at Plaintiff's Exhibit 41, if you would, and I think that's in the same binder?

A. It is.

Q. And this article was published in the Journal of the American Medical Association in August of 1998; is that right?

A. Yes.

Q. You cite this article in your expert report for the proposition that medical inductions after 21 weeks have slightly lower mortality rates than D & E abortions at 21 weeks; is that correct?

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

Q. Sure. You cite this article in your expert report for

the proposition that medical inductions after 21 weeks have a slightly lower mortality rate than D & E abortion procedures at 21 weeks and higher?

A. Right. It's inclusive of 21 weeks, correct.

Q. And I would like to have you look at page 727 of this article on table four.

A. Yes.

Q. And this chart reports -- this reports the abortion-related mortality rates for induced abortion procedures at 13 weeks or later; is that correct?

A. Yes, that's in the title from 1974 to 1987.

Q. And the chart reports that for abortions performed at 21 weeks or greater, the mortality per 100,000 abortions is 11.9 for D & E; 10.3 for labor induction; and 274.3 for hysterotomy or hysterectomy; is that correct?

A. Yes, that's the third column in that table.

Q. And the authors describe the rates of mortality for D & E and labor induction at or after 21 weeks as comparable; is that right?

A. Say that one more time. I'm sorry.

Q. The authors of this article describe the mortality rates for D & E and labor induction at or after 21 weeks as comparable; is that correct?

A. I don't know. If you show me the sentence, I'll understand what you mean.

Q. Okay. If you will look on the same page under the heading of abortion related mortality and go to the last sentence in that section, and I'll just read it out loud. Mortality rates overall are higher for abortion related labor induction than D & E (7.1 and 3.7 respectively) but are comparable for induced abortions performed at 21 weeks or more, 11.9 and 10.3 respectively. That's how the authors characterize this information; is that right?

A. Yes. Without further analysis, that's what they did.

Q. Doctor, still on the same page now. I'm in the far right column. I'm looking at the third paragraph in that column, and I would like to read to you from that paragraph and see if you agree with some of the statements here. The paragraph states cervical incompetence and compromised subsequent pregnancies are important but unresolved concerns related to second or third trimester abortions. Little research exists on whether those complications are more likely to result from D & E (or intact D & X) or from labor induction methods. You agree with those statements, don't you, Doctor?

A. Yes.

MS. CREPPS: Your Honor, at this time, I would like to move Plaintiff's Exhibit 41 into evidence for the reasons that we have discussed previously.

THE COURT: The Government renews its objection.

MR. COPPOLINO: We renew our objection, Your Honor.

THE COURT: Mr. Henry is nodding. I'm getting a double objection. Mr. Henry is giving you the thumbs up.

MR. COPPOLINO: Speaking of Mr. Henry.

THE COURT: Yes, sir.

MR. COPPOLINO: We might even be able to address this issue today. If you would like, after the witness is concluded, this whole issue of what are we going to do with these articles -- I think we are prepared to address that in further detail.

THE COURT: I'll withhold ruling on 41. That's also 561, I think of the defendant's as well.

MR. COPPOLINO: Yes, it is, Your Honor.

THE COURT: I'll withhold ruling. Go ahead.

MS. CREPPS: Your Honor, I'm close to being finished. May I have just a moment.

THE COURT: Sure.

BY MS. CREPPS:

Q. Doctor, I believe it was your testimony that the practice at the University of Michigan has shifted away from doing D & E procedures after 20 weeks towards the performance of induction; is that correct?

A. Yes.

Q. But you're not aware of the exact number of physicians at the University of Michigan who perform abortions; is that

right?
A. I could count them up probably.
Q. Well, in your deposition, you estimated that it was five or six; is that right?
A. Correct.
Q. And of those, you do not now how many perform abortions after 20 weeks; is that correct?
A. I don't know specifics on cases, correct.
Q. In formulating your opinion regarding a practice at the University of Michigan shifting away from D & E at 20 weeks and towards induction, you did not speak with the chair of your own department, Dr. Johnson; is that correct?
A. Correct. I talked to a different colleague.
Q. Doctor, it's fair to say, is it not, that your opinion that induction is safer than D & X for abortions at 20 weeks and later is a hypothesis you have developed from looking at studies that don't look at D & X but look at other aspects of abortion procedure?
A. That is correct.
Q. It would have been possible to make the same kind of hypothetical comparison between D & X and D & E?
A. Yes, we could have done that as well. I could have done that as well.
MS. CREPPS: I don't have any other questions, Your Honor.

THE COURT: Redirect?

REDIRECT EXAMINATION

THE COURT: Mr. Coppolino, I have criminal matters over the noon hour, but I'm okay to go into the noon hour a little bit. But if you want to take a break and come back at 1:30, if that's your preference, that's fine with me.

MR. COPPOLINO: Your Honor, I expect to have only about five minutes maybe.

THE COURT: Oh, that's fine.

MR. COPPOLINO: Five or ten minutes then. If you have questions, that may force us to go -- if we have to leave right at noon, I suppose we would have to come back. But if you had a few minutes, we could wrap this witness up by 12:15 or so.

THE COURT: That would be fine.

BY MR. COPPOLINO:

Q. Doctor, on the last point Ms. Crepps was asking you about, with respect to your opinion on the relative safety of D & X and induction, is it in part because there was no studies on D & X that you believe medical induction is a safer procedure?

A. That's correct.

Q. Ms. Crepps asked you a question about reliance on clinical experience by the doctors who perform abortions. Is it your opinion that clinical experience alone is a sound

basis on which to evaluate the D & X procedure?
A. No, it is not.
Q. Ms. Crepps asked you about Dr. Johnson. He's your chairman of the department at Michigan?
A. Yes, he is.
Q. And someone you respect?
A. Yes.
Q. You disagree with him on this issue?
A. Very much so.
Q. But he hired you; is that correct?
A. I have known Tim almost 20 years, yes.
Q. He's placed his trust in you to care for women at the University of Michigan; is that correct?
A. Yes.
Q. Now, Doctor, you were asked about a reference on page 141 of your deposition. It was on page 141, line 11 and your answer went down through line 17. Do you recall being asked about that?
A. Yes.
Q. And I think you indicated that you wanted to add something to put that answer into fuller context. So let me just ask you -- I'll give you that opportunity now to put that answer in a fuller context. Just for the record let's make it clear. The question was, how long on average does the surgical removal of the fetus take? Answer: Again, it

depends on the gestational age and other factors, meaning if the woman has a uterine anomaly, it may take longer if there's a complication. However, on the basic usual circumstances, it can take between 30 minutes and two hours.

A. Yes. I think what I meant to say, and I didn't notice this when I read the deposition again, but she asked about you know what's normal, and then what's, you know, other things that may take longer. So I said gestational age may take longer, but I was also thinking of the abnormality of uterine anomalies, which always take longer. So I said however, in the basic usual circumstances, and I think I meant to say in the basic and unusual circumstances. Because we were talking about normal and abnormal. I think I was just thinking normal and abnormal. So, you know, if I was to say it better today, I would say in the normal and abnormal and 30 to -- minutes to two hours. So in the basic and unusual circumstances.

Q. Ms. Crepps asked you about the Epner article which is Defendant's Exhibit 561. You have it up there. It's also a Plaintiff's Exhibit.

A. I have it.

Q. I would like just to call your attention to a couple of sentences at the end of 727. Ms. Crepps had asked you about the sentences concerning abortion related mortality. The Epner article also comments on abortion related morbidity.

Is that correct?
A. Yes.
Q. Just for the record, what's the difference between complications from mortality and morbidity?
A. Mortality means when a woman dies as a direct result of a procedure, and morbidity is when there are other complications that don't cause her death but may cause serious consequences such as infections or hemorrhages.
Q. Calling your attention to the bottom of page 727. There is a sentence which reads -- would you just read where it says abortion related morbidity. Would you read that over to the conclusion of the paragraph on the next page?
A. I would be glad to. Abortion related morbidity is lower for D & E procedures than for labor induction methods used in second trimester abortions. However, the rates are similar for procedures performed at 20 weeks gestation and beyond. More research on complications and complication rates associated with various procedures and by gestational age is needed before firm conclusions about the relative safety of procedures can be drawn.
Q. Now, do you agree with those statements in the Epner article?
A. Yes.
Q. Ms. Crepps asked you if you have seen the Kalish and Chasen article on subsequent relationship between dilation

and evacuation and subsequent pregnancy outcome?

A. Yes.

Q. Have you reviewed that article?

A. Yes, I have.

Q. I would like you to turn to Defendant's Exhibit 596. Your Honor, can I assist the witness in finding the article?

THE COURT: Sure.

MR. COPPOLINO: Seem to be missing a notebook over here.

THE COURT: Oh, my, somebody stole a notebook.

BY MR. COPPOLINO:

Q. Doctor, Defendant's Exhibit 596, is this the article by Doctors Kalish and Chasen, et al., entitled Impact of Mid Trimester Dilation and Evacuation on Subsequent Pregnancy Outcome?

A. Yes.

Q. And have you read this article before?

A. Yes.

Q. What does this article conclude about pre-term birth as a long-term complication of induced abortion?

A. May I read from it?

Q. Well, where are you going to read from? The conclusion?

A. Just the conclusion.

Q. Sure, you can read that.

A. Their conclusion was that second trimester D & E was not

a risk factor mid trimester pregnancy loss or spontaneous pre-term birth.

Q. I would like you to -- well, first of all, having read the article, does it change your view about the complication of subsequent pre-term birth resulting from an abortion?

A. No, it did not.

Q. Why not?

A. There were several flaws in this study. I also did not have too much time to look at that, but on the time that I had -- would you like me to do an analysis of why I didn't think it helped me?

Q. To the extent you can recall. And I have a specific sentence that I want to call to your attention. Why don't I do that first, and then we can go to your whatever thoughts you have. Take a look at page 884. Under the caption comment, starts on the bottom of the left-hand column.

A. Yes.

Q. Where it says our study reviewed the medical records of 600 patients.

A. Yes.

Q. Do you see that?

A. Yes.

Q. And it also indicates -- well, why don't you read that over. Why don't you read from there. Just read it to yourself to refresh your recollection on what they did in

this study in part.
A. Yes, I remember now.
Q. Over to the carryover paragraph on the right-hand column.
A. Yes.
Q. And this section of the article talks about follow-up with patients who were involved in the study; is that correct?
A. Yes.
Q. How would you characterize the follow-up of the patients who were involved in this study for purposes of evaluating long-term risks of pre-term birth after their abortion?
A. Right, so what they did was they studied the medical records of 600 patients in a particular institution and found that there were 96 subsequent pregnancies just at that institution. So they didn't bother to ask other institutions, even in the same town, if women had delivered there who had had prior procedures at this particular institution. And this is part of an analysis of many of these kinds of studies is, you know, you have to look bigger than the one hospital that you practice at because people's insurance change all the time. They have to go to the hospital across the street. And, also, just in the greater metropolitan area, or they could have called people later and said, have you had another pregnancy or where. They had

other information. They could have gone and actually followed women in those ways. And because they didn't do that, it's hard to draw any conclusions because it's just limited to one institution.

Q. Do you think the follow-up in this study is inadequate; is that right?

A. Absolutely.

Q. All right. One last question, Doctor. Ms. Crepps identified the ACOG statement. Take a look at where on page three of the ACOG policy statement?

A. Yes.

Q. Ms. Crepps asked you to read a sentence on page three. I would like you to read the sentence before it where it begins a select panel convened by ACOG. Would you read that sentence, please?

A. I would be glad to. A select panel convened by ACOG could identify no circumstances under which this procedure, as defined above, would be the only option to safe the life or preserve the health of the woman.

Q. Do you agree with the conclusion of the select panel with ACOG?

THE COURT: With that sentence --

BY MR. COPPOLINO:

Q. Let me rephrase the question. Can you identify any circumstances in which the D & X procedure would be the only

option to save the life or preserve the health of the woman?
A. I cannot.

MR. COPPOLINO: Thank you, Your Honor.

EXAMINATION

THE COURT: Doctor, I have a few questions. The first has to do with the 17th week of gestation. And assume -- well, assume you have got a board certified OB/GYN or well qualified surgeon who does abortions; typically does D & Es, 17th week. He or she doesn't think they can use Digoxin, at that point in time, to cause fetal demise, because they have concerns about the safety of doing that because of the small size of the fetus. This is done in a clinic setting for a wide variety of reasons. Typically, the doctor does an intact or pardon me, typically a D & E, but there are a fair number in his or her practice of circumstance at which at the 17th week, the doctor reaches up and he has the fetus delivered to the point where the cervix, where the calvarium lodges against the cervix. Okay.

THE WITNESS: Yes.

THE COURT: Now, I realize, do we have the facts pretty well. Do you understand the facts as I have given them to you?

THE WITNESS: I think so.

THE COURT: Okay. What does the physician do at

that point?

THE WITNESS: Do you mean to try to get the rest of the baby to deliver at that point?

THE COURT: Well, the physician's intent is to do an abortion.

THE WITNESS: Right.

THE COURT: So I have given you the circumstance. You have got the head lodged in the cervix. It may be relatively uncommon, but that's the circumstance. What does the physician do?

THE WITNESS: Well, the physician can use all their other techniques in their armamentarium to continue the procedure. So they may want to gently turn the baby's head and try to change the angle of the head such that if it's open enough to admit the rest of the body so quickly, as you describe, then it may be just with these certain techniques we have -- we use at term birth also. Pinard maneuvers and some of these other maneuvers we use for breeches that they could try those maneuvers and see if they could get the baby to come. That would be the first thing I bet people would do.

THE COURT: What if that doesn't work?

THE WITNESS: Then they may want -- they could probably try to use medicine to try to increase the chance that the uterine contractions themselves may help the baby

come out. And, in addition, there is medicine such as Nitroglycerin that actually relaxes the cervix and the uterus, and may with a single dose of Nitroglycerin, may, in fact, have the baby get dislodged, and we have done that before when necessary.

THE COURT: And what if that doesn't work, 15 minutes, 20 minutes passes, the woman is bleeding. What do you do next.

THE WITNESS: Right. Another thing I didn't say, you didn't initially say the woman was bleeding. You said just that the head was lodged.

THE COURT: Well, are you telling me that in the circumstance that I described it would be atypical to have bleeding?

THE WITNESS: It would be less typical. It would be. Another thing --

THE COURT: Uncommon?

THE WITNESS: It would be uncommon to have so much bleeding that you have to necessitate a very quick delivery.

THE COURT: But there is bleeding going on, generally speaking, at the 17th weak in the circumstance that I have described; isn't that right.

THE WITNESS: Yes, there can be bleeding as the baby is delivering and the placenta is coming out.

THE COURT: So we have gone through the

circumstance in which you try a physical manipulation, and the Nitroglycerin or other labor-induction medicines. What is the next step that the doctor should consider.

THE WITNESS: Well, the doctor could merely do a disarticulation procedure, if they so chose to.

THE COURT: How would the doctor do that, at that point?

THE WITNESS: They could just start pulling the pieces out.

THE COURT: Pull read hard?

THE WITNESS: Yes, they could pull harder. What might happen instead of using their hands, they may actually use one of those Soffer forceps. Rather than grasp the head, because again, if it's struck, it's not easy to put it in there. But they could grasp a different part of the baby try and change the angle and pull it as well.

THE COURT: Under any of that, in that circumstance that I have described, are you telling me that it would violate the standard of care to collapse the skull?

THE WITNESS: No, I didn't say that. Which standard of care are we talking about?

THE WITNESS: Whatever standard of care you use at the University of Michigan.

THE WITNESS: If the baby, if you really -- if she's hemorrhaging and you need to get the baby out, that

could be possible to collapse the skull.

THE COURT: All right. I'm going to let the lawyers follow up first for the Government, then the defendant, then the Government. I mean the plaintiff. You'll appreciate why I use the word defendant. Go ahead.

REDIRECT EXAMINATION

BY MR. COPPOLINO:

Q. Doctor, you characterize, can you characterize, for lack of a better word, the malleability of the fetal head at 17 weeks?

A. At 17 weeks, there is less ossification so the head is much softer and more cartilaginous rather than bony.

Q. And would that permit the physician to manipulate the head a little easier than he could at later stages in gestation?

A. Yes.

Q. Doctor, is the primary cause of bleeding or a primary cause of bleeding in second trimester abortion the removal of the placenta from the uterine wall?

A. Yes.

Q. If the placenta has not yet removed or been removed from the uterine wall, how much bleeding is there typically at that stage in gestation, at that point in the procedure?

A. Very little.

Q. Doctor, if the head is stuck solid in the cervical os at

that stage of 17 weeks under the Judge's hypothetical, how easy is it to get forceps in there to remove it? Would it depend on how tight the head is against the cervix?

A. Yes, and you would maybe need to even push the head back in to get your instrument in there.

MR. COPPOLINO: Thank you, Your Honor.

THE COURT: Plaintiffs?

MS. CREPPS: No questions, Your Honor.

THE COURT: All right. Thank you, Doctor. I found your testimony very helpful. You may stand down.

THE WITNESS: Thank you, sir.

THE COURT: Counsel, it's now 10 after 12. Mr. Henry, you have -- you want to talk about exhibits?

MR. COPPOLINO: If I could answer for Mr. Henry. Do you want to do it now? If you have work to do in the noon hour, we can come back. It could take a few minutes.

THE COURT: If you don't mind, that would be my preference. If you would come back at 2:00 o'clock, that would give me a chance to sentence two people and eat a sandwich. I probably ought not to describe with that connection. Doctor, you can step down.

MS. SMITH: Your Honor, could I do it tomorrow morning?

MR. COPPOLINO: I'm a little reluctant to eat into the witness time tomorrow morning.

THE COURT: You want to come back later this afternoon?

MS. SMITH: That's fine. 2:00 o'clock is fine.

THE COURT: Come on back at the 2:00 o'clock. We'll stand in recess.

(Recess from 12:10 to 2:00 p.m.; all parties present)

THE COURT: Please be seated. We are back on the record now in Carhart versus Ashcroft. Counsel, I have placed on your benches a list of exhibits which have been offered but not received which we hope is accurate, and I understand we are here now to discuss the question of those exhibits and perhaps others. Who would like to go first?

MS. SMITH: I guess we are offering, so perhaps it makes sense for me.

THE COURT: Well, actually, I'm not sure, but that both sides -- It doesn't make any difference to me who goes first.

MS. SMITH: Your Honor, with reference to the list, plaintiffs were under the impression we had also offered Exhibit 44, the Grimes article on, I believe that was on April 1st in conjunction with Dr. Vibhakar's testimony.

THE COURT: Yes, I do show that is offered myself.

MS. SMITH: Okay.

THE COURT: Someone on my staff will be punished. You see how fearful they are.

MS. SMITH: Your Honor, learned treatises such as excerpts from medical texts are not inadmissible hearsay where they are not offered for the truth, and, in fact, courts have admitted scientific articles and medical articles where they were offered not for the truth but for existence of knowledge in the community, for example. In a case in this circuit called, I don't know how to pronounce it, Buttice or Buttice vs. --

THE COURT: Anybody who can say Henriet.

MS. SMITH: Henriet Buttice, I don't know. I'm trying to make use of my high school French, and the only thing I ever could do was the accent, so --

THE COURT: Very well done.

MS. SMITH: It's B-u-t-t-i-c-e, and the cite for that is 938 F. Supp. 561. That's from the Eastern District of Missouri. It's a 1996 case, and in that case, the Court stated that the excerpts from medical texts were not inadmissible hearsay because they weren't offered for the truth. They were offered to establish the existence of medical literature, and thus the knowledge of the medical community concerning in that case IUD use and pelvic inflammatory disease at a particular point in time.

Similarly, the Seventh Circuit case, it's 940 F.2d 207, allowed design standards that were in existence at the time of the manufacturing of a product to be offered for -- to

show the defendant's knowledge, actual and constructive knowledge.

The Tenth Circuit at 866 F.2d 319 allowed scientific articles to show defendant's notice that products posed a certain health threat.

And the Fifth Circuit at 415 F.2d 1009, allowed medical articles to show that defendants should have known of a particular disease and its causation or products cause; and in this case, we are offering these articles for existence of the substantial body of medical opinion, perhaps to support the reasonableness of that opinion, and also as evidence of the debate in the community, and also for what Congress should have known and considered at the time and didn't. Courts in this Circuit, including the Eighth Circuit have, while not ruling on the evidentiary issue, have considered medical texts in determining knowledge of the medical community concerning a particular issue and that's the King versus Nashua case at 763 F.2d 332, and that was a 1985 case, and I think all of those cases really support our position here that we are offering them for knowledge in the community, opinion in the community, even less for the truth in some ways because it's just evidence of opinion.

THE COURT: Well, I think the opinion in the community, to be more precise is, what you're really talking

about is the community here are doctors.

MS. SMITH: Um-hm, yes.

THE COURT: So that's the community you're referring to.

MS. SMITH: That's right, the medical opinion, medical community, and that there is a debate about these issues, and there is a substantial body that holds that the intact D & Xs in some circumstances is safer.

THE COURT: Well, at least informs us as to whether that's true or not.

MS. SMITH: That's right. I think it, at least, even though the Chasen article is the only article that is specifically on that issue, the other articles all inform the debate, they establish, you know, we have heard a lot about intuition and doctors' intuition about what is safer. Well, if evidence of this intuition doesn't come from, you know, Mother Nature or something, it doesn't come from some amorphous source. It's really medical opinion based on medical articles that are well respected in the community, and that that means that that opinion carries weight.

It's not some, you know, one doctor. We talked at the TRO hearing about could you just have one doctor who thought something, and would that be a substantial body? No. But it is a substantial body when you have a number of doctors, especially now that we have seen people at medical schools

all over the country teaching intact D & X.

We also have, you know, articles that support --

THE COURT: Who said that?

MS. SMITH: Well, actually, Your Honor, in the testimony that you'll receive from Dr. Chasen, Dr. Westhoff, Dr. Frederiksen, Dr. Hammond, their teaching, and actually Dr. Lockwood tomorrow, they are teaching and doing intact D & Xs at very well-respected institutions.

THE COURT: I haven't been presented with that yet.

MS. SMITH: No, that's right, Your Honor. That's right.

THE COURT: Well, and I take it you also offer it because, whether it's right or not, your view is to the extent the Congressional Record does not make an effort to examine these papers which were in existence at the time of the Congressional findings, that informs me whether I'm persuaded that the articles are correct or not, about the degree of deference that I ought to give Congress.

MS. SMITH: That's right, Your Honor.

THE COURT: All right. Now, I take it that you think the articles that the defendant are offering ought to be received in the same fashion?

MS. SMITH: Yes.

THE COURT: Okay.

MS. SMITH: They ought to be received in the same

fashion, Your Honor.

THE COURT: For example, fetal pain articles.

MS. SMITH: May I consult for one moment, Your Honor?

THE COURT: Sure.

MS. SMITH: Yes, Your Honor. As long as they are being offered with the same limitations. They are not offered for the truth. They are offered for evidence of a debate in the medical community or opinions in the medical community.

THE COURT: Mr. Henry?

MR. HENRY: Thank you, Your Honor. Your Honor, just for clarification, although the defendant's case is still open, I don't believe that we have offered fetal pain articles. I think the only thing on the list that you provided that we have offered is up till now is that American College of Surgeons' statement toward the very end. I think the fetal pain articles were offered by plaintiffs as part of their cross-examination of Dr. Anand.

THE COURT: Well, okay. Let me hear you and then I'll ask -- I'll ask if you -- Well, let me hear what your position is, and perhaps that will better inform me. Go ahead.

MR. HENRY: Your Honor, based on even the -- Ms. Smith's comments today, I think they are attempting to have

these articles admitted for the truth of the matters asserted therein.

There is basically no distinction between offering them to show a debate in the medical community and offering them for the truth. If an article or any other statement that's otherwise hearsay is not offered for its truth, then the significance lies in the fact that the statement was made, the credibility of the whoever made the statement. Credibility of the statement itself is just not an issue, but here that's not the case. The materials that we are talking about, they are being offered, indeed, they are really only relevant as proof that the authors, as experts, you know, as doctor, physicians, whatever, believe that something is safe or not or needed or not.

I believe Ms. Smith made multiple references to there being a body of medical authority, a substantial body of medical authority, and that all goes to the truth, the weight or however you want to put it, of what is contained in those articles. It's just the same as what went on with respect to the experts the defendant offered and the plaintiffs offered. We put them on the stand, we asked them about their views as to whether some particular issue was safe or needed or not, and these articles are basically being offered for that very same point.

The debate issue basically becomes just a shorthand for

the truth of what's contained in the articles.

THE COURT: I don't think that's what the Justice meant when he wrote it. Do you think that's what Justice Breyer meant to say?

MR. HENRY: Well, Your Honor, you mean in the prior Stenberg case?

THE COURT: Yes. I think what the Justice was saying, far be it from me to put words in Justice Breyer's mouth or anybody else's, but in essence, I think what he was saying was that at least where you have a debate among experts, you may never ever know what the truth is, and so the question becomes, then, what do you do in a circumstance when it may never be possible to prove the existence of an ultimate fact; in other words, one may never know whether this procedure is safe or not safe if the community that deals with that issue is uncertain as well, so I don't think -- I don't think that they are one and the same things.

MR. HENRY: Well, if I may, Your Honor, I think the issues are quite different because in the prior Stenberg case, the materials that were before this Court and before the Supreme Court were basically admitted for -- as I recall, by stipulation on a lot of things, most particularly, the ACOG policy statement, those kind of things.

THE COURT: Um-hm.

MR. HENRY: And Justice Breyer of the Supreme Court relied upon those in saying, well, this procedure may be appropriate in some circumstance, and then there was a competing statement, I think, from the AMA where they said something a little different, so those, that evidence was being considered for the truth of the matter asserted, and it showed a debate, and I guess what I'm saying is that in this case --

THE COURT: But let's assume -- Let me interrupt you for a moment.

MR. HENRY: Sure.

THE COURT: Let's assume that it is relevant to prove a debate. Let's assume that at least you and I can agree that the Justice said the existence of the debate is relevant.

MR. HENRY: Yes.

THE COURT: Are you saying that the only way you can prove the existence of that debate is with a witness?

MR. HENRY: I'm saying that while the existence of the debate is relevant, any evidence that this Court takes in regarding that issue or any other issue has to be according to the Federal Rules of Evidence, and that means that with respect to expert testimony and those sort of things, it would have to be through an expert witness, and that's what's been done here. Witnesses have been on the

stand, they have talked about the literature, you know, they have quoted from it, they have done things in accordance with the learned treatise exception to the hearsay rule.

THE COURT: We have got far beyond that today with this young woman who testified. I mean, we were reading huge portions of the thing into evidence.

MR. HENRY: That's what the rule contemplates, Your Honor.

THE COURT: I have read the rule. I understand the rule, but go ahead.

MR. HENRY: Okay. The point is, is that with under plaintiffs' proposal, we are moving far beyond that. They want to admit articles in their entirety beyond what was read into the record through an expert witness talked about through an expert witness, that sort of thing, and our position remains that that is inappropriate, that the hearsay rule says what it says, the articles are hearsay unless there is an exception, and the learned treatise exception is the only one we are dealing with here, and the point that I was trying to make starting out was that we really are dealing with a truth issue. I mean, basically, the plaintiffs want the Court to look at these articles to establish that the authors are halfway credible and believe something, and that's a truth issue.

If I could go back to the Court's comment from a few

days ago, you were concerned about the parties kind of eliminating any kind of fringe, or I believe you used the term goof ball articles.

THE COURT: Um-hm.

MR. HENRY: That, I think, makes evident that we are dealing with a truth issue because --

THE COURT: I think that's more foundational. It seems to me that, obviously, you can have a debate under -- if it is a relevant question to prove the existence of a debate, then we get into the question of what does that debate mean. What are the parameters of that debate, and what I was suggesting is I could conceive of some circumstances where the foundation for an article is not sufficient either from its face or from collateral evidence to conclude that it is a part of some alleged debate, a reasonable part of it. It seems to me, one doesn't -- one is not asked to determine whether or not what the article says is accurate or not, but rather that the speaker is a participant in the debate, and that's where I think you and I disagree about whether we are talking about the truth or something else.

MR. HENRY: Your Honor, if I could, let me just bring the Court's attention to a case.

THE COURT: Sure.

MR. HENRY: And I have a couple of copies if you

want.

THE COURT: That would be great.

MR. HENRY: I have already given that to opposing counsel.

THE COURT: If you'll give that to Ms. Beran. She'll make certain I get a copy.

MR. HENRY: The case is --

THE COURT: I'm going to tease you now for just a minute. I just love the fact you have cited a Ninth Circuit case to me. I'm just so pleased.

MR. HENRY: It was late at night. I was running out of time.

THE COURT: Certain instructions my law clerks have and they'll take particular -- Pardon me. Go ahead.

MR. HENRY: It is a case from the Ninth Circuit, United States vs. An Article of Drug, 661 F.2d 422, Ninth Circuit, 1981. Your Honor, this was a case involving the Food, Drug and Cosmetic Act. It involved an issue as to whether the drug that was actually being seized in this case was generally recognized by experts as safe and effective. It had that recognition, and it was being legally marketed or whatever.

If you look on page 745 under the paragraph that's headnote 5, the Court stated, said the district court allowed expert witnesses to read excerpts from treatises

into evidence during the course of their testimony but refused to admit the treatises themselves as exhibits, this following the learned treatises to the hearsay rule, F.R.E. 803(18). The defendant in that case contends, however, that the mere existence of the published studies and investigations regarding the drugs involved was probative, and therefore the treatises were not hearsay. That, I submit, is similar to the situation we are in here. The defendants in this case thought that the existence of these articles, these treatises was probative on the issue of whether experts generally thought something was safe and effective. I think that's analogous to a debate situation. Then the Court went on to say --

THE COURT: No, no, no. It's analogous to safe --

MR. HENRY: Safe and --

THE COURT: What's the magic language?

MR. HENRY: Safe and effective.

THE COURT: Yeah. I mean, if it was relevant that the FDA wanted to know if there was a debate, that's a different question. Here these folks were offering these as back door experts.

MR. HENRY: Well, they were, and the Court goes on to say, the treatises were relevant only as proof that the authors as experts believed the drugs were safe and effective or for the fact of things being safe or effective,

but the Court said --

THE COURT: For the purpose that it was offered. Here, the question before the Court was whether it was safe and effective. That is one of the questions before me, and I think Breyer said one of the other questions is, if you don't know but there is a debate in the community, Government loses, so counsel says as to the second point, not whether it's safe because it can't prove that with an expert who is not here and subject to cross-examination. I can prove it by showing the debate, and one of the ways you show a debate is in the medical journals.

MR. HENRY: Your Honor, if I could respectfully disagree. In this case, the United States versus An Article of Drug case, if you look in the first column of page 745, the end of the first full paragraph, the Court says, the sole issue for trial, therefore, was whether the drugs were generally recognized by experts as safe and effective. The issue was not whether it was safe and effective. The issue is whether experts generally recognized it as safe and effective.

THE COURT: Where does it say that? Pardon me.

MR. HENRY: On the first column on page 745, and the first full paragraph, at the very end of that paragraph.

THE COURT: Okay.

MR. HENRY: And so I submit to you that that is

analogous to the situation we have here. The plaintiffs purport not to offer the materials for the truth of the matter asserted or for the truth of whether any particular procedure is, you know, safe or whatever, but for the existence of a debate. Here we had this same issue. It was whether experts in the field generally recognize something as safe and effective, and I think that would be implied in that is whether there was a substantial body of experts who thought drugs were safe and effective.

And the Ninth Circuit, again going back to the last paragraph on page 745 where it's talking about the defendant's desire to have these studies in, it says the treatises were relevant only as proof that their authors as experts believed the drugs were safe and effective or for the actual fact there, and then it concludes that paragraph by saying either way, they were hearsay, and we have that same situation here. We have had experts on the stand talking about the medical literature, so with respect to a debate or the lack thereof, the Court has been presented with evidence, and it will be presented with more as the parties submit the trial testimony and that sort of thing.

THE COURT: Pardon me for interrupting you.

MR. HENRY: Yes.

THE COURT: Has this issue arose in San Francisco or New York?

MR. HENRY: The issue of admissibility of articles, it has arisen. There were briefs filed yesterday on it. To my knowledge, Judge Hamilton has not ruled.

THE COURT: And Judge Casey has not made a --

MR. HENRY: May I consult?

THE COURT: Sure.

MR. HENRY: Your Honor, our understanding is Judge Casey in New York has rejected the admission of medical articles, but don't hold me to that. I'm not exactly sure.

THE COURT: Do the plaintiffs know?

MS. SMITH: I don't know, Your Honor.

MR. HENRY: So again, we believe we are dealing with a truth issue here, and that the articles are hearsay, and basically what we are doing or what the plaintiffs are proposing is to create an exception that goes way beyond the learned treatise exception that's stated in the rule, and we don't believe that's appropriate.

If I could just talk briefly about the case that Ms. Smith brought to the Court's attention.

THE COURT: The IUD case?

MS. SMITH: Could I give you a copy, Your Honor?

THE COURT: You haven't, but I would like to see one, sure.

MS. SMITH: I have one.

THE COURT: Who is the judge in the IUD case? I'll

find it. That's fine.

MR. HENRY: Did you ask the judge?

THE COURT: Yeah.

MR. HENRY: It was Judge Shaw from the Eastern District of Missouri.

THE COURT: Thank you. Go ahead.

MR. HENRY: Yes, sir. That case is distinguishable to my understanding the other cases that the plaintiff has mentioned are distinguishable in that those situations involved products liability cases where the issue, either in this Eastern District of Missouri case, the issue was statute of limitations and whether the plaintiff had notice of IUD problems.

THE COURT: I think they are different too. I think the products cases are different. I tried enough of those to understand that's a slightly different issue, although frankly, the whole question of a state-of-the-art defense in a products liability case or a notice defense in a products liability case, we go through this same thing about whether this stuff is really going to a poor jury who is trying to be, you know, you instruct them about state-of-the-art or notice, and it's not offered to prove X or Y but whether somebody was placed on notice. I mean, you run into this same analytic question about what are you really trying to prove, but go ahead.

MR. HENRY: I think, as Your Honor said the other day, I'm not sure anyone understands the hearsay rule.

THE COURT: There is a law professor at Creighton whose brother is a federal judge down in Western Missouri who gives the funniest lecture that there just really is no hearsay rule because no one understands it, and if you don't understand a rule, it can't exist, and it's his conclusion after 25 years of studying it that no one understands it, but go ahead.

MR. HENRY: Well, I'm doing my best here today, Judge.

THE COURT: You're doing fine. Go ahead.

MR. HENRY: I think we have pretty much made our points.

THE COURT: You wanted to distinguish this IUD case though.

MR. HENRY: Yes, sir, and as I mentioned, in this particular case we were dealing with a statute of limitations, a time barred situation where the issue was did the plaintiff have notice that there may have been problems caused by these IUFDs (sic), and so the state of the medical literature was relevant whether it was true or not as to the notice the plaintiff should have had under, you know, the applicable products liability cases or case law.

And with respect to other products liability cases

including some of the ones the plaintiff cited, it does deal with this state-of-the-art defense, and so the issue is not really is it true or not so much as the manufacturer's on notice one way or the other and has to react in some fashion or another.

THE COURT: Tell me how something can be the state-of-the-art and not be true.

MR. HENRY: Well, Your Honor, I think it's a situation of is it right, is it wrong? We don't know but the manufacturer had notice that at least some people thought it was right and needed to react in some fashion to that as far as the design of the product.

THE COURT: Well, I understand what the theory is. But just think about it. If it is the state-of-the-art that you design something this way, and there is nothing to contradict it's the state-of-the-art, is it not true?

MR. HENRY: Well, perhaps not because the state-of-the-art changes, so you know.

THE COURT: Does truth change?

MR. HENRY: Truth, as men understand it, does, I suppose, when you're dealing with factual situations.

THE COURT: Yeah.

MR. HENRY: And that's one of the reasons, you know, the parties bring in experts. We put on the evidence, we try to get them to walk the Court through the literature

to understand what the literature says what its strengths are, what its weaknesses are, and the evidence in this case should be limited to that and not to just kind of doing away with the constraints of the learned treatise rule and just bringing in all these medical articles without the benefit of experts on the stand guiding the Court as to, you know, whether those articles do reflect the truth of what's asserted therein or reflect the legitimate debate or whatever, so Your Honor, we are constrained to stand on our objection with respect to the exhibits.

THE COURT: Let me ask you sort of a silly hypothetical, but let's assume Congress banned this partial-birth abortion technique, and it relied on the statement of one physician that it called to testify, and then we know that there are ten physicians who were not called who say the exact opposite thing. Congress didn't call them, and I want to know whether Congress was serious about its effort to determine whether physician one was correct or not. Are you telling me that if I want to know the existence of that fact that I have got to call all 11 physicians and talk to them in a courtroom?

MR. HENRY: I don't believe the plaintiffs would have to do that, Your Honor. I mean, they could have their own expert, one expert, I assume, if that expert had a sufficient knowledge base to say that there are, you know,

11 or 100 or two, how many ever doctors that believe this, and they published articles on it, and these are things that Congress did not consider. I think it's gone on to some degree in this trial, but going beyond that and just saying that the plaintiffs can come in and put in, you know, all these articles without, in their entirety without appropriate testimony from an expert witness, I think is kind of beyond the appropriate confines of what the Court can do within the rules of evidence.

Now, the issue of deference to Congress is, you know, that's kind of a different issue in that, you know, the Court can look at what Congress did and give Congress whatever level of deference is appropriate under the case law, but as far as taking in the evidence to determine, you know, for example, if the evidence you take in, you can use in that determination of whether you think Congress's findings are based on substantial evidence or any other kind of evidence, I think in taking in that evidence, the Court has to do it through the courtroom as constrained, rather, by the rules of evidence.

THE COURT: Oh, sure.

MR. HENRY: That's all we are asking for here.

THE COURT: You'll agree with me that the rules of evidence are inclusive, not exclusive. That's the general proper way to look at the rules of evidence; right?

MR. HENRY: I'm afraid to say yes, but I think generally that is correct.

THE COURT: And the reason why that is is because the rules of evidence really try to help us do two things to get at the truth but do it in a way that's fair to both sides, and there is, sometimes, in order to make things fair to both sides that you've got to -- you've got to limit the truth-seeking effort because, I mean, you just can't beat the confession out of somebody, even though it might be truthful. That's the sense, and so I appreciate what you're saying, and the question here is for me to puzzle through the question of whether this is really back door hearsay or whether it truly is something different.

MR. HENRY: Well, Your Honor, the only thing I would say in response is that, yes, sometimes the truth-finding function has to be adjusted to account for things, and that's what the exceptions to the hearsay rule, for example, do.

THE COURT: Right.

MR. HENRY: All we are asking for is that with respect to the potentially applicable exceptions, which would be the learned treatise rule, that that be adhered to because that's what Congress and the Supreme Court determined the rule to be, and that's all we are seeking here.

THE COURT: And categorically, if it's not hearsay, then we don't have to worry about whether the exception applies.

MR. HENRY: That's true.

THE COURT: The other thing is, the other question I have for you is what about -- Well, I think you've answered it. Thank you.

MR. HENRY: Thank you.

THE COURT: Well, I'm prepared to rule to admit these things in a general way for two reasons: Not to prove that these articles are true or not true, but one, to prove or disprove the existence of a substantial body of medical opinion or to prove or disprove questions related to the Congressional effort to ascertain the true facts. Now, that doesn't mean that each of these articles is admissible, but I think it means that most of them are.

Now, let me ask the plaintiffs, are you offering all of the exhibits on the exhibits-offered-but-not-received list that I gave you, including Exhibit 44, given the limitations that I've just stated?

MS. SMITH: Yes, Your Honor.

THE COURT: Now, that includes the fetal pain stuff and everything else?

MS. SMITH: Yes. Yes.

THE COURT: All right. Do the parties want any

further ruling? In a minute I'll identify what's coming into the record. Do the parties want any further ruling?

MR. HENRY: No, Your Honor. I think that's sufficient.

THE COURT: I receive into evidence Exhibits 3, 4, 5 which is also defendant's 652, 6, 651 -- 6 and 651 which are the same thing, 7 and 653 which are the same thing, 8 and 672 which are the same thing, 9 and 673 which are the same thing, 10 and 669 which are the same thing, 44, 11 and 670 which are the same thing, 13, 14, 15, 16, 17, 178, 19 and 545 which are the same thing, 25, 26, 27, 28, 30, 38, 39 and 650 which are the same thing, 41 and 561, 40, 42, 45, 46 and 577 which are the same thing, 55 and 596 which are the same thing, 64 and 608 which are the same thing, 114, 538, 544, 563, 566, 609, 625, 633, 648, and once again, I receive those not for -- to prove that what is said in those articles are true but for the limited purposes I have previously explained.

Now, to make it clear to the defendant, I will receive into evidence similar exhibits offered subject to the limitation that I have admitted these articles on and other things without, from my perspective, thinking that you've waived your objection. Now, I don't know what some other court will make of that, but from my perspective I won't feel whipsawed if you get before the Court of Appeals and

say that idiot shouldn't have received these and we put this other junk in simply because he forced us into that circumstance, but I'll leave that to your tactical judgment about what you want to do.

All right. Is there anything further that we should take up at this time?

MS. SMITH: Your Honor, with respect to rebuttal.

THE COURT: Um-hm.

MS. SMITH: At this point there is one issue which has arisen recently with two of the defendant's attorneys that we may want to put some live rebuttal testimony on about, and I wanted to raise --

THE COURT: About two of the defendant's attorneys?

MS. SMITH: I'm sorry. Two of the defendant's witnesses.

THE COURT: Okay.

MS. SMITH: And I wanted to raise with the Court if the Court would at all be open to a telephonic, a very short telephonic rebuttal rather than live-witness-sitting-in-the-chair rebuttal.

THE COURT: If you all, you know, and you run into problems with that, but if you all can work it out, I'm not opposed. We do have video conference capacity, not in this courtroom, although we do have video conferencing capacity in the courtrooms in Omaha, I think. Is that right,

Colleen? I think in at least two of the courtrooms in Omaha we do, and we do have video conferencing capacity here in another room although it's not in the courtroom. We can pipe telephone into this courtroom. I mean, if the other side has the appropriate switching equipment, they can be speaking and we can be speaking. I just don't know how that can be set up, but I'm not opposed to doing that by phone, but there are legitimate logistic problems such as, I think Mr. Coppolino said once he had a concern about exhibits.

MS. SMITH: Exhibits, yeah. Well, I will discuss it with counsel and I didn't mean to, you know, surprise them, but I just wanted to raise it because it just came up.

THE COURT: Who is the witness?

MS. SMITH: It might be Dr. Vibhakar, but it would be very limited.

THE COURT: Call her in rebuttal?

MS. SMITH: It would be a very, very limited point, 15 minutes at most, but I don't know how things are going to go tomorrow. I don't know if I'm going to feel that I need it, but I wanted to raise it today at least to give you a -- find out if you are open to it before, and then we'll discuss it with counsel and see if they have an objection.

THE COURT: Yeah. I mean, you run into some mechanical questions about how you swear the witness.

MS. SMITH: Right.

THE COURT: Although that's never been in a case like this something that I'm terribly concerned about. We could have somebody --

MS. SMITH: We could get a court reporter in Iowa or something.

THE COURT: Perhaps. We could do it that way, and then the question is how do you know it's a court reporter in Iowa? All right. You visit with Mr. Ashcroft's lawyers and see if you can't work something else. Anything else?

MS. SMITH: That's it.

THE COURT: Anything else, counsel?

MR. HENRY: No, Your Honor.

THE COURT: Thank you. We stand in recess.

(Recess at 2:46 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 8, 2004

Official Court Reporter

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