IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

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| LEROY CARHART, M.D., WILLIAM G. FITZHUGH, M.D., WILLIAM H. KNORR, M.D., and JILL L. VIBHAKAR, M.D., on behalf of themselves and the patients they serve,<br><br>Plaintiffs,<br><br>vs.<br><br>JOHN ASHCROFT, in his official capacity as Attorney General of the United States, and his employees, agents and successors in office,<br><br>Defendant. | 4:03CV3385<br>March 31, 2004<br>9:00 a.m.<br>Lincoln, Nebraska |

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

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

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(Wednesday, March 31, 2004, at 9:00 a.m.)

THE COURT: Good morning. Counsel, you may call your next witness.

MS. STRAUSS: Thank you, Your Honor. Good morning, Your Honor.

THE COURT: Good morning.

MS. STRAUSS: Good morning, counsel. Your Honor, I would like to call the first witness.

THE COURT: Yes. Go ahead. Counsel, could I trouble you to pull the microphone just about to the level of your mouth. Be aware that while it's directional, it's not entirely directional.

MS. STRAUSS: All right.

THE COURT: Good morning, sir. If you will state your name for the record and spell it, this lady will swear you in.

THE WITNESS: My name is Joel Howell, J-o-e-l, H-o-w-e-l-l.

JOEL HOWELL, PLAINTIFFS' WITNESS, SWORN

DIRECT EXAMINATION

BY MS. STRAUSS:

Q. Good morning, Dr. Howell. What state do you live in?

A. Michigan.

Q. Where do you work?

A. The University of Michigan.

Q. Doctor, I would like you to take a look at what's been marked as Plaintiff's Exhibit 104. It's in the binders next to you.

MS. STRAUSS: Your Honor, if I may approach to assist the witness with the binder.

THE COURT: Yes, and you may have continuing leave to do that. Are we talking about 104?

MR. WARDEN: Yeah. Okay.

BY MS. STRAUSS:

Q. Dr. Howell, is this your current curriculum vitae?

A. Yes, it is.

THE COURT: For the record, we are talking about Exhibit 97. Go ahead.

MS. STRAUSS: Yes. Thank you, Your Honor.

BY MS. STRAUSS:

Q. Can you briefly describe for your medical education and training?

A. I received my M.D. degree from the University of Chicago. I remained there as an intern and resident in internal medicine. I then went to the University of Pennsylvania, where I was a Robert Wood Johnson Clinical Scholar, obtained my Ph.D. in the history and sociology of science.

Q. Are you licensed to practice medicine in any states?

A. Yes, I am.

Q. What states are those?
A. Michigan.
Q. Since when have you been licensed?
A. 1984.
Q. Are you board certified in any areas?
A. I'm board certified in internal medicine.
Q. And after your residency, you also pursued a Ph.D.?
A. That is correct.
Q. Can you tell us what field you received your Ph.D. in, please?
A. I studied the history and sociology of science.
Q. While there, can you tell us a little bit about what you did as a Robert Wood Johnson Clinical Scholar?
A. I was both a Ph.D. candidate in the history and sociology of science as well as a fellow in the Robert Wood Johnson Clinical Scholars' Program, which is a two-year post-graduate program designed to teach physicians in any specialty how to do research on the nonbiological aspects of health care.
Q. You mentioned you currently work at the University of Michigan; is that right?
A. That is correct.
Q. What is your current profession?
A. I'm a physician and a historian.
Q. And can you tell me about all your positions there at

the University of Michigan, please?

A. I'm a professor in the Department of Internal Medicine in the medical school. I'm also a professor in the Department of History in the College of Literature Science and the Arts, as well as a professor in the Department of Health Management and Policy in the School of Public Health. In addition, I am the Victor Vaughn Collegiate Professor of the History of Medicine at the University of Michigan, and I direct the Robert Wood johnson Clinical Scholars' Program at the University of Michigan.

Q. And do your duties as a professor at the University of Michigan include teaching?

A. Yes, they do. I teach in all three of those venues. I also do research on the history of medicine. I practice internal medicine, and I also am involved in administering programs that I mentioned.

Q. Regarding your clinical responsibilities, how much time do you spend seeing and caring for patients in your internal medicine practice?

A. I see patients one day a week, and I typically see somewhere between around 40 patients a day, in conjunction with house staff. And I also attend on the inpatient wards approximately one month a year.

Q. And when did you start teaching at the University of Michigan?

A. In 1984.
Q. Have you received awards or honors for your teaching?
A. Yes, I have.
Q. Let's talk for a moment about the Clinical Scholars' Program. What is the Clinical Scholars' Program?
A. Clinical Scholars' Program is a program that has been supported by the Robert Wood Johnson Foundation for some 30 years now, and they are now committed to support for another ten years. It's a program that takes physicians in any clinical specialty, and this can include people in internal medicine, pediatrics, surgery, the surgical subspecialties, obstetrics and gynecology, psychiatry, and others, and teaching them how to do research that will benefit the health of all Americans. It's a two-year fellowship training program. It involves a structured curriculum and it involves doing a research project in one of those areas.
Q. And what is your position with the Clinical Scholars' Program?
A. I am in a state of transition. We originally got the grant in 1995, at which point, I was the co-director. We are now funded to continue through another ten years, and I will be transitioning to become the director during that period.
Q. Okay. And what have your responsibilities been as the Co-director and now Director, or soon to be Director of the

Clinical Scholars' Program?

A. My responsibilities are essentially to administer the program and to oversee the projects done by the clinical scholars. So I am responsible for the oversight of the program. I'm responsible for helping to select the scholars. I'm responsible for overseeing their research projects; the kinds of research they do, helping them choose an appropriate research topic, choose an appropriate mentor. Pursue that research, get it approved, and eventually get it published, and hopefully have it have an impact to improve health care.

Q. Do you also help prepare curriculum material for the program?

A. Yes, I do.

Q. Do you teach some of the sessions as well, in that program?

A. Yes, do I.

Q. Now, I think you mentioned the scholars come from all fields of medicine; is that right?

A. That's correct.

Q. Do some of the scholars conduct research in the field of surgery?

A. Yes, they do.

Q. And do some of the scholars conduct research in the field of obstetrics and gynecology?

A. Yes, they do.
Q. How often do you meet with the scholars about their research?
A. On an informal basis, basically every day. My university office is located in the same office suite as the scholars, and as recently as yesterday, I met with a couple them about their research projects. I meet with them formally several times a year in which we sit down and go over their progress to date, as well as writing periodic reports and interim reportings outlining their progress.
Q. Are you the Director of the Program in Society of Medicine?
A. Yes, I am.
Q. What is the program in Society of Medicine?
A. The program in Society of Medicine is a medical school program designed to enhance research and interest in the broader social and humanistic aspects of health and health care.
Q. You're also a member of the core faculty of the Bioethics Program at the University of Michigan; is that right?
A. That is correct.
Q. What does that entail?
A. The program in bioethics has been in existence for a few years now. It's a new program that was set up to focus

attention on bioethics, and the director of that program asked me and a handful of other faculty to assist her in the selection and recruitment of new faculty in the seminar series that we conduct, as well as in helping them in some of the research that's done in that area.

Q. And how long have you been a member of the core faculty of that program?

A. It's around four or five years.

Q. Is that since it began?

A. Since it began, yes.

Q. And before that, did you have a role on the University of Michigan Hospital Ethics Committee?

A. No. I have never been a member of the University of Michigan Hospital Ethics Committee.

Q. Have you been the Chair of the Internal Medicine Ethics Committee?

A. Yes, I did chair the -- I was asked to continue the chair of Department of International Medicine Ethics Committee.

Q. Thank you. You testified that you also conduct research in addition to supervising the research of your students. Is that right?

A. Yes.

Q. What particular areas does your research focus on?

A. My research focuses on the history of medicine,

particularly in the late 19th and 20th centuries in the United States and England, and on the development of technologies, and therapeutics to take care of patients.

Q. Doctor, I see that you've lectured extensively. Have you lectured on the subject of medical technology?

A. Yes, I have.

Q. And have you lectured on the development of surgical techniques?

A. Yes, I have.

Q. And have some of your lectures concerned the history of and current practices in human experimentation?

A. Yes, they have.

Q. And have your writings been published?

A. Yes, they have.

Q. Where have your writings been published? What types of publications?

A. I have published books, I have published peer reviewed articles in most of the major medical journals, as well as the historical journals.

Q. Have you written and published papers about the development of surgical techniques?

A. Yes, I have.

Q. Can you tell me approximately how many?

A. Well, it would depend on whether -- what part of it would be involved, but probably half-a-dozen or a dozen. I

would have to look through.

Q. Are these listed on your CV?

A. Yes, they are.

Q. Thank you. Were these published in peer reviewed publications?

A. Yes, they are.

Q. Have you written articles about how medical research is conducted?

A. Yes, I have.

Q. Approximately how many?

A. At least a dozen, maybe more.

Q. And are these listed on your CV?

A. Yes, they are.

Q. Were these published in peer reviewed publications?

A. Yes, they were.

Q. Thank you. Have you written and published articles about ethical issues in human experimentation?

A. Yes, I have.

Q. Approximately how many?

A. Again, I would have to go count them up, but half-a-dozen or something in that vicinity.

Q. Are these listed on your CV?

A. Yes, they are.

Q. Are these published in peer reviewed publications?

A. Yes, they are.

Q. Can you just give us a sampling of the -- if you have the major peer reviewed journals in which your publications have appeared?

A. The Journal of the American Medical Association, the Annals of Internal Medicine, the Bulletin of the History of Medicine, the New England Journal of Medicine.

Q. Thank you. We have been talking about peer reviewed publications. Can you please explain what it means for a journal to be published in a peer reviewed journal?

A. Sure. What peer review essentially means is that when somebody writes an article, a faculty member or fellow, it is then sent to the editor of that journal. The editor then makes a quick determination as to whether the topic is appropriate for the journal. Hopefully, if it's not appropriate, they send it back at that point. But if they think the topic is appropriate, they send it out to peers to evaluate the quality of the article. The peers will send back a report. It could be a half a page, it could be two or three pages, outlining the strengths and weaknesses of the article, any problems they see with the articles, as well as usually a confidential recommendation to the editor as to whether or not that journal should publish that article.

Q. Doctor, you are a member of the editorial board of several journals or have been. Can you explain what that

means?
A. Being a member of the editorial board really means a couple of different things. It is, on one hand, an honorific title. It's usually offered to people who are thought to have some standing in that field. You also, as a member of the editorial board, are expected to be available to consult with the editor about formally and informally. For example, just last week, I responded to a note from the editor of a journal who sent me a manuscript, and simply wanted to know if this was a manuscript he should even send out for peer review.
Q. Which journals are you or have you been on the editorial board?
A. I'm on the Editorial Board of the Journal of the History of Medicine. May I consult my CV for a moment just to see?
Q. Yes. You may.
A. I want to make sure I'm accurate. Technology and Culture. I'm a member of the editorial board there. I have been a member of the Editorial Board for the Journal of general Internal Medicine Caduceus, and Biomedical Instrumentation. I apologize. I'll try to slow down.
Q. And how are people selected to be on the editorial board of a peer review journal?
A. They are selected by the editor.
Q. Are you also a reviewer for any professional peer review

journal?
A. Yes, I am.
Q. Have you been cited for the high quality of your views?
A. Yes, I have.
Q. Reviews. What are some of the well known journals for which you have been a reviewer? You can just highlight a few?
A. The New England Journal of Medicine, the Journal of the American Medical Association, Lancet, the Annals of Internal Medicine.
Q. And is your role as a reviewer that which you already described in the process of peer review?
A. Yes, it is.
Q. Does part of your professional activity involve reading and keeping abreast of professional literature, concerning experimental design as used to study clinical medicine?
A. Yes, it does.
Q. Are you currently a member of any professional organizations?
A. Yes, I am.
Q. Are you currently a member of the American Association for the History of Medicine?
A. Yes, I am.
Q. Are you a member of Council?
A. I have been a member of Council. I'm not currently a

member of Council.

Q. What does it mean to be a member of Counsel?

A. The Council of the American Association of the History of Medicine is a group that basically runs the association, makes policy decisions as necessary, makes decisions about the awarding of awards, etc. The American Association of the History of Medicine is the premiere Medical History Association in the United States.

Q. And what is the American College of Physicians?

A. The American College of Physicians is an organization of internists that have been has been in existence since, I believe, around 1915, it's an honorary organization that serves to promote education and practice of internal medicine.

Q. Are you a fellow of the American College of Physicians?

A. Yes, I am.

Q. What's the significance of being a fellow of that organization?

A. To be a member of the organization, basically if you are an internist, you can apply to be a fellow. You have to establish that you have done something additional in terms of research or teaching, or you can become a fellow on the basis of outstanding practice as well.

Q. And what is the American Society for Bioethics and Humanities?

A. The American Society for Bioethics and Humanities is a society that promotes research and teaching in bioethics and humanities.

Q. Are you a member of that society?

A. Yes, I am.

Q. And the American Society for Clinical Investigation, what is its membership?

A. The American Society of Clinical Investigation is an honorary society, a quite selective society, that recognizes people who have achieved excellence in biomedical research, and I was selected to that society. I believe it is accurate to say, as the first, and to my knowledge, the only person ever asked to become a member of that society based on historical research.

Q. Thank you, Doctor. Doctor, is the document that you have been looking at, up to this point, an up-to-date copy of your CV?

A. It is up-to-date as of December, 2003. I don't think anything substantive has changed. I have given some talks that are probably not indicated on here and had a couple of things accepted, but the substance would not be significantly different.

Q. And so it accurately reflects your professional education and experience up to that point when you submitted it?

A. Yes, it does.
Q. Okay. It includes a list of the publications up to that point?
A. That is correct.
Q. Including your publications on the study and modification of surgical techniques?
A. Yes.
MS. STRAUSS: Your Honor, at this point, I would like to move for an admission of Plaintiff's Exhibit 97.
MR. WARDEN: No objection, Your Honor.
THE COURT: 97 is received.
MS. STRAUSS: Thank you, Your Honor.
BY MS. STRAUSS:
Q. Dr. Howell, can you tell us how do surgeons learn to perform surgical procedures?
A. Surgeons start to learn to perform surgical procedures when they are in medical school. They study surgery as part of their third year rotation, in which every medical student would normally spend some time on a surgical service. If they are interested in surgery, they'll spend more time as a fourth year student, and will then enter a residency train program, during which time they'll have progressively more responsibility for care of patients under the supervision of an attending physician.
Q. After medical school and residency, how do practicing

surgeons update their skills, either to learn an emerging technique or just expanding the skills they are capable of performing?

A. They would update their skills by keeping abreast of the relevant medical literature, and there are a variety of ways of doing that. They would meet and consult with colleagues on a day-to-day basis, if they work in an environment in which there are other surgeons or other people doing those procedures around. They would attend professional meetings and discuss ongoing techniques with their colleagues. Sometimes informally; sometimes they would here formal presentations. In some circumstances they would attend specific courses to learn how to do procedures or would arrange to work alongside someone doing the particular procedure.

Q. What are some of the common ways that surgical techniques change and develop over time?

A. The craft of surgery can change in a variety of different ways. Sometimes a brand new idea will come along and it will be adopted and picked up. That happens rather infrequently. Much more often, people, in the course of doing a procedure, will find that it is easier, safer, better in some way, to do it slightly differently than the way they had been doing it before. They'll adopt that method. If it seems to work, they'll talk to their --

excuse me -- they'll talk to their colleagues about it. They'll present it and, eventually, it may become accepted or it may not.

Q. Can you think of some examples of surgical techniques that offer an alternative to an established method of accomplishing the same surgical goal?

A. Well, in the case of coronary artery bypass surgery or the case of coronary revascularization -- let me explain what I mean by that. It has been recognized for about a century now that coronary disease or heart attack is caused by the interruption of blood flow to some part of the heart. And it has been thought that it would be a good idea to improve blood flow to areas that don't get enough. The technical term for the tissue that doesn't get enough blood is ischemia. And if it dies, it's infarction. Myocardium is the heart and, hence, myocardial infarction is the logical consequence of what happens to the heart when you don't get enough blood to the heart. How to improve the blood flow to the heart, it's a fairly straightforward question. And over the years, there have been a variety of methods that have been tried to try to improve blood flow to the heart, all with the same essential golf getting the blood there. Whether you want to implant an artery or sew an artery in, or interpose a vein between the artery and the blocked area, or whether you want to stick a device up

inside the artery and expand it to increase the blood flow. These are all different ways of accomplishing the same goal, which is to improve the blood flow.

Q. And can you talk about how some of those changes developed over time?

A. Well, they started by somebody thinking this might be a good idea. In order to identify the area that is blocked, you need to be able to see where the blockage is, and that discovery came about by a purely serendipitous fashion. It was thought, at the time, that it would be dangerous, probably fatal to inject dye into a coroner artery, into the artery supplying blood to the heart. During the course of an attempt to inject dye into the aorta, the large blood vessel leading from the heart, the catheter accidentally slipped into the coronary artery. The people who were doing the procedure thought they had made a mistake and the patient would probably die. The patient did not. Instead, they saw that there was an obstruction there from the dye that had been injected. So by this purely serendipitous even came the knowledge that if we see the blockage, we can relieve it. People tried, as I mentioned, interposing one kind of blood vessel. They tried imposing another kind of blood vessel. They tried doing one or two or three or four different kinds of blood vessels. They tried different methods of sewing the blood vessels together. Over time,

developed the procedure that is now absolutely standard, which is coronary artery bypass grafting.

Q. Was that technique studied?

A. Was it studied? It was studied in the sense that when people first tried the different approaches, they took note of what happened. They took note of whether they saw an improvement in the patient or not. The technique rapidly expanded, and within a few decades, within a decade of its being introduced, it was being performed on probably hundreds of thousands of patients. It was only after that point that systematic standardized trials began to be done. And when they were performed, there was a considerable amount of controversy about whether or not those trials needed to be done.

Q. Thank you. What are some of the different types of clinical studies that are used to conduct medical research?

A. Well, we can divide them in a couple of different ways. One could talk about studies of prospective versus retrospective studies. One can talk about experimental or observational studies. And either one of those dividings works. Perhaps the most elementary and least powerful form of talking about something new would be simply the case report. And this is an often found in medical journals in which typically is a single case. I did this, it worked. Or I did this and it didn't work. Surgeons tend to like to

publish more often on things that did. If something works, then perhaps you would publish a case series. You would take note of how things happened over time. So if you were trying something new, you would try it five, ten, 15 or 20 times or more. You would present that information to your peers. You might present it informally. And a lot of education goes on informally. A lot of it people is talking to each other. I talk to my colleagues all the time. When I'm taking care of patients, I frequently turn to them and say, what do you think about this. That's how I learn, and that's I think how many physicians learn. So you would have a case series that could be presented or published.

Q. Can you also explain, please, what a retrospective case controlled study would be?

A. Well, a retrospective study is what the name implies. It's a study that's an observational study. It's not an experimental study. You're looking at something that has happened in the past. Now, it may happen that the event you want to study is relatively uncommon, or it may happen that a prospective study is simply inappropriate. So if the event is relatively uncommon, then you would do what is called a case controlled study to ascertain what was causing the event. Would you like me to supply an example?

Q. If you think it would be helpful, sure.

A. There is a relatively rare form of tumor called

mesothelioma. What causes mesothelioma. One way to find out would be to prospectively study -- let's say all the citizens of the State of Nebraska over their lifetime, and conduct and gets lots of information about each one of them, and I would guess that over a hundred years, you would expect to find probably 10 or 15 cases, if that. That's not a very effective way of getting the answer. It takes a long time, and it's not going to help you very much. A case controlled study would say, let's find cases of people with mesothelioma. Lets find controls and match them for -- for factors that we think might be responsible for causing mesothelioma. For example, we would match on gender, we would match on age. Let's say we think that drinking too much diet Coke causes mesothelioma. We would find controls that drank a lot of diet coke or didn't drink any diet Coke. Let's say we think smoking causes mesothelioma. We would, match the controls on that basis. And then we would look to see if there was something systematically different about the cases and the controls, and we might find that exposure was found to a particular toxin that was found more often in the cases than the controls. That would be an example of a case controlled study.

Q. Thank you, Doctor. And could you explain what's a retrospective cohort study is, please?

A. Well, again, a retrospective simply means looking back.

A cohort would be a group of people. It could be a cohort of people living in a particular community. It could be a cohort of people descended from a common set of ancestors. It could be a cohort of people who underwent a particular surgical or medical procedure. And a retrospective cohort study would be describing what these findings were for that particular group of people.

Q. And what is a retrospective chart review?

A. Well, a retrospective chart review would be an example of a retrospective cohort study, in which the information was gathered from the patient's charts.

Q. And can you tell me what a prospective randomized clinical trial is?

A. Now we are moving into the area of experimental as opposed to observational studies. A prospective is simply another way of saying we are planning the study to start from this point and move forward. A randomized trial means the allocation of interest is assigned randomly. And this is important, because it serves to remove biases that may be introduced into the selection of whatever it is that you're choosing. Let's say we are comparing drug A and drug B. I may think that drug A works better in tall people, and drug B works better in short people. I prescribe drug A to tall people and drug B to short people. It turns out what I'm studying is more serious in tall people. I conclude that

drug A is ineffective. That's a silly example, but there are a lot of biases that are introduced. By randomly allocating the treatment, then as we possibly can, we remove the biases inherent in the choice of the treatment.

Q. Do these different types of studies have different strengths and weaknesses?

A. Absolutely.

Q. Can you please describe the strengths and weaknesses of the different types of case -- of studies beginning with the case series?

A. Well, the case series has the advantage that it is the simplest easiest and most straightforward of the studies to do. It doesn't require randomizing patients. It doesn't require -- it allows people to proceed as they normally would. The disadvantage of a case series is, obviously, that it is uncontrolled, and it's typically limited in its range of patients. It may be limited in its range of providers. It might reflect my particular expertise or lack thereof, or if it's done in my institution, maybe my institution's particular expertise or lack thereof. It also suffers from potential bias in terms of confounders.

Q. Okay. The retrospective cohort study or chart review?

A. That would suffer from all of the problems that -- advantages and disadvantages I just mentioned. The other problem, and I should have mentioned this with the

retrospective case series because it's the same for both, is that if you don't know what you're studying, you might not record it. So you are limited, obviously, to the information you can garner about events in the past. This would contrast it with the advantages of a prospective study in which you can define in advance what it is you want to record, the information you want to have, the outcome of interest that you want to study.

Q. And the retrospective case control study?

A. A retrospective case control study suffers from all the same advantages and disadvantages I just mentioned for retrospective studies in general. Obviously, the case control study is only as good as your ability to identify potential confounders. If you missed a potential confounder, let's say an example of mesothelioma, that you don't believe that smoking has anything to do with lung cancer, then you wouldn't control for smoking and you would come up potentially with a result that was erroneous.

Q. Okay. And if you are looking at the retrospective studies as a group, it seems like you're identifying a number of strengths and weaknesses that are true of retrospective studies as a group. Can you explain how -- withdrawn. You mentioned earlier that it allows the physicians, when you're performing a retrospective study, a retrospective study seems to allow the physicians to proceed

as they wish. Can you explain why that's a strength of those studies?

A. When doctors are taking care of patients, there is obviously an interaction that goes on, and that the patient and doctor achieve a relationship, and the patient trusts the doctor to do what's best for her or him. Enrolling a patient in a clinical trial that is prospective, and that it involves the allocation between two different -- I know we haven't talked about prospective. Can I use that as an example to help answer your question?

Q. Yes. Perhaps I shouldn't have interrupted you in your flow.

THE COURT: Go ahead.

THE WITNESS: All right.

BY MS. STRAUSS:

Q. Please, go ahead.

A. The problem is that you have to believe that these choices are reasonable ones to make, if you want to compare two different treatment choices. And that's going to mean that some patients won't want to enroll and some physicians won't want to do the study. Whereas in a retrospective study, what you have is physicians using all of their art, and skill, and knowledge, to take care of patients as best they can. Then you're trying to figure out, in retrospect, if it worked or not. I should point out many -- it's

certainly possible for retrospective studies to come up with the conclusion that the procedure is dangerous and should not be done. And there are examples in the history of medicine where precisely that has taken place.

Q. And I should have given you the opportunity before, but would you like to now take the opportunity to discuss some of the strengths and weaknesses of the randomized clinical trial, prospective randomized clinical trial?

A. A randomized clinical trial must be prospective, by definition. The strengths are similar to what I have described here, when you're eliminating bias by randomization. Because it's prospective, you can decide, in advance, not only what you want to record in terms of data; what you think is important. But also what your outcome of interest is. And this is a much more powerful statistical technique than simply looking for differences. If I flip a coin 200 times, it's very likely that four times in a row, will come up heads or tails. That is simply -- that doesn't mean that I have a coin that doesn't work, it just means there is a certain amount of random variation in any statistical analysis. An advantage of prospective study is that you define the outcome that you're interested in. So that if we want to study, for example, lipid lowering, lowering cholesterol to prevent heart attacks, we define that in advance. We don't -- if we see something else

happening, it may be due to chance or it may be -- the outcome that really wants to be studied. Those are some of the advantages. The disadvantage of doing prospective randomized controlled studies is that it i -- obviously, in any clinical investigation, any time you want to study the care of patients, you're dealing with risks and benefits. It cannot be otherwise. And you have to ask yourself what are the benefits of doing the study, and what are the risks of doing the study. And you have to convince yourself that the benefits are worth the considerable costs involved in doing a prospective randomized controlled study.

Q. Are there particular situations that are especially receptive to performing a randomized clinical trial?

A. Absolutely. The classic example of a prospective randomized clinical trial or RCT, as it's commonly referred to, randomized clinical trial, are drug studies. That is, in fact -- I'm sorry. Drug studies. That is, in fact, where the concept of the RCT came into existence. And drug studies are particularly susceptible to the study for a number of reasons.

Q. Can you tell me what those reasons are?

A. One reason is that they are operator independent. If I give a red pill or a blue pill, and my colleague gives a red pill or a blue pill, it's -- absent the suggestive value I may be more or less convincing in giving the pill to the

patient than my colleague, the pill is going to have roughly the same physiological effect no matter who gives it. That is a critical aspect for some of this things we are talking about today. Doesn't matter who gives the pill. It's also very easy to give a placebo. We sometimes don't know. Does this procedure -- does this pill -- does this medicine work. I don't know. So we can give a placebo, a pill that looks like the real pill but isn't. And there is a lot of work that goes into figuring how to make a placebo that is convincing. This is important, not only for the benefits but also for the risks. Does this pill, does this medicine cause serious side effects? Well, it may sound silly, but you have got to give a placebo at the same time because we know, for example, that a significant number of patients given placebo will experience headache, will experience diarrhea, will experience rash. We are talking often double digit percentages here. So before concluding your pill is responsible for a side effect, you would like to know it causes the side effect more than placebo does.

Q. And what's the importance of conducting a blind comparison?

A. The reason for blind comparison, and it can be either single or double blinded -- well, let me -- in theory, it can be single or double blinded. In practice, many circumstances, it can't be either. Is that it eliminates

bias on the part of the patient, as well as on the part of the provider. For example, if you deeply believe that this medicine is going to help you, you may feel better. You may come back to me and say I have more energy. Whatever I'm being treated for is much better. So if it's the same with the placebo as it is with the pill, the reactive pill, then we know that it's not the medicine, it's simply the interaction with the health care provider that's making you feel better. Conversely, I may believe this is a great new medicine. Maybe I developed it. Maybe my colleagues developed it. Maybe I just believe because I have read the science, and it just makes sense that it works. And if I know who's getting the pill and who is not, then there is going to be a tendency for me to say, when somebody who's getting the active pill comes in, I'm going to search them out. Are you feeling better? Are you sure? You know, you are evidently going to be more aggressive at looking for the good things and maybe I'm not going to be so quick to quiz them on the bad things. So that would be a classic example of a double blind study. If I don't know whose getting the pill and the patient doesn't know who's getting the pill.

Q. How, if at all, are studies are new drug therapies different from studies of new surgical techniques?

A. Well, one I've already alluded to, and that is the standardization question, and this is absolutely critical.

Surgical techniques are, by their very nature difficult, to standardize. There are different operators who have different skill levels. The same operator has different skill levels. Because as you do more procedures, you get better at it. And ever -- well, my reading is that the preponderance of the evidence shows that for most surgical procedures, there is what we term a volume effect. So as you do more, you get better. Not terribly surprising. So that the same operator will have different skills levels. So if you are doing a study, rather than the drug I give you that is the same every time, the operator's skill level changes. Standardization is also extraordinarily different in surgery because patients are different. They are different when you give medicines too, but there is not an interaction between the medicine and the person. Whereas in performing a procedure, there is an interaction between the surgeon and the patient that, as the procedure is going on, it's very likely to change or be done slightly differently. So the standardization issue is key. Another difference is the regulatory format. The FDA monitors and manages the introduction of new drugs. There is no equivalent for surgical procedures.

Q. On the topic of randomization?

A. Um-hm.

Q. Is that a different factor in conducting a study of a

new drug therapy as opposed to a study of a new surgical technique?

A. Right, because as I mentioned, the interaction between the patient and the surgeon may require that during the performs of the operation, the surgeon may have to change her or his approach to the patient. It may be changed in a way that is trivial, and it may be changes in a way that is somewhat more substantive. Whereas the interaction between the drug and the physician, that's not going to be coming into effect.

Q. Does patient preference play a different role in conducting those two kinds of studies?

A. Sure. Most patients, most of the time, if they are taking two different drugs, may not have or most won't know or care about the particular physiological mechanisms of the drug, and won't have a very strong preference. For example, the treatment of hypertension, you may start with a diuretic, a beta blocker. Diuretic is a pill, beta blocker slows the heart. They are different spectrums of side effects, but you're taking a pill a day. Whereas asking patients to randomize themselves to surgical procedure is asking them to have a very different sort of interaction with the surgeon than is the case for a drug study. They are asking, in a sense, the surgeon is asking the patient to agree to the surgeon being constrained in terms of what she

or he might want to do, when they actually are in the course of performing that particular operation. And some patients, I think, would be less likely to want to agree to that.

Q. I believe you testified before that sometimes modifications or variations develop to change existing surgical procedures. Is that correct?

A. That is correct.

Q. After a physician develops a modification of an existing surgical procedure, what could that physician do to begin to study the safety of that procedure?

A. Well, initially, when performing it for the first time, the physician would obviously take note of what the consequences were. After performing it a number of times, the physician would want to share his or her knowledge with the medical community; would want to take note of what has happened. If they seem to be seeing a lot of problems, they probably will stop doing the procedure. That, then, would be shared in both an informal and in a formal way. Informally, as I said, in the hallway and the conference rooms. Formally is at meetings. And eventually published in a peer review journal for people to read it and study.

Q. Has this method of presenting case reports and presenting information to colleagues, in the way you just described, been long accepted in the medical community?

A. Yes, it has.

Q. How long has it been part of accepted medical practice?
A. A long time. How long, is a difficult question to answer. I think certainly for a century. If you want, I could speculate as to how many centuries.
Q. That's fine. Thank you. And is it currently accepted in the medical community?
A. Yes, it is.
Q. And is this model currently considered reliable in the field?
A. That depends on the question that's being asked. I think it's considered very reliable for some questions and probably would be considered not reliable for others.
Q. And if a case series or several case series have been done to demonstrate the safety of a modification of a surgical technique, would doctors always continue to study the safety of that modification?
A. The short and honest answer is, it depends.
Q. On what does it depend?
A. It would depend -- that was the question that was asked. It would depend, first of all, on the extent of the modification. Let us say, for example, that somebody has invented a new hemostat that is simply a little easier to use to clamp off blood vessels. Is that a modification? Yes, it's a change. I used to use this hemostat, now I use that hemostat. This hemostat works. That hemostat works.

I don't think anybody would really expect a whole lot more than that to go on. In the case of modifications that are being discussed and presented in case reports, it would depend on how much difference one sees between the two, and what the baseline level is. If you have two procedures that seem to work, and one of them has a very high complication rate or a lot of problems, you have a new procedure that appears to have lower complications, I think you would want to do some very careful study to make sure you're really seeing a significant difference. If, on the other hand, you have two procedures and both have very, very low complication rates, then I think there would be considerably less interest or less importance in investing the costs to keep doing studies. And by costs, let me emphasize, I do not mean just monetary costs. I mean costs in terms of physician time, in terms of patient time, in terms of relationship between doctors and physician. And in terms of the fact that the time to do that study is time that is not spent doing something else that could potentially be a more productive use of the time.

Q. What circumstances might suggest that additional research on a surgical modification would be helpful?

A. As I mentioned, I think if you are seeing, if you are making a significant difference in terms of the outcomes of that procedure, if -- let's say you're doing a procedure

that's only efficacious 50% of the time, let's say operation for a cure of a cancer, and 50% of the time the cancer comes back. Now you have a new procedure and you think this time it's efficacious 60% of the time. 40% of the time, the cancer comes back. That, I think, would be a very, very important question to answer. Is that simply, this is where the biases of the case controlled study come into play. Maybe, if I'm the surgeon doing better, maybe I happen to be seeing patients who weren't as sick whose cancer wasn't as far a long. Maybe I'm just so good, that's why we are seeing the difference in effects. That's something very important to study and that, in fact, is what has been done.

Q. What problems might confront a physician who wanted to study a modification of a surgical technique?

A. Well, we are going back to what we talked about before. The first problem would those of standardization. The problems of patient recruitment. Be problems of study design. Before doing the study, you would want to convince yourself that the question was important. That the answers would be useful to patients, and that the study design would help you achieve those goals. And you would want to answer those questions before you started the study.

Q. Are there particular challenges associated with conducting a study that compared two procedures where both of those procedures appear, from initial study, to have very

low complication rates?

A. Yes.

Q. And what are those?

A. As I mentioned, you have to ask yourself, what is the question you're trying to answer. And if you have significant complication rates, then you have a long way to go to knock them down. You may want very desperately to figure out a way to reduce those complication rates. If you have differences in efficacy, I think we have to include efficacy in this case as well as complication rates. Because you are not just studying the risks of the procedure, but you are studying the benefits of the procedure. If, on the other hand, you don't have any question about efficacy, that then comes out of your equation, so there is nothing to be learned about efficacy, because the goal is achieved with procedure A, the goal is achieved with procedure B, then you want to look at risks. You have to say, if you are starting at a very low-level, what's a meaningful drop. If we -- and this gets us to the concept of absolute versus relative risk reduction. If your risk is dropped by 50%, that doesn't really tell you a whole lot by itself. Because if my risk of dying is, over the next ten years, is 10%, you drop by 50% to 5%, I think that's a meaningful reduction. On the other hand, if my risk of dying over the next ten years is one in 10,000, it's probably higher. One in 10,000, and I

drop it to one in 20,000, is that a meaningful reduction in risk? And in order to study that, let's say -- let's make it a procedure now in which the risks are at a very low level. Let's say less than one in a hundred of any significant risk. You want to make sure when you do your study you have what's called the power to differentiate between two procedures.

Q. And can you explain to us what that means?

A. Sure. When we are doing any comparison, we want to answer two questions about our conclusions. What is the likelihood that this difference is due to chance alone? If I flip that coin and it comes up heads three times and tails once, do I have a phony coin or is it just reasonably likely that I'll get three heads in a row? Obviously, in that case, it's reasonably likely and we might want to get a bigger study to conclude the coin is really flawed. Now, if I flip it a hundred times and it comes up heads 95, now we conclude that I probably have a phony coin. So the first question is, is the difference that we are seeing simply due to chance alone. So if the complication rate is higher in one group and lower in another group, was that simply due to chance? That's the common under -- that's the first, usually is the first question. Power is a different question. Power is what is the likelihood if you do the study and you don't see -- that you will see a difference if

it's clinically significant. And then you have to define a priori what you mean by clinically significant. This gets back to the relative and absolute risks. How much of a difference do I want to see in these two mortality rates? How much of a difference do I want to see in these two complication rates? If the, you know, do I really care if the complication rate drops from one in 500 to one in 700? Is that a meaningful difference? That's a policy decision. You may tell me that you do care and it's important to do that study. Fine. If you want to do that study, and you want to be sure that you're going to get that, you're going to need a huge number of patients, because otherwise, you're simply not going to be able to make that differentiation.

Q. Thank you. Are there any particular challenges associated with conducting a retrospective chart review?

A. Yes.

Q. Can you tell me what those are, please?

A. Well, first of all, you have got to find the charts which may or may not be easy to do. It would depend, depending upon what you're studying, you would want to know the information you wished to gather was adequately presented in the charts. And then the other problems with observational studies would all arise. It's not an experimental study, you can have, you know, observe operator effects -- one operator may be different than another

operator.
Q. If the small number of -- withdrawn. If the number of procedures performed at any given institution is small, but in order to conduct the study you would like to conduct to get a significant power in the study, you needed a large number of patients, would that add another complication to conducting a retrospective chart review?
A. Well, we wouldn't -- power is usually talked about in terms of prospective studies. But in terms of getting an adequate sampling, yes, you would need to find an adequate number of examples of the charts you wanted to look at.
Q. Is the randomized clinical trial suitable for use in evaluating variations in surgical techniques?
A. It depends. It can be. If one can solve or at least adequately address the many issues that we have discussed. It is often held up as a goal. It is rarely achieved.
Q. Can you explain, please, what the concept of equipoise is in a randomized clinical trial?
A. Let's say I'm seeing a patient and I want to do a study. In order for me to ask them to be randomly allocated to one of two treatment arms, be they drugs, surgery, there has to be a state I clinical equipoise. I have to honestly believe that I don't know the answer to the question. In other words, I don't know whether drug A is better than drug B, and I don't know if drug A is better than placebo. Absent

that equipoise, I'm asking the patient to take a step which may potentially be detrimental to their health.

Q. So absent equipoise, would it be ethically acceptable for a physician to decline to enter their patients in a study comparing two treatments?

A. Absolutely.

Q. Could a physician ethically enter patients into a study comparing two treatments when the physician does not believe that equipoise exists?

A. No. I believe that if I honestly believe, based on my knowledge and reading that a particular line of treatment is better, I cannot ethically ask my patient to take -- well, I cannot enter them into a clinical trial. If my patient says I choose to take this other treatment course, and I believe that it's not as good but it's still within the parameters of ethical practice, I might do that, but I could not ask them to be randomly assigned to the other, unless I believe that equipoise existed between the two treatment options.

Q. And if a large number of doctors believes that one of two treatment options is safer and, therefore, does not believe that equipoise exists, how would that affect the studies that could be performed to compare those two treatments?

A. Well, if you can't enroll patients in the study, then you can't do the study. And if the study is to -- requires

a large number of patients as we were discussing earlier, then you're not going to be able to enroll enough doctors in the study to do the study, or enough patients in the study to do the study.

Q. Doctor, you were talking before about absolute and relative risk. Can you just explain briefly, again, what the difference is between absolute risk and relative risk?

A. Well, absolute risk, risk reduction. Absolute relative risk reduction. The absolute risk is simply the result of a particular event happening. The relative risk reduction is when we express or it could be an increments for that matter. The change in the risk in terms of a percentage change in the risk. And it's often -- one often sees relative risks touted prominently, when I think rational human beings would look at the absolute risk reduction and see it as being of no value.

Q. Are there any reasons that a patient would choose to undertake an increased relative risk, if the absolute risk is very low?

A. Absolutely. Patients do it all the time.

Q. Can you think of like some examples of what those reasons are?

A. I see somebody for high blood pressure. I say you need to take medicine for your high blood pressure. He asks me what the side effects are, and I tell him and he doesn't

like that answer. He says is there anything else I can do? I say well, yeah. If you exercise regularly, lose 20 pounds, your blood pressure might come down.

THE COURT: You have to stop talking to my doctor.

THE WITNESS: Yes, Your Honor.

THE COURT: Go ahead.

THE WITNESS: All right. Then the patient is taking a risk. If the patient would take the medicines I prescribed, I can get, you know, this is one of the unusual situations in medicine in which we actually have very, very good randomized control, double blind placebo controlled clinical trials that show if you lower your blood pressure, you're less likely to have a stroke and you're likely to live longer. The patient is taking a risk because he would rather avoid the side effects than modify his behavior. The absolute risk -- over what time period. Over a lifetime, that is a very significant increase in risk. Over two months, I'm willing to go say fine. Let's come back, do that, come back in two months and let's see. So the patient has chosen voluntarily to incur an increased risk for reasons that's important to them. That's fine.

Q. Might there be some other benefits a patient might want to consider when choosing between alternative therapies?

A. There is the relationship with the physician. The belief that the physician is taking their best interest at

heart, and I think most patients would want to believe the doctor is doing whatever he can to improve their health. I'm not sure exactly.

Q. Would the length of time of recovery affect that decision?

A. Sure. And some patients may choose -- we see this as well. It may be very important to some patients to have less time in recovery. Others may not care. May be willing to accept a better result for more time in recovery.

Q. Is discomfort or pain a factor that often place into patient choice, in this type of situation?

A. Absolutely, and patients differ. Some patients would wish to avoid any amount of pain at all costs and would rather wait and see what happens. Other patients will say, I would like to get the answer. I would like to find out what's going on and I don't care about the pain. Patients differ in their preferences.

Q. Is there any disadvantage to withholding a medical treatment until after it has been studied?

A. Well, first of all, in order to study it, you have to do it. So if you -- if you withhold it and don't allow anyone to do it, then you'll never study it, then you'll never know. This, again, is one of those balancing acts. If a new treatment is efficacious and you think it's good, and you don't use it because you want to study it, and then the

people who could benefit from that treatment will not benefit from it. And to go back for a moment to the previous coronary artery bypass graft, that exploded on the scene before it was studied because physicians believed that it was good for their patients and did not believe it was ethical to subject them to a clinical trial.

Q. How would a physician progress, if he or she wants to study a medical procedure, and still wants to offer that procedure to all the patients for whom that physician thinks it would be appropriate?

A. One would publish the results of the case series of patients that one was offering the procedure to and put that out and let people talk about it. You would talk about it. You would present it at meetings and have it be part of the public discourse.

Q. So observational studies would be appropriate in those circumstances?

A. Yes.

Q. We talked about this little bit before, but can you tell me how you determine how a physician is going to determine how many patients they'll need to do a study?

A. This is what is termed a power calculation. I assume you're talking about a prospect rather than an experimental study.

Q. Both kinds, both retrospective and prospective studies.

A. What you would do is you would have to decide what is the question that you want to answer. And that's really important, and it's often missed because the question can be how much pain is there? The question can be how long is somebody laid off from an operation. The question can be how long do you live? The question could be do you have a stroke or not? So you have want to define what the question ask. You then want to define and give the statistical parameters that I explained. How confident do you want to be that you have the right answer? How much -- how much of statistical certainty do you need? If you want to have 100% statistical certainly, you'll have to wait until infinity and that's not likely to happen. You have got to be willing to live with a certain amount of statistical uncertainty and how much do you want? Do you want to be 20, and how much of a difference matters? And the other sorts of questions that we need to answer the what's the magnitude of the problem? How important is it to study this question?

Q. If you wish to research a procedure that had a serious complication rate around .5%, how, if at all, would that affect the sample size that you would need to get a significant result?

THE COURT: You're talking now about a surgical procedure; is that right?

MS. STRAUSS: A surgical procedure.

THE WITNESS: The complication rate is about .5% and you're comparing it with another surgical procedure, let us say?

BY MS. STRAUSS:

Q. Okay.

A. With a similar surgical complication rate? You would have to ask the question how much of a decrease do you really need to see before you care. If it goes from .5% or to .4% or to .6%, is that important to you or not? Most people -- let us say that you want a 50% change in order to be meaningful. I didn't come prepared to do the power calculation. One, in fact, could do such calculations, but you would need hundreds to thousands of patients enrolled to have any chance at all of coming up with a meaningful answer.

Q. Doctor, are all clinical procedures subject to clinical trials?

A. No, ma'am.

Q. Can you think of some examples of clinical procedures that have changed, and where that variation has not been subject to clinical trials?

A. Sure. Let me take one procedure, for example, that would be a procedure that we do in internal medicine which is removal of fluid from a lung, from around the lung. It's called thoracentesis; called sticking a needle into the

chest and pulling out fluid. Should we do it from the side or should we do it from the back? Should we do it under ultrasound guidance or should we do it simply by virtue of physical examination, localizing the fluid adequately? This is a procedure that is done every day in hospitals all around the country. It's done with a low but not insignificant rate of complications. And it's one that is learned by craft, by doing it side-by-side. And to the best of my knowledge, nobody has ever done a systematic study to say is it better to do it one way or the other way. Typically, you learn how to do it one way, as I did, and then you teach others how to do it that way and maybe somebody does it slightly differently at another institution. And we see this all the time, particularly in people who are trained in different institutions work together. We see minor variations in the way that a procedure is done. It's very common.

Q. If a doctor is using a new type of the same instrument in -- as part of an established surgical technique, would that constitute a variation that needed to be studied, in your opinion?

A. It would depend upon the variation in the instrument. I mean if one is talking a huge difference then, yes, but we see these kind of incremental improvement in instrumentation all the time. What size needle do you want to use, for

example, to do the thoracentesis? What size needle to you want to use to give the local anesthesia? These are variations that are not studied or innovated. What kind of syringe does one use when doing the procedure? What kind of tube do you use? These are all minor variations that don't change the essential element of the procedure, and do not think -- I do not, I think, need to be formally studied.

Q. In your opinion, what would constitute a brand new surgical technique warranting additional study?

A. A brand new surgical technique would be one that represents a distinct shift from the way things were being done in the past. Perhaps a different approach. Perhaps a different intent of the operation and, again, the outcome would also differ. If the outcome in question is in doubt, then you would want to know if the new surgical innovation resulted in a different outcome or not.

Q. And in contrast, in your opinion, what would constitute a variation of an existing surgical technique?

A. Well, as I have discussed using, a different kind of a clamp, using a different kind of a suture. Suturing may be end-to0end versus end to side. Using a slightly different positioning, making your incision a little bit longer, making your incision a little bit shorter, both of which might be beneficial.

Q. Are there different concerns when assessing the safety

of the new technique as compared to assessing the safety of a surgical variation?

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

Q. Are there different concerns when assessing the safety of a new technique, compared to when you're assessing the safety of a surgical variation?

A. If it is truly a new technique, then I think that you have a much higher standard to pass in terms of assessing the safety concerns. If it's a variation on an established surgical technique and your initial findings are that you have a similar safety record, then I don't think you have the same sorts of concerns.

Q. And what are those initial steps that a doctor could take to ensure patient safety when introducing a variation of a surgical technique that has been established?

A. Well, observing the patient to see what the results are. You have a sense, presumably, if you have been doing an established technique, of what the sorts of complications are likely to occur. And so, obviously, looking for those to see if they occur.

Q. So when a physician is developing a modification to a well known commonly performed surgical technique, might the physician want to document or test the safety of the modification using observational studies?

A. Yes.

Q. And how might this variation, the surgical technique, be disseminated so that other physicians can learn to perform it?

A. It would be disseminated locally by talking about the new technique, by having other physicians observe the new technique. It would be disseminated by presentation at meetings of professionals who are interested in that particular technique. It would eventually be disseminated by virtue of publication in the medical literature.

Q. Doctor, are you familiar with the terms D & E and intact D & E?

A. Yes, I am.

Q. Do you perform gynecological procedures yourself?

A. As part of my role as a general internist in the care of adult patients, I do perform gynecological examinations and very simple gynecological procedures, but I do not perform operational gynecological procedures.

Q. Have you ever performed an abortion?

A. No, I have not.

Q. What do you base your understanding of the D & E and intact D & E procedures on?

A. On the material that was supplied to me in preparation for my presentation in this court.

Q. And can you briefly describe to me what you understand the D & E procedure to entail?

A. My understanding of the D & E is that it's a procedure in which the cervix is dilated by the insertion of a substance that will expand and will permit the fetus to be removed from the woman's body.

Q. And can you please describe the intact variation of the D & E?

A. My understanding of the intact variation of the D & E is that it's a procedure that starts, as I described with the D & E, but in which the fetus is removed intact or as intact as possible.

Q. And do you have an understanding of how the intact D & E variation was developed?

A. My understanding is that it came about as a logical consequence of physicians doing the D & E procedure, and finding that in some instances, they were able to remove the fetus intact, and feeling that this offered advantages to the woman.

Q. What is this understanding based on?

A. It's based on the material that I was given that's cited in my expert report.

Q. Do you recall --

A. What that material was?

Q. What the material was?

A. There is a chapter in the textbook by Haskell, I believe his name was. There was an expert report submitted by Dr.

Carhart and Dr. Westhoff. I also read the Court decisions from the case that came before this Court, I believe it was four years ago, as well as the Supreme Court consideration of that same case.

Q. And based on your review of those documents, do you have an opinion about the way that the D & E variation developed?

A. The intact D & E?

Q. Yes.

A. The way, you mean a value judgment as to whether it is the way that most surgical procedures develop?

Q. Do you have an opinion as to whether the way that the intact variation developed has been in accordance with currently accepted medical practice?

A. Yes, I believe it has been well within the bounds of currently accepted medical practice.

Q. And would you consider the intact D & E to be a variation, a new technique or something else?

A. A variation.

Q. And how common do you believe it is for variations on surgical techniques to evolve or develop in this way?

A. Very common.

Q. How do you think that the development of the intact variation of the D & E compares with the development of other variations of surgical techniques?

A. I believe it is a very typical pattern. Surgeons,

operators in attempting to achieve a certain goal might find there are small variations that enable them to achieve the same goal that has advantages for their patients.

Q. Did the intact variation involve a manner that reflects accepted contemporary medical practice for developing new surgical techniques?

A. Yes, it did.

Q. Can you explain, please?

A. New surgical techniques come along when people are trying to achieve the same goal. When somebody finds a way that may work a little bit better, they then -- if it continues to work better, they tell people about it. They talk to their colleagues about it. Their colleagues try it. They may find that it works better as well. In that way, the knowledge disseminates throughout the community of practitioners.

Q. And is this consistent or inconsistent with historical medical practice?

A. This is very consistent with historical medical practice.

Q. Doctor, how difficult or easy do you believe it would be to structure a study comparing the intact D & E and D & E variations to compare their complication rates?

A. It would be difficult.

Q. Why would it be difficult?

A. Well, a retrospective study would be difficult for the reasons we have discussed involving finding the cases. Establishing, you know, exactly the material that had been collected. A prospective study would be extraordinarily difficult because, first of all, you have to standardize the procedure. You have to have agreement on what is one and what is the other. Then you have got to find surgeons and women who are willing to have the surgeons have constraint in comparing the two procedures. In other words, you have got to have somebody who agrees that I'm going to do it this way, I'm not going to do it that way, even if in the course of performing the procedure, I might wish to do it the other way. I'm not sure that physicians would want to do that, and I'm not sure that women would agree. Then you would need a lot of women to agree, because as we have discussed, if the rates of complications are low -- well, the efficacy is 100%. There is -- so you're not comparing efficacy. You're looking at risk benefit. The benefit of the efficacy is there. The risk is very low. So you're going to need a an awful lot of people, in order to find any meaningful difference in the risk. So it would be a very, very difficult study to actually carry out.

Q. Doctor, do you believe it would be possible to structure a randomized prospective study comparing the intact D & E and D & E variation in such a way that it would yield

meaningful results?
A. It would be possible to structure such a study. I think it would be extraordinarily difficult or impossible nor would it be desirable, in my opinion, to carry such a study out. Yes, I can write down the protocol for a study that would do that. I wouldn't do it. I think it would take a long time. It would involve considerable cost. And, again, by cost, I don't just mean the money cost. I mean all of the cost involved in doing a trial. And at the end of the day, I don't think that the findings you would come up with would be worth the study. And I think that you would be highly likely to come up, and this is pure speculation. You would be highly likely to come up with the finding that there was no difference.
Q. And you testified, I believe, that in your opinion, it would not be desirable to do such a study, after weighing the costs and benefits?
A. That's correct.
Q. And can you just explain why it would not be desirable, in your opinion?
A. Because I do not believe that the knowledge that would be gained would be worth -- would be worth what it would take to actually do such a study. I think that the risks are already low enough. We know are low enough on both sides, and we know the problems of doing this sort of a

study would be considerable.

Q. Dr. Howell, in your opinion, what's the most important thing for a physician to ask when designing a study to research a medical procedure?

A. Is this the most important thing to ask? Can I come up with more than one important thing? All right. The most important thing to ask is having clearly defined the question one wants to ask. Is this an important enough question to devote the necessary time and resources to answering.

Q. And, Dr. Howell, do you have an opinion as to whether patients would benefit from the knowledge gained of a randomized study of the intact D & E procedure?

A. Were such knowledge available as of right this moment? I think that, at this point, that it would be unlikely that the information that would be gained would be of value.

Q. And what about a retrospective study?

A. I think a retrospective study would be very useful.

Q. Doctor, if there were a federal law banning the performance of all intact D & Es, do you have an understanding of how that would affect the ability of physicians to conduct further study of the intact D & E procedure?

A. I believe that if it was illegal to perform the procedure, one could not then study it.

MS. STRAUSS: Your Honor, may I confer with counsel for a moment?

THE COURT: Sure.

MS. STRAUSS: I have no further questions, Your Honor.

THE COURT: Counsel, would you like us to take our break now?

MR. WARDEN: That would be my preference, Your Honor.

THE COURT: We'll take our 15-minute break now and we'll start again in 15 minutes. We stand in recess.

(Recess from 10:23 to 10:40 a.m.; all parties present).

THE COURT: Please be seated. Doctor, if you will retake the witness stand. Mr. Warden, you don't need to worry about my geriatric court reporter giving you instructions about question speed.

MR. WARDEN: No, that's fine, Your Honor. Yesterday was my first appearance in court, so I appreciate all the advice I can get.

THE COURT: Don't listen to them.

MR. WARDEN: Probably knows more than I do.

THE COURT: Go ahead.

CROSS-EXAMINATION

BY MR. WARDEN:

Q. Doctor, you're not a surgeon, correct?

A. That is correct.
Q. You don't presently perform surgical procedures, correct?
A. I perform minor surgical procedures, but I do not perform procedures in the operating room, if that's what you mean.
Q. Okay. Correct. Other than when you were a medical trainee, you haven't performed operating room surgical procedures; is that correct?
A. That's correct.
Q. You're not board certified in surgery?
A. That's correct.
Q. You're not a fellow of the American College of Surgeons, correct?
A. Correct.
Q. You're not a faculty member of the University of Michigan Department of Surgery?
A. Correct.
Q. You have never been qualified as an expert in surgery by a court of law, is that correct?
A. Correct.
Q. Doctor, I believe you said on direct you have never performed an abortion, correct?
A. Correct.
Q. You have never seen an abortion performed, correct?

A. Correct.
Q. And you're not an obstetrician or gynecologist, correct?
A. Correct.
Q. You have never published any articles on the topic of abortion, correct?
A. I can't be sure that in all the articles I have published, the word abortion has not appeared somewhere, but certainly it's never been the topic or the focus of anything I have ever published.
Q. Doctor, your knowledge of the D & E abortion procedure is based on information that has been given to you by plaintiffs in this case; is that correct?
A. That is correct.
Q. Your knowledge of the intact D & E or D & X procedure is also based on information that has been given to you by the plaintiffs; is that correct?
A. That is correct. I read the newspaper like everybody else, but other than that, no.
Q. Okay. Prior to your deposition, you conducted no independent research into either the D & E or the intact D & E procedure; is that correct?
A. That is correct.
Q. Doctor, if you could look at the binder marked Defendant's Exhibit there, please, and turn to Exhibit 580.
A. So this is a quiz to see if I can figure out which

volume it's in.

Q. Okay.

A. I have it.

Q. Okay.

A. Yes, sir.

Q. Could you turn to page 127 of that exhibit. Could you read the title page for that, please?

A. Dilation and Extractions for Late Second Trimester Abortions, Martha -- Martha Haskell, M.D., presented at the National Abortion Federation Risk Management Seminar, September 13, 1992.

Q. Doctor, have you read that publication?

A. No, sir.

Q. Could you turn to Defendant's Exhibit 608? I'm not sure if that's in the same binder or not?

A. It is not. Should I leave this out?

Q. No, I'm finished with that. Thank you.

A. Okay.

Q. Would you read the title page?

A. Intact D & E, The First Decade, presented April 2nd, 1995, NAF Conference, New Orleans, Louisiana, James T. McMahon, M.D., Surgical Centers, Los Angeles, California.

Q. Have you read that document?

A. No. I have seen it referred to, but I'm not read the document, no.

Q. Thank you. You can put that aside. Doctor, you have never been a member of an institutional review board during your career; is that correct?

A. That is correct.

Q. And you have never been a member of an innovative practice committee during your career; is that correct?

A. That is correct.

Q. Doctor, would you agree that physicians should use the best evidence available to them in treating their patients?

A. Absolutely.

Q. Doctor, would you agree in the field of surgery that intuition is not a reliable method of comparing to surgical procedures?

A. I believe the comparisons of surgical procedures should be done using the best possible methods, and I believe that intuition is often a fallible technique.

Q. Would you consider intuition to be the least reliable form of evidence?

A. I would have to consider what all the other options were. I could think of less reliable, yes.

Q. Okay. Doctor, after a surgical innovation occurs, would you expect to see more surgical centers doing that procedure and thus more patients available for study?

A. It would depend upon the procedure.

Q. And why is that?

A. Well, surgical techniques disseminate at varying rates of speed, depending on what the technique is, who is doing it, what the means of dissemination are, what factors either facilitate or impede the dissemination of a particular procedure.

Q. Doctor, you talked about some of the different methods that are available to study surgical procedures, and I believe you said retrospective case series review is one of those studies; is that correct?

A. That is correct.

Q. And I believe you said it's easy to conduct a retrospective series; is that correct?

A. Easier than some other forms of study.

Q. And, Doctor, would you agree that peer review plays an important role in the development of surgical procedures?

A. In theory, peer review should play an important role in the development of all medical procedures. I think the precise way that it plays out depends upon the procedure and depends at what stage of its development it is. Obviously, you can't have peer review at the very beginning of any new medical innovation.

Q. Would you expect peer review to occur earlier in the -- innovation period?

A. Earlier than what?

Q. Earlier than, say, randomized control trials?

A. It would vary.
Q. You would expect perhaps a randomized control trial to appear before a peer review?
A. I wouldn't be surprised to see either one as the initial response.
Q. Doctor, would you agree that peer review plays an important role in reviewing the data underlying a journal article submitted for publication?
A. If it is submitted to a peer review journal, yes.
Q. And in the absence of peer review, I believe you said there are certain biases in those publications?
A. I believe my discussion of biases didn't have to do with peer review or not peer review. I believe it had to do with experimental design.
Q. Okay. Doctor, in the absence of peer review, would you agree that selection bias in the patients being treated is a limitation of a non-peer review journal article?
A. Selection bias can come into play -- selection bias is a characteristic of how one does the study. Peer review is an attribute of how one disseminates the study. One can have selections bias with or without peer review. One can have peer review with or without selection bias. Those are two different -- those are two different characteristics. Now they are related, obviously, because when we're doing the peer review, one of the things the peer reviewer will do is

look to see if there is selection bias. Then make an informed judgment as to whether there is selection bias, whether it's significance selection bias, and whether or not the paper ought to be published, even if there is selection bias. That's part of the process of peer review, and for often for innovative surgical procedures, there is clearly selection bias. But the peer reviewer may say publish the paper because it's an important innovation. Conversely, if it's an important question that has been out there for awhile, the reviewer may say the selection bias serves to invalidate the study. Peer review -- not peer review, selection bias, not selection bias are not the same -- all in the same axis.

Q. Doctor, you as a physician, would you place more weight on an article that's been peer reviewed as opposed to an article that's not been peer reviewed?

A. In general, yes.

Q. Doctor, you have talked on direct about a procedure known as coronary artery bypass grafting; is that correct? CABG, we can refer to it as that?

A. Yes.

Q. And that procedure was developed in the late 1960s; is that correct?

A. 60s and 70s, yeah.

Q. Doctor, in 1970, is it correct that a group of Veterans

Administration surgeons began a randomized control trial of the CABG procedure?

A. That is absolutely correct.

Q. That study compared CABG to establish medical treatments for coronary artery obstruction; is that correct?

A. That's correct.

Q. That study was published in 1977 is that correct?

A. That's correct.

Q. Doctor, in the 60s an 70s, coronary artery disease caused the death of millions of people; is that correct?

A. That is correct.

Q. And through the 1960s, and up to the early 70s, doctors had found no satisfactory treatments for coronary artery disease; is that correct?

A. It depends on what you mean by satisfactory. We have different treatments now than they did then. They certainly were treating patients with coronary artery disease then. If by satisfy, you mean a cure for the disease, we don't have it now and they didn't have it then. We believe now that we have better treatments than they did in the 1970s. But I don't believe that physicians in the 1970s stood back and said, I have no treatment for you, whatever happens happens. They treated it as best they could as we do today.

Q. This treatment generally had high morbidity and high mortality rates; is that correct?

A. It would depend on what particular treatments you're asking about. Some of them, in fact, did not have high morbidity and high mortality rates. Some of them had very morbidity and mortality rights. The inherent disease would have a significance risk. But some of the treatments have high risks and some didn't. Some had no risk.

Q. And CABG was developed to treat the obstructions in coronary arteries; is that correct?

A. That's correct.

Q. Just so we are clear, when there is an obstruction, the blood can't flow through that artery. Is that accurate? It's limited in its flow?

A. Yeah. Sometimes -- if it can't flow, then the tissue beyond -- if there is not a blood supply somewhere else, will die. It's an obstruction.

Q. And in the CABG procedure, the physician or surgeons uses a substitute vein or artery to bypass that obstruction; is that correct?

A. That's right.

Q. When the procedure is performed correctly, the physician can visually see the blood flow move around the obstruction; is that correct?

A. That's right.

Q. So the physician has visual evidence that the blood flow is restored to the heart; is that correct?

A. The physician has visual evidence. The meaning of that visual evidence has been hotly contested, as you may be aware.

Q. Doctor, you relied on an article in your expert report, David S. Jones, Vision of a Cure, Visualization of Clinical Trials, and Controversy in Cardiac Therapeutics, 1968 to 1998. You're familiar with that article; is that correct?

A. I'm familiar with that article.

Q. I'm going to ask you if you agree to the article's conclusion. I can point to the citation, but the article states one of the lessons of the CABG procedures that certain kinds of surgical techniques, and I'm quoting, particularly those supported by physiological common sentence and visual demonstration could be incorporated into medical practice without trials. Do you agree with that statement?

A. You have asked me two questions. You have asked me if I agree with the article and you have asked me if I agree with that statement.

Q. Let me rephrase. Would you agree with the conclusion that certain kinds of surgical techniques, particularly those supported by physiological common sense and visual demonstration, can be incorporated into medical practice without trials?

A. My expert report is based in part on that article and in

part on many of the other papers I have got in my CV writing specifically about the history of coronary artery disease. That article is exemplary but by no means exhaustive. The article itself, I think takes a fairly nuanced view of the controversy surrounding the use of randomized clinical trials for the treatment of coronary disease. And I don't think that the authors would intend that the conclusion be stated quite so succinctly. Now, the statement as you have read it says that this can happen, and the answer is obviously, yes, it can happen.

Q. Doctor, would you agree that a new surgical procedure should be measured in part by the safety it confers to patients?

A. Yes.

Q. Would you agree part of the evaluation process should include comparison with existing and proven procedures that deal with similar clinical problems?

A. Yes.

Q. Doctor, is it possible for a new surgical procedure to carry more risks than an established procedure for a given indication?

A. Yes.

Q. An is it's possible for a new surgical procedure to be less effective than an existing procedure?

A. Yes.

Q. Doctor, do you consider it important that the results of studies of new surgical procedures be peer reviewed in scientific literature so the medical community at large can evaluate whether to incorporate those procedures into their individual practices?

A. At some stage in the development of surgical procedure , I think that would be a good idea.

Q. Doctor, do you consider it important that the safety of a new procedure be established in some fashion before it's used on patients?

A. You can't establish the safety without using it on patients, in most cases. Laboratory studies are not adequate to completely define the safety, so you would have to use a procedure on patients, in order to define whether it was safe or not.

Q. Before there is wide dissemination of the procedure in a large patient population, would you agree that the procedure should be established? The safety of the procedure should be established in some fashion before it's disseminated in a wide patient population?

A. It depends on what you mean by wide. It depends on what you mean by safety being established. I think that the answer depends on the initial findings. If you have a very high rate of problems, then the dissemination should be much more circumscribed or should stop. If you have a low rate

of complications, then I think it will naturally disseminate more widely, before you will see the actual formal studies. And as I suggested in the direct examination, in some cases innovations are simply minor innovations are on existing procedures for which safety is already well demonstrated.

Q. Doctor, would you agree that only with clinical trials and observations can a conclusion be reached that a new surgical procedure is a safe and effective substitute for an established alternative?

A. No.

Q. Doctor, when you were discussing the D & E and D & X procedures, you believe you said the efficacy of those procedures is 100%; is that correct?

A. My understanding is the purpose of the procedure is to terminate pregnancy, and my understanding is that that is successful in approximately 100% of the cases.

Q. Other than the termination of pregnancy, there are other efficacies that one called look at in evaluating those procedures, correct?

A. What would you be thinking about.

Q. Could one look at procedure time?

A. By efficacy, I mean the point of the procedure. How efficacious it is at achieving the reason for which one did the procedure. So procedure time is not a measure. And I use the term -- that would certainly be an important element

to consider in the evaluation of the procedure, but that would not be a measure of its efficacy, per se.

Q. So certainly, in your opinion, just so we are clear, efficacy is only the purpose of a procedure. So the given procedure would have only one efficacy, in your opinion?

A. No, I didn't say that. Procedures can have many goals. I mean I can imagine procedures that could have multiple goals. The purpose of coronary artery bypass grafting, for example, which you just brought up, is both to relieve pain and to prolong life. We can debate, and people have debated at great length, if whether it's valuable or for one or the other. Those are both goals that you can measure efficacy this both of those ways, and there are many others examples where there is more than one goal. My understanding of the procedures under discussion hear is there is only one goal.

Q. Doctor, when you were discussing modifications, I believe on your direct you said you would expect physicians to take note of the consequences of that modification; is that correct?

A. Yes, sir.

Q. And so you would expect physicians to make accurate notations in their patient records of the modification; is that correct?

A. If they thought it was a significant enough modification, yes.

Q. Would you expect the physicians, if they performed the modifications, to follow up on their patients?

A. I would hope physicians would follow-up on all of their patients. How long they would follow up would depend on what they were doing and what the expected time course would be.

MR. WARDEN: Just one moment, Your Honor.

THE COURT: Sure.

MR. WARDEN: No further questions, Your Honor.

THE COURT: Redirect?

MS. STRAUSS: May we have just a moment to confer?

THE COURT: Sure.

MS. STRAUSS: Thank you, Your Honor.

REDIRECT EXAMINATION

BY MS. STRAUSS:

Q. Doctor, when you have a peer group of fewer than 50 doctors who are familiar with the practice or who could use a particular procedure, what would be considered a peer group?

A. The way -- you mean in terms of peer review?

Q. Yes.

A. Peer review need not only be done by people who actually do what is being evaluated. You can have statisticians who evaluate the statistical validity of a procedure without having the ability to do it themselves. The way that I

would think of the term peer group are people who are qualified to evaluate the study that is being presented, and that would depend upon the study and the qualifications of the people who are doing the evaluation.

Q. Is it possible that, in order to compare some procedures that both have very low risks, that a comparison would be impossible prior to those, both of those procedures being widely disseminated?

A. If you need a large enough sample size, then you have got to have -- the answer is yes. You would have to have enough people who are doing those procedures in order to effect a meaningful comparison.

Q. Approximately how many patients underwent CABG before randomized clinical trials were performed?

A. Hundreds of thousands.

Q. Doctor, do you think that a retrospective chart review comparing the intact D & E and the D & E would be helpful and appropriate, at this point in the development of intact D & E?

A. Yes, I do.

MS. SMITH: Just a moment.

BY MS. STRAUSS:

Q. Doctor, when you said before -- when you testified that you would not expect to see a safety advantage in a prospective randomized clinical trial of intact D & E, what

did you mean by that?

A. Well, when I said I would not expect to see an advantage, what I meant by that is that any statistical measure carries with it a certain amount of variability. We never know exactly what the number is. And if the numbers are low enough, then it's going to be hard enough to see a difference that one simply, as I was suggesting before, it simply may not be worthwhile to carry out enough people to see a small, and essentially unimportant difference. But I also should point out that in terms of benefits, there are many benefits that could incur to a procedure being done in different ways that would not be captured by that statistic, and I think those would be very important to take into account in the evaluation of two different procedures.

MS. STRAUSS: Thank you. And thank you, Your Honor. We have no further questions.

EXAMINATION

THE COURT: Doctor, I have a couple of questions. This whole business about studies doesn't -- will not tell you what an individual surgeon does best as between two competing techniques; is that fair.

THE WITNESS: Do you mean to surgeons have relative skills in one procedure versus another?

THE COURT: Right.

THE WITNESS: Yes, absolutely.

THE COURT: So if you do these studies, that's not going to tell you very much about what an individual surgeon, what his or her skill level is with respect to a particular procedure?

THE WITNESS: You could answer that question.

THE COURT: How would you do that?

THE WITNESS: Well, this is the volume studies, the volume outcome studies that have been being done in which you look at individual surgeons' complication rates as they do more and more of a procedure and see if they go down, and they tend to do that. And you could do that either retrospectively by saying how did you do for your first 100, your second hundred. Or you could do it prospectively, by tracking the expertise. Is that responsive to your question?

THE COURT: I think that it is. In that regard, I don't think you were provided with this material, but, Dr. Mahon, you're familiar with -- he's now dead.

THE WITNESS: Yes, I'm familiar with him having presented a study, yes.

THE COURT: All right. He gave Congress a good deal of statistical information looking backwards at his practice, and this was done in 1995, June 8th to be precise. And in that information that he gave, it included charts and graphs and other things that he described as technical

matters. He provided data which showed to him in his practice, as gestation increases, the number of fetuses exhibiting significant fetal abnormalities increased. Out of the 2000 or so intact D & E procedures he had done, five women suffered major complications but all survived. That blood loss increased with gestational age, but not substantially. And that he presented a table providing a general guide for surgeons as to the average amount of cerebral spinal fluid that should be removed from the fetus before intact delivery of the calvarium could be expected. Is that the sort of retrospective examination that -- and I realize I have just generally described it to you, that would be fairly typical among surgeons?

THE WITNESS: With the obvious caveat that I have not read this document.

THE COURT: No --

THE WITNESS: Yeah, the answer is yes, although, I point out that I don't know if he did it retrospectively or prospectively. He could have done this prospectively. I just don't know.

THE COURT: If he said it was retrospective.

THE WITNESS: I'm sorry. He did say it was retrospective.

THE COURT: Yeah, would that be fairly typical, the description I gave you about what surgeons do?

THE WITNESS: That would be typical of something at this stage of development. I'm an innovator, I am a pioneer. I did this 200 times. And this is what I saw. Here of are some general guidelines you might want to think about when you go out and do this. And this would then be a benchmark against which further studies could be compared.

THE COURT: How would one go about disseminating that information, if you were the surgeon who thought he or she had come across a better way of doing something?

THE WITNESS: Well, I think the logical steps would be, first of all, to present it for a discussion, something that's fairly commonly done. My own work is very often presented at seminars before I publish it. And often at the seminars, I will get suggestions that help. And sometimes if it's controversial -- and I have a particular article in mind here. My colleague and I, we are not sure we had it right, and so we presented it to audiences in hopes that if we had it wrong, they would tell us where our mistake was. We eventually concluded in the face of people who disagreed but couldn't tell us where we were wrong, that we were probably right, and have since published it. So that would be doing, it presenting it at meetings, and then publishing it would be the logical sequence of events.

THE COURT: When you do one of these retrospective studies and if you intend to publish it in a peer review

journal, what is the peer review, tell me about the peer review process. You're looking at a doc that has done these things 2,000 times. He's got his files in the office. He says these are the results. What's does the peer reviewer do?

THE WITNESS: Okay. So let's say it was sent to me to peer review. In this area, it would not be sent to me but other areas it might well be. You get the manuscript. It may or may not be blinded. In other words, depending on the journal, you may know who the author is, you may not. You read the article and you answer some very specific questions that the editor has. They sometimes break it down; how important is this issue? How valid are the methods the author has used? How valid are there conclusions? Typically, you confidentially tell the editor I would publish this as it stands. I wouldn't publish it every, or by far, the most common answer is it needs some work, and have them resubmit. And then typically, it gets sent back to you. Now, in terms -- implied in your question is a question about the validity of the data. Would you like me to talk about that?

THE COURT: I would.

THE WITNESS: In terms of the validity of the data, one does not typically then go out and recheck the data. Now, if it's from case, clinical cases, obviously, one would

have to go back and look at the charts. HIPA regulations would make that difficulty in today's day and age, but in general, the procedure is based on the assumption that people are being honest in their presentation of data. If they are not, it's fraud, and it's a very, very big deal. In terms of the validity of the day that that is being extracted from the charts, there are some very standard ways in which one goes about doing that. If it's something like the patient's age and sex and height and weight, I don't think we worry a whole lot about that. If it's a question, for example, in the current literature, there is an enormous amount of discussion of medical errors. And, obviously, what is a medical error -- when is it a medical error and when is it simply an unfortunate complication of a bad disease. So you would have multiple people look at the charts. And there are statistical techniques you can use to ascertain how consistent various reviewers are for that sort of thing. For the studies under -- for the topic under discussion here today, I would think that absent outright fraud, that the data that is being presented would be taken at face value. Were I peer reviewer for a similar study, it would not occur to me to question the data that was being presented, and the kinds of data you have described would not occur to me to question the validity of that data.

THE COURT: Is that sort of data that I have

described, assuming that my description is accurate, fairly typical of what you see from physicians who are talking about their prior cases among their peers, either in a journal or otherwise?

THE WITNESS: Yes.

THE COURT: In that circumstance, how would one know whether McMahon was just simply really good as opposed to the procedure itself was, in his view, relatively better?

THE WITNESS: One -- from that data that you have presented, one would have no way of answering that question. One could infer it, perhaps. If the -- well, one could infer it from comparison with baseline rates using traditional procedures. One could infer it by looking at predictors of difficulty. Let us say just, for example, that half of these women had a condition that was known to predispose to complications. Let's say half of them had a bleeding disorder. And he got the same results. You would say either the procedure is really good or this guy is really good. My guess is that's not the case. The answer to your question would have to come from having other people do the procedure and seeing what their results were.

THE COURT: Thank you, Doctor. I'm going to let the lawyers follow-up briefly on my questions, only first for the plaintiff, then the Government, then the plaintiff. Counsel.

MS. STRAUSS: No further questions at this time, Your Honor.

THE COURT: Mr. Warden?

MR. WARDEN: No further questions, Your Honor.

THE COURT: Thank you, Doctor. You may step down. May the doctor be excused?

MS. STRAUSS: Yes.

THE COURT: You're excused, Doctor. Thank you.

MS. CREPPS: Your Honor, at this time we would like to call Dr. Knorr to the stand.

DR. WILLIAM H. KNORR, PLAINTIFFS' WITNESS, SWORN.

THE COURT: You may inquire.

DIRECT EXAMINATION

BY MS. CREPPS:

Q. Thank you. Dr. Knorr, can you tell the Court what state you live in?

A. I live in the State of New York.

Q. And what is your profession?

A. I'm a board certified obstetrician gynecologist.

Q. Can you find Plaintiff's Exhibit notebook up there that has 98 in it?

MS. CREPPS: And may I approach, Your Honor, to help him?

THE COURT: Yes, and you may have continuing leave.

MS. CREPPS: Thank you.

BY MS. CREPPS:

Q. Dr. Knorr, is this a copy of your CV?

A. Yes, it is.

Q. And does it accurately document your experience and background?

A. Yes, it does.

Q. At the bottom of the page, there is a list of hospitals indicating which hospitals you have privileges at; is that correct?

A. Yes. The exception is that since this time, Saint Agnes Hospital has gone bankrupt and is no longer working.

Q. All right. Thank you.

MS. CREPPS: Your Honor, at this time, I would move Exhibit 98 into evidence.

MS. NORONHA: No objection.

THE COURT: 98 is received.

BY MS. CREPPS:

Q. I would like to have you describe for the Court your medical education and training beginning with your medical school education?

A. I started medical school in 1975, at the University of Autonoma de Guadalajara, Mexico, Tuoro College, where I attended until December of 1979.

Q. And after medical school, what did you do?

A. After medical school, I did something called a fifth

pathway, which is an a additional year of clinical training, in order to come back to the states to practice.

Q. And where did you complete your fifth pathway?

A. I completed it with New York Hospital at Mt. Vernon Hospital in Mt. Vernon, New York.

Q. And after you completed your fifth pathway, did you undertake internship?

A. Yes. I had started an internship at Mt. Vernon Hospital. I did that for three months, and then moved onto an internship of three months on the neonatal unit at Cornell, and subsequently went on to internship at Jamaica Hospital, Queens, in OB-GYN.

Q. Can you tell the Court about your residency training?

A. My residency training was three years of straight OB-GYN, again, at Jamaica Hospital in Queens, New York.

Q. What year were you board certified?

A. I was board certified two years after becoming board eligible, which would be 1997. I'm sorry, '87.

Q. Okay. And in what states are you licensed to practice?

A. At this time, I'm licensed to practice in Alabama, South Carolina and New York.

Q. How long have you been licensed in New York?

A. Since 1981.

Q. And in what states do you currently practice?

A. Only in New York.

Q. Can you describe your practice starting with the locations where you practice?

A. I practice at three locations. The first place where I'm at most often is the office in White Plains. It's known as All Women's Health. It has my own private practice, which is a separate corporation, Nora Dresden, P.C., that is strictly OB/GYN. Then I work for the All Women's Health Corporation doing abortion procedures Thursdays and Fridays of every week. My second office is in Forest Hills, Queens. All Women's Medical Pavilion, and I do abortion procedures there every Monday and Tuesday. And a third office is a Brooklyn Women's Medical Pavilion, and I do abortions there on Saturdays.

Q. Do you do gynecological surgeries --

A. I do.

Q. -- at those locations?

A. At most locations, we do colposcopy, we do leep procedure; basically treatment of precancerous lesions of the cervix or cancerous lesions of the cervix. We also do laparoscopy in the White Plains office.

Q. And are these locations privately owned?

A. Yes, they are.

Q. And do you have an ownership interest in any of them?

A. I have an ownership interest in Nora Dresden. M.D., P.C. I have an ownership interest in All Women's Medical Pavilion

in Forest Hills, and I have an ownership interest in the Brooklyn office.

Q. And do you have any ownership interest in any other clinics where you don't provide services yourself?

A. Yes. I have a clinic in Savannah, Georgia.

Q. And what types of services are provided there?

A. It's an abortion clinic.

Q. You mentioned that your private practice in White Plains is an OB-GYN practice. Can you tell the Court the amount of OB care you're currently providing?

A. Very little. I'm making attempts to get out of obstetrics. I'm getting older. It's time to let that go. I believe I have two or three obstetrical patients left to deliver.

Q. And was there a time in your practice that you spent a larger percentage of your time on obstetrics?

A. Definitely in the early 90s, I was delivering between a hundred and 120 babies a year.

Q. And during that time, did you treat women with high risk pregnancies?

A. Yes, I did.

Q. Now, you have indicated that among the services you provide are abortions. What gestational age range do you do abortions?

A. Up to 24.0 weeks.

Q. And when did you first start providing abortions?
A. I first started doing abortions in residency. We had training available, so I partook of that.
Q. Since your residency, did you have any additional training?
A. Yes. After 1985, when I finished residency, I think that year I went to work in a clinic in Dobbs Ferry, New York, and received additional training in abortion, as well as before finishing residency, I did some training with an outside private doc.
Q. And can you tell the Court what methods of abortion you currently provide?
A. We provide first trimester abortions by suction and sharp curettage. We provide first trimester medical abortions using both RU 486, as well as occasionally Methotrexate. And we provide second trimester abortions to include straight dilatation and evacuation, as well as the use of cytotec for later abortions up to 20 weeks. And beyond 20 weeks, we use a combination of laminaria mixed with cytotec.
Q. Can you tell the Court approximately how many abortions you performed last year?
A. Somewhere between five and six thousand.
Q. Of those, can you estimate how many were second trimester abortions?

A. Somewhere between 12 and 15%.
Q. Do you receive referrals from other physicians for abortions in cases of maternal health problems over fetal anomalies?
A. Yes, frequently.
Q. Can you tell the Court some of the health conditions of women that you see who have been referred to you?
A. There as fairly good number of them, but we see a lot of pregnant women with hypertension, diabetes, and not in good control. We see heart conditions, whether it be palpitations, somebody having PVCs controlled with medications. Abnormal heart rates controlled with medication. Any number of medical conditions that a woman would see a perinatologist for.
Q. So some of these referrals are from perinatologists?
A. Yes, indeed.
Q. And can you tell the Court what some of the fetal abnormalities are that you've done abortions on?
A. Well, I think the most common ones are Downs Syndrome, as well as Trisomy 18, and Trisomy 13, which are other forms of Trisomic gestations that are not compatible with life after birth.
Q. Can you briefly describe the facilities where you provide second trimester abortions, the actual physical facilities?

A. All of our facilities are private offices. They all have an OR suite equipped with mechanical OR table, anesthesia equipment. We have monitoring equipment such as pulse ox symmetry, carbon dioxide monitoring, blood pressure, heart rate. Basically the same equipment that one would have in a hospital.

Q. I would like to have you now describe for the Court how you perform abortions in the second trimester, and what I would like to have you start with is the description of different methods of dilation you use in second trimester.

A. In the second trimester, I commonly would dilate the cervix to a 43 Pratt dilator. A Pratt dilator is just a mechanical dilator, a metal dilator. That would accommodate a number 14 millimeter suction cannula that could be used to complete abortion up to 16 weeks.

Q. And when you say you dilate to a 43 Pratt dilator, is there a process that you use to get to that?

A. Yes. We start with a small dilator or the smallest dilator that a cervix will easily accommodate, and we go up in size until we reach the size that we can accommodate that cannula.

Q. And for up to what weeks of pregnancy do you use this process?

A. Basically 12.1 to 16 weeks, when we are talking about the second trimester.

Q. And then for procedures after 16 weeks, do you use just a single method of dilation or do you have different methods of dilation?

A. No. Between 16 and 20 weeks, we utilize cytotec. We give that to the woman in the morning, and we let her sit for three to five hours with the cytotec on board. It has a tendency of softening the cervix. We then bring her to the OR, and we use mechanical dilators up to 63 Pratt or larger, depending on whether the case is 19 weeks or 20 weeks, and we do a straight D & E type of procedure.

Q. And how long have you been using cytotec as part of your second trimester abortion procedures?

A. It's going on six years.

Q. And what did you do before that?

A. Before that, we put in laminaria beyond 16 weeks routinely.

Q. And why did you change your procedure?

A. Basically because of information provided to me at a NAF meeting which was being attended by a European doctor who advised me that the use of cytotec was more efficient and less discomfort for the patient, and that he successfully performed abortions up to 21 weeks with cytotec and dilatation alone.

Q. What advantages do you see using the cytotec for dilation between 16 and 20 weeks?

A. I'm sorry, what?
Q. In your experience, have you seen advantages to using the cytotec instead of the laminaria for the 16 to 20 weeks dilation?
A. Yes, there are distinct advantages. The first one is that you're not sending a woman home with laminaria in her cervix, which are eventually dilating, causing cramping, pain all night long. And so you're significantly cutting down on the time that the woman undertakes for the abortion process. In addition, cytotec not only dramatically softens the cervix, it also dilates the cervix. Dilatation of the cervix comes about mostly through tetanic type of contractions caused at the level of the uterus.
Q. Can you tell the Court what tetanic contractions are?
A. Yes, tetanic contractions simply means that unlike labor, which is a contraction, a forceful contraction every three to five minutes, tetanic contraction is the uterus contracting down and not relaxing.
Q. When you administer the cytotec, do you know how much dilation you're going to get?
A. No.
Q. And what can affect the amount of dilation that you get?
A. Things that affect dilatation are the gravity and parity of the woman having the abortion. Perhaps the age of the person with the gravity and parity. When I say gravity and

parity, I'm talking about how many vaginal deliveries the woman has had or the number of pregnancies that she's had. In general, a woman who has had one or two vaginal deliveries has a cervix that's already been dilated to ten centimeters, so it's softer, may dilate more rapidly.

Q. And if you don't get enough dilation with just the cytotec, you use mechanical dilators; is that correct?

A. I use mechanical dilators almost on every case.

Q. Now, can you describe to the Court how you achieve dilation for procedures at 20 weeks and greater?

A. Yes. At 20 weeks or greater, I do something that not too much physicians do. I pre-dilate the cervix with mechanical dilators, almost standardly, to a size 63 Pratt, which enables me to put three jumbo laminaria, as well as three large laminaria, within the cavity of the cervix.

Q. And then what happens after that?

A. They stay overnight. The woman comes back the following morning. She's given 600 milligrams of cytotec orally and she's left either in our waiting room or in one of our exam rooms, if she wants to lie down for three to five hours.

Q. And why do you do the additional step of laminaria for abortions at 20 weeks and later?

A. To achieve greater dilatation.

Q. And how long have you been using the combination of laminaria and cytotec?

A. Also for approximately six years.
Q. And do you have any opinion about whether -- about the effectiveness of laminaria when used in combination with cytotec?
A. Yes, I do. Without the cytotec, and before I was doing procedures in this manner, it was not uncommon to have what's known as dumbelling of the laminaria. In other words, the end of the laminaria would be inside the internal cervical opening, the os. And the outer portion would be outside the cervix. And, typically, one would leave a smaller laminaria as a key laminaria that one could remove to create enough room because the diameter of the laminaria inside would be much greater than the laminaria in the middle of the cervix, thus the so-called dumbelling effect of laminaria. With the use of cytotec, since it works to dilate and soften the cervix, the laminaria can absorb more water and can expand more freely. Therefore, it's a rare day, we have any dumbelling with the use of the cytotec.
Q. Doctor, I'd like to ask you a couple of questions now about cervical incompetence. Do you know what causes cervical incompetence? I better have you start by defining cervical incompetence for the Court.
A. Cervical incompetence means that a cervix will not hold a pregnancy. Typically these women will spontaneously abort in the second trimester, usually after 14 weeks. It must

meet certain criteria to be called an incompetent cervix, and that criteria generally includes intact membranes, lack of any noticed contractions or pains by the woman, who generally shows up either having just ruptured her membranes and being well dilated, and about to abort or with bulging membranes, and not knowing -- she's having a funny sensation down there, and has come to the office or come to the hospital for evaluation.

Q. And what causes cervical incompetence?

A. I don't know.

Q. Do people within your profession generally understand the causes?

A. There have been a lot of papers written years ago suggesting that abortion could be a cause of cervical incompetence, but I would take those papers with a grain of salt, simply because a woman having a perfectly normal childbirth, could go on to develop an incompetent cervix without ever having had an abortion.

Q. Do you think that your methods of dilation increase a woman's risk of cervical incompetence?

A. No, I don't.

Q. I would like to move on now to the next steps that you take after the dilation is completed to your satisfaction and before you begin removal of the fetus. Can you describe those steps for the Court, please?

A. For which gestational period would you like to discuss?
Q. 16 weeks and later.
A. Okay. At 16 weeks, we start by doing a pelvic exam, just to get a digital assessment of what the cytotec has accomplished over time, and to gauge, you know, whether the cytotec has done an effective job. And most cases, it has. We'll put a speculum into the vagina after the woman is asleep, as all of our second trimester cases are done with general anesthesia. And we'll wash out the vagina with Betadine, if the woman is allergic to Betadine or has allergies to seafood, we will use an alternative solution. I then attach a tenaculum to the cervix. Tenaculum is a grasping instrument. I will then gently pull forward on the cervix to straighten the cervical canal and I will use dilators generally up to 63 Pratt or beyond, depending on whether the case is up to 19 weeks, or 19 to 20 weeks.
Q. Let me ask you a couple of questions about that. Do you always use a tenaculum, in your second trimester abortions for 16 weeks and later?
A. Sometimes I use a sponge forceps, if we have exceptional dilatation from the cytotec. But in most cases, I'm using the tenaculum.
Q. When you say you pull the tenaculum, is this, can you quantify for the Court the kind of force you're putting on the cervix and whether you think that it's harmful to the

cervix?
A. It's not meant to put force on the cervix. It's actually meant to do two things; straighten the canal and provide counter traction for your dilator. In other words, if you are trying to open the cervix with a mechanical dilator, you don't have a means to hold the cervix. You're pushing that up and applying undue stress. The stress forces the ligaments that hold the uterus, so it's mainly meant as a counter traction.
Q. Can the use of the sponge stick or tenaculum you described change the distance between the cervix and the vaginal introitus?
A. Yes, it can.
Q. In what way?
A. In general, as pregnancy advances, things get more relaxed, the cervix and ligaments in preparation for childbirth. So, yes, by putting the tenaculum on, it can shorten the distance between the opening of the vagina and the outer cervix.
Q. Doctor, can you tell the Court what did descensus is?
A. Descensus is something that's defined in stages. A first degree descensus simply means the cervix is not in its usual place. That with a Valsalva maneuver, which means coughing, sneezing, the cervix would drop down lower in the vagina. A second degree descensus means that, to the best

of my knowledge, that the cervix is within a centimeter of the opening of the vagina at the hymenal ring, at the hymen area. Or within the centimeter of the hymen at the opening of the vagina.

Q. And are there --

A. And then when we discuss the third degree and fourth degree descensus, we are also talking about procidentia.

Q. Would you spell that, please?

A. P-r-o-c-i-d-e-n-t-i-a, which simply means third degree, there is part of a cervix and possibly part of the uterus extending out of the vagina. And a fourth degree procidentia means that the uterus and vagina are totally outside of the cavity where it belongs.

Q. How common is it for you to see second, third or fourth degree descensus in your second trimester abortion patients?

A. I would say probably about four to 6% of the time. Are we talking about a second degree? Probably about 4% of the time.

Q. And what causes the procidentia that you described?

A. Well, the descensus and the procidentia are likely related to childbirth and likely associated with other hernias in the vagina.

Q. Can you tell the Court how common it is during your abortion procedures to have the cervix within an inch of the introitus?

A. In later cases, it's fairly common. Again, somewhere on the order of 4%.

Q. And is the distance ever short enough that if you bring the fetus out through the cervix feet first, that the fetus past the navel can be past the introitus with the head still in the cervix?

A. Yes.

Q. Dr. Knorr, before you begin to remove the fetus during a D & E procedure, is the fetus typically alive?

A. We do some referral cases for fetal demise. Some physicians would rather send us that case than sit in a hospital all day doing an induction procedure, but the most part, the majority of the fetuses are alive.

Q. And you don't routinely induce fetal demise, as part of your second trimester abortion procedures, is that right?

A. That's right. Very rarely.

Q. And why not?

A. I just don't believe in it. I think that it's an extra procedure and, you know, we first have to remember, don't do any harm. Harm can be -- can be accomplished in the most benign type of procedure. So, again, I think that adding an extra procedure that I don't deem to be necessary can be harmful.

Q. And can you explain to the Court what harms you're concerned about?

A. Yes, I would be concerned about whether or not somebody has had prior surgery, has had pelvic inflammatory disease with adhesions in the pelvis. I would be concerned about putting that needle through a loop of bowel. I would be concerned about putting that needle into a maternal vessel and injecting, I use Lanoxin. Some people use KCL or Digoxin; whatever is being injected into the mother could have consequences, drug reactions. One could develop sepsis from puncturing a bowel. There is risk involved.

MS. CREPPS: Your Honor, I'm at a spot now where my next section would take longer than five minutes, but I'm happy to continue if you like.

THE COURT: Counsel, is it all right with you if we take our noon break?

MS. NORONHA: Yes, Your Honor.

THE COURT: I do have criminal matter in here over the noon hour. You can leave your things but push them forward so other lawyers may use the benches. Doctor, you may step down.

(Recess from 11:56 to 1:30 p.m.; all parties present)

THE COURT: Please be seated.

MS. CREPPS: May I proceed, Your Honor?

THE COURT: Let the witness get seated. Now you may.

BY MS. CREPPS:

Q. Thank you. Dr. Knorr, I wanted to ask you one question about the locations that you described earlier where you provide abortions. Are those offices members of the National Abortion Federation?

A. Yes, they are.

Q. All right. I would like to have you now describe for the Court how you proceed after you've placed a tenaculum or sponge stick and speculum and are proceeding after the dilation is complete, and can you start with the anesthesia that is administered to the patient.

A. All of our offices use general anesthesia and have anesthesiologists fulltime, so the majority of them use like Brevital and Propofol to induce anesthesia. They may also add some Fentanyl for pain relief.

Q. Is the patient intubated as part of the anesthesia process?

A. No. The patients are asked to not have anything to eat or drink after midnight to allow for sufficient emptying of the abdominal contents to make general anesthesia safe.

Q. Now, can you go on to describe how you actually remove the fetus as part of your second trimester abortion procedures, and we can talk about 16 weeks and later?

A. Okay. Basically we're using either a Soffer or Bierer forceps. These instruments are designed to remove fetal parts. Once we have the speculum in the vagina and the

tenaculum on the cervix, the speculum is inserted into the uterine cavity and the fetus is manually extracted.

Q. Do you use ultrasound during these procedures?

A. We do. It's a guideline in our office for anything 12.1 weeks and above. We do that under a sonographic guidance. We also document at the end of the procedure that the cavity is empty through a picture that we take.

Q. Can you continue, then, to describe how you typically then remove the fetus?

A. Basically whatever is the presenting part, whether it's a breech or a vertex presenting at the internal cervical os, that's the part of the fetus that we would start removing. If it's the fetal cranium, the forceps would be applied around the head, and in most cases crushing technique is used to decrease the cerebral volume so that it will pass through the cervical canal.

Q. Go ahead.

A. If it's a breech or some form of breech, we'll go after the closest presenting part to the internal cervical opening.

Q. Do you take any steps to remove the amniotic fluid?

A. I do routinely. I would start by suctioning out as much amniotic fluid as I could remove. I cannot prove this, but I believe that it decreases the risk of amniotic embolus, fluid that can enter a vascular channel in the uterus and

cause severe complications to the mother.
Q. And so you do that before you insert your forceps?
A. Yes.
Q. And after you've grasped the part with the forceps, what do you do next?
A. In most cases, I'm trying to disarticulate limbs and the fetus in utero. It's not always the case, but that is my goal. Because of the dilatation technique that I use, we gain, we gain -- I gain a significant amount of dilatation and therefore I remove fewer pieces of fetal tissue than the average person doing this procedure.
Q. And what's the range of time it takes you to remove the fetus?
A. Generally from 16 to 24 weeks, I would say 10 minutes to 20 minutes.
Q. And does it ever occur that the fetus comes out entirely intact?
A. Yes, that has happened.
Q. Is that a common occurrence?
A. No.
Q. Does it ever occur that the fetus comes out intact except that the head is too large to pass through the cervix?
A. Yes. Actually, I would say often, probably on the order of every six weeks or so.

Q. And when that occurs, is that at all related to the amount of dilation you've achieved?
A. Yes, it is. Typically, each patient I do is dilated at least about four centimeters, sometimes more, depending on the parity of the woman.
Q. Have you ever had a situation in which the fetus has come through the cervix intact except for the head, and the fetal body passed the navel, was outside the vaginal introitus?
A. Oh, yes, absolutely.
Q. When it happens and the fetus comes through the cervix except for the head, how do you proceed?
A. I first evaluate the cervix to see if I have enough room to slip a finger between the cervix and the fetal head, and if I can do that, I can then insert my crushing forcep around the head, crush the head and extract it. If the cervix is very tight, I can't do that, I will use a craniotomy procedure, will turn the fetus so the back is up and find the area that I want to open, and either with a finger, a dilator or a scissor will open that area and gently pull down. That pressure alone is enough to empty the cranium and extract the head.
Q. So when you puncture the skull as you just described, you don't apply a suction cannula or anything at that point?
A. No, I have never done that.

Q. Would it be possible in that situation for you to wait and see if the head would pass through the cervix?
A. We could wait, but we have the woman under general anesthesia. She's not intubated, and adding dose upon dose of this medication would eventually become toxic, so we do not wait.
Q. In a given case prior to removing the fetus, do you have an expectation as to whether the fetus will be removed either largely intact or in pieces?
A. I have an expectation that I'm doing an abortion procedure, and that most likely, the fetus is going to be removed in large parts. I don't have an expectation that I'm going to remove every fetus intact, but it does happen because of the technique that I use for dilatation.
Q. Do you try to bring the fetus out as intact as possible?
A. Again, you know, with the amount of dilatation, the fewer passes that I make inside the uterine cavity, I would consider that to be safer.
Q. Does your ability to bring the fetus out largely intact affect the amount of time it takes you to remove the fetus?
A. Those cases are generally a bit faster because we're not disarticulating piece-by-piece. It's fairly easy to do that. It's not our intention to -- to have an abortion in that manner every time. It's more likely that we are going to be disarticulating the fetus.

Q. Do you think there is an advantage to shorter operation time?

A. Oh, definitely.

Q. Why do you think that?

A. Well, I think that anybody under anesthesia for any length of time, the longer they are under anesthesia, the more risk there is.

Q. Can you tell the Court what the earliest ages that you have had the experience of the fetus coming out intact except for the head remaining inside the cervix?

A. The earliest, I would say about 16 weeks or so.

Q. If the fetus does come out that way, could it be alive prior to your compression of the skull or your puncturing of the skull?

A. Yes.

Q. What do you do after you finish removing the fetus?

A. I then turn my attention to removing the placenta.

Q. And how do you do that?

A. Basically after sono guidance, I'm going in again with my forcep to pull down the placenta. I also use a large sharp curette again with a sono guidance to make sure that the cavity the empty and then go back with a suction curette.

Q. And at that point, do you feel that you've completed the procedure?

A. Yes.
Q. Going back just for a moment, in the cases in which the fetus is removed in large pieces, does that give you a shorter operation time than if it's brought out in smaller pieces?
A. Definitely.
Q. During an abortion procedure, a second trimester abortion procedure when you're able to remove the fetus intact but for the head, do you consider that a distinct medical procedure from the D & E procedure?
A. No, I really don't.
Q. Do you feel that you're still doing a D & E procedure even if you don't dismember it in order to bring it out?
A. Well, to me, extraction means to remove, so with D & E means to extract the fetus.
Q. Do you believe that the D & E procedures you perform in which you remove the fetus intact but for the skull, then either puncture the skull or use compression poses serious risks to women's health?
A. No, I really don't.
Q. I would like to have you talk about your experience with induction abortions. Are you currently performing second trimester abortions by induction?
A. No, I'm not.
Q. Have you in the past?

A. Using induction abortion as a term, I have in the past. When I was doing more obstetrics, we all have instances where we have somebody rupture membranes at 20 to 24 weeks or 22 weeks, and we know that we're not going to obtain a viable fetus where a survivable fetus, and therefore, it just becomes an amount of time before one has to deal with infection, so yes, I have done that type of abortion procedure which, generally, when you limit it to doing cases in the hospital.

Q. And what kind of drugs did you use to accomplish those?

A. Generally Pitocin.

Q. And why don't you routinely do second trimester abortions by induction?

A. I don't really have the ability to do that. I cannot put a woman in the hospital where I have privileges and admit her for an elective abortion beyond 12 weeks of gestation, and even if I wanted to do 12 weeks and under, I can usually never find a nurse that will accompany me to the OR to do it.

Q. Why is it you can't do elective abortions after 12 weeks at the hospital where you have privileges?

A. Shortly after I came on board, they moved the bylaws to 12 weeks from 20 weeks.

Q. Do you have an opinion about the safety of induction abortions versus D & E abortions?

A. I think D & E is safer. When asked to take into account that when you're doing an induction abortion, the likelihood of having the placenta come out complete is probably about 80% of the time, but the general limit of time that one would allow would be about half an hour. While you're waiting for that placenta to come out over that half hour, generally that woman is bleeding, and there have been several times where I have been involved in that kind of procedure and have had to take the woman to the OR hemorrhaging to remove that placenta and stop the blood flow, so I just believe that if you take that factor with the time limit to get the placenta out, I don't believe that it's safer. I think the D & E procedure is safer.

Q. Do you know why the placenta would only come out in 80$ of the induction procedures?

A. Well, it's an immature placenta. Its attachment is probably firmer than a more mature placenta, and then the other problem is that the cord that one gently pulls on to deliver the placenta is very viable. It has more of a tendency to break than to extract the placenta, and once it breaks, then you're faced with, okay, I can allow time for the placenta to be delivered by uterine contraction, or I can take the woman back to the OR either deliver it manually with her asleep or with a sharp curettage.

Q. Do you ever treat miscarriages?

A. Yes, all the time.
Q. Is that in both the first and second trimester?
A. Yes.
Q. And how do you typically -- or what's the range of treatments you would provide for a miscarriage in the second trimester?
A. Well, miscarriage in a second trimester, I'm assuming the fetus is already out and the woman has retained products, so it's basically a dilatation and curettage procedure. If it's something called an impending abortion where there may be a fetal demise and the patient may already be bleeding, it's done in a similar manner to the D & E procedure.
Q. Is there ever an occasion where a woman would be in the process of miscarrying and the fetus is still in the uterus or partly in the uterus and alive?
A. Yes.
Q. And in that circumstance, how do you proceed?
A. By extracting the fetus.
Q. And do you do that in a similar manner that you would do for a D & E abortion?
A. Depends on where I am. If the event is occurring in the hospital, I'm really not allowed to use the instruments that I would already have available in my office. That would be more of an induction process and avoid your pitting out the

fetus. There is no possibility that you're going to get a live fetus here. In the office it occasionally occurs with the use of Cytotec where the woman will say to us that she's suddenly having severe vaginal pain and starting to bleed, and we know at that time that we'll either find the sack in the vagina or we might find fetal parts already in the vagina, so we would do that case right away.

Q. Dr. Knorr, I'm going to ask you to look at the Act that's in issue from this case, and I think I need to get it from the clerk. I'm not sure where it is. It's Exhibit 69.

A. Okay.

Q. Now, Doctor, you've reviewed this Act before; is that correct?

A. Yes, I have.

Q. Looking at the definition of partial-birth abortion in the Act, do you think that any of the abortion procedures you currently perform would be prohibited if the Act were allowed to take effect?

A. Yes.

Q. Can you explain to the Court why you believe that?

A. Well, let me just get to the --

Q. The operative section is probably on page S-6?

A. Yeah. Well, starting off with the bottom of the page, the term partial-birth abortion which, by the way, I do not recognize as an actual medical term, means an abortion in

which the person performing the abortion deliberately and intentionally vaginally delivers a living fetus until, in the case of a head-first presentation, the entire fetal head is outside the body of the mother. I would have to agree that once the head is outside the body, I would stop. I would resuscitate that infant if that infant were resuscitatable. However, in the breech presentation, the fetal trunk past the navel is outside the body of the mother for the purpose of performing an overt act that the person knows will kill the partially delivered living fetus. That, to me, is very vague. I have to wonder, is an overt act committed when I have removed a fetal limb such as an arm which is above the umbilicus that's at the level of the vaginal opening? I might have done that previously to delivering the rest of the fetus through the fetus still being a live. It's just a vague wording that I feel I would come under scrutiny with this wording.

Q. Do you think the Act would apply to the procedures that you described in which you deliver the fetus intact except for the head and then take an action to reduce the size of the skull?

A. Oh, absolutely.

Q. Do you think that the language of the Act could cover potentially all of the D & E procedures you perform?

A. I think it could cover a majority of D & Es that I

perform where, if not a majority, a large number.
Q. Do you think it's possible that the Act would cover procedures where you are able to bring out a part of a fetus and then in another pass bring out the remainder of the fetus, for example, up to the head?
A. The way I read it, I think that would fall under the Act.
Q. Do you think that the Act could cover any of the miscarriage treatment for second trimester miscarriages that you described earlier?
A. Miscarriages, or I would prefer the term impending abortion.
Q. Yes, that's better.
A. You know, we have to be clear about our terms. Impending abortion where the fetus is still alive but within the vagina or partially extruded from the vagina and having the head stuck, yes.
Q. Doctor, I would like to have you look at the Act again and look at the sentence that contains a statement about the partial-birth abortion and explains a live exception. Do you see that language?
THE COURT: Why don't you point it out to the Doctor?
MS. CREPPS: I'm sorry. It's on page S-6 just above the definition of partial-birth abortion.

THE WITNESS: That's below.
BY MS. CREPPS:
Q. Subsection right here.
A. Okay.
Q. Doctor, what do you think the word necessary in this subsection means?
A. Necessary to save the live of a mother whose life is endangered by a physical disorder, physical illness or physical injury including alive-endangering physical condition caused by or arising from the pregnancy itself. Personally, I think that's rather vague. I would consider something like a poorly controlled diabetic as continuing pregnancy as being life endangering, but again, it's vague in the sense that, well, if I said I was doing that abortion, that it were, with the head stuck in the cervix, somebody might come along and say, well, that wasn't a life-threatening risk to the mother. It's just awfully vague as to, you know, what I can and can't do.
Q. Do you think this -- does this exception relieve your concerns about the application of the Act to your practice?
A. No, not at all. Was it meant to do that?
Q. Do you think it would allow you to provide the safest abortion procedures to your patients?
A. No, I do not.
Q. Doctor, I would like to go back just to clarify

something. We had -- I had asked you a moment ago if it was possible to remove part of the fetus and then in another pass remove the remainder of the fetus intact up to the head. Does that ever happen in your practice?

A. Yes, it has happened.

Q. Doctor, I would like to ask you if there were ways that you feel you could change your practice in order to avoid the Act, and let me start by asking you whether you think that you could change your dilation processes in a way that would allow you to avoid prosecution under the Act?

A. No, I really would not be interested in changing my dilatation process because I think it's a safe and effective method of dilatation, and I honestly believe that, you know, the fewer passes I make inside the uterus, the larger the parts that I remove, the safer the procedure is.

Q. And what would you think, assuming just for a moment that the Act would not apply to inductions, do you think that it would be a reasonable alternative for you to try and provide inductions in the second trimester for your patients seeking abortions?

A. No, I think that would be taking a step backwards. I really do, and you know, people doing inductions for fetal reasons such as rupture of membranes can get to the point where the fetus is alive and hanging out of the vagina, and being impatient because they have got office hours to go to,

and you know, can do harm to the fetus if that was their intent to shorten the time of the procedure.

Q. So do you think that abortions by induction would be readily available to women if the Act were to take effect?

A. They are not now, so why would they be in the future?

Q. Do you think enforcement of the Act would affect the quality of care you're able to provide to your patients?

A. Definitely. Definitely. I would have to rethink my decisions as to whether I'm going to be doing D & E procedures and/or possibly risk going to jail, or worse yet, being sued by every member of the family.

MS. CREPPS: All right. Thank you, Doctor. I don't have any further questions at this time.

THE COURT: Counsel?

CROSS-EXAMINATION

MS. NORONHA: Thank you, Your Honor.

BY MS. NORONHA:

Q. Good afternoon, Dr. Knorr.

A. Good afternoon, Preeya.

Q. Doctor, you consider yourself to be an expert on the relative safety of abortion procedures after 20 weeks; right?

A. Relative safety, I would have to say yes.

Q. But you haven't written any publications on abortion methods?

A. No, I have not.
Q. And you haven't published any studies on abortion?
A. No, I have not.
Q. And you testify that you believe that you should deliver the fetus in as few passes as possible; right?
A. That's right.
Q. And that's because there is probably an association between the number of instrument passes and the risk of uterine perforation?
A. That's a relatively true statement.
Q. Doctor, you're not familiar with any studies of safety of intact extraction versus a dismemberment procedure; are you?
A. Intact versus, no, I'm not.
Q. So your opinion is based on logic and personal experience, wouldn't you say?
A. I would.
Q. In fact, your opinion on safety is based on conjecture, isn't it?
A. No, I wouldn't say that.
Q. So you wouldn't say your opinion on safety is based on conjecture; is that your testimony today?
A. That's my testimony, yes.
Q. Dr. Knorr, did you give a deposition in this case on February 25th of this year, I believe?

A. Probably. I don't recall the exact date.
Q. And in that deposition, I asked you questions and you gave me answers; correct?
A. Correct.
Q. And at the beginning of that deposition, you took an affirmation to tell the truth?
A. Correct.
Q. And that's the same affirmation that you took today?
A. Correct.
MS. NORONHA: Your Honor, may I approach the witness?
THE COURT: Sure.
MS. NORONHA: Your Honor, would you like a copy of Dr. Knorr's deposition as well.
THE COURT: No, unless it's going to be -- not unless it's going to be real long, and if it's just for a minor impeachment purpose, that's fine, but do give counsel a page and line, would you?
MS. NORONHA: Sure.
BY MS. NORONHA:
Q. Dr. Knorr, please turn to page 197 of your deposition, and I'm reading from line 13. Question: Are you familiar -- Are you there, Dr. Knorr?
A. No, hold on. What page? 197.
Q. Page 197, line 13?

A. Go ahead.
Q. It reads from line 13, Question: Are you familiar with any studies about the safety of intact extraction versus a dismemberment procedure? Answer: Safety, I would have to say, is conjecture, and also based on personal experience and personal experience of others. Logically, though, it seems to be a safe thing to me. Again, just like a lot of things I'm telling you today, it's personal experience.
Is that the testimony that you gave at your deposition, Dr. Knorr?
A. Yes, it is, and your point is?
Q. The question was, is that the testimony that you gave at your deposition?
A. Yes, it is.
Q. Okay. Dr. Knorr, you encourage a follow-up visit after your patients come to you for an abortion procedure; right?
A. That's right.
Q. And that's to make sure that everything went smoothly with the procedure?
A. Yes.
Q. And you get lots of referrals for D & E abortions from other providers?
A. Yes, we do.
Q. And you get them from places as far as Buffalo, New York, and Canada?

A. Yes, we do.
Q. So you typically don't see those patients for a follow-up visit, right, because they are so far away?
A. They are asked what their plans are for follow up. Are they coming back to the office or are they following up with their own physician. It is not a mandatory requirement that you follow up with us.
Q. Now, you have other local patients that are also referred to you?
A. Yes, we do.
Q. And these patients, they often schedule follow-up visits with their referring physicians; right?
A. Sometimes, yes. Sometimes they come back to us. If they are local, we would encourage them to come back and see us. We are not trying to steal the patient. In fact, if that was our intent, we wouldn't have a practice locally.
Q. So of the patients that are left who actually do schedule with you, wouldn't you say that only about a third of them actually return for a follow-up visit?
A. That's absolutely right.
Q. Doctor, you testified that you performed D & E procedures under sonographic guidance; is that right?
A. Yes.
Q. That's routine for all D & E's after 12.1 weeks?
A. Yes.

Q. AND that includes the D & Es in which you remove the fetus in pieces?
A. Yes.
Q. Once you remove the fetus, you use the sonogram to check the uterus to see if there are any pieces remaining?
A. Well, conversely, we are checking to see that the uterine cavity is empty.
Q. In fact, you can see a fine white line on the sonogram and that represents an air interface that tells you that the walls of the uterus aren't separated by any pieces?
A. That's right.
Q. And this also helps you detect uterine perforation during the procedure because you can see if your forceps have entered the abdominal cavity?
A. That would be a correct statement.
Q. So you would agree that the use of sonography has improved the use of the D & E procedure?
A. Absolutely.
Q. And you testified that you also after the procedure is complete, that you use a curette, a jumbo curette to feel around in the uterus to make sure there aren't any parts remaining; correct?
A. Mostly placenta, yes.
Q. Also when you bring out a fetus in pieces, you make sure that you have got all the parts that you want; right? You

kind of --

A. Yes.

Q. You try and lay them out and put them back together as best you can to see if you have everything?

A. Not necessarily. Some of us keep track on the way out.

Q. So Doctor, you would consider the D & E procedure in which there is dismemberment to be a safe procedure from 20 to 24 weeks of gestation?

A. Yes.

Q. And you consider yourself to be skilled in performing this D & E procedure?

A. Yes.

Q. It's true, Doctor, that you rarely perforate the uterus during a D & E procedure in which there is dismemberment?

A. That's true.

Q. In fact, your complication rate is very small?

A. That's very true.

Q. And you can't really recall any complications you have had with this dismemberment D & E procedure in the past three years?

A. In the past three years, let me say, I had a complication not too long ago where I had excessive bleeding and thought I might have a laceration in the cervix.

Q. Is that the only one you can remember?

A. In the past three years, yes.

Q. Doctor, you testified that between 16 and 20 weeks of gestation, to dilate the cervix before a D & E procedure, you use just Cytotec and no laminaria; is that correct?
A. That's right.
Q. But after 20 weeks, you have an unusual dilation regime?
A. Yes.
Q. And after 20 weeks, you start by dilating to what you said was a number 63 Pratt dilator size. About how many centimeters would that be?
A. That would be approximately a little over two centimeters.
Q. Would it be closer to three?
A. Well, the last time I divided 63 by 3, it was 2.1.
Q. So you dilate to the 63 Pratt dilator size, and you use that so you can insert laminaria; is that right?
A. That's right.
Q. You testify that you use a set of three jumbo laminaria at first?
A. Yes, and additionally, three large laminaria.
Q. So that's six total?
A. In the usual patient, yes.
Q. But if you can fit more in, you'll add more depending on the patient?
A. Not usually, but if I can put another one in because the cervix is soft or the laminaria are not staying where I'm

putting them properly, yes, I would put another one in.
Q. And then you leave the laminaria in overnight, and the patient comes back the second day?
A. That's right.
Q. The second day you would administer Cytotec. That's also known as Misoprostol; correct?
A. Correct.
Q. You administer 600 grams orally. That's your standard dose?
A. Yes.
Q. Then you wait about four hours, sometimes more for the Cytotec to work?
A. Three to five hours, yes.
Q. While the Cytotec is working, don't you and maybe your staff check in on the patient from time-to-time?
A. Yes, we do.
Q. And that's to see if they are feeling uncomfortable or feeling any pain?
A. Well, the majority of them are feeling uncomfortable.
Q. And the more uncomfortable they are feeling, it means the more the Cytotec is working?
A. Not necessarily so. Might just mean they have very poor pain tolerance.
Q. But it might be an indication that the dilation is moving along faster than you anticipated?

A. Could be.
Q. So in this regime of yours between 20 and 24 weeks gestation, the dilation and the removal of the fetus is completed within a 24-hour period generally?
A. Or a little bit more, yeah.
Q. And as you stated, you consider this to be an atypical dilation regime for abortions through 24 weeks?
A. Yes.
Q. Because, in fact, your technique allows for greater dilation over a shorter period of time?
A. That's right.
Q. And even physicians that work for you don't even use this technique?
A. Some do; some don't.
Q. The ones that don't, they put in fewer laminaria than you do?
A. Yes, or they are smaller.
Q. Smaller laminaria. Okay. So they end up pulling out smaller fetal parts at the end of the procedure?
A. To my knowledge, yes.
Q. Doctor, you would agree that the longer you are in pregnancy, the more dilation you need to extract the fetus?
A. Up to a certain point, yes.
Q. So for between 18 and 20 weeks, you said you dilate to a 63 Pratt?

A. Yes.
Q. And then for 20 to 24 weeks, you would like to get maybe four centimeters?
A. Yes.
Q. And, Doctor, with this regime, you always seek to limit the amount of dilation to less than the biparietal diameter of the head of the fetus?
A. Yes, that is a point.
Q. And you're usually successful in doing this?
A. Yes, I am.
Q. In fact, in the majority of cases, almost all of your cases, the head gets stuck?
A. Yeah.
Q. Doctor, you give Cytotec to all of your patients at 16 weeks and beyond; correct?
A. The vast majority, yes.
Q. You would agree that Cytotec causes cervical ripening?
A. Yes.
Q. And cervical dilation?
A. Yes.
Q. It also causes the uterus to contract?
A. Yes.
Q. These are pretty big contractions, aren't they, Doctor?
A. Well, they are long contractions. They run one into another.

Q. You even describe them as tetanic contractions?
A. Yes.
Q. That means they are contractions that just don't go away?
A. That's right.
Q. And the force of these contractions would be enough to expel the fetus eventually?
A. Eventually, yes. That's a true statement.
Q. So there is constant pressure on the head of the fetus if it's in the breech position, let's say?
A. I can't agree with that statement. You know, we live in a world where there is pressure around us when we are in here sitting in this room. There is pressure on a fetus inside a uterus all the time.
Q. But this is pressure from tetanic contractions; correct?
A. So it's more pressure.
Q. You testified that you don't wait for these tetanic contractions to push the fetus out?
A. No.
Q. Because you don't do that in your abortion practice?
A. No.
Q. But you have done it in your obstetrics practice?
A. Yes, on a very limited basis.
Q. Doctor, are there any side effects from the use of Cytotec?

A. Cytotec, yes, absolutely.
Q. What are those?
A. Chills, fever, nausea, vomiting, diarrhea.
Q. What about laminaria? Are there any side effects from that?
A. Sure.
Q. What are those?
A. Infection, hemorrhage, uterine perforation.
Q. Doctor, your patients sometimes ask you about the D & E procedure; right?
A. Yes.
Q. And you tell them that it is a destructive type of procedure; don't you?
A. You know, I very rarely have that type of conversation with a patient.
Q. Say you do. Would that be what you tell them?
A. If the patient says that she would like to see the fetus after the procedure, I would discourage that.
Q. So you tell them?
A. Because of the destructive nature, yes.
Q. You tell them that the fetus is taken out in pieces?
A. When they ask, yes.
Q. Doctor, you would agree that dismemberment is the predominant characteristic of second trimester D & Es?
A. I would.

Q. And when you're performing a D & E, you remove fragments of the fetus from the uterus?
A. That's right.
Q. And you testify that you use a Soffer or Bierer forceps to remove the fetal parts?
A. Yes.
Q. And you grasp whatever part is presenting at the cervical os; right?
A. That's right.
Q. It could be an arm or a leg or even the fetal head?
A. Right.
Q. If it's the head, you would put the forceps in and crush the head and then bring it out?
A. Yes.
Q. And generally, you pull straight out of the uterus?
A. As opposed to --
Q. Well, sometimes you may twist and rotate?
A. On occasion.
Q. Doctor, sometimes you plan to bring the fetus out intact during the second trimester?
A. Rarely, yes.
Q. And you do that, for example, when there is a malformation and the physician who referred the abortion to you wants to do anatomical studies on the fetus?
A. Yes.

Q. Or, for instance, the referring doctors want to have pictures of the fetus for teaching purposes?
A. Yes.
Q. And sometimes even a patient may ask you for an intact fetus?
A. Yes.
Q. And those procedures you do differently from the D & E in which there is a dismembered fetus?
A. Differently in that my intent would be to sufficiently dilate to remove an intact fetus.
Q. So you would perform excessive dilation beyond what's needed for a D & E procedure?
A. I don't know if I would agree with your term excessive. I perform the dilatation necessary to accomplish the goal.
Q. Doctor, would you turn to page 145 of your deposition, please?
A. Yup.
Q. Reading from line 6, question?
A. Can you tell me what steps you take to make sure the fetus does come out intact, excessive dilatation beyond that needed to do with the procedure.
Q. So Doctor, was your testimony at your deposition you used excessive dilatation beyond that needed to do a D & E procedure in order to ensure the fetus does come out intact?
A. Preeya, I'm only agreeing with the term excessive.

Q. But you did say excessive at your deposition; is that correct?
A. I guess I did.
Q. So this dilation that's helped along by the use of Cytotec?
A. Yes.
Q. And, Doctor, you also need to be careful with your forceps when you're extracting the fetus intact; right?
A. Yes.
Q. You use smaller forceps with large serrated teeth?
A. I don't recall. We are talking about a very few cases, Preeya.
Q. You use these forceps to cradle the fetus through the cervix?
A. That would be a good description, yes.
Q. In addition to this, do you reach up and bring the arms down to complete the extraction?
A. If that were a breech delivery, yes.
Q. And, Doctor, you testified that sometimes in a breech delivery, the head gets stuck at the cervix?
A. Yes.
Q. Right, and there are different ways that you can remove the head?
A. That's right.
Q. And if you can fit your forceps through the cervix, you

would get them in around the head, and you would crush the skull before you bring out the fetus; right?

A. If I could safely do that, yes.

Q. But other times you can't fit the forceps in the cervix?

A. That's right.

Q. So then you would open up the skull and you would pull down with traction?

A. That's right.

Q. And you said there were different ways that you can open up the skull; right?

A. That's right.

Q. You can use a scissors, or you can use your finger, or you can even use a dilator?

A. That's right.

Q. You also said that you don't even need to suction the skull; right?

A. That is absolutely right.

Q. Because the traction of bringing the fetus out will actually collapse the head?

A. That's right.

Q. Doctor, you testified in your deposition that you actually don't prefer to have an intact fetus with an intact head?

A. I don't recall. You would have to show me, Preeya.

Q. Could you look at page 159, please? At line 6, I asked

you, would you prefer to have a complete intact extraction, meaning without collapsing the head? And you answered again, I thought I answered that, but I'll go back to that. Would I prefer that? No, for several reasons, one of which is we went in to do an abortion procedure and not a live delivery.

Do you see that, Doctor?

A. I do.

Q. Doctor, could you please turn to Defendant's Exhibit 651? It's in the binder right in front of you.

A. Preeya, with all due respect, if you go back and read line 6.

Q. Line 6?

A. Yes.

Q. On page 159?

A. Yeah. You were asking me, would you prefer to have a complete intact extraction meaning without collapsing the head, meaning not opening the skull and extracting the cerebral contents, and my answer was no.

THE COURT: Doctor, let me interrupt you here for just a minute and suggest to you, I appreciate that counsel has taken your deposition before, and during the taking of that deposition, you might not have used surnames, but it puts her in an awkward position if you use her first name. I will not permit her to be informal with you, and there is

an interesting dynamic that goes on between a lawyer and a witness in the courtroom, so if you just want to refer to counsel as counsel or by her surname, I would appreciate that. Go ahead, counsel.

THE WITNESS: Okay, Your Honor.

BY MS. NORONHA:

Q. Thank you, Your Honor. Doctor, getting back to the topic we were on earlier, you said that you don't prefer to have a complete intact extraction, meaning without collapsing the head, and one of the reasons for that is because you're doing an abortion procedure and not a live delivery; correct?

A. Well, there is another reason. The other reason is that that head coming through the cervix without collapsing it first will cause damage to the cervix. It is the largest diameter you're removing from the uterine cavity. That's what I was talking about.

Q. Doctor, would you please turn to Defendant's Exhibit 651? It's in the binder that's on the corner of the bench there.

A. This one?

Q. Yes.

A. 651.

Q. Yes, that's correct.

A. Okay.

Q. Now, this is ACOG, the American College of Obstetricians and Gynocologists' statements of policy on intact dilatation and extraction. You have seen this before, haven't you, Doctor?

A. Yes.

Q. And in the middle of the page, ACOG has listed four steps that are required in their definition of intact dilatation and extraction, and they describe the procedure as containing all of the following four elements: Number one, deliberate dilatation of the cervix, usually over a sequence of days; number two, instrumental conversion of the fetus to a footling breech; number three, breech extraction of the body excepting the head; and four, partial evacuation of the intracranial contents of a living fetus to effect vaginal delivery of a dead but otherwise intact fetus. Now, Doctor, you think that step number two, the instrumental conversion of the fetus to a footling breech is not a necessary part of this description?

A. With all due respect, counsel, I don't accept the terminology of partial-birth abortions, and my objection is not to the ACOG statement of policy.

Q. But, Doctor, I'm asking you about the ACOG statement of policy?

THE COURT: Counsel, don't interrupt him.

MS. NORONHA: I'm sorry, Your Honor.

THE COURT: That's all right. Let him complete his thought.

THE WITNESS: It's a statement of policy. I note that in the law, this statement of policy is not followed, so I'm here today to talk about the law, not somebody's policy that's irrelevant to the law.

BY MS. NORONHA:

Q. But, Doctor, my question was, you think the second step is not a necessary part of this definition; correct?

MS. CREPPS: Your Honor, I object. I don't see how counsel can say it's not part of the definition when the definition is an ACOG statement of policy.

THE COURT: Well, the objection will be sustained as to form. Counsel, I think what you're getting at is that what the Doctor does is different than from what the procedure does as described in ACOG, ACOG's statement, and he doesn't believe that you have to do an instrumental conversion to a footling breech in order to do his procedure, and therefore, there is a difference between what he does and what ACOG does. Is that essentially what you're trying to point out?

MS. NORONHA: Yes, Your Honor.

THE COURT: So it really is, the question is, is the procedure that you use, whatever it is, consistent with whatever the procedure described by ACOG. Do you do it the

same way or not? And I think maybe that's a way around the interesting linguistic problem of do you agree with, so I have sustained it as to form, and perhaps you can go at it a slightly different way.

MS. NORONHA: Yes, Your Honor.

BY MS. NORONHA:

Q. Dr. Knorr, is the procedure you perform consistent with this definition in DX 651?

A. No.

Q. In what way?

A. Well, I do have deliberate dilatation of the cervix and not necessarily over a sequence of days, and instrumental conversion of the fetus to a footling breech. It either is going to come out that way, or I'm not interested in going in there and converting it. Breech extraction of the body excepting the head, well, according to the way I do my procedure, that sometimes occurs. Partial evacuation of the intracranial contents of a living fetus to effect delivery of a dead but otherwise intact fetus, yes, I do do that.

Q. Dr. Knorr, you're not a maternal fetal medicine subspecialist between OB/GYN -- within OB/GYN. Excuse me.

A. No, I'm not.

Q. You're also not an expert in critical care obstetrics?

A. No, I'm not.

Q. And you testified that you have performed inductions as

part of your obstetrics practice, but you don't do them in your abortion practice?

A. Right.

Q. By the way, Doctor, I'm finished with that exhibit. You want to put it aside?

A. Okay.

Q. Doctor, sometimes you refer some of your patients to a hospital for an abortion?

A. On rare occasion, yes.

Q. Because using your method of dilation, sometimes it's not a good idea to do that procedure in the office?

A. No, that was not the reason.

Q. What are some of the reasons why you would refer a patient to a hospital to get an abortion?

A. If, indeed, she had an unstable medical condition such that she is not medically cleared by an outside doctor to have the procedure done in our office, or we determine that she poses excessive risk doing her as an outpatient in our office, we would then refer her to a hospital facility where she could have the abortion.

Q. What sort of uncontrolled health conditions would those be?

A. They could be hyperthyroidism. For example, the woman comes in and says, well, she's hyperthyroid and she hasn't been to see the doctor, and she's coming for a procedure at

21 weeks and her pulse rate is starting at 110, then she could have a thyroid storm on our table. It would be a much better idea that she still be able to have the abortion procedure, but first she needs to get the thyroid condition under control or have other medications on board that could prevent thyroid storm. Having a heart condition where we attach our monitors and we're seeing premature ventricular contractions every other beat, that poses a significant risk. Why should we take that risk when the woman can be placed on medication and be done in the hospital such that if there is an emergency, we cut out the transport, she's already there.

Q. Any other examples you can think of?

A. Uncontrolled diabetes. Uncontrolled hypertension. There are just a number of things that in the past that we have sent the patient out of our facility.

Q. And, in fact, you make about two to three referrals a week for these sorts of situations?

A. I believe that that's probably a correct number.

Q. I'm sorry. You said it was a correct number?

A. I would think it's appropriate, yeah. I mean, each week varies. Sometimes we have none. Sometimes we have more than three.

Q. Doctor, you perform a fraction of 1% of your abortions for the reasons of medical indications of the mother?

A. That's true.
Q. When you're writing up the patient's chart, you don't necessarily note what that medical indication is on the chart?
A. It's not always our policy to document why that woman is coming for an abortion. It would probably be indicated somewhere in her medical history as a check mark followed by maybe a brief note on the front of the chart.
Q. So you typically don't even ask a patient why she wants an abortion?
A. No. On the contrary, I ask her if she is very sure about her decision today to have the abortion.
Q. But you don't ask her why she wants it?
A. No.
Q. That's because she's there to have an abortion?
A. She's there to have an abortion.
Q. It's also because you're just too busy?
A. Not at all. I always have time to talk to the patient.
Q. So you say you're not too busy to ask your patients?
A. I rather think it's sufficient to make sure of her intention to go through with the abortion procedure. I'm sure she's made up her mind to have the abortion. I would focus more on, you know, if she asked me a question about the reason for the abortion, to make sure that her doctor has given her the proper information or that she is given

the proper information. An example would be somebody has had an immunization in early pregnancy. They have had mumps, measles, rubella injection. The rubella part is under study by the CDC, and there is a patient ongoing log there, so many doctors would recommend to the woman that since we don't know what that would do, the patient should have an abortion. On the other hand, I would tell her that the risk is relatively small based on the numbers at the CDC. I always have time to talk to the patient, Preeya. I'm sorry. Counsel.

Q. Doctor, you're not a geneticist; correct?

A. No, I'm not.

Q. You're also not a pathologist?

A. No, I'm not.

Q. You don't consider yourself to be an expert in fetal anomalies?

A. No, not by a long shot.

Q. You don't necessarily document a genetic anomaly as a reason for an abortion on a patient's chart?

A. No.

Q. You don't really know how many abortions you perform for genetic anomalies?

A. No, I really don't.

Q. Doctor, you send all of your fetal tissue to a pathologist after the abortion; right?

A. Yes.
Q. But you don't send all of the fetal tissue to a geneticist?
A. No. There is no reason to.
Q. So would you say that about less than 2% of your fetal the issues are sent to a geneticist?
A. I would say probably less than 1%.
Q. Doctor, you also can't estimate how many abortions you performed for fetal malformations?
A. Generally somewhere on the chart, there is a notation about an anomaly. It may be on the sonogram, or it may be on the front sheet that she's being referred for that, but it's difficult to go back prospectively and to pull up those charts.
Q. Doctor, you've performed abortions for fetuses with cleft palate; correct?
A. I have, yes.
Q. But you don't know how many of these you've performed?
A. No.
Q. You've also performed abortions for Trisomy 21 which is Downs Syndrome?
A. Yes, quite a number.
Q. But you don't know how many?
A. No.
Q. You've also performed D & Es for hydrocephalus?

A. Yes. Not as common.
Q. And the D & Es that you have performed for this have resulted in a dismembered fetus?
A. In the vast majority, yes.
Q. You've also performed abortions for anencephalic fetuses?
A. Yes, quite a number.
Q. What's an anencephalic fetus?
A. An anencephalic fetus is a neurotube defect in the head associated with a lack of the posterior cranium and lack of fetal brain, and it's a very commonly associated with uncontrolled diabetes.
Q. So you would agree with those fetuses that the head would actually be the smallest part of the fetus?
A. I don't believe that I would agree with fetuses, but the head is the small part of the fetus.
Q. So usually the head doesn't get stuck at the cervix when you're performing an abortion on an anencephalic fetus?
A. Usually not.
Q. Dr. Knorr, if the fetus is in the vertex position and the head has come outside the body of the mother, you would call that a delivery; right?
A. Yes, I would.
Q. And you would most likely do everything in your power to keep that fetus alive if it is resuscitatable?

A. Yes.
Q. And you don't think it's appropriate to kill the fetus once the head is outside the body of the mother in the vertex position?
A. No, I do not.
Q. Dr. Knorr, you testified that in some instances the fetus came out in the breech position to the head unexpectedly?
A. Yes.
Q. So you weren't planning to do an intact extraction with those?
A. Intact again meaning the decompression of the fetal skull and delivery? Is that what you're asking me?
Q. Is that your interpretation of intact?
THE COURT: Counsel, his concern is this: You have just asked him a question in which the head had been delivered. Now he's asking you, are you talking about the intact procedure that he does, or are you talking about something else, and so I think that's where the confusion comes. Go ahead.
BY MS. NORONHA:
Q. Doctor, I think I'm referring to when the fetus is pulled out in the breech position and the head becomes stuck at the cervical os?
A. Okay. Then what was the question.

Q. You didn't plan for that to happen?
A. No, I really don't plan for that to happen.
Q. So you weren't setting out for that to happen?
A. No.
Q. You didn't know it was going to be intact to the head?
A. No.
Q. And you didn't take the steps that you would have taken if you actually planned it to be intact like we talked about earlier today?
A. I really don't plan it to be intact, and I don't have a crystal ball to tell which ones are going to come out like that. You're faced with a decision to make because of the presentation, and you must have a plan as to how you are going to complete an abortion that you didn't expect to be like that.
Q. Now, in those situations you administered Cytotec and laminaria as you usually do?
A. Yes.
Q. And the Cytotec caused the tetanic contractions that you described?
A. Yes.
Q. And those contractions assisted in the expulsion of the fetus?
A. They did what?
Q. It assisted in the expulsion of the fetus to the head?

A. No, not necessarily so. It just might be that the dilatation was more than anticipated.
Q. Doctor, when you do have an intact extraction and the head gets stuck at the cervical os and then you do something to bring the head out, you testified on direct that sometimes the fetus is alive before you open the skull?
A. Yes.
Q. Right. How can you tell? What signs of life are there?
A. Well, as I think I stated in my testimony, these fetuses are grossly obtunded, meaning that they have a lack of oxygen due to the tetanic contraction. They have some oxygen, there will be a fetal heartbeat, but they are generally limp. Does that answer your question?
Q. Yes. Thank you. Just to clarify, Doctor, I asked you earlier if you would actually plan to have an intact extraction in certain cases, and you said that you do in rare circumstances you do; is that correct?
A. Very rare, yes.
Q. Doctor, you perform --
MS. CREPPS: Excuse me. I'm going to have to impose a late objection there. Now I'm confused when counsel just said an intact extraction. I'm not sure that was the same question that she asked before which was completely intact or intact up to the head, and I'm sorry to pose that objection so late.

THE COURT: Well, the objection is overruled. I'll permit you to clear it up on redirect. The doctor has said he -- frankly, as I listened to the testimony, there are times when he can do, later in the gestational ages for which he does these procedures, he can achieve sufficient dilation intentionally to deliver a fetus entirely intact including the head. That's one subset.

Then there is another subset of circumstances in which he achieves sufficient dilation but not sufficient to deliver the head, and that's another subset.

I think your point was, counsel has just now confused those two things with the witness, and maybe she has and maybe she hasn't, but you can clear it up on redirect. Go ahead.

MS. NORONHA: Thank you, Your Honor.

BY MS. NORONHA:

Q. Dr. Knorr, you have performed an injection of Digoxin -- you use Lanoxin -- to cause fetal demise in certain circumstances; right?

A. Yes.

Q. You've actually done this numerous times?

A. Yes.

Q. You actually have experience from this when you practiced abortions in Alabama?

A. That's right.

Q. Currently, you primarily use Digoxin/Lanoxin as you use it in procedures after 22 weeks?
A. That's pretty much right.
Q. But you would agree that it safe to injection Digoxin or Lanoxin as early as 18 weeks?
A. I don't think I ever said that I considered it safe.
Q. Would you consider it to be the standard of care?
A. No, absolutely not.
Q. Doctor, you submitted a declaration in this case; correct?
THE COURT: He probably doesn't know what you mean.
BY MS. NORONHA:
Q. A declaration is a statement -- Well, let me show it to you and you can tell me.
A. Okay.
MS. NORONHA: May I approach, Your Honor?
THE COURT: Certainly.
BY MS. NORONHA:
Q. Do you recognize this document, Dr. Knorr?
A. Yes.
Q. Is this the declaration that you submitted in this case?
A. Just give me one minute.
Q. Sure.
A. It appears to be.
Q. Doctor, would you turn to paragraph 32 of your

declaration, and I apologize. There aren't any page numbers on this, and if you turn to the page after where the paragraph begins before paragraph 33, at the top of that page you've stated, therefore, while the use of Digoxin is within the standard of care after 18 weeks LMP, it is neither my practice nor the practice of many other doctors to use it on all patients.

A. Give me one minute. And your question is again? I'm sorry.

Q. My question is, did you state that in this declaration?

A. Taking it in its context, yes, I did say that, and I would respectfully request that you put the whole statement in, not just a little piece of my statement in the record. What may be a standard of care in Alabama may not be a standard of care in the country.

Q. Doctor, when do you believe that the fetus is able to survive outside the mother?

THE COURT: You're asking for a gestational age?

MS. NORONHA: Yes, Your Honor.

THE COURT: All right.

THE WITNESS: I believe late in the 23rd week

BY MS. NORONHA:

Q. On direct examination, Doctor, you testified that there are certain risks to the injection of Digoxin or Lanoxin; right?

A. Yes, I did.
Q. And some of these were puncturing a bowel or puncturing a vein or an artery, or in the case where there is a bowel adhesions or prior surgery; right?
A. Yes.
Q. And you also believe that this injection can be expensive and frightening to the patient?
A. Yes.
Q. Doctor, you have never had any sepsis result from a Digoxin injection; have you?
A. No.
Q. And you have never punctured a bowel?
A. No.
Q. Have you ever seriously punctured a woman's vein or artery?
A. Not to my knowledge.
Q. Doctor, you have developed a different technique for administering Digoxin; correct?
A. Yes.
Q. And that technique is for delivering the Digoxin through the vagina?
A. Yes, when there is a presenting part at the lowest point of the uterus.
Q. And you do this with the use of sonography?
A. Yes.

Q. And you numb the area of the vagina before you begin the procedure?
A. Yes.
Q. So you would say this procedure reduces the anxiety to the patient of having a needle coming through her abdomen?
A. She's not looking at a needle being directly inserted, and because the vaginal skin is numb, then she's felt a little pinch, that's about all she's feeling, so yes, I do think it's --
Q. And you have used this procedure safely?
A. I think so.
Q. Dr. Knorr, you were formerly a member of Physicians for Reproductive Choice; correct?
A. Yes.
Q. You're currently a member of the National Abortion Federation?
A. Yes.
Q. You stated that you're a partial owner of the All Women's Medical Pavilion in Queens, New York?
A. Yes.
Q. You've owned that clinic since 1993?
A. My portion, yes.
Q. And you also perform abortions at the Brooklyn Women's Medical Pavilion in Brooklyn, New York?
A. Yes.

Q. You are a partial owner of the Brooklyn clinic?
A. Yes.
Q. And you also own 90% of the Savannah Women's Medical Clinic in Savannah, Georgia?
A. Yes. I would like to just state that actually, my wife owns 90% of that.
Q. Doctor, would you please turn to what has been marked as Defendant's Exhibit 686 in the binder in front of you?
A. Yes.
Q. This is a document you produced to the defendant in response to our request for documents?
A. My office staff produced it, yes.
Q. This document lists the fees that you charge for abortions that you provide?
A. I believe that is true.
Q. And the first column starts with 14.1 weeks, and it ends at 24.0 weeks?
A. Yes.
Q. And the rows give military amounts, and the top row there has three letters, Q, B, and WP. Am I correct Q stands for the Queens office, B for the Brooklyn office, and WP for the White Plains office?
A. I believe so.
Q. So for your Queens office, you charge, at 14.1 weeks gestation $590 up to 24 weeks gestation which is $2,500 for

an abortion?

A. I guess that's right.

Q. And in your Brooklyn clinic, you charge $575 at 14.1 weeks gestation all the way up to $1,875 at 24.0 weeks gestation?

A. I guess that's right.

Q. In your White Plains clinic, you charge $750 at 14.1 weeks gestation up to $2,300 at 24 weeks gestation?

A. I think the White Plains 24 week, actually all the figures above 20 weeks have been increased by $300.

Q. So you would agree that this chart reflects that as gestational age increases, the price of the abortion also increases?

A. Yes, it does. That's right.

Q. Doctor, 95% of your medical practice is abortion related; right?

A. At this point in my life, yes, that's a true analysis.

Q. You stated you perform between 5,000 to 6,000 abortions per year?

A. That's right.

MS. NORONHA: May I have a moment, Your Honor?

THE COURT: Sure.

MS. NORONHA: I have no further questions at this time. Thank you.

THE COURT: Redirect?

MS. CREPPS: Yes, Your Honor.

REDIRECT EXAMINATION

BY MS. CREPPS:

Q. Dr. Knorr, do you still have your declaration in front of you?

THE COURT: That's that statement the other lawyer showed you.

THE WITNESS: Yes.

THE COURT: Paragraph 30 something.

BY MS. CREPPS:

Q. That would be paragraph 32.

A. Yes.

Q. I would like to draw your attention back to that and have you read the last two sentences of that, of paragraph 32, and then I would like to ask you some questions about that, if you could read those out loud for the record, please.

A. Okay. Therefore, while the use of Digoxin is within the standard of care after 18 weeks LMP, it is neither my practice nor the practice of many other doctors to use it on all patients. In my best medical judgment, I believe it would subject my patients to unnecessary discomfort and medical risk.

Q. Let me start by asking, you indicated that you did Digoxin or Lanoxin injections more frequently when you

practiced in Alabama. Why is that?
A. Unfortunately, the laws of abortion practice are different from state-to-state, the number of weeks that are allowed to have an abortion are different from state-to-state, and the laws of the land are set by the state, not the Federal Government. Therefore, I believe the laws in Alabama at the time stated that one must use Digoxin to have fetal demise after 18 weeks gestation.
Q. So your use of Digoxin in Alabama, was that motivated by medical concerns or legal concerns?
A. Legal concerns.
Q. I would like to have you focus now on the language in the first sentence at the top of the first sentence that you read which was starting with therefore, and it states that while Digoxin is within the standard of care. Doctor, is there a difference between something being within the standard of care and being the standard of care?
A. Yes. I think the standard of care, as a statement implies, more of a comparison of what somebody is doing in New York compared to what somebody could be doing in California. Within the standard of care is a statement that says that if one is doing abortion procedures, one can or may not use a certain technique because it is within the standard of care. Big difference.
Q. Thank you, Doctor. I would like to turn your attention

back to a question that you were asked during your deposition about the use of dilation when you intend to get an intact removal of the fetus and the quote was excessive dilation beyond that needed to do a D & E procedure. Do you recall that discussion on your cross?

A. Yes.

Q. Can you explain what you meant by that excessive dilation beyond that needed to do a D & E procedure?

A. Depending on the gestational age of the abortion procedure, one needs different degrees of dilatation to accomplish D & E, and it varies from doctor to doctor. Some doctors dilate a lot less, others dilate a lot more. The successive was for me to do a particular procedure at the request of an institution who wanted to see intact fetuses with a very rare fetal anomaly.

Q. And when you use the word excessive in that statement, did you mean excessive in terms of harmful?

A. Oh, no, not at all, and that was my point as well.

Q. Doctor, you were talking about -- asked extensively, actually, about cases in which you refer patients who have come to you for second trimester abortions to the hospital to have their procedure done. What I would like to ask you is, when you make that referral, is that because you think that the woman should have an induction rather than a D & E procedure, or that she should have the procedure done in the

hospital setting?

A. No, it would never be my intention to refer for an induction procedure, and the referrals are made specifically to a hospital-based doctor or several doctors in the greater Manhattan area that have the ability to do abortion to 24 weeks because of the bylaws of the hospital. Since I don't have privileges there, I would not be able to take the patient myself to do the abortion.

Q. All right. And, Doctor, you were asked some questions about the reasons why your patients have abortions. Do you always agree with the reasons why your patients are having abortions?

A. If they are asking me specifically about why they are there for the abortion, and they had an intention of keeping the pregnancy, but for medical reasons they were advised to have an abortion, you know, I would just want to make sure that they had all the information available to them to make the proper decision. Another example would be a pregnant woman having chicken pox in the first trimester of pregnant. Well, if the outbreak of chicken pox has not caused a spontaneous abortion, there is one other rare complication that she might have a fetus afflicted by. To tell you the truth, I have never seen one, and her chances of having that are very slim, so if her doctor has not explained that to her, it's an important reason for her to reconsider why

she's having the abortion.
Q. All right. Now --
A. Otherwise --
Q. I'm sorry. Go ahead.
A. Otherwise, you know, I honestly do not judge. If I had to judge why I'm doing abortions and why I would be turning a woman away, I might as well not do them. I'm there to help the woman. I'm not there to sit in judgment.
Q. You were asked some questions about the safety of your D & E procedures. First of all, do you think that you're doing a different procedure when you're able to remove the fetus intact but for the head from a D & E procedure?
A. No, and we don't reflect this in the charting as well, nor does a pathologist differentiate tissues, whether they are intact or in pieces. Our intent is to do the abortion, and our intent is not necessarily to document every little bric-a-brac information about how and when, you know, how the fetus came out. We just do not do that. The D & E procedure is what I would consider that to be. It is a dilatation and an extraction.
Q. You do chart the information you think is medically relevant; is that right?
A. Absolutely.
Q. When you talk about D & E procedures that you perform being safe, is it true that you're lumping together all of

the D & Es you perform when you talk about the safety, and you're not distinguishing between removal and small pieces, large pieces, intact?

MS. NORONHA: Objection; leading.

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

THE WITNESS: I consider my abortion practice, my own procedures to be very safe, and my complication rate is almost zero, so I would have to say yes. I can't speak for every abortion provider. There is a learning curve to the ability to do a D & E, and unfortunately, in most hospitals, these things are never taught, so I can only speak for myself. I consider this procedure to be very safe.

BY MS. CREPPS:

Q. You were asked if you agreed that dismemberment is the predominant characteristic of a D & E. What did you mean by that, that dismemberment is the predominant characteristic of a D & E?

A. Because we are doing these in the office, and in between, let's take, for instance, the laminaria insertion after 20 weeks. The goal is to accomplish the abortion in the office the following day. In between, the woman is leaving the office and has access to us on a 24-hour basis, but again, we don't want an outside delivery.

Q. All right. I just have one more question for you. Does

the fact that your D & E procedures in which you have some dismemberment are safe mean that you have no desire to make it safer by bringing the fetus out largely intact?

A. No, I really don't. Honestly, the sonometer dilatation I'm able to achieve with my technique is sufficient to accomplish the D & E procedure. Unfortunately, though, there is a new law, and because I obtain probably a greater dilatation than most doctors doing the same procedure, I run into this form of so-called partial-birth abortion on a fairly regular basis.

Q. All right. Thank you.

A. It's not my intent --

Q. I'm sorry. Were you finished, Doctor? I'm sorry.

A. I'm done.

MS. CREPPS: I don't have any other questions. Thank you.

EXAMINATION

THE COURT: Doctor, I have some briefly. A moment ago the lawyers were talking with you about what your intention is. I want to just focus on that for just a minute. When you're doing a D & E, if you had a preference, would you prefer to do the D & E as you describe it where the head lodges in the cervix, and you then crush or reduce the cervix (sic), or would you prefer to remove the fetus in additional parts; in other words, do you have a preference?

THE WITNESS: Yeah. If everything were perfect, Your Honor, I would prefer the delivery to the head and then removal of the cerebral contents, whether it be crushing or opening the skull. It's easier, it goes quickly, and there is far fewer chance that you're going to be pulling sharp shards of skull through the cervix which can sometimes cause a laceration. That would be an ideal world, but since we are in a world where abortion is restricted in most hospitals in the United States, and access in the majority of states in every state is restricted due to lack of providers, you know, I don't have the ability to keep the woman in the hospital overnight. I do have to send her home, and delivery on the outside would not be wise.

THE COURT: Okay. Now, I want to ask you, and I realize that terminology sometimes gets imprecise. I want to talk about an intact D & E or an intact D & X. One of those circumstances where from 16 to 24 weeks, you're going to do the procedure that you've described, and you do it and the head lodges in the cervix. That's what I want to define the procedure to be that I want to be asking you a question about.

THE WITNESS: Okay.

THE COURT: Okay. And I realize that you have been asked a lot of "give us numbers," and it's difficult to do that, but I would like to ask you for each gestational age,

beginning with 16 weeks through 24 weeks, your estimate of how many times that occurs in a year. Begin with 16.

THE WITNESS: You know, unfortunately, Your Honor, I don't think I can break it down by that. I would be guessing. I would hate to.

THE COURT: Do you have another way of giving me a range then?

THE WITNESS: Well, first of all, because I'm using Cytotec between 16 and 20 weeks, and the vast majority of those pregnancies are terminated using further dilatation, and that doesn't really present as a feature of this rarely. From 20 weeks to 24 weeks, the dilatation can be four centimeters, it could be five centimeters. That's where you break the water to empty the uterine cavity, and you're presented with two legs dangling down through the cervical opening, and there is really no way to do a disarticulation procedure. What you're left with doing is delivering the fetus to the head, and, you know, the head is going to get stuck, and you're faced with doing this procedure although that may not be what you set out to do.

THE COURT: I understand, and here I'm not talking about intention. I'm just talking about numbers, so from 20 to 24 weeks and in a given year, can you give me a number of times this occurs?

THE WITNESS: I would probably have to say about

ten times a year.

THE COURT: Okay. And much less than that between 16 and 20 weeks.

THE WITNESS: I would say yes.

THE COURT: All right. I'm going to let the lawyers follow up, Doctor, briefly. Counsel for the plaintiff and then the Government and then --

MS. CREPPS: No, thank you. I'm sorry, Your Honor. No further questions.

THE COURT: All right. Counsel?

MS. NORONHA: No further questions, Your Honor.

THE COURT: Thank you, Doctor. You may step down. I'm going to excuse the doctor unless there is some reason not to. Hearing none, you're excused, Doctor.

THE WITNESS: Thank you.

MS. SMITH: Your Honor, we have discussed with counsel, we are going to be starting with Dr. Carhart tomorrow morning since he does have, although he's here now, he has patients shortly and needs to get back to his office for that. We just hadn't anticipated we would be moving so quickly.

THE COURT: Because you're moving quickly, I won't punish you.

MS. SMITH: Okay. Thank you. Thank you, Your Honor.

THE COURT: I take it counsel for the Government doesn't mind.

MR. COPPOLINO: No, Judge.

MS. SMITH: I think, Your Honor, that also means that we'll probably finish up our case tomorrow, and because we made the agreement that defendants would start on Monday, we'll be dark on Friday and maybe for some of tomorrow afternoon depending on how long we all take tomorrow.

THE COURT: And I take it you're going to have a bunch of depositions to give us to at some point?

MS. SMITH: Yes, we talked about doing the deposition designations with the post-trial briefing. I think that was my understanding. We have discussed that at the pretrial conference, Your Honor. I don't know if you recall.

THE COURT: Well, but we need to receive into evidence the deposition testimony. We need to make a record of that. I mean, I didn't understand that you were wanting to withhold your rest.

MS. SMITH: We can certainly submit the depositions tomorrow so they would be part of the evidence if we can then do the markings of that along with our post-trial briefs.

THE COURT: I just don't want to get into a situation in which after your rest, somebody says okay, here

comes a deposition from X, and then there is an objection, so if you all agree what the depositions are, let's just list them, and if you want to provide the specific designations later, that's okay with me, but let's just make a record of what those are.

MS. SMITH: Very well, Your Honor.

MR. COPPOLINO: I believe they are already in the pretrial.

MS. SMITH: They are in the pretrial order.

MR. COPPOLINO: In the conference, I don't believe there is a difference in what's been designated. I thought the instruction at the pretrial conference was when the transcripts are submitted, the objections will be listed in the margin.

THE COURT: Right, and sometimes lawyers don't want every deposition that's listed in the pretrial conference order, and that's why I'm being kind of careful because I thought maybe some of these had not yet been completed, and -- but we'll take that up.

MS. SMITH: We'll do that tomorrow. I think we are in agreement about those, but we'll inform the Court tomorrow. I'll have time to confer with counsel.

THE COURT: Tell me about, are you going to --

MS. SMITH: Rebuttal?

THE COURT: Yeah.

MS. SMITH: We have one rebuttal witness who is one of the ones that's testifying by trial transcript, Your Honor, from the other cases, and then we also may put on another -- Dr. Carhart as a rebuttal witness.

THE COURT: And I should be looking for a week from this coming Tuesday?

MS. SMITH: Well, I think we are hoping we are going to be able to do the rebuttal in the afternoon of next Friday.

THE COURT: So you think we'll be able to get this thing submitted next Friday, then, maybe?

MR. COPPOLINO: I would not give up that hope yet. There is a chance. It's just four hours. There is hope yet we should try this.

MS. SMITH: We are going to make all of our efforts best efforts to do that, Your Honor.

THE COURT: Very good. Anything else we ought to take up at this time? Hearing nothing, then, we stand in recess. We'll see you tomorrow morning at 9:00.

(Recess at 3:24 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: March 31, 2004

Official Court Reporter (Ret)

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