IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

LEROY CARHART, M.D., WILLIAM G. FITZHUGH, M.D., WILLIAM H. KNORR, M.D., and JILL L. VIBHAKAR, M.D., on behalf of themselves and the patients they serve, Plaintiffs, vs. JOHN ASHCROFT, in his official capacity as Attorney General of the United States, and his employees, agents and successors in office, Defendant.	4:03CV3385 April 5, 2004 9:00 a.m. Lincoln, Nebraska

VOLUME V,
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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(Monday, April 5, 2004, at 9:00 a.m.)

THE COURT: Good morning.

MR. WARDEN: Good morning.

THE COURT: The defendant may proceed.

MR. WARDEN: Your Honor, the defendant calls Dr. George Mazariegos to the stand, please.

GEORGE MAZARIEGOS DEFENDANT'S WITNESS, SWORN

MR. WARDEN: Your Honor, before we proceed, I neglected to include Dr. Mazariegos's CV on the witness list so I move to have that marked at this time.

THE COURT: That's fine. We'll give you a number here.

MR. WARDEN: Your Honor, would you like a copy for yourself?

THE COURT: If you have one, that would be great. I tell you what. Why don't you give it to my law clerk? What number is it?

COURTROOM DEPUTY: 890.

THE COURT: The doctor's CV is 890. You may inquire.

DIRECT EXAMINATION

BY MR. WARDEN:

Q. Doctor, what is your occupation?

A. I'm a physician and surgeon.

Q. And where do you presently practice medicine?

A. I practice in Pennsylvania; Pittsburgh, Pennsylvania.
Q. Doctor, if you could look at what's been marked as Defendant's Exhibit 890, could you tell the Court what that is, please?
A. This is my CV.
Q. And does that reflect your employment, education, teaching and publication history?
A. It does.
Q. And is it current and accurate?
A. It is.
MR. WARDEN: Your Honor, at this time I would move to admit defendant's Exhibit 890.
MS. CREPPS: No objection.
THE COURT: 890 is received.
BY MR. WARDEN:
Q. Doctor, I would like to walk through some of your credentials on your CV. Where did you attend medical school?
A. I attended medical school at Northwestern University in Chicago, Illinois.
Q. When did you obtain your medical degree?
A. 1986.
Q. Following graduation from medical school, did you accept an internship?
A. I did in Michigan State University in Grand Rapids,

Michigan.
Q. And what area of medicine was your internship in?
A. It was in general surgery.
Q. And following your internship, did you enroll in a residency program?
A. I did also in general surgery in the same program.
Q. And following your residency, did you participate in a medical fellowship program?
A. I did. I entered a critical care fellowship program at the University of Pittsburgh and then that was followed by a transplantation fellowship in organ transplantation at the University of Pittsburgh.
Q. Could you describe what critical care medicine is, please?
A. Critical care medicine is the care of the patient who requires intensive care, either in our situation as surgery was before or after a surgical process or surgical procedure, and that typically involves a multi-disciplinary group of physicians that apply more intensive therapies to these more critically ill patients.
Q. And following your fellowship did you then take a position with the University of Pittsburgh Hospitals?
A. I did.
Q. And what was your position?
A. I took a position at the University of Pittsburgh School

of Medicine and at the Presbyterian University Hospital in Pittsburgh, Pennsylvania, as a faculty member in the department of surgery.

Q. And what were your duties in that position?

A. My duties there were the care of patients who presented with transplant-related illnesses that required an evaluation for transplant during transplant surgery and following transplant surgery their post-operative management.

Q. Did your practice eventually begin to shift towards pediatrics?

A. Yes, in 1995 and 1996, I began to shift some of my practice to the care of children who presented with possible need for transplantation, and that has become my focus of my work.

Q. And, Doctor, what hospital do you presently practice surgery?

A. I hold appointments at the Childrens Hospital, Pittsburgh, and also at the Presbyterian University Hospital at the University of Pittsburgh Medical Center.

Q. Could you describe for the Court your basic duties at those institutions?

A. Certainly. The duties that I'm responsible for include the evaluation of patients and children who present with medical illnesses that may require transplantation of either

the liver or the intestine and the evaluation of their candidacy for transplantation, the support and offering of alternative therapies to these children that might spare them from transplant, and if deemed necessary, the carrying out of transplantation procedures and the care that is required after this procedure.

Q. Doctor, what types of surgery do you presently perform?

A. I perform surgery related to transplants such as transplantation of the liver, transplantation of the intestine, transplantation of combinations of those organs such as liver-intestine transplantation, or abdominal organ compounded transplants that are required in more unusual conditions that may require replacement of the entire abdominal viscera such as the stomach, liver, intestine, pancreas and small bowel. And I perform surgery related to care of these patients that may be needed such as vascular procedures, surgery to remove tumors of the liver or the intestine, surgery to provide access for venous catheters for these children who present with a need for such procedures, and then surgery related to any complication that may arise from -- related to transplant.

Q. Any given month, for example, how frequently are you performing surgery?

A. We perform surgery several times a week.

Q. Doctor, over the course of your career, do you have

experience with innovative or new surgical techniques?
A. Because of its nature as an innovative area of medicine and surgery, I have had exposure to the development of innovative processes through transplantation such as living donor transplantation or intestinal transplantation which is a new development in care of these children.
Q. Doctor, are you board certified in surgery?
A. I am.
Q. And what does it mean to be board certified in surgery?
A. A board certification means that you have completed, in America, means that you have completed a certified training program in surgery in the United States that has met the requirements of the American Board of Surgery which is the credentialing organization for surgeons, and that you have subsequent to this training have passed the written oral examinations that are offered by the board and maintain a recertification.
Q. And are you board certified in other areas of medicine besides surgery?
A. I have an added qualification which is also offered by the American Board of Surgery in surgery critical care.
Q. In which states are you licensed to practice medicine in?
A. Pennsylvania.
Q. And are you a member of any professional organizations

related to the practice of surgery?
A. I'm a member of the American College of Surgeons, the Association for Academic Surgery, the Society of University Surgeons, Transplantation Society such as the American Society of Transplantation and the Transplantation Society.
Q. Doctor, could you explain what the American College of Surgeons is?
A. Sure. It's an organization that exists to provide and optimize the care of the surgical patient by providing a certification of the surgeons who submit for Fellowship as members of the college and provides for educational materials that may help both the practitioner and the patient, and as such, is one of the largest organizations for surgeons in the country.
Q. And how does one become a Fellow in the American College of Surgeons?
A. There is a fairly rigorous process in which the applicant submits documentation of their experience, their clinical training, their clinical experience that they have had in the past five years, and then through a process of this written application and personal interview, go before a board that reviews your qualifications and submits that you're a surgeon in professional and ethical standing within the community that merits the Fellowship designation.
Q. Are you a member of the Society of University Surgeons?

A. Yes.
Q. And what is that organization?
A. The Society of University Surgeons is a group that helps to develop the practice of academic surgery by distinguishing those surgeons who work in research endeavors and have particular investigation -- investigation directions that have allowed them to contribute to the scholarly development of surgery through their clinical or basic science investigations, and it promotes the development of this work to advance knowledge in the area of surgical care.
Q. And are you a member of the Association for Academic Surgery?
A. Yes.
Q. And what is that organization?
A. That's a somewhat larger organization that similarly encourages the development of academically-oriented research programs and clinical initiatives by surgeons not only in the university surgeon, in the setting, excuse me, but also in the setting of the private hospital where such work may also be needed but not as encouraged as in the university setting.
Q. And, Doctor, are you presently affiliated with the University of Pittsburgh School of Medicine in a teaching capacity?

A. Yes.
Q. And what is your present position with the University?
A. My position is Associate Professor of Surgery and Anesthesiology and Critical Care Medicine.
Q. And what are your basic duties in that position?
A. My duties include teaching in the didactic setting with medical students as well as clinical teaching to our trainees which includes residence or advanced faculty -- advanced residence training such as Fellows and in some points, a junior faculty development as well.
Q. Do you teach surgical techniques to your students?
A. Yes.
Q. Doctor, if you could turn in your CV to page 7. There are a list of publications there. Can you just briefly explain what types of publications you have authored?
A. Our University and Medical School asks that we designate our articles as refereed or peer-reviewed articles versus those that are abstract or presentations only, so that first category refers to articles that have been submitted to some type of peer review process by the medical literature or the boards that review the particular medical literature and have reviewed it and accepted it for publication.
Q. And has your writing focused on any particular areas of surgery?
A. My main areas of interest are in the areas of

immunosuppression following liver transplant and the particular ability of liver patients to tolerate less or no immunosuppression, the ability to predict which patients can do this, and the impact of quality of life following the ability to withdraw some medications. It also is focused on the techniques of pediatric liver and intestine transplant and the area of bioartificial liver support to support those patients who don't have the option of transplant at the time.

Q. Have any of your publications focused on innovative surgical practices and techniques?

A. They would focus on that in terms of these areas that I mentioned such as the living donor transplantation, intestinal transplantation, and some of the technology such as the liver support systems which are not in widespread use and are considered innovative or experimental.

Q. Do you serve as a reviewer for any journals, Doctor?

A. I do.

Q. What journals are those?

A. I review manuscripts for pediatric transplantation for the American Journal of Transplantation and for some smaller gastroenterology journals.

Q. Can you describe what it means to be a journal reviewer, what those duties are?

A. Certainly. It involves the review, the confidential

review of manuscripts that are submitted for consideration for publication in that respective journal, and it involves assessing the manuscript for the content for the accuracy for the scientific method for any potential bias with the purpose of both providing a document that has integrity as well as reproducibility and hopefully in an effort to also improve the quality of the manuscript once it finally is in publication if it is accepted for publication.

Q. And, of course, in your practice, Doctor, do you stay current with the current medical literature regarding the practice of surgery?

A. Yes.

Q. Doctor, over the course of your career, do you have experience reviewing new and innovative surgical procedure in a peer-reviewed setting?

A. I do. One of those settings would include this review of manuscript or scientific material that's submitted for publication in medical journals. It may also include participation in hospital committees that serve to overview innovative practice or scientific research as well as discussing those processes within societies that you belong to -- that I belong to, for example, the Society of Transplantation.

MR. WARDEN: Your Honor, at this time I would move to qualify Dr. Mazariegos as an expert in the field of

surgery including the standards and methods by which surgical procedures are admitted into practice.

THE COURT: As I think you recall, as I told plaintiffs' counsel, it's not my practice to accept or reject a tender of expert qualifications. If somebody objects, I'll rule on that. Speaking of different techniques. There is a Midwestern technique in which typically the expert is not tendered and an East Coast and West Coast technique in which the expert is tendered. When you play in my ballpark, we'll play by my rules. Go ahead.

MR. WARDEN: I understand. Thank you, Your Honor.

BY MR. WARDEN:

Q. Doctor, could you explain to the Court how surgical procedures have historically developed?

A. Certainly. The development of surgery is marked by the progressive innovation of procedures designed to meet the patients which we cared for and has included the development of new procedures based on creative solutions to problems encountered in surgery, demonstrated needs of medical situations encountered in the large population at large, and sometimes through the unique encountering of a problem by an individual surgeon that was able to establish that as something applicable on a more wide scale, wide scale basis. The development is -- has proceeded rapidly in many cases because of the need to support and help the patients who

present with these medical conditions.
Q. And in your experience, has the development of surgical procedures changed in any fashion?
A. The area of surgery is clearly changing. Transplantation, for example, in the area in which I'm familiar with is a very rapidly evolving field and a very rapidly growing field, and as such, it has had a large share of it contribute to this development or new procedures innovation. And with this, we are seeing in our practice environment a definite request for oversight and for review for accountability for full patient disclosure and for proper informed consent as these areas develop, and then for a reassessment of the procedures as they develop to demonstrate that they truly are meeting a need and not just a procedure that is looking for a disease, for example.
Q. Could you explain the meaning of the term evidence-based medicine, Doctor?
A. Evidence-based medicine refers to the concept that there are varying degrees of support for different practices that we do in medicine. For example, there may be commonly held treatments for various diseases that have varying degrees of support, and one of the ways to judge the evidence for that therapy is by the quality of the support that is behind that therapy. Some therapist have very well established rationales that are proven by randomized controlled trials,

by careful med-analysis of various different trials, and have as such substantial support in the literature and would have a high grade of evidence behind them. Others may have less so, but may be valid therapies or equivalent therapies as far as the literature could recommend. Then other therapies may have little support in that they lack objective verifiable or producible data in literature to support it.

The term evidence-based medicine refers to the increasing desire to have our therapies and our decisions based on appropriately grounded rationale and is evidence in the internal medical community, treatment of medical diseases with medications, for example, but is also, it is also important in the surgical community where surgical therapies also are facing increasing scrutiny to demonstrate their effectiveness, one or the other, or overt medical therapies, for example.

Q. How has the concept of evidence-based medicine been extended into the practice of surgery?

A. There are many -- there are many ways in which at times medical or surgical therapies may both offer a possible solution, and as such, the need to demonstrate the evidence behind doing a surgical procedure is important to demonstrate its efficacy and safety as compared to perhaps a less invasive medical procedure.

Q. Doctor, does evidence-based medicine reflect the entire universe of criteria that should be taken into account when implementing a new surgical procedure?

A. No, I don't think so. I think as practitioners, there is a wide body of care and standard of care that we apply to our patients that may include the clearly evidence-based therapies that are well documented but may also include a large experience with alternative therapies that may be supported by other strong data or by therapies that are well known but have not yet been subject to a formalized testing, so those -- that would be important in really contributing to the whole spectrum of what options you have to treat and to explain to patients.

Q. Why do you think it's important to study the safety and efficacy of new surgical procedures?

A. As surgeons and as physicians, we are beholden to the patient to provide the best therapy that is available. In our community, what that practically means is that we are expected to uphold the standard of care to apply to our particular patient in a particular medical condition as judged by the community in which we practice, and this is logical, but it applies in the practice or extension to new procedures that the implication of that is that any -- any development of a procedure that is outside the standard of care should then be expected to meet the minimal criteria of

providing a safe approach, an effective approach, and one that has been -- has been evaluated in some manner.

Q. In the absence of comparative analysis, can a physician know whether one surgical procedure is safer than another?

A. We have intuition that a procedure may be safe. We have a hunch that it may be -- it may be effective, but without comparative data, it's impossible to objectively state that a procedure is better or safer.

Q. And are there adverse medical consequences that can arise from they or rising in the absence of comparative analysis that a new procedure is safer than another?

A. Certainly. I think that again, we as physicians hopefully only undertake procedures that we believe have a -- have a possible benefit, have a, in the innovative setting, or have an established benefit in a documented setting. However, the -- without proper study of some sort, and this could include various types of analysis, but without proper investigation, our intuition and our bias may -- may color our presentation and the outcome that we would perceive and that may not be -- that may not be actually what is found when you do study the safety or efficacy of a procedure, and you may be surprised by the complication that arises that you did not expect or one that others might have expected but that you did not anticipate.

Q. In your area of practice, Doctor, are there any

procedures that were developed based on theory that the procedure was, in fact, safer, but after experience and study, the procedure turned out to be unsafe?

A. In my experience of transplantation, there certainly are areas where we have had to regulate the development of a procedure so as to assure its safety. One example of this would be the extension of live donor transplantation from an adult to a child. Extending that process from an adult to an adult is something that is theoretically the same principle but may involve more risk and has required more study in order, more study and more accountability in order to maintain its safety.

In our pediatric community and in our general surgical community, one example of that might include laparoscopy and the use of laparoscopic techniques to perform general -- previously general surgical open procedures and the need to register and to document complications from this procedure that were not anticipated because it was the combination of previously used procedures such as laparoscopy for pelvic surgery in a new application, the abdomen. These would be two examples.

Q. Doctor, you mentioned laparoscopy. Could you explain what a procedure known as laparoscopic cholecystectomy is?

A. Sure. Laparoscopic cholecystectomy refers to the removal of the gallbladder by a minimally invasive approach

using telescopes and viewing instruments placed through small incisions in the abdomen with instrumentation also placed through small incisions in the abdomen to allow the removal of the gallbladder.

Q. Could you explain how this procedure developed in the United States?

A. The procedure developed in the setting of there being a large population of patients who undergo and have undergone open cholecystectomy, the standard previously, the standard approach for to remove the diseased gallbladder which is a common ailment in the United States and common general surgical procedure. The development of the laparoscopic approach to removing is the minimally invasive approach developed through the application of what was being done by the laparoscopic GYN community to the patient with gallbladder disease, and this spread because of the large patient demand and the intuitive sense that it would be less risky to take the procedure that previously caused some inpatient need for an inpatient stay of about a week, open recovery from an open incision, and the complications of surgery related to a large incision, and minimize that with small incisions where patients could go home the next day.

Q. Did those intuitive theories turn out to be correct?

A. In many ways, the efficacy of the procedure has been shown. However, there was unexpected adverse events that

were not anticipated, and for example, one of the major ones that was encountered was inadvertent injury to the adjacent structures around the gallbladder. That would be difficult to injure in an open investigation, in open surgery, but more easy to injure in the limited setting that was the laparoscopic approach.

Q. In your opinion, are there any lessons to be learned from the development of laparoscopic cholecystectomy procedures?

A. Some lessons you can learn unless you subject the study or the procedure to some form of prospective study, whether it would be a register, registry of data resulting from that procedure, a comparative trial or a -- that some documentation and assessment of procedure, that you would be likely to introduce procedure that may not have a strong foundation or may be subject to bias.

Q. Doctor, to what extent does the existence of a proven, safe surgical procedure for a given indication impact a need to study a potential new alternative procedure?

A. I believe that the main impact of having an established procedure is that, as I mentioned before, the medical community and the surgical community, in my case, have to show that a new procedure truly has as safe of a record or as effective before subjecting patients to it. For example, if there was no alternative therapy available to a patient,

then I would be able to explain this to my patient and say that this innovative procedure may meet their need, and that there is really know other alternative to their situation, and in that way try to give them as much of an informed consent as possible, and argue that it may be in their best interest to consider this because of the lack of suitable alternative therapy, whether it's medical therapy or the surgical options, but in the case of a treatment where there is a safe effective therapy, then I have to, number one, explain that to the patient or the family, and explain the projected outcomes with those procedures, and then, and then discuss the pros and cons of those procedures with them in order to really satisfy their requirement of informed consent and properly help the patient reach a -- reach a decision that they feel comfortable with.

Q. Doctor, if you could open the binder, I think, in front of you to Exhibit 648, please?

A. 648?

Q. Yes.

A. May be in a different binder.

Q. Oh. Is that the wrong one?

A. Yes, this goes through 640.

MR. WARDEN: May I approach, Your Honor?

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

BY MR. WARDEN:

Q. Doctor, what is this document, Defendant's 648?

A. This is a statement by the American College of Surgeons that relates to issues that are to be considered when a new surgical technology is a applied to the care of patients.

Q. And did you rely on this document in forming your opinions in this case?

A. Actually, I did, yes.

Q. What is the significance of statements like this from the American College of Surgeons?

A. These statements, again by the organization of the College of Surgeons, serve as guidelines that are voluntarily taken by the college to encourage the correct application of new technologies, or may include statements on other topics of care to their surgical patients or of issues that practitioners face commonly in our -- that may not have been present ten years ago but have come into clinical discussion in more recent times.

Q. Are statements by the American College reliable authority within the field of surgery?

A. They are accepted by, again, by the board of the College of Surgeons which is the largest surgical organization in the country or perhaps the world.

Q. Are their publications and statements relied on by practicing surgeons?

A. Yes.
Q. Doctor, when was this statement published in front of you?
A. I believe that this exhibit was accepted at -- in June of 1995.
Q. Do you know why this statement was published at this time?
A. The impetus for this particular statement came about partly through the problems that we described regarding laparoscopic surgery where there was more than a doubling of bile duct injuries in a short period of time, very unacceptable complication rate compared to a standard complication rate that had been fairly well standardized, and in American surgery, and it focused on ways to credential, ways to identify what aspects of a procedure should be codified in a way to demonstrate important factors such as safety and efficacy.
Q. The document the title of the document contains the phrase new surgical technology. Does that term have an accepted definition within the surgical profession?
A. The college uses the term surgical technology, I believe, to include a new procedure as well as the use of technology, in this case, minimally invasive instrumentation to the operating room.
Q. Doctor, could you just briefly provide a summary of this

document to the Court, what it is?

A. Certainly. The statement states that as new technology is developed and made available, that there is need to ask several issues and questions regarding its use by surgeons and/or hospitals that would include the following, the following areas, and they list as number one, has the new technology been adequately tested for safety and efficacy, and in this regard, they discuss the use of data from trials to assess safety and efficacy. They ask, is the new technology at least as safe and effective as existing or proven techniques, and they mention within that paragraph that there is enormous public pressure that is being brought to bear to reduce the extent of invasive surgical procedures, and yet while we need to assess this new technique, safety is the major consideration; and then finally at number three, is the individual who is proposing to perform this act properly credential and trained to do so; and finally, the fourth point is the question, is the new technology cost effective.

Q. Thank you, Doctor. Could you turn to Defendant's Exhibit 647, please?

THE COURT: Now, but for the hearsay objection, you would be offering this, right?

MR. WARDEN: Yes.

THE COURT: Okay. It's offered. Do you have an

objection?

MS. STRAUSS: We do, Your Honor. We object on the basis that it's hearsay.

THE COURT: Okay. Why shouldn't I receive this, not for the truth of the matter asserted, but as to the question of whether or not there is a legitimate debate?

MS. STRAUSS: Because he hasn't indicated, Your Honor, that he's only offering it for the basis of the opinion.

THE COURT: All right. I'll withhold ruling but once again --

MR. WARDEN: I would offer it for the limited purpose of going to the larger medical debate within the community and not for the truth of the matter asserted in these documents.

MS. STRAUSS: Then we have no objection, Your Honor. Your Honor --

THE COURT: I'll withhold ruling on all of these, but Doctor, this doesn't really involve you other than I'm just giving the lawyers a hard time, frankly. This goes back to the issue we discussed earlier.

MR. WARDEN: Certainly.

THE COURT: So have you all talked about whether -- Have you made any effort to get this issue resolved?

MR. WARDEN: I believe we are still in ongoing

discussions on that, and no conclusion has been reached on that.

THE COURT: All right. I'll withhold ruling, but another example of why I would think that it would be a good idea to see if we could resolve this.

MR. WARDEN: Yes, Your Honor.

THE COURT: Pardon me. Go ahead.

BY MR. WARDEN:

Q. Doctor, could you turn to Defendant's 647, please?

A. Yes.

Q. And what is this document?

A. This is the statement by the College of Surgeons on emerging surgical technologies and the evaluation of credentials.

Q. Could you provide a summary of this document for the Court, please?

A. The statement describes that in conjunction with the prior, the prior statement, there are important questions and evaluation processes that the college is offering for the credentialing of new surgical procedures and their performance by the respective surgeons. That statement briefly states that the development of a new technology must be accompanied by some type of scientific assessment of safety efficacy and need, that its diffusion or its extension into clinical practice should be and requires

appropriate education of surgeons and evaluation of their use of this procedure, and that that includes a knowledge of the disease processes that are involved in treating this disease, that there should be some training, some clinical experience as a prerequisite, and that there must be a program of acquiring this skill either in training or in post-graduate training, and that there should be, number three, a widespread assessment of this application of new technology in some continuing ongoing manner that would allow a comparison with alternative therapies to make sure that it's appropriate and it's cost effective. That would typically mean some type of outcome studies they mention.

Q. What are outcome studies, Doctor?

A. Outcome studies deal with the result of a surgical procedure both in terms of its immediate efficacy and patient survival in some cases, or may focus on some other aspects of the care of the outcome of these patients that might have a different aspect for example, quality of life or morbidities after surgery, or a cost both to the patient or society, or all issues that might come under that category of outcome.

MR. WARDEN: I think I'm all finished with that one for now. You can put it aside if you like.

BY MR. WARDEN:

Q. Doctor, could you explain what role peer review plays in

the development of new surgical procedures?
A. Peer review plays a role in the development of surgical procedures in a few different ways. We may use peer review in the process of evaluating a manuscript or a submitted documentation of results that were done clinically or in a laboratory setting to question and develop the data further. To assess its method of scientific investigation, does it have inherent flaws, or does it have an obvious problem or deficiency or bias and thus contribute to the review of that procedure. Peer review would also include the use of hospital committees such as review boards to assess a research proposal or proposals that fall outside of research and are designated more as, say, innovative practice that's not yet a standard of care. Peer review could also include evaluation of a procedure through discussion at presentations of the particular societies that are involved that would be due, open to review, constructive criticism, and debate about the procedure.
Q. You mentioned a few types of bodies in that answer. I just wanted to focus on a few for a moment. What is an institutional review board?
A. An institutional review board, or IRB as we sometimes refer to it, is a body that functions within a hospital setting usually to allow for the review and protection of patients who may be subjects in an investigation of a

procedure, device, medicine or new therapy. It includes both medical and surgical patients. It generally is comprised of your peers in that they include physicians from your specialty and other specialties, and they opine on the appropriateness of the investigation in which you're proposing and try to assure that patients have a complete or as safe as possible understanding of the procedure in the consent forms by looking at terminology and those kind of things. Then they may direct the investigator to supply different types of outcome data to them, sometimes to a data safety monitoring board which functions as an adjunct to the IRB and which provides ongoing assessment of a study in order to report to the IRB if there are any significant adverse effects that are being noted, if there are any violations of protocol that are on going so the IRB can take an action to correct that.

Q. Doctor, for surgical procedures that don't fall within the category of research, are there other types of peer review bodies that are available to review new surgical techniques and procedures?

A. Yes. These would include what hospitals have designated as innovative practice committees, and they may have different names for them, but often that's the name they call those committees. They may be innovative surgical practice, medical practice or innovative pharmacology

committees which, just as an example, would require or would give oversight to physicians using medications in an off label or not-yet-approved use. In the case of surgical innovative procedure, this would be, this would apply, for example, to a procedure that is a significant modification of an established standard of care but is deemed by the peer review committee not to be a modification rather than a complete, novel procedure that should be studied in a research setting which would then make it fall under the purview of the IRB, so it's designed as a more flexible but yet accountable body to support and review these very common innovations that are ongoing.

Q. Doctor, in the area of published medical literature, what role does peer review play?

A. In the literature, there is a large -- there is a large body of literature, obviously, in medicine. It would include standard textbooks of medicine and surgery. It would include the literature that is perhaps more current because it's published with less turn around time, and that would be the journals that we have talked about earlier. Peer review is a term we know when it's applied to the medical literature that describes the type of medical journal that does require outside evaluation and critique of submitted data in an effort to improve the data in an effort to assure more that there are uniform standards for

presentation of that data such as assuring that there was some type of IRB approval to the study, if needed, and functions to really allow some type of improvement and review of any submitted data that comes to it, so therefore, when a manuscript is accepted in a peer review journal, in general, it would have a greater worth to clinicians in terms of using it to base their judgments because it would have gone through this type of process as opposed to some journals which may be also available in the medical literature that do not have a peer review process. This would be -- this would be literature that might accept a submission from a group or an institution or an individual at the face value without subjecting it to any kind of review process.

Q. What are the limitations of a study or a report that's not been subjected to the peer review process you just described?

A. Those type of studies may be limited by a lack of accountability of the investigators to uphold certain standards of informed consent. They may be subject to or more prone to bias if there is no -- if there is no subjective, or I'm sorry, if there is no objective review of this prompting questions about the process that was carried out to answer the question, the proper use of the statistical methods, were they accurate, were they the right

method to use to answer the question, and indeed, was there, or why was there not a control group to look at the opposite side of the question, so these are just areas that -- deficiencies that that type of work would be subject to.

Q. You mentioned bias. What are the types of bias that could be involved in a nonpeer-reviewed article or study?

A. Well, perhaps this would be -- it would be best to talk about types of studies that you may encounter. When we have a possible hierarchy of studies, you might think of it as beginning with a very simple case series, then moving to, secondly, a case series without any controls, that is retrospective in nature, and then moving on to some type of series with a control group. And then finally, a more -- a more organized or structured randomized trial. The biases that are inherent in the first types of trial are, number one, bias of the selections of patients that you use. For example, you may, without knowing, select a healthier patient to undergo this procedure that you're trying and not choose the sicker patient because you feel it may not be appropriate, etc. However, this introduces a significant bias in the terms of the outcome of the procedures, and what you have then subsequently is an outcome that you promote which may be as likely to be an erroneous outcome as it is to be a true outcome, even though the data may show that all these patients did well, and so that generally is accepted

that these types of studies would introduce that type of bias. Generally, when there isn't a control group, the outcome that is being studied tends to have a very good outcome or a better outcome than may be found by a more thorough review.

Q. Thank you. Doctor, does peer review guarantee that a peer-reviewed study is without flaws?

A. No, it doesn't guarantee it at all. It just -- it just adds an additional layer of review and hopefully integrity to that work because it requires -- it requires the authors to comment upon common questions that would be agreed on as being more likely to support the veracity of that -- of their outcome, more likely to support what they suggest is, in fact, not due to chance but due to a true benefit of the procedure or the drug or the surgery that's being proposed.

Q. Doctor, is the raw data underlying a journal article ever peer reviewed by the editors or someone else?

A. It is sometimes. For example, in studies of or various investigations that may be funded by the Government, by the National Institutes of Health or by industry, those investigators are required to support and supply data at either regularly scheduled or impromptu audits in which the original case files are called the source documents for the data that is subsequently entered is reviewed by an auditing agency.

Q. Doctor, in your previous answer, you mentioned some of the various types of studies. I would like to ask you a little bit, a few more questions about some of those. What is a case series?

A. A case series refers to an experience with a procedure or a medical therapy that is -- that is greater than a case report which would be -- would be the report of an isolated use of device an initial or preliminary experience with one patient or very small number. In this case, the case series would typically be a greater number of patients and -- but would not usually be controlled in that it may or may not have a control group, and it's what is called retrospective, meaning you go back in time after the procedures are done and you ask some questions about the outcome of that procedure.

Q. And is a case series comparative to another group?

A. It can only generally be compared to what's called a historical control group, and that would mean the comparison of therapy A to a group of patients who had the therapy in the past, so it would be doing two retrospective studies, essentially, of outcomes in one group versus another group and then putting that together.

Q. Doctor, for those case series that don't involve a comparison in any way, how would a reader know in reading the results of the case series whether the surgeon was just

very good at performing that procedure or, in fact, whether the new procedure was safe and beneficial to the patient?

A. You may not know whether the answer to that question, you may not know if the procedure is inherently better or if it's how much of the -- of the effect is operator dependent. This is one of the -- one of the flaws or deficiencies in that type of study that they typically come from a single operator or single institution, and as such, are extremely variable due to the either individual operator's characteristics or the patient population that that practitioner or that hospital sees. Understanding, understanding those potential deficiencies, you may still have a sense based on the complexity of the procedure or the complexity of the illness whether this might be extrapolatable to a larger community, for example, if the procedure comes from a single institution but is relatively standardized and easy to perform procedure, let's say, a tonsillectomy or appendectomy, then that may be, in your eyes, more likely to extrapolate to a larger community than if you are talking about a complex, complex procedure that might not be so easily extrapolatable based on a single case report.

Q. Would a case series documenting one's experience with a new procedure without a comparison group, in your opinion, would that be a reliable basis from which to conclude that

the new procedure is safer than an existing alternative?
A. You would use that information to guide your decision without comparative group in a prospective manner. It would be unlikely that you could, with certainty, or with some degree of assuredness support that to a family because you wouldn't be able to exclude those biases that we talked about, so you would have to -- you would have to factor that into your evaluation that you are unable to document the safety or efficacy in a true way because you haven't yet compared it to, in any sense, to the standard.
Q. Doctor, on Wednesday, I believe Dr. Howell was here and he was a surgical historian, and he testified that one of the difficulties associated with doing a retrospective chart review is that a surgeon does not necessarily know what he's supposed to be studying when he's doing the procedure, and he might not record the necessary facts. When you're performing surgery, what types of information do you record?
A. What we are required to document in the patient record, the performance of the procedure, in general, we are asked to describe enough of the detail of the procedure that would -- would, in a community of peers, communicate how to carry out that procedure. As an example, you would be required to supply enough detail in your operative record that would describe how to manage a complication that might arise in that patient, so that readers of the record could determine

what was done anatomically in a way that either, A, they could repeat it, or B, they could correct anything that was -- that arose from subsequent to it.

Q. And if it's a surgeon who performs a new or innovative procedure, how does that impact the type of information that's recorded?

A. Because sometimes these procedures, as you mention, may arise in a new setting where a finding is done, is seen that is not anticipated, then that would, it would require documenting what was found, either what anatomy was found that required a different approach, what clinical situation in the patient changed that altered the need to proceed in this manner, and the rationale behind your actions that resulted in something different than may otherwise have been expected.

Q. Doctor, you also mentioned the control prospective trial as one of the types of studies. Can you explain briefly what that is?

A. Sure. The controlled prospective trial allows the prospective, meaning from this point in time onward, evaluation of a surgical procedure or drug or therapy in a way to try to answer certain questions. It may be structured first to answer the question of safety, or secondly, to answer the question of efficacy, and it includes a current control group. It typically may include

randomization so that there is not the selection bias about which patient you're going to treat with which therapy, and in some cases, it may be blinded to the observer so the patient may not know what therapy they receive to try to remove the placebo effect of certain therapies or of all therapies, or in some cases blinded even to the practitioner so that the practitioner cannot be biased in how they interpret the outcome of a patient to a drug or to a surgical procedure, so these would be considered a very reliable source of information but obviously not the only one.

Q. Are controlled prospective trials performed in the field of surgery?

A. Yes.

Q. And do you find, are they controlled prospective trials are they more difficult or easier to form than the case series or the series you just mentioned?

A. They clearly are more involved because they do involve the prospective identification of the issues that you're going to identify. They may in the ideal setting where there is randomization involved, say, a process to do that, to randomize patients, it involves the then analysis of the information, and if it's a large study with multiple centers, then the costs would reflect that, too, in terms of doing this across more than one institution.

Q. When Dr. Howell was here, he testified that controlled trials in the field of surgery are difficult to perform because of the variations in skill and technique from one surgeon to another. Do you agree with that assessment?
A. I wouldn't agree with that assessment in that there is a certain standard which we are expected to uphold in surgery. It's the standard by which we obtain our certification. It's the standard by which we reach our credentialing, and that's the standard, generally, that's applicable to the surgeon working in that given community or our community, for example, and so this, this standard would be what would be being tested, not the particular skill of the surgeon. Also, because you include other operators and perhaps other institutions, then you take away the effect of the individual operator as a bias to a certain, to a great degree, and therefore, I would not find that to be a deterrent, you know, to performing a proper trial in surgery.
Q. Doctor, in deciding which type of study to use, what factors are appropriate for surgeons to consider?
A. One important factor that you need to consider is the question in which you are -- that you are trying to ask or answer. For example, are you trying to determine the impact of this procedure on the outcome such as survival from cancer, or are you trying to determine the efficacy of this

procedure in terms of time spent in the operating room or other issues such as this. That would guide you because you would have a sense of what differences you were expected to see. If you are expecting a large difference in therapies, that would guide you and your statisticians in developing a study that would be properly designed to answer that question with some degree of statistical power.

Q. Doctor, do you believe that every modification to establish surgical techniques should be subjected to the kinds of study and peer review that you've just described?

A. No. I think that really those should be limited to a major modification.

Q. So what factors determine whether a new or innovative procedure should be subject to the kinds of review and study you talked about?

A. Generally when we refer to a major modification, we would be referring to something that would alter the risk to a patient in a perceptible the manner or in a possible manner particularly because this procedure, if it is -- if it is coming as an alternative therapy and is a significant modification because of this risk factor does have to be compared to the standard, so I use that as a benchmark in determining the, whether something is major or merely a refinement of an established procedure. If there is any possible change in the risk to the patient, then that is

something that needs to be reviewed.
Q. And in deciding whether a new technique or procedure should be subjected to study or review, who do you feel is best equipped to make that determination?
A. Medical personnel, I think, are best equipped to answer that question, but it's important because we do all have inherent bias that we, that we have review done by those who don't have any conflict of interest with our study. For example, review done by colleagues outside of our practice group or by colleagues, that may include those in your discipline, but also those of outside disciplines so they would give you a least of a biased opinion on the potential risk to patients as possible, and that really best comes from medical personnel but those that can look at it objectively and say I understand that you're saying this isn't a risk, but I see some pretty significant modifications here, and we should test this.
Q. Okay. Doctor, what role does informed consent play in implementation of new technique or surgical procedures?
A. Well, informed consent is required and expected in our community now, and that includes description of alternatives to therapy and the expected outcome of this procedure when you're performing something that hasn't been subjected to study, and informed consent really means describing that, that it is a procedure that may not -- may not give a

benefit. It may not reach the desired outcome. It may have unexpected adverse events associated with it because of its -- that can't be anticipated or you might be able to anticipate some and you would describe those, but to the extent that it has not been studied and that you're not aware of other issues, then informed consent means describing that uncertainty to the patient and family.

Q. I think you mentioned some of the information that should be disclosed, but are there any particular types of information that should be disclosed to the patient when performing a new or innovative surgical procedure?

A. You would want to document the established results with the established alternatives. You would want to document why you feel that this procedure may be of use in this patient, and you would want to document that you've reasonably explained alternatives to the family and patient.

Q. Doctor, how long after a new procedure is initially developed would you typically expect to see some type of published peer-reviewed study of that procedure?

A. That can vary. It would vary based on the prevalence of the process that you were studying, the prevalence of the disease, how common was it. It could vary based on the acuity of the need to have that information relayed, for example, if you had a process that was likely to make a major impact immediately, then that time to try to

disseminate that information might be faster, within months, weeks or months, whereas if the questions were more difficult to answer or required a lot more comprehensive study, then that might require a period of months or years to really be disseminated and be in the literature for review.

Q. Are there any adverse consequences to not conducting some type of timely peer-reviewed study of a new procedure?

A. Well, although there is great varying among the time that would still be useful, I think that there is a -- that there is certainly a practical limit that clinicians use because the time that something is perhaps developed to the time that they expect to see some type of documentation in the literature, and within that time, that doesn't happen, then many clinicians would not begin to use that in their clinical practice because of a lack of substantiation that it is effective, and we really question the initial results or whatever was presented initially as perhaps not being reproducible.

Q. Doctor, how do you determine the number of patients that's needed for a comparative study?

A. I'm not a statistician, but the general approach is to determine the percent difference that you wish -- that you expect to see in your comparing A versus B and then using that percentage in a statistical formula to derive the

number of patients, then, that you would need to enroll to get that anticipated outcome. Again, the main idea is that you're trying to show that the differences between the groups are more than just would occur by chance, and so there are statistical formulas to determine the number of subjects that would be required to gain the necessary power it's called, and the power just means that there is a greater chance than -- a far greater chance than not, specifically 85%, that it is a true effect that you're detecting.

Q. Would the number of patients that you would need for a comparative study depend in any way on the outcome that you were looking for?

A. Sure, you know. If the -- like I said, if the difference was very small, you would need a larger group. If you wanted to show a small difference that that was real, if you wanted to look at other outcomes besides -- besides commonly-accepted outcome measures like survival, those would also be very valid questions to ask and to hypothesize a benefit or a change in the therapy, and again, the outcome difference between the groups would guide you in choosing the number of patients, so you could conceivably have an issue where if you were asking the proper question, you might be able to have a study smaller than if you asked in the same therapies different question or the wrong question,

perhaps, would require many, many more patients, so it's important to prospectively design the studies so that you can, at the end, then have some data that is strong enough to stand on its own and be subject to these kind of common tests.

Q. And in the practice of surgery, what are some other end points besides maybe major morbidity and mortality that are relevant to study and look for?

A. Currently, other areas that we are looking at that are important in commonly and assertic literature are the recovery time, would include the -- so that would be measured by length of stay in the hospital, cost, it could include other additional complications that would be marked by a surrogate marker such as blood transfusion or the need for readmission subsequently, need for reoperation, the unanticipated issues of wound healing or finally, a very important area is just the subjective sense of the patient to well being or their quality of life as measured by some surveys that are standardized in the medical community.

Q. Doctor, once a physician has some new data that a procedure may be safe or effective, what's the proper way to disseminate that data?

A. Typically, this occurs through a peer review setting. It may initiate in a presentation of data to colleagues at meetings and generally should be then followed by a report

of this in the medical literature. To the extent that it's reported in substantial body such as a peer review journal, that would guide the typical acceptance of that or the -- give additional weight to those clinicians who are trying to decide about different therapies.

Q. Once that initial data was disseminated, what factors would impact whether additional and further study of the procedure would be appropriate?

A. If there are typically, for example, if the initial, if the initial case series suggest the possible role for the therapy, then that would typically spur on the development of comparative trial. It may, in order to document with more certainty that this is a beneficial therapy, that could be applied to a broader patient population, and typically that's, that has occurred in transplantation with some drug therapies. It's occurred with some surgical techniques to a lesser degree, but is common in that regard.

MR. WARDEN: Just one moment, Your Honor.

THE COURT: Sure.

MR. WARDEN: Just one more question, Your Honor.

BY MR. WARDEN.

Q. Doctor, when you were discussing the timing of the studies, is there a ballpark time period for which surgeons expect to see peer reviewed studies of new procedures?

A. Generally, we would expect to see something within one

to two years. Beyond that time it is unlikely that something is going to -- that something is going to be demonstrated in the literature, and that may vary, depending, there may be exceptions to that, of course, with large studies that have required follow up, or if you are asking a question about not immediate benefit but rather long-term, such as five-year benefit down the road as in cancer therapy, for example, so it does depend a lot on the outcome measure, but in terms of immediate peri-operative or hospital mortality, those types of evaluations, there is no reason to expect it shouldn't be available within a reasonable period of time such as one to two years.

MR. WARDEN: Your Honor, I believe that's all I have at this time.

THE COURT: All right. Counsel, do you want to start now or do you want to take our break now?

MS. STRAUSS: I would prefer, Your Honor, to take our break now if that's okay with you.

THE COURT: All right. That will be fine. I take it that's acceptable with you, counsel?

MR. WARDEN: Yes.

THE COURT: We'll take our 15-minute break now and we'll start again. Doctor, you may step down, sir.

(Recess from 10:19 to 10:38 a.m.; all parties present)

THE COURT: Doctor, would you retake the witness

stand, please?

(Dr.Mazareigos resumed the witness stand)

THE COURT: Counsel, you may inquire.

CROSS-EXAMINATION

BY MS. STRAUSS:

Q. Thank you, Your Honor. Good morning, Doctor.

A. Good morning.

Q. I'm Nan Strauss for the plaintiffs. Doctor, you're not an expert in obstetrics or gynecology; is that correct?

A. That's correct.

Q. And you have never performed an abortion; correct?

A. Correct.

Q. And approximately how many abortions have you seen performed?

A. Less than five.

Q. And all of those were during medical school before or during 1986; is that right?

A. That's correct.

Q. And all of those were first trimester procedures; correct?

A. I believe so, um-hm.

Q. You have never been taught how to perform an abortion; correct?

A. Correct.

Q. And you have never studied abortion at all; is that

right?
A. That's right.
Q. You have never written any papers on abortion?
A. No.
Q. And you've never conducted any peer review for a journal with respect to any articles on abortion procedures; have you?
A. I have not.
Q. You have never given lectures on abortion; is that correct?
A. That's correct.
Q. And you have never taught medical students or residents about abortion; correct?
A. That's correct.
Q. And so you wouldn't consider yourself an expert on abortions; would you?
A. I would not.
Q. Doctor, you first became involved in this case when Dr. Curtis Cook, one of the defendant's expert witnesses, called you and asked you to consider testifying; is that correct?
A. That's true.
Q. And so the Government learned about you from Dr. Cook; is that right?
A. I believe so.
Q. The Government subsequently contacted you and asked you

to be an expert witness in this case; is that correct?
A. That's correct.
Q. And you agreed to testify for them; correct?
A. Yes.
Q. And you understand that this case is challenging the constitutionality of the Federal Partial Birth Abortion Ban Act of 2003, is that correct?
A. That's correct.
Q. And you submitted an expert report in this case; correct?
A. Yes.
Q. But when you prepared your expert report, you had not yet reviewed a copy of the Act; isn't that right?
A. That's correct.
Q. And you testified at a deposition in this case; didn't you?
A. Yes.
Q. But before testifying at the deposition, you hadn't read the Act; had you?
A. That's correct.
Q. Have you read the Act now, Doctor?
A. I have received a copy of the Act, but I have not read the Act.
Q. Thank you. And in preparing your expert report for this case, you did not review any articles about abortion

procedures; did you?
A. No, I didn't.
Q. And you did not review any studies about abortion procedures; did you?
A. No.
Q. And you did not review any of the statements made by plaintiffs or experts in this case who perform abortions; did you?
A. Only those expert reports that were submitted by the -- Dr. Howell and Dr. Newland.
Q. Okay. You did not review any other documents about abortion procedures; did you?
A. I did not.
Q. Doctor, you don't know how a D & E abortion is performed; do you?
A. I don't.
Q. And you don't know how the intact variation of the D & E abortion is performed; do you?
A. No.
Q. Doctor, you have no opinion on the safety of a D & E as opposed to the safety of the intact D & E variation; do you?
A. No, I don't.
Q. And you have no opinion as to whether the intact D & E technique is outside the standard of care; do you?
A. No.

Q. And you have no opinion on whether the intact D & E is an innovative surgical technique or a minor variation on an established technique; do you?

A. No.

Q. You have no opinion as to whether the intact D & E is a significant modification of a standard technique; do you?

A. No.

Q. And you have no opinion as to whether the intact D & E is a new technology; do you?

A. No.

Q. And you have no opinion as to whether the intact D & E procedure is an experimental therapy; do you?

A. No.

Q. In fact, Doctor, you have no opinion about the Partial Birth Abortion Ban Act of 2003, the Act that's being challenged in this case; do you?

A. That's correct.

Q. Doctor, do you currently sit on the institutional review board or IRB of the University of Pittsburgh?

A. I don't currently sit on it. I have sat on the corresponding board for the Childrens Hospital of Pittsburgh.

Q. Thank you. And you testified that you've participated on only one data safety monitoring board; is that correct?

A. That's correct.

Q. And approximately how much time have you spent working on matters related to the data safety monitoring board?
A. It's relatively limited time. For example, in the study, it takes approximately about three hours of time per review session, so that may be over three months' time, and it reviews one particular protocol that's in question by the IRB of the hospital.
Q. And so you testified just now that you spent about three hours over three months; is that to date, on that data safety monitoring board?
A. That's correct.
Q. Your didactic teaching has been limited to classes involving anatomy of the chest, thorax, pelvis, head and neck; is that correct?
A. Yes, generally the human anatomy, correct.
Q. And your clinical teaching involves supervising the training of medical students, residents, clinical Fellows in transplant surgery; is that correct?
A. That's correct.
Q. And you have no experience teaching courses in bioethics or the ethics of experimentation; is that correct?
A. That's correct.
Q. And you're not a bioethicist; is that correct?
A. No.
Q. So you don't consider yourself an expert in bioethics;

do you?
A. I would not consider myself an expert in that, no.
Q. And you have no experience teaching about the history of medicine; correct?
A. I have not taught about the history of medicine.
Q. So you don't consider yourself an expert in the history of surgical evolution; do you?
A. Not in general, only as it would pertain to transplantation, for example.
Q. And you have no experience teaching specifically about the design of clinical studies; correct?
A. That's correct.
Q. Thank you. Doctor, you specialize in performing liver transplants; is that right?
A. That's correct.
Q. I would like to just ask you a few questions about liver transplants generally. Liver transplant procedures are very complex and have a significant rate of complications, organ rejection, and even death; isn't that correct?
A. That's true.
Q. And how long does a liver transplant usually take?
A. It may vary between six to 12 hours.
Q. How many doctors usually participate in a single liver transplant surgery?
A. There is the lead surgeon and then his assistant, his or

her assistants which may include one, two or sometimes three assistants.

Q. And then there are also anesthesiologists?

A. Correct.

Q. Are there also additional residents, or would that be included in the number you already gave?

A. Those would be included among the assistants.

Q. And about how many nurses participate in these procedures?

A. At least two, one scrub nurse and one circulating nurse.

Q. I would just like to go through some of the risks that are inherent in undergoing a liver transplant. As I understand it, bleeding requiring a reoperation occurs in somewhere around 20 to 30% of cases; is that right?

A. The incidences vary, but that has been reported to be that incidence in the literature, yeah.

Q. And there are various types of infection that occur including bacterial, viral and fungal infections?

A. Yes.

Q. And these occur in somewhere around 10% of patients; is that correct?

A. At least 10%.

Q. And although it's much more common that this infection would occur within the first six months after a transplant, the infection could theoretically occur at anytime for the

rest of the patient's life; is that correct?
A. That is true.
Q. And the literature reports rejection in about 40% of cases; is that right?
A. That's correct.
Q. And graph nonfunctions typically report about 5% of the time; is that correct?
A. Right.
Q. In terms of one-year survival rates, which I understand are a little bit different at your institution, but the national data reports about a 13% mortality rate; is that correct?
A. Yes.
Q. So overall, many of the liver transplants, many of the complications of liver transplants could occur weeks, months, or even years after the surgery is completed; is that correct?
A. They are much more common early, but they could occur at any time point.
Q. And in order to assess the morbidity and mortality associated with liver transplants, it would be important to follow up with the patients for many years; is that right?
A. Yes.
Q. And, in fact, you participate in the long-term care of your patients in order to manage their immunosuppression,

manage the medicines used to prevent rejection, and manage the short- and long-term complications related to the surgery and their disease; is that right?

A. That's right.

Q. You agree, Doctor, there are some variations that may occur in the performance of any surgical procedures; isn't that correct?

A. Yes.

Q. For instance, Doctor, you previously testified that sometimes you might need to modify your plan if you find that during the performance of a procedure that one of the vessels of the liver is not suitable for use; is that right?

A. That's correct.

Q. You might also use different or longer instruments depending on the plaintiff's anatomy. I'm sorry. The patient's anatomy; is that correct?

A. Certainly.

Q. And you believe that every body is unique; is that right?

A. Every individual is obviously unique, yes.

Q. And the uniqueness of every patient affects how you go about performing the particular liver transplant surgery; correct?

A. Yes. In transplant, though, as in most procedures, there are general expected findings that would be what you

would be anticipating, and you would -- you would be prepared to encounter those frequently.

Q. But the situation might come up during a procedure where the patient might require you to do something different from what you usually do; correct?

A. It might, yes.

Q. For instance, during a liver transplant, a patient will suffer from excessive bleeding and require transfusion during the procedure, but on other occasions, that would not be necessary; is that right?

A. Yes.

Q. You testified that a liver transplant generally takes between six and 12 hours; correct?

A. Yes.

Q. And you explained in your testimony, in your prior testimony that the difference in length of operating time can be due to the disease state of the recipient and the possibility of a vascular issue that requires a different kind of graft instead of the traditional end-to-end graft; is that correct?

A. That's correct.

Q. And I understand that prior to the transplant surgery, you perform ultrasound tests and angiographic studies to help you formulate a surgical plan for that patient; is that right?

A. Yes.
Q. But even though you performed these pre-operative tests, you may still find that you may need to modify your surgical procedure at the time of the surgery; is that right?
A. Sure.
Q. And on some occasions, you assist other physicians performing liver transplant surgery; is that right?
A. Yes.
Q. When you assist these other surgeons, you sometimes notice differences in how the other physician performs the surgery; isn't that right?
A. Small differences, yes.
Q. For instance, some surgeons like to tie off leading vessels using a suture where others might use electric or heat cautery to control the vessel instead; is that right?
A. Yes.
Q. For example, you prefer to tie off abnormal veins or collaterals as you take down the attachments of the liver, but others might cauterize the veins as they do that, eliminating the need to use ties; is that right?
A. Yes.
Q. And some surgeons may use a knife to make the incision on the skin whereas others may use cautery on the skin; is that correct?
A. Yes.

Q. And a physician may prefer one of these techniques to the other based on the speed of the technique and based on the cosmetic results; isn't that correct?
A. Yes.
Q. And might -- the speed of the technique would affect the overall procedure time; would it not?
A. Yes.
Q. And the overall procedure time would affect the amount of bleeding and the amount of anesthesia given to a particular patient; is that right?
A. The amount of anesthesia time, yes, but not necessarily the bleeding encountered by the patient.
Q. Okay. And is it possible that extending or reducing the anesthesia time or the overall procedure time would have a small impact on the rate of complications or the risk of future complications to a patient?
A. Theoretically, it could be possible, but it would have to be such a large amount of time that practically, we wouldn't really encounter that situation.
Q. And is it less important in this context because the overall risks involved in performing a liver transplant are quite substantial?
A. I would not agree with that. I would say that if every facet that can be controlled in our patients may -- may make an impact, so if it is something that is small but yet

important, it should be carried out. If it's something that is small but not important on the outcome, then it may not, then it doesn't really factor into the decision about whether you do it or not.

Q. And you would agree that there may be variations in skill level from one surgeon to another?

A. To some degree.

Q. Doctor, you agree that some modifications of surgical procedures would be so small that they would not be described in the medical literature; isn't that correct?

A. I do.

Q. And you would agree that not all minor modification in surgery should be put before IRB boards; is that correct?

A. I agree with that.

Q. You would agree that there are disagreements among surgeons and uncertainties as to what is an acceptable variation on a surgical technique versus what is a new or innovative technique that warrants prior IRB review; is that correct?

A. Yes.

Q. And you would agree that there is no consensus among doctors about how to distinguish between variations on existing techniques and true innovations; isn't that correct?

A. There is some -- I should say that the broader the

criteria are, the more agreement that there would be about what constitutes a new procedure and that those, in a broad sense, would be understandable and applicable by most practitioners.

Q. One of the things that doctors do seem to agree on is that change in surgical techniques falls on a spectrum or a continuum between the truly innovative or novel at one end and minor changes that are inherent in and appropriate in surgical practice at the other end; isn't that right?

A. Yes.

Q. And, in fact, this very ambiguity and lack of -- this very ambiguity in the matter is, in part, why the issues are interesting enough for doctors to write articles about the subject; isn't that right?

A. The impetus for writing it is really the clear need for protection of patients and not so much the academic discussion, but really, the patient protection in an age of innovation.

Q. And you would also agree that the articles on this subject that address the issue of novel surgical techniques and variations on established surgical techniques call for further study of procedures that have already been disseminated into practice?

A. Yes.

Q. And the articles also note the higher rate of

complications when a surgeon begins to perform a practice, begins to practice a new surgical technique that typically declines with greater experience; isn't that right?

A. That may be true, yes.

Q. And so the conclusion of these authors who write on these matters has been frequently, including in the case of laparoscopic cholecystectomies, to call for adequate training and expertise before performing such procedures; isn't that right?

A. Yes.

Q. But these -- And the articles including those on performing laparoscopic rather than open cholecystectomies have not called for a legislative body to ban laparoscopic cholecystectomies; have they?

A. They have not.

Q. And the fact that these articles call for additional trials of widely disseminated surgical techniques indicate that there is not a clearly established practice of widespread clinical trials in the field of surgery; isn't that correct?

A. Could you repeat that question, please?

Q. The fact that these articles call for additional trials of widely disseminated surgical techniques, such as the laparoscopic cholecystectomy, indicates that there is not a clearly established practice of widespread clinical trials

in the field of surgery?
A. I would disagree in that clinical trials have played an important role in surgery as they have in medicine, and the call for additional trials is more of an emphasis on how to improve rather than a statement that there hasn't been prior clinical trial experience to document practice in surgery.
Q. In your testimony today, you discuss two statements made by the American College of Surgeons, statement 18 and statement 23 which are also designated as Defendant's Exhibits 647 and 648; is that right?
A. That's correct.
Q. Now, the ACS statement 23 is titled Statements on Issues to be Considered Before New Surgical Technology is Applied to the Care of Patients; is that correct?
A. That's correct.
Q. And statement 18 is titled Statement on Emerging Surgical Technologies in the Evaluation of Credentials; is that correct?
A. Yes.
Q. Now, you would agree that these statements were drafted to guide doctors' use of new technological tools rather than variations or modifications of surgical techniques; isn't that right?
A. They don't use the word tools but use the word technology, and I believe that that is referring to the --

to the specific example referred to, laparoscopic surgery, but is inclusive of a new procedure that might not be anticipated to require new instrumentation but might be a new application of a previously-established procedure and a new indication or other such settings so that the new technology, I don't believe, is only meant to be limited to the use of a new instrument, for example.

Q. But the statements themselves do not refer to variations or modifications on an established surgical techniques or methods; do they?

A. I'm sorry. Could you repeat that one more time?

Q. The statements themselves do not extend their reach from new technology and new tools to modifications or variations on established surgical techniques; do they?

A. Again, they don't mention tools, as far as I'm aware, but they simply use the word technology to describe what would be considered, in the surgeon's mind, a new procedure that hasn't been evaluated before.

Q. But that's your opinion. You don't know that; is that correct?

A. That is my opinion, correct.

Q. In fact, you don't know of any authority for extending the suggestions that the ACS regarding new technologies into the realm of innovative surgical practice other than a single article; do you?

A. Again, I would base my opinion on my general experience with the interpretation of these statutes, and in our surgical practice, the use of these statements like these or these specific ones in residency preparation committees that talk about how to credential students who are learning new procedures, so -- and that some authors extend that in the published literature as well.

Q. You would agree with ACS statement that it is essential that the process of evaluation not impede the timely development or use of the new treatment; wouldn't you?

A. Absolutely.

Q. Doctor, you testified before that the current environment mandates review of innovative surgical practice, but by mandate, you don't mean legally mandated, do you?

A. That's correct.

Q. Now, for a procedure that does not constitute experimentation on humans but could be referred to as innovative surgery, there are no mandatory or legally binding guidelines about how that should be studied; isn't that correct?

A. Hospitals have guidelines that you are required -- that are mandating in terms of their physician staff to follow in terms of presenting innovative practice.

Q. You would agree that voluntary studies and peer review and informed consent sets the guidelines for innovative

surgical practice; isn't that right?
A. Please repeat that for me.
Q. You would agree that voluntary study, peer review and informed consent set the guidelines for innovative surgical practice; isn't that right?
A. I would agree with that.
Q. When designing a clinical study, a doctor would want to consider the statistical power needed to demonstrate that the results of that study were not due to chance; isn't that right?
A. Yes.
Q. And you would agree that when you expect to see major differences between two treatment options, then you would need a smaller study, but when the differences between treatment options will be smaller, then you would need a larger number of patients; isn't that right?
A. Yes.
Q. And, in fact, in some circumstances, because of a very low rate of complications, or because very few patients undergo a particular procedure, it might be impossible within a single institution to get the statistical power that's required to demonstrate the relative safety of a given variation of the surgical procedure; is that correct?
A. Yes, although you would need to design a study, perhaps, to answer the safety issue in a slightly different way or

address that lack of power in the traditional sense by formulating a study to answer the question given the constraints that you have, the smaller patient population or whatever, what-have-you.

Q. One example of this might be the laparoscopic cholecystectomies when they were studied in a single institution, the increase rate of complication that you've described earlier was not initially detected by those single institution studies; is that right?

A. That's correct.

Q. Now, if the condition is one that's unlikely to occur in enough cases to require the statistical power required as you suggested, a doctor might still want to do an observation study; is that correct?

A. Yes.

Q. That's because an observational study would be beneficial to understanding the safety of the procedure; is that right?

A. It could be, um-hm.

Q. So, for instance, if a case series of 1,300 patients was presented where the 1,300 patients obtained a specific procedure -- Withdrawn. I'm going to rephrase that. The case series of 1,300 patients obtaining a procedure were presented and that case series showed a lower rate of complications than the norm, wouldn't that at least suggest

that the procedure was safe and begin to suggest that the procedure was safer than the procedure that it had modified?

A. Could you tell me where it would be presented and what type of setting that would be that you're describing?

Q. It's a hypothetical question, so I'm just asking you about the study itself.

A. The reason I ask would be that the setting in which that study would be described would be important in gauging that answer to the safety or perhaps increased safety because if the data were presented in a published manner, that would be important to gauge. If the data were presented in a peer-reviewed published manner, that would give increased weight to that possible conclusion. If they were not, then it would be difficult to draw conclusions except to say that it has been done at this rate, and that there is this experience. It would be not good to draw a conclusion, you know, based on safety from a noncontrolled type of study, especially if it wasn't published or published in a peer-reviewed setting.

Q. Wouldn't, at least, wouldn't it at least show that in that operator's hands, it was a very safe procedure?

A. Because of the bias that I mentioned earlier in terms of choosing very healthy, the possibility of choosing very healthy patients, the danger in that conclusion would be that the 5,000 operators in the United States would begin to

apply this procedure to their patients which may be radically different than that patient population or themselves in their ability to carry out that procedure not as skilled, and that the results would not be applicable to their situation.

Q. Doctor, you would agree that under certain circumstances, it may be difficult to get a sufficient number of patients who would agree to be randomized between two different treatment options; isn't that right?

A. Yes.

Q. And you agree that it can be incredibly difficult to do a randomized control prospective trial to compare two surgical procedures; isn't that right?

A. It may be difficult, yes.

Q. A randomized prospective clinical trial performed in a hospital would require IRB oversight; isn't that correct?

A. Yes.

Q. IRBs review research that takes place in a particular hospital; isn't that correct?

A. That's correct.

Q. And that's because IRB are generally hospital specific; is that right?

A. Hospital or institution specific, that's correct, yes.

Q. And so a doctor who does not practice at a hospital would not be affiliated with an IRB; is that right?

A. The -- Actually, the way that the -- the IRB who may include oversight of a physician who may have an opinion or is relating to care or relating to the study of a patient, although that doctor may not be affiliated with the hospital, may be from a different institution or may be from an outside center, so it would -- it would survey practice of patients cared for in the hospital but not necessarily by the staff only of that hospital.

Q. I understand your testimony to be that the doctor need not be specifically and permanently affiliated with a given hospital for the care to fall under the IRB, but the care would have to be given at a hospital, affiliated center or facility for that care to fall under IRB guidance; is that right?

A. That's correct, yes.

Q. So a doctor who does not practice at a hospital were at an affiliated center would be unable to conduct a study under IRB guidance; is that right?

A. That physician, if they were conducting studies, would have an informed consent process or depending on the type of study, would have some other type of oversight typically and not necessarily be barred from conducting studies.

Q. But they wouldn't be under IRB guidance; is that right?

A. That's correct.

Q. Now, you're aware many abortions are performed outside

of hospital settings?
A. Yes.
Q. You're aware there are many circumstances in which doctors are not allowed to perform abortions at hospitals; isn't that right?
A. I'm sorry. Could you give me an example?
Q. Of a situation? Can I give you an example?
A. Or just explain that second question.
Q. Why don't I restate it.
THE COURT: Why don't you ask him simply to assume that as true.
MS. STRAUSS: Thank you, Your Honor.
BY MS. STRAUSS:
Q. If it were the case that there are many circumstances in which doctors are not allowed to perform abortions at hospitals, then it would likely make it impossible for doctors who provide abortions outside of hospitals to conduct a study under IRB guidance; is that right?
A. They wouldn't be under IRB guidance, that's correct.
Q. Doctor, I know that you have no experience with abortions, but I would like to discuss with you some of the numbers that might be required to perform a randomized clinical trial in order to compare the intact D & E variation with the D & E. For the sake of this hypothetical, please assume that D & E abortions have a

major complication rate of less than 1%, and assume that physician experience and data collected by practitioners in their own practices showed a comparably very low rate of complications for intact D & Es. Now, do you have any opinion as to how many patients you would need to do a randomized clinical trial comparing the safety of two such procedures involving these low rates of complication?

A. Because I'm not a statistician, I don't have a number that comes to mind except to say it would be larger than if you had expected a greater difference. I just don't know the exact numbers.

Q. Would it be a very, very large number?

A. I would expect that it would be, would require a thousand patients or more.

Q. And, in fact, you don't think that people would want to do such a randomized clinical trial; do you?

A. There may be other ways to evaluate it other than the randomized control trial, but I wouldn't agree that people would not want to do that. I think it may be that the community would -- of professionals would see value in that.

Q. Doctor, I would like to show you a copy of the deposition transcript from the deposition you gave in this case.

MS. STRAUSS: Your Honor, would you like a copy?

THE COURT: If it's just going to be short, I don't

need one.

MS. STRAUSS: Counsel?

MR. WARDEN: I have got one.

BY MS. STRAUSS:

Q. Doctor, if you could turn to page 143, please.

A. Yes.

Q. And if you could read to me the testimony beginning on page 143 at line 17 and continue on to the next page, please.

A. Given the question, given the statistics I gave you, do you think doing such a study is feasible? I would probably say people would not want to do that study with those end points and would choose either a different end point or a different type of study that would show a difference. A different type of study might show for safety alone rather than for efficacies or safeties being in a cohort of patients, that there was no difference compared to a historically known data that you may compare it to, that you have or they have.

Q. Thank you. Do you agree with that testimony today?

A. Yes.

Q. Thank you. So you agree that doctors might want to study end points other than major complication rates when determining whether a particular procedure is beneficial to patients; isn't that right?

A. Yes.
Q. And you would agree that some of these other end points would include the time of the procedure, the cost of the procedure and the ease of the procedure; is that correct?
A. Yes.
Q. And other valuable end points to consider might include the amount of blood loss to the patient; is that correct?
A. Yes.
Q. You would also agree that another important end point to consider would be patient satisfaction; is that correct?
A. Yes.
Q. Doctor, you believe the more flexible forms of review, including peer review, provide objective, reliable information about the benefits and risks of surgical procedures to guide surgeons as to the safety and efficacies of new procedure; is that right?
A. Yes.
Q. And some of these more practical forms of review also include observational studies in retrospective reviews; isn't that right?
A. Those are a part of it, yes.
Q. In fact, many studies in the surgical arena are retrospective in design; isn't that right?
A. Yes.
Q. And a large number of retrospective reports regarding

surgery involve single institution case experience; isn't that right?

A. Yes.

Q. And given the challenges and costs of conducting multi-center trials, there will likely be a continued dependence on observational data in shaping clinical practice; isn't that right?

A. In my opinion, those have an important role, but there is an important role for the randomized trial that is supported through other sources, government and industry, to answer questions that are deemed important.

Q. You believe that both overzealous regulation and costly requirements can stifle innovation; isn't that correct?

A. They certainly could stifle.

Q. And you believe that stifling innovation would be bad for medicine; is that right?

A. Yes.

Q. Do you know Dr. Thomas E. Starzl?

A. Yes.

Q. Can you please tell me who Dr. Starzl is?

A. He's the pioneer of liver transplantation and our clinical surgeon and investigator who founded the Transplant Institute in the University of Pittsburgh.

Q. And he's very well respected in the medical profession; is that right?

A. He is very well esteemed as a pioneer in transplantation.

Q. And you consider him to be a brilliant surgeon and a very driven clinician; is that right?

A. Yes.

Q. And in fact, you work at the Thomas E. Starzl Transplantation Institute?

A. I do.

Q. Are you familiar with some of Dr. Starzl's opinions on randomized control trials?

A. I am.

Q. Dr. Starzl believes that if a doctor knows a certain therapy is superior, it would be unethical to subject it to a randomized controlled trial because that would mean denying some patients' aspect to the best treatment; isn't that correct?

A. That's correct.

Q. And you understand this to be Dr. Starzl's position even if he's never before provided the treatment in question; is that correct?

A. He may have that opinion, yes.

Q. You would agree that there is some cases where you as a clinician would feel that there is enough data to support the introduction of a surgical process without conducting a randomized controlled trial; isn't that right?

A. Yes.
Q. Regarding IRB review of innovative treatments, you relied in your expert report on an article titled Introducing New Technologies: Protecting the Subjects of Surgical Innovation and Research for which the lead author is McKnealy; is that correct?
A. That's correct.
Q. And you agree that that article is critical of the IRB process in general; isn't that correct?
A. The general thrust I view as being demonstrative of the need to supplement the IRB, not really focusing on criticizing the IRB, but noting the needs for assessing the innovation that we base commonly how to properly do that, how to keep that accountable, what structures are needed to do that.
Q. And the authors believe that where an innovative surgical procedures falls within a gray zone between a variation on a standard procedure and a unique departure from accepted standards, such procedures should be reviewed in a more flexible manner than is possible under the current formal IRB process; is that correct?
A. Yes.
Q. And do you agree with that opinion?
A. I do. That's why the hospitals have established things like innovative practice committees to sort of fit and fill

that void.

Q. And now, isn't it correct that even a retrospective study of a technique with a very low complication rate may not offer statistically significant results until that technique has been used in an appropriately large number of cases?

A. That is true.

Q. And you agree that in order to properly conduct your retrospective study of the technique, some passage of time must occur after the technique is introduced so that a sufficient number of cases in which the technique is used have occurred; correct?

A. Right.

Q. And that period of time can be years; correct?

A. It can be.

Q. And that period of time depends on the facts and circumstances of the technique involved such as the nature of the procedure; isn't that right?

A. Yes.

Q. And you agree that if a procedure is outlawed before it has been performed a sufficient number of times to properly conduct a retrospective case control study, then such a study could never be performed; is that right?

A. If the procedure is outlawed, then it wouldn't be performed, yes.

Q. If a procedure is outlawed, then --
A. I'm sorry. I thought your question was if a procedure is outlawed, then the studies could not be performed.
Q. Yes.
A. If it's not performed, then the studies would not be able to be done, that's correct.
Q. Thank you. Now, Doctor, I notice in an early draft of your expert report the phrase modern preference towards evidence-based review was struck through and deleted from the first paragraph so that this phrase does not appear in the first paragraph of your later and final drafts of that report; is that correct?
A. That's correct.
Q. And you believe that the term evidence-based medicine is very much in vogue now, but it has mainly applied to internal medicine and drug therapies; isn't that right?
A. That's where it originated, yes.
Q. And, in fact, you removed that phrase from the first paragraph of your expert report because you didn't feel evidence-based review was the common expectation in surgical care; isn't that correct?
A. I don't know if I phrased it in that way, but I think if I would -- I removed it because the term is a little bit misleading in that it suggests that we would not want to suggest, for example, that everything in surgery is done by

-- because of evidence-based randomized trials. That would be misleading. However, to say that evidence-based approaches to surgery aren't important would be not true, and that the focus, I think what I replaced that with was an emphasis on some type of accountability and some type of proper informed consent guiding an absolute across-the-board type of requirement.

Q. Doctor, could you please turn to your deposition again?

A. Um-hm, sure.

Q. And take a look at the top of page 61, please.

A. Okay.

Q. And could you please read from line 2 to line 7?

A. I didn't feel it was the common expectation reflected in our surgical care as opposed to peer review or informed consent, so I thought it more accurately reflected the state of where we are now to put peer review guidelines and informed consent in that section.

Q. And that was your answer to the question of why you made that change in your expert report; is that correct?

A. Yes.

Q. Do you agree with that statement today?

A. Yes.

MS. STRAUSS: Thank you very much. Just a moment. May I confer with counsel, Your Honor?

THE COURT: Sure.

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

REDIRECT EXAMINATION

BY MR. WARDEN:

Q. Doctor, while you have your deposition right there, I would like to just briefly read the next question that followed the discussion of evidence-based review. I'll ask the question. Perhaps you could read your answer in your own words. The question presented to you there was, do I understand you correctly that you don't think evidence-based review is the standard for surgery, study of surgery; is that correct? And there is an objection there by me to that question, and what was your answer to that?

A. I said I wouldn't say that. I would prefer to clarify that we care about evidence-based approaches to surgery, but that there is a clear and established area of requisite guidelines for informed consent and peer review research or of innovative practice that exists today. Evidence-based surgery would be considered important by any practitioner now but doesn't cover all of the surgery that is done.

Q. Doctor, you were asked to be a rebuttal expert in this case; is that your understanding?

A. Yes.

Q. And do you know who you were asked to be a rebuttal expert to?

A. I suppose to the experts of reports that I reviewed of Dr. Howell and Dr. Newland.

Q. And do you recall in responding to specifically Dr. Newland's report, do you recall he mentioned the laparoscopic cholecystectomy example?

A. I believe he did.

Q. Doctor, just generally, what's the basis for your knowledge about the development of new surgical techniques?

A. Because transplant is a field that's inherently innovative and has been at the forefront of innovation and of controversy in some regards to care of patients who need innovative procedures, we, by our daily or regular work with these issues of proper study design, proper investigative methods, oversight that is being required by hospitals and the IRB to satisfy requirements, this is our usual environment in which we have to apply our care in order to both innovate but do so safely.

Q. Would you say that your basis is based more upon your own clinical experience or just pure academic research?

A. My basis is, the basis for my opinion is based on my practical clinical experience and day-to-day execution of these protocols and carrying out of both surgical techniques and in patients on a very practical level, not so much an academic level.

Q. Doctor, back to the laparoscopic illustration for a

moment. Are you aware of any legislative bodies or state medical associations or boards that took steps to regulate that procedure in any way?

A. The registries that were established did include some bodies of state authority that were involved in some states, I believe, particularly New York, because the data were detected in that body.

Q. Doctor, we touched on the American College of Surgeons' guidelines, and I believe you said those guidelines are voluntary?

A. Yeah.

Q. How would you characterize the existence of those guidelines as well as innovative practice committees within the field of surgery?

A. Those guidelines are used very seriously by practicing surgeons and hospital committees that seek to make sure that the surgical procedures being carried out in their -- under their auspices are in compliance with quality surgeon guidelines, that their residency programs are in compliance with these stated guidelines, and that -- so that their care is delivered in an optimal fashion or at least a fashion that would be recognized as a goal by such bodies such as the College of Surgeons.

Q. I wanted to clarify the point on the institutional review board. Could a physician outside of the hospital

setting bring a potential protocol to a hospital to submit that for study and analysis?

A. Absolutely, yeah.

Q. Doctor, would you -- Would disagreement between physicians in the relevant discipline be a reason to conduct a peer-reviewed study of a new procedure?

A. I think so, because there is enough of uncertainty about certain issues that that may prompt, then, a more definitive answer to that question, and that could be done in the form of a study.

Q. Doctor, on cross-examination, Dr. Thomas Starzl's name was brought up, and I would just like to ask you briefly what your relationship is with Dr. Starzl.

A. I'm a faculty member, you know, on his staff, and he's a clinical director emeritus, not active clinician at this time, but we interact in terms of patient issues that may relate to more innovation such as newer protocols, how we can bring newer therapies to the clinic because, for example, I have the responsibility of the direct patient care, and so we interact regularly about those type of ideas.

Q. And could you explain what Dr. Starzl's views are, to the extent you know them, on study of new surgical procedures?

A. As mentioned by the attorney, his view often may be that

it would be considered unethical to study a procedure that the surgeon felt would be inherently optimal or inherently superior to another one even though data may not exist to support that assumption.

Q. And are there any disadvantages to that philosophy with respect to applying surgical procedures in a very widespread application to a very large patient population?

A. There are many, many disadvantages to that. Dr. Starzl is a brilliant physician, many times is right. And -- but the disadvantages of that are that the hunches may be, A, wrong, and therefore bring about unexpected side effects to patients who might have another alternative therapy that might be less than 100% successful but successful in the majority of patients, whereas the projected therapy might bring about a significant change in therapy but also cause mortality, say, in a greater than expected number of patients.

The second problem with that would be even if you are right, that if you institute study or institute a practice without proper documentation, the general acceptance in the medical community may suffer, and so the perception of Dr. Starzl in the wider medical community in regards to the efficacy and veracity of some research outcomes is widely questioned because of the lack of randomized controlled studies to document his findings, though he may, because of

his unique insight, be true, it hinders the advancement of that idea in the widespread medical community who look for some evidence, look for some study that documents the hunches of investigators.

Q. Thank you. Doctor, are you aware of any published literature that supplies the statements from the American College of Surgeons to innovative practice or new surgical procedures?

A. One of the articles I relied on in my testimony is the statements to form a basis for some of their discussion on the need for study an oversight of innovative procedures.

Q. Could you look at the Defendant's 618? Is that in that binder there?

A. I think it's in the other one.

Q. Just so it's clear for the record, was this the article that you were referring to just a moment ago?

A. Yes, this is the article, Ethical Regulations for Innovative Surgery by Reitsma and Moreno.

Q. What publication did that appear in; do you know?

A. This is in the Journal of the College of Surgeons.

Q. Is that a reliable publication within the field of surgery?

A. Yes, very reliable.

Q. Doctor, just briefly on cross-examination, you were asked about the size of certain studies. You said there

were other end points that you could look at. Would that impact the size of the study depending on the end points that you were looking at?

A. Yes, it could. For example, if you chose, if you chose a different type of safety end point other than just survival, that you may be able to structure a proper study with fewer number of patients.

Q. And, Doctor, just final question, could you just summarize again the current state of affairs with respect to the development of new surgical procedures?

A. Certainly. I believe that the best way to summarize it would be to say that we are in an age that is has been characterized by dramatic innovation which has helped to improve patient care for many, many, many patients. However, the dramatic drive and the proliferation of such innovation has resulted in a clear call, a clear need that is passed on to us as practitioners to properly document the safety of these innovative procedures, to properly document the rationale, and not only going beyond informed consent, but describing in some kind of accountable process whether it be through an IRB or innovative practice committee or a peer review process of presenting the results of your study so that an assessment can be made in the general community about its potential role, and that then decisions from that can be made about further study.

MR. WARDEN: Thank you very much, Doctor. No further questions, Your Honor.

EXAMINATION

THE COURT: Thank you. Doctor. I just have a few questions of you. Once in a while I have a conversation with physicians and surgeons and academic physicians and surgeons, and they frequently tell me how tedious and obvious lawyers are, and I'll try not to be. It brings me in mind of the pathologist who testified in a murder case, and the defense lawyer got up and asked the pathologist whether the victim was dead when he began the autopsy, and the pathologist looked at the guy and said, you moron, he was screaming throughout it, so I'll try to avoid that.

I want to ask you about the performance of laparoscopic gallbladder surgery for a moment. Do I recall correctly that there was some bit of a turf battle about who was doing those, that not only surgeons were doing that but that sometimes nonsurgical folks, nonsurgeons were doing that?

THE WITNESS: That has occurred in some of the noninvasive procedures, but that generally was the issue with vascular procedures such as radiologic treatment of aneurysms versus vascular surgical treatment. It generally wasn't an issue in the treatment of laparoscope -- or of gallbladder surgery. That was generally always under the care of general surgeons who were learning the laparoscopic

techniques.

THE COURT: All right. In that connection, well, in the connection of that innovation or that new surgical technique, obviously, it was done before it was studied.

THE WITNESS: Yes.

THE COURT: And I presume that there was a fair number of those laparoscopic procedures done in the hospitals throughout the country; is that right?

THE WITNESS: That's correct.

THE COURT: Now, for the surgeon, the surgeons who participated in those procedures prior to the time that they were studied, they wouldn't have violated the standard of care; would they?

THE WITNESS: No. They, in some cases, they did proceed through some type of review process that was perhaps local in their own hospital and the -- because they estimated that they were doing the same procedure within another established technique, they often concluded that it was not differing from the standard of care but would be more of a modification.

THE COURT: And that brings me to your definition of major modification. I understood you to say that major modification arises when you alter the -- you change the risk/reward ratio to the patient; is that right?

THE WITNESS: Yes.

THE COURT: And that's a perceptual question on the part of the surgeon, I take it?

THE WITNESS: That is true. I think that it is important, for that reason, because you may have a misperception or we may have a tendency to under estimate the potential risk, as was the case in this situation, that this has prompted the need for these type of review boards from being comprised of individuals outside the immediate surgical group or the immediate discipline to assess whether there may be unanticipated risks.

THE COURT: If you have a small group of surgeons who -- if your universe is very small, which is the case, I think, in this legal case.

THE WITNESS: Um-hm.

THE COURT: Fairly small universe of people who are doing D & Es or intact D & Es, and there is a general consensus among that small group, not saying there is or isn't, but assume that there is, that there is no appreciable risk, how does your testimony fit in that circumstance?

THE WITNESS: One would caution that, as has been the case, say, for example, in this situation, that until there is -- until there is either an outside body of review or until there is a demonstration of the safety efficacy of a procedure, even though there is consensus within the small

body that there exists such a high likelihood of bias that it's impossible to draw a conclusion to support that without some type of peer review literature to support that or some type of outside review that would be more objective, so that the similar or a parallel mistake may not occur as did in the case of the gallbladder surgery.

THE COURT: The smaller the population, the less the population is going to be aware of its bias, I presume. Is that fair?

THE WITNESS: I think that's very, very true.

THE COURT: Okay. Let me ask you about your own practice. Have you made major modifications in a technique?

THE WITNESS: I have made some minor modifications in a technique.

THE COURT: No, I'm talking about major modifications now.

THE WITNESS: Yes. I have participated in that development, but I have not authored on a particular major modification to transplant, for example.

THE COURT: Have you done case studies on your modifications, whether major or minor?

THE WITNESS: Yes.

THE COURT: Would you give me an example?

THE WITNESS: Sure. The modification of the live donor transplantation from an adult to child, extending that

to adult to adult donation, extending that modification into a different patient population, for example, has required study that we have done.

THE COURT: Pardon me for interrupting. I'm more concerned with not population selection but surgical technique.

THE WITNESS: Um-hm. One technique that I have authored on is the modification of a type of shunt surgery that is used to treat portal hypertension in children, and we -- I and my colleagues participated in a modification of that technique in terms of how the anatomy was hooked up to facilitate the procedure.

THE COURT: How you dissected to put the shunt in?

THE WITNESS: Exactly.

THE COURT: And I take it there is two different dissection techniques or maybe multiple dissection techniques.

THE WITNESS: Correct.

THE COURT: You favored a particular dissection technique and other surgeons at other transplant hospitals have written another.

THE WITNESS: That's correct.

THE COURT: What did you do to test the hypothesis yours was superior?

THE WITNESS: Our analysis consisted of a

retrospective case series with historical controls to look at patients who had had shunts, shunt surgery using this adrenal approach versus those who had not. The population is somewhat small because children don't have this disease process very often, so it was limited to about 30 patients in total.

THE COURT: So you didn't have statistical significance?

THE WITNESS: No, we could only demonstrate that the efficacy seemed to be a long -- long term in terms of patency and those types of analysis that we do on these vascular procedures.

THE COURT: So you're still doing the procedure you wrote on.

THE WITNESS: Yes.

THE COURT: And the other institutions, are they still doing the procedure that you compared against?

THE WITNESS: I believe so, yes. Yes. There may be some, there is some new other institutions have subsequently written on their experience with it to substantiate it, but there may still be a varying practice of that.

THE COURT: Sure. With this shunt procedure, did you submit it to a peer-reviewed journal?

THE WITNESS: I did.

THE COURT: All right. And it was published?

THE WITNESS: It's published in the American College of Surgeon -- Journal of the American College of Surgeons.

THE COURT: Thank you, Doctor. I found your testimony very helpful. I will let the lawyers follow up, first for the Government, then the defendant, then the Government. Go ahead, counsel.

REDIRECT EXAMINATION

BY MR. WARDEN:

Q. A few questions, Your Honor. May I approach, Your Honor?

THE COURT: Sure.

BY MR. WARDEN:

Q. Would you identify that document, Doctor, please?

A. This is an article that I authored called A Technique for Distal Splenoadrenal, s-p-l-e-n-o-a-d-r-e-n-a-l, Shunting in Pediatric Portal Hypertension.

Q. Was that the article that you authored that you were just discussing with the judge?

A. It is, and there is another article that I was not a co-author on that compliments this article in our patient population, yes.

Q. Okay. Doctor, why would it be or why should doctors outside of physicians who actually perform these surgical

procedures be involved with reviewing the safety and efficacy of a surgical technique?

A. I believe that it helps in assuring as minimal a bias as possible and optimizing a more objective review of the procedure in question.

Q. Doctor, I don't know if the binder is there, Defendant's 627. Is that there as well?

THE COURT: No, it won't be. You'll need to get him volume, get the doctor volume 3, I think. I'm wrong again.

THE WITNESS: I see it.

BY MR. WARDEN:

Q. Doctor, what is that article?

A. This is an article by Strasberg and Ludbrook entitled Who Oversees Innovative Practice: Is there a structure that meets the monitoring needs of new techniques.

Q. Do you know what journal this was published in?

A. This was published in the -- also in the Journal of the American College of Surgeons.

Q. I believe you said earlier this is a reliable publication?

A. Yes.

Q. And, Doctor, you relied on this article in forming your expert opinions in this case; is that correct?

A. I did, yes.

Q. And does this article accurately summarize, at least in part, the development of the laparoscopic cholecystectomy procedure on pages 938 and 939?

A. It gives an overview of that, yes.

MR. WARDEN: Okay. That's all, Your Honor. Thank you.

MS. STRAUSS: I have just one question, Your Honor.

THE COURT: Go ahead.

RECROSS-EXAMINATION

BY MS. STRAUSS:

Q. Doctor, despite the fact that laparoscopic cholecystectomies showed an increased rate of complications, they are still quite frequently performed; is that correct?

A. Yes.

MS. STRAUSS: Thank you. That's all. Thank you, Your Honor.

THE COURT: Redirect?

REDIRECT EXAMINATION

THE COURT: Just because you have the opportunity doesn't mean you have to.

MR. WARDEN: I get all the bang for my buck I can get here, Your Honor. There is my last witness.

THE COURT: Now, listen. Doctor, you are a guinea pig is what you are.

THE WITNESS: I haven't signed an informed consent

for this question.

BY MR. WARDEN:

Q. Right. Doctor, although laparoscopy is performed presently today, how would you characterize the development of that procedure to the point we are today?

A. Right. The issue that is important there is that it has been extended beyond the field of cholecystectomy or gall-bladder removal to many, many different operations in the abdomen which are now being attempted by laparoscopic approach, and this has then raised serious questions about whether it's truly beneficial to do these approaches so that in the laparoscopic technique, because it can be done, it is being done, but there is no data to support the extension of the laparoscopic technique, and this is what is being questioned in several trials to look at what evidence exists for extending this approach to others, other operations such as splenectomy or colon resection, for example.

MR. WARDEN: Thank you, Your Honor. That's all. Thank you.

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

MR. WARDEN: He may, Your Honor.

THE COURT: You're excused, sir. All right. Counsel, it's about noon. Shall we take our break?

MR. WARDEN: Yes, that's fine with me, Your Honor.

THE COURT: Is that agreeable?

MS. SMITH: Yes, Your Honor. We have one issue that we'll need to raise with the Court before the testimony of the next witness, but we can do that when we come back.

THE COURT: Well, we can do it now as well. I have got a criminal sentencing over the noon hour. It will start at 1:00. I should be done at 1:30. If you want to take it now, why don't we?

MS. SMITH: Why don't we. Your Honor, I was just informed by the defendants this weekend that Dr. Bowes who is their next witness --

THE COURT: Um-hm.

MS. SMITH: -- will be testifying about Dr. Chasen's article. That's the article that we moved into evidence recently. It's the retrospective study.

THE COURT: Give me the number again.

MS. SMITH: I believe it's 27 or 47 -- I'm sorry, Your Honor. I think it's 27.

THE COURT: 27 is called Dilation and Evacuation.

MS. SMITH: That's it.

THE COURT: Plus or minus 20 weeks, comparison of operative techniques.

MS. SMITH: That's it, Your Honor. That's the one.

THE COURT: I have not received that.

MS. SMITH: Right. That is one we moved and you

had withheld.

THE COURT: Until --

MS. SMITH: Your ruling until the further briefing.

THE COURT: Well, hopefully you all will agree though that before -- before we go to the briefing thing.

MS. SMITH: That would be nice. Your Honor, here is the issue.

THE COURT: Hold it.

MS. SMITH: I'm sorry.

THE COURT: To put it in perspective, Chasen's article was used in sort of a learned treatise. Part of it was used in a previous witness.

MS. SMITH: That's right.

THE COURT: So now --

MS. SMITH: Dr. Chasen himself is testifying in the New York case, and he's one of the witnesses whose transcript we are offering here.

THE COURT: Um-hm.

MS. SMITH: And Dr. Lockwood who is one of the defendant's witnesses who had expressed opinions about that article at his deposition and disclosed that he was reviewing it and relying on it, and that he would have opinions about it. None of the other witnesses of the defendants disclosed that they didn't supplement their disclosures in any way. They never told me Dr. Bowes had

even seen it. I have no idea what his opinions are about it. There is one hypothetical question that was raised in the deposition that arguably relates to this article and issues around it, and so that I perfectly, of course, he can testify about that. That's an issue that was explored at the deposition, and I'm happy to have him testify about it and to cross-examine him on it, but other than that, I have had no opportunity to find out what Dr. Bowes thinks of this article, what criticism's he's going to have. I can try to guess.

THE COURT: Was this article in existence at the time the doctor was deposed?

MS. SMITH: Yes, Your Honor. And in fact, Dr. Lockwood's deposition was two days before Dr. Bowes' deposition, and Dr. Lockwood had received a copy of the article, had reviewed it. There is issues about protective orders, but he was able to see the article, sign the protective order, go through all that rigmarole and we had, you know, noticed the deposition of Dr. Chasen previously, we listed him as an expert, we noticed it as a trial dep. It was clear that -- that the plaintiffs were anticipating having him testify in some capacity, if not through deposition, then some other way.

THE COURT: So what do you understand Dr. Bowes is going to talk about?

MS. SMITH: Well, I have no idea what he's going to say about the article.

THE COURT: Did you get a written supplementation to his written report?

MS. SMITH: No, Your Honor, I got nothing. I understood from the defendants last week that their experts wanted to be able to talk about this. I assumed that meant Dr. Lockwood because Dr. Lockwood had disclosed that, and we had deposed him on it and had an opportunity. It was only this weekend talking, consulting with Mr. Henry that I learned that Dr. Bowes and, I believe, Dr. Sprang were expected to testify about it and not Dr. Lockwood.

THE COURT: Did Dr. Bowes express an opinion either in his report or his deposition about the comparative risks of operative techniques?

MS. SMITH: Yes, Your Honor. He says that he thinks the intact procedure is comparable, has the same level of risk as the other procedures.

THE COURT: So the subject matter doesn't surprise you.

MS. SMITH: No, not the subject matter, but what his specific criticisms or comments will be about this article, I have had no opportunity to depose him on. I'll do my best, Your Honor, if that's what Your Honor wants, but I just -- I want everyone to know I don't know what's

coming.

THE COURT: Okay. Here is typically how I deal with these.

MS. SMITH: Um-hm.

THE COURT: If the subject area was clearly a part of the doctor's disclosure to you and he was deposed on it, and he didn't mention an article that now he wants to mention, two things: As the finder of fact, I wonder why. I mean, if this is a big enough deal to mention it during your testimony, why in the world wouldn't you visit with counsel about that, so it affects the doctor's credibility conceivably, but it doesn't seem to me that it ought to -- you ought to be terribly surprised. It seems to me the subject matter is, you know, the area of comparative surgical risk, there is a whole body of evidence and an expert designated to testify on that subject ought not be required to laboriously identify each thing he's read, so that's my general sense. Tell me why I'm wrong.

MS. SMITH: Well, Your Honor, I wouldn't say you were wrong completely. I would say you're wrong if he's going to come in now and say now I have looked at this other document, and my opinion previously these were comparable risks has changed. I think this shows something else. I think this study was flawed for the following 25 reasons. That's the kind of thing I'm concerned about. If he comes

in and says here is another example of something in the literature that supports my view that they are only comparable, one isn't better than the other, then, now, I can deal with that. I have no idea if he was going to come in and say it suddenly changed his opinion in some way or if he has some procedure, sort of structural comments and criticisms of the study that I haven't had a chance to post on.

THE COURT: Here's what we are going to do. I'm going to let you talk to the doctor over the noon hour in the presence of defense counsel. It's not a deposition, but the doctor will, I'm sure, and the lawyers can give you a brief thumbnail sketch of what he's intending to do, and then if you think it's a big deal, we can take it up at 1:30. I'll hear from Government's counsel before I finally rule.

MS. SMITH: Okay. Thanks.

THE COURT: Counsel?

MR. HENRY: That's fine, Your Honor.

THE COURT: All right. If you would have the doctor just in a -- give a fair summary of what he's going to say about this Chasen article so counsel has a sense of it, that would help us move things along.

MS. SMITH: That's great, and Your Honor, just one housekeeping thing also which is that I neglected, I need to

put on the cover of the exhibit a statement that protects the copyright of the journal, and so I have --

THE COURT: Of which one?

MS. SMITH: Of the Chasen article of Exhibit 27.

THE COURT: Oh, my, I don't want to violate copyright rules. Please do.

MS. SMITH: We got special permission to use it ahead of its publication date.

THE COURT: Yes, please do whatever you need to do.

MS. SMITH: I would like to substitute that and I will show it to counsel first obviously.

THE COURT: Do it in conjunction with the courtroom deputy.

MS. SMITH: Thank you.

THE COURT: All right. As I indicated, I do have matters in here over the noon hour. You can leave your things, but take anything that's real important. We stand in recess.

MS. SMITH: Thank you, Your Honor.

THE COURT: You're welcome.

(Recess from 12:03 to 1:35 p.m.; all parties present)

THE COURT: Mr. Henry?

MR. HENRY: Thank you, Your Honor. Defendant calls Dr. Watson Bowes.

DR. WATSON A. BOWES, JR., DEFENDANT'S WITNESS, SWORN

THE COURT: Before we proceed, Ms. Smith, did you have an opportunity to visit with the doctor over the noon hour?

MS. SMITH: Yes, I did. Thank you.

THE COURT: Will that be sufficient?

MS. SMITH: Yes, Your Honor.

THE COURT: Thank you. Go ahead, counsel.

DIRECT EXAMINATION

BY MR. HENRY:

Q. Thank you, Your Honor. Good afternoon, Dr. Bowes. Could you tell us what your profession is?

A. I'm an obstetrician/gynecologist.

Q. And can you tell us your current position?

A. My current position is Professor Emeritus of Obstetrics and Gynecology at the University of North Carolina in Chapel Hill.

Q. Are you licensed to practice medicine?

A. I am.

Q. In what states?

A. North Carolina.

Q. Are you board certified in any particular field?

A. I'm board certified in obstetrics and gynecology and in the subspecialty of maternal fetal medicine.

Q. Can you tell the Court what maternal fetal medicine is?

A. Maternal fetal medicine is the subspecialty of

obstetrics and gynecology with deals largely with high risk pregnancy and fetal diagnosis and fetal therapy.

Q. Doctor, could I ask you to take a look at Defendant's Exhibit 525? It should be in the binder right there in the corner.

A. Yes.

Q. And, Doctor, can you tell us what that is?

A. This is my curriculum vitae.

Q. And it has certain personal information that has been redacted; is that correct?

A. Yes, it has.

Q. Other than that redaction, is the Defendant's Exhibit 525, is it complete?

A. It is complete.

Q. And is your CV up-to-date?

A. Yes, it is.

Q. And does it accurately reflect the matters depicted therein?

A. Yes, it does.

MR. HENRY: Your Honor, defendant moves for the admission of Defendant's Exhibit 525.

MS. SMITH: No objection, Your Honor.

THE COURT: It's received.

BY MR. HENRY:

Q. Dr. Bowes, can you briefly provide us with a summary of

your educational and residency background beginning with your graduation from medical school?

A. Yes. My graduation from medical school was -- My medical school was the University of Colorado Medical Center in Denver, Colorado. I graduated in 1959 after which I did a year of residency, of internship at the Mary Hitchcock Hospital in Hanover, New Hampshire, which is associated with Dartmouth Medical School. That was followed by one year of general practice residency at the University of Colorado in Denver, after which I did a Fellowship at the same institution in fetal physiology after I spent three years in the obstetrical and gynecological residency at the University of Colorado completing that in 1965.

Q. What did you do after your residency?

A. After my residency, I entered a private practice in partnership with one other person practicing obstetrics and gynecology, and at the same time was part-time faculty member at the University of Colorado. Then in 1967, I was inducted into the Army Medical Corps and was stationed at Madigan General Hospital for two years. That was in Seattle, Washington, and Seattle/Tacoma area during the Vietnam War, and I completed that service in 1969 whereupon I returned to the fulltime faculty in the Department of Obstetrics and Gynecology at the University of Colorado.

Q. Can you tell us a little bit about your responsibilities

as a faculty member at the University of Colorado?
A. My responsibilities were in teaching obstetrics and gynecology to medical students, to residents and to Fellows in training in obstetrics and gynecology, and also to conduct, we conducted a practice there among the members of the faculty, we had a practice in obstetrics and gynecology.
Q. And what position did you obtain?
A. Initially, I was an assistant professor, eventually promoted to associate professor, and finally to full professor at the University of Colorado.
Q. And you stayed there through 1982, I believe you said?
A. 1982, yes. I was then hired by the University of North Carolina to become a member of the fulltime faculty in the Department of Obstetrics and Gynecology.
Q. And can you give the Court an idea of your responsibilities there at UNC?
A. My responsibilities were similar to those at the University of Colorado. I was involved in the teaching of residents, students and Fellows. I was also a member of the group practice among the faculty members at the University of Colorado, and I might add that at both institutions we conducted certain amounts of research which I participated in and supervised.
Q. I take it that research was in the OB/GYN field?
A. Yes, it was.

Q. And you have remained at UNC up through the current?
A. I have been at UNC until my retirement as a fulltime faculty member in 1999. I still have positions on some committees, especially the IRB, the institutional review board, that reviews research projects for the medical school.
Q. And, Doctor, are you currently involved in any professional or scholarly activities in the field of medicine?
A. My primary -- primary scholarly activity at this time is serving as a co-editor-in-chief of a medical journal and obstetrical journal called Obstetrical and Gynecological Review.
Q. Is that the Obstetrical and Gynecological Survey?
A. Obstetrical and Gynecological Survey. I beg your pardon. I misspoke.
Q. And can you tell us what the Survey is?
A. The Survey is a journal that's published monthly. It abstracts articles from the obstetrical and gynecological literature, and to each abstract is appended an editorial comment. In addition to that, each month are published two or three review articles about obstetrical or gynecological topics.
Q. And can you give the Court an idea of what your responsibilities are on the Survey?

A. Well, as one of the four co-editors, we review the medical literature pertinent to obstetrics and gynecology and select the articles that are to be abstracted. We then write the editorial comments that are appended to those abstracts. We also review all of the manuscripts that are sent to us for publication as review articles.

Q. And how long have you been in your current position on the Survey?

A. Since 1992.

Q. Doctor, have you yourself published any scholarly articles?

A. Yes, I have.

Q. Can you give us an idea of how many?

A. I believe my CV records approximately 140 to 145 articles that have been submitted to journals and accepted for publication, and I have authored or co-authored approximately 25 chapters of textbooks.

Q. And the articles you've written, that sort of thing, have those been published in peer review journals?

A. Yes. Not all of them in peer review journals, but the predominant number are, and those are designated on my CV.

Q. Okay. Have you served as a peer reviewer for other journals?

A. Yes, I serve as a peer reviewer currently for two journals primarily. Obstetrics and Gynecology is the name

of one journal; the other is the American Journal of Obstetrics and Gynecology. From time-to-time I review articles in other journals, but my primary review responsibilities are for the two journals I just mentioned.

Q. With respect to those two journals, can you describe their status in this country?

A. Well, they would be considered the two major journals in obstetrics and gynecology in the United States.

Q. And, Doctor, are you a member of any professional organizations?

A. Yes. I'm a member of the -- I'm a Fellow or a member of the American College of Obstetricians and Gynecologists, and I'm a member of the Society for Maternal Fetal Medicine.

Q. With respect to your being a Fellow at ACOG, have you served in any special capacities with that organization?

A. I served for a number of years, for five years in total, as a member of the committee on ethics, and for three years I was the chairman of that committee.

Q. What does that committee do?

A. That committee is, its primary responsibility is to write opinion papers about matters that deal with various topics of ethics in the field of obstetrics and gynecology.

Q. Doctor, are you familiar with the medical techniques used to perform abortions or terminations of pregnancy?

A. Yes.

Q. May I ask how you're familiar with those procedures?
A. I'm familiar with those procedures by virtue of my residency training and my subsequent practice of obstetrics and gynecology. Those procedures are not involve such things as terminating what are called incomplete miscarriages, and this would be a procedure called a D & C or a dilatation of the cervix and curettage of the uterus. That is the same procedure that has been used for terminating pregnancies, induced abortions. I'm also familiar with the procedure of suction curettage which we use in both of those settings, and I have also am familiar with and have participated in procedures in the second trimester of pregnancy such as induction of labor for fetal deaths, procedures which are similar to procedures that can be used for induced abortions.
Q. You have used the term induced abortions. Do you -- Does that term distinguish something you're doing from other types of --
A. Well, I use that term in distinction to distinguish between abortions which are performed on a live -- when there is a live fetus, and the procedures that are performed after a fetus has died, fetal deaths in utero or earlier in pregnancy are called miscarriages.
Q. And so you have performed the latter; is that correct?
A. I have performed the latter and on some number of

occasions performed those on induced abortions.
Q. Have you supervised induced abortions or terminations of pregnancy?
A. I have.
Q. In what capacity did you do that?
A. I first did that in my capacity as a resident at the University of Colorado where I was supervising junior residents in the performance of induced abortions. Most of those or at least some of those were in the first trimester, and some were in the second trimester, almost all of which were -- had medical indications for abortion. Later, as in my role as a faculty member at the University of Colorado -- excuse me, at the University of North Carolina, I supervised a few abortions when I was the attending physician on the obstetrical service.
Q. Doctor, are you familiar with the term evidence-based medicine?
A. Yes, I am.
Q. Can you tell us how you're familiar with that?
A. Well, I'm familiar with it because of my general acquaintance with the recent medical literature and because it is a term that has been applied to the way in which we are more currently evaluating new medical procedures, new techniques that are introduced into medicine.
Q. You said currently. How long has this been around?

A. Well, evidence-based medicine, to some extent, has been present for many, many years, but that term has been applied more recently in the last 15 to 20 years. That's an approximation, to certain specific epidemiological methods for evaluating new methodologies for evaluating old methodologies which have been reevaluated.

Q. And let me ask you this: Why is the evaluation or reevaluation taking place?

A. I think it has been recognized that -- I know it has been recognized that certain types of studies are more reliable in determining the efficacy and safety of medical practices, whether it be the use of medications or the use of surgical procedures.

Q. Does peer review play a role in evidence-based medicine?

A. Peer review, indeed, does play a role, not only in the formal way of reviewing reports about studies that have been submitted for publication in the medical literature. Peer review means that colleagues with expertise in the general area are asked to review the manuscripts to ensure the studies have been done in a credible manner and that sufficient care has been taken to review the -- to do proper statistics on the data and that sort of thing. There is also peer review of sorts in designing studies. Studies are often designed with consultants or colleagues reviewing the design for the study to be sure it's being done in a way

that it will be substantial and meaningful research.
Q. Could you comment on the role, if any, of intuition and anecdotal evidence under the evidence-based medicine rubric?
A. Well, intuition is often a way that new procedures or innovative procedures are developed. A physician will, by his or her experience, feel that a new procedure, a new manner of dealing with a particular disease, or in the case of new medications, innovations that have come out of the pharmacological research often which begins in intuitive methodology, intuitive insights, and so many of our innovations in medicine have begun as intuition about what probably will be a better way to do something.
Q. Is the approach that you just discussed, is it limited to a pharmacological situations?
A. Oh, no. I didn't mean for it to be limited to that. It applies to innovations of surgical therapy, innovations of selection of patients, innovations of current ways of modifying current techniques or practices of medicine.
Q. Dr. Bowes, could you explain for the Court the types of studies that are typically done in the medical field?
A. There is several levels of studies that are recognized as being of increasingly important value in assessing medical innovations. One is the so-called case series where a physician may report a few patients in which he or she has applied a new method of treatment. That is just simply

reported as a case series. Then the next level are called retrospective studies in which a population of patients in whom a particular type of treatment or a particular surgical procedure has been performed, and that data is collected from records that are kept about those patients, and that is compared with -- to what is called the control group or the standard of care or the care that has been in practice for sometime. Those are retrospective, and that's the next level. At the top of this evidence-based medicine is the randomized controlled trial. Randomized controlled trial is the most elegant type of study because it randomizes patients before the treatment has been applied. By randomizing means it's selected like you would flip a coin so that nobody is biased in their insertion of patients or subjects into the study. That's all done blinded and random, and then the treatment is applied, whether it be a surgical treatment or a drug treatment or whatever, and the patients are followed to a designated end point whereupon one looks for the agreed-upon outcomes, whether it be improvement in the diseased condition, death, duration of hospital stay or whatever. That is called the randomized controlled trial.

Q. Couple of questions on some of the points you mentioned. You mentioned bias. Can you explain what you're talking about in that case?

A. Well, bias has to do with how subjects are included into a study.

Q. And we are talking about a retrospective study?

A. We can be talking about either kind of a study, a retrospective study or a prospective study. You try to avoid bias as much as you can and bias has to do with selecting patients or subjects which have a greater degree of susceptibility to the condition you're trying to study, who may be of different racial mixtures, patients who may be of different, in some studies, the sexual difference makes a difference in outcome, and if you have, in the study, patients that tend to predict a good outcome, you may be biasing the study to an outcome that was, you may do this unconsciously, it's not -- there is no maliciousness about this, but you may end up with a study in which you can't rely on the results because of the way the patients were put into the study.

Now, often in a randomized controlled trial, the most elegant of the studies, this can be avoided because you are trying to eliminate bias by doing this random allocation, flipping the coin, so this patient goes here and that patient goes there, but it's based not on anything but the randomization.

Q. Doctor, a question. You were talking about retrospective studies. Is there also a type of study known

as a retrospective cohort study?

A. Well, there is two types of retrospective controlled studies. And control is a very important thing in this. In other words, if you are looking at a new procedure or you're trying to evaluate a way of doing something, you have to compare it to something, and the cohort and case controlled studies are the kind that are done retrospectively. Let me describe that. The cohort study is where you have, since it's retrospective, the treatments have already been accomplished, but you go back and pick the patients at the onset of the treatment.

Now, let's say we are trying to study radiation therapy against chemotherapy, so you would take patients for a certain kind of cancer. You would take patients who had radiation therapy, and you would take a group of patients who had chemotherapy, and then you would look at how many of them survived, or what their five-year or ten-year survival was. That's called the cohort study. You take these two cohorts of patients and compare them.

Now case controlled study is where you start at the other end. You take the outcome to begin with. By that is, let's say you are going to do a study on patients who have had infections, and you would take all patients who had the infection and then you would go backwards and find out what factors in their histories were different between patients

who had infections against the group of patients who did not have infection. See, the outcome is infection, so you compare the two groups of patients who had infections with patients who had none. That's called case control. You're taking cases and controlling them with those who did not have that outcome. Then you go backwards and see what might have influenced the ability or the likelihood of their getting infection. Were they older, were they younger, did they have certain things happen to them and so forth. That is a case controlled study.

Q. Doctor, you have mentioned things like infection and radiology and that sort of thing. Do the type of study or types of studies that you're talking about, they apply with respect to the surgical field; is that correct?

A. Yes, they apply to the surgical field, obstetrical field. I only use those examples to try to illustrate what type of study it is.

Q. But, Doctor, aren't surgical techniques typically developed through the innovation of surgeons?

A. Yes.

Q. So what's the role of the studies you've talked about with respect to the development of new surgical techniques?

A. Well, a new surgical technique is developed to treat a disease, and by its very nature it's treating it differently than with theretofore being used in the surgical community,

so at some point, one has to determine whether the new innovation is a better way to treat the disease. Are more patients successfully treated? Do more patients get over their diseases, and are there fewer complications than with the old procedure, and you compare them in that way.

Q. And, but isn't it possible that physicians using or developing a technique could make an intuitive assessment as to whether that technique is better or not?

A. Well, I daresay it was, the surgeon's or the physician's intuition that led him or her to develop the innovation, so the answer to that would be yes.

Q. But under the evidence-based medicine rubric, do you have an opinion as to whether it should stop at that point or what should be done?

A. Well, no. The procedure, once introduced, or the new treatment, once attempted, there comes a point at which you really need to confirm with some good evidence that it is a better procedure, or perhaps not a better procedure, and that's where evidence-based medicine gets applied to these new innovations.

Q. Are you aware of any examples in which a surgical or medical technique was thought as an intuitive matter to be safe and effective but was later, or later on that judgment was proven to be untrue after it was subjected to study?

A. Yes. Actually, there are a number of examples. One

very classic example is the use of episiotomy. Episiotomy is a procedure where in the birth of the baby, the obstetrician makes an incision in the lower part of the birth canal to allow easier, to facilitate the delivery of the baby. For years this was a very common, almost routine procedure, particularly in women having their first infant, and it was thought to not only facilitate the delivery but also protect the birth canal from more serious injuries or lacerations, and for 30 to 40 years, that was the common practice until somebody subjected that practice to modern evidence-based medicine. In fact, a randomized controlled trial was set up in which women were randomized to either having the procedure performed or having no episiotomy performed, and it turned out, lo and behold, that the women who had the episiotomy had far more serious lacerations of the kind that eventually can lead to rectal incontinence than women who didn't have an episiotomy, so the procedure was, has now been very strictly limited in the practice of obstetrics. Rather than being used routinely, it's now restricted to very selected patients.

That was a classic example of evidence-based medicine changing practice about a procedure that had long been thought to be clearly in the benefit of the women in whom it was done.

Q. Thank you. Dr. Bowes, are you familiar with the issue

of, we'll call it partial-birth abortion?
A. Yes.
Q. How is that?
A. Well, here I am. I mean -- I was -- first became aware of it in 1995 when I was asked by Congressman Canady at the time that the Congress was having hearings about this procedure, and I was asked to critique some of the statements about the procedure that had been submitted in its behalf, and I wrote a letter critiquing those various statements, giving my opinion about it, and in doing so, I had to become familiar with the procedure.
Q. And have you subsequently been involved in the issue in any way?
A. Yes, I have. I was also asked by the comparable committee in the Senate to submit a letter, and I submitted basically the same letter, and I have also been asked to testify in several of the cases in the federal courts in which state laws were passed banning the procedure and then were enjoined.
Q. Do you know about how many cases you have been involved in?
A. Overall, I think four -- three or four.
Q. And so did you, if I'm understanding you correctly, were you involved in presenting expert testimony to the Court in those cases?

A. Yes, I was.
Q. And to your knowledge, did the Court ever disqualify you as being an expert in those cases?
A. No, they did not.
Q. Now, Doctor, I want to ask you, what exactly do you mean by partial-birth abortion? What does that term mean to you?
A. Well, as I understand that term, it is the -- as it was originally described in going back to 1995 when I was asked to write those letters to the Congressman and to the Senate, it was a procedure which had been described by two physicians in particular, Dr. Haskell and a Dr. McMahon, and that procedure, and there was slight variations on it in their descriptions, but at the time of the abortion procedure, it would begin with the insertion of devices in the cervix called laminaria. These are little bits of sterilized seaweed that expand and make the cervix dilate, open the cervix up. Those were placed in the woman's cervix generally 24 to 48 hours before the actual procedure. During the procedure itself, it was described as the physician making an attempt, and whenever possible, accomplishing what was a conversion of the fetus to a breech presentation where the bottom was coming first, the legs or the bottom and the buttocks. The fetus was then delivered up to the point where the head would impinge on the cervix that was not fully enough dilated for the entire baby to

deliver, and then an incision was made in the fetal skull to allow the insertion of a tube called a suction device, and the brain of the fetus was then suctioned out to diminish the size of the skull so that the baby would then deliver, and that's how it got its name or was termed partial-birth abortion; in other words, the baby was partially delivered and was still alive up to the point when this procedure was done to decompress the head which, then, of course, killed the fetus. Now, that was originally the description that I recalled from my 1995 involvement.

There have been other descriptions of this procedure, one of which was by the American College of Obstetrics and Gynecologists. It's similar to that, but there is some minor modifications. I would have to look at the document that they published, but they describe the procedure and the current Act describes a slightly different procedure, but fundamentally, it involves delivery of partial delivery of a fetus who, at the time of that delivery, is still alive, and then some procedure or some act is performed by the physician that not only ends the delivery but also kills the fetus.

Q. You mentioned earlier Drs. Haskell and McMahon. How did you know that they had described the procedure in a certain way?

A. Well, I read, I read descriptions of it that they had

presented, not together. These were separate, at meetings, and I had copies of their descriptions that they had submitted to the -- for their presentations at the meeting.

Q. Could I ask you to turn to Defendant's Exhibit 580 which is also Plaintiff's Exhibit 70?

MR. HENRY: Your Honor, may I approach?

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

BY MR. HENRY:

Q. Doctor, do you have Exhibit 580?

A. I do.

Q. Could you read the title of that?

A. The title is Dilation and Extraction for Late Second Trimester Abortion. Martin Haskell, M.D., presented at the National Abortion Federation risk management seminar, September 13th, 1992.

Q. And is that the title of the paper that you are referring to when you talk about reading a description by Dr. Haskell?

A. It is.

Q. Okay. Could you turn to Defendant's Exhibit 608 which is also Plaintiff's Exhibit 64? And, Doctor, could you read the title of that document?

A. This document is Intact D & E, the first decade. This was written by James T. McMahon, and presented on April 2nd,

1995, to NAF Conference, the NAF Conference in New Orleans, Louisiana.

Q. And is that the title of the document that you were referring to when you talk about reading a description by Dr. McMahon?

A. Yes, it is.

Q. And could you now turn to Exhibit 651 which is also Plaintiff's Exhibit 6?

A. I think I'm going to need another book here.

Q. Dr. Bowes, looking at Defendant's Exhibit 651, I believe that's the statement of the American College of Obstetricians and Gynecologists, the statement on intact dilation and extraction. Is that the statement you were talking about awhile ago?

A. Correct. This is the one they published in 1997.

Q. Okay. Now, with respect to your familiarity with partial-birth abortion, have you, in this litigation over the Partial-Birth Abortion Ban Act of 2003, reviewed declarations or expert reports submitted by the plaintiffs in this lawsuit as well as the other two companion cases that have gone on?

A. Yes, I have.

Q. Do you know about how many of those you've looked at?

A. Probably 20 or more.

Q. Okay.

A. I can't remember the exact number, but there were a lot.
Q. And are you familiar with the intact D & X or intact D & E procedures described in those materials?
A. Yes.
Q. And you're familiar with it by reviewing, by your review of those documents?
A. By my review of those documents, yes.
Q. Doctor, based on your review and your own knowledge, would you distinguish between an intact D & X, intact D & E on the one hand and a normal, for lack of a better word, D & E resulting in disarticulation?
A. Well, my understanding, these terms, the two first terms you mentioned, intact D & X and tell me --
Q. Intact D & E.
A. And intact D & E are similar procedures. They are describing the same procedure. The issue is that the fetus is delivered intact, I mean, whereas the procedure known as D & E, dilatation and extraction, the fetus is actually removed piecemeal or disarticulated, as the term is often referred to within the uterus, and then various bits and pieces of the fetus are removed in that procedure rather than its being removed more or less intact.
Q. Have you used D & Es in your medical career?
A. Yes.
Q. Have you ever used an intact D & E in your career?

A. No.
Q. Have you ever seen any situation where you perceived the need to use an intact D & E in your career?
A. No.
Q. And have you ever seen a situation where you perceived any advantage to using an intact D & E over other methods of abortion?
A. No, I have not.
THE COURT: Counsel, I'll be very interested in knowing whether the doctor performs abortions now or in the recent past, and whether he uses any of those techniques to do that, and I understand that we can play around with the terminology, but in order for me to fully appreciate his testimony, I'll need to know in depth his background about performing these techniques as opposed to people who have, for example, have come before him.
BY MR. HENRY:
Q. Dr. Bowes, could you address that particular issue as to the techniques you have used for terminations of pregnancy?
A. Yes. I have, my experience in performing these procedures is predominantly in situations where the fetus has died, fetal death in utero, and in which the procedure is done to complete the pregnancy or terminate the pregnancy. In a very few instances, two or three, I have been supervising physician and assisting in the procedure

when it was done on a live fetus while I was a faculty member at the University of North Carolina, so my experience in live fetuses in which D & E have been done is limited to only two or three. My experience in doing it with fetuses that have already died, in which many of the same techniques are involved in doing that procedure, would probably amount to over my entire career a hundred to 150.

Q. Doctor, is it your understanding that certain safety advantages are claimed for the intact D & E procedure over nonintact procedures such as the dismemberment D & E?

A. Yes.

Q. How about, is it your understanding that safety advantages are claimed for the intact D & E over, say, labor induction methods of abortion?

A. Yes.

Q. And can you just give us a summary of what you believe the advantages that are asserted for the intact D & E procedure are?

A. As I understand it, advantages asserted of the intact procedure versus the D & E procedure is that it involves fewer passes of instruments into the uterus itself, and that thereby reducing the risk of injuring the uterus in performing the abortion procedure.

Another advantage is that in removing the fetus intact, a pathologist has a better specimen to evaluate in cases

where there may be some question about fetal diseases or anomalies for which the abortions have been performed and to obtain more information about that. Those are two of the advantages that have been asserted.

Now, in relationship to the procedures performed by labor induction, it's my understanding that the alleged or the asserted advantage of the intact D & E procedure is equivalent to the advantages that the D & E procedure has over those. It has been shown, I think, in some fairly convincing studies that when you compare labor induction procedures to D & E procedures at equivalent gestational ages, there is a lower incidence of complications using the D & E procedure, and because the intact dilatation is a surgical procedure rather than a medical induction procedure, the assertion has been made that they are safer. I don't know of any comparison between those two groups.

Q. Dr. Bowes, are you aware of any published peer review study in the medical literature that has evaluated the safety of an intact D & E versus a disarticulation D & E?

A. No.

Q. Would that include prospective studies?

A. It includes prospective studies and retrospective studies.

Q. Are you aware of any published peer review studies comparing the safety of intact D & E with labor induction

abortion methods?

A. No.

Q. With respect to the medical literature, are you aware of any case series that concerned the safety of intact D & E, peer reviewed or otherwise?

A. Well, the two reports that we just mentioned by Dr. Haskell and Dr. McMahon, both of these physicians have submitted or have compiled series of their own personal experience with it in which they assert that these procedures are safer. Neither of these reports were controlled studies of the kind I mentioned, of any of the kind I mentioned before, any kind of controlled studies I mentioned before.

Q. Do you know, have those case series been published in any kind of publication, or is it just papers that we talked about earlier?

A. Well, the reports have been published in one recent textbook about abortion methods, but they were not published in peer review journals. They were not submitted for peer review in publication in one or the other of the obstetrical or gynecological publications.

Q. The textbook you're talking about, A Clinician's Guide to Medical and Surgical Abortions?

A. Yes, it is.

Q. Dr. Maureen Paul is the editor of that book; is that

correct?
A. There is several editors. She was the main editor. She was the first author or first editor listed.
Q. Do you own a copy of that book?
A. I do.
Q. Do you have an opinion regarding the value of the case series that were reported by Drs. Haskell and McMahon from an evidence-based medicine standard?
A. Well, as I stated before, I think this is, as you're grading quality of evaluation, this is at the low-level because there is no comparison comparable or concurrent control group. They simply stated their results but didn't compare it to a group that they had matched with similar kinds of patients and so forth, so it's a case series, and it was not peer reviewed, so we don't know whether there was selection bias in selecting the patients for the study. We don't know how many patients were lost to follow up, etc., etc. There were a lot of critiques of those series, but they are series in which they presented their results.
Q. Would it be safe to draw any conclusions from those series?
A. Well, you could conclude, certainly, that two physicians were able to accomplish a substantial number of these procedures with, at least, their assertion that there were very few complications. I mean, that's the only conclusion

I can draw.

Q. Doctor, during the course of this case, were you made aware of a study that has been submitted, and I believe accepted, for publication that compares complications between intact D & E and the traditional disarticulation D & E?

A. Yes, I have.

Q. Could I ask you to turn to Plaintiff's Exhibit number 27? Dr. Bowes, does that appear to be the study that you just mentioned?

A. Yes, it is.

Q. And can you -- Have you reviewed that study?

A. I have.

Q. Could you briefly summarize for the Court what it states?

A. This study is entitled Dilation and Evacuation at greater than or equal to 20 weeks: Comparison of Operative Techniques. The authors were Dr. Steven T. Chasen and several co-authors, and it's from the Department of Obstetrics and Gynecology at the Weill Medical College of Cornell University. This study was a retrospective cohort study in which included a total of about 383, if I remember the total number correctly, patients, 120 of which had the so-called intact dilatation and -- I'm sorry, the dilatation and intact evac -- intact D & E procedure. The other, the

remainder, 263 patients, had the traditional D & E procedure, and they, in their study, compared the outcomes of these two groups of patients with regard to surgical complications, amount of bleeding, cervical lacerations and so forth, infections and so forth. That was one part of their study.

The second was they followed up the -- a certain number of patients thereafter who had pregnancies after the abortion procedures and evaluated the outcomes of those pregnancies, particularly related to premature birth in the two groups. Their conclusion was that they found no difference in the complication rate between the two procedures which was about 5% in each group, and they found no difference, statistically significant difference in the incidents of premature birth in those women who they followed up at their hospital who had subsequent deliveries.

Q. Are you aware of any, or do you have an opinion concerning any limitations regarding the study and the reliability of its results?

A. Yes, I do. I have -- In looking at this study, I felt there were several limitations to it. The first was, and I think the most important, is that the number of patients they have in their study is too small to allow them to state that there is no difference in outcomes in a statistically valid degree -- to a statistically valid degree.

Now, this takes a little bit of explanation. When you're comparing two groups with a relatively low incidence of complications, in order to show that there is no difference and that that difference, that nondifference is significant, you need a substantially greater number of patients than they had in their study, so when they say there was no difference, there, in fact, there was none in their data, but that does not mean there is not a difference in complication rates between these two procedures, and you just can't prove that statistically with the number of patients they had. Another critique I have of this study is that the authors did not state clearly what their follow up procedure was; in other words, how many patients in this study did they actually see after they had their abortions, how long did they follow them and so forth. In other words, did they lose, were there adverse events that they didn't know about; in other words, the patient may have had a complication and went to some other hospital. They simply do not document how they followed the patients up. Third, the groups in these two, the patients in these two groups were quite different. They were different in age, they were different in the gestational duration of pregnancy at which the procedures were done, they were different in the indications for which the abortions were performed, so that means that the populations were quite heterogenous, and it's

difficult to compare them in that situation to know if these differences might have been confounding factors in the study.

Q. Doctor, can I ask you with respect to that point, is there a way in studies in medical literature, or is it possible to control or to account for --

A. Yeah. One of the -- one of the epidemiological methods of adjusting for those so-called confounding features is a method called regression techniques or regression analysis. I'm not a statistician, so I only know that they use these, but what this does, it takes into account all of those differences and adjusts for them. There weren't enough patients in this study to do that really, and the authors admit that. I mean, they say that, but that is a limitation of the study; and finally, in following up the patients who eventually became pregnant, not all those patients came back to their hospital for obstetrical care, so the ones who didn't, they didn't follow up, plus there was a small number of them. They had so few patients in that study that it was very clear they could not state unequivocally with any statistical validity that there was any difference in outcoming those pregnancies, so I think that overall summarizes my critique of Dr. Chasen's and his co-author's article.

Q. Let me ask you this: You previously in your testimony

talked about the issue of, I believe, selections bias. Do you have any concerns in that regard from this study?

A. Well --

MS. SMITH: Objection, Your Honor. There was no opinion expressed on opinion bias in either the expert report I was given at the lunch break or in our conversation with Dr. Bowes, unless I'm not understanding where you're going with that. Okay, Your Honor. We have resolved it. I have withdrawn my objection.

THE COURT: Thank you. Go ahead.

THE WITNESS: Well, the criticism I have already mentioned in that, the populations were homogenous because of the difference in indication for the procedures that were done and so forth is a form of selection bias. I mean, it's just that the patients were not selected with equivalent indications, with equivalent ages and so forth, so there is a bias there in that, and so I think that's an important thing. One critique I did not mention, if I may.

BY MR. HENRY:

Q. Go ahead.

A. Is that the way in which they decided which patient would have which procedure is not dealt with in any great detail; in other words, although only two of the authors were involved in performing the abortions, according to the article, they did not say what were the precise criteria.

They said in general it had to do with how far the cervix was dilated and the position of the fetus, but they made that decision at the time they were about to perform the procedure, but they didn't go into any great detail about the very specific objective criteria suggesting there may not have been any one. It may have been just their intuition. We go back to intuition, or their hunch that one procedure would be better than the other, and I think that's a limitation.

Q. Doctor, are you familiar with the author or one of the authors of this study, Dr. Chasen?

A. Only in my awareness that he's written this article. I do not know Dr. Chasen personally or professionally.

Q. Do you know whether or not he's involved in any of the cases challenging the Partial-Birth Abortion Ban Act of 2003?

A. Well, he is because I read his -- I think he has one of those statements that I was --

Q. Like an expert report?

A. An expert report.

Q. And does -- Do you have an opinion as to whether Dr. Chasen's role in this litigation in any way impacts the study or value of the study or that sort of thing?

A. Well, I can't -- I could not state that. I don't want to impune Dr. Chasen for any ulterior motives here, but I

think it would be appropriate for the author in this circumstance to at least have disclosed to the journal to which he's submitting this that he was involved in this case. I say that because, for example, if an author of a study is in the employment of a drug company and they are studying a drug, a drug that company manufactures, it's mandatory that the journal knows and that it's disclosed in the article when it's published so the readers know. Now, they can draw any conclusions they want to about that. I'm not going to draw any conclusion about Dr. Chasen though.

Q. Doctor, do you have an opinion regarding whether this study proves or does not prove the comparative superiority and efficacy or safety of intact D & E versus D & E by disarticulation?

A. I have an opinion, yes.

Q. Can you tell the Court what that is?

A. Yeah, I believe this study does not prove the superiority of one of these procedures over the other. I think for the reasons I have mentioned, the lack of sufficient numbers and of the other criticisms. I have said that I don't think it proves that one procedure is better than the other.

Q. Doctor, a general question. Just because an article is being published in a peer-reviewed journal, does that mean it's without flaws?

A. No. It does not mean it's without flaws. The peer review process is just one level of scrutiny. Often an article that gets into the peer review journal after being -- in a journal after being peer reviewed will be pilloried by letters to the editor pointing out all kinds of things the peer reviewers either overlooked or the editors overlooked, so I don't mean it's -- Peer review is certainly not without its value, but it doesn't mean that every article is absolutely spotless after it has been accepted for a peer review journal.

Q. Doctor, I believe you testified before, you're aware of claims or arguments that -- of potential safety advantages for intact D & E versus other methods of abortion. Do you have an opinion as to the validity of those claims from an evidence-based medicine standpoint?

A. Well, I don't think those claims can be supported by evidence-based medicine. If I may expand on that, I know that Dr. Chasen and his colleagues suggested that because the group of patients who had the intact D & E procedures, the intact procedure were about two weeks further along in their gestations than the group that had D & Es, and that they found no difference between the populations in terms of complications, and because there is a general impression that the further you get in pregnancy, the more complicated an abortion procedure becomes, then, therefore, because

there was no difference, this procedure must be safer because they had more patients who were done later. My response to that is, A, to begin with, they don't have statistical validity to their claim that there was no difference in these procedures; and secondly, it's pure conjecture to make those leaps between those, those foundation arguments that I just mentioned.

You would have to prove that with good statistical analysis in a comparative study that was designed to do that.

Q. Doctor, could a study sufficient to draw some reliable conclusions be done comparing intact D & E with D & E? Do you have an opinion about that?

A. I believe it could be done.

Q. How about a study comparing intact D & E with labor induction abortion methods?

A. I believe that could be done, too.

Q. What types of studies could be done with regard to those issues?

A. Well, although it would not be easy, I didn't claim it would be easy, I believe you could conduct a study under proper circumstances and with proper design of the study that would be prospective. You could assign patients randomly to one procedure or the other at various gestational ages and look at the outcome. Also, you could

do, I think, a very credible retrospective study if you had the data on the records from sufficient number of patients who had had very, study very similar to Dr. Chasen's with just more subjects in the study, a bigger study, and better epidemiological and statistical methods to evaluate the data.

Q. Let's talk about a prospective study. Wouldn't it be difficult to recruit patients into a randomized study involving abortion procedures, surgical procedures, that sort of thing where the patient didn't know, you know, at the outset, didn't know which of the two procedures they were going to get?

A. It might be difficult, but it could certainly be done, just as it's difficult to do any randomized controlled study. For example, if I can give you another example, one of the best recent randomized controlled trials was done on breech delivery. Now, for years, breech deliveries were conducted predominantly by allowing the baby to deliver vaginally. That is when the mother has a breech presentation. Then there were studies that suggested that in some situations, it was safer to deliver the baby by cesarean delivery, but nobody could really answer the question of which really was the best way to start off to intend to deliver the baby. Shall we intend to deliver it vaginally, or shall we just go ahead and do a cesarean

delivery? Well, they developed a large randomized controlled trial, multi-centered, involved many institutions, not only in this country and Canada and abroad, all collaborating together in which women were actually agreed to be randomized. They said okay. Since we can be -- we are convinced that you don't know which is the best way for it to be delivered, we'll be in the study. And they accomplished this in a remarkably short period of time and basically published what, why they regarded it as the definitive study on how to deliver a breech baby is by cesarean section. Cesarean won. Now, it seems to me you have a very similar situation with this procedure, with these two procedures. You have, except for certain insertions by people who have their own intuition about them, we don't have any good epidemiological proof, and that you could, in all good conscience, develop a study, it would be quite ethical, in which you randomized women to one or the other procedures.

Q. Doctor, could I ask you to take a look at Plaintiff's Exhibit 44?

A. 44?

Q. Yes. Doctor, taking a look at Plaintiff's Exhibit 44, do you know what that is?

A. Yes, I do.

Q. Can you tell us what it is?

A. This is a study that was published in the British Journal of Obstetrics and Gynecology entitled Mefipristone and Misoprostol versus dilation and evacuation for mid-trimester abortion, a pilot randomized controlled trial. The authors were Dr. David A. Grimes, M. Susan Smith and Angela D. Withham.

Q. Can you briefly summarize what the article is about?

A. Well, this was as described here, is a feasibility study. They were using this study to see if they could do a sort of a pilot to comparing a method of abortion using these two drugs Mifepristone and Misoprostol. That is basically a labor-induction kind of abortion against or versus the dilatation and evacuation. The classic D & E procedure is what they were describing here, and what they did is, they offered this to about 47 patients, I think, if I recall. I will have to look at this, and only 18 of the women agreed to been randomized, and although they conducted the study in that small number, what they did is acknowledged that that was too few patients to make the comparison between these two procedures and suggested that this study would probably have to be done in a different setting. They didn't say you couldn't do this study. They simply said it would have to be done in a slightly different setting than they had chosen.

Q. Doctor, I think there has been prior testimony in this

case that this article would support the notion that it's impossible or extremely difficult to construct a randomized trial comparing abortion methods. Do you agree with that?

A. Well, I have already acknowledged that it's not easy, so they are difficult studies to put together, but I don't think this article in any way precludes or says that it precludes performing such a study. In fact, Dr. Grimes and his colleagues in here say that the study should be done, and it's very necessary that it be done, and it simply would have to be done in a different setting. If I can elaborate a little further, I happen to know Dr. Grimes. We are on the same faculty together, and he has been a champion of and has done a lot of good research on the difference between the abortion procedure done as a D & E and that done by the labor induction methods, and he was the one of the first to point out that the D & E method was safer, and because he has been, is widely known in our area, it's not surprising that women weren't convinced that that's the best method to have done, so you would almost have to do this in a setting where that kind of almost cultural bias wasn't built into the patients who were being offered the procedure.

Q. Are you saying that that was Dr. Grimes' fault?

A. It's not Dr. Grimes' fault. Dr. Grimes would be the first to say you need to study this procedure. He's not responsible. All I'm saying is, people have heard Dr.

Grimes support of the D & E procedure. He makes a very important point that this Mifepristone and Misoprostol method of doing labor induction abortion methods in his view is safer than the old induction techniques, so he felt it was very ethical to do this study.

I'm just saying that the culture out there among physicians and others, he's had an impact on that.

Q. You said he felt it was ethical to do this study. What do you mean by ethical to do the study?

A. Well, you have to be at a point where you truly believe that there is not good epidemiological evidence that supports one type of treatment or another. You have to be, and we call that equipoise where you can go to a patient and in all good conscience and say, look, we are not sure what the best method of treatment is. We have to study it, and would you be willing to be in our study? That's the lingo they use is called equipoise, and I think he believes truly that's where we are with these two procedures.

Q. Doctor, in a prospective randomized trial, is it possible to control, or a variation, in skill of doctors performing, say, two procedures that are being studied?

A. Yes. The answer to that is yes. You can't control completely from any one day to the next or so forth, but what the randomized controlled trial does is by randomizing the patients to the two groups, and you have accounted for

or you have adjusted for, or you have eliminated the bias of different techniques, that's why you do the randomized controlled trial.

Q. Doctor, could -- Kind of switching topics here, could a retrospective study be done comparing intact D & E to, say, D & E or other abortion methods?

A. Yes.

Q. And how would one go about doing that kind of study?

A. Well, as I have said, I think you would take populations of patients in which these two procedures were being done, collect enough of them together and with adequate data from those procedures and their outcomes, and then use epidemiological techniques to adjust for the differences in the populations, the differences in the selection of patients for the procedure, age of the patients and so forth, and when you do it retrospectively, it's harder to control for differences in surgical technique. That's a more difficult thing. That's why these studies are not as good as the prospective studies, but you could do it.

Q. Doctor, to your knowledge, do you know, or do you know how long the intact D & E procedure has been around being used?

A. Well, it must be for about 15 years because Dr. Haskell wrote his paper in 1992, and Dr. McMahon's reported a ten-year experience in 1995, so they were doing these procedures

that much time, so there has been 15 years or more, perhaps up to 20 years of actually of someone having experience with this procedure.

Q. Does that fact impact your opinion concerning whether a retrospective study would be possible?

A. Yes, because you have to have enough patients in the study to make it statistically valid, so and when I said it has been around that long, I don't know how many of these procedures were done other than those that were reported by Dr. McMahon and Dr. Haskell, so I'm not sure I can -- I have no estimate of that.

MR. HENRY: Your Honor, may I have a minute?

THE COURT: Sure.

BY MR. HENRY:

Q. Doctor, just one final question. Earlier on you were talking about Dr. Chasen's study, and I believe that you mentioned that there was a relatively low incidence of complications for the two procedures that this study talked about. Do you know what the level of out patients was in the study?

A. I believe it was approximately 5% in each group.

Q. And 5% is a low complication rate?

A. Well, yes.

MR. HENRY: I have no further questions.

THE COURT: Counsel, would you like to begin, or do

you want to take a break?

MS. SMITH: Well, we might as well take our break now, Your Honor. Then we'll just been able to go straight through.

THE COURT: Is that agreeable with you, counsel?

MR. HENRY: Yes, Your Honor.

THE COURT: Doctor, you may step down. We'll take a 15-minute break, and we'll start again. We stand in recess.

(Recess from 2:57 to 3:17 p.m.; all parties present)

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

(Dr. Bowes resumed the witness stand)

THE COURT: You may inquire.

CROSS-EXAMINATION

BY MS. SMITH:

Q. Thank you, Your Honor. Good afternoon, Doctor. We met over the lunch break, and we also met ten years ago which I know you don't remember in another case when I deposed you, then, way back in 1994. Nice to see you again, sir.

A. Thank you.

Q. Doctor, I just have one first question about the example that you gave about a randomized controlled trial of C section versus labor delivery for the breech presentation.

A. Yes, ma'am.

Q. And you said that the fact that women agreed to be randomized was evidence that it would be possible to get women to agree to be randomized in a study of induction versus D & E; is that right?

A. Yes.

Q. But, Doctor, it seems to me that the choices in those two situations are very different. In one situation you have C section, which is major abdominal surgery versus labor, neither of which are particularly great choices, and in the other situation, you have labor versus a 15-minute procedure. Now, doesn't it seem like those two situations are very different?

A. Well, of course, they are different, yes.

Q. And so from the patient's perspective, I think, wouldn't you agree, Doctor, that choosing between major abdominal surgery like a C section and labor might be something that you would be more likely to be randomized, agree to be randomized on than induction versus a 15-minute procedure that doesn't involve a major abdominal incision?

A. A 15-minute procedure that involves a major -- I may have not understood your question. I'm sorry.

Q. That's okay. I'll move on. I'll move on, Doctor.

THE COURT: Counsel, I think where you confused the Doctor, and frankly confused me --

MS. SMITH: I'm sorry.

THE COURT: -- you were comparing cesarean to labor.

MS. SMITH: That's right.

THE COURT: Then you said okay. The implication was you got two bad choices, or at least two fairly painful choices, and then compare D & E to induction where there is labor, but you added something about a larger significant incision, and I think it was the reference to the incision that probably threw the doctor off.

MS. SMITH: I'm sorry. I must have mucked it up a bit there. What I meant to say was the difference between C section, a major incision versus induction of labor is one choice, and the other is induction of labor versus a D & E, a 15-minute procedure that does not involve a major abdominal incision, so it seems to me those choices are very, very different, and I asked if you would agree with that.

THE WITNESS: May I comment a bit on it?

BY MS. SMITH:

Q. Yes, sir.

A. I agree they are quite different. In the one case, if you are comparing the two surgical procedures in a randomized thing, you would have procedures that are relatively comparable in time. Okay, so if you were making that comparison. Now, if you are comparing the intact D & X

procedure with a labor procedure, indeed, those are different in terms of the amount of time and what's involved for the patient, and there it would be incumbent upon the physicians or the people presenting the study to the women to point out that the important thing is, what are the serious complications to them after the procedure is over, and that's what we don't know about, but I agree with you that they are different settings, and it might be more difficult to do that study.

Q. Thank you, and I just was referring to the choice between induction versus D & E.

A. Yes, ma'am.

Q. As you discussed in terms of Dr. Grimes' study really.

A. Okay.

Q. Doctor, you haven't seen any patients or performed any patient care since you retired in 1999; is that right?

A. That's correct.

Q. And you haven't supervised any residents since that time either; is that right?

A. Yes, ma'am.

Q. And your only formal training in abortion techniques was during your residency between 1962 and 1965; is that correct?

A. Correct.

Q. And you haven't received any formal training on abortion

techniques or procedures since 1965?

A. That's correct.

Q. And the only abortion technique you received training in the 1960s, that is still used today is the induction method; is that right?

A. I also received training in D & Cs for first trimester abortions.

Q. Now, the preferred method in the first trimester is either medical abortion or vacuum aspiration; is that right, Doctor?

A. Yes.

Q. And you weren't trained --

A. Well, we were using vacuum aspirations, too.

Q. Oh, you were?

A. Yes, ma'am.

Q. Thank you, Doctor. Thanks for clarifying that. You weren't trained in the D & E procedure during your residency?

A. No, I was not.

Q. You have never taught abortion didactically; isn't that right?

A. That's correct.

Q. And you haven't authored any articles on abortion?

A. I have not.

Q. And you haven't conducted any peer review for any

journal with respect to any articles on abortion procedures?
A. I have not.
Q. And the only two materials you reviewed in authoring your expert report in this case were the NAF book, the Maurine Paul textbook, Clinician's Guide; right?
A. Yes.
Q. And the papers by Dr. Haskell and Dr. McMahon; is that correct?
A. That's correct.
Q. And you yourself, Doctor, have never performed, actually performed an abortion yourself in the second trimester of pregnancy on a fetus that hasn't already naturally demised; isn't that right?
A. No, I have supervised but not performed by myself.
Q. Thank you. And over your entire 40-year career, Doctor, you have supervised approximately between four and six second trimester abortions on fetuses that hadn't already naturally demised; isn't that right?
A. That's correct.
Q. So that was about one or one-and-a-half each decade, if you averaged it out; right?
A. I haven't done the average, but I'll agree with that.
Q. Thanks, Doctor. And some of those four to six second trimester abortions were inductions, and the others were D & Es; is that right?

A. That's correct.
Q. So given the fact you haven't performed any, and you have supervised fewer than six D & Es on a fetus that has not naturally demised, you agree, don't you, Doctor, that your experience with D & Es on a live fetus is quite limited?
A. Yes.
Q. And you agree that following fetal death, the composition and consistency of the fetal body is different than is when an abortion is begun with a living fetus; isn't that right?
A. Yes.
Q. And you agree, at least intuitively, that fetal demise and the passage of time changes the fetal tissue such that it would dismember more easily than the tissue after fetus that has not demised; isn't that correct?
A. In general, that's true, yes.
Q. By the way, Doctor, in your experience, the bony structures of the fetus are not involved as much in the maceration process; isn't that right?
A. Yes.
Q. And with regard to the procedures you have had experience with to remove a fetus that has demised from a woman's body, you testified that over your 40-year career, you have been involved in the performance of 150 second

trimester abortions on fetuses that have already demised; is that right?

A. Yes, ma'am.

Q. So that's about 15 every ten years?

A. That's correct.

Q. And most of those were done by induction; isn't that right, Doctor?

A. That's correct, yes.

Q. In fact, only one or two each year were done using the D & E method; isn't that right?

A. Yes, ma'am.

Q. And, of course, you haven't been involved in the performance of any abortions, whether on a demised fetus or a non since 1999 when you retired?

A. That's correct, yes.

Q. And in the one or two D & Es you were involved in each year before 1999, the resident was performing the procedure and you were supervising; isn't that right?

A. Yes.

Q. And, Doctor, you agree, don't you, that you're not an expert on induced abortion; isn't that right?

A. I agree with that.

Q. In fact, when you were first questioned at your deposition whether you were an expert on abortion technique, you said no, didn't you, when you were first questioned?

A. Yes, when I was first questioned. I assume they were talking about induced abortions.

Q. That's right. Then during a break in the deposition, counsel for defendant advised you to clarify your answer and insert that you do have expertise in abortion techniques because you have performed similar procedures on fetuses that had already demised; isn't that right?

A. Yes, ma'am.

Q. And that expertise is based on the D & Es that we discussed that you supervised?

A. Yes.

Q. And those were the two or three a year where the resident performed the abortion?

A. Yes.

Q. But you still limited your expertise after consultation with counsel by saying you're not an expert by having either studied or published on induced abortion; is that right?

A. That's correct.

Q. And you limited your statement to induced abortion because the term abortion itself also includes spontaneous abortions, and incomplete abortions in addition to induced abortion; isn't that right, Doctor?

A. That's correct.

Q. And you would agree that a physician with more experience performing abortions than you would have greater

experience than you; don't you?

A. Yes.

Q. And despite your limited experience, you've offered expert testimony about induced abortion in several cases challenging partial-birth abortion bans; isn't that right, Doctor?

A. Yes.

Q. In fact, these were, you've offered some sort of sworn testimony in six cases where state partial-birth abortion bans have been challenged; isn't that right?

A. I believe you reviewed the record and know that, yes, ma'am.

Q. These cases -- Why don't I list the states and you tell me if you remember. Is that okay, Doctor?

A. All right.

Q. Rhode Island?

A. Yes.

Q. Wisconsin?

A. Yes.

Q. West Virginia?

A. Yes.

Q. New Jersey?

A. Yes.

Q. Virginia?

A. Yes.

Q. And Montana?
A. Yes.
Q. And you agree, don't you, that the bans about which you testified apply only to induced abortion and not to situations where the fetus has demised; is that right?
A. Yes.
Q. And you have uniformly testified in support of the constitutionality of those bans; haven't you?
A. Yes.
Q. And the bans in those cases were held to apply not to just intact D & Es but also to abortions performed using the D & E method itself as early as 12 weeks of pregnancy; isn't that right, Doctor, if you know?
A. That was not my impression.
Q. Okay. In fact, you've also testified in support of other state statutes imposing restrictions on abortions in other cases; haven't you?
A. Yes.
Q. For example, the Michigan mandatory 24-hour delay where we first made our acquaintance.
A. Yes, ma'am.
Q. The Pennsylvania case, Planned Parenthood versus Casey that went to the Supreme Court.
A. Yes.
Q. And that was a case that included a spousal consent

requirement?
A. Yes.
Q. Have you ever opposed a restriction on abortion, Dr. Bowes?
A. No, I have not.
Q. Doctor, you know Dr. Grimes, you mentioned at the staff at UNC; is that right?
A. Yes.
Q. You agree that Dr. Grimes is a well respected practitioner in the field of obstetrics and gynecology; is that right?
A. Yes.
Q. You agree he's a competent researcher and a prolific writer in the field of induced abortion; is that right?
A. Yes, he is.
Q. Doctor, would you like some water?
A. No. Maybe I would like some water.
Q. Yes.
A. Excuse me while I learn how to use this.
MS. SMITH: May I approach?
THE COURT: Sure.
BY MS. SMITH:
Q. Doctor, despite the fact that you have Dr. Grimes, an expert on induced abortion right at your fingertips at UNC, you have not spoken to him about D & Es, either intact or

nonintact, in preparation for the testimony you've offered around the country in support of partial-birth abortion laws; isn't that right?

A. That's correct.

Q. And it's true, Doctor, isn't it, that you have never personally observed or supervised the intact variation of a D & E; is that right?

A. That's correct.

Q. You call the intact variation intact D & E, I notice, in some of your writings; is that right, Doctor?

A. Yes.

Q. And when you've referred to an intact D & E, you're referring to the procedure described by Drs. Haskell and McMahon; is that right?

A. Yes.

Q. And those were in the papers that you reviewed earlier this morning?

A. Yes, ma'am.

Q. But you have never spoken to any physician who actually performs intact D & Es about intact D & Es; is that correct?

A. That's correct.

Q. You're not aware of any study or other valid scientific evidence that establishes that intact D & E is a less safe procedure than a classical D & E or an induction; are you?

A. That's true.

Q. And you agree that there is no reliable medical basis on which to say that intact D & E is more dangerous to a woman than any other abortion method; isn't that right?

A. I would agree with that.

MS. SMITH: May I have Plaintiff's Exhibit 69?

THE COURT: You may.

BY MS. SMITH:

Q. Doctor, I have just given you Plaintiff's Exhibit 69 which is a copy of the Act that's at issue in this case, and you've seen this before, I assume; is that right?

A. Yes, ma'am, I have.

Q. And I would like to direct your attention to finding number two on page one, and do you find that?

A. Yes, I do.

Q. And in part, that finding states, "partial-birth abortion remains a disfavored procedure that is not only unnecessary to preserve the health of the mother but, in fact, poses serious risks to the long-term health of women and in some circumstances their lives." You don't agree with that finding; do you, Doctor?

A. I do not.

Q. Could you turn to page four of the same exhibit, Doctor? And because it's quite long, could you read finding 14A to yourself and tell me when you've finished?

A. Excuse me. 14?

Q. No, page four?
A. Page four.
Q. The numbers are at the top of the page, Doctor.
A. Okay, I have it.
Q. Do you see 14A?
A. Yes.
Q. And tell me when you have finished.
A. I have finished.
Q. Thank you, Doctor, and you don't believe that there is a reliable scientific basis upon which that statement can be made since it doesn't compare, "partial-birth abortion to other abortion procedures," isn't that right?
A. That's the key issue. There is no comparison there.
Q. And could you turn to page five, please, of the same exhibit and look at finding 14F. Do you see it says, "A ban on the partial-birth abortion procedure will therefore advance the health interests of pregnant women seeking to terminate a pregnancy?"
A. Yes, ma'am, I see that.
Q. In your opinion, there is no valid scientific evidence that supports that statement; isn't that correct?
A. That's correct.
Q. In fact, Doctor, you think that intact D & E is comparable in terms of relative safety to other second tri abortion procedures; isn't that right?

A. No. I don't think we have proved that yet.
Q. Okay. Doctor, could you -- Okay.
MS. SMITH: May I approach, Your Honor?
THE COURT: Yes, and I would like a copy if you have one.
MS. SMITH: 112.
BY MS. SMITH:
Q. Okay. Doctor, if you turn the first page of that exhibit, do you recognize the letter that's there?
A. Yes, ma'am.
Q. And that's a March 12th, 2003, letter to Rick Santorum, a Senator; is that right?
A. Yes, ma'am.
Q. That's about Senate 3, the bill that's at issue, the Act at issue in this case?
A. Yes.
Q. And is that the letter you sent to Senator Santorum?
A. Yes, ma'am.
Q. Now, Doctor, I know this is very hard to read, and I apologize for the small text. At the bottom of the second paragraph, there is a sentence that states, acknowledging that there can be differences of opinion on this matter, the important point is that if the technique of partial-birth abortion, and in quotes, intact D & E, were not available, there would be alternative methods available to terminate

the pregnancies described by Dr. Darney with comparable levels of risk in the patients. Isn't that what you wrote, Doctor?

THE COURT: To the patients.

MS. SMITH: Sorry.

THE WITNESS: You said in the patients.

MS. SMITH: To the patients. Sorry

BY MS. SMITH.

Q. So you never testified to Congress that intact D & E would be dangerous to women; did you?

A. No.

Q. You don't believe that; do you?

A. I don't believe we have proven that.

Q. Okay. And by the way, Doctor, I notice that when you wrote this letter to Congress, you felt it was necessary to define partial-birth abortion as intact D & E; didn't you?

A. Well, because those terms are often used interchangeably, I mentioned that in the parenthesis.

Q. But Congress didn't use the term in the statute; did they?

A. No, ma'am.

Q. Nor did they use the term D & X or intact D & X, did they?

A. I don't believe I saw those terms, no.

MS. SMITH: May I approach, Your Honor?

THE COURT: Yes.

BY MS. SMITH:

Q. And, Doctor, I have now handed you Plaintiff's Exhibit 113, and this is a letter to Representative Canady that you sent supporting an earlier version of Senate 3 that was pending in Congress in 1995. That was a July 11th, 1995, letter. Do you recognize that?

A. Yes, ma'am.

Q. And that was in order to support that earlier version of the bill; wasn't it?

A. Yes.

Q. And you didn't say anything in that letter about the comparable risks of the procedure; did you?

A. It has been sometime since I have read this letter. If you said, I didn't, I would agree with you.

Q. Please, go ahead and read the letter. I don't want so put words in your mouth, Doctor.

THE COURT: Oh, yes, you do.

MS. SMITH: Sorry?

THE COURT: Oh, yes, you do.

MS. SMITH: Well, that would be improper, Your Honor.

THE COURT: God knows we all want to be proper.

THE WITNESS: Let me say in explanation of this letter, I was asked to comment on various aspects of the

Bill that, in turn, had been commented upon by people who made testimony in Congress. I was not asked, as I recall, to make a thorough evaluation of my position on the Bill or supporting it, so, but you're right, I did not comment upon comparable safety.

BY MS. SMITH:

Q. So you were responding to specific questions that were asked you?

A. Yes, ma'am, and those were in the headings in the letter.

Q. Okay. And you didn't feel the necessity to talk about the comparable risks of the procedure in that letter; is that right?

A. That's correct.

Q. Doctor, when you say in this letter your opinion was based on a discussion with "colleagues who perform second trimester abortions," to whom were you referring?

A. Well, on our service at the University of North Carolina, second trimester abortions are performed and using various techniques, and several faculty members or colleagues of mine were -- who I'm in daily contact with from time-to-time, I would discuss these. Now, I can't remember, Dr. Grimes was not one of those at that time, I might add, but those are the people I was talking about, the people who were supervising the abortion service.

Q. Okay. Thank you. Doctor, by the way, on page four of that letter, did you also state that there are wide interinstitutional variations in viability?

A. Neonatal viability? Yes, I did.

Q. And you agree with that statement; don't you, Doctor?

A. Yes, I do.

Q. Now, Doctor, because you believe that the intact D & E procedure has comparable risk to other available procedures, your support for the partial-birth abortion act is not based on any concerns for protecting maternal health; isn't that right?

A. That's correct.

Q. Rather, your support is based on your ethical opposition to abortion, in particular, and particularly post-viability abortions other than those performed to save the life of the mother; is that right?

A. That's right.

Q. And your ethical opposition pre-viability is not particular to the intact D & E procedure as opposed to other methods of abortion; is it?

A. I'm sorry. Would you restate that question?

Q. Your ethical opposition to abortions pre-viability is not particular or limited to the intact D & E procedure as opposed to other methods of abortion?

A. That's correct.

Q. And you would support a ban on all abortions as long as it contained an exception for when the woman's life was at risk; isn't that right?

A. Yes.

Q. And in fact, you would only perform an abortion where the life of the pregnant woman is in danger; is that right?

A. That's correct.

Q. Isn't it true you would not perform an abortion to save your patient's life unless you're satisfied the likelihood the woman will die is over 50%?

A. Yes.

Q. And yes or no, please, Doctor, you would favor a ban on abortions even in cases where the pregnancy was a result of rape or incest; wouldn't you?

A. Yes.

Q. And you agree, Doctor, that in starting an abortion procedure, whether it be an induction, a D & E or an intact D & E or some other procedure, that the physician's intent is to end the pregnancy in the safest way possible for the woman; is that right?

A. Yes.

Q. And you also agree, at least intuitively, don't you, that minimization of instrumentation in the uterine cavity is a good thing?

A. Intuitively, yes.

Q. And you agree you that physicians, when performing D & Es, try to use as few insertions of the forceps as possible; isn't that right?

A. Yes.

Q. And you agree, don't you, that medical authority in the field of obstetrics and gynecology indicate that intact delivery of a fetus during abortions in pregnancies over 18 weeks reduces the number of instrument passes necessary to extract a fetus?

A. Yes.

Q. And, in fact, isn't it true that medical authority in the field of obstetrics and gynecology also indicates that the aim of an intact D & E is to minimize instrumentation within the uterine cavity and achieve vaginal delivery of an intact fetus?

A. That has been stated by those who perform them, yes.

Q. You also agree that when a physician performs a D & E, he or she tries to do it with as little trauma and blood loss as possible; isn't that right?

A. That's correct.

Q. And he or she tries, within the bounds of safety, to complete the procedure as quickly as possible; isn't that correct?

A. Yes.

Q. And, in fact, you agree, don't you, that there is a body

of medical opinion consisting of the position taken by the American College of Obstetrics and Gynecologists and a responsible group of physicians practicing at a variety of hospitals and teaching at a variety of medical schools that believe that an intact D & E may be the safest abortion procedure for some women in some circumstances; isn't that right?

A. So stated.

Q. And you agree that there is no consensus in the medical community that an intact D & X is never medically necessary; isn't that right?

A. Not everyone agrees with that statement although several important medical associations have stated that.

Q. There is no consensus, in other words?

A. There is not a consensus, yes.

Q. That's right. Doctor, do you still have Dr. Grimes's study, Plaintiff's Exhibit 44, in front of you?

A. No, but I can --

THE COURT: Why don't you help the doctor.

THE WITNESS: It's right here.

THE COURT: Okay. Okay.

BY MS. SMITH:

Q. That's the article you were discussing earlier with defense counsel; is that right?

A. Yes, ma'am.

Q. And you agree that the British Journal of Obstetrics and Gynecology is a reputable journal; isn't that right?

A. It is.

Q. And Dr. Grimes, as you already discussed, discontinued the study because he couldn't get a sufficient number of patients who would agree to randomization; isn't that right?

A. Yes.

Q. And you agree that in general, it would be difficult in any setting to do a randomized prospective study to compare inductions to D & Es; is that right?

A. I said it would not be easy.

Q. And earlier, I believe you said in a different setting, it might be able to be done. Did Dr. Grimes point out that it would need to be done in a different country, in fact?

A. Yes.

Q. Because you would need to do it somewhere where induction was the norm?

A. Yes.

Q. And that would be so that you had equipoise?

A. Yes.

Q. And given the fact that 96% of all second trimester abortions are D & Es, is one likely to find such a setting in this country?

A. I thought you said he suggested it would be done in other countries where it's more common.

Q. Yes. I'm just asking if you would agree, especially because 96% of all D & Es performed in this country, 96% of all second trimester abortions in this country, rather, are performed by D & E?

A. Yes, I would agree it would be difficult to do it in this country.

Q. Now, you indicated, I think, that you felt it might have been particularly difficult for Dr. Grimes to get women to agree to randomization because he's so well known as an advocate of D & E; is that right?

A. Yes.

Q. And so your contention is that his patients, the women who live in Chapel Hill or Durham or wherever they are coming from to have an abortion with Dr. Grimes, are keeping up with the literature and know he's an advocate of D & Es?

A. No. It's not that clear cut. It's just that as you have pointed out, D & Es are the common practice. Women know that's the common practice, and they are, I would think, reluctant because that has been established. They haven't read the literature, but their own physicians have talked to them. Many of these patients are referred. They are not Dr. Grimes' primary patients, but they have -- that's why I called it the culture, is that this is the procedure, this is the preferred procedure, so I just think that had an influence on his study and why he had difficulty

completing it.
Q. I see. Thank you, Doctor. Are you aware, Doctor, of the difficulties a physician had, physicians had in conducting a randomized study to compare early first trimester medical abortions with surgical abortions?
A. Early medical abortions with surgical abortions. Well, there had been studies in which they have done that.
Q. Are you aware that it was very difficult to get women to randomize in those types of studies?
A. No, I'm not specifically aware of that.
Q. Doctor, you agree that a properly conducted case controlled study is a valid and accepted basis on which a particular procedure could become widely used; right?
A. Yes.
Q. And it's your belief, isn't it, that either before or soon after a new procedure, technique or substance is used in medicine, it must be subjected to a randomized or case controlled study before it becomes widely used; is that right?
A. Yes.
Q. Before the D & E method of abortion was introduced, no randomized controlled study had been done concerning its safety; isn't that correct?
A. You can't do a randomized study before it's introduced.
Q. Thank you, Doctor. And you're not sure how long after

the D & E was first introduced that a case controlled study was performed concerning its safety; isn't that right?

A. Dr. Grimes' initial study was done quite a long time ago, not too long after D & Es were first attempted. He did one of the early studies that showed that there was some advantage to it.

Q. Thank you. And to your knowledge, before physicians began applying Misoprostol to the cervix in connection with the D & E procedure, no randomized controlled study had been done concerning its safety; isn't that right?

A. Of course not. I mean, you can't do a study before it's introduced.

Q. It's an obvious point; isn't it, Doctor?

A. Yes, it's an obvious point.

Q. You don't know how long after the use of Misoprostol applied to the cervix in connection with a D & E was introduced, a case controlled study was performed concerning its safety; do you?

A. I can't give you the specific time, but it was a relatively short time because there is lots of studies on the use of Misoprostol in abortion use.

Q. And you would agree in the field of obstetrics and gynecology, in particular, there are many examples where new techniques have been used and become widespread without a prior prospective randomized controlled study concerning

their safety; is that right?

A. Yes, and often to our disservice, it's happened.

Q. Laparoscopy is an example of that?

A. Laparoscopy, fetal monitoring.

Q. Hysteroscopy?

A. Hysteroscopy, yes.

Q. You talked about episiotomy as an example of a technique that was not effective after randomized trials; didn't you, Doctor?

A. Yes.

Q. In fact --

A. Excuse me. It's not so much its effectiveness, its safety.

Q. Its safety. Of course, it's quite effective.

A. It's very effective.

Q. It achieves the intended purpose?

A. Yes, ma'am.

Q. But, in fact, episiotomies are still frequently performed; just not in all cases?

A. That's right.

Q. In fact, about 30% of all women going through labor and delivery have episiotomies; isn't that right?

A. It varies widely with the region of the country and institution, there are indications for episiotomy. I didn't mean to imply that there is no role for it at all, but its

routine use has been limited.

Q. And you wouldn't support a criminal ban on episiotomies; would you, Doctor?

A. No, ma'am.

Q. And, in fact, you think it's a perfectly appropriate when the indication is there as you have just stated; is that right?

A. Yes.

Q. Now, you would agree, Doctor, that in order to properly conduct a retrospective case controlled study of a technique, some passage of time must occur after the technique is introduced so that you have sufficient number of cases so that you can study it; right?

A. Yes.

Q. And that period of time can be years; right?

A. Yes.

Q. And that period of time would depend on the facts and circumstances of the technique involved such as the nature of the procedure, the number of procedures done; isn't that right?

A. That's correct.

Q. And you would, of course, agree that if a procedure is outlawed before it has been performed a sufficient number of times to properly conduct a retrospective case controlled study, then such a study could never been performed; is that

right?
A. Well, you could never perform it in that setting or in that type. You might be able, as Dr. Grimes suggests, to do it in another setting.
Q. In a different country?
A. In a different country, or you modify the procedure so it didn't, it didn't fall into the ban.
Q. But then you wouldn't be able to study the procedure before it was modified; would you?
A. No, you would be studying a modified procedure, but it would relate to the surgical technique that's being studied.
Q. And you would agree, Doctor, don't you, that as long as there isn't a high rate of complications from a new technique or a variation of a technique, that until there's a sufficient number of times in which the technique has been performed, such that it can be properly studied retrospectively, it's appropriate to leave the use of the technique to the informed judgment of responsible physicians; don't you? That was a very long question.
A. Yeah. I guess what you're asking, I don't want to put words in your mouth either, but are you asking me that until you have enough patients to do the study, you can't accomplish it, so you assume that it's going to be performed in the community by some physicians? Yes.
Q. And I added a little bit to that which is that if there

is not a high rate of complications coming along with the procedure, that you would continue with the procedure until you could study it?

A. Yes.

Q. And, Dr. Bowes, you haven't figured out how many intact D & Es that would need to be performed before you could do a retrospective case controlled study; have you?

A. No.

Q. And you would agree that if a retrospective study were published in a peer-reviewed journal such as the American Journal of Obstetrics and Gynecology, the peer review process would provide some assurance that the study had been responsibly and reliably conducted; wouldn't you?

A. Some assurance.

Q. Before we talk about Dr. Chasen's study, which I know we are dying to do, I wanted to ask you a few questions about fetal demise and inducing fetal demise prior to a procedure. In the handful of second trimester abortions that you've participated in since your residency, you didn't inject potassium chloride into the fetal heart or Digoxin into the amniotic sack or into the fetus to cause fetal demise before you began the procedure; did you?

A. Not those specific drugs, but the drugs we were using for induced abortions by the labor techniques involved either saline or urea which in their own right cause fetal

demise.
Q. But in the D & Es that you were involved in, Doctor, you didn't ensure fetal demise prior to the extraction?
A. I'm sorry, as you said D & E. No, we did not.
Q. I didn't clarify it, so you were correct. I thank you, Doctor. And you didn't do that because you don't believe there is any medical benefit to the woman of injecting such substances to cause fetal demise in the second trimester; isn't that right?
A. There is no benefit to the woman.
Q. And there is no medical benefit -- Sorry. There is no medical reason to subject a woman to an extra procedure that affords her no benefit; isn't that right?
A. That's correct.
Q. And you agree that such injections cannot practicably be given to all women in all circumstances; don't you?
A. That's correct.
Q. For example, it would be difficult to use those injections in a morbidly obese woman; isn't that right?
A. Yes, ma'am.
Q. And with respect to injections of KCL into the heart, you would agree, Dr. Bowes, would you not, that not all physicians have the skill to perform such injections?
A. I would agree with that.
Q. And, in fact, defense counsel asked you if you would

state in your expert report that it's easy to administer potassium chloride into a fetal heart, and you refused; didn't you?

A. I did. I didn't write that in my final report.

Q. You took it out?

A. Yes. I took it out.

Q. Thank you, Doctor.

A. Not easy.

Q. It's not easy. And it's your opinion, isn't it, that one needs some expertise to administer potassium chloride into a fetal heart to cause fetal demise before an abortion; don't you?

A. I agree with that.

Q. And you yourself have never effected an injected into a heart after 20-week fetus; have you?

A. I have not.

Q. Nor have you taught any of your students to do that?

A. No, ma'am.

Q. And in fact, at UNC, potassium chloride injections are given only by the maternal fetal medicine specialist, not by the attending OB/GYN; is that right?

A. All of the obstetrics is done by the maternal fetal medicine, primarily by the maternal fetal medicine. I don't mean entirely, so I think the answer to your question is yes.

Q. But that's because the maternal fetal medicine people are the ones doing the obstetrics; is what you're saying?
A. Yes, that have the expertise for doing that.
Q. Thank you. And you have never personally used Digoxin to caution fetal demise before an abortion; have you?
A. I have not.
Q. And you have never observed anyone using Digoxin to cause fetal demise before an abortion; have you?
A. Not personally observed them doing that, no.
Q. And you have never taught anyone how to induce fetal demise with Digoxin?
A. I have not.
Q. And you agree that nausea and vomiting are known side effects of Digoxin; is that right?
A. That's correct.
Q. And you would agree that in any procedure, a physician would like to avoid unpleasant side effects such as nausea and vomiting when possible; isn't that right?
A. That's correct.
Q. And, in fact, you agree, don't you, that there are risks to the woman, though small, that are associated with the injection of potassium chloride or Digoxin to ensure fetal demise before a second trimester abortion risk such as puncturing a bowel?
A. Exceedingly small.

Q. And you agree that there is no medical reason to subject a woman to such risks; correct?

A. No medical reason, no.

Q. Doctor, you agree, don't you, that the time it takes a physician to complete a D & E varies from patient to patient?

A. Yes.

Q. And you agree that physicians vary in the types of instruments they use for D & Es?

A. Yes.

Q. And you agree that a physician may grasp different fetal parts in performing a D & E depending on the presentation of the fetus?

A. Yes.

Q. And you agree, don't you, that during a D & E, even if the physician doesn't expect the fetus to be removed entirely intact, it can occur that with merely one pass with forceps, the entirety of the fetal body can be extracted up to the fetal head?

A. Yes.

Q. And, Doctor, I believe you testified earlier today that overall, you believe D & E is a safer procedure than induction; is that right?

A. Yes.

Q. And you also agree, don't you, that there are certain

contraindications for induction in the second trimester of pregnancy; don't you?

A. Yes.

Q. And you agree, don't you, that inductions are not always successful?

A. On rare occasions they are not, but those are rare.

Q. And you agree that when an induction is not successful, a physician may have to perform a separate procedure to complete the abortion; is that right?

A. That's correct.

Q. And you agree that retained placenta is a complication of induction abortion; right?

A. Yes.

Q. And, Dr. Bowes, you agree, don't you, that the safest and most appropriate abortion procedure for a particular woman depends in part on the stage of the woman's pregnancy?

A. In general, yes.

Q. And you agree, don't you, that the safest and most appropriate abortion procedure for a particular woman depends in part on that woman's health?

A. Yes.

Q. And you would agree that the safest and most appropriate abortion procedure for a particular woman depends in part on any medical contraindications the woman might have?

A. If she has a medical contraindication means you don't do

it at all.
Q. To a particular procedure?
A. Oh, to a particular procedure. Oh. Okay. I misunderstood you. Yes.
Q. Um-hm, and do you agree that the safest and most appropriate abortion procedure for a particular woman would depend in part also on the training, skill and experience of her physician?
A. Yes.
Q. And do you agree that the safest and most appropriate abortion procedure for a particular woman depends in part on her prior surgical history, if any?
A. Yes.
Q. I only have two more of these, Doctor.
A. Okay.
Q. You agree, don't you, that the safest and most appropriate abortion procedure for a particular woman depends in part on whether she and her doctor, she or her doctor desires to remove the fetus intact to complete or permit pathological testing?
A. Yes.
Q. And you agree, don't you, Doctor, that with respect to any medical emergency exception to a procedure ban, a physician should be permitted to rely on his or her own best medical judgment to determine if there is an emergency?

A. Yes.
Q. Dr. Bowes, I have some questions for you about Plaintiff's Exhibit 27 which is the Dr. Chasen study that we were discussing earlier.
THE COURT: Pardon me, counsel. Those were the plaintiffs' books which means you're subject to the federal tort claim act. Go ahead.
BY MS. SMITH:
Q. Doctor, do you have the study in front of you?
A. Yes, I do.
Q. When did you first review this article?
THE COURT: I'm sorry. Go ahead.
MS. SMITH: Are you okay, Your Honor?
THE COURT: Well, yeah. Go ahead. It's 4:00 o'clock.
THE WITNESS: Roughly two weeks ago. A week, a week to two weeks ago. I don't remember the exact date.
BY MS. SMITH:
Q. Okay. Defense counsel supplied it to you; is that correct?
A. That's correct.
Q. And did you also ask to review Dr. Chasen's deposition testimony concerning his article?
A. No.
Q. Wouldn't that have been helpful, Doctor?

A. I did review it.
Q. His deposition testimony?
A. Yes.
Q. I thought you said no.
A. No, I didn't ask to.
Q. Okay. Ah. So you reviewed also Dr. Chasen's deposition testimony?
A. Yes.
Q. That was given to you as well?
A. Yes.
Q. I didn't understand that. Thank you.
A. At a later time.
Q. Thank you. When was that?
A. Oh, that's about three or four days ago.
Q. Okay. Thank you. Now, Doctor, you're not saying that Dr. Chasen's study is not useful at all; are you?
A. No.
Q. In fact, this study would help a physician design a prospective randomized controlled trial; wouldn't it?
A. Yes, because it establishes the general level of complications in the two groups of patients, and that would be important information to have.
Q. So a retrospective study is often the first step in the process towards a randomized controlled trial, a prospective study; is that right?

A. Yes, it is.
Q. And your main criticism, if I understand it, I know you had a few, but your main criticism of the Chasen study is that he had too few patients to study; isn't that right?
A. Too few patients to draw the conclusions that he did.
Q. That's right.
A. With the certainty with which they seem to be stated in the study.
Q. Isn't that what peer review is for, Doctor, to ensure that a study is useful to the field before it gets accepted for publication in an esteemed journal like the American Journal of Obstetrics and Gynecology?
A. Yes.
Q. How many patients would he have had to have, Doctor, to make it, to increase the power, as you stated before, of the study?
A. Well, clearly, you would need far more than they had here. I cannot tell you exactly how many without doing a formal power analysis which I'm not qualified to do, but it would be well over 500. I mean, and that is an estimate, but it would be a lot more patients than they had here.
Q. Doctor, you also criticized the study for failing to follow up completely with all of the patients; is that right, so that you -- they might have missed some complications?

A. They might have, and I don't know that he failed to follow up. He simply does not state that in what they call the methodology, the method section, so one would not know how many patients were lost to follow up.

Q. If they did lose some patients to follow up, you have no reason to think that would apply differently to the intact group as opposed to the nonintact group; would you?

A. No, there is no reason to believe that, but without knowing it and having some evidence of that assurance, you can't state that.

Q. Doctor, did you notice whether the complications associated with D & E were more or less severe than the complications associated with the intact D & E?

A. Well, they were different. There was a variety of complications.

Q. Um-hm?

A. And as far as severity, no patients died. All patients recovered, so in terms of -- it's a little hard to know how to quantitate severity in this. There were certainly different complications in the two groups.

Q. Well, for example, a laceration that requires two stitches, would that be less severe than a hemorrhage that required --

A. A blood transfusion.

Q. -- a blood transfusion. Thank you, Doctor.

A. Yes.
Q. Doctor, now, I may have misunderstood you, so I don't mean to mischaracterize your testimony, but I believe you also criticized the study because more of the women getting intact D & Es were getting the procedure for some condition that compromised their pregnancy such as premature rupture of the membranes or premature labor while the women in the nonintact D & E group were receiving an abortion for fetal anomaly; is that right?
A. I pointed out that is a limitation because it makes the groups nonhomogenous in terms of comparison.
Q. And wouldn't the women presenting with conditions such as premature rupture of the membranes or premature labor at the time of the abortion who therefore fell into the intact, were more likely to fall into the intact D & E group, wouldn't they also be more likely to have those conditions in subsequent pregnancies as well?
A. They would.
Q. Okay. Doctor, you also criticized Dr. Chasen because it's not revealed, I guess, in the transcript, that he was a plaintiff in this lawsuit; is that right?
A. Well, I mentioned that it is customary for authors to mention any potential conflict of interest when they submit or publish a study. In almost all situations, that tends to be a conflict of interest that relates to such things as

being employed by a drug company when you're doing a study about that particular drug.

Q. Where there is some financial gain involved, in particular?

A. Yes, ma'am.

Q. Is that right?

A. So that's the usual thing.

Q. Um-hm.

A. This is an unusual circumstance where the completion of this study, and I believe that Dr. Chasen in his testimony stated that it was submitted for publication, if I'm not right, in the fall of 2003. That unusual -- may have been a coincidence, but at least it should be acknowledged. That was all I said.

Q. Don't you think, Doctor, that a reviewer who was -- had the expertise to be a reviewer on this type of article would have to have their head in the sand not to know that the intact D & E is a very political issue in this country?

A. Well, in fact, one of the reviewers actually brought that up. I mean, they were not -- I don't think they were blind to that information because they mentioned it in their review. One reviewer mentioned it as an issue.

Q. So they knew?

A. Well, at least one reviewer knew.

Q. Okay. And would it ease your concerns to know that the

journal itself knows of Dr. Chasen's involvement in this case?

A. Would it ease my concerns?

Q. Um-hm, about bias.

A. Well, I'm not saying that it made Dr. Chasen biased. I mean, I don't think that's the issue. The issue is disclosure, that readers need to know that, and if I were the editor of the journal that accepted this, given the circumstances, I would suggest that that be mentioned as a footnote when the article is published, and generally, that's on, included in the footnote on the title page of a manuscript.

Q. Okay. Thank you, Doctor. Now, Doctor, you would agree, wouldn't you, that the risks of mortality and morbidity from abortion, while very low, increase each week of gestation; wouldn't you?

A. There is a gradual increase, yes.

Q. And, in fact, the risk of mortality, in particular, increases exponentially with increasing gestational age and increases each additional week of gestation by 38%; doesn't it?

A. I could -- I don't challenge that. I don't have that figure in my head, the exact.

Q. You haven't reviewed the new CDC data on that, then, Doctor?

A. I have seen that, but I don't recall that specific figure.

Q. Okay. Doctor, if the highest risks of mortality came from one or two complications, let's say, for example, the highest risk of hemorrhage, the highest risk of mortality came from hemorrhage and infection, 25% each, in terms of mortality, if you were a physician trying to reduce the risk of death to your patients, wouldn't you seek to reduce the risk of those complications if you could?

A. Yes.

Q. Doctor, over your long career, you have been an advocate for numerous restrictions and prohibitions on abortions; is that fair to say?

A. Yes, ma'am.

Q. And as we discussed, you submitted written testimony in support of the Act that's at issue here and a number of the previous versions; is that right?

A. That's correct.

Q. And we discussed you testified in favor of the law challenged in Planned Parenthood versus Casey, and you're a member of the American Association of Pro-Life OB/GYNs; is that right?

A. Yes, ma'am.

Q. You have regularly financially contributed to the Right to Life Committee?

A. I have.
Q. And you've written several letters to Doug Johnson, the chair of the National Right to Life Committee?
A. We have communicated, yes.
Q. And you have financially contribute to Americans United for Life; is that right?
A. Yes, ma'am.
Q. Thank you, Doctor. Just one moment, Your Honor.
THE COURT: Yes.
MS. SMITH: I have no further questions, Your Honor.
THE COURT: Counsel?

REDIRECT EXAMINATION

BY MR. HENRY:
Q. Thank you. Doctor, on cross-examination there was some discussion about techniques that minimize instrumentation in the uterine cavity being a good thing intuitively. Let me ask you this: Does that mean that a procedure that minimizes instrumentation in the cavity is necessarily safer than a procedure that does not?
A. Well, again, it's intuitive, and it's interesting that none of the retrospective studies have -- of the large retrospective studies on D & E that I recall have actually studied that, so we don't know. This is intuitive knowledge. I mean, it's intuitive assumption, but that

issue of number of times you've introduced the curette or the forceps or whatever instrument versus outcome, I'm not aware of that study.

Q. Where does intuition fall on the scale of usefulness in the evidence-based medicine grouping?

A. Of course, it's not evidence, but it's a way of using your general knowledge and your general education to guide you in certain situations, you know, where there is not convincing evidence, so intuition is the lowest level, if I have to put it on a level, it's not -- in the descriptions of evidence-based medicine, I don't recall it's being mentioned specifically, so I'm giving you my opinion.

Q. Do you have an opinion whether intuitive-based assumptions about the safety of procedures should be studied?

A. Well, absolutely. The classic examples in medicine, fetal monitoring is one of them where intuitively, it made very good sense that fetal monitoring would save babies and was not harmful to mother, and it turned out when it was studied in controlled prospective trials, turned out to be just the opposite. Compared to standard auscultation, listening to the baby's heart with the old-fashioned stethoscope versus hooking electrodes to the baby's heart and comparing them, there were far more cesarean sections when the fetal heart rate monitor was used; i.e., more

dangerous to the mother, and there was no difference in the outcome for the baby, so that was where intuition was way off the mark.

Q. Dr. Bowes, do you believe that the risk of intact D & E and disarticulation D & E are comparable?

A. We don't know. The studies, by comparable, you mean equal. There is no difference in them. I'm saying we do not know that in a way that substantiates it with what we have now described many times over as evidence-based medicine. We simply don't know that. We can't prove that. We haven't proved it so far.

Q. And, Doctor, what is your opinion concerning the medical necessity of partial-birth abortion procedures such as intact D & E with regard to preserving the health of the mother?

A. Well, I will restate what the American College of Obstetricians and Gynecologists said in their statement. They know of no instance where it's necessary to use this procedure to -- they could think of no specific instance when this procedure would be necessary to protect the health of the mother.

Q. Doctor, are you familiar with the side effects of the use of Misoprostol?

A. I believe so.

Q. Can you tell the Court what those are?

A. One of the common side effects is nausea, hypertonic uterine contractions, meaning making the uterus -- nausea and vomiting, excuse me, to go back. Another one is the -- it will make the uterus contract overactively in some situations, and when you don't want that to happen, so those are two of the common complications.

Q. Doctor, I believe you were asked a question by Ms. Smith concerning -- or the assertion was made that you can't study a procedure if it's outlawed. With respect to intact D & E, do you have any thoughts as to how the procedure could be modified so that it could be studied even in the face of a ban?

A. Well, you can modify the procedure by introducing a feticide method to note the baby was dead before the procedure was started. I think I mentioned that in my response, or you could -- It wouldn't be modifying the procedure. You would be doing it in a different setting.

Q. Now, Doctor, the views that you have expressed here today, are they based on your experience and expertise regarding evidence-based medicine?

A. Yes.

Q. Is there something in the medical literature or with respect to evidence-based medicine that you're not telling us because of your ethical views concerning abortion?

A. No.

MR. HENRY: Thank you.

EXAMINATION

THE COURT: Doctor, before you step down, the lawyer for the plaintiffs asked you some questions about the Act and asked you, and I think you have got a copy of the Legislative Bill.

THE WITNESS: Yes.

THE COURT: The law that passed. And I recall you to tell her that you disagreed with certain of the findings in the Bill. Did I understand you correctly?

THE WITNESS: Yes, sir, you did.

THE COURT: Now, I have had the opportunity, counsel have given me the opportunity to review before this trial much of the Congressional Record, perhaps not all of it, but a good deal of it, so I have had the opportunity to review your letters to Congressman Canady and then Senator Santorum, and the questions I'm about to ask you now really have to do with how you came to have that interaction. How did you -- How was it that you first came to write Senator -- or pardon me -- Congressman Canady this letter of July 11th, 1995.

THE WITNESS: Well, Your Honor, I don't remember specifically what happened. I know that it was a call from his office, someone in his office. I never spoke to Congressman Canady personally.

THE COURT: Um-hm.

THE WITNESS: Who asked if I would be willing to comment on these assertions that were being made about this Bill.

THE COURT: Um-hm.

THE WITNESS: And I said, well, let me read the Bill and let me read it and the assertions, and I agreed to do it. Now, how his office got my name, quite frankly, I do not know. I have made no secret that of my pro-life world view and they may have known that or they may not have. I don't know, and I was also in active medicine at the University of North Carolina, so I think they felt I might have some expertise in responding to those assertions, but I cannot tell you specifically how my name came up.

THE COURT: With respect to this law, and I'm talking now only about the Congressman or his staff, other than this letter, did you have any input to Congressman Canady? Did you talk to him, did you provide him any other letters, information?

THE WITNESS: No, and I did not personally testify.

THE COURT: I noticed that.

THE WITNESS: This was my only input, and I did not talk to Congressman Canady personally.

THE COURT: So this letter represents your total input to the Congressman; is that fair to say?

THE WITNESS: Yes, sir.

THE COURT: Same series of questions with respect to Senator Santorum, and from the letter and from reading the record, I know that a physician in San Francisco had submitted a letter, and apparently the Senator submitted that letter to you for comment. Is that how it came about?

THE WITNESS: Yes. Yes, sir, that is.

THE COURT: Do you know, once again, how the Senator came to know of you or how that arose?

THE WITNESS: I do not.

THE COURT: And once again, I take it somebody from his staff contacted you?

THE WITNESS: It was somebody from his staff office, yes. I did not speak to Senator Santorum personally.

THE COURT: And other than this letter, is there any -- Did you provide the Senator with any additional information other than this letter?

THE WITNESS: No, sir, I didn't.

THE COURT: Okay. Now, the disagreement that you had with some of the findings in this Bill from my perspective are fairly significant. Did you tell either Canady or Santorum or anybody else in the House or Senate that you held those views?

THE WITNESS: When I -- when I wrote my letter to

Congressman Canady, of course, this document wasn't available. That was in 1995. At the time Senator Santorum's office asked me, I had not seen this Act, so I did not know of it, the total content of it. I knew the issue was being discussed, and he asked a very specific question. Please look at Dr. Darney's -- what Dr. Darney said. What is your response to that? So it was only later that I viewed it, and I did not recontact them about that.

THE COURT: And that, and I'm not -- I didn't mean to imply any criticism of you.

THE WITNESS: Yes, sir.

THE COURT: This Bill appears to have been approved on or about the 5th of November, 2003, and what I want to know is whether either Canady -- or Congressman Canady or Senator Santorum or any other member of the House or Senate were aware of your disagreement with the findings in this Bill prior to November 5, 2003.

THE WITNESS: To my knowledge, they are not. I mean, and certainly, I didn't communicate with them in any way they would have known that.

THE COURT: All right. Thank you very much, Doctor. I appreciate your testimony. I'm going to let the lawyers follow up on my questions, first for the Government, then the defendant, then the Government. Go ahead.

REDIRECT EXAMINATION

BY MR. HENRY:

Q. Doctor, there has been testimony today that you have disagreed with various findings in the Act. When you say you disagree with those findings, are you saying that the findings are wrong as an absolute matter; are you saying that more study is required?

A. The statements here, I think, are statements that cannot be supported by evidence-based medicine. That's what I'm saying. They say that the procedure may be more dangerous for mothers, for the patients. It may be, but it's not proven, so to the extent that I disagree with it, it's that I would disagree with the way it's being stated, and as I tried to say over and over again, I don't think we know the relative risks of these procedures, and what they have stated in these findings is suggesting that it's known that the one procedure is more dangerous than the other. I don't think we know that yet.

BY MR. HENRY.

Q. So you're saying it hasn't been adequately studied?

A. Hasn't been adequately studied, yes.

MR. HENRY: Thank you.

THE COURT: Counsel?

MS. SMITH: I have nothing, Your Honor.

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

MR. HENRY: He may, Your Honor.

MS. SMITH: Yes.

THE COURT: You're excused, Doctor. Thank you. It's now about 4:25, counsel. We should take our break here in a moment, but let me inquire of defendant's counsel, what do we have in store for tomorrow? Can you give me kind of a preview?

MR. HENRY: Yes, Your Honor. Dr. Anand, the fetal pain expert is scheduled to begin his testimony tomorrow morning, and tomorrow afternoon it would be Dr. Sprang.

THE COURT: All right. Okay. Shall we take our break now?

MR. HENRY: Well, Your Honor, Dr. Anand is not here ready to start today, so --

THE COURT: No, that's what I mean. Shall we take our break now?

MR. HENRY: The break for the evening?

THE COURT: Yes.

MR. HENRY: Okay. That would be fine.

THE COURT: No, no, I wasn't -- if you think I'm going to work after -- into the evening to take this doc's testimony --

MR. HENRY: I'm sorry.

THE COURT: -- you haven't been with the Government long enough.

MR. HENRY: I'm sorry. The word break was confusing.

THE COURT: I'm teasing you, counsel. All right. We'll stand in recess until 9:00 o'clock in the morning.

(Recess at 3:27 p.m.)

C E R T I F I C A T E

I, David C. Francis, certify that the foregoing is an accurate transcription of the record of proceedings made in the above-entitled matter.

s/ David C. Francis DATE: April 5, 2004

Official Court Reporter (Ret)

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