UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI, et al.
vs
HERBERT H. SLATERY III, Attorney General of Tennessee, in his official capacity, et al.,

Case No. 3:20-cv-00740

- -

BEFORE THE HONORABLE

WILLIAM L. CAMPBELL, JR., U.S. DISTRICT COURT

TRANSCRIPT OF PROCEEDINGS

January 25, 2021

VOLUME V

- -

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The above-styled cause came to be heard on Monday, January 25, 2021, at 2:05 p.m., before the Honorable William L. Campbell, Jr., District Judge, when the following proceedings were had, to-wit:

THE COURT: All right. Good afternoon. We're resuming the hearing on the motion for a preliminary injunction in Case 3:20-cv-740. It looks like we've got the same line-up here, so we'll dispense with the introductions, unless somebody really wants to say hello again.

A couple of things I want to talk about before we get started. We had a notice filed by the plaintiffs of an intention to call Dr. Schreiber in rebuttal and the defendant's objection to that. This is a hearing that has been unorthodox, to say the least, in terms of how we've conducted it, and that's by necessity, both COVID and scheduling and location of witnesses and lawyers and had we gone in the ordinary course of things, we -- this sounds as if it would be rather run of the mill -- all right. We've got an audio issue here.

THE WITNESS: Can you hear me?

THE COURT: I can, yes. You cannot hear me?

THE WITNESS: I can't hear anything.

THE COURT: Okay.

MR. CASTELLI: Our co-counsel also said they

cannot hear, Your Honor.

THE COURT: Okay. Are they saying they can see me, but just not hear me?

MR. CASTELLI: Yes, Your Honor, they can see. They just can't hear. I think they can hear Dr. Harrison.

COURTROOM DEPUTY: Can you just ask them if they can log in again.

(Off-the-record.)

THE COURT: Just so that I understand the line-up, we're going to finish this witness, Dr. Harrison, and then who's got Dr. Joffe?

MR. CASTELLI: Joffe will be called as our last witness.

THE COURT: And how long do you think he'll take?

MR. CASTELLI: Direct should take about an hour, hour and 15 minutes.

THE COURT: And then do you expect this rebuttal to be today?

MR. CASTELLI: We'd like for it to be today. I think it will be about ten minutes. We want to address one point.

THE COURT: And that witness is available at the tail end of whenever we finish?

MR. CASTELLI: She will be available at the end of the day.

THE WITNESS: Okay. I can hear you now.
THE COURT: Oh, you can?
THE WITNESS: I can hear you now, yes.
THE COURT: So now looks like we've got -- Dr. Harrison, can you hear me okay?
THE WITNESS: Yes, I can hear you now.
THE COURT: All right. What about your --
MR. CASTELLI: They seem to be able to hear, Your Honor.
THE COURT: All right.
MR. CASTELLI: Thank you.
THE COURT: Okay. Looks like we've got folks back up and running with audio and video, so we will proceed. As I was saying before we dealt with that issue, in terms of rebuttal, this has been an unusual hearing for lots of reasons, COVID, scheduling and the like, and both lawyers and witnesses, and we've done a lot of things out of order. It sounds to me like Dr. Schreiber, the anticipated testimony would be fairly run-of-the-mill rebuttal that the plaintiffs would offer. I'll allow it for the purposes that you set forth in your notice. Then, of course, if the defendants seek to cross-examine her on that testimony, I'll certainly give you sufficient latitude to do that. And if that for some reason brings up new information that the defendants feel like they need to address, then let me know. I don't

want to prolong this any more than we have to, but I want to be fair to both sides. So we'll just kind of see where we find ourselves after her testimony.

MR. CASTELLI: Thank you, Your Honor.

THE COURT: All right. We've got a couple of wrap-up things we'll do, but we'll hold those till the end of the hearing so we can go ahead and get the witnesses -- their testimony in the record.

So who do we got next?

MR. CASTELLI: Your Honor, I'll continue my examination.

DR. DONNA HARRISON,

called as a witness, having been previously duly sworn, was examined and testified as follows:

CROSS-EXAMINATION CONT.

BY MR. CASTELLI:

Q. Dr. Harrison, can you hear me okay?

A. Yes, I can.

Q. All right, great. I'm going to try to pick up where we left off over a month ago. I only have hopefully just a little bit left to ask. But when we were last talking -- and again, my name is Thomas Castelli for the plaintiff. When we last spoke, we were talking about some animal studies, various animal studies, and I think I had asked if you were aware of any animal studies that explicitly set out to study

this -- this theory of reversal of abortion in animals.

And you were not aware of any; is that correct?

A. That's correct.

Q. All right. And then there's no ethical bar to doing the experiments on animals that would be necessary for that type of study; correct?

A. That's correct. Yes. Can you hear me?

Q. Yes. Sorry.

A. Okay.

Q. Thank you. Now, I believe you've testified in the past that there are animal studies concerning a different topic that we had discussed briefly, I think toward the end of your testimony last time, which is whether an ectopic pregnancy can be reimplanted. Is that your understanding?

A. There are ongoing studies on that right now, animal studies, that is correct.

Q. And I believe there are also some papers concerning transplanting ectopic pregnancies in humans; is that right?

A. Yes, there are papers that exist.

Q. At your deposition, though, you testified that despite the research that is ongoing, you would not tell a patient that it may be possible to reimplant an ectopic pregnancy; is that correct?

A. That is correct.

Q. And that's because at this point in time right now, the

technology just hadn't been developed to accomplish that reimplantation; is that correct?
A. That is correct.
Q. All right.
A. That is correct.
Q. And even though it's theoretically possible, you would not -- you would agree that it would not be appropriate to tell a patient with an ectopic pregnancy that it may be possible to reimplant it?
A. That is correct.
Q. And I believe there was a question during your deposition about whether it would be appropriate for an oncologist, for example, to tell a patient about a possible treatment method based solely on anecdotal evidence found on the internet, and you -- you stated that you would hope a doctor would dig a little deeper into that issue before they would recommend treatment to a patient; is that correct?
A. That's correct.
Q. I believe you have testified in the past that -- or you agree that you cannot rule out the possibility that a patient who has been told about the abortion reversal, that they may think that -- if they are not entirely sure what they want to do, that they might go ahead and take the first pill and then -- thinking they might be able to change their mind later; is that correct?

A. That's a lot of speculation.
Q. But you can't rule that out as something that a patient might -- might do if you give them that information?
A. That's correct.
Q. And you would agree that there's ultimately just so much a doctor can do to make patients understand certain information when they're giving informed consent?
A. (Inaudible.)
Q. And, I'm sorry, you broke up for us in the courtroom there. Could you repeat your answer?
A. Sure. It is the role of a physician to give accurate information especially answering patients' questions.
Q. But when we're dealing with that role, there's only so much information, so far they can go, in order to make a patient understand whatever procedure they're giving informed consent about; do you agree with that?
A. Well, yes, of course. You can't -- you can't be in the mind of somebody else. You can use words to communicate information, but you can't get into the mind. That's just not possible.
Q. Thank you. Now, you had previously written in an email about mifepristone, that 70 -- 7 to 40 percent of the time that a pregnancy would continue with mifepristone, is that correct? Or that the baby would be -- would be alive after taking mifepristone?

A. You're going to have to show me that email because I don't -- I don't recall saying that. So go ahead and show it to me.
Q. I believe we -- your counsel should have emailed that to you earlier today. Do you have that with you?
A. Hold on just a second. Okay. Which one is it? I've got Cross Tab A --
Q. I believe it's Cross Tab A.
A. I've got Defendant's Exhibit --
Q. It's Cross Tab A, if you'll look at that.
A. Okay, yes.
Q. And I believe it's at the top of --
A. So is it what is in yellow?
Q. I'm sorry?
A. Is it what is in yellow or is it what's below that?
Q. I may have you looking at the wrong thing. Can you see what's on the screen in the courtroom or --
A. No. Hold on. Let me -- I was looking at the -- let me see what's on the screen. When it says -- I'll read what I have. It says (as read): I'll break it down here. 60 to 80 percent of the time, the fetus dies and is expelled, and nothing is left. 30 to 60 percent of the time, there's a dead fetus left, there's some placental tissue left inside --
Q. I think you're looking at the right -- you're looking at the right email. So --

A. 7 to 40 percent of the time, yeah. Okay. So now that I have the email, what is your question?
Q. That is an email that you -- you have made that statement before about 7 to 40 percent of the time?
A. Yeah, that's -- that's an approximate.
Q. Okay.
A. And it's based on the paper. So I'm answering the question in the paper. So what I was doing was explaining what the numbers in the paper mean.
Q. Okay. In that same email also, you wrote that mifepristone has an extremely long half-life, which means that mifepristone stays active?
A. Yes.
Q. And that's something else you agree with that's true?
A. Well, it's nuanced, but -- it's a little more complicated than that, but yes.
Q. Okay. Do you know a Dr. Matthew Harrison?
A. I know him.
Q. Are you aware of whether he's ever made any statements about the type of laws that are at issue in this case?
A. I do not know. I've met him once.
Q. Who is he?
A. Matthew Harrison is an OB-GYN.
Q. Okay. When you met him, did you have any conversations with him about laws mandating this type of -- this type of

law talking about reversal treatment?
A. Oh, my goodness. I met him years ago. I have no idea what I talked to him about.
Q. Fair enough. You've testified previously that you personally would not use the term "reversal" when talking to patients; is that correct?
A. Yeah, it's not -- it's not as -- it's not as precise. I would rather be more precise. And I wouldn't say I wouldn't use it when talking to patients, but in general, it would be better to say exactly what's going on, which is that progesterone blocks the action of mifepristone and its breakdown products at the progesterone receptor. So it depends on who I was talking to how simple a language I would use.
Q. And do you have a copy of your -- of the declaration that you submitted in this case?
A. Yes, I do.
Q. Okay. And do you also have a copy of the AAPLOG practice bulletin? I believe we discussed that at your last -- during your last testimony, Defendant's Exhibit 2?
A. Plaintiffs' Exhibit 18? Plaintiffs' Exhibit 18 is what it's labeled as, I think.
Q. That's correct. And I believe it's admitted in the court as Defendant's Exhibit 2.
Just really quickly about that, those two

documents, it's true that -- well, first of all, you didn't write the practice bulletin; right?
A. No, I didn't write it.
Q. But it's true that every one of the medical arguments -- I'm sorry, medical articles or websites that you cited in your declaration are also cited in the practice bulletin, except for maybe one or two?
A. I don't know. I never compared them. I did edit the practice bulletin.
Q. Okay. And is it also true that many of the paragraphs in your declaration are basically word for word from that practice bulletin?
A. Well, I supplied my information to the people that wrote the practice bulletin, and they thought that it was good information.
Q. So are you saying that the practice bulletin --
A. And useful.
Q. -- practice bulletin was based off of your declaration in this case?
A. No, the practice bulletin is based off of research that the people who authored the practice bulletin did. One -- I did offer them information. And so -- and I edited the practice bulletin.
Q. Okay. And then when you were submitting your declaration in this case, you used the language in that

practice bulletin in your declaration; is that correct?
A. Some of it. I mean, it's language that I wrote. So -- I write my own declarations. I don't have somebody else write my declaration.
MR. CASTELLI: If you'll give me a moment, Your Honor, I may be done with my questioning. Your Honor, those are my questions. Thank you.
THE COURT: Okay.
MR. RIEGER: Last time we were here, Your Honor, I believe that you had questions. Would you like me to redirect first?
THE COURT: Go ahead.
MR. RIEGER: All right. Thank you.

REDIRECT EXAMINATION

BY MR. RIEGER:
Q. Hi, Dr. Harrison. Can you hear me?
A. Hi.
Q. Just a few more questions for you.
A. Yes, I can hear you.
Q. Excellent. Thank you. Dr. Harrison, did the early stages of testing Mifeprex's efficacy as an abortifacient use animal studies?
A. Yes, they did because that's the --
Q. I'm sorry. Please --
A. That is the normal course -- okay. The normal course of

drug development is you use animal studies for safety and efficacy before you go to human studies. So it's the normal part of drug development.

Q. Do you know if the animal studies used to test Mifeprex -- do you know what those animals were?

A. They used rats, and I believe there may have been -- I would have to go back and look at the studies. I believe there may have been mice and rabbits.

Q. Do you know why --

A. May have even been one study on a cat. Yes, go ahead.

Q. I'm sorry. Do you know why -- do you know why a group wanting to use animal studies would choose rats?

A. Rat physiology is close to human physiology. So when you look at endocrine-type studies, rats are a commonly used lab animal. They breed quickly. They are -- they're just -- their physiology is pretty close to humans. Not perfect, but pretty close.

Q. Are you aware of any studies or other evidence that would disprove the use of using supplemental progesterone to counteract the effects of mifepristone?

A. No. No.

Q. Do you think --

A. And, in fact -- go ahead.

Q. Please, go ahead.

A. Well, in fact, there are some other papers that have not

looked at the use of progesterone, but there's a couple of papers that have looked at giving Depo-Provera, which is a kind of progestin, immediately after Mifeprex. And what it shows is that those women that were given Mifeprex and then injected with Depo-Provera had a higher ongoing pregnancy rate. Now, progestins are not progesterone, as we -- as I made clear in my declaration. However, it's very interesting that progestins produce the same kind of higher ongoing pregnancy rate. And that study was done by people who support abortion.

So it's not that there was any motivation in there. In fact, they -- they noted that progestins can perhaps interfere with the metabolism of progesterone. And that was actually cited in the ACOG practice bulletin on medical abortion.

Q. Do you think that any of the required disclosures in the law would mislead a patient?

A. No, I don't. It's very clear. We're not saying that there's a miracle going to happen. What you're saying is it might, may, perhaps be possible to increase the chances of survival if progesterone is taken quickly after Mifeprex. That's pretty clear.

Q. Do you think that any of the required disclosures in the law would hurt or harm a patient or prevent them from having an abortion that they wanted to have?

A. No. And the reason I don't is because you're not saying you have to have progesterone. You're not saying you have to reverse the abortion. You're saying if you change your mind. And if a woman's not going to change her mind, then no harm is done, she has this information, but if she was to change her mind, and she wanted to make a different choice, then this allows her at least some ability to increase the chances that her baby might survive a Mifeprex ingestion.

MR. RIEGER: Thank you. That's it for me, Your Honor.

THE COURT: I've got a couple of questions I'm going to ask. Can you hear me okay, Dr. Harrison?

THE WITNESS: Yes, Your Honor.

THE COURT: Okay. This goes back to when you testified on a previous date, and I want to make sure I understood that testimony. You described a process of mifepristone attaching and unattaching perhaps more than once. Did I understand that correctly?

THE WITNESS: That's correct. Yes, that's correct.

THE COURT: And so in that process, if it unattaches, then progesterone, if there's sufficient amounts there, might attach to that receptor before the mifepristone reattaches?

THE WITNESS: That's correct. It's a competitive

binding.

THE COURT: Right.

THE WITNESS: And the other thing that is a little more complicated is that it's not just mifepristone that's attaching. So mifepristone has a very high affinity for the progesterone receptor, but mifepristone in the body breaks down, and it breaks down into some byproducts. Like, I was -- like, if you look back at the email that I sent, it breaks down into some metabolites, and those metabolites also bind to the progesterone receptor. But whereas mifepristone itself is very, very strongly attached to the progesterone receptor, the metabolites that it breaks down to are not as strongly attached.

In fact, they -- progesterone itself can outcompete those metabolites. So when it says that mifepristone lasts in the body, it's actually the mifepristone effects that last in the body, but mifepristone itself probably doesn't hang around in the body for more than a day or two before it breaks down. So if you have mifepristone, and you kept giving mifepristone, you may not be able to reverse it with progesterone, but because you give mifepristone once, and then it breaks down into these other products that attach, those other products don't attach as tightly as progesterone, and progesterone can outcompete those products. I hope -- I hope was more clear than

confusing.

THE COURT: No, I understand. I understand what you're saying. Previous testimony in this hearing used the analogy of a key and a lock, that mifepristone attaches to the receptor and occupies that lock, if you will, but it doesn't turn the lock, it just sits in the lock.

THE WITNESS: Correct.

THE COURT: Okay. So if I understood your testimony earlier, the key might insert in the lock, come out, insert in the lock, come out, and at some point, the progesterone may slide into that lock using that analogy and then actually turn it and do what progesterone does to -- that the testimony has been about in terms of the ripple effect of the progesterone in that receptor and the consequences of that.

Is that -- do you agree with that?

THE WITNESS: Yes. Yes, that's correct.

THE COURT: So is mifepristone doing anything other than occupying the lock, or is it just taking the space of it, and that's the -- that's what causes the beginning process of the abortion process? Does that make any sense?

THE WITNESS: Yes, it does. It's just occupying the space of it. Because it -- when progesterone binds to the receptor, it makes the receptor change its shape, and that's what starts the whole cascade of DNA transcription,

but mifepristone has a slightly different shape. And so it doesn't cause a progesterone receptor to change its shape and then initiate the cascade. So, as you said, it is just simply occupying the spot and blocking the progesterone from getting in and causing the beginning of transcription.

THE COURT: So is there anything -- let's take this situation you describe where the prog -- sorry, mifepristone attaches -- unattaches to the receptor, and then progesterone attaches to that same receptor. Is there anything that the mifepristone has done that the progesterone is undoing?

THE WITNESS: No.

THE COURT: Okay.

THE WITNESS: No. It just simply blocks the receptor.

THE COURT: Okay. All right. Any other questions in light of my questions from counsel?

MR. CASTELLI: No, Your Honor.

MR. RIEGER: No, Your Honor.

THE COURT: All right. Thank you, Dr. Harrison.

THE WITNESS: Thank you. Should I just X out of the meeting?

THE COURT: Yes, ma'am.

(Witness excused.)

MR. RIEGER: Your Honor, if I may, since that was

the final defense witness, before the defense rests in this case, I would note to the Court that in between our last hearing date and today, and as required by the law, the Department of Health website that the law required has gone live. If Your Honor would like a -- if Your Honor would like to have a copy of the web page into evidence, I have one.

THE COURT: I believe I have it.

MR. RIEGER: Your Honor, has beat me to it.

THE COURT: Actually, she did.

MR. RIEGER: Thank you.

THE COURT: But we are going to talk about that at the end of the hearing. I want to hear some thoughts on that issue as well because it's been hanging out there.

All right, who's next?

MR. CASTELLI: Your Honor, plaintiffs would call Dr. Joffe.

THE COURT: All right. Who do we have -- hold on. Who's going to be handling this witness?

MS. BAJRAMOVIC: I will be, Your Honor. Hana Bajramovic for plaintiffs.

THE COURT: Okay. Let's go ahead and call that witness then.

MS. BAJRAMOVIC: Dr. Joffe is logging in right now.

THE COURT: Okay.

MR. GROVES: Your Honor, this is Alan Groves. I'll also be cross-examining this witness on behalf of the defendants.

THE COURT: Okay. My suggestion would be, because all of the questions and answers are provided by video, that you be deliberate about slowing down for our court reporter and just so that there's -- in case there's any lag at all, the question and the answer is heard by everybody.

All right. We're showing that the witness is logged on, but muted. Are you able to get him --

MS. BAJRAMOVIC: Yes, I'm on the phone texting him. He's trying to figure it out right now.

THE COURT: Okay.

MS. BAJRAMOVIC: Dr. Joffe is logging out and logging back in. He hopes that will fix it.

THE COURT: Me too. All right. It looks like we've got everybody. Go ahead.

MS. BAJRAMOVIC: Thank you, Your Honor.

BY MS. BAJRAMOVIC:

Q. Good afternoon, Dr. Joffe. Could you please turn to the exhibit marked --

THE COURT: Oh, wait. Hold on. We need to swear him in first.

COURTROOM DEPUTY: Raise your right hand, please.

///

DR. STEVEN JOFFE,

called as a witness, having been duly sworn, was examined and testified as follows:

THE WITNESS: I do.

COURTROOM DEPUTY: State your full name for the record, please, and spell your last.

THE WITNESS: Steven Joffe, J-O-F-F-E.

THE COURT: All right, counsel.

DIRECT EXAMINATION

BY MS. BAJRAMOVIC:

Q. Thank you. Good afternoon, Dr. Joffe. Could you please turn to the document marked for identification as Plaintiffs' Exhibit 46. Just let me know when you have it up.

A. Okay. I have it.

Q. Do you recognize that document?

A. I do. That's my CV.

Q. Did you prepare it?

A. I did.

Q. Is it a true and accurate summary of your educational and professional history?

A. It is current as of August 7th, when it was prepared.

Q. Are there any updates you'd like to add since then?

A. I would -- I'm sure there are a number of publications that I have published since then that would not be on it. I think there may be a committee or two that I've been added to

since I've been on it, one of which I know is Oversight Monitoring Committee for the COVID Vaccine Trials that the federal government is running. So there may be some other updates. I would have to go through in detail to be sure.

MS. BAJRAMOVIC: Your Honor, plaintiffs move to enter Plaintiffs' Exhibit 46 into evidence.

MR. GROVES: No objection, Your Honor.

THE COURT: All right. Without objection, Plaintiffs' Exhibit 46 is admitted.

(Plaintiffs' Exhibit 46 received in evidence.)

BY MS. BAJRAMOVIC:

Q. Dr. Joffe, I know the Court has your resume, but could you briefly describe your professional history for the Court?

A. Sure. I started -- I was a college student at Harvard, after which I went to the University of California at San Francisco as a medical student to study medicine. During -- after I finished my medical school training, I did training in general pediatrics, also at the University of California, San Francisco. It's called Internship and Residency. That lasted three years. And then spent a couple of years getting a Bachelor of Public Health degree in epidemiology at University of California, Berkeley. During those couple of years, I also did research at Kaiser Permanente in Northern California.

After that, I went to the Dana-Farber Cancer

Institute and Boston Children's Hospital, which are Harvard affiliated, to train in pediatric hematology-oncology or cancer and blood diseases of children. I stayed on the faculty at Harvard, or at those hospitals, for the next, I believe, 13 years practicing hematology-oncology, but also spending most of my time actually working in medical ethics.

And then in 2013, I moved to the University of Pennsylvania, the School of Medicine, where I became chief of the Division of Medical Ethics, professor -- or at least initially associate professor and subsequently professor of medical ethics and also continued to work in pediatric hematology-oncology, organ transplantation until 2019, when I stopped my clinical practice.

That's the short summary of my career.

Q. And what is your current position?

A. I'm professor of medical ethics and health policy at the University of Pennsylvania, School of Medicine. I also have a title of Professor of Pediatrics. And I'm the interim chair of the Department of Medical Ethics and Health Policy, which is a department in the medical school.

Q. You mentioned that you practiced cancer medicine. As a bioethicist, do you limit your ethics opinions to cancer?

A. No, my ethics work has ranged over a wide range of areas, including but not limited to cancer. I have done research on issues that extend beyond cancer. I've been an

ethics consultant on issues that extend well beyond cancer during the time that I was at Boston Children's Hospital and Dana-Farber and also the Children's Hospital in Philadelphia and have written about issues that extend well beyond cancer.

I would note that many people who work in bioethics are not themselves clinicians, not physicians or nurses or others with a clinical specialty, and have worked across a whole bunch of diseases, even though they are not themselves specialists in those diseases.

Q. In addition to the positions we've just discussed, do you publish in peer review journals?

A. Part of my academic job for the last 20 years has been to publish in peer review journals. So I write extensively on a range of topics, mostly in bioethics, and I think if you look at my CV, I have something on the order of 200 publications in peer review journals.

Q. Do you conduct research for those publications?

A. I do. Many of those involve conducting original research, where either myself or together with colleagues, collecting data and then analyzing those data and recording the data. Some of them are more conceptual or policy oriented and don't have the component of original research, but many of them certainly do.

Q. How many of them would you say incorporate original research, approximately?

A. I would estimate that probably half of them incorporate original research. Obviously, I would have to go through them in detail to be sure, but that's a -- that's a rough estimate.
Q. Now, I know you mentioned that you've written on bioethics, but what other topics do you publish on?
A. I publish on health services research, practice of cancer medicine and policy issues related to cancer medicine, but again most of my publications have been related to bioethics either in biomedical research or related to the practice of clinical medicine.
Q. Have you published in informed consent?
A. Extensively. Many of my articles have been related to the question of informed consent.
Q. What background or preparation does someone need to publish or do research on the ethics of human research?
A. I think there's a range of areas that are relevant to doing research or publishing on human research, one of which is an understanding of ethical norms and codes and literature on the morally appropriate thing to be doing in various medical or research context. I think also an understanding of the regulations governing human subject research or governing medical care is important, although again, as you know, I'm not a lawyer; an understanding of the practice of clinical medicine, which obviously I have through my clinical

work and training, and importantly an understanding of the methods of doing research, the statistical methods, the study design methods for conducting, for gathering data and for analyzing research.

Q. Aside from the publications we talked about, do you have other experience relating to informed consent?

A. I do. In my capacity as a physician and somebody who's actually participated in research, I've sought informed consent from research participants or from patients or, as a pediatrician, often from the parents. I have served on a number of committees where the issue of informed consent would come up, in those ethic committees at various hospitals or institutional review boards, committees that oversee the conduct of research, and I've been on several national committees, where one of the topics that those committees would take on is issues of informed consent.

Q. Have you served on any institutional review boards?

A. I have. During the years that I was at Dana-Farber, I served on the IRB, or the institutional review board, there for essentially all of my 13 or 14 years at Dana-Farber, with a couple of years of breaks, but for most of the time that I was there, I was a member of one of the panels of their IRB.

Q. And I should have asked you this before, but could you define an institutional review board for the Court?

A. Sure. An institutional review board is a committee that

typically, although not always, sits within an institution that conducts research and is responsible for the oversight of research that happens within that institution for making sure that it is conducted or designed in an ethical way, that it's scientifically sound and well-grounded, that it is consistent with the regulations governing research.

And those regulations might come from the Department of Health and Human Services. They might come from the Food and Drug Administration. They might come from the Department of Defense or other entities that sponsor research, but they are charged by those either funders or regulators with overseeing the ethics and the conduct of research.

Q. What do you do in your role at the IRB?

A. The IRB that I was on would meet typically twice a month, and we would be given protocols to review, a combination of protocols that were not yet approved that were being reviewed for the first time and protocols that were already approved but needed their annual sort of renewal, if you will, or amendments that the researcher wanted to make. And as a member of the IRB, I would be charged with being a primary reviewer for several of the protocols that we were asked to review and then was also expected to look at and to share any opinions that I might have about all of the protocols that were included in that week's meeting.

Q. How many protocols did you review per year?
A. Typically, we had about five or six protocols, new protocols, fresh protocols, and many other, what are called, continuing reviews or amendments at each meeting. So focusing on the new protocols, if we had six per meeting, typically maybe 24 meetings a year, that works out to something like 140, 150 protocols a year. Multiply that by 12 years. I would say it was at least 1500 protocols over the course of the years that I was on the IRB.
Q. And when you were reviewing protocols, did you give feedback on study design?
A. Yes. When we had questions or concerns about study design, which was sometimes true and sometimes everything was fine, but sometimes there were concerns about study design, and we would share that with the investigators through the IRB channels. And if the investigator agreed, then they would revise the protocol in ways that met our concerns or objections.
Q. Have you designed studies yourself?
A. I have. I've designed a number of original research studies of my own, many of them which involved surveys or other forms of data collection like that, but several of which would have involved clinical trials where I actually was involved in the design of an experiment where we were actually investigating some sort of a therapeutic approach

with a patient.

For example, now I'm principal investigator of a study that enrolls young adult cancer patients and that compares to different strategies for identifying which of those young adult cancer patients might have genetic risk for their cancer, might have a genetic -- something in their family, and we designed that and sought funding from the National Cancer Institute and have now begun that protocol. Together with my coinvestigator, I designed that study.

Q. How many studies have you designed?

A. I would estimate somewhere on the order of 15 to 20 studies over the course of my career, perhaps more. I'd have to look back in detail.

Q. Have you ever served as a peer reviewer of manuscripts sent to journals?

A. I frequently serve as a peer reviewer. I get probably several requests a month to serve as a peer reviewer. I can't do them all, but I'm frequently asked. But I would say 12 to 20 times a year I accept those invitations and function as a peer reviewer for a journal at their request.

Q. Do you have any other experience that would require knowledge of research methods and study design?

A. I served on a number of national committees that involve supervision of research or research policies or how research is conducted, whether they be advisory committee to the Food

and Drug Administration. I'm a member of a committee that is available to the FDA on request to look at the ethics of pediatric research, when they have questions or concerns. I'm a member, as I said earlier, of the monitoring board for the COVID vaccine trials that the federal government is running that we're also concerned about, and have been a member of several other monitoring committees for other studies for the federal government, several of them related to HIV trials internationally. I think those are some of the key committees or roles that I've been in.

MS. BAJRAMOVIC: Your Honor, plaintiffs move to qualify Dr. Joffe as an expert in the areas of medical ethics, informed consent and research design and study methods -- I'm sorry, research methods and study design.

THE COURT: Mr. Groves.

MR. GROVES: Yes, Your Honor. Defendants acknowledge that Dr. Joffe does have expertise in these areas, but as Your Honor knows, expertise alone does not qualify an individual to provide expert testimony, and an expert must have testimony that will help the Court understand the evidence in a particular case, and the testimony must also be the product of reliable principles or methods.

And as we mentioned in our motion in limine, Dr. Joffe's testimony is not going to help the Court

understand the evidence in this case. He's stated in his declaration that he's not opining on whether medication abortion and reversal is biologically possible or whether it's safe. And so he can't testify as to whether the disclosures required by Tennessee's law are truthful or non-misleading.

And as the Sixth Circuit held in Beshear, the state, not medical professionals, really gets to decide how to define the contours of informed consent. So if the Court would like to hear his testimony, we understand that. We think our cross-examination would also show that his testimony is not based on reliable principles and methods because he's really not familiar with the plaintiffs in this case and their informed consent protocols or their -- or the federal regulations governing medication abortion, in particular.

THE COURT: Any response to that, counsel?

MS. BAJRAMOVIC: Sure, Your Honor. As to the first point about relevance, an expert on medical ethics and informed consent, which all parties agree Dr. Joffe is, has substantial insight into a question all parties agree is relevant, whether a patient given specific information prior to a procedure will be misled by that information. An expert in informed consent is ultimately an expert in understanding what kind of information is relevant and necessary for

patients, how people process different kinds of medical information under different circumstances and how it affects medical decision making. Dr. Joffe does have extensive insight into the question of whether the disclosures required by the reversal law are false and misleading.

Regarding counsel's point about the biological plausibility of reversal, Dr. Joffe, you know, readily admits that he is not presenting opinions about the biological plausibility of reversal, but as an expert in research methods and study design, he has reviewed the Delgado papers and come to conclusions about them. He is amply qualified to do so by virtue of the hundreds of study protocols he has reviewed as an IRB member, peer reviewer and grant reviewer, by his extensive list of publications on medical ethics and informed consent, many of which rely on his empirical understanding of research methods and study design and by the many studies he, himself, has designed and by his training in public health school as well.

THE COURT: Okay. I will allow Dr. Joffe to testify as an expert on the areas that you identified. If defendants feel that he has -- the testimony solicited on direct steps outside of those, then you're certainly free to raise any objections at that time, Mr. Groves. And then, of course, as you mentioned, some of this may be good subject matter for cross-examination. So I will allow him to testify

as an expert in the areas that counsel identified when proffering him as an expert.

MS. BAJRAMOVIC: Thank you, Your Honor.

BY MS. BAJRAMOVIC:

Q. Dr. Joffe, I'd like to direct your attention to the document marked for identification as Plaintiffs' Exhibit 45. Let me know when you have that up.

A. I do.

Q. Do you recognize this document?

A. I do.

Q. What is it?

A. It's the declaration that I filed in this case. I don't recall the precise date, but some months ago, the first declaration.

Q. Does this document accurately reflect your expert opinions in the case?

A. It does.

MS. BAJRAMOVIC: Your Honor, plaintiffs now move to enter Plaintiffs' Exhibit 45 into evidence.

MR. GROVES: No objection.

THE COURT: Without objection, Plaintiffs' Exhibit 45 is admitted.

(Plaintiffs' Exhibit 45 received in evidence.)

BY MS. BAJRAMOVIC:

Q. Now, I'd like to direct your attention to the document

marked for identification as Plaintiffs' Exhibit 96. Let me know when you have that up.
A. I do.
Q. Do you recognize this document?
A. I do.
Q. What is it?
A. This is the rebuttal declaration that I filed in response to declarations from some other experts in the case.
Q. Does this document accurately reflect your expert opinions in rebuttal to those other declarations?
A. It does.
MS. BAJRAMOVIC: Your Honor, plaintiffs move to enter Plaintiffs' Exhibit 96 into evidence.
MR. GROVES: No objection.
THE COURT: Without objection, Plaintiffs' Exhibit 96 is admitted.
(Plaintiffs' Exhibit 96 received in evidence.)
BY MS. BAJRAMOVIC:
Q. Turning to the issues at hand, Dr. Joffe, why are you here today?
A. I'm here because I have substantial concerns about the ethics and the implications of the Tennessee law that is the subject of this case. I am concerned about the requirements that information be communicated to women who are considering medication abortions that may be misleading, that are not in

my view grounded in solid scientific evidence from human experiments or human studies. And one of my -- one of my major concerns about the law, or implications of the law, is the possibility that it will lead women who might be uncertain about the -- their abortion or going forward with an abortion, instead of taking the time and having further discussions to be certain whether they want to proceed with the abortion or not, whether it might lead them to believe that, in fact, since they're told the abortion may be reversible, that they may decide to go forward in the face of uncertainty in their own minds. And I think this would be a tragic outcome for -- for women and their families.

I also am concerned about the implications of the law or the messages that are required by the law for the integrity of the physicians or clinicians who are forced or required to communicate this information and for the trust relationship between them and their patients.

Q. Do you have an understanding of whether medication abortion, in fact, can be reversed?

A. My understanding of whether it can be reversed is that there are a couple of papers from Dr. Delgado and his colleagues that purport to show that it can be reversed, or at least that the administration of high-dose progesterone can increase the likelihood that it will be reversed. In my view, these papers don't convincingly show or don't -- don't

provide strong evidence that, in fact, administering progesterone makes it more likely that the pregnancy will continue than not administering the progesterone. I understand that the single drug mifepristone by itself does not always lead to termination of a pregnancy. The open question is whether administration of progesterone can increase the odds of continuing the pregnancy. And my view is that the evidence does not support that.

Q. What is the basis of that understanding?

A. The basis of the understanding that there is not such evidence?

Q. Your understanding, yes.

A. My understanding based on the Delgado, et al. articles, the first one of which was -- involved really just reports on six women with not a lot of details provided and no comparison group in that case series, and then the second one published in 2018, which was a much larger case series, but without the kind of detail data on the intervention, without a control group that would allow us to make some judgments about what would have happened in the absence of progesterone, and without the kind of clarity about the quality of the data collection, who the women were, about what their situations were to allow us to make any judgments about whether the progesterone was actually effective in changing the outcome of pregnancies for some women.

Q. Aside from your expertise in study design and research methods, do you have any other basis for your understanding of the biological plausibility of abortion reversal?
A. Again, I can't testify about the biological plausibility. I understand there are some theories about competitive inhibition of receptors, but given that I'm not an expert in that area, I'd be reluctant to make any statements.
Q. Dr. Joffe, we'll talk in more detail about the Delgado studies later in your testimony, but for now, could you pull up Plaintiffs' Exhibit 10, which was previously entered into evidence.
A. Okay. I have it.
Q. Is this the law you've been talking about?
A. It is.
Q. If I refer to it as the "reversal law," will you know what I'm talking about?
A. I will.
Q. What do you understand this law to require?
A. I understand the law to require four things. First, that at least 48 hours prior to when a woman would take the first pill of the medication abortion protocol, the physician or the abortion provider who is going to be prescribing the pill or administering the pill must inform her that there's a possibility that the abortion could be reversed, and that she

should -- she should be aware of that, and she should let people know if -- if that is something that she would like to consider.

Second, there's a requirement that there be certain signage posted in both the waiting rooms and the clinic examination rooms of clinics that provide at least certain minimum number of elective abortions in the state of Tennessee that have specified text about the possibility that the abortion might be reversed, with detailed specifications about font and that sort of thing.

Third, that those same instructions, or something very similar to them, must be included with the discharge instructions that a woman is given when she leaves the clinic after taking that first pill.

And finally, that the State of Tennessee's Department of Public Health is required to post information on its website about the possibility of reversal of medication abortions.

Q. We'll get into this in more detail later, but for now, does the reversal law comport with the physician's ethical duties?

A. I think it is very problematic when I think about physicians' ethical duties. I think physicians' ethical duties are to provide patients, or in this case women, with information that they believe to be truthful, that is

grounded in solid scientific evidence, and not to provide them with information that the physician believes to be untrue or insufficiently grounded in the scientific evidence.

Q. Do you believe that the reversal law will help pregnant women?

A. I don't. I think it will harm pregnant women in a number of ways. First, by confusing them and complicating their decision-making, which it's the physician's duty to help women make decisions, but I think this law and the language of the law and the messages that are communicated will complicate women's abilities to make informed decisions because they're given information that is not well-grounded in evidence, and that the physician may not believe to be truthful.

I believe that any effort by the physician to later say, "Well, that's what the State of Tennessee requires, but here's what I believe and here's why I believe it not to be true" will only further confuse and complicate women's decision-making and threaten the trust that we want to be built between patients and their doctors. And then as I said earlier, I have grave fear that some women, I don't know how many, but some women will decide to go ahead with the pregnancy when -- excuse me, with the abortion when they are uncertain about whether that is the right thing for them, and that it would have been better for those women to believe

or to understand that the abortion is likely to be permanent and to be continued through to completion if they begin down that road and only to begin down that road if, in fact, they are certain that that's the right thing for them.

Q. Stepping back slightly, Dr. Joffe, how would you define medical ethics?

A. To me, medical ethics is a series of principles, a series of codes that work to make sure that doctors or other health professionals are working in the interest of patients. And that when I say the interest of patients, I should add in the interest of research subjects and others who they might come into contact. And that means a number of things, including that they ought to be acting in patients' best interests, acting in ways that are likely to be beneficial to patients and to help them and not harm them, and also to be truthful with patients and to help patients, whether it be in the context of abortion or any other medical intervention or procedure, to make decisions that are right for them.

We're all different. Each of us might make different decisions when confronted with serious health conditions or serious health questions, and it's the doctor's job to help a patient make the decision that is right for him or her. And this gets to the core focus, or one core focus, of medical ethics, which is on how doctors and other health professionals can facilitate the autonomous decision-making

and the genuine decision-making of patients making important decisions.

Q. How would you define informed consent?

A. Informed consent is, in its simplest terms, the point at which a patient or a research participant gives permission to the doctor or the researcher or the nurse to do something that would not be permissible otherwise. So nobody can cut into my body, operate on my body, unless I give them permission to do that. But that's the kind of procedural informed consent.

More fundamentally it's a series of conversations, information exchanges between a doctor, a patient, often other health professionals, that help patients through the process of understanding what's at issue in their decision, what the possible outcomes might be, and figuring out what the right decision is for them.

Q. What are the goals of the informed consent process?

A. Most importantly, it is to help patients make genuine decisions that are the right decisions for those patients, decisions that are based upon factual and accurate information, that respect their values, which, again, are going to be different from one patient to the next, and decisions that patients are really -- believe are the right decisions for them.

Q. What kinds of information are usually provided to

patients as part of the informed consent process?
A. I think there's a number of components of the informed consent process or a number of kinds of information that are typically provided; one of which is what is the nature of the procedure that you are considering undergoing? What can you expect if you actually decide to go this route and undertake this procedure or take this medication? What's the goal of it? What's the outcome that we're trying to achieve, recognizing that that outcome might not be achieved in every case? What are the potential risks? So if things go wrong, how could this be risky to you? How might you be harmed by undergoing the procedure? Most medical procedures or treatments do have risks. What are the alternatives? If you decide not to do this thing, what else could you do? And what are your other options if you decide not to do the thing.

And -- so I think those are -- that's not a comprehensive list, but I think those are the core elements.
Q. You mentioned the nature of the procedure. Does that include a procedure's permanence?
A. I think it does. If a -- one would not want a patient to make a decision about a procedure believing, for example, that that procedure or the outcome of that procedure is short-lived, temporary, and then only later told that it was a permanent outcome, and when the patient made the decision,

they didn't realize that. So that would, I think, be a very important part of the consequences of a procedure that a patient should understand.

Q. What does the informed consent process usually look like?

A. It varies from one study to the next. Typically, it is going to involve the exchange of a conversation between doctor and patient or clinician and patient. The physician may share information, typically the information that the physician has that the patient may not have, and the patient will have questions. The physician will answer those questions.

Often, though not always, there is written information that is shared, certainly more often in the research context, where there's typically a written informed consent form. And depending upon the nature of the procedure, whether it's research or not research, the patient -- the patient's informed consent might be a verbal yes, yes, I would like to go forward with this procedure, or in the research context or for higher-stakes procedures, often it will be a written signature, signature on a form to acknowledge permission to move forward.

Q. Does informed consent require a physician to mention all possible outcomes no matter how rare?

A. No, that would be, I think, an impossibility to mention

every possible outcome of a procedure. It would be time that I think patients and physicians could not devote to that conversation. Every possible consequence would take a very long time. It also would confuse patients. I think one of the physician's jobs is to help patients identify the things that are most salient, most material.

And so the physician has to be able to use their discretion to be able to say these are the important outcomes, these are the important risks. And by important, I might mean some combination of these are the ones that are particularly serious, you really should know these as you decide to move forward, or maybe they're less serious, but they're very common. And so they're things that everybody should understand.

Of course, if the patient asks a question about something that the physician has not listed, the physician should do their best to answer that question, but the physician is always using judgment about what is the salient information.

Q. I'd like you now to apply these principles of medical ethics and informed consent to the reversal law. So let's pull up Plaintiff's Exhibit 10, which we looked at earlier.

A. Okay. I have it.

Q. Okay. If you could direct your attention to Section (e), which starts at the bottom of page 3. Do you see that?

A. I do.
Q. It includes various things that a physician must tell a patient 48 hours before the procedure; is that right?
A. Yes.
Q. Okay. Do you have any concerns about this section of the reversal law from an informed consent point of view?
A. I do. In (e)(1), the language I'm quoting here reads (as read): It may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind, but that time is of the essence.

And my view is that as women are likely to understand that statement as it is made by the physician, they are likely to understand it as believing that there is a plausible or evidence-based -- or evidence basis for the statement that it's possible to release -- to reverse the intended effects of the chemical abortion, and women will take that to be a message that this is a potentially reversible procedure. And I believe that what women really need to understand is that this is likely to be a permanent procedure, and they should proceed with it on the belief that it is, in fact, a permanent procedure. And I'm concerned that this statement undermines that important message that the woman needs to hear.

Q. Do you have any other concerns about this section of the reversal law?

A. Well, it points women to a statement or more information about this supposed reversal procedure on the Department of Health website, and I have some concerns about the language on the website. So the fact that this is pointing women to the website is itself problematic.

Q. Turning now to section (b) of the law and the signage requirement, which starts at the top of page 3. Do you see that?

A. I do.

Q. Do you have any concerns about this provision from an informed consent standpoint?

A. I do. The first -- excuse me, the second sentence, "It may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion utilizing mifepristone if the second pill has not been taken," again, like my concern with the statement that physicians are required to make to their patients is a, in my view, misleading statement. It conveys the message of potential reversal relating to women at a time when what they really need to understand is the likely permanence and the importance of moving forward is connected to the permanence of that procedure.

Q. And now turning to section (f) of the law, the discharge paper requirements, which starts on page 4. Do you see that?

A. I do.

Q. Dr. Joffe, do you have any concerns about this provision

from an informed consent standpoint?
A. This language is identical, or at least very similar, to the language that is required to be posted on the signs, and I have concerns about requirement that a physician share information with a patient that the physician may likely believe is not actually grounded in medical evidence in accurate data.

I think one of our obligations as physicians is to share information with patients that we believe to be true, that we believe to be evidence-based. So the requirement of sharing information that is not, in fact, evidence-based is a violation of medical ethics.

Q. So are these discharge papers part of informed consent?
A. They're not exactly part of informed consent in the sense that informed consent was the information of a process and the conversation that led to a woman making a decision about whether to move forward with her medication abortion or with her abortion. They're a part of the ongoing process of conversation and education that physicians have with their patients.

So they're an important part of -- done right, they're an important part of preparing a patient for what comes next, what might happen, but they're not, strictly speaking, part of the informed consent process in my view.
Q. Is it always a medical ethics violation of a state to

force doctors to give patients information?
A. I don't think it's always a medical ethics violation. If the information is accurate, evidence-based, endorsed by the expert physicians, expert clinicians, then I think it is acceptable. I believe that physicians should have the discretion to share information, when, for example, the FDA for certain high-risk drugs requires that physicians provide patients with certain information about those drugs if they're going to prescribe those drugs, and I think that's perfectly acceptable.
Q. Is it good practice to tell patients about every possible treatment that anyone may be offering?
A. No. I think a physician has to be able to provide patients with information about treatments or procedures that they believe to be part of the standard of care for that patient's condition, treatments that they believe are evidence-based, and treatments that they believe are reasonable options for patients to consider.

If a physician were forced to provide information about every possible treatment, that might force them to provide information about treatments that they believe to be harmful, not evidence-based and, again, would be only confusing to patients because that would be a very, very long list of things, most of which are likely to be irrelevant to the decisions that most patients would make.

In my days practicing cancer medicine, I frequently would talk with patients about their treatment options, and there were lots of things that people might find on the internet, treatment that somebody somewhere might want to offer. I can't imagine being forced to require -- to be required to provide information to my patients about every one of those things, some of which I believe to be really problematic and not in my patient's best interest.

Q. Does a physician have to be certain that a treatment works to ethically tell a patient about it?

A. No. We very rarely are certain that any of our treatments will work. And so we tell patients about treatments that we believe are likely to be helpful, or that are treatments that patients ought to consider, with all the appropriate caveats of this doesn't work in every case, this is how likely it is to work. But, again, it's almost never the case that we can say a treatment will always work.

Q. But the disclosure in the reversal law says it, quote, may be possible to reverse a medication abortion. Isn't that accurate, unless you know one hundred percent that it cannot work?

A. I think the way a reasonable patient and typical patient is likely to understand that information is to be receiving the message that we have evidence to believe, scientific studies show, there are data to support that it is actually

plausible, that there are data to support that the treatment will actually achieve the result, which in this case is (inaudible).

THE REPORTER: Excuse me --

MR. GROVES: Your Honor, I didn't hear the end of that answer.

THE COURT: Yeah, hold on just a minute.

So we lost you a little bit, Dr. Joffee, after you said "Will actually achieve the result, which in this case," and then you trailed off. So if you can remember what you were saying at that point and then repeat that, that would be helpful.

THE WITNESS: My apologies. My microphone cut out for a moment.

I think a patient is likely to take the message from that statement, even though in some abstract philosophical sense (indiscernible).

THE COURT: All right. We're still getting a little choppiness there. I think we got it up through "Abstract philosophical sense," and then again you trailed off a little. Can we give it one more shot there?

THE WITNESS: Sure. How is my sound now?

THE COURT: Good.

THE WITNESS: Okay. So in some abstract philosophical sense of view, read the words very precisely,

it seems to say, well, it's not impossible that the treatment could reverse the effects of the chemical abortion, but that is not how vast majority of patients are likely to understand it. They're likely to understand it as saying there is evidence to support that this is potentially more likely to be an effective treatment in reversal intervention.

MS. BAJRAMOVIC: Is the audio okay for the Court now?

THE COURT: Yeah, we hung in there on that, but we'll just keep -- we'll take it a question at a time.

BY MS. BAJRAMOVIC:

Q. Okay. Dr. Joffe, maybe it's your bluetooth mic that might be -- that maybe you could try talking to the camera -- or the computer.

A. (Indicating.)

Q. We'll see if that helps.

So Dr. Joffe, do you believe it is misleading for the reversal law to say it, quote, may be possible to reverse the medication abortion?

A. Can you hear me?

THE COURT: Yes.

THE WITNESS: Okay. I do believe it is misleading. I think the way that the majority of patients are likely to receive that information, they're likely to be misled by that statement.

BY MS. BAJRAMOVIC:
Q. So what is the harm of this misleading language?
A. Well, one harm is to the professional integrity of the clinician, who is -- I think part of our professional integrity as doctors is to be sharing information they believe to be truthful, but I think equally or more important is the harm to women who are needing to make decisions on the basis of truthful and accurate and evidence-based information. And if this information is misleading, if it confuses them, it only makes their decision-making task harder.

And in the worst care scenario, which I believe is entirely plausible mainly in women who proceed with the abortion, when really what they ought to do is take the time and have conversations to be certain that that's what they want. I would see it as tragic if a woman decided to go ahead with an abortion on the belief that it was potentially reversible, but, in fact, the truth is it is not reversible and had she known that, she might never have considered that to happen.

Q. Dr. Joffe, I'm going to read to you from a deposition of one of the state's experts, and then I'm going to ask you your opinion on it. I'm reading from Dr. Donna Harrison's deposition, which has been marked for identification purposes as Plaintiffs' Exhibit 95. I don't plan to introduce it into

evidence. I'm reading starting at page 111, line 24. Dr. Joffe, you don't have to pull it up. I don't think you have the exhibit. I'll just read it to you.

So it says (as read):

Q. Do you agree that there is any risk that people who are told about reversal, no matter what their doctor tells them, will ultimately think, "You know, I'm not entirely sure. Why don't I take it and see how I feel. And if I change my mind, I can always reverse it"?

A. That would be a failure of informed consent.

Could you provide your, sort of, feedback or opinion on that quote?

A. I think it would be a failure of informed consent if a woman found herself or acted on that belief, that false belief. And my concern is that if the reason for that failure of the informed consent is because the woman was given information by her physician as required by the State of Tennessee or information that she saw on a website, led her to that false belief, that would be a failure of informed consent caused by the requirement of this law. At the end of the day, that's the aspect of this law that I am most troubled by and most concerned with.

Q. You mentioned sterilization procedures like tubal ligation and vasectomy in your declaration. Could you just tell me why you mentioned those procedures?

A. Those are in some ways analogous procedures that -- where it is really important for a man or a woman who's considering undergoing procedures for themselves to make a decision on the assumption that the procedure is likely to be permanent, even though they're different from the abortion reversal context because my understanding is that it is, in fact, sometimes possible, not always, but sometimes possible to reverse the effects of a vasectomy or a tubal ligation, but nonetheless, in the decision-making for a man or woman to go ahead with that or not go ahead with that in the first place, people should only go ahead if they are convinced that they, in fact, would like a sterilization procedure for themselves, not counting on the possibility of reversal there.

Differed from -- similar to the abortion reversal context we're talking about in the sense that moving forward on the assumption of permanence is really important; different in that in those cases, there actually is evidence to support that the procedures can be reversed. In this case, it's even worse because in my view the evidence to support medication abortion is potentially reversible is simply not there.

Q. So let's assume that the vast majority of people who get abortions are sure of their decision. What is the harm of telling them that the abortion might be reversible?

A. Well, I would start by saying that even if one patient or five patients, a very small number of patients, make a decision to go ahead on the false belief that the procedure is potentially reversible or induced to go ahead or encouraged to go ahead by the state, that's one too many or five too many, but even for those women who are sure and who would not have made a different decision given different information, it is still information that is potentially -- that is extreme in the decision, that it is confusing to them or potentially confusing to them, and that if the physician feels the need to disclaim the information to say, you know, that's information that was required by the state, but not information that I personally believe to be true or evidence-based, that threatens the trust relationship between patients and doctor. And so that's a harm to the patient, even if they would have made the same decision in the absence of the information.

Q. Why couldn't a doctor just say, you know, there's this reversal theory, but you shouldn't worry about it, just make sure you're sure?

A. I think it is -- it's so far out of standard medical practice and ethical medical practice for a physician to give a patient information that the physician believes not to be true based on some external requirement, and then try to undo that information if the patient -- that's just outside the

context of any reasonable ethical -- excuse me, ethical medical practice and not what patients expect here. They expect to talk with their doctors and to be given information that the doctor believes to be true and willing to stand behind. So very confusing to a patient, very trust violating or trust threatening to a patient to hear that information from a doctor.

Q. Why wouldn't a patient be able to understand the difference between what a doctor is saying and what the state is making them say?

A. I would say two things in response to that. First, the -- even if the patient can understand, and many patients may, in fact, understand the distinction, it is still undermining of their trust in the doctor to hear the doctor is telling me X, but now the doctor is telling me Y. You know, shouldn't my doctor tell me what they believe to be true?

And secondly, the State of Tennessee, or any state carrying certain authority behind it, so that if the information is coming from a state, many patients are going to be "I respect my state, I trust my state, I trust the authorities in the state, and if they're saying this information, there must be some truth to it."

So the source of the information, the fact that it's coming from the state or (indiscernible) procedure, I

think is a source of authority that patients are likely to take seriously.

Q. So, Dr. Joffe, just to be clear, can a doctor save the disclosures from being misleading by explaining to patients that the doctor disagrees?

A. The doctor can do his or her best to undo the damage done by that disclosure, but they can't completely say -- they can't completely reverse the effects of that disclosure because at a minimum it is likely to be confusing and create problems for trust for the patient. And for some patients, that attempt to change -- to change the patient's understanding and undo the words that were just said may be unsuccessful, and those are the patients I worry most about, the ones who may go forward because of the information, when they should, in fact, take more time to be sure.

Q. So assuming that there's a possibility that reversal might work, is that information relevant to a patient seeking an abortion?

A. I think the information that a patient needs and the understanding that a patient needs in order to move forward is this is a procedure that is likely to be permanent, that is likely -- if you start down this road of a medication abortion, overwhelmingly the outcome is that your pregnancy will terminate. And all messengers should support that message, which is this is likely to be a procedure that leads

to a permanent outcome. And any messages that undermine that are problematic.

Q. So if a physician doesn't tell a patient about this reversal treatment, how will the patient know?

A. The patient might not know. Again, it is -- because this is something that is not based upon science, scientific evidence. Again, I don't think it's necessary that a patient know about or a doctor disclose every possible treatment known to him or her not based upon scientific evidence. Now, the patient might hear it from someone in her circle, through word of mouth. They might see it in the media. They might see it on a website some place. People have lots of ways of getting information.

But given my concerns about the source and accuracy and evidence behind it, I don't actually think it is essential or a violation or a problem if a patient moves forward with her abortion and continues with the subsequent aspects of the abortion without ever receiving this information.

Q. What should a patient do if they change their mind after taking the first pill in a medication abortion?

A. Any time a patient has -- undergoes a medical procedure or medical treatment and then has questions or concerns, something they think is important or they're uncertain about, or something that they're experiencing, they should be able

to call their doctor or somebody acting on behalf of the doctor and talk that over with them, get more information. So this is just like any other time. Patients should be able to call the doctor or call the clinic where the procedure was done and say, "You know, I'm having these thoughts. I'm having these concerns. And please advise me as to what to do."

And I understand that the standards of care or statements from a professional organization in OB-GYN are, what we call, expectant management, which is (indiscernible).

THE REPORTER: I'm sorry --

THE COURT: Hold on, Dr. Joffe. Hold on just a second. Why don't we try slowing down a little bit. The microphone you're using now is -- we can hear you, but it's just slightly more muffled than what you were using before.

So you want to pick up with -- you were saying "Standards of care or statements from a professional organization in OB-GYN." Can you remember where you were going after that?

THE WITNESS: Yes. Can you hear me better now?

THE COURT: Yes.

THE WITNESS: I'll try to move a little closer.

Standards in or guidance from professional organizations are expectant management, which is to observe or not giving the second pill or any problems that you might

have at that point for what happens with the pregnancy, to watch her closely. And I think presumably if that's the professional guidance, that's what the OB-GYN or the abortion provider ought to do at that point if they were to be called with that question.

Q. Turning to the document marked Plaintiffs' Exhibit 7, which is already in evidence, Dr. Joffe. Could you pull that up?

A. Okay.

Q. What is this document?

A. This is titled "Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone." It was published in the journal Issues in Law & Medicine by Dr. Delgado and some colleagues. I believe this is the revised or the resubmitted version. There was an earlier version that was retracted, but this is the article.

Q. And if I refer to this article as the "Delgado 2018 paper," will you know what I'm referring to?

A. Yes.

Q. The "Revised Delgado 2018 paper."

A. Yes.

Q. Have you read this paper?

A. I have.

Q. Do you have an opinion -- you mentioned it was published in Issues in Law & Medicine. Do you have an opinion of that

journal?
A. I had not heard of that journal until this case. It is not a widely known, widely respected journal in medicine. It has a relatively low impact factor, which is a measure of how often it's cited, how often articles are cited. It is an odd journal to publish an article on progesterone reversal or medication abortion. I would have expected a journal entitled Issues in Law & Medicine to be publishing articles about law and medicine, but this is actually a clinical study or a clinical case series and not the kind of thing that I would expect in a journal like this. So that caught my eye as potentially problematic.
Q. Do the activities described in the 2018 Delgado paper constitute research on human subjects?
A. I believe they do for a couple of reasons. The intervention in this case, the progesterone, after a woman took the mifepristone, was an acknowledged experimental intervention at the time that they did the study. It was administered according to a set of plans or instructions, although very (indiscernible). There was clearly a prospective plan to collect data from the women who were participating in this study. There's actually a statement some place in the method that the women gave informed consent for data collection. And that implies that there was a prospective intent to collect data and created kind of

prospective study. And women are actually referred to as subjects throughout the study, which is typically a phrase (indiscernible).

Q. Do researchers need to get IRB approval when conducting research on human subjects?

A. It is clearly the norm to get IRB approval, particularly when conducting prospective medication on human subjects that involves (indiscernible).

THE REPORTER: I'm sorry --

THE COURT: I'm sorry. We're -- Hold on just a second, Dr. Joffe. Why don't we try this, because we're just having -- on our end, it's getting progressively more muffled. Probably the best thing to do is to try to log off and log back in, and we'll see if maybe the connection somehow works. We're hearing counsel just fine. It's just your feed isn't particularly clear at times, and it's making it very challenging on our court reporter to take everything down. So if you wouldn't mind trying that, Dr. Joffe, just log out, log back in, and then we'll see how we do.

THE WITNESS: Sure. Before I do that, would you like me to just try that previous headset to see if we have any better luck this time?

THE COURT: Have you been -- yeah, sure, why don't we do that and see if it's better. Have you been charging it or anything since you took it out?

THE WITNESS: Yes.
THE COURT: Okay. Let's try that.
While he's doing that, counsel, how much more do you have on direct?
MS. BAJRAMOVIC: I would say ten minutes.
THE COURT: Okay. All right. Let's try to wrap him up, and then we'll take a break. We've been going almost two hours.
MS. BAJRAMOVIC: Okay.
THE WITNESS: Can you hear me now?
THE COURT: Yes. We'll give that a shot. Go ahead.
BY MS. BAJRAMOVIC:
Q. Okay. Thanks, Dr. Joffe.
THE COURT: Hold on just a second. Hold on. Part of that last answer was trailing off. So we want to make sure we got it down.
THE WITNESS: So it is clearly the professional and ethical norm to get IRB approval for research on human subjects. There may be situations where that can be waived or some exceptions, but in the case where there's a prospective intent to study a drug or study an intervention that conveys a risk on a patient, and that would be the case with the progesterone procedure here, in a situation where there's clearly an intent to collect data on that process,

and where people are considered subjects, rather than simple patients, it is clearly the professional norm, not just nationally, but internationally, to seek IRB approval or some sort of ethics committee approval for the research that one does.

BY MS. BAJRAMOVIC:

Q. What are the consequences of not obtaining IRB approval for a study?

A. I think those vary from one situation to the next. One potential consequence is the journals may not publish the research, or if they do publish it, they may be required to retract it. Depending upon the regulatory context, there may be adverse regulatory actions that are taken by the funding agency or by the FDA. And I think for physicians or scientists who are reviewing the results of studies, not seeing evidence of IRB approval is a red flag about potential problems either with the science or the ethics of what was done.

Q. So why is it important to obtain prospective IRB approval for a prospective study?

A. Especially when you are putting people at risk, whether it be from medication or other intervention, I, as an investigator, if I'm doing a study, may be very convinced in the rightness of what I'm doing, that it's good for patients, that I understand the risks, I may be very enthusiastic about

it, but my judgment may be biased by my investment and my commitment to the study and my desire to get it done. And so it is important to have expert peers who are looking at a study and saying, yes, the risks of the study are minimized, yes, the informed consent of the study is handled in an appropriate way, yes, the science is of high quality, and therefore we allow it to go forward. And that's not something that you can undo after the fact if things weren't done right from the start.

Q. Do you have any concerns about whether the 2018 Delgado paper obtained the appropriate IRB approval?

A. I do. In the beginning of the method section of that paper, there is a statement that the study was reviewed and approved by an institutional review board. That was a quote.

Q. Which page are you on, Dr. Joffe?

A. Excuse me. I'm on page 24 of the -- this is in the first paragraph, under the heading Methods. It reads (as read): The study was reviewed and approved by an institutional review board. And if I'm reading a paper or peer-reviewing a paper, I expect the paper to disclose which institutional review board reviewed the study and approved the study. And to not see that is -- it's just very unusual. It's hard for me to think about other times that I've seen that lack of transparency about who approved the study. So I really want to know more about the approval.

It also doesn't say that it was prospectively approved. This is presented in a confusing way about the study being prospective or retrospective. I'd really want to know that the study was approved in advance, and I'd want to know which IRB did it.

Q. Turning to the document marked for identification as Plaintiffs' Exhibit 42. Could you pull that up?

A. Okay.

Q. What is this document?

A. This is an earlier version of that same paper, also in the same journal that was subsequently retracted and then republished.

MS. BAJRAMOVIC: Your Honor, plaintiffs move to enter Plaintiffs' Exhibit 42 into evidence.

MR. GROVES: No objection.

THE COURT: All right. Without objection, Plaintiffs' Exhibit 42 is admitted.

(Plaintiffs' Exhibit 42 received in evidence.)

BY MS. BAJRAMOVIC:

Q. Dr. Joffe, what does this retracted version of Delgado's 2018 paper say about IRB approval?

A. I'm scrolling down to -- I'm now on page 6 of the paper. And in the first paragraph under Methods, it says (as read): This is an observational case series with data analysis that received an institutional review board waiver. And there's a

footnote 33. And if you look down at that footnote, it mentions the name of the IRB that apparently approved the study, which was University of San Diego.

Q. Now, turning back our attention to the revised study, do you have any other concerns about the Delgado 2018 paper?

A. Give me one moment to pull that back up.

THE COURT: Which number was that, counsel?

MS. BAJRAMOVIC: That's Plaintiffs' Exhibit 7.

THE COURT: Okay.

THE WITNESS: I have concerns about the -- as I mentioned, I have concerns about the ethics or the IRB approval of the study. I also have concern about the statement about informed consent, the statement that they gave the -- that the women gave written informed consent to their physicians for the treatment that also included informed consent for data collection. And this raises questions for me about did the women give informed consent, did they understand that they were undergoing an experimental medical procedure.

And I also -- separate from these issues of ethics and informed consent and IRB approval, I have concerns about the science of the study. I have concerns about the design of the study, the fact that there is no comparison or control group that is -- allows us to make a convincing judgment about whether women were more likely to continue their

pregnancy given this progesterone treatment than they would have been without it. I think it's an uncontrolled study. It is described as a retrospective analysis of clinical data. It's a case series, a large case series, but a case series. And based on the design, it's really difficult to know what to make of the findings that are reported in the study.

BY MS. BAJRAMOVIC:

Q. What sort of study design would allow for a strong claim that administration of progesterone increases the chances of a continued pregnancy?

A. By far, the strongest study design would be one in which there was a randomized comparison group, and ideally the patients or the participants would be randomized to either receive the progesterone or receive a placebo progesterone. And then you'd be able to compare the two groups and to be able to say that the women in the progesterone group either did or did not have a greater likelihood of pregnancy continuation than those not in the -- than those in the placebo group.

There are other designs that might not be quite as strong, for example, collecting a parallel group of women who the data showed were similar in all the relevant ways to the women who received progesterone. It's possible to do something that is somewhat short of a randomized trial that is still useful, but this is so far short of a randomized

trial that I don't actually think it's particularly useful or informative.

Q. Would the study designs you describe be ethical?

A. They would, absolutely.

Q. Could pro-life researchers conduct such studies?

A. I think if a -- a researcher, whatever their own personal views about abortion were, really believed that it was important to have a treatment available for women who wished to -- who changed their minds about undergoing a medication reversal procedure or to reverse a medication abortion, I think it would be ethical for any such physician to actually want to study interventions in ways that were convincing and rigorous and really answered the question.

And I think for a, to use your words, pro-life researcher who really believed that that was a necessary thing to do, he or she should want to prove it so that patients and physicians all around the world could actually use it.

Q. Do study authors have to disclose their conflicts of interest in the articles they publish?

A. There's a very -- when the study author has financial conflicts of interest, let's say they have an investment or are receiving consulting fees from a company that makes a drug, there's a very clear, crystal clear norm of disclosing those conflicts of interest. And there have been some high

profile cases recently where people's failure to disclose their conflicts of interest led to very negative outcomes for them.

Things are a little bit less clear with other types of conflicts of interest that are nonfinancial, and I think there's more variation in the norms, but I think it is best practice that when you have some substantial relationship to the -- to an entity or the state in a study, that ought to be disclosed.

Q. So if the author of the study were on the board of an organization that sponsored the journal in which the study was published, would that be a conflict of interest that should be disclosed?

A. I think that is something that should be disclosed. I think to give you a somewhat analogous example, if an editor of a journal publishes a study in his or her own journal, that ought to be made clear to the readers, "I am an editor of this journal." And I think being on the board of an organization that sponsors a journal is analogous to being an editor of a journal.

Q. So turning to the last document that I want to go through with you, it's marked as Plaintiffs' Exhibit 16, which is already in evidence. What is this to be, once you have it up?

A. Sure. This is a study, randomized control trial of

progesterone, asking the question can it actually result in a greater likelihood of continued pregnancies, published by Creinin, et al., in the Journal of Obstetrics and Gynecology in January of 2020.

Q. And have you read the study?

A. I have.

Q. Is this study design ethical?

A. Yes, this study design is ethical.

Q. But are the patients in the study getting no medical benefit out of participating?

A. I think it's important to understand that that is -- it's actually very common in medical research for patients or participants in studies to do so without the expectation of personal medical benefit from them, for them. It's actually explicitly stated in our federal regulations governing human subjects research that the risk of the research must be justified -- I'm paraphrasing now -- by the benefits to the individual participant, if any, and the benefits of the knowledge to be gained.

So you don't actually need benefits to the individual participant in order for a study to be ethical or fair, substantial benefits to society. Patients give informed consent, and they willingly accept the risks. That is ethical and entirely consistent with our norms and regulations.

Q. Dr. Joffe, just a couple more questions. Defendants have suggested that the reversal law is analogous to a right-to-try law. Could you explain to me what a right-to-try law is?

A. A right-to-try law, there are state versions of that in most states and federal right-to-try law that was passed a few years ago. And essentially prior to the right-to-try law, speaking about the federal law, if a patient wanted access to a drug or a drug that was not yet approved, that was experimental and was under study by investigators, but they wanted access to it outside of the study, one of the steps that they would need to accomplish would be to get -- to ask the FDA, or their physician would ask the FDA, for permission for them to get the drug from the manufacturer. And the FDA would almost always say yes, but they had to require that -- they were required to get the permission of the FDA.

The fundamental thing that the right-to-try law changed is it said the patient no longer needs the FDA's permission. If the physician agrees, if the manufacturer agrees, if the patient agrees, they can receive the drug without the FDA's permission. It doesn't mean -- that law doesn't give the patient actually a right to the drug. The manufacturer can still say no for any number of reasons. And it doesn't actually require that anybody tell the patient

about the existence of that drug. It just requires -- it just changes the law so that the patient no longer needs the FDA's permission in order to get the drug.
Q. So is the reversal law analogous to a right-to-try law?
A. I don't understand the analogy to the right-to-try law, to be quite honest.
Q. Why is that?
A. Because, again, the right-to-try law is -- people have said it's a right-to-ask law, and patients have a right to ask the manufacturer, their physician for access to the drug. People can say no. But it doesn't actually entitle anybody to anything, and it doesn't require that anybody tell the patient about the existence of this drug that hypothetically might be helpful. And so this abortion reversal law in the state of Tennessee doesn't engage the FDA in the same way and is different from right-to-try in that it requires the physician to tell the patient something; whereas, the right-to-try law doesn't actually require the physician to tell the patient anything at all.
Q. So we talked earlier about your concerns about the content of the law's requirements, but what about some of the mandated requirements of the law? For example, that the law requires that patients be told about the possibility of reversal at least 48 hours in advance. Does that concern you, the timing?

A. Well, I think one reason that it concerns me is it is telling women in -- during the informed consent process, during time when they're considering their abortion, whether to go forward or not, it's conveying the message that they don't actually have to be certain, or at least some women are going to take away the message that they don't have to be certain. And so that requirement that women need to be given 48 hours to sit with this message, I think risks women making decisions that they might later regret.

Q. Dr. Joffe, just to wrap up, do you see any benefit to the reversal law?

A. I don't.

Q. Will this requirement help women seeking abortion?

A. I don't see how it will help women seeking abortion. I think the important thing is for women seeking abortion to be given truthful information by their physicians, evidence-based information by their physicians, and to have the message reinforced that if you're going to go down this pathway, you should accept the overwhelming likelihood that it's going to result in the termination of pregnancy. And anything that undermines that core message I think is harmful and not helpful.

MS. BAJRAMOVIC: That's all I have. Thank you.

THE WITNESS: Thank you.

THE COURT: All right. Before we go with

cross-examination, do you have any sense, Mr. Groves, how long your cross-examination may take?

MR. GROVES: Your Honor, I believe plaintiffs went about an hour and 20 minutes with the direct. I think I could get my cross done in 30 to 45.

THE COURT: Okay. Then let's -- it's almost ten after four local time. So we'll take a break until 20 after, and then we'll resume with cross-examination of Dr. Joffe.

(Recess taken from 4:10 p.m. to 4:20 p.m.)

THE COURT: All right. Cross-examination.

MR. GROVES: Good afternoon, Dr. Joffe.

And, Your honor, I just want to say I appreciate the flexibility with allowing me to conduct this cross-examination virtually today. I know that wasn't the initial plan.

THE COURT: Well, happy to accommodate.

CROSS-EXAMINATION

BY MR. GROVES:

Q. Dr. Joffe, you studied medical ethics in medical school; correct?

A. Correct. Medical school and since then, but yes.

Q. But you don't recall studying how to obtain informed consent from a medication abortion patient; correct?

A. I don't recall specifically in medical school studying informed consent for the specific setting of a medication

abortion patient.
Q. And you've never been licensed to practice medicine in Tennessee?
A. Correct.
Q. You've never performed a medication abortion; correct?
A. Correct.
Q. You've never obtained informed consent from a medication abortion patient?
A. Correct.
Q. And you don't know how the FDA regulates informed consent for medication abortion; right?
A. I don't know in detail how the FDA regulates informed consent for a medication abortion patient.
Q. And you don't know whether patients have to give written informed consent before getting a medication abortion; right?
A. I'm not certain whether a patient has to give written informed consent before a medication abortion.
Q. So I'm going -- with the help of my co-counsel, who's present in the courtroom, I'm going to show you what's been previously admitted as Defense Exhibit 51. And did you receive the package of exhibits that we mailed to you?
A. I did.
Q. Okay.
A. Back in December, yes.
Q. If you need to refer to an exhibit if you can't see it

properly when my co-counsel displays it, you can refer to that exhibit in the mailing.
A. Okay.
Q. Are you able to see that document, Dr. Joffe?
A. I can -- I cannot, but I have the paper version in front of me.
Q. Okay. And the top of that form says "Patient Agreement Form"?
A. Correct.
Q. And Mifeprex, or mifepristone in parentheses, is also at the top of that form?
A. Correct.
Q. You've never seen this form before; correct?
A. I don't believe I've seen this form before, no.
Q. Okay. Do you see at the bottom of the form, where it says "I have given her the medication guide for Mifeprex"?
A. Item 9. Yes, I see --
Q. I'm sorry. Can you complete your answer? I was talking over you.
A. I see it. That appears to be item 9 on the bulleted list, but yes.
Q. And do you also see that language underneath the patient signature line in italics?
A. Yes.
Q. Okay. You've never seen that medication guide the form

is referring to; correct?
A. I don't -- I do not believe I've seen that medication guide.
Q. Okay. And you've never taught classes on how to obtain informed consent from a medication abortion patient; right?
A. I taught classes extensively on how to obtain informed consent generally, but not specifically in the context of a medication abortion patient.
Q. And earlier, I believe you testified that there's about 200 publications listed on your CV?
A. I was estimating, but that's about right.
Q. Okay. And none of those publications relate to medication abortion; correct?
A. None of them specifically relate to medication abortion.
Q. And in your declaration that you filed in this case, you didn't cite to a single publication listed on your CV; right?
A. I don't recall specifically whether I did or did not.
Q. Other than prescribing oral contraceptives, you have no memory of prescribing progesterone to a patient; right?
A. Correct.
Q. None of the academic or clinical teaching responsibilities that are listed on your CV relate to progesterone; right?
A. Nothing relates specifically to progesterone as a single agent, no.

Q. You've never given a lecture on progesterone; right?
A. I don't believe I've ever given a lecture specifically on progesterone.
Q. And none of the publications listed on your CV discuss the use of progesterone; right?
A. I don't believe any of the publications on my CV specifically discuss the use of progesterone.
Q. You testified on behalf of the plaintiffs in a Kentucky lawsuit challenging Kentucky's Ultrasound Informed Consent Act; isn't that right?
A. That's right.
Q. And are you aware whether the Court struck down the law that you were testifying against?
A. I don't have a certain memory of what the outcome of that case was. I have a memory, but I'm not certain that it's correct of exactly at what point in the legal process certain decisions were made.
Q. You never worked with any of the plaintiffs named in this Tennessee lawsuit, have you?
A. I don't believe so, no.
Q. You've never been employed by any of them?
A. I don't believe so, no.
Q. And with respect to the Tennessee plaintiffs, you don't know what their procedures are regarding informed consent for medication abortion procedures; correct?

A. I don't have firsthand knowledge of what their procedures are for informed consent for medication abortions.
Q. And you've never observed informed consent for an abortion procedure in Tennessee?
A. Correct.
Q. You don't know what procedures the plaintiffs utilized when determining a patient's decisional certainty; right?
A. I don't have specific knowledge of that in the context of this case, no.
Q. And you don't know if the Tennessee plaintiffs have any posters in their patient waiting or consultation rooms?
A. I don't specifically know if they have posters or if they do, what they say.
Q. And you don't know whether they have any pamphlets or other literature in their clinics?
A. I don't have specific knowledge of what literature they have in their clinics.
Q. And you also don't know what Tennessee plaintiffs are trained to tell medication abortion patients about potential birth defects if the second set of pills is not taken?
A. I don't know specifically what they're trained to tell about potential birth defects.
Q. And you don't know if the Tennessee abortion providers typically provide follow-up prenatal care for the patients whose abortions are not successful or who change their minds;

right?
A. I don't know what the practices are of the Tennessee abortion providers with respect to follow-up care, no.
Q. And because you're not an OB-GYN, you're not offering an opinion as to the biological possibility for medication abortion reversal via progesterone; right?
A. Correct.
Q. And because you're not an OB-GYN, you're also not offering an opinion about the safety of medication abortion reversal via progesterone; right?
A. Correct. I've offered no opinion, I don't believe, about the safety of administering progesterone in the setting.
Q. Okay. If my co-counsel could show you Plaintiffs' Exhibit 53, which has already been admitted into evidence. And I believe in your packet, Dr. Joffe, that we sent you, this is going to be Defense Exhibit 4.

And so that everyone is clear, I believe the defense exhibit page numbers are slightly different than the plaintiffs' exhibit page numbers, but I'm going to refer to both so that everyone is on the same page.
A. I have a D-4 and a D-53. What is the document you're asking me to look at? ACOG Practice Bulletin. I have that as D-4.
Q. Yes, please have that in front of you.

A. Okay.
Q. You cited this ACOG Practice Bulletin in your declaration; right?
A. I did.
Q. And you view ACOG practice bulletins as authoritative guidelines that establish the norm for various issues in the field of obstetrics and gynecology; right?
A. I view ACOG as an authoritative organization in the field of obstetrics and gynecology; and, therefore, I view their practice bulletins as authoritative statements in that field.
Q. And do you also believe that they establish the norm for various issues that arise in the field of obstetrics and gynecology?
A. I believe that their statements from this organization are authoritative statements of the norms of practice within that field.
Q. And you relied on this practice bulletin in informing the opinions expressed in your declaration; right?
A. In forming certain opinions, yes.
Q. But you're not a member of ACOG; right?
A. Correct.
Q. And you don't know how many individuals are members of ACOG; correct?
A. Correct.

Q. And you don't know how many ACOG members actually perform medication abortions; right?
A. Correct.
Q. If you can look at the first page of that exhibit, it's page e31 in the plaintiffs' exhibit. And I don't have the page number for this one, but it's the very first page in the defense exhibit, or the title is on the page.
A. Okay.
Q. The first paragraph of this practice bulletin, at the bottom of the paragraph says that only 14 percent of ACOG fellows and junior fellows have provided medication abortion in the past year.

You don't have any reason to dispute that; correct?
A. I'm going to the citation for that. So that cites an article published in 2019 in Obstetrics and Gynecology. Assuming that that is an accurate one-sentence statement of that article they cited, I don't have any reason to dispute it, no.
Q. The first page of the practice bulletin also states near the top, above the title of the article, that it was developed in collaboration with Dr. Creinin and Dr. Grossman; is that correct?
A. Correct.
Q. But you don't know whether the ACOG Practice Bulletin

was voted on by ACOG membership; correct?
A. I don't know -- I don't know what procedures were used. I don't know if it was voting that occurred in adopting this practice bulletin.
Q. And you don't know whether any dissenting viewpoints would have been recorded during that process of drafting the bulletin?
A. I don't know what happened behind the scenes of drafting this bulletin.
Q. Okay. If you can turn to page -- in your copy of the exhibit, page 3 of the practice bulletin. And in the courtroom, if we could turn to page e-33.
Are you there?
A. Yes.
Q. So the first sentence of the second full paragraph underneath the heading, if I can say that word, "Teratogeni" -- well, you see the heading that I'm talking about, "And Ongoing Pregnancy"? Okay. In the first sentence of the second full paragraph, it says (as read): In the very rare case that patients change their mind about having an abortion after taking mifepristone and want to continue the pregnancy, they should be monitored expectantly, with citation footnote 40.
Did I read that correctly?
A. You did.

Q. And in medical terminology, "monitored expectantly" means provide no treatment; right?
A. Means without further intervention.
Q. And that sentence again cites footnote 40?
A. Correct.
Q. So if you could turn to footnote 40, which is on page 12 of your copy of the exhibit and page e42 of the plaintiffs' exhibit.
A. Okay.
Q. Footnote 40 cites the National Abortion Federation, 2020 Clinical Policy Guidelines; right?
A. Correct.
Q. And that's listed in parentheses next to the citation as merely Level III evidence?
A. It says "Level III." I'd have to look at the actual document to know exactly what that Level III meant in that context. But it says "Level III."
Q. So in evidence-based medicine, the levels of evidence typically correlate to the strength of particular evidence; correct?
A. Setting aside the specifics of this case or this citation where I haven't looked at that document, that is generally true, that we discuss levels of evidence, with some levels being higher and some levels being lower.
Q. And generally, Level I evidence is the highest level of

evidence; correct?
A. That's typically the way things are written or stated, although again I want to acknowledge that I haven't looked specifically at what Level III was in this context.
Q. Okay. If you can go -- maybe keep your hand on this page, but go back to the other page that we were looking at, page 3 of your exhibit and page e33 of the plaintiffs' exhibit.
A. Okay.
Q. You have it?
A. I do.
Q. Okay. The next sentence in that paragraph that we were reading says (as read): There is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy continuing.
Did I read that correctly?
A. You did.
Q. Okay. And the citations are to footnotes 41 and 42; correct?
A. Correct.
Q. Okay. Let's look at those two footnotes on the same page that we were previously looking at, e42 in plaintiffs' exhibit and page 12, I believe, in your exhibit.
A. Correct.
Q. In those two footnotes, the authors of the practice

bulletin are citing to two Grossman articles, Dr. Grossman articles; is that right?
A. That's right.
Q. So Dr. Grossman, who helped develop this practice bulletin, is citing his own articles as authority here?
A. Correct.
Q. And the 2015 Grossman article that's cited in footnote 42 was published before Dr. Delgado's 2018 study; right?
A. Correct.
Q. And then the 2018 Grossman article that's cited in footnote 41, that was also classified as Level III evidence; right?
A. Well, it says Level III. I'd have to go in detail to know exactly what Level III means in this context, but it does say Level III.
Q. Okay. So going back to the page that we were previously looking at, e33 and defense exhibit page 3. The third sentence in that paragraph says (as read): However, limited available evidence suggests that the use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage.
Did I read that correctly?
A. You did.
Q. And it cites to footnote 43?
A. Correct.

Q. Okay. Let's look at footnote 43, which is on the same page that we were looking at before. This is referring to the 2020 Creinin study?
A. Correct.
Q. And that study, which you briefly testified about, was based on the results of three patients out of ten?
A. It was based on the results -- the study intended to enroll 40. In fact, they enrolled 12. Three of them had serious bleeding complications, and the study was stopped early because of concerns about safety.
Q. Okay. And two of those three patients who had heavy bleeding took mifepristone alone, but they didn't take progesterone; right?
A. I recall that some of the patients took mifepristone alone without progesterone. I don't remember if it was two and one or one and two, but as I recall they were split between the two groups.
Q. So we're going to look at, on your copy of this exhibit, pages 9 and 10. There's a list of summary recommendations. In the plaintiffs' exhibit, it's on page e39. Do you have that, Dr. Joffe?
A. I do.
Q. Okay. Under the heading "Summary of Recommendations, it says (as read): The following recommendations are based on good and consistent scientific evidence, Level A.

Did I read that correctly?
A. You did.
Q. And then Level B recommendations, it says (as read): The following recommendations are based on limited or inconsistent scientific evidence.
Correct?
A. Correct.
Q. And then for Level C on the next page, it says (as read): The following recommendations are based primarily on consensus and expert opinion.
Is that correct?
A. Correct.
Q. The fifth bullet point under the Level C recommendations says (as read): In the very rare case that patients change their mind about having an abortion after taking mifepristone and want to continue the pregnancy, they should be monitored expectantly.
Is that correct that that's a level C recommendation?
A. Correct.
Q. Now, I want you to turn to the last page of this exhibit, which has three paragraphs all in italic.
A. Okay.
Q. I'm going to read the first three sentences of the first paragraph. (As read:) This information is designed as an

educational resource that aids clinicians in providing obstetric and gynecologic care, and use of this information is voluntary. This information should not be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. It is not intended to substitute for the independent professional judgment of the treating clinician.

Did I read that correctly?

A. You did.

Q. Now, when you prepared your declaration, you weren't aware of any other professional medical organizations who believed that progesterone may be able to reverse the effects of mifepristone; right?

A. I don't recall any statements from professional organizations making that claim.

Q. But you didn't conduct any research to see if there were such organizations; correct?

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

Q. So if a patient chooses to begin chemotherapy, that patient has the right to withdraw consent to the treatment; correct?

A. That is generally true. I'm going to assume for the moment that we're talking about an adult patient. And in general, a patient can begin a course of chemotherapy and say after a cycle or two cycles or whatever it might be, you

know, this is not right for me, I changed my mind, there may be some narrow situations where it may be more complicated than that. For example, I used to practice bone marrow transplantation, and there were situations in which a patient might begin the course of bone marrow transplantation, and if they changed their mind at certain points along the treatment, there would be an overwhelming likelihood or a certainty that they would actually die without continuing with the planned treatment. So that would be a situation where at a minimum we'd want to have a very careful conversation about it and strongly advise a patient not to do that.

But setting aside those special situations, in general, if a patient has begun a course of chemotherapy and has changed their mind, that is their right to do, obviously after discussion and consultation with their doctor and others.

Q. And so even taking your example, if the patient was advised that stopping chemo could be dangerous, the patient could still decide to stop treatment; right?

A. Ultimately, competent adult patients have the right to refuse treatment, to change their mind about treatment. That is something that is within their rights.

Q. And a doctor would be able to explain to the patient all the risks and the benefits of that decision; right?

A. Hopefully, a doctor would be able to help a patient understand the implications, including risks and benefits, of a decision to stop chemotherapy or some other treatment.
Q. And the patient, if they decided to stop chemo treatment, would have the right to seek medical care from another provider; right?
A. Ultimately, it's the patient's right to seek medical care from a provider -- licensed provider with whom they feel comfortable.
Q. I'd like to have my co-counsel hand -- or show you on the screen Defense Exhibit 57, which you also should have in your packet.
A. Under that same number?
Q. Defense Exhibit 57.
A. Okay.
Q. And I'll give the folks in the courtroom a minute to put that up. You cited this article on page 15 of your declaration; correct?
A. I did.
MR. GROVES: Your Honor, I'd like to ask that this exhibit be moved into evidence as Defense Exhibit 57.
THE COURT: Any objection?
MS. BAJRAMOVIC: No objection, Your Honor.
THE COURT: Without objection, Defense Exhibit 57 is admitted.

(Defendants' Exhibit 57 received in evidence.)
BY MR. GROVES:
Q. This article was published in a journal called Plastic and Reconstructive Surgery; right?
A. Correct.
Q. But you don't practice in the field of plastic surgery; right?
A. Correct.
Q. But the article does discuss evidence-based medicine as applied to this specific --
A. It discusses evidence-based medicine in general. I don't actually recall the specific discussion about its application to plastic and reconstructive surgery. I recall it as a general discussion of evidence-based medicine and levels of evidence.
Q. Did you read this article before you cited it in your declaration?
A. I did.
Q. Okay. Can you please look at page 306 of the article. And you see the heading "Interpretation of Levels"?
A. I do.
Q. Please follow along as I read the third sentence under that heading. (As read:) It is important that readers not assume that Level I evidence is always the best choice or appropriate for the research question.

Did I read that correctly?
A. You did.
Q. Later in that same paragraph, it says (as read): By design, our designated surgical specialty will always have important articles that may have a lower level of evidence. Because of the level of innovation and technique, articles are needed to move our surgical specialty forward.
Did I read that correctly?
A. You did.
Q. Turn to page 308 of that exhibit. The first full paragraph of this page, right above the heading "Clinical Examples Using Levels of Evidence," it says (as read): Although the goal is to improve the overall level of evidence in plastic surgery, this does not mean that all lower level evidence should be discarded. Case series and case reports are important for hypothesis generation and can lead to more controlled studies.
Did I read that correctly?
A. You did.
Q. Turn to page 309 of that exhibit. Under the Conclusions paragraph, the article says, about halfway through that paragraph (as read): This is not to say that all Level IV evidence should be ignored and all Level I evidence accepted as fact. The levels of evidence provide a guide, and the reader needs to be cautious when interpreting these results.

Did I read that correctly?
A. You did.
Q. Now, you mentioned earlier that -- you mentioned earlier about randomized clinical trials. The FDA has approved several medical treatments without a randomized clinical trial; right?
A. Correct.
Q. Including some cancer treatments?
A. Correct.
Q. Earlier you also raised some concerns about the manner in which Dr. Delgado conducted his 2018 study, but you can't draw a definitive conclusion that that study was conducted unethically; right?
A. I don't know the details of that study as described in the article, and then some of the press around it raised serious questions for me about what went on behind the scenes in that article. I can't definitively say that there were ethical problems with the article or with the study, but I am very suspicious and concerned based upon what I know both from the article and from the reporting around it.
Q. So during the informed consent process, shouldn't clinicians give more detailed information to patients who are considering a high stakes medical decision?
A. I think it is appropriate to take into account the stakes of the medical decision in the informed consent

process and in the information that is disclosed. So in a very low stakes situation -- and I don't consider the situation of an abortion, whether medication or otherwise, to be low stakes, but in some other low stakes situation, may be a very brief conversation with very little information shared. When we're talking about a higher stake -- higher stakes kind of procedure or treatment, it is appropriate to share more information about the risks, the benefits, what the patient can expect, the alternatives, all the things that I talked about earlier.

Q. And that's especially true when the decision is going to implicate a patient's core values or beliefs; right?

A. I think one way a procedure or a treatment or a medical decision could be high stakes is because it likely implicates a patient's core values. Not the only way that can make something high stakes, but it is certainly one way.

Q. Earlier you testified that informed consent is a series of conversations. So those conversations don't all occur on the same day; correct?

A. I think that varies from situation -- from one situation to the next. The nature of some medical situations might mean that actually everything does occur on the same day, and in other situations, where there's a conversation that has gone on over time between the physician and the patient, it is a longer series of conversations.

So I can't give you a general answer to that. There are some times when out of the situation or out of necessity it all happens at once, and other times where it's more of a protracted conversation.

Q. So in those instances where it's a protracted conversation, the patient's not being misled by their physician by having a conversation before the day that patient is treated; correct?

A. The patient is not being misled by the physician if the information that the physician shares is information the physician believes to be truthful and evidence-based and grounded in medical evidence. If, on the other hand, the patient is being given information that does not meet this criteria, then, yes, the patient is being misled.

Q. So what matters is whether the information itself is truthful and non-misleading, not necessarily when the information is provided?

A. What matters is the veracity of the information.

Q. I'm going to have my co-counsel pull up Defense Exhibit 31. And I believe this is that exhibit that we asked plaintiffs' counsel to email you today. Did you receive a copy of that?

A. I did.

Q. Can you go ahead and pull that up? So this is a declaration that was submitted in this case that's already

been admitted into evidence. It's already in the record. And it contains a screenshot of Planned Parenthood's website discussing medication abortion reversal. But you did not review or rely on this -- this website as it appears in this exhibit when you prepared your declaration; right?

A. I don't believe that I did.

Q. Okay. Can you look at the second to last page of the exhibit. And the heading of that page says "Can the abortion pill be reversed after you have taken it?"

A. Okay.

Q. Do you see that?

A. I do.

Q. Okay. I'm going to read the second paragraph under that heading. (As read): Claims about treatments that reverse the effects of medication abortion are out there, and a handful of states require doctors and nurses to tell their patients about them before they can provide abortion care, but these claims haven't been proven in reliable medical studies, nor have they been tested for safety, effectiveness or the likelihood of side effects. So experts like the American College of Obstetricians and Gynecologists reject these untested supposed treatments.

Did I read that correctly?

A. You did.

Q. So isn't it fair to say that Planned Parenthood is

voluntarily telling women that claims about medication abortion reversal are out there?
A. Planned Parenthood in this document is sharing information or is mentioning the fact that there are claims about medication abortion reversal, in their language, out there.
Q. Uh-huh. And isn't it fair to say that Planned Parenthood in this document is expressing its disagreement with the evidence-based validity of the studies that supposedly support reversal?
A. It is saying that there are, in their view, no reliable medical studies to support the effectiveness of the reversal procedure.
Q. I'm going to read the next paragraph too. (As read): Studies on the abortion pill do show that if you take the first medicine, but not the second, the abortion pill is less likely to work. So if you've begun the process of having an abortion using the abortion pill, but are having second thoughts, contact the doctor or nurse you saw for the abortion right away to talk about your best next steps and what to expect.
Did I read that correctly?
A. You did.
Q. So is it fair to say that in this paragraph, Planned Parenthood is also telling women that if you take the first

pill alone, that the abortion pill might not work, might not result in a terminated pregnancy?
A. They're saying if you take only the first medication, but not the second, it's less likely to work than if you take both. In other words, I interpret that to mean you're more likely to have a continued pregnancy.
Q. So you're not aware of any patient -- a single patient who was misled by this information on Planned Parenthood's website; right?
A. I recall seeing a declaration by a patient who talked about abortion reversal. Whether -- I don't recall specifically whether anybody claimed to be misled by this particular statement, but I recall seeing a declaration by a patient who talked about her experience with abortion reversal.
Q. But you don't have any specific knowledge of an individual who looked at this website and was misled by it?
A. I don't recall whether the declaration or declarations that I read specifically referred to this website and said "I read this website, and I believe I was misled by it."
Q. But aside from the declarations, just putting those aside, you're not aware of any other woman who's been misled by the information in this website?
A. I'm not aware of any other women, besides possibly the women who wrote the declarations that I'm referring to.

Q. And you're not aware of any specific woman who has read that information on Planned Parenthood's website who experienced damage to her physician-patient relationship; correct?
A. I'm not aware of that specifically, no.
Q. Do you know of any woman who has ever had a medication abortion who was not sure she wanted to have the abortion?
A. I seem to recall that being part of what was addressed in one or more of the declarations that I read. Apart from those, no.
Q. So patient autonomy is a key element of informed consent; right?
A. Patient autonomy is closely related to informed consent. Informed consent is a procedure or a process that is intended to support and reinforce patient autonomy.
Q. So you're saying it's not a key element, it's just related to informed consent?
A. Informed consent is a key procedure that supports the value of patient autonomy.
Q. So you just mentioned that you have reviewed the declarations submitted by Ms. Hurm and Ms. Dunavant in this case; right?
A. I don't recall. I'd have to look back to know if those are the names of the declarations that I'm referring to, but I do recall -- I believe it was two. I could be wrong about

the number of declarations.
Q. And you have no reason to dispute the accuracy of those declarations; right?
A. I have no reason to dispute what the women said in those declarations, that they were being truthful to their own experiences.
Q. And as a matter of medical ethics, women like Ms. Hurm and Ms. Dunavant, they have the right to change their mind and not take the second set of pills; right?
A. As we've discussed, patients, with potentially rare exceptions, but adult patients who have decision-making capacity can begin a course of medical procedures and then change their mind and not continue.
MR. GROVES: Your Honor, I think I'm getting really close to the end of my cross-examination, but if it's amenable to the Court, can I have maybe five minutes or so to confer with co-counsel? And maybe not even that long, maybe three to four.
THE COURT: We'll call it three because we got one more witness to get on today. Right? So we'll take about a three-minute break, and then we'll see where we are.
MR. GROVES: Thank you, Your Honor.
(Recess taken from 5:06 p.m. to 5:09 p.m.)
THE COURT: All right. Mr. Groves, any other questions?

MR. GROVES: I believe I have two or three other questions, Your Honor.

THE COURT: Okay.

BY MR. GROVES:

Q. Dr. Joffe, in your opinion, is it ever ethical for an abortion provider to give a patient information about abortion pill reversal?

A. I believe that if a patient asks about abortion pill reversal, then a doctor should share what he or she believes or knows to be the case, what they know to be the evidence. If a physician has a belief about abortion pill reversal, either in support of it or critical of it, it would be acceptable for that physician to share that belief based on his or her individual judgment with the patient. I respect people's -- physicians' ability to give information based upon their own views of the evidence.

Q. And so unless a patient specifically asks, it would never be ethical for an abortion provider to talk about the subject at all?

A. I'm sorry if I was not clear in my answer. Certainly, if a patient asks, the provider should answer the question to the best of their ability. But even if a patient doesn't ask, if the physician judges that it is salient, or this is important information for them to share. Again, that might be a physician who wants to raise this as an issue or a

physician who wants to say "You may have heard about this being out there. I don't believe that it's valid. Here are the reasons," like is done on the Planned Parenthood screenshots that you showed me. I wouldn't fault a physician for being unethical if they shared information based upon their own beliefs about the evidence.

MR. GROVES: Your Honor, I have no further questions. I don't know if you heard me the first time, or if I was muted.

THE COURT: I don't think I did, but okay. Any redirect, counsel?

MS. BAJRAMOVIC: I think I just have two redirect questions, Your Honor.

THE COURT: Okay.

REDIRECT EXAMINATION

BY MS. BAJRAMOVIC:

Q. First, Dr. Joffe, Mr. Groves asked you about those Planned Parenthood screenshots, frequently asked questions, one of which concerned this so-called reversal treatment. Remember that?

A. Yes.

Q. So is there a difference between information contained in a frequently asked questions document like this and information that must be given by one's treating physician 48 hours before an abortion during the informed consent

process?
A. I think there is an important difference. This is information that -- this meaning the information that is in the screenshot and on the Planned Parenthood website -- is there for the patient who -- who looks for it. And if it's there as a frequently asked question, presumably that's because the question perhaps sometimes comes up, and there's a need to be clear about it to the extent that they can.

So there's nothing mandating a patient to look at this. There's nothing mandating a physician to point a patient to this website. This is entirely optional information that a patient may choose to go look for. I see a big difference between that and information that is mandated to be provided to patients.

In addition, the content of the information is really different. Information that is here on this screenshot is consistent with what I believe to be the state of the evidence. What professional organizations like ACOG say was the information that's mandated to be provided to women by the State of Tennessee is information that is contradicted by authoritative statements but not supported by the evidence.
Q. And just one final question, Dr. Joffe. Mr. Groves asked you some questions about whether it is the veracity versus the timing of information that matters for informed

consent. Do you remember that?
A. I do.
Q. So if the information in question is untrue or misleading, is it possible for the timing of when that information is delivered to aggravate the harm of providing it?
A. I think that information that is untrue or misleading, whether it is provided in advance of a decision being made or at the time or shortly before a decision is being made, the problem is that it is untrue, misleading, confusing, might induce or cause a patient to make a decision that is not ultimately the decision that they would have made based on accurate information. I think that is the important thing, the veracity as opposed to the timing.

MS. BAJRAMOVIC: That's all I have. Thank you, Your Honor.

THE COURT: All right. Thank you, Dr. Joffe. You can sign off of the video feed now.

THE WITNESS: Okay. Thank you, Your Honor.

(Witness excused.)

THE COURT: All right. Are the plaintiffs still intending to call this rebuttal witness? And if so, is that witness ready?

MS. MORIARTY: Yes, Your Honor. Michelle Moriarty.

THE COURT: Okay. I'm looking at the wrong place here. They were looking at me like I had three heads. So let's -- let's go to the correct lawyer I should be looking at. Is it still your intention to call this rebuttal witness? Let's start there.

MS. MORIARTY: Yes, Your Honor, for very brief rebuttal testimony.

THE COURT: And she's available; is that correct?

MS. MORIARTY: I believe she should be on the line. Dr. Schreiber, if you could come on video and unmute.

THE COURT: Dr. Schreiber, can you see and hear me okay?

THE WITNESS: Yes. Can you hear me and see me?

THE COURT: Yes. Counsel --

THE WITNESS: Yes, I can hear you too, Your Honor. Thank you.

THE COURT: And who's -- you?

MR. RIEGER: I am.

THE COURT: All right. So we've got everybody able to see and hear each other. Welcome back. And we'll go ahead and proceed with this questioning.

THE WITNESS: Thank you, Your Honor.

MS. MORIARTY: Thank you, Your Honor.

///

DR. COURTNEY SCHREIBER,

called as a rebuttal witness, having been previously duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. MORIARTY:

Q. Dr. Schreiber, thank you for coming back. You previously testified regarding your expert opinion that it is biologically implausible for progesterone to outcompete mifepristone. The state's witnesses testified about this conflict as well. And Judge Campbell asked one of the state's witnesses, Dr. Brent Boles, to discuss an analogy involving locks and keys. I'm going to read you an exchange between Judge Campbell and Dr. Boles starting on page 97, line 18 of hearing transcript Volume III.

(As read:) The Court: And I want to -- another analogy has been used through the course of this hearing earlier of a key -- a lock, sorry, and then a key, and the mifepristone is like a fake key and it doesn't turn the lock, but just occupies the lock, and the progesterone would be like the legitimate key that can turn the lock.

The Witness: That's correct.

The Court: You follow what I'm saying?

The Witness: Yes.

The Court: Okay.

The Witness: That's an analogy that's frequently

used in medical education to explain this concept to people.

Dr. Schreiber, can you explain using this lock and key analogy why the reversal theory still doesn't make sense?

A. Yes, I can. And I think it just becomes very important to understand some of the subtleties in how the lock and the key work.

So first off, let's remember that mifepristone binds with a higher affinity to the progesterone receptor. It outcompetes progesterone at the receptor. So from the key perspective, it's actually a better key. It's like a key with some WD-40 on it. And secondly and critically, the binding of mifepristone to the receptor, it does turn the lock, unlike what Dr. Boles had said. Mifepristone turns the lock. And when it turns the lock, it leads to a conformational change in actually the DNA binding site of the progesterone receptor. It actually makes molecular changes in the shape of the lock, when we're thinking of the lock and key analogy. So now the old key, progesterone, no longer fits into the lock due to the changes induced by mifepristone.

I think the other point to consider here is also to not forget that progesterone levels are already very high in pregnancy, and there's no evidence that adding more would have any biological effect. You may remember my swimming analogy. You know, a pregnant woman is swimming in a pool of

progesterone. That's just the biology of pregnancy. Adding another bucket of water into the pool doesn't make that woman more wet.

Q. And Dr. Harrison testified about this lock and key analogy. She testified that the mifepristone key doesn't turn the lock, doesn't change the lock, rather it just occupies it; whereas, the progesterone key turns the lock and sets off this series of changes.

What I hear you saying is that that is not accurate; is that correct?

A. Correct, that description that you just recited is not accurate. Mifepristone does turn the lock. And let's think about what happens once that lock is turned. The door is opened, and the guests are let in. So really what's happening is that once that door is opened, and the guests are let in, it's those downstream consequences that change the feeling of the room and change the population in the house.

So it's the turning of that lock and the opening of the door, which mifepristone does, but when mifepristone alters the way that turning happens, it's different mechanisms that occur downstream, different guests that are let in. And what happens is that there are, you know, binding -- after the binding of the mifepristone, there's a whole response that's triggered at the cellular level.

Enzymes are released. Blood vessels are constricted. And the pregnancy starts to separate from the uterus. This all occurs after the receptor binding, after the key has turned the lock, when mifepristone turns that lock. And once the process is activated, it can't be stopped.

Maybe an analogy for this is like the game of Dominoes. So when you knock down that first domino, an irreversible chain reaction is started. So that's mifepristone turning the lock its way. Even if you were to set that first domino upright again, that wouldn't stop all the downstream dominoes from falling because the chain reaction has already begun. Those cellular mechanisms that happen after mifepristone binds to the receptor cannot be undone.

Q. Judge Campbell also asked Dr. Boles about a different analogy involving football. I'm going to read you the exchange between Judge Campbell and Dr. Boles starting on page 98, line 24 of hearing transcript Volume III.

(As read:) The Court: Is the idea that you put more folks on the offensive line, say an extra tight end or something, and the defense doesn't do that, the success rate of that play might go up because you have blockers?

The Witness: That's an extremely good analogy.

The Court: Okay. So the way that this process works is, it's not necessarily to undo a tackle, it's to

prevent the tackle from happening in the first place?

The Witness: Correct.

Using this football analogy, could you explain the problems with the reversal theory?

A. Well, I'm not a football player, but I'll try. So I guess if you think of it that mifepristone is the offense, for example, and progesterone is the defense, once mifepristone has made it into the end zone, it doesn't matter if you put a million new defensive players behind mifepristone, the touchdown has already been scored. So it's sort of, you know, too late. Once you're in the end zone, mifepristone, that is the play, and the touchdown has been scored.

Q. And what is the touchdown in this analogy?

A. The touchdown is mifepristone binding and the abortion process being initiated. No matter how many more defensive players you put after that touchdown, no matter how much more progesterone you put on the field, that's not going to undo what's already occurred.

Q. Thank you. Dr. Harrison also testified about binding stating -- and I'm reading from page 28, line 19 on hearing transcript, Volume IV -- (as read): In biochemistry, the way things happen is you have -- you have a binding and release. Okay. Mifepristone binds tighter to the progesterone receptor than -- progesterone receptor than progesterone

does, but it binds and releases. And you can outcompete mifepristone at the progesterone receptor if you have a sufficient amount of progesterone.

What is your response to that?

A. Again, the pregnant woman is already in a pool of progesterone. Adding another bucket of it doesn't make her more wet. Furthermore, that binding affinity, the higher likelihood that mifepristone has to bind to the receptor that's inherent to the molecule, that stays there whether it's popping on or off because the affinity is always going to be higher.

Finally, I'll remind you that once mifepristone binds the receptor, it changes the shape of the receptor. The receptor is now a better shape for mifepristone than it is for progesterone. Now the old key, progesterone, doesn't fit in the receptor anymore.

Q. Dr. Harrison also testified -- and I'll read to you from page 25, line 8 of hearing transcript Volume IV -- (as read): So mifepristone binds for a certain time, and then it releases and gets taken out of the system. Progesterone binds for a certain time and releases. But it's the binding of progesterone to the progesterone receptor that turns on transcription. The binding of Mifeprex to the progesterone receptor does not turn on transcription.

Question: So if Mifeprex were to bind with the

receptor and prevent transcription of the pregnant instructions, if it releases, could progesterone then come in and turn that receptor -- that cell back on?

Answer: Correct. That is correct.

In your opinion, Dr. Schreiber, is that answer accurate?

A. It's inaccurate because as I previously stated, mifepristone also has its own signal transduction, cellular changes that happen after binding, that issue of which guests are let through the door. So the effects that mifepristone has in the cell are such that an inflammatory process starts. Blood vessels in the uterus are constricted. Those events occur after the receptor binding. And that cascade, like the dominoes, cannot be stopped once it's started.

So when Dr. -- I think you said this was from Harrison -- states that no transcription occurs when mifepristone binds the receptor, that is grossly inaccurate.

Q. Thank you. So, in other words, when mifepristone binds to the receptor, is that the beginning of the abortion?

A. Yes, that is the beginning of the abortion. That primes the uterus and cervix for the abortion to start. It starts the pregnancy to separate from the uterine lining. That is the result of the mifepristone on the pregnant uterus.

Q. And can those effects be reversed once the mifepristone is no longer bound to the progesterone receptor?

A. Not reversed in the way that you just described to me that Dr. Harrison testified. They're not undone. Whether or not mifepristone by itself results in an abortion is a complex process. So it can be, you know, depending on gestational age. It can be depending on dosage of the mifepristone. And it can be individual factors that we may not even fully understand scientifically.

However, on a population-base level, the reason why mifepristone works to improve the effects of misoprostol and start the abortion process is because of these cellular changes that mifepristone starts when it binds to the receptor. That's how it works.

Q. Thank you. Now I'd like to ask you a few brief questions about a study the state's witnesses discussed during their testimony. If you could please turn to DX76, Defense Exhibit 76, which you should find in the binder of documents the state sent you prior to your initial testimony.

A. Yes, I have it.

Q. Are you familiar with this study?

A. I am familiar with this study.

Q. And what is this study? Can you identify it for the Court?

A. This is a Japanese study, first author, Yamabe. The Effect of RU486 and Progesterone on Luteal Function during Pregnancy.

Q. Dr. Schreiber, in general, did this study provide any support for the safety and efficacy of the reversal theory in humans?
A. No, it doesn't. This is an animal study. It's a study in rats specifically. Animal studies are absolutely insufficient. They are not sufficient for making practice changes in human medical care. I mean, in fact, to do so would be dangerous because the findings that we see in animal studies are often disproven when we get to human clinical trials. This is exactly why we do trials in humans. We wouldn't have to do human subject research if we could rely on animal studies.

Studies like this are often not replicated when they're taken to human trials. And there are many reasons for that, but, for example, on this instance, they can present differences, for example, in how the hormones behave in rats and in humans. There are differences in progesterone receptors across species. So we just can't make assumptions that what's seen in the small cohort of rats would be seen on a large population-based level in humans. There's just no basis to draw that conclusion.
Q. Okay. Now, Dr. Harrison testified about this study, and she opined that the fact that the mifepristone and progesterone were administered simultaneously to the rats in this study doesn't matter when it comes to the study

providing support for the reversal theory.

Do you agree with that?

A. No, I disagree with that as well. I mean, timing really is critical sort of in the same way that we just described previously what happens when these different -- when the molecules bind to the receptor and what happens at the cellular level. So the fact that in this rat study, mifepristone and progesterone were given at the same time, we can't extrapolate -- it doesn't mimic at all. Not only is it in rats, but the timing sheet does not mimic what is happening in the purported medical abortion reversal methodology.

Those clinicians are giving women progesterone any amount of elapsed time, but certainly hours to days, perhaps even till weeks, after the mifepristone has been taken, not at the same time. So we don't know what happens when those two things are given at the exact same time in humans, and this information from rats is not useful to extrapolate to humans.

Q. Thank you, Dr. Schreiber.

MS. MORIARTY: We have no further questions, Your Honor.

THE WITNESS: Thank you.

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CROSS-EXAMINATION

BY MR. RIEGER:

Q. Hello, Dr. Schreiber. You testified earlier in this case; correct?

A. Yes.

Q. Do you know if you were officially released as a witness at that time?

A. I beg your pardon?

Q. Do you know if you were officially released as a witness at that time?

A. I don't understand the question. I'm sorry. Can you clarify?

Q. We can move on. Did you discuss your testimony with anyone between when you testified and today?

A. No.

Q. Not anyone?

A. I discussed -- I may have discussed the testimony briefly with counsel. That would be it.

Q. So you did discuss your testimony with someone between then and now; correct?

A. We very briefly discussed it. That was about the size of it. And what the plans were for going forward.

Q. Were you given access to the transcript before today?

A. I don't recall.

Q. You don't recall whether or not you were given access to

the transcript before today?
A. No.
Q. Okay.
A. I don't -- I don't believe I was, actually.
Q. Were you told about anything involving the testimony before today?
A. I'm not sure what you mean by anything. I don't recall any specific discussions.
Q. Did anyone discuss testimony other than yours with you before today?
A. We may have very briefly discussed, for example, that information about Dr. Harrison's testimony, but I don't exactly recall the order of things to be honest. The declarations and the testimony are not always clear to me regarding the timing of events.
Q. Were you given any of the Court's questions before today, questions that the Court asked other witnesses?
A. Not that I recall.
Q. Were you given any analogies that the Court asked before today?
A. Counsel did mention to me this football analogy.
Q. When did you know that you would be back to give rebuttal testimony?
A. I don't recall. In fact, actually, it wasn't until today that I was sure if I would be invited back.

Q. When did you know that there was a possibility that you would be invited back to give rebuttal testimony?
A. I don't recall.
Q. Do you know if it was before you gave testimony on the first day?
A. I don't recall.
Q. Do you know if it was before the new year?
A. I don't recall.
Q. Were you given any suggestions regarding the subject of your testimony today?

MS. MORIARTY: Objection, Your Honor. I'd just like to object to the extent that this calls for privileged communications between counsel and witness.

MR. RIEGER: Your Honor, this witness was not released officially, and for her to sit and get information from the Court proceeding, if she was coached in any way, we get an opportunity to develop that.

THE COURT: All right. So the objection is one to protect privilege? Is that what you're saying?

MS. MORIARTY: Yes, Your Honor.

THE COURT: Is this counsel and a witness or counsel and a client? Because there's a difference.

MS. MORIARTY: A witness. And further to preserve attorney work product with regard to preparing witness for rebuttal testimony.

THE COURT: Well, is she a client?

MS. MORIARTY: Your Honor, the plaintiffs are our clients, but we work with the experts to represent our plaintiffs and put forth our case here.

THE COURT: I understand that you represent the plaintiffs, but is this witness a party to the lawsuit or a client of yours?

MS. MORIARTY: No, she's not a party to the lawsuit, Your Honor. However, we would take the position that our conversations in preparation for rebuttal testimony with her constitute attorney work product and are therefore protected from discovery.

THE COURT: And if it's disclosed to a third party like a witness, then that attorney work product is then released; correct?

MS. MORIARTY: Your Honor, when the expert is part of the team preparing to put forth the case, we would argue that that work product extends to the expert.

THE COURT: Is the point of this questioning, counsel, that what -- I mean, I gather you're trying to establish some manner of coaching, whether it was inappropriate or not, just to --

MR. RIEGER: Your Honor, I would note we're simply inquiring as to how she received this information and whether or not they're using the concept of rebuttal testimony as a

way to get around -- for example, in between when we had Dr. Harrison give her examination the first day and then we came back, we were very, very clear and careful to make sure we did not discuss her testimony with her at all. It makes no sense for us to, for example, go back now to Dr. Harrison, coach her up, coach her up, coach her up, and then present her as rebuttal testimony to this because for us that creates -- it's a manipulation of rebuttal testimony to use a witness in a way where you can coach them up based on the transcript, even though they've already given testimony for the first time here.

THE COURT: No, I get the -- I get the point you're making. You know, I think this -- without having any authority in front of me, it's a gray area as to the -- how far work product reaches, if it's disclosed to a third party, then -- then that would eliminate the protection given to that information. I guess the reason I even suggest it might be in a gray area -- and I don't have anything in front of me saying one way or the other -- if it's a retained expert, whether that falls under the -- I just hadn't looked at that in a long time. Nobody's asked me to, and I haven't independently.

MR. RIEGER: Your Honor, if it may make your life easier, perhaps we can discuss it without getting into the content of any suggestions, just to establish whether or not

there were and perhaps whom they came from.

THE COURT: Right. Well, I mean, that's fine. I mean, if you're going to put the witness back up, she's going to have to deal with what comes her way. I'm sure Dr. Schreiber is more than capable of holding her own. But ask away. And if you don't want to get into the specific discussions that they had, then I'm not sure that would get too close to the work product. So you can go ahead.

BY MR. RIEGER:

Q. Were you given any suggestions by anyone about your rebuttal testimony today?

A. What I recall is this football analogy being described to me, and me being asked could I understand that analogy and did it make sense to me and how would I respond to that, which is --

Q. Please go ahead.

A. -- what I did.

Q. And the people who told you to -- who gave you that example and asked you to prep a question, that was counsel?

A. Yes.

Q. Okay. Dr. Schreiber, what is the half life of mifepristone?

A. 72 hours, if I recall correctly.

Q. What are the metabolites of mifepristone?

A. I don't remember the metabolites specifically.

Q. Okay. Do you know if mifepristone metabolites also bond to progesterone receptors?
A. I would say that -- that the function -- to the extent that the mifepristone after it is metabolized binds, then, yes, it does.
Q. Do you know if those metabolites have less affinity for progesterone receptors than mifepristone itself does?
A. No. I mean, biologically, the question doesn't make sense because the importance is what we see clinically based on knowing the way that mifepristone acts. Mifepristone binds the receptors and has all of the effects that I've discussed today and also discussed in my testimony previously.
Q. So you don't know what the metabolites of mifepristone are, and you don't know whether or not those metabolites have less affinity for progesterone receptors than mifepristone; is that correct?
A. I think I would need to understand the context of this question a little bit better. I'm not exactly sure where you're going. I know what biological activity of mifepristone is, and that's been the subject of this hearing.
Q. When mifepristone breaks down based upon its half life, it creates metabolites; correct? It breaks down into metabolites?
A. Well, the half life has to do with the clearance of the

molecule from the system. It's not specifically referring to metabolites in any way. So those are . . .
Q. Well, let's take the half life out of it. When mifepristone breaks down, it breaks down into metabolites; correct?
A. I'm, you know, not aware of that process, and I cannot give you a yes or no answer to that question.
Q. So you don't know how mifepristone biologically breaks down -- sorry, chemically breaks down? You don't know?
A. Well, it's really clear, and the process by which that's exactly done, it's really clear as anything is.
Q. I'd like to talk to you about the Yamabe study again. You've testified that -- and that is Defense Exhibit 76, if you could pull that up in front of you. You've testified that this study is irrelevant; is that correct?
A. I testified that no human clinical data or information can be extrapolated from this study, and because the question at hand is related to human women, that this study does not provide any direct evidence for how mifepristone behaves in human women.
Q. Are you aware that during early testing of RU486 that rat studies were used by Danco?
A. No, I'm not aware of that.
Q. Are you aware of any animal studies that were used during the early stage testing of RU486?

A. So that is a completely normal and usual process. The way most of science works and discovery works is to do initial animal studies, can be rats, can be other animals, and then generate hypotheses, meaning, okay, these are what we're finding in this species. Let's see by doing human tests whether or not we find similar findings, or efficacy, toxicity, whatever the clinical question may be, that was evident in animals translates to humans. That would be a normal process in science.

Q. So going back to my question, are you aware of any animal studies that were occurring during the early stage testing of RU486?

A. I may be aware of them. I can't recall specific studies at the moment.

Q. Do you have an idea as to what animal the animal studies that you're thinking of, but aren't quite sure if you know, might be?

A. Because I can't recall specific studies at the moment, no, I wouldn't conjecture about which animal.

Q. Would it surprise you if some of the animals used in those studies were rats?

A. I would not be surprised by that.

Q. Okay. Would the use of a rat in one of those studies render that study automatically invalid?

A. It would depend on what conclusions were being drawn

from that study.
Q. So simply because they use rats does not mean that any conclusion is automatically irrelevant?
A. If the appropriate conclusion is drawn, and it's relevant to the question being asked, then it would not be irrelevant. If an inappropriate conclusion is drawn, and it's not supported by the data of the study, then it would be irrelevant to the question.
Q. In the Yamabe study, which is Defense Exhibit 76, rats -- pregnant rats were injected with both mifepristone and progesterone at the same time; correct?
A. In one of the arms of the study, that is correct.
Q. In that arm of the study, the rat who was injected simultaneously with progesterone and mifepristone, all of that rat's pups survived; correct?
A. I actually don't recall that. Could you -- would you mind pointing me to the part of the study where it describes that?
Q. Certainly, if you'll give me just a second. If I could point you to page 14 of Defense Exhibit 76. Am I reading this correctly (as read): But in the group which was injected with RU and progesterone at the same time, abortion did not occur at all, and uterine weights increased over time, the same as in the control?
Did I read that correctly?

A. I apologize, but I don't -- my page numbers somehow may be different than yours.
Q. Certainly. It will be the page that the first full paragraph starts "To that end." And it's also on that Elmo if you need to take a look.
A. Yes.
Q. Let me make sure I'm reading this correctly.
(As read:) To that end, in the group that was injected with just RU, abortion occurred in most of the rats just like in experiment 1, and a reduction in uterine weight was seen, but in the group which was injected with RU and progesterone at the same time, abortion did not occur at all, and uterine weights increased over time, the same as in the control.
Did I read that correctly?
A. That is what's stated. Yes, you read it correctly.
Q. And RU is the earlier name of mifepristone; correct?
A. Yes. From this paper, my understanding is they were referring to RU486, which does refer to mifepristone --
Q. So --
A. -- in compound.
Q. So for the rat that was injected with both mifepristone and progesterone at the same time, even though mifepristone outcompetes progesterone, no abortion occurred; correct?
A. So the way that they classified whether or not an

abortion occurred in this paper was by -- I mean, they euthanized the rats. So there's -- there's no way to know for sure whether or not the abortion occurred. This uterine weight idea is sort of a surrogate marker or a proxy, I think. They don't really describe it that well in the method, but I infer that because the weight of the uterus itself was less in the mifepristone only group than it was in the mifepristone plus progesterone group, that they surmise that that meant that that pregnancy was healthier than the one in the mifepristone alone group.

But there is no actual objective way of evaluating whether or not an abortion occurred. I think actually later, somewhere else in the paper, they state "has the appearance of the abortion occurring."

Q. Do you have any reason to doubt -- any hard concrete reason to doubt that the statement "abortion did not occur at all" was incorrect in the Yamabe study?

A. Well, yeah, because the rats were not left to see what the natural history was. Again, they were euthanized. So these rats didn't live. They had hysterectomies. The uteruses were taken out of the rats. So this was all assessed by microscope, as opposed to actually being able to compute the likelihood of an ongoing pregnancy or a delivery of the pups.

So we don't -- I mean, unless you can point me to,

which is why I asked for that, I was not aware in this paper of this, of -- I think you originally asked me about live born mice.

Q. Just one more question for you. You filed a rebuttal declaration in this case; correct?

A. Yes.

Q. Okay. And that's already been introduced as Plaintiffs' Exhibit 4. And I would like you to refer to it with me. And please let me know if I'm reading this correctly from your rebuttal declaration. (As read:) This may be the same for the mifepristone-progesterone combination. The bottom line is that we don't know and we won't know unless appropriately-designed studies are conducted.

That is your expert opinion; correct? The end of paragraph 10.

A. I hope I'm in the right document. I apologize. Maybe I should just look up on the screen and look at that again because I don't --

Q. Certainly.

A. -- see those.

Q. Certainly. Please let me know if --

A. Oh, I did find it. I found it. I found it.

Q. I'll ask the question again. Please let me know if this accurately reflects the words of your expert declaration.

(As read:) This may be the same for the

mifepristone-progesterone combination. The bottom line is that we don't know and we won't know unless appropriately-designed studies are conducted.

That's your opinion; correct?

A. Yeah, I mean, the statement that you read is in a discussion about the interaction between mifepristone, leucovorin and pregnancy.

Q. That sentence refers to mifepristone-progesterone combination, does it not?

A. Well, would it be okay if I read the full sentence?

Q. Sure.

A. (As read:) Applying Dr. Harrison's analogy to the case of mifepristone reversal, using progesterone as a rescue medication in parentheses, demonstrates that the effect of mifepristone on the pregnancy may not be reversed, despite theoretical efficacy. Leucovorin does not reverse methotrexate's effects on a pregnancy, and this may be the same for the mifepristone-progesterone combination. The bottom line is that we don't know, and unless appropriately-design studies are conducted -- we won't know, I'm sorry, unless appropriately-designed studies are conducted.

Yes, that sentence reflects my opinion.

Q. Okay. So it is your opinion that you don't know whether or not the mifepristone-progesterone combination works as

described by Dr. Harrison's analogy?
A. It is my opinion that the evidence does not exist to draw that conclusion.
Q. So you don't know?
A. I don't know because --
MS. MORIARTY: Your Honor, asked and answered.
THE WITNESS: It's based on the evidence, but I don't know it not because of an ignorance, but because there's no evidence to suggest it.
MR. RIEGER: I'm good. Thank you, Your Honor.
THE COURT: Any redirect?
MS. MORIARTY: No, Your Honor.
THE COURT: All right. Thank you, Dr. Schreiber. You can log off now.
THE WITNESS: Thank you very much, Your Honor.
THE COURT: Have a good rest of the day.
THE WITNESS: You too.
(Witness excused.)
THE COURT: All right. I gather that's it on our witnesses; correct?
MR. RIEGER: Yes, Your Honor.
MR. CASTELLI: Yes, Your Honor.
THE COURT: All right. Here's what I want to do -- you know, one of the downsides of using analogies is sometimes they are misunderstood, or they break down at some

point, but just to clarify my football analogy, progesterone was the offensive line, not the defensive line. But that may clarify that. Anyway . . .

One of the issues that we've talked about at previous hearings is the state's publication of information that we talked about earlier today. That's -- do you know when that went up on the website?

MR. RIEGER: Your Honor, I do not, other than that it occurred before the new year. I can get that date for the Court if the Court needs it.

THE COURT: It's fine. I mean, we had gotten the bulk of our testimony in. And as I look at the notification, it's, in sum and substance, pretty similar to what the language is in the statute that's at issue anyway. I don't see significant differences. But what I would like to do, because it's additional information, is let the parties, if you would like, to file a short filing as to the import of this one way or the other, or maybe it doesn't change anything at all, but I'd like to give you a chance to do that because we just haven't really -- that wasn't part of the original briefing. And we'll limit that to five pages.

I think I get the issues in the case by now. I don't need a restatement of all of your arguments again, even if you could cram all those into five pages. Just limit it to your position with respect to this particular website

information that is incorporated in the disclosure to patients via the statute because there's a reference to it. That's the whole reason. It's essentially adopting by asking the physician, as I understand it, to adopt by reference the content of the website. Does that change your position or do you think it's perfectly suitable from the defendants' standpoint, or further information about why this is inappropriate from the plaintiffs' standpoint, or whatever your position may be. But I'll give you a chance to at least weigh in on that.

Let's set that for -- let me look at a calendar real quick. Why don't we have those due on February the 12th. That will give everybody a couple weeks plus to look at that. And I know you got other things you got going on in your practices. So we'll just keep the previous order that was in place in place until I have those briefs and can issue a ruling on the substance of the motion for the injunction. And that way we can get everything -- everybody will have the chance to be heard on all the issues that are invoked in this statute, which now includes this referenced website information.

All right. Any questions about that? Any concerns?

MR. CASTELLI: None with that, Your Honor. I'm wondering if the Court wants findings of fact --

THE COURT: Are you okay doing that? Because we can't hear you.

MR. CASTELLI: Would the Court like us to submit proposed findings of fact, conclusions of law?

THE COURT: Not at this point I don't. If I change my mind, I'll let you know and give you plenty of time to do them, but I think -- I don't really think that that's necessary. You-all have worked very hard on this and over a couple of months now and done a lot of briefing. I think we can take it from there. If I change my mind on that, then I'll let you know, but . . .

MR. CASTELLI: Okay.

THE COURT: All right. Anything else?

MR. RIEGER: I think we're good.

MR. CASTELLI: I think given that, the only other issue that plaintiff had is just, I guess, wanted to bring it to the Court's and to the State's attention that should the temporary restraining order be dissolved, there would be some compliance that our clients would have to do. So since we're not doing any post-briefing at this point in time, we just wanted to put it on the record that, you know, we'd ask for or like to have some sort of period of compliance when this TRO -- whatever happens, if the TRO were to dissolve and not be converted to a preliminary injunction, so that our clients can get everything ready so that they're not breaking the

law.

THE COURT: I hear you. I hear you. In other words, they're not in violation of the law the next day because there's placard requirements and --

MR. CASTELLI: Yes, sir.

THE COURT: -- discharge paperwork that has to be reprinted and all that? So I understand what you're saying. Is that really what you're getting at, is --

MR. CASTELLI: That's exactly what I'm getting at.

THE COURT: All right.

MR. CASTELLI: We don't want anybody going to jail because of something --

THE COURT: That sounds -- any concern with that from the State, that we have some period of time for them to adjust to get into compliance if the TRO is --

MR. RIEGER: No, Your Honor, there's no issue with that provided that it's, you know, not more than the time they need to get up to compliance should the TRO get dissolved.

THE COURT: Right. All right. I think we're all on the same page. Everybody have a good rest of the evening.

MR. CASTELLI: Thank you, Your Honor.

MR. RIEGER: Thank you, Your Honor.

(Proceedings concluded at 6:00 p.m.)

REPORTER'S CERTIFICATE

I, Patricia A. Jennings, Official Court Reporter for the United States District Court for the Middle District of Tennessee, with offices at Nashville, do hereby certify:

That I reported on the Stenograph machine the proceedings held in open court on January 25, 2021, in the matter of *PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI, et al. vs. HERBERT H. SLATERY III, Attorney General of Tennessee, in his official capacity, et al.*, Case No. 3:20-cv-00740; that said proceedings in connection with the hearing were reduced to typewritten form by me; and that the foregoing transcript (pages 1 through 139) is a true and accurate record of said proceedings.

This the 11th day of February, 2021.

/s/ Patricia A. Jennings
Patricia A. Jennings, RMR, CRR
Official Court Reporter