IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI; *et al*.,	
Plaintiffs,	CASE NO. 3:20-cv-00740
v.	JUDGE CAMPBELL
Herbert H. SLATERY III, Attorney General of Tennessee, in his official capacity; *et al.*,	MAGISTRATE JUDGE NEWBERN
Defendants.	

PLAINTIFFS' SUPPLEMENTAL BRIEFING

Plaintiffs submit this supplemental briefing concerning the Tennessee Department of Health ("DOH") website ("Website")[1] posted pursuant to Tennessee Code Annotated Section 39-15-218(e). The Website's reference to the Abortion Pill Reversal Network ("APRN") and its omission of crucial information increase the dangers that the Act's requirements will lead someone to start a medication abortion under the mistaken belief that it is reversible. By requiring Plaintiffs' physicians to direct patients to the Website, the Act requires them "to adopt by reference the content of the website," as this Court noted at the conclusion of the preliminary injunction hearing. Prelim. Inj. Hr'g Tr. ("Hr'g Tr.") Vol. V at 137:3–5. The Act requires Plaintiffs' physicians to do this at least 48 hours in advance of performing medication abortions, upon penalty of a criminal felony conviction. Tenn. Code Ann. §§ 39-15-218(e), (j).[2]

A. Referral to APRN

The Website provides only a single resource[3] for a patient who is "questioning or change[s] [their] mind . . . after taking mifepristone" and is seeking "further information, guidance, or assistance": APRN. APRN is a referral service for "abortion reversal" treatments run by a private religious organization. *See infra* at 3. The First Amendment does not permit the State to force physicians to advertise the services of or refer patients to a private third party. Yet the Act does precisely this—requiring Plaintiffs to participate in referring patients not only to

[1] Attached as Exhibit A to the Declaration of Christine Clarke ("Clarke Decl.").
[2] In the interest of economy, Plaintiffs will not address Website language similar to that required by other portions of Section 39-15-218 ("the Act"), which have been the subject of prior briefing. *Compare* DOH Website, *with* Tenn. Code Ann. §§ 39-15-218(b), (e), (f).
[3] The DOH claims not to "recommend medical providers," yet it lists APRN as the *sole* resource for patients with questions. The Website does not list Plaintiffs, though they are among the Tennessee health care providers most knowledgeable about the effects of mifepristone because they actually administer it to patients. Though someone who is pregnant and wishes to remain pregnant should consult an obstetrician, the Website does not list any.

APRN, but also to the unknown individuals to whom APRN sends people for experimental medication abortion "reversal" treatment.[4]

APRN does not publish a list of its providers.[5] Not even Dr. Boles, who sits on APRN's Medical Advisory Board, can name APRN's "reversal" providers in Tennessee, besides himself. Pls.' Hr'g Ex. 93 ("Boles Dep.") at 327:11–13, 336:21–24; Hr'g Tr. Vol. III at 35:14–21 (Boles). As a result, the Act forces Plaintiffs to refer their patients for treatment by unknown individuals.

It is unclear what qualifications, if any, APRN requires of these individuals, *see* Clarke Decl. Ex. C, Dep. of Donna Harrison M.D. (Nov. 13, 2020) ("Harrison Dep.") at 206:6–9, aside from the apparent requirement that they not provide or even refer patients for abortions.[6] APRN's website indicates that providers need not be physicians at all.[7] Dr. Boles became a "reversal" provider after reading a package of information sent to him by APRN. Boles Dep. 317:4–15.

It is also unclear what policies and procedures, if any, APRN requires of its providers. *See* Delgado Dep. 268:12–24 (noting APRN "can't mandate anything"); Harrison Dep. 228:8–12. Dr. Boles provides "reversal" treatment through APRN largely by calling in prescriptions for patients he has never examined, many of whom are out of state, and with whom

[4] The APRN website is also rife with misinformation, not only about supposed "reversal" but also about medication abortion itself, including making false claims about the side effects of mifepristone. *See, e.g.*, Pls.' Hr'g Ex. 1 (Schreiber Decl.) ¶ 58. Forcing physicians to adopt this misinformation by reference harms not only patients who may be misled into thinking their abortion is reversible, but all medication abortion patients.

[5] Abortion Pill Rescue, *Join Our Medical Network*, https://www.abortionpillreversal.com/medical-network (last accessed Feb. 12, 2021) ("We do not share your information publicly but may share when needed within the APR network.").

[6] The form that APRN asks people to fill out in order to become an APRN provider includes a short questionnaire including, "Do you perform or refer for abortion?" That question, unlike others, has the answer pre-marked, "No." *Id.*

[7] *Id.* ("If you are a . . . nurse midwife, nurse practitioner or physician assistant and are interested in joining the Abortion Pill Rescue network and help women who want to reverse the effects of the abortion pill, please fill out the form below."); *see also* Hr'g Tr. Vol. III at 38:16–19 (Boles); Clarke Decl. Ex. B, Dep. of George Delgado M.D. (Nov. 17, 2020) at 323:11–324:1.

he never follows up. Hr'g Tr. Vol. III at 65:7–66:11 (Boles). His practices are likely in line with APRN policies, if any, given that he is on APRN's Medical Advisory Board. *Id.* at 35:14–21.[8]

The evidence demonstrates that APRN's activities—referring women for and collecting data from experimental treatments of unknown safety and efficacy, *see* Boles Dep. 341:4—25; Hr'g Tr. Vol. II at 202:13–16 (Delgado) — constitutes medical experimentation, *see, e.g.*, Pls.' Hr'g Ex. 45 (Joffe Decl.) ¶ 57. It is not at all clear that APRN providers obtain patients' informed consent to participate in such experimentation before administering medication. Delgado Dep. 324:9–325:19, 326:21–327:17 (noting that patients are not told the treatment is experimental, that its safety and efficacy have not been proven, or that they are participating in a study). These failures to obtain informed consent violate ethical standards for medical experimentation on human subjects. *See* Hr'g Tr. Vol. V at 64:13–65:3, 70:4–19 (Joffe).

Finally, APRN is run not by a healthcare organization, but by Heartbeat International, Hr'g Tr. Vol. III at 68:3–7 (Boles), a private religious organization that opposes abortion, as well as all forms of birth control—regardless of whether used for family planning or "health issues, including disease prevention."[9] Heartbeat International explicitly promotes "God's Plan for our sexuality," which states that "sexual intimacy" must "go together" with heterosexual marriage, having children, and a "relationship with God."[10]

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[8] The Co-Director of Plaintiff Knoxville Center for Reproductive Health described a call from a patient who said that she was referred by APRN to a man's home, rather than a medical office, and that she was provided a phone number that had no "medical office answering machine or service as she would have expected." Pls.' Mem. of Law in Support of Mot. for TRO and/or Prelim. Inj. ("Pls.' TRO Br."), Ex. 5 (Decl. of Rovetti) ¶¶ 12–13. "Ultimately, she went inside this man's home, where he performed an injection, instructed her not to take the second pill in the medication abortion regimen, and sent her home." *Id.*

[9] Heartbeat Int'l, *About Us*, https://www.heartbeatinternational.org/about-us/commitment-of-care/item/28-welcome-to-heartbeat (last accessed Feb. 12, 2021).

[10] Heartbeat Int'l, *Our Commitment*, https://www.heartbeatinternational.org/about/our-commitment (last accessed Feb. 12, 2021) (noting "[a]ll Heartbeat International policies and materials are consistent with Biblical principles and with orthodox Christian (Catholic, Protestant, and Orthodox) ethical principles").

Because the Website lists only APRN, the Act forces Plaintiffs to refer patients to a private, third-party organization fundamentally opposed to the reproductive health care Plaintiffs provide. Moreover, because APRN is a referral service, the Act also forces Plaintiffs to ultimately refer patients to unknown individuals, with unknown qualifications, who provide an unproven experimental medical treatment, likely without first obtaining informed consent.

B. Lack of Clarifying Context

As Plaintiffs have argued throughout this litigation, the Act's mandated speech is false, misleading, and irrelevant to a person's decision to have an abortion and undermines informed consent by suggesting that it is possible to take mifepristone during pregnancy and "reverse" its effects later if one changes their mind. *See generally, e.g.*, Pls.' TRO Br. Defendants have argued that this harm is effectively mitigated because Plaintiffs' physicians may provide context—by explaining that the physician herself disagrees with the speech and that it is mandated by the State of Tennessee. *See, e.g.*, Hr'g Tr. Vol. I at 25:5–26:25 (colloquy). In response, Plaintiffs have presented evidence that such disavowal and disassociation are insufficient, as patients will be given wildly contradictory statements and left to try to figure out who to believe as between two authoritative sources—their physician and the State of Tennessee's public health department. Hr'g Tr. Vol. I at 94:19–96:125 (Lance); Hr'g Tr. Vol. V at 49:6–60:2 (Joffe).

This tension is heightened by the contents of the Website, which is rife with false and misleading statements. These statements are provided by a government agency without any hint that they are controversial, let alone that they contradict the overwhelming medical consensus and the positions of the nation's leading medical organizations. *See, e.g.*, Pls.' TRO Br. 7–9.

The Website tells women it "may be possible" to reverse their abortion and directs them to an organization exclusively devoted to providing abortion "reversal."[11] Yet, the Website provides no indication that the treatment is experimental or that its safety and efficacy are unproven.[12] Nor does it give the crucial warning that a woman should come to a firm and final decision to terminate her pregnancy *before* starting the medication abortion because taking mifepristone *is likely* to terminate a pregnancy, no matter what a woman does thereafter. *See, e.g.,* Hr'g Tr. Vol. II at 65:13–66:5, 170:24–171:10 (Schreiber).

The Act requires physicians to direct patients to the Website at least 48 hours *before* taking mifepristone. Tenn. Code Ann. § 39-15-218(e). By the time mifepristone is taken, a patient will have heard about the possibility of abortion reversal from her physician, from large signs in the health center, and on the State government's public health website. The Website thus compounds the most serious danger the Act's mandates pose—that women who are not certain of their decision will take mifepristone because they erroneously believe they can "reverse" its effects later. In so doing, the Website further clarifies that the Act is not an informed consent statute, nor does it mandate the provision of truthful, non-misleading and relevant information; it therefore cannot pass constitutional muster. *See generally, e.g.*, Pls.' TRO Br. 12–20.

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[11] *About Us*, Abortion Pill Rescue, https://abortionpillreversal.com/about/our-team (last accessed Feb. 12, 2021) (noting as its first "Founding Principle[]" that "[p]rogesterone can reverse the effects of mifepristone").

[12] Clinical trials of reversal have never even been completed on *animals*, let alone on humans. Hr'g Tr. Vol. V at 7:22–8:3 (Harrison). The only clinical trial even begun on the subject had to be suspended after one quarter of enrolled patients suffered hemorrhage so severe, they were transported to the hospital by ambulance. *See* Schreiber Decl. ¶¶ 65–66. The omission of context about the risks and experimental nature of "reversal" is glaring in light of Defendants' insistence that the Act is an informed consent statute, and yet the Website is so misleading as to undermine informed consent not only for a medication abortion, but even for abortion "reversal." *See, e.g.*, Defs.' Resp. in Opp. to Pls.' Mot. for TRO and/or Prelim. Inj. at 13, 26–27.

Dated: February 12, 2021

Respectfully submitted,

By: */s/ Thomas H. Castelli*

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CERTIFICATE OF SERVICE

I hereby certify that on February 12, 2021 a true and correct copy of the foregoing Motion was served on the Tennessee Attorney General's Office, counsel for all Defendants, via the Court's ECF/CM system.

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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI; *et al.*, Plaintiffs, v. Herbert H. SLATERY III, Attorney General of Tennessee, in his official capacity; *et al.*, Defendants.	CASE NO. 3:20-cv-00740 JUDGE CAMPBELL MAGISTRATE JUDGE NEWBERN

DECLARATION OF CHRISTINE CLARKE IN SUPPORT OF
PLAINTIFFS' SUPPLEMENTAL BRIEF

I, Christine Clarke, declare under penalty of perjury that the following is true and accurate to the best of my knowledge:

1. I am an attorney at Planned Parenthood Federation of America ("PPFA") and am counsel of record for Plaintiffs Planned Parenthood of Tennessee and North Mississippi and Dr. Audrey Lance in the above-captioned matter.

2. I make this declaration in good faith based upon documents that are provided here for the convenience of the Court and the parties.

3. Attached hereto as Exhibit A is a true and correct copy of the Tennessee Department of Health website posting reflecting the requirements of Tennessee Code Annotated Section 39-15-218(e), which I downloaded from the Tennessee Department of Health Website on February 12, 2020, and which is available at https://www.tn.gov/health/health-program-areas/hcf-professionals/alerts.html.

4. Attached hereto as Exhibit B is a true and correct copy of the transcript of the deposition of Defendants' witness Dr. George Delgado, taken on November 17, 2020.

5. Attached hereto as Exhibit C is a true and correct copy of the transcript of the deposition of Defendants' witness Dr. Donna Harrison, taken on November 13, 2020.

Dated: February 12, 2020

By: */s/ Christine Clarke*

Christine Clarke
Planned Parenthood Federation of America

Counsel for Plaintiffs Planned Parenthood of Tennessee and North Mississippi and Audrey Lance, M.D., M.S.

EXHIBIT A

FIND COVID-19 INFORMATION AND RESOURCES

INFORMATION FROM TN DEPT OF HEALTH ABOUT THE ONGOING NOVEL CORONAVIRUS OUTBREAK

Alerts and Updates

- Patient Certification Form As Required By 2020 Tennessee Public Acts Ch. 764 Relative To Abortion
- 2009 H1N1 Pandemic Health Care Provider Section 1135 Waiver Authorization (Memo # 10-06-All)
- CMS Survey & Certification Transmittals
- CDC Alerts
- CMS National Providers Identifier Notice
- FDA Alerts
- Sample Facility Flu Vaccination Consent/Declination Form
- Sample Individual Flu Vaccination Consent/Declination Form
- Nursing Home Training

****Information Disclaimer: Please be advised that the alerts contained in the links that follow were transmitted to the Tennessee Department of Health, Division for Licensing Health Care Facilities by the agency listed under which the link is located. The enclosed information is being provided to you/your facility for its use as received and the Department of Health takes no legal responsibility for the information contained therein.****

INFORMATION REGARDING CHEMICAL ABORTION

As required by 2020 Public Acts C. 764, relative to abortion:

The most common form of a chemical, non-surgical abortion (also called a medication abortion) typically involves administering two medications, mifepristone and misoprostol.

Mifepristone temporarily blocks the hormone progesterone, which is necessary to maintain pregnancy.

Mifepristone alone is not always effective in ending a pregnancy. If Misoprostol has not been taken, it may be possible to avoid, cease, or even reverse the intended effects of a chemical abortion.

If you are questioning or change your mind about your decision to terminate your pregnancy after taking mifepristone and would like further information, guidance, or assistance concerning your pregnancy, you should immediately contact a healthcare professional.

The following resources are available:

The Abortion Pill Reversal Hotline*: 1-877-558-0333 www.abortionpillreversal.com

*The Tennessee Department of Health does not operate the hotline or website and is not affiliated with either. It does not endorse the content of either. The information provided by either does not necessarily reflect the official policy or position of the Department. The Department does not endorse or recommend medical providers. The Department encourages all patients to discuss risks and benefits of any potential medications or procedures with their medical providers.

- Spanish
- Arabic
- Chinese

NOTICE TO ALL HEALTH CARE FACILITIES:

Effective May 27, 2009, the Health Data Reporting Act of 2002 was amended by Public Chapter 318. The new law provides that all licensed health care facilities are no longer required to report "unusual events" as the term was defined in the 2002 Act, but that each facility, except for those facilities required to report abuse, neglect or misappropriation pursuant to federal laws and rules (42 CFR §483.13), shall only report incidents of abuse, neglect, and misappropriation that occur at the facility to the Department. The facility is required to make the report within seven (7) business days from the date that the facility identifies the incident. The new law removes the requirement that the facility shall submit a corrective action report to the Department. Although reporting requirements for facilities have been changed, the Department is still required to investigate the incidents of abuse, neglect or misappropriation reported to the Department as complaints for certification purposes.

The new law did not change the requirements contained in the 2002 Act that require all licensed health care facilities to report the following to the Department: strike by the staff at the facility; external disaster impacting the facility; disruption of any services vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and fires at the facility that disrupt the provisions of patient care services or cause harm to the patients or staff, or that are reported by the facility to any entity, including but not limited to a fire department charged with preventing fires. These incidents must be reported to the Department of Health within seven (7) business days after the facility becomes aware of the incident. Public Acts of 2009, Chapter 318 .

NOTICE TO HOSPITALS AND NURSING HOMES

Amendments to the Hospital and Nursing Home Rules and Regulations became effective October 1, 2007 which include new requirements regarding influenza vaccination and declination documentation, hand hygiene practices, and central line insertion practices. These amended rules and regulations can be accessed from this website by selecting *Rules and Regulations* on the left menu, then *State Rules*, and the appropriate chapter.

Please note that documentation of influenza vaccination or declination is required for both facility types. Under those amended regulations, hospitals and nursing homes are also required to calculate influenza vaccination coverage rates

among their healthcare workers as of December 31 each year. This requirement applies to all facility staff, including licensed independent contractors.

Below are links to sample forms that can be downloaded and used/modified as needed by your facility to document this required information. Other health care providers or individuals may also use these forms to document receipt of an influenza vaccination at another health care facility, physician office, clinic or pharmacy. Such facility forms are to be maintained in the facility and should not be sent to the Division.

- Sample Individual Flu Vaccination Consent/Declination Form
- Sample Facility Flu Vaccination Consent/Declination Form and Sign-In Sheet

NOTICE TO ALL HEALTH CARE FACILITIES REGARDING CHAPTER NUMBER 804 OF THE PUBLIC ACTS OF 2006 AND CHAPTER NUMBER 446 OF THE PUBLIC ACTS OF 2007:

Effective July 1, 2007, all health care facilities licensed by the State of Tennessee Board for Licensing Health Care Facilities shall post a sign that must be at least eight and one-half inches (8-1/2") in width and fourteen inches (14") in height in the main public entrance of the facility containing the following information:

1. The statewide toll-free number of the Tennessee Division of Adult Protective Services (APS), 1-888-APS-TENN (1-888-277-8366), and number for the local district attorney's office;

2. A statement that a person of advanced age who may be the victim of abuse, neglect, or exploitation may seek assistance or file a complaint with the APS Division concerning such; and,

3. A statement that any person, regardless of age, who may be a victim of domestic violence may call the nationwide domestic violence hotline, 1-800-799-SAFE (7233) or 1-800-787-3224 (TTY), or the Tennessee Domestic Violence Hotline, 1-800-356-6767, for immediate assistance, with the hotline number printed in boldface type.

4. A statement that a teen involved in a relationship that includes dating violence may also call the national toll-free domestic violence hotline or the national teen dating abuse helpline, 1-866-331-9474, for immediate assistance.

In addition, all nursing homes, assisted living facilities and any other residential facility licensed by the Board for Licensing Health Care Facilities are required to provide upon admission to each resident the Division of Adult Protective Services' statewide toll-free number. Nursing homes which comply with the requirements of Tennessee Code Annotated 68-11-254 are exempt from the posting requirements in 1 and 2 above.

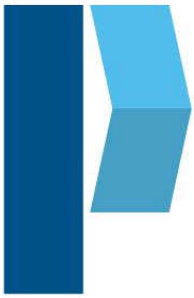
Toll-Free Hotline Numbers Example Sign: If you wish to have a copy of this statement mailed to you, please contact the State of Tennessee Board for Licensing Health Care Facilities toll-free at 1-800-778-4504 or 1-615-741-7221 to request the Toll-Free Hotline Numbers Notice and Example Sign.

CMS National Provider Identifiers (NPI) Notice

CMS National Provider Identifiers (NPI) Notice

The Division of Health Care Facilities is responsible for licensing health care facilities and for certifying providers for participation in federal Medicare and/or Medicaid Programs. The Division monitors facility compliance with state minimum standards and federal regulations through the conducting of facility surveys, patient care inspections and complaint investigations. This division also provides administrative support to the Board for Licensing Health Care Facilities.

EXHIBIT B



PohlmanUSA®
Court Reporting and Litigation Services

George Delgado, M.D.

November 17, 2020

Planned Parenthood of Tennessee and North Mississippi, et al.

vs.

Herbert H. Slatery, III, et al.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT TENNESSEE

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI, MEMPHIS CENTER FOR REPRODUCTIVE HEALTH, KNOXVILLE CENTER FOR REPRODUCTIVE HEALTH, FEMHEALTH USA, INC., d/b/a CARAFEM, and AUDREY LANCE,	)	
Plaintiffs,	)	Case No. 3:20-CV-00740
v.	)	
HERBERT H. SLATERY III, Attorney General of Tennessee, in his official capacity; LISA PIERCEY, M.D., Commissioner of the Tennessee Department of Health, in her official capacity; RENE SAUNDERS, M.D., Chair of the Board for Licensing Health Care Facilities, in her official capacity; W. REEVES JOHNSON, JR., M.D., President of the Tennessee Board of Medical Examiners, in his official capacity; HONORABLE AMY P. WEIRCH, District Attorney General of Shelby County, Tennessee, in her official capacity; GLENN FUNK, District Attorney General of Davidson County, Tennessee, in his official capacity; CHARME P. ALLEN, District Attorney General of Knox County, Tennessee, in her official capacity; and TOM P. THOMPSON, JR., District Attorney General for Wilson County, Tennessee, in his official capacity,	)	
Defendants.	)	

VIDEOTAPED ZOOM DEPOSITION OF
GEORGE DELGADO, M.D.
November 17, 2020

Deposition of GEORGE DELGADO, M.D., taken at the offices of Zoom Videoconference at 9:00 a.m. (CST) on the above date before Stephanie A. Branim, LCR, CRI, CPE, Tennessee Licensed Court Reporter, pursuant to the Federal Rules of Civil Procedure.

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Ms. Sara Shapiro

On Behalf of Center for Reproductive Rights:

Mr. Mark Herron
Ms. Shayna Medley
Ms. Michelle Moriarty

Also Present:
Brian Primavera, Videographer

INDEX

VIDEOGRAPHER: We are on the record. This is the videotaped deposition of Dr. George Delgado. Today's date is November 17th, 2020. The time is 9:09 Central time. This is a case of Planned Parenthood of Tennessee and Mississippi, et al., v. Herbert H. Slatery, III, Attorney General of Tennessee, et al. Case No. is 3:20-CV-00740. It's pending in the United States District Court for the Middle District of Tennessee, Nashville Division. This deposition is being held remotely. All counsel will be reflected op the stenographic record. And will the court reporter please swear in the witness.

GEORGE DELGADO, M.D.,
having been first duly sworn, testified as follows:

EXAMINATION

BY MR. BECK:

Q. Good morning, Dr. Delgado. My name is Andrew Beck. I am with the ACLU, and I'm representing the plaintiffs for purposes of this deposition.

MR. BECK: I'm going to just run through the list of counsel for plaintiffs

also attending the deposition.

We have Rebecca Chan, Christine Clarke, Hana Bajramovic, Mark Herron, Michelle Moriarty, Sara Shapiro, Shayna Medley, Stella Yarborough, and Tom Castelli. I think I have them all.

Charlotte, do you want to --

MS. DAVIS: Sure. For the defendants we have Charlotte Davis, Alex Rieger, Steve Hart, and Alan Groves.

BY MR. BECK:

Q. Wonderful. Doctor, would you please state your full name for the record?

A. George Delgado.

Q. Dr. Delgado, your testimony today -- well, you've been deposed before, I know, because I took your deposition five years ago. We'll -- we'll explore other opportunities you've had to be deposed. So I'm going to say some stuff that will probably sound familiar to you, but just laying out some ground rules, okay?

A. Okay.

Q. So your testimony is going to be taken down by the court reporter who's going

to be recording everything we say. So especially in a Zoom deposition, we have to be particularly careful not to talk one -- over one another. So I'll try and let you finish your answers, and if you could try and let me finish my questions, that will make her work much easier, okay?

A. Okay.

Q. You'll need to give oral responses so that the court reporter can take them down. So you can't nod your head or shake your head or make hand gestures. Does that make sense?

A. Yes, it does.

Q. Great. Again, we are on Zoom today, so we have to adhere to those rules with particular care.

What device are you using to access the deposition today?

A. A MacBook Air laptop computer.

Q. Great. And you haven't had any internet troubles lately? We expect that the -- the internet will sustain us over the course of the deposition?

A. I do. And if the wireless

fails, I have a backup of a possibility of an Ethernet cable with another computer. But I've not had any problems.

Q. Wonderful. And during the deposition we're going to be loading exhibits into the chat. I'm not sure if you've had a chance to talk about this with -- with your counsel, counsel for the attorney general's office.

But are you able to download documents onto the computer that you're -- that you're on right now? None are there, I'm --

A. I presume I am --

Q. Great.

A. I presume I am able.

Q. Good. Well, we will cross that bridge when we come to it. You understand that while we are on the record you are not allowed to communicate electronically with anyone, that means by text, email, chat, anything along those lines?

A. I understand.

Q. Great. Your counsel may object at various points. If she does, please go ahead and answer the question that has been

objected to unless she instructs you not to answer. Do you understand?

A. I understand.

Q. And if I ask a question that you don't understand, just let me know and I'll try and ask a better version of the question. And if you do answer, I'm going to assume that you've understood the question. Is that okay?

A. That's correct. That's fine.

Q. Okay. Except when a question is pending, if at any other point you need to take a break, just let me know. We plan to take breaks over the course of the deposition, including the two half hour breaks for lunches on the various coasts. But -- but if you ever -- if you need to go take a break or stretch your legs, just let me know and I will be sure to accommodate that. The only request I make is that you not ask for a break while a question is pending, all right?

A. Very good.

Q. And you understand that you're under oath today?

A. I understand.

Q. And are you taking any

medications that would affect your ability to think and speak clearly today?

A. No.

Q. So you were deposed in a case concerning an Arizona law about medication abortion in 2015, correct?

A. Yes.

Q. And that case also concerned a law requiring abortion providers to make statements about medication abortion reversal; is that correct?

A. That's correct.

Q. And that case was called Planned Parenthood of Arizona versus Brnovich. Does that sound familiar to you?

A. Sounds familiar.

Q. And if I refer to that as the Arizona case during this deposition, can we agree that that refers to the Planned Parenthood of Arizona versus Brnovich matter?

A. Yes.

Q. Great. Now, when I deposed you in that case, you were under oath and -- like you are today, correct?

A. Yes.

Q. And you testified truthfully in that case?

A. Yes.

Q. So to speed our work along here, I'd like to show you some of your testimony from that case and make sure -- assess whether or not you still agree with it. Does that work?

A. Yes.

Q. Great.

MR. BECK: So, Rebecca, if we could introduce into the chat Tab A.

And I believe we're up to -- this is for Stephanie, the court reporter. We're -- we're marking exhibits sequentially, so I think we're up to Exhibit 25.

THE COURT REPORTER: Thank you.

(Whereupon, the document was marked as Exhibit No. 25 to the testimony of the witness.)

BY MR. BECK:

Q. Do you see, Doctor, a PDF called A Delgado PP, et cetera, that appeared in the chat?

A. Yes.

Q. Okay. Can you download that, please? Let me know when you have it open.

A. It's open.

Q. Great. There are some documents we're going to be referring to over the course of the deposition today. So we're not going to put them away and be done with them forever. So you may want to keep track of them in a way where you have easy access to them.

So this is a document, which has been marked Exhibit 25, which is a deposition transcript from the Planned Parenthood v. Brnovich matter. Do you see on the top right quadrant where it says, "Deposition of George Delgado, MD"?

A. Yes.

Q. In the middle of the page at line 17. Apologies, I'm -- I'm cutting you off here.

A. Yes.

Q. Okay. Can you turn to page 85, please? And that's 85 of the little numbers that appear -- there are sort of four pages per page here. So 85 is actually page 22 of the

PDF. Tell me when you're there.

A. I'm at page 85.

Q. Great. So do you see where the question was at line 7, "Have you ever served as a peer reviewer for any medical publication?"

And the answer was "No."

A. I see that.

Q. And is that still true?

A. Yes.

Q. And you also testified that you have never served on an institutional review board to review medical research. Is that still true today?

A. Yes.

Q. And you also testified that you haven't wanted to serve in such a capacity. Is that also still correct?

A. Yes.

Q. Look at page 88, please, at line 14. You were asked, "Would you say you have expertise in designing studies for medical research?"

And you answered "No."

Is that still correct today?

A. Not correct today.

Q. Was that testimony correct when you gave it under oath in 2015?

A. Yes.

Q. Okay. So five years ago you did not have expertise in designing studies for medical research, correct?

MS. DAVIS: Objection. Hey, Andrew, can you -- can you point us to what line you're looking at on these pages?

MR. BECK: Sure. That's line 13.

MS. DAVIS: Expertise in designing?

MR. BECK: That's line 14.

MS. DAVIS: On page 86?

MR. BECK: 88.

MS. DAVIS: Oh, okay.

BY MR. BECK:

Q. The transcript reads -- why don't you read question -- the question and answer starting at line 14, Dr. Delgado, for the record.

A. "Q, would you say you have expertise in designing studies for medical

research?"

"A, no."

Q. Okay. So that testimony was truthful when you gave it five years ago, correct?

A. That's correct.

Q. And have you developed that expertise within the last five years?

A. Yes.

Q. Can you tell me everything that you've done over the last five years to become an expert in designing studies for medical research?

A. That's not what I've said.

Q. I apologize. You -- you said that you have become -- you -- you do have expertise in designing studies for medical research now, correct?

A. Correct.

Q. And you did not in 2015, correct?

A. Correct.

Q. And so can you tell me what has changed between 2015 and now such that you now have expertise in designing studies for

medical research?

A. Since then I have been in involved in designing research studies, have gained experience in designing research studies, and studied how to design research studies.

Q. And can you identify the research studies that you've designed in the last five years?

A. A 2018 large case series that was published in "Issues in Law & Medicine," as well as assisting Dr. Mary Davenport in a literature review published in 2017, as well as helping design a -- designing a study that has not been yet conducted, as well as considering planning other studies.

Q. So I just want to make sure that I have it down. The things that you've done between 2015 and now are designing -- in terms of honing your expertise in designing medical research are the 2018 case series, assisting Dr. Davenport with the literature review, and designing studies that have not yet been conducted, correct?

A. That's correct.

Q. And how many studies that have

not been conducted have you designed?

A. I've played a role in designing at least two.

Q. What are those two studies?

A. One is a study looking at the use of CBD in Hospice patients. And the other is an abortion pill reversal study.

Q. Distinct from the literature review and the 2018 case series?

A. Can you repeat that question, please.

Q. Yes. Sorry. The abortion pill reversal study is distinct from the 2018 case series and the 2017 literature review?

A. That's correct.

Q. Okay. So I count one, two -- two studies that you have conducted since 2015, and three that you have designed -- I'm sorry, two that you have designed, but not executed. And that is what you would point to as reflecting your -- the change between 2015 and now in terms of your expertise in designing medical research; is that correct?

A. I would state it more clearly, one that I have designed, one that I have helped

design, as well as researching how to design studies.

Q. What do you mean by researching how to design studies?

A. Well, in general, looking at other studies critically and thinking how principles applied to other studies might be useful for future studies.

Q. Okay. So in addition to looking at that matter and designing -- and conducting 2018 case series, assisting with the literature review, and designing but not yet conducting two studies, that's the -- I just want to make sure I understand. That's the universe of what you have done between 2015 and now to -- to make yourself an expert in study design; is that correct?

A. That's not what I stated.

Q. Can you tell me where I got it wrong?

A. Well, you're saying that I made myself an expert. And I -- I would say, I have developed expertise. I would not say I'm an expert. There's a difference.

Q. So if I -- if I just change

the phrasing of that original question to say that you have expertise, but not that you're an expert, would you agree with the way I framed it?

A. Yes.

Q. Okay. What do you see the difference between being an expert and having expertise is?

A. Expertise is having some special knowledge of -- of a certain category, while in -- I think in common parlance, being an expert makes you at the head of those who have some expertise.

Q. So you would put yourself in the category of those who have some expertise, but not at the -- the leading expert in that area; is that correct?

A. That's correct.

Q. Okay. And so you'd agree with me that in performing medical research there can be degrees of expertise?

A. That's correct.

Q. And so someone could be the world leading expert on a particular type of study design where someone else might have more

limited expertise, and so have expertise, but not be an expert or the expert; is that correct?

A. That's correct.

Q. Would you consider why your -- so I think I heard you say that you wouldn't consider yourself one of the country's leading experts on designing studies for medical research. Is that fair?

A. Yes.

Q. Would you agree with me that your expertise on that subject is more limited?

A. Which subject?

Q. Designing studies for medical research?

A. Yes.

Q. And so on a scale of 1 to 10, with 10 being the country's leading expert on designing studies for medical research, where would you rank your expertise?

A. I think that would be a difficult estimation to make.

Q. Could you give a ballpark estimate? It's obviously just an estimation.

A. I think it would be a guess.

Q. That's fine.

A. I don't think guesses are useful.

Q. No, it's okay. I actually am interested -- I just want to know where you would rank yourself on that scale?

A. Could you repeat the scale, please?

Q. Sure. On a scale of 1 to 10, with 10 being the country's leading expert on designing studies for medical research, where would you rank your own expertise?

MS. DAVIS: Objection.

THE WITNESS: And would the pool -- pool of people among who I -- amongst whom I was being ranked, would that -- who would that include?

BY MR. BECK:

Q. Anyone in the category of someone with expertise that you were talking about earlier.

A. Can you be more specific, please?

Q. Physicians with expertise. So physicians with some expertise in designing studies for medical research, we can talk about

that as the -- the pool. With that being the pool, and number 10 being the country's leading expert on designing studies for medical research, how would you rank your expertise?

A. Five.

Q. Can you turn to page 82 of the deposition transcript? Let me know when you're there.

A. I'm there.

Q. So at lines 6 to 17 you talk about how when you were a pre-med student in the 1980s you helped work on studies performed on rats; is that correct?

A. That's correct.

Q. And then if you look at page 84 and look at line 7, it says, Question, "And then between 1986 and 2012 you did not publish any studies in peer reviewed publications; is that correct?"

Answer, "That's correct."

That testimony was truthful when you gave it?

A. Yes.

Q. And you also did not submit any research to professional medical

publications during that period, correct?

A. That's correct.

Q. Okay. And you didn't conduct any medical research of any kind during that period, right?

A. I may have participate -- I did participate in some -- at least one clinical trial with a pharmaceutical company where I -- I did not publish any article and I was not cited as an author. I was a clinical cite.

Q. So at line 23 when it says, Question, "Did you conduct medical research of any kind during that period?"

Answer, "No."

Is that something that you're now remembering that you didn't know back then or does that not fall in the category of conducting medical research?

A. That would not fall in the category of conducting medical research.

Q. And then on the next page it says, Question, "Did you collect any data during that period with publication in mind?"

Answer, "No."

That was correct when you

testified to that as well, right?
A. I don't recall if I collected data during that project with the pharmaceutical company.
Q. Okay. But apart from the work on the -- with the pharmaceutical company, your testimony back in 2015 on this point was correct; is that right?
A. Correct.
Q. Would you turn to page 87?
A. I'm there.
Q. Actually, sorry, let's look at page 86 very quickly. At line 15, you describe a study on postpartum depression that you designed, but did not institute, right?
A. That's right. I forgot about that.
Q. And have you made any progress on that study since 2015?
A. No.
Q. And then since 2015, you've published a larger case series on medication abortion reversal, correct?
A. Correct.
Q. And the research on that was

underway in 2015, but you've yet to analyze or publish that data, right?
A. That's correct.
Q. Okay. So now turning to page 87 at line 21. The questions and answers read as follows:
Question, "So in addition to your postpartum research and the 2012 case series and the research that's presently underway, would you say there's any -- would you say anything else as demonstrating or contributing to your expertise as it relates to performing medical research?"
Answer, "I wouldn't discount the exposure I had during college with various -- with the various researchers. So other than those, there's nothing else."
Was that testimony truthful when you gave it in 2015?
A. That's correct.
Q. And then since then you've analyzed the data from the research on medication abortion reversal that was then underway, right?
A. That's correct.

Q. And that was published as your 2018 case series?
A. That's correct.
Q. And then you assisted Dr. Davenport with the publication of a literature review also on that subject matter, correct?
A. That's correct.
Q. And have you conducted any other -- apart from what we talked about earlier, any other medical research since your 2015 testimony that we haven't covered today?
A. No.
Q. Would you turn to page 89 of your deposition? Are you there?
A. Yes. Sorry.
Q. Great. At line 5 you were asked, Question, "Do you think you could teach a course on how to interpret and analyze data through a continuing medical education program?"
And your answer was, "I could probably teach a course to nurses, but not to physicians."
Did I read that correctly?
A. That's correct.

Q. Was that statement truthful when you testified to it in 2015?
A. Yes.
Q. Is it still correct today?
A. Yes.
Q. And then further down on page 89 at line 10, the testimony went as follows:
Question, "And so you've taken courses including CME. Is that an abbreviation you recognize?"
Answer, "Yes."
Question, "Courses related to CME and read journals or read articles, I think you said?"
Answer, "Yes."
"Is there anything else that you would cite or pinpoint as indicative of your expertise in the subject of analyzing data from studies?"
Answer, "That, and I'm also including my expertise with APR research that we discussed already."
Question, "Which is ongoing, which is the subject of this case?"
Answer, "Right."

Question, "Anything in addition to that?"
Answer, "No."
Was that testimony I just read truthful when you gave it in 2015?
A. Yes.
Q. And since then you've published the additional APR or abortion pill reversal research that you referenced here as part of your 2018 case series, right?
A. Yes.
Q. And conducted the literature review with Dr. Davenport, correct?
A. Correct.
Q. And so apart from the fact that the APR research has since been published, as well as the publication with Dr. Davenport, adding those as cav- -- as sort of additions to that testimony, is that statement now accurate if we sort of supplement it with the 2018 and 2017 publications?
A. To which statement do you refer?
Q. Sorry, the testimony that we were just looking at?

MS. DAVIS: Objection.
THE WITNESS: I'm not sure which statement to which you were referring.
BY MR. BECK:
Q. So your expertise in analyzing data from studies stems from taking courses, including continuing medical education courses, reading journal articles, your work on abortion pill reversal, including the 2018 and 2017 studies. Is there anything in addition to that?
MS. DAVIS: Objection.
BY MR. BECK:
Q. I'm sorry, I didn't hear the answer.
A. Someone spoke right before. My answer is no.
Q. Thank you. Apart from the Arizona deposition, how many other times have you given testimony in a deposition?
A. I would estimate five to ten times.
Q. And were those five to ten times -- what was the most recent of those five to ten times?
A. Approximately two weeks ago.

Q. And what was the case two weeks ago?
A. It was an employment case.
Q. Were you a party to the case?
A. No.
Q. Were you an expert in the case?
A. No.
Q. Were you a fact witness related to the case, but not a party?
A. Yes.
Q. Okay. Who -- who was -- who was the dispute between?
A. The dispute was between my employer and a former employee of the employer.
Q. And which employer and which former employee are you talking about?
A. The employer is the Elizabeth Hospice, and the former employee is Anne Marlotte (phonetic).
Q. So that one was two weeks ago. Let's work backwards. What was the next most recent deposition?
A. Let's see. I believe it may have been the Arizona case, but I'm not

positive.
Q. Have you, that you can recall, served as an expert witness in any deposition besides the Arizona case?
A. Yes.
Q. When was -- when -- sorry. What matter are you referring to there?
A. This was a malpractice case where I served as a -- as an expert witness for the defense.
Q. What was that case about?
A. I don't recall.
Q. Do you remember what your -- what you were asked to be an expert in for purposes of that case?
A. I was asked to be an expert in the area of family medicine.
Q. And was that case before -- I'm sorry.
Was the deposition in that case before you testified in the Arizona deposition?
A. Yes.
Q. Okay. And apart from the

malpractice case that you just referenced and the Arizona case, have you -- are there any other cases in which you've served -- when you've served as an expert and given deposition testimony?

A. Not that I recall.

Q. Have you ever been -- have you been a party to a lawsuit?

A. Currently, I am a party -- yes, I've been a party to two small claims court cases. And I may have been a party to a class action lawsuit regarding consumer rights.

Q. Can you tell me about all three of those? Let's start with the class action lawsuit.

A. I don't recall the details.

Q. Do you recall approximately when that class action concerning consumer rights took place?

A. Sometime in the last 20 years.

Q. And you remember that it concerned consumer rights and that it was a class action, but you don't know anything more about it?

A. That's correct.

Q. And you said you might have been a plaintiff -- I'm sorry, you might have been a party?

A. Yes. One -- one of the members of the class.

Q. I see. Do you have any papers or documentation that would refresh your recollection as to what that class action concerned?

A. I do not.

Q. What about the two small claims court cases, are those -- tell me about those.

A. One was approximately 40 years ago where I was involved in a car accident.

Q. And were you a plaintiff or a defendant in that case?

A. I believe I was a defendant, but I'm not entirely sure.

Q. Okay. And what about the second one?

A. The second one is a pending small claims case regarding a patient who is alleging that he was harmed by me when I cleaned wax out of his ear.

Q. What kind of harm is he claiming?

A. He's claiming that he developed tinnitus, or ringing in the ears, after I cleaned wax out of his ear.

Q. Is he -- do you know the term "pro se"? Does he have a lawyer in that case?

A. He does not have a lawyer.

Q. Okay. Have you ever given testimony other than in a deposition?

A. Yes.

Q. How many times?

A. I believe once.

Q. And tell me about that one time.

A. I testified before a legislative committee at the state of Colorado.

Q. Do you remember when that was?

A. That was sometime around 2017, I believe.

Q. What was the subject matter of your testimony?

A. The Colorado state legislature was considering a bill requiring abortion providers to inform women about the possibility

of abortion pill reversal.

Q. Did you testify in person or by video or telephone?

A. In person.

Q. And do you have -- did you write down a text of your testimony?

A. Did I write down a text of my testimony?

Q. Sure. Did you have prepared remarks that you testified to and did you write that down, or were you there just to answer questions?

A. I had prepared remarks.

Q. Do you still have those prepared remarks somewhere, perhaps on a computer?

A. I'm not sure.

Q. We can come back to that. But it was before a committee. Do you remember what the name of the committee was in Colorado?

A. I do not.

Q. Apart from the Arizona case, this case, and the malpractice case in which you were an expert for the defense, have you ever acted as an expert in relation to any other

lawsuit?
A. Yes.
Q. On how many occasions?
A. Approximately six or seven.
Q. And so these are cases in which you've served as an expert, but have not given testimony; is that correct?
A. That's correct.
Q. And do these cases all post-date the 2015 deposition in Arizona?
A. Yes.
Q. Okay. Do these six to seven cases share a common subject matter, or are they on different subjects?
A. I would say they share a common subject matter.
Q. And what is that subject matter?
A. These all are groups or individuals suing states regarding COVID-19 restrictions.
Q. So you've served as an expert in six to seven cases involving groups suing states regarding COVID-19 restrictions?
A. That's correct.

Q. And did you submit expert declarations or reports in all six to seven of those cases?
A. Yes.
Q. But have not yet testified?
A. That's correct.
Q. And can you summarize -- well, let's start with, what's -- what's the nature of the expertise that you are asserting in those cases?
A. Medical expertise.
Q. Can you be more specific?
A. How do you want me to be more specific?
Q. So what medical insights are you offering in the declarations that you've submitted in those cases? If you could give me a summary, for example, of the argument made in your -- in your declaration in one of these cases?
A. Well, the arguments vary depending on the cases, because each case has its own specific details and context.
Q. Okay. Where are these cases pending? Are these lawsuits pending or are they

over and done with?
A. Both.
Q. Okay. The cases that are pending, where are they? What locations in the country?
A. California.
Q. That's the only one that's pending?
A. Yes.
Q. Okay. Is there one lawsuit in California or more than one lawsuit in California?
A. More than one.
Q. Okay. How many lawsuits are pending in California?
A. I believe three.
Q. And -- and who are you representing in this -- I'm sorry.
Who has retained your expert services in those three California services? Who are the -- are you serving on behalf of the plaintiffs in each of those cases?
A. Yes.
Q. And who are the plaintiffs in each? So let's start with whichever one you

want.
A. One of the cases is Grace Community Church. Another case is South Bay Pentecostal Church. And another plaintiff in -- in the case is RMP Enterprises.
Q. Is RMP Enterprises also a religious organization like Grace Community Church and South Bay Pentecostal?
A. No.
Q. What kind of entity is RMP Enterprises?
A. It's a restaurant holding company.
Q. And -- so you've offered medical expert testimony in all of those cases concerning COVID-19 restrictions; is that right?
A. That's correct.
Q. What was your -- well, can you summarize the expert testimony that you offered in the South Bay Pentecostal Church case?
A. It would be difficult to summarize and give it justice. However, my expert medical declaration pointed out that restrictions were arbitrary and unfairly biased against religious groups when you look at the

data of actual outbreaks that have occurred in the context of worship services.

Q. So you were looking at the -- the data from an epidemiological perspective; is that correct?

A. That's correct.

Q. You're not an epidemiologist, correct?

A. Correct.

Q. Your training is in family medicine and palliative medicine?

A. Family medicine, Hospice, and palliative medicine.

Q. I think I saw that you offered a comparative risk analysis about catching COVID-19 at a church service versus engaging in a variety of other activities. Was that in the South Bay United Pentecostal Church case?

A. I believe it was.

Q. Did you offer a kind of comparative risk analysis in some of the other six to seven cases as well?

A. Yes.

Q. Did you offer a comparative risk analysis in all of those six or seven

cases?

A. No.

Q. Which one -- which ones didn't you offer a comparative risk analysis?

A. I would have to review my declarations to answer that accurately.

Q. So you talked about you offered expert opinions, but on something other than comparative risk analyses in some number of cases of those six to seven, correct?

A. That's correct.

MR. BECK: Okay. Rebecca, can we introduce Tab B, please, into the chat?

BY MR. BECK:

Q. Do you see that, Doctor?

A. Yes.

Q. Great. Can you download that, please? It's a big file so it might take a second.

MR. BECK: Sorry, let's do C as well, Rebecca. We can just do this collectively.

BY MR. BECK:

Q. So let's start with C, Doctor. Let me know when you have that open.

A. I have it open.

Q. Does this look like the declaration you submitted in the South Bay United Pentecostal Church case?

A. Yes.

Q. And if you look at the blue text at the top, it's filed May 5 -- sorry, May 11th, 2020?

A. I see that.

Q. Okay. If you'll turn to paragraph 6, please. Let me know when you're there.

A. I'm there.

Q. Okay. At paragraph 6 it states, "It is clear that due to mitigation measures carried throughout California, the trajectory of the COVID-19 pandemic has been altered. The curve had been flattened."

Correct?

A. Correct.

Q. Would you read paragraph 12 aloud, please?

A. "Los Angeles County has reported about 1,200 deaths, parenthesis, out of California's approximate total of 2,200, close

parenthesis. Thereto, however, the curve of new deaths has flattened, similar to the California curve. The Monte Carlo model predicts that total deaths in Los Angeles County will be approximately 1,900 for this year."

Q. And you submitted this figure predicting a total of 1900 COVID deaths for this year in Los Angeles County, correct?

A. Correct.

MR. BECK: Okay. Let's look at the next Tab, Rebecca, Tab D.

BY MR. BECK:

Q. Let me know when you have Tab D open.

A. It's open.

Q. Okay. And before we get there -- actually, no, let's -- let's do this first.

So Tab D, this is Los Angeles County Public Health -- the Los Angeles County Public Health Department's website with daily COVID data. This one is dated from November 11th. Would you read what it reports for total deaths reported to date, which is sort of on the left-hand column in the middle -- I'm sorry, at

the bottom?
A. Total deaths reported 7,221.
Q. So that's approximately 5,000 deaths more than you predicted in your declaration to the Court, correct?
MS. DAVIS: Objection.
THE WITNESS: That would be correct arithmetic, yes.
BY MR. BECK:
Q. And the year is not over yet, correct?
A. The year 2020 is not over yet.
MR. BECK: And I realize that I haven't been marking these exhibits. So we marked the Arizona deposition as Exhibit 25. Delgado -- Dr. Delgado's declaration from the South Bay Pentecostal Church matter can be Exhibit 26.
(Whereupon, the document was marked as Exhibit No. 26 to the testimony of the witness.)
MR. BECK: This exhibit on Los Angeles Department of Health daily COVID data can be 27.
(Whereupon, the document was

marked as Exhibit No. 27 to the testimony of the witness.)
MS. DAVIS: Objection to Exhibit 27.
MR. BECK: And let's look at Exhibit -- let's mark as Exhibit 28 the first -- I'm sorry, the second file that was placed in the chat. We're getting a little out of order here, and I apologize for that, Doctor.
(Whereupon, the document was marked as Exhibit No. 28 to the testimony of the witness.)
BY MR. BECK:
Q. But this -- this is the one that entered the chat just after your deposition, which says 2020 West Law 6081733 at the top. Do you see that?
A. Oh, the tabs are labeled by letters? I see --
Q. Yes. Sorry. So -- sorry. This one is letter B. That's a better way to do this.
A. Okay. It's open.
Q. Okay. Can you turn -- sorry. This is -- this is an opinion

of the Court in the South Bay United Pentecostal Church case. Have you seen this before?
A. I don't believe so.
Q. Are you aware that the Court rendered a ruling in which she discussed your -- the judge discussed your testimony?
A. I believe so.
Q. Okay. But you haven't seen the actual text of the ruling itself?
A. I don't believe so.
Q. Okay. Let's turn to page 9 of this document.
A. I'm there.
Q. Okay. So the last paragraph on that page states, "The Court assigns Dr. Delgado's declaration minimal weight. Although he may have treated people with infectious diseases, including viral illnesses such as influenza, which tend to occur in epidemics, Dr. Delgado lacks sufficient expertise in epidemiology." I'm omitting the citation. "Moreover, he does not explain the basis for his model used to assess the precise comparative risk of religious services and other activities, nor does he provide any supporting

data for his conclusions."
So it appears that the Court gave little weight to your opinions, in part, because you were weighing in on matters outside of your expertise. Do you agree with that characterization?
MS. DAVIS: Objection.
BY MR. BECK:
Q. You can go ahead and answer, Doctor.
A. That -- that is -- that is a reasonable characterization.
Q. And the Court also appears to have given your opinions little weight because you didn't have adequate data to back up those opinions. Is that also a reasonable characterization?
MS. DAVIS: Objection.
THE WITNESS: That's a reasonable characterization.
BY MR. BECK:
Q. Do you think that you were testifying on matters outside of your expertise in that case?
A. No.

Q. So the Court got that wrong. You were within your expertise, but the Court was wrong to think otherwise?
A. Yes.
Q. On the -- on the distinction you drew earlier between being an expert and having expertise, on the subject of epidemiology that you were offering opinions on in that case, would you characterize yourself as an expert or someone who happens to have some expertise?
MS. DAVIS: Objection.
THE WITNESS: I would say that analyzing the situation requires more than just epidemiology.
BY MR. BECK:
Q. What other -- what other considerations does it require?
A. A broad knowledge of the medical and the psychosocial effects of mitigation measures on the population.
Q. And do you believe that you have that broad knowledge?
A. Yes.
Q. But the Court seems to have thought otherwise, correct?

MS. DAVIS: Objection.
THE WITNESS: That's a reasonable characterization.
BY MR. BECK:
Q. Okay. Let's turn to the next paragraph. In the middle of that next paragraph that begins with, "And, finally," it says, "it is one thing for an expert to explain why epidemiologists believe there is a higher risk of transmission of SARS COV2 in large gatherings, indoor spaces, and where groups are singing indoors. It is quite another for someone to purport to calculate without data that the risk of contracting COVID-19 at a house of worship is, quote, 12.5 percent the risk at the grocery store, end quote, or, quote, 1 percent the risk at public protests, end quote. Skipping citations. "Probabilities are not derived from only, quote, common scientific sense, end quote," quoting your declaration.
Did I read that correctly, minus the citations?
A. Yes.
Q. And so this seems to reflect the Court's conclusion that you were relying on

common sense without adequate data to back it up. Is that a fair characterization?
MS. DAVIS: Objection.
THE WITNESS: That's -- that's a reasonable characterization.
BY MR. BECK:
Q. And do you think that you had sufficient data to back up your conclusions in that case?
A. Taking into account the amount of data available at that time with regards to the risk of acquiring the virus, yes.
Q. Does that mean that you revised your opinion with the passage of time and the creation of more data?
A. That's a very complicated question that defies a simple yes or no answer.
Q. Well, do you stand by the opinions that the Court rejected or would you offer different opinions today?
A. I would offer different opinions today for some of the specifics.
Q. In terms of the specific data?
A. In terms of some of the risks of acquiring the Coronavirus.

Q. Is your opinion that the risks are more serious than you estimated or less serious?
A. Neither.
Q. Just different?
A. Correct.
Q. How are they different?
A. Well, for example, since the -- that declaration in May, we have more data suggesting that acquiring the virus by touching surfaces is not as important as the airborne route is important.
Q. And so would that alter the comparative risk analysis that you generated in that case?
A. It might.
Q. Do you know which way it would alter it? By making, for example, church attendance riskier as compared to going to a grocery store than you had estimated or safer?
A. I think that would be a guess at this point without in-depth study of the issue.
Q. Okay. So you understand that this case concerns a Tennessee law regulating

abortion providers?
A. I do.
Q. And the law we're talking about is called House Bill 2263 or HB2263?
A. I did not recall that specific designation.
Q. Can we agree to refer to it as The Act or The Law during this deposition and you'll know what I'm referring to?
A. Yes.
Q. Okay. How did you become familiar with The Act?
A. I was informed about The Act by members of the Tennessee Attorney General's office.
Q. Do you remember who informed you of The Act?
A. I believe it was Mr. Steven Hart.
Q. And that was after it became law? When was that?
A. Yes.
Q. So it had already been enacted into law, and at a certain point Steve Hart reached out to you?

A. That's correct.
Q. Okay. Did you communicate with anyone about The Act before its passage?
A. Not that I recall.
Q. So no communications with regulators?
A. No.
Q. Or advocates?
A. No.
Q. Have you had any communications about either this case or the Tennessee Act with Dr. Donna Harrison?
A. Not that I recall.
Q. So no emails about -- concerning this case or The Act with Dr. Harrison?
A. Not that I recall.
Q. And no text messages?
A. No.
Q. And no oral conversations either in person or over the phone?
A. Not that I recall.
Q. Do you think you would recall if you had the conversations?
A. Yes.

Q. What about with Dr. Brent Boles, have you had any communications with him about either this case or the Tennessee Act?
A. No.
Q. What about Dr. Michael Petrozza (phonetic)?
A. No.
Q. And what about Martha Shuping?
A. No.
Q. What about Dr. Mary Davenport?
A. No.
MR. BECK: Rebecca, can we drop Tab E into the chat, which is -- this has already been marked as Plaintiff's Exhibit 2 in our effort at sequential exhibit numbering.
We seem to be having technical difficulties. Let me see if I can -- can someone -- someone has put it in. Great. Thank you, Shayna.
BY MR. BECK:
Q. Let me know when you have this open, Doctor.
A. There seems to be an error with this. It's not downloading. Got right to the end and then an error icon appeared.

Q. Why don't you try it again, because it's working with me. There's also another version of it as exhibit -- as Tab E in the chat if you want to try a different document.
A. Okay. Now it's open.
Q. Great. We can skip past the first page. But if we get to the second page, does this look like a familiar document to you?
A. Yes.
Q. What is it?
A. Declaration of Dr. George Delgado.
Q. So this is the declaration of yours submitted in the Tennessee case, correct?
A. Correct.
Q. Okay. And how was this document, Exhibit 2, prepared?
A. How was it prepared? Can you be more specific, please?
Q. Did you prepare this document?
A. Yes.
Q. And can you tell me how you went about preparing this document?
A. I received some documents

related to the lawsuit, and I then presented my -- my perspective on the case, as well as I looked to counter some of the points made by the plaintiffs.

Q. When you said you received some documents related to the lawsuit, what documents are those?

A. I would have to find them again to tell you exactly what they were. But they were statements made on behalf of the plaintiff and by the plaintiffs in regards to this case.

Q. So maybe, like, declarations or legal filings?

A. There were filings, declarations, and also the complaint.

Q. Okay. And so apart from the complaint and declarations and legal filings from the plaintiffs, did you receive any other documents for review?

A. At the time of writing this, I do not believe so.

Q. Did you receive documents from the attorney general's office at a later time?

A. Yes.

Q. What documents are those?

A. I received a transcript of my Arizona testimony. And I think I received one or two others, and I don't recall what they were at this point.

Q. One or two other what?

A. Documents.

Q. Okay. But you don't remember what they were?

A. No. I -- yes. One of them was this -- this -- my -- my own medical declaration so that I would have it for reference.

Q. And you can't remember what the other one was?

A. No.

Q. When did you receive the transcript from the Arizona testimony?

A. Probably about a week ago.

Q. Did you draft each and every provision of Exhibit 2?

A. By Exhibit 2, are you referring to my medical declaration?

Q. Yeah. Tab E, Exhibit 2, your declaration. Did you draft each and every

provision?

A. By each and every provision, do you mean each and every paragraph?

Q. Yeah.

A. I don't recall.

Q. Who else might have played a role in drafting it?

A. The -- the members of the attorney general's office may have given me advice on how to word things.

Q. Did they draft something and send it to you for review, or did you draft something yourself and discuss with them?

A. I drafted something myself.

Q. And then you had discussions?

A. If you include email discussions, yes, as well as telephonic.

Q. Okay. Did you discuss the contents of the declaration with anyone besides lawyers from the Tennessee attorney general's office?

A. I may have made some passing comments to my wife.

Q. And apart from passing comments to your wife and conversations with the

Tennessee attorney general's office counsel, have you discussed the contents of the declaration with anyone else?

A. No.

Q. Apart from the process you engaged in via email and telephone conversation with lawyers from the attorney general's office, did you have any other assistance in preparing the declaration?

A. No.

Q. Do you know how the Tennessee attorney general's office had a copy of your Arizona deposition testimony?

A. No.

Q. The declaration here lists certain medical opinions that you reached in the case, correct?

A. Can you reword that, please?

Q. Sure. You -- you formed some medical opinions in -- that are relevant to this case; is that correct?

A. That's correct.

Q. And you've included them in the declaration that we've been looking at, Exhibit 2?

A. Yes.

Q. Okay. And do you intend to testify to the points highlighted or set forth in your declaration at a hearing in this case?

A. I intend to testify.

Q. Have you -- do you intend to testify about the things that you've said in your declaration or something else?

A. My understanding is that when I testify, I will be asked questions. So I may not have control over exactly what the topics will be.

Q. Have you formed any opinions about the Tennessee law that are not reflected in your declaration?

A. No.

Q. And have you formed any opinions about the sort of broader subject matter at issue in this case that are not reflected in your declaration?

A. No.

Q. Okay. And so you've at this point included all of the significant points that you plan to testify to at the hearing? I understand that you're not in control of what

questions are asked of you. But in terms of what you have planned to testify to, you tried to include that in your declaration, correct?

A. I think the premise of your question's incorrect.

Q. So, Doctor, we are entitled to know and ask you about the opinions that you're going to be offering live on the stand in court. And I just want to make sure there's no gap between what we know that you've set forth in writing and what you plan to talk about. Is there a gap?

A. Well, again, I have no plan to talk about anything except the questions I'm asked. So that's why your question's puzzling to me.

Q. But you -- assuming you wouldn't be asked about opinions that you haven't formed in this case, you have set forth all of the opinions that you've formed in this case in your declaration, correct?

A. To the best of my knowledge, yes.

Q. Okay. And you made an effort to include in your declaration all of the

relevant facts and data upon which your opinions are based, correct?

A. To the best of my knowledge, yes.

Q. Are there any facts or data that you have not included in your declaration that you might -- that you're intending to testify to that we should know about?

A. I am not aware of any.

Q. In that declaration Exhibit 2, can we turn to page 32 -- I'm sorry, page 11?

A. I'm there.

Q. Above paragraph 32 is a sentence that says, "We note that bleeding is an expected consequence of medical abortion."

Did I read that correctly?

A. Yes, you read it correctly.

Q. Who is the we referenced there?

A. The we would refer to myself and those knowledgeable about medical abortion.

Q. You're speaking on behalf of people knowledgeable about medical abortion? I guess my -- my question is more, really, did that language come from a different text that

you jointly wrote with multiple authors originally?

A. That's possible.

Q. What text might that possibly be?

A. This may have come from a -- the verbiage, I may have taken it from a rebuttal I wrote responding to the article published by Dr. Creinin.

Q. Was that rebuttal something that wound up being published somewhere?

A. Yes.

Q. Where was it published?

A. In the Green Journal.

Q. So that sentence probably comes or possibly comes from the rebuttal that you published in the Green Journal in response to Dr. Creinin?

A. Possibly, yes.

Q. Did you draw upon that -- your -- your published rebuttal for more than just that sentence in the declaration?

A. I may have also used the -- the preceding sentence may also have come from that, from that text.

Q. So that -- that's all -- the preceding sentence and the, "We note that bleeding," sentence, are those the only things that came from that rebuttal, or were you drawing -- did you draw upon that rebuttal in any larger way for purposes of setting out the opinions in your declaration?

A. Well, in the portion of my declaration where I mention Dr. Creinin's study and draw conclusions about it, I had given this significant thought and study and analysis in the past, so I logically drew on it when I composed this declaration.

Q. Does the rebuttal -- was the rebuttal that you submitted to the Green Journal just on behalf of you or was it on behalf of others?

A. It was on behalf of myself, Dr. Mary Davenport, and Dr. Matthew Harrison.

Q. So the we note, the we in that is actually the three of you, not the community of physicians aware of the side effects of medication abortion, correct?

A. Most likely.

Q. Okay. So were you

misremembering that when you said earlier that's who the we in that sentence referred to?

A. Well, no, because those three authors are all knowledgeable about medical abortion and the bleeding that's expected in it. So it -- I don't think it's a misremembrance. I think it's just a different characterization.

Q. Okay. But the we is the three of you, Doctors Harrison, Davenport, and Delgado?

A. I suppose it is.

Q. On page 6, paragraph 16, let me know when you're there.

A. I'm there.

Q. Okay. So you state here, "Three pillars of evidence support the use of progesterone to reverse the effects of mifepristone in women who choose to attempt reversal of their mifepristone abortion." And those three pillars that you develop later are biologic logic, animal studies, and research in humans, correct?

A. That's correct.

Q. Okay. Let's start with the first of those, biologic logic, which you

suggest in paragraph 17 on the next page.

Doctor, would you agree with me that mifepristone binds to progesterone receptors with higher affinity than progesterone does?

A. Yes.

MR. BECK: Okay. Let's introduce into the chat Tab F, which is -- has previously been marked as Plaintiff's Exhibit 7.

BY MR. BECK:

Q. Let me know when you're able to download that, Doctor.

A. F is open.

Q. Great. This -- Plaintiff's Exhibit 7 is a study called, "A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone."

You recognize this document, right, Doctor?

A. Yes.

Q. And you authored it?

A. Yes.

Q. Along with these other authors?

A. Correct.

Q. And can we refer to this, as I have been, as your 2018 case series?

A. Yes.

Q. And you'll know what I'm referring to?

A. Yes.

Q. Great. Turn to page 22, please.

A. I'm there.

Q. Okay. Can you read the first two sentences under "Pharmacology" aloud?

A. "Mifepristone is a competitive antagonist of progesterone at the progesterone receptor, parenthesis, PR, close parenthesis. It binds to the PR twice as avidly as progesterone. Mifepristone is --

Q. You can stop there.

A. Okay.

Q. Thanks. Do you agree with the statement you just read?

A. Yes.

Q. Okay. And, actually, doesn't mifepristone bind to progesterone receptors more than twice as avidly as progesterone?

A. Different articles may quote

different rates of binding. But one of the -- the research substantiates that it -- it binds twice as avidly.

Q. Okay. So what -- you -- you actually have a footnote for that point about the twice as avidly. It's footnote 5. And if we go to the end there, my Finnish is not very good, but I believe it's Heikinheimo is the -- is the name of the first author of footnote 5, correct?

A. That's correct.

MR. BECK: Can we introduce Tab G?

BY MR. BECK:

Q. So here is that tab. Let me know when you have that.

MR. BECK: And we can mark, sorry, Heikinheimo as Exhibit 28.

THE COURT REPORTER: Excuse me, I already have an Exhibit 28. I have that as --

MR. BECK: You're right. Thank you. 29.

(Whereupon, the document was marked as Exhibit No. 29 to the testimony of the

witness.)

BY MR. BECK:

Q. Doctor, let me know when you have that article open.

A. It's open.

Q. Okay. Does this appear to be a study by Heikinheimo, et al., called pharmaco- --

(Phone ringing.)

THE WITNESS: Yes.

BY MR. BECK:

Q. Does this appear to be an article by Heikinheimo, et al., called, "The Pharmacokinetics of Mifepristone in Humans Reveal Insights into Differential Mechanisms of Antiprogesterone Action"?

A. Yes.

Q. And this is the source that you cite at footnote 5 of your 2018 case series, correct?

A. I would have to look at my footnote and back at this to verify that.

Q. Okay. Why don't you do that just so we can make sure. Have you been able to verify it, Doctor?

A. Almost. Okay. Yes, it appears to be the article I've referenced.

Q. Great. It was published in the Journal of Contraception, correct?

A. Yes.

Q. Is that a reliable publication?

MS. DAVIS: Objection.

THE WITNESS: I guess it would depend on what you mean by reliable.

BY MR. BECK:

Q. Well, you cited it in your 2018 case series. Would you have cited something from an unreliable source?

A. Well, a journal could publish articles that are reliable and also publish articles that are not reliable.

Q. And is that your opinion of the Contraception Journal, that it publishes some reliable and some unreliable articles?

A. That's correct.

Q. And is this a reliable article?

A. For the purposes, yes. Yes.

Q. Okay. If you can turn to page

425, and look at table 1 with me. Let me know when you're there.

A. I'm there.

Q. This is a table entitled, "Relative Binding Affinities, parenthesis RBAs, end parenthesis, of Mifepristone and its Three Metabolites to the Human Uterine Progesterone Receptor," correct?

A. That's correct.

Q. What does it show is the relative binding affinity of progesterone?

A. 43.

Q. And if mifepristone's relative binding affinity were twice as avid as progesterone, then its RBA would be 86, correct?

A. That's correct.

Q. But, in fact, the relative binding affinity of mifepristone to progesterone receptors is much more than 86. It's 100 percent, correct?

A. What do you mean by much more?

Q. We can take out the much. It is more than 80 -- it's more than twice as avid if there's a 14 percent difference if it were 86. It's actually 100, correct?

A. So it is a bit more than twice the binding capacity, correct.

Q. What does it mean that the relative binding affinity of mifepristone to the progesterone receptor is 100 as compared to 43 percent for progesterone?

A. It means that the mifepristone binds to the receptor more avidly than the progesterone does.

Q. But what does that mean? When -- when you say that it binds more avidly, what does that mean?

A. It means that it has a higher affinity for the receptor than does the progesterone.

Q. In biochemistry, what does "ligand" mean? Do you know that term?

A. Yes. Something that binds -- binds to a receptor. Ligand is -- is the pronunciation.

Q. Thank you. Ligand?

A. Yes.

Q. Let me read something and you can tell me if you agree with it. "In general, high affinity ligand binding results from

greater attractive forces between the ligand and its receptor, while low affinity ligand binding involves less attractive force."

Do you agree with that statement?

A. Yes.

Q. Okay. And then here's another statement. "In general, high affinity binding results in a stronger occupancy of the receptor by its ligand than is the case for low affinity binding."

Do you agree with that statement?

A. Yes.

Q. Okay. Your 2018 case series references mifepristone's high affinity for progesterone receptors, correct?

A. Yes.

Q. Why did you include that point in the study?

A. Just to give a scientifically accurate foundation for medical abortion with mifepristone.

Q. Was it -- is it relevant for the reader to know that information?

A. Yes.

Q. So your declaration does not mention mifepristone's higher affinity for progesterone receptors in the discussion of biologic logic or anywhere else. Why not?

A. Because the -- for the intended audience, that would not be a point that necessarily would be as important as for someone reading a medical journal.

Q. Doesn't the fact that there is -- it's sort of -- isn't it sort of inherent in the theory that you're offering in the case? The plausibility of your theory -- isn't it relevant to the plausibility of your therapy?

MS. DAVIS: Objection.

THE WITNESS: Is what relative to the plausibility of my theory?

BY MR. BECK:

Q. Isn't the strength of the bond between mifepristone and the progesterone receptor relevant to the theory that you're offering in this case?

A. It's relative in regards to the dosing of progesterone. Because if mifepristone bound more weakly to the

progesterone receptor than progesterone does, then you could use lower doses of progesterone. However, with its higher affinity for the receptor, then that would support using higher doses of progesterone.

Q. But you agreed a moment ago that high affinity binding results in a stronger occupancy of the receptor by its ligand than is the case with a low affinity binding, right?

A. That's correct.

Q. And we've established from Dr. Heikinheimo's study the strength of the occupancy of mifepristone as compared to the binding affinity of progesterone, correct?

A. Correct.

Q. Isn't that relevant information to the plausibility of your theory behind medication abortion reversal?

A. It's relative information with regards to the dosing of progesterone. What you have to keep in mind is that the binding to the receptor is a reversible phenomenon. And, therefore, the -- the ligand goes on and off the receptor.

The one that has the higher

affinity will stay on the receptor longer. However, it still comes off and on. When it comes off and on, that's the opportunity for the competing ligand to then bind to the receptor. If you increase the concentration of the competing ligand, then that molecule will win the battle of the receptor. So that's why the affinities are important for dosing, but not for the plausibility of the entire theory.

Q. Are you familiar with the term "drug target residence time"?

A. I'm sorry, can you repeat the question, please.

Q. Are you familiar with the term "drug target residence time"?

A. I am not familiar with that -- with that term, but I think I know what it means.

Q. What do you think it means?

A. I think it probably means how long a drug stays on a receptor.

Q. I think that's what it means as well. And that's what -- kind of what you're talking about just now, right?

A. That's correct.

Q. Do we know what the drug target residence time for mifepristone or progesterone receptors is?

A. I'm not aware.

Q. Do you think it's relevant to the plausibility of your theory?

A. No.

Q. If we didn't have animal studies and research in humans, would the biologic logic set forth in paragraph 17 of your declaration be sufficient to prove that medication abortion is reversible?

A. Not to prove it.

Q. So, in your opinion, the principles laid out in paragraph 17 alone are not enough to establish that mifepristone can be reversed, correct?

A. Paragraph 17 discusses the biologic logic?

Q. Yep.

A. That would be -- it would provide support, but not proof.

Q. Right. It's not sufficient in and of itself, correct?

A. Correct.

Q. So let's turn to the second pillar that you discuss, which is animal studies.

MS. DAVIS: Hey, Andrew?

MR. BECK: Yeah.

MS. DAVIS: Sorry. If -- if you're about to switch topics, can we take a quick break?

MR. BECK: Sure.

MS. DAVIS: Okay. Do y'all want to do ten minutes?

MR. BECK: Ten minutes, that's good.

VIDEOGRAPHER: Off the record at 10:43.

(A recess was taken.)

VIDEOGRAPHER: We are back on the record at 10:53.

BY MR. BECK:

Q. Doctor, during the break did you have any interactions with counsel for Tennessee?

A. No.

Q. Okay. I believe before we

took a break you stated that the drug target residence time of mifepristone on progesterone receptors is not relevant to the theory you're articulating in this case. Did I state that correctly?

A. It's not relevant to the plausibility of the theory.

Q. Why not?

A. Because as long as the ligand or drug to receptor interaction is reversible, and there is the potential of competition at the receptor with the agonist or antagonist, however you might want to call it, so the increase in the concentration of the competing molecule will lead to increased binding of that molecule to receptor.

Q. But if the bond, which we've said is stronger, lasts for 5 minutes or 24 hours, doesn't that impact whether or not there is the opportunity for the competition you're referencing?

A. The longer the occupancy, the -- the more difficult it would be to compete against it. That would be a correct statement.

Q. And you don't know the length

of the occupancy of mifepristone on the receptor, the progesterone receptor, correct?

A. That's correct.

Q. Okay. So it would be relevant then -- sorry.

The -- the length of time that it stays on the receptor would be relevant to the plausibility of the theory we're talking about here, correct?

A. I suppose at the extremes it would -- it would be one of the -- it could be one of the relevant factors. There would be many other factors in addition to that.

Q. Okay. You mentioned earlier in the deposition that you spoke to your wife about your testimony today. Is your wife involved in the Abortion Pill Reversal Network?

A. She's involved with the Abortion Pill Rescue Network.

Q. Thank you for the correction. What is her involvement with the Abortion Pill Rescue Network?

A. She is a hotline nurse.

Q. And so she is someone who answers calls from people who contact the

hotline with questions; is that correct?

A. Yes.

Q. And does she still play that role?

A. Yes.

Q. How long has she been in that role?

A. Approximately eight years.

Q. Is that about as long as the network has existed -- or the hotline has existed?

A. About.

Q. Okay. What is her training -- you say she's a nurse?

A. Yes.

Q. Can you just give me an overview of her nursing background?

A. She's a registered nurse who's worked in various areas in nursing during her career.

Q. What various areas?

A. She worked on a -- what's called a telemetry unit. She's worked on medical floors. She's worked in a clinical research setting. She's worked in utilization

review. She's worked in a gastroenterology lab -- procedure laboratory. She has, perhaps, done a few other things.

Q. And she is one of how many nurses who staffs the abortion pill rescue hotline?

A. I don't know the number.

Q. Do you have a guess?

A. My guess would be if I -- well, I don't know if my guess means anything, but I would guess, perhaps, 30.

Q. Who would know how many nurses staff the hotline?

A. The director of the Abortion Pill Rescue Network.

Q. Who is that?

A. Christa Brown.

Q. And does Christa Brown work for Heartbeat International?

A. Yes.

Q. What is -- what is Christa Brown's position at Heartbeat International, if you know?

A. I -- I believe she's the director of the Abortion Pill Rescue Network.

Q. Okay. Let's go back to -- we were discussing the different pillars of evidence that you cite in your declaration concerning abortion pill reversal, correct?

A. Correct.

Q. And one was biologic logic and then the second one was animal studies, correct?

A. Correct.

MR. BECK: Can we put Tab H into the chat, please?

BY MR. BECK:

Q. Let me know when you have Tab H open, Doctor.

A. I have it.

MR. BECK: Okay. So we can mark Tab H as Exhibit No. 30.

(Whereupon, the document was marked as Exhibit No. 30 to the testimony of the witness.)

BY MR. BECK:

Q. And Exhibit No. 30 is an article entitled, "Why Animal Studies are Often Poor Predictors of Human Reaction to Exposure," by Michael B. Bracken, published in the Journal of the Royal Society of Medicine.

Are you familiar with the Journal of the Royal Society of Medicine?

A. No.

Q. The first sentence of this article states, "The concept that animal research, particularly that relating to pharmaceuticals and environmental agents, may be a poor predictor of human experience is not new."

Did I read that correctly?

A. Yes.

Q. Do you agree with that statement?

A. Yes.

Q. Okay. And then the third sentence states, "Pharmacologists, in particular, have long recognized the difficulties inherent in extrapolating drug data from animals to man."

Did I read that correctly?

A. Yes.

Q. Do you agree with that statement?

A. Yes.

Q. One reason to be cautious in

extrapolating drug data from animals to humans is because human and animal physiology may be different, correct?

A. Correct.

Q. The first sentence of that next paragraph states, "One reason why animal experiments often do not translate into replications in human trials or into cancer chemo prevention is that many animal experiments are poorly designed, conducted, and analyzed."

Did I read that correctly?

A. You did.

Q. Do you agree with that statement?

A. I have no basis to base my agreement or disagreement.

Q. Does it sound plausible to you that many animal experiments are poorly designed, conducted, and analyzed?

MS. DAVIS: Objection.

THE WITNESS: I would say it sounds possible.

BY MR. BECK:

Q. Okay. If we didn't have research on human subjects, do you think that

animal studies standing alone would be enough to prove that medication abortion in humans is reversible?

A. It would not be enough to prove it, but it would certainly give support to it.

Q. But I just want the record to be clear. It would not on its own without human trials be sufficient to prove it, correct?

A. Correct.

Q. In paragraph 18 of your declaration -- do you have that in front of you?

A. Yes.

Q. You cite a study by Yamabe concerning administration of mifepristone and progesterone to rats, correct?

A. Correct.

MR. BECK: Can we have Tab I in the chat?

BY MR. BECK:

Q. Let me know when you have Tab I open, Doctor.

A. I have it open.

Q. Okay. Tab I, which was previously marked in exhibits as Exhibit No. 19

is an article entitled the Effect of RU40 -- let's start that over.

An article entitled, "The Effects of RU486 and Progesterone on Luteal Function During Pregnancy," by Yamabe, et al.

This is the study that you cite in your declaration, correct?

A. I believe it is.

Q. Okay. This was published in the "Folia Endocrinologica Japonica." Is that a reliable publication?

A. To my knowledge, it is.

Q. Do you subscribe to it?

A. No.

Q. Why not?

A. I subscribe to very few medical journals because there's so many. And it's more efficient for me to seek out articles of interest and not to subscribe to the -- to all the journals.

Q. Have you ever relied on any other studies from the "Folia Endocrinologica Japonica" in your work?

A. Not that I'm aware.

Q. In this study, some rats were

given mifepristone, some were given mifepristone plus progesterone, and some were given ethanol. Does that sound like an accurate summary to you?

A. What was the last -- some were given?

Q. Ethanol.

A. Ethanol. I would have to review the ethanol part, but I -- but I am aware of the progesterone with the mifepristone or the RU486 and then simply RU486.

Q. Okay. We can leave the ethanol to the side. But you would agree that at least some rats in the study were given mifepristone and some were given mifepristone plus progesterone, correct?

A. That's correct.

Q. Okay. The rats that were given mifepristone and progesterone were given both of those substances at the same time, correct?

A. Yes.

Q. And you don't cite in your declaration any animal studies addressing the administration of progesterone after mifepristone, correct?

A. Correct.

Q. Do you think this study of simultaneous administration of mifepristone and progesterone in rats is a study about mifepristone reversal?

A. It's a study about the hindering of the intended effect of the mifepristone by the progesterone.

Q. So it's hindering, but it's not reversing in this case because it's happening at the same time?

A. Possibly.

Q. Do you know that the cover page to this article which you submitted with your declaration called it Yamabe reversal?

A. No.

Q. Would you choose a different word for that if you were submitting that cover page yourself?

A. I'm not sure.

Q. Well, I think you used a word other than reversal just a second ago, right? Counteracting?

A. Yes.

Q. This is not -- I mean, you --

I assume that you think the study is relevant to the subject we're talking about today, correct?

A. Correct.

Q. But it's not about reversal because it's happening -- because the mifepristone and progesterone are being administered simultaneously, correct?

A. That's a possibility.

Q. I think you agreed earlier that one reason for being cautious in extrapolating drug data from animals to humans is possible physiological differences between animals and humans. Does that sound right?

A. That's right.

Q. Do you think that such caution is warranted here with respect to the Yamabe study concerning rats?

A. It's all -- caution is always -- caution is always a virtue whenever you're looking at animal studies.

Q. So one should be cautious extrapolating data from rats to humans based on the possibility of a difference between rat and human physiology, correct?

A. Yes.

MR. BECK: Can we introduce Tab J to the chat?

BY MR. BECK:

Q. Let me know when you have this one open, Doctor.

MS. DAVIS: Andrew, was this previously offered as an exhibit? And if so, what number?

MR. BECK: It has not previously been offered as an exhibit. We can mark this as Exhibit 31.

(Whereupon, the document was marked as Exhibit No. 31 to the testimony of the witness.)

BY MR. BECK:

Q. Do you have it open, Doctor?

A. Still loading.

Q. Okay.

A. It's open.

Q. Okay. So what has been marked as Exhibit 31 is -- is a chapter by Baulieu, B-A-U-L-I-E-U, called "RU486: An Antiprogestin Steroid with Contragestive Activity in Women."

Have you seen this document before, Doctor?

A. I believe I have.
Q. Okay. Can you turn to page 5?
A. I'm there.
Q. So do you see the -- the heading "Binding to Steroid Receptors" in the middle of the page?
A. Yes.
Q. Okay. The last sentence of the first paragraph under that states, "Among steroid receptors, progesterone receptors are those for which relative affinities of different ligands vary the most among species."
Did I read that correctly?
A. Yes.
Q. Do you have any basis for disagreement with that statement?
A. No.
Q. Did you know about the wide difference -- differences in progesterone receptors among species when you included the discussion of animal studies in your declaration?
A. I did not. But I don't think it would have changed my general opinion.
Q. Why wouldn't it have changed

your general opinion?
A. Because the three pillars are all consistent with one other, the biologic logic, the fact that mifepristone RU486 was developed as a medical abortion drug precisely because it binds to progesterone receptors, and that binding is reversible, and because the animal data are consistent with that, that its effects can be blocked by progesterone, and that that's consistent with the experience we've had in humans.
Q. But focus just on the animal data for the moment. We're going to turn to the human data in a second.
If progesterone receptors are among the steroid receptors that vary most widely among species, we should be especially cautious in extrapolating about the impact of the drug on progesterone receptors in rats and drawing conclusions about humans, correct?
A. I don't agree with that assertion. I think that this is just consistent with my previous statement that we must be cautious extrapolating animal data to humans. I think the usual caution would be enough.

Q. The usual -- well, if the relative binding affinity of mifepristone to progesterone receptors in rats were substantially different than its binding affinity in humans, the regular caution wouldn't be enough, right?
A. I think the regular caution would encompass that sort of variability.
Q. So we should just be very cautious in extrapolating from rat data to human data, including with respect to the study by Yamabe at issue here, correct?
A. I would characterize it as cautious, not very cautious.
Q. Even if the receptors interact with mifepristone in a completely different way in rats than humans, you don't think serious caution is warranted?
A. If they -- if they interacted in a totally different way, for example, if the mifepristone bound irreversibly or if the mifepristone actually had a progesterone like effect, totally opposite of what happens in humans, then I would say we would have to be extremely cautious.

However, the evidence suggests that what happens in the rats is consistent with what happens in humans. So I think regular caution is warranted. I think you're overstating caution.
Q. Let me read you something and you can tell me if you agree with this. "Many studies on rats have generated promising theories that later turn out not to be successful, or worse, turn out to be harmful when studied in humans. This is precisely why clinical trials are performed. We need evidence showing that a particular treatment is safe and effective for humans before clinicians begin providing their patients the treatment."
As a general matter, do you agree with that statement?
A. Yes.
Q. Your 2018 study, you've characterized that as a case series, correct?
A. That's correct.
Q. What is a case series?
A. Case series is a study of a number of different cases of a particular phenomenon or treatment with which -- in which

you are interested.

Q. And how does a case series different from a -- differ from a randomized control trial?

A. A case series looks at different cases that were collected that -- where the treatment was not assigned in a randomized manner where patients and clinicians may have had a choice in what treatment was offered, while the randomized control trial would be where the -- there were a process that would assign a particular subject to receive a particular treatment based on a randomization process.

Q. Is a case series prospective or retrospective or both or neither?

A. It could be both.

Q. Let me read you a statement and you can tell me if you agree with it. "In the hierarchy of evidence, a case series would definitely fall below a case controlled study series, and also fall below a randomized controlled study. So in the hierarchy, it would be given less power."

Do you agree with that

statement?

A. Yes.

Q. And how about this statement. "In a case series, there certainly is more possibility of bias than there is in a controlled trial. There is no doubt about that."

Do you agree with that statement?

A. Yes.

Q. So good that you agree with those statements because they are your prior statements from the 2015 deposition.

You also testified that a case series can suggest causation, but generally can't prove causation. Do you still agree with that statement?

A. Yes.

Q. And we discussed in the 2015 deposition, while you don't agree with this, some doctors believe that in a case series no causal inferences should be made about the relationship between the treatment and the outcome, correct?

A. Correct.

Q. But you disagree with that, correct?

A. Yes.

Q. And, instead, you think that very great care should be taken before making causal inferences from a case series, right?

A. That's correct.

Q. And you still believe that?

A. Yes.

Q. And you are drawing causal inferences from the case series here?

A. Yes.

Q. But you believe that because you've been taking very great care in drawing those inferences, it's acceptable to do so?

A. That's one of the reasons.

Q. What are the other reasons?

A. Another reason is that for women who want to stop or reverse their medical abortions, there is no other treatment available. And since all the evidence points to using progesterone to reverse the effects of mifepristone, it is safe and effective, that it is a reasonable conclusion to make and to offer it to women.

Q. Correct me if I'm wrong, but that seems to be a reason to offer the treatment -- for you, for example, as a treating physician to offer that to a patient, but that would be different than as a methodological matter whether or not you can draw causal inferences from a study as a matter of medical inference. Am I correct?

MS. DAVIS: Objection.

THE WITNESS: I think you would be doing both at the same time because I would only offer it if I was inferring causal effect.

BY MR. BECK:

Q. Well, didn't you offer it before you could infer causal effect from your studies because you started doing it and that became the subject of your studies?

A. At that -- at the early juncture there was a supposition of a causal effect based on the biologic logic, as well as animal studies and how progesterone acts in humans. With the accumulation of evidence over the years, now that causal inference can be stronger and not just a supposition.

Q. So you think that with respect to a case series, you can draw causal inferences by building on other categories of evidence like animal studies and biologic logic?

A. Based on the case series, yes, and as well as the accumulated evidence besides that.

Q. Might scientists look at the methodology in and of itself and disagree with you?

MS. DAVIS: Objection.

THE WITNESS: They might. However, again, if there were randomized control trials concluding otherwise, then I would have a different conclusion. However, at this juncture, we have one randomized control trial that actually supports what we do.

And so it would, therefore, be -- it would be logical to offer a safe and effective treatment when women are desiring to reverse their medical abortions.

BY MR. BECK:

Q. So we'll talk about the randomized control trial shortly. But you -- my question just a moment ago was, might scientists

look at the study design in and of itself and say that you have to look at that design and evaluate and -- let me start over.

Scientists could look at the idea of a case series and conclude that you can't draw causal inferences from a case series, correct?

A. And I -- yes. I already answered they might.

Q. And would it be reasonable for a scientist to draw that conclusion?

A. Perhaps it would be.

MR. BECK: Okay. Can we mark tab -- sorry, can we introduce Tab K?

BY MR. BECK:

Q. And before we turn to Tab K. Is it your testimony that patients should be offered reversal irrespective of whether or not it works because it is essentially harmless and patients really are desperate for it?

A. No.

Q. You would want evidence showing that it had a causal effect to justify prescribing it, correct?

MS. DAVIS: Objection.

THE WITNESS: I have evidence that it is effective.

BY MR. BECK:

Q. Right. But physicians should want evidence showing that it is effective before prescribing it, correct?

A. Yes.

Q. Okay. So let's turn to Tab K. Let me know when you have that downloaded.

A. It's open.

Q. Tab K, which we can mark as Exhibit 32.

(Whereupon, the document was marked as Exhibit No. 32 to the testimony of the witness.)

BY MR. BECK:

Q. Is an excerpt of a publication by the National Academies of Science, Engineering, and Medicine called, "The Safety and Quality of Abortion Care in the United States."

Have you seen this before?

A. I believe I've heard of it and read excerpts, but I've not seen the entire report.

Q. Are you familiar with the National Academies of Science, Engineering, and Medicine?

A. Yes.

Q. What -- what is that -- what is the National Academies of Sciences, Engineering, and Medicine?

A. It's a national group of scientists, engineers, and physicians that seeks to establish standards, as well as to influence public opinion, public policy, and other aspects of our society.

Q. Do you think it's a reliable authority, generally speaking?

A. In some instances.

Q. But not in general?

A. In general, I would say it is a reliable body.

Q. Can we turn to page 54 of Exhibit 32, which is the National Academy's report? Let me know when you're there.

A. I'm there.

Q. Okay. So in the middle of that paragraph under reversal of medication abortion, it says, "Case series are descriptive

reports that are considered very low quality evidence for drawing conclusions about a treatment's effects."

Did I read that correctly?

A. Yes.

Q. And so I know you disagree that this applies to your own case series, but as a general matter, is the National Academy correct to say case series are low quality evidence for drawing conclusions about the effects of a treatment?

A. I agree that they are considered low quality evidence, yes.

Q. Your 2018 case series was published in a journal called "Issues in Law & Medicine" --

A. Yes.

Q. -- is that correct?

A. Yes.

Q. And that same journal published your 2017 literature review article called, "Embryo Survival After Mifepristone: A Systematic Review of the Literature," correct?

A. Correct.

Q. Do you regard "Issues in Law &

Medicine" as a reliable authority?

A. Yes.

Q. Is it a widely read publication?

A. I think that's probably a relative term.

Q. Is it a popular journal in the medical field?

A. I would say amongst the general medical field it is not well known.

MR. BECK: Let's have Tab L introduced into the chat. We can mark as Exhibit 33.

(Whereupon, the document was marked as Exhibit No. 33 to the testimony of the witness.)

THE WITNESS: I would point out that in the exhibit you just have here, that same paragraph they cite Grossman's study of 2015, which we have shown to be a totally inadequate review of survival of embryos. So that, in my mind, makes this whole safety and quality of abortion care in the United States a biased and suspect opinion piece.

BY MR. BECK:

Q. Citing Grossman makes this piece biased and what -- and what was the other word you used?

A. Makes it a biased opinion piece, essentially.

Q. Simply because it cited Dr. Grossman's article?

A. Well, that's one -- that's one of the -- one of the evidences of bias in this piece.

Q. So your opinion is that because the National Academy cited an article by Dr. Grossman, it is biased and that that renders the entire discussion in that document biased and suspect?

A. It certainly renders that paragraph quite suspect, absolutely.

Q. Why?

A. Because the Grossman article had several deficiencies.

Q. And so citation of an article with deficiencies demonstrates bias?

A. Well, it does when they cite it to support their -- their point, which is a point that is not supported by an unbiased look

at the literature and the evidence.

Q. Are your articles free from deficiencies?

A. No article is free of deficiencies.

Q. Including yours and including Dr. Grossman's, correct?

A. Including all articles ever published.

Q. So how could citation of Dr. Grossman's article be demonstrative of bias simply because it contains deficiencies?

A. Because Dr. Grossman's article is not just simply biased. It draws erroneous conclusions, does not include very pertinent studies, makes erroneous conclusions about the studies that were included, includes studies that were not support -- that do not support what he claims to -- to -- to support.

Q. And that collection of traits demonstrates that the National Academy is biased for having cited Grossman?

A. Yes, it does. Especially in that paragraph on reversal of medication abortion.

Q. Okay. Do you have Tab L open?
A. It's downloading.
Q. Let me know when it's open.
A. Okay. It's open.
Q. So Exhibit 33 is the spring 2018 issue of "Issues in Law & Medicine" in which your case series was published. Have you seen it before?
A. Yes.
Q. Okay. At the bottom of the first page it says, "A publication of the Watson Bowes Research Institute and the National Center -- I'm sorry, the National Legal Center for the Medically Dependent and Disabled, Inc."
Did I read that correctly?
A. Yes.
Q. Okay. Are you familiar with the Watson Bowes Research Institute?
A. Yes.
Q. Have you ever applied for a grant with the Watson Bowes Research Institute?
A. Not as -- not as a lead researcher, no.
Q. Have you applied for a grant from the Watson Bowes Research Institute in

something other than a lead researcher role?
A. Yes.
Q. Can you tell me the circumstances there?
A. It was an application for an abortion pill reversal study.
Q. And when was that application submitted?
A. I believe earlier this year.
Q. And who submitted it?
A. Dr. Joseph Stanford.
Q. Stanford?
A. Yes.
Q. Is Joseph Stanford the lead author -- or the lead investigator on this proposed study?
A. Yes.
Q. And you are anticipating collaborating with Mr. -- Dr. Stanford?
A. Yes.
Q. What's the APR study? What -- what -- what are you anticipating or proposing to study?
A. What am I proposing?
Q. Yeah. What -- what is the --

so Dr. Stanford submitted an application for research -- I'm sorry, for funding to conduct an APR study earlier this year. What are the details of that study?
A. The -- the proposal is for a randomized control trial of progesterone reversal of mifepristone abortion.
Q. And what -- what are the -- what are the groups that are going to be randomized under this proposal?
A. Under the proposal, there will be a group randomized to receive oral progesterone and another group to receive vaginal progesterone.
Q. Those are the two arms of the study?
A. Yes.
Q. Would there be a placebo studying the effect of no progesterone?
A. No.
Q. And there wouldn't be an intramuscular injection arm of the study?
A. No.
Q. Why not?
A. Because in our previous

research, the high dose oral protocol was as or more effective than the intramuscular injection protocol, and shots hurt more than pills.
Q. But wasn't -- weren't the injections more effective than the vaginal route of administration?
A. That's correct.
Q. So why wouldn't you compare the two most effective or the two -- why wouldn't you compare two more effective routes of administration rather than sort of skipping the -- the second most effective route?
A. Because the vaginal progesterone group in -- in our previous study was very heterogenous, people taking different doses, low doses.
And so with -- since there was evidence from broader research that vaginal progesterone meets the higher uterine levels of progesterone, we felt it was very important to study that to make sure that we -- we knew if that were effective. So we needed more information on the vaginal -- or we need more information on the vaginal, I should say.
Q. So would it be correct to say

that you have a hypothesis that the low reversal rate for vaginal administration in your 2018 case series stemmed, in part, from the heterogenous nature of the administration there?

A. Yes.

Q. And talk more about the heterogenous nature of the administration. What did you say were the -- sort of the array of factors that made it nonuniform?

A. Varying doses, varying durations of the -- of the progesterone, varying forms of the progesterone.

Q. And so the fact that there was an array of doses, forms of progesterone, means that you need to study it more now?

A. Of the vaginal progesterone, that's correct.

Q. Yeah. Do you think that your data when it comes to vaginal progesterone, at least with respect to the 2018 case series, is less solid than the data with respect to other routes of administration or do you think -- do you have concerns about heterogeneity with respect to all routes of administration?

MS. DAVIS: Objection.

THE WITNESS: My concern with heterogeneity is with the vaginal progesterone.

BY MR. BECK:

Q. Does that mean that your ability to draw conclusions from the 2018 case series at least -- at least with respect to vaginal progesterone, is lower than your ability to draw conclusions from the other routes of administration?

A. Yes.

Q. Dr. Stanford submitted this proposal to the Watson Bowes Research Institute earlier this year; is that correct?

A. That was earlier this year.

Q. And you are someone who would work on the study with Dr. Stanford?

A. Yes.

Q. Who are the other co-investigators, if any?

A. I don't know their names at this point.

Q. Because you haven't identified your co-investigators or you -- they -- they exist, but you don't know who they are?

A. I don't think -- well, I'm not sure if Dr. Stanford has identified all the co-investigators.

Q. Do you have concerns about the ethics of prescribing less effective routes of progesterone, such as the vaginal route, for people who are trying to save their pregnancies?

A. I have concerns, but those concerns are tempered by the previous literature showing that vaginal progesterone leads to increased intrauterine levels of progesterone.

Vaginal progesterone is often favored by physicians who use progesterone for other reasons, such as for treatment of -- or for prevention of miscarriage in women who have conceived by virtue of invitro fertilization.

So because of these well standing preferences for vaginal progesterone, I think it would be safe to offer that as a treatment arm in a very carefully controlled trial that will have safety monitoring so that if there's any indication that the vaginal is significantly inferior, then that arm of the study could be terminated early.

Q. Have you already started considering terminating it early if it's shown

to be less effective?

A. Well, the study has not been launched, but we've discussed it. You know, we would have safety monitoring. And that's -- that's the reason for having safety monitoring is to terminate the study early if -- especially if one arm is significantly better than the other arm.

Q. Correct me if I'm wrong, but that sounds like efficacy monitoring, not safety monitoring? I would think that the safety monitoring would be if one route shows a huge number of side effects that you don't anticipate, whereas, efficacy is we know that -- or at least from study, it indicates that one arm is likely to be more effective than another?

MS. DAVIS: Objection.

THE WITNESS: The -- the monitoring -- you're -- you're correct. The monitoring actually monitors both safety and efficacy at the same time. So any study of this sort could be terminated early if there were signals that there were significant adverse effects.

Also, it could be terminated

early if there's significant difference between two of the arms, and one was significantly inferior.

BY MR. BECK:

Q. Do you plan to terminate the study early if the vaginal route of administration is yielding less effective results?

A. We plan to terminate early if -- if it's significant following all of the -- the directions that will be given by the institution review board monitoring the ethics of the study, yes.

Q. Do you already have an IRB engaged?

A. Yes.

Q. What -- what IRB is engaged?

A. The IRB of the University of Utah.

Q. Did you submit a written study proposal to the IRB of University of Utah?

A. I did not personally, no.

Q. Did someone else?

A. Yes.

Q. Who?

A. Dr. Stanford.

Q. Okay. Is Dr. Stanford affiliated with the University of Utah?

A. Yes.

Q. And is he in the OB/GYN department there?

A. He's in the office of -- I believe it's called the office of reproductive health.

Q. Have you seen a copy of the IRB application?

A. I believe so.

Q. And do you have a copy of that in your computer files somewhere?

A. I don't recall.

Q. But you might?

A. I might.

Q. Okay. How much was the grant you sought or Dr. Stanford sought from the Watson Bowes Research Institute for this study?

A. I'd have to review my records.

Q. Was it more than $10,000?

A. Yes.

Q. Was it more than $50,000?

A. Yes.

Q. Was it more than $100,000?

A. Yes.

Q. Was it more than $500,000?

A. I don't recall.

Q. Could it have been more than 500,000?

A. It's possible.

Q. Is that just because conducting a study is really expensive?

A. Yes.

Q. And this application was submitted. Has there been any action from Watson Bowes Research Institute on this application?

A. The grant has been partially funded.

Q. What -- what does that mean? How much has it been partially funded?

A. I'd have to check my records.

Q. Was it 50 percent?

A. Less than 50 percent.

Q. 25 percent?

A. Perhaps.

Q. Did you get a grant of more than $200,000?

A. The grant award, I -- I'm not sure.

Q. Possible that it could have been in the $200,000 range?

A. It's possible.

Q. Okay. Apart from this application from Dr. Stanford earlier this year, have you ever applied for any other grants from the Watson Bowes Research Institute?

A. No.

Q. Would you agree with me that the Watson Bowes Research Institute funds pro-life research?

A. Yes.

Q. If we can look back at Exhibit 33, which is the "Issues in Law & Medicine" issue in which your case series was published. If we turn to the second page, tell me when you're there.

A. I'm there.

Q. Okay. So this is something like a mast head for the publication, correct?

A. Yes.

Q. And it lists Barry A. Bostrom as editor-in-chief, correct?

A. Yes.
Q. Do you know Barry Bostrom?
A. Yes.
Q. How do you know him?
A. I've -- I don't recall if I've met him in person or have simply talked to him on the phone or via email.
Q. Have you had just from a stray interaction with him, or have you had sustained interaction with him?
A. Well, I had sustained interactions when we were submitting our article for publication. So it was the usual kind of back and forth. And he would email me different reviewers' comments and that sort of thing that happens when you -- you submit an article for publication to a peer reviewed journal.
Q. And so is that the -- the universe of your communication with Barry Bostrom, this sort of email back and forth around your publication?
A. There may have been other communications regarding the journal in general.
Q. Do you still have copies of that correspondence?

A. The correspondence with -- regarding the journal article?
Q. Yeah.
A. I don't recall.
Q. Okay. Would it be in email folders if you did?
A. If I did, it probably would be there.
Q. Okay. Is it fair to say that Barry Bostrom is an advocate for pro-life causes?
A. I -- I don't know him well enough to -- to make that assertion.
Q. Are you aware -- Barry Bostrom is a lawyer, right?
A. I believe so.
Q. Are you aware of his work on behalf of pro-life legal organizations?
A. I think he has an association with the National Legal Center for the Medically Dependent and Disabled.
Q. Are you aware that he previously served as counsel for the National Right to Life political action committee?
A. No.

Q. Are you familiar with the National Right to Life political action committee?
A. Yes.
Q. If he had been counsel to that organization, would it be a fair supposition that he is an advocate for pro-life causes?
A. That would be a fair supposition.
Q. And then the other editorial role is associate Donna Harrison, MD, correct?
A. That's correct.
Q. And you know Dr. Harrison?
A. Yes.
Q. How do you know her?
A. I've known her through the American Association of Pro-Life OB/GYNs.
Q. And you both serve on the board of that organization, correct?
A. That's correct.
Q. And she's the executive director of that organization?
A. Yes.
Q. And she's a witness with you in this case?

A. I believe she is.
Q. To your knowledge, has she ever provided medication abortion reversal treatment?
A. I don't know.
Q. Did she treat any of the reversal patients in your 2018 case series?
A. I don't believe so.
Q. So between Barry Bostrom and Dr. Harrison, the two editorial roles listed on the mast head are filled by a lawyer for the National Right to Life political action committee or someone who's at least previously served in that role, and the executive director of the American Association of Pro-Life Obstetricians and Gynecologists, correct?
A. That's correct.
Q. And so is it a fair summary to say that the journal is edited by people who are active in the pro-life movement?
A. Just like you could say that the Journal of Contraception is edited by people who are active in the abortion movement.
Q. So that's a roundabout way of saying, yes, it is fair to say that the journal

is edited by people who are active in the pro-life movement?
A. That's correct.
Q. And one of the editors is an expert witness with you in this case?
A. I believe she is.
Q. And then below the editorial staff on the mast head is a list of 18 referees, correct?
A. I haven't counted them, but it looks like about 18.
Q. Yeah. And I understand -- it's my understanding that referees are the folks who are responsible for a publication's peer review. Does that sound correct to you?
A. Yes.
Q. Do you know any of the referees listed here?
A. I do.
Q. How many do you know? Or if it's easier, how many do you not know?
A. Let's see. I know five.
Q. Which five?
A. Byron Calhoun, Monique Chireau, Priscilla Coleman, Michelle Cretella,

Martin McCaffrey.
Q. And how do you -- do you know them all in the same way or do you know each of those through different routes?
A. I would say more or less in the same way.
Q. Which is?
A. Which is through the American Association of Pro-Life OB/GYNs and their conferences that they hold.
Q. So the five people you listed attend -- can we call it AAPLOG? Will -- will you understand the abbreviation AAPLOG?
A. Yes.
Q. And so the five people you named you have interacted with AAPLOG conferences; is that correct?
A. That's correct.
Q. Okay. Do you know whether any of them -- any of the people that you know were peer reviewers for any of your publications at "Issues in Law & Medicine"?
A. No. That's not disclosed to the authors.
Q. You -- you don't know who your

reviewers were?
A. No.
Q. Okay. But those five would know that you are sort of the leading author when it comes to abortion pill reversal studies, correct?
A. I would assume so.
Q. Are any of those five people that you know in the Abortion Pill Rescue Network?
A. I know that some of them aren't and I don't know if any of them are.
Q. So you don't know whether any of them have provided abortion pill reversal treatment?
A. No, I do not.
Q. Okay. Let's turn to the table of contents. And I'm mindful of the time for folks on the east coast. I probably have another five or ten minutes here and then we can talk about breaking for lunch.
But if we turn to the table of contents here, which is page -- the fourth page of the PDF of Exhibit 33. Are you there?
A. Yes.

Q. So this lists one, two, three, four, five, six items in the table of contents, correct?
A. Correct.
Q. And there are four items under "Articles" and two under "Verbatim," right?
A. That's correct.
Q. What's the second item listed under Verbatim in the table of contents? Can you read that aloud?
A. "Amicus curiae brief of the American Association of Pro-Life Obstetricians and Gynecologists in Karungi vs. Ejalu, parenthesis, Michigan Court of Appeals 2017, close parenthesis. The Thomas More Society and Rita Lowery Gitchell, comma, Special Counsel."
Q. So the issue of the journal in which your 2018 case series was published also included the text of a legal brief of the American Association of Pro-Life Obstetricians and Gynecologists?
A. That's correct.
Q. And that is a pro-life organization, correct?
A. That's correct.

Q. And you serve on its board?
A. That's correct.
Q. Have you seen pro-life legal briefs published in past issues of "Issues in Law & Medicine"?
A. I don't recall.
Q. In your experience, is it common for peer reviewed medical journals to publish copies of legal briefs alongside scientific papers?
A. No. But I would note that the title of the journal is "Issues in Law & Medicine." So this is a unique journal in that it has both.
Q. Have you ever seen any other peer reviewed medical journals publish copies of legal briefs alongside scientific papers?
A. I don't believe so.
Q. Would you agree with the characterization that "Issues in Law & Medicine" is a journal with a pro-life policy focus?
A. I think policy -- I would say no.
Q. What -- what aspect of that is something you disagree with?

A. I think the policy focus -- policy has a certain connotation. And I don't necessarily think that the focus is on policy.
Q. Do you agree that it has a -- that "Issues in Law & Medicine" has a pro-life focus?
A. Yes.
Q. And why do you think that it doesn't have a focus on policy if it includes, as you said, I mean, it concerns both law and medicine from a pro-life perspective, and it includes legal briefs. What aspect of saying that it has a policy focus is unfair?
A. Well, if you look at two of the articles here, our article and the induced abortions and the risk factor for breast cancer, those are not policy papers. Those are medical scientific papers. So I think -- I think they have a variety of -- of different pro-life foci.
Q. One of those pro-life foci would be medicine and another would be policy. Is it fair to say that it includes a focus on pro-life policy?
A. I don't think I know the journal well enough to give that opinion.

Q. Did you -- did I ask you already, do you subscribe to this journal?
A. I do.
Q. And do you read it regularly?
A. I read it -- I don't read the entire journal regularly.
Q. How many medical journals do you subscribe to?
A. Probably three. That's the ones that come in paper. But I receive lots of things online that I read.
Q. What are the other two?
A. "Journal of the American Medical Association." And I get "New England Journal of Medicine" online. And Linacre Journal.
Q. What was the last one?
A. Linacre.
Q. Linacre.
A. I also receive American Family Physician online, Journal of Family Practice I believe comes online, and maybe a couple of others.
Q. Before the --
A. Actually, pardon me. I'm

sorry. I don't know if you want me to be exclusive. But then there's -- I think there's Journal of Palliative Care that comes to me. So if I -- the longer I think about it, the more -- the more extensive the list could become.
Q. So more than just a few journals?
A. Yes.
Q. Before the -- so you published two articles in "Issues in Law & Medicine," a 2017 literature review and a 2018 case series; is that correct?
A. That's correct.
Q. Before the 2017 literature review was submitted, did you communicate in any way with anyone affiliated with "Issues in Law & Medicine" about that article?
A. No.
Q. Did Dr. Davenport?
A. I suppose she inquired on how to submit the article for publication.
Q. But you're not aware of any other communications between Dr. Davenport and anyone at "Issues in Law & Medicine" prior to the publication?

A. No.

Q. Okay. Same question for the 2018 case series. Before that was published, did you -- or before it was submitted, did you communicate in any way with anyone affiliated with the journal about that article?

A. I don't recall a specific communication, but I -- I think I can reasonably assume that I reached out to -- before starting the formal submission process, I reached out to see if this might be an article that might interest them.

Q. Who would you have reached out to?

A. I believe to Donna Harrison.

Q. And she encouraged you to submit the article?

A. I believe she did.

Q. Was that communication via email? Do you recall?

A. I don't recall.

Q. Might it have been via email?

A. It might have.

Q. Was "Issues in Law & Medicine" your first choice for publishing your 2018 case

series?

A. No.

Q. Where else did you submit a manuscript?

A. I submitted to Journal of Emergency Medicine, I believe, and to American Journal of Emergency Medicine, and I think I submitted to the Journal of Family Practice.

Q. And what kind of input did you get from those publications?

A. What -- I'm sorry, I didn't hear the question.

Q. What kind of input did you get from those publications in response to your submission?

A. The emergency medicine journals indicated -- at least one of them indicated that they did not feel that this was suitable for their -- for their journal. The American Family Physician indicated that they only publish review articles. And I don't recall other -- other comments as far as what they felt about it.

Q. When you said you were told that they said it was not suitable -- did -- did

I get that word right? Did you say it wasn't suitable for the publication?

A. Yes.

Q. What does that mean?

A. Yes. They did not feel it was within their scope of -- of what they usually cover.

Q. Because it didn't deal with emergency medicine?

A. It -- because a large number of the patients studied were not seen in emergency departments.

Q. Was that the only reason they offered you?

A. I believe so.

MR. BECK: Let's go off the record and take a lunch break for folks on the east coast.

VIDEOGRAPHER: Off the record at 12:06.

(A recess was taken.)

VIDEOGRAPHER: We are back on the record at 12:38.

BY MR. BECK:

Q. Good morning, Doctor.

A. Good morning.

Q. Morning for you, afternoon for us. Did you have any correspondence or contact with attorneys for Tennessee during the break?

A. No.

Q. Just a quick follow-up on your submission of your 2018 case series to different journals prior to "Issues in Law & Medicine." Did you submit it to the "Journal of the American Medical Association"?

A. No.

Q. Why not?

A. I didn't think it would get published there.

Q. Why?

A. Because it's a very broad based journal that usually publishes articles from authors that are well known to them. And so since I'm not well known to them, I didn't think it would be worthwhile spending the time submitting there.

Q. What about the "New England Journal of Medicine," did you submit it there?

A. No.

Q. Similar reasons as to why not?

A. Yes.

Q. Had you heard about -- I know that you said that you didn't know about the law that we're discussing in this case before you were contacted by attorneys from the Tennessee attorney general's office; is that correct?

A. That's correct.

Q. Had you heard about proposed legislation that would become this law in Tennessee prior to that point?

A. Not that I'm aware. Not that I recall.

Q. So let's see. Let's pull up Tab F, Exhibit 7, which is your case series, which you should have somewhere accessible. Let me know when you have that.

A. I have it.

Q. Okay. Great. Turn to page 24, please.

A. I'm there.

Q. Okay. So the last sentence on this page continuing onto the next page reads, "This study is designed to ascertain which progesterone treatments clinicians have offered to women seeking mifepristone reversal that

demonstrate efficacy beyond the 25 percent embryo survival rate and compares the relatively -- relative efficacies of different treatment protocols to the historical control."

So the -- the 25 percent embryo survival statistic, that's used as a historical control for your case series; is that correct?

A. Yes.

MS. DAVIS: Objection.

BY MR. BECK:

Q. And let's see. Page 24. Earlier in that paragraph it says, "We selected a 25 percent embryo or fetus survival rate if mifepristone alone is administered as a control because it is at the upper range of mifepristone survival rates and close to the 23 percent survival rate of the one early study that used a single 200 milligram dose, the dose currently favored for medical abortions."

Is it fair to say that 25 percent is a ballpark figure?

A. Yes.

Q. Great. Let's introduce a new tab, which is Tab O, previously marked as

Exhibit 11. Let me know when you have that open.

A. It's open.

Q. Okay. So this a document called "Guidance for Industry: E10 Choice of Control Group and Related Issues in Clinical Trials," issued by the U.S. Department of Health and Human Services Food and Drug Administration. Are you familiar with these guidelines?

A. No.

Q. Have you seen this document before?

A. No.

Q. Okay. Do you consider the FDA to be a reliable authority?

A. For the most part, yes.

Q. Okay. Let's turn to page 6.

A. So 6 on the thumbnails is labeled as 2 on the actual document. Is that where you want me?

Q. Sorry, 6 at the bottom of the page, which is 10 of the PDF. So page 6 in this document's internal numbering.

A. Okay. I have it.

Q. Are you there?

A. Yes.

Q. And this is a -- it has 4, 5, and 6 as headings throughout the page. Do you see that?

A. Yes.

Q. Okay. Great. Can you read the first sentence under heading 5 aloud?

A. "An externally controlled trial compares a group of subjects receiving the best treatment with a group of patients eternal to the study rather than to an internal control group consisting of patients from the same population assigned to a different treatment."

Q. And I might have misheard you, but I think you said best treatment, not test treatment, right? Receiving the test treatment. I might have misheard you. But the -- it says, "receiving the test treatment," right, in the first sentence?

A. Yes. Receiving the test treatment.

Q. And then can you read the next sentence, please?

A. "The external control can be a group of patients treated at a earlier time,

parenthesis, historical control, close parenthesis, or a group treated during the same time period, but in another setting."

Q. Would you say that what you've just read is an accurate definition of a historical control?

A. Well, I think it's an accurate definition of an external control.

Q. And then the sort of subpart with -- do you agree that a historical control is a type of external control?

A. Yes.

Q. And so the part of that that's referencing historical control, do you agree with that as a definition of a historical control?

A. Yes.

MS. DAVIS: Objection.

BY MR. BECK:

Q. Okay. And historical control, again, is the type of control utilized in your 2018 study?

A. Yes.

Q. Okay. Turn to page 4, please.

A. I'm there.

Q. And would you read the last four sentences on that page, beginning with the words "This document"?

A. "This document categorizes control groups into five types. The first four are concurrently controlled, parenthesis, the control group and test group are chosen from the same population and treated concurrently, close parenthesis, usually with random assignment to treatment. They are distinguished by the type of control treatment, parenthesis, listed above, close parenthesis, used. External, parenthesis, historical, close parenthesis, control groups regardless of the comparative treatment are considered together as the fifth type because of serious concerns about the ability of such trials to ensure comparability of tests and control groups, and their ability to minimize important biases, making this design useable only in unusual circumstances."

Q. Thank you. Excuse me. Thank you. So I'd like to focus on the last sentence that you just read.

And my first question is, do you agree that, in general, there are serious

concerns about the ability of studies with historical controls to ensure comparability of the test group and the control group?

A. In general, yes.

Q. Is the FDA correct that, in general, there are serious concerns about historical controls ability to minimize important biases?

A. Yes.

Q. And is the FDA correct that, in general, a historical control group design is useable only in unusual circumstances?

A. That's correct. Such as our circumstances.

Q. The subject of randomized control trials came up earlier. Can you just again define the term "randomized control trial" for me?

MS. DAVIS: Objection.

THE WITNESS: Randomized control trial is the study where the subjects do not get to choose what treatment they will receive, rather they are assigned to particular treatment groups using some sort of randomization protocol.

BY MR. BECK:

Q. Let's look at page 3 of the FDA guidance that we're looking at. So the -- are you there?

A. Yes.

Q. The first sentence under heading one states, "Assurance that subject populations are similar in test and control groups is best attained by randomly dividing a single sample population into groups that receive the test or control treatments. Randomization avoids systematic differences between groups with respect to known or unknown baseline variables that could affect outcome."

In general, do you agree with the FDA's statement that I just read?

A. Yes.

MR. BECK: Okay. Can we introduce Tab P, please, which is -- has previously been marked as Plaintiff's Exhibit 15?

MS. DAVIS: Andrew, did you say 15 or 50?

MR. BECK: 1-5, 15.

BY MR. BECK:

Q. Let me know when you have it, Doctor.
A. It's open.
Q. Great. Exhibit 15 is a study called, "Embryo Survival after Mifepristone, Review of the Literature." It's authored by Dr. Davenport, you, and others, correct?
A. Correct.
Q. And this review is the source of the historical control 25 percent figure that you cite in your 2018 case series?
A. That's correct.
Q. Can you turn to page 12, please.
A. I'm there.
Q. So the last sentence continuing onto the next page reads, "Mifepristone was more successful as an abortifacient in larger doses and at earlier gestations."
Did I read that correctly?
A. That's correct.
Q. So patients who take a smaller dose of mifepristone are more likely to have a continuing pregnancy than those who take a

larger dose; is that correct?
A. That's correct.
Q. And patients who take mifepristone at a later gestational age are more likely to have a continuing pregnancy than those who take mifepristone at earlier gestations, correct?
A. That's correct.
Q. And what's the current mifepristone dosage used to induce -- as part of the two drug medication abortion regimen?
A. The FDA approved protocol was 200 milligrams mifepristone.
Q. And at what gestational age do those -- does the FDA authorize mifepristone's use on the label?
A. Seventy days or ten weeks after first day of the last menstrual period.
Q. And are you aware of an evidence based protocol authorizing its use up to 77 days?
A. I am.
Q. Okay. So let's turn to page 16 of the literature review.
A. Okay. I'm there.

Q. So this is where you -- wait. Hold on. It might be page 14. Yeah. Let's turn to page 14. Sorry. Where you have the table?
A. Okay. I'm there.
Q. So I counted 16 entries on this table representing studies addressing embryo survival after mifepristone. The most recent entry on here looks like it's from 1990, I believe. Does that sound right to you? That would be the Somell study. Do you see anything later than 1990?
A. No, I do not.
Q. Okay. So that's 30 years old?
A. That's correct.
Q. Is there more recent research on the efficacy of mifepristone that you did not include in this literature review?
A. Not that I'm aware because it was soon after then that misoprostol was added to the mifepristone.
Q. So the most recent data we have is from 30 years ago?
A. That's correct.
Q. And so there's not recent

developing research that's changed the understanding reflected at this table, correct?
A. The only other trial would be the recent Creinin trial.
Q. Right. But in terms of just studying the effects of mifepristone alone, the data we have is reflected in this study, which is -- in this table the most recent of which is 30 years old, right?
A. Other than the Creinin study, you're correct.
Q. Looking at this table, would you say that we have robust historical data on the efficacy of a single 200 milligram dose of mifepristone?
A. No.
Q. And, in fact, there's only one study that addresses a 200 milligram dose of mifepristone, correct?
A. A 200 single dose, yes.
Q. Yep. And that's the Maria study from the Journal of Gynecology, I guess, from 1988?
A. That's correct.
Q. And in many of these studies,

the total dose of mifepristone is higher than the dose used today, correct?
A. That's correct.
Q. Many of them examine the effects of 600 milligrams daily, correct?
A. Yes.
Q. And that's three times the present dosage for mifepristone?
A. That's right.
Q. Do you think it's possible that 600 milligrams of mifepristone is more effective at inducing fetal demise than 200 milligrams?
A. Certainly possible, yes.
Q. And so there are differences in the treatments in these studies versus the dosage of mifepristone used today, correct?
A. In some of the studies, yes.
Q. And, in fact, all but one of the studies, correct?
A. Correct.
Q. And that one study only went as high as 49 days, correct?
A. That's correct.
Q. And mifepristone is presently

prescribed for many weeks after 49 days today, correct?
A. That's correct.
Q. And we know that mifepristone is less likely to work later -- at later gestational ages, correct?
A. That's correct.
Q. Or at least induce fetal demise at later gestational ages, I should say. Do you agree with that?
A. I do.
Q. Okay.
A. Also point out that many of these studies only followed the embryo for six or seven days. And so, therefore, they would have overestimated fetal or embryologic survival by not waiting long enough to see if demise occurred. The Maria case is an example of that.
Q. Well, the Maria is seven days?
A. Right.
Q. And so seven -- a seven day window overestimates the likelihood of survival?
A. It does. Because if you wait and watch -- because at seven days they would perform surgical abortions if there were signs

of continuing pregnancy of viability. If you were to wait longer, like they did in some of the studies, the 14 day studies, then some of those embryos would die. And so they would overestimate embryologic survival if you only waited seven days.
Q. Doesn't your study, your 2018 case series, address only within 72 hours, a 72 hour window?
A. That's to start the progesterone. That's not -- this is a whole different timeframe here. This is monitoring if the embryo is going to survive past -- past a certain numbers of days. So you're comparing apples to oranges.
Q. Why would you limit it to a 72 hour window in your study if there is some possibility of the mifepristone working well past 72 hours, according to your characterization of these studies?
A. We mostly base that on the half life of the medication. And, also, just to make sure that we were not accused of -- of, you know, adding to our data, inflating our -- our success rates. So it's just an arbitrary line

that we drew there. That's all.
Q. Seventy-two hours is an arbitrary line?
A. Uh-huh.
Q. What is the half life of mifepristone?
A. The health life of mifepristone is about 18 hours.
Q. And what is the significance of an 18 half life for the 72 hour window you were just describing?
A. Well, half life is when half of it is gone. So at 18 hours you still have half. And in another 18 hours, you still have 25 percent. And then in another 18 hours then you'll have 12 percent. So, you know, by 72 hours most of it is gone.
Q. So going back to where this subject came up. Why would -- by seven days you'd have a negligible amount in your system, if any at all, wouldn't you?
A. But the studies -- the 14 day studies show that the -- although the drug is gone out of the system -- first of all, there's still some metabolites around, number one. And

number two, the effects of the drug are still there.

So the -- although the parent drug may be gone, the effects of the drug persist. And the -- it may take longer than seven days for the embryo to die.

It's as if you were shot with a gun. The shot takes place at time X, but your death may not take place, let's say, for several days, depending on how you're wounded. And so the longer you watch someone who's had at gunshot wound, then the longer you'll see really what the -- what the mortality is for that gunshot wound, if not treatment offered.

Q. What study would you point me to that supports the discussion you're talking about now in terms of the difference between 7 days and 14 days and longer?

A. Well, we discuss it and -- and Dr. Davenport discusses it in the current study.

Q. In the 2017 study?

A. Correct.

Q. Okay. But what I meant was, what underlying -- of the literature that you reviewed what would you point to as an example

of a study that compared a shorter amount of time to a longer amount of time and concluded that embryonic survival is more likely in a shorter window than a longer window?

A. I'd have to review the study to pull out the particular ones that support that.

Q. So sitting here today, you don't have an example that comes to mind?

A. No.

Q. Okay. The FDA guidance we were looking at a moment ago, Tab O, can we look back at that? Are you there?

A. No. I have got lots of things open so -- there we go.

Q. Yep. Sorry.

A. That's fine. All right.

Q. You have it?

A. Yes, I do.

Q. Great. Let's look at page 27, please. Are you there?

A. Yes.

Q. Okay. In the middle of the -- the large paragraph on the page above, number 3, is a sentence that begins, "The control

patients." Do you see that?

A. Let's see.

Q. It's about a third of the way down, the control patients --

A. Yes.

Q. Okay. So those two sentences state, "The control patients should be as similar as possible to the population expected to receive the test drug in the study, and should have been treated in a similar setting and in a similar manner, except with respect to the study therapy. Study observations should use timing and methodology similar to those used in the control patients."

Did I read that correctly?

A. Yes, you did.

Q. As a general matter, is the FDA's guidance on historical controls correct on these points?

A. Yes.

Q. And as we discussed earlier, the dosage of mifepristone in most of the studies forming a historical control is different from the dose used today?

A. That's correct.

Q. And there are few subjects after 49 weeks gestation in the -- 49 days -- let me start over.

And there are few subjects after 49 days gestation in the studies forming your historical control, correct?

A. That's correct.

Q. Although your case series includes patients after 49 weeks -- days, correct?

A. That's correct.

Q. And so there's a difference between your control population and your study population?

A. Yes.

Q. And as we discussed earlier, the mifepristone survival rate increases with increasing gestational age?

A. That's correct.

Q. And so actual failure rates under the current treatment regimen, which extends to higher gestational ages, are likely to be higher than those reported in the studies you analyzed, correct?

A. At the higher gestational

ages, yes.

Q. So your case series when it discusses the 25 percent failure rate says that it was close. We discussed this earlier, close to the 23 percent failure rate of the one study that used a single 200 milligram dose, which is the Maria study, correct?

A. Yes.

Q. What was the upper limit of the gestational age in the Maria study?

A. I believe it was 49 days.

Q. And do you remember how many patients were included in that study?

A. Not off the top of my head.

Q. Let's look -- it's at page 15 of tab -- gosh, where are we? Tab P, Exhibit 15, page 15.

A. It would have 30.

Q. Would you consider that to be a large sample size?

A. No.

Q. If we didn't have the rest of the studies cited in your literature review, would you think that a 30 person study standing alone would be sufficient to support the 25

percent control figure?

A. If that were the only data we had, yes.

Q. If that were the only data we had, a 30 person study would suffice?

A. To establish historical control -- yes, that would be the best we have.

Q. And do you think that would be a particularly reliable historical control?

A. It would be the most reliable we would have.

Q. And how reliable would that be? I mean, it would be all that we would have. But from an objective standpoint, would a 30 person study give us a reliable historical control?

A. It would give a somewhat reliable historical control.

Q. Do you think other scientists would conclude that a 30 person study is sufficient to give us a somewhat reliable historical control?

A. I think they would under the circumstances.

Q. Have you ever seen any other

study that relied upon a historical control with such a small sample size?

A. I don't recall.

Q. Okay. Well, you're going to be testifying next month at a hearing, right?

A. I believe so.

Q. I'm going to ask you there as well, or we will ask you there, if you're able to find a study that relied upon a historical control that had just 30 people in it. And so if you find anything between now and then that supports the conclusion that that would be a reasonable historical control, would you let me know?

A. Well, if I find it, I would tell the -- I would tell the -- the attorneys for the State of Tennessee, and I guess they could let you know, if that would be the proper thing to do.

Q. Great. Thank you. Can we agree to do that?

A. Well, not -- I'm not committing to search the literature for such a control group. I have lots of other things occupying my time.

Q. Okay. Well, if you do find anything that supports the sufficiency of a 30 person historical control between now and the hearing, please let the attorney general's office know and we will ask that they let us know. Does that sound reasonable?

A. Sounds reasonable.

Q. Let's look at page 1 of the literature review, where we have the abstract here and under methods?

A. Okay. So it's the page labeled 3 in the internal numbering, correct?

Q. Yep.

A. All right.

Q. You there?

A. Yes.

Q. So the third sentence, I think, in that method paragraph says, "The relevant studies that verified embryo survival utilized ultrasound as a criterion for continuing pregnancy."

Did I read that correctly?

A. Yes.

Q. And then on page 16?

A. I'm there.

Q. Yeah. I'm having trouble finding what I was looking for. But it's fine. I don't think I need it. We can just stick with the statement in the abstract.

So you determined whether to include studies in this literature review based on whether or not they used ultrasound; is that correct?

A. That's correct.

Q. What is the ultrasound used to measure in this context?

A. So the ultrasound was used to detect fetal heart tones, as well as to detect growth or continued presence of evidence of an embryo that's viable.

Q. Did the studies, in your view, detail which of those -- did they do both of those things or one of those things? Like, which of those was your primary criteria?

A. The detection of the heartbeat was the more important one, but the other ones were also important. So, I guess, of lesser importance, but still important in -- in determining that the embryo was -- was continuing to survive.

Q. At what gestational age can fetal cardiac activity be detected with ultrasound?

A. So currently it's about five and a half weeks, sometimes five weeks gestational age.

Q. And what about at the time when these studies were being performed in the 1980s?

A. So then the ability to detect cardiac activity was more limited. That's why the other criteria were still important.

Q. And so it's not your opinion that they were across the board in these studies using ultrasound to detect fetal cardiac activity, correct?

A. Correct.

Q. They were also, in your view, measuring growth in the size of pregnancy with ultrasound?

A. Growth and continued evidence of intrauterine pregnancy.

Q. One can't defect fetal cardiac activity with a transabdominal ultrasound at the gestational ages that we're talking about for

most of these studies, correct?

A. For -- probably for many of the subjects, you're correct.

Q. And did you systematically determine that each of those studies involved the use of transvaginal ultrasound, in particular?

A. I -- I don't recall. But I do recall that most of them used transabdominal ultrasound.

Q. So most of them couldn't detect fetal cardiac activity at all because they were using transabdominal ultrasound, correct?

A. Not at their early gestations, correct.

Q. And these are primarily concerning early gestations, like before 49 days, correct?

A. That's correct.

Q. And so in most of these studies, they are not using ultrasound to detect fetal cardiac activity, correct?

A. I'd have to -- I'd have to check that before I answer that definitively.

Q. Okay. But many of them were using transabdominal ultrasound in order to -- transabdominal ultrasound and, therefore, were not able to detect fetal cardiac activity prior to 49 days, correct?

A. Many, yes, that's correct.

Q. On page 9 of the literature review?

A. Yes, I'm here.

Q. So in the last sentence on that page you talk about some of the language that some of these studies used to describe ongoing pregnancies. So it says, "Surviving embryos are described with terminology such as ongoing pregnancies, growing conceptus, normal intact uterine -- intrauterine pregnancy, unaffected pregnancy, uninterrupted pregnancy, no indication of pregnancy interruption, continuing pregnancy, or intact pregnancy," correct?

A. That's correct.

Q. And if a study that used ultrasound included phrases like that, you used that as an indication that they -- the study authors differentiated continuing pregnancies

from incomplete or missed abortions. Is that fair?

A. Yes.

MR. BECK: Can we have Tab Q? This is a new exhibit, which we can mark as Exhibit 34.

(Whereupon, the document was marked as Exhibit No. 34 to the testimony of the witness.)

BY MR. BECK:

Q. Let me know when you have it open. Do you have it, Doctor?

A. It says it's downloaded, but I clicked and it's not opening. Let me see if it's just open in another window. I click on the -- the tab and it opens up the Davenport article. Let me close that and see if it's under it.

Q. It opened up the correct article for me, so maybe try -- try it again.

A. There we go. I just had to close that other one. That other one didn't want to leave the stage. Okay. I'm here.

Q. Okay. Excellent. This is Exhibit No. 34, an article by Swahn, S-W-A-H-N,

et al., called, "Effects of Oral Prostaglandin E, little 2, on Uterine Contractility and Outcome of Treatment in Women Receiving RU486, parenthesis, mifepristone, close parenthesis, for Termination of Early Pregnancy."

Are you familiar with this article?

A. I believe I've read it in the past.

Q. Okay. This is one of the articles mentioned in the literature review, correct?

A. I believe so.

Q. So turn to page 24 of this article.

A. Okay. I'm there.

Q. So the last sentence on that page says, "Levels of cortisol, parenthesis, figure 3, end parenthesis, in women with complete abortion, number 25, were similar to those in women with continuing pregnancy, number 15, at all sampling times."

So this uses the kind of continuing pregnancy terminology that you -- we just discussed that you referenced for -- as a

basis for inclusion of the literature review, correct?

A. Yes.

Q. And can you turn to page 22? There's a highlighted section there. Can you just read that?

A. "Women were allocated randomly to one of three treatment groups. The initial treatment with RU486, parenthesis, 25 milligram twice daily for four days was the same in all three groups. On the fourth day, the subjects received either placebo in the morning and in the evening, parenthesis, group A, close parenthesis, 1 milligram PGE2 in the morning and placebo in the evening, parenthesis, group B, close parenthesis, or 1 milligram PGE2 on both occasions, parenthesis, group C, close parenthesis."

Q. So group A here is clearly identified as the group that was given mifepristone alone in this study, correct?

A. That's right.

Q. All right. So turn to page 24 and look at table three.

A. Okay.

Q. Can you tell me what this table seems to reflect for group A?

A. So under the column group A, eight had complete abortions, one had an incomplete abortion, five characterized as failures, for a total of 14 in group A.

Q. And so this identifies the number of patients in group A who had complete abortions, who had incomplete abortions, and for whom mifepristone failed to work, correct?

A. That seems to be what they're indicating.

Q. Okay. Now, you didn't include this Swahn study among the studies that you included in your literature review. Does that sound right to you?

A. I'd have to look back and see which ones were included.

Q. Let's look back at page 11, please, of the literature review. Tell me when you're there.

A. I'm on page 11.

Q. Great. The third paragraph states, "Swahn in a 1989 study compared abortions with mifepristone alone to abortions

with mifepristone and prostaglandin E, but did not clearly delineate how many surviving embryos were in the group using mifepristone as a single agent."

Looking back at table 3 of Swahn study, does that sound correct to you?

A. It may be correct because she's using the term "failure" as opposed to embryo survival, ongoing -- ongoing pregnancy and those sorts of terms. So he did not make it clear like -- like many of the studies of the original 30 that were found with the initial search.

And that's why only 12 were included in the analysis because only 12 -- only with 12 could we be sure that they were actually measuring or noting true embryo survival. And that's what -- what, of course, is what we were looking to find to establish a historic control.

Q. What would be indicative of true embryo survival for this study? What more could they have done?

A. I'd have to -- I'd have to look at the Swahn study more carefully to -- to determine that.

Q. If they had evaluated ongoing fetal cardiac activity, would that be useful in assessing whether or not they're -- they had identifying true failures, in your terms?

A. If they had -- if they had, that would be one of the ways to -- to determine that.

Q. Okay. Well, then, let's look at page 26 of the Swahn study. Let me know when you're there.

A. I'm there.

Q. Okay. Could you read that highlighted portion aloud, please.

A. "In contrast to a previous study, Kovacs, et al., 1984, in which 11 of the 14 unsuccessfully treated women were classified as incomplete abortion, there were only two, parenthesis, out of 17, close parenthesis, such diagnoses in the present investigation. This difference may be ascribed to the systemic use of ultrasound examination in the present work."

Q. Keep going, actually. Read the next sentence, too, please.

A. "At the second follow-up visit, an intact amniotic sac was found in 15 of

the women, and 15 -- 15 of the women, and fetal heart activity was detected in 13 of them.

Q. So not only does the Swahn study clearly identify outcomes for the mifepristone only group, but it specifically says it uses ultrasound to confirm the presence of persisting pregnancies, correct?

A. That's what he -- the author is stating.

Q. And based on this passage, it seems that the Swahn researchers used ultrasound to detect fetal heart activity to determine whether or not a pregnancy was continuing, correct?

A. Based on this passage, yes.

Q. Which you indicated a moment ago would be a relevant consideration in determining whether or not their failure group was a true failure group, correct?

A. Correct.

Q. Given that the Swahn study used ultrasound to measure persisting pregnancies, wouldn't you agree that based on the methodology that you describe in your literature review, the results of the Swahn

study are particularly helpful for evaluating embryo survival?

A. Based that we -- since we did not include it, I would have to go back and review the study more carefully to see what the flaws were that we found that caused us to not include it.

Q. Well, we looked a moment ago at your study -- your study statement on the flaws, and it said that it didn't delineate how many surviving embryos were in the group using mifepristone as a single agent, when we just looked at table 3 and it does.

A. We're just -- you're picking passages and tables out, and so that can be fraught with danger.

Q. Okay.

A. So I'm not going to give an opinion based on just what you're pointing out to me.

Q. Will you agree with me that this study does identify and clearly delineate how many surviving embryos were in the group using mifepristone as a single agent?

A. I would say that that's what

that passage that you've highlighted says. But, again, I don't know what the rest of the study says at this point in time.

Q. Okay. If that passage is what we think it is, and if the chart -- the table at table 3 shows, frankly, the number of surviving pregnancies, if those hold up, would you agree that it appears that you have excluded from the literature review one study that ought to have been included?

A. I think that would be a premature conclusion just based on those series of suppositions.

Q. I'm asking you to assume the truth of the suppositions. You're allowed to go back later and figure out if you disagree with them. But assuming the truth of those suppositions, does it appear that you have improperly excluded from the literature review something that fell within your inclusion criteria?

MS. DAVIS: Objection.

THE WITNESS: I would say if the -- on further review of the study, if it appeared to have met our criteria for inclusion

but we excluded it, then that would have been an erroneous exclusion.

BY MR. BECK:

Q. And at least as we're going through it now with the short passages we've looked at, it appears it was improperly excluded, correct?

A. I'm saying I can't draw that conclusion. Perhaps you can, but I can't.

Q. Well, but we -- the study did use ultrasound, correct?

A. Yes.

Q. It used ultrasound to evaluate cardiac activity for ongoing pregnancies, correct?

A. That's what they state.

Q. It broke out the exact number of patients that fell into the mifepristone only group, correct?

A. Yes.

Q. And it distinguished within that group of mifepristone only patients incomplete abortion, ongoing pregnancy, and complete abortion, correct?

A. Well, it characterized one not

as ongoing pregnancy, but as failures.

Q. Right. And it -- with failures, it talked about the use of ultrasound and specifically distinguished other studies that didn't use ultrasound to explain why its failure were so high and its incomplete abortions were so low, correct?

A. That's not what the highlighted passage says.

Q. Well, let's look back at the highlighted passage. "In contrast to a previous study by Kovacs in which 11 of 14 unsuccessfully treated women were classified as incomplete abortion, there were only two such diagnoses in the present investigation. This difference may be ascribed to systematic use of ultrasound examination in the present work."

So they are saying, our use of ultrasound allowed us to determine whether or not these were ongoing pregnancies as opposed to incomplete abortions, correct?

MS. DAVIS: Objection.

THE WITNESS: That's your interpretation. I think -- again, I can't make a determination based on these -- and there's no

use of the world failure in that paragraph, either, as there is in that table. So I would not draw a conclusion based --

BY MR. BECK:

Q. Do you have a better interpretation of that paragraph?

MS. DAVIS: Objection.

THE WITNESS: I -- my conclusion is that this study needs to be examined more carefully.

BY MR. BECK:

Q. Okay. If -- so let's assume that this study did, in fact, evaluate and distinguish between ongoing pregnancies and incomplete abortions through the use of ultrasound. Let's -- let's -- actually, let's turn to -- that table reflects a percentage of ongoing pregnancies, correct, table 3, failures? What percent of patients -- in what percent of patients did mifepristone fail, according to this study?

A. So what they're categorizing as, quote, failures is 36 percent in group A.

Q. And they're -- sorry, go ahead.

A. 31 percent in group B, 40 percent in group C, all three 36 percent.

Q. But group A is the mifepristone only group, right?

A. That's correct.

Q. 36 percent is higher than the 25 percent figure you cited as your historical control, correct?

A. That's correct.

Q. And if this study ought to have been included, it would skew higher your historical control, correct?

A. Not necessarily. There are -- there was a range of -- of different survivals. This is on the high end for sure.

Q. Is it possible that your literature review appears to have excluded a study that ought to have been included?

A. It's possible.

Q. And that study has a 36 percent failure rate?

A. That's what it says in the table.

Q. And 36 percent is higher than the 25 percent that served as your historical

control, correct?

A. That's correct.

Q. Was the literature review subject to peer review in "Issues in Law & Medicine"?

A. Yes.

Q. Did any reviewer ever point out that the Swahn study doesn't seem to say what your literature review said about it?

A. I don't recall.

Q. If someone had pointed that out, would you have made a change?

A. I'm sure we would have.

MR. BECK: Let's introduce Tab R, please. And we can mark Tab R as Exhibit 35.

(Whereupon, the document was marked as Exhibit No. 35 to the testimony of the witness.)

BY MR. BECK:

Q. Let me know when you have it. Do you have that available?

A. I have it, yes.

Q. Great. Exhibit 35 is a study by Zheng, Z-H-E-N-G, et al., or not et al., just Zheng, called, "RU486 (Mifepristone): Clinical

Trials in China." You addressed this study in your literature review and excluded it from the studies that you reviewed, correct?

A. Yes.

Q. If we could turn to page 20, in the top right corner?

A. Okay.

Q. It breaks down the efficacy of the treatment into three categories: Complete abortion, incomplete abortion, and persisting pregnancy, correct?

A. That's correct.

Q. And you excluded this study from the literature review, right?

A. Right.

Q. Let's look at page 11 of the literature review for your basis for that. So in the last paragraph on page 11 -- are you there?

A. Not there, sir. I'll just go to the tab. Okay. Page 11.

Q. So starting at the third sentence, it states, "Ultrasound was not used at the end of the study to determine persisting pregnancies. Only clinical and HCG criteria we

used, the criteria for persisting pregnancy being the absence of expulsion of the conceptus and gradual increase in serum and urine HCG."

Other than throwing an additional the there, did I read correctly?

A. Yes.

Q. Okay. It seems, though, that you left off one of Zheng's criteria. So if we look back at the Zheng study at page 20. In addition to using expulsion of the conceptus and gradual increase in HCG, it also considered the size of the uterus, correct?

A. Yes. But I think we did mention clinical findings.

Q. Right. Although, it does not mention in your summary the fact that Zheng used the size of the uterus, correct?

A. Size of uterus is -- can be categorized under clinical findings.

Q. And that may be. But you didn't set it out specifically, correct?

A. Correct.

Q. What was the maximum gestational age in the Zheng study?

A. I'd have to look at the table.

Q. You can go ahead and do that.
A. Let's see. Looks like this table 1 lists up to 49 weeks -- 49 days, excuse me, 7 weeks.
Q. A clinician can't externally palpate the size of the uterus at 7 weeks and earlier, correct?
A. That would be -- most clinicians would not be able to.
Q. You would either need ultrasound or you'd need to perform a bimanual exam, correct?
A. Yes.
Q. How is a bimanual exam to assess uterine size performed?
A. Can you repeat that question, please?
Q. Can you describe, please, how a bimanual exam to assess uterine size would be performed?
A. The exam, if it's a right hand dominant examiner, the left hand is placed on the lower abdomen. The index and the middle fingers of the dominant right hand are placed into the vagina until the cervix is palpated.

And then the fingers are placed behind the cervix in what's called the posterior fornix. And then the left hand and the two fingers of the right hand are drawn together in order to feel the uterus between the two hands.
Q. And so it's invasive like a pelvic exam. It involves insertion of the practitioner's digits inside the woman's vagina, correct?
A. That's correct.
Q. And it's less accurate than ultrasound?
A. Yes.
Q. This study doesn't specify how the researchers measured the size of the uterus to assess continuing pregnancy, does it?
A. I am not sure.
Q. Well, do you see anywhere in the persisting pregnancy bullet that we were looking at earlier something that indicates how they measured the size of the uterus?
A. No.
Q. And the researchers had access to ultrasound, correct?
A. Yes, I believe so.

Q. And, in fact, in the bullet above that it says ultrasonic findings, correct -- ultrasonographic findings, correct?
A. Right.
Q. So if the study doesn't specify how they assess uterine size, and if a bimanual exam is more invasive and less accurate than ultrasound, why would one assume that they measured uterine size by bimanual exam?
A. Perhaps that wouldn't be a good assumption, but that doesn't really affect why this study was excluded. The reason it was excluded is because they had criteria for persisting pregnancy that were not indicative of embryo survival.
Q. Well, actually, what you say in your literature review is, "Ultrasound was not used at the end of the study to determine persisting pregnancies. Only clinical and HCG criteria were used. The criteria for persisting pregnancy being absence of the expulsion of the conceptus and gradual increase in serum and urine HCG."
And as we've been discussing, there was an additional factor, correct?

A. But those two in and of themselves are not adequate criteria for confirming continued viability of the pregnancy.
Q. Well, actually --
A. The conceptus and gradual rise in HCG.
Q. That's fine. I actually want to focus on the item that you didn't discuss rather than the ones you did.
So the one you didn't discuss is the size of the uterus, correct?
A. I believe so.
Q. And you mentioned earlier in the use of ultrasound discussion that measurement of the size of the uterus is one of the ways researchers would evaluate ongoing pregnancies, correct?
A. No. I said measurement of the size of the embryo.
Q. Well, when you put an ultrasound on the woman's body, you measure -- that -- the size of the embryo is what you're measuring?
A. You measure the embryo when you're -- when you're doing a first trimester

obstetrical ultrasound. It's typically -- typically, the uterus is not measured. It's the -- what's inside the uterus that's measured.

Q. So let me ask you this, Doctor. If you had access to ultrasound and you wanted to measure the size of the pregnancy before seven weeks, would you use ultrasound or would you use a bimanual exam?

A. I would use ultrasound.

Q. Can we rule out that these researchers used ultrasound?

A. Can we rule out they used ultrasound, no.

Q. Might someone looking at this study based on what we've been discussing think that it was at least a possibility these researchers used ultrasound to measure ongoing pregnancy?

A. I would say that's a possibility, yes.

Q. And it might be a reasonable conclusion?

A. Yes.

Q. What is the total rate of persisting pregnancy for patients in this study

using -- for those using mifepristone alone? Do you remember?

A. No, I don't.

Q. Let's look at page 21, table 4.

A. Okay.

Q. So you see the totals at the bottom and persisting pregnancy number at the right. What's the total percentage for persisting pregnancies as reflected in this study?

A. For RU486 alone is 46.3.

Q. Which is nearly double the 25 percent survival rate you relied upon for your historical control, correct?

A. Yes. But this study was not considered reliable for the -- for the aforementioned reasons.

Q. Yep.

MR. BECK: Can we have Tab V, which we can mark as Exhibit 36.

(Whereupon, the document was marked as Exhibit No. 36 to the testimony of the witness.)

MS. CHAN: Sorry, tab --

sorry. Tab V as in Victor?

MR. BECK: Yes.

MS. CHAN: Sorry, was that yes? I think you cut out.

MR. BECK: I'm sorry. Yes. I think actually -- you know what? Can we take a five minute break? I think actually -- you know what? That's -- we're nearing Dr. Delgado's lunch time. And now might be a good time for a quick break, or at least a break for him to have lunch.

MS. DAVIS: Does that work for you, Dr. Delgado?

THE WITNESS: Sure.

VIDEOGRAPHER: Off the record -- I'm sorry. Go ahead.

MR. BECK: No. Let's go off the record.

VIDEOGRAPHER: Off the record at 1:44.

(A recess was taken.)

VIDEOGRAPHER: We are back on the record at 2:16.

BY MR. BECK:

Q. Hi, Dr. Delgado. Did you

confer with counsel from the attorney general's office during the break?

A. No.

Q. So an article was left -- or an exhibit was left in the chat. Did you get a chance to open that one yet?

A. It was V?

Q. Yep.

A. No. Now it's open.

Q. Great.

MR. BECK: So we can mark that as -- I think -- has it already been marked as Exhibit 36, I think. If not, can we mark that one as 36?

BY MR. BECK:

Q. Do you have that one open?

A. Yes.

Q. Okay. Exhibit 36 is a chapter from a book entitled, "How to Report Statistics in Medicine: Annotated Guidelines for Authors, Editors, and Reviewers," by Lang and Secic, et al.

Have you seen this document before?

A. No.

Q. Okay. Can you turn to sort of the first page after the cover page, which is page 37.

A. Yes.

Q. Can you read that second paragraph that begins with, "A confidence interval," aloud?

A. "A confidence interval is the range of values consistent with the data that is believed to encompass the actual or true population value. This true population value is usually unknowable, but it does exist and can be estimated from an appropriately drawn sample. Confidence intervals around population estimates provide a sense of how good or precise the estimate is. Wider confidence intervals indicate lesser precision, and narrower intervals indicate greater precision."

Q. Do you agree with the statement you just read?

A. Yes.

Q. Okay. Your 28 case series said that you selected a 25 percent embryo or fetus survival rate if mifepristone alone is administered as a control because it is at the

upper range of mifepristone survival rates and close to the 23 percent survival rate of one of the early studies that used a single 200 milligram dose that was currently favored for medical abortions.

So you identified only a point estimate with that 25 percent, not a confidence interval, correct?

A. That's correct.

Q. Why?

A. Simply because it would -- it would facilitate comparisons to have a 1 value.

Q. Did you consider doing a comparison to the confidence interval?

A. I don't believe so.

Q. The early study you reference in that -- in your 2018 case series is the Maria study that we were talking about earlier, the one with the 200 milligram dose?

A. Right.

Q. And if we could look quickly at your 2017 literature review at the table at pages 14 to 15.

A. Okay.

Q. On page 15 Maria -- the Maria

study in question, it's three from the bottom. What's the confidence interval shown for that study?

A. 10.6 to 42.7.

Q. That's quite a large range for a confidence interval, correct?

A. I've seen larger.

Q. Would you agree with me that that is a large range for a confidence interval?

A. I think right now I wouldn't speculate on if I would classify that as large or not.

Q. It's much smaller than the range of the confidence interval in your 2018 case series, correct?

A. Which -- which confidence interval are you talking about?

Q. In your 2018 case series, your confidence interval for all groups was between 44 and -- 0.44 and 0.52, so a much narrower range because you had a much larger group --

A. Right.

Q. -- population, correct?

A. Right. Correct.

Q. And the Maria study, which

only had 30 patients, had a much larger confidence interval, correct?

A. Yes, it did.

Q. And so, you know, if we look back at the passage you just read from the -- from the How to Report Statistics in Medicine book, wider confidence intervals indicate lesser precision, and narrower confidence intervals indicate greater precision --

A. That's correct.

Q. -- correct?

And so because we have only a 30 point -- 30 person study in the Maria study we have a very large confidence interval because it's hard to draw conclusions from a study of 30 people. Do you agree with that?

A. It's harder, yes.

Q. Yeah. So you have your -- let's see. Tab F is your 2018 case series. Can you open that one up?

A. Okay.

Q. And if you look at page 27 just to confirm what I mentioned earlier, your confidence interval is 44 percent to 52 percent for all groups, correct?

A. That's correct.

Q. That 42 -- 44 percent at the lower end of your confidence interval, that overlaps if we look at your 2017 literature review with the upper bounds of the confidence interval of many of the studies listed here. Would you agree with that? Why don't you look at the literature review?

A. There is some overlap.

Q. I count seven of the early mifepristone studies where the confidence interval, the upper bound of the confidence interval for the early studies is higher than the lower bound of the confidence interval for your study. Do you want to check my math on that?

A. Could you hold on one second? Someone's knocking on the door. Sorry. Sorry about that.

Okay. Let me go back here. I count seven.

Q. So there are seven of your included studies in which the upper bound of the confidence interval overlaps with the lower bound of the confidence interval in -- for all

groups in your 2018 case series, correct?

A. That's correct.

MR. BECK: Okay. Can we mark -- introduce into the chat Tab W?

BY MR. BECK:

Q. Let me know when you have Tab W open, Doctor.

MR. BECK: And we can mark Tab W as Exhibit 37.

(Whereupon, the document was marked as Exhibit No. 37 to the testimony of the witness.)

THE WITNESS: It's open.

BY MR. BECK:

Q. Great. So if you could turn to the second page -- sorry, let me just quickly. This is a piece by Frederick Dorey called, "In Brief: Statistics in Brief. Confidence Intervals. What is the Real Result in the Target Population?"

Have you -- published in Clinical Orthopaedics.

A. No.

Q. No. Where is this published?

A. Oh. No, it is published --

yeah. I thought you said did I.

Q. No. No, you did not publish this. Have you seen this article before?

A. No.

Q. Okay. Can you turn to page -- the second page?

A. Okay.

Q. And in the conclusion, could you read the sentence beginning with, "The confidence interval takes into account"?

A. "The confidence interval takes into account possible differences in the sample sizes of the papers involved."

Q. Sorry. And go on to the next sentence, too, please.

A. "If there is considerable overlap in the confidence intervals with different studies, it becomes clear despite possible differences in the point estimates the results may not really differ much."

Q. May not really differ very much?

A. Sorry, differ very much.

Q. So the author here is saying that when comparing multiple data sets, an

investigator should look at the confidence intervals to accurately determine the difference between them; is that correct?

A. That's right.

Q. And that looking at just the point values can lead a researcher to overestimate the difference between the two data sets, correct?

A. That's correct.

Q. And so, therefore, potentially it can overstate the efficacy of a given treatment, correct?

A. That's possible.

Q. And do you agree with the principle set forth in the paragraph you just read?

A. Yes.

Q. Would you say that your assessment of the difference in the two treatment -- two treatment populations, which looks just at point estimates, is a better way of analyzing it than looking at the confidence intervals?

A. I would say that it's also important to look at P values that show

statistical significance, and ours showed that. And, also, you're looking at the all comers in our study. However, if you look at the -- the groups that are -- more are -- represent the real world treatment these days, those would be the high dose oral progesterone group and the -- and some people still use an injection group. Those have much higher rates of -- of reversal, and much less overlap in the confidence intervals.

Q. But there's still overlap between even the high dose oral groups, the lower bound of your confidence interval there, and some of the early mifepristone studies, correct?

A. There's some.

Q. And so, again, according to the text we just looked at, without looking at a confidence interval as opposed -- when you don't look at the confidence interval, it is possible to overstate and overestimate the efficacy of a treatment, correct?

A. Correct.

Q. And do you think that that's a possibility here?

A. It's a possibility.

Q. Okay. Let's talk about Dr. Creinin's study. In your declaration, if you want to pull that up, which is Tab C, Exhibit 26 -- no, wrong one. Tab E, Exhibit 22.

A. Okay. I have it.

Q. At paragraph 25 you state that Dr. Creinin, quote, Unsuccessfully undertook the first randomized controlled trial of abortion pill reversal, correct?

A. That's correct.

MR. BECK: Okay. So can we introduce that study into the chat, which has previously been marked as Plaintiff's Exhibit 16?

BY MR. BECK:

Q. And while we're waiting for it to download. Doctor, this study was published in the Journal of Obstetricians and -- Obstetrics and Gynecology. Does that sound consistent with your memory?

A. Yes.

Q. And that's also known as the Green Journal?

A. Yes.

Q. And is the Green Journal considered a reliable authority in the medical profession?

A. For the most part.

Q. Do you have it open?

A. Yes.

Q. Great. Will you turn to page 5, please.

A. Okay. I'm there.

Q. And will you read the second paragraph under discussion aloud?

A. "Second and most important are the lessons about treatment safety. Providing treatment in any medical situation requires a full understanding of the potential benefits and risks. Previous case series reports do not describe outcomes for the one-third or more patients without continuing pregnancies after progesterone treatment." Continue?

Q. Please.

A. "3 of 12 patients enrolled experienced very heavy bleeding resulting in ambulance transport to emergency department, a rate higher than reported with medical abortion in which 0.6 percent of patients have emergency

department visits. Patients who use mifepristone for a medical abortion should be advised that not using misoprostol could result in severe hemorrhage, even with progesterone treatment. We stopped the study because of these complications and, thus, could not quantify the full extent of this risk. Because of the potential dangers for patients who opt not to use misoprostol after mifepristone ingestion, any mifepristone antagonization treatment must be considered experimental."

Q. Thanks. So the study authors here characterize three patients as having very heavy bleeding resulting in ambulance transport to an emergency department, correct?

A. That's correct.

Q. And one -- that included one patient in the progesterone group and two in the placebo group?

A. Correct. And the one in the progesterone group went to the emergency department, but did not require further care. She just had a failed reversal and, therefore, really didn't need to be in the emergency department.

Q. Let's talk about that a little more. Let's look at page 3. The last paragraph on that page, the study describes that patient who had progesterone and went to the hospital. And it describes her as experiencing brisk bleeding in the middle of the paragraph, correct?

A. That's correct.

Q. And then later on in that paragraph it says, "She had heavy bleeding that lasted about three hours," correct?

A. That's correct.

Q. And that happened at the hospital after she called an ambulance, correct?

A. Correct.

Q. Although, she ultimately didn't need a blood transfusion or other intervention at the hospital, right?

A. That's correct.

Q. And in the paragraph that you just read a moment ago, the authors include this patient as among the three who experienced very heavy bleeding resulting in ambulance transport to an emergency department, correct?

A. Correct.

Q. And so by the author's own description, this patient's bleeding was very heavy, correct?

A. The author's own description seems to be contradictory. In one place he calls it brisk, in another one heavy, in another one very heavy.

Q. If -- isn't another reading of this that brisk bleeding, very heavy bleeding, and heavy bleeding are all synonymous for -- for purposes of the study and that it amounts to the patient experiencing hemorrhage?

A. That seems to be an imprecise use of language.

Q. Is that a potential interpretation of this author's language that doesn't lead to the inconsistency you just pointed out?

A. That's a potential interpretation, sure.

Q. And might that be a reasonable interpretation?

A. That those three terms are synonymous?

Q. Correct.

A. I -- I think -- I think it's a risky interpretation.

Q. What's the difference between heavy bleeding and hemorrhage, in your mind?

A. Hemorrhage is the medical term for bleeding. So heavy bleeding would be heavy hemorrhage.

Q. And the authors describe the patient who received progesterone as having heavy bleeding that lasted three hours. So that would be heavy hemorrhage that lasted three hours, correct?

A. Presumably.

Q. You would agree with me that a patient can experience heavy bleeding lasting three hours that falls short of a blood transfusion, correct? Falls short of requiring a blood transfusion?

A. Yes. That probably happens very frequently with women who undergo medical abortions, including those who take misoprostol.

Q. Is it your opinion that that happens frequently for patients before they even take misoprostol? In other words, is it your opinion that very heavy bleeding after taking

mifepristone alone is common?

A. I'm not sure.

Q. Do you have any evidence that you would point to suggesting that very heavy bleeding after taking mifepristone alone is common?

A. I do not.

Q. And so if there isn't such evidence, then what this patient experienced after taking mifepristone alone, very heavy bleeding for three hours, would be an uncommon product of taking mifepristone, correct?

A. In my mind, I don't know if she had very heavy bleeding, heavy bleeding, or brisk bleeding because of the three different terms used by the author. And I -- what I can see is that she did not require any intervention at all. She simply completed her medical abortion.

Q. Well, the author's term is "heavy bleeding." So let's stick with what the author says. And I'd like to ask the question again.

A. The author uses heavy bleeding, but like you pointed out, also uses

brisk bleeding and also uses very heavy bleeding. Are you going to pick -- choose one at a time or --

Q. Yeah. Let's stick with heavy bleeding for now.

A. Okay.

Q. Which is the author's term, which you've said is synonymous with heavy hemorrhage.

You would agree with me that heavy bleeding for three hours could be an adverse event, correct?

A. Potentially.

Q. If you were conducting a study and a patient experienced heavy hemorrhage resulting in ambulance transport to a hospital emergency department, but the patient didn't ultimately require a blood transfusion, would you treat that as an adverse event?

A. If the patient did not require any intervention, then I would be -- that would not necessarily be an adverse event.

Q. You would not regard heavy bleeding resulting in ambulance transfer to a hospital emergency department after taking

mifepristone alone as a heavy -- as an adverse event?

A. Well, you're -- you're saying there was -- ambulance transport was required. That's not what's stated here. It's that she called the ambulance. So it's very likely that she got scared because maybe she wasn't instructed on what to expect, not that ambulance transport was required. Because no intervention -- no medical intervention was required.

Q. But you just said that you can -- you could have heavy bleeding that could be an adverse event and, yet, that falls short of requiring a blood transfusion, correct?

A. I didn't call it an adverse event. You did. I said you could have heavy bleeding and not require transfusion or other medical intervention.

Q. And you wouldn't consider that to be an adverse event? If that happened in one of your studies, you would not consider that to be an adverse event?

A. I'd have to look at the criteria for adverse events for the particular

study I was -- I was designing.

Q. If one of your own patients experienced very heavy bleeding --

A. You are considering heavy bleeding, not very heavy bleeding, if I recall.

Q. If one of your patients experienced heavy bleeding and went to -- that lasted for three hours, would you consider that to be the normal product of -- of her course of treatment or would you consider that an adverse event for her?

A. I would consider it longer than usual. And generally we tell them two hours is what you might expect with a typical miscarriage.

Q. So it's longer than unusual, which is suggestive of something adverse happening, correct?

A. It's longer than usual, not necessarily adverse because she didn't require any medical intervention.

Q. Well, she required -- she went to an emergency room and they ultimately didn't do anything, -- they didn't have to do anything. But you think that that -- that if they didn't

have to perform a blood transfusion, then her hemorrhage did not amount to an adverse event?

A. They didn't have to perform a blood transfusion. They also did not have to perform a surgical aspiration abortion, which the other two did require. So there's a big difference in the ones who did not get the progesterone.

Q. So I just want to be clear. If this happened in your study, you would not consider this to be an adverse event in your study?

MS. DAVIS: Objection.

THE WITNESS: That's speculative and hypothetical, so hard to answer that.

BY MR. BECK:

Q. No. I actually am very curious. For your study, if a patient reported the scenario that is described here, we can use the term "heavy bleeding" for three hours, I just want to understand whether you would consider that an adverse event for your study?

MS. DAVIS: Objection.

THE WITNESS: I would not

necessarily consider it an adverse reaction.
BY MR. BECK:
Q. So let's look at Tab K, the National Academy's document that we were looking at earlier, which is Exhibit 32. Do you have that?
A. Yes.
Q. Turn to page 54. Actually, before we get there. Can you point me to any medical evidence showing that heavy bleeding lasting three hours is an ordinary consequence of a medication abortion?
A. I can't -- I can tell you I've heard many anecdotes of women in real life situations who've gone through the medical abortion procedure and have bled that long. And I would have to look and see about that, look at the literature. But I have -- am aware of many anecdotes of women who have experienced prolonged bleeding.
Q. So let me actually rephrase the question. Can you point me to any published medical evidence showing that heavy bleeding lasting three hours is the ordinary consequence of a medication abortion?

A. Not at the present time.
Q. And can you point me to any published medical evidence showing that heavy bleeding lasting three hours is the ordinary consequence of taking mifepristone alone as opposed to both drugs in the medication abortion regimen?
A. Not at the present time.
Q. Okay. So now let's look at the National Academy's report at page 54. Are you there?
A. Yes.
Q. In the first paragraph under expected side effects, the third sentence reads, "Vaginal bleeding is expected during and after an abortion and occurs in almost all patients during a medication abortion."
Did I read that correctly?
A. Yes.
Q. Turn to page 55.
A. Okay.
Q. After hemorrhage it states, "Prolonged heavy bleeding is rare, but may indicate an incomplete abortion or other complications. Hemorrhage requiring assessment

or treatment following medication abortion is also rare. The FDA advises that women contact a healthcare provider immediately if bleeding after a medication abortion soaks through two thick full size sanitary pads per hour for two consecutive hours, end quote.
So according to the National Academy, there's a distinction between expected regular vaginal bleeding and prolonged heavy bleeding, correct?
A. That's correct.
Q. Some vaginal bleeding is a regular side effect of mifepristone, whereas heavy bleeding requires immediate medical attention, correct?
A. Well, it says, "The FDA advises that women contact a healthcare provider immediately." That's right.
Q. So the answer to my question is, yes, that's correct?
A. Yes.
Q. Okay. And the FDA, as you just pointed to, focuses on heavy bleeding for two consecutive hours, correct?
A. That's correct.

Q. Do you have any reason to disagree with the FDA on that front?
A. No.
Q. How long did the progesterone patients' heavy bleeding last in the Creinin study?
A. Three hours, according to the study.
Q. And according to the National Academy, heavy bleeding for three hours after a medication abortion is hemorrhage requiring immediate medical attention, correct?
MS. DAVIS: Objection.
THE WITNESS: Can you restate that?
BY MR. BECK:
Q. Sure. According to what we just looked at in the National Academy's report, heavy bleeding for three hours after a medication abortion would count as a hemorrhage requiring immediate medical attention, correct?
A. Yes.
MS. DAVIS: Objection.
BY MR. BECK:
Q. And that's not an ordinary

side effect of mifepristone, correct?
A. I'm not sure.
Q. Not according to the FDA and according to the National Academies at least, right?
A. Not according to this article.
Q. By the National Academies?
A. Right.
Q. Which cites the FDA, correct?
A. Well, it cites a study by Upadhyay, et al.
Q. Well, it also references the fact that the FDA states that if patients have heavy bleeding soaking through a number of pads lasting for two hours, that they should contact a healthcare provider immediately, correct?
A. That's correct.
Q. Okay. And so according to the FDA, what the -- what the patient in the Creinin study experienced is beyond the ordinary course that one would expect after a medication abortion, correct?
MS. DAVIS: Objection.
THE WITNESS: I don't think that's what the -- the FDA is saying is that --

that women should have contacted a medical provider.
BY MR. BECK:
Q. Would you contact a medical provider if you were having the ordinary effects of a medication as opposed to something out of the ordinary?
A. Usually not.
Q. You usually are supposed to contact the healthcare provider when something is going wrong, correct?
A. When something's out of the ordinary.
Q. And the FDA and the National Academy use two hours of heavy bleeding as a proxy for out of the ordinary hemorrhaging, correct?
A. That's correct.
Q. And this patient in the Creinin study who had progesterone had three hours of heavy bleeding, correct?
A. That's correct.
Q. And so according to the criteria established or set forth in the National Academy and the FDA, her hemorrhaging

was out of the ordinary, correct?
MS. DAVIS: Objection.
THE WITNESS: That could be an interpretation, yes.
BY MR. BECK:
Q. Would it be a reasonable interpretation?
A. Yes.
Q. Doesn't it appear that the authors of the Creinin study regarded this patient's outcome as something different from the expected consequence of a medication abortion?
A. It appears that's the message they were trying to portray.
Q. Would you agree with me that the doctors conducting the study would be in the best position to know whether this patient's heavy bleeding was on the ordinary side of the spectrum or an adverse event?
MS. DAVIS: Objection.
THE WITNESS: Yes.
BY MR. BECK:
Q. Let's look at paragraph 32 of your declaration. Actually, before we do. Do

abortion pill rescue patients have to agree that they will seek emergency care if they experience heavy bleeding?
A. They're instructed to seek medical care if they're experiencing heavy bleeding.
Q. And if nurses -- those nurses who answer the abortion pill rescue hotline, if the patient says she's experiencing heavy bleeding, do they tell her to seek emergency treatment?
A. To my knowledge, yes.
Q. And are patients told to call their provider also or just to seek emergency treatment?
A. I guess you should define what you mean by emergency treatment.
Q. Contact an emergency department or call an ambulance, I guess, is what I mean by it.
A. Well, they're instructed to seek medical care. For some women, that means contacting their medical provider. For others, it means going to the emergency department. And for others, it might be calling an ambulance.

It all depends on the severity of it or -- and of the availability if she has a physician already -- a relationship with a physician already.

Q. So let's assume that your forms say emergency care, because I've seen some forms and I believe that's what they say. Would you call -- would you -- would you include just sort of contacting your physician as a form of emergency care or would you say emergency care means go to the hospital emergency department?

A. I would have to look at the form to make that determination.

Q. Well, let's -- let's work with the phrase "emergency care." What do you understand the phrase "emergency care" to mean?

A. Emergency care means care that's delivered right away. So that would mean if you can get someone on the phone right away to get further direction that would be adequate. But if that's -- if that's not possible, then it would mean going to an emergency department.

Q. And so are patients told to call the -- patients who go to the emergency room are they told to call -- let me start over.

Patients in the abortion pill rescue program who go to the emergency room, are they told to also call their healthcare provider or just go to the emergency room?

A. I don't know.

Q. So would you know if they sought emergency treatment?

A. You mean if they were a patient that I were caring for directly?

Q. No. I guess I mean, would the abortion pill rescue program know if a patient when to the emergency room?

A. I would suppose they would know. But I can't answer -- I can't answer for them.

Q. They might not?

A. I don't know. I would be speculating.

Q. Okay. So let's look back at -- at paragraph 32 of your declaration.

A. Okay.

Q. So it says, "In summary, the Creinin study safety results were: Two patients required suction aspiration. Both from in the placebo group. The single patient in the

progesterone group that went to the emergency department simply represented a reversal failure and did not need to be in the emergency department, since she required no intervention. The patient requiring transfusion was in the placebo group. Therefore, it was placebo, not the progesterone therapy that was unsafe. Mifepristone alone for abortion was unsafe in study. Attempting reversal was not proven to be unsafe."

Did I read that correctly?

A. Yes.

Q. Okay. You'd agree with me that this summary is different from the Creinin's study's own descriptions of its safety findings, correct?

A. Yes.

Q. And so a reader looking at paragraph 32 should know that this is your interpretation of the Creinin study's safety results, but not how the study itself describes those results, correct?

A. Well, this paragraph states the facts of the study, and -- and then the last three bullet points are interpretation.

Q. Well, the -- the authors of the Creinin study thought that the patient in the progesterone group who hemorrhaged experienced an adverse event, correct?

A. I don't think they stated that.

Q. They collectively refer to three patients experiencing very heavy bleeding requiring trips to the emergency room department, which is why they aborted their study, correct?

A. Right.

Q. They --

A. Brisk bleeding and heavy bleeding in another part.

Q. Right. But they lumped those three patients together as the cause of pulling the plug on the study, correct?

A. Yes. With the -- the final straw being the one who required transfusion.

Q. And so turning back to your declaration, the final three bullet points at minimum are interpretation. And, in fact, this is sort of your interpretation of the study in general, not the author's own description of

their findings, correct?

A. Well, I would say the author would probably agree with the mifepristone alone for abortion was unsafe in this study. In fact, I think he may even state that in other words.

Q. Right. You don't disagree with that, right? On that point you and Dr. Creinin agree, correct?

A. Correct.

Q. Right. The Creinin study states, "Patients in early pregnancy who use only mifepristone may be at high risk of significant hemorrhage." That's his words. You don't disagree with that, correct?

A. Correct.

Q. But in terms of your attribution to the placebo as the source of hemorrhage, there seems to be a disagreement between you and Dr. Creinin, correct?

A. I wouldn't say the placebo was the cause of hemorrhage.

Q. When you say, "Therefore, it was the placebo, not the progesterone therapy that was unsafe," what do you mean by that?

A. That those who did not receive

progesterone were the ones who -- or were in the unsafe group, not the progesterone therapy group.

Q. Well, two who didn't receive progesterone and one who did experienced hemorrhage?

A. Right. And the two in the placebo group had significantly -- were -- were significantly more risk because one of them required transfusion. The -- and both of them required suction aspiration.

One in the placebo group required no treatment at all and did not require it. So -- so there's no treatment, not even the suction aspiration. So she actually completed her abortion without needing any intervention at all, as opposed to the other two that required significant intervention.

Q. Well, but all three experienced what the National Academies refer to as hemorrhage requiring medical attention, correct?

A. That's correct.

Q. And the authors don't attribute that to -- the harm to the placebo

causing that adverse event. They say, like you said a moment ago, stop -- taking mifepristone and not taking misoprostol can cause hemorrhage. And you and Dr. Creinin seem to agree on that, correct?

MS. DAVIS: Objection.

THE WITNESS: I agree that taking mifepristone alone without following it by progesterone or misoprostol increased the risk of hemorrhage.

BY MR. BECK:

Q. Why would progesterone cause the abortion to complete for that progesterone patient?

A. It did not cause the abortion to complete.

Q. Why would progesterone -- why do you -- why would you conclude that progesterone made the progesterone patients' experience safer than the two placebo patients?

A. Well, in this study, if you just look at this study, the five remaining patients who are in the progesterone group, none of them required suction aspiration. None of them required transfusions. None of them had

heavy bleeding requiring intervention.

Q. Right. But the one who did, why would the progesterone -- why would you conclude that the progesterone made her experience safer than the placebo patients?

A. Well, just comparing her to the other two, she did not require any intervention while the other two required extensive intervention.

Q. But why would progesterone cause that? What -- what's your medical therapy for why progesterone is sort of the safety valve for that patient?

A. Well, that would simply be speculation in this individual case, of course. We know that progesterone stabilizes the lining of the uterus. And we know that the effects of the mifepristone, although not totally reversed because the embryo didn't survive, there was probably still some antagonism of the mifepristone. And so all of that could have led to less bleeding and the -- and less complications than the other ones.

Q. But she experienced heavy bleeding lasting three hours and the -- and the

abortion was completed. That doesn't sound like stabilizing the lining of the uterus to me. Does it sound like stabilizing the lining of the uterus happened here to you?

A. You know, we don't know in this -- in this particular case what exactly happened without being able to microscopically look inside what was going on. So that's why I told you it was just speculation in this particular patient.

Q. At paragraph 42 of your declaration?

A. I'm there.

Q. You say, "It is unethical to subject an embryo or fetus to the double jeopardy of mifepristone abortion, followed by a surgical abortion, if the mifepristone abortion is reversed."

So just to be clear, that's what Dr. Creinin was attempting to do in his study, correct?

A. That's correct.

Q. What do you mean by saying that it would be unethical to subject an embryo to double jeopardy?

MS. DAVIS: Objection.

THE WITNESS: You have a subject of a study, the embryo or the fetus, who does not give consent to the study, number one. Number two, it's put in the undignified position of being exposed to a potentially lethal medication. And then, if that lethality is not accomplished, then a surgical lethal procedure is then performed on that embryo or fetus.

BY MR. BECK:

Q. So is that -- is another way of looking at this just sort of a summary of your view that all abortion is unethical?

A. I think ending of the life of an innocent person is unethical. And it's doubly unethical to subject a person to a double lethal jeopardy.

Q. Why is that doubly -- I mean, why is -- why is doing that more unethical than just performing an abortion in the first place?

A. Like I stated before, this subject is unable to give informed consent. And you're subjecting that subject to two trials of extermination.

Q. If a woman had a medication

abortion that doesn't work and she follows it up with a surgical abortion, is that doubly unethical?

A. That is different than a study that is designed from the onset to provide a situation of double jeopardy, as opposed to a woman who undergoes a medical abortion thinking that this is the -- the one protocol or procedure she'll undergo to effect that abortion. Those are not good analogous situations.

Q. But she would be told in advance there's a chance that the medication won't work, right? We know that medication abortion has a failure rate?

A. Correct.

Q. And so she goes into it and the doctor goes into it knowing some small percentage of the time, a surgical intervention is going to be required, correct?

A. She's probably told that, yes.

Q. And so is that -- in -- in that subset when that happens, is that especially unethical because it's sort of subjecting the fetus to double jeopardy again?

A. Again, I don't -- I don't -- I don't see the connection with my previous statement. Because her intention is and her expectation that the medical abortion will be successful in terminating the pregnancy.

Q. All right. But just to be clear, you do believe that all abortions are unethical, correct?

A. All direct abortions, yes.

Q. What do you mean by direct abortions?

A. When the intent is to end the life of the pre-born baby.

Q. What would be an example of an indirect abortion?

A. An indirect abortion would be a woman who has a tubal pregnancy and the tube is removed in order to save the life of the mother. One action has two effects. First effect is saving the life of the mother. The second effect is ending the life of the embryo. And so that would be an indirect abortion that would be considered ethically appropriate by the principle of double effect.

Q. So all direct abortions are

unethical?
A. Yes.
Q. Switching gears for a second. Were any of the patients in your 2018 case series patients that you treated personally?
A. Yes.
Q. How many?
A. I don't recall the exact number.
Q. Could you give me a ballpark estimate?
A. Five to ten.
Q. What about Dr. Davenport, your co-author, were any of the patients in the 2018 case series patients of Dr. Davenport's?
A. I believe so.
Q. Do you have a ballpark estimate of how many?
A. No, I don't.
Q. Were the patients that you personally cared for, were they treated before or after you had it in mind to publish what would become the 2018 case series?
MS. DAVIS: Objection.
THE WITNESS: I don't recall.

BY MR. BECK:
Q. Did you care for any patients after you planned to publish the case -- the case series?
A. I don't recall.
Q. Is it possible?
A. I'm not sure. I -- I'd be speculating.
Q. It sounds like it's possible, but you just don't know?
A. That's a fair characterization.
Q. Okay. Your declaration at paragraph 20, are you there?
A. I'm getting to it. There -- I'm there.
Q. You state that your 2018 case series evaluated 261 successful mifepristone reversals that resulted in live births, correct?
A. That's right.
Q. So before we get into the details of that study, the 261 figure is the total number of births in that study population, correct?
A. That's right.

Q. And we agreed earlier that mifepristone alone does not always result in an abortion, correct?
A. That's right.
Q. And as we've discussed, your study used a historical control -- as a historical control an assumption of a 25 embryotic survival rate for mifepristone, correct?
A. That's correct.
Q. So some percentage of those 261 births would have happened whether or not the patient took progesterone at all, correct?
A. That's correct.
Q. It would only be if mifepristone --
A. Excuse me. Let me back up on that. That is not necessarily correct. So we don't know the number. Because in the early mifepristone studies, they only followed them out to 7 or 14 days. So we really don't know what percentage that would have gone on to actually be born.
Q. Well, you assumed as a historical control a 25 percent survival rate,

correct?
A. Correct.
Q. That's the whole point of your comparison, correct?
A. That's correct.
Q. And so are you -- so the premise of your study is that 25 percent of those pregnancies would have survived irrespective of progesterone intervention, correct?
A. That was the control we used, yes.
Q. And only if mifepristone resulted in fetal demise or embryotic demise 100 percent of the time would you be able to claim that 261 of your cases are successful reversals, correct?
A. Without certainty, yes.
Q. And no one thinks that mifepristone works and causes fetal demise 100 percent of the time, correct?
A. That's correct.
Q. So this statement in paragraph 20 that you had 261 successful mifepristone reversals is not exactly accurate, correct?

A. Not exactly. It -- it -- I think it conveys the point of what we're trying to say, but you're right. It's not exactly accurate in -- in the terms you're describing.

Q. Let's look at the 2018 case series. If you could turn to page 28 of that study?

A. Okay.

Q. At five weeks -- so table 2 is breakdown by gestational age, correct?

A. That's right.

Q. And at five weeks there were 76 patients with a 25 percent rate of ongoing pregnancy after progesterone, correct?

A. That's right.

Q. And 25 percent is equal to your historical control?

A. That's correct.

Q. The P value is 0.5, correct?

A. That's correct.

Q. What does a 0.5 P value mean?

A. It means that 5 out of 1,000 times the -- correction, 50 out of 100 times, that the stated result is possibly due to chance. So it means not statistically

significant.

Q. It means the result is just as likely to be attributable to chance as it is to the incident, correct?

A. That's correct.

Q. And so with respect to pregnancies at five weeks, your 2018 study doesn't give us statistically significant data on the efficacy of reversal, correct?

A. That's correct.

Q. Other than this study, do we have data establishing the efficacy of progesterone to reverse medication abortion for patients at five weeks?

A. No.

Q. Let's look at page 25 of the study.

A. Okay.

Q. Are you there?

A. Yes.

Q. In the second paragraph you state that you lost 112 subjects to follow-up prior to 20 weeks, correct?

A. That's correct.

Q. 14.9 percent of your study

population?

A. That's right.

Q. And they were excluded from the analysis in your study?

A. That's correct.

Q. Do you have any idea about what happened to those 112 women after you lost contact with them?

A. No. I -- you know, no, direct knowledge.

Q. They could have all given -- carried to term and given birth for all you know, correct?

A. They could have.

Q. Or all 112 of them could have been reversal failures, but you just don't know, correct?

A. That's possible, but unlikely.

Q. Just as unlikely as them all giving -- carrying to term and giving birth, correct?

A. Correct.

Q. And if some of them experienced heavy bleeding and hemorrhage like the three patients in Dr. Creinin's study, you

also wouldn't know about that, correct?

A. Not if they were lost to follow-up.

Q. And these 112 patients were lost to follow-up, correct?

A. That's right.

Q. And so if any of them experienced hemorrhage, you would not know about that, correct?

A. Correct.

Q. And you can't rule it out as a possibility?

A. Just like I can't rule out that they all gave birth as a possibility.

Q. Right. You just don't know?

A. You just don't know.

Q. Let's look back at Exhibit 25, which was tab A, your deposition from Arizona. And if you could turn to page 190. Let me know when you're there.

A. I'm at 190.

Q. Starting at line 6 -- well, before I do this. We've already covered this, but you were under oath that day swearing to the tell the truth, just as you have today, and as

you will in court next month, right?
A. Yes.
Q. Okay. So starting at line 6 the question states, Question, "Exhibit 23 before you is an article, 'User's Guide to Orthopedic Literature: How to Use an Article About a Randomized Trial --
A. Hold on a second.
Q. Am I at the wrong place?
A. Yeah. You said page 189 of the Arizona case?
Q. Sorry, 190 of the Arizona.
A. Okay. I'm sorry. I got that wrong. Okay. Now I see it.
Q. Okay. Do you see where I was reading?
A. Yes, Exhibit 23.
Q. Yep. I'll start over. Question, "Exhibit 23 before you is an article, 'User's guide to orthopaedic literature: How to use an article about a randomized trial?' On page 5 below the heading, 'Was follow-up complete?' states, 'During a clinical trial, investigators are interested in patients' outcome measures regardless of which group they

were assigned to. Patients with unknown data are classified as lost to follow-up. The greater the number patients lost to follow-up decreases the internal validity of a study. Data is rarely missing for trivial reasons. Subjects that are missing typically have a different prognosis than those who remain in the study. Patients could have been lost to follow-up because of an adverse outcome such as death or a very positive treatment outcome so that the patients did not return for further assessment. Incomplete follow-up biases the outcome measure.
Did I read that correctly?"
Answer, "Yes."
Question, "Do you agree with that statement?"
Answer, "Yes."
First of all, was that testimony truthful when you gave it?
A. Yes.
Q. And do you stand by it today?
A. Yes.
Q. And so you agree, in particular, that patients could have been lost

to follow-up because of an adverse outcome such as death or a very positive treatment outcome so that the patients did not return for further assessment, correct?
A. Yes. And it also could have been because the patients changed their minds and sought out surgical abortions and, therefore, did not return phone calls and other contacts that were possible.
Q. Those are also possible outcomes and ways in which your lost follow-up population might differ from your study population, correct?
A. That's correct.
Q. And you were next asked, "Do you think that the loss to follow-up in your study has, as it states here, potential to bias your results?"
And your answer was, "Any loss of follow-up has a potential to bias results."
And so, again, that testimony was truthful when you gave it, correct?
A. That's correct.
Q. And you stand by that today?
A. Yes.

Q. You were next asked whether this principal would apply to your case series, and you said, yes, right?
A. Yes.
Q. And that testimony was truthful when you gave it?
A. Yes.
Q. And you stand by it today?
A. Yes.
Q. Okay. At page 192, let me know when you're there.
A. I'm there.
Q. 192, line 1, you were asked whether it's possible that many of the women you lost contact with experienced a pregnancy loss. And your answer was, "It's possible."
And so, again, that testimony was truthful when you gave it, correct?
A. Correct.
Q. And you stand by that today?
A. Yes.
MR. BECK: Okay. Let's introduce Tab Y into the chat.
BY MR. BECK:
Q. Let me know when you have that

ready.
A. It's open, but it's upside down. Is yours upside down?
Q. It certainly is. I wonder if there is a way to flip that?
A. Let's see. If I go to view --
Q. Rotate view. So if you do rotate view a few times, we can fix that problem. Does that work for you?
A. Well, I don't see rotate view in my --
Q. For me, it's the first item that comes up under view.
A. Is show tab bar.
Q. Do you happen to have a printer in the room you're in?
A. I do, but I don't think I'm connected. Let me -- maybe I -- I can export it as a PDF and reopen it. I can try that.
Q. These are the challenges of Zoom depositions. Let me know if you're able to do that.
MS. CHAN: I just added a -- what is hopefully a rotated version of the PDF to the chat, if you want to download the latest

file and see if that worked.
THE WITNESS: Okay.
MR. BECK: Thank you. And while you're looking to see if that worked, let's mark the new version of Exhibit Y as Exhibit -- I'm sorry, the new version of Tab Y as Exhibit 38 before I forget.
(Whereupon, the document was marked as Exhibit No. 38 to the testimony of the witness.)
THE WITNESS: That one's also upside down. So I'll try -- let me see if I successfully downloaded. The downloaded is also upside down. Let's see. Oh, here's rotate. Okay. It's under tools in mine. Okay. I have it now.
BY MR. BECK:
Q. It's a miracle. Thank you for soldiering on with the upside down exhibit.
So this is another chapter from that same textbook, "How to Report Statics in Medicine," by Lang and Secic that we were looking at earlier. So let's look at page 209 of this chapter. Let me know when you're there.
A. Okay.

Q. Is it still sideways for you?
A. Well, some of them are sideways, some -- so I have to -- I had to rotate this one back. So now I'm okay.
Q. Okay. Great. At -- so are you on page 209?
A. Yes.
Q. Item 13.55, that's where I'm looking at.
A. Okay.
Q. And I just want to read that for the record. It states, "As is the case with participants whose care deviated from the protocol or who were withdrawn from the trial, patients lost to follow-up may differ systematically from those who are not, indicating potential bias."
Is -- is the statement I just read correct?
A. Yes.
Q. And I think at your 2015 deposition you said that it was appropriate to hold your study to standards like this one. Do you still think so?
A. It is.

Q. The next sentence says, "For example, participants lost to follow-up are likely to be those least satisfied with the results of the therapy."
Do you think that's a legitimate point?
A. That's a legitimate point.
Q. And in your case series, you lost contact with approximately 15 percent of the study population?
A. Yes.
Q. And, again, we don't know how many, if any, of those 112 women you lost contact with experienced an adverse event, correct?
A. That's correct.
Q. Could have been zero?
A. That's correct.
Q. It could have been a few?
A. That's correct.
Q. It could have been even 112, correct?
A. It could have been, but that seems unlikely.
Q. We don't have data to answer

the question, correct?
A. Correct.
Q. In your -- in the case series of page 29 it says, "Furthermore, although the number of women lost to follow-up was small, it could have affected the results."
So you sort of acknowledge that as one of the statements of the limitations of your study, correct?
A. That's correct.
Q. And you agree that there is a potential for bias as a result of those patients lost to follow-up?
A. Correct.
Q. When you state that the number of patients lost to follow-up was small, can you tell me why you think that 15 percent is a small number, in your opinion?
A. Well, because it's -- it's not unusual to lose, you know, somewhere in that order of patients in a -- in a trial, and especially in one of this nature that's a retrospective case study. It just -- that just -- that just can happen. And so it didn't seem to be a large -- large percentage.

The other -- the other thing to keep in mind is that because the trial was not a control trial, then there are, you know, fewer mechanisms set up to -- to try to -- in order to track them even though the efforts were very good to try to track them. Sometimes people are elusive and you just -- you can't control what they do.
So -- so that's why we felt, well, it's -- it seemed to be a small percentage, all things considered.
Q. Okay. Can you turn to the next page of the -- of Tab Y, Exhibit 38?
A. That's the one that was upside down?
Q. That is, yeah.
A. Okay. Which --
Q. Are you there?
A. Page 211 or 210?
Q. 210.
A. 210. Okay. I'm there.
Q. So the -- there's an exclamation point in the top left corner. Do you see that?
A. Yes.

Q. And the text next to the exclamation point reads, "Rarely" -- let me start over. "Rarely do follow-up efforts include 100 percent of the participants. However, studies in which more than about 15 percent of participants who completed the treatment, but who were lost to follow-up, for whatever reason, should be interpreted cautiously."
Would you agree that with this book on medical statistics, that it appears to treat a 15 percent loss to follow-up as a bit of a red flag?
A. Yes.
Q. And it seems to be saying that when you lose about 15 percent to -- of your study participants, you're at a point where the effect is a potentially serious concern, correct?
A. Well, they're saying that you should interpret the study cautiously.
Q. And they -- and they have an exclamation point indicating that this is cause for particular concern, correct?
A. I would imagine that's why they have an exclamation point there.

Q. This also seems to indicate that a 15 percent loss of participants is not a small number, that it's a sufficiently high figure that it warrants a cautionary exclamation point. Do you agree?
A. That seems to be what they're indicating, yes.
Q. And are you aware of any literature, medical literature that would support a contrary conclusion that a 15 percent loss of participants in a study is, in fact, a small number?
A. No.
Q. Can we look at page 24 of your study -- of your case series?
A. Okay. I'm there.
Q. Under the third paragraph under methods, the first sentence reads, "Data were collected for different variables, including gestational age at the time of mifepristone ingestion, mode of delivery progesterone given, and amounts of progesterone received, birth defects, and preterm delivery."
Did I read that correctly?

A. Yes.
Q. And you report on those variables in the study, correct?
A. That's correct.
Q. Did you collect data on side effects of the treatment?
A. We had incomplete reporting of side effects.
Q. So would it be fair to say that you did not collect data systematically for each participant on side effects?
MS. DAVIS: Objection.
THE WITNESS: I would say there was -- there was systematic collection of some -- some side effects.
BY MR. BECK:
Q. What do you mean by systematic collection of some side effects?
A. Well, for example, two that are very, very important, birth defects and preterm delivery.
Q. Right. So you -- so you collected -- and I want to put those ones in a category of stuff that you did report on and analyze in your study. But I'm interested in,

for example, side effects like nausea, vomiting, tiredness, dizziness, bleeding, those kinds of side effects.
Did you gather data on those types of side effects for each patient?
A. No.
Q. And what about for complications like heavy bleeding and hospitalization, did you gather data on a systematic basis for complications like that?
A. Not systematically. Only if -- if they arose.
Q. I'm sorry. I missed what you said. Can you -- can you repeat your answer?
A. Not systematically. Only if they arose.
Q. But if they did arise, did you -- were you aware -- how many instances of --
A. I --
Q. Sorry?
A. Not aware of any woman requiring hospitalization in our study.
Q. And do you think that you systematically gathered that data enough to be

able to answer the question?
A. I did not systematically gather it.
Q. And --
A. I would assume that the women we were able to follow, that they would have told us.
Q. So the women you were able to follow, in none of those -- so the ones who were not lost to follow-up did not experience any complications other than the birth -- the few birth defects that you identify in the study. Is that a fair statement?
A. That's a fair statement.
Q. And of the 112 with whom you lost contact, you don't know whether or not they experienced complications, correct?
A. I don't know.
Q. Okay. On page 29 of your 2018 case series, are you there?
A. Yes.
Q. The first sentence of the first full paragraph states, "One potential confounding variable is the use of ultrasound to select for living embryos prior to the first --

prior to the first progesterone dose." And then toward the end of that paragraph it states, "If ultrasound is readily available, sound practice would dictate that embryotic or fetal viability should be confirmed, or at least suggested, before treatment is started in order to avoid giving women progesterone unnecessarily and to exclude ectopic pregnancy before starting progesterone therapy."
Did I read that more or less correctly?
A. Yes.
Q. So would it be correct to say that when a woman contacts Abortion Pill Rescue -- the Abortion Pill Rescue Network and is referred for medication abortion pill -- medication abortion reversal, the clinician generally performs an ultrasound before administering progesterone if ultrasound is readily available? Should I ask that again because I think it was unclear. Let me ask that again.
Would it be correct to say that if a woman contacts the APR hotline and is referred to a clinician for medication abortion

reversal, if ultrasound is available, the clinician generally performs ultrasound before performing -- before administering progesterone?

A. That would be correct.

Q. And one purpose as you indicate here for that is to confirm that the embryo or fetus is still alive before administering progesterone, right?

A. That's correct.

Q. And another purpose is to exclude ectopic pregnancy?

A. That's correct.

Q. And then in the middle of that paragraph it states, "Our study also included some women who started progesterone therapy prior to sonographic documentation that the embryo was alive," right?

A. That's right.

Q. Do you know the percentage breakdown of women in your study who received progesterone after sonographic documentation that the embryo was alive versus before?

A. No.

Q. Would it be fair to say that most women in the study had an ultrasound to

confirm that the pregnancy is alive and not ectopic prior to starting progesterone?

A. I don't think so.

Q. You don't think that most patients in your study had an ultrasound before they received progesterone?

A. I don't know. Because many of the calls come late in the day. And so sometimes patients are started on progesterone and then they get the ultrasound later in order to not delay.

Q. So I guess I'm trying to figure out when you say here, "If ultrasound is readily available, sound practice would dictate that embryonic of fetal viability should be confirmed, or at least suggested, before treatment is started."

That's your -- the -- the program, the -- the hotline's preference, correct?

A. I assume that would be everybody's preference.

Q. And so I hear you saying that that preference isn't always realized?

A. That's correct.

Q. And you don't know what percentage of the time an ultrasound is performed prior to starting progesterone therapy. And it could be even less than 50 percent according to, I think, what you just said; is that correct?

A. Yes. I don't know.

Q. Could it be substantially less than 50 percent?

A. I would doubt it. But, again, I'm speculating.

Q. Could it be substantially more than 50 percent of the time?

A. It's possible.

Q. Okay. If it's your program's preference, presumably it's attempted most of the time, if possible, right?

A. If it's readily available. But, again, the -- the idea is that you don't -- you don't -- it's balanced by not wanting to delay the progesterone therapy, so.

Q. I understand. But you don't know exactly a number -- you -- does the program have data on that and you just don't know it in your mind now or is there just no data to know

that at all?

A. At the time of the study, I didn't have the data available. I don't know if the program has it -- this data now.

Q. Okay. So you didn't collect data on the percentage of the time that ultrasound was performed prior to starting progesterone therapy?

A. No.

Q. Okay. On page 25 of your case series, under results, it indicates that your hotline received 1,668 calls from women who had taken mifepristone and were interested in reversal, and that 754 initiated progesterone therapy, correct?

A. That's correct.

Q. And I've done what I think is the math there, and -- and with subtraction concluded that there are 914 women who called, but who did not start progesterone. Does that sound sort of ballpark correct?

A. That sounds ballpark correct.

Q. Okay. And I would assume that some of those women called the hotline, but ultimately chose not to visit a clinician about

reversal; is that correct?
A. I'm sorry. Can you repeat that again?
Q. Yeah. So I'm just trying to sort of unpack that 914 number. Some of those people probably called the hotline and just didn't take any action after that. They didn't see a doctor about reversible. They got information on the hotline and decided not to do anything. Is that -- is that some of those 914, presumably?
A. Presumably, yes.
Q. And some of them did visit a clinician, some of those 914, but did not start progesterone, correct?
A. That's a possibility. I don't know.
Q. Well, anyone -- anyone in that group who visited a clinician and had an ultrasound performed that showed no fetal -- no live fetus at that point wouldn't start progesterone, correct?
A. That's correct.
Q. And you don't know what percentage of your study population fell into

that category, correct?
A. Correct.
Q. So in some cases, mifepristone had already worked before the patient could get started on progesterone, correct?
A. That's correct.
Q. And I may have asked this already. But you don't know what percentage of those 914 callers visited a clinician, had an ultrasound that showed that the embryo was no longer alive, and so didn't start progesterone; is that correct?
A. That's correct.
Q. You didn't collect that data?
A. That's correct.
Q. Did you consider collecting that data?
A. I don't recall. And I don't recall if that data were actually available. So I can't say for sure.
Q. Okay. So looking at figure 1 on page 25 of your case series, these callers who fall into the category of women who couldn't even start progesterone because mifepristone had already worked, they would be excluded from that

754 patients who were included in your study, right?
A. Right. Because if we knew the -- that the embryo were not alive, then we would not initiate progesterone.
Q. And they would also, of course, then be excluded from the 547 who were eligible for analysis?
A. That's correct.
Q. And that 547 subjects make up the denominator of your study from which you assessed the percent survival of embryos with progesterone treatment, correct?
A. That's correct.
Q. And similarly, you know, looking back at those 914 callers who did not initiate progesterone, if someone called after 72 hours, they also would be ineligible for participation in the study, correct?
A. That's correct.
Q. And so if 96 hours had elapsed between a woman taking mifepristone and calling the hotline, she would be ineligible for participation -- for inclusion in the study, I should say?

A. Inclusion in the study, correct.
Q. And I think you say you had -- you excluded 38 -- I'm sorry, 38 women on that basis. Does that sound right?
A. That's correct.
Q. Okay. So let's take a hypothetical woman. She takes mifepristone, and unbeknownst to her, at exactly 23 hours after taking mifepristone it results in fetal demise, and at 24 hours, she starts to have second thoughts. Do you understand the hypothetical so far?
A. Yes.
Q. Okay. If this woman had been a subject in the early mifepristone studies we were speaking about earlier, she would be included in that study, correct?
MS. DAVIS: Objection.
THE WITNESS: I would have to look at the inclusion and exclusion criteria of the study to make that determination.
BY MR. BECK:
Q. Well, there's no reason sitting here to conclude that -- that you know

of right now that -- for excluding her from the study, right?

A. Correct.

Q. She would -- unless there were some unexpected exclusionary criteria, she would show up as a case in which mifepristone caused fetal death, correct?

A. That's correct.

Q. Okay. And if this same woman called your hotline, mifepristone caused fetal demise at 23 hours, at 24 hours she saw a clinician for reversal, and an ultrasound showed that fetal demise had already occurred, in that case, she would be excluded from your study because she was ineligible for progesterone, correct?

A. That's correct.

Q. And so she would not show up as a reversal failure because reversal would not have been attempted on her, correct?

A. That's correct.

Q. And so for purposes of your study, this study this woman wouldn't exist?

A. She wouldn't --

Q. She wouldn't show up in your

data?

A. That's correct.

Q. Okay. Now, we don't know the number of callers in your study whose situations resembled this hypothetical, right?

A. That's correct. We also don't know the number of women who, at 23 weeks, had a demise, an embryo died, called in late and got started on progesterone at 24 hours, and then got an ultrasound the next day showing the baby died, and that was -- that would count as a reversal failure.

Q. Right. And -- and, actually, we talked about that at your 2015 deposition. And your prediction was that those two biases canceled each other out. Does that sound like an accurate reflection of your testimony?

A. Yes.

Q. But you actually -- we don't have data to know that. That's just speculation, correct?

A. That's correct.

Q. Okay. And so we don't know number of callers in your study whose situations resembled either of these hypotheticals, right?

A. That's correct.

Q. It could be zero or it could be more than zero, correct?

A. That's correct.

Q. For purposes of patients who had fetal demise before they visited a clinician and so were ineligible for progesterone therapy, we know it certainly is not more than 914, because that was the number of people who -- who didn't make it into the analysis, but we don't know the exact number, right?

A. That's correct.

Q. And whatever the number is, if it's more than zero, there would be some difference between the population eligible for analysis in your study and the early mifepristone studies, correct?

A. Say that again, please.

Q. Sure. Whatever the number is, because we don't know, if it's more than zero, there would be some difference in the population eligible for analysis in your study versus the population eligible for analysis in the early mifepristone studies, correct?

MS. DAVIS: Objection.

THE WITNESS: If you -- if you're talking about the same patient sort of hypothetically in the two studies at the same time, yes.

MR. BECK: Okay. Should we take a five minute break? Do people need the restroom?

MS. DAVIS: Yeah.

MR. BECK: I do. Okay. Can we go off?

VIDEOGRAPHER: Off the record at 3:46.

(A recess was taken.)

VIDEOGRAPHER: We are back on the record at 3:55.

BY MR. BECK:

Q. Hi, Doctor. Did you have any correspondence or interaction with anyone from the Tennessee attorney general's office during the break?

A. No.

Q. Okay. Sorry, I'm trying to read something. Does the Abortion Pill Rescue Network provide for reversal after a patient takes misoprostol?

A. The -- what's done there is the patient is referred to a physician, and the physician and the patient decide what's in her best interest and what should be done.

Q. And so is there sometimes treatment that is administered for a patient after she takes misoprostol?

A. I think there have been cases where treatment has been administered, yes.

Q. What treatment?

A. Progesterone.

Q. And is there evidence to show that progesterone is effective at reversing medication abortion after misoprostol is taken?

A. I -- there are no published studies, so the evidence would only be anecdotal.

Q. Is there anecdotal evidence?

A. I believe so, but I'm not certain.

Q. Do you think that progesterone is effective for reversing an abortion after a patient takes misoprostol?

A. I'm uncertain.

Q. Okay. What about the

administration of methotrexate for an ectopic pregnancy, is that reversible?

A. Well, I don't think anyone would want to reverse methotrexate given for an ectopic pregnancy.

Q. And so that's not been practiced in your -- to your knowledge, in the network?

A. No.

Q. What about in the context of a nonectopic pregnancy where methotrexate is administered, is methotrexate used to induce an abortion in a nonectopic pregnancy reversible, in your opinion?

A. I think it probably is.

Q. Also with progesterone?

A. With folinic acid.

Q. And is there published data to support that?

A. There's published data supporting the reversal of the effects of methotrexate folinic acid. That's very well established in patients who suffer toxicity from methotrexate.

Q. I'm sorry, there's -- there's

published data to show that reversal of an abortion is effective in that context, or -- or data showing something else?

A. Data showing that the effects of methotrexate are reversible in patients who've received methotrexate and are experiencing toxicity from the methotrexate.

Q. But not -- but not data with respect to methotrexate's action when it comes to abortion in particular?

A. No published data.

Q. Okay. Does the Abortion Pill Rescue Network require clinicians who are in the network to meet in person with patients under all circumstances?

A. Well, the requirements for in person meeting have changed significantly in the last year. So telemedicine is now widely accepted. What the -- and the -- the Abortion Pill Rescue Network can't mandate anything. So it does have strong recommendations that a face-to-face meeting take place I believe it's within the first 72 hours of institution of treatment.

Q. And by face-to-face, you mean

in person face-to-face?

A. Yes.

Q. Does it -- does it sometimes occur that abortion pill reversal therapy is administered via telemedicine?

A. I -- I'm not aware of the network -- if the network has telemedicine policies.

Q. Are you aware of, like, would ever a patient be referred to a clinician who would just call into a pharmacy a prescription for progesterone and the patient never meet with the clinician in person?

A. I'm not aware of that ever happening by design, no.

Q. You -- you added -- or used the words "by design" there. Does that mean it's not written into the protocols, but it might sometimes happen, or am I misunderstanding you?

A. Well, it might happen that the prescription's called in and that the woman then changes her mind and it never -- never gets started, and so never sees the clinician.

Q. But, for example, if a -- if a

woman lives far away from a clinician, if she's in a remote rural area, would it ever happen that the clinician and the woman could have an interaction by a telemedicine platform, and she goes to her local pharmacy to which the clinician calls in a prescription for progesterone?

A. And that would be it? No. Because there is the strong recommendation that the woman have an ultrasound as soon as possible.

Q. Okay. So that would -- are you saying that would never happen, or it's unlikely to happen?

A. I would say it's unlikely to happen.

Q. Okay.

A. I can never say never.

Q. Is there ever, to your knowledge, a woman in one state where there isn't a -- an Abortion Pill Rescue Network clinician, but someone in another state could assist her via telemedicine? Does that ever take place, a scenario like that, or no?

A. I don't believe so.

Q. Okay. On page 29 of your case series, the last sentence of the carry over paragraph. Do you have it in front of you?

A. Yes.

Q. States, "In addition, some data collection was incomplete." This is in your discussion of study limitations. What is that referring to?

A. So I'm on page 29 and --

Q. It's the second full sentence on page 29.

A. Okay. Okay. I see it. "In addition, some data collection were incomplete." Well, that refers to the, for example, we talked about some data weren't available to us, like side effects and those sorts of things. So those were just incomplete. We didn't have it.

Q. So that -- that refers to things that we've already covered here and there's nothing we haven't covered that is encompassed within that sentence?

A. I believe so.

Q. Okay. Would it surprise you -- just going back to our earlier subject of conversation. Would it surprise you if

Dr. Boles stated that he had not met many of his reversal patients in person?

A. Yes.

Q. Okay. That would be inconsistent with the intended approach of the Abortion Pill Rescue Network?

A. Well, not necessarily. He may have had arrangements for associates or other clinicians to see patients.

Q. If he only spoke with them via telephone -- if he had patients he was treating for abortion -- abortion pill reversal and he only interacted with them over the phone, would that be inconsistent with the intended practice of the Abortion Pill Rescue Network?

A. If -- if they initiated treatment and continued treatment, yes, it would be. Because the recommendations are that they be seen in person.

Q. That practice would be outside the recommendations of your program?

A. Well, I -- I wouldn't be able to make that comment or conclusion without knowing specifics of -- of who was seeing the patients. You know, it may be doctors are

associated with clinics and that they have an arrangement with the clinic and the patient gets an ultrasound and is seen by another clinician. So I wouldn't want to assume or suppose anything.

Q. Hypothetically, if the sum total of the clinician's interaction with a patient was over telephone and there was no follow-up interaction in person by associates, would that be inconsistent with the intended practice of your program?

A. Yes.

Q. And why is that?

A. Because the intentions of our program are to have a visit with a clinician within 72 hours of initiating progesterone therapy. And --

Q. And -- sorry.

A. -- to have an ultrasound as soon as possible.

Q. And that is intended to be an in person interaction?

A. Well, the ultrasound has to be an in person interaction. In this age of telemedicine, the -- the visit doesn't

necessarily have to be because of the limitations of the COVID-19 pandemic.

Q. So has the APRN -- you -- can we use for APRN for Abortion Pill Rescue Network?

A. Okay.

Q. Has it -- has APRN made -- modified and -- and made accommodations to adapt to the COVID-19 context?

MS. DAVIS: Objection.

THE WITNESS: I don't know.

BY MR. BECK:

Q. Okay. Let's look at page 27 of your case series.

A. Okay.

Q. This is a table that lists different routes of administration of progesterone with different outcomes, correct?

A. Yes.

Q. And at the top for all groups the number is 547 analyzed subjects?

A. Correct.

Q. Yeah. And is it correct that, for example, the high dose oral group, which had 31 subjects, is a subset of oral all groups,

which had 119 subjects?

A. Yes.

Q. And so it looks like you have four overarching categories, but tell me if I have this wrong. There is the oral all groups; oral caps vaginally, all doses; intramuscular, all groups; and vaginal suppository. Are those -- are those all the main overarching groups?

A. Yes.

Q. Okay. What I'm a little confused by is, I couldn't get these numbers to add up to 547. Can you show me how these numbers of the different principal categories add up to 547?

A. Well, I could -- I would have to do some arithmetic right now to -- because it's been a while since I looked -- looked at these numbers.

Q. Well, so if we -- yeah. If you could help me with that arithmetic, I would appreciate it. Because I'm -- I've tried to get it to add up, and I'm not very good at math, but I couldn't make the math work.

So, for example, if you add

125, which is all the intramuscular groups, the -- to 119, which is all oral groups, to 156, which is oral caps vaginally, all doses, plus 34, which is vaginal suppository, you get 434.

Are you getting the same trouble that I am, Doctor?

A. My -- yeah. My initial quick tabulation, I -- I have a feeling -- and I have to think about this and maybe go back and read this, is that the all groups also includes patients that we found who had gotten progesterone, but the route was unspecified. I think that's probably what the balance is.

Q. So there's a category that seems maybe left off here, which is route unspecified, and that -- that makes up the difference between these different categories and all groups. Is that possible?

A. I would -- yeah. And -- yeah, I believe that's possible.

Q. Is it also possible that some patients received progesterone via multiple routes of administration?

A. Yes. That's -- that's also possible. In fact, I -- from memory, I know

that there were some who -- and we generally try to classify them based on the first one they got, but -- or predominant, but there were some that kind of got a mix and match. And I think those were also in the -- in the balance. Those probably make up the two groups that -- that would compose the balance.

Q. And so someone who got a mixture, for example, of high dose oral and vaginal suppository, or high dose oral and intramuscular, would she count as either a failure or a success in both categories?

A. No. We didn't put people in -- in two categories.

Q. And so it was whichever she got first or whichever was predominant?

A. Yes. If it was clear, yes.

Q. And if it wasn't clear, she'd fall into the sort of unspecified category, which isn't listed here?

A. That's correct.

Q. Okay. Your study, if I'm not mistaken, doesn't lay out this fact of some patients getting progesterone via an unclear route, or others getting a mixture of treatments

and falling into whatever the predominant category is. Am I correct that I didn't see that spelled out in the study?

A. I don't think we spelled it out that clearly.

Q. Did your peer reviewers ever raise that trouble with -- or that issue with the reporting of your -- your data here?

A. I don't recall.

Q. If you have a patient who's getting progesterone via multiple routes, does that make it hard to sort of put her firmly in the high dose oral category or the intramuscular category, for example?

A. It does. But the -- the high dose oral group, that was a group that really had a lot of homogeneity to it. So I'm not doubtful about that.

Q. So the -- there were 31 patients in that group, right?

A. Yes.

Q. And that one was perfectly homogenous or relatively homogenous?

A. I would say highly homogenous.

Q. Highly homogenous. And which

groups were less homogenous?

A. I would say -- well, certainly, the -- as you can see, the intramuscular group there was such heterogeneity that we subdivided them into how many injections they got. And then the other oral groups and the oral caps vaginal was -- was probably -- the oral caps vaginal was probably the most heterogenous group, I think. We discussed that earlier in the deposition.

Q. But just to be clear. When I -- when we're talking about heterogeneity here, are we saying that the people who primarily got oral caps vaginally were heterogenous in that they might have also gotten an injection?

A. Moreso that they all state they had varying doses and -- and frequencies.

Q. Uh-huh. And we talked about that earlier. I guess I'm just trying to really figure out the math here.

Do you have a percentage estimate of what -- what share of patients in this total of 547 received progesterone via multiple routes of administration?

A. No. I haven't done that calculation.

Q. Is it less than 50 percent, would you expect?

A. Oh, yes.

Q. Is it less than 10 percent?

A. Probably more than 10 percent.

Q. So somewhere between 10 and 50?

A. Probably.

Q. Did you -- did it -- did you consider spelling out what we're discussing here in the context of this study in terms of either -- either clarifying that some patients received multiple routes of administration or saying that this is a limitation of the study because your data had some heterogeneity?

A. Well, I don't recall if I specifically thought about it in those terms. I -- you know, when I made the comment in here about some data collection were incomplete, I also may have been referring to the -- the mode of the progesterone ingestion by the -- by the patients.

Q. I see. And we don't know -- I

think you said this already. But you don't know how many patients -- if my math is right, 547 minus 434 is 113. Is 113 the right number of patients who got progesterone via an unclear route?

A. I would say that's likely the number that got it by an unclear route or by multiple routes that didn't favor one or the other, or they would naturally go into one of the categories.

Q. Okay. We were speaking quite a long time ago about institutional review boards, or IRBs. We spoke about it with respect to your colleague's application to the Watson Bowes Institute and that he had sought IRB approval of the randomized control trial. Do you remember that?

A. Yes.

Q. Okay. What is an institutional review board?

A. It's a -- it's a group that reviews studies and gives guidelines for studies in order to protect the subjects of the studies.

MR. BECK: Can we have Tab Z introduced into the chat, which we can mark as

Exhibit 39?

(Whereupon, the document was marked as Exhibit No. 39 to the testimony of the witness.)

BY MR. BECK:

Q. Doctor, let me know when you have this one open.

A. I have it open.

Q. So this is a guidance document from the FDA regarding IRBs. Have you seen this before?

A. Not to my recollection.

Q. Okay. If you could turn to page 2, the second page, and read the first sentence aloud.

A. "The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research."

Q. And that sounds fairly similar to what you just said before looking at this. But do you agree that this is an accurate statement?

A. Yes.

Q. Then let's look at tab AA, which has now been introduced into the chat.

MR. BECK: And we can mark this document as Exhibit 40.

(Whereupon, the document was marked as Exhibit No. 40 to the testimony of the witness.)

THE WITNESS: Okay. I have it open.

BY MR. BECK:

Q. Okay. Hold on. I need to open it now. Okay. So this document, which has been marked as Exhibit 40, is printed from a website from the Health and Human Services administration. And if you look down in the middle of the page where it says, "Must investigators obtain IRB approval," could you just read that -- the question and the answer?

A. "Yes. Investigators are responsible for obtaining IRB approval before beginning any nonexempt human subjects research. Investigators are responsible for providing the IRB with sufficient information and related materials about the research, parenthesis, e.g., grant applications, research protocols, sample

consent documents, close parenthesis, so that the IRB can fulfill its regulatory obligations, including making the required determinations under 45 CFR 46.111 and, if applicable, subparts B, C, and D. Investigators should follow institutional policies and procedures for IRB review that are required by HHS regulations at 45 CFR 46.103(b)(4)."

Q. Thank you. For the 2018 case series, did you obtain IRB approval before involving human subjects in the research?

A. Yes.

Q. When did you obtain IRB approval for the 2018 case series?

A. I'll have to look at the date, but it was when we were analyzing the -- the -- during the retrospective analysis of the data.

Q. So not while the patients out in the country were being treated, but afterwards when you had the information and were analyzing the data; is that correct?

A. Correct. Because they were being treated -- they were just patients being treated by their -- by their physicians. We then were able to obtain data, so we got our IRB

approval to analyze the data.

Q. And they were being treated by physicians within the network that you had helped set up, correct?

A. Most of them.

Q. And they were being treated by physicians according to protocols that you helped to circulate, correct?

A. They were suggested protocols. But the physicians, since they were treating their own patients, had the right and the duty to treat their patients as they saw fit.

Q. And so do you think that that aspect of the program with you creating a network and issuing guidance to physicians within the network was exempt from the IRB requirements that we were just reading? Like, is there an exemption that applied or -- or what?

A. There's an exemption, but there's -- there's no IRB oversight required for treating patients. And the network is set up as a way to connect patients who are seeking reversal with clinicians who were willing and able to treat them.

So that -- that's not -- that's like if I -- if I have a medical practice and I refer patients to another doctor, do I have to get IRB approval to do that? No, of course not. That's just clinical practice.

Q. Did it ever occur to you to try and seek IRB approval before you started performing the retrospective analysis? As in, at an earlier stage when you were starting to collect this data?

A. Well, at that point it wasn't research. And so the IRB approval was not necessary. So, no, did not.

Q. It never occurred to you?

A. It never occurred because it wasn't necessary.

Q. You were collecting data on an ongoing basis, though, dating back to before 2015, correct?

A. Yes.

Q. It's not the case that in 2017 or 2018 you got a data dump of data and then asked for IRB approval and performed a retrospective analysis, correct?

MS. DAVIS: Objection.

THE WITNESS: Data, you know, came into the network as doctors saw their patients.

BY MR. BECK:

Q. Right. They were submitting -- the physicians were submitting data to you in the realtime basis as they were seeing patients, correct?

A. For the most part.

Q. And you were developing a database dating back several years prior to when you got IRB approval, correct?

A. That's right. But before I started the retrospective analysis.

Q. You had a lot of data, but weren't analyzing it, and that's the -- that's the line that you are drawing when it comes to the need for IRB approval; is that correct?

A. That's right.

Q. Did you perform any analysis on that data before you got IRB approval?

A. Just very high level analysis as -- as numbers came in as far as whether the treatment was being -- was successful or not.

Q. Was that high level analysis

something that raises a concern for you about the need for IRB approval?

A. No.

Q. What's the difference between performing a high level of analysis of data as it's coming in in realtime versus a more systematic analysis for which you sought IRB approval?

A. Because there's no potential harm to any patients.

Q. Is there potential harm to patients from the retrospective analysis that you performed pursuant to IRB approval in the lead up to your publication?

A. Not in my mind, no.

Q. So why did you seek IRB approval then?

A. Because IRB approval is customary for any significant publication.

Q. So it was not something you ever thought was important for your study, but it was sort of a box you had to check for publication; is that correct?

MS. DAVIS: Objection.

THE WITNESS: It was a

necessary step to have a legitimate article of the literature of -- of a case series this size. And -- and so it was naturally a thing to do.

BY MR. BECK:

Q. Did you ever seek advice from counsel about whether or not IRB approval was needed at any time?

A. What kind of counsel do you mean?

Q. Any kind of attorney?

A. No.

Q. Did you ever seek advice from anyone about whether or not IRB approval was necessary at any time?

A. I believe I did.

Q. Who did you consult about that?

A. I don't recall specifically.

Q. Do you remember the general category of person you might have asked?

A. Probably a physician who had some research experience.

Q. But you can't call to mind who that physician is today?

A. Not specifically, no.

Q. Did you ever ask either Dr. Harrison or Barry Bostrom about the need for IRB approval?

A. I may have asked Dr. Harrison, but I'm not certain. Barry Bostrom, no.

Q. Okay. Your 2018 case series was first published in the spring 2018 issue of "Issues in Law & Medicine" in April of 2018. Does that sound right?

A. That's correct.

Q. And it was at some point thereafter temporarily withdrawn?

A. That's correct.

Q. And thereafter it was republished, correct?

A. That's correct.

MR. BECK: Okay. Can we have exhibit -- sorry, Tab BB?

THE WITNESS: I have it.

MR. BECK: Just for the record, tab BB we can mark as Exhibit 41, that is "Issues in Law & Medicine" spring 2018 issue republication notice, which we'll talk about in a moment.

I don't know whether we marked

as Exhibit 40 investigator responsibilities from HHS. But if we could do that, that would be lovely. So let's do that.

BY MR. BECK:

Q. So Tab BB, which has been marked as Exhibit 41 --

THE COURT REPORTER: Hang on just a second. This is the court reporter. I have Tab AA, which is 40.

(Whereupon, the document was marked as Exhibit No. 41 to the testimony of the witness.)

MR. BECK: Yep.

THE COURT REPORTER: Okay. Just making sure.

MR. BECK: Yep. That's perfect. Thank you for keeping track of that. I have not done it in a particularly systematic way.

THE COURT REPORTER: No worries.

BY MR. BECK:

Q. So Exhibit 41 is -- so when your article was republished, this was -- Exhibit 41 was the notice posted on the website

for "Issues in Law & Medicine." And can you read the sentence beginning with, "The original article."

A. Are you talking about the sentence that says, "The original printed article"?

Q. Yes, please.

A. "The original printed article has an error in the first sentence of the methods section. This has been corrected here."

Q. And so this that we're looking at here is the second version of the article; is that right?

A. I believe so.

Q. And the second version corrects an error in the first sentence of the methods section of your first article, right?

A. That's correct.

Q. So let's look at your first article, the original version of it, which is Tab CC, which we can mark as Exhibit 42.

(Whereupon, the document was marked as Exhibit No. 42 to the testimony of the witness.)

BY MR. BECK:

Q. Let me know when you have that available.

A. It's open.

Q. Great. Does this document, Exhibit 42, look like the originally published version, first published version of your 2018 case series?

A. Yes.

Q. Okay. On page 6 --

A. Okay.

Q. -- under methods, it states, "This is an -- this is an observational case series with data analysis that received an institutional review board waiver." And it cites footnote 33, which if you scroll to the very bottom, footnote 33 is Institutional Review Board University of San Diego, San Diego, California, correct?

A. Correct.

Q. So is your study appropriately described as an observational case series as it said in the original version?

A. Yes. I think in the -- I think a -- the -- in the revised version, I think we also included this is a retrospective

observational case series with --

Q. Was --

A. -- case series was accurate.

Q. Sorry, I cut you off. Can you say what you just said again?

A. Yes. Observational case series is accurate.

Q. So that -- that is an accurate statement of your methodology?

A. Yes.

Q. Okay. Did you apply for IRB approval from University of San Diego?

A. Yes.

Q. When?

A. I don't recall.

Q. Was it close to the publication date?

A. No. It was significantly before the publication date.

Q. Was it after you began collecting the data that was coming in in realtime from physicians in the APRN?

A. It was while the --

MS. DAVIS: Objection.

THE WITNESS: -- were coming

in realtime.

BY MR. BECK:

Q. In the midst of collecting data, at that point you asked for IRB approval at -- at USB?

A. That's correct.

Q. Okay. And so it was after you began receiving data for the study?

A. Well, I was -- the -- the network was receiving data, but at that point, it was -- at the point we decided to do a study, then we sought IRB approval. Just collecting data is not doing a study.

Q. But you were conducting research on that dataset dating back to 2012, weren't you?

A. No, I was not.

Q. Can we look at your deposition from Arizona, which is Tab A, Exhibit 25, at page 229 to 230?

A. Okay. I have it here.

Q. So starting at line 20, question, "And is the IRB approval that you're seeking being UC San Diego intended to approve retroactively the research you've already done

or is it forward-looking?"

Answer, "It's the University of San Diego, not UC San Diego, just for the record. It's to look at our current cares series that we want to submit for publication."

Question, "So research that's been going on since 2012?"

Answer, "Existing dataset."

Question, "An existing dataset for research that dates back to 2012?"

Answer, "Correct."

Was that testimony correct when you gave it?

A. So it's correct the existing dataset did go back to 2012.

Q. For research that dates back to 2012?

A. That was your statement. I said it was an existing dataset.

Q. Right. And then you said correct after the characterization of an existing dataset for research that dates back to 2012?

A. The existing data date -- existing dataset dates back to 2012, and that

dataset I was planning to use for research.

Q. You were planning to use that dataset which dates back to 2012 for research starting in 2012?

A. I was planning to use it for research at the time I was applying for the IRB approval. When I was collecting -- or asking people to collect data, that was with the possibility, but not a certainty of -- of conducting any research.

Q. So you knew that it was a possibility that you would be conducting research on that data dating back to 2012, correct?

A. I knew it was a possibility, that's correct.

Q. But you didn't have a firm plan in mind starting in 2012 to perform analysis on that data, and so it was exempt from the need for IRB approval; is that correct?

A. That's correct.

Q. In your IRB application to University of San Diego, how did you characterize your research?

A. As a retrospective analysis of

case series.

Q. Did you indicate that you thought that the research was exempt from IRB requirements when you applied?

A. I believe so.

Q. Did the university agree with you?

A. Yes.

Q. The IRB?

A. Yes. The IRB agreed and declared it exempt.

Q. Okay. And then the University of San Diego asked you to withdraw the paper, correct?

A. They -- I believe that they initially asked for an addendum, and then -- then they requested withdrawal of the paper, that's correct.

MR. BECK: And let's -- can we introduce Exhibit DD -- sorry, Tab DD, which will be Exhibit 43.

(Whereupon, the document was marked as Exhibit No. 43 to the testimony of the witness.)

BY MR. BECK:

Q. Let me know when you have this open, Doctor.

A. It's open.

Q. Exhibit 43 is a BuzzFeed news article entitled, "A Study About The 'Abortion Reversal' Procedure Was Just Withdrawn for Ethical Issues." And on page 2.

A. Okay.

Q. The one, two, three, fourth paragraph states, "The University of San Diego asked for the paper to be withdrawn, spokesperson Pamela Payton told BuzzFeed news, because it had ambiguous wording regarding the university's ethics board, leading many readers to incorrectly conclude that the school reviewed and approved the entire study. In reality, Payton said, the ethics board had only approved analyzing pre-existing data, not collecting it."

Is that, in your mind, an accurate representation of what happened?

A. That -- that doesn't explain the reality clearly.

Q. What -- what about that doesn't explain the reality clearly?

A. Well, we -- so we had the IRB

approval, and the IRB approval was for a dataset from date 1 to date 2. Some more data came in subsequent to date 2. We included that not realizing that it was outside of the dataset, the two dates they had given us. And so that's why they wanted us -- wanted the paper withdrawn, because of that. So, essentially, a technicality.

Q. What do you mean by --

A. Not ethical, just -- just an oversight.

Q. What do you mean by date 1 and date 2?

A. Well, just for example, let's say the -- they approved the -- the -- the IRB gave approval for data on, let's say, patients who were treated, just to pick dates, between January 1, 2020 and December 31st, 2020. But then we got some data on January 5th, 2021 and included that in our analysis. And -- and so it was technically outside of their -- the dates that they had set for the dataset, but we included it, and it's because of an oversight.

And so when that was brought to light, they wanted us to withdraw it. And so

it's not that there was anything unethical. It was just an oversight. It didn't change anything in the paper. We went back and got another IRB approval and republished it. So, really, was one of those no harm, no foul situations that was made a big deal by news outlets such as the one you're displaying here as a -- as a -- as an item.

Q. Did you think about just correcting the error by excluding whatever new data after date 2 you had mistakenly included?

A. Well, at -- at that point, it didn't seem like the University of San Diego was interested in -- in moving forward. And it would have been probably more work to reanalyze the data.

So it just made more sense to have the new dataset reviewed again and have IRB approval so that it was -- there would be no -- no question and no doubt that everything was done appropriately.

Q. The second version, the republished version of your 2018 case series, is Exhibit -- is Tab F, Exhibit 7. Do you have that one available?

MS. DAVIS: Hey, Andrew, can we hold on just a second? Sorry, the lights are off in this room and I just need to move for a second.

MR. BECK: Yep.

MS. DAVIS: Thanks.

BY MR. BECK:

Q. So, Doctor, do you have Exhibit 7 available?

A. Yeah. That's the case series published in 2012 -- 2018 series.

Q. Correct. On page 24 you describe the methods -- under methods you describe it as, "a retrospective analysis of clinical data," and state, "The study was reviewed and approved by an institutional review board."

Is there a reason you didn't specify what -- which IRB review -- sorry, institutional review board approved this iteration of the study when you had done so with the previous study?

A. Yes. Because it became quite obvious that -- that there were groups out there who were trying to discredit our efforts and do

anything they could to sabotage us.

So I did not want the -- the new IRB to have to undergo a lot of untoward publicity and unwanted publicity. I just wanted them to be able to do their job, give us the IRB approval, and for them not to have to worry about things that normally don't come along with studies that are not as controversial as the topic that we are studying.

Q. I think I read in an article that the IRB you obtained approval from this time around was Aspire; is that correct?

Do you need to answer that, Doctor, or do you want to -- is there an emergency?

A. No. I'm sorry, I just -- I have both phones on silent mode, but for some reason, these -- do you mind just -- it may take a second to clear that message and then I think it'll stop.

Q. Sure. Why don't -- why don't we take five?

A. No, actually it'll just take me two seconds. If you just give me two seconds, that's all I need to do. Okay. That

should do it. Sorry about that.

Q. No worries. I read somewhere, I believe, that the IRB you obtained approval from the second time around is called Aspire; is that correct?

A. That's correct.

Q. And that's a -- what's the -- is it a commercial IRB? It's not -- it's not associated with an academic institution. It's a for profit IRB; is that correct?

A. I don't know if they're for profit.

Q. Okay. Did you -- I think you answered this, but let me just make sure the record is clear.

Before applying to Aspire, did you seek approval a second time around from the University of San Diego or no?

A. Well, I didn't formally submit another application, but I did communicate with them. And like I said, they were so distressed by the -- all the publicity that came their way, that they did not want to be a part of it anymore.

Q. So they -- I don't want to put

words in your mouth, but is it fair to say they informally declined to serve as your IRB the second time around because you hadn't formally submitted a second application?

A. That would be an accurate characterization.

Q. Did you disclose University of San Diego's informal denial or informal decision not to bless your study the second time around, did you disclose that fact to Aspire?

A. I don't believe so.

Q. Do you think you should have?

A. I don't think it was necessary.

Q. Your research was already complete by the time you applied for approval at Aspire, correct?

A. It was complete, but no longer published.

Q. Would you agree that it's unusual to seek IRB approval for a study after it was already completed?

A. It is unusual, and this was an unusual circumstance. And the fact of the matter was, we had IRB approval already. So in

essence, this was a second IRB -- it was a second IRB approval. So we were doubly approved.

Q. Well, but you had IRB approval that it sounds like you accidentally strayed from the first time around?

A. Yes. Technical oversight. No patients risk or harmed.

Q. Did you submit the same IRB application to Aspire that you submitted to University of San Diego's IRB?

A. No. They have different application processes.

Q. Did you make changes to -- I mean, obviously the processes are different. But did the content of your application differ in terms of your application to University of San Diego v. Aspire?

A. I don't recall.

Q. We went over this earlier, but the original case series before it was retracted called itself an observational case series with data analysis, and then when it was republished it called itself a retrospective analysis of clinical data. Are those two the same thing?

A. Not the same thing. Just one is more specific than the other.

Q. Can you explain how they are different?

A. Well, in the second instance, including the word retrospective emphasizes that it's a look back in time. So it doesn't change the nature of what was done, it just more explicitly describes it.

Q. And the first version of it when you called it observational, observational suggests forward looking, correct?

A. No, it does not.

Q. No?

A. No.

Q. So what -- so you added the word "retrospective," you called it a retrospective analysis of clinical data, and in your mind, that's just a little more clearer than observational case series with data analysis, but they're more or less the same thing?

A. Well, I'm saying that what we did was the same thing, but the second instance, we described it more clearly as far as the title and the description.

Q. Why did you change the description of the methods?

A. To be more clear.

Q. And in -- from a -- sort of a methodological standpoint as someone who doesn't -- I'm not a scientist, should I -- should I view a retrospective analysis of clinical data and an observational case series with data analysis to be the same type of study?

A. They both would go into the category of a case series analysis.

Q. But other than being more specific about one being retrospective, what's the difference between those two descriptions? Like, why make the change? I guess I'm trying to understand what the -- what the change is about other than adding the specificity of the word "retrospective"?

A. That's -- that was exactly the reason.

Q. So that's it, in your mind. Otherwise, the two study -- the descriptions of study design, in your mind, are essentially the same thing?

A. Except that one's more specific.

MR. BECK: Okay. Can we introduce Tab FF, which we can mark as Exhibit 44.

(Whereupon, the document was marked as Exhibit No. 44 to the testimony of the witness.)

BY MR. BECK:

Q. I don't -- well -- do you have that one downloaded, Doctor?

A. It's downloading right now.

Q. Okay.

A. It's a little slow. I'm going to close some of these windows, maybe it'll upload faster.

Q. A lot of tabs.

A. Yeah. It's more than 50 percent downloaded, so this is helping. It's like 90 percent there.

Q. We're straining your poor computer.

A. Yeah. It's getting a good workout today. Okay. So click to open. There it is.

Q. Great. So this is a declaration. This is Exhibit 44. It's a declaration of Courtney Schreiber in this case. Was this one of the documents that you many hours ago said was sent to you by lawyers in the attorney general's office for you to respond to in your declaration?

A. I believe so.

Q. Okay. I only want to ask you about one line here. If we turn to page 17, at paragraph 41?

A. Okay. I'm there.

Q. So paragraph 41 continues over from the previous page. But I just want to focus on the last two sentences where it says, "When the paper was republished, the authors describe their methods differently, calling it a retrospective of clinical data, but did not alter their described results or discussion. It is unheard of to withdraw a paper, rewrite its methods to describe an entirely different study design, and republish the remainder of the paper unchanged."

And I imagine you disagree with this statement. But I just wanted to ask

you about one part, which is, she says it's unheard of to withdraw a paper, rewrite its method, and republish the remainder of the paper unchanged.

Other than this case series of yours, have you ever seen that happen with another study?

A. Well, first of all, I disagree with the premise of the question.

Q. Tell me more about that. Why do you disagree with the premise?

A. To say we rewrote the methods is -- I think, is a mischaracterization. We simply changed a few words that more specifically described the kind of analysis it was.

So back to the question. If you're saying, is it unheard of to withdraw a paper, rewrite methods, to truly rewrite them, which is not what we did, then, yes, that is unusual. But to simply essentially relabel what we are calling what we did, is -- is really not that big of a deal.

Q. Do you have -- so accepting your -- your criticism of the -- the nature of

the question, do you have examples of the rewriting the methods to clarify in the matter -- in the manner that you're saying you did and republishing the remainder of the study unchanged? Do you have examples of that?

A. No, I do not.

MS. DAVIS: Objection.

BY MR. BECK:

Q. Do you disagree with Dr. Schreiber that it would be unheard of to do that?

A. I -- if -- again, if you interpret rewrite its methods to -- to mean a large change in the methods, yes, that -- that would be unusual.

MR. BECK: Okay. Can I get a check from Brian as to where we are on time?

VIDEOGRAPHER: I just checked and we're about 6 hours and 30 minutes.

MR. BECK: Okay.

BY MR. BECK:

Q. Just a little bit more, then, Doctor.

You're president of the board of Steno Institute, correct?

A. That's correct.

Q. What is Steno Institute?

A. Steno Institute is a nonprofit research and educational institute.

Q. So I saw on its website, let me know if this sounds correct to you, "Steno Institute will serve as scientific hub for pro-life medical and psychological research, and provide support and funding for pro-life researchers not previously available. Its work will support women -- women seeking a second chance at choice, as well as others whose lives are threatened by abortion or euthanasia."

Does that sound like an accurate description of its mission?

A. Yes.

Q. Does Steno Institute receive funding of any kind?

A. Yes.

Q. What are the sources of its funding?

A. Donations.

Q. Individual donations or institutional donations?

A. Both.

Q. What kinds of institutions make donations to Steno Institute?
A. Different nonprofit institutions.
Q. Sorry?
A. Different nonprofit institutions.
Q. Can you name some of those nonprofit institutions?
A. Well, they prefer to be anonymous.
Q. Okay. Yeah. We can come back to that, then.
Do you receive compensation from serving as president of the board of Steno Institute?
A. No.
MR. BECK: Can we introduce Exhibit GG into the chat?
THE WITNESS: It's ready.
BY MR. BECK:
Q. Okay. This is a page from Steno Institute's website. Does it look familiar to you?
A. Yes.

Q. It states, "Medical and psychological research communities are now dominated by individuals and organizations that do -- excuse me -- do not honor the sanctity of life and have a strong pro-abortion and generally anti-life bias. They either totally ignore pro-life perspectives or denigrate and marginalize anyone who would dare to question the status quo. Consequently, the pursuit, funding, and publication of unbiased research in the areas of abortion, euthanasia, and family planning is extremely difficult. The recent documentary by Vice News HBO reveals the bias inherent in the media and in mainstream medicine. Read more by clicking here."
Do you agree that -- or do you believe that medical and psychological research communities have a strong pro-abortion bias?
A. Yes.
Q. And do you believe that skepticism about your work on abortion pill reversal is the result of bias and not shortcomings of the evidence?
A. I believe it's, in part, due to bias.

Q. I'm sorry, I missed -- I missed your answer.
A. I believe it's partly due to bias.
Q. Does that mean it's partly due to bias and partly due to questions about the valid evidence?
A. Partly due to bias and partly due to the natural skepticism that all physicians have about new treatments.
Q. And that -- the bias that you reference here extends to the media and mainstream medicine according to the statement on the website, correct?
A. That's correct.
Q. And you agree with that?
A. Yes.
Q. Okay. You previously served as a voluntary clinical professor at UC San Diego, correct?
A. That's correct.
Q. That was an unpaid position?
A. That's correct.
Q. When did that appointment end?
A. 2012.

Q. Can we have Exhibit HH -- I'm sorry, Tab HH?
THE COURT REPORTER: Did you want to mark the last document?
MR. BECK: Yes. I was just realizing. That would be 45; is that right?
THE COURT REPORTER: Correct.
(Whereupon, the document was marked as Exhibit No. 45 to the testimony of the witness.)
MR. BECK: And then HH will be 46.
(Whereupon, the document was marked as Exhibit No. 46 to the testimony of the witness.)
BY MR. BECK:
Q. Let me know when you have this open, Doctor.
A. It's open.
Q. Great. So Exhibit 46 is an affidavit and attached exhibits from someone named Kim James filed in the South Bay United Pentecostal Church matter on August 31st, 2020. Have you seen this before?
A. Yes.

Q. Okay. Can you turn to page 7, please?

A. 7, that's the email?

Q. Uh-huh.

A. Okay.

Q. So on page 7 is an attachment with an email between -- or email correspondence between you and someone named -- no. Wait, this is the wrong one. No, it's not. I just miswrote it. Let's see. Sorry.

So at the bottom of that email chain is an email that you wrote to Scott Lafee inquiring about your status as part of the voluntary faculty at University of San Diego; is that correct -- I'm sorry, UCSD; is it that correct?

A. That's correct.

Q. And then the email responding to that says that your term has been expired for quite a number of years and they sent attached documentation of that, correct?

A. That's correct. And if you look at that letter they sent, it says addressed to George Delgado, MD, Solano Family Physician Medical Group, 2012 Columbus Parkway, Benicia,

California.

That office address was last my office in 2005. So they sent the letter to an address that had not been my address for seven years. So that's why I had no knowledge that my appointment had ended.

Q. Fair enough. But in 2018 you received email confirmation that the appointment had ended in 2012, correct?

A. That's right.

Q. So then if we go to the next -- to Exhibit C of the James declaration?

A. Exhibit C?

Q. Yeah. The very end of that.

A. Oh, the same -- I'm sorry, not Tab C.

Q. No. Sorry. No. Just the very end of that James -- Kim James declaration. There are three exhibits attached.

A. Okay. So this is an email from Scott Lafee.

Q. Right. Dated 2019, right?

A. Yes.

Q. And he states, "In April 2018, you received an email from UC San Diego School

of Medicine and another from me asking that you cease claims to an affiliation with the former as a voluntary associate clinical professor. That appointment ended in 2012, but apparently the affiliation has continued to be cited in biographical and other materials, which has again caused repeated confusion. The issue has arisen again with media mistakenly believing that you have faculty status at UC San Diego. I have clarified the situation, but must -- but again must ask, insist, that you review any places online or elsewhere where you may be citing and implying a current affiliation, for example, this page at Catholic Answers, which was posted on November 19th, 2018."

Did I read that correctly?

MS. DAVIS: Objection.

BY MR. BECK:

Q. Sorry, I didn't hear your answer, Doctor.

A. That's correct.

Q. Okay. And so it sounds from this email that UC San Diego asked you to stop making public statements citing or implying that you are currently affiliated with the medical

school. Is that a fair summary?

A. A fair summary is that your biography gets out on a lot of different places, and it's hard to track them all down. And so I -- as soon as I received the notice from Scott Lafee and from the other person, Angela, I did start -- I moved to change anything that I saw was outward facing, and gave instructions for people to no longer have that on the -- on websites.

However, there's some websites I didn't even know had my biography. People were grabbing my biography from other websites using it on theirs without my permission. Others were just not double checking with me that biographies were up to date.

So you can imagine those things can be difficult to control. But as soon as I knew that my appointment had ended, I did -- made great efforts to make sure that I was not misrepresenting myself.

Q. So it was just a matter of other people repurposing your bio improperly or by mistake, but you not affirmatively claiming an affiliation that no longer existed; is that

correct?

A. That's absolutely correct.

Q. Okay. And so the page that was posted at Catholic Answers on November 19th, 2018, that was an instance along the lines of what you just described?

A. That's correct. I had no knowledge of that page being posted.

Q. Okay. Do you have any idea why UC San Diego was so concerned about your representations or others' mistaken repurposing of your biography concerning an ongoing affiliation with the medical school?

A. Well, you know, it would be speculation.

Q. Does the Abortion Pill Rescue Network require that all clinicians in the network have admitting privileges at a local hospital?

MS. DAVIS: Objection.

THE WITNESS: I'm not sure.

BY MR. BECK:

Q. When -- you played a more active role in the network in previous years, correct?

A. That's correct.

Q. When you played a more active role in the network, did it -- did the network require that participating clinicians have admitting privileges at a local hospital?

A. Not that I recall.

Q. Are there physicians -- I guess we can broaden this to reflect that you used to -- I believe you used to have more involvement in the network.

Are there or have there ever been, to your knowledge, physicians in the Abortion Pill Rescue Network who are not OB/GYNs?

A. Yes.

Q. For example, some are family medicine doctors?

A. That's correct.

Q. And some are emergency room physicians?

A. I believe so.

Q. Are some non -- nonphysician clinicians?

A. There are nurse practitioners in the network, to -- to the best of my knowledge.

Q. If the physician -- if the Abortion Pill Rescue Network physician who is providing reversal services is, for example, an emergency room physician, then that doctor would not assume ongoing prenatal care for the patient if she continues her pregnancy, correct?

A. That's correct.

Q. Turning back to your 2018 paper, were patients included in that paper told that they were receiving an experimental treatment?

A. I believe that early on they were told it was experimental. And as time went on and the experience had broadened, I think the characterization changed to a novel treatment.

Q. So at the beginning of the treatment patients were informed that it was -- sorry, at the beginning of when you started the -- the hotline and the network, patients were informed that the treatment was experimental, and at a certain point it changed to them being informed that it was novel, but -- they were not told it was experimental; is that correct?

A. I believe so.

Q. Do you remember when approximately that change took place?

A. I do not.

Q. Was it before or after the 2018 paper was published?

A. Before.

Q. Was it before 2015?

A. Possibly.

Q. Were they ever -- were patients ever told that the safety and efficacy of the use of progesterone to reverse mifepristone had not been established?

MS. DAVIS: Objection.

THE WITNESS: They were told that there was -- depending on the stage of -- timeline of the development of APR, they were told that it was limited evidence and told there was some evidence and then more evidence.

BY MR. BECK:

Q. And those were at different points in time?

A. Yes. Different points in time.

Q. And so now patients are told

that there is -- I think you used the word "more evidence"?

A. Yes. They're told that there's been a -- that there has been a large case series published in the peer reviewed medical literature. They're aware of that, and they are aware of the -- some measure of the number of patients that have had successful reversals and births of -- of infants.

Q. So they are no longer told that it is -- are they still told that it is novel?

A. That I don't know.

Q. Do you think they should be told that it is novel?

A. I think whether they're told it's novel or not is not so important as that they're told what the experience has been up to now and what -- what's been published and how many babies have been born.

Q. Were patients who were included in the 2018 paper told that they were part of a study?

A. They were told that we were collecting data, and we asked permission to

collect data. But at that point it was not a study, so they were not told that they were in a study, to my knowledge.

Q. Were they told that the collection of data was for purposes of eventually publishing a study?

A. I don't recall.

Q. Did they give informed consent to receive experimental treatment?

A. They gave informed consent to receive the treatment. And early on it was described as experimental, later described as novel.

Q. So the -- the underlying data for your 2018 study, who has the repository of data for that?

A. Heartbeat International.

Q. Anyone else?

A. I don't believe so. I may have a copy, but I would have to look.

Q. But you're confident Heartbeat has a copy?

A. Fairly confident, yes.

Q. And you might have a copy, but you're not certain?

A. Correct.

Q. Would that be, like, on your computer files or paper copy?

A. On my computer files.

Q. Okay. I believe the 2018 paper indicates that data ends on June 21st, 2016. Does that sound right to you?

A. That the dataset ended on that date?

Q. Yes.

A. I believe so.

Q. For patients who received progesterone after that date, who has information on those patients?

A. Heartbeat International.

Q. And you as well or just Heartbeat International?

A. To my knowledge, just Heartbeat International.

Q. So you have not -- you haven't collected any of the data that has come in after June 21st, 2016?

A. I have not been collecting that data, no.

Q. Okay. Do you know how it was

sent to Heartbeat?

A. No, I don't.

Q. Do you know how Heartbeat stores that information?

A. No.

Q. We've spoken about patients lost to follow-up for purposes of your study. For patients after June 21st, 2016, does Heartbeat keep track of patients lost to follow-up and -- and log that in some way?

A. I don't know.

Q. Do you?

A. No.

Q. Do you know whether there's any way to know how many patients after June 21st, 2016 were lost to follow-up?

A. No.

Q. Do you know whether adverse events have been tracked after June 21st, 2016?

A. I believe that Heartbeat is tracking adverse events, but I'm not sure.

Q. And you mentioned a name earlier that I'm forgetting, Chris -- somebody at Heartbeat International as sort of the head of the Abortion Pill Rescue Network there?

A. Yes, Christa Brown.

Q. Christa Brown. Would Christa Brown be the person likely to know the answer to these questions that you don't know?

A. I believe so.

MR. BECK: Okay. Can we take just five minutes, and I'm -- I'm basically done. I just want to make sure I have everything we need.

MS. DAVIS: Sure.

VIDEOGRAPHER: Off the record at 5:24.

(A recess was taken.)

VIDEOGRAPHER: We are back on the record at 5:31.

MR. BECK: Thank you, Dr. Delgado. Those are all my questions.

THE WITNESS: All right. Thank you.

THE COURT REPORTER: Before we hang up, this is the reporter. Mr. Beck, I just wanted to confirm you want the rough tomorrow and an expedite not later than Friday, correct?

MR. BECK: That would be fantastic. Thank you.

THE COURT REPORTER: And the same for you, Ms. Davis?

MS. DAVIS: We definitely want to read and sign. Is it -- so you can get us a rough tomorrow? I'm impressed.

THE COURT REPORTER: I can. It'll probably be around lunchtime, but yes.

MS. DAVIS: Sure. Yeah, if they're getting it, sounds good. If you're doing it anyway.

THE COURT REPORTER: And do you want the expedite by Friday as well?

MS. DAVIS: Sure. Yeah.

THE COURT REPORTER: Okay. Thank you.

VIDEOGRAPHER: End of deposition. Off the record at 5:32 p.m.

(Whereupon, the proceeding was concluded at approximately 5:32 p.m.)

CERTIFICATE

STATE OF TENNESSEE)
)
COUNTY OF RUTHERFORD)

I, STEPHANIE A. BRANIM, LCR, CRI, CPE, CERTIFY:

The foregoing proceedings were taken before me at the time and place stated in the foregoing styled cause with the appearance as noted.

Being a Court Reporter, I then reported the proceedings in Stenotype, and the foregoing pages contain a true and correct transcript of my said Stenotype notes then and there taken.

I am not in the employ of and am not related to any of the parties or their counsel, and I have no interest in the matter involved.

I FURTHER CERTIFY that this transcript is the work product of this court reporting agency and any unauthorized reproduction AND/OR transfer of it will be in violation of Tennessee Code Annotated 39-14-104, Theft of Services.

Witness my signature, this, the 18th day of November, 2020.

Stephanie A. Branim, LCR, CRI, CPE
LCR No. 323, Expires June 30, 2022

SIGNATURE OF DEPONENT

I, GEORGE DELGADO, M.D., do hereby certify that I have read the foregoing deposition transcript and find it to be a true and accurate transcription of my testimony, with the following corrections, if any:

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George Delgado, M.D.

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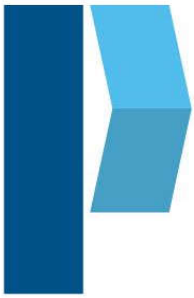

PohlmanUSA®
Court Reporting and Litigation Services

Donna Harrison, M.D.

November 13, 2020

Planned Parenthood of Tennessee and North Mississippi, et al.

vs.

Herbert H. Slatery, III, et al.

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

PLANNED PARENTHOOD OF TENNESSEE AND NORTH MISSISSIPPI, et al,	)	
Plaintiffs,	)	
v.	)	NO. 3:20-cv-00740
	)	JUDGE CAMPBELL
HERBERT H. SLATERY, III, Attorney General of Tennessee, in his official capacity, et al,	)	
Defendants.	)	

DEPOSITION OF DONNA HARRISON, M.D.

November 13, 2020

Taken on Behalf of the Plaintiffs

Videotaped deposition of DONNA HARRISON, M.D. held via Zoom video conference commencing at 9:00 a.m., on the above date, before Marilyn Morgan, Tennessee Licensed Court Reporter, pursuant to the Federal Rules of Civil Procedure governing depositions.

I N D E X

E X H I B I T S

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(Via Videoconference)

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Rebecca Chan

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APPEARING ON BEHALF OF PLAINTIFF, CENTER FOR REPRODUCTIVE RIGHTS:

Michelle Moriarty

Shayna Medley

VIDEOGRAPHER: We are on the record. This is the videotaped deposition of Dr. Donna Harrison. Today's date is November 13, 2020. The time is 9:09.

This is the case of Planned Parenthood of Tennessee and Mississippi versus Herbert Slatery, III, Attorney General of Tennessee, et al. Case number is 3:20-cv-00740, pending in the United States District Court for the Middle District of Tennessee, Nashville Division.

This deposition is being held remotely. All counsel will be reflected on the stenographic record.

Will the court reporter please swear in the witness.

DONNA HARRISON, M.D.,

after having been first duly sworn, was examined and testified as follows:

EXAMINATION

BY MS. CLARKE:

Q. Good morning, Dr. Harrison.

A. Good morning, Christine.

Q. Before I get started, the parties have agreed to stipulate that we will announce everyone who's on the Zoom at the beginning. I believe we have people who will be coming in and out, so I apologize for any dinging.

But for plaintiffs, aside from me, attending the deposition are Stella Yarbrough, Thomas Castelli, Michelle Moriarty, Shayna Medley, Marc Hearron, Andrew Beck, Rebecca Chan, Hana Bajramovic, Sara Shapiro; and they represent various parties in this litigation.

And, I'm sorry, Madam Court Reporter, what's your name?

COURT REPORTER: My name is Marilyn Morgan.

MS. CLARKE: Okay. Ms. Morgan, I apologize for any dinging that's happening, and I can send you the spelling of everyone's name after the deposition.

COURT REPORTER: I appreciate that. Thank you.

MS. CLARKE: Mr. Rieger, do you want to announce for --

MR. RIEGER: For defendants, we

have myself, Steve Hart, Alan Groves, and Charlotte Davis with the Tennessee Attorney General's office.

BY MS. CLARKE:

Q. Okay. So I know we've met before, Dr. Harrison. But I'm Christine Clarke, and I represent Planned Parenthood of Tennessee and North Mississippi as well as Dr. Lance in this litigation.

I know you've had a deposition taken before, but I'm going to go over some ground rules just so that you remember what we're about today.

I'll be asking you a series of questions. All of my questions and your answers will be taken down by the court reporter. So it's important for me to not talk too fast, but it's also important that we try not to talk over each other and that you answer verbally. So if you shake your head or nod or say uh-huh, that's not going to show up in the transcript.

Do you understand?

A. Yes.

Q. Okay. If you -- I know I tend to speak a little quickly. If you don't hear a

question or don't understand it, can you tell me so I can say it again?

A. Yes.

Q. If you need to take a break at any time, just let me know. I'm happy to take breaks. I'll just ask that you answer any pending questions before the break starts.

Is that okay?

A. Yes.

Q. So Mr. Rieger here is defending this deposition. He may make objections. Unless he instructs you not to answer, I'm going to ask that you still answer the question.

Do you understand?

A. Yes.

Q. You understand that you're testifying today under oath?

A. Yes.

Q. Okay. If during the course of the deposition today you realize that anything you've said is not correct or should be corrected, will you let me know?

A. Yes.

Q. Okay. Have you taken any medication today that might impair your ability to

give truthful and accurate testimony?

A. No.

Q. So I know in our new age, we're doing this remotely. Can you tell me what device are you using for this Zoom call?

A. I'm using a laptop computer.

Q. Do you have any other devices at your desk right now?

A. No.

Q. Do you have any windows open on your desktop other than the Zoom?

A. I have a folder open that says "Tennessee APR deposition," and it is empty.

Q. And is that where you are intending to save exhibits that I might give you in a chat today?

A. That's correct, yes.

Q. Have you spoken to anyone about the testimony you're giving today?

A. I have spoken to counsel.

Q. And who for the State of Tennessee have you spoken to about your testimony today?

A. Mr. Rieger and the other members of his team, who I can't recall their names right

at the moment.

Q. I know. There's a lot of people on this case.

Have you spoken with anyone at the American Association of ProLife OB/GYNs about the testimony you're giving today?

A. They're aware that I'm giving testimony because I had to have two days off. So they are aware that the testimony is happening today. I have not spoken about any details of the testimony.

Q. Okay. Did you speak to any of the other State's witnesses in the case about the testimony you're going to give today?

A. No.

Q. Before being retained in this case as an expert witness, did you know Dr. George Delgado?

A. Yes.

Q. For about how long have you known Dr. Delgado?

A. Probably 15 -- probably around 15 years. I would have to look back to see when I first met him.

Q. What about Dr. Charles Brent

Boles? Did you know him before you were retained in this case?

A. I think he is an AAPLOG member, but I do not know him personally.

Q. You've never spoken to him that you're aware of?

A. Not that I recall. But I speak to a lot of people, a lot of people. So -- but I don't recall any specific conversations with Dr. Boles.

Q. And what about Dr. Podraza? Did you know him before you were retained in this case?

A. No. Although he may be an AAPLOG member, but I don't have any personal -- I don't have any recall that I've spoken to him personally.

Q. What about Dr. Martha Shuping? Did you know her before you were retained in this case?

A. Yes.

Q. About for how long have you known Dr. Shuping?

A. Probably about ten or 15 years.

Q. Have you coauthored articles with

Dr. Shuping in the past?

A. Yes.

Q. Were those articles about medication abortion?

A. Yes.

Q. Have you ever coauthored an article with Dr. Delgado?

A. I don't recall. I don't think so.

Q. What did you do to prepare for your deposition today aside from speaking with counsel?

A. I reviewed my declaration, and I reviewed some of plaintiffs' statements, and I reviewed the medical literature that was pertinent to this case, some of the medical literature that's pertinent to this case.

Q. Would that medical literature include articles by Dr. Delgado?

A. Yes.

Q. Anything else in terms of medical literature that you've reviewed in preparation for your deposition today?

A. I'm sorry. Can you clarify that question a little?

Q. Did you review any other medical literature aside from Dr. Delgado's articles in preparation for your deposition today?

A. Yes. I reviewed all of the articles which I cited in my declaration.

Q. Anything else?

A. Well, I did another PubMed search. And in the course of my work, I review lots of medical literature.

Q. What did you do a PubMed search for in preparation for your deposition today?

A. Progesterone receptor.

Q. And did you read any of the articles that popped up as a result of the search?

A. Some of them, not all.

Q. About how many articles did you read that came up as a result of that search?

A. Oh, goodness. I don't recall.

Q. More than five?

A. Yes.

Q. More than ten?

A. Yes.

Q. More than 20?

A. I don't -- it would probably be in the 15 to 20 range. The issue is figuring out

what's pertinent and what is not pertinent. There's a lot of articles that come up when you Google or when you put a PubMed search in for progesterone receptor.

Q. Were there any articles you found that you think are pertinent to your deposition today that were not cited in your declaration?

A. There may be. I don't know. I would have to go back and look at the PubMed search again.

(Technical difficulty)

VIDEOGRAPHER: We'll go off the record at 9:20.

(Off-the-record)

VIDEOGRAPHER: We are back on the record at 9:22.

BY MS. CLARKE:

Q. So during the course of this deposition, our paralegal, Sara, is going to help me pop exhibits into the chat. So if you hear me talking to with her, that's what's going on. We have them internally labeled for ourselves as tabs. But for the purposes of the deposition, we'll number them.

We're also going to start

numbering where plaintiffs left off in the last deposition. So we're going to start at Exhibit 17.

Is that okay, Mr. Rieger?

MR. RIEGER: That is fine by me.

MS. CLARKE: So, Sara, if you could pop Tab A into the chat for me?

THE WITNESS: Christine, when she pops it in the chat, because I've not done a video deposition before, am I supposed to take that and then put it into the file to open it, or do you screen share? How do I see what you have?

MS. CLARKE: I believe you can click on it, and it will start downloading. And then if you click again, it will just open automatically. So why don't you try it and let me know if that works?

THE WITNESS: Okay. Gotcha.

MS. CLARKE: Do you see an image yet?

THE WITNESS: I do not, so let me get -- there it is in chat. Okay. Tab

B, Harrison CV; correct. So I'm supposed to click on it, and I'm supposed to download it. Gotcha. Download. Me one second here.

MS. CLARKE: Take your time.

THE WITNESS: All right. Harrison CV.

MS. CLARKE: Okay. I'm going to ask the court reporter to mark this as plaintiff's 17, please.

(Exhibit 17, Harrison Curriculum Vitae, was marked.)

BY MS. CLARKE:

Q. Dr. Harrison, could you look at this document and tell me what it is.

A. This is my curriculum vitae.

Q. And does this accurately represent your relevant qualifications and professional experience.

A. Yes, as of the date of the CV.

Q. Are there any professional affiliations or positions that aren't listed on here?

A. Give me a minute. I don't think there's anything pertinent not listed.

Q. Okay. So you completed your residency in obstetrics and gynecology at St. Joseph's Hospital; is that right?

A. St. Joseph's Mercy Hospital in Ypsilanti, yes.

Q. Mercy Hospital. And that's a Catholic affiliated hospital; is that right?

A. That's correct.

Q. And I believe you did one abortion while you were there, but not voluntarily; is that accurate?

A. That is correct.

Q. You were under the impression that it was for a maternal-fetal indication, but it was not?

A. Let me clarify that, because it was not performed at that hospital.

Q. Okay.

A. It was performed at another hospital.

Q. But as part of your residency?

A. As part of my residency. I did an outside rotation, yes.

Q. And you are a diplomate of the American Board of Obstetrics and Gynecology. What

does that mean?

A. That means I am board certified.

Q. And you're board certified in obstetrics and gynecology?

A. That's correct.

Q. Any subspecialty?

A. No.

Q. And you're licensed to practice medicine in Michigan; is that right?

A. That is correct.

Q. Anywhere besides Michigan?

A. No.

Q. And you practiced medicine after your residency for seven years; is that right? So not including your residency?

A. No. I practiced from -- I completed residency in 1990. I practiced until 2000.

Q. So that would be ten years?

A. That is correct.

Q. So since 2000, you've been -- you haven't been practicing medicine; is that right?

A. Well, let me clarify that, because there is a lot involved in the practice of medicine other than simply the care of patients.

So I have been actively involved and maintained my board certification continuously from the time I was board certified until now.

Q. But you haven't treated patients?

A. I have not treated patients. I have not been doing clinical medicine since 2000.

Q. All right. Are you currently an adjunct professor at Trinity International University in Deerfield?

A. Yes.

Q. What does that entail?

A. I am called upon to teach workshops and classes and give lectures occasionally at the Center for Bio Ethics and Human Dignity, which is a subset of Trinity International University.

Q. When you say "occasionally," about how often would that be?

A. Once a year.

Q. Do you have any other duties besides performing workshops once a year?

A. No.

Q. You're currently employed at the American Association of Pro-life Obstetricians and Gynecologists?

A. That's correct.

Q. We can call that AAPLOG; right?

A. Well, if you call it AAPLOG, most people spell it A-A-P, because they think of an app. So we have taken to saying A-Plog (ph) to distinguish from apps.

Q. If I say App-Log (ph) because I might forget, will you know what I'm talking about?

A. Yes.

Q. Okay. When did you start working at AAPLOG full-time?

A. When I stepped back from clinical medicine. I stepped back from clinical medicine in 2000 in order to fulfill a two-year public policy commitment that I had because I was a Truman Scholar.

So at that time, I stepped back and said I will take two years at this point, because I was also on maternity leave. I'll take two years to fulfill that commitment since I have not had a chance to fulfill that. With medical school, residency, private practice, there's just no time you can take two years off.

So I took a two-year maternity

leave and joined with AAPLOG at that time. Well, I had joined AAPLOG earlier but became more involved with AAPLOG at that time. And I have worked with AAPLOG ever since.

Q. As a Truman Public Policy Scholar, was it required that you spend two years working in public policy?

A. It's an honorary agreement. There's no legal written requirement. But the understanding was if you were given a two-year scholarship for graduate studies, then you will repay that two-year scholarship on your honor with two years of free work in public policy.

Q. I see. So you fulfilled that honorary agreement at AAPLOG; is that right?

A. Correct.

Q. And you were the chair of the Mifepristone Committee at AAPLOG in 2000; is that right?

A. That's correct.

Q. In 2006, you became the president of AAPLOG for a number of years; is that right?

A. That's correct, around 2006.

Q. And thereafter, you were the director of research and public policy at AAPLOG?

A. I think I held those titles simultaneously for a year or so.

Q. What does it mean to be the director of research and public policy at AAPLOG?

A. AAPLOG is primarily an educational organization, and we look at the medical literature. We look at the scientific literature. And we compile that literature in a way that our members can understand pertinent issues related to the life issues, beginning of life issues. That was my responsibility.

Q. So would that include writing AAPLOG practice bulletins?

A. I would certainly participate in the writing of AAPLOG practice bulletins.

Q. So would it include pulling articles to put on the AAPLOG website?

A. That was part of my responsibility, yes.

Q. What were your other responsibilities besides pulling articles relevant to the beginning of life issues to put on the website and participating in the writing of the practice bulletins?

A. Those were the primary

responsibilities. I needed to be familiar with the medical literature and all aspects of life issues pertinent to a practicing OB/GYN.

Q. And then at some point, you became the executive director of AAPLOG; is that right?

A. That's correct.

Q. What are your duties as executive director of AAPLOG?

A. I direct the running of AAPLOG. What does an executive director do? I am responsible for the legal and the day-to-day running of all the things that we do.

Q. Would that include fundraising?

A. Yes, although I'm not a very strong fundraiser.

Q. Would that include policy advocacy?

A. AAPLOG is a 501(c)(3). We do not do lobbying.

Q. So aside from directly lobbying legislatures, would your role as executive director include coming up with positions or position papers on behalf of AAPLOG on policy issues?

A. I would certainly participate in that.

Q. I'm sorry. I feel like you've already told me, but I didn't ask you. I would ask again to be clear.

What is AAPLOG?

A. AAPLOG is the American Association of Pro-life Obstetricians and Gynecologists.

Q. What does AAPLOG do?

A. We exist to provide our members with an evidence-based defense of both our pregnant female patient and her preborn child.

Q. So AAPLOG opposes abortion; right?

A. AAPLOG adheres to the Hippocratic medical principle that causing the death of a human being is not a therapeutic option.

Q. And "human being" for those purposes would be defined at fertilization?

A. "Human being" would be defined at the point of the scientific reality that a unique organism exists, which is indeed at the point of fertilization.

Q. How does one become a member at

AAPLOG?

A. Well, you have to sign up as a member of AAPLOG.

Q. How does one sign up?

A. You can sign up in a couple of different ways. You can let a member of AAPLOG -- you can communicate with a board member who can enroll you, you can put your name on a list at a conference with your email address, or you can go on the website and join.

Q. Do people who are members of AAPLOG need to pay dues?

A. We would like them to pay dues, yes.

Q. Is it required?

A. Well, to become a dues-paying member, you do have to pay dues.

Q. And are those dues paid annually?

A. Yes.

Q. Are all dues-paying members of AAPLOG OB/GYNs?

A. No. The majority are OB/GYNs.

Q. How do you know that the majority are OB/GYNs?

A. Because the majority of the

conferences that we've attended, we speak primarily to OB/GYNs. But they are not exclusively OB/GYNs. We do have members who are not OB/GYNs.

Q. Does AAPLOG have dues-paying members who aren't doctors at all?

A. Yes.

Q. Does AAPLOG have dues-paying members who are not clinicians, medical clinicians of any kind, so nurses --

A. Yes. Not many, but we have a few.

Q. Do people have to state when they become a member of AAPLOG whether they're an OB/GYN or a doctor or a nurse or a midwife?

A. When they join, there's a tiered level of membership, and they have to answer the question, I am an OB/GYN. I am a midwife. I am a nonmedical professional. They have to answer that question.

And there are tiers of membership dues. So OB/GYNs -- physicians in active practice pay the highest amount of dues, and people that are nonmedical pay a lower amount.

Q. So how many dues-paying members

does AAPLOG have total right now?

A. I would have to look it up.

Q. Could you estimate for me?

A. Over -- I'm sorry. Ask the question again.

Q. How many dues-paying members does AAPLOG have in total?

A. That, I would have to look up. I couldn't guess.

Q. Could you estimate it for me?

A. Not without looking it up.

Q. How many dues-paying members of AAPLOG are physicians, that you're aware of? If you could estimate for me, how many of AAPLOG's dues-paying members are doctors?

A. If I would estimate, I would say about 85 percent.

Q. Do you know what number? Is that like 5,000 people? 10,000 people?

A. I would have to look that up. I don't want to be more specific without the numbers in front of me.

Q. Sure. Do you know how many of AAPLOG's dues-paying members are OB/GYNs?

A. I'm sorry. I thought that was

actually your question before. I would say 85 percent of AAPLOG members in my estimation are OB/GYNs. I misunderstood your previous question.

Q. And that larger percentage would be doctors, right, of some kind or other?

A. Correct. Correct.

Q. Okay. And you have no rough idea of how many members there are of AAPLOG right now?

A. I have a rough idea, but I don't want to give you a number without looking at the numbers. I can't pull that out of my head. I did not prep that for this deposition.

Q. Fair enough. So I'm not asking for the precise number at all. I'm asking for your rough estimate.

A. Over 6,000.

Q. Okay. Less than 10,000, would you estimate?

A. Probably, yes. Probably less than 10,000.

Q. So if someone stops paying their dues, do they lose their AAPLOG membership?

A. They lose their dues-paying membership. They become associate members.

Q. So when you talk about the

probably over 6,000 members, are those all the members, or are those dues-paying members?

A. Those are all the members.

Q. So approximately how many dues-paying members of AAPLOG are there right now?

A. I don't know. I would have to look that up.

Q. Would you estimate it's less than 5,000?

A. Yes, I would estimate.

Q. Would you estimate that it's less than 3,000?

A. I don't know. I would have to look that up.

Q. So if people stop paying their dues, they become associate members?

A. Correct.

Q. Is there any way that people lose their membership in AAPLOG?

A. Well, if they die, they lose their membership. If they voluntarily withdraw, they, of course, lose their membership.

Q. How would one voluntarily withdraw?

A. Email me and say, Take me off the

list, or email whoever is at that particular point in time responsible for taking people off the list; and they would be taken off the list.

Q. If a member died, AAPLOG wouldn't know unless you knew that person or someone knew that person personally. Like how would AAPLOG know if a member had died?

A. We periodically go through the membership. It's a long process. So it may be delayed, but we will eventually find that person.

Q. Okay. You used to be a member of the American College of Obstetricians and Gynecologists; is that right?

A. That's correct.

Q. If I call them ACOG, you'll know what I'm talking about?

A. Yes.

Q. And you stopped being a member of ACOG; right?

A. That is correct.

Q. How did you go about ceasing your membership with ACOG?

A. I ceased paying dues in 2007.

Q. Did you email anyone at ACOG to say, Take me off your list?

A. I think I did. I think I vaguely recall that I emailed them and told them the reason why I ceased membership. That's my vague recall.

The reason that I ceased membership was because of ACOG Ethics Statement 385. ACOG Ethics Statement 385 required an OB/GYN to perform or refer for abortion or to be considered ethically unprofessional.

However, those statements bind ACOG members, and I could not support that kind of proabortion activism from ACOG.

Q. So you ceased your membership in ACOG because of their statement saying that physicians must, if asked, refer patients to abortion providers; right?

A. Perform the abortion, refer to an abortion provider; and if they don't perform, they're supposed to pick up their practice and move it next to someone who does perform abortions.

It was a ridiculous statement. And, yes, that is the reason why I quit ACOG.

Q. Okay. Does AAPLOG provide any training for pro-life expert witnesses?

A. Sometimes.

Q. How often, to your knowledge, has AAPLOG provided that kind of training?

A. Twice.

Q. What's the most recent time?

A. At our 2009 Matthew Bulfin Educational Conference.

Q. And what does that training entail?

A. Training to become an expert witness, the things that physicians need to understand before they agree to become an expert witness.

Q. What would those things be?

A. I don't recall everything that was said at that particular training session. But, in general, it would be this is what an expert witness does and doesn't do; this is how expert witnesses fit into the entire picture of a lawsuit; this is -- it's pretty basic stuff. But it's stuff that most physicians don't know.

So for a lawyer, it would be expert witness 101, mostly looking at the overview of how the expert witness testimony fits into a case.

Q. Was there any training on how to give or how to be deposed?

A. Yes, I think so.

Q. And do you remember who gave that training?

A. I'm sorry. Say again.

Q. Do you remember who gave the training on how to be deposed?

A. I don't remember. I think -- I think it was a lawyer from Alliance Defending Freedom.

Q. Do you know whether Brian Calhoun ever gave a training for AAPLOG on how to be deposed?

A. I don't know whether Brian Calhoun was at that training program or not in 2019. I don't know.

Q. Do you know if he was at the previous one before 2019?

A. He might have been. I would have to go back and look.

Q. Are there any materials that were given out to participants as part of this training?

A. I don't know. I would have to

look.

Q. Does AAPLOG ever connect state governments with potential expert witnesses for litigation?

A. Yes.

Q. Can you give me an example of some pieces where AAPLOG has connected a state government with an expert witness for litigation?

A. I would have to look. I did not prepare that for this deposition.

Q. Can you think of any examples where that's ever happened?

A. I would have to go back and look.

Q. So you can't think of any examples; right?

A. No. What's in my head right now is abortion pill reversal.

Q. Do you know if AAPLOG -- strike that.

Are you affiliated with the Charlotte Lozier Institute?

A. Yes.

Q. And the Charlotte Lozier Institute -- would you agree with the statement that, The Charlotte Lozier Institute functions to

provide scientific input for public policy about life issues of abortion and euthanasia?

Is that an accurate statement?

A. Yes.

Q. And would you agree with the statement that, It is a group that promotes pro-life guidance and legislation and in other areas of the public forum?

A. Maybe. I mean --

Q. Does that sound right to you?

A. If that's what they have on their website, then I would agree that's what they have on their website.

Q. Aside from whether it's on the website, does that sound like an accurate characterization of them to you?

A. The way I interdigitate with the Charlotte Lozier Institute is via the research. So that is how I interdigitate with Charlotte Lozier.

Q. So you don't know if it's accurate to describe them as a group that promotes go pro-life legislation?

A. I don't know.

Q. And the Charlotte Lozier

Institute, would you characterize that as the research arm of the Susan B. Anthony List?

A. Yes.

Q. And the Susan B. Anthony List, would you agree that they are an organization dedicated to electing candidates and pursuing policies that will reduce and ultimately end abortion? Is that accurate?

A. If that's what they have on their website, then that is accurate.

Q. Leaving aside looking on their website, would you agree that that's an accurate characterization of the Susan B. Anthony List?

A. I can't leave aside that, because I would have to go to their website to find out how they self-characterize.

Q. Why don't you tell me, how would you characterize the Susan B. Anthony List?

A. I would go to their website and see how they self-characterized, and then I would quote that, because I can't speak --

Q. You're aware --

A. I can't speak for the Susan B. Anthony List.

Q. I'm not asking you to speak for

them. I'm just asking you to tell me what's your understanding of what the Susan B. Anthony List is?

A. Whatever they have on their website.

Q. You have no idea what they do?

A. No. They do whatever they say on their website.

Q. If you couldn't look at the website, you would have absolutely no idea what the Susan B. Anthony List does?

A. The way I interdigitate with the Susan B. Anthony List is via the Charlotte Lozier Institute, and the way I interdigitate with the Charlotte Lozier Institute is via research.

So I know that the Charlotte Lozier Institute is committed to accurate scientific research. That's what I know. And I know that the Charlotte Lozier Institute is an arm or is a -- what's the legal term -- subset, whatever the legal term is, of the Susan B. Anthony List.

Q. When you say that the Charlotte Lozier Institute is committed to accurate scientific research, that's research about

abortion issues; right?

A. I don't know whether or not they're limited to abortion issues. That's how I interdigitate with them.

Q. Do you know if any Charlotte Lozier scholars are pro-choice?

A. I don't know.

Q. Would you be surprised if there was a Charlotte Lozier scholar who was pro-choice?

A. No.

Q. Would you agree that the Susan B. Anthony List is, quote, "an organization dedicated to electing candidates and pursuing policies that will reduce and end abortion." Does that sound right?

A. If that's what they self-characterize, then that sounds right.

Q. If that's how you testified in the Eastern District of Arkansas, would that sound right?

A. Whatever they self-characterize is how I would characterize them.

Q. You don't recall testifying about the Susan B. Anthony List in the Eastern District of Arkansas about two years ago?

A. I honestly don't. I don't. Whatever the Susan B. Anthony List self-characterizes, I would agree that is their characterization?

Q. So you have no idea if the Susan B. Anthony List advocates for ending abortion?

A. That's what they state on their website?

Q. So it's your understanding that that's what they do; correct?

A. Whatever they state on their website, that's what they do.

Q. So you have no idea outside their website what they do at all? Is that your testimony today?

A. No.

Q. Okay. So what's your testimony?

A. You asked me what the Susan B. Anthony List does. My interdigitation with the Susan B. Anthony List is via the Charlotte Lozier Institute. And my interdigitation with the Charlotte Lozier Institute is via research.

So if you're asking me what does_ that Susan B. Anthony List do outside of research,

I cannot speak to that, because I get involved via research with the Charlotte Lozier Institute.

Q. So when you say you can't speak to that, I'm not asking you to speak for them. I'm asking you, what's your understanding sitting here today of what the Susan B. Anthony List does? What do you --

A. I understand whatever they put on their website is what they do.

Q. So if they change their website today, your understanding of what they do would change a hundred percent; is that right?

A. It would change to whatever degree they change from what they had on their website previously.

Q. So without looking at their website, you cannot say at all what the Susan B. Anthony List does? Is that your testimony today? That's all I'm asking.

A. I cannot speak authoritatively for the Susan B. Anthony List.

Q. I'm not asking you to speak authoritatively for the Susan B. Anthony List. For the last time, I'm literally only asking what you personally, Dr. Donna Harrison, understand the

Susan B. Anthony List to do. I'm not asking you to speak for them. I won't hold it against them. I'm just asking what you understand that they do.

A. What I understand what they do is what they have on their website. So I wouldn't have an understanding of what they do or speak to what they do other than what they, themselves, say that they do.

Q. So without looking at the website, you have no understanding of what the Susan B. Anthony List does?

A. I'm not sure I understand your question.

Q. Without looking at the website, do you have any idea what the Susan B. Anthony List does?

A. Yes. I have an understanding of one thing that they do.

Q. What's the one thing that they do?

A. From my understanding, the one thing that they do is they have a research arm, which is the Charlotte Lozier Institute. And the way I understand the Charlotte Lozier Institute is that it is committed to accurate research in the

life issues. And that's how I interdigitate with the Susan B. Anthony List.

I can't speak for the Susan B. Anthony List other than the way I interdigitate with them.

Q. Okay. So let's say the Charlotte Lozier Institute website said that -- you know what? Strike that.

Does the Charlotte Lozier Institute provide training for pro-life expert witnesses?

A. I think so.

Q. Have you ever attended one?

A. Yes.

Q. When did you attend a training for pro-life expert witnesses conducted by the Charlotte Lozier Institute?

A. Goodness, I don't remember. Several years ago.

Q. Okay. What did you learn in that training?

A. The responsibilities of an expert witness.

Q. What other responsibilities of an expert witness -- strike that.

What did you learn about the responsibilities of an expert witness from that expert witness training provided by the Charlotte Lozier Institute?

A. It's the responsibility of an expert witness to speak truthfully, to have their research well documented, to communicate clearly with counsel. That's our responsibility.

Q. Do you remember who gave the training, like what person or people?

A. I don't know. I would have to look back.

Q. You don't remember any of the people who spoke during that training?

A. I'm going to have to think about this a minute because, again, this is not stuff I prepared for this deposition.

I know that there were lawyers present, and I believe one of the lawyers was from Americans United for Life.

Q. Do you know -- did you receive any materials at this training?

A. I don't keep paper. So if there were materials given out, I do my very best to throw it way. So there may have been. I don't --

I have a small office, and it has to all be digital.

Q. Okay. Do you know if they emailed you any materials relevant to that --

A. I don't know.

Q. Okay. So we talked about -- well, strike that.

You're an associate scholar at the Charlotte Lozier Institute; right?

A. That's correct.

Q. What does that mean?

A. That means that I participate in talking about the research for the life issues and what is published and what needs to be published and what could be published and what -- we talk as scientists.

Q. When you say "we," you mean you and the other associate scholars at the Charlotte Lozier Institute?

A. Not all of them, because everybody is not interested in the same thing.

Q. So, then, you would speak with other scholars who are interested in abortion issues?

A. Correct. Some of them.

Q. Do you know how many there are?
A. I don't.
Q. Are you paid for your work at the Charlotte Lozier Institute?
A. I'm trying to think if they've ever paid me. They may have paid me.
Q. But you're not sure?
A. I would have to go back and look. Sometimes there are specific things that they will fund, but most of my time is volunteer.
Q. Okay.
A. And it depends on what project, and I would have to go back and look.
Q. So what kind of specific things would they fund that you're aware of?
A. If we have a research document and there needs to be analysis of that document done by statisticians, they will cover that cost, because they have statisticians in-house so that they can do that.
Q. Anything else that you're aware of?
A. Not that I'm aware of right at this moment.
Q. Do you know whether the Charlotte

Lozier Institute connects state governments with pro-life expert witnesses for litigation?

A. If they state that on their website, then I believe that's what they do. But I don't know.

Q. Okay. You're an associate editor at the issues -- sorry.

You're an associate editor at Issues in Law and Medicine; is that right?

A. That's correct.

Q. I'm sorry. I want to go back for a second.

On the Charlotte Lozier Institute website, your associate scholar bio says that you have an interest in endometrial conception -- sorry -- endometrial contraception. What does that mean?

A. It means contraception that works at the level of the endometrium.

Q. Can you give me an example, just so I have an idea of what --

A. There are many drugs that work at the level of the endometrium, and I'm particularly interested in the interactions of those drugs with the endometrium.

Q. Can you give me an example of drugs that interact with the endometrium? I'm just curious what kinds of drugs we're talking about.

A. There are lots of drugs that interact at the level of the endometrium, Mifeprex being one of them. Mifeprex very specifically interacts at the level of the endometrium.

Q. Is there any other contraception that I might have heard of that interacts at the level of the endometrium?

A. Mifeprex is RU-486, mifepristone.

Q. Oh, yeah. Is there anything else that you can think of?

A. Progesterone receptor modulators work at the level of the endometrium. So Mifeprex is one; progesterone receptor modulator; ulipristal or Ella is another.

Q. Anything else? Any other kinds of contraception that would fall into that category?

A. I would have to go back and look. There's a lot of drugs that affect a lot of parts of the body. So if you're asking for a list of drugs that would affect the different parts of the

body, I would have to compile that.

Q. But if say -- let's say in your CV and on your Charlotte Lozier bio it says that your interests includes specifically endometrial contraception, that would be specifically referenced to mifepristone; is that right?

A. Those drugs do act at the level of the endometrium.

Q. Are those the primary drugs that you have a research interest in when it comes to endometrial contraception?

A. I'm interested in anything that affects the endometrium.

Q. Have you done research on any other drugs that affect the endometrium besides Ella and Mifeprex?

A. Yes.

Q. So what drugs?

A. I've done research on the effects on the endometrium from the birth control pill.

Q. That would be the (Zoom audio distortion) --

A. Yes.

Q. Anything else?

A. I've done research on the effect

on the endometrium from the IUD.

Q. Would that be the progesterone IUD or any IUD?

A. Any IUD.

Q. Anything else?

A. Not that I can recall at the moment.

Q. So I asked you earlier about being an associate editor at Issues in Law and Medicine. What does it mean to be an associate editor at Issues in Law and Medicine?

A. My responsibility includes contacting potential peer reviewers to see if they would be willing to do a peer review.

Q. Is there a sort of bank of potential peer reviewers?

A. I believe that's listed in Issues in Law and Medicine.

Q. Where would you go about finding a list of people to contact to see whether they would be a peer reviewer for an article?

A. Well, I start first with the people on the list at Issues in Law and Medicine. If I happen to know of a specific physician who has an expertise in the area of the manuscript,

then I would email them with the request to -- would they be willing to peer review this article?

Q. So when you talk about the list, is that a list that's published on the Issues in Law and Medicine website of peer reviewers?

A. I think it's in the paper copy. I don't know if it's on the website or not.

Q. Do you select articles for review at Issues in Law and Medicine?

A. Barry Bostrom is the editor, and he's the one who obtains the manuscript. I suggest peer reviewers. He makes the final decisions.

Q. Do you ever participate in peer review of articles for Issues in Law and Medicine?

A. Well, I'm the one who arranges for -- I mean, I'm the one who writes and says, Dr. Smith, would you be willing to peer review an article for Issues in Law and Medicine?

So in that way, yes, I participate in the peer review process.

Q. But you don't yourself act as a peer reviewer?

A. I don't recall right now whether I've ever peer reviewed for them. I may have.

Q. But you're not sure?

A. Not right at this moment. I would have to go back and ask Barry Bostrom, because he's the one who gets the reviews. He is the one who corresponds with the reviewers. He makes the decisions.

Q. Okay. What kinds of topics does Issues in Law and Medicine publish on?

A. Issues in law and medicine I mean, topics that pertain to law or medicine.

Q. So it will publish on any topics relating to law or medicine in any way?

A. I'm sorry. Can you ask that question again?

Q. Does Issues in Law and Medicine publish articles on any topic involving law or medicine?

A. Yes.

Q. It has no focus?

A. I'm sorry? I don't understand your question. They're focused on issues in law and medicine.

Q. There's like thousands of medical journals; right? And they publish on various things. So the Journal of Endocrinology will

publish articles about endocrinology.

So law and medicine is a pretty broad topic. So is it your testimony that Issues in Law and Medicine, the journal, if I read a year's worth of issues, I will find a broad array of issues involving law or medicine totally unrelated to abortion or contraception or euthanasia?

A. Abortion, contraception, and euthanasia are issues in law and medicine.

Q. Does Issues in Law and Medicine, the journal, publish about other issues?

A. Yes. I mean, you would have to go back at the journals for all the years to see what issues they publish on. They publish on a wide variety of issues.

Q. So you would not characterize Issues in Law and Medicine, the journal, as focusing primarily on issues of abortion, contraception, and euthanasia?

A. That's not the stated purpose of Issues in Law and Medicine.

Q. I understand. That's not the question. If I were to look at all the articles that Issues in Law and Medicine has published over

the last year, would I find that the majority of those articles concern abortion, contraception, or euthanasia?

MR. RIEGER: I'm going to object to the form of the question.

Go ahead and answer.

A. Issues in Law and Medicine only publishes two editions a year. So if you look in one year, you'll find whatever was published in that year. You will have to look over the broad range. I believe they've been publishing since around '73 or '74. So you would have to look back to '73 or '74 to get the spectrum of what Issues in Law and Medicine publishes on.

Q. Let's say over the last year, would you say that a majority of the articles that Issues in Law and Medicine has published in those two issues concern abortion, contraception, or euthanasia?

A. Actually, because of COVID, there was one combined issue that came out. So I would have to look back and see what the articles are on there.

Q. Would you be surprised to learn that over the last ten years, the majority of

articles published by Issues in Law and Medicine concern abortion, contraception, or euthanasia? Would that surprise you?

A. Those are issues in law and medicine.

Q. So it would not surprise you?

A. Those are issues in law and medicine. It's within the purview of what Issues in Law and Medicine publishes on.

Q. I'm just asking for a yes-or-no answer, whether you would be surprised to learn that the majority of issues published in Issues in Law and Medicine over the last ten years concern abortion, contraception, and euthanasia? Would you be surprised to learn that?

A. Well, I can't give you a yes-or-no answer to that. It is within the realm of publication of what Issues in Law and Medicine covers.

Q. I'm literally just asking whether you would be surprised to learn that fact. Would it surprise you that the majority --

MR. RIEGER: I'll object to the form of that question.

You can go ahead and answer.

A. I'm not surprised by much in life.

BY MS. CLARKE:

Q. Okay. So you would not be surprised. Is that your testimony?

A. No, my testimony is --

MR. RIEGER: Same objection.

You can go ahead and answer.

A. No. My testimony is that contraception, abortion, and euthanasia are issues in the law and medicine. They're issues in both.

BY MS. CLARKE:

Q. I completely understand that. I'm just asking whether the majority of articles, to your knowledge, that are published in the journal, Issues in Law and Medicine, concern abortion, contraception, or euthanasia.

A. I would have to go back and look at all the articles.

Q. And you have no idea sitting here today whether the majority of articles published in Issues in Law and Medicine in the last ten years concern abortion, euthanasia, or contraception?

A. Well, I didn't become editor

until five years ago.

Q. So that's --

MR. RIEGER: If we could go ahead and let the witness complete her answer. It didn't sound like she was done.

Thank you.

A. So I didn't become associate editor until about five years ago. During that time, the focus of concern for law and medicine has been these issues of abortion, contraception, and euthanasia. But that's not the only articles that have been published.

I believe they published an article on head transplants. There's been some other articles published that I've seen. So it's not the only thing.

And there's been some legal articles. Again, I don't interdigitate at all with the legal peer review process. That's all Barry Bostrom.

BY MS. CLARKE:

Q. So you only select peer reviewers for articles concerning medicine; is that right?

A. Correct.

Q. And so would it be accurate to

say that because the focus of concern in law and medicine for the last five years has been issues of contraception, abortion, and euthanasia, that, therefore, the majority of medical articles published in Issues in Law and Medicine in the last five years concern abortion, euthanasia, and contraception?

MR. RIEGER: I'll object to the form of that question.

Please go ahead and answer.

A. The problem that I'm having with your question is the issue of majority. Majority means more than 50 percent. So I would have to go back and look at the numbers of what papers are published in order for me to say, Has it been more than 50 percent? So I can't give you a numerical answer.

BY MS. CLARKE:

Q. I'm sorry. I didn't mean to interrupt you. Are you finished?

A. It very well may be more than 50 percent. But I would have to go back to look, because you've asked for a numerical answer, and I can't give you a numerical answer.

Q. So sitting here right now, you

have no idea whether it's the majority?

A. No. What I said was I can't give you a numerical answer. You've asked whether it's the majority. I would have to go back and look at the numbers and see which articles and put them on one side and see how many articles are on the other side. Then we would see is it more than 50 percent, the definition of majority.

Q. So over the last five years, you've been -- strike that.

Are you the only person who selects peer reviewers for medical articles in Issues in Law and Medicine?

A. No. Barry has a network of people that he talks to. I'm one of the people that he talks to about peer review. But as -- my job as an associate editor is, if he asks me, I find people that are qualified that can peer review the article. But he has more than me.

Q. So he selects peer reviewers for more medical articles in the journal than you do?

A. No. I think the question you asked was, is there anyone else that he would task for peer reviewers for medical articles? I'm one of, but I don't think I'm the only one that he

tabs for peer reviewers for medical articles.

Q. Okay. Do you know who else might tab peer reviewers for medical articles?

A. I don't. You'd have to ask Barry Bostrom.

Q. Do you know what the Watson Bowes Institute is?

A. Yes.

Q. What's the Watson Bowes Institute?

A. Watson Bowes Institute is an institute that's devoted to truth in life issues in research.

Q. When you say the life issues, we're talking about abortion and euthanasia?

A. Yes.

Q. Is the Watson Bowes Institute located within AAPLOG?

A. Yes.

Q. What does that mean?

A. Watson Bowes Institute is a DBA of AAPLOG.

Q. And the Watson Bowes Institute is a co-sponsor of Issues in Law and Medicine; is that correct?

A. That's correct.

Q. And the other co-sponsor of Issues in Law and Medicine is the National Legal Center for Medically Dependent and Disabled; is that right?

A. That's correct.

Q. And what is that?

A. I don't know.

Q. Do you have any idea what --

A. I know that Barry Bostrom knows. That is his organization. But I have not talked about what his organization does.

Q. When you say it's his organization, does he have like a leadership role in that organization?

A. You would have to ask Barry about the details of the National Center for Medically Dependent and Disabled.

Q. Were you aware that the National Legal Center for the Medically Dependent and Disabled was founded by James Bopp?

A. Okay.

Q. Do you know who James Bopp is?

A. Yes, I do.

Q. Who is James Bopp?

A. My understanding is that James Bopp is the legal counsel -- I don't know if he is currently. At some point, he was legal counsel for National Right to Life.

Q. So before we take a break -- actually, let's go ahead and take a break. Is this a good time for you guys?

VIDEOGRAPHER: Off the record at 10:19.

(A break was taken.)

VIDEOGRAPHER: Back on the record at 10:26.

BY MS. CLARKE:

Q. So, Dr. Harrison, you've been a defendant in three lawsuits; is that accurate?

A. Whatever list I put on my CV or, excuse me, in the declaration. I think it's been more than three. I believe -- go ahead.

Q. Were you finished with your answer? Sorry.

A. It's whatever list I put on the declaration.

Q. Have you ever been a plaintiff in a lawsuit? Have you ever sued anybody else?

A. No.

Q. Have you ever filed a complaint with a government agency?

A. Oh, okay. All right. I know what you're saying. Have I personally ever sued anyone else? No, I have not personally ever sued anyone else that I can recall.

Q. Have you ever filed a complaint with a government agency that's not a lawsuit?

A. In my capacity as executive director of AAPLOG, AAPLOG has filed complaints.

Q. Where has AAPLOG filed complaints?

A. They've filed complaints with the Office of Civil Rights. I think that's it.

Q. Would that be the Office of Civil Rights within HHS?

A. Yes, uh-huh. Sorry. Yes, within HHS.

Q. And you're referring to a complaint against ACOG?

A. Yes. We filed a complaint with the Office of Civil Rights against ACOG, yes.

Q. And what was that complaint about, briefly?

A. The complaint was about the

infringement of the right of conscience of AAPLOG members and physicians by ACOG Ethics Statement 385, because ACOG Ethics Statement 385 declares ethically unprofessional those physicians who choose not to kill human beings as a part of their medical practice. And we filed a complaint against them.

Q. That complaint also referred to the fact that the ethics statement says that physicians must refer patients to other providers --

A. It said three things, that they must perform or be unethical. Those who don't perform have to refer. Now, those who don't perform have to pick up their practice and move their practice next to somebody who does perform. That is egregious.

Q. So the ethics complaint that AAPLOG filed with HHS concerned all three of those points; is that right?

A. As far as I know. I mean, again, I did not refresh -- I didn't review the wording of that complaint for this particular deposition. I would have to go back and look at the specific wording of that complaint to be able to

specifically answer your question.

Q. Have you ever been the subject of a complaint filed by a government agency that you know of?

A. I don't think so.

Q. Aside from this case, you've served as an expert witness in a number of cases concerning abortion; is that right?

A. Yes.

Q. Have you served as an expert witness in other cases concerning medication abortion specifically?

A. I'm sorry. I'm trying to understand your question. So what you're asking is, have the cases that I've served in dealt with medication abortion? Yes, they have dealt with medication abortion.

Q. Have you ever served as an expert witness on a case about regulations concerning medication abortion?

A. Yes.

Q. Where did you -- where were those cases? What states were those cases in?

A. I think -- I would have to go back and generate a list. I think I mentioned all

of those that I did court testimony in, but I would have to generate a list as to what states I have testified in.

Q. Do you recall whether you served as an expert witness on a case concerning regulations about medication abortion in Oklahoma?

A. Yes.

Q. What was that case about?

A. Again, I did not review other cases before this deposition. So if you're going to question me about those cases, I would have to see my declaration from those cases.

Q. Do you recall anything about what that case was about?

A. My mind right now is on abortion pill reversal. So I did not review anything outside of abortion pro-versal for this deposition. But if you show me the declaration that I made in those cases, I'm happy to comment on that.

Q. I'm just asking if you remember anything about what that case is about, sitting here right now.

A. My mind right now -- my mind right now is on abortion pill reversal and not on

anything else.

Q. So is that a no?

MR. RIEGER: Object to the form.

A. I'm not going to be able -- my mind right now is on abortion pill reversal. I did not review any other cases prior to this deposition.

BY MS. CLARKE:

Q. I understand. I'm not asking you what you reviewed. I'm just asking you, sitting here right now, if you remember anything about what the case in Oklahoma was about that you served in as an expert witness.

A. Well, my mind has limited ram. And my ram right now is all full of abortion pill reversal. So I do not have any other case booted up in my brain right now.

Q. So you don't remember the substance of -- well, strike that.

Do you remember what any cases were about that you've served in as an expert witness prior to this case?

A. I can't make any comment on any other cases unless you show me the declaration that I filed in those cases.

Again, what I referred to or what I reviewed for this case and what is in my brain right now is abortion pill reversal.

Q. So in your declaration, you cite to a case called Tulsa Women's Reproductive Clinic, LLC versus Hunter, Oklahoma County District Court. That's in footnote 1 of your declaration.

You don't remember anything about what that case was about?

A. You'll have to pull up -- you're going to have to pull it up, pull up the document that -- I don't go by recall. I go by what I see in front of me. So you're going to have to pull up the document that you're citing.

Q. So you don't remember anything, sitting here right now, about what that case was about?

A. I don't go by recall. I go by what I see in front of me. So you're going to have to pull up the document for me to comment on the document.

Q. So in preparation for your deposition today, you didn't review everything that you had put in all of the footnotes in your

declaration?

A. I reviewed the scientific articles.

Q. Understood. So you don't have any memory of what the North Dakota case was about in which you served as an expert witness?

A. If you pull up the document and pull up my declaration, I am happy to comment on any case that I see my declaration in front of. But I did not review those cases in preparation for this deposition.

Q. Understood. Have you ever served as an expert witness in cases concerning abortion that do not relate specifically to regulating medication abortion?

A. I don't recall. I might have. I don't recall.

Q. Have you ever served as an expert witness in support of any abortion bans in any states?

A. Again, have I -- are you asking did I have a declaration or did I testify before Congress? What -- can you clarify your question?

Q. Absolutely. Have you ever submitted a declaration in support of a lawsuit

concerning an abortion ban?

A. I might have.

Q. In the last five years, have you served as an expert witness on any case that did not relate to abortion?

A. I don't think so.

Q. How did you come to serve as an expert witness on this case?

A. I was contacted by the AG's office of the State of Tennessee.

Q. Do you know how -- do you know if you were referred to them by some third-party like AAPLOG or Charlotte Lozier?

A. I don't know.

Q. So are you aware of Tennessee Annotated Code 39-15-218?

A. Yes. If that is the law that's under question, then, yes, I reviewed that law. But I don't know it by those numbers.

Q. So the law at question in this case, if I call it the reversal law, will you know what law I'm talking about?

A. Yes, I will know what law you're talking about.

Q. Were you aware of the reversal

law in Tennessee before you came to serve as an expert witness on this case?

A. I might have been.

Q. You don't have any specific recollection of being aware of it previously?

A. I don't have any specific recollection. I am aware of lots of things around the country. So it's possible.

Q. And that's sort of part of your job as executive director of AAPLOG, right, to be aware of various abortion laws popping up around the country.

A. To be aware of anything related to abortion that would touch on clinical practice for our members, yes. That's part of my job.

Q. Okay. And you're being compensated at $350 an hour for your work on this case; is that right?

A. That's correct.

Q. Are you being offered as an expert in this case?

A. Yes.

Q. And what are you an expert in on this case?

A. I'm an expert in the effects of

Mifeprex on progesterone receptors and the biological plausibility of the use of progesterone to displace Mifeprex from progesterone receptors and that effect in early pregnancy.

Q. Is that all, for the purposes of this case?

A. I think so.

Q. Looking at your CV, have you published any peer-reviewed articles concerning the biological plausibility of the use of progesterone to displace Mifeprex on progesterone receptors?

A. Not that I recall.

Q. But you've published peer-reviewed articles on Mifeprex generally; is that right?

A. Correct.

Q. Do you know about how many peer-reviewed articles you've published concerning Mifeprex?

A. It should be on my CV. But, again, that CV was a year ago. There may be some that aren't on there.

Q. So I see nine articles on your CV. I assume that that's not a full accounting of

all the articles you've published over the years; is that right?

A. I would have to look back at the CV and see what date it is and then rerun my list. I can do that.

Q. Your CV, I think, we've already pulled up as an exhibit in the chat. Could you just take a quick look at the publications and let me know if that's a complete list of your articles that you've published?

A. What I'm saying is I'm going to have to go back and look at my records to see if there's any that haven't been included in the CV. So even if I look at the CV now, I won't be able to tell you whether or not I've published another article since the last time I updated the CV.

Q. Okay. I understand.

So, Sara, could you pull up what's been previously marked as plaintiff's 3, Tab H?

A. Give me a second. I'm opening it. Give me a second.

Q. Sure.

A. Okay. I got it.

(Exhibit 3, Harrison Declaration,

was previously marked.)

BY MS. CLARKE:

Q. Okay. Go ahead and take a look at that document. When you're done, can you tell me what it is?

A. Well, it looks to be my declaration.

Q. And if you look at the last page, is that your signature?

A. Yep, that is my signature.

Q. Sitting here looking at it right now, is there any reason to believe that this is not a true and accurate copy of your declaration that you submitted?

A. No, no reason to believe that.

Let me clarify. This looks like a true and accurate representation of my declaration.

Q. Since submitting it, are you aware of any corrections that you want to make in this document?

A. No.

Q. How did you draft this declaration? What was your process?

A. My process of drafting this was

to review the literature and to look at other declarations that I have made on similar topics.

Q. Do you remember what other declarations you looked at?

A. I looked at the Oklahoma declaration.

Q. Any other ones that you can think of?

A. For the drafting of this document, I reviewed the declarations of plaintiffs. I reviewed the medical literature. I think that's it.

Q. Did anyone help you draft this document?

A. No.

Q. Did you consult with anyone in the course of drafting this document?

A. No.

Q. And all the citations in this document, are those all citations that you found yourself?

A. Yes, I think so. I mean, I do my own research.

Q. Okay. So in paragraph 5 of this declaration, it reads, The legal action challenges

of Tennessee law requiring abortion providers to inform medication abortion patients that it may be possible to --

A. Wait a minute.

Q. Go ahead.

A. I'm sorry. Are you on paragraph No. 5? I think it says that, I've been asked by Tennessee Attorney General.

Q. Yep. So the next sentence after that.

A. I'm sorry. Yes, I see it.

Q. Okay. So, The legal action challenges of Tennessee law requiring abortion providers to inform medication abortion patients that it may be possible to reverse the intended effects of mifepristone, the first drug taken, if the second pill or tablet, misoprostol, has not been taken or administered.

Is that an accurate representation of your understanding of the reversal law?

A. Yes.

Q. Do you know if the reversal law requires anything else?

A. Yes. The law requires that

abortion providers -- okay. I would have to pull up the law to see if there's anything else.

What I have in that paragraph is what I was focusing on for purposes of my declaration. So I read the Tennessee law, looking specifically at what I was supposed to comment on. So if there's anything else in the Tennessee law, then I would have to -- you would have to pull up the law for me to be able to say whether there exists any other thing in the Tennessee law.

Q. Okay. But this is the sentence that you focused on, right, for your declaration?

A. That is what I focused on, yes.

Q. So I'm going to read a sentence to you, and I would like you to tell me what you understand that sentence to mean. Okay?

The sentence is, It may be possible to reverse the intended effects of a chemical abortion utilizing mifepristone if the woman changes her mind.

What does that sentence mean to you?

A. That means if a woman takes mifepristone and she decided after she takes it that she doesn't want to abort her baby, that it

is possible for her to be able to do things to make it likely for -- that it's possible, not that it does, but that it is possible for her to take some action that may help increase the chances of survival for her baby.

Q. And would that action include seeing a doctor and getting progesterone treatment?

A. Yes.

Q. So whenever --

A. But that's not -- wait, wait, wait. Whoa. Let me clarify that.

Q. Sure.

A. That's not what it said in the sentence you just read.

Q. I understand.

A. So the sentence you just read does not include the clause, See a doctor, get progesterone treatment. It doesn't include that in what you read.

So insofar as the sentence you read goes, that's where my answer is.

Q. Okay. Are you aware of any other action that someone could take to reverse the effects of mifepristone other than getting

progesterone treatment?

A. No.

Q. I'm going to read you another sentence, and let me know what it means to you.

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.

Does that mean the same thing as the last sentence you read?

A. Yes. It may be possible to avoid -- I don't have the whole thing in front of me, but avoid the effects of mifepristone if the second drug hasn't been taken. Yes, it means the same thing with more words in it than the first sentence that you read.

Q. Okay. What is medication abortion reversal treatment?

A. When mifepristone is given to a woman, mifepristone acts at the level of a nuclear -- progesterone receptor on the nucleus of a cell. The way it acts is it acts by changing actually the DNA that's transcribed in that cell.

So the change that progesterone is supposed to make in cells to adapt a woman's

body to pregnancy, that change is blocked by mifepristone. But mifepristone reversibly binds to the progesterone receptor, which means that it will bind and block and then it will unbind and bind and block, and it will unbind. So it's a reversible blockade. You can use progesterone to displace mifepristone from the progesterone receptor if there's sufficient progesterone.

And so that's what it means.

Q. When we talk about medication abortion reversal treatments, we're talking about providing progesterone in high doses to someone who has taken mifepristone and is pregnant; is that accurate?

A. Within a certain time frame.

Q. And that time frame is about 72 hours?

A. That's correct.

Q. Does it matter when within that 72-hour window the progesterone treatment is given?

A. The sooner, the better.

Q. Okay. Have you ever provided medication abortion reversal treatment to anyone?

A. No.

Q. Have you ever referred someone for medication abortion reversal treatment?

A. Oh, I don't know. Maybe. I don't -- what I do, if someone asks me does this exist, I tell them to contact the Heartbeat Hotline, because that's who runs the network.

Q. And by "the network," that would be the abortion pill rescue network?

A. The network of physicians that are familiar with abortion pill -- with progesterone to reverse the affects of mifepristone.

Q. Do you know what that network is called?

A. APR. But actually I can't remember what the initials stand for, whether it's abortion pill rescue or abortion pill reversal. They've changed the acronym, and I can't remember the current acronym.

Q. So if I say APR or APRN, you'll know what I'm talking about?

A. Yes. APRN, the abortion pill reversal network.

Q. Do you know, how long has APRN been around?

A. I don't know. A couple of years, three or four years, maybe longer. I don't know when it actually started. I could find that out, but I don't know off the top of my head when it started.

Q. And it's affiliated somehow with Heartbeat International. Is that what you just said?

A. That's correct, yes. Not just a head not, but yes.

Q. Mifepristone alone is not always effective at terminating a pregnancy; is that right?

A. That's correct.

Q. So how long have we known that fact?

A. Since the drug development back in the late '70s, early '80s, at least.

Q. Do you know whether there's any recent research showing that it's more effective or less effective than we had previously thought?

A. I'm sorry. I honestly don't understand your question. One more time.

Q. So we've known since the '70s that mifepristone alone is not always effective at

terminating a pregnancy. In the last five or six years, are you aware of any research showing that mifepristone is even less effective than we had previously thought at terminating a pregnancy by itself?

A. What I don't understand is when you say "less effective than what we had previously thought." I mean, which papers are you comparing?

Because mifepristone efficacy varies per paper, per population, per gestational age, so that the efficacy -- that's what I don't understand.

Q. Okay. Has your understanding of the general efficacy of mifepristone alone to terminate a pregnancy changed in the last five years?

A. At what gestational age?

Q. In the first trimester.

A. Well, if mifepristone efficacy varies in the first trimester, it's less effective at seven weeks than it is at six weeks; it's less effective at eight weeks than it is at seven weeks; it's less effective at nine weeks than it is at ten weeks.

You know, so the efficacy of mifepristone depends on the gestational age of pregnancy.

Q. And we've known that fact for decades; is that accurate? We've known that mifepristone effectiveness at terminating pregnancy varies based on gestational age?

A. I can say that as of the approval -- as of the approval in 2000, we have known that fact.

Q. Do you know if anyone provides reversal treatment besides doctors affiliated with APRN?

A. I don't know.

Q. Do you know if the Obria Network provides reversal treatment?

A. I don't know.

Q. Okay. Are you affiliated with APRN?

A. No. I'm not a practicing -- I'm not doing clinical practice. So I'm not.

Q. Do you serve any advisory function for them? Are you on an advisory committee or --

A. That's a very good question. I

have given them advice before. I don't know if I'm enrolled on an official advisory committee, but I certainly have given them advice.

Q. About what have you given them advice?

A. About the plausibility of progesterone effects on the mifepristone receptor.

Q. Have you given them any advice about reversal protocols?

A. Not that I know of.

Q. We talked briefly about Heartbeat International. What is Heartbeat International?

A. Heartbeat International -- it is whatever it says on its website. But Heartbeat International, as I understand it, is a network of pregnancy care centers.

Q. Are pregnancy care centers what are sometimes referred to as crisis pregnancy care centers?

A. Yeah. I think that some people refer to them as crisis pregnancy centers.

Q. If someone were seeking reversal treatment from a doctor through the APRN hotline, do you know how they would pay for their reversal treatment?

A. I don't know.

Q. Do you know whether insurance covers reversal treatment?

A. I don't know.

Q. Do you know whether APRN or Heartbeat International provides subsidies for people who can't afford it?

A. I don't know.

Q. Okay. So the reversal protocol can consist of either oral progesterone or intramuscular injections of progesterone; is that right?

A. That's my understanding.

Q. And you have no idea how much an injection of progesterone costs?

A. No. Actually, I don't.

Q. Does the standard protocol -- well, strike that.

Do you know where I could find the standard protocol for medication abortion reversal?

A. You would have to contact the APRN Network.

Q. Do you know whether the doctors that they refer patients to as part of a network

all receive some kind of standardized material telling them how to do this?

A. I don't know.

Q. So you don't know whether APRN refers people only to physicians that follow a particular protocol?

A. I don't know.

Q. For medication reversal to be effective, does the amount of progesterone given depend on the gestational age of the pregnancy?

A. That's an interesting scientific question that I can't answer with a paper.

Q. Do you think it would be more effective if you gave people more progesterone at later gestational ages, just based on your knowledge and expertise?

A. Well, that's kind of a difficult question to answer because there are sources of progesterone production that kick in later in the pregnancy.

So I can't answer -- I don't know. I don't know.

Q. Do you think that reversal would be more effective -- strike that.

Do you think it would make sense

to give someone at eight weeks gestational age more progesterone to reverse mifepristone than someone at five weeks?

A. I don't know. I don't know if that's been studied.

Q. Just based on your general knowledge and expertise, would you expect that it would be more effective to give more progesterone at eight weeks than five weeks?

A. I don't know. I don't know whether it would be or not.

Q. For medication abortion reversal, should the dose of progesterone vary based on a patient's weight?

A. As far as I know, the efficacy of mifepristone does not vary with weight. So since the efficacy of mifepristone does not vary with weight, I would suspect that the efficacy of progesterone given exogenously -- given from outside, not made by the body -- I would expect that that would also not vary with weight.

That's just my speculation.

Q. For a medication abortion reversal protocol, would you expect to want to receive more progesterone if it had been more time

since they had taken the mifepristone?

A. The medication abortion protocol -- the administration of progesterone needs to take place within 72 hours. So within 72 hours, that is the time period where the mifepristone binding to the nuclear progesterone receptor, it will start to affect transcription, DNA transcription, within those 72 hours.

So the progesterone has to be present to displace mifepristone from that receptor within 72 hours to restore the normal DNA transcription that has to happen for the woman's body to be able to adapt to a pregnancy.

Q. So is there any reason to give someone more progesterone if it's been 72 hours since mifepristone versus if it had only been 12 hours since mifepristone?

A. I don't think any studies have looked at that.

Q. Based on your general knowledge and expertise, would you expect that someone should get more progesterone if it's been 72 hours since the mifepristone versus 12 hours?

A. Based on my knowledge, I don't see any reason why you would need to give more

progesterone.

The issue is displacing the mifepristone from the progesterone receptor. So you need to give sufficient progesterone to displace the mifepristone from the progesterone receptor so that transcription of DNA can resume.

So whatever quantity of progesterone is sufficient to displace the mifepristone from the progesterone receptor, that should be the quantity within 72 hours.

Q. Correct me if I misunderstood. So the 72 hours is sort of the time frame when mifepristone is effective; right? If the time frame were --

A. The 72 -- at 72 hours, you can see a decrease in progesterone effect on the baby, on production. Okay? So the way that progesterone effect is mediated is it's mediated because the progesterone receptor in the nucleus tells the DNA what genes to transcribe.

So if you can block that, then you cause a change in DNA transcription. That change in DNA transcription is not immediate. It's not like a metabolic poison. It takes time to take effect.

So because it takes time to take effect, there's also time to mitigate its effect. So after 72 hours, it appears from animal studies that you have passed the point where you can meaningfully change the transcription that's happening.

So before 72 hours appears to be the time when you can meaningfully change it and cause the normal progesterone-induced transcription to resume and -- you may have skipped a beat, but you still pick up the same song.

Q. So when you say that 72 hours appears to be the window based on animal studies, which animal studies are those?

A. I quoted them. Yamabe -- I would have to look at some others. There's others that Baulieu quotes.

Q. So your understanding of the Yamabe study, it studies the effects of mifepristone after 72 hours?

A. My understanding of the Yamabe study is that it shows that later effects of -- that later administration of progesterone was not effective.

But, again, I would have to go back and look at that study specifically, because you're asking me a specific numerical answer to a specific study and I can't pull that out of my head. I have to look back and look at the study.

Q. So when you said that 72 hours appears to be the window based on the animal studies, Yamabe was one of those animal studies that you were referring to?

A. Correct.

Q. Do you know is there anyone for whom abortion reversal treatment is contraindicated?

A. If you look at the label for progesterone, progesterone is a very widely used hormone, and I don't believe that there are any contraindications to progesterone. But, again, I would have to look on the label.

If there would be, it would be previous allergy to progesterone. But you make progesterone, so it's going to be unlikely that you have an allergy to progesterone since you make progesterone.

Q. Do you know whether there's any small number of people who do actually have an

allergy to exogenous progesterone?

A. I would have to look that up.

Q. So it's your opinion that medication abortion patients should be told about reversal treatment; right?

A. Yes.

Q. And that's so that if they change their mind after taking the mifepristone, they can seek treatment to save the pregnancy; right?

A. That's correct.

Q. When should they be told about reversal treatment?

A. When they're in a process of getting informed consent. Because part of the informed consent process -- as any physician knows, with informed consent, you're supposed to talk about what you're going to do to the patient, what are the alternatives, what are the side effects. That's just part of informed consent.

Q. So if informed consent were given -- strike that.

So informed consent is like a continuous process; right?

A. Informed consent is a process. It's not a piece of paper; it's a process. And

it's a process of making sure that the patient understands what it is she's doing, what are the effects of what she's doing, what can she expect afterwards. So, yes, it is a process.

Q. And so if the informed consent process starts two weeks before the patient is scheduled to get the mifepristone, would it make sense to tell them about the reversibility of medication abortion two weeks before they're scheduled to take their mifepristone?

A. Whenever she goes through the informed consent process prior to consent, it would -- I mean prior to her saying, writing on the bottom-line and writing her check, prior to committing to the procedure, informed consent should take place prior to committing to the procedure or to the drug or whatever else you're consenting the patient for.

Q. So --

A. Informed consent has to take place before. It can't take place after. It has to be a part of the informed consent process.

Q. So do you think it matters whether a patient is told about the reversibility of medication abortion an hour before they take

the mifepristone or a week before they take the mifepristone? Does it make a difference?

A. I think when she's getting the informed consent process, she needs to be aware of the possibility that, if she changes her mind, then there is a drug which may increase the likelihood that her baby will survive.

Q. So if the informed consent process lasts over the course of a few days -- you come in and get some information, you talk to someone, you come back, you talk to someone again about the risks and benefits before you committed -- would it matter when, in the course of those few days, the patient learns the medication abortion is reversible?

A. Well, generally, my understanding is that the informed consent process takes place at one point in time prior to abortion. That's when they sign the form. Okay. They sign the form, yes, I want to do this. So prior to her putting her signature on the form, that is when she needs that information.

Q. So, then, does it matter whether she gets that information an hour before she signs the form or a week before she signs the form?

A. I think it's -- I think -- I will say what I said again, that when the informed consent process takes place prior to her putting her signature on that documentation of informed consent, she should be made aware of abortion pill reversal?

Q. Is there any benefit to telling patients a week before they sign their informed consent form that medication abortion is reversible?

A. There is benefit in presurgical procedures, pre-procedures, to giving a patient time to think about the information that is given to them.

So it is poor form in surgery to talk to the patient for the first time about risks, alternatives because, at that point, they are committed. They are in process. Especially after they've paid for it.

So the informed consent process is supposed to give time for patients to think about what's said, ask questions about it. That's just the nature of consenting a person to surgery or to a procedure.

Q. Okay. That makes sense.

So with respect -- well, strike that.

You have supervised residents in the resident in the past; correct?

A. Yes.

Q. Did you teach those residents about informed consent?

A. Yes.

Q. What did you teach them about what they should tell patients to obtain informed consent?

A. Well, my understanding of the standard of informed consent is that it's what a patient would want to know to make their decision.

Q. How does one know what a patient would want to know to make their decision?

A. You talk to them.

Q. And before making the decision to have an abortion, is it your understanding that patients would want to know that medication abortion is reversible?

A. My understanding is that patients would want to know any information that pertains to the risks, the benefits, the alternatives. That's what most patients want to know.

Q. Did you ever teach residents about how to deliver informed consent information? By that, I mean, how complicated their language should be and how much jargon to use or not use?

A. Yes.

Q. And what did you teach them about that?

A. I taught them by example. And I also would teach them that the principle of informed consent is to make sure that this patient, this patient, understands what she's signing up for and what she can expect afterward.

So whatever it takes for this patient to understand, that's what you need to do. You're ethically responsible for making sure she comprehends the procedure, what's going to be done, the risks, the benefits, the alternatives. That's the imperative for the treating physician.

Sometimes that means getting a translator. Sometimes that means other things. But your responsibility is to make sure that this patient understands.

Q. Okay. So if one uses too much medical jargon in the course of informed consent, is there a risk that the patient won't understand?

A. It depends on if you're talking to a physician or not.

Q. Let's say --

A. The language you use depends on the patient that you're talking to.

Q. So if you were to provide abortion -- medication abortion reversal treatment to a patient, what would you tell them as part of informed consent?

A. I would tell them this is how Mifeprex works, that it works by blocking the progesterone receptor on the cell, that it works by changing how the cell responds to progesterone; that that blockage, like a false key in a door, can be -- the false key, the progesterone -- excuse me. Let me start this over again.

The false key, the Mifeprex, can be displaced by the true key, progesterone. But it will only affect the baby's survival if it's done quickly, because there's a point beyond which it probably won't make any difference.

So if you're before 72 hours, you know, what's the time you took -- not just the date, but the time that you took the progesterone -- the Mifeprex, excuse me -- if that's within 72

hours and the baby is still alive, because you don't give progesterone -- it would be pointless to give progesterone if the baby has already died.

If the baby is still alive, there is a chance that progesterone may increase the chances of survival of that baby. It's not a guarantee. It's not a hundred percent. But it can increase the chances of survival. And if you're interested in increasing the chances of survival, progesterone is one thing that we can do, something that we can do.

Q. Sure. Would you tell patients that there's, as you mentioned to me earlier, a very unlikely possibility that they might be allergic to progesterone?

A. I would ask them if they have any allergies in their history. That's just part of normal patient care. You ask them if they have any allergies.

Q. People don't always know what they're allergic to, right, when it comes to medication?

A. Correct.

Q. So would you advise patients that there might be a risk that they might be allergic

to progesterone?

A. I think the allergy to progesterone would be something that would be discovered after they would take it, just like the allergy to aspirin or the allergy to Mifeprex, as a matter of fact. Mifeprex itself has allergies.

Q. So you wouldn't tell a patient before they take progesterone that there's some chance that they might be allergic to it without knowing?

MR. RIEGER: Object to the form of the question.

Go ahead.

A. Routinely, you ask a patient, do you have any allergies? You explain to them -- okay.

And then every -- I mean, part of giving a patient or prescribing a medication to a patient is to say, We shouldn't give this to you if you're allergic. But we don't know ahead of time whether someone is allergic, and it is vanishingly unusual for someone to have an allergic reaction to something that their own body produces.

BY MS. CLARKE:

Q. So it wouldn't make sense to give someone information as part of informed consent about a vanishingly unusual side effect that they might have?

MR. RIEGER: Object to the form of the question.

Go ahead and answer.

A. What I would say is allergies are always possible before you give a medication. Okay? But there's some things like progesterone, which is a hormone that your body naturally produces, that it would be vanishingly rare to have an allergy to something that your body normally produces.

BY MS. CLARKE:

Q. So it wouldn't make sense to tell everyone who takes it that there is a one in a million chance you might have an allergy to this?

MR. RIEGER: Objection to the form of the question.

Go ahead and answer.

A. I doubt that it's even that high.

BY MS. CLARKE:

Q. So, then, it wouldn't make sense to tell patients about it in advance; is that

right?

MR. RIEGER: Objection.

Go ahead and answer.

A. When you say "tell patients about it in advance," what you tell patients about are things that they want to know. If in my conversation the patient says, Look, is there any chance I could be allergic to this, I'd say, Yes, there's a vanishingly small chance. But it is a natural hormone that your body makes, so you're not having an allergic reaction to what your body is already making right now. So I sincerely doubt that you're going to have an allergic reaction to the same chemical that your body is making right now.

BY MS. CLARKE:

Q. I understand. So you would discuss it if asked by a patient; is that accurate?

A. Correct.

Q. If you were not asked by a patient, you would not discuss it as part of the risks and benefits of progesterone treatment; is that right?

MR. RIEGER: Same objection.

Go ahead and answer.

A. Understanding the physiology of a human body and how allergic reactions happen, allergic reactions happen to things that are foreign to the human body.

Progesterone is not a foreign compound. Progesterone is a compound that the human body makes. So, physiologically, it would not make sense that the human body would have an allergic reaction to something -- to a hormone that the human body already makes.

BY MS. CLARKE:

Q. Have you ever obtained informed consent to an abortion?

A. What do you mean by the term "abortion"?

Q. Have you ever obtained informed consent to an abortion unrelated to an ectopic pregnancy?

A. Well, again, it depends on what you're using for the term "abortion." Abortion has about, oh, 15 or 18 different definitions. So it depends on what definition you're using.

BY MS. CLARKE:

Q. Did you ever obtain informed

consent from a patient for medication abortion?

A. No.

Q. Have you ever obtained informed -- actually, strike that.

Have you ever performed a tubal ligation on a patient?

A. Yes.

Q. Have you obtained informed consent for a tubal ligation?

A. Yes.

Q. And were those tubal ligations medically indicated, or were they elective?

A. Elective.

Q. And when patients -- when you obtain informed consent from patients for elective tubal ligations, do you tell them that the process is reversible?

A. Yes, I do.

Q. About -- what would you say is the rate of effective reversibility of a tubal ligation?

A. You know, I haven't looked at that literature recently, and I'm sure it's much higher now. But it does depend on the type of tubal ligation that's done; you know, how much

tube that they have left; and where in the tube the ligation was done.

So to quote you a number, it depends. It's patient-specific.

Q. Okay. So for any patient who undergoes a tubal ligation, it may or may not be reversible; is that right?

A. Well, for any procedure, yes, it may or may not be reversible.

Q. Okay. So when you obtain informed consent from patients for tubal ligations and you tell them it's reversible, do you also tell them that it may not be reversible?

A. Yes.

Q. Do you tell them that it's important that they make -- come to a final decision about whether or not they want the tubal ligation before they undergo it?

A. Yes.

Q. Do you tell them not to rely on its potential reversibility when they make that decision?

A. Yes.

Q. Do you know if any of your patients has ever undergone a tubal ligation

thinking, Well, it's reversible, I can change my mind later?

A. Not my patients.

Q. Do you know for a fact that no patients have ever done that, that you've seen?

MR. RIEGER: I'm going to object to the form of the question.

Go ahead.

A. I can't possibly know that.

MS. CLARKE: Do we want to take lunch. I know that Dr. Harrison and I are on the East Coast. It's 12:30ish here.

MR. RIEGER: That is fine by me.

THE WITNESS: That works for me.

MS. CLARKE: Do we want to take about 45 minutes for lunch? Is that enough? Or like do you want to come back at 1:00 Eastern?

THE WITNESS: That works for me.

MR. RIEGER: 1:00 Eastern is fine by me.

MS. CLARKE: Can we go off the record?

VIDEOGRAPHER: Off the record at

11:23.

(A break was taken.)

VIDEOGRAPHER: Back on the record at 12.01.

BY MS. CLARKE:

Q. Dr. Harrison, did you communicate with anyone during this lunch break?

A. No.

Q. Okay. Do you know whether APRN refers patients only to physicians for reversal treatment?

A. I don't know.

Q. Do you think it would be appropriate for someone who's not a physician to provide a reversal treatment?

A. I think the scope of practice for each state is different. So it would depend on the scope of practice for the state.

Q. If it were legally permitted, do you think it would be appropriate for a physician assistant to provide reversal treatment?

A. If whoever is providing it does an ultrasound to show that the baby is alive and can, with all reasonable degree of accuracy, determine that it's been less than 72 hours, then

the actual administration of progesterone, if it's within the scope of practice for that state for the advanced practice clinician to prescribe, then they should be able to prescribe. But you have to meet the criteria.

Q. So one of those criteria is having an ultrasound to confirm pregnancy?

A. No. A criteria is having an ultrasound to make sure that the baby is alive. If the baby is dead, it is irrelevant. Progesterone isn't going to work, and you wouldn't prescribe it.

Q. Do you think it would be appropriate to prescribe someone progesterone before you've given them the ultrasound?

A. Yes. I think that would be appropriate depending on how quickly you can get them in and what the gestational age is at which she took the Mifeprex.

So, for example, prescribers of Mifeprex are prescribing Mifeprex before they even know the intrauterine location of the pregnancy. They're prescribing it at four and a half weeks gestation.

And so if a woman at four and a

half weeks gestation took Mifeprex and said, I've changed my mind, then it would be appropriate to give her progesterone in the hope that it would increase her chances of survival of the baby.

Q. So what about a patient at eight weeks gestational age? Would it be appropriate to give them reversal treatment prior to doing an ultrasound?

A. It depends on the timing. The progesterone has to be administered within 72 hours. So the initial dose of progesterone may -- it has to be given within 72 hours to act.

So if it turns out that she's 68 hours and she can't get in within 72 hours to confirm intrauterine pregnancy that's alive, then it is appropriate to administer at that point.

Q. Then would it be appropriate to do an ultrasound afterwards at some point?

A. Yes.

Q. Do you know about how long somebody will be receiving progesterone treatments as part of a reversal protocol?

A. I don't know.

Q. Is it more than one day?

A. Yes.

Q. Do you know -- strike that.

You're aware that a Dr. Michael Podraza is an expert witness in this case; correct?

A. Yes.

Q. And did you read his declaration?

A. I probably skimmed it. I don't recall it in detail.

Q. Okay. Are you aware that Dr. Podraza has previously testified that he does not believe that information about reversal should be given to patients before they take the Mifeprex?

A. If that's what he states, okay.

Q. I'm going to read you some statements, and I want you to tell me if you agree with them. Okay?

A. Yes.

Q. Okay. You may end up causing more problems and you may actually end up increasing the amount of people who take mifepristone because they think they can change their minds.

Do you agree with that statement with respect to telling patients about reversal

before they've taken mifepristone?

A. That's his speculation.

Q. Do you agree with that statement?

A. No.

Q. But you don't think that it could increase the number of people who take mifepristone because they think they can change their mind later?

A. Not if they're appropriately receiving informed consent.

Q. I'm going to read you another statement.

It could actually be considered a way of trying to convince someone to take the mifepristone if you told them, Well you should just take it because you can change your mind later. You can take this other medication and be okay.

Do you agree that that's a risk that comes with telling patients about reversal prior to taking mifepristone?

A. That is a failure of informed consent.

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.

Q. So if the doctor gives the patient the right information, there is no risk that any patient would ever think that? Is that your testimony?

A. In the whole universe of ever patients -- any patient ever in the whole history of the human race, I can't make that kind of a statement.

The purpose of informed consent is to make sure that the patient understands what she is doing, the risks and alternatives, and that she freely and fully consents.

Q. But, ultimately, there's only so much a doctor can do in terms of providing information to a patient to make them understand things; right?

A. Yes.

Q. I'm going to give you another quote. Let me know if you agree.

It would be probably inappropriate to give patients information about reversal as a way out if they change their mind before they've actually completely decided to take the medication.

Do you agree with that statement?

A. No.

Q. And why not?

A. Because I don't think it would be inappropriate to give them information during the informed consent process. I think that's the purpose of informed consent, is to give the patient all the information. And that informed consent process needs to take place before the procedure.

Q. Okay. So I'm going to do one last quote. Let me know if you agree with this.

Giving someone information about informed -- sorry. Strike that.

Giving someone information about reversal before taking mifepristone might encourage someone who, say, doesn't really want to have an abortion but their boyfriend, father, mother, whoever brought them to the clinic and is trying to coerce them, they might think, Well,

I'll take the mifepristone to placate my person who is pressuring me and then, you know, go home and call and get the progesterone so I can reverse it.

Do you agree with that statement, that that's a risk?

A. That is a failure of appropriate screening for coercion. Coercion for abortion is not legal in any state in the country. So if you are giving a person mifepristone and you have not appropriately screened for coercion, that is a failure of the informed consent process.

Q. If someone is being pressured by their boyfriend to have an abortion and let's say they don't tell anyone about it, do you think that if they're aware that mifepristone can be reversed, they might think, Fine, I'll go ahead and take it; tomorrow, he's not looking; I'll go and get it reversed? Is that a --

MR. RIEGER: Object to the form of the question.

Go ahead and answer.

A. That's a failure of the informed consent process. It is part of the physician responsibility prior to administering medication

abortion to screen for coercion.

BY MS. CLARKE:

Q. Is there any way for physicians to know what's happening in the patient's life if she doesn't tell them?

A. Yes. There's many ways you can know. If she has bruises around her neck, if she's 12, if -- there are many ways of screening for abuse and coercion.

You can know or you can heavily suspect that if the person who is coercing won't leave the patient alone. That's why you separate patients. There's many other ways that the patient can actually physically tell you.

And it is the responsibility of the abortion provider to screen for coercion, which is against the law in every state in the United States, prior to administering Mifeprex abortion.

Q. So do you think that a physician can be 100 percent certain that a patient isn't being pressured at all by anyone?

A. That's not what I said.

Q. That's what I'm asking. Do you think it's possible for a physician to be 100

percent sure that a patient is not being pressured at all by anyone?

A. It's not possible for any human being to be a hundred percent certain of anything, even if the sun will rise tomorrow.

Q. Have you read the declarations of Ms. Herman (ph) and Ms. Donovan submitted in this case?

A. I don't recall those names.

Q. Did you read any declarations submitted in this case by people who took mifepristone and then got a reversal?

A. I did not. I did not review those.

Q. So in your declaration, you noted that abortion reversal is 68 percent effective if offered by mouth or intramuscular injection; is that right?

A. That's what was published in the Delgado case series.

Q. Is that accurate, though, so far as you're aware?

A. That's what they published.

Q. Do you think -- well, strike that.

So that means about 32 percent of the time, even if it's administered by mouth or intramuscular injection, it won't work to save the pregnancy; right?

A. That's what their -- well, yes. That's what their study implies.

Q. Do you think it would be appropriate to tell patients that there is a 68 percent chance that they could reverse the mifepristone if they decided to change their minds?

A. I think if the patient was told there is a study which shows -- which demonstrates a 68 percent chance of -- I will use the term "reversing" mifepristone. I would say there's a 68 percent chance of continuing survival of your baby. Then that's what I think they should be told. They should be told exactly what the study shows and what the source of information is.

Q. Why wouldn't you use the term "reversal"?

A. Because I tend to say explicitly what the study says. Okay? So if you give progesterone, this is what happens. It's an issue of not using jargon.

Is there anything wrong with the term "reversal"? No. But I try as best as I humanly can to avoid jargon.

Q. And that's just to make sure that people can understand what you're saying; is that right?

A. That is the best I can -- that is my personality. As long as the patient understands what reversal means, which means that there is a chance that giving this medicine can increase the chances that you're baby will survive, as long as they understand that, you can use any term you want.

The thing that I try to do is to make sure that the patient understands.

Q. So -- okay. Do you think it would be appropriate to put billboards up around Tennessee saying, If you take mifepristone, there is a 68 percent chance that you can still have a live birth or you can still have a baby? Would that be appropriate?

A. That's not a scientific question. That's a policy question.

Q. All right. Do you think it would be appropriate?

A. I'm not going to opine on a policy question.

Q. I'm asking you the question, and I'm going to ask you to answer it. Do you think it would be appropriate to put billboards up around Tennessee saying, If you take mifepristone, there's a 68 percent chance if you get the right treatment that you can still have the baby?

A. I'm not going to opine on a policy question.

MS. CLARKE: Mr. Rieger, can you instruct the witness to answer the question, please?

MR. RIEGER: Yes. Dr. Harrison, I know that that falls outside of an expert opinion; however, for the purposes of this deposition, you will need to answer those questions as best you're able.

A. Okay. Then I will say as long as the source of the information, the source of the number is clear, I think informing the public that it is possible to increase the chances of survival of a baby after mifepristone is administered, if the progesterone is given within 72 hours, if all

the information is on that billboard, then I think patients have a right to know that information. In fact, I think everybody should know that information.

BY MS. CLARKE:

Q. And you don't think that knowing that there's a two-thirds chance that you could reverse it might encourage any people to take mifepristone when they otherwise would not have?

A. I would hope that the informed consent process that the abortionist goes through before they give the woman Mifeprex would ascertain accurately how certain she is about this procedure.

Q. So knowing the variability in real life of patients and doctors and what happens in informed consent, do you think that there's any chance that people who hear that mifepristone is 68 percent reversible would take mifepristone when they otherwise would not have? Is there any chance in real life that that might happen?

MR. RIEGER: I'll object to the form of the question.

But please go ahead and answer.

A. There are a lot of odd things

that can happen. Is it possible in the whole entire universe of the human race that someone might say that to themselves? It is possible. Is it likely? No.

BY MS. CLARKE:

Q. Is it accurate for any given individual who takes mifepristone, that that individual, as long as they get progesterone treatment within 72 hours, has a 68 percent chance of having a baby?

MR. RIEGER: Object to the form of the question.

Go ahead and answer.

A. No. What is accurate is that this study demonstrated a 62 percent increase -- no, not a 62 percent increase, a 68 percent overall survival after administration of Mifeprex. That's all gestational ages. It's an average number.

So an individual person's chances of being able to mitigate the effects of Mifeprex, an individual's person's chances of her baby surviving the Mifeprex poisoning is dependent upon the gestational age of the baby; it's dependent on factors we don't know; her individual metabolism.

But what we can say is just what we can say overall at that point. It is one -- it's one of the only things that we can do to help a woman save her baby if she has changed her mind after ingesting the Mifeprex but before ingesting the misoprostol.

BY MS. CLARKE:

Q. So is it accurate to say that for any given patient, an individual who takes mifepristone, that we know for sure that there is a chance that if gets progesterone after she takes mifepristone, that she might still have a baby?

A. I'm sorry. I'm not not answering your question. I'm trying to figure out what the question means. Could you try it one more time?

Q. So medication abortion reversal is not a hundred percent effective; right?

A. Correct.

Q. Some people who take mifepristone and then get the reversal treatment will still terminate their pregnancies; right?

A. That's correct.

Q. So for any given person prior to then taking the mifepristone, we can't say whether reversal treatment will or will not work for them;

is that right?

A. That is correct.

Q. If patients are told that medication abortion may be reversible -- well, strike that.

Is surgical abortion reversible?

A. No.

Q. So is it possible that a patient who is told that medication abortion may be reversible but surgical abortion is not that they will choose medication abortion so that they can change their mind later? Do you think that might happen?

MR. RIEGER: Object to the form of the question.

Go ahead and answer.

A. Again, in the whole universe of the entire human race, is it possible that somebody might think that? It is possible. Is it likely? No.

If they fully intend to terminate that pregnancy, then it would make sense, if they had any question at all, that they would choose a surgical abortion. If they fully intend to terminate that pregnancy, only those woman who

fully intend to terminate the pregnancy should be given the Mifeprex in the first place.

So it's a failure of informed consent.

BY MS. CLARKE:

Q. Okay. Sorry. Correct me if I'm wrong. If a patient is told that medication abortion is reversible but surgical abortion is not, do you think any patients will choose surgical abortion for that reason?

MR. RIEGER: Object to the form of the question.

Please go ahead and answer it.

A. Maybe.

BY MS. CLARKE:

Q. Do you know if anyone provides reversal treatments to patients who have taken both mifepristone and misoprostol?

A. I don't know.

Q. Do you think that would be effective?

A. I don't know of any drug that reverses misoprostol. So not that I know of.

Q. So information about the reversibility of a medication abortion, do you

think that information should be given to a patient by a physician?

A. I think ideally, the physician is the one with the most training and the most ability to answer a patient's questions. I personally think that informed consent should be done by the physicians themselves.

That's what I think, based on my training as a physician.

Q. Okay. Do you think that crisis pregnancy centers should be required to tell patients about the use of medication abortion as an option?

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

Q. Do you think that crisis pregnancy centers, which I think you called pregnancy care centers, should be required to tell patients that medication abortion is an option?

A. An option for what?

Q. For any patient who might ask about it.

A. I'm sorry. The purpose of a crisis pregnancy center is not to refer patients for abortion. So a crisis pregnancy center isn't

administering treatment. So no, I don't.

Q. Do you think if someone walks into a crisis pregnancy center pregnant and they're like, I don't know what to do, and they ask about what their abortion options are, do you think that anyone should tell them that medication abortion is an option?

A. It would defy plausibility that a woman in this day and age with the Internet would not know that abortion is an option for her. That would defy believability. No, I don't.

Q. So she wouldn't need to learn about it from the crisis pregnancy center; she could just look it up on the internet?

A. To know that she has an option for abortion?

Q. Correct.

A. I have never met a woman yet in my whole entire practice that didn't know that abortion was an option.

Q. Have you ever met anyone who didn't know that medication abortion was an option?

A. Yes.

Q. So if no one at the crisis

pregnancy center is telling this hypothetical pregnant person that medication abortion is an option, how would she know that?

A. I'm sorry. I --

MR. RIEGER: Object to the form of the question.

You can answer.

A. I misheard your question that I said yes to.

When you said, Have you heard about people who haven't heard about medication abortion, what I heard was medication abortion reversal.

BY MS. CLARKE:

Q. Okay.

A. So I've heard many patients who did not know that the effects of Mifeprex could be mitigated by progesterone.

Now, are there patients that don't know that medication abortion is an option? Maybe.

Q. But you don't think that crisis pregnancy centers should be legally required to tell people who ask about their options that medication abortion is an option?

A. No.

Q. Why not?

A. Because that's not within the purview of what a crisis pregnancy center does.

Q. What do you mean by that?

A. Crisis pregnancy centers are not offering treatments to patients.

Q. So what do they offer patients?

A. It isn't an issue of informed consent.

Q. Okay. Well, leaving aside the question of informed consent, what do crisis --

A. Well, that is the question. I'm sorry. I didn't mean to talk over you.

Q. What is the purpose of a crisis pregnancy center? What services do they offer patients?

A. They offer patients information, and they offer patients diapers, and they offer patients social work consults, and they do all kinds of things. And it depends on the individual crisis pregnancy center what options they offer patients.

Q. Okay. As a part of the information that they offer patients, you don't

think that should be a legal requirement that they tell a patient who asks about her options that medication abortion is an option; right?

A. No, I don't.

Q. Why is that?

A. Because they're not giving informed consent.

Q. Do you think that OB/GYNs should be legally required to tell pregnant patients who ask about their options that medication abortion is an option?

A. I'm sorry. I'm thinking about your question.

So do I think that OB/GYNs should be legally required to tell patients that medication abortion is an option? Well, an option for what?

Q. An option for terminating their pregnancies.

A. If the patient wants to know how pregnancies are terminated, then an OB/GYN will tell them, This is how pregnancies are terminated.

Q. So do you think that it would be appropriate for the law to require OB/GYNs to tell patients, pregnant patients, who ask about their

options about the existence of a medication abortion?

A. I think the people should decide the laws in their state, and I think the state determines the practice of medicine within the boundaries of its boundaries.

Q. Okay. But do you think that that would be an appropriate law?

A. That's a legal question, and that's a question for the people of that state to answer and for the state to decide.

Q. So filed a complaint with HHS against ACOG --

A. Yes.

Q. -- for saying that OB/GYNs are ethically required to refer patients who ask to abortion providers; right?

A. I did.

Q. Do you think it would be appropriate for the law to require OB/GYNs to refer patients who ask to an abortion provider?

A. No.

Q. Why is that?

A. Because as a physician, when you make a referral, you are legally liable for the

actions of the person you refer to. If I refer to a doctor who I know is prescribing heroin for his patients, I have a legal liability for the life of that patient. If she dies from a heroin overdose, I stand legally liable for the person to whom I referred.

And I do not think that -- let me put it in a different way. Physicians who practice according to the Hippocratic Oath do not think that killing human beings is a viable therapeutic option. To refer to an abortionist is to refer to someone who is doing something that an Hippocratic OB/GYN would not consider a viable therapeutic option.

Q. So if an OB/GYN is unwilling to refer a patient to an abortion provider, how would a patient who wants an abortion go about finding out where to go?

A. My goodness. There's the internet.

MR. RIEGER: Object to the form of the question.

Please answer.

BY MS. CLARKE:

Q. You said that you would refer a

person to APRN for a reversal treatment; right?

A. No.

Q. Would you?

A. It depends on what that patient's options were in what period of time.

Q. Okay. So let's say a patient who is at six weeks gestational age, took mifepristone five hours ago, decides she's changed her mind. Would you refer her to APRN for treatment?

A. Oh, I'm sorry. Again, I misheard your question.

What I heard was advanced practice nurse. Okay? So would I refer a patient to the abortion pill reversal network? Yes, I would.

Q. Do you know all of the doctors who provide reversal as part of the abortion pill reversal network?

A. No.

Q. So you don't know if any of those doctors might practice unethically?

A. I don't know. But if I were to have a patient, I would know the doctors in my area. So if a patient came to me and said, Where can I get this, I would tell her the ethical

doctors in my area who are also part of the abortion pill reversal network.

If the patient were not in my area, I trust the abortion pill reversal network has done screening to screen for ethical practitioners. So I do trust that the abortion pill reversal network would send her to an ethical physician.

In the same way that I trust the Mayo Clinic -- if I had a patient that needed specialty treatment for which Mayo Clinic was the premier, will I know the exact doc who is taking care of her at Mayo Clinic? No, I won't.

But I will know that Mayo Clinic I can rely on and I can trust. And I have the same trust of the abortion pill reversal network as I would have of Mayo Clinic.

Q. Okay. Do you know who provides abortion reversal as part of the abortion pill reversal network in Tennessee?

A. No.

Q. Do you know any people who provide abortion pill reversal in Tennessee?

A. Yes, I do.

Q. And who provides abortion

reversal -- abortion pill reversal in Tennessee, that you know?

A. We have a couple of AAPLOG doctors who provide abortion pill reversal. I have confidentiality agreements. AAPLOG does not disclose the name of its membership to anybody, and that is something that we have promised to our membership.

I can't give you names of AAPLOG members. You would have to -- I can't do it.

Q. Understood. So if I were in Tennessee, would there be any way for me to know who the abortion pill reversal network would refer -- if I were a doctor, would refer my patients to if I sent my patients to that hotline? Is there any way for me to know the universe of doctors that might be connected to that patient through the abortion pill reversal hotline?

MR. RIEGER: Object to the form of the question.

Go ahead and answer, please.

A. I don't know.

BY MS. CLARKE:

Q. So I'm going to go back to your declaration. It's, I think, the most recent thing

in the chat, if you don't have it open.

A. I have it opened.

Q. Could you go ahead and read to yourself paragraph 10? It starts on page 4.

A. Read it out loud or read it to myself?

Q. Read it to yourself. You can let me know when you're done.

A. Yes, I'm done.

Q. Okay. So you write that, The term "may" is particularly notable as it is a measured term that calls to mind scientific possibility rather than absolute scientific proof.

Did I read that correctly?

A. That's correct.

Q. So, generally speaking, is it acceptable for a physician to tell their patients that something may be possible absent absolute scientific proof so long as there is scientific possibility to support what they're saying?

A. Yes.

Q. So would it be appropriate for an oncologist to tell a cancer patient that hypnotherapy may cure their cancer?

MR. RIEGER: Object to the form

of the question.

Go ahead and answer.

A. I'm not an oncologist.

BY MS. CLARKE:

Q. Do you know whether it's scientifically possible for hypnotherapy to cure cancer?

A. I don't think so, but I'm not an oncologist. So I'm not going to comment on oncology-related literature because I don't know what the oncology literature shows.

Q. Would there be -- could one design an ethical study to determine whether hypnotherapy is effective at curing aggressive otherwise terminal cancers?

MR. RIEGER: Object to the form of the question.

Please answer.

A. If you could find a body of patients who refuse any kind of treatment but they would be willing to participate with hypnotherapy, if they would be willing to participate in such a trial, then that could be used as a comparative group.

BY MS. CLARKE:

Q. Okay. That makes sense. If there were no such group of patients -- let's say everybody who gets a particular form of cancer goes for treatment -- would there be any ethical way to perform a study to determine whether hypnotherapy could cure the cancer instead?

MR. RIEGER: Object to the form.

You can answer.

A. You can't perform a study without the consent of the patient.

BY MS. CLARKE:

Q. Okay. So in a scenario like that where it's, let's say impossible to perform an ethical study to determine whether or not hypnotherapy can cure a certain cancer, would it be ethical for an oncologist to say, You know, I can't prove it's impossible, so it might be possible; and, thereafter, tell his patients, Hypnotherapy may cure your cancer?

MR. RIEGER: Object to the form of the question.

You can answer.

A. You have to have some basis for saying it may be possible, yes.

BY MS. CLARKE:

Q. So it's not enough to say it hasn't been proven impossible; you have to have some independent basis for belief that it's possible?

A. Yes.

Q. Let's say that there were hundreds of people in the United States who are convinced that hypnotherapy had cured their cancer. Would that be enough of a basis?

A. That's not a study.

MR. RIEGER: Object to the form.

THE WITNESS: I'm sorry.

Mr. Rieger, I didn't hear what you said.

MR. RIEGER: I'm sorry. I objected to the form, and then I instructed you to please answer.

A. That's not a study.

BY MS. CLARKE:

Q. So that wouldn't constitute sufficient basis?

MR. RIEGER: Same objection. Please answer.

A. Sufficient basis for what?

BY MS. CLARKE:

Q. For an oncologist to say, You

know, hypnotherapy has not been proven impossible as a way to cure cancer. There's a handful of people who are totally convinced it cured their cancer. I'm going to tell all my patients hypnotherapy may cure their cancer. Would that be appropriate?

MR. RIEGER: Same objection.

You can answer.

A. That's not a study.

BY MS. CLARKE:

Q. So it wouldn't be appropriate?

A. Physicians -- it is appropriate for a physician to base their opinion on physiological plausibility, the known actions of drugs and interactions with the body, the known ways that those drugs work. And that's what you base your opinion on. You base your understanding on how the human body works.

Physiology doesn't change. Physiology is physiology. Our bodies work the same way today as they did yesterday as they did 50 years ago. So physiology doesn't change.

So we study physiology as physicians. We understand how drugs interact with that physiology. Yes, new things are discovered,

but we have a pretty good understanding, especially nowadays, of even the cellular molecular details of where drugs interact.

So as a physician, you base your opinion and what you tell your patients on what's known, and you are honest about what isn't known. So that's what you're supposed to do as part of the informed consent process.

Q. So, then, would it be inappropriate for a physician to tell a patient that something may be possible based exclusively on a handful of anecdotes?

A. A handful of anecdotes about what?

Q. About the proposed treatment working.

MR. RIEGER: Object to the form of the question.

Please answer.

A. I'm going to have to have more information about what is actually being said before answering whether or not it's appropriate or inappropriate.

BY MS. CLARKE:

Q. Okay. So let's say an oncologist

reads on the internet a whole bunch of people who say, I didn't do chemo, I didn't do radiation therapy, I did hypnosis, it cured my cancer. Would it be appropriate on that basis for that oncologist to tell their patients hypnotherapy may cure your cancer?

MR. RIEGER: Object to the form of the question.

Please answer.

A. That's not a study. So you would hope that the oncologist would dig a little deeper into that issue before they include it in informed consent.

BY MS. CLARKE:

Q. Are you aware that there are studies showing that medical marijuana can alleviate people's nausea?

A. Yes.

Q. Do you think it would be appropriate to tell a pregnant patient that smoking marijuana may alleviate her morning sickness?

A. No.

MR. RIEGER: Object to the form of the question.

Please answer.

BY MS. CLARKE:

Q. And why not?

A. Because -- let me qualify that a little bit. Okay?

If she came to me and said, Hey, Dr. Harrison, I heard that smoking marijuana, smoking a joint, can alleviate my morning sickness, I would say, Well, marijuana does contain a powerful chemical that does act to alleviate nausea. But these are the consequences of doing it.

We have a growing body of evidence that smoking a joint has effects on your baby. It also has effects on your own nervous system. And this is not something that I would recommend.

Q. If a patient came to you and didn't ask about marijuana but just said, I have incredible morning sickness, nothing I've tried works, I don't know what to do, would you tell her that medical marijuana was a possible treatment for her morning sickness?

MR. RIEGER: Object to the form of the question.

Please answer.

A. If I'm responsible for prescribing for her, I would not prescribe medical marijuana. If she wanted medical marijuana, she would have to go to another doctor. I would not prescribe it.

BY MS. CLARKE:

Q. Would you tell her that it was an option?

A. No, because it does -- for the reasons that I told you. It would actually -- there's a growing body of evidence that medical marijuana produces harm to her baby and may even harm herself long-term.

Q. So why wouldn't you --

A. I would give her another anti-nausea.

Q. So wouldn't you tell her, Medical marijuana may alleviate your nausea, but it's really, really bad for the baby; don't do it. Wouldn't that be enough?

A. Enough for me to tell a patient about medical marijuana?

Q. Correct.

A. Maybe. It depends on the

patient.

Q. So there's some patients you wouldn't feel comfortable even saying that to; is that right?

A. That's correct.

Q. Is that because for some patients, you would be worried that their primary thought is about curing their morning sickness, and they would ignore the warnings about their pregnancy?

A. We're getting pretty deep into the hypothetical here.

Q. Is that why?

A. What is that?

MR. RIEGER: I'll object to that. Please answer.

A. So I think I already told you I think that the risks to the patient and to her unborn child, preborn child, are greater than the benefits that will come to her from medical marijuana. So that's the physician judgment. If she asks me, I would answer her completely. But I would not ordinarily suggest such a course to a patient.

BY MS. CLARKE:

Q. And you wouldn't suggest it to her and then let her figure out the risks and benefits for herself?

A. I'm sorry. Say again.

Q. You wouldn't tell her it has these benefits, it has these risks, and then let her weigh it for herself?

MR. RIEGER: Object to the form. You can answer.

A. I might. It depends a little bit on the patient.

BY MS. CLARKE:

Q. There's some patients for whom you would not, though; right?

A. There are.

MR. RIEGER: Same objection.

BY MS. CLARKE:

Q. Why is that?

MR. RIEGER: Same objection. Christine, for all, if we can take a small side bar. Given that we're not -- given that we're asking her to opine as to hypotheticals involving the nature of informed consent and so forth and so on,

and to avoid making this more difficult than it has to be with us talking over each other, would you be willing to agree that I've got a continuing objection to any hypotheticals down these lines since at this point, as Dr. Harrison has testified, her expertise lies in progesterone receptors and Mifeprex and the like.

MS. CLARKE: So is the State not intending to submit her as an expert on informed consent?

Alex, did you freeze?

MR. RIEGER: I think I did for a second. I'm sorry. Could you repeat your question?

MS. CLARKE: Is the State not intending to submit Dr. Harrison as an expert in informed consent?

MR. RIEGER: At this time, I can tell you we're not sure what we're going to try to admit her as in terms of the full scope of the hearing. I'm just trying to find a way to where I don't have to interject on every single one of

these questions due to the hypothetical in case she is not subsequently admitted as an expert witness in this context. She can only opine as to what she is qualified as an expert as.

I prefer not to interrupt your flow on the questioning. So my thought is, if we can just for any of these very, very deep hypotheticals, if we could just agree that there's a continuing objection as to form, she'll be instructed to answer at the conclusion of every objection that would have been -- that would have been made.

And then we can determine if it comes up, since this isn't a depo in lieu of testimony, we can address that as it comes up later if we need to get into each individual objection or whether or not that becomes important.

MS. CLARKE: So that objection would be to questions about informed consent if the State chooses not to submit her as an expert on informed consent? Is that the objection?

MR. RIEGER: That's correct, unless the question about informed consent has to do with her practice and not a hypothetical situation.

So if the situation is entirely hypothetically and outside of her practice area in the, you know, ten years in which she was practicing medicine, clinical medicine, for treating patients, then, at that point, that question would be fair game even if we weren't going to use her as an expert witness on informed consent.

But the other hypotheticals outside of her practice area would not be unless we were going to use her as an expert on informed consent.

MS. CLARKE: And her practice area would be obstetrics and gynecology?

MR. RIEGER: Dr. Harrison, is that a fair -- is obstetrics and gynecology a fair descriptor of your years of practice in the clinical setting?

THE WITNESS: Yes.

MS. CLARKE: Okay. We can move on from the medical marijuana, I think, if we're done.

MR. RIEGER: We're done.

MS. CLARKE: Okay.

MR. RIEGER: Sorry to interrupt.

MS. CLARKE: That's okay.

BY MS. CLARKE:

Q. Do you think it would be appropriate for an OB/GYN to tell a patient with an ectopic pregnancy that it may be possible to reimplant her pregnancy in the uterus?

A. No.

Q. Why not?

A. Because at this point in time, the technology has not been developed to accomplish those reimplantations.

Q. Are you aware that there's a handful of doctors over the years who have claimed to have successfully reimplanted an ectopic pregnancy in the uterus?

A. Yes.

Q. But you don't think that's sufficient to indicate that it's possible to do so, with our current technology?

A. I do not think that is sufficient to indicate that it is possible to do so with our current technology.

Q. So even though it's theoretically possible, you don't think it would be appropriate to tell a patient with an ectopic pregnancy that it may be possible to reimplant it, but I don't know how to do it?

A. Correct.

Q. I'm going to read you a quote, and let me know if you agree with it.

ACOG would support an ectopic transfer procedure if it were scientifically validated through the usual channels of animal studies to prove safety and efficacy and then human trials to prove safety and efficacy. If such a procedure followed that protocol and if such a procedure were then validated to be safe and effective in a human being, AAPLOG would support that.

Do you agree with that statement?

A. Yes.

Q. Are you aware of whether there has been any research conducted on animal studies to determine whether it's possible to reimplant an

ectopic pregnancy in the uterus?

A. There is ongoing research.

Q. But one can't conclude from that research that's happened so far that it's actually possible to do this with humans; is that right?

A. Correct.

Q. Okay. So we'll leave the hypotheticals and go back to medication abortion reversal.

We talked about the efficacy of mifepristone alone to terminate a pregnancy in the first 11 weeks of pregnancy. Does the effect of mifepristone in terminating an early pregnancy depend on the dose of mifepristone given?

A. Yes.

Q. So would a thousand milligrams of mifepristone be more likely to terminate an early pregnancy than 200 milligrams of mifepristone?

A. I'm trying to think if I've ever seen a study using a thousand milligrams. Certainly, 600 milligrams is more effective than 200 milligrams.

Q. Do you know what the efficacy is of 600 milligrams of mifepristone to terminate a pregnancy at nine weeks?

A. I would have to pull -- there's a number of different studies looking at mifepristone, 600 milligrams. I would have to pull them and then pull their average to give you a number. I can't do that without pulling the studies.

Q. So in your declaration, you referenced Dr. Delgado's historical control number of 25 percent for continued pregnancy after mifepristone?

A. Correct.

Q. Did you read the article that you cited to come to that number? Did you read the underlying study?

A. Yes.

Q. Do you know if any of those studies concerned 200 milligrams of mifepristone?

A. I would have to look back at the study. It's the Davenport study. I believe she did have a couple that had 200 -- I would have to look at the study.

Q. If one is trying to determine how effective abortion reversal is, medication abortion reversal, would it make sense to compare the rate of continuing pregnancy after

progesterone with the rate of continuing pregnancy before 600 milligrams of mifepristone, given that today a medication abortion consists of only 200 milligrams of mifepristone?

A. Ask that question again.

Q. Sure.

A. That was complicated.

Q. So medication abortion used to involve 600 milligrams of mifepristone; right?

A. Yes.

Q. It now involves 200 milligrams of mifepristone; right?

A. Yes.

Q. So if we're trying to compare the rate of continuing pregnancy after mifepristone alone versus mifepristone plus progesterone, would it make sense to use studies that concern only 600 milligrams of mifepristone if that's not part of the current regimen?

A. They could give you a rough idea of what mifepristone survival might be. The studies with the 600 milligrams can give you a rough idea. It will tell you whether it's a 90 percent of survival or a 10 percent survival.

It won't refine it -- it won't

refine it perfectly.

Q. So if the studies on 600 milligrams of mifepristone showed a 25 percent survival rate, let's just say, would one expect that 200 milligrams of mifepristone would have a higher survival rate?

A. It's possible.

Q. You just said that mifepristone -- that 600 milligrams of mifepristone is more effective at terminating a pregnancy than 200 milligrams; right?

A. Yes. You have to understand -- what do you mean by terminating a pregnancy?

The efficacy -- the end point of those studies in 200 and 600 milligrams, the efficacy end point was complete evacuation of the contents of the uterus without need for surgical abortion.

It has -- there's very little written on embryo survival, that is, documenting whether or not an embryo had a heartbeat after the administration of 200 or 600. There are very few studies.

Q. So is it fair to say that we really have no idea what the survival rate is of

an embryo after 200 milligrams of mifepristone?

A. No. It's not fair to say that because the survival rate is going to be a subset. It's going to be less than the amount of women who need additional treatment after mifepristone.

So I'm just going to make up numbers here. Okay? I'm not making them up for a percent. Okay? So if you want a percent, I've got to pull the papers.

Q. I know.

A. But if you have a hundred women and it says that the efficacy of complete abortion is 75 percent, that means 25 percent of those women had something left and had to have something else done at that point.

Now, within that 25 who had to have something else done, a subset of those will have a live pregnancy. That will be a small subset. The vast majority will have tissue left inside.

Q. So would we expect more people to have a continuing pregnancy after 200 milligrams of mifepristone than after 600 milligrams of mifepristone administered in early pregnancy?

A. Well, depending on just

gestational age specific, yes, you would expect that.

MS. CLARKE: Okay. I just drank an entire mug of coffee. Can we take a five-minute break? I'm sorry. I know we just took a break.

VIDEOGRAPHER: Off the record at 12:58.

(A break was taken.)

VIDEOGRAPHER: Stand by. We are back on the record at 1:05.

BY MS. CLARKE:

Q. So, Dr. Harrison, would it be accurate to say that mifepristone is a competitive receptor antagonist for progesterone receptors?

A. Yes.

Q. Do you know of any other competitive receptor antagonists for any other receptors?

A. Well, I'm sure I could come up with a list. There's a lot of them. But off the top of my head, I don't have a list prepared.

Q. I think in your declaration, you referred mifepristone acting in the same -- you referred to reversal acting in the same manner as

an anecdote to a toxicant, i.e., a poison. Does that sound familiar?

A. That's correct.

Q. Do you know of any anecdotes to poisons where the poison is a competitive receptor antagonist?

A. Well, if you look at binding, for example, with carbon monoxide, so carbon monoxide binds to hemoglobin. And it binds tightly to hemoglobin. It actually binds tighter than oxygen.

But if you give -- the treatment for carbon monoxide poisoning is to give the person a lot of oxygen. That kicks the carbon monoxide off of the hemoglobin where it's bound, and that's how you reverse carbon monoxide poisoning.

The example I gave in here of methotrexate -- so methotrexate, it intercalates into the DNA. It goes into the DNA where folate goes in, and it interferes with DNA synthesis.

So if you give folate, you can cause the methotrexate to be competitive -- to be out-competed by folate. So you restore the DNA synthesis.

Q. I think your example of the folate, if I don't pronounce this wrong, leucovorin --

A. Leucovorin.

Q. Leucovorin. Okay. Methotrexate is commonly used to treat ectopic pregnancies; right?

A. Yes.

Q. Is methotrexate and leucovorin together commonly used to treat ectopic pregnancies?

A. No.

Q. Do you know if it's ever used, both of those together, to treat an ectopic pregnancy?

A. It depends on whether the person gets toxic from the treatment of the methotrexate. So if the person gets toxic from the treatment of an ectopic pregnancy, then you would use leucovorin.

Q. Would administering leucovorin prevent the methotrexate from terminating the ectopic pregnancy?

A. Theoretically, I don't think that's ever been looked at. Why would you look at

that? That doesn't make any sense.

Q. So you're aware that some cancer patients receive methotrexate; right? I think that was your example.

A. Yes.

Q. If a patient receives methotrexate and leucovorin, do you know whether their pregnancy would be terminated by methotrexate?

A. I don't know. I mean, probably. It depends on the gestational age of the pregnancy. It depends on how much methotrexate they've been given.

Most likely, if you're talking an early pregnancy, then most likely it would be effective; but it's not as effective as Mifeprex is -- mifepristone is.

So there have been studies looking at the efficacy of methotrexate alone, and I think it gets into the like 60ish percent efficacy in terminating an early pregnancy.

But that's the reason methotrexate wasn't used, plus it has some toxicities.

Q. Okay. But so if a cancer patient

needed to receive methotrexate and she were pregnant and we gave her leucovorin, also, would that prevent the methotrexate from terminating her pregnancy if it was early?

A. I don't think that study has ever been done, because there would be no reason to do it. If you give leucovorin simultaneous with the methotrexate, then you prevent the methotrexate from acting at the level the cancer is. So why would you do such a study?

Q. Okay. So if a cancer patient received methotrexate for her cancer and she were pregnant in the early pregnancy and then you gave her leucovorin afterwards, would that reverse the effects of the methotrexate?

A. I don't know. Would it reverse the effects of the methotrexate in regard to the pregnancy or in regard to the cancer? Because it depends on the timing.

So methotrexate is not like something that goes in and instantly kills the cancer cells. The way methotrexate works is that it prevents DNA synthesis in rapidly dividing cells.

So cancer cells are rapidly

dividing cells. Baby cells are rapidly dividing cells. They both are rapidly dividing cells. So the way methotrexate works is it prevents DNA synthesis.

So the time it takes -- that's why you don't give them simultaneously, because it takes some time for a DNA synthesis to be inhibited. And you want to treat the cancer, so you treat the rapidly dividing cells and you don't give them any oxygen.

The reason you give leucovorin is that normal cells of the body aren't as rapidly dividing. So because they're not as rapidly dividing, they're not as affected by methotrexate.

But some areas of the body do have rapidly dividing cells, like your mouth and your gut. So giving methotrexate causes rapidly dividing cells in your mouth and your gut, and you get sores from it, or you can get sores from it. Not everybody gets sores, but you can. You can lose your hair.

So, again, a lot of this depends on timing. But as far as if a pregnant woman received methotrexate to treat her cancer, you would not give her leucovorin, because then you

would prevent the methotrexate from treating the cancer.

Does that make sense?

Q. Okay. It does.

Do you know if you gave her leucovorin anyway, do you know if that would save her pregnancy if you did it within 72 hours of her taking the methotrexate?

A. I don't think that's ever been looked at.

Q. Would you expect that to work, based on your experience and expertise?

A. I don't know. I don't know. It's never been looked at.

Q. Okay. Do you know whether the abortion pill reversal network provides reversal treatments for methotrexate?

A. I don't know.

Q. Okay. So I think you testified before -- strike that.

So mifepristone binds to progesterone receptors, and in that way prevents the body from absorbing progesterone; is that accurate?

A. No. The progesterone receptor is

around the nucleus. When something binds to that progesterone receptor -- well, when the progesterone binds to the progesterone receptor, it tells the DNA what DNA to transcribe.

So the DNA that's transcribed determines how the cell functions. So when progesterone binds to a progesterone receptor, it changes cells that weren't doing something into cells that do something else.

So, for example, in the endometrium, in the lining of the uterus, the cells that were not receptive when progesterone binds become receptive.

The reason I'm not being more specific is that there's like probably over 500 different ways in which progesterone changes the lining of the uterus to affect the receptivity or not receptivity to implant a patient.

So -- but the way in which it happens is that the progesterone tells these individual cells, make this protein or don't make that protein. It's in what DNA is transcribed.

So when something comes in and blocks progesterone from telling those cells, then it prevents those cells from doing their

progesterone thing. Okay? It prevents the cells in doing what they would have done in the presence of progesterone.

In the case of Mifeprex, the way Mifeprex works to cause the death of the embryo, the fetus, is that Mifeprex binds to the mother's endometrial decidua, so to the mother's decidual cells, and causes those decidual cells to shrink, to atrophy.

But that isn't instant. That's not like within an hour. That's within days. So the shrinkage -- how much Mifeprex causes shrinkage depends on where the woman is in her pregnancy.

That's probably more information than you wanted.

Q. So that process is called decidual necrosis; is that right?

A. That's correct, yes.

Q. And can progesterone reverse decidual necrosis if it's already begun?

A. Well, if progesterone is given within 72 hours, there's some evidence that it can prevent further decidual necrosis.

Q. And so if there's not too much

that's happened already, then the trophoblast remains attached to the endometrium; is that right? I'm not a doctor.

A. Yeah. That's a general view.

Q. Is it accurate that mifepristone also causes softening and dilatation of the cervix?

A. Yes.

Q. Can progesterone reverse that if given within 72 hours?

A. I don't know.

Q. Is it accurate that mifepristone also leads to myometrial contractions?

A. Not without prostaglandin mediation. So mifepristone in and of itself would have to have either endogenous prostaglandin -- prostaglandin is made by the woman's body herself or by being given prostaglandins.

So Mifeprex alone is a poor agent to cause sufficient contractions to expel the fetus, which is why misoprostol is given as a second drug.

Q. If contractions -- well, what are myometrial contractions?

A. Okay. The myometrium is the

muscle wall of the uterus. "Myo" is muscle, and "metrium" is uterus. So it's the muscle wall of the uterus.

Myometrial contractions is just the uterus contracting.

Q. So enough contractions will expel the contents of the uterus; is that right?

A. Depending on how firmly adherent the trophoblast is to the decidua.

Q. Is it accurate to say that mifepristone increases myometrial sensitivity to prostaglandins --

A. Yes.

Q. What does that mean?

A. I should have let you finish. I'm so sorry. Will you finish that question before I say yes to it?

Q. Okay. So is it accurate to say that mifepristone increases myometrial sensitivity to prostaglandins?

A. Yes.

Q. And that means -- what does that mean?

A. That means that for some reason, blocking the progesterone receptors causes the

uterus to be more sensitive than it would otherwise be to prostaglandins.

So the reverse of that, progesterone has been used throughout pregnancy in women who have miscarried to decrease the sensitivity of the uterus to other things that would cause the uterus to contract.

Q. And those things like prostaglandins; is that right?

A. Like prostaglandins are released when you have infection, when you have tissue damage. So prostaglandins are released in a lot of different physiological states.

Q. Is it accurate to say that mifepristone increases the disinhibition of prostaglandin synthesis by the myometrium?

A. Can you state that question one more time? Because there's a lot of negatives in there.

Q. I know. Tell me about it. Forget it.

You're just saying that mifepristone leads to disinhibition of prostaglandin synthesis by the myometrium.

A. Well, the inhibition is

prostaglandin synthesis is progesterone mediated. So yes.

Mifepristone, by blocking progesterone, would function to decrease inhibition. That's a lot of negatives in there.

Q. Okay. So, again, I'm not a doctor. But does that mean that by blocking progesterone, mifepristone might cause the body to synthesize more endogenous prostaglandin?

A. Yes, it might.

Q. And misoprostol is a prostaglandin; right?

A. Yes.

Q. So prostaglandins, whether endogenous or exogenous, cause, among other things, uterine contractions; is that right?

A. Yes. Yes.

Q. So if mifepristone caused the body to produce more prostaglandin, would progesterone prevent that prostaglandin from having its effect of causing contractions?

A. It depends. And it depends on how much prostaglandin is there and when the progesterone is administered.

Again, the inhibition of the

sensitivity of the myometrium to prostaglandins is progesterone remediated. In other words, if you have a lot of progesterone, the uterus is not going to be as sensitive to prostaglandin action.

Q. Okay. So regardless sort of of how much prostaglandins there are, if there's a ton of progesterone in there, the prostaglandin is not going to have as much effect?

A. Not as much. I'm not saying it won't have any effect, but it won't have as much. The uterus won't be as sensitive to the actions of the prostaglandin.

Q. Okay. That makes sense.

So you have read the 2018 Delgado paper on abortion pill reversal; right?

A. Yes.

Q. And is it your opinion that that study supports the efficacy of progesterone treatments to reverse mifepristone if given within 72 hours?

A. It supports it, yes.

Q. Okay. So I know we've talked around this a little bit. But how do we know that the live birth that happened with the patients in the Delgado study wouldn't have happened anyway

without progesterone treatment?

A. So let me unpack that a little bit.

So what you would have a very rough idea about is the live embryos that follow after the administration of mifepristone alone. We have a little bit of information, and that was published in the Davenport study.

She ends up saying I think somewhere -- again, I would have to see the study. But my recall is somewhere in the 8 to 23 percent range for survival at various different doses of Mifeprex alone.

So to be -- to take the highest number, the Delgado authors said, Okay, well, if the range that she got in those studies was 8 to 23 percent, we'll take a comparator of 25 percent, which is higher than their highest study. So we'll compare that number with the number of women who -- I believe their end point was 20 weeks -- the number of women who receive APR who end up with a live fetus at 20 weeks.

So that's what they compared to. So it was a 25 percent comparison to 68 with the best protocol, 40 something, 43 with all protocols

combined.

Q. So if we're looking at the 68 percent, what's the sort of -- what's the numerator and denominator that gets us to 68 percent? We're dividing what by what?

A. We're dividing the number of -- can you give me the study? If you could pull up that study, then I can look at their materials and then we can be specific as to the numbers they used to get the 68 percent.

Q. Okay. Before we get to the study, just for the sake of time, do you know whether that study, in coming to the 68 percent or any efficacy number, did they count patients whose pregnancies had already been terminated by mifepristone before they got to the reversal provider?

A. No.

Q. So the numerator wouldn't include the people whose pregnancies were terminated by mifepristone alone within the time frame before they sought treatment?

A. It would be ridiculous to do so, because the issue is -- the scientific question is if you have a baby who is still alive -- so that's

the premise. The premise is you start with a baby who is still alive within 72 hours of taking the Mifeprex.

So if that's your starting point, then if we intervene with progesterone, how many of those babies will continue to be alive to the end point of 20 weeks?

So it would be completely invalid to include dead babies in that study. It doesn't make any sense, because your starting point for the study -- the inclusion criteria is babies who are alive at that point.

You would never give progesterone to somebody who had a dead baby or who had simply retained products. It doesn't make any sense.

Q. So are you aware of whether there are any studies about the rate of continuing pregnancy after injection of mifepristone where those pregnancies have survived the first 48 hours of mifepristone, let's say?

A. The only study I know of was the study by Creinin, who attempted to prove that abortion pill reversal didn't work. My understanding is that his inclusion criteria for that study was -- he only included in that study

babies who were alive at, you know, when they -- it was within 72 hours.

Q. Okay. I'm trying to process all of the science. Okay.

Do you know whether a significant percentage of people who take mifepristone have their pregnancies terminated within 48 hours without taking misoprostol?

A. My understanding from earlier studies and from the original FDA approval -- this is, again, a recall. So in order to give you an exact number, I would have to go back and look at the exact studies.

But my recall is it's somewhere like 4 to 5 percent are terminated within -- are completely terminated within 72 hours. But I think actually the end point was more like 48 hours, because they were looking at how many would terminate prior to misoprostol administration at 48 hours.

And I think it's only like -- it's somewhere between like 3 and 5 percent.

Q. Okay.

A. That's my recall. Again, if you need an exact number, I've got to go back and look

at the exact studies. So I can't keep those numbers in my head.

Q. I understand that you're not an encyclopedia.

Do you know whether there are studies that determine the percentage of people whose pregnancies continue 72 hours after injection of 200 milligrams of mifepristone alone, leaving aside the Creinin study?

A. Well, I think that was what the Delgado paper was about, trying to determine that. So she had a number of papers that had different end points of when they actually saw the patient back. So I don't think any of them saw the patient back in 72 hours. I think the interval was more like a week.

That's my recall, again, without looking at the actual paper. My recall is that most of the studies she reviewed saw the patient back a week or two weeks.

Q. So -- okay. In your declaration, you state that Dr. Delgado and his fellow authors analyzed the interval of time between mifepristone injection and progesterone administration and found that success rates were the same as long as

the progesterone was given within 72 hours of the use of mifepristone.

Is that right? Does that sound right?

A. That's my understanding.

Q. So would that mean that it doesn't matter when the progesterone is given as long as it's within 72 hours of the mifepristone?

A. Well, actually, physiology -- understanding the mechanism of how mifepristone works and how progesterone works to counteract it, common sense would tell you the sooner, the better.

The longer the time the mifepristone binds the progesterone receptor, the less progesterone-dependent transcription you have, the more damage.

So as far as gross numbers, coming up with a gross number, you know, they lumped it all together. But as far as if you really wanted to scientifically define this, you would have to look at studies broken down by the hour, but there are so many factors involved.

So, anyway, it does make sense that the sooner, the better.

Q. So when you say that they sort of lumped everything together, is it accurate to say that they analyzed the interval of time between the mifepristone injection and the progesterone administration?

A. Yes.

Q. So if they analyzed the interval of time between mifepristone injection and progesterone administration and found no difference in the success rate, wouldn't that indicate that it doesn't actually matter when the progesterone is given as long as it's within 72 hours?

A. Well, if you're going to say it doesn't matter, then you need a study broken out by one hour, two hours, three hours, four hours, five hours. You need to actually determine what's the curve for a large number of patients.

So when I say they lumped it -- they lumped it by their categories, okay, 24, 48, 72, whatever. They lumped it by categories, but they didn't break it down to say, Well, there's actually a better survival rate at six hours than there is at ten hours. They didn't -- it wasn't that -- they weren't able to discern to that

level.

So physiologically speaking, knowing how progesterone works and knowing how Mifeprex works, it would make the most sense the sooner, the better. Because you want to minimize the damage from blocking progesterone receptors that Mifeprex has caused.

And Mifeprex's damage is time dependent, because it affects DNA transcription which takes time. So the longer the progesterone receptor is blocked, the more ultimate damage there is. So you minimize that.

Q. Would it be accurate to say that the Delgado study has shown that there's no difference between administering progesterone 24 hours versus 72 hours after ingestion of mifepristone?

A. Within the limits of his study.

Q. What are the limits of his study?

A. You can't -- well, the number of patients. And he didn't stratify per hour. So within the limits of his study, he didn't show a difference between those groups, those groupings that he chose. Okay?

But that doesn't mean there

exists no difference. It just means his studies didn't demonstrate a difference.

Q. Okay. I think I understand.

So in looking at sort of how likely it is that someone who is taking mifepristone will be able to have a live birth after progesterone is administered within 72 hours and figuring out that number, if we divided the number of patients in Dr. Delgado's study by the total number of patients whose pregnancies had already been terminated by mifepristone, we would get a lower number than 68 percent or 48 percent; right?

A. What question would you be answering with that math? How would that -- what question would that math answer?

Q. So if the question was, in advance of taking mifepristone, how likely in a group of a thousand women would it be, after they took mifepristone, for them to successfully get progesterone treatment and then have a live birth?

If that were the question you were asking, would you want to divide the number of live births after progesterone by the total number of people who took mifepristone?

A. No, because you wouldn't administer mifepristone to anyone who didn't have a living fetus.

So the issue isn't administering mifepristone to all abortion patients. The issue is administering mifepristone to those women who have taken it, whose babies are still alive, and they regret it; and they want to do something, anything, to help increase the chances that their baby will survive.

So that's -- the question is, what can we do to increase the chances that those women who have a live baby still and they regret it and they want to do what they can, what can we do to increase the chances that that baby will survive?

That's the question we're trying to answer.

Q. What if I were trying to answer a different question and the question were not what percentage of people who appear for treatment at a reversal provider and still have a live baby can go on to have a live birth after progesterone treatment.

If instead the question were, If

a thousand women took mifepristone and then all of them got progesterone treatment thereafter, what percentage of them would have a live birth? If that were the question I was trying to figure out, what would my -- how would I figure that out?

A. Okay. So you look -- you could get a rough idea. Are you talking design study? But if you wanted some rough mathematical idea, you would take the number of patients who have ongoing pregnancies at the time they return to the abortion clinic, which I think depends on gestational age at which it's administered -- and I can't pull the number up out of my head right now. I want to say it's like -- I don't know.

If I were forced to have a number, I would say it's somewhere like 1 or 2 percent. So of the universe of a thousand patients, we get 1 percent of that or 2 percent, that's 200. Okay?

Of those 200, that would administer mifepristone, then 68 percent of those -- again, depending on the individual factors of gestational age, 68 percent of those would respond to the mifepristone treatment.

Without mifepristone, the rough

number would be 25 percent of that 200. Because that's the highest -- that's the highest estimate that the Delgado paper used.

Q. So -- sorry. I think I've confused myself.

A. I'm sorry.

Q. It's not your fault.

In the study that you just mentioned, we would be still comparing people or looking only at a subset of people who had a continuing pregnancy after mifepristone at some point in time; right?

A. Correct.

Q. And if we were instead looking at the total universe of people who took mifepristone, how do we determine for that entire group of people what their likelihood would be of having their pregnancy continue after progesterone treatment? Wouldn't we have to --

A. Okay. So -- go ahead.

Q. Wouldn't we have to include the people whose pregnancies terminate early before they reach the provider just to figure out prospectively the percent chance for a given group of people?

A. No, because the percent chance -- the percent chance for a given group of people, the group is who's got a live baby. So that's the group. The group isn't all Mifeprex ingesters.

So the group that you're trying to figure out the percent increased chance is those who have a live baby. So we're taking from that -- that's the beginning point. The beginning point is, you took Mifeprex, baby is dead or alive. Baby is dead, nothing you can do. Baby is alive, we can increase your chances from approximately 25 percent to approximately 68 percent.

That's all we know. We can't say it's a hundred percent. But we can say it's the only thing we have to help you with.

Q. All right. Okay. So for the people whose pregnancies terminate before they reach the reversal provider, obviously, reversal can't be effective with them; right? It's too late?

A. Too late.

MS. CLARKE: Sara, if you're still there, could you pop Tab CC into

the chat?

THE WITNESS: Give me a second here.

MS. CLARKE: Sure. Take your time.

THE WITNESS: Then go to full screen and then chat.

Again, give me just a second here. I'm opening it up.

MS. CLARKE: Take your time.

THE WITNESS: Okay. I got it.

BY MS. CLARKE:

Q. Take a look at this and let me know when you're ready.

A. Okay. I'm ready.

Q. Okay. What is this document?

A. This document is AAPLOG Practice Bulletin 6, the reversal of the effects of mifepristone by progesterone.

Q. Did you write this document?

A. No, but I was on a committee to help edit it.

Q. What is an AAPLOG practice bulletin?

A. An AAPLOG practice bulletin is a

compiling of the scientific literature for pro-life docs to understand and inform their practice.

Q. So under Practice Bulletin, it says, Evidence directing pro-life obstetricians and gynecologists. Does that accurately -

A. That's correct.

Q. Does that accurately describe what a practice bulletin is?

A. Yes. I'm sorry. I'll wait for your question next time.

Q. It's getting late. I understand.

Can you turn to page 4 of this document?

A. I'm getting there. Yes.

Q. Okay. So sort of two-thirds of the way down on the left, it reads, Dr. Delgado and his co-authors also analyzed their results by gestational age at the time of reversal attempt and found that the success rate increased with increasing gestational age. Right.

A. Good point. Yeah, I see that.

Q. Is that accurate?

A. Well, let me pull up the Delgado paper.

Q. So you don't know without looking whether that's accurate?

A. I don't. I'd have to pull up the Delgado paper.

Q. So leaving the Delgado paper aside, is it accurate to say that the rate of continuing pregnancy after ingestion of mifepristone alone is also higher at later gestational ages?

A. Yes.

Q. I have a quick question about the sixth page.

Actually, I forgot to ask the court reporter to mark this exhibit. Can we mark this as Exhibit 18, please?

COURT REPORTER: Yes, ma'am. 18.

(Exhibit 18, AAPLOG Practice Bulletin, was marked.)

BY MS. CLARKE:

Q. Are you on page 6?

A. I am. I'm sorry. Yes, I'm on page 6.

Q. So on the top right under intramuscular protocol, it reads, Some clinicians may choose to continue intramuscular treatment

longer since this recommendation is based on relatively small numbers.

Did I read that right?

A. **Yes, that's correct.**

Q. What does that mean?

A. **Well, if you look at the IVF literature, which is where a lot of progesterone has been used for about 50 years, when a woman undergoes in vitro fertilization, the ovary is stimulated so that they can retrieve an egg or many eggs. But that stimulation tends to prevent the woman from making progesterone with her ovaries.**

So not a hundred percent, but it induces what's called a relative luteal phase defect. So some IVF doctors will give progesterone supplements only through 12 weeks of pregnancy. Because, after that time, the placenta takes over the production of progesterone. Some IVF doctors will continue giving progesterone later.

It's kind of an individual judgment call, and it's up to the individual clinician. But the evidence for how long to treat luteal defect rests on the IVF literature use of

progesterone in induced luteal phase defect for IVF patients.

It's similar because what you have with Mifeprex is you have an induced luteal phase defect. So it's a similar kind of physiological insult. So that's why there's some room for judgment because, even in the IVF literature, there's room for judgment.

Q. Okay. So I'm going to sort of try to parse this out in facts, because I think I still don't understand.

When it says, This recommendation is based on relatively small numbers, what does that mean?

A. That means there aren't a lot of studies looking at how long you should treat a luteal phase defect with progesterone.

Q. And because there's not a lot of studies, some clinicians might think, well, I don't know if it works later, but you might as well try it. Is that accurate?

A. Well, when you say "later," you mean for a longer duration?

Q. Sorry. Yeah, for a longer duration.

A. Correct. There's not consensus right now in the IVF literature as to how long to treat -- let me try that again -- an induced luteal phase defect for IVF patients.

Q. Okay. I think I understand. At the very bottom of that page under references, at the end of that sentence or the end of that paragraph, it reads, When high quality evidence is unavailable, opinions from members of AAPLOG were sought.

What does that mean?

A. Well, AAPLOG is composed of a number of different subspecialists within OB/GYN. We have reproductive endocrinologists. We have a few gynecologic oncologists, although they don't deal so much with the life issues. We have maternal fetal medicine physicians.

So when we create these practice bulletins, we also run them by, for editing purposes, those physicians who we know have expertise in that area.

Q. Okay. Are you one of those physicians that this would be run by?

A. Yep.

Q. And that would be because of your

expertise in Mifeprex, among other things?

A. That's correct.

Q. Did you give input into this other than to edit it?

A. Well, in editing, you give input. But I did not do the initial drafts, no. I did the editing.

Q. So when it says, When high quality evidence was unavailable, do you know sort of what that's referring to in this document?

A. Well, as you know, there aren't a lot of studies which looked at the survival rate after giving Mifeprex. So those studies are summarized in the Davenport -- sorry. It's late -- the Davenport publication.

So when we talk about high quality, we're talking about large, large, large numbers of patients looked at very, very specifically over multiple, multiple studies over multiple, multiple years. That, we're not there yet. It's coming, but we're not there yet.

MS. CLARKE: Okay. So I know we talked about the Yamabe study briefly.

Sara, could you drop Tab P into the chat room, please?

A. Just give me a second. Tab P. I got it.

MS. CLARKE: While you're looking at this document, Ms. Morgan, would you mind marking this as Exhibit 19.

COURT REPORTER: 19. Yes.

(Exhibit 19, Yamabe Study, was marked.)

BY MS. CLARKE:

Q. Okay. So this is a study of mifepristone in rats; is that right?

A. That's correct.

Q. And in this study --

A. Yes.

Q. In this study, do you know whether any group of rats was given mifepristone followed up some later time by progesterone?

A. Give me a second. Hold on a second. I'm reading the materials and methods.

Q. Okay.

A. I'm looking to try to find the time at which the progesterone was administered.

Okay. The progesterone was administered simultaneously with the RU-486.

Q. So is it, then, inaccurate to say

that this study involves a group of rats that was given mifepristone followed by natural progesterone?

A. That is correct. It was given simultaneous.

Q. In your declaration, you refer to manufacturers' studies concerning the reversibility of mifepristone; is that right?

A. That is correct.

Q. What do you mean by "manufacturer studies"?

A. Baulieu is the author. He compiled manufacturer studies from Roussel-Uclaf into a document which he authored. So when I refer to manufacturer studies, I'm referring to the combination of different studies compiled by Baulieu.

Q. The manufacturer of what?

A. Mifepristone.

Q. Okay. And so you're saying that in the Baulieu and Segal book, all of those tracters (ph) are studies done by the manufacturer of Mifeprex?

A. There certainly -- were they all done by Roussel-Uclaf? They certainly were relied

on by Roussel-Uclaf. I can't tell you exactly where all of those studies were done. They may have been done at different universities, but they are the manufacturer studies from Roussel-Uclaf.

Q. So when you say they are the manufacturer studies, what you mean is these are the studies that were ultimately relied on by Danco?

A. They were ultimately relied upon by Roussel-Uclaf. These are the studies that were also reviewed by the FDA for the approval.

Q. But you don't know if these were all studies that were conducted by the manufacturer?

A. I don't know exactly the location of the labs that did the studies. I don't.

Q. I gotcha. So the citation you give -- if you want to refer back to your declaration, although you don't have to if you don't want to. But it was page 6, paragraph 16.

A. Hold on just a second. I'm there.

Q. And it's footnote 8.

A. Yes. Okay.

Q. So you cite to the Baulieu and

Segal book for the proposition that reversibility of mifepristone binding is backed up by manufacturer studies; is that right?

A. Correct. That's correct.

Q. It turns out a large book?

A. It is a very large book. It will take me awhile to get to the studies, but I can give you -- it's like in about the mid two-thirds. So I would have to get -- I would have to pull up that, and it will take me a little bit of time to find the study. But, yes, I can do that.

Q. Well, if I gave you a table of contents, would you be able to point me to the chapter that you were referencing?

A. Maybe.

MS. CLARKE: Okay. Let's try that.

Sara, I know you made a tab for me, and now I don't know what it is. You dropped Tab S down.

I would ask the court reporter to mark this as Plaintiff's 20, please.

THE WITNESS: Tab S.

(Exhibit 20, Baulieu & Segal Table of Contents, was marked.)

BY MS. CLARKE:

Q. Does this look like the table of contents for the Baulieu and Segal book cited in your footnote 8?

A. I'm still pulling it up. Hold on.

Yes, it looks like it.

Q. So could you let me know which chapter in here you were referencing in your footnote 8?

A. I'm looking.

Q. I'm sorry. While you're looking, let me close my curtains.

A. I'm not going to be able to figure it out without looking at the actual papers. So I will have to go back and look at the actual papers. I'm really sorry. I don't track my title. I track by what the abstract says.

Q. So whatever portion of this book you were citing, does it support the proposition that mifepristone is reversible by progesterone?

A. Yes, it does.

I hate to ask, but I had a lot of water. Can I go to the bathroom?

MS. CLARKE: Sure. Do you want

to take a five-minute break everybody?

VIDEOGRAPHER: Off the record at 2 o'clock.

(A break was taken.)

VIDEOGRAPHER: We are back on the record at 2:05.

BY MS. CLARKE:

Q. Okay. Dr. Harrison, in that same -- well, sorry. Did you communicate with anyone during that break?

A. No. There's nobody here.

Q. Did you look at any documents?

A. No.

Q. Okay. So looking back at paragraph 16 of your declaration, it reads, The reversibility of mifepristone binding is backed up by manufacturer studies as well as National Institute of Health studies.

What did you mean by National Institute of Health studies?

A. Sternberg is, I think, the one I cited. Hold on just a second. Let me look up my citation.

Yeah. Sternberg works at the NIH.

Q. Was that study that you cite in footnote 9, was that an NIH study?

A. Well, it was performed by an NIH doctor. So I would assume it was an NIH study. I mean, that's where she works.

Q. But you don't know if that study was conducted by the NIH or published by the NIH?

A. I don't. I don't. I just know that she's a well-respected physician who works at the National Institute of Health.

Q. Okay. And that's a study concerning -- okay -- the effect of mifepristone on glucocorticoid receptors; is that right?

A. That's correct. So mifepristone -- yes, that's correct.

Q. Okay. In that same footnote 9, after the Sternberg citation, it reads, The Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and National Institute of Health (NIH), Emerging Clostridial Disease Workshop, May 11, 2006.

A. That's correct.

Q. Was the Emerging Clostridial Disease Workshop a study conducted by HHS?

A. The Emerging Clostridial Disease Workshop was a workshop held by the CDC and FDA after the death of the four women from clostridium sordelli sepsis who had taken mifepristone. There was a workshop held to look at the mechanisms by which those deaths might have occurred.

Q. Okay. So your citation here, was this a citation to the transcript of that workshop?

A. Yeah. It should say "transcript," but I don't see it saying transcript.

Okay. Yes.

Q. So it's not a study?

A. Well, she presented the results of her study -- so her study was published in the Journal of Endocrinology, and she was one of the presenters at the Emerging Clostridial Disease Workshop.

Q. By "she," you mean Dr. Sternberg?

A. Sternberg; correct.

Q. So when I looked at page 23 of this transcript, I saw a Dr. Dale Gerding's testimony. Is that not what you intended to cite to?

A. I don't think so. She presented. I'll have to go back and look for the -- she has her presentation in there. I would have to see it and go through the transcript.

But she did -- I was there. She presented.

Q. Did she present about her work studying the effect of mifepristone on glucocorticoids?

A. Correct.

Q. And then there were members of the public also speaking at that workshop; right?

A. Yes.

Q. And their statements are also in the transcript?

A. I don't know. I don't know if their statements are in the transcript or not.

Q. Okay. In paragraph 12 of your declaration, footnote 3, you cite to Spilman and Gibson et al; is that right?

A. That's correct.

Q. And that study that you cite concerns the effect of steroids on rabbit uteruses; is that right?

A. Yes.

Q. Was mifepristone one of the drugs studied in that study?

A. Yes, it was.

You have to understand mifepristone in its development has different drug names. So RU38486 is mifepristone. It was given another name by Upjohn, which was like U9933, something or another. So that's mifepristone.

Q. Okay. So is there any way to know what all RU names mifepristone has been given over the years?

A. Well, I've -- you have to go back to the original chemistry literature, and you just have to know what names it was given in development. So it is a challenge.

It was given like four or five different names, depending on which pharmaceutical was studying it at the time. So RU means Roussel-Uclaf.

Q. So RU38486 is mifepristone?

A. That's mifepristone.

Q. In your declaration, you also cite a study by Garratt out of Australia; is that right?

A. Yes.

Q. Did that study draw any conclusions about the efficacy of reversal treatments?

A. Boy, I would have to pull up the study.

MS. CLARKE: Okay. Let's pull up the study.

Sara, can you drop Tab Q into the chat, please.

And if we could mark this as plaintiff's 21, please.

(Exhibit 21, Garratt Study, was marked.)

Garratt Study

BY MS. CLARKE:

Q. Do you recognize this document?

A. Yes, uh-huh. Yes, I do.

Q. And this is the Garratt study that you cited in your declaration?

A. That's correct.

Q. So what conclusions, if any, does this study draw about the efficacy of progesterone to reverse mifepristone?

A. What they state is, Women have changed their mind after commencing medical

abortion. Progesterone used in early pregnancy is low risk and its application to counter the effects of mifepristone in such circumstances may be clinically beneficial in preserving her threatened pregnancy. Further research is required, however, to provide definitive evidence.

Q. Okay. So on page 3 of --

A. Which document?

Q. -- the Garratt article --

A. Okay.

Q. -- under "future questions," do you see that on the bottom right?

A. Hold on. I'm getting there. Yes.

Q. Okay. So that reads, There is currently no definitive evidence for the success of using progesterone to prevent the abortifacient effects of mifepristone; is that right?

A. That's correct. That's what it says. That's what the study says, yes.

Q. Would you agree with that statement?

A. You would have to define "definitive evidence." Is there physiological reason to think that it would work? Yeah, there

is.

Q. Would you consider there to be definitive evidence that it works?

A. At the time of her publication of the study -- let me look back. I'm looking for a study date here, 2017.

I wouldn't say definitive evidence. I would say there is evidence for the action. There is evidence. What I would agree with her is that definitive, to me as a scientist, implies that something has been done over a very, very, very long period of time; and it's always gotten the same results. It's been checked and cross-checked and cross-checked. That's not where we're at right now.

But there is definite evidence and growing evidence for the success in using progesterone to prevent the abortifacient effects of mifepristone.

Q. Okay. I'm sorry. Is that how you pronounce that? Abortifacient?

A. Yes. Well, that's how I pronounce it.

Q. Okay. Would you say that there is evidence that abortion reversal or medication

abortion reversal is safe for women?

A. Yes.

Q. And what is that based on, that opinion?

A. That's based on almost 50 years of use in OB/GYN as well as extensive use in the IVF industry. Almost every woman who undergoes IVF is placed on progesterone.

Q. So that would be evidence of the safety of progesterone; right?

A. Correct. The safety of progesterone in the early pregnancy.

Q. Okay. Is it your opinion that it is safe for a woman to take mifepristone and then not take misoprostol?

A. It's never safe for any woman to take mifepristone for -- I mean, let me qualify that.

If you're asking me is a mifepristone abortion safe, I will say no. It is not safe for the woman, and it's definitely not safe for the child who is being killed by mifepristone.

Q. Are there greater risks to the woman for taking mifepristone and not taking

misoprostol than for taking none?

A. I have seen no studies on that yet.

Q. So we don't know?

A. We don't know. But in my own opinion, I would like to see a study before such conclusions are drawn.

Q. Okay. I think -- well, do you know whether patients who are referred to physicians through the abortion pill reversal network, if they have an adverse event, is that reported back to the abortion pill reversal network?

A. I don't know.

Q. So if a patient -- well, strike that.

Is there any way to know whether the patients who obtain reversal treatment through APRN, whether any of them experienced a hemorrhage?

A. I don't know.

Q. Do you know whether the abortion pill reversal network requires reversal providers to have back contracted backup physicians in case the reversal provider is unavailable and the

patient is having an emergency?

A. I don't know.

Q. Do you know whether the abortion pill reversal network requires reversal providers to have admitting privileges at a local hospital in case the patient gets admitted to the hospital?

A. I don't know.

Q. Do you think that would be appropriate?

A. Well, most OB/GYNs in clinical practice have admitting privileges. That's just the standard. So as an OB/GYN, if you're practicing, you've got privileges.

My understanding, though I don't have intimate understanding, is that most of the doctors who are part of the abortion pill reversal network are practicing OB/GYNs. So one would assume that a practicing OB/GYN has admitting privileges.

Q. Would it be appropriate for APRN to require that they do to practice in the network?

A. They're not intervening to -- okay. Let me back up.

Would it be appropriate for an

OB/GYN who's taking care of a patient to have admitting privileges? Yes. It would be appropriate for an OB/GYN who is taking care of a patient, who is doing patient care, to have admitting privileges. Or -- yeah.

No, I would say that that is appropriate. But I don't know that they don't. I don't know what the criteria is for the abortion pill reversal network.

Q. If the abortion pill reversal network did not require participating providers to have local admitting privileges, would you still refer patients there?

A. Yes. And I'll tell you why. Because the abortion pill reversal network physician is not intervening to cause an event which necessitates surgical intervention. They're trying to avoid an event that necessitates surgical intervention.

Most practicing physicians have a network of specialists that they would refer to. So if you have a practicing physician who is taking responsibility for the abortion pill reversal network patient -- again, I would assume that most of those are OB/GYNs in practice,

because they're providing prenatal care -- I would assume that they would have admitting privileges.

If they didn't, they're probably practicing with someone with admitting privileges. Because when you do the abortion pill reversal network, you're causing this patient to go on and have prenatal care, hopefully.

So they would already be in a system with docs who would have admitting privileges. It wouldn't be something foreign to what they are already doing.

Q. So if you learned that the abortion pill reversal network refers patients to midwives, who are not doctors and who do not have admitting privileges, would you still refer patients there?

A. Well, it would depend on the scope of practice. But in all the states that I know of, midwives work with OB/GYN physicians. So I don't know of a state where a midwife is independently working outside of a network of OB/GYN physicians.

Q. So as long as there's an OB/GYN physician working with the midwife, you would feel comfortable referring patients there?

A. Yeah. I refer patients for prenatal care to midwives. I think midwives have a great place in obstetrics and gynecology, but they also need the backup of an OB/GYN physician network. Not one physician but, you know, as many physicians as they work for.

Q. So if someone got reversal treatment and then went to the hospital with a hemorrhage, is there any way that the abortion pill reversal network would know that that happened?

A. Well, when you say the abortion pill reversal network, or do you mean the individual physician who is taking the responsibility? The network is not the treating physician. The treating physician takes responsibility for their patient. So that treating physician should know that his or her patient went to the ER.

Probably, the patient would call the doctor first. So normally, what happens in practice is that a patient calls the doctor first and says, Hey, I'm hemorrhaging. He says, Okay, go to the ER -- he or she, Go to the ER. And then the doctor calls the ER and says, I'm sending in

Jane Smith. She's hemorrhaging. This is her history. Give me a report.

So that's the normal patient care that one expects with prenatal care. The doctor themselves takes responsibility for the patient.

Q. Okay. So I'm going to read you a quote, and I want you to let me know if you agree with it. It concerns abortion pill reversal.

The authors of these studies assumed that all the women who didn't come back to the treating physician were completely free of problems. It is more likely that these women had problems that were handled by another doctor. So the follow-up was done by another doctor. The original doctor has no mechanism for tracking complications handled by emergency rooms or other doctors. So they would have no record of problems for these women. This makes the rate of complications seem much lower than they are in reality.

Do you agree with that criticism?

A. Did I write that?

Q. Do you agree with that criticism?

A. It's out of context.

Q. Would you agree with that as

criticism of the safety of abortion pill reversal?

A. Read it to me again.

Q. Sure. So let's -- we'll say the author of the Delgado study assumed that women who didn't come back to the treating physician were completely free of problems. It is more likely that these women had problems that were handled by another doctor. So the follow-up was done by another doctor. The original doctor has no mechanism for tracking complications handled by emergency rooms or other doctors. So they have no record of problems for these women. This makes the rate of complications seem much lower than they are in reality.

A. Okay. I would have to actually see where this quote is coming from and see what studies they're talking about. So I can't give you an out-of-the-blue, out-of-context, agree or disagree. I would have to see where that's coming from.

Q. Okay. So if someone got abortion pill reversal, went to the hospital with a hemorrhage, and didn't call her doctor, there would be no way for her reversal doctor to know that she'd had a hemorrhage; right?

A. Abortion pill reversal isn't one stop. When a doctor takes care of a patient for abortion pill reversal, they follow them through the pregnancy. It's prenatal care.

So that doctor is intimately involved in the life of that patient. Unlike abortion, where it's an one-stop shop. She never sees the doctor beforehand. She never sees the doctor after. She may not even see the doctor until she's in the stirrups.

Unlike that, abortion pill reversal doctors actually take care of their patients.

Q. Okay. Would you be surprised to learn that Dr. Boles has given reversal to patients he's never met.

A. I'm sorry. Say again.

Q. Would you be surprised to learn that Dr. Boles has given reversal treatments to patients he's never met.

MR. RIEGER: Object to the form.

Go ahead and answer.

A. That is a difficult question to answer because if he is giving reversal through midwives who are under his supervision, then he is

taking clinical responsibility for that patient.

I mean, I did have midwives work under me who took care of patients through prenatal care, who delivered their baby, who I did admit; and yet I was ultimately responsible for the care of that patient.

So I would have to understand the context in which he's working.

BY MS. CLARKE:

Q. Would you be surprised to learn that there are any doctors in the abortion pill reversal network who have provided reversal treatments to patients that neither they nor anyone on their staff has ever met?

A. I don't know. I'd have to see the clinical scenario. Because when you provide abortion pill reversal care, you're providing a kind of prenatal care. And, ultimately, you, as a physician are responsible for that care.

Q. So do you recall in the Delgado 2018 studies that about 15 percent of patients were lost to follow-up?

A. For the number, I would have to see the study, but there were patients lost to follow-up.

Q. So for the patients who were lost to follow-up, we would have no way to know whether those patients experienced adverse events; right?

A. That's correct.

Q. So you mentioned that a patient who is hemorrhaging, before she goes to the emergency room, would probably call her reversal provider first and say, Here's what's going on; right?

A. Well, she would call her OB/GYN doc. She's pregnant. She's hemorrhaging. She's going to call the OB/GYN doc who is taking care of her.

Q. Well, so let's say she got reversal treatment this morning, hasn't been to any other OB/GYN yet. If she were hemorrhaging that night, do you think that she would call the reversal provider?

MR. RIEGER: Object to the form.

Go ahead and answer.

A. I don't know. It would depend, I think, a little bit on whether she has another doctor that she would call. If she has an OB/GYN already, I would hope that she would call her OB/GYN doctor or her family medicine doctor. But

I don't know.

BY MS. CLARKE:

Q. So if she called another OB/GYN, there's no way that her reversal provider would know that she had a hemorrhage; right?

A. Unless there was communication.

Q. Do you know when patients receive treatment from doctors referred through the abortion pill reversal network, do you know whether those patients sign a legal waiver before they get treatment?

A. I don't know.

Q. Would it makes sense to you -- strike that.

Would it surprise you to learn that all those patients signed a waiver that claims to waive any legal claims of any kind that they, their baby, or any surviving family members might have?

MR. RIEGER: Object to the form.

Go ahead and answer.

A. I don't know.

BY MS. CLARKE:

Q. Would that cause any concern for you if you learned that that was the case?

A. I would have to see the form and see exactly how it's expressed and how it's used.

Q. So let's say, for purposes of this question, that the form says that they waive any legal claims of any kind that they, their baby, or surviving relatives may have against Heartbeat International or the abortion pill reversal network. Would that give you any cause for concern?

A. That is going to depend on the consent for abortion pill reversal. So I would hope that the consent was adequate and -- yeah.

Q. So it wouldn't raise any red flags for you, that kind of waiver for a doctor?

A. I can't speak for all doctors, and I'm not a legal expert. So it's not my area of expertise. So I don't have any comment on that.

Q. So you had mentioned previously a Mitch Creinin study; right?

A. Yes.

Q. So I'm going to refer you actually back to the AAPLOG Practice Bulletin 6, which is Exhibit 18, Tab CC.

A. Okay.

Q. On page 5 --

A. I'm getting there.

Q. Okay.

A. Page 5.

Q. At the top left --

A. Yes.

Q. -- it reads in bold and underlined, It was due to the severe hemorrhage in the mifepristone alone group, not the progesterone group, that the study was halted.

A. That's correct.

Q. Is that an accurate characterization of why the Mitch Creinin study was halted?

A. It was halted for safety. It was halted for safety regarding hemorrhage.

The patient in the progesterone arm bled for three hours. But by the time she got to the ER, the abortion was complete, and there was no treatment. So that was not a safety treatment.

The safety issue was the two that required a D & Cs to stop and the woman that required the transfusion. Those were in the placebo, not the progesterone arm.

Q. So does that -- was the study stopped by researchers exclusively because of hemorrhaging suffered by people not in the progesterone group?

A. They said they stopped the study for safety. The safety concern was hemorrhage. The hemorrhage that needed treatment was all in the placebo and not the progesterone arm.

Q. So the patient who bled for three hours and went to the hospital after taking progesterone, was she admitted to the hospital when she got there?

A. I don't think so. They said no treatment. She had stopped hemorrhaging.

Q. So that would be considered an adverse event?

A. Of course.

Q. Would that be reason to stop the study if that had been the extent of hemorrhage suffered by all three hemorrhage patients?

A. No.

Q. And why not?

A. Because that was so limited, and there was no treatment required.

Q. So if, let's say, one in five

people who took mifepristone and did not take misoprostol suffered that level of hemorrhage, would you consider it safe to take mifepristone and not misoprostol?

A. I've already commented on the use of the term "safe." Safe is a relative term. I don't consider mifepristone ever safe, either for the woman or for her unborn child who is killed. So I will not say that mifepristone is ever safe.

Q. Would you say that it's -- well, if there was a one-in-five chance that a given treatment caused that kind of hemorrhage, would you say that that treatment was dangerous?

A. But the treatment didn't cause the hemorrhage. The hemorrhage was caused because the mifepristone in that patient caused the fetal demise, which then resulted in expulsion. The hemorrhage was from the expulsion.

So the other four out of five patients had living pregnancies at 20 weeks -- excuse me, at two weeks, which is an 80 percent success rate for APRN.

Q. Is it your opinion that one in five people who take mifepristone and misoprostol in early pregnancy will have that level of

hemorrhaging?

A. In his study, 40 percent of the mifepristone alone group had severe hemorrhage that required D & C to stop the hemorrhage and one required a transfusion. That's mifepristone alone.

Q. So my question was, is it your opinion that one in five people who take mifepristone and misoprostol will have the kind of hemorrhage experienced by the one patient in the progesterone group?

A. I'm sorry. But that doesn't make sense, because the women who took mifepristone had severe hemorrhage requiring a D & C.

The one that took mifepristone plus progesterone did not have a severe hemorrhage. She hemorrhaged while she was expelling, and then that bleeding stopped. She received no further products of conception, and she received no treatment.

Q. Okay. So I --

A. Maybe I'm missing your question. Sorry.

Q. My question is actually if you take mifepristone and misoprostol. So none of the

patients in the Creinin study took misoprostol; right?

A. Correct.

Q. For all the hundreds of thousands of people who have taken mifepristone followed by misoprostol, is the rate of hemorrhage one in five?

A. The rate -- well, it depends on which study you look at. The best study is Niinimáki, 2009, out of Finland, because they used hospital records. It's a registry- based study. In that study, one out of five patients ended up having some kind of a complication.

So whether the number is one out of five or one out of six, you've got the best studies which are registry-based. That was 42,000 abortion patients, half of which were surgical, half of which were medical. The medical abortion patients had five times the rate of complications that the surgical patients had.

And my recall of the study is that one out of five had hemorrhage. I would have to go back and look at the study to confirm the numbers. But, yes, that was mifepristone and misoprostol. It was vaginal use of misoprostol.

Q. Was that 200 milligrams of mifepristone?

A. Correct. You won't find that in the study. If you go look back at that study, you have to go back to her actual Ph.D. thesis to find out what the patients used. So that's a different paper. But the Ph.D. thesis is what she based her paper on.

Q. Do you know her name?

A. Maarit, M-a-a-r-i-t, Niinimaki, N-i-i-m-a-k-i, I think.

Q. So based on that study plus your expertise and your general knowledge, would you expect that 20 percent of all the people who've taken medication abortions since 2000 have hemorrhaged?

A. It would be nice to know, wouldn't it?

Q. So you're not --

A. There's no systematic tracking of complications after mifepristone. There's none.

Q. And there's no way to look at, you know, NIH data or other health care data to see whether there has been a dramatic rise in miscarriage-related hemorrhaging at hospitals

since medication abortion was approved by the FDA?

A. I would love to have my hands on that data.

Q. So we don't know?

A. We don't know, because nobody tracks complications after Mifeprex. It's not systematically tracked. It's only voluntary.

Q. And that's not tracked because the patient may not tell their doctor when they go to the emergency room and have the hemorrhage?

A. I don't know why it's not tracked. I mean, there's a thousand reasons why it's not tracked.

Q. And the fact that we don't track it means we don't know how safe it is; right?

A. The fact that we don't track it means I can't give you a number, because I can't give you a number without data.

Q. Without the data, you can't make a determination of how safe you think it is?

A. When you say "it," what do you mean?

Q. Taking Mifeprex and misoprostol in early pregnancy.

A. I don't think taking Mifeprex and

misoprostol is safe for the woman at all. I don't think taking Mifeprex and misoprostol is safe for the unborn child, who is killed.

If you compare studies looking at complication rates after Mifeprex and misoprostol, comparing those complication rates after surgical abortion, of which Niinimaki is probably the best because it's registry-based, you get a four-fold increase in complication rate after Mifeprex abortion as compared to surgical abortion. That's what I can tell you.

Q. Okay. So going back to your declaration, you note that there is -- that the Delgado 2018 study -- this is page 10, paragraph 28.

A. 28?

Q. Yes. So you say that the Delgado study found no increase of birth defects when compared to the general population of births, which is consistent with other studies which have found no increase in malformation rate over the general population in infants who are born after exposure to mifepristone in utero. Is that right?

A. Yes.

Q. Did I mention mifepristone?

A. Yes.

Q. So in that footnote 16, you cite Bernard et al; right?

A. Yes.

Q. Does that study show no difference in rates of major malformation after exposure to mifepristone in utero?

A. Can you pull the study?

Q. I can.

A. I'd like to see the study.

MS. CLARKE: Sara, could you draw up Tab W into the chat? And we will mark this as Plaintiff's 22, please.

(Exhibit 22, Bernard Study, was marked.)

A. Yes.

BY MS. CLARKE:

Q. Do you recognize this document?

A. I do.

Q. What is it?

A. This is the Bernard study.

Q. Okay. So on the first page of that study in their little summary of the study, under "conclusions," it says, The first prospective study found that the rate of major

malformations after first trimester exposure to mifepristone is only slightly higher than the expected 2 to 3 percent rate in the general population.

Does that sound right?

A. That's correct.

Q. So it is, in fact, higher but only slightly higher; is that right?

A. It's slightly higher. If you look at the next sentence, it says, Such findings provide reassuring data for risk evaluation for continuation of pregnancy after mifepristone exposure.

So the authors themselves interpret that number. And if you look at the confidence intervals, which are very wide, it shows you that this is not a significant -- statistically significant increase in major malformation.

Q. So is it still accurate to say that this is a study that found no increase in malformation rate over the general population of infants who were born after exposure to mifepristone in utero?

A. There's no statistically

significant increased rate.

Q. You also cite at the end of that same sentence to Sitruk-Ware; is that right?

A. Okay. Yes. I would need to see that study.

MS. CLARKE: Okay. Let's pop that study into the chat. That's Tab X, and we will mark that as plaintiff's Exhibit 23, please.

(Exhibit 23, Sitruk-Ware Correspondence, was marked.)

A. Yes.

BY MS. CLARKE:

Q. What is this document?

A. This is the Sitruk-Ware correspondence.

Q. Okay. So in the very middle of the document, middle column, it reads, There were no reported cases of malformation associated with the use of misoprostol when used with mifepristone.

Is it your understanding that misoprostol is actually teratogenic?

A. Yes.

Q. So it didn't show up in this

study, but it actually does cause birth defects; correct?

A. Yes.

Q. So in paragraph 30 of your declaration -- we're jumping around here -- you write, in essence, that complaints about the possibility of teratogenicity reversal is misplaced because those criticisms concern synthetic progestins rather than progesterone.

Is that accurate? Is that an accurate summary of what you wrote?

A. Yes.

Q. Do you know whether all abortion reversal providers use natural progesterone rather than synthetic progestin?

A. There would be no reason to use synthetic progestins. As I understand the abortion pill reversal protocol, the drug used is natural progesterone. You wouldn't use a progestin.

It's the same kind of protocol that you use for the IVF industry. The IVF industry doesn't use -- they use natural progesterone.

Q. But there is no way to know

whether any given doctor associated with the abortion pill reversal network prescribed synthetic progestins rather than natural progesterone?

A. My understanding of the protocols used by the abortion pill reversal network all involve natural progesterone.

Q. We don't know if the abortion pill reversal network conducts audits of their physicians to determine whether they're following protocols?

A. I don't know.

Q. Earlier, you had mentioned the term "statistical significance." What does that mean?

A. That means the chances that your results may be -- that you may have gotten these results just by happenstance and that they may not reflect the truth.

So at any time you do scientific studies, your results come on a bell curve. And if you're within the 95 percent confidence interval, this means that you are 95 percent confident that your results are actually erecting reality.

That's kind of one way to put it.

Q. Okay. Do you know how statistical significance was calculated?

A. By confidence interval. You look at the confidence interval.

Q. How do you obtain a confidence interval?

A. It's a statistical -- it's a statistical answer depending on how many patients you have. So if you have a small number of patients and you've got a conclusion, then that is not as statistically significant as a very, very large number of patients. So the larger your number of patients, the smaller your confidence intervals, the more likely that your results are statistically significant -- more likely that your results reflect reality.

Q. So a confidence interval, is that the same as a P value?

A. I'm sorry. The same as a PI?

Q. A P value. You had mentioned P value earlier.

A. There is a relationship, but I'm going to have to go back to the statistics. I'm not going to do that on a tired brain. I can't.

I have to go back and pull up relationships between PI and confidence intervals. My brain is not going to do that right now.

Q. So when you said confidence interval a couple of minutes ago, you did not mean -- I'm sorry. When you said P value a few minutes ago, did you mean confidence interval or did you mean P value?

A. I think the study -- let me go back and look at it.

The confidence interval, 1.2 to 10.4 percent. So that's in the results of the Bernard study. Confidence interval, 1.2 to 10.4.

Q. Okay. That makes more sense.

A. If I said P value, it was a mistake.

Q. Okay. No problem.

So I am nearing the end of this, I promise. Can we take a break and go off the record? Is that okay?

A. It's fine with me.

VIDEOGRAPHER: Off the record at 2:54.

(A break was taken.)

VIDEOGRAPHER: We are back on the

record at 3:03.

BY MS. CLARKE:

Q. Okay. Dr. Harrison, did you find the peer reviewers for Delgado's 2018 paper published in Issues in Law and Medicine?

A. I was probably the one that contacted them, because it is a scientific paper.

Q. And you're aware that that article was published and then taken down and then put back up; is that right?

A. Yes. I'm aware of that.

Q. Why was it taken down?

A. The authors requested that it be removed.

Q. Do you know why?

A. Because they were changing some of the wording of the paper.

Q. And that wording referred to internal review board approval; is that right?

A. That's correct.

Q. Sorry. Insufficient review board approval?

A. Yes. IRB approval, yes.

Q. Do you know what they wanted to change about the wording concerning IRB approval?

A. I would have to compare the wording between the one before and the one after. I would have to go back and look.

Q. Okay. So if I told you that the original paper said that it had received an IRB waiver from San Diego and that the revised paper did not say that, does that sound right to you?

MR. RIEGER: Object to form.

Go ahead and answer.

A. Yes.

Did you object to form? Because that didn't come through.

MR. RIEGER: I did object to form, and then I instructed you to answer. I'm sorry.

BY MS. CLARKE:

Q. In your declaration, you note that complaints about IRB approval for the 2018 paper are, quote, "spurious"; right?

A. That's correct.

Q. And you say that because the final paper says clearly the study was reviewed and approved by an institutional review board right?

A. That's correct.

Q. Do you know which institutional review board approved the final study?

A. No, not right off the top of my head. I wouldn't be able -- I don't even know if I would be able to find out. You would have to ask the authors.

Q. Did you edit this article at all before it was published?

A. Not that I know of.

Q. Did you see any of the peer review reports that the peer reviewers wrote about it?

A. I may have because, even though I instruct them to respond to Barry Bostrom, sometimes they reply to me; in which case, I just forward it to Barry. So I may have seen them, but I don't think I read any of them in detail.

Q. Was the article peer reviewed again after that statement about IRB approval was changed?

A. Not that I know of. Now, that is not to say -- I don't know what Barry did. He may have sent it back, but I don't know.

Q. Would you -- does it strike you as unusual for a paper to say that it was IRB

approved without saying what institutions IRB approved it?

A. My understanding is that IRB approval is confidential.

Q. So --

A. I think in most papers, I think IRB approval is confidential.

Q. All right. So you think that most papers would not tell you what institution gave that study IRB approval?

A. I wouldn't say that. I would say that my understanding is that IRB approval is confidential.

Q. Do you have any understanding as to whether most scientific papers that obtain IRB review will state in their paper what institution gave them IRB approval?

A. There are lots of papers that do say what institution gave them IRB approval.

Q. So it doesn't strike you as unusual for a paper not to?

A. No.

Q. In your declaration, I believe that you say that the double standard to require a placebo control group in medication abortion

reversal studies but not in studies determining the efficacy of medication abortion itself. Is that a accurate?

A. Is that a quote?

Q. The double standard part is a quote.

A. What is the exact quote? That doesn't sound like my wording. That's why I'm asking.

Q. Okay. So let's see if I can find it. In paragraph 37 of your declaration -- well, strike that.

Do you think that a placebo controlled study is necessary to show that medication abortion is effective at terminating an early pregnancy?

A. I don't think you can ethically do a placebo controlled study for abortion -- excuse me. It's getting late -- for abortion pill reversal for use of progesterone because the population group that you're looking at is women who want to save their baby.

We have very little to offer them. But one thing that we can offer them is progesterone. So you can do what's been done in

the abortion industry, which is to do a dose comparator. That can ethically be done, and that can ethically be randomized.

But to say to this woman who wants a chance to save her baby, which is a -- it's a binary yes/no, you know, baby lives/baby dies. To say to that woman, We're going to give you a placebo and see what happens in two weeks, that's not ethical, especially if you're dealing with a human life and interventions to try to save that human life, that pre-born child. It's not ethical to do a placebo control.

Q. So it's your opinion that the Creinin study was unethical, not for that reason but because it requires women who choose abortion to delay their abortion; is that accurate?

A. That's correct. Because, as is commonly known, the further along in gestation, the higher your risk of complications. So in those women who he gave placebo to instead of the progesterone -- so he's giving progesterone and then placebo -- the placebo group continued further and further in their pregnancy. And if he wanted to abort them, he should have just aborted them.

You know, you can't -- this is a life and death thing. So the ones you give progesterone to that had continuing pregnancies, well, you've got four women who are now two weeks further along than they would have been had he simply aborted them at the beginning. So two weeks does increase the risk of the complications.

So I do not think that was an ethical study, no. I understand it had IRB approval. I don't think it was ethical.

Q. So because the risks and complications increase with gestational age, do you think it's unethical to delay abortions for people who are seeking abortions?

A. I think that -- okay. I know where you're going with that.

I don't think it's ethical to do a study that uses a placebo in a trial where the use of the placebo results in increasing complications.

Q. Okay. So for all placebo controlled studies, some people get a treatment and some people get a placebo; right?

A. Correct.

Q. The people who get the placebo

are not getting the treatment that may or may not cure whatever they might have; right?

A. That's correct.

Q. Is it ethical to conduct those studies?

A. It depends on what the treatment is and what the consequences are of not getting that treatment. It completely depends.

Q. So in this instance, would we have known before the study started that, in your words, the placebo caused an increased rate of complications for the patients in that Creinin study? Did we know that in advance of the study?

A. No.

Q. So was it unethical at the time the study was designed?

A. Let me think about the answer to that. Was it unethical in its design?

If one looks at -- I'm going to say I'm going to have to think about that.

Q. Okay.

A. I can't answer categorically yes or no at this time.

Q. Okay. So in determining the efficacy of medication abortion, mifepristone and

misoprostol, is it fair to say that we can determine its efficacy based on a robust historical control group? Is that fair to say?

A. I'm sorry. Ask the question again, because I'm trying to figure out -- I'm trying to figure out exactly what you're saying.

Q. So when determining how effective the two-drug medication abortion regimen is at terminating early pregnancy, is it fair to say that we can determine its efficacy by comparing it to a robust historical control group rather than a placebo?

A. Can you specify which study you're talking about?

Q. I'm not talking about a particular study. So if we're just trying to figure out does medication abortion work at terminating early pregnancies, can we figure that out by looking at a historical control group?

A. Yes. You can get some estimate of efficacy.

Q. Efficacy. What would the historical control group be in that instance?

A. It would be those who don't take mifepristone and misoprostol.

Q. That would be the many, many women over the course of time who have been pregnant and carried their pregnancies and never taken mifepristone or misoprostol; right?

A. Right.

Q. And we have a pretty good sense of how often women experience spontaneous abortion in the first ten weeks of pregnancy. Is that fair to say?

A. I wouldn't say we have a great idea of that, because that's actually a very under-studied subject, what is the actual spontaneous miscarriage rate. But we have some feeling for it, yes, we do.

Q. What is a retrospective series based on chart review? What does that mean?

A. That means that the investigators had charts of women who have already been treated where they looked back through those charts to do their study. That's a retrospective chart review.

Q. So when you say "their charts," what do you mean by their charts?

A. Their records, their record of treatment.

Q. So is it your understanding that

for the 2018 study, Delgado looked at these patients' charts?

A. He looked at their records of treatment. That's my understanding, that the authors did that, yes.

Q. If a patient received an ultrasound as part of -- during the course of their reversal treatment, would that show up in their chart?

A. It should show up in their record.

Q. And so if in the 2018 study Delgado noted that he doesn't know how many patients in the study received ultrasound, would that indicate that he didn't look at their charts?

MR. RIEGER: Object to the form.

Go ahead and answer.

A. No, not necessarily.

BY MS. CLARKE:

Q. It could mean that the person -- that he doesn't know whether people were consistently documenting ultrasounds in the chart? Is that what it means?

MR. RIEGER: Object to the form.

Go ahead and answer.

A. It's possible. That's one possible explanation.

BY MS. CLARKE:

Q. What are some other possible explanations?

A. That they did an ultrasound and didn't record --

MR. RIEGER: Object to the form. Go ahead and answer.

A. That they did an ultrasound and didn't record the gestational age.

BY MS. CLARKE:

Q. If the Delgado 2018 paper said that they didn't know how many patients had received ultrasounds to confirm pregnancy or not, would that indicate that he didn't look at the patients' charts?

MR. RIEGER: Object to the form. You can answer.

A. Not necessarily.

BY MS. CLARKE:

Q. What else could that mean?

A. It could mean that the treating physician didn't document. So when you're gathering data, you can only deal with the data

that's been documented.

Q. Would you expect any physician who does an ultrasound on a patient to document that ultrasound in the patient's charts?

A. That would be the usual practice.

Q. Would it be usual practice to document the number of progesterone injections given to a patient?

A. Yes.

Q. And if for some patients in the 2018 study, Delgado noted that he did not know how many progesterone injections they got, would that indicate he didn't look at their charts?

MR. RIEGER: Object to the form.

Go ahead and answer.

A. Not necessarily.

BY MS. CLARKE:

Q. When you say "retrospective analysis," if someone decides to study something, gets consent from patients to be studied, and then looks at their charts, is that a retrospective analysis?

A. I'm sorry. I'm trying to understand what you're asking.

So if a person has -- ask the

question again just so I'm clear as to what question you're asking.

Q. If someone wants to study something and they obtain patients' informed consent to be studied and then they look through their charts as they were allowed to do by the patient and compile that data, is that a retrospective analysis?

A. If you have a study that looks at records that have already been obtained, that have already been generated, when you look back at those records, that's a retrospective analysis.

Q. If you decide to do the study before those patients have been treated, obtain their consent to have their data sent to you, and then look at their charts, is that a retrospective analysis?

A. Whether it's retrospective or prospective depends on whether you have designed it with a certain protocol in mind.

So a prospective study is one that you say on Day X, I have given this patient this drug, and then I'm going to follow her results for a particular period of time.

But that's not what the Delgado

study was. The Delgado study was looking at patients who had already been treated and seeing what their outcomes were.

Q. Okay. So the fact that --

A. He was not the treating physician.

Q. He was not the treating physician for any of the patients in this study?

A. Well, I shouldn't say any. He wasn't the treating physician for all the patients in the study.

Q. So for the patients in the study for whom he was the treating physician, if he had determined that he wanted to do a study, obtained informed consent from those patients, and then treated them, and then looked at their chart, would that still constitute a retrospective analysis?

A. I don't think that's what happened.

Q. If it were --

A. It's a hypothetical.

Q. Hypothetically, if that were what happened, would that constitute a retrospective analysis?

A. He didn't have a particular intervention and then -- from a particular date and then follow them prospectively. He did not follow them prospectively.

The information he got was for information of patients who were already treated. That makes it a retrospective study.

Q. Okay. Let's say hypothetically that he decided he wanted to conduct the study, treated some patients, followed them, got their consent to study their data, and then studied it, would that still be a retrospective analysis?

A. Retrospective analysis is when you institute a treatment and then you follow the patient for the results of that treatment.

A retrospective analysis is when a patient has already been treated, and you look at the chart, and you say, Oh, this is what happened with these patients.

So his -- as best I understand, his study was a retrospective chart review.

Q. So if instead he had studied patients to whom he gave treatment and followed up with them and then reported their results, that would be a prospective study; right?

MR. RIEGER: Object to the form.

Go ahead and answer.

A. But that's not what his study did.

BY MS. CLARKE:

Q. But if it were, that would be a prospective study?

A. So a prospective studied is where you institute a treatment and then you follow patients after that treatment for the results.

But that's not what the study was. These are women who sought abortion pill reversal as almost a compassionate use. Because it was the only thing that the doctors in the network had to offer these patients who regretted taking mifepristone and wanted to do anything that they could to try to increase the chances that their baby would survive what they considered to be a mistake.

So whether or not they were being studied was irrelevant, not related to their use of mifepristone -- oh, boy -- their use of progesterone. Their use of progesterone -- they were going to use progesterone to try to save their baby regardless of whether they were studied

or not. It was not a part of the study protocol.

However, having used the progesterone, Dr. Delgado, is my understanding, said, We have information about patients who have used this treatment, regardless -- not within a study, but because they themselves wanted whatever possible help they could to save their baby.

So why not look at that data, which I think is a very reasonable thing to do. You have information about patients who have received this treatment. Let's look at it. That's not a prospective study. So . . .

Q. If that were the case, that somebody were only collecting data on treatments that had already happened, would that mean that those patients had not signed an informed consent to participate in a study if that study hadn't happened yet?

A. The study hadn't happened yet.

Q. If those patients had signed an informed consent to participate in that study, would that change your opinion as to whether it was a prospective study?

A. Depends on what the consent is. If the consent is the release of records for

educational purposes, which, frankly, anybody that signs into a teaching hospital signs to release their records for educational purposes -- if it was that kind of a consent, then that's not a research study.

So I signed a consent when I had a C-section that my records could be released for study. Okay? I wasn't part of a study. That wasn't a study. But could people go back and look a my chart? Absolutely, because I signed a consent to release my information for educational purposes or for research purposes, whatever purposes the hospital wanted to use my information for.

So the fact that a consent is signed to release information does not in and of itself make something a research study.

Q. Okay. That makes sense. So, then, if we're looking at a retrospective study, we would expect that the patients in the study would not have signed a consent to participate in an experimental research protocol or study; right? Because the study hadn't happened yet?

MR. RIEGER: Object to the form.

Go ahead and answer.

A. I guess, yes.

MS. CLARKE: Okay. Sara, can you pull up Tab R? And we'll mark this as plaintiff's 24, please.

(Exhibit 24, Practice Bulletin 8, was marked.)

BY MS. CLARKE:

Q. Let me know when you're --

A. I'm sorry. Which tab is this?

Q. Tab R.

A. Tab R. Okay. Almost. No, that doesn't look right.

Q. It's titled ACOG -- but that's me reading it wrong. When you open it, do you see AAPLOG Practice Bulletin 8?

A. Yes. I was going to say that's not ACOG.

Q. Take a look at this document and let me know if you recognize it.

A. Yes, I do.

Q. What is this document?

A. This is Practice Bulletin 8, medical management of elective induced abortion.

Q. Did you write this document?

A. No.

Q. Did you edit this document?

A. I think that is different than the other document. Hold on just a second.

Is this different than the other document that you gave me?

Q. It is different.

A. Yeah. If I -- I probably did edit it, but this was probably one I didn't edit much.

Q. If I tell you that it was published in February 2020, would that refresh your recollection as to whether you edited this document?

A. Yeah. I probably didn't edit it much.

Q. Have you seen it before?

A. Yes, I have seen it before.

Q. What's the purpose of this document?

A. The purpose of this document, as in all practice bulletins, is to give the practicing pro-life OB/GYN information about to what is in the medical literature about particular topics that affect their practice.

Q. So this is not a practice

bulletin that would tell physicians how to provide medication abortion; right?

A. No. This is not -- that's not the purpose of this document.

Q. And it's not a document that tells practicing physicians how to manage complications of medication abortion; is that right?

A. I don't think they mention management of complications in this document.

Q. So I would like to direct your attention to page 8, the first document, please.

A. Okay. Yes.

Q. So on the left, it says, Summary of recommendations and conclusions: The following recommendations are based on good and consistent scientific evidence, Level A.

Did I read that right?

A. Yes, you did.

Q. What does that mean, Level A?

A. Well, if you -- what that means is that there are studies which are good, like randomized control trials or systematic reviews of good literature, which mean that we have a lot of confidence that what's being said here is

supported by the medical literature.

Q. At the bottom of that first paragraph, it reads, Local abortion advocates are aggressively using the court system and pro-choice media sources to advocate for removal of safety restrictions on medical abortions.

Is that a statement that's based on good and consistent scientific evidence?

A. Yes, it is.

Q. What is the --

A. If you look at what's in the literature, if you look at what's being published in medical journals, you will find that that is consistent with what we're seeing.

Q. So there have been scientific studies concerning the degree to which abortion advocates use the court system to advocate removal of safety restrictions?

A. You say is there a randomized control trial? No, it's not a randomized control trial. But it doesn't take much look at the medical literature. You don't have to look very far in the medical literature to see that there is a very concerted effort toward no-touch abortion and -- yeah. So you're seeing a lot of trials

that way.

Q. So on the next page on the right, you'll see it says, The following recommendations are based on good and consistent scientific evidence, Level B. What does that mean?

A. That means that you don't have -- you don't have as strong scientific evidence. You don't have a lot of publications, but you have some publications that are consistent with what you're seeing.

Q. Okay. So here it says, Biased studies performed by those who profit from abortion provisions seek to downplay the common nature of complications.

Is that supported by good and consistent scientific evidence?

A. I can show you a lot of studies, yes, that are produced by the abortion industry that downplay the risks of complications from abortion, from medical abortion.

Q. But the good and consistent scientific evidence doesn't support this statement as not as strong as those that support the statements under Level A; is that right?

A. That's correct.

Q. Is it your opinion that studies performed by people who profit off the treatments and their studies are biased?

A. It's my opinion that that introduces a level of financial bias, yes.

Q. And that financial bias usually, you would hope, would be disclosed in the study; right?

A. You would hope. But it's not always.

Q. Do you know whether Dr. Delgado profits from the provision of abortion reversal treatment?

A. I don't know.

Q. Do you know if Mary Davenport profits from the provision of reversal treatment?

A. I don't know.

Q. Do you know whether Dr. Boles profits from the provision of reversal treatment?

A. I don't know.

Q. So at the very bottom of page 8, under Level A, it reads, The abortion industry is aggressively working for complete over-the-counter access for Mifeprex.

Is that a statement supported by

good and consistent scientific evidence?

A. I can show you a lot of studies which are published in peer review journals where abortion advocates are advocating for complete over-the-counter access, for complete access without medical intervention.

Q. Okay. So when you say the "abortion industry," you mean abortion providers?

A. That is the abortion industry.

Q. When you talk about the studies concerning that, do you mean that those studies were written by abortion providers?

A. The vast majority of publications on abortion, medical abortion, are written by abortion providers.

Q. Do abortion providers have a financial incentive to work for over-the-counter access to Mifeprex?

A. Well, it turns out that Planned Parenthood was given the right to manufacture and distribute Mifeprex. And my understanding is that Planned Parenthood still holds that right, although they gave it to a company they created called Danco.

So is there a financial

provision? You would have to pierce the corporate veil to know if Planned Parenthood is still profiting from the sale of Mifeprex.

My understanding is they are still profiting from the sale of Mifeprex, but I don't have the legal background to pierce the corporate veil.

Q. I want to go -- I'm sorry. I'm jumping around a little bit, because it's late. I want to go back to the 2018 Delgado study briefly.

A. So which tab?

Q. Oh, I'm just talking about it generally.

MR. RIEGER: Christine, would now be a good time to take a ten-minute break real quick?

MS. CLARKE: Sure, absolutely.

VIDEOGRAPHER: Off the record at 3:38.

(A break was taken.)

VIDEOGRAPHER: We are back on the record at 3:47.

MS. CLARKE: I have no more questions.

MR. RIEGER: I hate to do that,

but I was expecting you to have a little bit more. Can we take a quick fiver?

MS. CLARKE: Absolutely.

VIDEOGRAPHER: Off the record at 3:48.

(A break was taken.)

VIDEOGRAPHER: We're back on the record at 3:55.

MR. RIEGER: Christine, for purposes of the transcript, we have no questions for Dr. Harrison. We are going to request that we read and sign the transcript.

COURT REPORTER: Would you mind putting your orders on the record, please?

MR. RIEGER: Certainly.

MS. CLARKE: Do you know when would it be possible to get a rough by Monday?

COURT REPORTER: It will be difficult. I will try. This is a new one for me, but I'm sure I can try.

MS. CLARKE: If you can't, that's fine. If you can, that would be great.

COURT REPORTER: Okay.

MS. CLARKE: Otherwise, you can send the transcript to me when you're done.

MR. RIEGER: And defendants would also like a rough and the final whenever it gets done.

COURT REPORTER: Okay. And are any of the other parties online, are they parties that need a copy, or no?

MS. CLARKE: I think they can get my copy, but you can just email the copy to me.

COURT REPORTER: Okay.

VIDEOGRAPHER: End of deposition. Off the record at 3:57.

(Deposition concluded 3:57 p.m.)

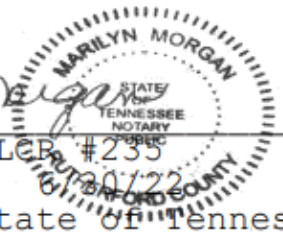
CERTIFICATE OF COURT REPORTER

I, Marilyn Morgan, Licensed Court Reporter and Notary Public for the State of Tennessee, do certify that the above deposition was reported by me and that the foregoing transcript is a true and accurate record to the best of my knowledge, skills, and ability.

I further certify that I am not an employee of counsel or any of the parties, nor a relative or employee of any attorney or counsel connected with the action, nor financially interested in the action.

I further certify that I am duly licensed by the Tennessee Board of Court Reporting as a Licensed Court Reporter as evidenced by the LCR number and expiration date following my name below.

Subscribed and sworn to before me when taken, this 13th day of November, 2020.



MARILYN MORGAN, LCR #235
Expiration Date: 6/30/22
Notary Public, State of Tennessee
Commission expires: 5/15/21

DEPOSITION ERRATA SHEET

DECLARATION UNDER PENALTY OF PERJURY

I declare under penalty of perjury that I have read the entire transcript of my Deposition taken in the captioned matter or the same has been read to me, and the same is true and accurate, save and except for changes and/or corrections, if any, as indicated by me on the DEPOSITION ERRATA SHEET hereof, with the understanding that I offer these changes as if still under oath.

Signed on the _____ day of _____, 2020.

_____

DONNA HARRISON, M.D.

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