

**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

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 resource³ 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

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.

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
Thomas H. Castelli (No. 24849)
Stella Yarbrough (No. 33637)
American Civil Liberties Union
Foundation of Tennessee
P.O. Box 120160
Nashville, TN 37212
Tel: (615) 320-7142
tcastelli@aclu-tn.org

Attorneys for Plaintiffs

Christine Clarke*
Jennifer Sandman*
Hana Bajramovic*
Planned Parenthood Federation of America
123 William St., 9th Floor
New York, NY 10038
Tel: (212) 261-4749
Tel: (212) 261-4405
Fax: (212) 247-6811
christine.clarke@ppfa.org
jennifer.sandman@ppfa.org

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

Andrew Beck*
Rebecca Chan*
American Civil Liberties Union Foundation
125 Broad Street, 18th Floor
New York, NY 10004
Tel: (212) 549-2633
abeck@aclu.org

*Attorneys for Plaintiffs Knoxville Center for
Reproductive Health and
FemHealth USA, Inc.*

Michelle Moriarty*
Shayna Medley-Warsoff*
Center for Reproductive Rights

199 Water St., 22nd Floor
New York, NY 10038
Tel: (917) 637-3695
mmoriarty@reprorights.org
smedley@reprorights.org

Marc Hearron*
Center for Reproductive Rights
1634 Eye St., N.W., Suite 600
Washington, DC 20006
Tel: (202) 524-5539
mhearron@reprorights.org

*Attorneys for Plaintiff Memphis Center for
Reproductive Health*

*Admitted *pro hac vice*

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.

Alexander S. Rieger
Charlotte Davis
Edwin A. Groves, Jr
Steven A. Hart
Office of the Attorney General and Reporter
P.O. Box 20207
Nashville, TN 37202
alex.rieger@ag.tn.gov
charlotte.davis@ag.tn.gov
alan.groves@ag.tn.gov
steve.hart@ag.tn.gov

/s/ Thomas H. Castelli
Thomas H. Castelli

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PLANNED PARENTHOOD OF
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Herbert H. SLATERY III, Attorney General
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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.

Case 3:20-cv-00740 Document 82-2 Filed 02/12/21 Page 2 of 5 PageID #: 2513

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](#)

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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,)

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.)

Case No.
3:20-CV-00740

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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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REMOTE APPEARANCES

On Behalf of the ACLU:
Mr. Andrew Beck
Ms. Rebecca Chan
Mr. Tom Castelli
Attorneys at Law
ACLU
125 Broad Street
New York, NY 10004
212-284-7318
abeck@aclu.org

On Behalf of the Defendants:

Ms. Charlotte Davis
Mr. Steven A. Hart
Mr. Alex Rieger
Mr. Alan Groves
Attorneys at Law
Tennessee Attorney General's Office
P.O. Box 20207
Nashville, TN 37202
615-741-2408
charlotte.davis@ag.tn.gov

On Behalf of Planned Parenthood Federation of
America:

Ms. Christine Clarke
Ms. Hana Bajramovic
Ms. Sara Shapiro

On Behalf of Center for Reproductive Rights:

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

Also Present:

Brian Primavera, Videographer

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1 also attending the deposition.
 2 We have Rebecca Chan,
 3 Christine Clarke, Hana Bajramovic, Mark Herron,
 4 Michelle Moriarty, Sara Shapiro, Shayna Medley,
 5 Stella Yarborough, and Tom Castelli. I think I
 6 have them all.
 7 Charlotte, do you want to --
 8 MS. DAVIS: Sure. For the
 9 defendants we have Charlotte Davis, Alex Rieger,
 10 Steve Hart, and Alan Groves.
 11 BY MR. BECK:
 12 Q. Wonderful. Doctor, would you
 13 please state your full name for the record?
 14 A. **George Delgado.**
 15 Q. Dr. Delgado, your testimony
 16 today -- well, you've been deposed before, I
 17 know, because I took your deposition five years
 18 ago. We'll -- we'll explore other opportunities
 19 you've had to be deposed. So I'm going to say
 20 some stuff that will probably sound familiar to
 21 you, but just laying out some ground rules,
 22 okay?
 23 A. **Okay.**
 24 Q. So your testimony is going to
 25 be taken down by the court reporter who's going

1 VIDEOGRAPHER: We are on the
 2 record. This is the videotaped deposition of
 3 Dr. George Delgado. Today's date is November
 4 17th, 2020. The time is 9:09 Central time.
 5 This is a case of Planned Parenthood of
 6 Tennessee and Mississippi, et al., v. Herbert H.
 7 Slatery, III, Attorney General of Tennessee, et
 8 al. Case No. is 3:20-CV-00740. It's pending in
 9 the United States District Court for the Middle
 10 District of Tennessee, Nashville Division. This
 11 deposition is being held remotely. All counsel
 12 will be reflected on the stenographic record.
 13 And will the court reporter please swear in the
 14 witness.
 15 GEORGE DELGADO, M.D.,
 16 having been first duly sworn, testified as
 17 follows:
 18 EXAMINATION
 19 BY MR. BECK:
 20 Q. Good morning, Dr. Delgado. My
 21 name is Andrew Beck. I am with the ACLU, and
 22 I'm representing the plaintiffs for purposes of
 23 this deposition.
 24 MR. BECK: I'm going to just
 25 run through the list of counsel for plaintiffs

1 to be recording everything we say. So
 2 especially in a Zoom deposition, we have to be
 3 particularly careful not to talk one -- over one
 4 another. So I'll try and let you finish your
 5 answers, and if you could try and let me finish
 6 my questions, that will make her work much
 7 easier, okay?
 8 A. **Okay.**
 9 Q. You'll need to give oral
 10 responses so that the court reporter can take
 11 them down. So you can't nod your head or shake
 12 your head or make hand gestures. Does that make
 13 sense?
 14 A. **Yes, it does.**
 15 Q. Great. Again, we are on Zoom
 16 today, so we have to adhere to those rules with
 17 particular care.
 18 What device are you using to
 19 access the deposition today?
 20 A. **A MacBook Air laptop computer.**
 21 Q. Great. And you haven't had
 22 any internet troubles lately? We expect that
 23 the -- the internet will sustain us over the
 24 course of the deposition?
 25 A. **I do. And if the wireless**

1 **fails, I have a backup of a possibility of an**
 2 **Ethernet cable with another computer. But I've**
 3 **not had any problems.**
 4 Q. Wonderful. And during the
 5 deposition we're going to be loading exhibits
 6 into the chat. I'm not sure if you've had a
 7 chance to talk about this with -- with your
 8 counsel, counsel for the attorney general's
 9 office.
 10 But are you able to download
 11 documents onto the computer that you're -- that
 12 you're on right now? None are there, I'm --
 13 **A. I presume I am --**
 14 Q. Great.
 15 **A. I presume I am able.**
 16 Q. Good. Well, we will cross
 17 that bridge when we come to it. You understand
 18 that while we are on the record you are not
 19 allowed to communicate electronically with
 20 anyone, that means by text, email, chat,
 21 anything along those lines?
 22 **A. I understand.**
 23 Q. Great. Your counsel may
 24 object at various points. If she does, please
 25 go ahead and answer the question that has been

1 objected to unless she instructs you not to
 2 answer. Do you understand?
 3 **A. I understand.**
 4 Q. And if I ask a question that
 5 you don't understand, just let me know and I'll
 6 try and ask a better version of the question.
 7 And if you do answer, I'm going to assume that
 8 you've understood the question. Is that okay?
 9 **A. That's correct. That's fine.**
 10 Q. Okay. Except when a question
 11 is pending, if at any other point you need to
 12 take a break, just let me know. We plan to take
 13 breaks over the course of the deposition,
 14 including the two half hour breaks for lunches
 15 on the various coasts. But -- but if you
 16 ever -- if you need to go take a break or
 17 stretch your legs, just let me know and I will
 18 be sure to accommodate that. The only request I
 19 make is that you not ask for a break while a
 20 question is pending, all right?
 21 **A. Very good.**
 22 Q. And you understand that you're
 23 under oath today?
 24 **A. I understand.**
 25 Q. And are you taking any

1 medications that would affect your ability to
 2 think and speak clearly today?
 3 **A. No.**
 4 Q. So you were deposed in a case
 5 concerning an Arizona law about medication
 6 abortion in 2015, correct?
 7 **A. Yes.**
 8 Q. And that case also concerned a
 9 law requiring abortion providers to make
 10 statements about medication abortion reversal;
 11 is that correct?
 12 **A. That's correct.**
 13 Q. And that case was called
 14 Planned Parenthood of Arizona versus Brnovich.
 15 Does that sound familiar to you?
 16 **A. Sounds familiar.**
 17 Q. And if I refer to that as the
 18 Arizona case during this deposition, can we
 19 agree that that refers to the Planned Parenthood
 20 of Arizona versus Brnovich matter?
 21 **A. Yes.**
 22 Q. Great. Now, when I deposed
 23 you in that case, you were under oath and --
 24 like you are today, correct?
 25 **A. Yes.**

1 Q. And you testified truthfully
 2 in that case?
 3 **A. Yes.**
 4 Q. So to speed our work along
 5 here, I'd like to show you some of your
 6 testimony from that case and make sure -- assess
 7 whether or not you still agree with it. Does
 8 that work?
 9 **A. Yes.**
 10 Q. Great.
 11 MR. BECK: So, Rebecca, if we
 12 could introduce into the chat Tab A.
 13 And I believe we're up to --
 14 this is for Stephanie, the court reporter.
 15 We're -- we're marking exhibits sequentially, so
 16 I think we're up to Exhibit 25.
 17 THE COURT REPORTER: Thank
 18 you.
 19 (Whereupon, the document was
 20 marked as Exhibit No. 25 to the testimony of the
 21 witness.)
 22 BY MR. BECK:
 23 Q. Do you see, Doctor, a PDF
 24 called A Delgado PP, et cetera, that appeared in
 25 the chat?

1 **A. Yes.**
 2 Q. Okay. Can you download that,
 3 please? Let me know when you have it open.
 4 **A. It's open.**
 5 Q. Great. There are some
 6 documents we're going to be referring to over
 7 the course of the deposition today. So we're
 8 not going to put them away and be done with them
 9 forever. So you may want to keep track of them
 10 in a way where you have easy access to them.
 11 So this is a document, which
 12 has been marked Exhibit 25, which is a
 13 deposition transcript from the Planned
 14 Parenthood v. Brnovich matter. Do you see on
 15 the top right quadrant where it says,
 16 "Deposition of George Delgado, MD"?
 17 **A. Yes.**
 18 Q. In the middle of the page at
 19 line 17. Apologies, I'm -- I'm cutting you off
 20 here.
 21 **A. Yes.**
 22 Q. Okay. Can you turn to page
 23 85, please? And that's 85 of the little numbers
 24 that appear -- there are sort of four pages per
 25 page here. So 85 is actually page 22 of the

1 PDF. Tell me when you're there.
 2 **A. I'm at page 85.**
 3 Q. Great. So do you see where
 4 the question was at line 7, "Have you ever
 5 served as a peer reviewer for any medical
 6 publication?"
 7 And the answer was "No."
 8 **A. I see that.**
 9 Q. And is that still true?
 10 **A. Yes.**
 11 Q. And you also testified that
 12 you have never served on an institutional review
 13 board to review medical research. Is that still
 14 true today?
 15 **A. Yes.**
 16 Q. And you also testified that
 17 you haven't wanted to serve in such a capacity.
 18 Is that also still correct?
 19 **A. Yes.**
 20 Q. Look at page 88, please, at
 21 line 14. You were asked, "Would you say you
 22 have expertise in designing studies for medical
 23 research?"
 24 And you answered "No."
 25 Is that still correct today?

1 **A. Not correct today.**
 2 Q. Was that testimony correct
 3 when you gave it under oath in 2015?
 4 **A. Yes.**
 5 Q. Okay. So five years ago you
 6 did not have expertise in designing studies for
 7 medical research, correct?
 8 MS. DAVIS: Objection. Hey,
 9 Andrew, can you -- can you point us to what line
 10 you're looking at on these pages?
 11 MR. BECK: Sure. That's line
 12 13.
 13 MS. DAVIS: Expertise in
 14 designing?
 15 MR. BECK: That's line 14.
 16 MS. DAVIS: On page 86?
 17 MR. BECK: 88.
 18 MS. DAVIS: Oh, okay.
 19 BY MR. BECK:
 20 Q. The transcript reads -- why
 21 don't you read question -- the question and
 22 answer starting at line 14, Dr. Delgado, for the
 23 record.
 24 **A. "Q, would you say you have**
 25 **expertise in designing studies for medical**

1 **research?"**
 2 **"A, no."**
 3 Q. Okay. So that testimony was
 4 truthful when you gave it five years ago,
 5 correct?
 6 **A. That's correct.**
 7 Q. And have you developed that
 8 expertise within the last five years?
 9 **A. Yes.**
 10 Q. Can you tell me everything
 11 that you've done over the last five years to
 12 become an expert in designing studies for
 13 medical research?
 14 **A. That's not what I've said.**
 15 Q. I apologize. You -- you said
 16 that you have become -- you -- you do have
 17 expertise in designing studies for medical
 18 research now, correct?
 19 **A. Correct.**
 20 Q. And you did not in 2015,
 21 correct?
 22 **A. Correct.**
 23 Q. And so can you tell me what
 24 has changed between 2015 and now such that you
 25 now have expertise in designing studies for

1 medical research?

2 **A. Since then I have been in**

3 **involved in designing research studies, have**

4 **gained experience in designing research studies,**

5 **and studied how to design research studies.**

6 Q. And can you identify the

7 research studies that you've designed in the

8 last five years?

9 **A. A 2018 large case series that**

10 **was published in "Issues in Law & Medicine," as**

11 **well as assisting Dr. Mary Davenport in a**

12 **literature review published in 2017, as well as**

13 **helping design a -- designing a study that has**

14 **not been yet conducted, as well as considering**

15 **planning other studies.**

16 Q. So I just want to make sure

17 that I have it down. The things that you've

18 done between 2015 and now are designing -- in

19 terms of honing your expertise in designing

20 medical research are the 2018 case series,

21 assisting Dr. Davenport with the literature

22 review, and designing studies that have not yet

23 been conducted, correct?

24 **A. That's correct.**

25 Q. And how many studies that have

1 not been conducted have you designed?

2 **A. I've played a role in**

3 **designing at least two.**

4 Q. What are those two studies?

5 **A. One is a study looking at the**

6 **use of CBD in Hospice patients. And the other**

7 **is an abortion pill reversal study.**

8 Q. Distinct from the literature

9 review and the 2018 case series?

10 **A. Can you repeat that question,**

11 **please.**

12 Q. Yes. Sorry. The abortion

13 pill reversal study is distinct from the 2018

14 case series and the 2017 literature review?

15 **A. That's correct.**

16 Q. Okay. So I count one, two --

17 two studies that you have conducted since 2015,

18 and three that you have designed -- I'm sorry,

19 two that you have designed, but not executed.

20 And that is what you would point to as

21 reflecting your -- the change between 2015 and

22 now in terms of your expertise in designing

23 medical research; is that correct?

24 **A. I would state it more clearly,**

25 **one that I have designed, one that I have helped**

1 **design, as well as researching how to design**

2 **studies.**

3 Q. What do you mean by

4 researching how to design studies?

5 **A. Well, in general, looking at**

6 **other studies critically and thinking how**

7 **principles applied to other studies might be**

8 **useful for future studies.**

9 Q. Okay. So in addition to

10 looking at that matter and designing -- and

11 conducting 2018 case series, assisting with the

12 literature review, and designing but not yet

13 conducting two studies, that's the -- I just

14 want to make sure I understand. That's the

15 universe of what you have done between 2015 and

16 now to -- to make yourself an expert in study

17 design; is that correct?

18 **A. That's not what I stated.**

19 Q. Can you tell me where I got it

20 wrong?

21 **A. Well, you're saying that I**

22 **made myself an expert. And I -- I would say, I**

23 **have developed expertise. I would not say I'm**

24 **an expert. There's a difference.**

25 Q. So if I -- if I just change

1 the phrasing of that original question to say

2 that you have expertise, but not that you're an

3 expert, would you agree with the way I framed

4 it?

5 **A. Yes.**

6 Q. Okay. What do you see the

7 difference between being an expert and having

8 expertise is?

9 **A. Expertise is having some**

10 **special knowledge of -- of a certain category,**

11 **while in -- I think in common parlance, being an**

12 **expert makes you at the head of those who have**

13 **some expertise.**

14 Q. So you would put yourself in

15 the category of those who have some expertise,

16 but not at the -- the leading expert in that

17 area; is that correct?

18 **A. That's correct.**

19 Q. Okay. And so you'd agree with

20 me that in performing medical research there can

21 be degrees of expertise?

22 **A. That's correct.**

23 Q. And so someone could be the

24 world leading expert on a particular type of

25 study design where someone else might have more

1 limited expertise, and so have expertise, but
 2 not be an expert or the expert; is that correct?
 3 **A. That's correct.**
 4 Q. Would you consider why your --
 5 so I think I heard you say that you wouldn't
 6 consider yourself one of the country's leading
 7 experts on designing studies for medical
 8 research. Is that fair?
 9 **A. Yes.**
 10 Q. Would you agree with me that
 11 your expertise on that subject is more limited?
 12 **A. Which subject?**
 13 Q. Designing studies for medical
 14 research?
 15 **A. Yes.**
 16 Q. And so on a scale of 1 to 10,
 17 with 10 being the country's leading expert on
 18 designing studies for medical research, where
 19 would you rank your expertise?
 20 **A. I think that would be a**
 21 **difficult estimation to make.**
 22 Q. Could you give a ballpark
 23 estimate? It's obviously just an estimation.
 24 **A. I think it would be a guess.**
 25 Q. That's fine.

1 **A. I don't think guesses are**
 2 **useful.**
 3 Q. No, it's okay. I actually am
 4 interested -- I just want to know where you
 5 would rank yourself on that scale?
 6 **A. Could you repeat the scale,**
 7 **please?**
 8 Q. Sure. On a scale of 1 to 10,
 9 with 10 being the country's leading expert on
 10 designing studies for medical research, where
 11 would you rank your own expertise?
 12 MS. DAVIS: Objection.
 13 THE WITNESS: And would the
 14 pool -- pool of people among who I -- amongst
 15 whom I was being ranked, would that -- who would
 16 that include?
 17 BY MR. BECK:
 18 Q. Anyone in the category of
 19 someone with expertise that you were talking
 20 about earlier.
 21 **A. Can you be more specific,**
 22 **please?**
 23 Q. Physicians with expertise. So
 24 physicians with some expertise in designing
 25 studies for medical research, we can talk about

1 that as the -- the pool. With that being the
 2 pool, and number 10 being the country's leading
 3 expert on designing studies for medical
 4 research, how would you rank your expertise?
 5 **A. Five.**
 6 Q. Can you turn to page 82 of the
 7 deposition transcript? Let me know when you're
 8 there.
 9 **A. I'm there.**
 10 Q. So at lines 6 to 17 you talk
 11 about how when you were a pre-med student in the
 12 1980s you helped work on studies performed on
 13 rats; is that correct?
 14 **A. That's correct.**
 15 Q. And then if you look at page
 16 84 and look at line 7, it says, Question, "And
 17 then between 1986 and 2012 you did not publish
 18 any studies in peer reviewed publications; is
 19 that correct?"
 20 Answer, "That's correct."
 21 That testimony was truthful
 22 when you gave it?
 23 **A. Yes.**
 24 Q. And you also did not submit
 25 any research to professional medical

1 publications during that period, correct?
 2 **A. That's correct.**
 3 Q. Okay. And you didn't conduct
 4 any medical research of any kind during that
 5 period, right?
 6 **A. I may have participate -- I**
 7 **did participate in some -- at least one clinical**
 8 **trial with a pharmaceutical company where I -- I**
 9 **did not publish any article and I was not cited**
 10 **as an author. I was a clinical cite.**
 11 Q. So at line 23 when it says,
 12 Question, "Did you conduct medical research of
 13 any kind during that period?"
 14 Answer, "No."
 15 Is that something that you're
 16 now remembering that you didn't know back then
 17 or does that not fall in the category of
 18 conducting medical research?
 19 **A. That would not fall in the**
 20 **category of conducting medical research.**
 21 Q. And then on the next page it
 22 says, Question, "Did you collect any data during
 23 that period with publication in mind?"
 24 Answer, "No."
 25 That was correct when you

1 testified to that as well, right?
 2 **A. I don't recall if I collected**
 3 **data during that project with the pharmaceutical**
 4 **company.**
 5 Q. Okay. But apart from the work
 6 on the -- with the pharmaceutical company, your
 7 testimony back in 2015 on this point was
 8 correct; is that right?
 9 **A. Correct.**
 10 Q. Would you turn to page 87?
 11 **A. I'm there.**
 12 Q. Actually, sorry, let's look at
 13 page 86 very quickly. At line 15, you describe
 14 a study on postpartum depression that you
 15 designed, but did not institute, right?
 16 **A. That's right. I forgot about**
 17 **that.**
 18 Q. And have you made any progress
 19 on that study since 2015?
 20 **A. No.**
 21 Q. And then since 2015, you've
 22 published a larger case series on medication
 23 abortion reversal, correct?
 24 **A. Correct.**
 25 Q. And the research on that was

1 Q. And that was published as your
 2 2018 case series?
 3 **A. That's correct.**
 4 Q. And then you assisted
 5 Dr. Davenport with the publication of a
 6 literature review also on that subject matter,
 7 correct?
 8 **A. That's correct.**
 9 Q. And have you conducted any
 10 other -- apart from what we talked about
 11 earlier, any other medical research since your
 12 2015 testimony that we haven't covered today?
 13 **A. No.**
 14 Q. Would you turn to page 89 of
 15 your deposition? Are you there?
 16 **A. Yes. Sorry.**
 17 Q. Great. At line 5 you were
 18 asked, Question, "Do you think you could teach a
 19 course on how to interpret and analyze data
 20 through a continuing medical education program?"
 21 And your answer was, "I could
 22 probably teach a course to nurses, but not to
 23 physicians."
 24 Did I read that correctly?
 25 **A. That's correct.**

1 underway in 2015, but you've yet to analyze or
 2 publish that data, right?
 3 **A. That's correct.**
 4 Q. Okay. So now turning to page
 5 87 at line 21. The questions and answers read
 6 as follows:
 7 Question, "So in addition to
 8 your postpartum research and the 2012 case
 9 series and the research that's presently
 10 underway, would you say there's any -- would you
 11 say anything else as demonstrating or
 12 contributing to your expertise as it relates to
 13 performing medical research?"
 14 Answer, "I wouldn't discount
 15 the exposure I had during college with
 16 various -- with the various researchers. So
 17 other than those, there's nothing else."
 18 Was that testimony truthful
 19 when you gave it in 2015?
 20 **A. That's correct.**
 21 Q. And then since then you've
 22 analyzed the data from the research on
 23 medication abortion reversal that was then
 24 underway, right?
 25 **A. That's correct.**

1 Q. Was that statement truthful
 2 when you testified to it in 2015?
 3 **A. Yes.**
 4 Q. Is it still correct today?
 5 **A. Yes.**
 6 Q. And then further down on page
 7 89 at line 10, the testimony went as follows:
 8 Question, "And so you've taken
 9 courses including CME. Is that an abbreviation
 10 you recognize?"
 11 Answer, "Yes."
 12 Question, "Courses related to
 13 CME and read journals or read articles, I think
 14 you said?"
 15 Answer, "Yes."
 16 "Is there anything else that
 17 you would cite or pinpoint as indicative of your
 18 expertise in the subject of analyzing data from
 19 studies?"
 20 Answer, "That, and I'm also
 21 including my expertise with APR research that we
 22 discussed already."
 23 Question, "Which is ongoing,
 24 which is the subject of this case?"
 25 Answer, "Right."

1 Question, "Anything in
 2 addition to that?"
 3 Answer, "No."
 4 Was that testimony I just read
 5 truthful when you gave it in 2015?
 6 **A. Yes.**
 7 Q. And since then you've
 8 published the additional APR or abortion pill
 9 reversal research that you referenced here as
 10 part of your 2018 case series, right?
 11 **A. Yes.**
 12 Q. And conducted the literature
 13 review with Dr. Davenport, correct?
 14 **A. Correct.**
 15 Q. And so apart from the fact
 16 that the APR research has since been published,
 17 as well as the publication with Dr. Davenport,
 18 adding those as cav- -- as sort of additions to
 19 that testimony, is that statement now accurate
 20 if we sort of supplement it with the 2018 and
 21 2017 publications?
 22 **A. To which statement do you**
 23 **refer?**
 24 Q. Sorry, the testimony that we
 25 were just looking at?

1 MS. DAVIS: Objection.
 2 THE WITNESS: I'm not sure
 3 which statement to which you were referring.
 4 BY MR. BECK:
 5 Q. So your expertise in analyzing
 6 data from studies stems from taking courses,
 7 including continuing medical education courses,
 8 reading journal articles, your work on abortion
 9 pill reversal, including the 2018 and 2017
 10 studies. Is there anything in addition to that?
 11 MS. DAVIS: Objection.
 12 BY MR. BECK:
 13 Q. I'm sorry, I didn't hear the
 14 answer.
 15 **A. Someone spoke right before.**
 16 **My answer is no.**
 17 Q. Thank you. Apart from the
 18 Arizona deposition, how many other times have
 19 you given testimony in a deposition?
 20 **A. I would estimate five to ten**
 21 **times.**
 22 Q. And were those five to ten
 23 times -- what was the most recent of those five
 24 to ten times?
 25 **A. Approximately two weeks ago.**

1 Q. And what was the case two
 2 weeks ago?
 3 **A. It was an employment case.**
 4 Q. Were you a party to the case?
 5 **A. No.**
 6 Q. Were you an expert in the
 7 case?
 8 **A. No.**
 9 Q. Were you a fact witness
 10 related to the case, but not a party?
 11 **A. Yes.**
 12 Q. Okay. Who -- who was -- who
 13 was the dispute between?
 14 **A. The dispute was between my**
 15 **employer and a former employee of the employer.**
 16 Q. And which employer and which
 17 former employee are you talking about?
 18 **A. The employer is the Elizabeth**
 19 **Hospice, and the former employee is Anne**
 20 **Marlotte (phonetic).**
 21 Q. So that one was two weeks ago.
 22 Let's work backwards. What was the next most
 23 recent deposition?
 24 **A. Let's see. I believe it may**
 25 **have been the Arizona case, but I'm not**

1 **positive.**
 2 Q. Have you, that you can recall,
 3 served as an expert witness in any deposition
 4 besides the Arizona case?
 5 **A. Yes.**
 6 Q. When was -- when -- sorry.
 7 What matter are you referring
 8 to there?
 9 **A. This was a malpractice case**
 10 **where I served as a -- as an expert witness for**
 11 **the defense.**
 12 Q. What was that case about?
 13 **A. I don't recall.**
 14 Q. Do you remember what your --
 15 what you were asked to be an expert in for
 16 purposes of that case?
 17 **A. I was asked to be an expert in**
 18 **the area of family medicine.**
 19 Q. And was that case before --
 20 I'm sorry.
 21 Was the deposition in that
 22 case before you testified in the Arizona
 23 deposition?
 24 **A. Yes.**
 25 Q. Okay. And apart from the

1 malpractice case that you just referenced and
 2 the Arizona case, have you -- are there any
 3 other cases in which you've served -- when
 4 you've served as an expert and given deposition
 5 testimony?
 6 **A. Not that I recall.**
 7 Q. Have you ever been -- have you
 8 been a party to a lawsuit?
 9 **A. Currently, I am a party --**
 10 **yes, I've been a party to two small claims court**
 11 **cases. And I may have been a party to a class**
 12 **action lawsuit regarding consumer rights.**
 13 Q. Can you tell me about all
 14 three of those? Let's start with the class
 15 action lawsuit.
 16 **A. I don't recall the details.**
 17 Q. Do you recall approximately
 18 when that class action concerning consumer
 19 rights took place?
 20 **A. Sometime in the last 20 years.**
 21 Q. And you remember that it
 22 concerned consumer rights and that it was a
 23 class action, but you don't know anything more
 24 about it?
 25 **A. That's correct.**

1 Q. And you said you might have
 2 been a plaintiff -- I'm sorry, you might have
 3 been a party?
 4 **A. Yes. One -- one of the**
 5 **members of the class.**
 6 Q. I see. Do you have any papers
 7 or documentation that would refresh your
 8 recollection as to what that class action
 9 concerned?
 10 **A. I do not.**
 11 Q. What about the two small
 12 claims court cases, are those -- tell me about
 13 those.
 14 **A. One was approximately 40 years**
 15 **ago where I was involved in a car accident.**
 16 Q. And were you a plaintiff or a
 17 defendant in that case?
 18 **A. I believe I was a defendant,**
 19 **but I'm not entirely sure.**
 20 Q. Okay. And what about the
 21 second one?
 22 **A. The second one is a pending**
 23 **small claims case regarding a patient who is**
 24 **alleging that he was harmed by me when I cleaned**
 25 **wax out of his ear.**

1 Q. What kind of harm is he
 2 claiming?
 3 **A. He's claiming that he**
 4 **developed tinnitus, or ringing in the ears,**
 5 **after I cleaned wax out of his ear.**
 6 Q. Is he -- do you know the term
 7 "pro se"? Does he have a lawyer in that case?
 8 **A. He does not have a lawyer.**
 9 Q. Okay. Have you ever given
 10 testimony other than in a deposition?
 11 **A. Yes.**
 12 Q. How many times?
 13 **A. I believe once.**
 14 Q. And tell me about that one
 15 time.
 16 **A. I testified before a**
 17 **legislative committee at the state of Colorado.**
 18 Q. Do you remember when that was?
 19 **A. That was sometime around 2017,**
 20 **I believe.**
 21 Q. What was the subject matter of
 22 your testimony?
 23 **A. The Colorado state legislature**
 24 **was considering a bill requiring abortion**
 25 **providers to inform women about the possibility**

1 **of abortion pill reversal.**
 2 Q. Did you testify in person or
 3 by video or telephone?
 4 **A. In person.**
 5 Q. And do you have -- did you
 6 write down a text of your testimony?
 7 **A. Did I write down a text of my**
 8 **testimony?**
 9 Q. Sure. Did you have prepared
 10 remarks that you testified to and did you write
 11 that down, or were you there just to answer
 12 questions?
 13 **A. I had prepared remarks.**
 14 Q. Do you still have those
 15 prepared remarks somewhere, perhaps on a
 16 computer?
 17 **A. I'm not sure.**
 18 Q. We can come back to that. But
 19 it was before a committee. Do you remember what
 20 the name of the committee was in Colorado?
 21 **A. I do not.**
 22 Q. Apart from the Arizona case,
 23 this case, and the malpractice case in which you
 24 were an expert for the defense, have you ever
 25 acted as an expert in relation to any other

1 lawsuit?

2 **A. Yes.**

3 Q. On how many occasions?

4 **A. Approximately six or seven.**

5 Q. And so these are cases in

6 which you've served as an expert, but have not

7 given testimony; is that correct?

8 **A. That's correct.**

9 Q. And do these cases all

10 post-date the 2015 deposition in Arizona?

11 **A. Yes.**

12 Q. Okay. Do these six to seven

13 cases share a common subject matter, or are they

14 on different subjects?

15 **A. I would say they share a**

16 **common subject matter.**

17 Q. And what is that subject

18 matter?

19 **A. These all are groups or**

20 **individuals suing states regarding COVID-19**

21 **restrictions.**

22 Q. So you've served as an expert

23 in six to seven cases involving groups suing

24 states regarding COVID-19 restrictions?

25 **A. That's correct.**

1 Q. And did you submit expert

2 declarations or reports in all six to seven of

3 those cases?

4 **A. Yes.**

5 Q. But have not yet testified?

6 **A. That's correct.**

7 Q. And can you summarize -- well,

8 let's start with, what's -- what's the nature of

9 the expertise that you are asserting in those

10 cases?

11 **A. Medical expertise.**

12 Q. Can you be more specific?

13 **A. How do you want me to be more**

14 **specific?**

15 Q. So what medical insights are

16 you offering in the declarations that you've

17 submitted in those cases? If you could give me

18 a summary, for example, of the argument made in

19 your -- in your declaration in one of these

20 cases?

21 **A. Well, the arguments vary**

22 **depending on the cases, because each case has**

23 **its own specific details and context.**

24 Q. Okay. Where are these cases

25 pending? Are these lawsuits pending or are they

1 over and done with?

2 **A. Both.**

3 Q. Okay. The cases that are

4 pending, where are they? What locations in the

5 country?

6 **A. California.**

7 Q. That's the only one that's

8 pending?

9 **A. Yes.**

10 Q. Okay. Is there one lawsuit in

11 California or more than one lawsuit in

12 California?

13 **A. More than one.**

14 Q. Okay. How many lawsuits are

15 pending in California?

16 **A. I believe three.**

17 Q. And -- and who are you

18 representing in this -- I'm sorry.

19 Who has retained your expert

20 services in those three California services?

21 Who are the -- are you serving on behalf of the

22 plaintiffs in each of those cases?

23 **A. Yes.**

24 Q. And who are the plaintiffs in

25 each? So let's start with whichever one you

1 want.

2 **A. One of the cases is Grace**

3 **Community Church. Another case is South Bay**

4 **Pentecostal Church. And another plaintiff in --**

5 **in the case is RMP Enterprises.**

6 Q. Is RMP Enterprises also a

7 religious organization like Grace Community

8 Church and South Bay Pentecostal?

9 **A. No.**

10 Q. What kind of entity is RMP

11 Enterprises?

12 **A. It's a restaurant holding**

13 **company.**

14 Q. And -- so you've offered

15 medical expert testimony in all of those cases

16 concerning COVID-19 restrictions; is that right?

17 **A. That's correct.**

18 Q. What was your -- well, can you

19 summarize the expert testimony that you offered

20 in the South Bay Pentecostal Church case?

21 **A. It would be difficult to**

22 **summarize and give it justice. However, my**

23 **expert medical declaration pointed out that**

24 **restrictions were arbitrary and unfairly biased**

25 **against religious groups when you look at the**

1 **data of actual outbreaks that have occurred in**
 2 **the context of worship services.**
 3 Q. So you were looking at the --
 4 the data from an epidemiological perspective; is
 5 that correct?
 6 **A. That's correct.**
 7 Q. You're not an epidemiologist,
 8 correct?
 9 **A. Correct.**
 10 Q. Your training is in family
 11 medicine and palliative medicine?
 12 **A. Family medicine, Hospice, and**
 13 **palliative medicine.**
 14 Q. I think I saw that you offered
 15 a comparative risk analysis about catching
 16 COVID-19 at a church service versus engaging in
 17 a variety of other activities. Was that in the
 18 South Bay United Pentecostal Church case?
 19 **A. I believe it was.**
 20 Q. Did you offer a kind of
 21 comparative risk analysis in some of the other
 22 six to seven cases as well?
 23 **A. Yes.**
 24 Q. Did you offer a comparative
 25 risk analysis in all of those six or seven

1 **A. I have it open.**
 2 Q. Does this look like the
 3 declaration you submitted in the South Bay
 4 United Pentecostal Church case?
 5 **A. Yes.**
 6 Q. And if you look at the blue
 7 text at the top, it's filed May 5 -- sorry, May
 8 11th, 2020?
 9 **A. I see that.**
 10 Q. Okay. If you'll turn to
 11 paragraph 6, please. Let me know when you're
 12 there.
 13 **A. I'm there.**
 14 Q. Okay. At paragraph 6 it
 15 states, "It is clear that due to mitigation
 16 measures carried throughout California, the
 17 trajectory of the COVID-19 pandemic has been
 18 altered. The curve had been flattened."
 19 Correct?
 20 **A. Correct.**
 21 Q. Would you read paragraph 12
 22 aloud, please?
 23 **A. "Los Angeles County has**
 24 **reported about 1,200 deaths, parenthesis, out of**
 25 **California's approximate total of 2,200, close**

1 cases?
 2 **A. No.**
 3 Q. Which one -- which ones didn't
 4 you offer a comparative risk analysis?
 5 **A. I would have to review my**
 6 **declarations to answer that accurately.**
 7 Q. So you talked about you
 8 offered expert opinions, but on something other
 9 than comparative risk analyses in some number of
 10 cases of those six to seven, correct?
 11 **A. That's correct.**
 12 MR. BECK: Okay. Rebecca, can
 13 we introduce Tab B, please, into the chat?
 14 BY MR. BECK:
 15 Q. Do you see that, Doctor?
 16 **A. Yes.**
 17 Q. Great. Can you download that,
 18 please? It's a big file so it might take a
 19 second.
 20 MR. BECK: Sorry, let's do C
 21 as well, Rebecca. We can just do this
 22 collectively.
 23 BY MR. BECK:
 24 Q. So let's start with C, Doctor.
 25 Let me know when you have that open.

1 **parenthesis. Thereto, however, the curve of new**
 2 **deaths has flattened, similar to the California**
 3 **curve. The Monte Carlo model predicts that**
 4 **total deaths in Los Angeles County will be**
 5 **approximately 1,900 for this year."**
 6 Q. And you submitted this figure
 7 predicting a total of 1900 COVID deaths for this
 8 year in Los Angeles County, correct?
 9 **A. Correct.**
 10 MR. BECK: Okay. Let's look
 11 at the next Tab, Rebecca, Tab D.
 12 BY MR. BECK:
 13 Q. Let me know when you have Tab
 14 D open.
 15 **A. It's open.**
 16 Q. Okay. And before we get
 17 there -- actually, no, let's -- let's do this
 18 first.
 19 So Tab D, this is Los Angeles
 20 County Public Health -- the Los Angeles County
 21 Public Health Department's website with daily
 22 COVID data. This one is dated from November
 23 11th. Would you read what it reports for total
 24 deaths reported to date, which is sort of on the
 25 left-hand column in the middle -- I'm sorry, at

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

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

1 marked as Exhibit No. 27 to the testimony of the
 2 witness.)
 3 MS. DAVIS: Objection to
 4 Exhibit 27.
 5 MR. BECK: And let's look at
 6 Exhibit -- let's mark as Exhibit 28 the first --
 7 I'm sorry, the second file that was placed in
 8 the chat. We're getting a little out of order
 9 here, and I apologize for that, Doctor.
 10 (Whereupon, the document was
 11 marked as Exhibit No. 28 to the testimony of the
 12 witness.)
 13 BY MR. BECK:
 14 Q. But this -- this is the one
 15 that entered the chat just after your
 16 deposition, which says 2020 West Law 6081733 at
 17 the top. Do you see that?
 18 **A. Oh, the tabs are labeled by**
 19 **letters? I see --**
 20 Q. Yes. Sorry. So -- sorry.
 21 This one is letter B. That's a better way to do
 22 this.
 23 **A. Okay. It's open.**
 24 Q. Okay. Can you turn -- sorry.
 25 This is -- this is an opinion

1 data for his conclusions."
 2 So it appears that the Court
 3 gave little weight to your opinions, in part,
 4 because you were weighing in on matters outside
 5 of your expertise. Do you agree with that
 6 characterization?
 7 MS. DAVIS: Objection.
 8 BY MR. BECK:
 9 Q. You can go ahead and answer,
 10 Doctor.
 11 **A. That -- that is -- that is a**
 12 **reasonable characterization.**
 13 Q. And the Court also appears to
 14 have given your opinions little weight because
 15 you didn't have adequate data to back up those
 16 opinions. Is that also a reasonable
 17 characterization?
 18 MS. DAVIS: Objection.
 19 THE WITNESS: That's a
 20 reasonable characterization.
 21 BY MR. BECK:
 22 Q. Do you think that you were
 23 testifying on matters outside of your expertise
 24 in that case?
 25 **A. No.**

1 Q. So the Court got that wrong.
 2 You were within your expertise, but the Court
 3 was wrong to think otherwise?
 4 **A. Yes.**
 5 Q. On the -- on the distinction
 6 you drew earlier between being an expert and
 7 having expertise, on the subject of epidemiology
 8 that you were offering opinions on in that case,
 9 would you characterize yourself as an expert or
 10 someone who happens to have some expertise?
 11 MS. DAVIS: Objection.
 12 THE WITNESS: I would say that
 13 analyzing the situation requires more than just
 14 epidemiology.
 15 BY MR. BECK:
 16 Q. What other -- what other
 17 considerations does it require?
 18 **A. A broad knowledge of the**
 19 **medical and the psychosocial effects of**
 20 **mitigation measures on the population.**
 21 Q. And do you believe that you
 22 have that broad knowledge?
 23 **A. Yes.**
 24 Q. But the Court seems to have
 25 thought otherwise, correct?

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

1 common sense without adequate data to back it
 2 up. Is that a fair characterization?
 3 MS. DAVIS: Objection.
 4 THE WITNESS: That's -- that's
 5 a reasonable characterization.
 6 BY MR. BECK:
 7 Q. And do you think that you had
 8 sufficient data to back up your conclusions in
 9 that case?
 10 **A. Taking into account the amount**
 11 **of data available at that time with regards to**
 12 **the risk of acquiring the virus, yes.**
 13 Q. Does that mean that you
 14 revised your opinion with the passage of time
 15 and the creation of more data?
 16 **A. That's a very complicated**
 17 **question that defies a simple yes or no answer.**
 18 Q. Well, do you stand by the
 19 opinions that the Court rejected or would you
 20 offer different opinions today?
 21 **A. I would offer different**
 22 **opinions today for some of the specifics.**
 23 Q. In terms of the specific data?
 24 **A. In terms of some of the risks**
 25 **of acquiring the Coronavirus.**

1 Q. Is your opinion that the risks
 2 are more serious than you estimated or less
 3 serious?
 4 **A. Neither.**
 5 Q. Just different?
 6 **A. Correct.**
 7 Q. How are they different?
 8 **A. Well, for example, since**
 9 **the -- that declaration in May, we have more**
 10 **data suggesting that acquiring the virus by**
 11 **touching surfaces is not as important as the**
 12 **airborne route is important.**
 13 Q. And so would that alter the
 14 comparative risk analysis that you generated in
 15 that case?
 16 **A. It might.**
 17 Q. Do you know which way it would
 18 alter it? By making, for example, church
 19 attendance riskier as compared to going to a
 20 grocery store than you had estimated or safer?
 21 **A. I think that would be a guess**
 22 **at this point without in-depth study of the**
 23 **issue.**
 24 Q. Okay. So you understand that
 25 this case concerns a Tennessee law regulating

1 abortion providers?
 2 **A. I do.**
 3 Q. And the law we're talking
 4 about is called House Bill 2263 or HB2263?
 5 **A. I did not recall that specific**
 6 **designation.**
 7 Q. Can we agree to refer to it as
 8 The Act or The Law during this deposition and
 9 you'll know what I'm referring to?
 10 **A. Yes.**
 11 Q. Okay. How did you become
 12 familiar with The Act?
 13 **A. I was informed about The Act**
 14 **by members of the Tennessee Attorney General's**
 15 **office.**
 16 Q. Do you remember who informed
 17 you of The Act?
 18 **A. I believe it was Mr. Steven**
 19 **Hart.**
 20 Q. And that was after it became
 21 law? When was that?
 22 **A. Yes.**
 23 Q. So it had already been enacted
 24 into law, and at a certain point Steve Hart
 25 reached out to you?

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

1 **A. That's correct.**
 2 Q. Okay. Did you communicate
 3 with anyone about The Act before its passage?
 4 **A. Not that I recall.**
 5 Q. So no communications with
 6 regulators?
 7 **A. No.**
 8 Q. Or advocates?
 9 **A. No.**
 10 Q. Have you had any
 11 communications about either this case or the
 12 Tennessee Act with Dr. Donna Harrison?
 13 **A. Not that I recall.**
 14 Q. So no emails about --
 15 concerning this case or The Act with
 16 Dr. Harrison?
 17 **A. Not that I recall.**
 18 Q. And no text messages?
 19 **A. No.**
 20 Q. And no oral conversations
 21 either in person or over the phone?
 22 **A. Not that I recall.**
 23 Q. Do you think you would recall
 24 if you had the conversations?
 25 **A. Yes.**

1 Q. Why don't you try it again,
 2 because it's working with me. There's also
 3 another version of it as exhibit -- as Tab E in
 4 the chat if you want to try a different
 5 document.
 6 **A. Okay. Now it's open.**
 7 Q. Great. We can skip past the
 8 first page. But if we get to the second page,
 9 does this look like a familiar document to you?
 10 **A. Yes.**
 11 Q. What is it?
 12 **A. Declaration of Dr. George**
 13 **Delgado.**
 14 Q. So this is the declaration of
 15 yours submitted in the Tennessee case, correct?
 16 **A. Correct.**
 17 Q. Okay. And how was this
 18 document, Exhibit 2, prepared?
 19 **A. How was it prepared? Can you**
 20 **be more specific, please?**
 21 Q. Did you prepare this document?
 22 **A. Yes.**
 23 Q. And can you tell me how you
 24 went about preparing this document?
 25 **A. I received some documents**

1 related to the lawsuit, and I then presented
 2 my -- my perspective on the case, as well as
 3 I looked to counter some of the points made by
 4 the plaintiffs.
 5 Q. When you said you received
 6 some documents related to the lawsuit, what
 7 documents are those?
 8 A. I would have to find them
 9 again to tell you exactly what they were. But
 10 they were statements made on behalf of the
 11 plaintiff and by the plaintiffs in regards to
 12 this case.
 13 Q. So maybe, like, declarations
 14 or legal filings?
 15 A. There were filings,
 16 declarations, and also the complaint.
 17 Q. Okay. And so apart from the
 18 complaint and declarations and legal filings
 19 from the plaintiffs, did you receive any other
 20 documents for review?
 21 A. At the time of writing this, I
 22 do not believe so.
 23 Q. Did you receive documents from
 24 the attorney general's office at a later time?
 25 A. Yes.

1 provision?
 2 A. By each and every provision,
 3 do you mean each and every paragraph?
 4 Q. Yeah.
 5 A. I don't recall.
 6 Q. Who else might have played a
 7 role in drafting it?
 8 A. The -- the members of the
 9 attorney general's office may have given me
 10 advice on how to word things.
 11 Q. Did they draft something and
 12 send it to you for review, or did you draft
 13 something yourself and discuss with them?
 14 A. I drafted something myself.
 15 Q. And then you had discussions?
 16 A. If you include email
 17 discussions, yes, as well as telephonic.
 18 Q. Okay. Did you discuss the
 19 contents of the declaration with anyone besides
 20 lawyers from the Tennessee attorney general's
 21 office?
 22 A. I may have made some passing
 23 comments to my wife.
 24 Q. And apart from passing
 25 comments to your wife and conversations with the

1 Q. What documents are those?
 2 A. I received a transcript of my
 3 Arizona testimony. And I think I received one
 4 or two others, and I don't recall what they were
 5 at this point.
 6 Q. One or two other what?
 7 A. Documents.
 8 Q. Okay. But you don't remember
 9 what they were?
 10 A. No. I -- yes. One of them
 11 was this -- this -- my -- my own medical
 12 declaration so that I would have it for
 13 reference.
 14 Q. And you can't remember what
 15 the other one was?
 16 A. No.
 17 Q. When did you receive the
 18 transcript from the Arizona testimony?
 19 A. Probably about a week ago.
 20 Q. Did you draft each and every
 21 provision of Exhibit 2?
 22 A. By Exhibit 2, are you
 23 referring to my medical declaration?
 24 Q. Yeah. Tab E, Exhibit 2, your
 25 declaration. Did you draft each and every

1 Tennessee attorney general's office counsel,
 2 have you discussed the contents of the
 3 declaration with anyone else?
 4 A. No.
 5 Q. Apart from the process you
 6 engaged in via email and telephone conversation
 7 with lawyers from the attorney general's office,
 8 did you have any other assistance in preparing
 9 the declaration?
 10 A. No.
 11 Q. Do you know how the Tennessee
 12 attorney general's office had a copy of your
 13 Arizona deposition testimony?
 14 A. No.
 15 Q. The declaration here lists
 16 certain medical opinions that you reached in the
 17 case, correct?
 18 A. Can you reword that, please?
 19 Q. Sure. You -- you formed some
 20 medical opinions in -- that are relevant to this
 21 case; is that correct?
 22 A. That's correct.
 23 Q. And you've included them in
 24 the declaration that we've been looking at,
 25 Exhibit 2?

1 **A. Yes.**
2 Q. Okay. And do you intend to
3 testify to the points highlighted or set forth
4 in your declaration at a hearing in this case?
5 **A. I intend to testify.**
6 Q. Have you -- do you intend to
7 testify about the things that you've said in
8 your declaration or something else?
9 **A. My understanding is that when**
10 **I testify, I will be asked questions. So I may**
11 **not have control over exactly what the topics**
12 **will be.**
13 Q. Have you formed any opinions
14 about the Tennessee law that are not reflected
15 in your declaration?
16 **A. No.**
17 Q. And have you formed any
18 opinions about the sort of broader subject
19 matter at issue in this case that are not
20 reflected in your declaration?
21 **A. No.**
22 Q. Okay. And so you've at this
23 point included all of the significant points
24 that you plan to testify to at the hearing? I
25 understand that you're not in control of what

1 questions are asked of you. But in terms of
2 what you have planned to testify to, you tried
3 to include that in your declaration, correct?
4 **A. I think the premise of your**
5 **question's incorrect.**
6 Q. So, Doctor, we are entitled to
7 know and ask you about the opinions that you're
8 going to be offering live on the stand in court.
9 And I just want to make sure there's no gap
10 between what we know that you've set forth in
11 writing and what you plan to talk about. Is
12 there a gap?
13 **A. Well, again, I have no plan to**
14 **talk about anything except the questions I'm**
15 **asked. So that's why your question's puzzling**
16 **to me.**
17 Q. But you -- assuming you
18 wouldn't be asked about opinions that you
19 haven't formed in this case, you have set forth
20 all of the opinions that you've formed in this
21 case in your declaration, correct?
22 **A. To the best of my knowledge,**
23 **yes.**
24 Q. Okay. And you made an effort
25 to include in your declaration all of the

1 relevant facts and data upon which your opinions
2 are based, correct?
3 **A. To the best of my knowledge,**
4 **yes.**
5 Q. Are there any facts or data
6 that you have not included in your declaration
7 that you might -- that you're intending to
8 testify to that we should know about?
9 **A. I am not aware of any.**
10 Q. In that declaration Exhibit 2,
11 can we turn to page 32 -- I'm sorry, page 11?
12 **A. I'm there.**
13 Q. Above paragraph 32 is a
14 sentence that says, "We note that bleeding is an
15 expected consequence of medical abortion."
16 Did I read that correctly?
17 **A. Yes, you read it correctly.**
18 Q. Who is the we referenced
19 there?
20 **A. The we would refer to myself**
21 **and those knowledgeable about medical abortion.**
22 Q. You're speaking on behalf of
23 people knowledgeable about medical abortion? I
24 guess my -- my question is more, really, did
25 that language come from a different text that

1 you jointly wrote with multiple authors
2 originally?
3 **A. That's possible.**
4 Q. What text might that possibly
5 be?
6 **A. This may have come from a --**
7 **the verbiage, I may have taken it from a**
8 **rebuttal I wrote responding to the article**
9 **published by Dr. Creinin.**
10 Q. Was that rebuttal something
11 that wound up being published somewhere?
12 **A. Yes.**
13 Q. Where was it published?
14 **A. In the Green Journal.**
15 Q. So that sentence probably
16 comes or possibly comes from the rebuttal that
17 you published in the Green Journal in response
18 to Dr. Creinin?
19 **A. Possibly, yes.**
20 Q. Did you draw upon that --
21 your -- your published rebuttal for more than
22 just that sentence in the declaration?
23 **A. I may have also used the --**
24 **the preceding sentence may also have come from**
25 **that, from that text.**

1 Q. So that -- that's all -- the
 2 preceding sentence and the, "We note that
 3 bleeding," sentence, are those the only things
 4 that came from that rebuttal, or were you
 5 drawing -- did you draw upon that rebuttal in
 6 any larger way for purposes of setting out the
 7 opinions in your declaration?
 8 **A. Well, in the portion of my**
 9 **declaration where I mention Dr. Creinin's study**
 10 **and draw conclusions about it, I had given this**
 11 **significant thought and study and analysis in**
 12 **the past, so I logically drew on it when I**
 13 **composed this declaration.**
 14 Q. Does the rebuttal -- was the
 15 rebuttal that you submitted to the Green Journal
 16 just on behalf of you or was it on behalf of
 17 others?
 18 **A. It was on behalf of myself,**
 19 **Dr. Mary Davenport, and Dr. Matthew Harrison.**
 20 Q. So the we note, the we in that
 21 is actually the three of you, not the community
 22 of physicians aware of the side effects of
 23 medication abortion, correct?
 24 **A. Most likely.**
 25 Q. Okay. So were you

1 suggest in paragraph 17 on the next page.
 2 Doctor, would you agree with
 3 me that mifepristone binds to progesterone
 4 receptors with higher affinity than progesterone
 5 does?
 6 **A. Yes.**
 7 MR. BECK: Okay. Let's
 8 introduce into the chat Tab F, which is -- has
 9 previously been marked as Plaintiff's Exhibit 7.
 10 BY MR. BECK:
 11 Q. Let me know when you're able
 12 to download that, Doctor.
 13 **A. F is open.**
 14 Q. Great. This -- Plaintiff's
 15 Exhibit 7 is a study called, "A Case Series
 16 Detailing the Successful Reversal of the Effects
 17 of Mifepristone Using Progesterone."
 18 You recognize this document,
 19 right, Doctor?
 20 **A. Yes.**
 21 Q. And you authored it?
 22 **A. Yes.**
 23 Q. Along with these other
 24 authors?
 25 **A. Correct.**

1 misremembering that when you said earlier that's
 2 who the we in that sentence referred to?
 3 **A. Well, no, because those three**
 4 **authors are all knowledgeable about medical**
 5 **abortion and the bleeding that's expected in it.**
 6 **So it -- I don't think it's a misremembrance. I**
 7 **think it's just a different characterization.**
 8 Q. Okay. But the we is the three
 9 of you, Doctors Harrison, Davenport, and
 10 Delgado?
 11 **A. I suppose it is.**
 12 Q. On page 6, paragraph 16, let
 13 me know when you're there.
 14 **A. I'm there.**
 15 Q. Okay. So you state here,
 16 "Three pillars of evidence support the use of
 17 progesterone to reverse the effects of
 18 mifepristone in women who choose to attempt
 19 reversal of their mifepristone abortion." And
 20 those three pillars that you develop later are
 21 biologic logic, animal studies, and research in
 22 humans, correct?
 23 **A. That's correct.**
 24 Q. Okay. Let's start with the
 25 first of those, biologic logic, which you

1 Q. And can we refer to this, as I
 2 have been, as your 2018 case series?
 3 **A. Yes.**
 4 Q. And you'll know what I'm
 5 referring to?
 6 **A. Yes.**
 7 Q. Great. Turn to page 22,
 8 please.
 9 **A. I'm there.**
 10 Q. Okay. Can you read the first
 11 two sentences under "Pharmacology" aloud?
 12 **A. "Mifepristone is a competitive**
 13 **antagonist of progesterone at the progesterone**
 14 **receptor, parenthesis, PR, close parenthesis.**
 15 **It binds to the PR twice as avidly as**
 16 **progesterone. Mifepristone is --**
 17 Q. You can stop there.
 18 **A. Okay.**
 19 Q. Thanks. Do you agree with the
 20 statement you just read?
 21 **A. Yes.**
 22 Q. Okay. And, actually, doesn't
 23 mifepristone bind to progesterone receptors more
 24 than twice as avidly as progesterone?
 25 **A. Different articles may quote**

1 **different rates of binding. But one of the --**
 2 **the research substantiates that it -- it binds**
 3 **twice as avidly.**
 4 Q. Okay. So what -- you -- you
 5 actually have a footnote for that point about
 6 the twice as avidly. It's footnote 5. And if
 7 we go to the end there, my Finnish is not very
 8 good, but I believe it's Heikinheimo is the --
 9 is the name of the first author of footnote 5,
 10 correct?
 11 **A. That's correct.**
 12 MR. BECK: Can we introduce
 13 Tab G?
 14 BY MR. BECK:
 15 Q. So here is that tab. Let me
 16 know when you have that.
 17 MR. BECK: And we can mark,
 18 sorry, Heikinheimo as Exhibit 28.
 19 THE COURT REPORTER: Excuse
 20 me, I already have an Exhibit 28. I have that
 21 as --
 22 MR. BECK: You're right.
 23 Thank you. 29.
 24 (Whereupon, the document was
 25 marked as Exhibit No. 29 to the testimony of the

1 **A. Almost. Okay. Yes, it**
 2 **appears to be the article I've referenced.**
 3 Q. Great. It was published in
 4 the Journal of Contraception, correct?
 5 **A. Yes.**
 6 Q. Is that a reliable
 7 publication?
 8 MS. DAVIS: Objection.
 9 THE WITNESS: I guess it would
 10 depend on what you mean by reliable.
 11 BY MR. BECK:
 12 Q. Well, you cited it in your
 13 2018 case series. Would you have cited
 14 something from an unreliable source?
 15 **A. Well, a journal could publish**
 16 **articles that are reliable and also publish**
 17 **articles that are not reliable.**
 18 Q. And is that your opinion of
 19 the Contraception Journal, that it publishes
 20 some reliable and some unreliable articles?
 21 **A. That's correct.**
 22 Q. And is this a reliable
 23 article?
 24 **A. For the purposes, yes. Yes.**
 25 Q. Okay. If you can turn to page

1 witness.)
 2 BY MR. BECK:
 3 Q. Doctor, let me know when you
 4 have that article open.
 5 **A. It's open.**
 6 Q. Okay. Does this appear to be
 7 a study by Heikinheimo, et al., called
 8 pharmaco- --
 9 (Phone ringing.)
 10 THE WITNESS: Yes.
 11 BY MR. BECK:
 12 Q. Does this appear to be an
 13 article by Heikinheimo, et al., called, "The
 14 Pharmacokinetics of Mifepristone in Humans
 15 Reveal Insights into Differential Mechanisms of
 16 Antiprogestosterone Action"?
 17 **A. Yes.**
 18 Q. And this is the source that
 19 you cite at footnote 5 of your 2018 case series,
 20 correct?
 21 **A. I would have to look at my**
 22 **footnote and back at this to verify that.**
 23 Q. Okay. Why don't you do that
 24 just so we can make sure. Have you been able to
 25 verify it, Doctor?

1 425, and look at table 1 with me. Let me know
 2 when you're there.
 3 **A. I'm there.**
 4 Q. This is a table entitled,
 5 "Relative Binding Affinities, parenthesis RBAs,
 6 end parenthesis, of Mifepristone and its Three
 7 Metabolites to the Human Uterine Progesterone
 8 Receptor," correct?
 9 **A. That's correct.**
 10 Q. What does it show is the
 11 relative binding affinity of progesterone?
 12 **A. 43.**
 13 Q. And if mifepristone's relative
 14 binding affinity were twice as avid as
 15 progesterone, then its RBA would be 86, correct?
 16 **A. That's correct.**
 17 Q. But, in fact, the relative
 18 binding affinity of mifepristone to progesterone
 19 receptors is much more than 86. It's 100
 20 percent, correct?
 21 **A. What do you mean by much more?**
 22 Q. We can take out the much. It
 23 is more than 80 -- it's more than twice as avid
 24 if there's a 14 percent difference if it were
 25 86. It's actually 100, correct?

1 **A. So it is a bit more than twice**
 2 **the binding capacity, correct.**
 3 Q. What does it mean that the
 4 relative binding affinity of mifepristone to the
 5 progesterone receptor is 100 as compared to 43
 6 percent for progesterone?
 7 **A. It means that the mifepristone**
 8 **binds to the receptor more avidly than the**
 9 **progesterone does.**
 10 Q. But what does that mean?
 11 When -- when you say that it binds more avidly,
 12 what does that mean?
 13 **A. It means that it has a higher**
 14 **affinity for the receptor than does the**
 15 **progesterone.**
 16 Q. In biochemistry, what does
 17 "ligand" mean? Do you know that term?
 18 **A. Yes. Something that binds --**
 19 **binds to a receptor. Ligand is -- is the**
 20 **pronunciation.**
 21 Q. Thank you. Ligand?
 22 **A. Yes.**
 23 Q. Let me read something and you
 24 can tell me if you agree with it. "In general,
 25 high affinity ligand binding results from

1 greater attractive forces between the ligand and
 2 its receptor, while low affinity ligand binding
 3 involves less attractive force."
 4 Do you agree with that
 5 statement?
 6 **A. Yes.**
 7 Q. Okay. And then here's another
 8 statement. "In general, high affinity binding
 9 results in a stronger occupancy of the receptor
 10 by its ligand than is the case for low affinity
 11 binding."
 12 Do you agree with that
 13 statement?
 14 **A. Yes.**
 15 Q. Okay. Your 2018 case series
 16 references mifepristone's high affinity for
 17 progesterone receptors, correct?
 18 **A. Yes.**
 19 Q. Why did you include that point
 20 in the study?
 21 **A. Just to give a scientifically**
 22 **accurate foundation for medical abortion with**
 23 **mifepristone.**
 24 Q. Was it -- is it relevant for
 25 the reader to know that information?

1 **A. Yes.**
 2 Q. So your declaration does not
 3 mention mifepristone's higher affinity for
 4 progesterone receptors in the discussion of
 5 biologic logic or anywhere else. Why not?
 6 **A. Because the -- for the**
 7 **intended audience, that would not be a point**
 8 **that necessarily would be as important as for**
 9 **someone reading a medical journal.**
 10 Q. Doesn't the fact that there
 11 is -- it's sort of -- isn't it sort of inherent
 12 in the theory that you're offering in the case?
 13 The plausibility of your theory -- isn't it
 14 relevant to the plausibility of your therapy?
 15 MS. DAVIS: Objection.
 16 THE WITNESS: Is what relative
 17 to the plausibility of my theory?
 18 BY MR. BECK:
 19 Q. Isn't the strength of the bond
 20 between mifepristone and the progesterone
 21 receptor relevant to the theory that you're
 22 offering in this case?
 23 **A. It's relative in regards to**
 24 **the dosing of progesterone. Because if**
 25 **mifepristone bound more weakly to the**

1 **progesterone receptor than progesterone does,**
 2 **then you could use lower doses of progesterone.**
 3 **However, with its higher affinity for the**
 4 **receptor, then that would support using higher**
 5 **doses of progesterone.**
 6 Q. But you agreed a moment ago
 7 that high affinity binding results in a stronger
 8 occupancy of the receptor by its ligand than is
 9 the case with a low affinity binding, right?
 10 **A. That's correct.**
 11 Q. And we've established from
 12 Dr. Heikinheimo's study the strength of the
 13 occupancy of mifepristone as compared to the
 14 binding affinity of progesterone, correct?
 15 **A. Correct.**
 16 Q. Isn't that relevant
 17 information to the plausibility of your theory
 18 behind medication abortion reversal?
 19 **A. It's relative information with**
 20 **regards to the dosing of progesterone. What you**
 21 **have to keep in mind is that the binding to the**
 22 **receptor is a reversible phenomenon. And,**
 23 **therefore, the -- the ligand goes on and off the**
 24 **receptor.**
 25 **The one that has the higher**

1 **affinity will stay on the receptor longer.**
 2 **However, it still comes off and on. When it**
 3 **comes off and on, that's the opportunity for the**
 4 **competing ligand to then bind to the receptor.**
 5 **If you increase the**
 6 **concentration of the competing ligand, then that**
 7 **molecule will win the battle of the receptor.**
 8 **So that's why the affinities are important for**
 9 **dosing, but not for the plausibility of the**
 10 **entire theory.**
 11 Q. Are you familiar with the term
 12 "drug target residence time"?
 13 **A. I'm sorry, can you repeat the**
 14 **question, please.**
 15 Q. Are you familiar with the term
 16 "drug target residence time"?
 17 **A. I am not familiar with that --**
 18 **with that term, but I think I know what it**
 19 **means.**
 20 Q. What do you think it means?
 21 **A. I think it probably means how**
 22 **long a drug stays on a receptor.**
 23 Q. I think that's what it means
 24 as well. And that's what -- kind of what you're
 25 talking about just now, right?

1 **A. Correct.**
 2 Q. So let's turn to the second
 3 pillar that you discuss, which is animal
 4 studies.
 5 MS. DAVIS: Hey, Andrew?
 6 MR. BECK: Yeah.
 7 MS. DAVIS: Sorry. If -- if
 8 you're about to switch topics, can we take a
 9 quick break?
 10 MR. BECK: Sure.
 11 MS. DAVIS: Okay. Do y'all
 12 want to do ten minutes?
 13 MR. BECK: Ten minutes, that's
 14 good.
 15 VIDEOGRAPHER: Off the record
 16 at 10:43.
 17 (A recess was taken.)
 18 VIDEOGRAPHER: We are back on
 19 the record at 10:53.
 20 BY MR. BECK:
 21 Q. Doctor, during the break did
 22 you have any interactions with counsel for
 23 Tennessee?
 24 **A. No.**
 25 Q. Okay. I believe before we

1 **A. That's correct.**
 2 Q. Do we know what the drug
 3 target residence time for mifepristone or
 4 progesterone receptors is?
 5 **A. I'm not aware.**
 6 Q. Do you think it's relevant to
 7 the plausibility of your theory?
 8 **A. No.**
 9 Q. If we didn't have animal
 10 studies and research in humans, would the
 11 biologic logic set forth in paragraph 17 of your
 12 declaration be sufficient to prove that
 13 medication abortion is reversible?
 14 **A. Not to prove it.**
 15 Q. So, in your opinion, the
 16 principles laid out in paragraph 17 alone are
 17 not enough to establish that mifepristone can be
 18 reversed, correct?
 19 **A. Paragraph 17 discusses the**
 20 **biologic logic?**
 21 Q. Yep.
 22 **A. That would be -- it would**
 23 **provide support, but not proof.**
 24 Q. Right. It's not sufficient in
 25 and of itself, correct?

1 took a break you stated that the drug target
 2 residence time of mifepristone on progesterone
 3 receptors is not relevant to the theory you're
 4 articulating in this case. Did I state that
 5 correctly?
 6 **A. It's not relevant to the**
 7 **plausibility of the theory.**
 8 Q. Why not?
 9 **A. Because as long as the ligand**
 10 **or drug to receptor interaction is reversible,**
 11 **and there is the potential of competition at the**
 12 **receptor with the agonist or antagonist, however**
 13 **you might want to call it, so the increase in**
 14 **the concentration of the competing molecule will**
 15 **lead to increased binding of that molecule to**
 16 **receptor.**
 17 Q. But if the bond, which we've
 18 said is stronger, lasts for 5 minutes or 24
 19 hours, doesn't that impact whether or not there
 20 is the opportunity for the competition you're
 21 referencing?
 22 **A. The longer the occupancy,**
 23 **the -- the more difficult it would be to compete**
 24 **against it. That would be a correct statement.**
 25 Q. And you don't know the length

1 of the occupancy of mifepristone on the
 2 receptor, the progesterone receptor, correct?
 3 **A. That's correct.**
 4 Q. Okay. So it would be relevant
 5 then -- sorry.
 6 The -- the length of time that
 7 it stays on the receptor would be relevant to
 8 the plausibility of the theory we're talking
 9 about here, correct?
 10 **A. I suppose at the extremes it**
 11 **would -- it would be one of the -- it could be**
 12 **one of the relevant factors. There would be**
 13 **many other factors in addition to that.**
 14 Q. Okay. You mentioned earlier
 15 in the deposition that you spoke to your wife
 16 about your testimony today. Is your wife
 17 involved in the Abortion Pill Reversal Network?
 18 **A. She's involved with the**
 19 **Abortion Pill Rescue Network.**
 20 Q. Thank you for the correction.
 21 What is her involvement with the Abortion Pill
 22 Rescue Network?
 23 **A. She is a hotline nurse.**
 24 Q. And so she is someone who
 25 answers calls from people who contact the

1 **review. She's worked in a gastroenterology**
 2 **lab -- procedure laboratory. She has, perhaps,**
 3 **done a few other things.**
 4 Q. And she is one of how many
 5 nurses who staffs the abortion pill rescue
 6 hotline?
 7 **A. I don't know the number.**
 8 Q. Do you have a guess?
 9 **A. My guess would be if I --**
 10 **well, I don't know if my guess means anything,**
 11 **but I would guess, perhaps, 30.**
 12 Q. Who would know how many nurses
 13 staff the hotline?
 14 **A. The director of the Abortion**
 15 **Pill Rescue Network.**
 16 Q. Who is that?
 17 **A. Christa Brown.**
 18 Q. And does Christa Brown work
 19 for Heartbeat International?
 20 **A. Yes.**
 21 Q. What is -- what is Christa
 22 Brown's position at Heartbeat International, if
 23 you know?
 24 **A. I -- I believe she's the**
 25 **director of the Abortion Pill Rescue Network.**

1 hotline with questions; is that correct?
 2 **A. Yes.**
 3 Q. And does she still play that
 4 role?
 5 **A. Yes.**
 6 Q. How long has she been in that
 7 role?
 8 **A. Approximately eight years.**
 9 Q. Is that about as long as the
 10 network has existed -- or the hotline has
 11 existed?
 12 **A. About.**
 13 Q. Okay. What is her training --
 14 you say she's a nurse?
 15 **A. Yes.**
 16 Q. Can you just give me an
 17 overview of her nursing background?
 18 **A. She's a registered nurse who's**
 19 **worked in various areas in nursing during her**
 20 **career.**
 21 Q. What various areas?
 22 **A. She worked on a -- what's**
 23 **called a telemetry unit. She's worked on**
 24 **medical floors. She's worked in a clinical**
 25 **research setting. She's worked in utilization**

1 Q. Okay. Let's go back to -- we
 2 were discussing the different pillars of
 3 evidence that you cite in your declaration
 4 concerning abortion pill reversal, correct?
 5 **A. Correct.**
 6 Q. And one was biologic logic and
 7 then the second one was animal studies, correct?
 8 **A. Correct.**
 9 MR. BECK: Can we put Tab H
 10 into the chat, please?
 11 BY MR. BECK:
 12 Q. Let me know when you have Tab
 13 H open, Doctor.
 14 **A. I have it.**
 15 MR. BECK: Okay. So we can
 16 mark Tab H as Exhibit No. 30.
 17 (Whereupon, the document was
 18 marked as Exhibit No. 30 to the testimony of the
 19 witness.)
 20 BY MR. BECK:
 21 Q. And Exhibit No. 30 is an
 22 article entitled, "Why Animal Studies are Often
 23 Poor Predictors of Human Reaction to Exposure,"
 24 by Michael B. Bracken, published in the Journal
 25 of the Royal Society of Medicine.

1 Are you familiar with the
 2 Journal of the Royal Society of Medicine?
 3 **A. No.**
 4 Q. The first sentence of this
 5 article states, "The concept that animal
 6 research, particularly that relating to
 7 pharmaceuticals and environmental agents, may be
 8 a poor predictor of human experience is not
 9 new."
 10 Did I read that correctly?
 11 **A. Yes.**
 12 Q. Do you agree with that
 13 statement?
 14 **A. Yes.**
 15 Q. Okay. And then the third
 16 sentence states, "Pharmacologists, in
 17 particular, have long recognized the
 18 difficulties inherent in extrapolating drug data
 19 from animals to man."
 20 Did I read that correctly?
 21 **A. Yes.**
 22 Q. Do you agree with that
 23 statement?
 24 **A. Yes.**
 25 Q. One reason to be cautious in

1 animal studies standing alone would be enough to
 2 prove that medication abortion in humans is
 3 reversible?
 4 **A. It would not be enough to
 5 prove it, but it would certainly give support to
 6 it.**
 7 Q. But I just want the record to
 8 be clear. It would not on its own without human
 9 trials be sufficient to prove it, correct?
 10 **A. Correct.**
 11 Q. In paragraph 18 of your
 12 declaration -- do you have that in front of you?
 13 **A. Yes.**
 14 Q. You cite a study by Yamabe
 15 concerning administration of mifepristone and
 16 progesterone to rats, correct?
 17 **A. Correct.**
 18 MR. BECK: Can we have Tab I
 19 in the chat?
 20 BY MR. BECK:
 21 Q. Let me know when you have Tab
 22 I open, Doctor.
 23 **A. I have it open.**
 24 Q. Okay. Tab I, which was
 25 previously marked in exhibits as Exhibit No. 19

1 extrapolating drug data from animals to humans
 2 is because human and animal physiology may be
 3 different, correct?
 4 **A. Correct.**
 5 Q. The first sentence of that
 6 next paragraph states, "One reason why animal
 7 experiments often do not translate into
 8 replications in human trials or into cancer
 9 chemo prevention is that many animal experiments
 10 are poorly designed, conducted, and analyzed."
 11 Did I read that correctly?
 12 **A. You did.**
 13 Q. Do you agree with that
 14 statement?
 15 **A. I have no basis to base my
 16 agreement or disagreement.**
 17 Q. Does it sound plausible to you
 18 that many animal experiments are poorly
 19 designed, conducted, and analyzed?
 20 MS. DAVIS: Objection.
 21 THE WITNESS: I would say it
 22 sounds possible.
 23 BY MR. BECK:
 24 Q. Okay. If we didn't have
 25 research on human subjects, do you think that

1 is an article entitled the Effect of RU40 --
 2 let's start that over.
 3 An article entitled, "The
 4 Effects of RU486 and Progesterone on Luteal
 5 Function During Pregnancy," by Yamabe, et al.
 6 This is the study that you
 7 cite in your declaration, correct?
 8 **A. I believe it is.**
 9 Q. Okay. This was published in
 10 the "Folia Endocrinologica Japonica." Is that a
 11 reliable publication?
 12 **A. To my knowledge, it is.**
 13 Q. Do you subscribe to it?
 14 **A. No.**
 15 Q. Why not?
 16 **A. I subscribe to very few
 17 medical journals because there's so many. And
 18 it's more efficient for me to seek out articles
 19 of interest and not to subscribe to the -- to
 20 all the journals.**
 21 Q. Have you ever relied on any
 22 other studies from the "Folia Endocrinologica
 23 Japonica" in your work?
 24 **A. Not that I'm aware.**
 25 Q. In this study, some rats were

1 given mifepristone, some were given mifepristone
 2 plus progesterone, and some were given ethanol.
 3 Does that sound like an accurate summary to you?
 4 **A. What was the last -- some were**
 5 **given?**
 6 Q. Ethanol.
 7 **A. Ethanol. I would have to**
 8 **review the ethanol part, but I -- but I am aware**
 9 **of the progesterone with the mifepristone or the**
 10 **RU486 and then simply RU486.**
 11 Q. Okay. We can leave the
 12 ethanol to the side. But you would agree that
 13 at least some rats in the study were given
 14 mifepristone and some were given mifepristone
 15 plus progesterone, correct?
 16 **A. That's correct.**
 17 Q. Okay. The rats that were
 18 given mifepristone and progesterone were given
 19 both of those substances at the same time,
 20 correct?
 21 **A. Yes.**
 22 Q. And you don't cite in your
 23 declaration any animal studies addressing the
 24 administration of progesterone after
 25 mifepristone, correct?

1 **A. Correct.**
 2 Q. Do you think this study of
 3 simultaneous administration of mifepristone and
 4 progesterone in rats is a study about
 5 mifepristone reversal?
 6 **A. It's a study about the**
 7 **hindering of the intended effect of the**
 8 **mifepristone by the progesterone.**
 9 Q. So it's hindering, but it's
 10 not reversing in this case because it's
 11 happening at the same time?
 12 **A. Possibly.**
 13 Q. Do you know that the cover
 14 page to this article which you submitted with
 15 your declaration called it Yamabe reversal?
 16 **A. No.**
 17 Q. Would you choose a different
 18 word for that if you were submitting that cover
 19 page yourself?
 20 **A. I'm not sure.**
 21 Q. Well, I think you used a word
 22 other than reversal just a second ago, right?
 23 Counteracting?
 24 **A. Yes.**
 25 Q. This is not -- I mean, you --

1 I assume that you think the study is relevant to
 2 the subject we're talking about today, correct?
 3 **A. Correct.**
 4 Q. But it's not about reversal
 5 because it's happening -- because the
 6 mifepristone and progesterone are being
 7 administered simultaneously, correct?
 8 **A. That's a possibility.**
 9 Q. I think you agreed earlier
 10 that one reason for being cautious in
 11 extrapolating drug data from animals to humans
 12 is possible physiological differences between
 13 animals and humans. Does that sound right?
 14 **A. That's right.**
 15 Q. Do you think that such caution
 16 is warranted here with respect to the Yamabe
 17 study concerning rats?
 18 **A. It's all -- caution is**
 19 **always -- caution is always a virtue whenever**
 20 **you're looking at animal studies.**
 21 Q. So one should be cautious
 22 extrapolating data from rats to humans based on
 23 the possibility of a difference between rat and
 24 human physiology, correct?
 25 **A. Yes.**

1 MR. BECK: Can we introduce
 2 Tab J to the chat?
 3 BY MR. BECK:
 4 Q. Let me know when you have this
 5 one open, Doctor.
 6 MS. DAVIS: Andrew, was this
 7 previously offered as an exhibit? And if so,
 8 what number?
 9 MR. BECK: It has not
 10 previously been offered as an exhibit. We can
 11 mark this as Exhibit 31.
 12 (Whereupon, the document was
 13 marked as Exhibit No. 31 to the testimony of the
 14 witness.)
 15 BY MR. BECK:
 16 Q. Do you have it open, Doctor?
 17 **A. Still loading.**
 18 Q. Okay.
 19 **A. It's open.**
 20 Q. Okay. So what has been marked
 21 as Exhibit 31 is -- is a chapter by Baulieu,
 22 B-A-U-L-I-E-U, called "RU486: An Antiprogesterone
 23 Steroid with Contragestive Activity in Women."
 24 Have you seen this document
 25 before, Doctor?

1 **A. I believe I have.**
 2 Q. Okay. Can you turn to page 5?
 3 **A. I'm there.**
 4 Q. So do you see the -- the
 5 heading "Binding to Steroid Receptors" in the
 6 middle of the page?
 7 **A. Yes.**
 8 Q. Okay. The last sentence of
 9 the first paragraph under that states, "Among
 10 steroid receptors, progesterone receptors are
 11 those for which relative affinities of different
 12 ligands vary the most among species."
 13 Did I read that correctly?
 14 **A. Yes.**
 15 Q. Do you have any basis for
 16 disagreement with that statement?
 17 **A. No.**
 18 Q. Did you know about the wide
 19 difference -- differences in progesterone
 20 receptors among species when you included the
 21 discussion of animal studies in your
 22 declaration?
 23 **A. I did not. But I don't think**
 24 **it would have changed my general opinion.**
 25 Q. Why wouldn't it have changed

1 Q. The usual -- well, if the
 2 relative binding affinity of mifepristone to
 3 progesterone receptors in rats were
 4 substantially different than its binding
 5 affinity in humans, the regular caution wouldn't
 6 be enough, right?
 7 **A. I think the regular caution**
 8 **would encompass that sort of variability.**
 9 Q. So we should just be very
 10 cautious in extrapolating from rat data to human
 11 data, including with respect to the study by
 12 Yamabe at issue here, correct?
 13 **A. I would characterize it as**
 14 **cautious, not very cautious.**
 15 Q. Even if the receptors interact
 16 with mifepristone in a completely different way
 17 in rats than humans, you don't think serious
 18 caution is warranted?
 19 **A. If they -- if they interacted**
 20 **in a totally different way, for example, if the**
 21 **mifepristone bound irreversibly or if the**
 22 **mifepristone actually had a progesterone like**
 23 **effect, totally opposite of what happens in**
 24 **humans, then I would say we would have to be**
 25 **extremely cautious.**

1 your general opinion?
 2 **A. Because the three pillars are**
 3 **all consistent with one other, the biologic**
 4 **logic, the fact that mifepristone RU486 was**
 5 **developed as a medical abortion drug precisely**
 6 **because it binds to progesterone receptors, and**
 7 **that binding is reversible, and because the**
 8 **animal data are consistent with that, that its**
 9 **effects can be blocked by progesterone, and that**
 10 **that's consistent with the experience we've had**
 11 **in humans.**
 12 Q. But focus just on the animal
 13 data for the moment. We're going to turn to the
 14 human data in a second.
 15 If progesterone receptors are
 16 among the steroid receptors that vary most
 17 widely among species, we should be especially
 18 cautious in extrapolating about the impact of
 19 the drug on progesterone receptors in rats and
 20 drawing conclusions about humans, correct?
 21 **A. I don't agree with that**
 22 **assertion. I think that this is just consistent**
 23 **with my previous statement that we must be**
 24 **cautious extrapolating animal data to humans. I**
 25 **think the usual caution would be enough.**

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

1 **you are interested.**
 2 Q. And how does a case series
 3 different from a -- differ from a randomized
 4 control trial?
 5 **A. A case series looks at**
 6 **different cases that were collected that --**
 7 **where the treatment was not assigned in a**
 8 **randomized manner where patients and clinicians**
 9 **may have had a choice in what treatment was**
 10 **offered, while the randomized control trial**
 11 **would be where the -- there were a process that**
 12 **would assign a particular subject to receive a**
 13 **particular treatment based on a randomization**
 14 **process.**
 15 Q. Is a case series prospective
 16 or retrospective or both or neither?
 17 **A. It could be both.**
 18 Q. Let me read you a statement
 19 and you can tell me if you agree with it. "In
 20 the hierarchy of evidence, a case series would
 21 definitely fall below a case controlled study
 22 series, and also fall below a randomized
 23 controlled study. So in the hierarchy, it would
 24 be given less power."
 25 Do you agree with that

1 statement?
 2 **A. Yes.**
 3 Q. And how about this statement.
 4 "In a case series, there certainly is more
 5 possibility of bias than there is in a
 6 controlled trial. There is no doubt about
 7 that."
 8 Do you agree with that
 9 statement?
 10 **A. Yes.**
 11 Q. So good that you agree with
 12 those statements because they are your prior
 13 statements from the 2015 deposition.
 14 You also testified that a case
 15 series can suggest causation, but generally
 16 can't prove causation. Do you still agree with
 17 that statement?
 18 **A. Yes.**
 19 Q. And we discussed in the 2015
 20 deposition, while you don't agree with this,
 21 some doctors believe that in a case series no
 22 causal inferences should be made about the
 23 relationship between the treatment and the
 24 outcome, correct?
 25 **A. Correct.**

1 Q. But you disagree with that,
 2 correct?
 3 **A. Yes.**
 4 Q. And, instead, you think that
 5 very great care should be taken before making
 6 causal inferences from a case series, right?
 7 **A. That's correct.**
 8 Q. And you still believe that?
 9 **A. Yes.**
 10 Q. And you are drawing causal
 11 inferences from the case series here?
 12 **A. Yes.**
 13 Q. But you believe that because
 14 you've been taking very great care in drawing
 15 those inferences, it's acceptable to do so?
 16 **A. That's one of the reasons.**
 17 Q. What are the other reasons?
 18 **A. Another reason is that for**
 19 **women who want to stop or reverse their medical**
 20 **abortions, there is no other treatment**
 21 **available. And since all the evidence points to**
 22 **using progesterone to reverse the effects of**
 23 **mifepristone, it is safe and effective, that it**
 24 **is a reasonable conclusion to make and to offer**
 25 **it to women.**

1 Q. Correct me if I'm wrong, but
 2 that seems to be a reason to offer the
 3 treatment -- for you, for example, as a treating
 4 physician to offer that to a patient, but that
 5 would be different than as a methodological
 6 matter whether or not you can draw causal
 7 inferences from a study as a matter of medical
 8 inference. Am I correct?
 9 MS. DAVIS: Objection.
 10 THE WITNESS: I think you
 11 would be doing both at the same time because I
 12 would only offer it if I was inferring causal
 13 effect.
 14 BY MR. BECK:
 15 Q. Well, didn't you offer it
 16 before you could infer causal effect from your
 17 studies because you started doing it and that
 18 became the subject of your studies?
 19 **A. At that -- at the early**
 20 **junction there was a supposition of a causal**
 21 **effect based on the biologic logic, as well as**
 22 **animal studies and how progesterone acts in**
 23 **humans. With the accumulation of evidence over**
 24 **the years, now that causal inference can be**
 25 **stronger and not just a supposition.**

1 Q. So you think that with respect
 2 to a case series, you can draw causal inferences
 3 by building on other categories of evidence like
 4 animal studies and biologic logic?
 5 **A. Based on the case series, yes,
 6 and as well as the accumulated evidence besides
 7 that.**
 8 Q. Might scientists look at the
 9 methodology in and of itself and disagree with
 10 you?
 11 MS. DAVIS: Objection.
 12 THE WITNESS: They might.
 13 However, again, if there were randomized control
 14 trials concluding otherwise, then I would have a
 15 different conclusion. However, at this
 16 juncture, we have one randomized control trial
 17 that actually supports what we do.
 18 And so it would, therefore,
 19 be -- it would be logical to offer a safe and
 20 effective treatment when women are desiring to
 21 reverse their medical abortions.
 22 BY MR. BECK:
 23 Q. So we'll talk about the
 24 randomized control trial shortly. But you -- my
 25 question just a moment ago was, might scientists

1 look at the study design in and of itself and
 2 say that you have to look at that design and
 3 evaluate and -- let me start over.
 4 Scientists could look at the
 5 idea of a case series and conclude that you
 6 can't draw causal inferences from a case series,
 7 correct?
 8 **A. And I -- yes. I already
 9 answered they might.**
 10 Q. And would it be reasonable for
 11 a scientist to draw that conclusion?
 12 **A. Perhaps it would be.**
 13 MR. BECK: Okay. Can we mark
 14 tab -- sorry, can we introduce Tab K?
 15 BY MR. BECK:
 16 Q. And before we turn to Tab K.
 17 Is it your testimony that patients should be
 18 offered reversal irrespective of whether or not
 19 it works because it is essentially harmless and
 20 patients really are desperate for it?
 21 **A. No.**
 22 Q. You would want evidence
 23 showing that it had a causal effect to justify
 24 prescribing it, correct?
 25 MS. DAVIS: Objection.

1 THE WITNESS: I have evidence
 2 that it is effective.
 3 BY MR. BECK:
 4 Q. Right. But physicians should
 5 want evidence showing that it is effective
 6 before prescribing it, correct?
 7 **A. Yes.**
 8 Q. Okay. So let's turn to Tab K.
 9 Let me know when you have that downloaded.
 10 **A. It's open.**
 11 Q. Tab K, which we can mark as
 12 Exhibit 32.
 13 (Whereupon, the document was
 14 marked as Exhibit No. 32 to the testimony of the
 15 witness.)
 16 BY MR. BECK:
 17 Q. Is an excerpt of a publication
 18 by the National Academies of Science,
 19 Engineering, and Medicine called, "The Safety
 20 and Quality of Abortion Care in the United
 21 States."
 22 Have you seen this before?
 23 **A. I believe I've heard of it and
 24 read excerpts, but I've not seen the entire
 25 report.**

1 Q. Are you familiar with the
 2 National Academies of Science, Engineering, and
 3 Medicine?
 4 **A. Yes.**
 5 Q. What -- what is that -- what
 6 is the National Academies of Sciences,
 7 Engineering, and Medicine?
 8 **A. It's a national group of
 9 scientists, engineers, and physicians that seeks
 10 to establish standards, as well as to influence
 11 public opinion, public policy, and other aspects
 12 of our society.**
 13 Q. Do you think it's a reliable
 14 authority, generally speaking?
 15 **A. In some instances.**
 16 Q. But not in general?
 17 **A. In general, I would say it is
 18 a reliable body.**
 19 Q. Can we turn to page 54 of
 20 Exhibit 32, which is the National Academy's
 21 report? Let me know when you're there.
 22 **A. I'm there.**
 23 Q. Okay. So in the middle of
 24 that paragraph under reversal of medication
 25 abortion, it says, "Case series are descriptive

1 reports that are considered very low quality
 2 evidence for drawing conclusions about a
 3 treatment's effects."
 4 Did I read that correctly?
 5 **A. Yes.**
 6 Q. And so I know you disagree
 7 that this applies to your own case series, but
 8 as a general matter, is the National Academy
 9 correct to say case series are low quality
 10 evidence for drawing conclusions about the
 11 effects of a treatment?
 12 **A. I agree that they are**
 13 **considered low quality evidence, yes.**
 14 Q. Your 2018 case series was
 15 published in a journal called "Issues in Law &
 16 Medicine" --
 17 **A. Yes.**
 18 Q. -- is that correct?
 19 **A. Yes.**
 20 Q. And that same journal
 21 published your 2017 literature review article
 22 called, "Embryo Survival After Mifepristone: A
 23 Systematic Review of the Literature," correct?
 24 **A. Correct.**
 25 Q. Do you regard "Issues in Law &

1 Medicine" as a reliable authority?
 2 **A. Yes.**
 3 Q. Is it a widely read
 4 publication?
 5 **A. I think that's probably a**
 6 **relative term.**
 7 Q. Is it a popular journal in the
 8 medical field?
 9 **A. I would say amongst the**
 10 **general medical field it is not well known.**
 11 MR. BECK: Let's have Tab L
 12 introduced into the chat. We can mark as
 13 Exhibit 33.
 14 (Whereupon, the document was
 15 marked as Exhibit No. 33 to the testimony of the
 16 witness.)
 17 THE WITNESS: I would point
 18 out that in the exhibit you just have here, that
 19 same paragraph they cite Grossman's study of
 20 2015, which we have shown to be a totally
 21 inadequate review of survival of embryos. So
 22 that, in my mind, makes this whole safety and
 23 quality of abortion care in the United States a
 24 biased and suspect opinion piece.
 25 BY MR. BECK:

1 Q. Citing Grossman makes this
 2 piece biased and what -- and what was the other
 3 word you used?
 4 **A. Makes it a biased opinion**
 5 **piece, essentially.**
 6 Q. Simply because it cited
 7 Dr. Grossman's article?
 8 **A. Well, that's one -- that's one**
 9 **of the -- one of the evidences of bias in this**
 10 **piece.**
 11 Q. So your opinion is that
 12 because the National Academy cited an article by
 13 Dr. Grossman, it is biased and that that renders
 14 the entire discussion in that document biased
 15 and suspect?
 16 **A. It certainly renders that**
 17 **paragraph quite suspect, absolutely.**
 18 Q. Why?
 19 **A. Because the Grossman article**
 20 **had several deficiencies.**
 21 Q. And so citation of an article
 22 with deficiencies demonstrates bias?
 23 **A. Well, it does when they cite**
 24 **it to support their -- their point, which is a**
 25 **point that is not supported by an unbiased look**

1 **at the literature and the evidence.**
 2 Q. Are your articles free from
 3 deficiencies?
 4 **A. No article is free of**
 5 **deficiencies.**
 6 Q. Including yours and including
 7 Dr. Grossman's, correct?
 8 **A. Including all articles ever**
 9 **published.**
 10 Q. So how could citation of
 11 Dr. Grossman's article be demonstrative of bias
 12 simply because it contains deficiencies?
 13 **A. Because Dr. Grossman's article**
 14 **is not just simply biased. It draws erroneous**
 15 **conclusions, does not include very pertinent**
 16 **studies, makes erroneous conclusions about the**
 17 **studies that were included, includes studies**
 18 **that were not support -- that do not support**
 19 **what he claims to -- to -- to support.**
 20 Q. And that collection of traits
 21 demonstrates that the National Academy is biased
 22 for having cited Grossman?
 23 **A. Yes, it does. Especially in**
 24 **that paragraph on reversal of medication**
 25 **abortion.**

1 Q. Okay. Do you have Tab L open?
 2 **A. It's downloading.**
 3 Q. Let me know when it's open.
 4 **A. Okay. It's open.**
 5 Q. So Exhibit 33 is the spring
 6 2018 issue of "Issues in Law & Medicine" in
 7 which your case series was published. Have you
 8 seen it before?
 9 **A. Yes.**
 10 Q. Okay. At the bottom of the
 11 first page it says, "A publication of the Watson
 12 Bowes Research Institute and the National
 13 Center -- I'm sorry, the National Legal Center
 14 for the Medically Dependent and Disabled, Inc."
 15 Did I read that correctly?
 16 **A. Yes.**
 17 Q. Okay. Are you familiar with
 18 the Watson Bowes Research Institute?
 19 **A. Yes.**
 20 Q. Have you ever applied for a
 21 grant with the Watson Bowes Research Institute?
 22 **A. Not as -- not as a lead**
 23 **researcher, no.**
 24 Q. Have you applied for a grant
 25 from the Watson Bowes Research Institute in

1 something other than a lead researcher role?
 2 **A. Yes.**
 3 Q. Can you tell me the
 4 circumstances there?
 5 **A. It was an application for an**
 6 **abortion pill reversal study.**
 7 Q. And when was that application
 8 submitted?
 9 **A. I believe earlier this year.**
 10 Q. And who submitted it?
 11 **A. Dr. Joseph Stanford.**
 12 Q. Stanford?
 13 **A. Yes.**
 14 Q. Is Joseph Stanford the lead
 15 author -- or the lead investigator on this
 16 proposed study?
 17 **A. Yes.**
 18 Q. And you are anticipating
 19 collaborating with Mr. -- Dr. Stanford?
 20 **A. Yes.**
 21 Q. What's the APR study? What --
 22 what -- what are you anticipating or proposing
 23 to study?
 24 **A. What am I proposing?**
 25 Q. Yeah. What -- what is the --

1 so Dr. Stanford submitted an application for
 2 research -- I'm sorry, for funding to conduct an
 3 APR study earlier this year. What are the
 4 details of that study?
 5 **A. The -- the proposal is for a**
 6 **randomized control trial of progesterone**
 7 **reversal of mifepristone abortion.**
 8 Q. And what -- what are the --
 9 what are the groups that are going to be
 10 randomized under this proposal?
 11 **A. Under the proposal, there will**
 12 **be a group randomized to receive oral**
 13 **progesterone and another group to receive**
 14 **vaginal progesterone.**
 15 Q. Those are the two arms of the
 16 study?
 17 **A. Yes.**
 18 Q. Would there be a placebo
 19 studying the effect of no progesterone?
 20 **A. No.**
 21 Q. And there wouldn't be an
 22 intramuscular injection arm of the study?
 23 **A. No.**
 24 Q. Why not?
 25 **A. Because in our previous**

1 **research, the high dose oral protocol was as or**
 2 **more effective than the intramuscular injection**
 3 **protocol, and shots hurt more than pills.**
 4 Q. But wasn't -- weren't the
 5 injections more effective than the vaginal route
 6 of administration?
 7 **A. That's correct.**
 8 Q. So why wouldn't you compare
 9 the two most effective or the two -- why
 10 wouldn't you compare two more effective routes
 11 of administration rather than sort of skipping
 12 the -- the second most effective route?
 13 **A. Because the vaginal**
 14 **progesterone group in -- in our previous study**
 15 **was very heterogenous, people taking different**
 16 **doses, low doses.**
 17 **And so with -- since there was**
 18 **evidence from broader research that vaginal**
 19 **progesterone meets the higher uterine levels of**
 20 **progesterone, we felt it was very important to**
 21 **study that to make sure that we -- we knew if**
 22 **that were effective. So we needed more**
 23 **information on the vaginal -- or we need more**
 24 **information on the vaginal, I should say.**
 25 Q. So would it be correct to say

1 that you have a hypothesis that the low reversal
 2 rate for vaginal administration in your 2018
 3 case series stemmed, in part, from the
 4 heterogenous nature of the administration there?
 5 **A. Yes.**
 6 Q. And talk more about the
 7 heterogenous nature of the administration. What
 8 did you say were the -- sort of the array of
 9 factors that made it nonuniform?
 10 **A. Varying doses, varying**
 11 **durations of the -- of the progesterone, varying**
 12 **forms of the progesterone.**
 13 Q. And so the fact that there was
 14 an array of doses, forms of progesterone, means
 15 that you need to study it more now?
 16 **A. Of the vaginal progesterone,**
 17 **that's correct.**
 18 Q. Yeah. Do you think that your
 19 data when it comes to vaginal progesterone, at
 20 least with respect to the 2018 case series, is
 21 less solid than the data with respect to other
 22 routes of administration or do you think -- do
 23 you have concerns about heterogeneity with
 24 respect to all routes of administration?
 25 MS. DAVIS: Objection.

1 THE WITNESS: My concern with
 2 heterogeneity is with the vaginal progesterone.
 3 BY MR. BECK:
 4 Q. Does that mean that your
 5 ability to draw conclusions from the 2018 case
 6 series at least -- at least with respect to
 7 vaginal progesterone, is lower than your ability
 8 to draw conclusions from the other routes of
 9 administration?
 10 **A. Yes.**
 11 Q. Dr. Stanford submitted this
 12 proposal to the Watson Bowes Research Institute
 13 earlier this year; is that correct?
 14 **A. That was earlier this year.**
 15 Q. And you are someone who would
 16 work on the study with Dr. Stanford?
 17 **A. Yes.**
 18 Q. Who are the other
 19 co-investigators, if any?
 20 **A. I don't know their names at**
 21 **this point.**
 22 Q. Because you haven't identified
 23 your co-investigators or you -- they -- they
 24 exist, but you don't know who they are?
 25 **A. I don't think -- well, I'm not**

1 **sure if Dr. Stanford has identified all the**
 2 **co-investigators.**
 3 Q. Do you have concerns about the
 4 ethics of prescribing less effective routes of
 5 progesterone, such as the vaginal route, for
 6 people who are trying to save their pregnancies?
 7 **A. I have concerns, but those**
 8 **concerns are tempered by the previous literature**
 9 **showing that vaginal progesterone leads to**
 10 **increased intrauterine levels of progesterone.**
 11 **Vaginal progesterone is often**
 12 **avored by physicians who use progesterone for**
 13 **other reasons, such as for treatment of -- or**
 14 **for prevention of miscarriage in women who have**
 15 **conceived by virtue of invitro fertilization.**
 16 **So because of these well**
 17 **standing preferences for vaginal progesterone, I**
 18 **think it would be safe to offer that as a**
 19 **treatment arm in a very carefully controlled**
 20 **trial that will have safety monitoring so that**
 21 **if there's any indication that the vaginal is**
 22 **significantly inferior, then that arm of the**
 23 **study could be terminated early.**
 24 Q. Have you already started
 25 considering terminating it early if it's shown

1 to be less effective?
 2 **A. Well, the study has not been**
 3 **launched, but we've discussed it. You know, we**
 4 **would have safety monitoring. And that's --**
 5 **that's the reason for having safety monitoring**
 6 **is to terminate the study early if -- especially**
 7 **if one arm is significantly better than the**
 8 **other arm.**
 9 Q. Correct me if I'm wrong, but
 10 that sounds like efficacy monitoring, not safety
 11 monitoring? I would think that the safety
 12 monitoring would be if one route shows a huge
 13 number of side effects that you don't
 14 anticipate, whereas, efficacy is we know that --
 15 or at least from study, it indicates that one
 16 arm is likely to be more effective than another?
 17 MS. DAVIS: Objection.
 18 THE WITNESS: The -- the
 19 monitoring -- you're -- you're correct. The
 20 monitoring actually monitors both safety and
 21 efficacy at the same time. So any study of this
 22 sort could be terminated early if there were
 23 signals that there were significant adverse
 24 effects.
 25 Also, it could be terminated

1 early if there's significant difference between
 2 two of the arms, and one was significantly
 3 inferior.
 4 BY MR. BECK:
 5 Q. Do you plan to terminate the
 6 study early if the vaginal route of
 7 administration is yielding less effective
 8 results?
 9 **A. We plan to terminate early**
 10 **if -- if it's significant following all of**
 11 **the -- the directions that will be given by the**
 12 **institution review board monitoring the ethics**
 13 **of the study, yes.**
 14 Q. Do you already have an IRB
 15 engaged?
 16 **A. Yes.**
 17 Q. What -- what IRB is engaged?
 18 **A. The IRB of the University of**
 19 **Utah.**
 20 Q. Did you submit a written study
 21 proposal to the IRB of University of Utah?
 22 **A. I did not personally, no.**
 23 Q. Did someone else?
 24 **A. Yes.**
 25 Q. Who?

1 **A. Dr. Stanford.**
 2 Q. Okay. Is Dr. Stanford
 3 affiliated with the University of Utah?
 4 **A. Yes.**
 5 Q. And is he in the OB/GYN
 6 department there?
 7 **A. He's in the office of -- I**
 8 **believe it's called the office of reproductive**
 9 **health.**
 10 Q. Have you seen a copy of the
 11 IRB application?
 12 **A. I believe so.**
 13 Q. And do you have a copy of that
 14 in your computer files somewhere?
 15 **A. I don't recall.**
 16 Q. But you might?
 17 **A. I might.**
 18 Q. Okay. How much was the grant
 19 you sought or Dr. Stanford sought from the
 20 Watson Bowes Research Institute for this study?
 21 **A. I'd have to review my records.**
 22 Q. Was it more than \$10,000?
 23 **A. Yes.**
 24 Q. Was it more than \$50,000?
 25 **A. Yes.**

1 Q. Was it more than \$100,000?
 2 **A. Yes.**
 3 Q. Was it more than \$500,000?
 4 **A. I don't recall.**
 5 Q. Could it have been more than
 6 500,000?
 7 **A. It's possible.**
 8 Q. Is that just because
 9 conducting a study is really expensive?
 10 **A. Yes.**
 11 Q. And this application was
 12 submitted. Has there been any action from
 13 Watson Bowes Research Institute on this
 14 application?
 15 **A. The grant has been partially**
 16 **funded.**
 17 Q. What -- what does that mean?
 18 How much has it been partially funded?
 19 **A. I'd have to check my records.**
 20 Q. Was it 50 percent?
 21 **A. Less than 50 percent.**
 22 Q. 25 percent?
 23 **A. Perhaps.**
 24 Q. Did you get a grant of more
 25 than \$200,000?

1 **A. The grant award, I -- I'm not**
 2 **sure.**
 3 Q. Possible that it could have
 4 been in the \$200,000 range?
 5 **A. It's possible.**
 6 Q. Okay. Apart from this
 7 application from Dr. Stanford earlier this year,
 8 have you ever applied for any other grants from
 9 the Watson Bowes Research Institute?
 10 **A. No.**
 11 Q. Would you agree with me that
 12 the Watson Bowes Research Institute funds
 13 pro-life research?
 14 **A. Yes.**
 15 Q. If we can look back at Exhibit
 16 33, which is the "Issues in Law & Medicine"
 17 issue in which your case series was published.
 18 If we turn to the second page, tell me when
 19 you're there.
 20 **A. I'm there.**
 21 Q. Okay. So this is something
 22 like a mast head for the publication, correct?
 23 **A. Yes.**
 24 Q. And it lists Barry A. Bostrom
 25 as editor-in-chief, correct?

1 **A. Yes.**
 2 Q. Do you know Barry Bostrom?
 3 **A. Yes.**
 4 Q. How do you know him?
 5 **A. I've -- I don't recall if I've**
 6 **met him in person or have simply talked to him**
 7 **on the phone or via email.**
 8 Q. Have you had just from a stray
 9 interaction with him, or have you had sustained
 10 interaction with him?
 11 **A. Well, I had sustained**
 12 **interactions when we were submitting our article**
 13 **for publication. So it was the usual kind of**
 14 **back and forth. And he would email me different**
 15 **reviewers' comments and that sort of thing that**
 16 **happens when you -- you submit an article for**
 17 **publication to a peer reviewed journal.**
 18 Q. And so is that the -- the
 19 universe of your communication with Barry
 20 Bostrom, this sort of email back and forth
 21 around your publication?
 22 **A. There may have been other**
 23 **communications regarding the journal in general.**
 24 Q. Do you still have copies of
 25 that correspondence?

1 Q. Are you familiar with the
 2 National Right to Life political action
 3 committee?
 4 **A. Yes.**
 5 Q. If he had been counsel to that
 6 organization, would it be a fair supposition
 7 that he is an advocate for pro-life causes?
 8 **A. That would be a fair**
 9 **supposition.**
 10 Q. And then the other editorial
 11 role is associate Donna Harrison, MD, correct?
 12 **A. That's correct.**
 13 Q. And you know Dr. Harrison?
 14 **A. Yes.**
 15 Q. How do you know her?
 16 **A. I've known her through the**
 17 **American Association of Pro-Life OB/GYNs.**
 18 Q. And you both serve on the
 19 board of that organization, correct?
 20 **A. That's correct.**
 21 Q. And she's the executive
 22 director of that organization?
 23 **A. Yes.**
 24 Q. And she's a witness with you
 25 in this case?

1 **A. The correspondence with --**
 2 **regarding the journal article?**
 3 Q. Yeah.
 4 **A. I don't recall.**
 5 Q. Okay. Would it be in email
 6 folders if you did?
 7 **A. If I did, it probably would be**
 8 **there.**
 9 Q. Okay. Is it fair to say that
 10 Barry Bostrom is an advocate for pro-life
 11 causes?
 12 **A. I -- I don't know him well**
 13 **enough to -- to make that assertion.**
 14 Q. Are you aware -- Barry Bostrom
 15 is a lawyer, right?
 16 **A. I believe so.**
 17 Q. Are you aware of his work on
 18 behalf of pro-life legal organizations?
 19 **A. I think he has an association**
 20 **with the National Legal Center for the Medically**
 21 **Dependent and Disabled.**
 22 Q. Are you aware that he
 23 previously served as counsel for the National
 24 Right to Life political action committee?
 25 **A. No.**

1 **A. I believe she is.**
 2 Q. To your knowledge, has she
 3 ever provided medication abortion reversal
 4 treatment?
 5 **A. I don't know.**
 6 Q. Did she treat any of the
 7 reversal patients in your 2018 case series?
 8 **A. I don't believe so.**
 9 Q. So between Barry Bostrom and
 10 Dr. Harrison, the two editorial roles listed on
 11 the mast head are filled by a lawyer for the
 12 National Right to Life political action
 13 committee or someone who's at least previously
 14 served in that role, and the executive director
 15 of the American Association of Pro-Life
 16 Obstetricians and Gynecologists, correct?
 17 **A. That's correct.**
 18 Q. And so is it a fair summary to
 19 say that the journal is edited by people who are
 20 active in the pro-life movement?
 21 **A. Just like you could say that**
 22 **the Journal of Contraception is edited by people**
 23 **who are active in the abortion movement.**
 24 Q. So that's a roundabout way of
 25 saying, yes, it is fair to say that the journal

1 is edited by people who are active in the
 2 pro-life movement?
 3 **A. That's correct.**
 4 Q. And one of the editors is an
 5 expert witness with you in this case?
 6 **A. I believe she is.**
 7 Q. And then below the editorial
 8 staff on the mast head is a list of 18 referees,
 9 correct?
 10 **A. I haven't counted them, but it**
 11 **looks like about 18.**
 12 Q. Yeah. And I understand --
 13 it's my understanding that referees are the
 14 folks who are responsible for a publication's
 15 peer review. Does that sound correct to you?
 16 **A. Yes.**
 17 Q. Do you know any of the
 18 referees listed here?
 19 **A. I do.**
 20 Q. How many do you know? Or if
 21 it's easier, how many do you not know?
 22 **A. Let's see. I know five.**
 23 Q. Which five?
 24 **A. Byron Calhoun, Monique**
 25 **Chireau, Priscilla Coleman, Michelle Cretella,**

1 reviewers were?
 2 **A. No.**
 3 Q. Okay. But those five would
 4 know that you are sort of the leading author
 5 when it comes to abortion pill reversal studies,
 6 correct?
 7 **A. I would assume so.**
 8 Q. Are any of those five people
 9 that you know in the Abortion Pill Rescue
 10 Network?
 11 **A. I know that some of them**
 12 **aren't and I don't know if any of them are.**
 13 Q. So you don't know whether any
 14 of them have provided abortion pill reversal
 15 treatment?
 16 **A. No, I do not.**
 17 Q. Okay. Let's turn to the table
 18 of contents. And I'm mindful of the time for
 19 folks on the east coast. I probably have
 20 another five or ten minutes here and then we can
 21 talk about breaking for lunch.
 22 But if we turn to the table of
 23 contents here, which is page -- the fourth page
 24 of the PDF of Exhibit 33. Are you there?
 25 **A. Yes.**

1 **Martin McCaffrey.**
 2 Q. And how do you -- do you know
 3 them all in the same way or do you know each of
 4 those through different routes?
 5 **A. I would say more or less in**
 6 **the same way.**
 7 Q. Which is?
 8 **A. Which is through the American**
 9 **Association of Pro-Life OB/GYNs and their**
 10 **conferences that they hold.**
 11 Q. So the five people you listed
 12 attend -- can we call it AAPLOG? Will -- will
 13 you understand the abbreviation AAPLOG?
 14 **A. Yes.**
 15 Q. And so the five people you
 16 named you have interacted with AAPLOG
 17 conferences; is that correct?
 18 **A. That's correct.**
 19 Q. Okay. Do you know whether any
 20 of them -- any of the people that you know were
 21 peer reviewers for any of your publications at
 22 "Issues in Law & Medicine"?
 23 **A. No. That's not disclosed to**
 24 **the authors.**
 25 Q. You -- you don't know who your

1 Q. So this lists one, two, three,
 2 four, five, six items in the table of contents,
 3 correct?
 4 **A. Correct.**
 5 Q. And there are four items under
 6 "Articles" and two under "Verbatim," right?
 7 **A. That's correct.**
 8 Q. What's the second item listed
 9 under Verbatim in the table of contents? Can
 10 you read that aloud?
 11 **A. "Amicus curiae brief of the**
 12 **American Association of Pro-Life Obstetricians**
 13 **and Gynecologists in Karungi vs. Ejalu,**
 14 **parenthesis, Michigan Court of Appeals 2017,**
 15 **close parenthesis. The Thomas More Society and**
 16 **Rita Lowery Gitchell, comma, Special Counsel."**
 17 Q. So the issue of the journal in
 18 which your 2018 case series was published also
 19 included the text of a legal brief of the
 20 American Association of Pro-Life Obstetricians
 21 and Gynecologists?
 22 **A. That's correct.**
 23 Q. And that is a pro-life
 24 organization, correct?
 25 **A. That's correct.**

1 Q. And you serve on its board?
 2 **A. That's correct.**
 3 Q. Have you seen pro-life legal
 4 briefs published in past issues of "Issues in
 5 Law & Medicine"?

6 **A. I don't recall.**
 7 Q. In your experience, is it
 8 common for peer reviewed medical journals to
 9 publish copies of legal briefs alongside
 10 scientific papers?

11 **A. No. But I would note that the
 12 title of the journal is "Issues in Law &
 13 Medicine." So this is a unique journal in that
 14 it has both.**

15 Q. Have you ever seen any other
 16 peer reviewed medical journals publish copies of
 17 legal briefs alongside scientific papers?

18 **A. I don't believe so.**
 19 Q. Would you agree with the
 20 characterization that "Issues in Law & Medicine"
 21 is a journal with a pro-life policy focus?

22 **A. I think policy -- I would say
 23 no.**
 24 Q. What -- what aspect of that is
 25 something you disagree with?

1 **A. I think the policy focus --
 2 policy has a certain connotation. And I don't
 3 necessarily think that the focus is on policy.**
 4 Q. Do you agree that it has a --
 5 that "Issues in Law & Medicine" has a pro-life
 6 focus?

7 **A. Yes.**
 8 Q. And why do you think that it
 9 doesn't have a focus on policy if it includes,
 10 as you said, I mean, it concerns both law and
 11 medicine from a pro-life perspective, and it
 12 includes legal briefs. What aspect of saying
 13 that it has a policy focus is unfair?

14 **A. Well, if you look at two of
 15 the articles here, our article and the induced
 16 abortions and the risk factor for breast cancer,
 17 those are not policy papers. Those are medical
 18 scientific papers. So I think -- I think they
 19 have a variety of -- of different pro-life foci.**
 20 Q. One of those pro-life foci
 21 would be medicine and another would be policy.
 22 Is it fair to say that it includes a focus on
 23 pro-life policy?

24 **A. I don't think I know the
 25 journal well enough to give that opinion.**

1 Q. Did you -- did I ask you
 2 already, do you subscribe to this journal?

3 **A. I do.**
 4 Q. And do you read it regularly?
 5 **A. I read it -- I don't read the
 6 entire journal regularly.**
 7 Q. How many medical journals do
 8 you subscribe to?

9 **A. Probably three. That's the
 10 ones that come in paper. But I receive lots of
 11 things online that I read.**
 12 Q. What are the other two?
 13 **A. "Journal of the American
 14 Medical Association." And I get "New England
 15 Journal of Medicine" online. And Linacre
 16 Journal.**
 17 Q. What was the last one?
 18 **A. Linacre.**
 19 Q. Linacre.
 20 **A. I also receive American Family
 21 Physician online, Journal of Family Practice I
 22 believe comes online, and maybe a couple of
 23 others.**
 24 Q. Before the --
 25 **A. Actually, pardon me. I'm**

1 **sorry. I don't know if you want me to be
 2 exclusive. But then there's -- I think there's
 3 Journal of Palliative Care that comes to me. So
 4 if I -- the longer I think about it, the more --
 5 the more extensive the list could become.**
 6 Q. So more than just a few
 7 journals?

8 **A. Yes.**
 9 Q. Before the -- so you published
 10 two articles in "Issues in Law & Medicine," a
 11 2017 literature review and a 2018 case series;
 12 is that correct?

13 **A. That's correct.**
 14 Q. Before the 2017 literature
 15 review was submitted, did you communicate in any
 16 way with anyone affiliated with "Issues in Law &
 17 Medicine" about that article?

18 **A. No.**
 19 Q. Did Dr. Davenport?
 20 **A. I suppose she inquired on how
 21 to submit the article for publication.**
 22 Q. But you're not aware of any
 23 other communications between Dr. Davenport and
 24 anyone at "Issues in Law & Medicine" prior to
 25 the publication?

1 **A. No.**
 2 Q. Okay. Same question for the
 3 2018 case series. Before that was published,
 4 did you -- or before it was submitted, did you
 5 communicate in any way with anyone affiliated
 6 with the journal about that article?
 7 **A. I don't recall a specific**
 8 **communication, but I -- I think I can reasonably**
 9 **assume that I reached out to -- before starting**
 10 **the formal submission process, I reached out to**
 11 **see if this might be an article that might**
 12 **interest them.**
 13 Q. Who would you have reached out
 14 to?
 15 **A. I believe to Donna Harrison.**
 16 Q. And she encouraged you to
 17 submit the article?
 18 **A. I believe she did.**
 19 Q. Was that communication via
 20 email? Do you recall?
 21 **A. I don't recall.**
 22 Q. Might it have been via email?
 23 **A. It might have.**
 24 Q. Was "Issues in Law & Medicine"
 25 your first choice for publishing your 2018 case

1 series?
 2 **A. No.**
 3 Q. Where else did you submit a
 4 manuscript?
 5 **A. I submitted to Journal of**
 6 **Emergency Medicine, I believe, and to American**
 7 **Journal of Emergency Medicine, and I think I**
 8 **submitted to the Journal of Family Practice.**
 9 Q. And what kind of input did you
 10 get from those publications?
 11 **A. What -- I'm sorry, I didn't**
 12 **hear the question.**
 13 Q. What kind of input did you get
 14 from those publications in response to your
 15 submission?
 16 **A. The emergency medicine**
 17 **journals indicated -- at least one of them**
 18 **indicated that they did not feel that this was**
 19 **suitable for their -- for their journal. The**
 20 **American Family Physician indicated that they**
 21 **only publish review articles. And I don't**
 22 **recall other -- other comments as far as what**
 23 **they felt about it.**
 24 Q. When you said you were told
 25 that they said it was not suitable -- did -- did

1 I get that word right? Did you say it wasn't
 2 suitable for the publication?
 3 **A. Yes.**
 4 Q. What does that mean?
 5 **A. Yes. They did not feel it was**
 6 **within their scope of -- of what they usually**
 7 **cover.**
 8 Q. Because it didn't deal with
 9 emergency medicine?
 10 **A. It -- because a large number**
 11 **of the patients studied were not seen in**
 12 **emergency departments.**
 13 Q. Was that the only reason they
 14 offered you?
 15 **A. I believe so.**
 16 MR. BECK: Let's go off the
 17 record and take a lunch break for folks on the
 18 east coast.
 19 VIDEOGRAPHER: Off the record
 20 at 12:06.
 21 (A recess was taken.)
 22 VIDEOGRAPHER: We are back on
 23 the record at 12:38.
 24 BY MR. BECK:
 25 Q. Good morning, Doctor.

1 **A. Good morning.**
 2 Q. Morning for you, afternoon for
 3 us. Did you have any correspondence or contact
 4 with attorneys for Tennessee during the break?
 5 **A. No.**
 6 Q. Just a quick follow-up on your
 7 submission of your 2018 case series to different
 8 journals prior to "Issues in Law & Medicine."
 9 Did you submit it to the "Journal of the
 10 American Medical Association"?
 11 **A. No.**
 12 Q. Why not?
 13 **A. I didn't think it would get**
 14 **published there.**
 15 Q. Why?
 16 **A. Because it's a very broad**
 17 **based journal that usually publishes articles**
 18 **from authors that are well known to them. And**
 19 **so since I'm not well known to them, I didn't**
 20 **think it would be worthwhile spending the time**
 21 **submitting there.**
 22 Q. What about the "New England
 23 Journal of Medicine," did you submit it there?
 24 **A. No.**
 25 Q. Similar reasons as to why not?

1 **A. Yes.**
 2 Q. Had you heard about -- I know
 3 that you said that you didn't know about the law
 4 that we're discussing in this case before you
 5 were contacted by attorneys from the Tennessee
 6 attorney general's office; is that correct?
 7 **A. That's correct.**
 8 Q. Had you heard about proposed
 9 legislation that would become this law in
 10 Tennessee prior to that point?
 11 **A. Not that I'm aware. Not that**
 12 **I recall.**
 13 Q. So let's see. Let's pull up
 14 Tab F, Exhibit 7, which is your case series,
 15 which you should have somewhere accessible. Let
 16 me know when you have that.
 17 **A. I have it.**
 18 Q. Okay. Great. Turn to page
 19 24, please.
 20 **A. I'm there.**
 21 Q. Okay. So the last sentence on
 22 this page continuing onto the next page reads,
 23 "This study is designed to ascertain which
 24 progesterone treatments clinicians have offered
 25 to women seeking mifepristone reversal that

1 demonstrate efficacy beyond the 25 percent
 2 embryo survival rate and compares the
 3 relatively -- relative efficacies of different
 4 treatment protocols to the historical control."
 5 So the -- the 25 percent
 6 embryo survival statistic, that's used as a
 7 historical control for your case series; is that
 8 correct?
 9 **A. Yes.**
 10 MS. DAVIS: Objection.
 11 BY MR. BECK:
 12 Q. And let's see. Page 24.
 13 Earlier in that paragraph it says, "We selected
 14 a 25 percent embryo or fetus survival rate if
 15 mifepristone alone is administered as a control
 16 because it is at the upper range of mifepristone
 17 survival rates and close to the 23 percent
 18 survival rate of the one early study that used a
 19 single 200 milligram dose, the dose currently
 20 favored for medical abortions."
 21 Is it fair to say that 25
 22 percent is a ballpark figure?
 23 **A. Yes.**
 24 Q. Great. Let's introduce a new
 25 tab, which is Tab O, previously marked as

1 Exhibit 11. Let me know when you have that
 2 open.
 3 **A. It's open.**
 4 Q. Okay. So this a document
 5 called "Guidance for Industry: E10 Choice of
 6 Control Group and Related Issues in Clinical
 7 Trials," issued by the U.S. Department of Health
 8 and Human Services Food and Drug Administration.
 9 Are you familiar with these guidelines?
 10 **A. No.**
 11 Q. Have you seen this document
 12 before?
 13 **A. No.**
 14 Q. Okay. Do you consider the FDA
 15 to be a reliable authority?
 16 **A. For the most part, yes.**
 17 Q. Okay. Let's turn to page 6.
 18 **A. So 6 on the thumbnails is**
 19 **labeled as 2 on the actual document. Is that**
 20 **where you want me?**
 21 Q. Sorry, 6 at the bottom of the
 22 page, which is 10 of the PDF. So page 6 in this
 23 document's internal numbering.
 24 **A. Okay. I have it.**
 25 Q. Are you there?

1 **A. Yes.**
 2 Q. And this is a -- it has 4, 5,
 3 and 6 as headings throughout the page. Do you
 4 see that?
 5 **A. Yes.**
 6 Q. Okay. Great. Can you read
 7 the first sentence under heading 5 aloud?
 8 **A. "An externally controlled**
 9 **trial compares a group of subjects receiving the**
 10 **best treatment with a group of patients eternal**
 11 **to the study rather than to an internal control**
 12 **group consisting of patients from the same**
 13 **population assigned to a different treatment."**
 14 Q. And I might have misheard you,
 15 but I think you said best treatment, not test
 16 treatment, right? Receiving the test treatment.
 17 I might have misheard you. But the -- it says,
 18 "receiving the test treatment," right, in the
 19 first sentence?
 20 **A. Yes. Receiving the test**
 21 **treatment.**
 22 Q. And then can you read the next
 23 sentence, please?
 24 **A. "The external control can be a**
 25 **group of patients treated at a earlier time,**

1 **parenthesis, historical control, close**
 2 **parenthesis, or a group treated during the same**
 3 **time period, but in another setting."**
 4 Q. Would you say that what you've
 5 just read is an accurate definition of a
 6 historical control?
 7 **A. Well, I think it's an accurate**
 8 **definition of an external control.**
 9 Q. And then the sort of
 10 subpart with -- do you agree that a historical
 11 control is a type of external control?
 12 **A. Yes.**
 13 Q. And so the part of that that's
 14 referencing historical control, do you agree
 15 with that as a definition of a historical
 16 control?
 17 **A. Yes.**
 18 MS. DAVIS: Objection.
 19 BY MR. BECK:
 20 Q. Okay. And historical control,
 21 again, is the type of control utilized in your
 22 2018 study?
 23 **A. Yes.**
 24 Q. Okay. Turn to page 4, please.
 25 **A. I'm there.**

1 Q. And would you read the last
 2 four sentences on that page, beginning with the
 3 words "This document"?
 4 **A. "This document categorizes**
 5 **control groups into five types. The first four**
 6 **are concurrently controlled, parenthesis, the**
 7 **control group and test group are chosen from the**
 8 **same population and treated concurrently, close**
 9 **parenthesis, usually with random assignment to**
 10 **treatment. They are distinguished by the type**
 11 **of control treatment, parenthesis, listed above,**
 12 **close parenthesis, used. External, parenthesis,**
 13 **historical, close parenthesis, control groups**
 14 **regardless of the comparative treatment are**
 15 **considered together as the fifth type because of**
 16 **serious concerns about the ability of such**
 17 **trials to ensure comparability of tests and**
 18 **control groups, and their ability to minimize**
 19 **important biases, making this design useable**
 20 **only in unusual circumstances."**
 21 Q. Thank you. Excuse me. Thank
 22 you. So I'd like to focus on the last sentence
 23 that you just read.
 24 And my first question is, do
 25 you agree that, in general, there are serious

1 concerns about the ability of studies with
 2 historical controls to ensure comparability of
 3 the test group and the control group?
 4 **A. In general, yes.**
 5 Q. Is the FDA correct that, in
 6 general, there are serious concerns about
 7 historical controls ability to minimize
 8 important biases?
 9 **A. Yes.**
 10 Q. And is the FDA correct that,
 11 in general, a historical control group design is
 12 useable only in unusual circumstances?
 13 **A. That's correct. Such as our**
 14 **circumstances.**
 15 Q. The subject of randomized
 16 control trials came up earlier. Can you just
 17 again define the term "randomized control trial"
 18 for me?
 19 MS. DAVIS: Objection.
 20 THE WITNESS: Randomized
 21 control trial is the study where the subjects do
 22 not get to choose what treatment they will
 23 receive, rather they are assigned to particular
 24 treatment groups using some sort of
 25 randomization protocol.

1 BY MR. BECK:
 2 Q. Let's look at page 3 of the
 3 FDA guidance that we're looking at. So the --
 4 are you there?
 5 **A. Yes.**
 6 Q. The first sentence under
 7 heading one states, "Assurance that subject
 8 populations are similar in test and control
 9 groups is best attained by randomly dividing a
 10 single sample population into groups that
 11 receive the test or control treatments.
 12 Randomization avoids systematic differences
 13 between groups with respect to known or unknown
 14 baseline variables that could affect outcome."
 15 In general, do you agree with
 16 the FDA's statement that I just read?
 17 **A. Yes.**
 18 MR. BECK: Okay. Can we
 19 introduce Tab P, please, which is -- has
 20 previously been marked as Plaintiff's Exhibit
 21 15?
 22 MS. DAVIS: Andrew, did you
 23 say 15 or 50?
 24 MR. BECK: 1-5, 15.
 25 BY MR. BECK:

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

1 larger dose; is that correct?
 2 **A. That's correct.**
 3 Q. And patients who take
 4 mifepristone at a later gestational age are more
 5 likely to have a continuing pregnancy than those
 6 who take mifepristone at earlier gestations,
 7 correct?
 8 **A. That's correct.**
 9 Q. And what's the current
 10 mifepristone dosage used to induce -- as part of
 11 the two drug medication abortion regimen?
 12 **A. The FDA approved protocol was**
 13 **200 milligrams mifepristone.**
 14 Q. And at what gestational age do
 15 those -- does the FDA authorize mifepristone's
 16 use on the label?
 17 **A. Seventy days or ten weeks**
 18 **after first day of the last menstrual period.**
 19 Q. And are you aware of an
 20 evidence based protocol authorizing its use up
 21 to 77 days?
 22 **A. I am.**
 23 Q. Okay. So let's turn to page
 24 16 of the literature review.
 25 **A. Okay. I'm there.**

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

1 developing research that's changed the
 2 understanding reflected at this table, correct?
 3 **A. The only other trial would be**
 4 **the recent Creinin trial.**
 5 Q. Right. But in terms of just
 6 studying the effects of mifepristone alone, the
 7 data we have is reflected in this study, which
 8 is -- in this table the most recent of which is
 9 30 years old, right?
 10 **A. Other than the Creinin study,**
 11 **you're correct.**
 12 Q. Looking at this table, would
 13 you say that we have robust historical data on
 14 the efficacy of a single 200 milligram dose of
 15 mifepristone?
 16 **A. No.**
 17 Q. And, in fact, there's only one
 18 study that addresses a 200 milligram dose of
 19 mifepristone, correct?
 20 **A. A 200 single dose, yes.**
 21 Q. Yep. And that's the Maria
 22 study from the Journal of Gynecology, I guess,
 23 from 1988?
 24 **A. That's correct.**
 25 Q. And in many of these studies,

1 the total dose of mifepristone is higher than
 2 the dose used today, correct?
 3 **A. That's correct.**
 4 Q. Many of them examine the
 5 effects of 600 milligrams daily, correct?
 6 **A. Yes.**
 7 Q. And that's three times the
 8 present dosage for mifepristone?
 9 **A. That's right.**
 10 Q. Do you think it's possible
 11 that 600 milligrams of mifepristone is more
 12 effective at inducing fetal demise than 200
 13 milligrams?
 14 **A. Certainly possible, yes.**
 15 Q. And so there are differences
 16 in the treatments in these studies versus the
 17 dosage of mifepristone used today, correct?
 18 **A. In some of the studies, yes.**
 19 Q. And, in fact, all but one of
 20 the studies, correct?
 21 **A. Correct.**
 22 Q. And that one study only went
 23 as high as 49 days, correct?
 24 **A. That's correct.**
 25 Q. And mifepristone is presently

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

1 prescribed for many weeks after 49 days today,
 2 correct?
 3 **A. That's correct.**
 4 Q. And we know that mifepristone
 5 is less likely to work later -- at later
 6 gestational ages, correct?
 7 **A. That's correct.**
 8 Q. Or at least induce fetal
 9 demise at later gestational ages, I should say.
 10 Do you agree with that?
 11 **A. I do.**
 12 Q. Okay.
 13 **A. Also point out that many of**
 14 **these studies only followed the embryo for six**
 15 **or seven days. And so, therefore, they would**
 16 **have overestimated fetal or embryologic survival**
 17 **by not waiting long enough to see if demise**
 18 **occurred. The Maria case is an example of that.**
 19 Q. Well, the Maria is seven days?
 20 **A. Right.**
 21 Q. And so seven -- a seven day
 22 window overestimates the likelihood of survival?
 23 **A. It does. Because if you wait**
 24 **and watch -- because at seven days they would**
 25 **perform surgical abortions if there were signs**

1 **that we drew there. That's all.**
 2 Q. Seventy-two hours is an
 3 arbitrary line?
 4 **A. Uh-huh.**
 5 Q. What is the half life of
 6 mifepristone?
 7 **A. The health life of**
 8 **mifepristone is about 18 hours.**
 9 Q. And what is the significance
 10 of an 18 half life for the 72 hour window you
 11 were just describing?
 12 **A. Well, half life is when half**
 13 **of it is gone. So at 18 hours you still have**
 14 **half. And in another 18 hours, you still have**
 15 **25 percent. And then in another 18 hours then**
 16 **you'll have 12 percent. So, you know, by 72**
 17 **hours most of it is gone.**
 18 Q. So going back to where this
 19 subject came up. Why would -- by seven days
 20 you'd have a negligible amount in your system,
 21 if any at all, wouldn't you?
 22 **A. But the studies -- the 14 day**
 23 **studies show that the -- although the drug is**
 24 **gone out of the system -- first of all, there's**
 25 **still some metabolites around, number one. And**

1 number two, the effects of the drug are still
 2 there.
 3 So the -- although the parent
 4 drug may be gone, the effects of the drug
 5 persist. And the -- it may take longer than
 6 seven days for the embryo to die.
 7 It's as if you were shot with
 8 a gun. The shot takes place at time X, but your
 9 death may not take place, let's say, for several
 10 days, depending on how you're wounded. And so
 11 the longer you watch someone who's had at
 12 gunshot wound, then the longer you'll see really
 13 what the -- what the mortality is for that
 14 gunshot wound, if not treatment offered.
 15 Q. What study would you point me
 16 to that supports the discussion you're talking
 17 about now in terms of the difference between 7
 18 days and 14 days and longer?
 19 A. Well, we discuss it and -- and
 20 Dr. Davenport discusses it in the current study.
 21 Q. In the 2017 study?
 22 A. Correct.
 23 Q. Okay. But what I meant was,
 24 what underlying -- of the literature that you
 25 reviewed what would you point to as an example

1 of a study that compared a shorter amount of
 2 time to a longer amount of time and concluded
 3 that embryonic survival is more likely in a
 4 shorter window than a longer window?
 5 A. I'd have to review the study
 6 to pull out the particular ones that support
 7 that.
 8 Q. So sitting here today, you
 9 don't have an example that comes to mind?
 10 A. No.
 11 Q. Okay. The FDA guidance we
 12 were looking at a moment ago, Tab O, can we look
 13 back at that? Are you there?
 14 A. No. I have got lots of things
 15 open so -- there we go.
 16 Q. Yep. Sorry.
 17 A. That's fine. All right.
 18 Q. You have it?
 19 A. Yes, I do.
 20 Q. Great. Let's look at page 27,
 21 please. Are you there?
 22 A. Yes.
 23 Q. Okay. In the middle of the --
 24 the large paragraph on the page above, number 3,
 25 is a sentence that begins, "The control

1 patients." Do you see that?
 2 A. Let's see.
 3 Q. It's about a third of the way
 4 down, the control patients --
 5 A. Yes.
 6 Q. Okay. So those two sentences
 7 state, "The control patients should be as
 8 similar as possible to the population expected
 9 to receive the test drug in the study, and
 10 should have been treated in a similar setting
 11 and in a similar manner, except with respect to
 12 the study therapy. Study observations should
 13 use timing and methodology similar to those used
 14 in the control patients."
 15 Did I read that correctly?
 16 A. Yes, you did.
 17 Q. As a general matter, is the
 18 FDA's guidance on historical controls correct on
 19 these points?
 20 A. Yes.
 21 Q. And as we discussed earlier,
 22 the dosage of mifepristone in most of the
 23 studies forming a historical control is
 24 different from the dose used today?
 25 A. That's correct.

1 Q. And there are few subjects
 2 after 49 weeks gestation in the -- 49 days --
 3 let me start over.
 4 And there are few subjects
 5 after 49 days gestation in the studies forming
 6 your historical control, correct?
 7 A. That's correct.
 8 Q. Although your case series
 9 includes patients after 49 weeks -- days,
 10 correct?
 11 A. That's correct.
 12 Q. And so there's a difference
 13 between your control population and your study
 14 population?
 15 A. Yes.
 16 Q. And as we discussed earlier,
 17 the mifepristone survival rate increases with
 18 increasing gestational age?
 19 A. That's correct.
 20 Q. And so actual failure rates
 21 under the current treatment regimen, which
 22 extends to higher gestational ages, are likely
 23 to be higher than those reported in the studies
 24 you analyzed, correct?
 25 A. At the higher gestational

1 **ages, yes.**
 2 Q. So your case series when it
 3 discusses the 25 percent failure rate says that
 4 it was close. We discussed this earlier, close
 5 to the 23 percent failure rate of the one study
 6 that used a single 200 milligram dose, which is
 7 the Maria study, correct?
 8 **A. Yes.**
 9 Q. What was the upper limit of
 10 the gestational age in the Maria study?
 11 **A. I believe it was 49 days.**
 12 Q. And do you remember how many
 13 patients were included in that study?
 14 **A. Not off the top of my head.**
 15 Q. Let's look -- it's at page 15
 16 of tab -- gosh, where are we? Tab P, Exhibit
 17 15, page 15.
 18 **A. It would have 30.**
 19 Q. Would you consider that to be
 20 a large sample size?
 21 **A. No.**
 22 Q. If we didn't have the rest of
 23 the studies cited in your literature review,
 24 would you think that a 30 person study standing
 25 alone would be sufficient to support the 25

1 study that relied upon a historical control with
 2 such a small sample size?
 3 **A. I don't recall.**
 4 Q. Okay. Well, you're going to
 5 be testifying next month at a hearing, right?
 6 **A. I believe so.**
 7 Q. I'm going to ask you there as
 8 well, or we will ask you there, if you're able
 9 to find a study that relied upon a historical
 10 control that had just 30 people in it. And so
 11 if you find anything between now and then that
 12 supports the conclusion that that would be a
 13 reasonable historical control, would you let me
 14 know?
 15 **A. Well, if I find it, I would**
 16 **tell the -- I would tell the -- the attorneys**
 17 **for the State of Tennessee, and I guess they**
 18 **could let you know, if that would be the proper**
 19 **thing to do.**
 20 Q. Great. Thank you. Can we
 21 agree to do that?
 22 **A. Well, not -- I'm not**
 23 **committing to search the literature for such a**
 24 **control group. I have lots of other things**
 25 **occupying my time.**

1 percent control figure?
 2 **A. If that were the only data we**
 3 **had, yes.**
 4 Q. If that were the only data we
 5 had, a 30 person study would suffice?
 6 **A. To establish historical**
 7 **control -- yes, that would be the best we have.**
 8 Q. And do you think that would be
 9 a particularly reliable historical control?
 10 **A. It would be the most reliable**
 11 **we would have.**
 12 Q. And how reliable would that
 13 be? I mean, it would be all that we would have.
 14 But from an objective standpoint, would a 30
 15 person study give us a reliable historical
 16 control?
 17 **A. It would give a somewhat**
 18 **reliable historical control.**
 19 Q. Do you think other scientists
 20 would conclude that a 30 person study is
 21 sufficient to give us a somewhat reliable
 22 historical control?
 23 **A. I think they would under the**
 24 **circumstances.**
 25 Q. Have you ever seen any other

1 Q. Okay. Well, if you do find
 2 anything that supports the sufficiency of a 30
 3 person historical control between now and the
 4 hearing, please let the attorney general's
 5 office know and we will ask that they let us
 6 know. Does that sound reasonable?
 7 **A. Sounds reasonable.**
 8 Q. Let's look at page 1 of the
 9 literature review, where we have the abstract
 10 here and under methods?
 11 **A. Okay. So it's the page**
 12 **labeled 3 in the internal numbering, correct?**
 13 Q. Yep.
 14 **A. All right.**
 15 Q. You there?
 16 **A. Yes.**
 17 Q. So the third sentence, I
 18 think, in that method paragraph says, "The
 19 relevant studies that verified embryo survival
 20 utilized ultrasound as a criterion for
 21 continuing pregnancy."
 22 Did I read that correctly?
 23 **A. Yes.**
 24 Q. And then on page 16?
 25 **A. I'm there.**

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

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

9 **A. That's correct.**

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

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

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

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

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

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

7 Q. And what about at the time
8 when these studies were being performed in the
9 1980s?

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

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

17 **A. Correct.**

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

21 **A. Growth and continued evidence
22 of intrauterine pregnancy.**

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

1 most of these studies, correct?

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

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

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

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

15 **A. Not at their early gestations,
16 correct.**

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

20 **A. That's correct.**

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

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

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

6 **A. Many, yes, that's correct.**

7 Q. On page 9 of the literature
8 review?

9 **A. Yes, I'm here.**

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

21 **A. That's correct.**

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

1 from incomplete or missed abortions. Is that
 2 fair?
 3 **A. Yes.**
 4 MR. BECK: Can we have Tab Q?
 5 This is a new exhibit, which we can mark as
 6 Exhibit 34.
 7 (Whereupon, the document was
 8 marked as Exhibit No. 34 to the testimony of the
 9 witness.)
 10 BY MR. BECK:
 11 Q. Let me know when you have it
 12 open. Do you have it, Doctor?
 13 **A. It says it's downloaded, but I**
 14 **clicked and it's not opening. Let me see if**
 15 **it's just open in another window. I click on**
 16 **the -- the tab and it opens up the Davenport**
 17 **article. Let me close that and see if it's**
 18 **under it.**
 19 Q. It opened up the correct
 20 article for me, so maybe try -- try it again.
 21 **A. There we go. I just had to**
 22 **close that other one. That other one didn't**
 23 **want to leave the stage. Okay. I'm here.**
 24 Q. Okay. Excellent. This is
 25 Exhibit No. 34, an article by Swahn, S-W-A-H-N,

1 basis for inclusion of the literature review,
 2 correct?
 3 **A. Yes.**
 4 Q. And can you turn to page 22?
 5 There's a highlighted section there. Can you
 6 just read that?
 7 **A. "Women were allocated randomly**
 8 **to one of three treatment groups. The initial**
 9 **treatment with RU486, parenthesis, 25 milligram**
 10 **twice daily for four days was the same in all**
 11 **three groups. On the fourth day, the subjects**
 12 **received either placebo in the morning and in**
 13 **the evening, parenthesis, group A, close**
 14 **parenthesis, 1 milligram PGE2 in the morning and**
 15 **placebo in the evening, parenthesis, group B,**
 16 **close parenthesis, or 1 milligram PGE2 on both**
 17 **occasions, parenthesis, group C, close**
 18 **parenthesis."**
 19 Q. So group A here is clearly
 20 identified as the group that was given
 21 mifepristone alone in this study, correct?
 22 **A. That's right.**
 23 Q. All right. So turn to page 24
 24 and look at table three.
 25 **A. Okay.**

1 et al., called, "Effects of Oral Prostaglandin
 2 E, little 2, on Uterine Contractility and
 3 Outcome of Treatment in Women Receiving RU486,
 4 parenthesis, mifepristone, close parenthesis,
 5 for Termination of Early Pregnancy."
 6 Are you familiar with this
 7 article?
 8 **A. I believe I've read it in the**
 9 **past.**
 10 Q. Okay. This is one of the
 11 articles mentioned in the literature review,
 12 correct?
 13 **A. I believe so.**
 14 Q. So turn to page 24 of this
 15 article.
 16 **A. Okay. I'm there.**
 17 Q. So the last sentence on that
 18 page says, "Levels of cortisol, parenthesis,
 19 figure 3, end parenthesis, in women with
 20 complete abortion, number 25, were similar to
 21 those in women with continuing pregnancy, number
 22 15, at all sampling times."
 23 So this uses the kind of
 24 continuing pregnancy terminology that you -- we
 25 just discussed that you referenced for -- as a

1 Q. Can you tell me what this
 2 table seems to reflect for group A?
 3 **A. So under the column group A,**
 4 **eight had complete abortions, one had an**
 5 **incomplete abortion, five characterized as**
 6 **failures, for a total of 14 in group A.**
 7 Q. And so this identifies the
 8 number of patients in group A who had complete
 9 abortions, who had incomplete abortions, and for
 10 whom mifepristone failed to work, correct?
 11 **A. That seems to be what they're**
 12 **indicating.**
 13 Q. Okay. Now, you didn't include
 14 this Swahn study among the studies that you
 15 included in your literature review. Does that
 16 sound right to you?
 17 **A. I'd have to look back and see**
 18 **which ones were included.**
 19 Q. Let's look back at page 11,
 20 please, of the literature review. Tell me when
 21 you're there.
 22 **A. I'm on page 11.**
 23 Q. Great. The third paragraph
 24 states, "Swahn in a 1989 study compared
 25 abortions with mifepristone alone to abortions

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

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

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

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

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

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

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

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

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

11 **A. I'm there.**

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

14 **A. "In contrast to a previous**
15 **study, Kovacs, et al., 1984, in which 11 of the**
16 **14 unsuccessfully treated women were classified**
17 **as incomplete abortion, there were only two,**
18 **parenthesis, out of 17, close parenthesis, such**
19 **diagnoses in the present investigation. This**
20 **difference may be ascribed to the systemic use**
21 **of ultrasound examination in the present work."**

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

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

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

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

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

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

15 **A. Based on this passage, yes.**

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

20 **A. Correct.**

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

1 study are particularly helpful for evaluating
2 embryo survival?

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

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

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

17 Q. Okay.

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

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

25 **A. I would say that that's what**

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

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

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

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

22 MS. DAVIS: Objection.

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

1 as ongoing pregnancy, but as failures.

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

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

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

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

22 MS. DAVIS: Objection.

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

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

3 BY MR. BECK:

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

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

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

12 A. Yes.

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

16 A. That's what they state.

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

20 A. Yes.

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

25 A. Well, it characterized one not

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

4 BY MR. BECK:

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

7 MS. DAVIS: Objection.

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

11 BY MR. BECK:

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

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

24 Q. And they're -- sorry, go
25 ahead.

1 **A. 31 percent in group B, 40**
2 **percent in group C, all three 36 percent.**
3 Q. But group A is the
4 mifepristone only group, right?
5 **A. That's correct.**
6 Q. 36 percent is higher than the
7 25 percent figure you cited as your historical
8 control, correct?
9 **A. That's correct.**
10 Q. And if this study ought to
11 have been included, it would skew higher your
12 historical control, correct?
13 **A. Not necessarily. There are --**
14 **there was a range of -- of different survivals.**
15 **This is on the high end for sure.**
16 Q. Is it possible that your
17 literature review appears to have excluded a
18 study that ought to have been included?
19 **A. It's possible.**
20 Q. And that study has a 36
21 percent failure rate?
22 **A. That's what it says in the**
23 **table.**
24 Q. And 36 percent is higher than
25 the 25 percent that served as your historical

1 Trials in China." You addressed this study in
2 your literature review and excluded it from the
3 studies that you reviewed, correct?
4 **A. Yes.**
5 Q. If we could turn to page 20,
6 in the top right corner?
7 **A. Okay.**
8 Q. It breaks down the efficacy of
9 the treatment into three categories: Complete
10 abortion, incomplete abortion, and persisting
11 pregnancy, correct?
12 **A. That's correct.**
13 Q. And you excluded this study
14 from the literature review, right?
15 **A. Right.**
16 Q. Let's look at page 11 of the
17 literature review for your basis for that. So
18 in the last paragraph on page 11 -- are you
19 there?
20 **A. Not there, sir. I'll just go**
21 **to the tab. Okay. Page 11.**
22 Q. So starting at the third
23 sentence, it states, "Ultrasound was not used at
24 the end of the study to determine persisting
25 pregnancies. Only clinical and HCG criteria we

1 control, correct?
2 **A. That's correct.**
3 Q. Was the literature review
4 subject to peer review in "Issues in Law &
5 Medicine"?
6 **A. Yes.**
7 Q. Did any reviewer ever point
8 out that the Swahn study doesn't seem to say
9 what your literature review said about it?
10 **A. I don't recall.**
11 Q. If someone had pointed that
12 out, would you have made a change?
13 **A. I'm sure we would have.**
14 MR. BECK: Let's introduce Tab
15 R, please. And we can mark Tab R as Exhibit 35.
16 (Whereupon, the document was
17 marked as Exhibit No. 35 to the testimony of the
18 witness.)
19 BY MR. BECK:
20 Q. Let me know when you have it.
21 Do you have that available?
22 **A. I have it, yes.**
23 Q. Great. Exhibit 35 is a study
24 by Zheng, Z-H-E-N-G, et al., or not et al., just
25 Zheng, called, "RU486 (Mifepristone): Clinical

1 used, the criteria for persisting pregnancy
2 being the absence of expulsion of the conceptus
3 and gradual increase in serum and urine HCG."
4 Other than throwing an
5 additional the there, did I read correctly?
6 **A. Yes.**
7 Q. Okay. It seems, though, that
8 you left off one of Zheng's criteria. So if we
9 look back at the Zheng study at page 20. In
10 addition to using expulsion of the conceptus and
11 gradual increase in HCG, it also considered the
12 size of the uterus, correct?
13 **A. Yes. But I think we did**
14 **mention clinical findings.**
15 Q. Right. Although, it does not
16 mention in your summary the fact that Zheng used
17 the size of the uterus, correct?
18 **A. Size of uterus is -- can be**
19 **categorized under clinical findings.**
20 Q. And that may be. But you
21 didn't set it out specifically, correct?
22 **A. Correct.**
23 Q. What was the maximum
24 gestational age in the Zheng study?
25 **A. I'd have to look at the table.**

1 Q. You can go ahead and do that.
 2 **A. Let's see. Looks like this**
 3 **table 1 lists up to 49 weeks -- 49 days, excuse**
 4 **me, 7 weeks.**
 5 Q. A clinician can't externally
 6 palpate the size of the uterus at 7 weeks and
 7 earlier, correct?
 8 **A. That would be -- most**
 9 **clinicians would not be able to.**
 10 Q. You would either need
 11 ultrasound or you'd need to perform a bimanual
 12 exam, correct?
 13 **A. Yes.**
 14 Q. How is a bimanual exam to
 15 assess uterine size performed?
 16 **A. Can you repeat that question,**
 17 **please?**
 18 Q. Can you describe, please, how
 19 a bimanual exam to assess uterine size would be
 20 performed?
 21 **A. The exam, if it's a right hand**
 22 **dominant examiner, the left hand is placed on**
 23 **the lower abdomen. The index and the middle**
 24 **fingers of the dominant right hand are placed**
 25 **into the vagina until the cervix is palpated.**

1 **And then the fingers are placed behind the**
 2 **cervix in what's called the posterior fornix.**
 3 **And then the left hand and the two fingers of**
 4 **the right hand are drawn together in order to**
 5 **feel the uterus between the two hands.**
 6 Q. And so it's invasive like a
 7 pelvic exam. It involves insertion of the
 8 practitioner's digits inside the woman's vagina,
 9 correct?
 10 **A. That's correct.**
 11 Q. And it's less accurate than
 12 ultrasound?
 13 **A. Yes.**
 14 Q. This study doesn't specify how
 15 the researchers measured the size of the uterus
 16 to assess continuing pregnancy, does it?
 17 **A. I am not sure.**
 18 Q. Well, do you see anywhere in
 19 the persisting pregnancy bullet that we were
 20 looking at earlier something that indicates how
 21 they measured the size of the uterus?
 22 **A. No.**
 23 Q. And the researchers had access
 24 to ultrasound, correct?
 25 **A. Yes, I believe so.**

1 Q. And, in fact, in the bullet
 2 above that it says ultrasonic findings,
 3 correct -- ultrasonographic findings, correct?
 4 **A. Right.**
 5 Q. So if the study doesn't
 6 specify how they assess uterine size, and if a
 7 bimanual exam is more invasive and less accurate
 8 than ultrasound, why would one assume that they
 9 measured uterine size by bimanual exam?
 10 **A. Perhaps that wouldn't be a**
 11 **good assumption, but that doesn't really affect**
 12 **why this study was excluded. The reason it was**
 13 **excluded is because they had criteria for**
 14 **persisting pregnancy that were not indicative of**
 15 **embryo survival.**
 16 Q. Well, actually, what you say
 17 in your literature review is, "Ultrasound was
 18 not used at the end of the study to determine
 19 persisting pregnancies. Only clinical and HCG
 20 criteria were used. The criteria for persisting
 21 pregnancy being absence of the expulsion of the
 22 conceptus and gradual increase in serum and
 23 urine HCG."
 24 And as we've been discussing,
 25 there was an additional factor, correct?

1 **A. But those two in and of**
 2 **themselves are not adequate criteria for**
 3 **confirming continued viability of the pregnancy.**
 4 Q. Well, actually --
 5 **A. The conceptus and gradual rise**
 6 **in HCG.**
 7 Q. That's fine. I actually want
 8 to focus on the item that you didn't discuss
 9 rather than the ones you did.
 10 So the one you didn't discuss
 11 is the size of the uterus, correct?
 12 **A. I believe so.**
 13 Q. And you mentioned earlier in
 14 the use of ultrasound discussion that
 15 measurement of the size of the uterus is one of
 16 the ways researchers would evaluate ongoing
 17 pregnancies, correct?
 18 **A. No. I said measurement of the**
 19 **size of the embryo.**
 20 Q. Well, when you put an
 21 ultrasound on the woman's body, you measure --
 22 that -- the size of the embryo is what you're
 23 measuring?
 24 **A. You measure the embryo when**
 25 **you're -- when you're doing a first trimester**

1 **obstetrical ultrasound. It's typically --**
 2 **typically, the uterus is not measured. It's**
 3 **the -- what's inside the uterus that's measured.**
 4 Q. So let me ask you this,
 5 Doctor. If you had access to ultrasound and you
 6 wanted to measure the size of the pregnancy
 7 before seven weeks, would you use ultrasound or
 8 would you use a bimanual exam?
 9 **A. I would use ultrasound.**
 10 Q. Can we rule out that these
 11 researchers used ultrasound?
 12 **A. Can we rule out they used**
 13 **ultrasound, no.**
 14 Q. Might someone looking at this
 15 study based on what we've been discussing think
 16 that it was at least a possibility these
 17 researchers used ultrasound to measure ongoing
 18 pregnancy?
 19 **A. I would say that's a**
 20 **possibility, yes.**
 21 Q. And it might be a reasonable
 22 conclusion?
 23 **A. Yes.**
 24 Q. What is the total rate of
 25 persisting pregnancy for patients in this study

1 sorry. Tab V as in Victor?
 2 MR. BECK: Yes.
 3 MS. CHAN: Sorry, was that
 4 yes? I think you cut out.
 5 MR. BECK: I'm sorry. Yes. I
 6 think actually -- you know what? Can we take a
 7 five minute break? I think actually -- you know
 8 what? That's -- we're nearing Dr. Delgado's
 9 lunch time. And now might be a good time for a
 10 quick break, or at least a break for him to have
 11 lunch.
 12 MS. DAVIS: Does that work for
 13 you, Dr. Delgado?
 14 THE WITNESS: Sure.
 15 VIDEOGRAPHER: Off the
 16 record -- I'm sorry. Go ahead.
 17 MR. BECK: No. Let's go off
 18 the record.
 19 VIDEOGRAPHER: Off the record
 20 at 1:44.
 21 (A recess was taken.)
 22 VIDEOGRAPHER: We are back on
 23 the record at 2:16.
 24 BY MR. BECK:
 25 Q. Hi, Dr. Delgado. Did you

1 using -- for those using mifepristone alone? Do
 2 you remember?
 3 **A. No, I don't.**
 4 Q. Let's look at page 21, table
 5 4.
 6 **A. Okay.**
 7 Q. So you see the totals at the
 8 bottom and persisting pregnancy number at the
 9 right. What's the total percentage for
 10 persisting pregnancies as reflected in this
 11 study?
 12 **A. For RU486 alone is 46.3.**
 13 Q. Which is nearly double the 25
 14 percent survival rate you relied upon for your
 15 historical control, correct?
 16 **A. Yes. But this study was not**
 17 **considered reliable for the -- for the**
 18 **aforementioned reasons.**
 19 Q. Yep.
 20 MR. BECK: Can we have Tab V,
 21 which we can mark as Exhibit 36.
 22 (Whereupon, the document was
 23 marked as Exhibit No. 36 to the testimony of the
 24 witness.)
 25 MS. CHAN: Sorry, tab --

1 confer with counsel from the attorney general's
 2 office during the break?
 3 **A. No.**
 4 Q. So an article was left -- or
 5 an exhibit was left in the chat. Did you get a
 6 chance to open that one yet?
 7 **A. It was V?**
 8 Q. Yep.
 9 **A. No. Now it's open.**
 10 Q. Great.
 11 MR. BECK: So we can mark that
 12 as -- I think -- has it already been marked as
 13 Exhibit 36, I think. If not, can we mark that
 14 one as 36?
 15 BY MR. BECK:
 16 Q. Do you have that one open?
 17 **A. Yes.**
 18 Q. Okay. Exhibit 36 is a chapter
 19 from a book entitled, "How to Report Statistics
 20 in Medicine: Annotated Guidelines for Authors,
 21 Editors, and Reviewers," by Lang and Secic, et
 22 al.
 23 Have you seen this document
 24 before?
 25 **A. No.**

1 Q. Okay. Can you turn to sort of
 2 the first page after the cover page, which is
 3 page 37.
 4 **A. Yes.**
 5 Q. Can you read that second
 6 paragraph that begins with, "A confidence
 7 interval," aloud?
 8 **A. "A confidence interval is the**
 9 **range of values consistent with the data that is**
 10 **believed to encompass the actual or true**
 11 **population value. This true population value is**
 12 **usually unknowable, but it does exist and can be**
 13 **estimated from an appropriately drawn sample.**
 14 **Confidence intervals around population estimates**
 15 **provide a sense of how good or precise the**
 16 **estimate is. Wider confidence intervals**
 17 **indicate lesser precision, and narrower**
 18 **intervals indicate greater precision."**
 19 Q. Do you agree with the
 20 statement you just read?
 21 **A. Yes.**
 22 Q. Okay. Your 28 case series
 23 said that you selected a 25 percent embryo or
 24 fetus survival rate if mifepristone alone is
 25 administered as a control because it is at the

1 study in question, it's three from the bottom.
 2 What's the confidence interval shown for that
 3 study?
 4 **A. 10.6 to 42.7.**
 5 Q. That's quite a large range for
 6 a confidence interval, correct?
 7 **A. I've seen larger.**
 8 Q. Would you agree with me that
 9 that is a large range for a confidence interval?
 10 **A. I think right now I wouldn't**
 11 **speculate on if I would classify that as large**
 12 **or not.**
 13 Q. It's much smaller than the
 14 range of the confidence interval in your 2018
 15 case series, correct?
 16 **A. Which -- which confidence**
 17 **interval are you talking about?**
 18 Q. In your 2018 case series, your
 19 confidence interval for all groups was between
 20 44 and -- 0.44 and 0.52, so a much narrower
 21 range because you had a much larger group --
 22 **A. Right.**
 23 Q. -- population, correct?
 24 **A. Right. Correct.**
 25 Q. And the Maria study, which

1 upper range of mifepristone survival rates and
 2 close to the 23 percent survival rate of one of
 3 the early studies that used a single 200
 4 milligram dose that was currently favored for
 5 medical abortions.
 6 So you identified only a point
 7 estimate with that 25 percent, not a confidence
 8 interval, correct?
 9 **A. That's correct.**
 10 Q. Why?
 11 **A. Simply because it would -- it**
 12 **would facilitate comparisons to have a 1 value.**
 13 Q. Did you consider doing a
 14 comparison to the confidence interval?
 15 **A. I don't believe so.**
 16 Q. The early study you reference
 17 in that -- in your 2018 case series is the Maria
 18 study that we were talking about earlier, the
 19 one with the 200 milligram dose?
 20 **A. Right.**
 21 Q. And if we could look quickly
 22 at your 2017 literature review at the table at
 23 pages 14 to 15.
 24 **A. Okay.**
 25 Q. On page 15 Maria -- the Maria

1 only had 30 patients, had a much larger
 2 confidence interval, correct?
 3 **A. Yes, it did.**
 4 Q. And so, you know, if we look
 5 back at the passage you just read from the --
 6 from the How to Report Statistics in Medicine
 7 book, wider confidence intervals indicate lesser
 8 precision, and narrower confidence intervals
 9 indicate greater precision --
 10 **A. That's correct.**
 11 Q. -- correct?
 12 And so because we have only a
 13 30 point -- 30 person study in the Maria study
 14 we have a very large confidence interval because
 15 it's hard to draw conclusions from a study of 30
 16 people. Do you agree with that?
 17 **A. It's harder, yes.**
 18 Q. Yeah. So you have your --
 19 let's see. Tab F is your 2018 case series. Can
 20 you open that one up?
 21 **A. Okay.**
 22 Q. And if you look at page 27
 23 just to confirm what I mentioned earlier, your
 24 confidence interval is 44 percent to 52 percent
 25 for all groups, correct?

1 **A. That's correct.**
2 Q. That 42 -- 44 percent at the
3 lower end of your confidence interval, that
4 overlaps if we look at your 2017 literature
5 review with the upper bounds of the confidence
6 interval of many of the studies listed here.
7 Would you agree with that? Why don't you look
8 at the literature review?
9 **A. There is some overlap.**
10 Q. I count seven of the early
11 mifepristone studies where the confidence
12 interval, the upper bound of the confidence
13 interval for the early studies is higher than
14 the lower bound of the confidence interval for
15 your study. Do you want to check my math on
16 that?
17 **A. Could you hold on one second?**
18 **Someone's knocking on the door. Sorry. Sorry**
19 **about that.**
20 **Okay. Let me go back here. I**
21 **count seven.**
22 Q. So there are seven of your
23 included studies in which the upper bound of the
24 confidence interval overlaps with the lower
25 bound of the confidence interval in -- for all

1 **yeah. I thought you said did I.**
2 Q. No. No, you did not publish
3 this. Have you seen this article before?
4 **A. No.**
5 Q. Okay. Can you turn to page --
6 the second page?
7 **A. Okay.**
8 Q. And in the conclusion, could
9 you read the sentence beginning with, "The
10 confidence interval takes into account"?
11 **A. "The confidence interval takes**
12 **into account possible differences in the sample**
13 **sizes of the papers involved."**
14 Q. Sorry. And go on to the next
15 sentence, too, please.
16 **A. "If there is considerable**
17 **overlap in the confidence intervals with**
18 **different studies, it becomes clear despite**
19 **possible differences in the point estimates the**
20 **results may not really differ much."**
21 Q. May not really differ very
22 much?
23 **A. Sorry, differ very much.**
24 Q. So the author here is saying
25 that when comparing multiple data sets, an

1 groups in your 2018 case series, correct?
2 **A. That's correct.**
3 MR. BECK: Okay. Can we
4 mark -- introduce into the chat Tab W?
5 BY MR. BECK:
6 Q. Let me know when you have Tab
7 W open, Doctor.
8 MR. BECK: And we can mark Tab
9 W as Exhibit 37.
10 (Whereupon, the document was
11 marked as Exhibit No. 37 to the testimony of the
12 witness.)
13 THE WITNESS: It's open.
14 BY MR. BECK:
15 Q. Great. So if you could turn
16 to the second page -- sorry, let me just
17 quickly. This is a piece by Frederick Dorey
18 called, "In Brief: Statistics in Brief.
19 Confidence Intervals. What is the Real Result
20 in the Target Population?"
21 Have you -- published in
22 Clinical Orthopaedics.
23 **A. No.**
24 Q. No. Where is this published?
25 **A. Oh. No, it is published --**

1 investigator should look at the confidence
2 intervals to accurately determine the difference
3 between them; is that correct?
4 **A. That's right.**
5 Q. And that looking at just the
6 point values can lead a researcher to
7 overestimate the difference between the two data
8 sets, correct?
9 **A. That's correct.**
10 Q. And so, therefore, potentially
11 it can overstate the efficacy of a given
12 treatment, correct?
13 **A. That's possible.**
14 Q. And do you agree with the
15 principle set forth in the paragraph you just
16 read?
17 **A. Yes.**
18 Q. Would you say that your
19 assessment of the difference in the two
20 treatment -- two treatment populations, which
21 looks just at point estimates, is a better way
22 of analyzing it than looking at the confidence
23 intervals?
24 **A. I would say that it's also**
25 **important to look at P values that show**

1 **statistical significance, and ours showed that.**
2 **And, also, you're looking at the all comers in**
3 **our study. However, if you look at the -- the**
4 **groups that are -- more are -- represent the**
5 **real world treatment these days, those would be**
6 **the high dose oral progesterone group and the --**
7 **and some people still use an injection group.**
8 **Those have much higher rates of -- of reversal,**
9 **and much less overlap in the confidence**
10 **intervals.**

11 Q. But there's still overlap
12 between even the high dose oral groups, the
13 lower bound of your confidence interval there,
14 and some of the early mifepristone studies,
15 correct?

16 **A. There's some.**

17 Q. And so, again, according to
18 the text we just looked at, without looking at a
19 confidence interval as opposed -- when you don't
20 look at the confidence interval, it is possible
21 to overstate and overestimate the efficacy of a
22 treatment, correct?

23 **A. Correct.**

24 Q. And do you think that that's a
25 possibility here?

1 **A. It's a possibility.**

2 Q. Okay. Let's talk about
3 Dr. Creinin's study. In your declaration, if
4 you want to pull that up, which is Tab C,
5 Exhibit 26 -- no, wrong one. Tab E, Exhibit 22.

6 **A. Okay. I have it.**

7 Q. At paragraph 25 you state that
8 Dr. Creinin, quote, Unsuccessfully undertook the
9 first randomized controlled trial of abortion
10 pill reversal, correct?

11 **A. That's correct.**

12 MR. BECK: Okay. So can we
13 introduce that study into the chat, which has
14 previously been marked as Plaintiff's Exhibit
15 16?

16 BY MR. BECK:

17 Q. And while we're waiting for it
18 to download. Doctor, this study was published
19 in the Journal of Obstetricians and --
20 Obstetrics and Gynecology. Does that sound
21 consistent with your memory?

22 **A. Yes.**

23 Q. And that's also known as the
24 Green Journal?

25 **A. Yes.**

1 Q. And is the Green Journal
2 considered a reliable authority in the medical
3 profession?

4 **A. For the most part.**

5 Q. Do you have it open?

6 **A. Yes.**

7 Q. Great. Will you turn to page
8 5, please.

9 **A. Okay. I'm there.**

10 Q. And will you read the second
11 paragraph under discussion aloud?

12 **A. "Second and most important are**
13 **the lessons about treatment safety. Providing**
14 **treatment in any medical situation requires a**
15 **full understanding of the potential benefits and**
16 **risks. Previous case series reports do not**
17 **describe outcomes for the one-third or more**
18 **patients without continuing pregnancies after**
19 **progesterone treatment." Continue?**

20 Q. Please.

21 **A. "3 of 12 patients enrolled**
22 **experienced very heavy bleeding resulting in**
23 **ambulance transport to emergency department, a**
24 **rate higher than reported with medical abortion**
25 **in which 0.6 percent of patients have emergency**

1 **department visits. Patients who use**
2 **mifepristone for a medical abortion should be**
3 **advised that not using misoprostol could result**
4 **in severe hemorrhage, even with progesterone**
5 **treatment. We stopped the study because of**
6 **these complications and, thus, could not**
7 **quantify the full extent of this risk. Because**
8 **of the potential dangers for patients who opt**
9 **not to use misoprostol after mifepristone**
10 **ingestion, any mifepristone antagonization**
11 **treatment must be considered experimental."**

12 Q. Thanks. So the study authors
13 here characterize three patients as having very
14 heavy bleeding resulting in ambulance transport
15 to an emergency department, correct?

16 **A. That's correct.**

17 Q. And one -- that included one
18 patient in the progesterone group and two in the
19 placebo group?

20 **A. Correct. And the one in the**
21 **progesterone group went to the emergency**
22 **department, but did not require further care.**
23 **She just had a failed reversal and, therefore,**
24 **really didn't need to be in the emergency**
25 **department.**

1 Q. Let's talk about that a little
 2 more. Let's look at page 3. The last paragraph
 3 on that page, the study describes that patient
 4 who had progesterone and went to the hospital.
 5 And it describes her as experiencing brisk
 6 bleeding in the middle of the paragraph,
 7 correct?
 8 **A. That's correct.**
 9 Q. And then later on in that
 10 paragraph it says, "She had heavy bleeding that
 11 lasted about three hours," correct?
 12 **A. That's correct.**
 13 Q. And that happened at the
 14 hospital after she called an ambulance, correct?
 15 **A. Correct.**
 16 Q. Although, she ultimately
 17 didn't need a blood transfusion or other
 18 intervention at the hospital, right?
 19 **A. That's correct.**
 20 Q. And in the paragraph that you
 21 just read a moment ago, the authors include this
 22 patient as among the three who experienced very
 23 heavy bleeding resulting in ambulance transport
 24 to an emergency department, correct?
 25 **A. Correct.**

1 Q. And so by the author's own
 2 description, this patient's bleeding was very
 3 heavy, correct?
 4 **A. The author's own description**
 5 **seems to be contradictory. In one place he**
 6 **calls it brisk, in another one heavy, in another**
 7 **one very heavy.**
 8 Q. If -- isn't another reading of
 9 this that brisk bleeding, very heavy bleeding,
 10 and heavy bleeding are all synonymous for -- for
 11 purposes of the study and that it amounts to the
 12 patient experiencing hemorrhage?
 13 **A. That seems to be an imprecise**
 14 **use of language.**
 15 Q. Is that a potential
 16 interpretation of this author's language that
 17 doesn't lead to the inconsistency you just
 18 pointed out?
 19 **A. That's a potential**
 20 **interpretation, sure.**
 21 Q. And might that be a reasonable
 22 interpretation?
 23 **A. That those three terms are**
 24 **synonymous?**
 25 Q. Correct.

1 **A. I -- I think -- I think it's a**
 2 **risky interpretation.**
 3 Q. What's the difference between
 4 heavy bleeding and hemorrhage, in your mind?
 5 **A. Hemorrhage is the medical term**
 6 **for bleeding. So heavy bleeding would be heavy**
 7 **hemorrhage.**
 8 Q. And the authors describe the
 9 patient who received progesterone as having
 10 heavy bleeding that lasted three hours. So that
 11 would be heavy hemorrhage that lasted three
 12 hours, correct?
 13 **A. Presumably.**
 14 Q. You would agree with me that a
 15 patient can experience heavy bleeding lasting
 16 three hours that falls short of a blood
 17 transfusion, correct? Falls short of requiring
 18 a blood transfusion?
 19 **A. Yes. That probably happens**
 20 **very frequently with women who undergo medical**
 21 **abortions, including those who take misoprostol.**
 22 Q. Is it your opinion that that
 23 happens frequently for patients before they even
 24 take misoprostol? In other words, is it your
 25 opinion that very heavy bleeding after taking

1 mifepristone alone is common?
 2 **A. I'm not sure.**
 3 Q. Do you have any evidence that
 4 you would point to suggesting that very heavy
 5 bleeding after taking mifepristone alone is
 6 common?
 7 **A. I do not.**
 8 Q. And so if there isn't such
 9 evidence, then what this patient experienced
 10 after taking mifepristone alone, very heavy
 11 bleeding for three hours, would be an uncommon
 12 product of taking mifepristone, correct?
 13 **A. In my mind, I don't know if**
 14 **she had very heavy bleeding, heavy bleeding, or**
 15 **brisk bleeding because of the three different**
 16 **terms used by the author. And I -- what I can**
 17 **see is that she did not require any intervention**
 18 **at all. She simply completed her medical**
 19 **abortion.**
 20 Q. Well, the author's term is
 21 "heavy bleeding." So let's stick with what the
 22 author says. And I'd like to ask the question
 23 again.
 24 **A. The author uses heavy**
 25 **bleeding, but like you pointed out, also uses**

1 **brisk bleeding and also uses very heavy**
 2 **bleeding. Are you going to pick -- choose one**
 3 **at a time or --**
 4 Q. Yeah. Let's stick with heavy
 5 bleeding for now.
 6 **A. Okay.**
 7 Q. Which is the author's term,
 8 which you've said is synonymous with heavy
 9 hemorrhage.
 10 You would agree with me that
 11 heavy bleeding for three hours could be an
 12 adverse event, correct?
 13 **A. Potentially.**
 14 Q. If you were conducting a study
 15 and a patient experienced heavy hemorrhage
 16 resulting in ambulance transport to a hospital
 17 emergency department, but the patient didn't
 18 ultimately require a blood transfusion, would
 19 you treat that as an adverse event?
 20 **A. If the patient did not require**
 21 **any intervention, then I would be -- that would**
 22 **not necessarily be an adverse event.**
 23 Q. You would not regard heavy
 24 bleeding resulting in ambulance transfer to a
 25 hospital emergency department after taking

1 mifepristone alone as a heavy -- as an adverse
 2 event?
 3 **A. Well, you're -- you're saying**
 4 **there was -- ambulance transport was required.**
 5 **That's not what's stated here. It's that she**
 6 **called the ambulance. So it's very likely that**
 7 **she got scared because maybe she wasn't**
 8 **instructed on what to expect, not that ambulance**
 9 **transport was required. Because no**
 10 **intervention -- no medical intervention was**
 11 **required.**
 12 Q. But you just said that you
 13 can -- you could have heavy bleeding that could
 14 be an adverse event and, yet, that falls short
 15 of requiring a blood transfusion, correct?
 16 **A. I didn't call it an adverse**
 17 **event. You did. I said you could have heavy**
 18 **bleeding and not require transfusion or other**
 19 **medical intervention.**
 20 Q. And you wouldn't consider that
 21 to be an adverse event? If that happened in one
 22 of your studies, you would not consider that to
 23 be an adverse event?
 24 **A. I'd have to look at the**
 25 **criteria for adverse events for the particular**

1 **study I was -- I was designing.**
 2 Q. If one of your own patients
 3 experienced very heavy bleeding --
 4 **A. You are considering heavy**
 5 **bleeding, not very heavy bleeding, if I recall.**
 6 Q. If one of your patients
 7 experienced heavy bleeding and went to -- that
 8 lasted for three hours, would you consider that
 9 to be the normal product of -- of her course of
 10 treatment or would you consider that an adverse
 11 event for her?
 12 **A. I would consider it longer**
 13 **than usual. And generally we tell them two**
 14 **hours is what you might expect with a typical**
 15 **miscarriage.**
 16 Q. So it's longer than unusual,
 17 which is suggestive of something adverse
 18 happening, correct?
 19 **A. It's longer than usual, not**
 20 **necessarily adverse because she didn't require**
 21 **any medical intervention.**
 22 Q. Well, she required -- she went
 23 to an emergency room and they ultimately didn't
 24 do anything, -- they didn't have to do anything.
 25 But you think that that -- that if they didn't

1 have to perform a blood transfusion, then her
 2 hemorrhage did not amount to an adverse event?
 3 **A. They didn't have to perform a**
 4 **blood transfusion. They also did not have to**
 5 **perform a surgical aspiration abortion, which**
 6 **the other two did require. So there's a big**
 7 **difference in the ones who did not get the**
 8 **progesterone.**
 9 Q. So I just want to be clear.
 10 If this happened in your study, you would not
 11 consider this to be an adverse event in your
 12 study?
 13 MS. DAVIS: Objection.
 14 THE WITNESS: That's
 15 speculative and hypothetical, so hard to answer
 16 that.
 17 BY MR. BECK:
 18 Q. No. I actually am very
 19 curious. For your study, if a patient reported
 20 the scenario that is described here, we can use
 21 the term "heavy bleeding" for three hours, I
 22 just want to understand whether you would
 23 consider that an adverse event for your study?
 24 MS. DAVIS: Objection.
 25 THE WITNESS: I would not

1 necessarily consider it an adverse reaction.
 2 BY MR. BECK:
 3 Q. So let's look at Tab K, the
 4 National Academy's document that we were looking
 5 at earlier, which is Exhibit 32. Do you have
 6 that?
 7 A. Yes.
 8 Q. Turn to page 54. Actually,
 9 before we get there. Can you point me to any
 10 medical evidence showing that heavy bleeding
 11 lasting three hours is an ordinary consequence
 12 of a medication abortion?
 13 A. I can't -- I can tell you I've
 14 heard many anecdotes of women in real life
 15 situations who've gone through the medical
 16 abortion procedure and have bled that long. And
 17 I would have to look and see about that, look at
 18 the literature. But I have -- am aware of many
 19 anecdotes of women who have experienced
 20 prolonged bleeding.
 21 Q. So let me actually rephrase
 22 the question. Can you point me to any published
 23 medical evidence showing that heavy bleeding
 24 lasting three hours is the ordinary consequence
 25 of a medication abortion?

1 A. Not at the present time.
 2 Q. And can you point me to any
 3 published medical evidence showing that heavy
 4 bleeding lasting three hours is the ordinary
 5 consequence of taking mifepristone alone as
 6 opposed to both drugs in the medication abortion
 7 regimen?
 8 A. Not at the present time.
 9 Q. Okay. So now let's look at
 10 the National Academy's report at page 54. Are
 11 you there?
 12 A. Yes.
 13 Q. In the first paragraph under
 14 expected side effects, the third sentence reads,
 15 "Vaginal bleeding is expected during and after
 16 an abortion and occurs in almost all patients
 17 during a medication abortion."
 18 Did I read that correctly?
 19 A. Yes.
 20 Q. Turn to page 55.
 21 A. Okay.
 22 Q. After hemorrhage it states,
 23 "Prolonged heavy bleeding is rare, but may
 24 indicate an incomplete abortion or other
 25 complications. Hemorrhage requiring assessment

1 or treatment following medication abortion is
 2 also rare. The FDA advises that women contact a
 3 healthcare provider immediately if bleeding
 4 after a medication abortion soaks through two
 5 thick full size sanitary pads per hour for two
 6 consecutive hours, end quote.
 7 So according to the National
 8 Academy, there's a distinction between expected
 9 regular vaginal bleeding and prolonged heavy
 10 bleeding, correct?
 11 A. That's correct.
 12 Q. Some vaginal bleeding is a
 13 regular side effect of mifepristone, whereas
 14 heavy bleeding requires immediate medical
 15 attention, correct?
 16 A. Well, it says, "The FDA
 17 advises that women contact a healthcare provider
 18 immediately." That's right.
 19 Q. So the answer to my question
 20 is, yes, that's correct?
 21 A. Yes.
 22 Q. Okay. And the FDA, as you
 23 just pointed to, focuses on heavy bleeding for
 24 two consecutive hours, correct?
 25 A. That's correct.

1 Q. Do you have any reason to
 2 disagree with the FDA on that front?
 3 A. No.
 4 Q. How long did the progesterone
 5 patients' heavy bleeding last in the Creinin
 6 study?
 7 A. Three hours, according to the
 8 study.
 9 Q. And according to the National
 10 Academy, heavy bleeding for three hours after a
 11 medication abortion is hemorrhage requiring
 12 immediate medical attention, correct?
 13 MS. DAVIS: Objection.
 14 THE WITNESS: Can you restate
 15 that?
 16 BY MR. BECK:
 17 Q. Sure. According to what we
 18 just looked at in the National Academy's report,
 19 heavy bleeding for three hours after a
 20 medication abortion would count as a hemorrhage
 21 requiring immediate medical attention, correct?
 22 A. Yes.
 23 MS. DAVIS: Objection.
 24 BY MR. BECK:
 25 Q. And that's not an ordinary

1 side effect of mifepristone, correct?
 2 **A. I'm not sure.**
 3 Q. Not according to the FDA and
 4 according to the National Academies at least,
 5 right?
 6 **A. Not according to this article.**
 7 Q. By the National Academies?
 8 **A. Right.**
 9 Q. Which cites the FDA, correct?
 10 **A. Well, it cites a study by**
 11 **Upadhyay, et al.**
 12 Q. Well, it also references the
 13 fact that the FDA states that if patients have
 14 heavy bleeding soaking through a number of pads
 15 lasting for two hours, that they should contact
 16 a healthcare provider immediately, correct?
 17 **A. That's correct.**
 18 Q. Okay. And so according to the
 19 FDA, what the -- what the patient in the Creinin
 20 study experienced is beyond the ordinary course
 21 that one would expect after a medication
 22 abortion, correct?
 23 MS. DAVIS: Objection.
 24 THE WITNESS: I don't think
 25 that's what the -- the FDA is saying is that --

1 was out of the ordinary, correct?
 2 MS. DAVIS: Objection.
 3 THE WITNESS: That could be an
 4 interpretation, yes.
 5 BY MR. BECK:
 6 Q. Would it be a reasonable
 7 interpretation?
 8 **A. Yes.**
 9 Q. Doesn't it appear that the
 10 authors of the Creinin study regarded this
 11 patient's outcome as something different from
 12 the expected consequence of a medication
 13 abortion?
 14 **A. It appears that's the message**
 15 **they were trying to portray.**
 16 Q. Would you agree with me that
 17 the doctors conducting the study would be in the
 18 best position to know whether this patient's
 19 heavy bleeding was on the ordinary side of the
 20 spectrum or an adverse event?
 21 MS. DAVIS: Objection.
 22 THE WITNESS: Yes.
 23 BY MR. BECK:
 24 Q. Let's look at paragraph 32 of
 25 your declaration. Actually, before we do. Do

1 that women should have contacted a medical
 2 provider.
 3 BY MR. BECK:
 4 Q. Would you contact a medical
 5 provider if you were having the ordinary effects
 6 of a medication as opposed to something out of
 7 the ordinary?
 8 **A. Usually not.**
 9 Q. You usually are supposed to
 10 contact the healthcare provider when something
 11 is going wrong, correct?
 12 **A. When something's out of the**
 13 **ordinary.**
 14 Q. And the FDA and the National
 15 Academy use two hours of heavy bleeding as a
 16 proxy for out of the ordinary hemorrhaging,
 17 correct?
 18 **A. That's correct.**
 19 Q. And this patient in the
 20 Creinin study who had progesterone had three
 21 hours of heavy bleeding, correct?
 22 **A. That's correct.**
 23 Q. And so according to the
 24 criteria established or set forth in the
 25 National Academy and the FDA, her hemorrhaging

1 abortion pill rescue patients have to agree that
 2 they will seek emergency care if they experience
 3 heavy bleeding?
 4 **A. They're instructed to seek**
 5 **medical care if they're experiencing heavy**
 6 **bleeding.**
 7 Q. And if nurses -- those nurses
 8 who answer the abortion pill rescue hotline, if
 9 the patient says she's experiencing heavy
 10 bleeding, do they tell her to seek emergency
 11 treatment?
 12 **A. To my knowledge, yes.**
 13 Q. And are patients told to call
 14 their provider also or just to seek emergency
 15 treatment?
 16 **A. I guess you should define what**
 17 **you mean by emergency treatment.**
 18 Q. Contact an emergency
 19 department or call an ambulance, I guess, is
 20 what I mean by it.
 21 **A. Well, they're instructed to**
 22 **seek medical care. For some women, that means**
 23 **contacting their medical provider. For others,**
 24 **it means going to the emergency department. And**
 25 **for others, it might be calling an ambulance.**

1 **It all depends on the severity of it or -- and**
 2 **of the availability if she has a physician**
 3 **already -- a relationship with a physician**
 4 **already.**
 5 Q. So let's assume that your
 6 forms say emergency care, because I've seen some
 7 forms and I believe that's what they say. Would
 8 you call -- would you -- would you include just
 9 sort of contacting your physician as a form of
 10 emergency care or would you say emergency care
 11 means go to the hospital emergency department?
 12 **A. I would have to look at the**
 13 **form to make that determination.**
 14 Q. Well, let's -- let's work with
 15 the phrase "emergency care." What do you
 16 understand the phrase "emergency care" to mean?
 17 **A. Emergency care means care**
 18 **that's delivered right away. So that would mean**
 19 **if you can get someone on the phone right away**
 20 **to get further direction that would be adequate.**
 21 **But if that's -- if that's not possible, then it**
 22 **would mean going to an emergency department.**
 23 Q. And so are patients told to
 24 call the -- patients who go to the emergency
 25 room are they told to call -- let me start over.

1 Patients in the abortion pill
 2 rescue program who go to the emergency room, are
 3 they told to also call their healthcare provider
 4 or just go to the emergency room?
 5 **A. I don't know.**
 6 Q. So would you know if they
 7 sought emergency treatment?
 8 **A. You mean if they were a**
 9 **patient that I were caring for directly?**
 10 Q. No. I guess I mean, would the
 11 abortion pill rescue program know if a patient
 12 when to the emergency room?
 13 **A. I would suppose they would**
 14 **know. But I can't answer -- I can't answer for**
 15 **them.**
 16 Q. They might not?
 17 **A. I don't know. I would be**
 18 **speculating.**
 19 Q. Okay. So let's look back
 20 at -- at paragraph 32 of your declaration.
 21 **A. Okay.**
 22 Q. So it says, "In summary, the
 23 Creinin study safety results were: Two patients
 24 required suction aspiration. Both from in the
 25 placebo group. The single patient in the

1 progesterone group that went to the emergency
 2 department simply represented a reversal failure
 3 and did not need to be in the emergency
 4 department, since she required no intervention.
 5 The patient requiring transfusion was in the
 6 placebo group. Therefore, it was placebo, not
 7 the progesterone therapy that was unsafe.
 8 Mifepristone alone for abortion was unsafe in
 9 study. Attempting reversal was not proven to be
 10 unsafe."
 11 Did I read that correctly?
 12 **A. Yes.**
 13 Q. Okay. You'd agree with me
 14 that this summary is different from the
 15 Creinin's study's own descriptions of its safety
 16 findings, correct?
 17 **A. Yes.**
 18 Q. And so a reader looking at
 19 paragraph 32 should know that this is your
 20 interpretation of the Creinin study's safety
 21 results, but not how the study itself describes
 22 those results, correct?
 23 **A. Well, this paragraph states**
 24 **the facts of the study, and -- and then the last**
 25 **three bullet points are interpretation.**

1 Q. Well, the -- the authors of
 2 the Creinin study thought that the patient in
 3 the progesterone group who hemorrhaged
 4 experienced an adverse event, correct?
 5 **A. I don't think they stated**
 6 **that.**
 7 Q. They collectively refer to
 8 three patients experiencing very heavy bleeding
 9 requiring trips to the emergency room
 10 department, which is why they aborted their
 11 study, correct?
 12 **A. Right.**
 13 Q. They --
 14 **A. Brisk bleeding and heavy**
 15 **bleeding in another part.**
 16 Q. Right. But they lumped those
 17 three patients together as the cause of pulling
 18 the plug on the study, correct?
 19 **A. Yes. With the -- the final**
 20 **straw being the one who required transfusion.**
 21 Q. And so turning back to your
 22 declaration, the final three bullet points at
 23 minimum are interpretation. And, in fact, this
 24 is sort of your interpretation of the study in
 25 general, not the author's own description of

1 their findings, correct?

2 **A. Well, I would say the author**

3 **would probably agree with the mifepristone alone**

4 **for abortion was unsafe in this study. In fact,**

5 **I think he may even state that in other words.**

6 Q. Right. You don't disagree

7 with that, right? On that point you and

8 Dr. Creinin agree, correct?

9 **A. Correct.**

10 Q. Right. The Creinin study

11 states, "Patients in early pregnancy who use

12 only mifepristone may be at high risk of

13 significant hemorrhage." That's his words. You

14 don't disagree with that, correct?

15 **A. Correct.**

16 Q. But in terms of your

17 attribution to the placebo as the source of

18 hemorrhage, there seems to be a disagreement

19 between you and Dr. Creinin, correct?

20 **A. I wouldn't say the placebo was**

21 **the cause of hemorrhage.**

22 Q. When you say, "Therefore, it

23 was the placebo, not the progesterone therapy

24 that was unsafe," what do you mean by that?

25 **A. That those who did not receive**

1 **progesterone were the ones who -- or were in the**

2 **unsafe group, not the progesterone therapy**

3 **group.**

4 Q. Well, two who didn't receive

5 progesterone and one who did experienced

6 hemorrhage?

7 **A. Right. And the two in the**

8 **placebo group had significantly -- were -- were**

9 **significantly more risk because one of them**

10 **required transfusion. The -- and both of them**

11 **required suction aspiration.**

12 **One in the placebo group**

13 **required no treatment at all and did not require**

14 **it. So -- so there's no treatment, not even the**

15 **suction aspiration. So she actually completed**

16 **her abortion without needing any intervention at**

17 **all, as opposed to the other two that required**

18 **significant intervention.**

19 Q. Well, but all three

20 experienced what the National Academies refer to

21 as hemorrhage requiring medical attention,

22 correct?

23 **A. That's correct.**

24 Q. And the authors don't

25 attribute that to -- the harm to the placebo

1 causing that adverse event. They say, like you

2 said a moment ago, stop -- taking mifepristone

3 and not taking misoprostol can cause hemorrhage.

4 And you and Dr. Creinin seem to agree on that,

5 correct?

6 MS. DAVIS: Objection.

7 THE WITNESS: I agree that

8 taking mifepristone alone without following it

9 by progesterone or misoprostol increased the

10 risk of hemorrhage.

11 BY MR. BECK:

12 Q. Why would progesterone cause

13 the abortion to complete for that progesterone

14 patient?

15 **A. It did not cause the abortion**

16 **to complete.**

17 Q. Why would progesterone -- why

18 do you -- why would you conclude that

19 progesterone made the progesterone patients'

20 experience safer than the two placebo patients?

21 **A. Well, in this study, if you**

22 **just look at this study, the five remaining**

23 **patients who are in the progesterone group, none**

24 **of them required suction aspiration. None of**

25 **them required transfusions. None of them had**

1 **heavy bleeding requiring intervention.**

2 Q. Right. But the one who did,

3 why would the progesterone -- why would you

4 conclude that the progesterone made her

5 experience safer than the placebo patients?

6 **A. Well, just comparing her to**

7 **the other two, she did not require any**

8 **intervention while the other two required**

9 **extensive intervention.**

10 Q. But why would progesterone

11 cause that? What -- what's your medical therapy

12 for why progesterone is sort of the safety valve

13 for that patient?

14 **A. Well, that would simply be**

15 **speculation in this individual case, of course.**

16 **We know that progesterone stabilizes the lining**

17 **of the uterus. And we know that the effects of**

18 **the mifepristone, although not totally reversed**

19 **because the embryo didn't survive, there was**

20 **probably still some antagonism of the**

21 **mifepristone. And so all of that could have led**

22 **to less bleeding and the -- and less**

23 **complications than the other ones.**

24 Q. But she experienced heavy

25 bleeding lasting three hours and the -- and the

1 abortion was completed. That doesn't sound like
 2 stabilizing the lining of the uterus to me.
 3 Does it sound like stabilizing the lining of the
 4 uterus happened here to you?
 5 **A. You know, we don't know in**
 6 **this -- in this particular case what exactly**
 7 **happened without being able to microscopically**
 8 **look inside what was going on. So that's why I**
 9 **told you it was just speculation in this**
 10 **particular patient.**
 11 Q. At paragraph 42 of your
 12 declaration?
 13 **A. I'm there.**
 14 Q. You say, "It is unethical to
 15 subject an embryo or fetus to the double
 16 jeopardy of mifepristone abortion, followed by a
 17 surgical abortion, if the mifepristone abortion
 18 is reversed."
 19 So just to be clear, that's
 20 what Dr. Creinin was attempting to do in his
 21 study, correct?
 22 **A. That's correct.**
 23 Q. What do you mean by saying
 24 that it would be unethical to subject an embryo
 25 to double jeopardy?

1 MS. DAVIS: Objection.
 2 THE WITNESS: You have a
 3 subject of a study, the embryo or the fetus, who
 4 does not give consent to the study, number one.
 5 Number two, it's put in the undignified position
 6 of being exposed to a potentially lethal
 7 medication. And then, if that lethality is not
 8 accomplished, then a surgical lethal procedure
 9 is then performed on that embryo or fetus.
 10 BY MR. BECK:
 11 Q. So is that -- is another way
 12 of looking at this just sort of a summary of
 13 your view that all abortion is unethical?
 14 **A. I think ending of the life of**
 15 **an innocent person is unethical. And it's**
 16 **doubly unethical to subject a person to a double**
 17 **lethal jeopardy.**
 18 Q. Why is that doubly -- I mean,
 19 why is -- why is doing that more unethical than
 20 just performing an abortion in the first place?
 21 **A. Like I stated before, this**
 22 **subject is unable to give informed consent. And**
 23 **you're subjecting that subject to two trials of**
 24 **extermination.**
 25 Q. If a woman had a medication

1 abortion that doesn't work and she follows it up
 2 with a surgical abortion, is that doubly
 3 unethical?
 4 **A. That is different than a study**
 5 **that is designed from the onset to provide a**
 6 **situation of double jeopardy, as opposed to a**
 7 **woman who undergoes a medical abortion thinking**
 8 **that this is the -- the one protocol or**
 9 **procedure she'll undergo to effect that**
 10 **abortion. Those are not good analogous**
 11 **situations.**
 12 Q. But she would be told in
 13 advance there's a chance that the medication
 14 won't work, right? We know that medication
 15 abortion has a failure rate?
 16 **A. Correct.**
 17 Q. And so she goes into it and
 18 the doctor goes into it knowing some small
 19 percentage of the time, a surgical intervention
 20 is going to be required, correct?
 21 **A. She's probably told that, yes.**
 22 Q. And so is that -- in -- in
 23 that subset when that happens, is that
 24 especially unethical because it's sort of
 25 subjecting the fetus to double jeopardy again?

1 **A. Again, I don't -- I don't -- I**
 2 **don't see the connection with my previous**
 3 **statement. Because her intention is and her**
 4 **expectation that the medical abortion will be**
 5 **successful in terminating the pregnancy.**
 6 Q. All right. But just to be
 7 clear, you do believe that all abortions are
 8 unethical, correct?
 9 **A. All direct abortions, yes.**
 10 Q. What do you mean by direct
 11 abortions?
 12 **A. When the intent is to end the**
 13 **life of the pre-born baby.**
 14 Q. What would be an example of an
 15 indirect abortion?
 16 **A. An indirect abortion would be**
 17 **a woman who has a tubal pregnancy and the tube**
 18 **is removed in order to save the life of the**
 19 **mother. One action has two effects. First**
 20 **effect is saving the life of the mother. The**
 21 **second effect is ending the life of the embryo.**
 22 **And so that would be an indirect abortion that**
 23 **would be considered ethically appropriate by the**
 24 **principle of double effect.**
 25 Q. So all direct abortions are

1 unethical?
 2 **A. Yes.**
 3 Q. Switching gears for a second.
 4 Were any of the patients in your 2018 case
 5 series patients that you treated personally?
 6 **A. Yes.**
 7 Q. How many?
 8 **A. I don't recall the exact**
 9 **number.**
 10 Q. Could you give me a ballpark
 11 estimate?
 12 **A. Five to ten.**
 13 Q. What about Dr. Davenport, your
 14 co-author, were any of the patients in the 2018
 15 case series patients of Dr. Davenport's?
 16 **A. I believe so.**
 17 Q. Do you have a ballpark
 18 estimate of how many?
 19 **A. No, I don't.**
 20 Q. Were the patients that you
 21 personally cared for, were they treated before
 22 or after you had it in mind to publish what
 23 would become the 2018 case series?
 24 MS. DAVIS: Objection.
 25 THE WITNESS: I don't recall.

1 BY MR. BECK:
 2 Q. Did you care for any patients
 3 after you planned to publish the case -- the
 4 case series?
 5 **A. I don't recall.**
 6 Q. Is it possible?
 7 **A. I'm not sure. I -- I'd be**
 8 **speculating.**
 9 Q. It sounds like it's possible,
 10 but you just don't know?
 11 **A. That's a fair**
 12 **characterization.**
 13 Q. Okay. Your declaration at
 14 paragraph 20, are you there?
 15 **A. I'm getting to it. There --**
 16 **I'm there.**
 17 Q. You state that your 2018 case
 18 series evaluated 261 successful mifepristone
 19 reversals that resulted in live births, correct?
 20 **A. That's right.**
 21 Q. So before we get into the
 22 details of that study, the 261 figure is the
 23 total number of births in that study population,
 24 correct?
 25 **A. That's right.**

1 Q. And we agreed earlier that
 2 mifepristone alone does not always result in an
 3 abortion, correct?
 4 **A. That's right.**
 5 Q. And as we've discussed, your
 6 study used a historical control -- as a
 7 historical control an assumption of a 25
 8 embryotic survival rate for mifepristone,
 9 correct?
 10 **A. That's correct.**
 11 Q. So some percentage of those
 12 261 births would have happened whether or not
 13 the patient took progesterone at all, correct?
 14 **A. That's correct.**
 15 Q. It would only be if
 16 mifepristone --
 17 **A. Excuse me. Let me back up on**
 18 **that. That is not necessarily correct. So we**
 19 **don't know the number. Because in the early**
 20 **mifepristone studies, they only followed them**
 21 **out to 7 or 14 days. So we really don't know**
 22 **what percentage that would have gone on to**
 23 **actually be born.**
 24 Q. Well, you assumed as a
 25 historical control a 25 percent survival rate,

1 correct?
 2 **A. Correct.**
 3 Q. That's the whole point of your
 4 comparison, correct?
 5 **A. That's correct.**
 6 Q. And so are you -- so the
 7 premise of your study is that 25 percent of
 8 those pregnancies would have survived
 9 irrespective of progesterone intervention,
 10 correct?
 11 **A. That was the control we used,**
 12 **yes.**
 13 Q. And only if mifepristone
 14 resulted in fetal demise or embryotic demise 100
 15 percent of the time would you be able to claim
 16 that 261 of your cases are successful reversals,
 17 correct?
 18 **A. Without certainty, yes.**
 19 Q. And no one thinks that
 20 mifepristone works and causes fetal demise 100
 21 percent of the time, correct?
 22 **A. That's correct.**
 23 Q. So this statement in paragraph
 24 20 that you had 261 successful mifepristone
 25 reversals is not exactly accurate, correct?

1 **A. Not exactly. It -- it -- I**
 2 **think it conveys the point of what we're trying**
 3 **to say, but you're right. It's not exactly**
 4 **accurate in -- in the terms you're describing.**
 5 Q. Let's look at the 2018 case
 6 series. If you could turn to page 28 of that
 7 study?
 8 **A. Okay.**
 9 Q. At five weeks -- so table 2 is
 10 breakdown by gestational age, correct?
 11 **A. That's right.**
 12 Q. And at five weeks there were
 13 76 patients with a 25 percent rate of ongoing
 14 pregnancy after progesterone, correct?
 15 **A. That's right.**
 16 Q. And 25 percent is equal to
 17 your historical control?
 18 **A. That's correct.**
 19 Q. The P value is 0.5, correct?
 20 **A. That's correct.**
 21 Q. What does a 0.5 P value mean?
 22 **A. It means that 5 out of 1,000**
 23 **times the -- correction, 50 out of 100 times,**
 24 **that the stated result is possibly due to**
 25 **chance. So it means not statistically**

1 **significant.**
 2 Q. It means the result is just as
 3 likely to be attributable to chance as it is to
 4 the incident, correct?
 5 **A. That's correct.**
 6 Q. And so with respect to
 7 pregnancies at five weeks, your 2018 study
 8 doesn't give us statistically significant data
 9 on the efficacy of reversal, correct?
 10 **A. That's correct.**
 11 Q. Other than this study, do we
 12 have data establishing the efficacy of
 13 progesterone to reverse medication abortion for
 14 patients at five weeks?
 15 **A. No.**
 16 Q. Let's look at page 25 of the
 17 study.
 18 **A. Okay.**
 19 Q. Are you there?
 20 **A. Yes.**
 21 Q. In the second paragraph you
 22 state that you lost 112 subjects to follow-up
 23 prior to 20 weeks, correct?
 24 **A. That's correct.**
 25 Q. 14.9 percent of your study

1 population?
 2 **A. That's right.**
 3 Q. And they were excluded from
 4 the analysis in your study?
 5 **A. That's correct.**
 6 Q. Do you have any idea about
 7 what happened to those 112 women after you lost
 8 contact with them?
 9 **A. No. I -- you know, no, direct**
 10 **knowledge.**
 11 Q. They could have all given --
 12 carried to term and given birth for all you
 13 know, correct?
 14 **A. They could have.**
 15 Q. Or all 112 of them could have
 16 been reversal failures, but you just don't know,
 17 correct?
 18 **A. That's possible, but unlikely.**
 19 Q. Just as unlikely as them all
 20 giving -- carrying to term and giving birth,
 21 correct?
 22 **A. Correct.**
 23 Q. And if some of them
 24 experienced heavy bleeding and hemorrhage like
 25 the three patients in Dr. Creinin's study, you

1 also wouldn't know about that, correct?
 2 **A. Not if they were lost to**
 3 **follow-up.**
 4 Q. And these 112 patients were
 5 lost to follow-up, correct?
 6 **A. That's right.**
 7 Q. And so if any of them
 8 experienced hemorrhage, you would not know about
 9 that, correct?
 10 **A. Correct.**
 11 Q. And you can't rule it out as a
 12 possibility?
 13 **A. Just like I can't rule out**
 14 **that they all gave birth as a possibility.**
 15 Q. Right. You just don't know?
 16 **A. You just don't know.**
 17 Q. Let's look back at Exhibit 25,
 18 which was tab A, your deposition from Arizona.
 19 And if you could turn to page 190. Let me know
 20 when you're there.
 21 **A. I'm at 190.**
 22 Q. Starting at line 6 -- well,
 23 before I do this. We've already covered this,
 24 but you were under oath that day swearing to the
 25 tell the truth, just as you have today, and as

1 you will in court next month, right?

2 **A. Yes.**

3 Q. Okay. So starting at line 6

4 the question states, Question, "Exhibit 23

5 before you is an article, 'User's Guide to

6 Orthopedic Literature: How to Use an Article

7 About a Randomized Trial --

8 **A. Hold on a second.**

9 Q. Am I at the wrong place?

10 **A. Yeah. You said page 189 of**

11 **the Arizona case?**

12 Q. Sorry, 190 of the Arizona.

13 **A. Okay. I'm sorry. I got that**

14 **wrong. Okay. Now I see it.**

15 Q. Okay. Do you see where I was

16 reading?

17 **A. Yes, Exhibit 23.**

18 Q. Yep. I'll start over.

19 Question, "Exhibit 23 before you is an article,

20 'User's guide to orthopaedic literature: How to

21 use an article about a randomized trial?' On

22 page 5 below the heading, 'Was follow-up

23 complete?' states, 'During a clinical trial,

24 investigators are interested in patients'

25 outcome measures regardless of which group they

1 were assigned to. Patients with unknown data

2 are classified as lost to follow-up. The

3 greater the number patients lost to follow-up

4 decreases the internal validity of a study.

5 Data is rarely missing for trivial reasons.

6 Subjects that are missing typically have a

7 different prognosis than those who remain in the

8 study. Patients could have been lost to

9 follow-up because of an adverse outcome such as

10 death or a very positive treatment outcome so

11 that the patients did not return for further

12 assessment. Incomplete follow-up biases the

13 outcome measure.

14 Did I read that correctly?"

15 Answer, "Yes."

16 Question, "Do you agree with

17 that statement?"

18 Answer, "Yes."

19 First of all, was that

20 testimony truthful when you gave it?

21 **A. Yes.**

22 Q. And do you stand by it today?

23 **A. Yes.**

24 Q. And so you agree, in

25 particular, that patients could have been lost

1 to follow-up because of an adverse outcome such

2 as death or a very positive treatment outcome so

3 that the patients did not return for further

4 assessment, correct?

5 **A. Yes. And it also could have**

6 **been because the patients changed their minds**

7 **and sought out surgical abortions and,**

8 **therefore, did not return phone calls and other**

9 **contacts that were possible.**

10 Q. Those are also possible

11 outcomes and ways in which your lost follow-up

12 population might differ from your study

13 population, correct?

14 **A. That's correct.**

15 Q. And you were next asked, "Do

16 you think that the loss to follow-up in your

17 study has, as it states here, potential to bias

18 your results?"

19 And your answer was, "Any loss

20 of follow-up has a potential to bias results."

21 And so, again, that testimony

22 was truthful when you gave it, correct?

23 **A. That's correct.**

24 Q. And you stand by that today?

25 **A. Yes.**

1 Q. You were next asked whether

2 this principal would apply to your case series,

3 and you said, yes, right?

4 **A. Yes.**

5 Q. And that testimony was

6 truthful when you gave it?

7 **A. Yes.**

8 Q. And you stand by it today?

9 **A. Yes.**

10 Q. Okay. At page 192, let me

11 know when you're there.

12 **A. I'm there.**

13 Q. 192, line 1, you were asked

14 whether it's possible that many of the women you

15 lost contact with experienced a pregnancy loss.

16 And your answer was, "It's possible."

17 And so, again, that testimony

18 was truthful when you gave it, correct?

19 **A. Correct.**

20 Q. And you stand by that today?

21 **A. Yes.**

22 MR. BECK: Okay. Let's

23 introduce Tab Y into the chat.

24 BY MR. BECK:

25 Q. Let me know when you have that

1 ready.

2 **A. It's open, but it's upside**

3 **down. Is yours upside down?**

4 Q. It certainly is. I wonder if

5 there is a way to flip that?

6 **A. Let's see. If I go to view --**

7 Q. Rotate view. So if you do

8 rotate view a few times, we can fix that

9 problem. Does that work for you?

10 **A. Well, I don't see rotate view**

11 **in my --**

12 Q. For me, it's the first item

13 that comes up under view.

14 **A. Is show tab bar.**

15 Q. Do you happen to have a

16 printer in the room you're in?

17 **A. I do, but I don't think I'm**

18 **connected. Let me -- maybe I -- I can export it**

19 **as a PDF and reopen it. I can try that.**

20 Q. These are the challenges of

21 Zoom depositions. Let me know if you're able to

22 do that.

23 MS. CHAN: I just added a --

24 what is hopefully a rotated version of the PDF

25 to the chat, if you want to download the latest

1 file and see if that worked.

2 THE WITNESS: Okay.

3 MR. BECK: Thank you. And

4 while you're looking to see if that worked,

5 let's mark the new version of Exhibit Y as

6 Exhibit -- I'm sorry, the new version of Tab Y

7 as Exhibit 38 before I forget.

8 (Whereupon, the document was

9 marked as Exhibit No. 38 to the testimony of the

10 witness.)

11 THE WITNESS: That one's also

12 upside down. So I'll try -- let me see if I

13 successfully downloaded. The downloaded is also

14 upside down. Let's see. Oh, here's rotate.

15 Okay. It's under tools in mine. Okay. I have

16 it now.

17 BY MR. BECK:

18 Q. It's a miracle. Thank you for

19 soldiering on with the upside down exhibit.

20 So this is another chapter

21 from that same textbook, "How to Report Statics

22 in Medicine," by Lang and Secic that we were

23 looking at earlier. So let's look at page 209

24 of this chapter. Let me know when you're there.

25 **A. Okay.**

1 Q. Is it still sideways for you?

2 **A. Well, some of them are**

3 **sideways, some -- so I have to -- I had to**

4 **rotate this one back. So now I'm okay.**

5 Q. Okay. Great. At -- so are

6 you on page 209?

7 **A. Yes.**

8 Q. Item 13.55, that's where I'm

9 looking at.

10 **A. Okay.**

11 Q. And I just want to read that

12 for the record. It states, "As is the case with

13 participants whose care deviated from the

14 protocol or who were withdrawn from the trial,

15 patients lost to follow-up may differ

16 systematically from those who are not,

17 indicating potential bias."

18 Is -- is the statement I just

19 read correct?

20 **A. Yes.**

21 Q. And I think at your 2015

22 deposition you said that it was appropriate to

23 hold your study to standards like this one. Do

24 you still think so?

25 **A. It is.**

1 Q. The next sentence says, "For

2 example, participants lost to follow-up are

3 likely to be those least satisfied with the

4 results of the therapy."

5 Do you think that's a

6 legitimate point?

7 **A. That's a legitimate point.**

8 Q. And in your case series, you

9 lost contact with approximately 15 percent of

10 the study population?

11 **A. Yes.**

12 Q. And, again, we don't know how

13 many, if any, of those 112 women you lost

14 contact with experienced an adverse event,

15 correct?

16 **A. That's correct.**

17 Q. Could have been zero?

18 **A. That's correct.**

19 Q. It could have been a few?

20 **A. That's correct.**

21 Q. It could have been even 112,

22 correct?

23 **A. It could have been, but that**

24 **seems unlikely.**

25 Q. We don't have data to answer

1 the question, correct?
 2 **A. Correct.**
 3 Q. In your -- in the case series
 4 of page 29 it says, "Furthermore, although the
 5 number of women lost to follow-up was small, it
 6 could have affected the results."
 7 So you sort of acknowledge
 8 that as one of the statements of the limitations
 9 of your study, correct?
 10 **A. That's correct.**
 11 Q. And you agree that there is a
 12 potential for bias as a result of those patients
 13 lost to follow-up?
 14 **A. Correct.**
 15 Q. When you state that the number
 16 of patients lost to follow-up was small, can you
 17 tell me why you think that 15 percent is a small
 18 number, in your opinion?
 19 **A. Well, because it's -- it's not**
 20 **unusual to lose, you know, somewhere in that**
 21 **order of patients in a -- in a trial, and**
 22 **especially in one of this nature that's a**
 23 **retrospective case study. It just -- that**
 24 **just -- that just can happen. And so it didn't**
 25 **seem to be a large -- large percentage.**

1 Q. And the text next to the
 2 exclamation point reads, "Rarely" -- let me
 3 start over. "Rarely do follow-up efforts
 4 include 100 percent of the participants.
 5 However, studies in which more than about 15
 6 percent of participants who completed the
 7 treatment, but who were lost to follow-up, for
 8 whatever reason, should be interpreted
 9 cautiously."
 10 Would you agree that with this
 11 book on medical statistics, that it appears to
 12 treat a 15 percent loss to follow-up as a bit of
 13 a red flag?
 14 **A. Yes.**
 15 Q. And it seems to be saying that
 16 when you lose about 15 percent to -- of your
 17 study participants, you're at a point where the
 18 effect is a potentially serious concern,
 19 correct?
 20 **A. Well, they're saying that you**
 21 **should interpret the study cautiously.**
 22 Q. And they -- and they have an
 23 exclamation point indicating that this is cause
 24 for particular concern, correct?
 25 **A. I would imagine that's why**

1 **The other -- the other thing**
 2 **to keep in mind is that because the trial was**
 3 **not a control trial, then there are, you know,**
 4 **fewer mechanisms set up to -- to try to -- in**
 5 **order to track them even though the efforts were**
 6 **very good to try to track them. Sometimes**
 7 **people are elusive and you just -- you can't**
 8 **control what they do.**
 9 **So -- so that's why we felt,**
 10 **well, it's -- it seemed to be a small**
 11 **percentage, all things considered.**
 12 Q. Okay. Can you turn to the
 13 next page of the -- of Tab Y, Exhibit 38?
 14 **A. That's the one that was upside**
 15 **down?**
 16 Q. That is, yeah.
 17 **A. Okay. Which --**
 18 Q. Are you there?
 19 **A. Page 211 or 210?**
 20 Q. 210.
 21 **A. 210. Okay. I'm there.**
 22 Q. So the -- there's an
 23 exclamation point in the top left corner. Do
 24 you see that?
 25 **A. Yes.**

1 **they have an exclamation point there.**
 2 Q. This also seems to indicate
 3 that a 15 percent loss of participants is not a
 4 small number, that it's a sufficiently high
 5 figure that it warrants a cautionary exclamation
 6 point. Do you agree?
 7 **A. That seems to be what they're**
 8 **indicating, yes.**
 9 Q. And are you aware of any
 10 literature, medical literature that would
 11 support a contrary conclusion that a 15 percent
 12 loss of participants in a study is, in fact, a
 13 small number?
 14 **A. No.**
 15 Q. Can we look at page 24 of your
 16 study -- of your case series?
 17 **A. Okay. I'm there.**
 18 Q. Under the third paragraph
 19 under methods, the first sentence reads, "Data
 20 were collected for different variables,
 21 including gestational age at the time of
 22 mifepristone ingestion, mode of delivery
 23 progesterone given, and amounts of progesterone
 24 received, birth defects, and preterm delivery."
 25 Did I read that correctly?

1 **A. Yes.**
 2 Q. And you report on those
 3 variables in the study, correct?
 4 **A. That's correct.**
 5 Q. Did you collect data on side
 6 effects of the treatment?
 7 **A. We had incomplete reporting of**
 8 **side effects.**
 9 Q. So would it be fair to say
 10 that you did not collect data systematically for
 11 each participant on side effects?
 12 MS. DAVIS: Objection.
 13 THE WITNESS: I would say
 14 there was -- there was systematic collection of
 15 some -- some side effects.
 16 BY MR. BECK:
 17 Q. What do you mean by systematic
 18 collection of some side effects?
 19 **A. Well, for example, two that**
 20 **are very, very important, birth defects and**
 21 **preterm delivery.**
 22 Q. Right. So you -- so you
 23 collected -- and I want to put those ones in a
 24 category of stuff that you did report on and
 25 analyze in your study. But I'm interested in,

1 for example, side effects like nausea, vomiting,
 2 tiredness, dizziness, bleeding, those kinds of
 3 side effects.
 4 Did you gather data on those
 5 types of side effects for each patient?
 6 **A. No.**
 7 Q. And what about for
 8 complications like heavy bleeding and
 9 hospitalization, did you gather data on a
 10 systematic basis for complications like that?
 11 **A. Not systematically. Only**
 12 **if -- if they arose.**
 13 Q. I'm sorry. I missed what you
 14 said. Can you -- can you repeat your answer?
 15 **A. Not systematically. Only if**
 16 **they arose.**
 17 Q. But if they did arise, did
 18 you -- were you aware -- how many instances of
 19 --
 20 **A. I --**
 21 Q. Sorry?
 22 **A. Not aware of any woman**
 23 **requiring hospitalization in our study.**
 24 Q. And do you think that you
 25 systematically gathered that data enough to be

1 able to answer the question?
 2 **A. I did not systematically**
 3 **gather it.**
 4 Q. And --
 5 **A. I would assume that the women**
 6 **we were able to follow, that they would have**
 7 **told us.**
 8 Q. So the women you were able to
 9 follow, in none of those -- so the ones who were
 10 not lost to follow-up did not experience any
 11 complications other than the birth -- the few
 12 birth defects that you identify in the study.
 13 Is that a fair statement?
 14 **A. That's a fair statement.**
 15 Q. And of the 112 with whom you
 16 lost contact, you don't know whether or not they
 17 experienced complications, correct?
 18 **A. I don't know.**
 19 Q. Okay. On page 29 of your 2018
 20 case series, are you there?
 21 **A. Yes.**
 22 Q. The first sentence of the
 23 first full paragraph states, "One potential
 24 confounding variable is the use of ultrasound to
 25 select for living embryos prior to the first --

1 prior to the first progesterone dose." And then
 2 toward the end of that paragraph it states, "If
 3 ultrasound is readily available, sound practice
 4 would dictate that embryonic or fetal viability
 5 should be confirmed, or at least suggested,
 6 before treatment is started in order to avoid
 7 giving women progesterone unnecessarily and to
 8 exclude ectopic pregnancy before starting
 9 progesterone therapy."
 10 Did I read that more or less
 11 correctly?
 12 **A. Yes.**
 13 Q. So would it be correct to say
 14 that when a woman contacts Abortion Pill
 15 Rescue -- the Abortion Pill Rescue Network and
 16 is referred for medication abortion pill --
 17 medication abortion reversal, the clinician
 18 generally performs an ultrasound before
 19 administering progesterone if ultrasound is
 20 readily available? Should I ask that again
 21 because I think it was unclear. Let me ask that
 22 again.
 23 Would it be correct to say
 24 that if a woman contacts the APR hotline and is
 25 referred to a clinician for medication abortion

1 reversal, if ultrasound is available, the
 2 clinician generally performs ultrasound before
 3 performing -- before administering progesterone?
 4 **A. That would be correct.**
 5 Q. And one purpose as you
 6 indicate here for that is to confirm that the
 7 embryo or fetus is still alive before
 8 administering progesterone, right?
 9 **A. That's correct.**
 10 Q. And another purpose is to
 11 exclude ectopic pregnancy?
 12 **A. That's correct.**
 13 Q. And then in the middle of that
 14 paragraph it states, "Our study also included
 15 some women who started progesterone therapy
 16 prior to sonographic documentation that the
 17 embryo was alive," right?
 18 **A. That's right.**
 19 Q. Do you know the percentage
 20 breakdown of women in your study who received
 21 progesterone after sonographic documentation
 22 that the embryo was alive versus before?
 23 **A. No.**
 24 Q. Would it be fair to say that
 25 most women in the study had an ultrasound to

1 Q. And you don't know what
 2 percentage of the time an ultrasound is
 3 performed prior to starting progesterone
 4 therapy. And it could be even less than 50
 5 percent according to, I think, what you just
 6 said; is that correct?
 7 **A. Yes. I don't know.**
 8 Q. Could it be substantially less
 9 than 50 percent?
 10 **A. I would doubt it. But, again,**
 11 **I'm speculating.**
 12 Q. Could it be substantially more
 13 than 50 percent of the time?
 14 **A. It's possible.**
 15 Q. Okay. If it's your program's
 16 preference, presumably it's attempted most of
 17 the time, if possible, right?
 18 **A. If it's readily available.**
 19 **But, again, the -- the idea is that you don't --**
 20 **you don't -- it's balanced by not wanting to**
 21 **delay the progesterone therapy, so.**
 22 Q. I understand. But you don't
 23 know exactly a number -- you -- does the program
 24 have data on that and you just don't know it in
 25 your mind now or is there just no data to know

1 confirm that the pregnancy is alive and not
 2 ectopic prior to starting progesterone?
 3 **A. I don't think so.**
 4 Q. You don't think that most
 5 patients in your study had an ultrasound before
 6 they received progesterone?
 7 **A. I don't know. Because many of**
 8 **the calls come late in the day. And so**
 9 **sometimes patients are started on progesterone**
 10 **and then they get the ultrasound later in order**
 11 **to not delay.**
 12 Q. So I guess I'm trying to
 13 figure out when you say here, "If ultrasound is
 14 readily available, sound practice would dictate
 15 that embryonic of fetal viability should be
 16 confirmed, or at least suggested, before
 17 treatment is started."
 18 That's your -- the -- the
 19 program, the -- the hotline's preference,
 20 correct?
 21 **A. I assume that would be**
 22 **everybody's preference.**
 23 Q. And so I hear you saying that
 24 that preference isn't always realized?
 25 **A. That's correct.**

1 that at all?
 2 **A. At the time of the study, I**
 3 **didn't have the data available. I don't know if**
 4 **the program has it -- this data now.**
 5 Q. Okay. So you didn't collect
 6 data on the percentage of the time that
 7 ultrasound was performed prior to starting
 8 progesterone therapy?
 9 **A. No.**
 10 Q. Okay. On page 25 of your case
 11 series, under results, it indicates that your
 12 hotline received 1,668 calls from women who had
 13 taken mifepristone and were interested in
 14 reversal, and that 754 initiated progesterone
 15 therapy, correct?
 16 **A. That's correct.**
 17 Q. And I've done what I think is
 18 the math there, and -- and with subtraction
 19 concluded that there are 914 women who called,
 20 but who did not start progesterone. Does that
 21 sound sort of ballpark correct?
 22 **A. That sounds ballpark correct.**
 23 Q. Okay. And I would assume that
 24 some of those women called the hotline, but
 25 ultimately chose not to visit a clinician about

1 reversal; is that correct?
 2 **A. I'm sorry. Can you repeat**
 3 **that again?**
 4 Q. Yeah. So I'm just trying to
 5 sort of unpack that 914 number. Some of those
 6 people probably called the hotline and just
 7 didn't take any action after that. They didn't
 8 see a doctor about reversible. They got
 9 information on the hotline and decided not to do
 10 anything. Is that -- is that some of those 914,
 11 presumably?
 12 **A. Presumably, yes.**
 13 Q. And some of them did visit a
 14 clinician, some of those 914, but did not start
 15 progesterone, correct?
 16 **A. That's a possibility. I don't**
 17 **know.**
 18 Q. Well, anyone -- anyone in that
 19 group who visited a clinician and had an
 20 ultrasound performed that showed no fetal -- no
 21 live fetus at that point wouldn't start
 22 progesterone, correct?
 23 **A. That's correct.**
 24 Q. And you don't know what
 25 percentage of your study population fell into

1 that category, correct?
 2 **A. Correct.**
 3 Q. So in some cases, mifepristone
 4 had already worked before the patient could get
 5 started on progesterone, correct?
 6 **A. That's correct.**
 7 Q. And I may have asked this
 8 already. But you don't know what percentage of
 9 those 914 callers visited a clinician, had an
 10 ultrasound that showed that the embryo was no
 11 longer alive, and so didn't start progesterone;
 12 is that correct?
 13 **A. That's correct.**
 14 Q. You didn't collect that data?
 15 **A. That's correct.**
 16 Q. Did you consider collecting
 17 that data?
 18 **A. I don't recall. And I don't**
 19 **recall if that data were actually available. So**
 20 **I can't say for sure.**
 21 Q. Okay. So looking at figure 1
 22 on page 25 of your case series, these callers
 23 who fall into the category of women who couldn't
 24 even start progesterone because mifepristone had
 25 already worked, they would be excluded from that

1 754 patients who were included in your study,
 2 right?
 3 **A. Right. Because if we knew the**
 4 **-- that the embryo were not alive, then we would**
 5 **not initiate progesterone.**
 6 Q. And they would also, of
 7 course, then be excluded from the 547 who were
 8 eligible for analysis?
 9 **A. That's correct.**
 10 Q. And that 547 subjects make up
 11 the denominator of your study from which you
 12 assessed the percent survival of embryos with
 13 progesterone treatment, correct?
 14 **A. That's correct.**
 15 Q. And similarly, you know,
 16 looking back at those 914 callers who did not
 17 initiate progesterone, if someone called after
 18 72 hours, they also would be ineligible for
 19 participation in the study, correct?
 20 **A. That's correct.**
 21 Q. And so if 96 hours had elapsed
 22 between a woman taking mifepristone and calling
 23 the hotline, she would be ineligible for
 24 participation -- for inclusion in the study, I
 25 should say?

1 **A. Inclusion in the study,**
 2 **correct.**
 3 Q. And I think you say you had --
 4 you excluded 38 -- I'm sorry, 38 women on that
 5 basis. Does that sound right?
 6 **A. That's correct.**
 7 Q. Okay. So let's take a
 8 hypothetical woman. She takes mifepristone, and
 9 unbeknownst to her, at exactly 23 hours after
 10 taking mifepristone it results in fetal demise,
 11 and at 24 hours, she starts to have second
 12 thoughts. Do you understand the hypothetical so
 13 far?
 14 **A. Yes.**
 15 Q. Okay. If this woman had been
 16 a subject in the early mifepristone studies we
 17 were speaking about earlier, she would be
 18 included in that study, correct?
 19 MS. DAVIS: Objection.
 20 THE WITNESS: I would have to
 21 look at the inclusion and exclusion criteria of
 22 the study to make that determination.
 23 BY MR. BECK:
 24 Q. Well, there's no reason
 25 sitting here to conclude that -- that you know

1 of right now that -- for excluding her from the
 2 study, right?
 3 **A. Correct.**
 4 Q. She would -- unless there were
 5 some unexpected exclusionary criteria, she would
 6 show up as a case in which mifepristone caused
 7 fetal death, correct?
 8 **A. That's correct.**
 9 Q. Okay. And if this same woman
 10 called your hotline, mifepristone caused fetal
 11 demise at 23 hours, at 24 hours she saw a
 12 clinician for reversal, and an ultrasound showed
 13 that fetal demise had already occurred, in that
 14 case, she would be excluded from your study
 15 because she was ineligible for progesterone,
 16 correct?
 17 **A. That's correct.**
 18 Q. And so she would not show up
 19 as a reversal failure because reversal would not
 20 have been attempted on her, correct?
 21 **A. That's correct.**
 22 Q. And so for purposes of your
 23 study, this study this woman wouldn't exist?
 24 **A. She wouldn't --**
 25 Q. She wouldn't show up in your

1 **A. That's correct.**
 2 Q. It could be zero or it could
 3 be more than zero, correct?
 4 **A. That's correct.**
 5 Q. For purposes of patients who
 6 had fetal demise before they visited a clinician
 7 and so were ineligible for progesterone therapy,
 8 we know it certainly is not more than 914,
 9 because that was the number of people who -- who
 10 didn't make it into the analysis, but we don't
 11 know the exact number, right?
 12 **A. That's correct.**
 13 Q. And whatever the number is, if
 14 it's more than zero, there would be some
 15 difference between the population eligible for
 16 analysis in your study and the early
 17 mifepristone studies, correct?
 18 **A. Say that again, please.**
 19 Q. Sure. Whatever the number is,
 20 because we don't know, if it's more than zero,
 21 there would be some difference in the population
 22 eligible for analysis in your study versus the
 23 population eligible for analysis in the early
 24 mifepristone studies, correct?
 25 MS. DAVIS: Objection.

1 data?
 2 **A. That's correct.**
 3 Q. Okay. Now, we don't know the
 4 number of callers in your study whose situations
 5 resembled this hypothetical, right?
 6 **A. That's correct. We also don't**
 7 **know the number of women who, at 23 weeks, had a**
 8 **demise, an embryo died, called in late and got**
 9 **started on progesterone at 24 hours, and then**
 10 **got an ultrasound the next day showing the baby**
 11 **died, and that was -- that would count as a**
 12 **reversal failure.**
 13 Q. Right. And -- and, actually,
 14 we talked about that at your 2015 deposition.
 15 And your prediction was that those two biases
 16 canceled each other out. Does that sound like
 17 an accurate reflection of your testimony?
 18 **A. Yes.**
 19 Q. But you actually -- we don't
 20 have data to know that. That's just
 21 speculation, correct?
 22 **A. That's correct.**
 23 Q. Okay. And so we don't know
 24 number of callers in your study whose situations
 25 resembled either of these hypotheticals, right?

1 THE WITNESS: If you -- if
 2 you're talking about the same patient sort of
 3 hypothetically in the two studies at the same
 4 time, yes.
 5 MR. BECK: Okay. Should we
 6 take a five minute break? Do people need the
 7 restroom?
 8 MS. DAVIS: Yeah.
 9 MR. BECK: I do. Okay. Can
 10 we go off?
 11 VIDEOGRAPHER: Off the record
 12 at 3:46.
 13 (A recess was taken.)
 14 VIDEOGRAPHER: We are back on
 15 the record at 3:55.
 16 BY MR. BECK:
 17 Q. Hi, Doctor. Did you have any
 18 correspondence or interaction with anyone from
 19 the Tennessee attorney general's office during
 20 the break?
 21 **A. No.**
 22 Q. Okay. Sorry, I'm trying to
 23 read something. Does the Abortion Pill Rescue
 24 Network provide for reversal after a patient
 25 takes misoprostol?

1 **A. The -- what's done there is**
 2 **the patient is referred to a physician, and the**
 3 **physician and the patient decide what's in her**
 4 **best interest and what should be done.**
 5 Q. And so is there sometimes
 6 treatment that is administered for a patient
 7 after she takes misoprostol?
 8 **A. I think there have been cases**
 9 **where treatment has been administered, yes.**
 10 Q. What treatment?
 11 **A. Progesterone.**
 12 Q. And is there evidence to show
 13 that progesterone is effective at reversing
 14 medication abortion after misoprostol is taken?
 15 **A. I -- there are no published**
 16 **studies, so the evidence would only be**
 17 **anecdotal.**
 18 Q. Is there anecdotal evidence?
 19 **A. I believe so, but I'm not**
 20 **certain.**
 21 Q. Do you think that progesterone
 22 is effective for reversing an abortion after a
 23 patient takes misoprostol?
 24 **A. I'm uncertain.**
 25 Q. Okay. What about the

1 published data to show that reversal of an
 2 abortion is effective in that context, or -- or
 3 data showing something else?
 4 **A. Data showing that the effects**
 5 **of methotrexate are reversible in patients**
 6 **who've received methotrexate and are**
 7 **experiencing toxicity from the methotrexate.**
 8 Q. But not -- but not data with
 9 respect to methotrexate's action when it comes
 10 to abortion in particular?
 11 **A. No published data.**
 12 Q. Okay. Does the Abortion Pill
 13 Rescue Network require clinicians who are in the
 14 network to meet in person with patients under
 15 all circumstances?
 16 **A. Well, the requirements for in**
 17 **person meeting have changed significantly in the**
 18 **last year. So telemedicine is now widely**
 19 **accepted. What the -- and the -- the Abortion**
 20 **Pill Rescue Network can't mandate anything. So**
 21 **it does have strong recommendations that a**
 22 **face-to-face meeting take place I believe it's**
 23 **within the first 72 hours of institution of**
 24 **treatment.**
 25 Q. And by face-to-face, you mean

1 administration of methotrexate for an ectopic
 2 pregnancy, is that reversible?
 3 **A. Well, I don't think anyone**
 4 **would want to reverse methotrexate given for an**
 5 **ectopic pregnancy.**
 6 Q. And so that's not been
 7 practiced in your -- to your knowledge, in the
 8 network?
 9 **A. No.**
 10 Q. What about in the context of a
 11 nonectopic pregnancy where methotrexate is
 12 administered, is methotrexate used to induce an
 13 abortion in a nonectopic pregnancy reversible,
 14 in your opinion?
 15 **A. I think it probably is.**
 16 Q. Also with progesterone?
 17 **A. With folinic acid.**
 18 Q. And is there published data to
 19 support that?
 20 **A. There's published data**
 21 **supporting the reversal of the effects of**
 22 **methotrexate folinic acid. That's very well**
 23 **established in patients who suffer toxicity from**
 24 **methotrexate.**
 25 Q. I'm sorry, there's -- there's

1 in person face-to-face?
 2 **A. Yes.**
 3 Q. Does it -- does it sometimes
 4 occur that abortion pill reversal therapy is
 5 administered via telemedicine?
 6 **A. I -- I'm not aware of the**
 7 **network -- if the network has telemedicine**
 8 **policies.**
 9 Q. Are you aware of, like, would
 10 ever a patient be referred to a clinician who
 11 would just call into a pharmacy a prescription
 12 for progesterone and the patient never meet with
 13 the clinician in person?
 14 **A. I'm not aware of that ever**
 15 **happening by design, no.**
 16 Q. You -- you added -- or used
 17 the words "by design" there. Does that mean
 18 it's not written into the protocols, but it
 19 might sometimes happen, or am I misunderstanding
 20 you?
 21 **A. Well, it might happen that the**
 22 **prescription's called in and that the woman then**
 23 **changes her mind and it never -- never gets**
 24 **started, and so never sees the clinician.**
 25 Q. But, for example, if a -- if a

1 woman lives far away from a clinician, if she's
 2 in a remote rural area, would it ever happen
 3 that the clinician and the woman could have an
 4 interaction by a telemedicine platform, and she
 5 goes to her local pharmacy to which the
 6 clinician calls in a prescription for
 7 progesterone?
 8 **A. And that would be it? No.**
 9 **Because there is the strong recommendation that**
 10 **the woman have an ultrasound as soon as**
 11 **possible.**
 12 Q. Okay. So that would -- are
 13 you saying that would never happen, or it's
 14 unlikely to happen?
 15 **A. I would say it's unlikely to**
 16 **happen.**
 17 Q. Okay.
 18 **A. I can never say never.**
 19 Q. Is there ever, to your
 20 knowledge, a woman in one state where there
 21 isn't a -- an Abortion Pill Rescue Network
 22 clinician, but someone in another state could
 23 assist her via telemedicine? Does that ever
 24 take place, a scenario like that, or no?
 25 **A. I don't believe so.**

1 Q. Okay. On page 29 of your case
 2 series, the last sentence of the carry over
 3 paragraph. Do you have it in front of you?
 4 **A. Yes.**
 5 Q. States, "In addition, some
 6 data collection was incomplete." This is in
 7 your discussion of study limitations. What is
 8 that referring to?
 9 **A. So I'm on page 29 and --**
 10 Q. It's the second full sentence
 11 on page 29.
 12 **A. Okay. Okay. I see it. "In**
 13 **addition, some data collection were incomplete."**
 14 **Well, that refers to the, for example, we talked**
 15 **about some data weren't available to us, like**
 16 **side effects and those sorts of things. So**
 17 **those were just incomplete. We didn't have it.**
 18 Q. So that -- that refers to
 19 things that we've already covered here and
 20 there's nothing we haven't covered that is
 21 encompassed within that sentence?
 22 **A. I believe so.**
 23 Q. Okay. Would it surprise
 24 you -- just going back to our earlier subject of
 25 conversation. Would it surprise you if

1 Dr. Boles stated that he had not met many of his
 2 reversal patients in person?
 3 **A. Yes.**
 4 Q. Okay. That would be
 5 inconsistent with the intended approach of the
 6 Abortion Pill Rescue Network?
 7 **A. Well, not necessarily. He may**
 8 **have had arrangements for associates or other**
 9 **clinicians to see patients.**
 10 Q. If he only spoke with them via
 11 telephone -- if he had patients he was treating
 12 for abortion -- abortion pill reversal and he
 13 only interacted with them over the phone, would
 14 that be inconsistent with the intended practice
 15 of the Abortion Pill Rescue Network?
 16 **A. If -- if they initiated**
 17 **treatment and continued treatment, yes, it would**
 18 **be. Because the recommendations are that they**
 19 **be seen in person.**
 20 Q. That practice would be outside
 21 the recommendations of your program?
 22 **A. Well, I -- I wouldn't be able**
 23 **to make that comment or conclusion without**
 24 **knowing specifics of -- of who was seeing the**
 25 **patients. You know, it may be doctors are**

1 **associated with clinics and that they have an**
 2 **arrangement with the clinic and the patient gets**
 3 **an ultrasound and is seen by another clinician.**
 4 **So I wouldn't want to assume or suppose**
 5 **anything.**
 6 Q. Hypothetically, if the sum
 7 total of the clinician's interaction with a
 8 patient was over telephone and there was no
 9 follow-up interaction in person by associates,
 10 would that be inconsistent with the intended
 11 practice of your program?
 12 **A. Yes.**
 13 Q. And why is that?
 14 **A. Because the intentions of our**
 15 **program are to have a visit with a clinician**
 16 **within 72 hours of initiating progesterone**
 17 **therapy. And --**
 18 Q. And -- sorry.
 19 **A. -- to have an ultrasound as**
 20 **soon as possible.**
 21 Q. And that is intended to be an
 22 in person interaction?
 23 **A. Well, the ultrasound has to be**
 24 **an in person interaction. In this age of**
 25 **telemedicine, the -- the visit doesn't**

1 **necessarily have to be because of the**
 2 **limitations of the COVID-19 pandemic.**
 3 Q. So has the APRN -- you -- can
 4 we use for APRN for Abortion Pill Rescue
 5 Network?
 6 **A. Okay.**
 7 Q. Has it -- has APRN made --
 8 modified and -- and made accommodations to adapt
 9 to the COVID-19 context?
 10 MS. DAVIS: Objection.
 11 THE WITNESS: I don't know.
 12 BY MR. BECK:
 13 Q. Okay. Let's look at page 27
 14 of your case series.
 15 **A. Okay.**
 16 Q. This is a table that lists
 17 different routes of administration of
 18 progesterone with different outcomes, correct?
 19 **A. Yes.**
 20 Q. And at the top for all groups
 21 the number is 547 analyzed subjects?
 22 **A. Correct.**
 23 Q. Yeah. And is it correct that,
 24 for example, the high dose oral group, which had
 25 31 subjects, is a subset of oral all groups,

1 which had 119 subjects?
 2 **A. Yes.**
 3 Q. And so it looks like you have
 4 four overarching categories, but tell me if I
 5 have this wrong. There is the oral all groups;
 6 oral caps vaginally, all doses; intramuscular,
 7 all groups; and vaginal suppository. Are
 8 those -- are those all the main overarching
 9 groups?
 10 **A. Yes.**
 11 Q. Okay. What I'm a little
 12 confused by is, I couldn't get these numbers to
 13 add up to 547. Can you show me how these
 14 numbers of the different principal categories
 15 add up to 547?
 16 **A. Well, I could -- I would have**
 17 **to do some arithmetic right now to -- because**
 18 **it's been a while since I looked -- looked at**
 19 **these numbers.**
 20 Q. Well, so if we -- yeah. If
 21 you could help me with that arithmetic, I would
 22 appreciate it. Because I'm -- I've tried to get
 23 it to add up, and I'm not very good at math, but
 24 I couldn't make the math work.
 25 So, for example, if you add

1 125, which is all the intramuscular groups,
 2 the -- to 119, which is all oral groups, to 156,
 3 which is oral caps vaginally, all doses, plus
 4 34, which is vaginal suppository, you get 434.
 5 Are you getting the same
 6 trouble that I am, Doctor?
 7 **A. My -- yeah. My initial quick**
 8 **tabulation, I -- I have a feeling -- and I have**
 9 **to think about this and maybe go back and read**
 10 **this, is that the all groups also includes**
 11 **patients that we found who had gotten**
 12 **progesterone, but the route was unspecified. I**
 13 **think that's probably what the balance is.**
 14 Q. So there's a category that
 15 seems maybe left off here, which is route
 16 unspecified, and that -- that makes up the
 17 difference between these different categories
 18 and all groups. Is that possible?
 19 **A. I would -- yeah. And -- yeah,**
 20 **I believe that's possible.**
 21 Q. Is it also possible that some
 22 patients received progesterone via multiple
 23 routes of administration?
 24 **A. Yes. That's -- that's also**
 25 **possible. In fact, I -- from memory, I know**

1 **that there were some who -- and we generally try**
 2 **to classify them based on the first one they**
 3 **got, but -- or predominant, but there were some**
 4 **that kind of got a mix and match. And I think**
 5 **those were also in the -- in the balance. Those**
 6 **probably make up the two groups that -- that**
 7 **would compose the balance.**
 8 Q. And so someone who got a
 9 mixture, for example, of high dose oral and
 10 vaginal suppository, or high dose oral and
 11 intramuscular, would she count as either a
 12 failure or a success in both categories?
 13 **A. No. We didn't put people**
 14 **in -- in two categories.**
 15 Q. And so it was whichever she
 16 got first or whichever was predominant?
 17 **A. Yes. If it was clear, yes.**
 18 Q. And if it wasn't clear, she'd
 19 fall into the sort of unspecified category,
 20 which isn't listed here?
 21 **A. That's correct.**
 22 Q. Okay. Your study, if I'm not
 23 mistaken, doesn't lay out this fact of some
 24 patients getting progesterone via an unclear
 25 route, or others getting a mixture of treatments

1 and falling into whatever the predominant
 2 category is. Am I correct that I didn't see
 3 that spelled out in the study?
 4 **A. I don't think we spelled it**
 5 **out that clearly.**
 6 Q. Did your peer reviewers ever
 7 raise that trouble with -- or that issue with
 8 the reporting of your -- your data here?
 9 **A. I don't recall.**
 10 Q. If you have a patient who's
 11 getting progesterone via multiple routes, does
 12 that make it hard to sort of put her firmly in
 13 the high dose oral category or the intramuscular
 14 category, for example?
 15 **A. It does. But the -- the high**
 16 **dose oral group, that was a group that really**
 17 **had a lot of homogeneity to it. So I'm not**
 18 **doubtful about that.**
 19 Q. So the -- there were 31
 20 patients in that group, right?
 21 **A. Yes.**
 22 Q. And that one was perfectly
 23 homogenous or relatively homogenous?
 24 **A. I would say highly homogenous.**
 25 Q. Highly homogenous. And which

1 groups were less homogenous?
 2 **A. I would say -- well,**
 3 **certainly, the -- as you can see, the**
 4 **intramuscular group there was such heterogeneity**
 5 **that we subdivided them into how many injections**
 6 **they got. And then the other oral groups and**
 7 **the oral caps vaginal was -- was probably -- the**
 8 **oral caps vaginal was probably the most**
 9 **heterogenous group, I think. We discussed that**
 10 **earlier in the deposition.**
 11 Q. But just to be clear. When
 12 I -- when we're talking about heterogeneity
 13 here, are we saying that the people who
 14 primarily got oral caps vaginally were
 15 heterogenous in that they might have also gotten
 16 an injection?
 17 **A. Moreso that they all state**
 18 **they had varying doses and -- and frequencies.**
 19 Q. Uh-huh. And we talked about
 20 that earlier. I guess I'm just trying to really
 21 figure out the math here.
 22 Do you have a percentage
 23 estimate of what -- what share of patients in
 24 this total of 547 received progesterone via
 25 multiple routes of administration?

1 **A. No. I haven't done that**
 2 **calculation.**
 3 Q. Is it less than 50 percent,
 4 would you expect?
 5 **A. Oh, yes.**
 6 Q. Is it less than 10 percent?
 7 **A. Probably more than 10 percent.**
 8 Q. So somewhere between 10 and
 9 50?
 10 **A. Probably.**
 11 Q. Did you -- did it -- did you
 12 consider spelling out what we're discussing here
 13 in the context of this study in terms of
 14 either -- either clarifying that some patients
 15 received multiple routes of administration or
 16 saying that this is a limitation of the study
 17 because your data had some heterogeneity?
 18 **A. Well, I don't recall if I**
 19 **specifically thought about it in those terms.**
 20 **I -- you know, when I made the comment in here**
 21 **about some data collection were incomplete, I**
 22 **also may have been referring to the -- the mode**
 23 **of the progesterone ingestion by the -- by the**
 24 **patients.**
 25 Q. I see. And we don't know -- I

1 think you said this already. But you don't know
 2 how many patients -- if my math is right, 547
 3 minus 434 is 113. Is 113 the right number of
 4 patients who got progesterone via an unclear
 5 route?
 6 **A. I would say that's likely the**
 7 **number that got it by an unclear route or by**
 8 **multiple routes that didn't favor one or the**
 9 **other, or they would naturally go into one of**
 10 **the categories.**
 11 Q. Okay. We were speaking quite
 12 a long time ago about institutional review
 13 boards, or IRBs. We spoke about it with respect
 14 to your colleague's application to the Watson
 15 Bowes Institute and that he had sought IRB
 16 approval of the randomized control trial. Do
 17 you remember that?
 18 **A. Yes.**
 19 Q. Okay. What is an
 20 institutional review board?
 21 **A. It's a -- it's a group that**
 22 **reviews studies and gives guidelines for studies**
 23 **in order to protect the subjects of the studies.**
 24 MR. BECK: Can we have Tab Z
 25 introduced into the chat, which we can mark as

1 Exhibit 39?
 2 (Whereupon, the document was
 3 marked as Exhibit No. 39 to the testimony of the
 4 witness.)
 5 BY MR. BECK:
 6 Q. Doctor, let me know when you
 7 have this one open.
 8 **A. I have it open.**
 9 Q. So this is a guidance document
 10 from the FDA regarding IRBs. Have you seen this
 11 before?
 12 **A. Not to my recollection.**
 13 Q. Okay. If you could turn to
 14 page 2, the second page, and read the first
 15 sentence aloud.
 16 **A. "The purpose of IRB review is**
 17 **to assure, both in advance and by periodic**
 18 **review, that appropriate steps are taken to**
 19 **protect the rights and welfare of humans**
 20 **participating as subjects in the research."**
 21 Q. And that sounds fairly similar
 22 to what you just said before looking at this.
 23 But do you agree that this is an accurate
 24 statement?
 25 **A. Yes.**

1 Q. Then let's look at tab AA,
 2 which has now been introduced into the chat.
 3 MR. BECK: And we can mark
 4 this document as Exhibit 40.
 5 (Whereupon, the document was
 6 marked as Exhibit No. 40 to the testimony of the
 7 witness.)
 8 THE WITNESS: Okay. I have it
 9 open.
 10 BY MR. BECK:
 11 Q. Okay. Hold on. I need to
 12 open it now. Okay. So this document, which has
 13 been marked as Exhibit 40, is printed from a
 14 website from the Health and Human Services
 15 administration. And if you look down in the
 16 middle of the page where it says, "Must
 17 investigators obtain IRB approval," could you
 18 just read that -- the question and the answer?
 19 **A. "Yes. Investigators are**
 20 **responsible for obtaining IRB approval before**
 21 **beginning any nonexempt human subjects research.**
 22 **Investigators are responsible for providing the**
 23 **IRB with sufficient information and related**
 24 **materials about the research, parenthesis, e.g.,**
 25 **grant applications, research protocols, sample**

1 **consent documents, close parenthesis, so that**
 2 **the IRB can fulfill its regulatory obligations,**
 3 **including making the required determinations**
 4 **under 45 CFR 46.111 and, if applicable, subparts**
 5 **B, C, and D. Investigators should follow**
 6 **institutional policies and procedures for IRB**
 7 **review that are required by HHS regulations at**
 8 **45 CFR 46.103(b)(4)."**
 9 Q. Thank you. For the 2018 case
 10 series, did you obtain IRB approval before
 11 involving human subjects in the research?
 12 **A. Yes.**
 13 Q. When did you obtain IRB
 14 approval for the 2018 case series?
 15 **A. I'll have to look at the date,**
 16 **but it was when we were analyzing the -- the --**
 17 **during the retrospective analysis of the data.**
 18 Q. So not while the patients out
 19 in the country were being treated, but
 20 afterwards when you had the information and were
 21 analyzing the data; is that correct?
 22 **A. Correct. Because they were**
 23 **being treated -- they were just patients being**
 24 **treated by their -- by their physicians. We**
 25 **then were able to obtain data, so we got our IRB**

1 **approval to analyze the data.**
 2 Q. And they were being treated by
 3 physicians within the network that you had
 4 helped set up, correct?
 5 **A. Most of them.**
 6 Q. And they were being treated by
 7 physicians according to protocols that you
 8 helped to circulate, correct?
 9 **A. They were suggested protocols.**
 10 **But the physicians, since they were treating**
 11 **their own patients, had the right and the duty**
 12 **to treat their patients as they saw fit.**
 13 Q. And so do you think that that
 14 aspect of the program with you creating a
 15 network and issuing guidance to physicians
 16 within the network was exempt from the IRB
 17 requirements that we were just reading? Like,
 18 is there an exemption that applied or -- or
 19 what?
 20 **A. There's an exemption, but**
 21 **there's -- there's no IRB oversight required for**
 22 **treating patients. And the network is set up as**
 23 **a way to connect patients who are seeking**
 24 **reversal with clinicians who were willing and**
 25 **able to treat them.**

1 **So that -- that's not --**
2 **that's like if I -- if I have a medical practice**
3 **and I refer patients to another doctor, do I**
4 **have to get IRB approval to do that? No, of**
5 **course not. That's just clinical practice.**
6 Q. Did it ever occur to you to
7 try and seek IRB approval before you started
8 performing the retrospective analysis? As in,
9 at an earlier stage when you were starting to
10 collect this data?
11 **A. Well, at that point it wasn't**
12 **research. And so the IRB approval was not**
13 **necessary. So, no, did not.**
14 Q. It never occurred to you?
15 **A. It never occurred because it**
16 **wasn't necessary.**
17 Q. You were collecting data on an
18 ongoing basis, though, dating back to before
19 2015, correct?
20 **A. Yes.**
21 Q. It's not the case that in 2017
22 or 2018 you got a data dump of data and then
23 asked for IRB approval and performed a
24 retrospective analysis, correct?
25 MS. DAVIS: Objection.

1 something that raises a concern for you about
2 the need for IRB approval?
3 **A. No.**
4 Q. What's the difference between
5 performing a high level of analysis of data as
6 it's coming in in realtime versus a more
7 systematic analysis for which you sought IRB
8 approval?
9 **A. Because there's no potential**
10 **harm to any patients.**
11 Q. Is there potential harm to
12 patients from the retrospective analysis that
13 you performed pursuant to IRB approval in the
14 lead up to your publication?
15 **A. Not in my mind, no.**
16 Q. So why did you seek IRB
17 approval then?
18 **A. Because IRB approval is**
19 **customary for any significant publication.**
20 Q. So it was not something you
21 ever thought was important for your study, but
22 it was sort of a box you had to check for
23 publication; is that correct?
24 MS. DAVIS: Objection.
25 THE WITNESS: It was a

1 THE WITNESS: Data, you know,
2 came into the network as doctors saw their
3 patients.
4 BY MR. BECK:
5 Q. Right. They were
6 submitting -- the physicians were submitting
7 data to you in the realtime basis as they were
8 seeing patients, correct?
9 **A. For the most part.**
10 Q. And you were developing a
11 database dating back several years prior to when
12 you got IRB approval, correct?
13 **A. That's right. But before I**
14 **started the retrospective analysis.**
15 Q. You had a lot of data, but
16 weren't analyzing it, and that's the -- that's
17 the line that you are drawing when it comes to
18 the need for IRB approval; is that correct?
19 **A. That's right.**
20 Q. Did you perform any analysis
21 on that data before you got IRB approval?
22 **A. Just very high level analysis**
23 **as -- as numbers came in as far as whether the**
24 **treatment was being -- was successful or not.**
25 Q. Was that high level analysis

1 necessary step to have a legitimate article of
2 the literature of -- of a case series this size.
3 And -- and so it was naturally a thing to do.
4 BY MR. BECK:
5 Q. Did you ever seek advice from
6 counsel about whether or not IRB approval was
7 needed at any time?
8 **A. What kind of counsel do you**
9 **mean?**
10 Q. Any kind of attorney?
11 **A. No.**
12 Q. Did you ever seek advice from
13 anyone about whether or not IRB approval was
14 necessary at any time?
15 **A. I believe I did.**
16 Q. Who did you consult about
17 that?
18 **A. I don't recall specifically.**
19 Q. Do you remember the general
20 category of person you might have asked?
21 **A. Probably a physician who had**
22 **some research experience.**
23 Q. But you can't call to mind who
24 that physician is today?
25 **A. Not specifically, no.**

1 Q. Did you ever ask either
 2 Dr. Harrison or Barry Bostrom about the need for
 3 IRB approval?
 4 **A. I may have asked Dr. Harrison,
 5 but I'm not certain. Barry Bostrom, no.**
 6 Q. Okay. Your 2018 case series
 7 was first published in the spring 2018 issue of
 8 "Issues in Law & Medicine" in April of 2018.
 9 Does that sound right?
 10 **A. That's correct.**
 11 Q. And it was at some point
 12 thereafter temporarily withdrawn?
 13 **A. That's correct.**
 14 Q. And thereafter it was
 15 republished, correct?
 16 **A. That's correct.**
 17 MR. BECK: Okay. Can we have
 18 exhibit -- sorry, Tab BB?
 19 THE WITNESS: I have it.
 20 MR. BECK: Just for the
 21 record, tab BB we can mark as Exhibit 41, that
 22 is "Issues in Law & Medicine" spring 2018 issue
 23 republication notice, which we'll talk about in
 24 a moment.
 25 I don't know whether we marked

1 for "Issues in Law & Medicine." And can you
 2 read the sentence beginning with, "The original
 3 article."
 4 **A. Are you talking about the
 5 sentence that says, "The original printed
 6 article"?**
 7 Q. Yes, please.
 8 **A. "The original printed article
 9 has an error in the first sentence of the
 10 methods section. This has been corrected here."**
 11 Q. And so this that we're looking
 12 at here is the second version of the article; is
 13 that right?
 14 **A. I believe so.**
 15 Q. And the second version
 16 corrects an error in the first sentence of the
 17 methods section of your first article, right?
 18 **A. That's correct.**
 19 Q. So let's look at your first
 20 article, the original version of it, which is
 21 Tab CC, which we can mark as Exhibit 42.
 22 (Whereupon, the document was
 23 marked as Exhibit No. 42 to the testimony of the
 24 witness.)
 25 BY MR. BECK:

1 as Exhibit 40 investigator responsibilities from
 2 HHS. But if we could do that, that would be
 3 lovely. So let's do that.
 4 BY MR. BECK:
 5 Q. So Tab BB, which has been
 6 marked as Exhibit 41 --
 7 THE COURT REPORTER: Hang on
 8 just a second. This is the court reporter. I
 9 have Tab AA, which is 40.
 10 (Whereupon, the document was
 11 marked as Exhibit No. 41 to the testimony of the
 12 witness.)
 13 MR. BECK: Yep.
 14 THE COURT REPORTER: Okay.
 15 Just making sure.
 16 MR. BECK: Yep. That's
 17 perfect. Thank you for keeping track of that.
 18 I have not done it in a particularly systematic
 19 way.
 20 THE COURT REPORTER: No
 21 worries.
 22 BY MR. BECK:
 23 Q. So Exhibit 41 is -- so when
 24 your article was republished, this was --
 25 Exhibit 41 was the notice posted on the website

1 Q. Let me know when you have that
 2 available.
 3 **A. It's open.**
 4 Q. Great. Does this document,
 5 Exhibit 42, look like the originally published
 6 version, first published version of your 2018
 7 case series?
 8 **A. Yes.**
 9 Q. Okay. On page 6 --
 10 **A. Okay.**
 11 Q. -- under methods, it states,
 12 "This is an -- this is an observational case
 13 series with data analysis that received an
 14 institutional review board waiver." And it
 15 cites footnote 33, which if you scroll to the
 16 very bottom, footnote 33 is Institutional Review
 17 Board University of San Diego, San Diego,
 18 California, correct?
 19 **A. Correct.**
 20 Q. So is your study appropriately
 21 described as an observational case series as it
 22 said in the original version?
 23 **A. Yes. I think in the -- I
 24 think a -- the -- in the revised version, I
 25 think we also included this is a retrospective**

1 **observational case series with --**
 2 Q. Was --
 3 **A. -- case series was accurate.**
 4 Q. Sorry, I cut you off. Can you
 5 say what you just said again?
 6 **A. Yes. Observational case**
 7 **series is accurate.**
 8 Q. So that -- that is an accurate
 9 statement of your methodology?
 10 **A. Yes.**
 11 Q. Okay. Did you apply for IRB
 12 approval from University of San Diego?
 13 **A. Yes.**
 14 Q. When?
 15 **A. I don't recall.**
 16 Q. Was it close to the
 17 publication date?
 18 **A. No. It was significantly**
 19 **before the publication date.**
 20 Q. Was it after you began
 21 collecting the data that was coming in
 22 realtime from physicians in the APRN?
 23 **A. It was while the --**
 24 MS. DAVIS: Objection.
 25 THE WITNESS: -- were coming

1 or is it forward-looking?"
 2 Answer, "It's the University
 3 of San Diego, not UC San Diego, just for the
 4 record. It's to look at our current cares
 5 series that we want to submit for publication."
 6 Question, "So research that's
 7 been going on since 2012?"
 8 Answer, "Existing dataset."
 9 Question, "An existing dataset
 10 for research that dates back to 2012?"
 11 Answer, "Correct."
 12 Was that testimony correct
 13 when you gave it?
 14 **A. So it's correct the existing**
 15 **dataset did go back to 2012.**
 16 Q. For research that dates back
 17 to 2012?
 18 **A. That was your statement. I**
 19 **said it was an existing dataset.**
 20 Q. Right. And then you said
 21 correct after the characterization of an
 22 existing dataset for research that dates back to
 23 2012?
 24 **A. The existing data date --**
 25 **existing dataset dates back to 2012, and that**

1 in realtime.
 2 BY MR. BECK:
 3 Q. In the midst of collecting
 4 data, at that point you asked for IRB approval
 5 at -- at USB?
 6 **A. That's correct.**
 7 Q. Okay. And so it was after you
 8 began receiving data for the study?
 9 **A. Well, I was -- the -- the**
 10 **network was receiving data, but at that point,**
 11 **it was -- at the point we decided to do a study,**
 12 **then we sought IRB approval. Just collecting**
 13 **data is not doing a study.**
 14 Q. But you were conducting
 15 research on that dataset dating back to 2012,
 16 weren't you?
 17 **A. No, I was not.**
 18 Q. Can we look at your deposition
 19 from Arizona, which is Tab A, Exhibit 25, at
 20 page 229 to 230?
 21 **A. Okay. I have it here.**
 22 Q. So starting at line 20,
 23 question, "And is the IRB approval that you're
 24 seeking being UC San Diego intended to approve
 25 retroactively the research you've already done

1 **dataset I was planning to use for research.**
 2 Q. You were planning to use that
 3 dataset which dates back to 2012 for research
 4 starting in 2012?
 5 **A. I was planning to use it for**
 6 **research at the time I was applying for the IRB**
 7 **approval. When I was collecting -- or asking**
 8 **people to collect data, that was with the**
 9 **possibility, but not a certainty of -- of**
 10 **conducting any research.**
 11 Q. So you knew that it was a
 12 possibility that you would be conducting
 13 research on that data dating back to 2012,
 14 correct?
 15 **A. I knew it was a possibility,**
 16 **that's correct.**
 17 Q. But you didn't have a firm
 18 plan in mind starting in 2012 to perform
 19 analysis on that data, and so it was exempt from
 20 the need for IRB approval; is that correct?
 21 **A. That's correct.**
 22 Q. In your IRB application to
 23 University of San Diego, how did you
 24 characterize your research?
 25 **A. As a retrospective analysis of**

1 **case series.**
 2 Q. Did you indicate that you
 3 thought that the research was exempt from IRB
 4 requirements when you applied?
 5 **A. I believe so.**
 6 Q. Did the university agree with
 7 you?
 8 **A. Yes.**
 9 Q. The IRB?
 10 **A. Yes. The IRB agreed and**
 11 **declared it exempt.**
 12 Q. Okay. And then the University
 13 of San Diego asked you to withdraw the paper,
 14 correct?
 15 **A. They -- I believe that they**
 16 **initially asked for an addendum, and then --**
 17 **then they requested withdrawal of the paper,**
 18 **that's correct.**
 19 MR. BECK: And let's -- can we
 20 introduce Exhibit DD -- sorry, Tab DD, which
 21 will be Exhibit 43.
 22 (Whereupon, the document was
 23 marked as Exhibit No. 43 to the testimony of the
 24 witness.)
 25 BY MR. BECK:

1 Q. Let me know when you have this
 2 open, Doctor.
 3 **A. It's open.**
 4 Q. Exhibit 43 is a BuzzFeed news
 5 article entitled, "A Study About The 'Abortion
 6 Reversal' Procedure Was Just Withdrawn for
 7 Ethical Issues." And on page 2.
 8 **A. Okay.**
 9 Q. The one, two, three, fourth
 10 paragraph states, "The University of San Diego
 11 asked for the paper to be withdrawn,
 12 spokesperson Pamela Payton told BuzzFeed news,
 13 because it had ambiguous wording regarding the
 14 university's ethics board, leading many readers
 15 to incorrectly conclude that the school reviewed
 16 and approved the entire study. In reality,
 17 Payton said, the ethics board had only approved
 18 analyzing pre-existing data, not collecting it."
 19 Is that, in your mind, an
 20 accurate representation of what happened?
 21 **A. That -- that doesn't explain**
 22 **the reality clearly.**
 23 Q. What -- what about that
 24 doesn't explain the reality clearly?
 25 **A. Well, we -- so we had the IRB**

1 **approval, and the IRB approval was for a dataset**
 2 **from date 1 to date 2. Some more data came in**
 3 **subsequent to date 2. We included that not**
 4 **realizing that it was outside of the dataset,**
 5 **the two dates they had given us. And so that's**
 6 **why they wanted us -- wanted the paper**
 7 **withdrawn, because of that. So, essentially, a**
 8 **technicality.**
 9 Q. What do you mean by --
 10 **A. Not ethical, just -- just an**
 11 **oversight.**
 12 Q. What do you mean by date 1 and
 13 date 2?
 14 **A. Well, just for example, let's**
 15 **say the -- they approved the -- the -- the IRB**
 16 **gave approval for data on, let's say, patients**
 17 **who were treated, just to pick dates, between**
 18 **January 1, 2020 and December 31st, 2020. But**
 19 **then we got some data on January 5th, 2021 and**
 20 **included that in our analysis. And -- and so it**
 21 **was technically outside of their -- the dates**
 22 **that they had set for the dataset, but we**
 23 **included it, and it's because of an oversight.**
 24 **And so when that was brought**
 25 **to light, they wanted us to withdraw it. And so**

1 **it's not that there was anything unethical. It**
 2 **was just an oversight. It didn't change**
 3 **anything in the paper. We went back and got**
 4 **another IRB approval and republished it. So,**
 5 **really, was one of those no harm, no foul**
 6 **situations that was made a big deal by news**
 7 **outlets such as the one you're displaying here**
 8 **as a -- as a -- as an item.**
 9 Q. Did you think about just
 10 correcting the error by excluding whatever new
 11 data after date 2 you had mistakenly included?
 12 **A. Well, at -- at that point, it**
 13 **didn't seem like the University of San Diego was**
 14 **interested in -- in moving forward. And it**
 15 **would have been probably more work to reanalyze**
 16 **the data.**
 17 **So it just made more sense to**
 18 **have the new dataset reviewed again and have IRB**
 19 **approval so that it was -- there would be no --**
 20 **no question and no doubt that everything was**
 21 **done appropriately.**
 22 Q. The second version, the
 23 republished version of your 2018 case series, is
 24 Exhibit -- is Tab F, Exhibit 7. Do you have
 25 that one available?

1 MS. DAVIS: Hey, Andrew, can
 2 we hold on just a second? Sorry, the lights are
 3 off in this room and I just need to move for a
 4 second.
 5 MR. BECK: Yep.
 6 MS. DAVIS: Thanks.
 7 BY MR. BECK:
 8 Q. So, Doctor, do you have
 9 Exhibit 7 available?
 10 **A. Yeah. That's the case series**
 11 **published in 2012 -- 2018 series.**
 12 Q. Correct. On page 24 you
 13 describe the methods -- under methods you
 14 describe it as, "a retrospective analysis of
 15 clinical data," and state, "The study was
 16 reviewed and approved by an institutional review
 17 board."
 18 Is there a reason you didn't
 19 specify what -- which IRB review -- sorry,
 20 institutional review board approved this
 21 iteration of the study when you had done so with
 22 the previous study?
 23 **A. Yes. Because it became quite**
 24 **obvious that -- that there were groups out there**
 25 **who were trying to discredit our efforts and do**

1 **anything they could to sabotage us.**
 2 **So I did not want the -- the**
 3 **new IRB to have to undergo a lot of untoward**
 4 **publicity and unwanted publicity. I just wanted**
 5 **them to be able to do their job, give us the IRB**
 6 **approval, and for them not to have to worry**
 7 **about things that normally don't come along with**
 8 **studies that are not as controversial as the**
 9 **topic that we are studying.**
 10 Q. I think I read in an article
 11 that the IRB you obtained approval from this
 12 time around was Aspire; is that correct?
 13 Do you need to answer that,
 14 Doctor, or do you want to -- is there an
 15 emergency?
 16 **A. No. I'm sorry, I just -- I**
 17 **have both phones on silent mode, but for some**
 18 **reason, these -- do you mind just -- it may take**
 19 **a second to clear that message and then I think**
 20 **it'll stop.**
 21 Q. Sure. Why don't -- why don't
 22 we take five?
 23 **A. No, actually it'll just take**
 24 **me two seconds. If you just give me two**
 25 **seconds, that's all I need to do. Okay. That**

1 **should do it. Sorry about that.**
 2 Q. No worries. I read somewhere,
 3 I believe, that the IRB you obtained approval
 4 from the second time around is called Aspire; is
 5 that correct?
 6 **A. That's correct.**
 7 Q. And that's a -- what's the --
 8 is it a commercial IRB? It's not -- it's not
 9 associated with an academic institution. It's a
 10 for profit IRB; is that correct?
 11 **A. I don't know if they're for**
 12 **profit.**
 13 Q. Okay. Did you -- I think you
 14 answered this, but let me just make sure the
 15 record is clear.
 16 Before applying to Aspire, did
 17 you seek approval a second time around from the
 18 University of San Diego or no?
 19 **A. Well, I didn't formally submit**
 20 **another application, but I did communicate with**
 21 **them. And like I said, they were so distressed**
 22 **by the -- all the publicity that came their way,**
 23 **that they did not want to be a part of it**
 24 **anymore.**
 25 Q. So they -- I don't want to put

1 words in your mouth, but is it fair to say they
 2 informally declined to serve as your IRB the
 3 second time around because you hadn't formally
 4 submitted a second application?
 5 **A. That would be an accurate**
 6 **characterization.**
 7 Q. Did you disclose University of
 8 San Diego's informal denial or informal decision
 9 not to bless your study the second time around,
 10 did you disclose that fact to Aspire?
 11 **A. I don't believe so.**
 12 Q. Do you think you should have?
 13 **A. I don't think it was**
 14 **necessary.**
 15 Q. Your research was already
 16 complete by the time you applied for approval at
 17 Aspire, correct?
 18 **A. It was complete, but no longer**
 19 **published.**
 20 Q. Would you agree that it's
 21 unusual to seek IRB approval for a study after
 22 it was already completed?
 23 **A. It is unusual, and this was an**
 24 **unusual circumstance. And the fact of the**
 25 **matter was, we had IRB approval already. So in**

1 **essence, this was a second IRB -- it was a**
 2 **second IRB approval. So we were doubly**
 3 **approved.**
 4 Q. Well, but you had IRB approval
 5 that it sounds like you accidentally strayed
 6 from the first time around?
 7 **A. Yes. Technical oversight. No**
 8 **patients risk or harmed.**
 9 Q. Did you submit the same IRB
 10 application to Aspire that you submitted to
 11 University of San Diego's IRB?
 12 **A. No. They have different**
 13 **application processes.**
 14 Q. Did you make changes to -- I
 15 mean, obviously the processes are different.
 16 But did the content of your application differ
 17 in terms of your application to University of
 18 San Diego v. Aspire?
 19 **A. I don't recall.**
 20 Q. We went over this earlier, but
 21 the original case series before it was retracted
 22 called itself an observational case series with
 23 data analysis, and then when it was republished
 24 it called itself a retrospective analysis of
 25 clinical data. Are those two the same thing?

1 **A. Not the same thing. Just one**
 2 **is more specific than the other.**
 3 Q. Can you explain how they are
 4 different?
 5 **A. Well, in the second instance,**
 6 **including the word retrospective emphasizes that**
 7 **it's a look back in time. So it doesn't change**
 8 **the nature of what was done, it just more**
 9 **explicitly describes it.**
 10 Q. And the first version of it
 11 when you called it observational, observational
 12 suggests forward looking, correct?
 13 **A. No, it does not.**
 14 Q. No?
 15 **A. No.**
 16 Q. So what -- so you added the
 17 word "retrospective," you called it a
 18 retrospective analysis of clinical data, and in
 19 your mind, that's just a little more clearer
 20 than observational case series with data
 21 analysis, but they're more or less the same
 22 thing?
 23 **A. Well, I'm saying that what we**
 24 **did was the same thing, but the second instance,**
 25 **we described it more clearly as far as the title**

1 **and the description.**
 2 Q. Why did you change the
 3 description of the methods?
 4 **A. To be more clear.**
 5 Q. And in -- from a -- sort of a
 6 methodological standpoint as someone who
 7 doesn't -- I'm not a scientist, should I --
 8 should I view a retrospective analysis of
 9 clinical data and an observational case series
 10 with data analysis to be the same type of study?
 11 **A. They both would go into the**
 12 **category of a case series analysis.**
 13 Q. But other than being more
 14 specific about one being retrospective, what's
 15 the difference between those two descriptions?
 16 Like, why make the change? I guess I'm trying
 17 to understand what the -- what the change is
 18 about other than adding the specificity of the
 19 word "retrospective"?
 20 **A. That's -- that was exactly the**
 21 **reason.**
 22 Q. So that's it, in your mind.
 23 Otherwise, the two study -- the descriptions of
 24 study design, in your mind, are essentially the
 25 same thing?

1 **A. Except that one's more**
 2 **specific.**
 3 MR. BECK: Okay. Can we
 4 introduce Tab FF, which we can mark as Exhibit
 5 44.
 6 (Whereupon, the document was
 7 marked as Exhibit No. 44 to the testimony of the
 8 witness.)
 9 BY MR. BECK:
 10 Q. I don't -- well -- do you have
 11 that one downloaded, Doctor?
 12 **A. It's downloading right now.**
 13 Q. Okay.
 14 **A. It's a little slow. I'm going**
 15 **to close some of these windows, maybe it'll**
 16 **upload faster.**
 17 Q. A lot of tabs.
 18 **A. Yeah. It's more than 50**
 19 **percent downloaded, so this is helping. It's**
 20 **like 90 percent there.**
 21 Q. We're straining your poor
 22 computer.
 23 **A. Yeah. It's getting a good**
 24 **workout today. Okay. So click to open. There**
 25 **it is.**

1 Q. Great. So this is a
 2 declaration. This is Exhibit 44. It's a
 3 declaration of Courtney Schreiber in this case.
 4 Was this one of the documents that you many
 5 hours ago said was sent to you by lawyers in the
 6 attorney general's office for you to respond to
 7 in your declaration?
 8 A. I believe so.
 9 Q. Okay. I only want to ask you
 10 about one line here. If we turn to page 17, at
 11 paragraph 41?
 12 A. Okay. I'm there.
 13 Q. So paragraph 41 continues over
 14 from the previous page. But I just want to
 15 focus on the last two sentences where it says,
 16 "When the paper was republished, the authors
 17 describe their methods differently, calling it a
 18 retrospective of clinical data, but did not
 19 alter their described results or discussion. It
 20 is unheard of to withdraw a paper, rewrite its
 21 methods to describe an entirely different study
 22 design, and republish the remainder of the paper
 23 unchanged."
 24 And I imagine you disagree
 25 with this statement. But I just wanted to ask

1 you about one part, which is, she says it's
 2 unheard of to withdraw a paper, rewrite its
 3 method, and republish the remainder of the paper
 4 unchanged.
 5 Other than this case series of
 6 yours, have you ever seen that happen with
 7 another study?
 8 A. Well, first of all, I disagree
 9 with the premise of the question.
 10 Q. Tell me more about that. Why
 11 do you disagree with the premise?
 12 A. To say we rewrote the methods
 13 is -- I think, is a mischaracterization. We
 14 simply changed a few words that more
 15 specifically described the kind of analysis it
 16 was.
 17 So back to the question. If
 18 you're saying, is it unheard of to withdraw a
 19 paper, rewrite methods, to truly rewrite them,
 20 which is not what we did, then, yes, that is
 21 unusual. But to simply essentially relabel what
 22 we are calling what we did, is -- is really not
 23 that big of a deal.
 24 Q. Do you have -- so accepting
 25 your -- your criticism of the -- the nature of

1 the question, do you have examples of the
 2 rewriting the methods to clarify in the
 3 matter -- in the manner that you're saying you
 4 did and republishing the remainder of the study
 5 unchanged? Do you have examples of that?
 6 A. No, I do not.
 7 MS. DAVIS: Objection.
 8 BY MR. BECK:
 9 Q. Do you disagree with
 10 Dr. Schreiber that it would be unheard of to do
 11 that?
 12 A. I -- if -- again, if you
 13 interpret rewrite its methods to -- to mean a
 14 large change in the methods, yes, that -- that
 15 would be unusual.
 16 MR. BECK: Okay. Can I get a
 17 check from Brian as to where we are on time?
 18 VIDEOGRAPHER: I just checked
 19 and we're about 6 hours and 30 minutes.
 20 MR. BECK: Okay.
 21 BY MR. BECK:
 22 Q. Just a little bit more, then,
 23 Doctor.
 24 You're president of the board
 25 of Steno Institute, correct?

1 A. That's correct.
 2 Q. What is Steno Institute?
 3 A. Steno Institute is a nonprofit
 4 research and educational institute.
 5 Q. So I saw on its website, let
 6 me know if this sounds correct to you, "Steno
 7 Institute will serve as scientific hub for
 8 pro-life medical and psychological research, and
 9 provide support and funding for pro-life
 10 researchers not previously available. Its work
 11 will support women -- women seeking a second
 12 chance at choice, as well as others whose lives
 13 are threatened by abortion or euthanasia."
 14 Does that sound like an
 15 accurate description of its mission?
 16 A. Yes.
 17 Q. Does Steno Institute receive
 18 funding of any kind?
 19 A. Yes.
 20 Q. What are the sources of its
 21 funding?
 22 A. Donations.
 23 Q. Individual donations or
 24 institutional donations?
 25 A. Both.

1 Q. What kinds of institutions
 2 make donations to Steno Institute?
 3 A. **Different nonprofit**
 4 **institutions.**
 5 Q. Sorry?
 6 A. **Different nonprofit**
 7 **institutions.**
 8 Q. Can you name some of those
 9 nonprofit institutions?
 10 A. **Well, they prefer to be**
 11 **anonymous.**
 12 Q. Okay. Yeah. We can come back
 13 to that, then.
 14 Do you receive compensation
 15 from serving as president of the board of Steno
 16 Institute?
 17 A. **No.**
 18 MR. BECK: Can we introduce
 19 Exhibit GG into the chat?
 20 THE WITNESS: It's ready.
 21 BY MR. BECK:
 22 Q. Okay. This is a page from
 23 Steno Institute's website. Does it look
 24 familiar to you?
 25 A. **Yes.**

1 Q. It states, "Medical and
 2 psychological research communities are now
 3 dominated by individuals and organizations that
 4 do -- excuse me -- do not honor the sanctity of
 5 life and have a strong pro-abortion and
 6 generally anti-life bias. They either totally
 7 ignore pro-life perspectives or denigrate and
 8 marginalize anyone who would dare to question
 9 the status quo. Consequently, the pursuit,
 10 funding, and publication of unbiased research in
 11 the areas of abortion, euthanasia, and family
 12 planning is extremely difficult. The recent
 13 documentary by Vice News HBO reveals the bias
 14 inherent in the media and in mainstream
 15 medicine. Read more by clicking here."
 16 Do you agree that -- or do you
 17 believe that medical and psychological research
 18 communities have a strong pro-abortion bias?
 19 A. **Yes.**
 20 Q. And do you believe that
 21 skepticism about your work on abortion pill
 22 reversal is the result of bias and not
 23 shortcomings of the evidence?
 24 A. **I believe it's, in part, due**
 25 **to bias.**

1 Q. I'm sorry, I missed -- I
 2 missed your answer.
 3 A. **I believe it's partly due to**
 4 **bias.**
 5 Q. Does that mean it's partly due
 6 to bias and partly due to questions about the
 7 valid evidence?
 8 A. **Partly due to bias and partly**
 9 **due to the natural skepticism that all**
 10 **physicians have about new treatments.**
 11 Q. And that -- the bias that you
 12 reference here extends to the media and
 13 mainstream medicine according to the statement
 14 on the website, correct?
 15 A. **That's correct.**
 16 Q. And you agree with that?
 17 A. **Yes.**
 18 Q. Okay. You previously served
 19 as a voluntary clinical professor at UC San
 20 Diego, correct?
 21 A. **That's correct.**
 22 Q. That was an unpaid position?
 23 A. **That's correct.**
 24 Q. When did that appointment end?
 25 A. **2012.**

1 Q. Can we have Exhibit HH -- I'm
 2 sorry, Tab HH?
 3 THE COURT REPORTER: Did you
 4 want to mark the last document?
 5 MR. BECK: Yes. I was just
 6 realizing. That would be 45; is that right?
 7 THE COURT REPORTER: Correct.
 8 (Whereupon, the document was
 9 marked as Exhibit No. 45 to the testimony of the
 10 witness.)
 11 MR. BECK: And then HH will be
 12 46.
 13 (Whereupon, the document was
 14 marked as Exhibit No. 46 to the testimony of the
 15 witness.)
 16 BY MR. BECK:
 17 Q. Let me know when you have this
 18 open, Doctor.
 19 A. **It's open.**
 20 Q. Great. So Exhibit 46 is an
 21 affidavit and attached exhibits from someone
 22 named Kim James filed in the South Bay United
 23 Pentecostal Church matter on August 31st, 2020.
 24 Have you seen this before?
 25 A. **Yes.**

1 Q. Okay. Can you turn to page 7,
 2 please?
 3 **A. 7, that's the email?**
 4 Q. Uh-huh.
 5 **A. Okay.**
 6 Q. So on page 7 is an attachment
 7 with an email between -- or email correspondence
 8 between you and someone named -- no. Wait, this
 9 is the wrong one. No, it's not. I just
 10 miswrote it. Let's see. Sorry.
 11 So at the bottom of that email
 12 chain is an email that you wrote to Scott Lafee
 13 inquiring about your status as part of the
 14 voluntary faculty at University of San Diego; is
 15 that correct -- I'm sorry, UCSD; is it that
 16 correct?
 17 **A. That's correct.**
 18 Q. And then the email responding
 19 to that says that your term has been expired for
 20 quite a number of years and they sent attached
 21 documentation of that, correct?
 22 **A. That's correct. And if you**
 23 **look at that letter they sent, it says addressed**
 24 **to George Delgado, MD, Solano Family Physician**
 25 **Medical Group, 2012 Columbus Parkway, Benicia,**

1 **California.**
 2 **That office address was last**
 3 **my office in 2005. So they sent the letter to**
 4 **an address that had not been my address for**
 5 **seven years. So that's why I had no knowledge**
 6 **that my appointment had ended.**
 7 Q. Fair enough. But in 2018 you
 8 received email confirmation that the appointment
 9 had ended in 2012, correct?
 10 **A. That's right.**
 11 Q. So then if we go to the
 12 next -- to Exhibit C of the James declaration?
 13 **A. Exhibit C?**
 14 Q. Yeah. The very end of that.
 15 **A. Oh, the same -- I'm sorry, not**
 16 **Tab C.**
 17 Q. No. Sorry. No. Just the
 18 very end of that James -- Kim James declaration.
 19 There are three exhibits attached.
 20 **A. Okay. So this is an email**
 21 **from Scott Lafee.**
 22 Q. Right. Dated 2019, right?
 23 **A. Yes.**
 24 Q. And he states, "In April 2018,
 25 you received an email from UC San Diego School

1 of Medicine and another from me asking that you
 2 cease claims to an affiliation with the former
 3 as a voluntary associate clinical professor.
 4 That appointment ended in 2012, but apparently
 5 the affiliation has continued to be cited in
 6 biographical and other materials, which has
 7 again caused repeated confusion. The issue has
 8 arisen again with media mistakenly believing
 9 that you have faculty status at UC San Diego. I
 10 have clarified the situation, but must -- but
 11 again must ask, insist, that you review any
 12 places online or elsewhere where you may be
 13 citing and implying a current affiliation, for
 14 example, this page at Catholic Answers, which
 15 was posted on November 19th, 2018."
 16 Did I read that correctly?
 17 MS. DAVIS: Objection.
 18 BY MR. BECK:
 19 Q. Sorry, I didn't hear your
 20 answer, Doctor.
 21 **A. That's correct.**
 22 Q. Okay. And so it sounds from
 23 this email that UC San Diego asked you to stop
 24 making public statements citing or implying that
 25 you are currently affiliated with the medical

1 school. Is that a fair summary?
 2 **A. A fair summary is that your**
 3 **biography gets out on a lot of different places,**
 4 **and it's hard to track them all down. And so**
 5 **I -- as soon as I received the notice from Scott**
 6 **Lafee and from the other person, Angela, I did**
 7 **start -- I moved to change anything that I saw**
 8 **was outward facing, and gave instructions for**
 9 **people to no longer have that on the -- on**
 10 **websites.**
 11 **However, there's some websites**
 12 **I didn't even know had my biography. People**
 13 **were grabbing my biography from other websites**
 14 **using it on theirs without my permission.**
 15 **Others were just not double checking with me**
 16 **that biographies were up to date.**
 17 **So you can imagine those**
 18 **things can be difficult to control. But as soon**
 19 **as I knew that my appointment had ended, I**
 20 **did -- made great efforts to make sure that I**
 21 **was not misrepresenting myself.**
 22 Q. So it was just a matter of
 23 other people repurposing your bio improperly or
 24 by mistake, but you not affirmatively claiming
 25 an affiliation that no longer existed; is that

1 correct?

2 **A. That's absolutely correct.**

3 Q. Okay. And so the page that

4 was posted at Catholic Answers on November 19th,

5 2018, that was an instance along the lines of

6 what you just described?

7 **A. That's correct. I had no**

8 **knowledge of that page being posted.**

9 Q. Okay. Do you have any idea

10 why UC San Diego was so concerned about your

11 representations or others' mistaken repurposing

12 of your biography concerning an ongoing

13 affiliation with the medical school?

14 **A. Well, you know, it would be**

15 **speculation.**

16 Q. Does the Abortion Pill Rescue

17 Network require that all clinicians in the

18 network have admitting privileges at a local

19 hospital?

20 MS. DAVIS: Objection.

21 THE WITNESS: I'm not sure.

22 BY MR. BECK:

23 Q. When -- you played a more

24 active role in the network in previous years,

25 correct?

1 **A. That's correct.**

2 Q. When you played a more active

3 role in the network, did it -- did the network

4 require that participating clinicians have

5 admitting privileges at a local hospital?

6 **A. Not that I recall.**

7 Q. Are there physicians -- I

8 guess we can broaden this to reflect that you

9 used to -- I believe you used to have more

10 involvement in the network.

11 Are there or have there ever

12 been, to your knowledge, physicians in the

13 Abortion Pill Rescue Network who are not

14 OB/GYNs?

15 **A. Yes.**

16 Q. For example, some are family

17 medicine doctors?

18 **A. That's correct.**

19 Q. And some are emergency room

20 physicians?

21 **A. I believe so.**

22 Q. Are some non -- nonphysician

23 clinicians?

24 **A. There are nurse practitioners**

25 **in the network, to -- to the best of my**

1 **knowledge.**

2 Q. If the physician -- if the

3 Abortion Pill Rescue Network physician who is

4 providing reversal services is, for example, an

5 emergency room physician, then that doctor would

6 not assume ongoing prenatal care for the patient

7 if she continues her pregnancy, correct?

8 **A. That's correct.**

9 Q. Turning back to your 2018

10 paper, were patients included in that paper told

11 that they were receiving an experimental

12 treatment?

13 **A. I believe that early on they**

14 **were told it was experimental. And as time went**

15 **on and the experience had broadened, I think the**

16 **characterization changed to a novel treatment.**

17 Q. So at the beginning of the

18 treatment patients were informed that it was --

19 sorry, at the beginning of when you started

20 the -- the hotline and the network, patients

21 were informed that the treatment was

22 experimental, and at a certain point it changed

23 to them being informed that it was novel, but --

24 they were not told it was experimental; is that

25 correct?

1 **A. I believe so.**

2 Q. Do you remember when

3 approximately that change took place?

4 **A. I do not.**

5 Q. Was it before or after the

6 2018 paper was published?

7 **A. Before.**

8 Q. Was it before 2015?

9 **A. Possibly.**

10 Q. Were they ever -- were

11 patients ever told that the safety and efficacy

12 of the use of progesterone to reverse

13 mifepristone had not been established?

14 MS. DAVIS: Objection.

15 THE WITNESS: They were told

16 that there was -- depending on the stage of --

17 timeline of the development of APR, they were

18 told that it was limited evidence and told there

19 was some evidence and then more evidence.

20 BY MR. BECK:

21 Q. And those were at different

22 points in time?

23 **A. Yes. Different points in**

24 **time.**

25 Q. And so now patients are told

1 that there is -- I think you used the word "more
 2 evidence"?

3 **A. Yes. They're told that**
 4 **there's been a -- that there has been a large**
 5 **case series published in the peer reviewed**
 6 **medical literature. They're aware of that, and**
 7 **they are aware of the -- some measure of the**
 8 **number of patients that have had successful**
 9 **reversals and births of -- of infants.**

10 Q. So they are no longer told
 11 that it is -- are they still told that it is
 12 novel?

13 **A. That I don't know.**

14 Q. Do you think they should be
 15 told that it is novel?

16 **A. I think whether they're told**
 17 **it's novel or not is not so important as that**
 18 **they're told what the experience has been up to**
 19 **now and what -- what's been published and how**
 20 **many babies have been born.**

21 Q. Were patients who were
 22 included in the 2018 paper told that they were
 23 part of a study?

24 **A. They were told that we were**
 25 **collecting data, and we asked permission to**

1 **collect data. But at that point it was not a**
 2 **study, so they were not told that they were in a**
 3 **study, to my knowledge.**

4 Q. Were they told that the
 5 collection of data was for purposes of
 6 eventually publishing a study?

7 **A. I don't recall.**

8 Q. Did they give informed consent
 9 to receive experimental treatment?

10 **A. They gave informed consent to**
 11 **receive the treatment. And early on it was**
 12 **described as experimental, later described as**
 13 **novel.**

14 Q. So the -- the underlying data
 15 for your 2018 study, who has the repository of
 16 data for that?

17 **A. Heartbeat International.**

18 Q. Anyone else?

19 **A. I don't believe so. I may**
 20 **have a copy, but I would have to look.**

21 Q. But you're confident Heartbeat
 22 has a copy?

23 **A. Fairly confident, yes.**

24 Q. And you might have a copy, but
 25 you're not certain?

1 **A. Correct.**

2 Q. Would that be, like, on your
 3 computer files or paper copy?

4 **A. On my computer files.**

5 Q. Okay. I believe the 2018
 6 paper indicates that data ends on June 21st,
 7 2016. Does that sound right to you?

8 **A. That the dataset ended on that**
 9 **date?**

10 Q. Yes.

11 **A. I believe so.**

12 Q. For patients who received
 13 progesterone after that date, who has
 14 information on those patients?

15 **A. Heartbeat International.**

16 Q. And you as well or just
 17 Heartbeat International?

18 **A. To my knowledge, just**
 19 **Heartbeat International.**

20 Q. So you have not -- you haven't
 21 collected any of the data that has come in after
 22 June 21st, 2016?

23 **A. I have not been collecting**
 24 **that data, no.**

25 Q. Okay. Do you know how it was

1 sent to Heartbeat?

2 **A. No, I don't.**

3 Q. Do you know how Heartbeat
 4 stores that information?

5 **A. No.**

6 Q. We've spoken about patients
 7 lost to follow-up for purposes of your study.
 8 For patients after June 21st, 2016, does
 9 Heartbeat keep track of patients lost to
 10 follow-up and -- and log that in some way?

11 **A. I don't know.**

12 Q. Do you?

13 **A. No.**

14 Q. Do you know whether there's
 15 any way to know how many patients after June
 16 21st, 2016 were lost to follow-up?

17 **A. No.**

18 Q. Do you know whether adverse
 19 events have been tracked after June 21st, 2016?

20 **A. I believe that Heartbeat is**
 21 **tracking adverse events, but I'm not sure.**

22 Q. And you mentioned a name
 23 earlier that I'm forgetting, Chris -- somebody
 24 at Heartbeat International as sort of the head
 25 of the Abortion Pill Rescue Network there?

1 **A. Yes, Christa Brown.**
 2 Q. Christa Brown. Would Christa
 3 Brown be the person likely to know the answer to
 4 these questions that you don't know?
 5 **A. I believe so.**
 6 MR. BECK: Okay. Can we take
 7 just five minutes, and I'm -- I'm basically
 8 done. I just want to make sure I have
 9 everything we need.
 10 MS. DAVIS: Sure.
 11 VIDEOGRAPHER: Off the record
 12 at 5:24.
 13 (A recess was taken.)
 14 VIDEOGRAPHER: We are back on
 15 the record at 5:31.
 16 MR. BECK: Thank you,
 17 Dr. Delgado. Those are all my questions.
 18 THE WITNESS: All right.
 19 Thank you.
 20 THE COURT REPORTER: Before we
 21 hang up, this is the reporter. Mr. Beck, I just
 22 wanted to confirm you want the rough tomorrow
 23 and an expedite not later than Friday, correct?
 24 MR. BECK: That would be
 25 fantastic. Thank you.

1 THE COURT REPORTER: And the
 2 same for you, Ms. Davis?
 3 MS. DAVIS: We definitely want
 4 to read and sign. Is it -- so you can get us a
 5 rough tomorrow? I'm impressed.
 6 THE COURT REPORTER: I can.
 7 It'll probably be around lunchtime, but yes.
 8 MS. DAVIS: Sure. Yeah, if
 9 they're getting it, sounds good. If you're
 10 doing it anyway.
 11 THE COURT REPORTER: And do
 12 you want the expedite by Friday as well?
 13 MS. DAVIS: Sure. Yeah.
 14 THE COURT REPORTER: Okay.
 15 Thank you.
 16 VIDEOGRAPHER: End of
 17 deposition. Off the record at 5:32 p.m.
 18 (Whereupon, the proceeding was
 19 concluded at approximately 5:32 p.m.)
 20
 21
 22
 23
 24
 25

1 CERTIFICATE
 2
 3 STATE OF TENNESSEE)
 4))
 5 COUNTY OF RUTHERFORD)
 6
 7 I, STEPHANIE A. BRANIM, LCR, CRI,
 8 CPE, CERTIFY:
 9 The foregoing proceedings were taken
 10 before me at the time and place stated in the
 11 foregoing styled cause with the appearance as
 12 noted.
 13 Being a Court Reporter, I then
 14 reported the proceedings in Stenotype, and
 15 the foregoing pages contain a true and
 16 correct transcript of my said Stenotype notes
 17 then and there taken.
 18 I am not in the employ of and am not
 19 related to any of the parties or their
 20 counsel, and I have no interest in the matter
 21 involved.
 22 I FURTHER CERTIFY that this
 23 transcript is the work product of this court
 24 reporting agency and any unauthorized
 25 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

1 SIGNATURE OF DEPONENT
 2 I, GEORGE DELGADO, M.D., do hereby
 3 certify that I have read the foregoing
 4 deposition transcript and find it to be a
 5 true and accurate transcription of my
 6 testimony, with the following corrections, if
 7 any:
 8
 9 PAGE LINE CHANGE
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 25 _____
 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.

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I N D E X

WITNESS	PAGE
DONNA HARRISON, M.D.	
Examination by Ms. Clarke.	5

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APPEARANCES

(Via Videoconference)

APPEARING ON BEHALF OF PLAINTIFF, PLANNED
PARENTWOOD FEDERATION OF AMERICA:

Christine Clarke, Esq.
Hana Bajramovic
Sara Shapiro (paralegal)
123 William Street, 9th Floor
New York, New York 10038-3804
212.261.4749
christine.clarke@ppfa.org

APPEARING ON BEHALF OF DEFENDANT:

Alex Rieger, Esq.
Tennessee Attorney General's Office
P. O. Box 20207
Nashville, Tennessee 37202
Alex.rieger@ag.tn.gov
615.741.2408

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APPEARANCES (Continued):

APPEARING ON BEHALF OF PLAINTIFF, ACLU:

Thomas Castelli

Stella Yarbrough

Rebecca Chan

Andrew Beck

APPEARING ON BEHALF OF PLAINTIFF, CENTER FOR
REPRODUCTIVE RIGHTS:

Michelle Moriarty

Shayna Medley

1 VIDEOGRAPHER: We are on the
2 record. This is the videotaped
3 deposition of Dr. Donna Harrison.
4 Today's date is November 13, 2020. The
5 time is 9:09.

6 This is the case of Planned
7 Parenthood of Tennessee and Mississippi
8 versus Herbert Slatery, III, Attorney
9 General of Tennessee, et al. Case
10 number is 3:20-cv-00740, pending in the
11 United States District Court for the
12 Middle District of Tennessee, Nashville
13 Division.

14 This deposition is being held
15 remotely. All counsel will be reflected
16 on the stenographic record.

17 Will the court reporter please
18 swear in the witness.

19 DONNA HARRISON, M.D.,
20 after having been first duly sworn, was examined
21 and testified as follows:

22 EXAMINATION

23 BY MS. CLARKE:

24 Q. Good morning, Dr. Harrison.

25 A. **Good morning, Christine.**

1 Q. Before I get started, the parties
2 have agreed to stipulate that we will announce
3 everyone who's on the Zoom at the beginning. I
4 believe we have people who will be coming in and
5 out, so I apologize for any dinging.

6 But for plaintiffs, aside from
7 me, attending the deposition are Stella Yarbrough,
8 Thomas Castelli, Michelle Moriarty, Shayna Medley,
9 Marc Hearron, Andrew Beck, Rebecca Chan, Hana
10 Bajramovic, Sara Shapiro; and they represent
11 various parties in this litigation.

12 And, I'm sorry, Madam Court
13 Reporter, what's your name?

14 COURT REPORTER: My name is
15 Marilyn Morgan.

16 MS. CLARKE: Okay. Ms. Morgan, I
17 apologize for any dinging that's
18 happening, and I can send you the
19 spelling of everyone's name after the
20 deposition.

21 COURT REPORTER: I appreciate
22 that. Thank you.

23 MS. CLARKE: Mr. Rieger, do you
24 want to announce for --

25 MR. RIEGER: For defendants, we

1 have myself, Steve Hart, Alan Groves,
2 and Charlotte Davis with the Tennessee
3 Attorney General's office.

4 BY MS. CLARKE:

5 Q. Okay. So I know we've met
6 before, Dr. Harrison. But I'm Christine Clarke,
7 and I represent Planned Parenthood of Tennessee
8 and North Mississippi as well as Dr. Lance in this
9 litigation.

10 I know you've had a deposition
11 taken before, but I'm going to go over some ground
12 rules just so that you remember what we're about
13 today.

14 I'll be asking you a series of
15 questions. All of my questions and your answers
16 will be taken down by the court reporter. So it's
17 important for me to not talk too fast, but it's
18 also important that we try not to talk over each
19 other and that you answer verbally. So if you
20 shake your head or nod or say uh-huh, that's not
21 going to show up in the transcript.

22 Do you understand?

23 **A. Yes.**

24 Q. Okay. If you -- I know I tend to
25 speak a little quickly. If you don't hear a

1 question or don't understand it, can you tell me
2 so I can say it again?

3 **A. Yes.**

4 Q. If you need to take a break at
5 any time, just let me know. I'm happy to take
6 breaks. I'll just ask that you answer any pending
7 questions before the break starts.

8 Is that okay?

9 **A. Yes.**

10 Q. So Mr. Rieger here is defending
11 this deposition. He may make objections. Unless
12 he instructs you not to answer, I'm going to ask
13 that you still answer the question.

14 Do you understand?

15 **A. Yes.**

16 Q. You understand that you're
17 testifying today under oath?

18 **A. Yes.**

19 Q. Okay. If during the course of
20 the deposition today you realize that anything
21 you've said is not correct or should be corrected,
22 will you let me know?

23 **A. Yes.**

24 Q. Okay. Have you taken any
25 medication today that might impair your ability to

1 give truthful and accurate testimony?

2 **A. No.**

3 Q. So I know in our new age, we're
4 doing this remotely. Can you tell me what device
5 are you using for this Zoom call?

6 **A. I'm using a laptop computer.**

7 Q. Do you have any other devices at
8 your desk right now?

9 **A. No.**

10 Q. Do you have any windows open on
11 your desktop other than the Zoom?

12 **A. I have a folder open that says**
13 **"Tennessee APR deposition," and it is empty.**

14 Q. And is that where you are
15 intending to save exhibits that I might give you
16 in a chat today?

17 **A. That's correct, yes.**

18 Q. Have you spoken to anyone about
19 the testimony you're giving today?

20 **A. I have spoken to counsel.**

21 Q. And who for the State of
22 Tennessee have you spoken to about your testimony
23 today?

24 **A. Mr. Rieger and the other members**
25 **of his team, who I can't recall their names right**

1 **at the moment.**

2 Q. I know. There's a lot of people
3 on this case.

4 Have you spoken with anyone at
5 the American Association of ProLife OB/GYNs about
6 the testimony you're giving today?

7 **A. They're aware that I'm giving**
8 **testimony because I had to have two days off. So**
9 **they are aware that the testimony is happening**
10 **today. I have not spoken about any details of the**
11 **testimony.**

12 Q. Okay. Did you speak to any of
13 the other State's witnesses in the case about the
14 testimony you're going to give today?

15 **A. No.**

16 Q. Before being retained in this
17 case as an expert witness, did you know Dr. George
18 Delgado?

19 **A. Yes.**

20 Q. For about how long have you known
21 Dr. Delgado?

22 **A. Probably 15 -- probably around 15**
23 **years. I would have to look back to see when I**
24 **first met him.**

25 Q. What about Dr. Charles Brent

1 Boles? Did you know him before you were retained
2 in this case?

3 **A. I think he is an AAPLOG member,**
4 **but I do not know him personally.**

5 Q. You've never spoken to him that
6 you're aware of?

7 **A. Not that I recall. But I speak**
8 **to a lot of people, a lot of people. So -- but I**
9 **don't recall any specific conversations with**
10 **Dr. Boles.**

11 Q. And what about Dr. Podraza? Did
12 you know him before you were retained in this
13 case?

14 **A. No. Although he may be an AAPLOG**
15 **member, but I don't have any personal -- I don't**
16 **have any recall that I've spoken to him**
17 **personally.**

18 Q. What about Dr. Martha Shuping?
19 Did you know her before you were retained in this
20 case?

21 **A. Yes.**

22 Q. About for how long have you known
23 Dr. Shuping?

24 **A. Probably about ten or 15 years.**

25 Q. Have you coauthored articles with

1 Dr. Shuping in the past?

2 **A. Yes.**

3 Q. Were those articles about
4 medication abortion?

5 **A. Yes.**

6 Q. Have you ever coauthored an
7 article with Dr. Delgado?

8 **A. I don't recall. I don't think**
9 **so.**

10 Q. What did you do to prepare for
11 your deposition today aside from speaking with
12 counsel?

13 **A. I reviewed my declaration, and I**
14 **reviewed some of plaintiffs' statements, and I**
15 **reviewed the medical literature that was pertinent**
16 **to this case, some of the medical literature**
17 **that's pertinent to this case.**

18 Q. Would that medical literature
19 include articles by Dr. Delgado?

20 **A. Yes.**

21 Q. Anything else in terms of medical
22 literature that you've reviewed in preparation for
23 your deposition today?

24 **A. I'm sorry. Can you clarify that**
25 **question a little?**

1 Q. Did you review any other medical
2 literature aside from Dr. Delgado's articles in
3 preparation for your deposition today?

4 A. Yes. I reviewed all of the
5 articles which I cited in my declaration.

6 Q. Anything else?

7 A. Well, I did another PubMed
8 search. And in the course of my work, I review
9 lots of medical literature.

10 Q. What did you do a PubMed search
11 for in preparation for your deposition today?

12 A. Progesterone receptor.

13 Q. And did you read any of the
14 articles that popped up as a result of the search?

15 A. Some of them, not all.

16 Q. About how many articles did you
17 read that came up as a result of that search?

18 A. Oh, goodness. I don't recall.

19 Q. More than five?

20 A. Yes.

21 Q. More than ten?

22 A. Yes.

23 Q. More than 20?

24 A. I don't -- it would probably be
25 in the 15 to 20 range. The issue is figuring out

1 **what's pertinent and what is not pertinent.**
2 **There's a lot of articles that come up when you**
3 **Google or when you put a PubMed search in for**
4 **progesterone receptor.**

5 Q. Were there any articles you found
6 that you think are pertinent to your deposition
7 today that were not cited in your declaration?

8 A. **There may be. I don't know. I**
9 **would have to go back and look at the PubMed**
10 **search again.**

11 **(Technical difficulty)**

12 VIDEOGRAPHER: We'll go off the
13 record at 9:20.

14 (Off-the-record)

15 VIDEOGRAPHER: We are back on the
16 record at 9:22.

17 BY MS. CLARKE:

18 Q. So during the course of this
19 deposition, our paralegal, Sara, is going to help
20 me pop exhibits into the chat. So if you hear me
21 talking to with her, that's what's going on. We
22 have them internally labeled for ourselves as
23 tabs. But for the purposes of the deposition,
24 we'll number them.

25 We're also going to start

1 numbering where plaintiffs left off in the last
2 deposition. So we're going to start at
3 Exhibit 17.

4 Is that okay, Mr. Rieger?

5 MR. RIEGER: That is fine by me.

6 MS. CLARKE: So, Sara, if you
7 could pop Tab A into the chat for me?

8 THE WITNESS: Christine, when she
9 pops it in the chat, because I've not
10 done a video deposition before, am I
11 supposed to take that and then put it
12 into the file to open it, or do you
13 screen share? How do I see what you
14 have?

15 MS. CLARKE: I believe you can
16 click on it, and it will start
17 downloading. And then if you click
18 again, it will just open automatically.
19 So why don't you try it and let me know
20 if that works?

21 THE WITNESS: Okay. Gotcha.

22 MS. CLARKE: Do you see an image
23 yet?

24 THE WITNESS: I do not, so let me
25 get -- there it is in chat. Okay. Tab

1 B, Harrison CV; correct. So I'm
2 supposed to click on it, and I'm
3 supposed to download it. Gotcha.
4 Download. Me one second here.

5 MS. CLARKE: Take your time.

6 THE WITNESS: All right.
7 Harrison CV.

8 MS. CLARKE: Okay. I'm going to
9 ask the court reporter to mark this as
10 plaintiff's 17, please.

11 (Exhibit 17, Harrison Curriculum
12 Vitae, was marked.)

13 BY MS. CLARKE:

14 Q. Dr. Harrison, could you look at
15 this document and tell me what it is.

16 **A. This is my curriculum vitae.**

17 Q. And does this accurately
18 represent your relevant qualifications and
19 professional experience.

20 **A. Yes, as of the date of the CV.**

21 Q. Are there any professional
22 affiliations or positions that aren't listed on
23 here?

24 **A. Give me a minute. I don't think**
25 **there's anything pertinent not listed.**

1 Q. Okay. So you completed your
2 residency in obstetrics and gynecology at St.
3 Joseph's Hospital; is that right?

4 A. **St. Joseph's Mercy Hospital in**
5 **Ypsilanti, yes.**

6 Q. Mercy Hospital. And that's a
7 Catholic affiliated hospital; is that right?

8 A. **That's correct.**

9 Q. And I believe you did one
10 abortion while you were there, but not
11 voluntarily; is that accurate?

12 A. **That is correct.**

13 Q. You were under the impression
14 that it was for a maternal-fetal indication, but
15 it was not?

16 A. **Let me clarify that, because it**
17 **was not performed at that hospital.**

18 Q. Okay.

19 A. **It was performed at another**
20 **hospital.**

21 Q. But as part of your residency?

22 A. **As part of my residency. I did**
23 **an outside rotation, yes.**

24 Q. And you are a diplomate of the
25 American Board of Obstetrics and Gynecology. What

1 does that mean?

2 **A. That means I am board certified.**

3 Q. And you're board certified in
4 obstetrics and gynecology?

5 **A. That's correct.**

6 Q. Any subspecialty?

7 **A. No.**

8 Q. And you're licensed to practice
9 medicine in Michigan; is that right?

10 **A. That is correct.**

11 Q. Anywhere besides Michigan?

12 **A. No.**

13 Q. And you practiced medicine after
14 your residency for seven years; is that right? So
15 not including your residency?

16 **A. No. I practiced from -- I
17 completed residency in 1990. I practiced until
18 2000.**

19 Q. So that would be ten years?

20 **A. That is correct.**

21 Q. So since 2000, you've been -- you
22 haven't been practicing medicine; is that right?

23 **A. Well, let me clarify that,
24 because there is a lot involved in the practice of
25 medicine other than simply the care of patients.**

1 **So I have been actively involved**
2 **and maintained my board certification continuously**
3 **from the time I was board certified until now.**

4 Q. But you haven't treated patients?

5 **A. I have not treated patients. I**
6 **have not been doing clinical medicine since 2000.**

7 Q. All right. Are you currently an
8 adjunct professor at Trinity International
9 University in Deerfield?

10 **A. Yes.**

11 Q. What does that entail?

12 **A. I am called upon to teach**
13 **workshops and classes and give lectures**
14 **occasionally at the Center for Bio Ethics and**
15 **Human Dignity, which is a subset of Trinity**
16 **International University.**

17 Q. When you say "occasionally,"
18 about how often would that be?

19 **A. Once a year.**

20 Q. Do you have any other duties
21 besides performing workshops once a year?

22 **A. No.**

23 Q. You're currently employed at the
24 American Association of Pro-life Obstetricians and
25 Gynecologists?

1 **A. That's correct.**

2 Q. We can call that AAPLOG; right?

3 **A. Well, if you call it AAPLOG, most**
4 **people spell it A-A-P, because they think of an**
5 **app. So we have taken to saying A-Plog (ph) to**
6 **distinguish from apps.**

7 Q. If I say App-Log (ph) because I
8 might forget, will you know what I'm talking
9 about?

10 **A. Yes.**

11 Q. Okay. When did you start working
12 at AAPLOG full-time?

13 **A. When I stepped back from clinical**
14 **medicine. I stepped back from clinical medicine**
15 **in 2000 in order to fulfill a two-year public**
16 **policy commitment that I had because I was a**
17 **Truman Scholar.**

18 So at that time, I stepped back
19 and said I will take two years at this point,
20 because I was also on maternity leave. I'll take
21 two years to fulfill that commitment since I have
22 not had a chance to fulfill that. With medical
23 school, residency, private practice, there's just
24 no time you can take two years off.

25 So I took a two-year maternity

1 leave and joined with AAPLOG at that time. Well,
2 I had joined AAPLOG earlier but became more
3 involved with AAPLOG at that time. And I have
4 worked with AAPLOG ever since.

5 Q. As a Truman Public Policy
6 Scholar, was it required that you spend two years
7 working in public policy?

8 A. It's an honorary agreement.
9 There's no legal written requirement. But the
10 understanding was if you were given a two-year
11 scholarship for graduate studies, then you will
12 repay that two-year scholarship on your honor with
13 two years of free work in public policy.

14 Q. I see. So you fulfilled that
15 honorary agreement at AAPLOG; is that right?

16 A. Correct.

17 Q. And you were the chair of the
18 Mifepristone Committee at AAPLOG in 2000; is that
19 right?

20 A. That's correct.

21 Q. In 2006, you became the president
22 of AAPLOG for a number of years; is that right?

23 A. That's correct, around 2006.

24 Q. And thereafter, you were the
25 director of research and public policy at AAPLOG?

1 **A. I think I held those titles**
2 **simultaneously for a year or so.**

3 Q. What does it mean to be the
4 director of research and public policy at AAPLOG?

5 **A. AAPLOG is primarily an**
6 **educational organization, and we look at the**
7 **medical literature. We look at the scientific**
8 **literature. And we compile that literature in a**
9 **way that our members can understand pertinent**
10 **issues related to the life issues, beginning of**
11 **life issues. That was my responsibility.**

12 Q. So would that include writing
13 AAPLOG practice bulletins?

14 **A. I would certainly participate in**
15 **the writing of AAPLOG practice bulletins.**

16 Q. So would it include pulling
17 articles to put on the AAPLOG website?

18 **A. That was part of my**
19 **responsibility, yes.**

20 Q. What were your other
21 responsibilities besides pulling articles relevant
22 to the beginning of life issues to put on the
23 website and participating in the writing of the
24 practice bulletins?

25 **A. Those were the primary**

1 **responsibilities. I needed to be familiar with**
2 **the medical literature and all aspects of life**
3 **issues pertinent to a practicing OB/GYN.**

4 Q. And then at some point, you
5 became the executive director of AAPLOG; is that
6 right?

7 A. **That's correct.**

8 Q. What are your duties as executive
9 director of AAPLOG?

10 A. **I direct the running of AAPLOG.**
11 **What does an executive director**
12 **do? I am responsible for the legal and the**
13 **day-to-day running of all the things that we do.**

14 Q. Would that include fundraising?

15 A. **Yes, although I'm not a very**
16 **strong fundraiser.**

17 Q. Would that include policy
18 advocacy?

19 A. **AAPLOG is a 501(c)(3). We do not**
20 **do lobbying.**

21 Q. So aside from directly lobbying
22 legislatures, would your role as executive
23 director include coming up with positions or
24 position papers on behalf of AAPLOG on policy
25 issues?

1 **A. I would certainly participate in**
2 **that.**

3 Q. I'm sorry. I feel like you've
4 already told me, but I didn't ask you. I would
5 ask again to be clear.

6 What is AAPLOG?

7 **A. AAPLOG is the American**
8 **Association of Pro-life Obstetricians and**
9 **Gynecologists.**

10 Q. What does AAPLOG do?

11 **A. We exist to provide our members**
12 **with an evidence-based defense of both our**
13 **pregnant female patient and her preborn child.**

14 Q. So AAPLOG opposes abortion;
15 right?

16 **A. AAPLOG adheres to the Hippocratic**
17 **medical principle that causing the death of a**
18 **human being is not a therapeutic option.**

19 Q. And "human being" for those
20 purposes would be defined at fertilization?

21 **A. "Human being" would be defined at**
22 **the point of the scientific reality that a unique**
23 **organism exists, which is indeed at the point of**
24 **fertilization.**

25 Q. How does one become a member at

1 AAPLOG?

2 **A. Well, you have to sign up as a**
3 **member of AAPLOG.**

4 Q. How does one sign up?

5 **A. You can sign up in a couple of**
6 **different ways. You can let a member of AAPLOG --**
7 **you can communicate with a board member who can**
8 **enroll you, you can put your name on a list at a**
9 **conference with your email address, or you can go**
10 **on the website and join.**

11 Q. Do people who are members of
12 AAPLOG need to pay dues?

13 **A. We would like them to pay dues,**
14 **yes.**

15 Q. Is it required?

16 **A. Well, to become a dues-paying**
17 **member, you do have to pay dues.**

18 Q. And are those dues paid annually?

19 **A. Yes.**

20 Q. Are all dues-paying members of
21 AAPLOG OB/GYNs?

22 **A. No. The majority are OB/GYNs.**

23 Q. How do you know that the majority
24 are OB/GYNs?

25 **A. Because the majority of the**

1 conferences that we've attended, we speak
2 primarily to OB/GYNs. But they are not
3 exclusively OB/GYNs. We do have members who are
4 not OB/GYNs.

5 Q. Does AAPLOG have dues-paying
6 members who aren't doctors at all?

7 A. Yes.

8 Q. Does AAPLOG have dues-paying
9 members who are not clinicians, medical clinicians
10 of any kind, so nurses --

11 A. Yes. Not many, but we have a
12 few.

13 Q. Do people have to state when they
14 become a member of AAPLOG whether they're an
15 OB/GYN or a doctor or a nurse or a midwife?

16 A. When they join, there's a tiered
17 level of membership, and they have to answer the
18 question, I am an OB/GYN. I am a midwife. I am a
19 nonmedical professional. They have to answer that
20 question.

21 And there are tiers of membership
22 dues. So OB/GYNs -- physicians in active practice
23 pay the highest amount of dues, and people that
24 are nonmedical pay a lower amount.

25 Q. So how many dues-paying members

1 does AAPLOG have total right now?

2 **A. I would have to look it up.**

3 Q. Could you estimate for me?

4 **A. Over -- I'm sorry. Ask the**
5 **question again.**

6 Q. How many dues-paying members does
7 AAPLOG have in total?

8 **A. That, I would have to look up. I**
9 **couldn't guess.**

10 Q. Could you estimate it for me?

11 **A. Not without looking it up.**

12 Q. How many dues-paying members of
13 AAPLOG are physicians, that you're aware of? If
14 you could estimate for me, how many of AAPLOG's
15 dues-paying members are doctors?

16 **A. If I would estimate, I would say**
17 **about 85 percent.**

18 Q. Do you know what number? Is that
19 like 5,000 people? 10,000 people?

20 **A. I would have to look that up. I**
21 **don't want to be more specific without the numbers**
22 **in front of me.**

23 Q. Sure. Do you know how many of
24 AAPLOG's dues-paying members are OB/GYNs?

25 **A. I'm sorry. I thought that was**

1 **actually your question before. I would say 85**
2 **percent of AAPLOG members in my estimation are**
3 **OB/GYNs. I misunderstood your previous question.**

4 Q. And that larger percentage would
5 be doctors, right, of some kind or other?

6 **A. Correct. Correct.**

7 Q. Okay. And you have no rough idea
8 of how many members there are of AAPLOG right now?

9 **A. I have a rough idea, but I don't**
10 **want to give you a number without looking at the**
11 **numbers. I can't pull that out of my head. I did**
12 **not prep that for this deposition.**

13 Q. Fair enough. So I'm not asking
14 for the precise number at all. I'm asking for
15 your rough estimate.

16 **A. Over 6,000.**

17 Q. Okay. Less than 10,000, would
18 you estimate?

19 **A. Probably, yes. Probably less**
20 **than 10,000.**

21 Q. So if someone stops paying their
22 dues, do they lose their AAPLOG membership?

23 **A. They lose their dues-paying**
24 **membership. They become associate members.**

25 Q. So when you talk about the

1 probably over 6,000 members, are those all the
2 members, or are those dues-paying members?

3 **A. Those are all the members.**

4 Q. So approximately how many
5 dues-paying members of AAPLOG are there right now?

6 **A. I don't know. I would have to
7 look that up.**

8 Q. Would you estimate it's less than
9 5,000?

10 **A. Yes, I would estimate.**

11 Q. Would you estimate that it's less
12 than 3,000?

13 **A. I don't know. I would have to
14 look that up.**

15 Q. So if people stop paying their
16 dues, they become associate members?

17 **A. Correct.**

18 Q. Is there any way that people lose
19 their membership in AAPLOG?

20 **A. Well, if they die, they lose
21 their membership. If they voluntarily withdraw,
22 they, of course, lose their membership.**

23 Q. How would one voluntarily
24 withdraw?

25 **A. Email me and say, Take me off the**

1 **list, or email whoever is at that particular point**
2 **in time responsible for taking people off the**
3 **list; and they would be taken off the list.**

4 Q. If a member died, AAPLOG wouldn't
5 know unless you knew that person or someone knew
6 that person personally. Like how would AAPLOG
7 know if a member had died?

8 **A. We periodically go through the**
9 **membership. It's a long process. So it may be**
10 **delayed, but we will eventually find that person.**

11 Q. Okay. You used to be a member of
12 the American College of Obstetricians and
13 Gynecologists; is that right?

14 **A. That's correct.**

15 Q. If I call them ACOG, you'll know
16 what I'm talking about?

17 **A. Yes.**

18 Q. And you stopped being a member of
19 ACOG; right?

20 **A. That is correct.**

21 Q. How did you go about ceasing your
22 membership with ACOG?

23 **A. I ceased paying dues in 2007.**

24 Q. Did you email anyone at ACOG to
25 say, Take me off your list?

1 A. I think I did. I think I vaguely
2 recall that I emailed them and told them the
3 reason why I ceased membership. That's my vague
4 recall.

5 The reason that I ceased
6 membership was because of ACOG Ethics Statement
7 385. ACOG Ethics Statement 385 required an OB/GYN
8 to perform or refer for abortion or to be
9 considered ethically unprofessional.

10 However, those statements bind
11 ACOG members, and I could not support that kind of
12 proabortion activism from ACOG.

13 Q. So you ceased your membership in
14 ACOG because of their statement saying that
15 physicians must, if asked, refer patients to
16 abortion providers; right?

17 A. Perform the abortion, refer to an
18 abortion provider; and if they don't perform,
19 they're supposed to pick up their practice and
20 move it next to someone who does perform
21 abortions.

22 It was a ridiculous statement.
23 And, yes, that is the reason why I quit ACOG.

24 Q. Okay. Does AAPLOG provide any
25 training for pro-life expert witnesses?

1 **A. Sometimes.**

2 Q. How often, to your knowledge, has
3 AAPLOG provided that kind of training?

4 **A. Twice.**

5 Q. What's the most recent time?

6 **A. At our 2009 Matthew Bulfin**
7 **Educational Conference.**

8 Q. And what does that training
9 entail?

10 **A. Training to become an expert**
11 **witness, the things that physicians need to**
12 **understand before they agree to become an expert**
13 **witness.**

14 Q. What would those things be?

15 **A. I don't recall everything that**
16 **was said at that particular training session.**
17 **But, in general, it would be this is what an**
18 **expert witness does and doesn't do; this is how**
19 **expert witnesses fit into the entire picture of a**
20 **lawsuit; this is -- it's pretty basic stuff. But**
21 **it's stuff that most physicians don't know.**

22 **So for a lawyer, it would be**
23 **expert witness 101, mostly looking at the overview**
24 **of how the expert witness testimony fits into a**
25 **case.**

1 Q. Was there any training on how to
2 give or how to be deposed?

3 A. **Yes, I think so.**

4 Q. And do you remember who gave that
5 training?

6 A. **I'm sorry. Say again.**

7 Q. Do you remember who gave the
8 training on how to be deposed?

9 A. **I don't remember. I think -- I
10 think it was a lawyer from Alliance Defending
11 Freedom.**

12 Q. Do you know whether Brian Calhoun
13 ever gave a training for AAPLOG on how to be
14 deposed?

15 A. **I don't know whether Brian
16 Calhoun was at that training program or not in
17 2019. I don't know.**

18 Q. Do you know if he was at the
19 previous one before 2019?

20 A. **He might have been. I would have
21 to go back and look.**

22 Q. Are there any materials that were
23 given out to participants as part of this
24 training?

25 A. **I don't know. I would have to**

1 **look.**

2 Q. Does AAPLOG ever connect state
3 governments with potential expert witnesses for
4 litigation?

5 **A. Yes.**

6 Q. Can you give me an example of
7 some pieces where AAPLOG has connected a state
8 government with an expert witness for litigation?

9 **A. I would have to look. I did not**
10 **prepare that for this deposition.**

11 Q. Can you think of any examples
12 where that's ever happened?

13 **A. I would have to go back and look.**

14 Q. So you can't think of any
15 examples; right?

16 **A. No. What's in my head right now**
17 **is abortion pill reversal.**

18 Q. Do you know if AAPLOG -- strike
19 that.

20 Are you affiliated with the
21 Charlotte Lozier Institute?

22 **A. Yes.**

23 Q. And the Charlotte Lozier
24 Institute -- would you agree with the statement
25 that, The Charlotte Lozier Institute functions to

1 provide scientific input for public policy about
2 life issues of abortion and euthanasia?

3 Is that an accurate statement?

4 **A. Yes.**

5 Q. And would you agree with the
6 statement that, It is a group that promotes
7 pro-life guidance and legislation and in other
8 areas of the public forum?

9 **A. Maybe. I mean --**

10 Q. Does that sound right to you?

11 **A. If that's what they have on their**
12 **website, then I would agree that's what they have**
13 **on their website.**

14 Q. Aside from whether it's on the
15 website, does that sound like an accurate
16 characterization of them to you?

17 **A. The way I interdigitate with the**
18 **Charlotte Lozier Institute is via the research.**
19 **So that is how I interdigitate with Charlotte**
20 **Lozier.**

21 Q. So you don't know if it's
22 accurate to describe them as a group that promotes
23 go pro-life legislation?

24 **A. I don't know.**

25 Q. And the Charlotte Lozier

1 Institute, would you characterize that as the
2 research arm of the Susan B. Anthony List?

3 **A. Yes.**

4 Q. And the Susan B. Anthony List,
5 would you agree that they are an organization
6 dedicated to electing candidates and pursuing
7 policies that will reduce and ultimately end
8 abortion? Is that accurate?

9 **A. If that's what they have on their
10 website, then that is accurate.**

11 Q. Leaving aside looking on their
12 website, would you agree that that's an accurate
13 characterization of the Susan B. Anthony List?

14 **A. I can't leave aside that, because
15 I would have to go to their website to find out
16 how they self-characterize.**

17 Q. Why don't you tell me, how would
18 you characterize the Susan B. Anthony List?

19 **A. I would go to their website and
20 see how they self-characterized, and then I would
21 quote that, because I can't speak --**

22 Q. You're aware --

23 **A. I can't speak for the Susan B.
24 Anthony List.**

25 Q. I'm not asking you to speak for

1 them. I'm just asking you to tell me what's your
2 understanding of what the Susan B. Anthony List
3 is?

4 **A. Whatever they have on their**
5 **website.**

6 Q. You have no idea what they do?

7 **A. No. They do whatever they say on**
8 **their website.**

9 Q. If you couldn't look at the
10 website, you would have absolutely no idea what
11 the Susan B. Anthony List does?

12 **A. The way I interdigitate with the**
13 **Susan B. Anthony List is via the Charlotte Lozier**
14 **Institute, and the way I interdigitate with the**
15 **Charlotte Lozier Institute is via research.**

16 **So I know that the Charlotte**
17 **Lozier Institute is committed to accurate**
18 **scientific research. That's what I know. And I**
19 **know that the Charlotte Lozier Institute is an arm**
20 **or is a -- what's the legal term -- subset,**
21 **whatever the legal term is, of the Susan B.**
22 **Anthony List.**

23 Q. When you say that the Charlotte
24 Lozier Institute is committed to accurate
25 scientific research, that's research about

1 abortion issues; right?

2 **A. I don't know whether or not**
3 **they're limited to abortion issues. That's how I**
4 **interdigitate with them.**

5 Q. Do you know if any Charlotte
6 Lozier scholars are pro-choice?

7 **A. I don't know.**

8 Q. Would you be surprised if there
9 was a Charlotte Lozier scholar who was pro-choice?

10 **A. No.**

11 Q. Would you agree that the Susan B.
12 Anthony List is, quote, "an organization dedicated
13 to electing candidates and pursuing policies that
14 will reduce and end abortion." Does that sound
15 right?

16 **A. If that's what they**
17 **self-characterize, then that sounds right.**

18 Q. If that's how you testified in
19 the Eastern District of Arkansas, would that sound
20 right?

21 **A. Whatever they self-characterize**
22 **is how I would characterize them.**

23 Q. You don't recall testifying about
24 the Susan B. Anthony List in the Eastern District
25 of Arkansas about two years ago?

1 **A. I honestly don't. I don't.**
2 **Whatever the Susan B. Anthony List self-**
3 **characterizes, I would agree that is their**
4 **characterization?**

5 Q. So you have no idea if the
6 Susan B. Anthony List advocates for ending
7 abortion?

8 **A. That's what they state on their**
9 **website?**

10 Q. So it's your understanding that
11 that's what they do; correct?

12 **A. Whatever they state on their**
13 **website, that's what they do.**

14 Q. So you have no idea outside their
15 website what they do at all? Is that your
16 testimony today?

17 **A. No.**

18 Q. Okay. So what's your testimony?

19 **A. You asked me what the Susan B.**
20 **Anthony List does. My interdigitation with the**
21 **Susan B. Anthony List is via the Charlotte Lozier**
22 **Institute. And my interdigitation with the**
23 **Charlotte Lozier Institute is via research.**

24 **So if you're asking me what does_**
25 **that Susan B. Anthony List do outside of research,**

1 **I cannot speak to that, because I get involved via**
2 **research with the Charlotte Lozier Institute.**

3 Q. So when you say you can't speak
4 to that, I'm not asking you to speak for them.
5 I'm asking you, what's your understanding sitting
6 here today of what the Susan B. Anthony List does?
7 What do you --

8 **A. I understand whatever they put on**
9 **their website is what they do.**

10 Q. So if they change their website
11 today, your understanding of what they do would
12 change a hundred percent; is that right?

13 **A. It would change to whatever**
14 **degree they change from what they had on their**
15 **website previously.**

16 Q. So without looking at their
17 website, you cannot say at all what the Susan B.
18 Anthony List does? Is that your testimony today?
19 That's all I'm asking.

20 **A. I cannot speak authoritatively**
21 **for the Susan B. Anthony List.**

22 Q. I'm not asking you to speak
23 authoritatively for the Susan B. Anthony List.
24 For the last time, I'm literally only asking what
25 you personally, Dr. Donna Harrison, understand the

1 Susan B. Anthony List to do. I'm not asking you
2 to speak for them. I won't hold it against them.
3 I'm just asking what you understand that they do.

4 **A. What I understand what they do is**
5 **what they have on their website. So I wouldn't**
6 **have an understanding of what they do or speak to**
7 **what they do other than what they, themselves, say**
8 **that they do.**

9 Q. So without looking at the
10 website, you have no understanding of what the
11 Susan B. Anthony List does?

12 **A. I'm not sure I understand your**
13 **question.**

14 Q. Without looking at the website,
15 do you have any idea what the Susan B. Anthony
16 List does?

17 **A. Yes. I have an understanding of**
18 **one thing that they do.**

19 Q. What's the one thing that they
20 do?

21 **A. From my understanding, the one**
22 **thing that they do is they have a research arm,**
23 **which is the Charlotte Lozier Institute. And the**
24 **way I understand the Charlotte Lozier Institute is**
25 **that it is committed to accurate research in the**

1 **life issues. And that's how I interdigitate with**
2 **the Susan B. Anthony List.**

3 **I can't speak for the Susan B.**
4 **Anthony List other than the way I interdigitate**
5 **with them.**

6 Q. Okay. So let's say the Charlotte
7 Lozier Institute website said that -- you know
8 what? Strike that.

9 Does the Charlotte Lozier
10 Institute provide training for pro-life expert
11 witnesses?

12 **A. I think so.**

13 Q. Have you ever attended one?

14 **A. Yes.**

15 Q. When did you attend a training
16 for pro-life expert witnesses conducted by the
17 Charlotte Lozier Institute?

18 **A. Goodness, I don't remember.**
19 **Several years ago.**

20 Q. Okay. What did you learn in that
21 training?

22 **A. The responsibilities of an expert**
23 **witness.**

24 Q. What other responsibilities of an
25 expert witness -- strike that.

1 What did you learn about the
2 responsibilities of an expert witness from that
3 expert witness training provided by the Charlotte
4 Lozier Institute?

5 **A. It's the responsibility of an**
6 **expert witness to speak truthfully, to have their**
7 **research well documented, to communicate clearly**
8 **with counsel. That's our responsibility.**

9 Q. Do you remember who gave the
10 training, like what person or people?

11 **A. I don't know. I would have to**
12 **look back.**

13 Q. You don't remember any of the
14 people who spoke during that training?

15 **A. I'm going to have to think about**
16 **this a minute because, again, this is not stuff I**
17 **prepared for this deposition.**

18 **I know that there were lawyers**
19 **present, and I believe one of the lawyers was from**
20 **Americans United for Life.**

21 Q. Do you know -- did you receive
22 any materials at this training?

23 **A. I don't keep paper. So if there**
24 **were materials given out, I do my very best to**
25 **throw it way. So there may have been. I don't --**

1 **I have a small office, and it has to all be**
2 **digital.**

3 Q. Okay. Do you know if they
4 emailed you any materials relevant to that --

5 **A. I don't know.**

6 Q. Okay. So we talked about --
7 well, strike that.

8 You're an associate scholar at
9 the Charlotte Lozier Institute; right?

10 **A. That's correct.**

11 Q. What does that mean?

12 **A. That means that I participate in**
13 **talking about the research for the life issues and**
14 **what is published and what needs to be published**
15 **and what could be published and what -- we talk as**
16 **scientists.**

17 Q. When you say "we," you mean you
18 and the other associate scholars at the Charlotte
19 Lozier Institute?

20 **A. Not all of them, because**
21 **everybody is not interested in the same thing.**

22 Q. So, then, you would speak with
23 other scholars who are interested in abortion
24 issues?

25 **A. Correct. Some of them.**

1 Q. Do you know how many there are?

2 A. I don't.

3 Q. Are you paid for your work at the
4 Charlotte Lozier Institute?

5 A. I'm trying to think if they've
6 ever paid me. They may have paid me.

7 Q. But you're not sure?

8 A. I would have to go back and look.
9 Sometimes there are specific things that they will
10 fund, but most of my time is volunteer.

11 Q. Okay.

12 A. And it depends on what project,
13 and I would have to go back and look.

14 Q. So what kind of specific things
15 would they fund that you're aware of?

16 A. If we have a research document
17 and there needs to be analysis of that document
18 done by statisticians, they will cover that cost,
19 because they have statisticians in-house so that
20 they can do that.

21 Q. Anything else that you're aware
22 of?

23 A. Not that I'm aware of right at
24 this moment.

25 Q. Do you know whether the Charlotte

1 Lozier Institute connects state governments with
2 pro-life expert witnesses for litigation?

3 **A. If they state that on their**
4 **website, then I believe that's what they do. But**
5 **I don't know.**

6 Q. Okay. You're an associate editor
7 at the issues -- sorry.

8 You're an associate editor at
9 Issues in Law and Medicine; is that right?

10 **A. That's correct.**

11 Q. I'm sorry. I want to go back for
12 a second.

13 On the Charlotte Lozier Institute
14 website, your associate scholar bio says that you
15 have an interest in endometrial conception --
16 sorry -- endometrial contraception. What does
17 that mean?

18 **A. It means contraception that works**
19 **at the level of the endometrium.**

20 Q. Can you give me an example, just
21 so I have an idea of what --

22 **A. There are many drugs that work at**
23 **the level of the endometrium, and I'm particularly**
24 **interested in the interactions of those drugs with**
25 **the endometrium.**

1 Q. Can you give me an example of
2 drugs that interact with the endometrium? I'm
3 just curious what kinds of drugs we're talking
4 about.

5 **A. There are lots of drugs that**
6 **interact at the level of the endometrium, Mifeprex**
7 **being one of them. Mifeprex very specifically**
8 **interacts at the level of the endometrium.**

9 Q. Is there any other contraception
10 that I might have heard of that interacts at the
11 level of the endometrium?

12 **A. Mifeprex is RU-486, mifepristone.**

13 Q. Oh, yeah. Is there anything else
14 that you can think of?

15 **A. Progesterone receptor modulators**
16 **work at the level of the endometrium. So Mifeprex**
17 **is one; progesterone receptor modulator;**
18 **ulipristal or Ella is another.**

19 Q. Anything else? Any other kinds
20 of contraception that would fall into that
21 category?

22 **A. I would have to go back and look.**
23 **There's a lot of drugs that affect a lot of parts**
24 **of the body. So if you're asking for a list of**
25 **drugs that would affect the different parts of the**

1 **body, I would have to compile that.**

2 Q. But if say -- let's say in your
3 CV and on your Charlotte Lozier bio it says that
4 your interests includes specifically endometrial
5 contraception, that would be specifically
6 referenced to mifepristone; is that right?

7 **A. Those drugs do act at the level**
8 **of the endometrium.**

9 Q. Are those the primary drugs that
10 you have a research interest in when it comes to
11 endometrial contraception?

12 **A. I'm interested in anything that**
13 **affects the endometrium.**

14 Q. Have you done research on any
15 other drugs that affect the endometrium besides
16 Ella and Mifeprex?

17 **A. Yes.**

18 Q. So what drugs?

19 **A. I've done research on the effects**
20 **on the endometrium from the birth control pill.**

21 Q. That would be the (Zoom audio
22 distortion) --

23 **A. Yes.**

24 Q. Anything else?

25 **A. I've done research on the effect**

1 **on the endometrium from the IUD.**

2 Q. Would that be the progesterone
3 IUD or any IUD?

4 **A. Any IUD.**

5 Q. Anything else?

6 **A. Not that I can recall at the**
7 **moment.**

8 Q. So I asked you earlier about
9 being an associate editor at Issues in Law and
10 Medicine. What does it mean to be an associate
11 editor at Issues in Law and Medicine?

12 **A. My responsibility includes**
13 **contacting potential peer reviewers to see if they**
14 **would be willing to do a peer review.**

15 Q. Is there a sort of bank of
16 potential peer reviewers?

17 **A. I believe that's listed in Issues**
18 **in Law and Medicine.**

19 Q. Where would you go about finding
20 a list of people to contact to see whether they
21 would be a peer reviewer for an article?

22 **A. Well, I start first with the**
23 **people on the list at Issues in Law and Medicine.**
24 **If I happen to know of a specific physician who**
25 **has an expertise in the area of the manuscript,**

1 **then I would email them with the request to --**
2 **would they be willing to peer review this article?**

3 Q. So when you talk about the list,
4 is that a list that's published on the Issues in
5 Law and Medicine website of peer reviewers?

6 A. **I think it's in the paper copy.**
7 **I don't know if it's on the website or not.**

8 Q. Do you select articles for review
9 at Issues in Law and Medicine?

10 A. **Barry Bostrom is the editor, and**
11 **he's the one who obtains the manuscript. I**
12 **suggest peer reviewers. He makes the final**
13 **decisions.**

14 Q. Do you ever participate in peer
15 review of articles for Issues in Law and Medicine?

16 A. **Well, I'm the one who arranges**
17 **for -- I mean, I'm the one who writes and says,**
18 **Dr. Smith, would you be willing to peer review an**
19 **article for Issues in Law and Medicine?**

20 **So in that way, yes, I**
21 **participate in the peer review process.**

22 Q. But you don't yourself act as a
23 peer reviewer?

24 A. **I don't recall right now whether**
25 **I've ever peer reviewed for them. I may have.**

1 Q. But you're not sure?

2 A. **Not right at this moment. I**
3 **would have to go back and ask Barry Bostrom,**
4 **because he's the one who gets the reviews. He is**
5 **the one who corresponds with the reviewers. He**
6 **makes the decisions.**

7 Q. Okay. What kinds of topics does
8 Issues in Law and Medicine publish on?

9 A. **Issues in law and medicine I**
10 **mean, topics that pertain to law or medicine.**

11 Q. So it will publish on any topics
12 relating to law or medicine in any way?

13 A. **I'm sorry. Can you ask that**
14 **question again?**

15 Q. Does Issues in Law and Medicine
16 publish articles on any topic involving law or
17 medicine?

18 A. **Yes.**

19 Q. It has no focus?

20 A. **I'm sorry? I don't understand**
21 **your question. They're focused on issues in law**
22 **and medicine.**

23 Q. There's like thousands of medical
24 journals; right? And they publish on various
25 things. So the Journal of Endocrinology will

1 publish articles about endocrinology.

2 So law and medicine is a pretty
3 broad topic. So is it your testimony that Issues
4 in Law and Medicine, the journal, if I read a
5 year's worth of issues, I will find a broad array
6 of issues involving law or medicine totally
7 unrelated to abortion or contraception or
8 euthanasia?

9 **A. Abortion, contraception, and**
10 **euthanasia are issues in law and medicine.**

11 Q. Does Issues in Law and Medicine,
12 the journal, publish about other issues?

13 **A. Yes. I mean, you would have to**
14 **go back at the journals for all the years to see**
15 **what issues they publish on. They publish on a**
16 **wide variety of issues.**

17 Q. So you would not characterize
18 Issues in Law and Medicine, the journal, as
19 focusing primarily on issues of abortion,
20 contraception, and euthanasia?

21 **A. That's not the stated purpose of**
22 **Issues in Law and Medicine.**

23 Q. I understand. That's not the
24 question. If I were to look at all the articles
25 that Issues in Law and Medicine has published over

1 the last year, would I find that the majority of
2 those articles concern abortion, contraception, or
3 euthanasia?

4 MR. RIEGER: I'm going to object
5 to the form of the question.

6 Go ahead and answer.

7 **A. Issues in Law and Medicine only**
8 **publishes two editions a year. So if you look in**
9 **one year, you'll find whatever was published in**
10 **that year. You will have to look over the broad**
11 **range. I believe they've been publishing since**
12 **around '73 or '74. So you would have to look back**
13 **to '73 or '74 to get the spectrum of what Issues**
14 **in Law and Medicine publishes on.**

15 Q. Let's say over the last year,
16 would you say that a majority of the articles that
17 Issues in Law and Medicine has published in those
18 two issues concern abortion, contraception, or
19 euthanasia?

20 **A. Actually, because of COVID, there**
21 **was one combined issue that came out. So I would**
22 **have to look back and see what the articles are on**
23 **there.**

24 Q. Would you be surprised to learn
25 that over the last ten years, the majority of

1 articles published by Issues in Law and Medicine
2 concern abortion, contraception, or euthanasia?
3 Would that surprise you?

4 **A. Those are issues in law and**
5 **medicine.**

6 Q. So it would not surprise you?

7 **A. Those are issues in law and**
8 **medicine. It's within the purview of what Issues**
9 **in Law and Medicine publishes on.**

10 Q. I'm just asking for a yes-or-no
11 answer, whether you would be surprised to learn
12 that the majority of issues published in Issues in
13 Law and Medicine over the last ten years concern
14 abortion, contraception, and euthanasia? Would
15 you be surprised to learn that?

16 **A. Well, I can't give you a**
17 **yes-or-no answer to that. It is within the realm**
18 **of publication of what Issues in Law and Medicine**
19 **covers.**

20 Q. I'm literally just asking whether
21 you would be surprised to learn that fact. Would
22 it surprise you that the majority --

23 MR. RIEGER: I'll object to the
24 form of that question.

25 You can go ahead and answer.

1 **A. I'm not surprised by much in**
2 **life.**

3 BY MS. CLARKE:

4 Q. Okay. So you would not be
5 surprised. Is that your testimony?

6 **A. No, my testimony is --**

7 MR. RIEGER: Same objection.

8 You can go ahead and answer.

9 **A. No. My testimony is that**
10 **contraception, abortion, and euthanasia are issues**
11 **in the law and medicine. They're issues in both.**

12 BY MS. CLARKE:

13 Q. I completely understand that.
14 I'm just asking whether the majority of articles,
15 to your knowledge, that are published in the
16 journal, Issues in Law and Medicine, concern
17 abortion, contraception, or euthanasia.

18 **A. I would have to go back and look**
19 **at all the articles.**

20 Q. And you have no idea sitting here
21 today whether the majority of articles published
22 in Issues in Law and Medicine in the last ten
23 years concern abortion, euthanasia, or
24 contraception?

25 **A. Well, I didn't become editor**

1 **until five years ago.**

2 Q. So that's --

3 MR. RIEGER: If we could go ahead
4 and let the witness complete her answer.
5 It didn't sound like she was done.

6 Thank you.

7 **A. So I didn't become associate**
8 **editor until about five years ago. During that**
9 **time, the focus of concern for law and medicine**
10 **has been these issues of abortion, contraception,**
11 **and euthanasia. But that's not the only articles**
12 **that have been published.**

13 I believe they published an
14 **article on head transplants. There's been some**
15 **other articles published that I've seen. So it's**
16 **not the only thing.**

17 And there's been some legal
18 **articles. Again, I don't interdigitate at all**
19 **with the legal peer review process. That's all**
20 **Barry Bostrom.**

21 BY MS. CLARKE:

22 Q. So you only select peer reviewers
23 for articles concerning medicine; is that right?

24 **A. Correct.**

25 Q. And so would it be accurate to

1 say that because the focus of concern in law and
2 medicine for the last five years has been issues
3 of contraception, abortion, and euthanasia, that,
4 therefore, the majority of medical articles
5 published in Issues in Law and Medicine in the
6 last five years concern abortion, euthanasia, and
7 contraception?

8 MR. RIEGER: I'll object to the
9 form of that question.

10 Please go ahead and answer.

11 **A. The problem that I'm having with**
12 **your question is the issue of majority. Majority**
13 **means more than 50 percent. So I would have to go**
14 **back and look at the numbers of what papers are**
15 **published in order for me to say, Has it been more**
16 **than 50 percent? So I can't give you a numerical**
17 **answer.**

18 BY MS. CLARKE:

19 Q. I'm sorry. I didn't mean to
20 interrupt you. Are you finished?

21 **A. It very well may be more than 50**
22 **percent. But I would have to go back to look,**
23 **because you've asked for a numerical answer, and I**
24 **can't give you a numerical answer.**

25 Q. So sitting here right now, you

1 have no idea whether it's the majority?

2 **A. No. What I said was I can't give**
3 **you a numerical answer. You've asked whether it's**
4 **the majority. I would have to go back and look at**
5 **the numbers and see which articles and put them on**
6 **one side and see how many articles are on the**
7 **other side. Then we would see is it more than 50**
8 **percent, the definition of majority.**

9 **Q. So over the last five years,**
10 **you've been -- strike that.**

11 Are you the only person who
12 selects peer reviewers for medical articles in
13 Issues in Law and Medicine?

14 **A. No. Barry has a network of**
15 **people that he talks to. I'm one of the people**
16 **that he talks to about peer review. But as -- my**
17 **job as an associate editor is, if he asks me, I**
18 **find people that are qualified that can peer**
19 **review the article. But he has more than me.**

20 **Q. So he selects peer reviewers for**
21 **more medical articles in the journal than you do?**

22 **A. No. I think the question you**
23 **asked was, is there anyone else that he would task**
24 **for peer reviewers for medical articles? I'm one**
25 **of, but I don't think I'm the only one that he**

1 **tabs for peer reviewers for medical articles.**

2 Q. Okay. Do you know who else might
3 tab peer reviewers for medical articles?

4 **A. I don't. You'd have to ask Barry**
5 **Bostrom.**

6 Q. Do you know what the Watson Bowes
7 Institute is?

8 **A. Yes.**

9 Q. What's the Watson Bowes
10 Institute?

11 **A. Watson Bowes Institute is an**
12 **institute that's devoted to truth in life issues**
13 **in research.**

14 Q. When you say the life issues,
15 we're talking about abortion and euthanasia?

16 **A. Yes.**

17 Q. Is the Watson Bowes Institute
18 located within AAPLOG?

19 **A. Yes.**

20 Q. What does that mean?

21 **A. Watson Bowes Institute is a DBA**
22 **of AAPLOG.**

23 Q. And the Watson Bowes Institute is
24 a co-sponsor of Issues in Law and Medicine; is
25 that correct?

1 **A. That's correct.**

2 Q. And the other co-sponsor of
3 Issues in Law and Medicine is the National Legal
4 Center for Medically Dependent and Disabled; is
5 that right?

6 **A. That's correct.**

7 Q. And what is that?

8 **A. I don't know.**

9 Q. Do you have any idea what --

10 **A. I know that Barry Bostrom knows.**
11 **That is his organization. But I have not talked**
12 **about what his organization does.**

13 Q. When you say it's his
14 organization, does he have like a leadership role
15 in that organization?

16 **A. You would have to ask Barry about**
17 **the details of the National Center for Medically**
18 **Dependent and Disabled.**

19 Q. Were you aware that the National
20 Legal Center for the Medically Dependent and
21 Disabled was founded by James Bopp?

22 **A. Okay.**

23 Q. Do you know who James Bopp is?

24 **A. Yes, I do.**

25 Q. Who is James Bopp?

1 **A. My understanding is that James**
2 **Bopp is the legal counsel -- I don't know if he is**
3 **currently. At some point, he was legal counsel**
4 **for National Right to Life.**

5 Q. So before we take a break --
6 actually, let's go ahead and take a break. Is
7 this a good time for you guys?

8 VIDEOGRAPHER: Off the record at
9 10:19.

10 (A break was taken.)

11 VIDEOGRAPHER: Back on the record
12 at 10:26.

13 BY MS. CLARKE:

14 Q. So, Dr. Harrison, you've been a
15 defendant in three lawsuits; is that accurate?

16 **A. Whatever list I put on my CV or,**
17 **excuse me, in the declaration. I think it's been**
18 **more than three. I believe -- go ahead.**

19 Q. Were you finished with your
20 answer? Sorry.

21 **A. It's whatever list I put on the**
22 **declaration.**

23 Q. Have you ever been a plaintiff in
24 a lawsuit? Have you ever sued anybody else?

25 **A. No.**

1 Q. Have you ever filed a complaint
2 with a government agency?

3 A. Oh, okay. All right. I know
4 what you're saying. Have I personally ever sued
5 anyone else? No, I have not personally ever sued
6 anyone else that I can recall.

7 Q. Have you ever filed a complaint
8 with a government agency that's not a lawsuit?

9 A. In my capacity as executive
10 director of AAPLOG, AAPLOG has filed complaints.

11 Q. Where has AAPLOG filed
12 complaints?

13 A. They've filed complaints with the
14 Office of Civil Rights. I think that's it.

15 Q. Would that be the Office of Civil
16 Rights within HHS?

17 A. Yes, uh-huh. Sorry. Yes, within
18 HHS.

19 Q. And you're referring to a
20 complaint against ACOG?

21 A. Yes. We filed a complaint with
22 the Office of Civil Rights against ACOG, yes.

23 Q. And what was that complaint
24 about, briefly?

25 A. The complaint was about the

1 **infringement of the right of conscience of AAPLOG**
2 **members and physicians by ACOG Ethics Statement**
3 **385, because ACOG Ethics Statement 385 declares**
4 **ethically unprofessional those physicians who**
5 **choose not to kill human beings as a part of their**
6 **medical practice. And we filed a complaint**
7 **against them.**

8 Q. That complaint also referred to
9 the fact that the ethics statement says that
10 physicians must refer patients to other
11 providers --

12 A. **It said three things, that they**
13 **must perform or be unethical. Those who don't**
14 **perform have to refer. Now, those who don't**
15 **perform have to pick up their practice and move**
16 **their practice next to somebody who does perform.**

17 **That is egregious.**

18 Q. So the ethics complaint that
19 AAPLOG filed with HHS concerned all three of those
20 points; is that right?

21 A. **As far as I know. I mean, again,**
22 **I did not refresh -- I didn't review the wording**
23 **of that complaint for this particular deposition.**
24 **I would have to go back and look at the specific**
25 **wording of that complaint to be able to**

1 **specifically answer your question.**

2 Q. Have you ever been the subject of
3 a complaint filed by a government agency that you
4 know of?

5 **A. I don't think so.**

6 Q. Aside from this case, you've
7 served as an expert witness in a number of cases
8 concerning abortion; is that right?

9 **A. Yes.**

10 Q. Have you served as an expert
11 witness in other cases concerning medication
12 abortion specifically?

13 **A. I'm sorry. I'm trying to**
14 **understand your question. So what you're asking**
15 **is, have the cases that I've served in dealt with**
16 **medication abortion? Yes, they have dealt with**
17 **medication abortion.**

18 Q. Have you ever served as an expert
19 witness on a case about regulations concerning
20 medication abortion?

21 **A. Yes.**

22 Q. Where did you -- where were those
23 cases? What states were those cases in?

24 **A. I think -- I would have to go**
25 **back and generate a list. I think I mentioned all**

1 of those that I did court testimony in, but I
2 would have to generate a list as to what states I
3 have testified in.

4 Q. Do you recall whether you served
5 as an expert witness on a case concerning
6 regulations about medication abortion in Oklahoma?

7 A. Yes.

8 Q. What was that case about?

9 A. Again, I did not review other
10 cases before this deposition. So if you're going
11 to question me about those cases, I would have to
12 see my declaration from those cases.

13 Q. Do you recall anything about what
14 that case was about?

15 A. My mind right now is on abortion
16 pill reversal. So I did not review anything
17 outside of abortion pro-versal for this
18 deposition. But if you show me the declaration
19 that I made in those cases, I'm happy to comment
20 on that.

21 Q. I'm just asking if you remember
22 anything about what that case is about, sitting
23 here right now.

24 A. My mind right now -- my mind
25 right now is on abortion pill reversal and not on

1 **anything else.**

2 Q. So is that a no?

3 MR. RIEGER: Object to the form.

4 **A. I'm not going to be able -- my**
5 **mind right now is on abortion pill reversal. I**
6 **did not review any other cases prior to this**
7 **deposition.**

8 BY MS. CLARKE:

9 Q. I understand. I'm not asking you
10 what you reviewed. I'm just asking you, sitting
11 here right now, if you remember anything about
12 what the case in Oklahoma was about that you
13 served in as an expert witness.

14 **A. Well, my mind has limited ram.**
15 **And my ram right now is all full of abortion pill**
16 **reversal. So I do not have any other case booted**
17 **up in my brain right now.**

18 Q. So you don't remember the
19 substance of -- well, strike that.

20 Do you remember what any cases
21 were about that you've served in as an expert
22 witness prior to this case?

23 **A. I can't make any comment on any**
24 **other cases unless you show me the declaration**
25 **that I filed in those cases.**

1 **Again, what I referred to or what**
2 **I reviewed for this case and what is in my brain**
3 **right now is abortion pill reversal.**

4 Q. So in your declaration, you cite
5 to a case called Tulsa Women's Reproductive
6 Clinic, LLC versus Hunter, Oklahoma County
7 District Court. That's in footnote 1 of your
8 declaration.

9 You don't remember anything about
10 what that case was about?

11 A. **You'll have to pull up -- you're**
12 **going to have to pull it up, pull up the document**
13 **that -- I don't go by recall. I go by what I see**
14 **in front of me. So you're going to have to pull**
15 **up the document that you're citing.**

16 Q. So you don't remember anything,
17 sitting here right now, about what that case was
18 about?

19 A. **I don't go by recall. I go by**
20 **what I see in front of me. So you're going to**
21 **have to pull up the document for me to comment on**
22 **the document.**

23 Q. So in preparation for your
24 deposition today, you didn't review everything
25 that you had put in all of the footnotes in your

1 declaration?

2 **A. I reviewed the scientific**
3 **articles.**

4 Q. Understood. So you don't have
5 any memory of what the North Dakota case was about
6 in which you served as an expert witness?

7 **A. If you pull up the document and**
8 **pull up my declaration, I am happy to comment on**
9 **any case that I see my declaration in front of.**
10 **But I did not review those cases in preparation**
11 **for this deposition.**

12 Q. Understood. Have you ever served
13 as an expert witness in cases concerning abortion
14 that do not relate specifically to regulating
15 medication abortion?

16 **A. I don't recall. I might have. I**
17 **don't recall.**

18 Q. Have you ever served as an expert
19 witness in support of any abortion bans in any
20 states?

21 **A. Again, have I -- are you asking**
22 **did I have a declaration or did I testify before**
23 **Congress? What -- can you clarify your question?**

24 Q. Absolutely. Have you ever
25 submitted a declaration in support of a lawsuit

1 concerning an abortion ban?

2 **A. I might have.**

3 Q. In the last five years, have you
4 served as an expert witness on any case that did
5 not relate to abortion?

6 **A. I don't think so.**

7 Q. How did you come to serve as an
8 expert witness on this case?

9 **A. I was contacted by the AG's**
10 **office of the State of Tennessee.**

11 Q. Do you know how -- do you know if
12 you were referred to them by some third-party like
13 AAPLOG or Charlotte Lozier?

14 **A. I don't know.**

15 Q. So are you aware of Tennessee
16 Annotated Code 39-15-218?

17 **A. Yes. If that is the law that's**
18 **under question, then, yes, I reviewed that law.**
19 **But I don't know it by those numbers.**

20 Q. So the law at question in this
21 case, if I call it the reversal law, will you know
22 what law I'm talking about?

23 **A. Yes, I will know what law you're**
24 **talking about.**

25 Q. Were you aware of the reversal

1 law in Tennessee before you came to serve as an
2 expert witness on this case?

3 **A. I might have been.**

4 Q. You don't have any specific
5 recollection of being aware of it previously?

6 **A. I don't have any specific**
7 **recollection. I am aware of lots of things around**
8 **the country. So it's possible.**

9 Q. And that's sort of part of your
10 job as executive director of AAPLOG, right, to be
11 aware of various abortion laws popping up around
12 the country.

13 **A. To be aware of anything related**
14 **to abortion that would touch on clinical practice**
15 **for our members, yes. That's part of my job.**

16 Q. Okay. And you're being
17 compensated at \$350 an hour for your work on this
18 case; is that right?

19 **A. That's correct.**

20 Q. Are you being offered as an
21 expert in this case?

22 **A. Yes.**

23 Q. And what are you an expert in on
24 this case?

25 **A. I'm an expert in the effects of**

1 **Mifeprax on progesterone receptors and the**
2 **biological plausibility of the use of progesterone**
3 **to displace Mifeprax from progesterone receptors**
4 **and that effect in early pregnancy.**

5 Q. Is that all, for the purposes of
6 this case?

7 A. I think so.

8 Q. Looking at your CV, have you
9 published any peer-reviewed articles concerning
10 the biological plausibility of the use of
11 progesterone to displace Mifeprax on progesterone
12 receptors?

13 A. Not that I recall.

14 Q. But you've published
15 peer-reviewed articles on Mifeprax generally; is
16 that right?

17 A. Correct.

18 Q. Do you know about how many
19 peer-reviewed articles you've published concerning
20 Mifeprax?

21 A. It should be on my CV. But,
22 again, that CV was a year ago. There may be some
23 that aren't on there.

24 Q. So I see nine articles on your
25 CV. I assume that that's not a full accounting of

1 all the articles you've published over the years;
2 is that right?

3 **A. I would have to look back at the**
4 **CV and see what date it is and then rerun my list.**
5 **I can do that.**

6 Q. Your CV, I think, we've already
7 pulled up as an exhibit in the chat. Could you
8 just take a quick look at the publications and let
9 me know if that's a complete list of your articles
10 that you've published?

11 **A. What I'm saying is I'm going to**
12 **have to go back and look at my records to see if**
13 **there's any that haven't been included in the CV.**
14 **So even if I look at the CV now, I won't be able**
15 **to tell you whether or not I've published another**
16 **article since the last time I updated the CV.**

17 Q. Okay. I understand.
18 So, Sara, could you pull up
19 what's been previously marked as plaintiff's 3,
20 Tab H?

21 **A. Give me a second. I'm opening**
22 **it. Give me a second.**

23 Q. Sure.

24 **A. Okay. I got it.**

25 **(Exhibit 3, Harrison Declaration,**

1 **was previously marked.)**

2 BY MS. CLARKE:

3 Q. Okay. Go ahead and take a look
4 at that document. When you're done, can you tell
5 me what it is?

6 A. **Well, it looks to be my
7 declaration.**

8 Q. And if you look at the last page,
9 is that your signature?

10 A. **Yep, that is my signature.**

11 Q. Sitting here looking at it right
12 now, is there any reason to believe that this is
13 not a true and accurate copy of your declaration
14 that you submitted?

15 A. **No, no reason to believe that.
16 Let me clarify. This looks like
17 a true and accurate representation of my
18 declaration.**

19 Q. Since submitting it, are you
20 aware of any corrections that you want to make in
21 this document?

22 A. **No.**

23 Q. How did you draft this
24 declaration? What was your process?

25 A. **My process of drafting this was**

1 **to review the literature and to look at other**
2 **declarations that I have made on similar topics.**

3 Q. Do you remember what other
4 declarations you looked at?

5 **A. I looked at the Oklahoma**
6 **declaration.**

7 Q. Any other ones that you can think
8 of?

9 **A. For the drafting of this**
10 **document, I reviewed the declarations of**
11 **plaintiffs. I reviewed the medical literature. I**
12 **think that's it.**

13 Q. Did anyone help you draft this
14 document?

15 **A. No.**

16 Q. Did you consult with anyone in
17 the course of drafting this document?

18 **A. No.**

19 Q. And all the citations in this
20 document, are those all citations that you found
21 yourself?

22 **A. Yes, I think so. I mean, I do my**
23 **own research.**

24 Q. Okay. So in paragraph 5 of this
25 declaration, it reads, The legal action challenges

1 of Tennessee law requiring abortion providers to
2 inform medication abortion patients that it may be
3 possible to --

4 **A. Wait a minute.**

5 Q. Go ahead.

6 **A. I'm sorry. Are you on paragraph**
7 **No. 5? I think it says that, I've been asked by**
8 **Tennessee Attorney General.**

9 Q. Yep. So the next sentence after
10 that.

11 **A. I'm sorry. Yes, I see it.**

12 Q. Okay. So, The legal action
13 challenges of Tennessee law requiring abortion
14 providers to inform medication abortion patients
15 that it may be possible to reverse the intended
16 effects of mifepristone, the first drug taken, if
17 the second pill or tablet, misoprostol, has not
18 been taken or administered.

19 Is that an accurate
20 representation of your understanding of the
21 reversal law?

22 **A. Yes.**

23 Q. Do you know if the reversal law
24 requires anything else?

25 **A. Yes. The law requires that**

1 **abortion providers -- okay. I would have to pull**
2 **up the law to see if there's anything else.**

3 **What I have in that paragraph is**
4 **what I was focusing on for purposes of my**
5 **declaration. So I read the Tennessee law, looking**
6 **specifically at what I was supposed to comment on.**
7 **So if there's anything else in the Tennessee law,**
8 **then I would have to -- you would have to pull up**
9 **the law for me to be able to say whether there**
10 **exists any other thing in the Tennessee law.**

11 Q. Okay. But this is the sentence
12 that you focused on, right, for your declaration?

13 **A. That is what I focused on, yes.**

14 Q. So I'm going to read a sentence
15 to you, and I would like you to tell me what you
16 understand that sentence to mean. Okay?

17 The sentence is, It may be
18 possible to reverse the intended effects of a
19 chemical abortion utilizing mifepristone if the
20 woman changes her mind.

21 What does that sentence mean to
22 you?

23 **A. That means if a woman takes**
24 **mifepristone and she decided after she takes it**
25 **that she doesn't want to abort her baby, that it**

1 is possible for her to be able to do things to
2 make it likely for -- that it's possible, not that
3 it does, but that it is possible for her to take
4 some action that may help increase the chances of
5 survival for her baby.

6 Q. And would that action include
7 seeing a doctor and getting progesterone
8 treatment?

9 A. Yes.

10 Q. So whenever --

11 A. But that's not -- wait, wait,
12 wait. Whoa. Let me clarify that.

13 Q. Sure.

14 A. That's not what it said in the
15 sentence you just read.

16 Q. I understand.

17 A. So the sentence you just read
18 does not include the clause, See a doctor, get
19 progesterone treatment. It doesn't include that
20 in what you read.

21 So insofar as the sentence you
22 read goes, that's where my answer is.

23 Q. Okay. Are you aware of any other
24 action that someone could take to reverse the
25 effects of mifepristone other than getting

1 progesterone treatment?

2 **A. No.**

3 Q. I'm going to read you another
4 sentence, and let me know what it means to you.

5 It may be possible to avoid,
6 cease, or even reverse the intended effects of a
7 chemical abortion utilizing mifepristone if the
8 second pill has not been taken.

9 Does that mean the same thing as
10 the last sentence you read?

11 **A. Yes. It may be possible to
12 avoid -- I don't have the whole thing in front of
13 me, but avoid the effects of mifepristone if the
14 second drug hasn't been taken. Yes, it means the
15 same thing with more words in it than the first
16 sentence that you read.**

17 Q. Okay. What is medication
18 abortion reversal treatment?

19 **A. When mifepristone is given to a
20 woman, mifepristone acts at the level of a
21 nuclear -- progesterone receptor on the nucleus of
22 a cell. The way it acts is it acts by changing
23 actually the DNA that's transcribed in that cell.**

24 **So the change that progesterone
25 is supposed to make in cells to adapt a woman's**

1 body to pregnancy, that change is blocked by
2 mifepristone. But mifepristone reversibly binds
3 to the progesterone receptor, which means that it
4 will bind and block and then it will unbind and
5 bind and block, and it will unbind. So it's a
6 reversible blockade. You can use progesterone to
7 displace mifepristone from the progesterone
8 receptor if there's sufficient progesterone.

9 **And so that's what it means.**

10 Q. When we talk about medication
11 abortion reversal treatments, we're talking about
12 providing progesterone in high doses to someone
13 who has taken mifepristone and is pregnant; is
14 that accurate?

15 **A. Within a certain time frame.**

16 Q. And that time frame is about 72
17 hours?

18 **A. That's correct.**

19 Q. Does it matter when within that
20 72-hour window the progesterone treatment is
21 given?

22 **A. The sooner, the better.**

23 Q. Okay. Have you ever provided
24 medication abortion reversal treatment to anyone?

25 **A. No.**

1 Q. Have you ever referred someone
2 for medication abortion reversal treatment?

3 A. Oh, I don't know. Maybe. I
4 don't -- what I do, if someone asks me does this
5 exist, I tell them to contact the Heartbeat
6 Hotline, because that's who runs the network.

7 Q. And by "the network," that would
8 be the abortion pill rescue network?

9 A. The network of physicians that
10 are familiar with abortion pill -- with
11 progesterone to reverse the affects of
12 mifepristone.

13 Q. Do you know what that network is
14 called?

15 A. APR. But actually I can't
16 remember what the initials stand for, whether it's
17 abortion pill rescue or abortion pill reversal.
18 They've changed the acronym, and I can't remember
19 the current acronym.

20 Q. So if I say APR or APRN, you'll
21 know what I'm talking about?

22 A. Yes. APRN, the abortion pill
23 reversal network.

24 Q. Do you know, how long has APRN
25 been around?

1 **A. I don't know. A couple of years,**
2 **three or four years, maybe longer. I don't know**
3 **when it actually started. I could find that out,**
4 **but I don't know off the top of my head when it**
5 **started.**

6 Q. And it's affiliated somehow with
7 Heartbeat International. Is that what you just
8 said?

9 **A. That's correct, yes. Not just a**
10 **head not, but yes.**

11 Q. Mifepristone alone is not always
12 effective at terminating a pregnancy; is that
13 right?

14 **A. That's correct.**

15 Q. So how long have we known that
16 fact?

17 **A. Since the drug development back**
18 **in the late '70s, early '80s, at least.**

19 Q. Do you know whether there's any
20 recent research showing that it's more effective
21 or less effective than we had previously thought?

22 **A. I'm sorry. I honestly don't**
23 **understand your question. One more time.**

24 Q. So we've known since the '70s
25 that mifepristone alone is not always effective at

1 terminating a pregnancy. In the last five or six
2 years, are you aware of any research showing that
3 mifepristone is even less effective than we had
4 previously thought at terminating a pregnancy by
5 itself?

6 **A. What I don't understand is when**
7 **you say "less effective than what we had**
8 **previously thought." I mean, which papers are you**
9 **comparing?**

10 **Because mifepristone efficacy**
11 **varies per paper, per population, per gestational**
12 **age, so that the efficacy -- that's what I don't**
13 **understand.**

14 **Q. Okay. Has your understanding of**
15 **the general efficacy of mifepristone alone to**
16 **terminate a pregnancy changed in the last five**
17 **years?**

18 **A. At what gestational age?**

19 **Q. In the first trimester.**

20 **A. Well, if mifepristone efficacy**
21 **varies in the first trimester, it's less effective**
22 **at seven weeks than it is at six weeks; it's less**
23 **effective at eight weeks than it is at seven**
24 **weeks; it's less effective at nine weeks than it**
25 **is at ten weeks.**

1 **You know, so the efficacy of**
2 **mifepristone depends on the gestational age of**
3 **pregnancy.**

4 Q. And we've known that fact for
5 decades; is that accurate? We've known that
6 mifepristone effectiveness at terminating
7 pregnancy varies based on gestational age?

8 **A. I can say that as of the**
9 **approval -- as of the approval in 2000, we have**
10 **known that fact.**

11 Q. Do you know if anyone provides
12 reversal treatment besides doctors affiliated with
13 APRN?

14 **A. I don't know.**

15 Q. Do you know if the Obria Network
16 provides reversal treatment?

17 **A. I don't know.**

18 Q. Okay. Are you affiliated with
19 APRN?

20 **A. No. I'm not a practicing -- I'm**
21 **not doing clinical practice. So I'm not.**

22 Q. Do you serve any advisory
23 function for them? Are you on an advisory
24 committee or --

25 **A. That's a very good question. I**

1 **have given them advice before. I don't know if**
2 **I'm enrolled on an official advisory committee,**
3 **but I certainly have given them advice.**

4 Q. About what have you given them
5 advice?

6 **A. About the plausibility of**
7 **progesterone effects on the mifepristone receptor.**

8 Q. Have you given them any advice
9 about reversal protocols?

10 **A. Not that I know of.**

11 Q. We talked briefly about Heartbeat
12 International. What is Heartbeat International?

13 **A. Heartbeat International -- it is**
14 **whatever it says on its website. But Heartbeat**
15 **International, as I understand it, is a network of**
16 **pregnancy care centers.**

17 Q. Are pregnancy care centers what
18 are sometimes referred to as crisis pregnancy care
19 centers?

20 **A. Yeah. I think that some people**
21 **refer to them as crisis pregnancy centers.**

22 Q. If someone were seeking reversal
23 treatment from a doctor through the APRN hotline,
24 do you know how they would pay for their reversal
25 treatment?

1 **A. I don't know.**

2 Q. Do you know whether insurance
3 covers reversal treatment?

4 **A. I don't know.**

5 Q. Do you know whether APRN or
6 Heartbeat International provides subsidies for
7 people who can't afford it?

8 **A. I don't know.**

9 Q. Okay. So the reversal protocol
10 can consist of either oral progesterone or
11 intramuscular injections of progesterone; is that
12 right?

13 **A. That's my understanding.**

14 Q. And you have no idea how much an
15 injection of progesterone costs?

16 **A. No. Actually, I don't.**

17 Q. Does the standard protocol --
18 well, strike that.

19 Do you know where I could find
20 the standard protocol for medication abortion
21 reversal?

22 **A. You would have to contact the**
23 **APRN Network.**

24 Q. Do you know whether the doctors
25 that they refer patients to as part of a network

1 all receive some kind of standardized material
2 telling them how to do this?

3 **A. I don't know.**

4 Q. So you don't know whether APRN
5 refers people only to physicians that follow a
6 particular protocol?

7 **A. I don't know.**

8 Q. For medication reversal to be
9 effective, does the amount of progesterone given
10 depend on the gestational age of the pregnancy?

11 **A. That's an interesting scientific
12 question that I can't answer with a paper.**

13 Q. Do you think it would be more
14 effective if you gave people more progesterone at
15 later gestational ages, just based on your
16 knowledge and expertise?

17 **A. Well, that's kind of a difficult
18 question to answer because there are sources of
19 progesterone production that kick in later in the
20 pregnancy.**

21 **So I can't answer -- I don't
22 know. I don't know.**

23 Q. Do you think that reversal would
24 be more effective -- strike that.

25 Do you think it would make sense

1 to give someone at eight weeks gestational age
2 more progesterone to reverse mifepristone than
3 someone at five weeks?

4 **A. I don't know. I don't know if**
5 **that's been studied.**

6 Q. Just based on your general
7 knowledge and expertise, would you expect that it
8 would be more effective to give more progesterone
9 at eight weeks than five weeks?

10 **A. I don't know. I don't know**
11 **whether it would be or not.**

12 Q. For medication abortion reversal,
13 should the dose of progesterone vary based on a
14 patient's weight?

15 **A. As far as I know, the efficacy of**
16 **mifepristone does not vary with weight. So since**
17 **the efficacy of mifepristone does not vary with**
18 **weight, I would suspect that the efficacy of**
19 **progesterone given exogenously -- given from**
20 **outside, not made by the body -- I would expect**
21 **that that would also not vary with weight.**

22 **That's just my speculation.**

23 Q. For a medication abortion
24 reversal protocol, would you expect to want to
25 receive more progesterone if it had been more time

1 since they had taken the mifepristone?

2 **A. The medication abortion**
3 **protocol -- the administration of progesterone**
4 **needs to take place within 72 hours. So within 72**
5 **hours, that is the time period where the**
6 **mifepristone binding to the nuclear progesterone**
7 **receptor, it will start to affect transcription,**
8 **DNA transcription, within those 72 hours.**

9 **So the progesterone has to be**
10 **present to displace mifepristone from that**
11 **receptor within 72 hours to restore the normal DNA**
12 **transcription that has to happen for the woman's**
13 **body to be able to adapt to a pregnancy.**

14 **Q. So is there any reason to give**
15 **someone more progesterone if it's been 72 hours**
16 **since mifepristone versus if it had only been 12**
17 **hours since mifepristone?**

18 **A. I don't think any studies have**
19 **looked at that.**

20 **Q. Based on your general knowledge**
21 **and expertise, would you expect that someone**
22 **should get more progesterone if it's been 72 hours**
23 **since the mifepristone versus 12 hours?**

24 **A. Based on my knowledge, I don't**
25 **see any reason why you would need to give more**

1 progesterone.

2 The issue is displacing the
3 mifepristone from the progesterone receptor. So
4 you need to give sufficient progesterone to
5 displace the mifepristone from the progesterone
6 receptor so that transcription of DNA can resume.

7 So whatever quantity of
8 progesterone is sufficient to displace the
9 mifepristone from the progesterone receptor, that
10 should be the quantity within 72 hours.

11 Q. Correct me if I misunderstood.
12 So the 72 hours is sort of the time frame when
13 mifepristone is effective; right? If the time
14 frame were --

15 A. The 72 -- at 72 hours, you can
16 see a decrease in progesterone effect on the baby,
17 on production. Okay? So the way that
18 progesterone effect is mediated is it's mediated
19 because the progesterone receptor in the nucleus
20 tells the DNA what genes to transcribe.

21 So if you can block that, then
22 you cause a change in DNA transcription. That
23 change in DNA transcription is not immediate.
24 It's not like a metabolic poison. It takes time
25 to take effect.

1 So because it takes time to take
2 effect, there's also time to mitigate its effect.
3 So after 72 hours, it appears from animal studies
4 that you have passed the point where you can
5 meaningfully change the transcription that's
6 happening.

7 So before 72 hours appears to be
8 the time when you can meaningfully change it and
9 cause the normal progesterone-induced
10 transcription to resume and -- you may have
11 skipped a beat, but you still pick up the same
12 song.

13 Q. So when you say that 72 hours
14 appears to be the window based on animal studies,
15 which animal studies are those?

16 A. I quoted them. Yamabe -- I would
17 have to look at some others. There's others that
18 Baulieu quotes.

19 Q. So your understanding of the
20 Yamabe study, it studies the effects of
21 mifepristone after 72 hours?

22 A. My understanding of the Yamabe
23 study is that it shows that later effects of --
24 that later administration of progesterone was not
25 effective.

1 But, again, I would have to go
2 back and look at that study specifically, because
3 you're asking me a specific numerical answer to a
4 specific study and I can't pull that out of my
5 head. I have to look back and look at the study.

6 Q. So when you said that 72 hours
7 appears to be the window based on the animal
8 studies, Yamabe was one of those animal studies
9 that you were referring to?

10 A. Correct.

11 Q. Do you know is there anyone for
12 whom abortion reversal treatment is
13 contraindicated?

14 A. If you look at the label for
15 progesterone, progesterone is a very widely used
16 hormone, and I don't believe that there are any
17 contraindications to progesterone. But, again, I
18 would have to look on the label.

19 If there would be, it would be
20 previous allergy to progesterone. But you make
21 progesterone, so it's going to be unlikely that
22 you have an allergy to progesterone since you make
23 progesterone.

24 Q. Do you know whether there's any
25 small number of people who do actually have an

1 allergy to exogenous progesterone?

2 **A. I would have to look that up.**

3 Q. So it's your opinion that
4 medication abortion patients should be told about
5 reversal treatment; right?

6 **A. Yes.**

7 Q. And that's so that if they change
8 their mind after taking the mifepristone, they can
9 seek treatment to save the pregnancy; right?

10 **A. That's correct.**

11 Q. When should they be told about
12 reversal treatment?

13 **A. When they're in a process of
14 getting informed consent. Because part of the
15 informed consent process -- as any physician
16 knows, with informed consent, you're supposed to
17 talk about what you're going to do to the patient,
18 what are the alternatives, what are the side
19 effects. That's just part of informed consent.**

20 Q. So if informed consent were given
21 -- strike that.

22 So informed consent is like a
23 continuous process; right?

24 **A. Informed consent is a process.
25 It's not a piece of paper; it's a process. And**

1 it's a process of making sure that the patient
2 understands what it is she's doing, what are the
3 effects of what she's doing, what can she expect
4 afterwards. So, yes, it is a process.

5 Q. And so if the informed consent
6 process starts two weeks before the patient is
7 scheduled to get the mifepristone, would it make
8 sense to tell them about the reversibility of
9 medication abortion two weeks before they're
10 scheduled to take their mifepristone?

11 A. Whenever she goes through the
12 informed consent process prior to consent, it
13 would -- I mean prior to her saying, writing on
14 the bottom-line and writing her check, prior to
15 committing to the procedure, informed consent
16 should take place prior to committing to the
17 procedure or to the drug or whatever else you're
18 consenting the patient for.

19 Q. So --

20 A. Informed consent has to take
21 place before. It can't take place after. It has
22 to be a part of the informed consent process.

23 Q. So do you think it matters
24 whether a patient is told about the reversibility
25 of medication abortion an hour before they take

1 the mifepristone or a week before they take the
2 mifepristone? Does it make a difference?

3 **A. I think when she's getting the**
4 **informed consent process, she needs to be aware of**
5 **the possibility that, if she changes her mind,**
6 **then there is a drug which may increase the**
7 **likelihood that her baby will survive.**

8 Q. So if the informed consent
9 process lasts over the course of a few days -- you
10 come in and get some information, you talk to
11 someone, you come back, you talk to someone again
12 about the risks and benefits before you committed
13 -- would it matter when, in the course of those
14 few days, the patient learns the medication
15 abortion is reversible?

16 **A. Well, generally, my understanding**
17 **is that the informed consent process takes place**
18 **at one point in time prior to abortion. That's**
19 **when they sign the form. Okay. They sign the**
20 **form, yes, I want to do this. So prior to her**
21 **putting her signature on the form, that is when**
22 **she needs that information.**

23 Q. So, then, does it matter whether
24 she gets that information an hour before she signs
25 the form or a week before she signs the form?

1 A. I think it's -- I think -- I will
2 say what I said again, that when the informed
3 consent process takes place prior to her putting
4 her signature on that documentation of informed
5 consent, she should be made aware of abortion pill
6 reversal?

7 Q. Is there any benefit to telling
8 patients a week before they sign their informed
9 consent form that medication abortion is
10 reversible?

11 A. There is benefit in presurgical
12 procedures, pre-procedures, to giving a patient
13 time to think about the information that is given
14 to them.

15 So it is poor form in surgery to
16 talk to the patient for the first time about
17 risks, alternatives because, at that point, they
18 are committed. They are in process. Especially
19 after they've paid for it.

20 So the informed consent process
21 is supposed to give time for patients to think
22 about what's said, ask questions about it. That's
23 just the nature of consenting a person to surgery
24 or to a procedure.

25 Q. Okay. That makes sense.

1 So with respect -- well, strike
2 that.

3 You have supervised residents in
4 the resident in the past; correct?

5 **A. Yes.**

6 Q. Did you teach those residents
7 about informed consent?

8 **A. Yes.**

9 Q. What did you teach them about
10 what they should tell patients to obtain informed
11 consent?

12 **A. Well, my understanding of the**
13 **standard of informed consent is that it's what a**
14 **patient would want to know to make their decision.**

15 Q. How does one know what a patient
16 would want to know to make their decision?

17 **A. You talk to them.**

18 Q. And before making the decision to
19 have an abortion, is it your understanding that
20 patients would want to know that medication
21 abortion is reversible?

22 **A. My understanding is that patients**
23 **would want to know any information that pertains**
24 **to the risks, the benefits, the alternatives.**
25 **That's what most patients want to know.**

1 Q. Did you ever teach residents
2 about how to deliver informed consent information?
3 By that, I mean, how complicated their language
4 should be and how much jargon to use or not use?

5 A. Yes.

6 Q. And what did you teach them about
7 that?

8 A. I taught them by example. And I
9 also would teach them that the principle of
10 informed consent is to make sure that this
11 patient, this patient, understands what she's
12 signing up for and what she can expect afterward.

13 So whatever it takes for this
14 patient to understand, that's what you need to do.
15 You're ethically responsible for making sure she
16 comprehends the procedure, what's going to be
17 done, the risks, the benefits, the alternatives.
18 That's the imperative for the treating physician.

19 Sometimes that means getting a
20 translator. Sometimes that means other things.
21 But your responsibility is to make sure that this
22 patient understands.

23 Q. Okay. So if one uses too much
24 medical jargon in the course of informed consent,
25 is there a risk that the patient won't understand?

1 A. It depends on if you're talking
2 to a physician or not.

3 Q. Let's say --

4 A. The language you use depends on
5 the patient that you're talking to.

6 Q. So if you were to provide
7 abortion -- medication abortion reversal treatment
8 to a patient, what would you tell them as part of
9 informed consent?

10 A. I would tell them this is how
11 Mifeprex works, that it works by blocking the
12 progesterone receptor on the cell, that it works
13 by changing how the cell responds to progesterone;
14 that that blockage, like a false key in a door,
15 can be -- the false key, the progesterone --
16 excuse me. Let me start this over again.

17 The false key, the Mifeprex, can
18 be displaced by the true key, progesterone. But
19 it will only affect the baby's survival if it's
20 done quickly, because there's a point beyond which
21 it probably won't make any difference.

22 So if you're before 72 hours, you
23 know, what's the time you took -- not just the
24 date, but the time that you took the progesterone
25 -- the Mifeprex, excuse me -- if that's within 72

1 hours and the baby is still alive, because you
2 don't give progesterone -- it would be pointless
3 to give progesterone if the baby has already died.

4 If the baby is still alive, there
5 is a chance that progesterone may increase the
6 chances of survival of that baby. It's not a
7 guarantee. It's not a hundred percent. But it
8 can increase the chances of survival. And if
9 you're interested in increasing the chances of
10 survival, progesterone is one thing that we can
11 do, something that we can do.

12 Q. Sure. Would you tell patients
13 that there's, as you mentioned to me earlier, a
14 very unlikely possibility that they might be
15 allergic to progesterone?

16 A. I would ask them if they have any
17 allergies in their history. That's just part of
18 normal patient care. You ask them if they have
19 any allergies.

20 Q. People don't always know what
21 they're allergic to, right, when it comes to
22 medication?

23 A. Correct.

24 Q. So would you advise patients that
25 there might be a risk that they might be allergic

1 to progesterone?

2 **A. I think the allergy to**
3 **progesterone would be something that would be**
4 **discovered after they would take it, just like the**
5 **allergy to aspirin or the allergy to Mifeprex, as**
6 **a matter of fact. Mifeprex itself has allergies.**

7 Q. So you wouldn't tell a patient
8 before they take progesterone that there's some
9 chance that they might be allergic to it without
10 knowing?

11 MR. RIEGER: Object to the form
12 of the question.

13 Go ahead.

14 **A. Routinely, you ask a patient, do**
15 **you have any allergies? You explain to them --**
16 **okay.**

17 And then every -- I mean, part of
18 giving a patient or prescribing a medication to a
19 patient is to say, We shouldn't give this to you
20 if you're allergic. But we don't know ahead of
21 time whether someone is allergic, and it is
22 vanishingly unusual for someone to have an
23 allergic reaction to something that their own body
24 produces.

25 BY MS. CLARKE:

1 Q. So it wouldn't make sense to give
2 someone information as part of informed consent
3 about a vanishingly unusual side effect that they
4 might have?

5 MR. RIEGER: Object to the form
6 of the question.

7 Go ahead and answer.

8 **A. What I would say is allergies are**
9 **always possible before you give a medication.**
10 **Okay? But there's some things like progesterone,**
11 **which is a hormone that your body naturally**
12 **produces, that it would be vanishingly rare to**
13 **have an allergy to something that your body**
14 **normally produces.**

15 BY MS. CLARKE:

16 Q. So it wouldn't make sense to tell
17 everyone who takes it that there is a one in a
18 million chance you might have an allergy to this?

19 MR. RIEGER: Objection to the
20 form of the question.

21 Go ahead and answer.

22 **A. I doubt that it's even that high.**

23 BY MS. CLARKE:

24 Q. So, then, it wouldn't make sense
25 to tell patients about it in advance; is that

1 right?

2 MR. RIEGER: Objection.

3 Go ahead and answer.

4 A. When you say "tell patients about
5 it in advance," what you tell patients about are
6 things that they want to know. If in my
7 conversation the patient says, Look, is there any
8 chance I could be allergic to this, I'd say, Yes,
9 there's a vanishingly small chance. But it is a
10 natural hormone that your body makes, so you're
11 not having an allergic reaction to what your body
12 is already making right now. So I sincerely doubt
13 that you're going to have an allergic reaction to
14 the same chemical that your body is making right
15 now.

16 BY MS. CLARKE:

17 Q. I understand. So you would
18 discuss it if asked by a patient; is that
19 accurate?

20 A. Correct.

21 Q. If you were not asked by a
22 patient, you would not discuss it as part of the
23 risks and benefits of progesterone treatment; is
24 that right?

25 MR. RIEGER: Same objection.

1 Go ahead and answer.

2 **A. Understanding the physiology of a**
3 **human body and how allergic reactions happen,**
4 **allergic reactions happen to things that are**
5 **foreign to the human body.**

6 Progesterone is not a foreign
7 compound. Progesterone is a compound that the
8 human body makes. So, physiologically, it would
9 not make sense that the human body would have an
10 allergic reaction to something -- to a hormone
11 that the human body already makes.

12 BY MS. CLARKE:

13 Q. Have you ever obtained informed
14 consent to an abortion?

15 **A. What do you mean by the term**
16 **"abortion"?**

17 Q. Have you ever obtained informed
18 consent to an abortion unrelated to an ectopic
19 pregnancy?

20 **A. Well, again, it depends on what**
21 **you're using for the term "abortion." Abortion**
22 **has about, oh, 15 or 18 different definitions. So**
23 **it depends on what definition you're using.**

24 BY MS. CLARKE:

25 Q. Did you ever obtain informed

1 consent from a patient for medication abortion?

2 **A. No.**

3 Q. Have you ever obtained informed
4 -- actually, strike that.

5 Have you ever performed a tubal
6 ligation on a patient?

7 **A. Yes.**

8 Q. Have you obtained informed
9 consent for a tubal ligation?

10 **A. Yes.**

11 Q. And were those tubal ligations
12 medically indicated, or were they elective?

13 **A. Elective.**

14 Q. And when patients -- when you
15 obtain informed consent from patients for elective
16 tubal ligations, do you tell them that the process
17 is reversible?

18 **A. Yes, I do.**

19 Q. About -- what would you say is
20 the rate of effective reversibility of a tubal
21 ligation?

22 **A. You know, I haven't looked at**
23 **that literature recently, and I'm sure it's much**
24 **higher now. But it does depend on the type of**
25 **tubal ligation that's done; you know, how much**

1 **tube that they have left; and where in the tube**
2 **the ligation was done.**

3 **So to quote you a number, it**
4 **depends. It's patient-specific.**

5 Q. Okay. So for any patient who
6 undergoes a tubal ligation, it may or may not be
7 reversible; is that right?

8 **A. Well, for any procedure, yes, it**
9 **may or may not be reversible.**

10 Q. Okay. So when you obtain
11 informed consent from patients for tubal ligations
12 and you tell them it's reversible, do you also
13 tell them that it may not be reversible?

14 **A. Yes.**

15 Q. Do you tell them that it's
16 important that they make -- come to a final
17 decision about whether or not they want the tubal
18 ligation before they undergo it?

19 **A. Yes.**

20 Q. Do you tell them not to rely on
21 its potential reversibility when they make that
22 decision?

23 **A. Yes.**

24 Q. Do you know if any of your
25 patients has ever undergone a tubal ligation

1 thinking, Well, it's reversible, I can change my
2 mind later?

3 **A. Not my patients.**

4 Q. Do you know for a fact that no
5 patients have ever done that, that you've seen?

6 MR. RIEGER: I'm going to object
7 to the form of the question.

8 Go ahead.

9 **A. I can't possibly know that.**

10 MS. CLARKE: Do we want to take
11 lunch. I know that Dr. Harrison and I
12 are on the East Coast. It's 12:30ish
13 here.

14 MR. RIEGER: That is fine by me.

15 THE WITNESS: That works for me.

16 MS. CLARKE: Do we want to take
17 about 45 minutes for lunch? Is that
18 enough? Or like do you want to come
19 back at 1:00 Eastern?

20 THE WITNESS: That works for me.

21 MR. RIEGER: 1:00 Eastern is fine
22 by me.

23 MS. CLARKE: Can we go off the
24 record?

25 VIDEOGRAPHER: Off the record at

1 11:23.

2 (A break was taken.)

3 VIDEOGRAPHER: Back on the record
4 at 12.01.

5 BY MS. CLARKE:

6 Q. Dr. Harrison, did you communicate
7 with anyone during this lunch break?

8 **A. No.**

9 Q. Okay. Do you know whether APRN
10 refers patients only to physicians for reversal
11 treatment?

12 **A. I don't know.**

13 Q. Do you think it would be
14 appropriate for someone who's not a physician to
15 provide a reversal treatment?

16 **A. I think the scope of practice for**
17 **each state is different. So it would depend on**
18 **the scope of practice for the state.**

19 Q. If it were legally permitted, do
20 you think it would be appropriate for a physician
21 assistant to provide reversal treatment?

22 **A. If whoever is providing it does**
23 **an ultrasound to show that the baby is alive and**
24 **can, with all reasonable degree of accuracy,**
25 **determine that it's been less than 72 hours, then**

1 the actual administration of progesterone, if it's
2 within the scope of practice for that state for
3 the advanced practice clinician to prescribe, then
4 they should be able to prescribe. But you have to
5 meet the criteria.

6 Q. So one of those criteria is
7 having an ultrasound to confirm pregnancy?

8 A. No. A criteria is having an
9 ultrasound to make sure that the baby is alive.
10 If the baby is dead, it is irrelevant.
11 Progesterone isn't going to work, and you wouldn't
12 prescribe it.

13 Q. Do you think it would be
14 appropriate to prescribe someone progesterone
15 before you've given them the ultrasound?

16 A. Yes. I think that would be
17 appropriate depending on how quickly you can get
18 them in and what the gestational age is at which
19 she took the Mifeprex.

20 So, for example, prescribers of
21 Mifeprex are prescribing Mifeprex before they even
22 know the intrauterine location of the pregnancy.
23 They're prescribing it at four and a half weeks
24 gestation.

25 And so if a woman at four and a

1 half weeks gestation took Mifeprex and said, I've
2 changed my mind, then it would be appropriate to
3 give her progesterone in the hope that it would
4 increase her chances of survival of the baby.

5 Q. So what about a patient at eight
6 weeks gestational age? Would it be appropriate to
7 give them reversal treatment prior to doing an
8 ultrasound?

9 A. It depends on the timing. The
10 progesterone has to be administered within 72
11 hours. So the initial dose of progesterone may --
12 it has to be given within 72 hours to act.

13 So if it turns out that she's 68
14 hours and she can't get in within 72 hours to
15 confirm intrauterine pregnancy that's alive, then
16 it is appropriate to administer at that point.

17 Q. Then would it be appropriate to
18 do an ultrasound afterwards at some point?

19 A. Yes.

20 Q. Do you know about how long
21 somebody will be receiving progesterone treatments
22 as part of a reversal protocol?

23 A. I don't know.

24 Q. Is it more than one day?

25 A. Yes.

1 Q. Do you know -- strike that.

2 You're aware that a Dr. Michael
3 Podraza is an expert witness in this case;
4 correct?

5 A. Yes.

6 Q. And did you read his declaration?

7 A. I probably skimmed it. I don't
8 recall it in detail.

9 Q. Okay. Are you aware that
10 Dr. Podraza has previously testified that he does
11 not believe that information about reversal should
12 be given to patients before they take the
13 Mifeprex?

14 A. If that's what he states, okay.

15 Q. I'm going to read you some
16 statements, and I want you to tell me if you agree
17 with them. Okay?

18 A. Yes.

19 Q. Okay. You may end up causing
20 more problems and you may actually end up
21 increasing the amount of people who take
22 mifepristone because they think they can change
23 their minds.

24 Do you agree with that statement
25 with respect to telling patients about reversal

1 before they've taken mifepristone?

2 **A. That's his speculation.**

3 Q. Do you agree with that statement?

4 **A. No.**

5 Q. But you don't think that it could
6 increase the number of people who take
7 mifepristone because they think they can change
8 their mind later?

9 **A. Not if they're appropriately**
10 **receiving informed consent.**

11 Q. I'm going to read you another
12 statement.

13 It could actually be considered a
14 way of trying to convince someone to take the
15 mifepristone if you told them, Well you should
16 just take it because you can change your mind
17 later. You can take this other medication and be
18 okay.

19 Do you agree that that's a risk
20 that comes with telling patients about reversal
21 prior to taking mifepristone?

22 **A. That is a failure of informed**
23 **consent.**

24 Q. Do you agree that there is any
25 risk that people who are told about reversal, no

1 matter what their doctor tells them, will
2 ultimately think, You know, I'm not entirely sure.
3 Why don't I take it and see how I feel. And if I
4 change my mind, I can always reverse it.

5 **A. That would be a failure of**
6 **informed consent.**

7 Q. So if the doctor gives the
8 patient the right information, there is no risk
9 that any patient would ever think that? Is that
10 your testimony?

11 **A. In the whole universe of ever**
12 **patients -- any patient ever in the whole history**
13 **of the human race, I can't make that kind of a**
14 **statement.**

15 **The purpose of informed consent**
16 **is to make sure that the patient understands what**
17 **she is doing, the risks and alternatives, and that**
18 **she freely and fully consents.**

19 Q. But, ultimately, there's only so
20 much a doctor can do in terms of providing
21 information to a patient to make them understand
22 things; right?

23 **A. Yes.**

24 Q. I'm going to give you another
25 quote. Let me know if you agree.

1 It would be probably
2 inappropriate to give patients information about
3 reversal as a way out if they change their mind
4 before they've actually completely decided to take
5 the medication.

6 Do you agree with that statement?

7 **A. No.**

8 Q. And why not?

9 **A. Because I don't think it would be**
10 **inappropriate to give them information during the**
11 **informed consent process. I think that's the**
12 **purpose of informed consent, is to give the**
13 **patient all the information. And that informed**
14 **consent process needs to take place before the**
15 **procedure.**

16 Q. Okay. So I'm going to do one
17 last quote. Let me know if you agree with this.

18 Giving someone information about
19 informed -- sorry. Strike that.

20 Giving someone information about
21 reversal before taking mifepristone might
22 encourage someone who, say, doesn't really want to
23 have an abortion but their boyfriend, father,
24 mother, whoever brought them to the clinic and is
25 trying to coerce them, they might think, Well,

1 I'll take the mifepristone to placate my person
2 who is pressuring me and then, you know, go home
3 and call and get the progesterone so I can reverse
4 it.

5 Do you agree with that statement,
6 that that's a risk?

7 **A. That is a failure of appropriate**
8 **screening for coercion. Coercion for abortion is**
9 **not legal in any state in the country. So if you**
10 **are giving a person mifepristone and you have not**
11 **appropriately screened for coercion, that is a**
12 **failure of the informed consent process.**

13 Q. If someone is being pressured by
14 their boyfriend to have an abortion and let's say
15 they don't tell anyone about it, do you think that
16 if they're aware that mifepristone can be
17 reversed, they might think, Fine, I'll go ahead
18 and take it; tomorrow, he's not looking; I'll go
19 and get it reversed? Is that a --

20 MR. RIEGER: Object to the form
21 of the question.

22 Go ahead and answer.

23 **A. That's a failure of the informed**
24 **consent process. It is part of the physician**
25 **responsibility prior to administering medication**

1 **abortion to screen for coercion.**

2 BY MS. CLARKE:

3 Q. Is there any way for physicians
4 to know what's happening in the patient's life if
5 she doesn't tell them?

6 A. Yes. There's many ways you can
7 know. If she has bruises around her neck, if
8 she's 12, if -- there are many ways of screening
9 for abuse and coercion.

10 You can know or you can heavily
11 suspect that if the person who is coercing won't
12 leave the patient alone. That's why you separate
13 patients. There's many other ways that the
14 patient can actually physically tell you.

15 And it is the responsibility of
16 the abortion provider to screen for coercion,
17 which is against the law in every state in the
18 United States, prior to administering Mifeprex
19 abortion.

20 Q. So do you think that a physician
21 can be 100 percent certain that a patient isn't
22 being pressured at all by anyone?

23 A. That's not what I said.

24 Q. That's what I'm asking. Do you
25 think it's possible for a physician to be 100

1 percent sure that a patient is not being pressured
2 at all by anyone?

3 **A. It's not possible for any human**
4 **being to be a hundred percent certain of anything,**
5 **even if the sun will rise tomorrow.**

6 Q. Have you read the declarations of
7 Ms. Herman (ph) and Ms. Donovan submitted in this
8 case?

9 **A. I don't recall those names.**

10 Q. Did you read any declarations
11 submitted in this case by people who took
12 mifepristone and then got a reversal?

13 **A. I did not. I did not review**
14 **those.**

15 Q. So in your declaration, you noted
16 that abortion reversal is 68 percent effective if
17 offered by mouth or intramuscular injection; is
18 that right?

19 **A. That's what was published in the**
20 **Delgado case series.**

21 Q. Is that accurate, though, so far
22 as you're aware?

23 **A. That's what they published.**

24 Q. Do you think -- well, strike
25 that.

1 So that means about 32 percent of
2 the time, even if it's administered by mouth or
3 intramuscular injection, it won't work to save the
4 pregnancy; right?

5 **A. That's what their -- well, yes.**
6 **That's what their study implies.**

7 Q. Do you think it would be
8 appropriate to tell patients that there is a 68
9 percent chance that they could reverse the
10 mifepristone if they decided to change their
11 minds?

12 **A. I think if the patient was told**
13 **there is a study which shows -- which demonstrates**
14 **a 68 percent chance of -- I will use the term**
15 **"reversing" mifepristone. I would say there's a**
16 **68 percent chance of continuing survival of your**
17 **baby. Then that's what I think they should be**
18 **told. They should be told exactly what the study**
19 **shows and what the source of information is.**

20 Q. Why wouldn't you use the term
21 "reversal"?

22 **A. Because I tend to say explicitly**
23 **what the study says. Okay? So if you give**
24 **progesterone, this is what happens. It's an issue**
25 **of not using jargon.**

1 **Is there anything wrong with the**
2 **term "reversal"? No. But I try as best as I**
3 **humanly can to avoid jargon.**

4 Q. And that's just to make sure that
5 people can understand what you're saying; is that
6 right?

7 A. **That is the best I can -- that is**
8 **my personality. As long as the patient**
9 **understands what reversal means, which means that**
10 **there is a chance that giving this medicine can**
11 **increase the chances that you're baby will**
12 **survive, as long as they understand that, you can**
13 **use any term you want.**

14 **The thing that I try to do is to**
15 **make sure that the patient understands.**

16 Q. So -- okay. Do you think it
17 would be appropriate to put billboards up around
18 Tennessee saying, If you take mifepristone, there
19 is a 68 percent chance that you can still have a
20 live birth or you can still have a baby? Would
21 that be appropriate?

22 A. **That's not a scientific question.**
23 **That's a policy question.**

24 Q. All right. Do you think it would
25 be appropriate?

1 **A. I'm not going to opine on a**
2 **policy question.**

3 Q. I'm asking you the question, and
4 I'm going to ask you to answer it. Do you think
5 it would be appropriate to put billboards up
6 around Tennessee saying, If you take mifepristone,
7 there's a 68 percent chance if you get the right
8 treatment that you can still have the baby?

9 **A. I'm not going to opine on a**
10 **policy question.**

11 MS. CLARKE: Mr. Rieger, can you
12 instruct the witness to answer the
13 question, please?

14 MR. RIEGER: Yes. Dr. Harrison,
15 I know that that falls outside of an
16 expert opinion; however, for the
17 purposes of this deposition, you will
18 need to answer those questions as best
19 you're able.

20 **A. Okay. Then I will say as long as**
21 **the source of the information, the source of the**
22 **number is clear, I think informing the public that**
23 **it is possible to increase the chances of survival**
24 **of a baby after mifepristone is administered, if**
25 **the progesterone is given within 72 hours, if all**

1 **the information is on that billboard, then I think**
2 **patients have a right to know that information.**
3 **In fact, I think everybody should know that**
4 **information.**

5 BY MS. CLARKE:

6 Q. And you don't think that knowing
7 that there's a two-thirds chance that you could
8 reverse it might encourage any people to take
9 mifepristone when they otherwise would not have?

10 A. I would hope that the informed
11 consent process that the abortionist goes through
12 before they give the woman Mifeprex would
13 ascertain accurately how certain she is about this
14 procedure.

15 Q. So knowing the variability in
16 real life of patients and doctors and what happens
17 in informed consent, do you think that there's any
18 chance that people who hear that mifepristone is
19 68 percent reversible would take mifepristone when
20 they otherwise would not have? Is there any
21 chance in real life that that might happen?

22 MR. RIEGER: I'll object to the
23 form of the question.

24 But please go ahead and answer.

25 A. **There are a lot of odd things**

1 that can happen. Is it possible in the whole
2 entire universe of the human race that someone
3 might say that to themselves? It is possible. Is
4 it likely? No.

5 BY MS. CLARKE:

6 Q. Is it accurate for any given
7 individual who takes mifepristone, that that
8 individual, as long as they get progesterone
9 treatment within 72 hours, has a 68 percent chance
10 of having a baby?

11 MR. RIEGER: Object to the form
12 of the question.

13 Go ahead and answer.

14 A. No. What is accurate is that
15 this study demonstrated a 62 percent increase --
16 no, not a 62 percent increase, a 68 percent
17 overall survival after administration of Mifeprex.
18 That's all gestational ages. It's an average
19 number.

20 So an individual person's chances
21 of being able to mitigate the effects of Mifeprex,
22 an individual's person's chances of her baby
23 surviving the Mifeprex poisoning is dependent upon
24 the gestational age of the baby; it's dependent on
25 factors we don't know; her individual metabolism.

1 But what we can say is just what
2 we can say overall at that point. It is one --
3 it's one of the only things that we can do to help
4 a woman save her baby if she has changed her mind
5 after ingesting the Mifeprex but before ingesting
6 the misoprostol.

7 BY MS. CLARKE:

8 Q. So is it accurate to say that for
9 any given patient, an individual who takes
10 mifepristone, that we know for sure that there is
11 a chance that if gets progesterone after she takes
12 mifepristone, that she might still have a baby?

13 A. I'm sorry. I'm not not answering
14 your question. I'm trying to figure out what the
15 question means. Could you try it one more time?

16 Q. So medication abortion reversal
17 is not a hundred percent effective; right?

18 A. Correct.

19 Q. Some people who take mifepristone
20 and then get the reversal treatment will still
21 terminate their pregnancies; right?

22 A. That's correct.

23 Q. So for any given person prior to
24 then taking the mifepristone, we can't say whether
25 reversal treatment will or will not work for them;

1 is that right?

2 **A. That is correct.**

3 Q. If patients are told that
4 medication abortion may be reversible -- well,
5 strike that.

6 Is surgical abortion reversible?

7 **A. No.**

8 Q. So is it possible that a patient
9 who is told that medication abortion may be
10 reversible but surgical abortion is not that they
11 will choose medication abortion so that they can
12 change their mind later? Do you think that might
13 happen?

14 MR. RIEGER: Object to the form
15 of the question.

16 Go ahead and answer.

17 **A. Again, in the whole universe of**
18 **the entire human race, is it possible that**
19 **somebody might think that? It is possible. Is it**
20 **likely? No.**

21 **If they fully intend to terminate**
22 **that pregnancy, then it would make sense, if they**
23 **had any question at all, that they would choose a**
24 **surgical abortion. If they fully intend to**
25 **terminate that pregnancy, only those woman who**

1 **fully intend to terminate the pregnancy should be**
2 **given the Mifeprex in the first place.**

3 **So it's a failure of informed**
4 **consent.**

5 BY MS. CLARKE:

6 Q. Okay. Sorry. Correct me if I'm
7 wrong. If a patient is told that medication
8 abortion is reversible but surgical abortion is
9 not, do you think any patients will choose
10 surgical abortion for that reason?

11 MR. RIEGER: Object to the form
12 of the question.

13 Please go ahead and answer it.

14 **A. Maybe.**

15 BY MS. CLARKE:

16 Q. Do you know if anyone provides
17 reversal treatments to patients who have taken
18 both mifepristone and misoprostol?

19 **A. I don't know.**

20 Q. Do you think that would be
21 effective?

22 **A. I don't know of any drug that**
23 **reverses misoprostol. So not that I know of.**

24 Q. So information about the
25 reversibility of a medication abortion, do you

1 think that information should be given to a
2 patient by a physician?

3 **A. I think ideally, the physician is**
4 **the one with the most training and the most**
5 **ability to answer a patient's questions. I**
6 **personally think that informed consent should be**
7 **done by the physicians themselves.**

8 **That's what I think, based on my**
9 **training as a physician.**

10 Q. Okay. Do you think that crisis
11 pregnancy centers should be required to tell
12 patients about the use of medication abortion as
13 an option?

14 **A. I'm sorry. Say that one more**
15 **time.**

16 Q. Do you think that crisis
17 pregnancy centers, which I think you called
18 pregnancy care centers, should be required to tell
19 patients that medication abortion is an option?

20 **A. An option for what?**

21 Q. For any patient who might ask
22 about it.

23 **A. I'm sorry. The purpose of a**
24 **crisis pregnancy center is not to refer patients**
25 **for abortion. So a crisis pregnancy center isn't**

1 **administering treatment. So no, I don't.**

2 Q. Do you think if someone walks
3 into a crisis pregnancy center pregnant and
4 they're like, I don't know what to do, and they
5 ask about what their abortion options are, do you
6 think that anyone should tell them that medication
7 abortion is an option?

8 **A. It would defy plausibility that a**
9 **woman in this day and age with the Internet would**
10 **not know that abortion is an option for her. That**
11 **would defy believability. No, I don't.**

12 Q. So she wouldn't need to learn
13 about it from the crisis pregnancy center; she
14 could just look it up on the internet?

15 **A. To know that she has an option**
16 **for abortion?**

17 Q. Correct.

18 **A. I have never met a woman yet in**
19 **my whole entire practice that didn't know that**
20 **abortion was an option.**

21 Q. Have you ever met anyone who
22 didn't know that medication abortion was an
23 option?

24 **A. Yes.**

25 Q. So if no one at the crisis

1 pregnancy center is telling this hypothetical
2 pregnant person that medication abortion is an
3 option, how would she know that?

4 **A. I'm sorry. I --**

5 MR. RIEGER: Object to the form
6 of the question.

7 You can answer.

8 **A. I misheard your question that I**
9 **said yes to.**

10 **When you said, Have you heard**
11 **about people who haven't heard about medication**
12 **abortion, what I heard was medication abortion**
13 **reversal.**

14 BY MS. CLARKE:

15 Q. Okay.

16 **A. So I've heard many patients who**
17 **did not know that the effects of Mifeprex could be**
18 **mitigated by progesterone.**

19 **Now, are there patients that**
20 **don't know that medication abortion is an option?**
21 **Maybe.**

22 Q. But you don't think that crisis
23 pregnancy centers should be legally required to
24 tell people who ask about their options that
25 medication abortion is an option?

1 **A. No.**

2 Q. Why not?

3 **A. Because that's not within the**
4 **purview of what a crisis pregnancy center does.**

5 Q. What do you mean by that?

6 **A. Crisis pregnancy centers are not**
7 **offering treatments to patients.**

8 Q. So what do they offer patients?

9 **A. It isn't an issue of informed**
10 **consent.**

11 Q. Okay. Well, leaving aside the
12 question of informed consent, what do crisis --

13 **A. Well, that is the question. I'm**
14 **sorry. I didn't mean to talk over you.**

15 Q. What is the purpose of a crisis
16 pregnancy center? What services do they offer
17 patients?

18 **A. They offer patients information,**
19 **and they offer patients diapers, and they offer**
20 **patients social work consults, and they do all**
21 **kinds of things. And it depends on the individual**
22 **crisis pregnancy center what options they offer**
23 **patients.**

24 Q. Okay. As a part of the
25 information that they offer patients, you don't

1 think that should be a legal requirement that they
2 tell a patient who asks about her options that
3 medication abortion is an option; right?

4 **A. No, I don't.**

5 Q. Why is that?

6 **A. Because they're not giving**
7 **informed consent.**

8 Q. Do you think that OB/GYNs should
9 be legally required to tell pregnant patients who
10 ask about their options that medication abortion
11 is an option?

12 **A. I'm sorry. I'm thinking about**
13 **your question.**

14 **So do I think that OB/GYNs should**
15 **be legally required to tell patients that**
16 **medication abortion is an option? Well, an option**
17 **for what?**

18 Q. An option for terminating their
19 pregnancies.

20 **A. If the patient wants to know how**
21 **pregnancies are terminated, then an OB/GYN will**
22 **tell them, This is how pregnancies are terminated.**

23 Q. So do you think that it would be
24 appropriate for the law to require OB/GYNs to tell
25 patients, pregnant patients, who ask about their

1 options about the existence of a medication
2 abortion?

3 **A. I think the people should decide**
4 **the laws in their state, and I think the state**
5 **determines the practice of medicine within the**
6 **boundaries of its boundaries.**

7 Q. Okay. But do you think that that
8 would be an appropriate law?

9 **A. That's a legal question, and**
10 **that's a question for the people of that state to**
11 **answer and for the state to decide.**

12 Q. So filed a complaint with HHS
13 against ACOG --

14 **A. Yes.**

15 Q. -- for saying that OB/GYNs are
16 ethically required to refer patients who ask to
17 abortion providers; right?

18 **A. I did.**

19 Q. Do you think it would be
20 appropriate for the law to require OB/GYNs to
21 refer patients who ask to an abortion provider?

22 **A. No.**

23 Q. Why is that?

24 **A. Because as a physician, when you**
25 **make a referral, you are legally liable for the**

1 actions of the person you refer to. If I refer to
2 a doctor who I know is prescribing heroin for his
3 patients, I have a legal liability for the life of
4 that patient. If she dies from a heroin overdose,
5 I stand legally liable for the person to whom I
6 referred.

7 And I do not think that -- let me
8 put it in a different way. Physicians who
9 practice according to the Hippocratic Oath do not
10 think that killing human beings is a viable
11 therapeutic option. To refer to an abortionist is
12 to refer to someone who is doing something that an
13 Hippocratic OB/GYN would not consider a viable
14 therapeutic option.

15 Q. So if an OB/GYN is unwilling to
16 refer a patient to an abortion provider, how would
17 a patient who wants an abortion go about finding
18 out where to go?

19 A. My goodness. There's the
20 internet.

21 MR. RIEGER: Object to the form
22 of the question.

23 Please answer.

24 BY MS. CLARKE:

25 Q. You said that you would refer a

1 person to APRN for a reversal treatment; right?

2 **A. No.**

3 Q. Would you?

4 **A. It depends on what that patient's**
5 **options were in what period of time.**

6 Q. Okay. So let's say a patient who
7 is at six weeks gestational age, took mifepristone
8 five hours ago, decides she's changed her mind.
9 Would you refer her to APRN for treatment?

10 **A. Oh, I'm sorry. Again, I misheard**
11 **your question.**

12 **What I heard was advanced**
13 **practice nurse. Okay? So would I refer a patient**
14 **to the abortion pill reversal network? Yes, I**
15 **would.**

16 Q. Do you know all of the doctors
17 who provide reversal as part of the abortion pill
18 reversal network?

19 **A. No.**

20 Q. So you don't know if any of those
21 doctors might practice unethically?

22 **A. I don't know. But if I were to**
23 **have a patient, I would know the doctors in my**
24 **area. So if a patient came to me and said, Where**
25 **can I get this, I would tell her the ethical**

1 doctors in my area who are also part of the
2 abortion pill reversal network.

3 If the patient were not in my
4 area, I trust the abortion pill reversal network
5 has done screening to screen for ethical
6 practitioners. So I do trust that the abortion
7 pill reversal network would send her to an ethical
8 physician.

9 In the same way that I trust the
10 Mayo Clinic -- if I had a patient that needed
11 specialty treatment for which Mayo Clinic was the
12 premier, will I know the exact doc who is taking
13 care of her at Mayo Clinic? No, I won't.

14 But I will know that Mayo Clinic
15 I can rely on and I can trust. And I have the
16 same trust of the abortion pill reversal network
17 as I would have of Mayo Clinic.

18 Q. Okay. Do you know who provides
19 abortion reversal as part of the abortion pill
20 reversal network in Tennessee?

21 A. No.

22 Q. Do you know any people who
23 provide abortion pill reversal in Tennessee?

24 A. Yes, I do.

25 Q. And who provides abortion

1 reversal -- abortion pill reversal in Tennessee,
2 that you know?

3 **A. We have a couple of AAPLOG**
4 **doctors who provide abortion pill reversal. I**
5 **have confidentiality agreements. AAPLOG does not**
6 **disclose the name of its membership to anybody,**
7 **and that is something that we have promised to our**
8 **membership.**

9 **I can't give you names of AAPLOG**
10 **members. You would have to -- I can't do it.**

11 Q. Understood. So if I were in
12 Tennessee, would there be any way for me to know
13 who the abortion pill reversal network would refer
14 -- if I were a doctor, would refer my patients to
15 if I sent my patients to that hotline? Is there
16 any way for me to know the universe of doctors
17 that might be connected to that patient through
18 the abortion pill reversal hotline?

19 MR. RIEGER: Object to the form
20 of the question.

21 Go ahead and answer, please.

22 **A. I don't know.**

23 BY MS. CLARKE:

24 Q. So I'm going to go back to your
25 declaration. It's, I think, the most recent thing

1 in the chat, if you don't have it open.

2 **A. I have it opened.**

3 Q. Could you go ahead and read to
4 yourself paragraph 10? It starts on page 4.

5 **A. Read it out loud or read it to
6 myself?**

7 Q. Read it to yourself. You can let
8 me know when you're done.

9 **A. Yes, I'm done.**

10 Q. Okay. So you write that, The
11 term "may" is particularly notable as it is a
12 measured term that calls to mind scientific
13 possibility rather than absolute scientific proof.

14 Did I read that correctly?

15 **A. That's correct.**

16 Q. So, generally speaking, is it
17 acceptable for a physician to tell their patients
18 that something may be possible absent absolute
19 scientific proof so long as there is scientific
20 possibility to support what they're saying?

21 **A. Yes.**

22 Q. So would it be appropriate for an
23 oncologist to tell a cancer patient that
24 hypnotherapy may cure their cancer?

25 MR. RIEGER: Object to the form

1 of the question.

2 Go ahead and answer.

3 **A. I'm not an oncologist.**

4 BY MS. CLARKE:

5 Q. Do you know whether it's
6 scientifically possible for hypnotherapy to cure
7 cancer?

8 **A. I don't think so, but I'm not an
9 oncologist. So I'm not going to comment on
10 oncology-related literature because I don't know
11 what the oncology literature shows.**

12 Q. Would there be -- could one
13 design an ethical study to determine whether
14 hypnotherapy is effective at curing aggressive
15 otherwise terminal cancers?

16 MR. RIEGER: Object to the form
17 of the question.

18 Please answer.

19 **A. If you could find a body of
20 patients who refuse any kind of treatment but they
21 would be willing to participate with hypnotherapy,
22 if they would be willing to participate in such a
23 trial, then that could be used as a comparative
24 group.**

25 BY MS. CLARKE:

1 Q. Okay. That makes sense. If
2 there were no such group of patients -- let's say
3 everybody who gets a particular form of cancer
4 goes for treatment -- would there be any ethical
5 way to perform a study to determine whether
6 hypnotherapy could cure the cancer instead?

7 MR. RIEGER: Object to the form.
8 You can answer.

9 **A. You can't perform a study without**
10 **the consent of the patient.**

11 BY MS. CLARKE:

12 Q. Okay. So in a scenario like that
13 where it's, let's say impossible to perform an
14 ethical study to determine whether or not
15 hypnotherapy can cure a certain cancer, would it
16 be ethical for an oncologist to say, You know, I
17 can't prove it's impossible, so it might be
18 possible; and, thereafter, tell his patients,
19 Hypnotherapy may cure your cancer?

20 MR. RIEGER: Object to the form
21 of the question.

22 You can answer.

23 **A. You have to have some basis for**
24 **saying it may be possible, yes.**

25 BY MS. CLARKE:

1 Q. So it's not enough to say it
2 hasn't been proven impossible; you have to have
3 some independent basis for belief that it's
4 possible?

5 A. Yes.

6 Q. Let's say that there were
7 hundreds of people in the United States who are
8 convinced that hypnotherapy had cured their
9 cancer. Would that be enough of a basis?

10 A. That's not a study.

11 MR. RIEGER: Object to the form.

12 THE WITNESS: I'm sorry.

13 Mr. Rieger, I didn't hear what you said.

14 MR. RIEGER: I'm sorry. I
15 objected to the form, and then I
16 instructed you to please answer.

17 A. That's not a study.

18 BY MS. CLARKE:

19 Q. So that wouldn't constitute
20 sufficient basis?

21 MR. RIEGER: Same objection.

22 Please answer.

23 A. Sufficient basis for what?

24 BY MS. CLARKE:

25 Q. For an oncologist to say, You

1 know, hypnotherapy has not been proven impossible
2 as a way to cure cancer. There's a handful of
3 people who are totally convinced it cured their
4 cancer. I'm going to tell all my patients
5 hypnotherapy may cure their cancer. Would that be
6 appropriate?

7 MR. RIEGER: Same objection.
8 You can answer.

9 **A. That's not a study.**

10 BY MS. CLARKE:

11 Q. So it wouldn't be appropriate?

12 **A. Physicians -- it is appropriate**
13 **for a physician to base their opinion on**
14 **physiological plausibility, the known actions of**
15 **drugs and interactions with the body, the known**
16 **ways that those drugs work. And that's what you**
17 **base your opinion on. You base your understanding**
18 **on how the human body works.**

19 **Physiology doesn't change.**
20 **Physiology is physiology. Our bodies work the**
21 **same way today as they did yesterday as they did**
22 **50 years ago. So physiology doesn't change.**

23 **So we study physiology as**
24 **physicians. We understand how drugs interact with**
25 **that physiology. Yes, new things are discovered,**

1 but we have a pretty good understanding,
2 especially nowadays, of even the cellular
3 molecular details of where drugs interact.

4 So as a physician, you base your
5 opinion and what you tell your patients on what's
6 known, and you are honest about what isn't known.
7 So that's what you're supposed to do as part of
8 the informed consent process.

9 Q. So, then, would it be
10 inappropriate for a physician to tell a patient
11 that something may be possible based exclusively
12 on a handful of anecdotes?

13 A. A handful of anecdotes about
14 what?

15 Q. About the proposed treatment
16 working.

17 MR. RIEGER: Object to the form
18 of the question.

19 Please answer.

20 A. I'm going to have to have more
21 information about what is actually being said
22 before answering whether or not it's appropriate
23 or inappropriate.

24 BY MS. CLARKE:

25 Q. Okay. So let's say an oncologist

1 reads on the internet a whole bunch of people who
2 say, I didn't do chemo, I didn't do radiation
3 therapy, I did hypnosis, it cured my cancer.
4 Would it be appropriate on that basis for that
5 oncologist to tell their patients hypnotherapy may
6 cure your cancer?

7 MR. RIEGER: Object to the form
8 of the question.

9 Please answer.

10 **A. That's not a study. So you would**
11 **hope that the oncologist would dig a little deeper**
12 **into that issue before they include it in informed**
13 **consent.**

14 BY MS. CLARKE:

15 Q. Are you aware that there are
16 studies showing that medical marijuana can
17 alleviate people's nausea?

18 **A. Yes.**

19 Q. Do you think it would be
20 appropriate to tell a pregnant patient that
21 smoking marijuana may alleviate her morning
22 sickness?

23 **A. No.**

24 MR. RIEGER: Object to the form
25 of the question.

1 Please answer.

2 BY MS. CLARKE:

3 Q. And why not?

4 A. Because -- let me qualify that a
5 little bit. Okay?

6 If she came to me and said, Hey,
7 Dr. Harrison, I heard that smoking marijuana,
8 smoking a joint, can alleviate my morning
9 sickness, I would say, Well, marijuana does
10 contain a powerful chemical that does act to
11 alleviate nausea. But these are the consequences
12 of doing it.

13 We have a growing body of
14 evidence that smoking a joint has effects on your
15 baby. It also has effects on your own nervous
16 system. And this is not something that I would
17 recommend.

18 Q. If a patient came to you and
19 didn't ask about marijuana but just said, I have
20 incredible morning sickness, nothing I've tried
21 works, I don't know what to do, would you tell her
22 that medical marijuana was a possible treatment
23 for her morning sickness?

24 MR. RIEGER: Object to the form
25 of the question.

1 Please answer.

2 **A. If I'm responsible for**
3 **prescribing for her, I would not prescribe medical**
4 **marijuana. If she wanted medical marijuana, she**
5 **would have to go to another doctor. I would not**
6 **prescribe it.**

7 BY MS. CLARKE:

8 Q. Would you tell her that it was an
9 option?

10 **A. No, because it does -- for the**
11 **reasons that I told you. It would actually --**
12 **there's a growing body of evidence that medical**
13 **marijuana produces harm to her baby and may even**
14 **harm herself long-term.**

15 Q. So why wouldn't you --

16 **A. I would give her another**
17 **anti-nausea.**

18 Q. So wouldn't you tell her, Medical
19 marijuana may alleviate your nausea, but it's
20 really, really bad for the baby; don't do it.
21 Wouldn't that be enough?

22 **A. Enough for me to tell a patient**
23 **about medical marijuana?**

24 Q. Correct.

25 **A. Maybe. It depends on the**

1 **patient.**

2 Q. So there's some patients you
3 wouldn't feel comfortable even saying that to; is
4 that right?

5 **A. That's correct.**

6 Q. Is that because for some
7 patients, you would be worried that their primary
8 thought is about curing their morning sickness,
9 and they would ignore the warnings about their
10 pregnancy?

11 **A. We're getting pretty deep into
12 the hypothetical here.**

13 Q. Is that why?

14 **A. What is that?**

15 MR. RIEGER: I'll object to that.
16 Please answer.

17 **A. So I think I already told you I
18 think that the risks to the patient and to her
19 unborn child, preborn child, are greater than the
20 benefits that will come to her from medical
21 marijuana. So that's the physician judgment.**

22 **If she asks me, I would answer
23 her completely. But I would not ordinarily
24 suggest such a course to a patient.**

25 BY MS. CLARKE:

1 Q. And you wouldn't suggest it to
2 her and then let her figure out the risks and
3 benefits for herself?

4 **A. I'm sorry. Say again.**

5 Q. You wouldn't tell her it has
6 these benefits, it has these risks, and then let
7 her weigh it for herself?

8 MR. RIEGER: Object to the form.
9 You can answer.

10 **A. I might. It depends a little bit**
11 **on the patient.**

12 BY MS. CLARKE:

13 Q. There's some patients for whom
14 you would not, though; right?

15 **A. There are.**

16 MR. RIEGER: Same objection.

17 BY MS. CLARKE:

18 Q. Why is that?

19 MR. RIEGER: Same objection.

20 Christine, for all, if we can
21 take a small side bar.

22 Given that we're not -- given
23 that we're asking her to opine as to
24 hypotheticals involving the nature of
25 informed consent and so forth and so on,

1 and to avoid making this more difficult
2 than it has to be with us talking over
3 each other, would you be willing to
4 agree that I've got a continuing
5 objection to any hypotheticals down
6 these lines since at this point, as
7 Dr. Harrison has testified, her
8 expertise lies in progesterone receptors
9 and Mifeprex and the like.

10 MS. CLARKE: So is the State not
11 intending to submit her as an expert on
12 informed consent?

13 Alex, did you freeze?

14 MR. RIEGER: I think I did for a
15 second. I'm sorry. Could you repeat
16 your question?

17 MS. CLARKE: Is the State not
18 intending to submit Dr. Harrison as an
19 expert in informed consent?

20 MR. RIEGER: At this time, I can
21 tell you we're not sure what we're going
22 to try to admit her as in terms of the
23 full scope of the hearing. I'm just
24 trying to find a way to where I don't
25 have to interject on every single one of

1 these questions due to the hypothetical
2 in case she is not subsequently admitted
3 as an expert witness in this context.
4 She can only opine as to what she is
5 qualified as an expert as.

6 I prefer not to interrupt your
7 flow on the questioning. So my thought
8 is, if we can just for any of these
9 very, very deep hypotheticals, if we
10 could just agree that there's a
11 continuing objection as to form, she'll
12 be instructed to answer at the
13 conclusion of every objection that would
14 have been -- that would have been made.

15 And then we can determine if it
16 comes up, since this isn't a depo in
17 lieu of testimony, we can address that
18 as it comes up later if we need to get
19 into each individual objection or
20 whether or not that becomes important.

21 MS. CLARKE: So that objection
22 would be to questions about informed
23 consent if the State chooses not to
24 submit her as an expert on informed
25 consent? Is that the objection?

1 MR. RIEGER: That's correct,
2 unless the question about informed
3 consent has to do with her practice and
4 not a hypothetical situation.

5 So if the situation is entirely
6 hypothetically and outside of her
7 practice area in the, you know, ten
8 years in which she was practicing
9 medicine, clinical medicine, for
10 treating patients, then, at that point,
11 that question would be fair game even if
12 we weren't going to use her as an expert
13 witness on informed consent.

14 But the other hypotheticals
15 outside of her practice area would not
16 be unless we were going to use her as an
17 expert on informed consent.

18 MS. CLARKE: And her practice
19 area would be obstetrics and gynecology?

20 MR. RIEGER: Dr. Harrison, is
21 that a fair -- is obstetrics and
22 gynecology a fair descriptor of your
23 years of practice in the clinical
24 setting?

25 THE WITNESS: Yes.

1 MS. CLARKE: Okay. We can move
2 on from the medical marijuana, I think,
3 if we're done.

4 MR. RIEGER: We're done.

5 MS. CLARKE: Okay.

6 MR. RIEGER: Sorry to interrupt.

7 MS. CLARKE: That's okay.

8 BY MS. CLARKE:

9 Q. Do you think it would be
10 appropriate for an OB/GYN to tell a patient with
11 an ectopic pregnancy that it may be possible to
12 reimplant her pregnancy in the uterus?

13 A. No.

14 Q. Why not?

15 A. **Because at this point in time,**
16 **the technology has not been developed to**
17 **accomplish those reimplantations.**

18 Q. Are you aware that there's a
19 handful of doctors over the years who have claimed
20 to have successfully reimplanted an ectopic
21 pregnancy in the uterus?

22 A. Yes.

23 Q. But you don't think that's
24 sufficient to indicate that it's possible to do
25 so, with our current technology?

1 **A. I do not think that is sufficient**
2 **to indicate that it is possible to do so with our**
3 **current technology.**

4 Q. So even though it's theoretically
5 possible, you don't think it would be appropriate
6 to tell a patient with an ectopic pregnancy that
7 it may be possible to reimplant it, but I don't
8 know how to do it?

9 **A. Correct.**

10 Q. I'm going to read you a quote,
11 and let me know if you agree with it.

12 ACOG would support an ectopic
13 transfer procedure if it were scientifically
14 validated through the usual channels of animal
15 studies to prove safety and efficacy and then
16 human trials to prove safety and efficacy. If
17 such a procedure followed that protocol and if
18 such a procedure were then validated to be safe
19 and effective in a human being, AAPLOG would
20 support that.

21 Do you agree with that statement?

22 **A. Yes.**

23 Q. Are you aware of whether there
24 has been any research conducted on animal studies
25 to determine whether it's possible to reimplant an

1 ectopic pregnancy in the uterus?

2 **A. There is ongoing research.**

3 Q. But one can't conclude from that
4 research that's happened so far that it's actually
5 possible to do this with humans; is that right?

6 **A. Correct.**

7 Q. Okay. So we'll leave the
8 hypotheticals and go back to medication abortion
9 reversal.

10 We talked about the efficacy of
11 mifepristone alone to terminate a pregnancy in the
12 first 11 weeks of pregnancy. Does the effect of
13 mifepristone in terminating an early pregnancy
14 depend on the dose of mifepristone given?

15 **A. Yes.**

16 Q. So would a thousand milligrams of
17 mifepristone be more likely to terminate an early
18 pregnancy than 200 milligrams of mifepristone?

19 **A. I'm trying to think if I've ever
20 seen a study using a thousand milligrams.
21 Certainly, 600 milligrams is more effective than
22 200 milligrams.**

23 Q. Do you know what the efficacy is
24 of 600 milligrams of mifepristone to terminate a
25 pregnancy at nine weeks?

1 **A. I would have to pull -- there's a**
2 **number of different studies looking at**
3 **mifepristone, 600 milligrams. I would have to**
4 **pull them and then pull their average to give you**
5 **a number. I can't do that without pulling the**
6 **studies.**

7 Q. So in your declaration, you
8 referenced Dr. Delgado's historical control number
9 of 25 percent for continued pregnancy after
10 mifepristone?

11 **A. Correct.**

12 Q. Did you read the article that you
13 cited to come to that number? Did you read the
14 underlying study?

15 **A. Yes.**

16 Q. Do you know if any of those
17 studies concerned 200 milligrams of mifepristone?

18 **A. I would have to look back at the**
19 **study. It's the Davenport study. I believe she**
20 **did have a couple that had 200 -- I would have to**
21 **look at the study.**

22 Q. If one is trying to determine how
23 effective abortion reversal is, medication
24 abortion reversal, would it make sense to compare
25 the rate of continuing pregnancy after

1 progesterone with the rate of continuing pregnancy
2 before 600 milligrams of mifepristone, given that
3 today a medication abortion consists of only 200
4 milligrams of mifepristone?

5 **A. Ask that question again.**

6 Q. Sure.

7 **A. That was complicated.**

8 Q. So medication abortion used to
9 involve 600 milligrams of mifepristone; right?

10 **A. Yes.**

11 Q. It now involves 200 milligrams of
12 mifepristone; right?

13 **A. Yes.**

14 Q. So if we're trying to compare the
15 rate of continuing pregnancy after mifepristone
16 alone versus mifepristone plus progesterone, would
17 it make sense to use studies that concern only 600
18 milligrams of mifepristone if that's not part of
19 the current regimen?

20 **A. They could give you a rough idea
21 of what mifepristone survival might be. The
22 studies with the 600 milligrams can give you a
23 rough idea. It will tell you whether it's a 90
24 percent of survival or a 10 percent survival.**

25 **It won't refine it -- it won't**

1 **refine it perfectly.**

2 Q. So if the studies on 600
3 milligrams of mifepristone showed a 25 percent
4 survival rate, let's just say, would one expect
5 that 200 milligrams of mifepristone would have a
6 higher survival rate?

7 **A. It's possible.**

8 Q. You just said that mifepristone
9 -- that 600 milligrams of mifepristone is more
10 effective at terminating a pregnancy than 200
11 milligrams; right?

12 **A. Yes. You have to understand --**
13 **what do you mean by terminating a pregnancy?**

14 **The efficacy -- the end point of**
15 **those studies in 200 and 600 milligrams, the**
16 **efficacy end point was complete evacuation of the**
17 **contents of the uterus without need for surgical**
18 **abortion.**

19 **It has -- there's very little**
20 **written on embryo survival, that is, documenting**
21 **whether or not an embryo had a heartbeat after the**
22 **administration of 200 or 600. There are very few**
23 **studies.**

24 Q. So is it fair to say that we
25 really have no idea what the survival rate is of

1 an embryo after 200 milligrams of mifepristone?

2 **A. No. It's not fair to say that**
3 **because the survival rate is going to be a subset.**
4 **It's going to be less than the amount of women who**
5 **need additional treatment after mifepristone.**

6 **So I'm just going to make up**
7 **numbers here. Okay? I'm not making them up for a**
8 **percent. Okay? So if you want a percent, I've**
9 **got to pull the papers.**

10 **Q. I know.**

11 **A. But if you have a hundred women**
12 **and it says that the efficacy of complete abortion**
13 **is 75 percent, that means 25 percent of those**
14 **women had something left and had to have something**
15 **else done at that point.**

16 **Now, within that 25 who had to**
17 **have something else done, a subset of those will**
18 **have a live pregnancy. That will be a small**
19 **subset. The vast majority will have tissue left**
20 **inside.**

21 **Q. So would we expect more people to**
22 **have a continuing pregnancy after 200 milligrams**
23 **of mifepristone than after 600 milligrams of**
24 **mifepristone administered in early pregnancy?**

25 **A. Well, depending on just**

1 **gestational age specific, yes, you would expect**
2 **that.**

3 MS. CLARKE: Okay. I just drank
4 an entire mug of coffee. Can we take a
5 five-minute break? I'm sorry. I know
6 we just took a break.

7 VIDEOGRAPHER: Off the record at
8 12:58.

9 (A break was taken.)

10 VIDEOGRAPHER: Stand by. We are
11 back on the record at 1:05.

12 BY MS. CLARKE:

13 Q. So, Dr. Harrison, would it be
14 accurate to say that mifepristone is a competitive
15 receptor antagonist for progesterone receptors?

16 A. Yes.

17 Q. Do you know of any other
18 competitive receptor antagonists for any other
19 receptors?

20 A. Well, I'm sure I could come up
21 with a list. There's a lot of them. But off the
22 top of my head, I don't have a list prepared.

23 Q. I think in your declaration, you
24 referred mifepristone acting in the same -- you
25 referred to reversal acting in the same manner as

1 an anecdote to a toxicant, i.e., a poison. Does
2 that sound familiar?

3 **A. That's correct.**

4 **Q. Do you know of any anecdotes to**
5 **poisons where the poison is a competitive receptor**
6 **antagonist?**

7 **A. Well, if you look at binding, for**
8 **example, with carbon monoxide, so carbon monoxide**
9 **binds to hemoglobin. And it binds tightly to**
10 **hemoglobin. It actually binds tighter than**
11 **oxygen.**

12 **But if you give -- the treatment**
13 **for carbon monoxide poisoning is to give the**
14 **person a lot of oxygen. That kicks the carbon**
15 **monoxide off of the hemoglobin where it's bound,**
16 **and that's how you reverse carbon monoxide**
17 **poisoning.**

18 **The example I gave in here of**
19 **methotrexate -- so methotrexate, it intercalates**
20 **into the DNA. It goes into the DNA where folate**
21 **goes in, and it interferes with DNA synthesis.**

22 **So if you give folate, you can**
23 **cause the methotrexate to be competitive -- to be**
24 **out-competed by folate. So you restore the DNA**
25 **synthesis.**

1 Q. I think your example of the
2 folate, if I don't pronounce this
3 wrong, leucovorin --

4 **A. Leucovorin.**

5 Q. Leucovorin. Okay. Methotrexate
6 is commonly used to treat ectopic pregnancies;
7 right?

8 **A. Yes.**

9 Q. Is methotrexate and leucovorin
10 together commonly used to treat ectopic
11 pregnancies?

12 **A. No.**

13 Q. Do you know if it's ever used,
14 both of those together, to treat an ectopic
15 pregnancy?

16 **A. It depends on whether the person
17 gets toxic from the treatment of the methotrexate.
18 So if the person gets toxic from the treatment of
19 an ectopic pregnancy, then you would use
20 leucovorin.**

21 Q. Would administering leucovorin
22 prevent the methotrexate from terminating the
23 ectopic pregnancy?

24 **A. Theoretically, I don't think
25 that's ever been looked at. Why would you look at**

1 **that? That doesn't make any sense.**

2 Q. So you're aware that some cancer
3 patients receive methotrexate; right? I think
4 that was your example.

5 **A. Yes.**

6 Q. If a patient receives
7 methotrexate and leucovorin, do you know whether
8 their pregnancy would be terminated by
9 methotrexate?

10 **A. I don't know. I mean, probably.**
11 **It depends on the gestational age of the**
12 **pregnancy. It depends on how much methotrexate**
13 **they've been given.**

14 **Most likely, if you're talking an**
15 **early pregnancy, then most likely it would be**
16 **effective; but it's not as effective as Mifeprex**
17 **is -- mifepristone is.**

18 **So there have been studies**
19 **looking at the efficacy of methotrexate alone, and**
20 **I think it gets into the like 60ish percent**
21 **efficacy in terminating an early pregnancy.**

22 **But that's the reason**
23 **methotrexate wasn't used, plus it has some**
24 **toxicities.**

25 Q. Okay. But so if a cancer patient

1 needed to receive methotrexate and she were
2 pregnant and we gave her leucovorin, also, would
3 that prevent the methotrexate from terminating her
4 pregnancy if it was early?

5 **A. I don't think that study has ever**
6 **been done, because there would be no reason to do**
7 **it. If you give leucovorin simultaneous with the**
8 **methotrexate, then you prevent the methotrexate**
9 **from acting at the level the cancer is. So why**
10 **would you do such a study?**

11 **Q.** Okay. So if a cancer patient
12 received methotrexate for her cancer and she were
13 pregnant in the early pregnancy and then you gave
14 her leucovorin afterwards, would that reverse the
15 effects of the methotrexate?

16 **A. I don't know. Would it reverse**
17 **the effects of the methotrexate in regard to the**
18 **pregnancy or in regard to the cancer? Because it**
19 **depends on the timing.**

20 **So methotrexate is not like**
21 **something that goes in and instantly kills the**
22 **cancer cells. The way methotrexate works is that**
23 **it prevents DNA synthesis in rapidly dividing**
24 **cells.**

25 **So cancer cells are rapidly**

1 dividing cells. Baby cells are rapidly dividing
2 cells. They both are rapidly dividing cells. So
3 the way methotrexate works is it prevents DNA
4 synthesis.

5 So the time it takes -- that's
6 why you don't give them simultaneously, because it
7 takes some time for a DNA synthesis to be
8 inhibited. And you want to treat the cancer, so
9 you treat the rapidly dividing cells and you don't
10 give them any oxygen.

11 The reason you give leucovorin is
12 that normal cells of the body aren't as rapidly
13 dividing. So because they're not as rapidly
14 dividing, they're not as affected by methotrexate.

15 But some areas of the body do
16 have rapidly dividing cells, like your mouth and
17 your gut. So giving methotrexate causes rapidly
18 dividing cells in your mouth and your gut, and you
19 get sores from it, or you can get sores from it.
20 Not everybody gets sores, but you can. You can
21 lose your hair.

22 So, again, a lot of this depends
23 on timing. But as far as if a pregnant woman
24 received methotrexate to treat her cancer, you
25 would not give her leucovorin, because then you

1 **would prevent the methotrexate from treating the**
2 **cancer.**

3 **Does that make sense?**

4 Q. Okay. It does.

5 Do you know if you gave her
6 leucovorin anyway, do you know if that would save
7 her pregnancy if you did it within 72 hours of her
8 taking the methotrexate?

9 **A. I don't think that's ever been**
10 **looked at.**

11 Q. Would you expect that to work,
12 based on your experience and expertise?

13 **A. I don't know. I don't know.**
14 **It's never been looked at.**

15 Q. Okay. Do you know whether the
16 abortion pill reversal network provides reversal
17 treatments for methotrexate?

18 **A. I don't know.**

19 Q. Okay. So I think you testified
20 before -- strike that.

21 So mifepristone binds to
22 progesterone receptors, and in that way prevents
23 the body from absorbing progesterone; is that
24 accurate?

25 **A. No. The progesterone receptor is**

1 around the nucleus. When something binds to that
2 progesterone receptor -- well, when the
3 progesterone binds to the progesterone receptor,
4 it tells the DNA what DNA to transcribe.

5 So the DNA that's transcribed
6 determines how the cell functions. So when
7 progesterone binds to a progesterone receptor, it
8 changes cells that weren't doing something into
9 cells that do something else.

10 So, for example, in the
11 endometrium, in the lining of the uterus, the
12 cells that were not receptive when progesterone
13 binds become receptive.

14 The reason I'm not being more
15 specific is that there's like probably over 500
16 different ways in which progesterone changes the
17 lining of the uterus to affect the receptivity or
18 not receptivity to implant a patient.

19 So -- but the way in which it
20 happens is that the progesterone tells these
21 individual cells, make this protein or don't make
22 that protein. It's in what DNA is transcribed.

23 So when something comes in and
24 blocks progesterone from telling those cells, then
25 it prevents those cells from doing their

1 progesterone thing. Okay? It prevents the cells
2 in doing what they would have done in the presence
3 of progesterone.

4 In the case of Mifeprex, the way
5 Mifeprex works to cause the death of the embryo,
6 the fetus, is that Mifeprex binds to the mother's
7 endometrial decidua, so to the mother's decidual
8 cells, and causes those decidual cells to shrink,
9 to atrophy.

10 But that isn't instant. That's
11 not like within an hour. That's within days. So
12 the shrinkage -- how much Mifeprex causes
13 shrinkage depends on where the woman is in her
14 pregnancy.

15 That's probably more information
16 than you wanted.

17 Q. So that process is called
18 decidual necrosis; is that right?

19 A. That's correct, yes.

20 Q. And can progesterone reverse
21 decidual necrosis if it's already begun?

22 A. Well, if progesterone is given
23 within 72 hours, there's some evidence that it can
24 prevent further decidual necrosis.

25 Q. And so if there's not too much

1 that's happened already, then the trophoblast
2 remains attached to the endometrium; is that
3 right? I'm not a doctor.

4 **A. Yeah. That's a general view.**

5 Q. Is it accurate that mifepristone
6 also causes softening and dilatation of the
7 cervix?

8 **A. Yes.**

9 Q. Can progesterone reverse that if
10 given within 72 hours?

11 **A. I don't know.**

12 Q. Is it accurate that mifepristone
13 also leads to myometrial contractions?

14 **A. Not without prostaglandin**
15 **mediation. So mifepristone in and of itself would**
16 **have to have either endogenous prostaglandin --**
17 **prostaglandin is made by the woman's body herself**
18 **or by being given prostaglandins.**

19 **So Mifeprex alone is a poor agent**
20 **to cause sufficient contractions to expel the**
21 **fetus, which is why misoprostol is given as a**
22 **second drug.**

23 Q. If contractions -- well, what are
24 myometrial contractions?

25 **A. Okay. The myometrium is the**

1 muscle wall of the uterus. "Myo" is muscle, and
2 "metrium" is uterus. So it's the muscle wall of
3 the uterus.

4 Myometrial contractions is just
5 the uterus contracting.

6 Q. So enough contractions will expel
7 the contents of the uterus; is that right?

8 A. Depending on how firmly adherent
9 the trophoblast is to the decidua.

10 Q. Is it accurate to say that
11 mifepristone increases myometrial sensitivity to
12 prostaglandins --

13 A. Yes.

14 Q. What does that mean?

15 A. I should have let you finish.
16 I'm so sorry. Will you finish that question
17 before I say yes to it?

18 Q. Okay. So is it accurate to say
19 that mifepristone increases myometrial sensitivity
20 to prostaglandins?

21 A. Yes.

22 Q. And that means -- what does that
23 mean?

24 A. That means that for some reason,
25 blocking the progesterone receptors causes the

1 uterus to be more sensitive than it would
2 otherwise be to prostaglandins.

3 So the reverse of that,
4 progesterone has been used throughout pregnancy in
5 women who have miscarried to decrease the
6 sensitivity of the uterus to other things that
7 would cause the uterus to contract.

8 Q. And those things like
9 prostaglandins; is that right?

10 A. Like prostaglandins are released
11 when you have infection, when you have tissue
12 damage. So prostaglandins are released in a lot
13 of different physiological states.

14 Q. Is it accurate to say that
15 mifepristone increases the disinhibition of
16 prostaglandin synthesis by the myometrium?

17 A. Can you state that question one
18 more time? Because there's a lot of negatives in
19 there.

20 Q. I know. Tell me about it.
21 Forget it.

22 You're just saying that
23 mifepristone leads to disinhibition of
24 prostaglandin synthesis by the myometrium.

25 A. Well, the inhibition is

1 **prostaglandin synthesis is progesterone mediated.**

2 **So yes.**

3 **Mifepristone, by blocking**
4 **progesterone, would function to decrease**
5 **inhibition. That's a lot of negatives in there.**

6 Q. Okay. So, again, I'm not a
7 doctor. But does that mean that by blocking
8 progesterone, mifepristone might cause the body to
9 synthesize more endogenous prostaglandin?

10 **A. Yes, it might.**

11 Q. And misoprostol is a
12 prostaglandin; right?

13 **A. Yes.**

14 Q. So prostaglandins, whether
15 endogenous or exogenous, cause, among other
16 things, uterine contractions; is that right?

17 **A. Yes. Yes.**

18 Q. So if mifepristone caused the
19 body to produce more prostaglandin, would
20 progesterone prevent that prostaglandin from
21 having its effect of causing contractions?

22 **A. It depends. And it depends on**
23 **how much prostaglandin is there and when the**
24 **progesterone is administered.**

25 **Again, the inhibition of the**

1 **sensitivity of the myometrium to prostaglandins is**
2 **progesterone remediated. In other words, if you**
3 **have a lot of progesterone, the uterus is not**
4 **going to be as sensitive to prostaglandin action.**

5 Q. Okay. So regardless sort of of
6 how much prostaglandins there are, if there's a
7 ton of progesterone in there, the prostaglandin is
8 not going to have as much effect?

9 A. **Not as much. I'm not saying it**
10 **won't have any effect, but it won't have as much.**
11 **The uterus won't be as sensitive to the actions of**
12 **the prostaglandin.**

13 Q. Okay. That makes sense.

14 So you have read the 2018 Delgado
15 paper on abortion pill reversal; right?

16 A. **Yes.**

17 Q. And is it your opinion that that
18 study supports the efficacy of progesterone
19 treatments to reverse mifepristone if given within
20 72 hours?

21 A. **It supports it, yes.**

22 Q. Okay. So I know we've talked
23 around this a little bit. But how do we know that
24 the live birth that happened with the patients in
25 the Delgado study wouldn't have happened anyway

1 without progesterone treatment?

2 A. So let me unpack that a little
3 bit.

4 So what you would have a very
5 rough idea about is the live embryos that follow
6 after the administration of mifepristone alone.
7 We have a little bit of information, and that was
8 published in the Davenport study.

9 She ends up saying I think
10 somewhere -- again, I would have to see the study.
11 But my recall is somewhere in the 8 to 23 percent
12 range for survival at various different doses of
13 Mifeprex alone.

14 So to be -- to take the highest
15 number, the Delgado authors said, Okay, well, if
16 the range that she got in those studies was 8 to
17 23 percent, we'll take a comparator of 25 percent,
18 which is higher than their highest study. So
19 we'll compare that number with the number of women
20 who -- I believe their end point was 20 weeks --
21 the number of women who receive APR who end up
22 with a live fetus at 20 weeks.

23 So that's what they compared to.
24 So it was a 25 percent comparison to 68 with the
25 best protocol, 40 something, 43 with all protocols

1 **combined.**

2 Q. So if we're looking at the 68
3 percent, what's the sort of -- what's the
4 numerator and denominator that gets us to 68
5 percent? We're dividing what by what?

6 **A. We're dividing the number of --**
7 **can you give me the study? If you could pull up**
8 **that study, then I can look at their materials and**
9 **then we can be specific as to the numbers they**
10 **used to get the 68 percent.**

11 Q. Okay. Before we get to the
12 study, just for the sake of time, do you know
13 whether that study, in coming to the 68 percent or
14 any efficacy number, did they count patients whose
15 pregnancies had already been terminated by
16 mifepristone before they got to the reversal
17 provider?

18 **A. No.**

19 Q. So the numerator wouldn't include
20 the people whose pregnancies were terminated by
21 mifepristone alone within the time frame before
22 they sought treatment?

23 **A. It would be ridiculous to do so,**
24 **because the issue is -- the scientific question is**
25 **if you have a baby who is still alive -- so that's**

1 the premise. The premise is you start with a baby
2 who is still alive within 72 hours of taking the
3 Mifeprex.

4 So if that's your starting point,
5 then if we intervene with progesterone, how many
6 of those babies will continue to be alive to the
7 end point of 20 weeks?

8 So it would be completely invalid
9 to include dead babies in that study. It doesn't
10 make any sense, because your starting point for
11 the study -- the inclusion criteria is babies who
12 are alive at that point.

13 You would never give progesterone
14 to somebody who had a dead baby or who had simply
15 retained products. It doesn't make any sense.

16 Q. So are you aware of whether there
17 are any studies about the rate of continuing
18 pregnancy after injection of mifepristone where
19 those pregnancies have survived the first 48 hours
20 of mifepristone, let's say?

21 A. The only study I know of was the
22 study by Creinin, who attempted to prove that
23 abortion pill reversal didn't work. My
24 understanding is that his inclusion criteria for
25 that study was -- he only included in that study

1 babies who were alive at, you know, when they --
2 it was within 72 hours.

3 Q. Okay. I'm trying to process all
4 of the science. Okay.

5 Do you know whether a significant
6 percentage of people who take mifepristone have
7 their pregnancies terminated within 48 hours
8 without taking misoprostol?

9 A. My understanding from earlier
10 studies and from the original FDA approval -- this
11 is, again, a recall. So in order to give you an
12 exact number, I would have to go back and look at
13 the exact studies.

14 But my recall is it's somewhere
15 like 4 to 5 percent are terminated within -- are
16 completely terminated within 72 hours. But I
17 think actually the end point was more like 48
18 hours, because they were looking at how many would
19 terminate prior to misoprostol administration at
20 48 hours.

21 And I think it's only like --
22 it's somewhere between like 3 and 5 percent.

23 Q. Okay.

24 A. That's my recall. Again, if you
25 need an exact number, I've got to go back and look

1 **at the exact studies. So I can't keep those**
2 **numbers in my head.**

3 Q. I understand that you're not an
4 encyclopedia.

5 Do you know whether there are
6 studies that determine the percentage of people
7 whose pregnancies continue 72 hours after
8 injection of 200 milligrams of mifepristone alone,
9 leaving aside the Creinin study?

10 A. Well, I think that was what the
11 Delgado paper was about, trying to determine that.
12 So she had a number of papers that had different
13 end points of when they actually saw the patient
14 back. So I don't think any of them saw the
15 patient back in 72 hours. I think the interval
16 was more like a week.

17 That's my recall, again, without
18 looking at the actual paper. My recall is that
19 most of the studies she reviewed saw the patient
20 back a week or two weeks.

21 Q. So -- okay. In your declaration,
22 you state that Dr. Delgado and his fellow authors
23 analyzed the interval of time between mifepristone
24 injection and progesterone administration and
25 found that success rates were the same as long as

1 the progesterone was given within 72 hours of the
2 use of mifepristone.

3 Is that right? Does that sound
4 right?

5 **A. That's my understanding.**

6 Q. So would that mean that it
7 doesn't matter when the progesterone is given as
8 long as it's within 72 hours of the mifepristone?

9 **A. Well, actually, physiology --**
10 **understanding the mechanism of how mifepristone**
11 **works and how progesterone works to counteract it,**
12 **common sense would tell you the sooner, the**
13 **better.**

14 **The longer the time the**
15 **mifepristone binds the progesterone receptor, the**
16 **less progesterone-dependent transcription you**
17 **have, the more damage.**

18 **So as far as gross numbers,**
19 **coming up with a gross number, you know, they**
20 **lumped it all together. But as far as if you**
21 **really wanted to scientifically define this, you**
22 **would have to look at studies broken down by the**
23 **hour, but there are so many factors involved.**

24 **So, anyway, it does make sense**
25 **that the sooner, the better.**

1 Q. So when you say that they sort of
2 lumped everything together, is it accurate to say
3 that they analyzed the interval of time between
4 the mifepristone injection and the progesterone
5 administration?

6 **A. Yes.**

7 Q. So if they analyzed the interval
8 of time between mifepristone injection and
9 progesterone administration and found no
10 difference in the success rate, wouldn't that
11 indicate that it doesn't actually matter when the
12 progesterone is given as long as it's within 72
13 hours?

14 **A. Well, if you're going to say it
15 doesn't matter, then you need a study broken out
16 by one hour, two hours, three hours, four hours,
17 five hours. You need to actually determine what's
18 the curve for a large number of patients.**

19 So when I say they lumped it --
20 they lumped it by their categories, okay, 24, 48,
21 72, whatever. They lumped it by categories, but
22 they didn't break it down to say, Well, there's
23 actually a better survival rate at six hours than
24 there is at ten hours. They didn't -- it wasn't
25 that -- they weren't able to discern to that

1 level.

2 So physiologically speaking,
3 knowing how progesterone works and knowing how
4 Mifeprex works, it would make the most sense the
5 sooner, the better. Because you want to minimize
6 the damage from blocking progesterone receptors
7 that Mifeprex has caused.

8 And Mifeprex's damage is time
9 dependent, because it affects DNA transcription
10 which takes time. So the longer the progesterone
11 receptor is blocked, the more ultimate damage
12 there is. So you minimize that.

13 Q. Would it be accurate to say that
14 the Delgado study has shown that there's no
15 difference between administering progesterone 24
16 hours versus 72 hours after ingestion of
17 mifepristone?

18 A. Within the limits of his study.

19 Q. What are the limits of his study?

20 A. You can't -- well, the number of
21 patients. And he didn't stratify per hour. So
22 within the limits of his study, he didn't show a
23 difference between those groups, those groupings
24 that he chose. Okay?

25 But that doesn't mean there

1 **exists no difference. It just means his**
2 **studies didn't demonstrate a difference.**

3 Q. Okay. I think I understand.

4 So in looking at sort of how
5 likely it is that someone who is taking
6 mifepristone will be able to have a live birth
7 after progesterone is administered within 72 hours
8 and figuring out that number, if we divided the
9 number of patients in Dr. Delgado's study by the
10 total number of patients whose pregnancies had
11 already been terminated by mifepristone, we would
12 get a lower number than 68 percent or 48 percent;
13 right?

14 **A. What question would you be**
15 **answering with that math? How would that -- what**
16 **question would that math answer?**

17 Q. So if the question was, in
18 advance of taking mifepristone, how likely in a
19 group of a thousand women would it be, after they
20 took mifepristone, for them to successfully get
21 progesterone treatment and then have a live birth?

22 If that were the question you
23 were asking, would you want to divide the number
24 of live births after progesterone by the total
25 number of people who took mifepristone?

1 A. No, because you wouldn't
2 administer mifepristone to anyone who didn't have
3 a living fetus.

4 So the issue isn't administering
5 mifepristone to all abortion patients. The issue
6 is administering mifepristone to those women who
7 have taken it, whose babies are still alive, and
8 they regret it; and they want to do something,
9 anything, to help increase the chances that their
10 baby will survive.

11 So that's -- the question is,
12 what can we do to increase the chances that those
13 women who have a live baby still and they regret
14 it and they want to do what they can, what can we
15 do to increase the chances that that baby will
16 survive?

17 That's the question we're trying
18 to answer.

19 Q. What if I were trying to answer a
20 different question and the question were not what
21 percentage of people who appear for treatment at a
22 reversal provider and still have a live baby can
23 go on to have a live birth after progesterone
24 treatment.

25 If instead the question were, If

1 a thousand women took mifepristone and then all of
2 them got progesterone treatment thereafter, what
3 percentage of them would have a live birth? If
4 that were the question I was trying to figure out,
5 what would my -- how would I figure that out?

6 A. Okay. So you look -- you could
7 get a rough idea. Are you talking design study?
8 But if you wanted some rough mathematical idea,
9 you would take the number of patients who have
10 ongoing pregnancies at the time they return to the
11 abortion clinic, which I think depends on
12 gestational age at which it's administered -- and
13 I can't pull the number up out of my head right
14 now. I want to say it's like -- I don't know.

15 If I were forced to have a
16 number, I would say it's somewhere like 1 or 2
17 percent. So of the universe of a thousand
18 patients, we get 1 percent of that or 2 percent,
19 that's 200. Okay?

20 Of those 200, that would
21 administer mifepristone, then 68 percent of
22 those -- again, depending on the individual
23 factors of gestational age, 68 percent of those
24 would respond to the mifepristone treatment.

25 Without mifepristone, the rough

1 **number would be 25 percent of that 200. Because**
2 **that's the highest -- that's the highest estimate**
3 **that the Delgado paper used.**

4 Q. So -- sorry. I think I've
5 confused myself.

6 **A. I'm sorry.**

7 Q. It's not your fault.

8 In the study that you just
9 mentioned, we would be still comparing people or
10 looking only at a subset of people who had a
11 continuing pregnancy after mifepristone at some
12 point in time; right?

13 **A. Correct.**

14 Q. And if we were instead looking at
15 the total universe of people who took
16 mifepristone, how do we determine for that entire
17 group of people what their likelihood would be of
18 having their pregnancy continue after progesterone
19 treatment? Wouldn't we have to --

20 **A. Okay. So -- go ahead.**

21 Q. Wouldn't we have to include the
22 people whose pregnancies terminate early before
23 they reach the provider just to figure out
24 prospectively the percent chance for a given group
25 of people?

1 A. No, because the percent chance --
2 the percent chance for a given group of people,
3 the group is who's got a live baby. So that's
4 the group. The group isn't all Mifeprex
5 ingesters.

6 So the group that you're trying
7 to figure out the percent increased chance is
8 those who have a live baby. So we're taking from
9 that -- that's the beginning point. The beginning
10 point is, you took Mifeprex, baby is dead or
11 alive. Baby is dead, nothing you can do. Baby is
12 alive, we can increase your chances from
13 approximately 25 percent to approximately 68
14 percent.

15 That's all we know. We can't say
16 it's a hundred percent. But we can say it's the
17 only thing we have to help you with.

18 Q. All right. Okay. So for the
19 people whose pregnancies terminate before they
20 reach the reversal provider, obviously, reversal
21 can't be effective with them; right? It's too
22 late?

23 A. Too late.

24 MS. CLARKE: Sara, if you're
25 still there, could you pop Tab CC into

1 the chat?

2 THE WITNESS: Give me a second
3 here.

4 MS. CLARKE: Sure. Take your
5 time.

6 THE WITNESS: Then go to full
7 screen and then chat.

8 Again, give me just a second
9 here. I'm opening it up.

10 MS. CLARKE: Take your time.

11 THE WITNESS: Okay. I got it.

12 BY MS. CLARKE:

13 Q. Take a look at this and let me
14 know when you're ready.

15 **A. Okay. I'm ready.**

16 Q. Okay. What is this document?

17 **A. This document is AAPLOG Practice**
18 **Bulletin 6, the reversal of the effects of**
19 **mifepristone by progesterone.**

20 Q. Did you write this document?

21 **A. No, but I was on a committee to**
22 **help edit it.**

23 Q. What is an AAPLOG practice
24 bulletin?

25 **A. An AAPLOG practice bulletin is a**

1 **compiling of the scientific literature for**
2 **pro-life docs to understand and inform their**
3 **practice.**

4 Q. So under Practice Bulletin, it
5 says, Evidence directing pro-life obstetricians
6 and gynecologists. Does that accurately -

7 **A. That's correct.**

8 Q. Does that accurately describe
9 what a practice bulletin is?

10 **A. Yes. I'm sorry. I'll wait for**
11 **your question next time.**

12 Q. It's getting late. I understand.
13 Can you turn to page 4 of this
14 document?

15 **A. I'm getting there. Yes.**

16 Q. Okay. So sort of two-thirds of
17 the way down on the left, it reads, Dr. Delgado
18 and his co-authors also analyzed their results by
19 gestational age at the time of reversal attempt
20 and found that the success rate increased with
21 increasing gestational age. Right.

22 **A. Good point. Yeah, I see that.**

23 Q. Is that accurate?

24 **A. Well, let me pull up the Delgado**
25 **paper.**

1 Q. So you don't know without looking
2 whether that's accurate?

3 A. I don't. I'd have to pull up the
4 Delgado paper.

5 Q. So leaving the Delgado paper
6 aside, is it accurate to say that the rate of
7 continuing pregnancy after ingestion of
8 mifepristone alone is also higher at later
9 gestational ages?

10 A. Yes.

11 Q. I have a quick question about the
12 sixth page.

13 Actually, I forgot to ask the
14 court reporter to mark this exhibit. Can we mark
15 this as Exhibit 18, please?

16 COURT REPORTER: Yes, ma'am. 18.

17 (Exhibit 18, AAPLOG Practice
18 Bulletin, was marked.)

19 BY MS. CLARKE:

20 Q. Are you on page 6?

21 A. I am. I'm sorry. Yes, I'm on
22 page 6.

23 Q. So on the top right under
24 intramuscular protocol, it reads, Some clinicians
25 may choose to continue intramuscular treatment

1 longer since this recommendation is based on
2 relatively small numbers.

3 Did I read that right?

4 **A. Yes, that's correct.**

5 **Q. What does that mean?**

6 **A. Well, if you look at the IVF**
7 **literature, which is where a lot of progesterone**
8 **has been used for about 50 years, when a woman**
9 **undergoes in vitro fertilization, the ovary is**
10 **stimulated so that they can retrieve an egg or**
11 **many eggs. But that stimulation tends to prevent**
12 **the woman from making progesterone with her**
13 **ovaries.**

14 So not a hundred percent, but it
15 induces what's called a relative luteal phase
16 defect. So some IVF doctors will give
17 progesterone supplements only through 12 weeks of
18 pregnancy. Because, after that time, the placenta
19 takes over the production of progesterone. Some
20 IVF doctors will continue giving progesterone
21 later.

22 It's kind of an individual
23 judgment call, and it's up to the individual
24 clinician. But the evidence for how long to treat
25 luteal defect rests on the IVF literature use of

1 progesterone in induced luteal phase defect for
2 IVF patients.

3 It's similar because what you
4 have with Mifeprex is you have an induced luteal
5 phase defect. So it's a similar kind of
6 physiological insult. So that's why there's some
7 room for judgment because, even in the IVF
8 literature, there's room for judgment.

9 Q. Okay. So I'm going to sort of
10 try to parse this out in facts, because I think I
11 still don't understand.

12 When it says, This recommendation
13 is based on relatively small numbers, what does
14 that mean?

15 A. That means there aren't a lot of
16 studies looking at how long you should treat a
17 luteal phase defect with progesterone.

18 Q. And because there's not a lot of
19 studies, some clinicians might think, well, I
20 don't know if it works later, but you might as
21 well try it. Is that accurate?

22 A. Well, when you say "later," you
23 mean for a longer duration?

24 Q. Sorry. Yeah, for a longer
25 duration.

1 **A. Correct. There's not consensus**
2 **right now in the IVF literature as to how long to**
3 **treat -- let me try that again -- an induced**
4 **luteal phase defect for IVF patients.**

5 Q. Okay. I think I understand. At
6 the very bottom of that page under references, at
7 the end of that sentence or the end of that
8 paragraph, it reads, When high quality evidence is
9 unavailable, opinions from members of AAPLOG were
10 sought.

11 What does that mean?

12 **A. Well, AAPLOG is composed of a**
13 **number of different subspecialists within OB/GYN.**
14 **We have reproductive endocrinologists. We have a**
15 **few gynecologic oncologists, although they don't**
16 **deal so much with the life issues. We have**
17 **maternal fetal medicine physicians.**

18 **So when we create these practice**
19 **bulletins, we also run them by, for editing**
20 **purposes, those physicians who we know have**
21 **expertise in that area.**

22 Q. Okay. Are you one of those
23 physicians that this would be run by?

24 **A. Yep.**

25 Q. And that would be because of your

1 expertise in Mifeprex, among other things?

2 **A. That's correct.**

3 Q. Did you give input into this
4 other than to edit it?

5 **A. Well, in editing, you give input.
6 But I did not do the initial drafts, no. I did
7 the editing.**

8 Q. So when it says, When high
9 quality evidence was unavailable, do you know sort
10 of what that's referring to in this document?

11 **A. Well, as you know, there aren't a
12 lot of studies which looked at the survival rate
13 after giving Mifeprex. So those studies are
14 summarized in the Davenport -- sorry. It's late
15 -- the Davenport publication.**

16 **So when we talk about high
17 quality, we're talking about large, large, large
18 numbers of patients looked at very, very
19 specifically over multiple, multiple studies over
20 multiple, multiple years. That, we're not there
21 yet. It's coming, but we're not there yet.**

22 MS. CLARKE: Okay. So I know we
23 talked about the Yamabe study briefly.

24 Sara, could you drop Tab P into
25 the chat room, please?

1 **A. Just give me a second. Tab P. I**
2 **got it.**

3 MS. CLARKE: While you're looking
4 at this document, Ms. Morgan, would you
5 mind marking this as Exhibit 19.

6 COURT REPORTER: 19. Yes.

7 (Exhibit 19, Yamabe Study, was
8 marked.)

9 BY MS. CLARKE:

10 Q. Okay. So this is a study of
11 mifepristone in rats; is that right?

12 **A. That's correct.**

13 Q. And in this study --

14 **A. Yes.**

15 Q. In this study, do you know
16 whether any group of rats was given mifepristone
17 followed up some later time by progesterone?

18 **A. Give me a second. Hold on a**
19 **second. I'm reading the materials and methods.**

20 Q. Okay.

21 **A. I'm looking to try to find the**
22 **time at which the progesterone was administered.**

23 **Okay. The progesterone was**
24 **administered simultaneously with the RU-486.**

25 Q. So is it, then, inaccurate to say

1 that this study involves a group of rats that was
2 given mifepristone followed by natural
3 progesterone?

4 **A. That is correct. It was given**
5 **simultaneous.**

6 Q. In your declaration, you refer to
7 manufacturers' studies concerning the
8 reversibility of mifepristone; is that right?

9 **A. That is correct.**

10 Q. What do you mean by "manufacturer
11 studies"?

12 **A. Baulieu is the author. He**
13 **compiled manufacturer studies from Roussel-Uclaf**
14 **into a document which he authored. So when I**
15 **refer to manufacturer studies, I'm referring to**
16 **the combination of different studies compiled by**
17 **Baulieu.**

18 Q. The manufacturer of what?

19 **A. Mifepristone.**

20 Q. Okay. And so you're saying that
21 in the Baulieu and Segal book, all of those
22 tractors (ph) are studies done by the manufacturer
23 of Mifeprex?

24 **A. There certainly -- were they all**
25 **done by Roussel-Uclaf? They certainly were relied**

1 on by Roussel-Uclaf. I can't tell you exactly
2 where all of those studies were done. They may
3 have been done at different universities, but they
4 are the manufacturer studies from Roussel-Uclaf.

5 Q. So when you say they are the
6 manufacturer studies, what you mean is these are
7 the studies that were ultimately relied on by
8 Danco?

9 A. They were ultimately relied upon
10 by Roussel-Uclaf. These are the studies that were
11 also reviewed by the FDA for the approval.

12 Q. But you don't know if these were
13 all studies that were conducted by the
14 manufacturer?

15 A. I don't know exactly the location
16 of the labs that did the studies. I don't.

17 Q. I gotcha. So the citation you
18 give -- if you want to refer back to your
19 declaration, although you don't have to if you
20 don't want to. But it was page 6, paragraph 16.

21 A. Hold on just a second. I'm
22 there.

23 Q. And it's footnote 8.

24 A. Yes. Okay.

25 Q. So you cite to the Baulieu and

1 Segal book for the proposition that reversibility
2 of mifepristone binding is backed up by
3 manufacturer studies; is that right?

4 **A. Correct. That's correct.**

5 Q. It turns out a large book?

6 **A. It is a very large book. It will**
7 **take me awhile to get to the studies, but I can**
8 **give you -- it's like in about the mid two-thirds.**
9 **So I would have to get -- I would have to pull up**
10 **that, and it will take me a little bit of time to**
11 **find the study. But, yes, I can do that.**

12 Q. Well, if I gave you a table of
13 contents, would you be able to point me to the
14 chapter that you were referencing?

15 **A. Maybe.**

16 MS. CLARKE: Okay. Let's try
17 that.

18 Sara, I know you made a tab for
19 me, and now I don't know what it is.
20 You dropped Tab S down.

21 I would ask the court reporter to
22 mark this as Plaintiff's 20, please.

23 THE WITNESS: Tab S.

24 (Exhibit 20, Baulieu & Segal
25 Table of Contents, was marked.)

1 BY MS. CLARKE:

2 Q. Does this look like the table of
3 contents for the Baulieu and Segal book cited in
4 your footnote 8?

5 A. **I'm still pulling it up. Hold**
6 **on.**

7 **Yes, it looks like it.**

8 Q. So could you let me know which
9 chapter in here you were referencing in your
10 footnote 8?

11 A. **I'm looking.**

12 Q. I'm sorry. While you're looking,
13 let me close my curtains.

14 A. **I'm not going to be able to**
15 **figure it out without looking at the actual**
16 **papers. So I will have to go back and look at the**
17 **actual papers. I'm really sorry. I don't track**
18 **my title. I track by what the abstract says.**

19 Q. So whatever portion of this book
20 you were citing, does it support the proposition
21 that mifepristone is reversible by progesterone?

22 A. **Yes, it does.**

23 **I hate to ask, but I had a lot of**
24 **water. Can I go to the bathroom?**

25 MS. CLARKE: Sure. Do you want

1 to take a five-minute break everybody?

2 VIDEOGRAPHER: Off the record at
3 2 o'clock.

4 (A break was taken.)

5 VIDEOGRAPHER: We are back on the
6 record at 2:05.

7 BY MS. CLARKE:

8 Q. Okay. Dr. Harrison, in that
9 same -- well, sorry. Did you communicate with
10 anyone during that break?

11 A. **No. There's nobody here.**

12 Q. Did you look at any documents?

13 A. **No.**

14 Q. Okay. So looking back at
15 paragraph 16 of your declaration, it reads, The
16 reversibility of mifepristone binding is backed up
17 by manufacturer studies as well as National
18 Institute of Health studies.

19 What did you mean by National
20 Institute of Health studies?

21 A. **Sternberg is, I think, the one I**
22 **cited. Hold on just a second. Let me look up my**
23 **citation.**

24 **Yeah. Sternberg works at the**
25 **NIH.**

1 Q. Was that study that you cite in
2 footnote 9, was that an NIH study?

3 **A. Well, it was performed by an NIH**
4 **doctor. So I would assume it was an NIH study. I**
5 **mean, that's where she works.**

6 Q. But you don't know if that study
7 was conducted by the NIH or published by the NIH?

8 **A. I don't. I don't. I just know**
9 **that she's a well-respected physician who works at**
10 **the National Institute of Health.**

11 Q. Okay. And that's a study
12 concerning -- okay -- the effect of mifepristone
13 on glucocorticoid receptors; is that right?

14 **A. That's correct. So mifepristone**
15 **-- yes, that's correct.**

16 Q. Okay. In that same footnote 9,
17 after the Sternberg citation, it reads, The
18 Department of Health and Human Services (HHS),
19 Centers for Disease Control and Prevention (CDC),
20 Food and Drug Administration (FDA), and National
21 Institute of Health (NIH), Emerging Clostridial
22 Disease Workshop, May 11, 2006.

23 **A. That's correct.**

24 Q. Was the Emerging Clostridial
25 Disease Workshop a study conducted by HHS?

1 **A. The Emerging Clostridial Disease**
2 **Workshop was a workshop held by the CDC and FDA**
3 **after the death of the four women from clostridium**
4 **sordelli sepsis who had taken mifepristone. There**
5 **was a workshop held to look at the mechanisms by**
6 **which those deaths might have occurred.**

7 Q. Okay. So your citation here, was
8 this a citation to the transcript of that
9 workshop?

10 **A. Yeah. It should say**
11 **"transcript," but I don't see it saying**
12 **transcript.**

13 **Okay. Yes.**

14 Q. So it's not a study?

15 **A. Well, she presented the results**
16 **of her study -- so her study was published in the**
17 **Journal of Endocrinology, and she was one of the**
18 **presenters at the Emerging Clostridial Disease**
19 **Workshop.**

20 Q. By "she," you mean Dr. Sternberg?

21 **A. Sternberg; correct.**

22 Q. So when I looked at page 23 of
23 this transcript, I saw a Dr. Dale Gerding's
24 testimony. Is that not what you intended to cite
25 to?

1 **A. I don't think so. She presented.**
2 **I'll have to go back and look for the -- she has**
3 **her presentation in there. I would have to see it**
4 **and go through the transcript.**

5 **But she did -- I was there. She**
6 **presented.**

7 Q. Did she present about her work
8 studying the effect of mifepristone on
9 glucocorticoids?

10 **A. Correct.**

11 Q. And then there were members of
12 the public also speaking at that workshop; right?

13 **A. Yes.**

14 Q. And their statements are also in
15 the transcript?

16 **A. I don't know. I don't know if**
17 **their statements are in the transcript or not.**

18 Q. Okay. In paragraph 12 of your
19 declaration, footnote 3, you cite to Spilman and
20 Gibson et al; is that right?

21 **A. That's correct.**

22 Q. And that study that you cite
23 concerns the effect of steroids on rabbit
24 uteruses; is that right?

25 **A. Yes.**

1 Q. Was mifepristone one of the drugs
2 studied in that study?

3 A. Yes, it was.

4 You have to understand
5 mifepristone in its development has different drug
6 names. So RU38486 is mifepristone. It was given
7 another name by Upjohn, which was like U9933,
8 something or another. So that's mifepristone.

9 Q. Okay. So is there any way to
10 know what all RU names mifepristone has been given
11 over the years?

12 A. Well, I've -- you have to go back
13 to the original chemistry literature, and you just
14 have to know what names it was given in
15 development. So it is a challenge.

16 It was given like four or five
17 different names, depending on which pharmaceutical
18 was studying it at the time. So RU means
19 Roussel-Uclaf.

20 Q. So RU38486 is mifepristone?

21 A. That's mifepristone.

22 Q. In your declaration, you also
23 cite a study by Garratt out of Australia; is that
24 right?

25 A. Yes.

1 Q. Did that study draw any
2 conclusions about the efficacy of reversal
3 treatments?

4 A. **Boy, I would have to pull up the**
5 **study.**

6 MS. CLARKE: Okay. Let's pull up
7 the study.

8 Sara, can you drop Tab Q into the
9 chat, please.

10 And if we could mark this as
11 plaintiff's 21, please.

12 (Exhibit 21, Garratt Study, was
13 marked.)

14 Garratt Study

15 BY MS. CLARKE:

16 Q. Do you recognize this document?

17 A. **Yes, uh-huh. Yes, I do.**

18 Q. And this is the Garratt study
19 that you cited in your declaration?

20 A. **That's correct.**

21 Q. So what conclusions, if any, does
22 this study draw about the efficacy of progesterone
23 to reverse mifepristone?

24 A. **What they state is, Women have**
25 **changed their mind after commencing medical**

1 **abortion. Progesterone used in early pregnancy is**
2 **low risk and its application to counter the**
3 **effects of mifepristone in such circumstances may**
4 **be clinically beneficial in preserving her**
5 **threatened pregnancy. Further research is**
6 **required, however, to provide definitive evidence.**

7 Q. Okay. So on page 3 of --

8 **A. Which document?**

9 Q. -- the Garratt article --

10 **A. Okay.**

11 Q. -- under "future questions," do
12 you see that on the bottom right?

13 **A. Hold on. I'm getting there.**
14 **Yes.**

15 Q. Okay. So that reads, There is
16 currently no definitive evidence for the success
17 of using progesterone to prevent the abortifacient
18 effects of mifepristone; is that right?

19 **A. That's correct. That's what it**
20 **says. That's what the study says, yes.**

21 Q. Would you agree with that
22 statement?

23 **A. You would have to define**
24 **"definitive evidence." Is there physiological**
25 **reason to think that it would work? Yeah, there**

1 is.

2 Q. Would you consider there to be
3 definitive evidence that it works?

4 A. At the time of her publication of
5 the study -- let me look back. I'm looking for a
6 study date here, 2017.

7 I wouldn't say definitive
8 evidence. I would say there is evidence for the
9 action. There is evidence. What I would agree
10 with her is that definitive, to me as a scientist,
11 implies that something has been done over a very,
12 very, very long period of time; and it's always
13 gotten the same results. It's been checked and
14 cross-checked and cross-checked. That's not where
15 we're at right now.

16 But there is definite evidence
17 and growing evidence for the success in using
18 progesterone to prevent the abortifacient effects
19 of mifepristone.

20 Q. Okay. I'm sorry. Is that how
21 you pronounce that? Abortifacient?

22 A. Yes. Well, that's how I
23 pronounce it.

24 Q. Okay. Would you say that there
25 is evidence that abortion reversal or medication

1 abortion reversal is safe for women?

2 **A. Yes.**

3 Q. And what is that based on, that
4 opinion?

5 **A. That's based on almost 50 years
6 of use in OB/GYN as well as extensive use in the
7 IVF industry. Almost every woman who undergoes
8 IVF is placed on progesterone.**

9 Q. So that would be evidence of the
10 safety of progesterone; right?

11 **A. Correct. The safety of
12 progesterone in the early pregnancy.**

13 Q. Okay. Is it your opinion that it
14 is safe for a woman to take mifepristone and then
15 not take misoprostol?

16 **A. It's never safe for any woman to
17 take mifepristone for -- I mean, let me qualify
18 that.**

19 **If you're asking me is a
20 mifepristone abortion safe, I will say no. It is
21 not safe for the woman, and it's definitely not
22 safe for the child who is being killed by
23 mifepristone.**

24 Q. Are there greater risks to the
25 woman for taking mifepristone and not taking

1 misoprostol than for taking none?

2 **A. I have seen no studies on that**
3 **yet.**

4 Q. So we don't know?

5 **A. We don't know. But in my own**
6 **opinion, I would like to see a study before such**
7 **conclusions are drawn.**

8 Q. Okay. I think -- well, do you
9 know whether patients who are referred to
10 physicians through the abortion pill reversal
11 network, if they have an adverse event, is that
12 reported back to the abortion pill reversal
13 network?

14 **A. I don't know.**

15 Q. So if a patient -- well, strike
16 that.

17 Is there any way to know whether
18 the patients who obtain reversal treatment through
19 APRN, whether any of them experienced a
20 hemorrhage?

21 **A. I don't know.**

22 Q. Do you know whether the abortion
23 pill reversal network requires reversal providers
24 to have back contracted backup physicians in case
25 the reversal provider is unavailable and the

1 patient is having an emergency?

2 **A. I don't know.**

3 Q. Do you know whether the abortion
4 pill reversal network requires reversal providers
5 to have admitting privileges at a local hospital
6 in case the patient gets admitted to the hospital?

7 **A. I don't know.**

8 Q. Do you think that would be
9 appropriate?

10 **A. Well, most OB/GYNs in clinical
11 practice have admitting privileges. That's just
12 the standard. So as an OB/GYN, if you're
13 practicing, you've got privileges.**

14 **My understanding, though I don't
15 have intimate understanding, is that most of the
16 doctors who are part of the abortion pill reversal
17 network are practicing OB/GYNs. So one would
18 assume that a practicing OB/GYN has admitting
19 privileges.**

20 Q. Would it be appropriate for APRN
21 to require that they do to practice in the
22 network?

23 **A. They're not intervening to --
24 okay. Let me back up.**

25 **Would it be appropriate for an**

1 OB/GYN who's taking care of a patient to have
2 admitting privileges? Yes. It would be
3 appropriate for an OB/GYN who is taking care of a
4 patient, who is doing patient care, to have
5 admitting privileges. Or -- yeah.

6 No, I would say that that is
7 appropriate. But I don't know that they don't. I
8 don't know what the criteria is for the abortion
9 pill reversal network.

10 Q. If the abortion pill reversal
11 network did not require participating providers to
12 have local admitting privileges, would you still
13 refer patients there?

14 A. Yes. And I'll tell you why.
15 Because the abortion pill reversal network
16 physician is not intervening to cause an event
17 which necessitates surgical intervention. They're
18 trying to avoid an event that necessitates
19 surgical intervention.

20 Most practicing physicians have a
21 network of specialists that they would refer to.
22 So if you have a practicing physician who is
23 taking responsibility for the abortion pill
24 reversal network patient -- again, I would assume
25 that most of those are OB/GYNs in practice,

1 because they're providing prenatal care -- I would
2 assume that they would have admitting privileges.

3 If they didn't, they're probably
4 practicing with someone with admitting privileges.
5 Because when you do the abortion pill reversal
6 network, you're causing this patient to go on and
7 have prenatal care, hopefully.

8 So they would already be in a
9 system with docs who would have admitting
10 privileges. It wouldn't be something foreign to
11 what they are already doing.

12 Q. So if you learned that the
13 abortion pill reversal network refers patients to
14 midwives, who are not doctors and who do not have
15 admitting privileges, would you still refer
16 patients there?

17 A. Well, it would depend on the
18 scope of practice. But in all the states that I
19 know of, midwives work with OB/GYN physicians. So
20 I don't know of a state where a midwife is
21 independently working outside of a network of
22 OB/GYN physicians.

23 Q. So as long as there's an OB/GYN
24 physician working with the midwife, you would feel
25 comfortable referring patients there?

1 A. Yeah. I refer patients for
2 prenatal care to midwives. I think midwives have
3 a great place in obstetrics and gynecology, but
4 they also need the backup of an OB/GYN physician
5 network. Not one physician but, you know, as many
6 physicians as they work for.

7 Q. So if someone got reversal
8 treatment and then went to the hospital with a
9 hemorrhage, is there any way that the abortion
10 pill reversal network would know that that
11 happened?

12 A. Well, when you say the abortion
13 pill reversal network, or do you mean the
14 individual physician who is taking the
15 responsibility? The network is not the treating
16 physician. The treating physician takes
17 responsibility for their patient. So that
18 treating physician should know that his or her
19 patient went to the ER.

20 Probably, the patient would call
21 the doctor first. So normally, what happens in
22 practice is that a patient calls the doctor first
23 and says, Hey, I'm hemorrhaging. He says, Okay,
24 go to the ER -- he or she, Go to the ER. And then
25 the doctor calls the ER and says, I'm sending in

1 **Jane Smith. She's hemorrhaging. This is her**
2 **history. Give me a report.**

3 **So that's the normal patient care**
4 **that one expects with prenatal care. The doctor**
5 **themselves takes responsibility for the patient.**

6 Q. Okay. So I'm going to read you a
7 quote, and I want you to let me know if you agree
8 with it. It concerns abortion pill reversal.

9 The authors of these studies
10 assumed that all the women who didn't come back to
11 the treating physician were completely free of
12 problems. It is more likely that these women had
13 problems that were handled by another doctor. So
14 the follow-up was done by another doctor. The
15 original doctor has no mechanism for tracking
16 complications handled by emergency rooms or other
17 doctors. So they would have no record of problems
18 for these women. This makes the rate of
19 complications seem much lower than they are in
20 reality.

21 Do you agree with that criticism?

22 **A. Did I write that?**

23 Q. Do you agree with that criticism?

24 **A. It's out of context.**

25 Q. Would you agree with that as

1 criticism of the safety of abortion pill reversal?

2 **A. Read it to me again.**

3 Q. Sure. So let's -- we'll say the
4 author of the Delgado study assumed that women who
5 didn't come back to the treating physician were
6 completely free of problems. It is more likely
7 that these women had problems that were handled by
8 another doctor. So the follow-up was done by
9 another doctor. The original doctor has no
10 mechanism for tracking complications handled by
11 emergency rooms or other doctors. So they have no
12 record of problems for these women. This makes
13 the rate of complications seem much lower than
14 they are in reality.

15 **A. Okay. I would have to actually**
16 **see where this quote is coming from and see what**
17 **studies they're talking about. So I can't give**
18 **you an out-of-the-blue, out-of-context, agree or**
19 **disagree. I would have to see where that's coming**
20 **from.**

21 Q. Okay. So if someone got abortion
22 pill reversal, went to the hospital with a
23 hemorrhage, and didn't call her doctor, there
24 would be no way for her reversal doctor to know
25 that she'd had a hemorrhage; right?

1 **A. Abortion pill reversal isn't one**
2 **stop. When a doctor takes care of a patient for**
3 **abortion pill reversal, they follow them through**
4 **the pregnancy. It's prenatal care.**

5 **So that doctor is intimately**
6 **involved in the life of that patient. Unlike**
7 **abortion, where it's an one-stop shop. She never**
8 **sees the doctor beforehand. She never sees the**
9 **doctor after. She may not even see the doctor**
10 **until she's in the stirrups.**

11 **Unlike that, abortion pill**
12 **reversal doctors actually take care of their**
13 **patients.**

14 **Q. Okay. Would you be surprised to**
15 **learn that Dr. Boles has given reversal to**
16 **patients he's never met.**

17 **A. I'm sorry. Say again.**

18 **Q. Would you be surprised to learn**
19 **that Dr. Boles has given reversal treatments to**
20 **patients he's never met.**

21 **MR. RIEGER: Object to the form.**

22 **Go ahead and answer.**

23 **A. That is a difficult question to**
24 **answer because if he is giving reversal through**
25 **midwives who are under his supervision, then he is**

1 taking clinical responsibility for that patient.

2 I mean, I did have midwives work
3 under me who took care of patients through
4 prenatal care, who delivered their baby, who I did
5 admit; and yet I was ultimately responsible for
6 the care of that patient.

7 So I would have to understand the
8 context in which he's working.

9 BY MS. CLARKE:

10 Q. Would you be surprised to learn
11 that there are any doctors in the abortion pill
12 reversal network who have provided reversal
13 treatments to patients that neither they nor
14 anyone on their staff has ever met?

15 A. I don't know. I'd have to see
16 the clinical scenario. Because when you provide
17 abortion pill reversal care, you're providing a
18 kind of prenatal care. And, ultimately, you, as a
19 physician are responsible for that care.

20 Q. So do you recall in the Delgado
21 2018 studies that about 15 percent of patients
22 were lost to follow-up?

23 A. For the number, I would have to
24 see the study, but there were patients lost to
25 follow-up.

1 Q. So for the patients who were lost
2 to follow-up, we would have no way to know whether
3 those patients experienced adverse events; right?

4 A. **That's correct.**

5 Q. So you mentioned that a patient
6 who is hemorrhaging, before she goes to the
7 emergency room, would probably call her reversal
8 provider first and say, Here's what's going on;
9 right?

10 A. **Well, she would call her OB/GYN**
11 **doc. She's pregnant. She's hemorrhaging. She's**
12 **going to call the OB/GYN doc who is taking care of**
13 **her.**

14 Q. Well, so let's say she got
15 reversal treatment this morning, hasn't been to
16 any other OB/GYN yet. If she were hemorrhaging
17 that night, do you think that she would call the
18 reversal provider?

19 MR. RIEGER: Object to the form.

20 Go ahead and answer.

21 A. **I don't know. It would depend, I**
22 **think, a little bit on whether she has another**
23 **doctor that she would call. If she has an OB/GYN**
24 **already, I would hope that she would call her**
25 **OB/GYN doctor or her family medicine doctor. But**

1 **I don't know.**

2 BY MS. CLARKE:

3 Q. So if she called another OB/GYN,
4 there's no way that her reversal provider would
5 know that she had a hemorrhage; right?

6 **A. Unless there was communication.**

7 Q. Do you know when patients receive
8 treatment from doctors referred through the
9 abortion pill reversal network, do you know
10 whether those patients sign a legal waiver before
11 they get treatment?

12 **A. I don't know.**

13 Q. Would it makes sense to you --
14 strike that.

15 Would it surprise you to learn
16 that all those patients signed a waiver that
17 claims to waive any legal claims of any kind that
18 they, their baby, or any surviving family members
19 might have?

20 MR. RIEGER: Object to the form.

21 Go ahead and answer.

22 **A. I don't know.**

23 BY MS. CLARKE:

24 Q. Would that cause any concern for
25 you if you learned that that was the case?

1 **A. I would have to see the form and**
2 **see exactly how it's expressed and how it's used.**

3 Q. So let's say, for purposes of
4 this question, that the form says that they waive
5 any legal claims of any kind that they, their
6 baby, or surviving relatives may have against
7 Heartbeat International or the abortion pill
8 reversal network. Would that give you any cause
9 for concern?

10 **A. That is going to depend on the**
11 **consent for abortion pill reversal. So I would**
12 **hope that the consent was adequate and -- yeah.**

13 Q. So it wouldn't raise any red
14 flags for you, that kind of waiver for a doctor?

15 **A. I can't speak for all doctors,**
16 **and I'm not a legal expert. So it's not my area**
17 **of expertise. So I don't have any comment on**
18 **that.**

19 Q. So you had mentioned previously a
20 Mitch Creinin study; right?

21 **A. Yes.**

22 Q. So I'm going to refer you
23 actually back to the AAPLOG Practice Bulletin 6,
24 which is Exhibit 18, Tab CC.

25 **A. Okay.**

1 Q. On page 5 --

2 A. **I'm getting there.**

3 Q. Okay.

4 A. **Page 5.**

5 Q. At the top left --

6 A. **Yes.**

7 Q. -- it reads in bold and
8 underlined, It was due to the severe hemorrhage in
9 the mifepristone alone group, not the progesterone
10 group, that the study was halted.

11 A. **That's correct.**

12 Q. Is that an accurate
13 characterization of why the Mitch Creinin study
14 was halted?

15 A. **It was halted for safety. It was
16 halted for safety regarding hemorrhage.**

17 **The patient in the progesterone
18 arm bled for three hours. But by the time she got
19 to the ER, the abortion was complete, and there
20 was no treatment. So that was not a safety
21 treatment.**

22 **The safety issue was the two that
23 required a D & Cs to stop and the woman that
24 required the transfusion. Those were in the
25 placebo, not the progesterone arm.**

1 Q. So does that -- was the study
2 stopped by researchers exclusively because of
3 hemorrhaging suffered by people not in the
4 progesterone group?

5 A. They said they stopped the study
6 for safety. The safety concern was hemorrhage.
7 The hemorrhage that needed treatment was all in
8 the placebo and not the progesterone arm.

9 Q. So the patient who bled for three
10 hours and went to the hospital after taking
11 progesterone, was she admitted to the hospital
12 when she got there?

13 A. I don't think so. They said no
14 treatment. She had stopped hemorrhaging.

15 Q. So that would be considered an
16 adverse event?

17 A. Of course.

18 Q. Would that be reason to stop the
19 study if that had been the extent of hemorrhage
20 suffered by all three hemorrhage patients?

21 A. No.

22 Q. And why not?

23 A. Because that was so limited, and
24 there was no treatment required.

25 Q. So if, let's say, one in five

1 people who took mifepristone and did not take
2 misoprostol suffered that level of hemorrhage,
3 would you consider it safe to take mifepristone
4 and not misoprostol?

5 **A. I've already commented on the use**
6 **of the term "safe." Safe is a relative term. I**
7 **don't consider mifepristone ever safe, either for**
8 **the woman or for her unborn child who is killed.**
9 **So I will not say that mifepristone is ever safe.**

10 Q. Would you say that it's -- well,
11 if there was a one-in-five chance that a given
12 treatment caused that kind of hemorrhage, would
13 you say that that treatment was dangerous?

14 **A. But the treatment didn't cause**
15 **the hemorrhage. The hemorrhage was caused because**
16 **the mifepristone in that patient caused the fetal**
17 **demise, which then resulted in expulsion. The**
18 **hemorrhage was from the expulsion.**

19 **So the other four out of five**
20 **patients had living pregnancies at 20 weeks --**
21 **excuse me, at two weeks, which is an 80 percent**
22 **success rate for APRN.**

23 Q. Is it your opinion that one in
24 five people who take mifepristone and misoprostol
25 in early pregnancy will have that level of

1 hemorrhaging?

2 **A. In his study, 40 percent of the**
3 **mifepristone alone group had severe hemorrhage**
4 **that required D & C to stop the hemorrhage and one**
5 **required a transfusion. That's mifepristone**
6 **alone.**

7 Q. So my question was, is it your
8 opinion that one in five people who take
9 mifepristone and misoprostol will have the kind of
10 hemorrhage experienced by the one patient in the
11 progesterone group?

12 **A. I'm sorry. But that doesn't make**
13 **sense, because the women who took mifepristone had**
14 **severe hemorrhage requiring a D & C.**

15 **The one that took mifepristone**
16 **plus progesterone did not have a severe**
17 **hemorrhage. She hemorrhaged while she was**
18 **expelling, and then that bleeding stopped. She**
19 **received no further products of conception, and**
20 **she received no treatment.**

21 Q. Okay. So I --

22 **A. Maybe I'm missing your question.**
23 **Sorry.**

24 Q. My question is actually if you
25 take mifepristone and misoprostol. So none of the

1 patients in the Creinin study took misoprostol;
2 right?

3 A. Correct.

4 Q. For all the hundreds of thousands
5 of people who have taken mifepristone followed by
6 misoprostol, is the rate of hemorrhage one in
7 five?

8 A. The rate -- well, it depends on
9 which study you look at. The best study is
10 Niinimáki, 2009, out of Finland, because they used
11 hospital records. It's a registry-based study.
12 In that study, one out of five patients ended up
13 having some kind of a complication.

14 So whether the number is one out
15 of five or one out of six, you've got the best
16 studies which are registry-based. That was 42,000
17 abortion patients, half of which were surgical,
18 half of which were medical. The medical abortion
19 patients had five times the rate of complications
20 that the surgical patients had.

21 And my recall of the study is
22 that one out of five had hemorrhage. I would have
23 to go back and look at the study to confirm the
24 numbers. But, yes, that was mifepristone and
25 misoprostol. It was vaginal use of misoprostol.

1 Q. Was that 200 milligrams of
2 mifepristone?

3 **A. Correct. You won't find that in**
4 **the study. If you go look back at that study, you**
5 **have to go back to her actual Ph.D. thesis to find**
6 **out what the patients used. So that's a different**
7 **paper. But the Ph.D. thesis is what she based her**
8 **paper on.**

9 Q. Do you know her name?

10 **A. Maarit, M-a-a-r-i-t, Niinimaki,**
11 **N-i-i-m-a-k-i, I think.**

12 Q. So based on that study plus your
13 expertise and your general knowledge, would you
14 expect that 20 percent of all the people who've
15 taken medication abortions since 2000 have
16 hemorrhaged?

17 **A. It would be nice to know,**
18 **wouldn't it?**

19 Q. So you're not --

20 **A. There's no systematic tracking of**
21 **complications after mifepristone. There's none.**

22 Q. And there's no way to look at,
23 you know, NIH data or other health care data to
24 see whether there has been a dramatic rise in
25 miscarriage-related hemorrhaging at hospitals

1 since medication abortion was approved by the FDA?

2 **A. I would love to have my hands on**
3 **that data.**

4 Q. So we don't know?

5 **A. We don't know, because nobody**
6 **tracks complications after Mifeprex. It's not**
7 **systematically tracked. It's only voluntary.**

8 Q. And that's not tracked because
9 the patient may not tell their doctor when they go
10 to the emergency room and have the hemorrhage?

11 **A. I don't know why it's not**
12 **tracked. I mean, there's a thousand reasons why**
13 **it's not tracked.**

14 Q. And the fact that we don't track
15 it means we don't know how safe it is; right?

16 **A. The fact that we don't track it**
17 **means I can't give you a number, because I can't**
18 **give you a number without data.**

19 Q. Without the data, you can't make
20 a determination of how safe you think it is?

21 **A. When you say "it," what do you**
22 **mean?**

23 Q. Taking Mifeprex and misoprostol
24 in early pregnancy.

25 **A. I don't think taking Mifeprex and**

1 **misoprostol is safe for the woman at all. I don't**
2 **think taking Mifeprex and misoprostol is safe for**
3 **the unborn child, who is killed.**

4 **If you compare studies looking at**
5 **complication rates after Mifeprex and misoprostol,**
6 **comparing those complication rates after surgical**
7 **abortion, of which Niinimaki is probably the best**
8 **because it's registry-based, you get a four-fold**
9 **increase in complication rate after Mifeprex**
10 **abortion as compared to surgical abortion. That's**
11 **what I can tell you.**

12 Q. Okay. So going back to your
13 declaration, you note that there is -- that the
14 Delgado 2018 study -- this is page 10, paragraph
15 28.

16 **A. 28?**

17 Q. Yes. So you say that the Delgado
18 study found no increase of birth defects when
19 compared to the general population of births,
20 which is consistent with other studies which have
21 found no increase in malformation rate over the
22 general population in infants who are born after
23 exposure to mifepristone in utero. Is that right?

24 **A. Yes.**

25 Q. Did I mention mifepristone?

1 **A. Yes.**

2 Q. So in that footnote 16, you cite
3 Bernard et al; right?

4 **A. Yes.**

5 Q. Does that study show no
6 difference in rates of major malformation after
7 exposure to mifepristone in utero?

8 **A. Can you pull the study?**

9 Q. I can.

10 **A. I'd like to see the study.**

11 MS. CLARKE: Sara, could you draw
12 up Tab W into the chat? And we will
13 mark this as Plaintiff's 22, please.

14 (Exhibit 22, Bernard Study, was
15 marked.)

16 **A. Yes.**

17 BY MS. CLARKE:

18 Q. Do you recognize this document?

19 **A. I do.**

20 Q. What is it?

21 **A. This is the Bernard study.**

22 Q. Okay. So on the first page of
23 that study in their little summary of the study,
24 under "conclusions," it says, The first
25 prospective study found that the rate of major

1 malformations after first trimester exposure to
2 mifepristone is only slightly higher than the
3 expected 2 to 3 percent rate in the general
4 population.

5 Does that sound right?

6 **A. That's correct.**

7 Q. So it is, in fact, higher but
8 only slightly higher; is that right?

9 **A. It's slightly higher. If you
10 look at the next sentence, it says, Such findings
11 provide reassuring data for risk evaluation for
12 continuation of pregnancy after mifepristone
13 exposure.**

14 **So the authors themselves
15 interpret that number. And if you look at the
16 confidence intervals, which are very wide, it
17 shows you that this is not a significant --
18 statistically significant increase in major
19 malformation.**

20 Q. So is it still accurate to say
21 that this is a study that found no increase in
22 malformation rate over the general population of
23 infants who were born after exposure to
24 mifepristone in utero?

25 **A. There's no statistically**

1 **significant increased rate.**

2 Q. You also cite at the end of that
3 same sentence to Sitruk-Ware; is that right?

4 **A. Okay. Yes. I would need to see**
5 **that study.**

6 MS. CLARKE: Okay. Let's pop
7 that study into the chat. That's Tab X,
8 and we will mark that as plaintiff's
9 Exhibit 23, please.

10 (Exhibit 23, Sitruk-Ware
11 Correspondence, was marked.)

12 **A. Yes.**

13 BY MS. CLARKE:

14 Q. What is this document?

15 **A. This is the Sitruk-Ware**
16 **correspondence.**

17 Q. Okay. So in the very middle of
18 the document, middle column, it reads, There were
19 no reported cases of malformation associated with
20 the use of misoprostol when used with
21 mifepristone.

22 Is it your understanding that
23 misoprostol is actually teratogenic?

24 **A. Yes.**

25 Q. So it didn't show up in this

1 study, but it actually does cause birth defects;
2 correct?

3 **A. Yes.**

4 Q. So in paragraph 30 of your
5 declaration -- we're jumping around here -- you
6 write, in essence, that complaints about the
7 possibility of teratogenicity reversal is
8 misplaced because those criticisms concern
9 synthetic progestins rather than progesterone.

10 Is that accurate? Is that an
11 accurate summary of what you wrote?

12 **A. Yes.**

13 Q. Do you know whether all abortion
14 reversal providers use natural progesterone rather
15 than synthetic progestin?

16 **A. There would be no reason to use
17 synthetic progestins. As I understand the
18 abortion pill reversal protocol, the drug used is
19 natural progesterone. You wouldn't use a
20 progestin.**

21 **It's the same kind of protocol
22 that you use for the IVF industry. The IVF
23 industry doesn't use -- they use natural
24 progesterone.**

25 Q. But there is no way to know

1 whether any given doctor associated with the
2 abortion pill reversal network prescribed
3 synthetic progestins rather than natural
4 progesterone?

5 **A. My understanding of the protocols**
6 **used by the abortion pill reversal network all**
7 **involve natural progesterone.**

8 Q. We don't know if the abortion
9 pill reversal network conducts audits of their
10 physicians to determine whether they're following
11 protocols?

12 **A. I don't know.**

13 Q. Earlier, you had mentioned the
14 term "statistical significance." What does that
15 mean?

16 **A. That means the chances that your**
17 **results may be -- that you may have gotten these**
18 **results just by happenstance and that they may not**
19 **reflect the truth.**

20 **So at any time you do scientific**
21 **studies, your results come on a bell curve. And**
22 **if you're within the 95 percent confidence**
23 **interval, this means that you are 95 percent**
24 **confident that your results are actually erecting**
25 **reality.**

1 **That's kind of one way to put it.**

2 Q. Okay. Do you know how
3 statistical significance was calculated?

4 A. **By confidence interval. You look
5 at the confidence interval.**

6 Q. How do you obtain a confidence
7 interval?

8 A. **It's a statistical -- it's a
9 statistical answer depending on how many patients
10 you have. So if you have a small number of
11 patients and you've got a conclusion, then that is
12 not as statistically significant as a very, very
13 large number of patients. So the larger your
14 number of patients, the smaller your confidence
15 intervals, the more likely that your results are
16 statistically significant -- more likely that your
17 results reflect reality.**

18 Q. So a confidence interval, is that
19 the same as a P value?

20 A. **I'm sorry. The same as a PI?**

21 Q. A P value. You had mentioned P
22 value earlier.

23 A. **There is a relationship, but I'm
24 going to have to go back to the statistics. I'm
25 not going to do that on a tired brain. I can't.**

1 **I have to go back and pull up relationships**
2 **between PI and confidence intervals. My brain is**
3 **not going to do that right now.**

4 Q. So when you said confidence
5 interval a couple of minutes ago, you did not mean
6 -- I'm sorry. When you said P value a few minutes
7 ago, did you mean confidence interval or did you
8 mean P value?

9 A. **I think the study -- let me go**
10 **back and look at it.**

11 **The confidence interval, 1.2 to**
12 **10.4 percent. So that's in the results of the**
13 **Bernard study. Confidence interval, 1.2 to 10.4.**

14 Q. Okay. That makes more sense.

15 A. **If I said P value, it was a**
16 **mistake.**

17 Q. Okay. No problem.

18 So I am nearing the end of this,
19 I promise. Can we take a break and go off the
20 record? Is that okay?

21 A. **It's fine with me.**

22 VIDEOGRAPHER: Off the record at
23 2:54.

24 (A break was taken.)

25 VIDEOGRAPHER: We are back on the

1 record at 3:03.

2 BY MS. CLARKE:

3 Q. Okay. Dr. Harrison, did you find
4 the peer reviewers for Delgado's 2018 paper
5 published in Issues in Law and Medicine?

6 **A. I was probably the one that**
7 **contacted them, because it is a scientific paper.**

8 Q. And you're aware that that
9 article was published and then taken down and then
10 put back up; is that right?

11 **A. Yes. I'm aware of that.**

12 Q. Why was it taken down?

13 **A. The authors requested that it be**
14 **removed.**

15 Q. Do you know why?

16 **A. Because they were changing some**
17 **of the wording of the paper.**

18 Q. And that wording referred to
19 internal review board approval; is that right?

20 **A. That's correct.**

21 Q. Sorry. Insufficient review board
22 approval?

23 **A. Yes. IRB approval, yes.**

24 Q. Do you know what they wanted to
25 change about the wording concerning IRB approval?

1 **A. I would have to compare the**
2 **wording between the one before and the one after.**
3 **I would have to go back and look.**

4 Q. Okay. So if I told you that the
5 original paper said that it had received an IRB
6 waiver from San Diego and that the revised paper
7 did not say that, does that sound right to you?

8 MR. RIEGER: Object to form.
9 Go ahead and answer.

10 **A. Yes.**
11 **Did you object to form? Because**
12 **that didn't come through.**

13 MR. RIEGER: I did object to
14 form, and then I instructed you to
15 answer. I'm sorry.

16 BY MS. CLARKE:

17 Q. In your declaration, you note
18 that complaints about IRB approval for the 2018
19 paper are, quote, "spurious"; right?

20 **A. That's correct.**

21 Q. And you say that because the
22 final paper says clearly the study was reviewed
23 and approved by an institutional review board
24 right?

25 **A. That's correct.**

1 Q. Do you know which institutional
2 review board approved the final study?

3 A. No, not right off the top of my
4 head. I wouldn't be able -- I don't even know if
5 I would be able to find out. You would have to
6 ask the authors.

7 Q. Did you edit this article at all
8 before it was published?

9 A. Not that I know of.

10 Q. Did you see any of the peer
11 review reports that the peer reviewers wrote about
12 it?

13 A. I may have because, even though I
14 instruct them to respond to Barry Bostrom,
15 sometimes they reply to me; in which case, I just
16 forward it to Barry. So I may have seen them, but
17 I don't think I read any of them in detail.

18 Q. Was the article peer reviewed
19 again after that statement about IRB approval was
20 changed?

21 A. Not that I know of. Now, that is
22 not to say -- I don't know what Barry did. He may
23 have sent it back, but I don't know.

24 Q. Would you -- does it strike you
25 as unusual for a paper to say that it was IRB

1 approved without saying what institutions IRB
2 approved it?

3 **A. My understanding is that IRB**
4 **approval is confidential.**

5 Q. So --

6 **A. I think in most papers, I think**
7 **IRB approval is confidential.**

8 Q. All right. So you think that
9 most papers would not tell you what institution
10 gave that study IRB approval?

11 **A. I wouldn't say that. I would say**
12 **that my understanding is that IRB approval is**
13 **confidential.**

14 Q. Do you have any understanding as
15 to whether most scientific papers that obtain IRB
16 review will state in their paper what institution
17 gave them IRB approval?

18 **A. There are lots of papers that do**
19 **say what institution gave them IRB approval.**

20 Q. So it doesn't strike you as
21 unusual for a paper not to?

22 **A. No.**

23 Q. In your declaration, I believe
24 that you say that the double standard to require a
25 placebo control group in medication abortion

1 reversal studies but not in studies determining
2 the efficacy of medication abortion itself. Is
3 that accurate?

4 **A. Is that a quote?**

5 Q. The double standard part is a
6 quote.

7 **A. What is the exact quote? That**
8 **doesn't sound like my wording. That's why I'm**
9 **asking.**

10 Q. Okay. So let's see if I can find
11 it. In paragraph 37 of your declaration -- well,
12 strike that.

13 Do you think that a placebo
14 controlled study is necessary to show that
15 medication abortion is effective at terminating an
16 early pregnancy?

17 **A. I don't think you can ethically**
18 **do a placebo controlled study for abortion --**
19 **excuse me. It's getting late -- for abortion pill**
20 **reversal for use of progesterone because the**
21 **population group that you're looking at is women**
22 **who want to save their baby.**

23 **We have very little to offer**
24 **them. But one thing that we can offer them is**
25 **progesterone. So you can do what's been done in**

1 the abortion industry, which is to do a dose
2 comparator. That can ethically be done, and that
3 can ethically be randomized.

4 But to say to this woman who
5 wants a chance to save her baby, which is a --
6 it's a binary yes/no, you know, baby lives/baby
7 dies. To say to that woman, We're going to give
8 you a placebo and see what happens in two weeks,
9 that's not ethical, especially if you're dealing
10 with a human life and interventions to try to save
11 that human life, that pre-born child. It's not
12 ethical to do a placebo control.

13 Q. So it's your opinion that the
14 Creinin study was unethical, not for that reason
15 but because it requires women who choose abortion
16 to delay their abortion; is that accurate?

17 A. That's correct. Because, as is
18 commonly known, the further along in gestation,
19 the higher your risk of complications. So in
20 those women who he gave placebo to instead of the
21 progesterone -- so he's giving progesterone and
22 then placebo -- the placebo group continued
23 further and further in their pregnancy. And if he
24 wanted to abort them, he should have just aborted
25 them.

1 You know, you can't -- this is a
2 life and death thing. So the ones you give
3 progesterone to that had continuing pregnancies,
4 well, you've got four women who are now two weeks
5 further along than they would have been had he
6 simply aborted them at the beginning. So two
7 weeks does increase the risk of the complications.

8 So I do not think that was an
9 ethical study, no. I understand it had IRB
10 approval. I don't think it was ethical.

11 Q. So because the risks and
12 complications increase with gestational age, do
13 you think it's unethical to delay abortions for
14 people who are seeking abortions?

15 A. I think that -- okay. I know
16 where you're going with that.

17 I don't think it's ethical to do
18 a study that uses a placebo in a trial where the
19 use of the placebo results in increasing
20 complications.

21 Q. Okay. So for all placebo
22 controlled studies, some people get a treatment
23 and some people get a placebo; right?

24 A. Correct.

25 Q. The people who get the placebo

1 are not getting the treatment that may or may not
2 cure whatever they might have; right?

3 **A. That's correct.**

4 Q. Is it ethical to conduct those
5 studies?

6 **A. It depends on what the treatment
7 is and what the consequences are of not getting
8 that treatment. It completely depends.**

9 Q. So in this instance, would we
10 have known before the study started that, in your
11 words, the placebo caused an increased rate of
12 complications for the patients in that Creinin
13 study? Did we know that in advance of the study?

14 **A. No.**

15 Q. So was it unethical at the time
16 the study was designed?

17 **A. Let me think about the answer to
18 that. Was it unethical in its design?**

19 **If one looks at -- I'm going to
20 say I'm going to have to think about that.**

21 Q. Okay.

22 **A. I can't answer categorically yes
23 or no at this time.**

24 Q. Okay. So in determining the
25 efficacy of medication abortion, mifepristone and

1 misoprostol, is it fair to say that we can
2 determine its efficacy based on a robust
3 historical control group? Is that fair to say?

4 **A. I'm sorry. Ask the question**
5 **again, because I'm trying to figure out -- I'm**
6 **trying to figure out exactly what you're saying.**

7 Q. So when determining how effective
8 the two-drug medication abortion regimen is at
9 terminating early pregnancy, is it fair to say
10 that we can determine its efficacy by comparing it
11 to a robust historical control group rather than a
12 placebo?

13 **A. Can you specify which study**
14 **you're talking about?**

15 Q. I'm not talking about a
16 particular study. So if we're just trying to
17 figure out does medication abortion work at
18 terminating early pregnancies, can we figure that
19 out by looking at a historical control group?

20 **A. Yes. You can get some estimate**
21 **of efficacy.**

22 Q. Efficacy. What would the
23 historical control group be in that instance?

24 **A. It would be those who don't take**
25 **mifepristone and misoprostol.**

1 Q. That would be the many, many
2 women over the course of time who have been
3 pregnant and carried their pregnancies and never
4 taken mifepristone or misoprostol; right?

5 **A. Right.**

6 Q. And we have a pretty good sense
7 of how often women experience spontaneous abortion
8 in the first ten weeks of pregnancy. Is that fair
9 to say?

10 **A. I wouldn't say we have a great**
11 **idea of that, because that's actually a very**
12 **under-studied subject, what is the actual**
13 **spontaneous miscarriage rate. But we have some**
14 **feeling for it, yes, we do.**

15 Q. What is a retrospective series
16 based on chart review? What does that mean?

17 **A. That means that the investigators**
18 **had charts of women who have already been treated**
19 **where they looked back through those charts to do**
20 **their study. That's a retrospective chart review.**

21 Q. So when you say "their charts,"
22 what do you mean by their charts?

23 **A. Their records, their record of**
24 **treatment.**

25 Q. So is it your understanding that

1 for the 2018 study, Delgado looked at these
2 patients' charts?

3 **A. He looked at their records of**
4 **treatment. That's my understanding, that the**
5 **authors did that, yes.**

6 Q. If a patient received an
7 ultrasound as part of -- during the course of
8 their reversal treatment, would that show up in
9 their chart?

10 **A. It should show up in their**
11 **record.**

12 Q. And so if in the 2018 study
13 Delgado noted that he doesn't know how many
14 patients in the study received ultrasound, would
15 that indicate that he didn't look at their charts?

16 MR. RIEGER: Object to the form.
17 Go ahead and answer.

18 **A. No, not necessarily.**

19 BY MS. CLARKE:

20 Q. It could mean that the person --
21 that he doesn't know whether people were
22 consistently documenting ultrasounds in the chart?
23 Is that what it means?

24 MR. RIEGER: Object to the form.
25 Go ahead and answer.

1 **A. It's possible. That's one**
2 **possible explanation.**

3 BY MS. CLARKE:

4 Q. What are some other possible
5 explanations?

6 **A. That they did an ultrasound and**
7 **didn't record --**

8 MR. RIEGER: Object to the form.
9 Go ahead and answer.

10 **A. That they did an ultrasound and**
11 **didn't record the gestational age.**

12 BY MS. CLARKE:

13 Q. If the Delgado 2018 paper said
14 that they didn't know how many patients had
15 received ultrasounds to confirm pregnancy or not,
16 would that indicate that he didn't look at the
17 patients' charts?

18 MR. RIEGER: Object to the form.
19 You can answer.

20 **A. Not necessarily.**

21 BY MS. CLARKE:

22 Q. What else could that mean?

23 **A. It could mean that the treating**
24 **physician didn't document. So when you're**
25 **gathering data, you can only deal with the data**

1 **that's been documented.**

2 Q. Would you expect any physician
3 who does an ultrasound on a patient to document
4 that ultrasound in the patient's charts?

5 **A. That would be the usual practice.**

6 Q. Would it be usual practice to
7 document the number of progesterone injections
8 given to a patient?

9 **A. Yes.**

10 Q. And if for some patients in the
11 2018 study, Delgado noted that he did not know how
12 many progesterone injections they got, would that
13 indicate he didn't look at their charts?

14 MR. RIEGER: Object to the form.
15 Go ahead and answer.

16 **A. Not necessarily.**

17 BY MS. CLARKE:

18 Q. When you say "retrospective
19 analysis," if someone decides to study something,
20 gets consent from patients to be studied, and then
21 looks at their charts, is that a retrospective
22 analysis?

23 **A. I'm sorry. I'm trying to
24 understand what you're asking.**

25 **So if a person has -- ask the**

1 **question again just so I'm clear as to what**
2 **question you're asking.**

3 Q. If someone wants to study
4 something and they obtain patients' informed
5 consent to be studied and then they look through
6 their charts as they were allowed to do by the
7 patient and compile that data, is that a
8 retrospective analysis?

9 A. **If you have a study that looks at**
10 **records that have already been obtained, that have**
11 **already been generated, when you look back at**
12 **those records, that's a retrospective analysis.**

13 Q. If you decide to do the study
14 before those patients have been treated, obtain
15 their consent to have their data sent to you, and
16 then look at their charts, is that a retrospective
17 analysis?

18 A. **Whether it's retrospective or**
19 **prospective depends on whether you have designed**
20 **it with a certain protocol in mind.**

21 **So a prospective study is one**
22 **that you say on Day X, I have given this patient**
23 **this drug, and then I'm going to follow her**
24 **results for a particular period of time.**

25 **But that's not what the Delgado**

1 **study was. The Delgado study was looking at**
2 **patients who had already been treated and seeing**
3 **what their outcomes were.**

4 Q. Okay. So the fact that --

5 **A. He was not the treating**
6 **physician.**

7 Q. He was not the treating physician
8 for any of the patients in this study?

9 **A. Well, I shouldn't say any. He**
10 **wasn't the treating physician for all the patients**
11 **in the study.**

12 Q. So for the patients in the study
13 for whom he was the treating physician, if he had
14 determined that he wanted to do a study, obtained
15 informed consent from those patients, and then
16 treated them, and then looked at their chart,
17 would that still constitute a retrospective
18 analysis?

19 **A. I don't think that's what**
20 **happened.**

21 Q. If it were --

22 **A. It's a hypothetical.**

23 Q. Hypothetically, if that were what
24 happened, would that constitute a retrospective
25 analysis?

1 **A. He didn't have a particular**
2 **intervention and then -- from a particular date**
3 **and then follow them prospectively. He did not**
4 **follow them prospectively.**

5 **The information he got was for**
6 **information of patients who were already treated.**
7 **That makes it a retrospective study.**

8 **Q. Okay. Let's say hypothetically**
9 **that he decided he wanted to conduct the study,**
10 **treated some patients, followed them, got their**
11 **consent to study their data, and then studied it,**
12 **would that still be a retrospective analysis?**

13 **A. Retrospective analysis is when**
14 **you institute a treatment and then you follow the**
15 **patient for the results of that treatment.**

16 **A retrospective analysis is when**
17 **a patient has already been treated, and you look**
18 **at the chart, and you say, Oh, this is what**
19 **happened with these patients.**

20 **So his -- as best I understand,**
21 **his study was a retrospective chart review.**

22 **Q. So if instead he had studied**
23 **patients to whom he gave treatment and followed up**
24 **with them and then reported their results, that**
25 **would be a prospective study; right?**

1 MR. RIEGER: Object to the form.

2 Go ahead and answer.

3 A. But that's not what his study
4 did.

5 BY MS. CLARKE:

6 Q. But if it were, that would be a
7 prospective study?

8 A. So a prospective studied is where
9 you institute a treatment and then you follow
10 patients after that treatment for the results.

11 But that's not what the study
12 was. These are women who sought abortion pill
13 reversal as almost a compassionate use. Because
14 it was the only thing that the doctors in the
15 network had to offer these patients who regretted
16 taking mifepristone and wanted to do anything that
17 they could to try to increase the chances that
18 their baby would survive what they considered to
19 be a mistake.

20 So whether or not they were being
21 studied was irrelevant, not related to their use
22 of mifepristone -- oh, boy -- their use of
23 progesterone. Their use of progesterone -- they
24 were going to use progesterone to try to save
25 their baby regardless of whether they were studied

1 or not. It was not a part of the study protocol.

2 However, having used the
3 progesterone, Dr. Delgado, is my understanding,
4 said, We have information about patients who have
5 used this treatment, regardless -- not within a
6 study, but because they themselves wanted whatever
7 possible help they could to save their baby.

8 So why not look at that data,
9 which I think is a very reasonable thing to do.
10 You have information about patients who have
11 received this treatment. Let's look at it.
12 **That's not a prospective study. So . . .**

13 Q. If that were the case, that
14 somebody were only collecting data on treatments
15 that had already happened, would that mean that
16 those patients had not signed an informed consent
17 to participate in a study if that study hadn't
18 happened yet?

19 **A. The study hadn't happened yet.**

20 Q. If those patients had signed an
21 informed consent to participate in that study,
22 would that change your opinion as to whether it
23 was a prospective study?

24 **A. Depends on what the consent is.**
25 **If the consent is the release of records for**

1 educational purposes, which, frankly, anybody that
2 signs into a teaching hospital signs to release
3 their records for educational purposes -- if it
4 was that kind of a consent, then that's not a
5 research study.

6 So I signed a consent when I had
7 a C-section that my records could be released for
8 study. Okay? I wasn't part of a study. That
9 wasn't a study. But could people go back and look
10 at my chart? Absolutely, because I signed a
11 consent to release my information for educational
12 purposes or for research purposes, whatever
13 purposes the hospital wanted to use my information
14 for.

15 So the fact that a consent is
16 signed to release information does not in and of
17 itself make something a research study.

18 Q. Okay. That makes sense. So,
19 then, if we're looking at a retrospective study,
20 we would expect that the patients in the study
21 would not have signed a consent to participate in
22 an experimental research protocol or study; right?
23 Because the study hadn't happened yet?

24 MR. RIEGER: Object to the form.

25 Go ahead and answer.

1 **A. I guess, yes.**

2 MS. CLARKE: Okay. Sara, can you
3 pull up Tab R? And we'll mark this as
4 plaintiff's 24, please.

5 (Exhibit 24, Practice Bulletin 8,
6 was marked.)

7 BY MS. CLARKE:

8 Q. Let me know when you're --

9 **A. I'm sorry. Which tab is this?**

10 Q. Tab R.

11 **A. Tab R. Okay. Almost. No, that**
12 **doesn't look right.**

13 Q. It's titled ACOG -- but that's me
14 reading it wrong. When you open it, do you see
15 AAPLOG Practice Bulletin 8?

16 **A. Yes. I was going to say that's**
17 **not ACOG.**

18 Q. Take a look at this document and
19 let me know if you recognize it.

20 **A. Yes, I do.**

21 Q. What is this document?

22 **A. This is Practice Bulletin 8,**
23 **medical management of elective induced abortion.**

24 Q. Did you write this document?

25 **A. No.**

1 Q. Did you edit this document?

2 A. I think that is different than
3 the other document. Hold on just a second.

4 Is this different than the other
5 document that you gave me?

6 Q. It is different.

7 A. Yeah. If I -- I probably did
8 edit it, but this was probably one I didn't edit
9 much.

10 Q. If I tell you that it was
11 published in February 2020, would that refresh
12 your recollection as to whether you edited this
13 document?

14 A. Yeah. I probably didn't edit it
15 much.

16 Q. Have you seen it before?

17 A. Yes, I have seen it before.

18 Q. What's the purpose of this
19 document?

20 A. The purpose of this document, as
21 in all practice bulletins, is to give the
22 practicing pro-life OB/GYN information about to
23 what is in the medical literature about particular
24 topics that affect their practice.

25 Q. So this is not a practice

1 bulletin that would tell physicians how to provide
2 medication abortion; right?

3 **A. No. This is not -- that's not**
4 **the purpose of this document.**

5 Q. And it's not a document that
6 tells practicing physicians how to manage
7 complications of medication abortion; is that
8 right?

9 **A. I don't think they mention**
10 **management of complications in this document.**

11 Q. So I would like to direct your
12 attention to page 8, the first document, please.

13 **A. Okay. Yes.**

14 Q. So on the left, it says, Summary
15 of recommendations and conclusions: The following
16 recommendations are based on good and consistent
17 scientific evidence, Level A.

18 Did I read that right?

19 **A. Yes, you did.**

20 Q. What does that mean, Level A?

21 **A. Well, if you -- what that means**
22 **is that there are studies which are good, like**
23 **randomized control trials or systematic reviews of**
24 **good literature, which mean that we have a lot of**
25 **confidence that what's being said here is**

1 **supported by the medical literature.**

2 Q. At the bottom of that first
3 paragraph, it reads, Local abortion advocates are
4 aggressively using the court system and pro-choice
5 media sources to advocate for removal of safety
6 restrictions on medical abortions.

7 Is that a statement that's based
8 on good and consistent scientific evidence?

9 A. **Yes, it is.**

10 Q. What is the --

11 A. **If you look at what's in the
12 literature, if you look at what's being published
13 in medical journals, you will find that that is
14 consistent with what we're seeing.**

15 Q. So there have been scientific
16 studies concerning the degree to which abortion
17 advocates use the court system to advocate removal
18 of safety restrictions?

19 A. **You say is there a randomized
20 control trial? No, it's not a randomized control
21 trial. But it doesn't take much look at the
22 medical literature. You don't have to look very
23 far in the medical literature to see that there is
24 a very concerted effort toward no-touch abortion
25 and -- yeah. So you're seeing a lot of trials**

1 **that way.**

2 Q. So on the next page on the right,
3 you'll see it says, The following recommendations
4 are based on good and consistent scientific
5 evidence, Level B. What does that mean?

6 A. **That means that you don't have --**
7 **you don't have as strong scientific evidence. You**
8 **don't have a lot of publications, but you have**
9 **some publications that are consistent with what**
10 **you're seeing.**

11 Q. Okay. So here it says, Biased
12 studies performed by those who profit from
13 abortion provisions seek to downplay the common
14 nature of complications.

15 Is that supported by good and
16 consistent scientific evidence?

17 A. **I can show you a lot of studies,**
18 **yes, that are produced by the abortion industry**
19 **that downplay the risks of complications from**
20 **abortion, from medical abortion.**

21 Q. But the good and consistent
22 scientific evidence doesn't support this statement
23 as not as strong as those that support the
24 statements under Level A; is that right?

25 A. **That's correct.**

1 Q. Is it your opinion that studies
2 performed by people who profit off the treatments
3 and their studies are biased?

4 **A. It's my opinion that that**
5 **introduces a level of financial bias, yes.**

6 Q. And that financial bias usually,
7 you would hope, would be disclosed in the study;
8 right?

9 **A. You would hope. But it's not**
10 **always.**

11 Q. Do you know whether Dr. Delgado
12 profits from the provision of abortion reversal
13 treatment?

14 **A. I don't know.**

15 Q. Do you know if Mary Davenport
16 profits from the provision of reversal treatment?

17 **A. I don't know.**

18 Q. Do you know whether Dr. Boles
19 profits from the provision of reversal treatment?

20 **A. I don't know.**

21 Q. So at the very bottom of page 8,
22 under Level A, it reads, The abortion industry is
23 aggressively working for complete over-the-counter
24 access for Mifeprex.

25 Is that a statement supported by

1 good and consistent scientific evidence?

2 **A. I can show you a lot of studies**
3 **which are published in peer review journals where**
4 **abortion advocates are advocating for complete**
5 **over-the-counter access, for complete access**
6 **without medical intervention.**

7 Q. Okay. So when you say the
8 "abortion industry," you mean abortion providers?

9 **A. That is the abortion industry.**

10 Q. When you talk about the studies
11 concerning that, do you mean that those studies
12 were written by abortion providers?

13 **A. The vast majority of publications**
14 **on abortion, medical abortion, are written by**
15 **abortion providers.**

16 Q. Do abortion providers have a
17 financial incentive to work for over-the-counter
18 access to Mifeprex?

19 **A. Well, it turns out that Planned**
20 **Parenthood was given the right to manufacture and**
21 **distribute Mifeprex. And my understanding is that**
22 **Planned Parenthood still holds that right,**
23 **although they gave it to a company they created**
24 **called Danco.**

25 **So is there a financial**

1 provision? You would have to pierce the corporate
2 veil to know if Planned Parenthood is still
3 profiting from the sale of Mifeprex.

4 My understanding is they are
5 still profiting from the sale of Mifeprex, but I
6 don't have the legal background to pierce the
7 corporate veil.

8 Q. I want to go -- I'm sorry. I'm
9 jumping around a little bit, because it's late. I
10 want to go back to the 2018 Delgado study briefly.

11 A. So which tab?

12 Q. Oh, I'm just talking about it
13 generally.

14 MR. RIEGER: Christine, would now
15 be a good time to take a ten-minute
16 break real quick?

17 MS. CLARKE: Sure, absolutely.

18 VIDEOGRAPHER: Off the record at
19 3:38.

20 (A break was taken.)

21 VIDEOGRAPHER: We are back on the
22 record at 3:47.

23 MS. CLARKE: I have no more
24 questions.

25 MR. RIEGER: I hate to do that,

1 but I was expecting you to have a little
2 bit more. Can we take a quick fiver?

3 MS. CLARKE: Absolutely.

4 VIDEOGRAPHER: Off the record at
5 3:48.

6 (A break was taken.)

7 VIDEOGRAPHER: We're back on the
8 record at 3:55.

9 MR. RIEGER: Christine, for
10 purposes of the transcript, we have no
11 questions for Dr. Harrison. We are
12 going to request that we read and sign
13 the transcript.

14 COURT REPORTER: Would you mind
15 putting your orders on the record,
16 please?

17 MR. RIEGER: Certainly.

18 MS. CLARKE: Do you know when
19 would it be possible to get a rough by
20 Monday?

21 COURT REPORTER: It will be
22 difficult. I will try. This is a new
23 one for me, but I'm sure I can try.

24 MS. CLARKE: If you can't, that's
25 fine. If you can, that would be great.

1 COURT REPORTER: Okay.

2 MS. CLARKE: Otherwise, you can
3 send the transcript to me when you're
4 done.

5 MR. RIEGER: And defendants would
6 also like a rough and the final whenever
7 it gets done.

8 COURT REPORTER: Okay. And are
9 any of the other parties online, are
10 they parties that need a copy, or no?

11 MS. CLARKE: I think they can get
12 my copy, but you can just email the copy
13 to me.

14 COURT REPORTER: Okay.

15 VIDEOGRAPHER: End of deposition.
16 Off the record at 3:57.

17 (Deposition concluded 3:57 p.m.)

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1 CERTIFICATE OF COURT REPORTER

2 I, Marilyn Morgan, Licensed Court
3 Reporter and Notary Public for the State of
4 Tennessee, do certify that the above deposition
5 was reported by me and that the foregoing
6 transcript is a true and accurate record to the
7 best of my knowledge, skills, and ability.

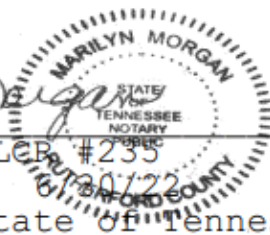
8 I further certify that I am not an
9 employee of counsel or any of the parties, nor a
10 relative or employee of any attorney or counsel
11 connected with the action, nor financially
12 interested in the action.

13 I further certify that I am duly
14 licensed by the Tennessee Board of Court Reporting
15 as a Licensed Court Reporter as evidenced by the
16 LCR number and expiration date following my name
17 below.

18 Subscribed and sworn to before me when
19 taken, this 13th day of November, 2020.

20
21
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Marilyn Morgan
MARILYN MORGAN, LCR #235
Expiration Date: 05/30/22
Notary Public, State of Tennessee
Commission expires: 5/15/21



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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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25 DONNA HARRISON

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25 DONNA HARRISON

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