

1 Charles S. LiMandri, SBN 110841
cslimandri@limandri.com
2 Paul M. Jonna, SBN 265389
pjonna@limandri.com
3 Jeffrey M. Trissell, SBN 292480
jtrissell@limandri.com
4 Brian M. McPherson, SBN 345196
bmcpherson@limandri.com
5 LiMANDRI & JONNA LLP
6 P.O. Box 9120
7 Rancho Santa Fe, CA 92067
8 Telephone: (858) 759-9930
Facsimile: (858) 759-9938

9 Peter Breen, *pro hac vice*
pbreen@thomasmoresociety.org
10 THOMAS MORE SOCIETY
11 309 W. Washington St., Ste. 1250
Chicago, IL 60606
12 Telephone: (312) 782-1680

13 *Attorneys for Defendants Heartbeat*
14 *International, Inc. & RealOptions, Inc.*

ELECTRONICALLY FILED
Superior Court of California,
County of Alameda
01/20/2026 at 12:00:00 AM
By: Andrel Gospel,
Deputy Clerk

Andrew S. Hollins, SBN 80194
ahollins@messner.com
Ethan A. Reimers, SBN 311020
ereimers@messner.com
MESSNER REEVES LLP
650 Town Center Drive, Suite 700
Costa Mesa, CA 92626
Telephone: (949) 612-9128
Facsimile: (310) 889-0896

Attorneys for Defendant RealOptions, Inc.

15 SUPERIOR COURT OF THE STATE OF CALIFORNIA

16 COUNTY OF ALAMEDA

17 THE PEOPLE OF THE STATE OF
18 CALIFORNIA,

19 Plaintiff,

20 v.

21 HEARTBEAT INTERNATIONAL, INC.,
22 AND REALOPTIONS, INC.,

23 Defendants.

Case No.: 23CV044940

**APPENDIX OF EVIDENCE IN
SUPPORT OF DEFENDANTS'
MOTION FOR SUMMARY
JUDGMENT OR SUMMARY
ADJUDICATION**

APPENDIX V(E): DEPOSITIONS

Judge: Hon. Patrick McKinney
Dept: 18

Action filed: September 21, 2023

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28

APPENDIX OF EVIDENCE VOLUME V(E): DEPOSITIONS	
No.	DESCRIPTION:
G.	Relevant portions of the deposition of the Attorney General's medical expert, Mitchell Creinin, M.D., volume 1, taken in this action on October 10, 2025.

EXHIBIT G

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

THE PEOPLE OF THE STATE OF)	
CALIFORNIA,)	
)	
Plaintiff,)	
)	
VS.)	Case No. 23CV044940
)	
HEARTBEAT INTERNATIONAL, INC., and)	
REALOPTIONS, INC.,)	
)	
Defendants.)	
_____)	

VIDEOTAPED DEPOSITION OF MITCHELL CREININ, M.D.,

APPEARING REMOTELY

Friday, October 10, 2025

REPORTED BY:

GRACE CHUNG, CSR No. 6246, RMR, CRR

APPEARING REMOTELY FROM LOS ANGELES, CALIFORNIA

FILE NO.: J13375352

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

THE PEOPLE OF THE STATE OF)	
CALIFORNIA,)	
)	
Plaintiff,)	
)	
VS.)	Case No. 23CV044940
)	
HEARTBEAT INTERNATIONAL, INC., and)	
REALOPTIONS, INC.,)	
)	
Defendants.)	
_____)	

Videotaped Deposition of MITCHELL CREININ, M.D.,
taken on behalf of Defendant, beginning at 8:31 a.m. and
ending at 5:35 p.m., on Friday, October 10, 2025, before
GRACE CHUNG, CSR No. 6246, RMR, CRR.

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

A P P E A R A N C E S

(All appearances via videoconference.)

For the Plaintiff:

ATTORNEY GENERAL OF CALIFORNIA
DEPUTY ATTORNEY GENERAL
BY: HALEY PENAN, ESQ.
LAUREN ZWEIER, ESQ.
ETHAN REIMERS, ESQ.
1300 "I" Street
Suite 125
Sacramento, California 94244
(916) 210-7755
hayley.penan@doj.ca.gov

For the Defendant:

LiMANDRI & JONNA
BY: PAUL M. JONNA, ESQ.
REBECCA OAKLEY, ESQ.
15236 San Dieguito Road
Building 3, Suite 3-15
Rancho Santa Fe, California 92067
(959) 759-9930
pjonna@limandri.com

Also Present: MARCELA SANDOVAL, Videographer

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

I N D E X

WITNESS	EXAMINATION	PAGE
MITCHELL CREININ, M.D.		
	BY MR. JONNA	8

EXHIBITS

NO.	DESCRIPTION	PAGE
Exhibit 1	The People's Expert Witness Designation and Declaration of Haley Penan	20
Exhibit 4	Article entitled "Mifepristone antagonization requires real studies to evaluate safety and efficacy"	73
Exhibit 2	Amended Expert Declaration of Dr. Mitchell D. Creinin	90
Exhibit 5	Mifeprex product label	99
Exhibit 6	Cytotec misoprostol tablets label	127
Exhibit 84	A document from Planned Parenthood titled "How long do you bled after an abortion?"	141
Exhibit 85	Article entitled "Bleeding patterns after misoprostol vs surgical treatment of early pregnancy failure: Results from a randomized trial"	143
Exhibit 86	Article entitled "Society of Family Planning Clinical Recommendation: Management of hemorrhage at the time of abortion"	151
Exhibit 92	Document entitled "Abortion Pill Reversal"	164
Exhibit 93A	RealOptions Standards	171
Exhibit 15	Appendix 1 to Dr. Creinin's studies	176

1	Exhibit 58	Progress notes for Subject 7	177
2	Exhibit 59	Progress notes for Subject 8	178
3	Exhibit 61	Subject 8's emergency room medical records	185
4			
5	Exhibit 35	Article titled "Clinical interventions are more accurate than quantitative measurements for defining hemorrhage with dilation and evacuation"	189
6			
7	Exhibit 70	Investigational Agent Disposition Record for Subject 8	254
8			
9	Exhibit 64	Medical records dated August 6, 2025	271
10	Exhibit 63	Subject 7's reversal log for visit number 2 on Study Day 3	273
11	Exhibit 65	Subject 11's records	280
12	Exhibit 14	Article titled "Mifepristone antagonization With Progesterone to Prevent Medical Abortion"	296
13			
14	Exhibit 16	Document with subheading "Protocol and SAP date: July 18, 2019 (version 10)"	338
15			
16	Exhibit 21	ACOG statement dated July 21, 2022	340
17	Exhibit 18	Current statement by ACOG	342
18	Exhibit 115	Warning letter from Health & Human Services	344
19	Exhibit 67	Mifepristone stakeholders' meeting	358
20	Exhibit 68	Email containing mifepristone stakeholders meeting	364
21			
22	Exhibit 69	Mifepristone reversal study talking points	366
23	Exhibit 38	Document titled "Receptors, agonists and antagonists"	377
24			
25	Exhibit 76	video	379

1	Exhibit 109	Article titled "The Antiprogestin Steroid RU 486 and Human Fertility Control"	382
2			
3	Exhibit 19	Expert Report of Monique Chireau Wubbenhorst	388
4			
5	Exhibit 9	Document titled "Effects of Depot Medroxyprogesterone Acetate Injection Timing on Medical Abortion Efficacy and Repeat Pregnancy"	393
6			
7	Exhibit 25	Document titled "Medication Abortion Up to 70 Days of Gestation"	398
8			
9	Exhibit 13	Dr. Creinin's analysis of study	404
10	Exhibit 110	Article entitled "Plasma Concentrations and Receptor Binding of RU 486 and Its Metabolites in Humans"	417
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

Friday, October 10, 2025

8:31 a.m.

08:31
08:31
08:31
08:31
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:32
08:33

THE VIDEOGRAPHER: We are now on the record. Today's date is October 10th, 2025, and the time is 8:32 a.m. Pacific Daylight Time. This is the video deposition of Mitchell D. Creinin, M.D., in the matter of The People of the State of California versus Heartbeat International, Inc., et al., filed in the Superior Court of the State of California, County of Alameda, Case Number 23CV044940.

This deposition is taking place via web videoconference with all participants attending remotely.

My name is Marcela Sandoval. I'm the videographer representing the Sullivan Group of Court Reporters.

Would counsel at the conference please identify yourself and state whom you represent, beginning with the questioning attorney.

MR. JONNA: Good morning, Paul Jonna on behalf of defendants, Heartbeat International and RealOptions.

MS. PENAN: Good morning, Hayley Penan on behalf of plaintiff, The People of the State of

1 California. And Karli Eisenberg from our office 08:33
2 will also be joining. 08:33

3 THE VIDEOGRAPHER: The court reporter will 08:33
4 now introduce herself and then swear in the 08:33
5 witness. 08:33

6 THE REPORTER: Yes. My name is Grace
7 Chung, CSR Number 6246, a code-compliant reporter. I
8 will be producing a transcript of this proceeding
9 that is automatically admissible in court.

10 MITCHELL CREININ, M.D.,
11 having been first duly sworn or affirmed, was
12 examined and testified as follows:

13
14 EXAMINATION

15 BY MR. JONNA:

16 Q. Good morning, Dr. Creinin. My name is 08:33
17 Paul Jonna. And as I said, I -- I represent the 08:33
18 defendants in this case. 08:33

19 Can we have you start off by stating and 08:33
20 spelling your full name for the record. 08:33

21 A. It's Mitchell Creinin; M-I-T-C-H-E-L-L,
22 C-R-E-I-N-I-N. 08:33

23 Q. Have you ever had your deposition taken 08:33
24 before? 08:33

25 A. Yes. 08:33

1 Q. Approximately how many times? 08:34

2 A. Once. 08:34

3 Q. And do you remember when that occurred? 08:34

4 A. It was for the partial birth abortion 08:34

5 cases, so whenever that was. 08:34

6 Q. Were you serving as an expert witness or a 08:34

7 fact witness or a party, if you remember? 08:34

8 A. I guess an expert witness. 08:34

9 Q. Can you briefly summarize your role in 08:34

10 that litigation? 08:34

11 A. I was an expert witness for Planned 08:34

12 Parenthood Federation of America, who was bringing 08:34

13 suit against the attorney general. 08:34

14 Q. Do you remember where that lawsuit was 08:34

15 filed? 08:34

16 A. In San Francisco. 08:34

17 Q. Do you remember the outcome of the 08:34

18 lawsuit? 08:34

19 A. That specific part of the case was won by 08:34

20 Planned Parenthood, it eventually went to the 08:35

21 Supreme Court, because there were three -- I 08:35

22 believe three cases going on across the country, 08:35

23 and the Supreme Court, I believe, then ruled 08:35

24 otherwise. 08:35

25 Q. Did you testify in a court proceeding or 08:35

1 just in a deposition? 08:35

2 A. In a deposition, and then in the court 08:35

3 proceeding, both. 08:35

4 Q. Can you briefly summarize what opinions 08:35

5 you provided in that case? 08:35

6 A. My opinions were related to what happens 08:35

7 during abortions that are performed in the 08:35

8 mid-to-late second trimester and the procedures and 08:35

9 how they are performed and what can be necessary or 08:35

10 not necessary to safely provide those procedures. 08:35

11 Q. Okay. Do you remember what year that -- 08:35

12 your deposition occurred in? 08:35

13 A. Honestly, it was probably around 20 years 08:36

14 ago. I don't remember the exact year. 08:36

15 Q. Okay. 08:36

16 A. But I can go online and look it up right 08:36

17 now, if you would like. 08:36

18 Q. No, that's all right. Let's just briefly 08:36

19 go through some of the admonitions and ground rules 08:36

20 for a deposition since it's been some time. 08:36

21 The first and most important thing to keep 08:36

22 in mind today is that you are under oath, and the 08:36

23 oath that you took has the same force and effect as 08:36

24 it would if you were testifying in court before a 08:36

25 judge and a jury, and the same penalties of perjury 08:36

1 apply. 08:36

2 Do you understand that? 08:36

3 A. Yes. 08:36

4 Q. As you can tell, there is a court reporter 08:36
5 transcribing the testimony today. So it's 08:36
6 important that we do our best not to talk over each 08:36
7 other. I will do my best not to interrupt you when 08:36
8 you're answering my question. And I just ask for 08:36
9 you to wait for my question to finish before you 08:36
10 start to answer. 08:36

11 In addition, the court reporter can't take 08:36
12 down any non-verbal gestures or shrugs of the 08:36
13 shoulder, "uh-huh" or "huh-uhs." So we need a clear 08:36
14 record today. 08:36

15 So does that make sense? 08:36

16 A. Yes. 08:37

17 Q. All right. If I ask a question that you 08:37
18 would like me to rephrase or clarify, please let me 08:37
19 know. I'd be happy to do so. Otherwise, if you 08:37
20 answer the question, it will be assumed that you 08:37
21 understood the question. Does that make sense? 08:37

22 A. Yes. 08:37

23 Q. I'm entitled to your best recollection. 08:37
24 Some of the questions might require you to go back 08:37
25 a few years, and I'm entitled to your best 08:37

1 estimate, but I don't want you to guess or 08:37
2 speculate. You understand the difference between 08:37
3 the two; correct? 08:37

4 A. Yes. 08:37

5 Q. At the end of the deposition, there will 08:37
6 be a transcript generated. You will have a chance 08:37
7 to review the transcript and make sure your 08:37
8 testimony is as accurate as possible. 08:37

9 I will just caution you that if you make 08:37
10 substantive changes to your testimony after the fact, 08:37
11 that can be commented on at a future proceeding and 08:37
12 it can affect your credibility. So I mean, like, 08:37
13 changing a yes to a no, something like that. So it's 08:37
14 our goal to get your best testimony today. 08:37

15 Does that make sense? 08:37

16 A. Yes. 08:37

17 Q. If you need to take a break today, just 08:37
18 let me know. I will be happy to accommodate you. 08:37
19 This will be a long day. I will try to take a 08:38
20 break every hour or so. I just ask that if there 08:38
21 is a question pending, you answer the question, and 08:38
22 then we take a break. Does that make sense? 08:38

23 A. Yes. Also, so you are aware, I'm 08:38
24 recovering from COVID, so I may need a few more 08:38
25 breaks than the average person. 08:38

1 Q. Sure. Just -- just let us know. 08:38

2 Your counsel, the attorney general, who is 08:38

3 present today, is likely going to make objections. 08:38

4 Those objections are for the record. They will be 08:38

5 ruled on at a later time by a judge. So I would just 08:38

6 encourage you to pause for a second, after I ask my 08:38

7 question, give Ms. Penan a chance to make her 08:38

8 objection. But then immediately proceed to answer 08:38

9 the question as long as you understand the question. 08:38

10 Does that make sense? 08:38

11 A. Yes. 08:38

12 Q. There are quite a bit of exhibits that we 08:38

13 are going to go through today, and I'm not sure if 08:38

14 we are going to finish today. I'm going to do my 08:38

15 best to. But there are a few things we can do to 08:38

16 make this process go by a little faster. I'm going 08:38

17 to suggest a few things. 08:39

18 If I ask you a question that calls for a 08:39

19 yes or no, and you can't answer with a yes or no, I 08:39

20 would ask you to do that and not anticipate the 08:39

21 next question. But you will have a chance, at a 08:39

22 later time, to give your full testimony when the 08:39

23 attorney general calls you as a witness. But 08:39

24 today, I would ask that you just focus on the 08:39

25 questions I'm asking and answer those questions, to 08:39

1 the extent you can. Of course, if you need to 08:39
2 provide more context besides a yes or no, please 08:39
3 do, I want you to have that opportunity, but that 08:39
4 will make the deposition go by faster today. 08:39

5 Is that fair? 08:39

6 A. Yes. 08:39

7 Q. I will be showing you exhibits through 08:39
8 this platform. Your counsel has asked me to also 08:39
9 put them on the chat, which we will do. A lot of 08:39
10 the exhibits are voluminous and a lot of them you 08:39
11 have seen. If you need time to review them, please 08:39
12 let me know. I want you to have the time that you 08:39
13 need to review the exhibits. But a lot of times, 08:39
14 I'm going to be focusing on specific segments of a 08:39
15 large document in asking a question, so what I 08:39
16 would encourage you to do is give me a chance to 08:39
17 ask the question, and if you still need to review 08:40
18 more of the deposition, just let me know and I will 08:40
19 be happy to accommodate that. Is that fair? 08:40

20 A. Yes. 08:40

21 Q. Just to clarify, is there anyone in the 08:40
22 room with you today, where you are at? 08:40

23 A. Not in this room. 08:40

24 Q. Okay. I would also ask that you please 08:40
25 put your phone on airplane mode or turn it off so 08:40

1 that we make sure that there is no interference. 08:40
2 Is that okay? 08:40
3 A. It's already done. 08:40
4 Q. Okay. 08:40
5 Are you under the influence of any 08:40
6 medications that could affect your ability to 08:40
7 recall facts today? 08:40
8 A. No. 08:40
9 Q. Is there any reason why you can't give 08:40
10 your best testimony today? 08:40
11 A. No. 08:40
12 Q. Did you speak with anyone to prepare for 08:40
13 your deposition today? 08:40
14 A. Yes. 08:40
15 Q. Who? 08:40
16 A. Haley and Karli, who are on the call with 08:40
17 us. 08:40
18 Q. Other than Haley and Karli, did you speak 08:40
19 to anyone else to prepare for your deposition 08:41
20 today? 08:41
21 A. No. 08:41
22 Q. And approximately how many times did you 08:41
23 speak to them to prepare for your deposition? 08:41
24 A. Three times. 08:41
25 Q. Do you remember approximately when those 08:41

1 conversations occurred? 08:41

2 A. Last weekend, earlier this week -- I'm 08:41

3 sorry, last week, yeah. 08:41

4 Q. Okay. Do you know approximately how long 08:41

5 those conversations lasted? 08:41

6 A. Anywhere from 45 to 90 minutes. 08:41

7 Q. Okay. 08:41

8 A. To the best of my recollection. 08:41

9 Q. Were these in-person meetings or phone 08:41

10 calls? 08:41

11 A. Virtual. 08:41

12 Q. Virtual meetings. Okay. 08:41

13 Did you review documents to prepare for 08:41

14 deposition? 08:41

15 A. Do you mean during those meetings or on my 08:41

16 own? 08:41

17 Q. Either. 08:41

18 A. Yes. 08:41

19 Q. Can you identify the ones you remember 08:41

20 viewing? 08:41

21 A. We went through my expert statement. We 08:41

22 reviewed the manuscript that I wrote related to my 08:42

23 study on mifepristone and progesterone or 08:42

24 mifepristone antagonization. We reviewed some 08:42

25 documents that have been -- were used in some of 08:42

1 the examinations of some of my colleagues, 08:42
2 specifically related to transgender care. And 08:42
3 those are the ones I can remember to the best of my 08:42
4 recollection right now. 08:42

5 Q. Which colleagues are you referring to? 08:42

6 A. I believe you took depositions from 08:42
7 Dr. Melody Hou and Dr. Melissa Chen and Courtney 08:42
8 Overstreet. 08:42

9 Q. Which documents from their deposition did 08:42
10 you review? 08:42

11 A. The ones that I just mentioned. 08:43

12 Q. Did you speak to those -- 08:43

13 A. I -- I believe we also reviewed some of 08:43
14 the medical records that you reviewed in their 08:43
15 depositions related to some of the participants in 08:43
16 the study. 08:43

17 Q. Had you reviewed those before -- 08:43

18 (Speakers talking simultaneously.) 08:43

19 BY MR. JONNA: 08:43

20 Q. -- the recent time? 08:43

21 A. Some of them, I had reviewed years ago at 08:43
22 the time of the study, but not subsequently. 08:43

23 Q. Some of them you hadn't reviewed before, 08:43
24 though? 08:43

25 A. No. 08:43

1 Q. Is that yes? 08:43
2 A. No. 08:43
3 Q. No, you had reviewed all of them before? 08:43
4 A. No, I had not reviewed -- 08:43
5 Q. Okay. I am just going to make -- 08:43
6 A. -- all of them. 08:43
7 Q. Sorry, I just want to make sure we have a 08:43
8 clear transcript. So which ones do you remember 08:43
9 reviewing before? 08:43
10 A. For the medical records? 08:43
11 Q. Yes. 08:43
12 A. The -- the ones that were from their 08:43
13 participant study records. 08:43
14 Q. Which one do you remember not reviewing 08:44
15 before? 08:44
16 A. Some of -- some of the records that were 08:44
17 in the participants' electronic medical records. 08:44
18 Q. Does anything stand out to you as -- that 08:44
19 you can identify as you sit here today, as a 08:44
20 document specifically you remember not seeing 08:44
21 before? 08:44
22 A. The ambulance transfer records for some of 08:44
23 the participants. 08:44
24 Q. Okay. Did you -- are there any other 08:44
25 documents that you haven't identified that you 08:44

1 remember reviewing to prepare for your deposition? 08:44

2 A. Not to the best of my recollection. 08:44

3 Q. I know you had three meetings, long 08:44

4 meetings with -- with counsel, but can you do your 08:44

5 best to give us a summary of what was discussed at 08:44

6 those meetings? 08:44

7 A. Some of the statements in my expert 08:44

8 statement that may be discussed today, and some of 08:44

9 -- and the questions that you raised during the 08:45

10 depositions of my colleagues and how -- and some of 08:45

11 the things you said earlier about how the texts 08:45

12 from some of the documents we are going to review 08:45

13 today may be communicated during the deposition. 08:45

14 Q. And did you review any deposition 08:45

15 transcripts from this case to prepare for your 08:45

16 deposition? 08:45

17 A. No. 08:45

18 Q. Did you speak to Drs. Chen or -- or Hou to 08:45

19 prepare? 08:45

20 A. No. 08:45

21 Q. Courtney Overstreet? 08:45

22 A. No. 08:45

23 Q. Okay. Did you speak to any of the other 08:45

24 expert witnesses in this case to prepare for the 08:45

25 deposition? 08:45

1 A. No. 08:45

2 Q. All right. I'm going to show you 08:45

3 Exhibit 1, which is The People's Expert Witness 08:46

4 Designation and Declaration of Haley Penan. Does 08:46

5 that show up on your screen? 08:46

6 A. It does. 08:46

7 (Deposition Exhibit 1 was marked for 08:46

8 identification by the reporter and is 08:46

9 attached hereto.) 08:46

10 BY MR. JONNA: 08:46

11 Q. Okay. We -- we removed the -- 08:46

12 A. Can I ask a question? 08:46

13 Q. Of course. 08:46

14 A. It came up on the chat as well. Is it 08:46

15 okay if I open up the one that came through on the 08:46

16 chat, or should I just be looking at the screen? 08:46

17 Q. Well, that's a good question. I think it 08:46

18 would be easier if you looked at the screen because 08:46

19 I'm going to direct you to certain pages. However, 08:46

20 if you want to pull up -- if you can pull up both 08:46

21 and you want to skim the document yourself, feel 08:46

22 free to, but I'm going to be directing you to 08:46

23 certain pages. Whatever is easier for you, 08:46

24 truthfully, but -- 08:46

25 A. Well, let's go through what you have on 08:46

1 the screen, and we will see if I need more 08:46

2 clarification. 08:46

3 Q. All right. So this is a document that had 08:46

4 the CVs of all the experts, but we removed the 08:46

5 others from here. So it's dated June 18th, 2025. 08:46

6 It's a 160-page PDF. But I'm going to go to page 9 08:47

7 here. Let me see something. For some reason, mine 08:47

8 is not showing page numbers on the top here. Oh, 08:47

9 I've got to look on the bottom. 08:47

10 All right. Does this appear to be your 08:47

11 CV, Dr. Creinin? 08:47

12 A. Yes. 08:47

13 Q. Okay. So you attended Northwestern 08:47

14 University from 1982 to 1988, and you got your BS 08:47

15 and M.D.; is that correct? 08:47

16 A. Yes. 08:47

17 Q. And it says that you were an undergraduate 08:47

18 from 1982 to 1984, but that you didn't get your BS 08:47

19 until 1986. Is that right? 08:47

20 A. Yes. 08:47

21 Q. Was this like a joint accelerated program, 08:47

22 where the two degrees were essentially combined in 08:48

23 one program? 08:48

24 A. Yes. 08:48

25 Q. You did your residency at UC San 08:48

1 Francisco; correct? 08:48

2 A. Yes. 08:48

3 Q. Did you perform abortions during this 08:48

4 time? 08:48

5 A. Yes. 08:48

6 Q. Okay. Was this something that you had an 08:48

7 early interest in as a medical student? 08:48

8 A. No. 08:48

9 Q. After your residency at UC San Francisco, 08:48

10 you did two fellowships there, in family planning 08:48

11 and clinical research. Is that correct? 08:48

12 A. Yes. 08:48

13 Q. Did you have a preference, at the time, 08:48

14 about going into patient care or research? 08:48

15 A. My plan was to do both. 08:48

16 Q. On pages 10 and 11 of your CV, we have a 08:48

17 little summary of your career path. You were at 08:48

18 the University of Pittsburgh from 1994 to 2011. Is 08:48

19 that right? 08:48

20 A. Yes. 08:48

21 Q. And then you went to UC Davis? 08:49

22 A. Yes. 08:49

23 Q. What was the reason for the switch to UC 08:49

24 Davis? 08:49

25 A. I was recruited to the chair of the 08:49

1 department of obstetrics and gynecology. 08:49

2 Q. Okay. And during your time in 08:49

3 Pennsylvania, you were also associated with -- is 08:49

4 it Maggie women's research center? 08:49

5 A. Magee-Womens -- 08:49

6 Q. Magee. 08:49

7 A. -- Research Institute, yes. 08:49

8 Q. And what is that? 08:49

9 A. The hospital -- the women's hospital at 08:49

10 the University of Pittsburgh is Magee-Womens 08:49

11 Hospital. The Magee-Womens Research Institute is a 08:49

12 research infrastructure for the department, which 08:49

13 is collaborative with other departments throughout 08:49

14 the university to perform clinical, translational, 08:49

15 and benchtop research. It's the largest 08:49

16 freestanding women's health-focused research 08:49

17 institute in the country. 08:49

18 Q. And what was your role there? 08:50

19 A. I was the director of the Center for 08:50

20 Family Planning Research, which was a clinical 08:50

21 research entity. 08:50

22 Q. And you were also the director of women's 08:50

23 health services in Pittsburgh? 08:50

24 A. Yes. 08:50

25 Q. What was your role there? 08:50

1 A. I was the medical director of the clinic. 08:50

2 Q. And you were the medical director of 08:50

3 Planned Parenthood of Western Pennsylvania; 08:50

4 correct? 08:50

5 A. Subsequent to the prior role, yes. 08:50

6 Q. And what did that role entail? 08:50

7 A. Being the medical director of a Planned 08:50

8 Parenthood clinic. 08:50

9 Q. Right. What were your responsibilities in 08:50

10 that position? 08:50

11 A. To provide services and to oversee medical 08:50

12 policies for the provision of reproductive and 08:50

13 other healthcare at the clinic. 08:50

14 Q. And in 2004, you were a founding member of 08:50

15 the Society of Family Planning; is that right? 08:50

16 A. Yes. 08:51

17 Q. And what is the Society of Family 08:51

18 Planning? 08:51

19 A. It is the academic society of the 08:51

20 subspecialty of complex family planning within 08:51

21 obstetrics and gynecology. 08:51

22 Q. All right. In 2011, when you moved to UC 08:51

23 Davis, it looks like you continued as a professor, 08:51

24 but you also became the chief of obstetrics and 08:51

25 gynecology in the hospital; is that right? 08:51

1 Q. Okay. Well, why did it end? 08:52

2 A. Because the -- first, the study was 08:52
3 finished, and then the company, which was a 08:52
4 subsidiary of Mithra, which is the larger company, 08:53
5 was bought out by another company. So the role 08:53
6 ended. 08:53

7 Q. You were also an advisor to Danco 08:53
8 Laboratories; is that right? 08:53

9 A. Yes. 08:53

10 Q. That's not in the CV; correct? 08:53

11 A. Well, I'm not -- that was not a 08:53
12 non-academic advisory role, given a title like 08:53
13 that. 08:53

14 Right, and I should step back. What do 08:53
15 you mean as "advisor"? 08:53

16 Q. Well -- why don't you just tell me what -- 08:53
17 what role you had with Danco Laboratories. 08:53

18 A. I have had two roles with them. One is 08:53
19 since mifepristone became available, as a small 08:53
20 pharmaceutical company, they have responsibilities 08:53
21 to -- that are required by the -- the FDA to have 08:53
22 medical -- to be able to provide medical advice to 08:53
23 anybody who calls their company. 08:54

24 And since they don't have that -- those 08:54
25 types of people in their company, they contract with, 08:54

1 I think it's four experts around the country to be 08:54
2 available for medical questions. 08:54

3 So I've been doing that since 08:54
4 mifepristone became -- roughly since mifepristone 08:54
5 became available. I get paid \$300 a month to answer 08:54
6 questions from outside clinicians related to the use 08:54
7 of mifepristone. 08:54

8 The second role was when Danco went to the 08:54
9 FDA, or has gone to the FDA, related to its product, 08:54
10 they -- they contracted with my department for my 08:54
11 time to provide services related to the FDA 08:54
12 interactions for their product. So that was a 08:55
13 contract with the department for my time. 08:55

14 Q. So I used the word "advisor." What -- 08:55
15 what word would you use to describe your 08:55
16 relationship with Danco Laboratories? 08:55

17 A. One is a medical consultant for the first 08:55
18 one, and the second one was a contracted expert. 08:55

19 Q. Okay. Have you served as a medical 08:55
20 consultant or contracted expert for any other 08:55
21 entities that are not listed on your CV? 08:55

22 A. For any other entities not listed on my CV 08:55
23 that I can think of at this current time. Let me 08:55
24 take that back. 08:55

25 I have -- the ones listed on my CV are 08:55

1 official roles. I am contracted as a consultant by 08:55
2 numerous pharmaceutical companies and have been for 08:55
3 the last 30 years. So I think that's probably a more 08:55
4 correct answer. 08:56

5 Q. Can you identify some of those 08:56
6 pharmaceutical companies? 08:56

7 A. Yeah. Mayne Pharma, Gedeon Richter, OLIC 08:56
8 in Thailand, Libbs in Brazil. Years -- let's see. 08:56
9 Organon, Merck. Give me a moment to think through 08:56
10 some others. Femasys, Timo Research in Spain -- 08:56
11 it's actually Chemo Research. Exeltis. Lupin. 08:56

12 Do you want more? 08:56

13 Q. Is there a common theme with the types of 08:56
14 drugs that you were providing consulting on? 08:56

15 A. Almost all of those are contraceptives. 08:57

16 Q. Any other types of drugs that you can 08:57
17 think of? 08:57

18 A. Not at the current time. 08:57

19 Q. Are there any other positions that -- 08:57
20 during your time in Pittsburgh or Davis, that are 08:57
21 not listed on the CV that we should know about? 08:57

22 A. Not that I can think of at the current 08:57
23 time. 08:57

24 Q. So currently at UC Davis, how do you split 08:57
25 your time between teaching and your practice? 08:57

1 A. I'm slightly more than 20 percent 08:57
2 clinical, and 20 percent time is the family 08:57
3 planning -- complex family planning fellowship 08:57
4 director -- excuse me -- and the remainder of my 08:57
5 time is research and teaching and administrative 08:58
6 work. 08:58

7 Q. Okay. For your clinical practice, what 08:58
8 does that involve? 08:58

9 A. It's kind of -- it's primarily focused on 08:58
10 complex family planning. I do -- also do 08:58
11 gynecological. And when I'm in the clinic with 08:58
12 residents in their general clinic, I do prenatal 08:58
13 care. 08:58

14 Q. How would you divide up between those 08:58
15 three? Like what percentage do you estimate -- how 08:58
16 does it break down? 08:58

17 A. My clinical time, I -- I'm probably in the 08:58
18 resident clinic once or twice, one or two half days 08:58
19 a month. The rest of the time is family 08:58
20 planning-focused. Some of it is my family planning 08:58
21 faculty clinic, in which I would say about a third 08:58
22 of the patients are general gynecology and not 08:58
23 family planning focused. 08:58

24 Q. So one-third general gynecology and then 08:59
25 two-thirds family planning? 08:59

1 A. Well, there is also some time that is 08:59
2 prenatal care when I'm in the resident clinic. 08:59

3 Q. Is that -- 08:59

4 A. I would say about 15 percent prenatal 08:59
5 care, 15 percent -- actually, 15 percent prenatal 08:59
6 care, 25 percent gynecology, and the rest family 08:59
7 planning. That's an estimate. 08:59

8 Q. How would you -- what is the best way you 08:59
9 characterize your clinical practice throughout your 08:59
10 career in terms of the breakdown between those 08:59
11 three, not just currently, but, you know, since 08:59
12 you've been a doctor? 08:59

13 A. Probably the vast majority is family 08:59
14 planning related, but probably about 75 percent 08:59
15 family planning, 20 percent gynecology, and 5 08:59
16 percent OB, prenatal care. It does vary over time, 08:59
17 depending on where I am -- where I was, excuse me. 09:00
18 But that's an estimate. 09:00

19 Q. I believe your declaration says that you 09:00
20 provided abortions to more than 5,000 women; is 09:00
21 that right? 09:00

22 A. That's my best estimate. 09:00

23 Q. Is it more than 10,000 women? 09:00

24 MS. PENAN: Objection. Asked and 09:00
25 answered. 09:00

1 A. I estimate, right now, more than 5,000. 09:00

2 BY MR. JONNA: 09:00

3 Q. Okay. Just to be clear on the 09:00

4 terminology, family planning refers to abortions; 09:00

5 correct? 09:00

6 A. Family planning includes abortions, but 09:00

7 it's much more than just abortions. 09:00

8 Q. What else does it include? 09:01

9 A. Family planning is early pregnancy care, 09:01

10 abortions, miscarriage, pregnancies of unknown 09:01

11 location, ectopic pregnancy, and then -- and that's 09:01

12 on the pregnancy side. And then contraception. It 09:01

13 -- it includes, at least in our practice, also 09:01

14 recurrent pregnancy loss. 09:01

15 Q. And what does "complex family planning" 09:01

16 refer to? 09:01

17 A. That's our subspecialty title. 09:01

18 Q. Rights. So what's the difference between 09:01

19 family planning and complex family planning? 09:01

20 A. That's the same thing. 09:01

21 Q. Would complex family planning also include 09:01

22 late-term abortions? 09:01

23 A. There is no such thing as late-term 09:01

24 abortions, so can you please clarify your 09:01

25 statement? 09:01

1 Q. You have no -- you've never referred to 09:01
2 "late-term abortions" in your practice? 09:02
3 A. The term for pregnancy is 40 weeks. So 09:02
4 can you please define what "late term" means? Late 09:02
5 term would refer to after 40 weeks. So if you want 09:02
6 to -- you can clarify your statement. I can answer 09:02
7 your question. 09:02
8 Q. Second- or third-trimester abortions. 09:02
9 A. So can you repeat the question, then, 09:02
10 using "second- or third-trimester abortions"? 09:02
11 Q. Would complex family planning include 09:02
12 second- and third-trimester abortions? 09:02
13 A. In our current practice, it includes 09:02
14 second-trimester abortions. 09:02
15 Q. Not third-trimester abortions? 09:02
16 A. If you want to define what you consider 09:02
17 the "third trimester." 09:02
18 Q. Do you have an understanding of what 09:02
19 "third trimester" means? 09:02
20 A. For some people, it's after 26 weeks. For 09:02
21 some people, it's after 28 weeks. So if you want 09:02
22 to clarify what you mean, I can answer the 09:02
23 question. 09:02
24 Q. How do you define it? 09:02
25 A. I define it as after 28 weeks. 09:02

1 Q. Okay. If we define it as after 26 weeks, 09:02
2 would your practice include third-trimester 09:03
3 abortions? 09:03

4 A. Right now, I don't provide those 09:03
5 procedures. I have in the past, but I don't 09:03
6 currently. 09:03

7 Q. Okay. Is there a reason for that? 09:03

8 A. I stopped doing surgery a couple of years 09:03
9 ago for the more advanced procedures. 09:03

10 Q. Okay. How would you divide your 09:03
11 practice -- your family planning practice, 09:03
12 specifically focusing on abortions between surgical 09:03
13 and medication? 09:03

14 A. My practice currently is office-based. So 09:03
15 when I provide abortions, I would say currently 09:03
16 about 80 percent of the abortions I provide are 09:03
17 medication and 20 percent are procedural. 09:03

18 Q. And has that changed over the course of 09:03
19 your practice? 09:03

20 A. And do you mean the course of my practice 09:04
21 going back to when I first started practicing? 09:04

22 Q. Yes. 09:04

23 A. Yes, because medication abortion has 09:04
24 increased in utilization. And also, my practice 09:04
25 wasn't office-based, only years ago. So it has 09:04

1 changed. It used to be primarily procedural with 09:04

2 less medication, and it's shifted over time. 09:04

3 Q. Okay. So focusing on the procedural 09:04

4 abortions, what percentage of the ones that you 09:04

5 performed were first trimesters, approximately? 09:04

6 A. In what time frame are you talking about? 09:04

7 Q. Just scanning your entire practice. 09:04

8 A. Probably 50 percent. 09:05

9 Q. How about second trimester? 09:05

10 A. The other 50 percent. 09:05

11 Q. And third trimester? 09:05

12 A. Less than 1 percent. 09:05

13 Q. Can you describe your prenatal practice? 09:05

14 A. So when I'm in the resident clinic 09:05

15 supervising residents. So it would be generally 09:05

16 low-risk obstetric patients, and some high-risk 09:05

17 mixed in, throughout pregnancy duration. 09:05

18 Q. Okay. How often do you deliver babies? 09:05

19 A. I don't. 09:05

20 Q. When is the last time you delivered a 09:06

21 baby? 09:06

22 A. 1994. 09:06

23 Q. About how many babies have you delivered 09:06

24 in the course of your career? 09:06

25 A. Four or 500. 09:06

1 Q. Is there a reason why you stopped in 1994? 09:06

2 A. When I moved from UCSF to UPMC, my role 09:06
3 was to primarily focus on family planning and 09:06
4 gynecology. I originally was hired with the intent 09:06
5 that I would still cover labor-and-delivery call, 09:06
6 but the way they decided to change how they were 09:06
7 staffing labor and delivery, when I moved there in 09:06
8 1984, that didn't work out. So I wasn't able to 09:06
9 continue the obstetric services as I had been doing 09:06
10 previously. 09:06

11 Q. Why did you decide to focus your practice 09:07
12 on family planning? 09:07

13 A. Because during my residency, it became my 09:07
14 focus of interest. 09:07

15 Q. What was it about it that interested you? 09:07

16 A. The care for women who were in need, at 09:07
17 crossroads in their life, was -- and the ability to 09:07
18 help women and their families at that point was 09:07
19 incredibly interesting, as well as the potential 09:07
20 research I could do really stimulated me. 09:07

21 Q. So in your current role, when you provide 09:07
22 abortions, who's compensating you? 09:07

23 A. I am paid a salary by the University of 09:07
24 California, Davis. 09:07

25 Q. So the State of California? 09:07

1 A. My paycheck comes from the State of 09:08

2 California. 09:08

3 Q. And who provides funding for the office 09:08

4 where you provide abortions? 09:08

5 A. What do you mean by "provides funding for 09:08

6 the office"?

7 Q. Where do you provide abortions? 09:08

8 A. At the University of California, Davis. 09:08

9 Q. Okay. And how many clinical trials have 09:08

10 you been the principal investigator with the 09:08

11 oversight of an institutional review board? 09:08

12 A. Pretty much every trial in my CV. And the 09:08

13 actual number is in my expert statement. I'd have 09:08

14 to go back and count again, just like I did for my 09:08

15 expert statement. But clinical trials are 09:08

16 always -- such as human clinical trials, every 09:08

17 single one is under the auspice of an IRB. 09:08

18 Q. Would you agree that you are very familiar 09:08

19 with how to conduct a safe clinical trial? 09:08

20 A. Yes. 09:08

21 Q. And you would agree that part of 09:09

22 conducting a safe clinical trial includes reporting 09:09

23 serious and adverse events to the IRB? 09:09

24 A. Yes. 09:09

25 Q. And would you say you are very familiar 09:09

1 with determining when a serious adverse event needs 09:09
2 to be reported to the IRB? 09:09
3 A. Yes. 09:09
4 Q. When would you report a safety event to 09:09
5 the IRB? 09:09
6 A. When it meets the criteria as established 09:09
7 by the FDA for a serious adverse event. 09:09
8 Q. Can you describe those criteria, to the 09:09
9 best of your ability? 09:09
10 A. Hospitalization, death, causing a fetal 09:09
11 anomaly, an event that -- or an intervention that 09:09
12 would otherwise prevent any other reason for 09:09
13 reporting an adverse event, a detailed one. For 09:09
14 example, an event that is performed to prevent 09:09
15 hospitalization, an event -- during the 09:10
16 hospitalization that prolongs hospitalization. 09:10
17 And there may be one more, but that's the 09:10
18 primary list. 09:10
19 MS. PENAN: I'm sorry. Just a quick 09:10
20 objection. Vague, ambiguous, and incomplete 09:10
21 hypothetical. 09:10
22 BY MR. JONNA: 09:10
23 Q. Is it generally the sponsor or the 09:10
24 investigator who reports to the IRB? 09:10
25 A. It is generally the investigator. 09:10

1 Q. Okay. So on page 4 of your CV here, 09:10

2 page 12 of the PDF, we see "Professional 09:10

3 Memberships." Do you see that? 09:10

4 A. Yes. 09:10

5 Q. And it includes National Abortion 09:10

6 Federation, the International Society of Abortion 09:10

7 Doctors, and Planned Parenthood. 09:10

8 A. The last one is misrepresented. 09:10

9 Q. In which way? 09:10

10 A. It's Planned Parenthood Federation of 09:10

11 American Medical Directors Council. You don't 09:11

12 belong to Planned Parenthood. 09:11

13 Q. Okay. And what is that organization? 09:11

14 A. That is the Council of Medical Directors 09:11

15 of Planned Parenthood Federation affiliates. 09:11

16 Q. Okay. 09:11

17 A. And you can see that I'm an emeritus 09:11

18 member, which means I used to be a medical 09:11

19 director. 09:11

20 Q. So other than this case and the partial 09:11

21 abortion case you mentioned, you haven't been an 09:11

22 expert witness in any other cases, as far as you 09:11

23 remember? 09:11

24 A. I did have another deposition. It just 09:11

25 dawned on me. That was a patent case. And I 09:11

1 apologize. It just dawned on me, because I was 09:11
2 thinking about these types of case. But I had an 09:11
3 oral contraceptive patent case, in which case I 09:11
4 gave a deposition. 09:12

5 Q. Were you an expert in that case? 09:12

6 A. Yes. 09:12

7 Q. Do you remember, generally, what you were 09:12
8 providing expert opinions on? 09:12

9 A. Pharmacology. 09:12

10 Q. I'm sorry? 09:12

11 A. Pharmacology. 09:12

12 Q. Okay. And you also spoke in favor of 09:12
13 Colorado's abortion pill reversal ban? 09:12

14 A. Yes. 09:12

15 Q. And have you spoken in other legislative 09:12
16 hearings? 09:12

17 A. Yes. 09:12

18 Q. Which ones? 09:12

19 A. I have testified in California, and I 09:12
20 honestly can't remember which bills they were. I 09:12
21 -- I can't remember. 09:12

22 Q. Did you offer testimony -- I'm sorry, go 09:12
23 ahead. 09:13

24 A. No. I said I could try to look them up at 09:13
25 some point, but I don't remember. 09:13

1 Q. Did you offer testimony before Congress in 09:13
2 opposition to the partial birth abortion ban? 09:13
3 A. For Congress, no. 09:13
4 Q. Before any other legislative body? 09:13
5 A. No. 09:13
6 Q. If we go back up a few pages here, it says 09:13
7 that your deposition fee is 250 an hour; is that 09:13
8 correct? 09:13
9 A. Yes. 09:13
10 Q. Is that the same rate you will charge the 09:13
11 attorney general for trial testimony? 09:13
12 A. Yes. 09:13
13 Q. And it's the same rate you charged the AG 09:13
14 for preparing your report, or was that 150 an hour? 09:13
15 A. That was 150 an hour. 09:13
16 Q. Okay. Is this a rate that you propose or 09:13
17 that the attorney general proposed to you? 09:13
18 A. It's a rate I proposed. 09:13
19 Q. Okay. It seems quite low for an 09:13
20 individual of your qualifications. How did you 09:14
21 determine that rate? 09:14
22 A. Because I was told that I had to come up 09:14
23 with some rate, and I was -- was willing to do this 09:14
24 for nothing. 09:14
25 Q. Why is that? 09:14

1 A. Because this is -- I consider this 09:14
2 important, that I don't need to profit off of this. 09:14

3 Q. Why do you consider this important? 09:14

4 A. Because this is -- this entire area from a 09:14
5 medical and intellectual and ethical standpoint is 09:14
6 very important to me, and there are times when your 09:14
7 time as an expert is worthy of compensation, and 09:14
8 there's times when you do it because it's the right 09:14
9 thing. 09:14

10 Q. Can you tell us why you think this is the 09:14
11 right thing and why it's important to you? 09:14

12 A. Those are all the -- part of the 09:15
13 information in my expert statement. 09:15

14 MS. PENAN: And objection. Compound. 09:15
15 BY MR. JONNA: 09:15

16 Q. Okay. Besides what's in your expert 09:15
17 statement, can you describe why you feel this issue 09:15
18 is so important to you? 09:15

19 A. Because this is my area of expertise, and 09:15
20 as one of the most qualified scientists and 09:15
21 clinicians in this area in the country, I feel this 09:15
22 is part of my responsibility to ensure that science 09:15
23 isn't twisted and that women get appropriate care 09:15
24 and counseling. It's just the right thing. 09:15

25 Q. Okay. Can you estimate approximately how 09:15

1 much time you've spent preparing your reports for 09:15
2 this case? And I guess there's two related cases 09:16
3 you provided reports -- is that right? -- those 09:16
4 federal lawsuits? 09:16
5 A. Whatever the other lawsuits were, yes. I 09:16
6 estimate my time -- I'd have to go back and look, 09:16
7 but probably somewhere in the range of 15 to 20 09:16
8 hours. 09:16
9 Q. Do you remember approximately how much 09:16
10 you've already invoiced the attorney general? 09:16
11 A. I thought it was 15 to 20 hours. You 09:16
12 multiply that by 150. 09:16
13 Q. Well, I'm wondering if you already 09:16
14 invoiced them or -- 09:16
15 A. In the prior time, yes. According to the 09:16
16 State of California, I'm supposed to invoice 09:16
17 monthly. 09:16
18 Q. Okay. 09:16
19 All right. Can you tell us when you first 09:16
20 learned about abortion pill reversal? 09:16
21 A. During the Nebraska -- when the Nebraska 09:16
22 law was passed. Excuse me. 09:16
23 Q. Do you remember approximately -- 09:16
24 A. Again, I'd have to look that up. 09:16
25 Q. Okay. Well, what's your understanding of 09:16

1 what the Nebraska law was? 09:16

2 A. It required -- 09:17

3 MS. PENAN: Objection. Calls for a legal 09:17

4 conclusion. 09:17

5 A. Okay. The law required physicians 09:17

6 providing medication abortion to inform patients 09:17

7 that there was the ability to reverse the effects 09:17

8 of mifepristone. 09:17

9 BY MR. JONNA: 09:17

10 Q. And how is it that you got involved with 09:17

11 that -- strike that. 09:17

12 When you -- how did you hear about that 09:17

13 Nebraska law? 09:17

14 A. On the news. 09:17

15 Q. Okay. And did you -- 09:17

16 A. And it's also possible that through emails 09:17

17 from national organizations or medical 09:17

18 organizations, I might have learned of it that way 09:17

19 as well. But I'm speculating for something that 09:17

20 was more than a decade ago, probably. I'm 09:17

21 actually -- yeah, way more than a decade ago. 09:17

22 Q. And about how much time have you spent 09:17

23 studying APR since -- since then? 09:18

24 A. Just this one study that you are going to 09:18

25 ask me about later. 09:18

1 Q. Okay. You also had a 2019 commentary 09:18
2 article with Dr. Chen about APR; isn't that right? 09:18

3 A. Yes. 09:18

4 Q. Did you write anything else about APR 09:18
5 before then? 09:18

6 A. Not that I can remember, to the best of my 09:18
7 recollection. 09:18

8 Q. There have been a series of other APR 09:18
9 lawsuits, but you weren't an expert witness in 09:18
10 those earlier cases; is that right? 09:18

11 A. No. 09:18

12 Q. That is right? 09:18

13 A. I was not. I apologize. 09:18

14 Q. Okay. So can you tell us why APR became 09:18
15 an interest of yours? 09:18

16 A. Because the science was horrible and laws 09:18
17 were being passed based on science that did not 09:18
18 support the laws. And as a researcher with an 09:19
19 expertise in this area, I felt that it was 09:19
20 important for someone who knew how to do research 09:19
21 to do this right, and if this really was something 09:19
22 that was real or not real, that women and 09:19
23 clinicians deserve to understand and know if 09:19
24 this -- whether it's real or not. 09:19

25 Q. Okay. What studies about APR have you 09:19

1 published? 09:19

2 A. Just the one study. 09:19

3 Q. Which -- which study? 09:19

4 A. The obstetrics and gynecology study. 09:19

5 Q. How -- how can we refer to that in 09:19

6 shorthand today? 09:19

7 A. You can call it my study, if you want, my 09:19

8 mifepristone, progesterone study, whatever you 09:19

9 want. You can -- you can just call it my 09:19

10 randomized trial. 09:19

11 Q. Have you published any other studies about 09:19

12 APR? 09:19

13 A. No. 09:19

14 Q. Do you consider yourself an expert on APR? 09:20

15 A. I don't think you can be an expert on 09:20

16 anything that is probably not real. So I have 09:20

17 my -- I have my expert opinions. 09:20

18 Q. Would you consider yourself an expert on 09:20

19 the subject of APR? 09:20

20 MS. PENAN: Objection. Vague, ambiguous. 09:20

21 Incomplete hypothetical. 09:20

22 BY MR. JONNA: 09:20

23 Q. I'm not asking you to assume that it's 09:20

24 real. I'm just asking if you consider yourself -- 09:20

25 a subject matter expert. 09:20

1 A. I would consider myself, given the 09:20
2 hormones and my expert knowledge of hormones and 09:20
3 pharmacology and pharmacodynamics and early 09:20
4 pregnancy and abortion and medication abortion, 09:20
5 that if that is what qualifies me as an expert, 09:20
6 then I would consider myself an expert under 09:20
7 those -- under that description. 09:20

8 Q. Is there anyone else that's opposed to the 09:20
9 concept of APR that you would consider more 09:20
10 knowledgeable about it than you are? 09:20

11 MS. PENAN: Objection. Vague, ambiguous, 09:21
12 incomplete hypothetical. 09:21

13 A. Yeah, I have to say that -- I would have 09:21
14 to say that's hypothetical, and I don't know -- we 09:21
15 don't sit around tables and compare our knowledge 09:21
16 on the topic. 09:21

17 BY MR. JONNA: 09:21

18 Q. But is there anyone that you can think of, 09:21
19 as you sit here today, that knows more about the 09:21
20 topic than you, who is opposed to APR? 09:21

21 MS. PENAN: Objection. Asked and 09:21
22 answered. 09:21

23 A. Yeah, I'd have to say I answered that. I 09:21
24 already answered your question. 09:21

25 BY MR. JONNA: 09:21

1 Q. And no one comes to mind? 09:21

2 MS. PENAN: Objection. Asked and 09:21

3 answered. 09:21

4 A. There are others who -- who know about the 09:21

5 subject and work on it, but whether they are more 09:21

6 knowledgeable than me or not, I can't answer that. 09:21

7 That's a comparative that -- that is unreal for me 09:21

8 to answer. 09:21

9 BY MR. JONNA: 09:21

10 Q. Okay. Would you agree that it would be 09:21

11 good if there was a safe and effective treatment 09:21

12 that reversed the effects of mifepristone? 09:21

13 MS. PENAN: Objection. Vague, ambiguous, 09:21

14 compound. Calls for speculation. Lacks 09:21

15 foundation. Incomplete hypothetical. 09:22

16 A. Yeah, I have no idea what you mean by 09:22

17 "good." 09:22

18 BY MR. JONNA: 09:22

19 Q. Would you agree that it would be a good 09:22

20 option for women who want to reverse the effects of 09:22

21 mifepristone to have a safe way to do so? 09:22

22 MS. PENAN: Same objections. 09:22

23 A. Would I agree it would be good? I agree 09:22

24 it would be good if we had medications that cured 09:22

25 cancer. I don't think this rises to the same 09:22

1 level. I mean, that's a vague question, because 09:22
2 it's an incredibly rare need. Whether it's good or 09:22
3 not is not my -- I don't have an expert opinion on 09:22
4 whether it's good or not, whether it's -- I don't 09:22
5 have an opinion. 09:22

6 BY MR. JONNA: 09:22

7 Q. Okay. Have you ever had a patient tell 09:22
8 you that they wanted to reverse their abortion 09:22
9 after taking mifepristone? 09:22

10 A. No. I've only had one patient approach 09:23
11 me, and it turns out she didn't want to reverse it; 09:23
12 she just decided she wanted surgery instead of 09:23
13 medications. But no. 09:23

14 Q. Have you ever heard of women being 09:23
15 involuntarily dosed with mifepristone? 09:23

16 A. No. 09:23

17 Q. What steps do you take in your practice to 09:23
18 make sure your patients aren't being pressured into 09:23
19 having an abortion? 09:23

20 A. I talk with them and I ask them. 09:23

21 Q. What do you tell them? 09:23

22 A. I make sure they know all of their 09:23
23 options, and ask them if they have support, and ask 09:23
24 them if they feel certain that this is how they 09:23
25 want to proceed. I try to do it in a setting where 09:23

1 they have already indicated. We always bring 09:23
2 patients back alone to the room, and if they have a 09:23
3 support person with them, we ask them first if they 09:23
4 feel comfortable, if they would rather talk with us 09:24
5 alone or with a support person. If there is 09:24
6 anything that's unusual, I will ask that other 09:24
7 person to leave. If I feel that there may be some 09:24
8 undue pressure. 09:24

9 But we ask women and we talk to them, and 09:24
10 they have had conversations, prior to being seen, 09:24
11 with somebody on the phone who they are making the 09:24
12 appointment with, the medical assistant who's 09:24
13 brought them back, as well as us, to provide -- and 09:24
14 in my current practice, all the counseling is done 09:24
15 by the physician, by us. 09:24

16 Q. Have you had patients who you've 09:24
17 determined were being pressured by a boyfriend or a 09:24
18 parent or someone else to have an abortion? 09:24

19 A. Yes. 09:24

20 MS. PENAN: Objection. Compound. 09:24

21 BY MR. JONNA: 09:24

22 Q. How do you approach those situations? 09:24

23 A. I usually will not provide the service, 09:24
24 especially at that initial visit. We'll have -- 09:24
25 ask them if they would be interested in talking to 09:24

1 a social worker or other support people. And if 09:24
2 somebody doesn't want to have an abortion, I won't 09:25
3 provide it. You know, even if somebody else is 09:25
4 pressuring them, even if they say, "No, I want to 09:25
5 because they're" -- you know, "it's the best thing 09:25
6 for me," we'll usually spend a lot more time, 09:25
7 multiple visits, before moving forward. 09:25

8 But it's not something where -- if people 09:25
9 -- the other thing that is important is that the 09:25
10 majority of people who are unsure will come in for 09:25
11 options counseling, not just come in for the 09:25
12 abortion. So they will come in with the idea that 09:25
13 they really want to talk about it first. 09:25

14 Q. Would you agree that it would be unethical 09:25
15 to perform an abortion on a patient who is being 09:25
16 pressured into having the abortion? 09:25

17 A. It would be unethical to provide an 09:25
18 abortion to a patient who independently decides she 09:25
19 really doesn't -- she does not want the abortion. 09:25
20 Whatever those reasons are, she doesn't want it, it 09:25
21 doesn't matter to me whether she's being pressured 09:25
22 or otherwise. If she doesn't want the abortion, 09:25
23 it's unethical to provide her with an abortion. 09:26

24 Q. How did you first learn -- 09:26

25 A. Just -- just like if she wants an 09:26

1 abortion, it's unethical to force her not to have 09:26
2 an abortion. 09:26

3 Q. Have you encountered those situations? 09:26

4 A. Yes, where patients have been manipulated 09:26
5 by their provider to try to delay -- an abortion to 09:26
6 the point where they couldn't have one, yes. 09:26

7 Q. Okay. All right. How did you first learn 09:26
8 about this lawsuit? 09:26

9 A. From, I believe -- again, this is to the 09:26
10 best of my recollection -- I was contacted by the 09:26
11 attorney -- the state attorney general's office. 09:26

12 Q. Shortly after the case was filed; correct? 09:26

13 A. I don't have expert knowledge of exactly 09:26
14 the timing of all those things. I'm sorry. 09:26

15 Q. Do you remember telling the attorney 09:27
16 general's office that you were excited to see that 09:27
17 the case was filed? 09:27

18 A. It's very possible I said I was excited, 09:27
19 because I'm very happy that the attorney general is 09:27
20 working to stop false advertising, whether it be in 09:27
21 this area or any other area that we, as consumers 09:27
22 in the State of California, are involved in. 09:27

23 Q. You understand that your role -- well, 09:27
24 actually, let me -- let me rephrase that question. 09:27

25 What is your understanding of what your 09:27

1 role is as an expert witness in a case? 09:27

2 A. To provide my expert opinion based on my 09:27

3 -- my expertise and knowledge. 09:27

4 Q. Do you have an understanding as to whether 09:27

5 you are supposed to be neutral and independent? 09:27

6 MS. PENAN: Objection. Compound. 09:27

7 A. What do you mean by "neutral and 09:27

8 independent"? 09:27

9 BY MR. JONNA: 09:27

10 Q. Do you have an understanding as to whether 09:27

11 an expert witness in a case should be providing 09:27

12 neutral and unbiased testimony to the court? 09:28

13 A. I provide -- 09:28

14 MS. PENAN: Objection. Compound. 09:28

15 A. I provide my opinions. 09:28

16 BY MR. JONNA: 09:28

17 Q. Right. My question is: Do you have an 09:28

18 understanding, for your role as an expert, as to 09:28

19 whether you are supposed to be providing neutral 09:28

20 and unbiased testimony? 09:28

21 MS. PENAN: Objection. Compound. Vague, 09:28

22 ambiguous. Asked and answered. 09:28

23 A. My role -- my understanding is that my 09:28

24 role is to provide my expert opinion. 09:28

25 BY MR. JONNA: 09:28

1 Q. So you don't have an understanding as to 09:28
2 whether your opinion should be neutral and 09:28
3 unbiased? 09:28

4 A. My opinion -- 09:28

5 MS. PENAN: Same objections. 09:28

6 A. My opinion is my opinion based on my 09:28
7 expertise. 09:28

8 BY MR. JONNA: 09:28

9 Q. Would you agree that, to some extent, your 09:28
10 reputation is at stake in this case as well? 09:28

11 MS. PENAN: Objection. Argumentative. 09:28
12 Misstates the witness's testimony. Ambiguous, 09:28
13 vague. 09:28

14 A. I don't have any concerns that my 09:28
15 reputation is at stake from providing expert 09:29
16 testimony for which I have expert knowledge. 09:29

17 BY MR. JONNA: 09:29

18 Q. What do you remember about the initial 09:29
19 conversation that you had with the attorney 09:29
20 general's office about being an expert in this 09:29
21 case? 09:29

22 A. To the best of my recollection, I can just 09:29
23 tell them I was more than happy to help them in any 09:29
24 way they needed. 09:29

25 Q. Do you remember who you spoke to 09:29

1 initially? 09:29

2 A. It may have been Haley. It may have been 09:29

3 someone else. I can't tell you. 09:29

4 Q. Did you know any of the attorney general's 09:29

5 lawyers on this case before you were retained as an 09:29

6 expert? 09:29

7 A. I may have encountered them in places, but 09:29

8 not that I really can remember, that I knew them. 09:29

9 Q. Okay. I'm going to turn to your 09:29

10 declaration. But we've been going about an hour. 09:29

11 Would you like a five-minute break, or should we 09:29

12 keep going? Are you doing okay? 09:29

13 A. I'm fine. We can -- maybe why don't we go 09:29

14 another 15, 20 minutes. 09:30

15 Q. Okay. 09:30

16 A. If you are okay with that. 09:30

17 Q. Sure. 09:30

18 All right. This is your amended expert 09:30

19 declaration. And if we scroll to page 29 -- is that 09:30

20 your signature there? 09:30

21 A. Yes, it is. 09:30

22 Q. All right. So in this declaration, you go 09:30

23 through your background, and then you discuss the 09:30

24 various drugs at issue, and then you turn to study 09:30

25 design and then APR. So I'll go in that order, 09:30

1 starting with progesterone. 09:30

2 Can you -- can you tell us the role of 09:30

3 progesterone in supporting pregnancy? 09:31

4 A. Progesterone -- 09:31

5 MS. PENAN: Objection. Incomplete 09:31

6 hypothetical. 09:31

7 A. Progesterone's role, in general, as an 09:31

8 overview, is to maintain the lining, the uterine 09:31

9 lining, so it doesn't shed during pregnancy. It 09:31

10 also has effects within the lining to ensure 09:31

11 maturation in a way that would -- that supports 09:31

12 pregnancy. Is that -- I think that's a basic 09:31

13 answer. 09:31

14 BY MR. JONNA: 09:31

15 Q. Can a woman get pregnant without 09:31

16 progesterone? 09:31

17 A. No. 09:31

18 Q. Can a woman remain -- 09:31

19 (Interruption.) 09:31

20 MS. PENAN: Apologies. 09:31

21 THE WITNESS: Neither can a dog. 09:31

22 BY MR. JONNA: 09:31

23 Q. Can a woman remain pregnant without 09:31

24 progesterone? 09:31

25 A. No. 09:31

1 Q. In order for progesterone to work to 09:31

2 maintain a pregnancy, is there a particular 09:31

3 receptor that it must bind to? 09:31

4 A. The progesterone receptor. 09:31

5 Q. Is there any known way for progesterone to 09:32

6 do its work without binding to that receptor? 09:32

7 A. Not that I'm aware of. 09:32

8 Q. Where are these progesterone receptors 09:32

9 located? 09:32

10 A. The ones specific to maintaining pregnancy 09:32

11 are in the -- in the lining of the uterus. 09:32

12 Q. Is there any known way for a pregnancy to 09:32

13 remain alive without progesterone binding to that 09:32

14 receptor? 09:32

15 A. There is no way for a pregnancy to 09:32

16 continue without progesterone binding to the 09:32

17 receptor. 09:32

18 Q. So you would agree that progesterone is 09:32

19 necessary for a pregnancy to survive? 09:32

20 MS. PENAN: Objection. Misstates the 09:32

21 witness's testimony. Asked and answered. 09:32

22 A. Progesterone is necessary for a pregnancy 09:32

23 to establish and to continue. 09:32

24 BY MR. JONNA: 09:32

25 Q. What indications is progesterone used for 09:32

1 in OB/GYN practice? 09:32

2 A. Menopause therapy, hormone therapy for 09:32
3 people that have premature ovarian insufficiency, 09:33
4 abnormal bleeding. And in select -- it's used in 09:33
5 assisted reproductive technologies, like IVF and 09:33
6 ovulation induction. It is used for miscarriage 09:33
7 prevention in select patients who meet specific 09:33
8 criteria. 09:33

9 I think those are the things that come to 09:33
10 the top of my head. 09:33

11 Q. Outside of the APR context, what is your 09:33
12 understanding of the risks of supplemental 09:33
13 progesterone during pregnancy? 09:33

14 MS. PENAN: Objection. Vague, ambiguous. 09:34
15 Incomplete hypothetical. Lacks foundation. 09:34

16 A. Do you -- can you specify short term or 09:34
17 long term, or what do you mean by "risks"? Because 09:34
18 -- when we talk about risks, we usually compare 09:34
19 risks to benefits. Everything is a risk-to-benefit 09:34
20 analysis, not just risks. But if you could 09:34
21 clarify, I'm happy to answer. 09:34

22 BY MR. JONNA: 09:34

23 Q. I mean, we can just break it down however 09:34
24 you think is most appropriate, short term first, I 09:34
25 guess. Basically, I want to get your -- what you 09:34

1 would tell a patient who asked you about the risks 09:34
2 of taking supplemental progesterone during 09:34
3 pregnancy. So how would you describe that? 09:34
4 MS. PENAN: Objection. Incomplete 09:34
5 hypothetical. Vague, ambiguous. 09:34
6 THE WITNESS: I'm sorry. Is that it? 09:34
7 Because I thought I heard somebody else talking, 09:34
8 too. 09:34
9 No, okay. 09:34
10 BY MR. JONNA: 09:34
11 Q. Go ahead, sir. 09:34
12 A. Okay. In the short term, from an adverse 09:34
13 event standpoint, there is minimal risks. From a 09:34
14 side effect standpoint, it can make people a little 09:34
15 sleepy, can slow bowel and cause constipation. 09:34
16 The -- in the long term, there are studies 09:35
17 that show that there is an association, although 09:35
18 it's -- they are not definitive -- with increased 09:35
19 risk of thyroid cancer. But that's an association. 09:35
20 That's it. 09:35
21 Q. Okay. And did you say it was used to 09:35
22 prevent preterm labor? 09:35
23 A. I didn't say that, but it was used in that 09:35
24 indication where the drug was taken off the market. 09:35
25 There are some -- there is some use in specific 09:35

1 patients -- and I thank you for adding that -- 09:35
2 where progesterone can be used with people with 09:35
3 short cervixes who are at increased risk of preterm 09:35
4 labor. So it's not just to prevent; it's used to 09:35
5 potentially decrease the risk -- the likelihood of 09:35
6 it happening. 09:35

7 Q. Is it safe and effective for that purpose? 09:35

8 MS. PENAN: Objection. Lacks foundation. 09:36
9 Incomplete hypothetical. Compound. Vague, 09:36
10 ambiguous. 09:36

11 A. It is safe in -- from the sense of 09:36
12 short-term side effects. Effectiveness is likely. 09:36
13 I'm not -- it's really specific. So vaginal 09:36
14 progesterone has been shown to be helpful in 09:36
15 patients with short cervixes at certain gestations 09:36
16 in pregnancy. So it's not universally beneficial. 09:36

17 Again, you have to meet -- it's only 09:36
18 beneficial in specific circumstances. 09:36

19 BY MR. JONNA: 09:36

20 Q. Is it used to treat secondary amenorrhea? 09:36

21 A. Yeah, that's one -- it's not a treatment 09:36
22 for secondary amenorrhea. People who have 09:36
23 secondary amenorrhea have reasons they are not 09:36
24 bleeding, as I said earlier, bleeding issues. So 09:36
25 it's used to help people -- some people, depending 09:36

1 on the cause of secondary amenorrhea, to -- it will 09:37
2 allow them to have a period or to shed their 09:37
3 lining, but it doesn't treat secondary amenorrhea. 09:37

4 Q. Is it used for abnormal bleeding in 09:37
5 menopausal women who have an overgrowth of uterine 09:37
6 lining? 09:37

7 A. It can be, as long as there is nothing 09:37
8 that is precancerous. But progesterone itself is 09:37
9 very -- it would be very rarely used. There would 09:37
10 be other progestins that would primarily be used in 09:37
11 that circumstance, but it can be. 09:37

12 Q. Is it used for excessive blood loss during 09:37
13 menstruation? 09:37

14 A. Typically not. Progesterone is weak 09:37
15 compared to other treatments for it. So can it be 09:37
16 used? Yes. If somebody was put on it, I would 09:37
17 have said that there's way better treatments, 09:37
18 because it doesn't work that well for that 09:38
19 indication compared to other progestin treatments. 09:38
20 It's just relatively weak for that. 09:38

21 Q. Is it used for hor -- hormonal therapy 09:38
22 after menopause? 09:38

23 A. Yes. That was part of my list earlier. 09:38

24 Q. And prevention and treatment of 09:38
25 endometrial hyperplasia? 09:38

1 A. Hyperplasia. 09:38

2 Q. Plasia. 09:38

3 A. That was similar to what you had said 09:38

4 earlier. It can be for people that have 09:38

5 hyperplasia that's not precancerous. Again, 09:38

6 there's way better treatments for it. 09:38

7 Q. And how about for treatment of luteal 09:38

8 phase defect? 09:38

9 (Reporter interruption for clarification.) 09:38

10 BY MR. JONNA: 09:38

11 Q. Luteal phase defect. 09:38

12 A. Luteal phase defect is -- it seems to be 09:38

13 very controversial, whether it's real or not -- 09:38

14 (Reporter interruption for clarification.) 09:39

15 A. -- whether it's real or not, because 09:39

16 people diagnose what luteal phase defects have the 09:39

17 same fertility as people who are not, which is why 09:39

18 decades ago we abandoned testing for it. 09:39

19 So there may be some people out there using 09:39

20 various treatments for it. 09:39

21 (Words garbled due to speakers talking 09:39

22 simultaneously.) 09:39

23 A. -- progesterone. 09:39

24 BY MR. JONNA: 09:39

25 Q. Sorry about that. 09:39

1	A. It may include progesterone.	09:39
2	Q. You did say it was used for IVF; correct?	09:39
3	A. Yes.	09:39
4	Q. And it's used as a form of birth control?	09:39
5	A. No. Progesterone is not used for birth	09:39
6	control.	09:39
7	Q. Okay. But progestins are?	09:39
8	A. Progestins are.	09:39
9	Q. What are progestins?	09:39
10	A. So they both fall under the -- the hormone	09:39
11	family of progestogens. So progestogens is the	09:39
12	family of -- progestogens come in natural types,	09:39
13	which includes -- which is progesterone or	09:39
14	synthetic types, which means they are not -- not	09:39
15	found naturally -- or not found in humans --	09:40
16	naturally, I guess. So those are purely	09:40
17	non-natural occurring hormones.	09:40
18	Q. So for the usages of progesterone that we	09:40
19	discussed, do you know which of these are off-label	09:40
20	usages?	09:40
21	MS. PENAN: Objection. Compound.	09:40
22	A. The pharmaceutical companies have sought	09:40
23	approval from regulatory authorities for their use	09:40
24	for hormone therapy, I believe, and for bleeding.	09:40
25	But I'd have to look at the label to tell you	09:40

1 exactly what it is, and you can pull the label up 09:40

2 just like I could. So... 09:40

3 BY MR. JONNA: 09:40

4 Q. What's your understanding of what 09:40

5 "off-label prescribing" refers to? 09:40

6 A. Off-label prescribing is a use of a drug 09:40

7 for a non-approved indication approval, meaning 09:41

8 that a company has gone to the regulatory 09:41

9 authorities, paid all the fees, gone through all 09:41

10 the required studies to gain approval to have a 09:41

11 label. So it's used beyond that in the setting of 09:41

12 appropriate scientific evidence that the treatment 09:41

13 is safe and effective for the indication. And you 09:41

14 should inform patients that it is off-label. Those 09:41

15 are the requirements of the FDA. 09:41

16 Q. And you would agree that off-label 09:41

17 prescribing is common practice across all fields of 09:41

18 medicine; correct? 09:41

19 MS. PENAN: Objection. Misstates the 09:41

20 witness's testimony. Argumentative. 09:41

21 A. Off-label prescribing is very common for 09:41

22 all indications. 09:41

23 BY MR. JONNA: 09:41

24 Q. And which of the usages that we discussed 09:41

25 of progesterone are you aware of are off-label 09:41

1 usages? 09:41

2 MS. PENAN: Objection. Asked and 09:41

3 answered. 09:42

4 A. It would be the ones I said that aren't in 09:42

5 the label. I mean, it's just a checklist. So... 09:42

6 BY MR. JONNA: 09:42

7 Q. Okay. Have you ever prescribed 09:42

8 progesterone? 09:42

9 A. Yes. 09:42

10 Q. For what purposes? 09:42

11 A. Hormone therapy, and in patients with 09:42

12 prior pregnancy losses who are currently pregnant 09:42

13 and bleeding, or patients who are pregnant who have 09:42

14 had three or more pregnancy losses. That is the 09:42

15 most of the -- I mean, there may be one or two 09:42

16 times where there was something, but that's the 09:42

17 majority of the time that I've prescribed 09:42

18 progesterone. 09:42

19 Q. And what do you tell those patients about 09:42

20 the risks and benefits of progesterone? 09:42

21 A. That there is -- 09:42

22 MS. PENAN: Objection. Compound. 09:42

23 A. In those circumstances, I tell them what 09:42

24 the risks are, just like you asked me earlier. I 09:42

25 tell them it's off-label, and I tell them the data 09:43

1 of -- from very large studies that show in their 09:43
2 circumstances what the potential benefit is, which 09:43
3 is, even if, for most of those patients, a very 09:43
4 minimal benefit, and that they can decide if the 09:43
5 benefit of using it for them outweighs the risks, 09:43
6 which largely -- I do mention the association, 09:43
7 long-term thyroid cancer, and largely its cost. 09:43

8 So it's up to them to decide if they want 09:43
9 it. The majority of people who have resources, who 09:43
10 meet the criteria for progesterone treatment, where 09:43
11 we know it's beneficial, will pay for it out of 09:43
12 pocket. But it becomes an issue for those who don't 09:43
13 have resources. 09:43

14 BY MR. JONNA: 09:43

15 Q. Is there any way you can estimate for us 09:43
16 how many times you've prescribed progesterone? 09:44

17 MS. PENAN: Objection. Calls for 09:44
18 speculation. 09:44

19 A. It's truly speculative. I don't know, a 09:44
20 few hundred, a thousand. I don't know. I really 09:44
21 don't. 09:44

22 BY MR. JONNA: 09:44

23 Q. Okay. How about progestins? Have you 09:44
24 prescribed progestins? 09:44

25 A. Yes. 09:44

1 Q. For what purpose? 09:44

2 A. Hormonal contraception most commonly, but 09:44
3 also for bleeding issues, heavy bleeding, 09:44
4 hyperplasia, endometriosis. Numerous. 09:44

5 Q. So we discussed a number of indications 09:44
6 for the use of progesterone. And my question for 09:44
7 you is: Do you know if any of those off-label uses 09:44
8 are supported by randomized clinical trials? 09:44

9 MS. PENAN: Objection. Misstates the 09:44
10 witness's testimony. Vague, ambiguous. Compound. 09:44
11 Incomplete hypothetical. 09:45

12 A. Yes, they are. 09:45

13 BY MR. JONNA: 09:45

14 Q. Which ones? 09:45

15 A. Bleeding issues. In fact, some of the 09:45
16 oral contraceptives are FDA-approved for bleeding 09:45
17 issues, so there -- there is approval for some. 09:45

18 I would have to do a literature search to 09:45
19 give you an exact answer. But randomized trials are 09:45
20 not necessary for all approvals. In fact, the FDA 09:45
21 doesn't require randomized trials for approval of 09:45
22 drugs. 09:45

23 Q. You would agree that there are many 09:45
24 indications for use of progesterone off-label that 09:45
25 have not been studied with randomized controlled 09:45

1 trials; correct? 09:45

2 MS. PENAN: Objection. Misstates the 09:45
3 witness's testimony. Argumentative. Asked and 09:45
4 answered. 09:45

5 A. Yes. 09:45

6 BY MR. JONNA: 09:46

7 Q. And in those cases, what scientific 09:46
8 evidence justifies those uses in the absence of 09:46
9 RCTs? 09:46

10 MS. PENAN: Objection. Vague, ambiguous. 09:46
11 Incomplete hypothetical. Calls for speculation. 09:46
12 Lacks foundation. 09:46

13 A. So to prove -- to have some proof of 09:46
14 effect, the most -- you need at least a prospective 09:46
15 clinical trial of some sort. That's what the FDA 09:46
16 approves. Like, for example, an oral 09:46
17 contraceptive, a new oral contraceptive being 09:46
18 approved, the pivotal study is a large, single-arm 09:46
19 clinical trial, not a randomized trial. There are 09:46
20 randomized trials comparing it to other products 09:46
21 done as part of the early clinical trials. Those 09:46
22 are smaller. So there are randomized trials 09:46
23 performed as part of the approval process. 09:46

24 For off-label use, which I believe was your 09:46
25 question, and I will stop here to ask for 09:46

1 clarification. 09:47

2 BY MR. JONNA: 09:47

3 Q. Yes, it was. 09:47

4 A. Okay. For off-label use, you usually need 09:47

5 a large -- you do need some kind of large trial 09:47

6 that shows that what you are looking at really does 09:47

7 work. And importantly, it needs to 09:47

8 be intervention -- it should be interventional. 09:47

9 Sometimes it will provide treatment off-label based 09:47

10 on observational studies. But, again, it needs to 09:47

11 be an observational study that supports the safety 09:47

12 and efficacy of the treatment if I'm going to 09:47

13 provide something off-label, because my 09:47

14 responsibility as a physician is to be able to 09:47

15 appropriately consult somebody on the treatment, 09:47

16 which means I need to be able to explain, in her 09:47

17 circumstances, what the risks are and the benefits 09:47

18 are. 09:47

19 Q. Okay. 09:47

20 MR. JONNA: Let's go off the record. 09:47

21 THE VIDEOGRAPHER: Going off the record at 09:47

22 9:47 a.m. 09:47

23 (Recess taken from 9:47 a.m. to 09:47

24 10:00 a.m.) 09:47

25 THE VIDEOGRAPHER: Back on the record at 10:00

1 10:00 a.m. 10:00

2 BY MR. JONNA: 10:00

3 Q. Now, Dr. Creinin, before we took a break, 10:00

4 I believe you said that observational studies can 10:00

5 sometimes support the use -- the off-label use of a 10:01

6 treatment; is that correct? 10:01

7 A. Yes. 10:01

8 MS. PENAN: Objection. Misstates the 10:01

9 witness's testimony. 10:01

10 BY MR. JONNA: 10:01

11 Q. In what circumstances? 10:01

12 A. They are large, and -- I mean, it's very 10:01

13 vague. It depends on the drug. It depends on the 10:01

14 indication. I mean, some drugs may need more than 10:01

15 others, depending on what you are looking at, I 10:01

16 mean, it's just too big. 10:01

17 Q. What do you consider to be "large"? 10:01

18 MS. PENAN: Objection. Vague, ambiguous. 10:01

19 Incomplete hypothetical. Calls for speculation. 10:01

20 Lacks foundation. 10:01

21 A. It depends on the drug and what you are 10:01

22 looking at. You know, if you -- for some 10:01

23 indications, it may be something with, you know, a 10:01

24 few hundred people. For some indications, you may 10:01

25 need thousands of people because of the various -- 10:01

1 the differences and when it might be used and what 10:02
2 circumstance. I mean -- so it's just a vague 10:02
3 question. 10:02

4 BY MR. JONNA: 10:02

5 Q. Did I understand, earlier you testified 10:02
6 that you sometimes recommend progesterone even when 10:02
7 the benefits are minimal? 10:02

8 MS. PENAN: Objection. Misstates the 10:02
9 witness's testimony. 10:02

10 A. I don't recommend it. I offer it to 10:02
11 patients and tell them the pros and cons, and it's 10:02
12 the patient who decides if she wants to use it. 10:02

13 BY MR. JONNA: 10:02

14 Q. And that's in situations that even when, 10:02
15 as you said, the benefits may be minimal? Is that 10:02
16 correct? 10:02

17 MS. PENAN: Objection. Misstates the 10:02
18 witness's testimony. Asked and answered. 10:02

19 A. I provide them with the actual data to 10:02
20 show what the benefit may be -- or the benefit is. 10:02
21 And in those circumstances, most of that data, most 10:02
22 of the times when I use it off-label, there is -- 10:02
23 there are randomized trials to -- to show what 10:02
24 those numbers are. So I can tell them, with 10:02
25 certainty, that in their specific circumstance, 10:02

1 this is what would happen if they didn't use it and 10:02
2 this is what would happen if they did use it, from 10:03
3 an outcome standpoint. 10:03

4 BY MR. JONNA: 10:03

5 Q. In those situations, did you testify that 10:03
6 generally progesterone is safe for those uses? 10:03

7 MS. PENAN: Objection. Misstates the 10:03
8 witness's testimony. Calls for speculation. Lacks 10:03
9 foundation. Incomplete hypothetical. Vague, 10:03
10 ambiguous. 10:03

11 A. In the short term, it's safe. In the long 10:03
12 term, there is an association with thyroid cancer. 10:03
13 So it's up to them to decide if the -- if the 10:03
14 potential benefit outweighs the potential risk. 10:03

15 BY MR. JONNA: 10:03

16 Q. Okay. And did I understand your earlier 10:03
17 testimony to say that when I asked you about the 10:03
18 different off-label uses of progesterone, and I 10:03
19 asked if any of them were supported by randomized 10:03
20 controlled trials, I think you identified one for 10:03
21 oral contraceptives; is that right? 10:03

22 MS. PENAN: Objection. Misstates the -- 10:03
23 witness's testimony. Asked and answered. 10:03

24 A. For progesterone. But for clarification, 10:04
25 the use of progesterone that I frequent -- that I 10:04

1 frequently use it for, that is studied in 10:04
2 randomized trials, is in patients who have had 10:04
3 prior miscarriages. 10:04

4 BY MR. JONNA: 10:04

5 Q. And what randomized trial are you 10:04
6 referring to? 10:04

7 A. There are multiple randomized trials 10:04
8 looking at progesterone versus placebo for people 10:04
9 that have had -- there are large U.K. randomized 10:04
10 trials. And I can look them up and tell you 10:04
11 exactly what they are, if you'd like. 10:04

12 Q. Okay. I think we were discussing what you 10:04
13 reviewed to prepare for deposition. You said 10:04
14 something about gender-affirming care. 10:04

15 Just to clarify, do you provide 10:04
16 gender-affirming care? 10:04

17 Do you provide referrals for 10:04
18 gender-affirming care? 10:04

19 (Reporter interruption for clarification.) 10:04

20 A. No. But do I provide referrals? My 10:05
21 practice is primarily a referral practice, so the 10:05
22 patients I'm seeing are referred to me. I cannot 10:05
23 think of anyone I -- even who's come to see me for 10:05
24 a referral for gender-affirming care. But that's 10:05
25 -- 10:05

1 So do I provide referrals, would have to 10:05
2 imply, as written -- to be fair, that question is not 10:05
3 appropriate, an appropriate question -- 10:05

4 (Technical glitch.) 10:05

5 A. -- provide a referral. 10:05

6 (Reporter interruption for clarification.) 10:06

7 A. The appropriate question would be: In the 10:06
8 past, have I ever provided a referral? Because the 10:06
9 only way I can really answer that is to go through 10:06
10 my past experience. So in my past experience, I 10:06
11 have not provided a referral for gender-affirming 10:06
12 care. 10:06

13 BY MR. JONNA: 10:06

14 Q. Okay. I'm going to pull up Exhibit 4. 10:06

15 A. Uh-huh. 10:06

16 Q. Which is -- does that show up for you? 10:06

17 A. Yes, it does. 10:06

18 (Deposition Exhibit 4 was marked for 10:06
19 identification by the reporter and is 10:06
20 attached hereto.) 10:06

21 BY MR. JONNA: 10:06

22 Q. Okay. This is your 2019 article, 10:06
23 "Mifepristone antagonization requires real studies 10:06
24 to evaluate safety and efficacy." 10:06

25 Do you see that? 10:06

1 A. Yes. 10:06

2 Q. Okay. If we go down to page 3, the 10:06

3 highlight there says "If a woman uses mifepristone 10:06

4 and then returns to the same provider's office 24 10:06

5 hours later stating she has changed her mind, what 10:06

6 should that provider tell her? Is progesterone 10:06

7 itself harmful? Likely not, based on widespread 10:07

8 use within obstetrics." 10:07

9 Do you see that? 10:07

10 A. Yes. 10:07

11 Q. And you still stand by that statement; 10:07

12 correct? 10:07

13 A. As I do with the following statement, yes. 10:07

14 Q. And progesterone is indicated by the FDA 10:07

15 as a Category B drug for pregnancy; correct? 10:07

16 MS. PENAN: Objection. Lacks foundation. 10:07

17 Incomplete hypothetical. 10:07

18 A. The FDA doesn't categorize pregnancy risks 10:07

19 using A, B, C, D, and X any longer, so it doesn't 10:07

20 currently categorize it as Category B. 10:07

21 BY MR. JONNA: 10:07

22 Q. Okay. But it did, though? 10:07

23 A. When that categorization was used, I would 10:07

24 presume, yes. I would have to look up to see 10:07

25 exactly whether it was A or B. 10:07

1 Q. Okay. 10:07

2 A. But I don't know if it was A or B. I 10:07

3 can't confirm your comment. 10:07

4 Q. You have prescribed mifepristone; correct? 10:07

5 A. Yes. 10:07

6 Q. For what indications? 10:07

7 A. For abortion and for miscarriage 10:07

8 treatment. 10:07

9 Q. Anything else? 10:08

10 A. Not that I can think of, to the best of my 10:08

11 recollection. 10:08

12 Q. Have you ever prescribed it off-label? 10:08

13 A. Well, if you consider miscarriage 10:08

14 treatment off-label, then yes. 10:08

15 Q. Okay. Is that use supported by RCTs? 10:08

16 A. Yes. 10:08

17 Q. Do you know which ones? 10:08

18 A. There are currently four RCTs that have 10:08

19 been published looking at mifepristone and 10:08

20 misoprostol versus misoprostol alone for 10:08

21 miscarriage treatment. 10:08

22 Q. Do you ever prescribe mifepristone alone 10:08

23 without misoprostol? 10:08

24 A. Never. 10:08

25 Q. Why not? 10:08

1 A. Actually, let me take that back. We do 10:08
2 when it's being used as part of cervical 10:08
3 preparation in the second trimester for procedural 10:09
4 abortions. So sometimes it's used to help in those 10:09
5 abortion circumstances. But for a medication 10:09
6 abortion, it's always used in combination with 10:09
7 misoprostol. 10:09

8 Q. Would you say that mifepristone is 10:09
9 probably the drug that you've prescribed the most 10:09
10 in your career? 10:09

11 MS. PENAN: Objection. Misstates the 10:09
12 witness's testimony. 10:09

13 A. I have no way of estimating whether I have 10:09
14 prescribed that more than an oral contraceptive or 10:09
15 anything else. I have no way of estimating that. 10:09

16 BY MR. JONNA: 10:09

17 Q. What's the oldest gestational age at which 10:09
18 you prescribed mifepristone and misoprostol to 10:09
19 terminate a pregnancy? 10:09

20 A. Well, I've used it in -- well, that's the 10:09
21 regimen that we use for labor induction abortion as 10:09
22 well. 10:09

23 You used the term "prescribe." So for 10:09
24 clarification, do you mean "prescribe" meaning I 10:09
25 wrote a prescription and they picked it up at the 10:10

1 pharmacy, or do you mean "prescribe" in the sense of 10:10
2 used the drug? 10:10

3 Q. Well, let's just start with prescription, 10:10
4 picked up at the pharmacy. 10:10

5 A. So up to 11 weeks. But it's very uncommon 10:10
6 to use it beyond 10. 10:10

7 Q. How about in any other circumstance that 10:10
8 you mentioned? 10:10

9 A. We use it for labor induction abortions. 10:10
10 So it would be -- it would be -- typically, then, 10:10
11 that's us providing or prescribing the mifepristone 10:10
12 for the patient, and then she gets misoprostol when 10:10
13 she's in the hospital. So that would be up to 26 10:10
14 weeks, or possibly even greater if somebody had 10:10
15 some -- well, that would be for fetal demises. So 10:10
16 the demises beyond 26 weeks, it's very possible I 10:10
17 saw somebody in the office and gave her, you know, 10:11
18 a demise beyond 26 weeks. 10:11

19 Q. Do you do an ultrasound to confirm 10:11
20 gestational age? 10:11

21 MS. PENAN: Objection. Incomplete 10:11
22 hypothetical. 10:11

23 A. In what circumstances? 10:11

24 BY MR. JONNA: 10:11

25 Q. When you are prescribing mifepristone and 10:11

1 misoprostol to terminate a pregnancy. 10:11

2 A. There is a variation in gestational age 10:11
3 range that we use the drugs, so I need more 10:11
4 specifics. 10:11

5 Q. When you are prescribing the abortion 10:11
6 pill, do you always perform an ultrasound to 10:11
7 confirm gestational age? 10:11

8 A. Do I personally, or what do you mean? 10:11

9 Q. No, not you personally. Do you make sure 10:11
10 an ultrasound is performed to confirm gestational 10:11
11 age? 10:11

12 A. For -- for later procedures, like if we 10:11
13 are using it in the second trimester, usually 10:11
14 people have had an ultrasound, so we would always 10:11
15 use it there for early procedures. Not always. It 10:11
16 depends on her last period and regularity of her 10:12
17 cycles and what she's using for contraception. But 10:12
18 I would say in our -- in my practice, the majority 10:12
19 of the time, I do. 10:12

20 Q. What is mifepristone? 10:12

21 A. It is an antiprogesterin, meaning that it is 10:12
22 a progesterin that doesn't activate the progesterone 10:12
23 receptor. It actually blocks the progesterone 10:12
24 receptor, meaning -- or rather than blocks, it 10:12
25 binds to the receptor and does not activate it. 10:12

1 So... 10:12

2 Q. You also refer to "medication abortion" in 10:12

3 your declaration. What's medication abortion? 10:12

4 A. The use of medications to cause a patient 10:12

5 to expel the pregnancy from her uterus. 10:12

6 Q. Okay. Does mifepristone inhibit both 10:12

7 natural and supplemental progesterone? 10:12

8 MS. PENAN: Objection. Compound. 10:12

9 A. Mifepristone, by binding to the 10:13

10 progesterone receptor, will block any progesterone 10:13

11 or any progestin, for that matter, from binding to 10:13

12 the receptor. 10:13

13 BY MR. JONNA: 10:13

14 Q. And how do we know that? 10:13

15 A. Because that's what science tells us of 10:13

16 how mifepristone works. 10:13

17 Q. Okay. What science tells us that? 10:13

18 A. I mean, that's a -- every pharmacologic 10:13

19 study to look at in all science states how 10:13

20 mifepristone works. 10:13

21 Q. Are there any studies that come to mind 10:13

22 that explain that? 10:13

23 MS. PENAN: Objection. Asked and 10:13

24 answered. 10:13

25 A. I can do a deep dive if you want an 10:13

1 explanation. 10:13

2 BY MR. JONNA: 10:13

3 Q. Generally, for today I'm only -- I'm only 10:13

4 interested in what you know as you sit here today. 10:13

5 I'm not going to ask you to do any homework. 10:13

6 A. Yeah, but no, no studies come to mind. 10:13

7 I've pretty well-established how mifepristone 10:13

8 works, just like when you turn the key in your car 10:13

9 -- well, actually now, you push a button, it's 10:14

10 pretty well-established that the car will turn on. 10:14

11 Q. Okay. How long does mifepristone remain 10:14

12 in the bloodstream? 10:14

13 MS. PENAN: Objection. Incomplete 10:14

14 hypothetical. Vague, ambiguous. 10:14

15 A. It will stay in the bloodstream typically 10:14

16 for any -- it depends on the person. One to two 10:14

17 days to -- but you can find it for longer. 10:14

18 BY MR. JONNA: 10:14

19 Q. How much longer can you find it? 10:14

20 A. I don't -- I can't tell you exactly 10:14

21 because, again, there's too many variations, too 10:14

22 many variables, you know, based on patient size, 10:14

23 dose, et cetera, but it will be -- it will be at an 10:14

24 effective dose for one to two days -- 10:14

25 Q. And how do we know that? 10:14

1 A. -- minimally. Again, binding -- this is 10:14
2 what the studies show us from studies that look at 10:14
3 elimination half-life pharmacology. That's what -- 10:14
4 why those studies are done. 10:14

5 Q. Any studies come to mind that explain how 10:14
6 long mifepristone remains in the bloodstream? 10:15

7 A. No. 10:15

8 Q. Is it fair to say that mifepristone peaks 10:15
9 in the bloodstream quickly? 10:15

10 A. Yes. 10:15

11 Q. Why does that matter? 10:15

12 A. That's absorption. 10:15

13 Q. Can you elaborate? 10:15

14 A. Well, ideally, when you take any drug, you 10:15
15 want it to be able to be absorbed quickly so it 10:15
16 will do what you want it to do. 10:15

17 Q. Are you familiar with the term "high 10:15
18 first-pass metabolism"? 10:15

19 A. I've never heard somebody talk about "high 10:15
20 first-pass metabolism." I've heard of first-pass 10:15
21 metabolism. 10:15

22 Q. What does "first-pass metabolism" refer 10:15
23 to? 10:15

24 A. It's -- first-pass metabolism is when you 10:15
25 swallow -- it's most commonly used related to 10:15

1 drugs. When you swallow a drug, it's how it's -- 10:15
2 it's the process, processing in the liver of the 10:15
3 drug. And for some drugs, they are processed 10:16
4 extensively. 10:16

5 So the active -- relatively little may get 10:16
6 out to the body. Some are processed less. Some more 10:16
7 if it gets out to the body. Some drugs that you take 10:16
8 are prodrugs, meaning they themselves are not active 10:16
9 and they have to be metabolized in the liver to the 10:16
10 active component. And the more extensive metabolism 10:16
11 that needs to go on, you also then get effects on the 10:16
12 liver from the process of metabolism. But that's 10:16
13 what first-pass metabolism is in basic terms. 10:16

14 Q. Would you agree that mifepristone has a 10:16
15 high first-pass metabolism? 10:16

16 MS. PENAN: Objection. Incomplete 10:16
17 hypothetical. Vague, ambiguous. 10:16

18 A. No, not necessarily. I mean -- 10:16

19 BY MR. JONNA: 10:16

20 Q. What -- what do you mean by that? 10:16

21 A. Well, "high" is subjective comparative. I 10:16
22 mean, high compared to what? 10:17

23 Q. How would you describe mifepristone's 10:17
24 first-pass metabolism? 10:17

25 A. I can't. I mean, it's just normal. I 10:17

1 mean, it doesn't matter. It gets absorbed pretty 10:17

2 well. I mean... 10:17

3 Q. Does mifepristone's effectiveness change 10:17

4 over time? 10:17

5 MS. PENAN: Objection. Vague, ambiguous. 10:17

6 Incomplete hypothetical. 10:17

7 A. Yeah, you have to describe "over time." 10:17

8 "Over time" can mean lots of things. 10:17

9 BY MR. JONNA: 10:17

10 Q. What's your understanding of how 10:17

11 mifepristone's effectiveness changes over time? 10:17

12 MS. PENAN: Same objections. Asked and 10:17

13 answered. 10:17

14 A. Again, "over time" could -- "over time" 10:17

15 could relate to lots of different things. I can 10:17

16 try to think of all the different things you could 10:17

17 mean, so I don't know what you mean by "over time." 10:17

18 BY MR. JONNA: 10:17

19 Q. Okay. How about over the first few days 10:17

20 after taking mifepristone, how does its 10:17

21 effectiveness change? 10:18

22 MS. PENAN: Same objections. 10:18

23 A. The studies that we have show that -- it's 10:18

24 still effective for at least 72 hours. Beyond 10:18

25 that, I don't have much data. But I would 10:18

1 expect -- part of it is that part of its effect is 10:18
2 immediate, rapid -- 10:18

3 You know, studies aren't done to say, if 10:18
4 you take mifepristone and then try to -- you know, 10:18
5 what's -- what's going to happen at five days or 10:18
6 seven days, because the studies are usually done for 10:18
7 people planning abortion. There are some early 10:18
8 phase, Phase 1 studies that were looking at dosing 10:18
9 regimens. Some of them even went out for seven days. 10:18
10 But, I mean, over time, like any drug, its effects 10:18
11 are going to wane. But we know that it's -- it has 10:18
12 its effects at least for 72 hours. 10:18

13 BY MR. JONNA: 10:18

14 Q. You would agree that it's extensively 10:18
15 metabolized in the first pass? 10:18

16 MS. PENAN: Objection. Misstates the 10:19
17 witness's testimony. Vague. Ambiguous. 10:19
18 Incomplete hypothetical. 10:19

19 A. I wouldn't necessarily say it's 10:19
20 "extensively." 10:19

21 BY MR. JONNA: 10:19

22 Q. How would you characterize it? 10:19

23 A. It's metabolized -- it goes through some 10:19
24 metabolism, just like other drugs. It's not -- I 10:19
25 mean, "extensively" also relates to how you would 10:19

1 compare to other drugs. I mean, it doesn't go 10:19
2 through an extensive first-pass metabolism compared 10:19
3 to some other drugs. No, I wouldn't say -- I 10:19
4 wouldn't qualify it as "extensive." 10:19

5 Q. You testified that mifepristone works by 10:19
6 binding to progesterone receptors; right? 10:19

7 A. Yes. 10:19

8 Q. Is that binding permanent? 10:19

9 A. No. 10:19

10 Q. Would you call it complete? 10:19

11 MS. PENAN: Objection. Vague, ambiguous. 10:19

12 Incomplete hypothetical. 10:19

13 A. Yeah. 10:19

14 MS. PENAN: Calls for speculation. 10:19

15 A. As best as anybody can tell, it's likely 10:19
16 very complete, meaning it binds and it stays, yes. 10:19

17 Actually, it's -- to be fair, I don't know 10:19
18 -- what do you mean by "complete"? I should have 10:20
19 asked that first. 10:20

20 BY MR. JONNA: 10:20

21 Q. Okay, but you do agree that it's -- you 10:20
22 would consider its binding permanent? 10:20

23 A. No. 10:20

24 MS. PENAN: Objection. Misstates the 10:20
25 witness's testimony. 10:20

1 BY MR. JONNA: 10:20

2 Q. Sorry. I meant to say the opposite. You 10:20

3 would agree its binding is not permanent? 10:20

4 A. That is correct. 10:20

5 MS. PENAN: Same objection. 10:20

6 BY MR. JONNA: 10:20

7 Q. What is the basis for that opinion? 10:20

8 A. Because eventually mifepristone is out of 10:20

9 the body. 10:20

10 Q. Are there any studies that show that? 10:20

11 A. I would have to look them up. 10:20

12 Q. Are there any randomized controlled trials 10:20

13 that come to mind? 10:20

14 A. Usually for pharmacology studies like 10:20

15 this, you don't do randomized controlled trials. 10:20

16 Q. Why is that? 10:20

17 A. You don't need to do a randomized trial to 10:20

18 figure out how long a product binds to a receptor. 10:20

19 That's not the purpose of a randomized trial. 10:20

20 Q. What's the purpose of a randomized trial? 10:20

21 A. It is to compare the outcomes in -- when 10:20

22 people get the drug versus not getting the drug. 10:21

23 So if your goal is to see what happens just when 10:21

24 you are using the drug, then not using the drug 10:21

25 doesn't make any sense. 10:21

1 Q. Mifepristone eventually comes off the 10:21
2 progesterone receptors; right? 10:21

3 MS. PENAN: Objection. Misstates the 10:21
4 witness's testimony. Asked and answered. 10:21
5 Argumentative. 10:21

6 A. That's what's believed to happen, yes. 10:21

7 BY MR. JONNA: 10:21

8 Q. And what happens then? 10:21

9 MS. PENAN: Objection. Vague, ambiguous. 10:21

10 A. There is -- the mifepristone is not 10:21
11 affecting the progesterone receptor. 10:21

12 It's done its work, just like if you do a 10:21
13 chemotherapy agent. You know, you give your 10:21
14 chemotherapy. It does its work, and then it's out of 10:21
15 the body, and then you have the results from the 10:21
16 chemotherapy agent. We don't -- people who have 10:21
17 cancer, we don't give them continuous infusions of 10:21
18 chemotherapy for months and months and months and 10:21
19 months. You give their treatment. The treatment has 10:21
20 its effect, and then you have a result of the effect 10:21
21 thereafter. 10:22

22 So just because it's not binding a receptor 10:22
23 any longer doesn't mean it hasn't done what it was 10:22
24 going to do. 10:22

25 BY MR. JONNA: 10:22

1 Q. Is the -- is the binding reversible? 10:22

2 MS. PENAN: Objection. Vague, ambiguous. 10:22

3 Incomplete hypothetical. 10:22

4 A. You have to define "reversible." 10:22

5 BY MR. JONNA: 10:22

6 Q. Based on your -- 10:22

7 A. That's not -- that's not a medical term we 10:22

8 use with receptors. So you have to explain that. 10:22

9 Q. Okay. We will -- we will get into that in 10:22

10 a little bit. 10:22

11 What are the side effects of mifepristone? 10:22

12 MS. PENAN: Objection. Incomplete 10:22

13 hypothetical. 10:22

14 A. We've established that some people can get 10:22

15 nausea, vomiting, headaches, tiredness, but again, 10:22

16 those rates -- it's hard to -- it's hard to find -- 10:22

17 you know, the -- the data is very hard to establish 10:22

18 because people are feeling that way from pregnancy 10:22

19 anyway. But there is a slight increase in those 10:23

20 side effects, but it is -- otherwise, that's pretty 10:23

21 much it, if you are looking for side effects. 10:23

22 BY MR. JONNA: 10:23

23 Q. Yeah. Are there any others that come to 10:23

24 mind? 10:23

25 A. Not that come to my mind right off the bat 10:23

1 based on looking at side effects. 10:23

2 Q. Okay. You never prescribed a mifepristone 10:23

3 to a woman who wants to keep her baby, have you? 10:23

4 A. No. 10:23

5 Q. That would be malpractice? 10:23

6 MS. PENAN: Objection. Vague, ambiguous. 10:23

7 Incomplete hypothetical. Argumentative. 10:23

8 A. "Malpractice" is a legal term. I think it 10:23

9 would be wrong practice, whether it's malpractice 10:23

10 or not is up to attorneys and the judge. 10:23

11 BY MR. JONNA: 10:23

12 Q. Have you ever prescribed mifepristone to a 10:23

13 woman without first checking to see if she has a 10:23

14 live intrauterine pregnancy? 10:23

15 A. Yes. 10:24

16 MS. PENAN: Objection. Vague. Incomplete 10:24

17 hypothetical. 10:24

18 A. Yes. 10:24

19 BY MR. JONNA: 10:24

20 Q. What dosage do you typically prescribe for 10:24

21 mifepristone? 10:24

22 A. 200 milligrams. 10:24

23 Q. Is that the standard dosage? 10:24

24 A. Yes. 10:24

25 Q. Do you ever vary the dosage by higher 10:24

1 weight or prior medical history? 10:24

2 A. No. 10:24

3 Q. Gestational age? 10:24

4 A. No. 10:24

5 Q. Have you ever used a higher dose in the 10:24
6 past? 10:24

7 A. I believe, to the best of my recollection, 10:24
8 even when it was first approved as a 600-milligram 10:24
9 dose, the abundance of literature already showed 10:24
10 200 milligrams was all you needed. 10:24

11 So to the best of my recollection, I 10:24
12 believe I have always prescribed 200 milligrams. 10:24

13 Q. What's your understanding of what the 10:25
14 literature said about why 200 milligrams was all 10:25
15 you needed? 10:25

16 A. Because there's studies with thousands and 10:25
17 thousands of patients showing efficacy comparable 10:25
18 to 600 milligrams, including randomized trials. 10:25

19 Q. Okay. I'm going to go back to your 10:25
20 declaration here, Exhibit 2. 10:25

21 (Deposition Exhibit 2 was marked for 10:25
22 identification by the reporter and is 10:25
23 attached hereto.) 10:25

24 BY MR. JONNA: 10:25

25 Q. So at paragraph 4, it says you obtained 10:25

1 your M.D. in 1988; is that right? 10:25

2 A. Yes. 10:25

3 Q. Scroll down to paragraph 10. It says that 10:25

4 you provided office-based procedural medication 10:25

5 abortions since 1986. Is that right? 10:25

6 A. Let's see -- wait. '86? Wait. That -- 10:26

7 no. That would be during medical school. So -- 10:26

8 yes, as a medical student -- no, that would 10:26

9 actually be -- it should be 1990. That is an 10:26

10 error. 10:26

11 Q. Okay. 10:26

12 A. It would be -- it would be during 10:26

13 residency. That is an error. Thank you. 10:26

14 Q. Okay. So that should read "1990"? 10:26

15 A. Yes. 10:26

16 Q. And what method did you use in 1990 for 10:26

17 medication abortion? 10:26

18 A. Methotrexate and misoprostol would have 10:26

19 been -- no, let me go back. So it's office-based 10:26

20 and medication since 1990. In 1990, we were 10:26

21 providing office-based procedures. In 1992, I 10:26

22 began studying methotrexate and misoprostol. So 10:27

23 the medication abortion part started later. 10:27

24 Q. Do you know what studies existed at the 10:27

25 time to support the use of methotrexate and 10:27

1 misoprostol as an abortifacient? 10:27

2 A. There were none, which is why I was doing 10:27
3 the studies. So providing it was through studies 10:27
4 at that time. 10:27

5 Q. Okay. And were you providing it in other 10:27
6 context besides those studies? 10:27

7 A. No, just in studies. 10:27

8 Q. Do you remember the generally acknowledged 10:27
9 incomplete abortion rate for the medication 10:27
10 abortion method you used in 1990? 10:27

11 MS. PENAN: Objection. Incomplete 10:28
12 hypothetical. Vague, ambiguous. 10:28

13 A. I did not use medication abortion in 1990. 10:28
14 The office-based procedures were in 1990, and in 10:28
15 1992 was the beginning of clinical trials looking 10:28
16 at medication abortion with methotrexate and 10:28
17 misoprostol. 10:28

18 BY MR. JONNA: 10:28

19 Q. When did you start prescribing it outside 10:28
20 the context of clinical trials? 10:28

21 A. Years later, as we continued -- all the 10:28
22 provision of it was during clinical studies. 10:28

23 Q. Do you remember approximately when those 10:28
24 studies ended and you started prescribing it in 10:28
25 other contexts? 10:28

1 A. It would have been a few years later. I 10:28
2 could look through at my CV and tell you when the 10:28
3 studies were done, that we said, "Okay, this is 10:28
4 enough; we can start doing it." But I don't know 10:28
5 off the top of my head from 30 years ago. 10:28

6 Q. Okay. And when you started prescribing 10:28
7 medication abortion outside of the clinical trials, 10:28
8 what -- what were you prescribing? 10:29

9 A. It was methotrexate, 50 milligrams, for me 10:29
10 to square-inject it. And then misoprostol, I 10:29
11 believe it was -- it was 800 micrograms vaginally. 10:29
12 I believe it was three days later. Again, that was 10:29
13 30 years ago. 10:29

14 Q. And when did you switch from methotrexate 10:29
15 to mifepristone? 10:29

16 A. When mifepristone became -- well, first, 10:29
17 from a clinical standpoint, we switched when 10:29
18 mifepristone became available in the United States, 10:29
19 which was 25 years ago. But I did do studies with 10:29
20 mifepristone. So I was using it in a study setting 10:29
21 prior to that. 10:29

22 Q. Do you remember the incomplete abortion 10:29
23 rate for the protocol that you just mentioned with 10:29
24 methotrexate and misoprostol? 10:29

25 MS. PENAN: Objection. Incomplete 10:29

1 hypothetical. Vague, ambiguous. 10:29

2 A. Do you mean specifically for the method we 10:29

3 use clinically or under different study protocols? 10:30

4 BY MR. JONNA: 10:30

5 Q. The one you used clinically. 10:30

6 A. Well, the overall incomplete abortion 10:30

7 rate, we use it primarily through seven weeks, was 10:30

8 low. The failure rate was about 90 to 90 -- 10:30

9 success rate is 90 to 92 percent. So some of those 10:30

10 pregnancies were ongoing; some were incomplete. 10:30

11 But that required weeks and weeks of follow-up 10:30

12 because some people passed the pregnancy right away 10:30

13 and some didn't pass it for weeks. 10:30

14 So when we look at the outcomes with 10:30

15 methotrexate and misoprostol, which is why 10:30

16 mifepristone and misoprostol is primarily used, 10:30

17 methotrexate and misoprostol -- 10:30

18 (Reporter interruption for clarification.) 10:30

19 A. So methotrexate and misoprostol -- I'm 10:31

20 trying to figure out where I was. So it has a -- 10:31

21 it works -- and when it's used in early pregnancy, 10:31

22 primarily up to seven weeks, it works 90 to 92 10:31

23 percent of the time, but you have to wait up to 10:31

24 three to four weeks for some people to pass their 10:31

25 pregnancy. So the incomplete rate is in that 8 10:31

1 percent range or so, which was -- because some of 10:31
2 those people have continuing pregnancies, and 10:31
3 that's in line with what mifepristone through seven 10:31
4 weeks showed. So it's pretty -- it's comparable 10:31
5 from an efficacy and incomplete rate, just not from 10:31
6 a timing rate. 10:31

7 (Speakers talking simultaneously.) 10:31

8 BY MR. JONNA: 10:31

9 Q. Finish your answer. I'm sorry. 10:31

10 A. Through seven weeks. 10:31

11 Q. Okay. Do you remember the risk of 10:31
12 hemorrhage for that protocol with methotrexate and 10:31
13 misoprostol, what was the risk of hemorrhage? 10:31

14 MS. PENAN: Objection. Vague, ambiguous. 10:32
15 Incomplete hypothetical. 10:32

16 A. It's over 30 years ago. I would have to 10:32
17 go back, but it was really low. 10:32

18 BY MR. JONNA: 10:32

19 Q. Do you know when the FDA approved that 10:32
20 protocol? 10:32

21 A. Yes. That was -- 10:32

22 MS. PENAN: Objection. Misstates the 10:32
23 witness's testimony. 10:32

24 A. Yes. It was off-label use. 10:32

25 BY MR. JONNA: 10:32

1 Q. So why -- why do you feel comfortable 10:32
2 using that protocol without FDA approval? 10:32

3 A. Because we have large prospective studies 10:32
4 looking at the outcomes, and provided information 10:32
5 based on different gestational ages and their 10:32
6 outcomes, which is why we restrict -- the clinical 10:32
7 recommendations were to use it primarily through 10:32
8 seven weeks and not further. 10:32

9 And I could tell a patient what side 10:32
10 effects she would have, how it works, what to expect, 10:32
11 because we did clinical trials to provide adequate 10:32
12 information for everybody that received the 10:32
13 treatment. 10:33

14 Q. Okay. So when you have a patient coming 10:33
15 to your office today who wants to start a 10:33
16 medication abortion, what do you tell them about 10:33
17 mifepristone? 10:33

18 A. I'm sorry. That's a very vague question. 10:33
19 I mean, it's -- when I explain -- do you mean when 10:33
20 I explain how medication abortion works? 10:33

21 Q. Well, what's your -- what's your typical 10:33
22 summary that you give a patient when they are -- 10:33
23 when you are describing mifepristone? 10:33

24 A. Mifepristone -- 10:33

25 MS. PENAN: Objection. Incomplete 10:33

1 hypothetical. Vague, ambiguous. Lacks foundation. 10:33

2 A. I explain mifepristone is the first drug, 10:33

3 and it works by weakening the attachment of the 10:33

4 pregnancy to the uterus. 10:33

5 BY MR. JONNA: 10:33

6 Q. Do you ever tell them that there is a 10:33

7 possibility that mifepristone might not work? 10:33

8 A. Yes, because when I go through the 10:33

9 efficacy of mifepristone and misoprostol, I explain 10:34

10 to them, based on their gestational age, the 10:34

11 likelihood that they may need a procedure to 10:34

12 complete the abortion process, because I have 10:34

13 detailed information on their outcome based on 10:34

14 their gestational age. 10:34

15 Q. What do you say about the different 10:34

16 outcomes for gestational ages? How do you explain 10:34

17 that? 10:34

18 MS. PENAN: Objection. Compound. Vague, 10:34

19 ambiguous. Incomplete hypothetical. 10:34

20 A. I tell them what their rate will be based 10:34

21 on their gestational age. You know, the label 10:34

22 shows it's from 92 to 97 percent effective, but 10:34

23 that efficacy is higher in early gestation and 10:34

24 lower as they get closer to 10 weeks. And I 10:34

25 explain to them -- based on where they are in the 10:34

1 pregnancy, I will tell them, "Yours -- your 10:34
2 likelihood of needing a procedure is 2 percent," or 10:34
3 "Your likelihood is 5 percent," or "Your likelihood 10:34
4 is 7 percent." I tell them based on the data 10:34
5 that's in the label, which is supported by 10:34
6 thousands and thousands of patients in the 10:35
7 literature. 10:35

8 BY MR. JONNA: 10:35

9 Q. And what -- what studies is that based on? 10:35

10 MS. PENAN: Objection. Vague, ambiguous. 10:35

11 Incomplete hypothetical. 10:35

12 A. The studies are -- most of those studies 10:35
13 are primarily summarized in a systemic review of 10:35
14 the mifepristone and misoprostol that I publish 10:35
15 with Dr. Chen. Those studies were used as part of 10:35
16 the 2016 label revision. 10:35

17 There were some additional studies that 10:35
18 came out from the time that we did the systemic 10:35
19 review and the FDA review that were added in. But 10:35
20 all those studies are listed in our systemic review. 10:35

21 BY MR. JONNA: 10:35

22 Q. Were there any RCTs? 10:35

23 A. Yes, there were. 10:35

24 Q. Which ones? 10:35

25 A. We would have to look at the systemic 10:35

1 review. And I can tell you which ones they are, 10:35

2 but I don't -- I don't know off the top of my head. 10:36

3 Q. All right. Let me pull up Exhibit 5 now. 10:36

4 (Deposition Exhibit 5 was marked for 10:36

5 identification by the reporter and is 10:36

6 attached hereto.) 10:36

7 BY MR. JONNA: 10:36

8 Q. This is the Mifeprex product label. You 10:36

9 recognize this; right? 10:36

10 A. Yes. 10:36

11 Q. Let me make this a little bigger. Sorry. 10:36

12 Okay. On page 2, Section 1 there, it says 10:36

13 that "Mifepristone is indicated through 70 days 10:36

14 gestation." Do you see that? 10:36

15 A. Yes. 10:36

16 Q. You've prescribed it more than -- more 10:36

17 than 70 days, though; right? 10:36

18 A. Very rarely, but yes. 10:36

19 Q. In what circumstances do you decide to do 10:36

20 that? 10:36

21 A. When somebody is between 71 and 77 days 10:36

22 and they have a strong preference for medication 10:37

23 over a procedure. So I explain the data that's 10:37

24 available to -- that looks at its use beyond 70 10:37

25 days. I treat them very differently. I give them 10:37

1 two doses of misoprostol sublingually, because the 10:37
2 best data that's out there suggests that that's the 10:37
3 best route, and pharmacologically that makes the 10:37
4 most sense as well. 10:37

5 But I explain that they have a higher rate 10:37
6 of failure, which may be as high as 15 percent. But 10:37
7 that is up to them to decide what they want to do in 10:37
8 those circumstances, because I have adequate 10:37
9 literature to support its use, and I usually will 10:37
10 recommend a procedure. But for some women, it can be 10:37
11 traumatizing, and they want to minimize the 10:37
12 likelihood of a procedure. 10:37

13 So for them, an 85 percent chance of 10:37
14 success is better than a zero percent chance. Let me 10:37
15 reverse that. A 15 percent chance of needing a 10:37
16 procedure is better than a hundred percent chance of 10:37
17 needing a procedure. 10:38

18 Q. Can you identify what data you are 10:38
19 referring to that supports its use in -- in that 10:38
20 context? 10:38

21 A. Yeah. The primary study is a Gynuity 10:38
22 study. There's two studies primarily that look at 10:38
23 use beyond 70th -- 70 days, that limits it to 70 to 10:38
24 77 days. And those are both Gynuity studies. 10:38

25 I think Erica Chang is one of the authors, 10:38

1 on one -- on one or both of them, but I can provide 10:38
2 those for you, if you want. But they are -- they are 10:38
3 published in peer-reviewed journals. One of them is 10:38
4 a prospective study, and the other is a retrospective 10:38
5 observational study. 10:38

6 Q. Okay. Scrolling down to page 4, Section 10:38
7 2.3 says "Patients should follow up with their 10:38
8 healthcare provider 7 to 14 days after the 10:38
9 administration of Mifeprex. This assessment is 10:38
10 very important to confirm the complete termination 10:38
11 of pregnancy has occurred and to evaluate the 10:39
12 degree of bleeding." 10:39

13 Do you see that? 10:39

14 A. Yes. 10:39

15 Q. Do you generally do that? 10:39

16 A. Yes. 10:39

17 Q. Do you always do that? 10:39

18 A. Yes. 10:39

19 Q. Do your patients always return? 10:39

20 A. No. 10:39

21 Q. Do you follow up when they don't? 10:39

22 A. Yes. 10:39

23 Q. How do you -- how do you follow up? 10:39

24 A. We will call them or message them. But 10:39
25 you know, "follow up" doesn't mean in the office. 10:39

1 "Follow up" means contact; right? So we offer 10:39
2 patients the ability to follow up in person or by 10:39
3 telemedicine or just through messaging through 10:39
4 their electronic medical record, but we usually 10:39
5 will do something. 10:39

6 And we also provide them with information 10:39
7 to self-assess so that if they don't follow up with 10:39
8 us, and again, that's their choice, they can ghost 10:39
9 me, just like anybody else can ghost you, at the 10:39
10 least they have the information to self-assess, but 10:39
11 we do try to provide follow-up. 10:39

12 Q. So you still lose some to follow-up; 10:39
13 right? 10:39

14 A. I'm sorry? Can you repeat the question? 10:40

15 Q. You still lose some patients to follow-up; 10:40
16 right? 10:40

17 MS. PENAN: Objection. Vague, compound -- 10:40
18 or vague, ambiguous. Incomplete hypothetical. 10:40

19 A. I wouldn't call it "lose," because if they 10:40
20 don't -- if we don't contact them, then they at 10:40
21 least have instructions for how to self-assess to 10:40
22 the best of their -- you know, their ability. But 10:40
23 some patients don't follow up. And in those it 10:40
24 says "Patients should follow up." It doesn't say 10:40
25 patients "must." 10:40

1 BY MR. JONNA: 10:40

2 Q. Okay. On page 5, Section 5.2 there, in 10:40

3 green, says "Uterine bleeding occurs in almost all 10:40

4 patients during a medical abortion. Prolonged 10:40

5 heavy bleeding (soaking through two thick full-size 10:40

6 sanitary pads per hour for two consecutive hours) 10:40

7 may be a sign of incomplete abortion or other 10:40

8 complications, and prompt medical or surgical 10:40

9 intervention may be needed." 10:40

10 Do you see that? 10:40

11 A. Yes. 10:41

12 Q. Do you agree with this? 10:41

13 MS. PENAN: Objection. Vague, ambiguous. 10:41

14 Incomplete hypothetical. 10:41

15 A. Yes. 10:41

16 BY MR. JONNA: 10:41

17 Q. You believe that a mifepristone, 10:41

18 misoprostol abortion is safe; right? 10:41

19 A. Yes. 10:41

20 Q. So treatment with Mifeprex can result in 10:41

21 prolonged heavy bleeding requiring medical or 10:41

22 surgical intervention, but you still consider it 10:41

23 safe; isn't that correct? 10:41

24 MS. PENAN: Objection. Misstates the 10:41

25 witness's testimony. Vague, ambiguous. Incomplete 10:41

1 hypothetical. 10:41

2 A. The treatment is not mifepristone. It's 10:41

3 mifepristone and misoprostol. And it says it 10:41

4 "may." And that's based on the likelihood that 10:41

5 something may happen. 10:41

6 BY MR. JONNA: 10:41

7 Q. Right. 10:41

8 A. So just -- just like a patient having a 10:41

9 miscarriage may have those same things happen. So 10:41

10 if you are trying to imply that I think 10:41

11 mifepristone and misoprostol can cause those issues 10:41

12 and it's not safe, then any pregnant woman in early 10:41

13 pregnancy is, quote/unquote, not safe because she 10:41

14 could have a miscarriage, and all those things 10:41

15 could happen. 10:41

16 Q. Right. But notwithstanding this statement 10:41

17 that we just looked at, you still consider 10:41

18 mifepristone safe; right? 10:42

19 MS. PENAN: Objection. Vague as to 10:42

20 "safe." Ambiguous. Incomplete hypothetical. 10:42

21 A. I consider the combined regimen of 10:42

22 mifepristone and misoprostol to be safe. 10:42

23 BY MR. JONNA: 10:42

24 Q. Despite the risk of uterine bleeding that 10:42

25 we just looked at; correct? 10:42

1 A. Because -- 10:42

2 MS. PENAN: Objection. Asked and 10:42
3 answered. 10:42

4 A. Because that risk is very low, I consider 10:42
5 it safe. 10:42

6 BY MR. JONNA: 10:42

7 Q. Okay. Below that, in yellow, we see 10:42
8 "Based on data from several large clinical trials, 10:42
9 vasoconstrictor drugs were used in 4.3 percent of 10:42
10 all subjects, there was a decrease in hemoglobin of 10:42
11 more than 2 grams per deciliter in 5.5 percent of 10:42
12 subjects, and blood transfusions were administered 10:42
13 to .1 percent of subjects." [Sic] 10:42

14 Do you see that? 10:42

15 A. You misquoted the statement, but, yes, I 10:42
16 see it. 10:42

17 Q. How did I misquote it? 10:42

18 A. Because "blood transfusions were 10:42
19 administered to less than 0.1 percent of subjects." 10:43

20 Q. Oh, I'm sorry. 10:43

21 A. Yeah. 10:43

22 Q. So notwithstanding that statement, you 10:43
23 still consider mifepristone safe as well; correct? 10:43

24 MS. PENAN: Objection. Asked and 10:43
25 answered. 10:43

1 A. Yes, because the risk of blood 10:43

2 transfusion, which, when somebody is bleeding, 10:43

3 that's the -- the severe event that you are worried 10:43

4 about -- is very, very low. 10:43

5 MS. PENAN: I'm sorry. Also objection. 10:43

6 Misstates the witness's testimony. 10:43

7 MR. JONNA: Can the court reporter please 10:43

8 read back the answer? I -- I didn't catch it. 10:43

9 (Reporter read back the requested text.) 10:43

10 BY MR. JONNA: 10:43

11 Q. Turning to page 7, it's in green there. 10:43

12 It states "Most women can expect bleeding more 10:44

13 heavily than they do during a heavy menstrual 10:44

14 period." Do you see that? 10:44

15 A. Yes. 10:44

16 Q. Do you agree with that? 10:44

17 A. Yes. 10:44

18 Q. Do you tell your patients that? 10:44

19 A. Yes. 10:44

20 Q. Table -- page 8, Table 2, has the adverse 10:44

21 reactions, and it says that "2.9 to 4.6 percent of 10:44

22 women administered mifepristone and misoprostol 10:44

23 went to the emergency room." Did I read that 10:44

24 correctly? 10:44

25 A. Based on the thousand people in the 10:44

1 evaluable studies, yes. 10:44

2 Q. But, nonetheless, you still consider the 10:44
3 medication to be safe; correct? 10:44

4 MS. PENAN: Objection. Asked and 10:44
5 answered. Vague, ambiguous. 10:44

6 A. Yes, because an ER visit doesn't 10:44
7 necessarily mean it -- first of all -- well, let me 10:44
8 start. An ER visit doesn't necessarily mean that 10:44
9 somebody has a severe event. People go to the ER 10:44
10 for multiple reasons. And there's, subsequent to 10:44
11 this, even larger evaluations looking at 10:45
12 emergency-room visits in larger populations. So 10:45
13 just because you go to the emergency room doesn't 10:45
14 mean something is bad. Sometimes people go to 10:45
15 emergency rooms for something unrelated. But, 10:45
16 yeah, it's very low. 10:45

17 BY MR. JONNA: 10:45

18 Q. And you've had patients that went to the 10:45
19 ER following the administration of mifepristone or 10:45
20 misoprostol -- misoprostol; correct? 10:45

21 MS. PENAN: Objection. Compound. Lacks 10:45
22 foundation. Incomplete hypothetical. Vague, 10:45
23 ambiguous. 10:45

24 A. I've had patients who have used 10:45
25 mifepristone and misoprostol in combination and 10:45

1 gone to the emergency room. 10:45

2 BY MR. JONNA: 10:45

3 Q. Approximately how many times, if you had 10:45
4 to provide your best estimate? 10:45

5 A. Less than 1 percent of the time. 10:45

6 Q. And in those situations, what -- what is 10:45
7 the reason, generally? 10:45

8 MS. PENAN: Objection. Vague, ambiguous. 10:45
9 Calls for speculation. Lacks foundation. 10:45
10 Incomplete hypothetical. 10:45

11 A. I would say sometimes it's related to pain 10:45
12 because they need additional pain medicine. 10:45

13 For example, in my practice, I offer people 10:46
14 nonsteroidal analgesics, like ibuprofen and narcotics 10:46
15 they have at home. So people don't want to have the 10:46
16 narcotics at home, and then later say "Oh, my God, I 10:46
17 should have had them." Some people take the 10:46
18 narcotics and say, "I never needed to use them," 10:46
19 because everybody is different. 10:46

20 So sometimes they are going to the ER 10:46
21 because they need more pain medicine. Sometimes they 10:46
22 go to the ER because they developed a fever from the 10:46
23 misoprostol and were worried, and it turns out 10:46
24 they're fine. And some people go to the ER for 10:46
25 bleeding. 10:46

1 Sometimes those people are bleeding so 10:46
2 heavily that they need a D&C. But the majority of 10:46
3 the time, they just need an evaluation and 10:46
4 reassurance. 10:46

5 BY MR. JONNA: 10:46

6 Q. If you had to provide your best estimate, 10:46
7 how many, approximately, of those less than 1 10:46
8 percent that you mentioned had transfusions? 10:46

9 MS. PENAN: Objection. Calls for 10:46
10 speculation. Incomplete hypothetical. Vague, 10:46
11 ambiguous. 10:46

12 A. To be fair, I can't remember the last 10:46
13 patient that I gave mifepristone and misoprostol to 10:47
14 for abortion that needed a transfusion. 10:47

15 So keep in mind, also, when you look at 10:47
16 these studies, it always has to do, also, with the 10:47
17 availability of care. You know, if somebody comes 10:47
18 from three hours away to get her medication abortion 10:47
19 because there is no provider near -- her, and she 10:47
20 starts to bleed heavily and she's worried, she's 10:47
21 going to go to an ER, versus if somebody lives close 10:47
22 to where they got their care, they are going to go 10:47
23 see that doctor. 10:47

24 So an ER visit in and of itself is not 10:47
25 necessarily a measure of a severe adverse event. 10:47

1 BY MR. JONNA: 10:47

2 Q. You have had patients who -- who you 10:47
3 administered mifepristone and misoprostol to who 10:47
4 had blood transfusions afterwards; correct? 10:47

5 MS. PENAN: Objection. Vague, ambiguous. 10:47
6 Incomplete hypothetical. Asked and answered. 10:47

7 A. I would say not that I can remember, but 10:47
8 it's highly unlikely in the decades of providing 10:47
9 this that there maybe hasn't been one, but not that 10:47
10 I can say, "Oh, I remember this one patient who got 10:47
11 a blood transfusion." 10:47

12 BY MR. JONNA: 10:47

13 Q. Do you have any patients that died after 10:48
14 the administration of mifepristone or misoprostol? 10:48

15 MS. PENAN: Objection. Compound. 10:48

16 A. Have I personally -- 10:48

17 MS. PENAN: Incomplete hypothetical. 10:48

18 A. Have I personally had any patients? Is 10:48
19 that what you're asking? 10:48

20 BY MR. JONNA: 10:48

21 Q. Yes. 10:48

22 A. Not that I can remember, no. 10:48

23 Q. Have you personally had any patients that 10:48
24 died after a procedural abortion? 10:48

25 A. Yes. 10:48

1 MS. PENAN: Objection. Incomplete 10:48

2 hypothetical. 10:48

3 BY MR. JONNA: 10:48

4 Q. Approximately how many? 10:48

5 A. One. 10:48

6 Q. Do you remember the circumstances? 10:48

7 A. She had a placenta accreta at 20-something 10:48

8 weeks and had a procedure done. Had bleeding. We 10:48

9 put a balloon -- I put a balloon in her uterus. 10:48

10 The bleeding slowed. She was admitted overnight 10:48

11 for observation. She was refusing a hysterectomy, 10:48

12 which is why we were just observing her with the 10:48

13 balloon. She -- the balloon -- she started to -- I 10:48

14 think the balloon popped or broke, and she started 10:49

15 to hemorrhage, and she ended up dying. 10:49

16 I can think of a -- so my patients that 10:49

17 I've done an abortion to, that's the only one that's 10:49

18 ever died. 10:49

19 Q. How about -- focusing, again, on 10:49

20 procedural abortions, have any patients required 10:49

21 blood transfusions? 10:49

22 A. Yes. 10:49

23 Q. Approximately what percentage? 10:49

24 A. It depends on the gestational age. 10:49

25 Q. Just overall in your practice. 10:49

1 A. That's unfair because it varies so very 10:49
2 tremendously by gestational age. 10:49

3 Q. Which gestational age range is it more 10:49
4 common in? 10:49

5 A. Later procedures, over -- over 18 weeks, 10:49
6 probably even more over 20 weeks. 10:49

7 Q. In those later procedures over 18 or 20 10:49
8 weeks, what -- approximately what percentage 10:49
9 required a blood transfusion? 10:49

10 A. Well, it has to be taken in context, so if 10:49
11 I -- because as a specialist at a referral center, 10:49
12 where we get the more complex patients, so I expect 10:49
13 our rates to be higher, because these are people 10:50
14 that have more significant medical issues, as 10:50
15 compared to the procedures that are done in the 10:50
16 community, a freestanding clinic or surgery center, 10:50
17 which are going to be lower risk. 10:50

18 So the transfusion rate, in my population, 10:50
19 is going to be different than the general 10:50
20 population because of the types of patients that 10:50
21 are referred to me as a specialist. So our 10:50
22 transfusion rate at later procedures is around the 10:50
23 order of 2 percent. 10:50

24 Q. What's your understanding of the 10:50
25 transfusion rate, more broadly, across other 10:50

1 practices? You mentioned entire briors [phonetic]. 10:50

2 A. Less than 1 percent. 10:50

3 Q. But even at 2 percent, you still consider 10:50
4 procedural abortions to be safe, don't you? 10:50

5 MS. PENAN: Objection. Vague, ambiguous. 10:50

6 A. In the context of somebody who has medical 10:50
7 complications, as I stated earlier, risk is always 10:50
8 compared to benefit, or you have to -- it's 10:50
9 comparative. 10:50

10 So at that point, it's what's the risk of 10:50
11 her abortion at that gestational age versus her risk 10:50
12 of continuing the pregnancy. And given the patients 10:51
13 that have higher transfusion risks also have higher 10:51
14 risks with continuing the pregnancy because they are 10:51
15 medically complicated. So comparing it at that 10:51
16 point, is it safe compared to continuing the 10:51
17 pregnancy? It certainly is. 10:51

18 BY MR. JONNA: 10:51

19 Q. How do you define risks of continuing a 10:51
20 pregnancy? Like, in other words, what are the -- 10:51
21 what are the common risks of continuing a pregnancy 10:51
22 that you've comprised the -- the complex procedures 10:51
23 that you are involved in? 10:51

24 MS. PENAN: Objection. Incomplete 10:51
25 hypothetical. Lacks foundation. Calls for 10:51

1 speculation. Vague, ambiguous. 10:51

2 A. Are you asking -- actually, I need 10:51

3 clarification. I can ask you what I think you are 10:51

4 asking, but I would rather you just clarify your 10:51

5 question. 10:51

6 BY MR. JONNA: 10:51

7 Q. You said that you get the more complex 10:51

8 later gestation procedural abortion cases; correct? 10:51

9 A. Yes. 10:51

10 Q. And you said that the risks of that 10:51

11 procedure have to be weighed against the risks of 10:51

12 continuing with the pregnancy. 10:51

13 A. Yes. 10:51

14 Q. So I'm just trying to get an understanding 10:51

15 of what risks of continuing the pregnancy you are 10:51

16 normally looking at. 10:52

17 MS. PENAN: Objection. Vague, ambiguous. 10:52

18 Incomplete hypothetical. 10:52

19 A. Yeah. It depends on their medical 10:52

20 situation, but, you know, that's very vague. 10:52

21 BY MR. JONNA: 10:52

22 Q. Just the more common ones that you've 10:52

23 encountered. 10:52

24 A. More common ones -- 10:52

25 MS. PENAN: Same objections. 10:52

1 BY MR. JONNA: 10:52

2 Q. The more common risks of continuing the 10:52
3 pregnancy that you're -- you're encountering in 10:52
4 your practice. 10:52

5 A. So -- 10:52

6 MS. PENAN: Same objections. 10:52

7 A. Yeah. If you -- the easy way to 10:52
8 understand this is that risks of any complication 10:52
9 increases as gestation advances. So there is a 10:52
10 risk of bleeding with an abortion at 20 weeks. 10:52
11 That risk of having significant bleeding -- and let 10:52
12 me go back. 10:52

13 There is a risk of bleeding to the point of 10:52
14 requiring a transfusion or some intervention or 10:52
15 something at 20 weeks' gestation for an abortion. 10:52
16 There is also a risk when somebody delivers at term. 10:52
17 The risk at term is much higher than it is perhaps at 10:52
18 20 weeks. But if somebody has a medical complication 10:52
19 or a medical thing going on, like severe pulmonary 10:52
20 disease or liver disease or a bleeding disorder, 10:52
21 those risks of her having problems later in pregnancy 10:53
22 are higher than the risks while we are doing a 10:53
23 procedure at 20 weeks. 10:53

24 So that is my quick answer. And if you 10:53
25 want more, you will have to ask another question. 10:53

1 BY MR. JONNA: 10:53

2 Q. Of the complex cases that you deal with, 10:53
3 what percentage of them don't have significant 10:53
4 risks of continuing the pregnancy? 10:53

5 MS. PENAN: Objection. Vague, ambiguous. 10:53
6 Incomplete hypothetical. Asked and answered. 10:53

7 A. This is going back to, again, when I was 10:53
8 providing those services up to a couple of years 10:53
9 ago. I would say 80 to 90 percent of our patients 10:53
10 had some kind of comorbidity. 10:53

11 BY MR. JONNA: 10:53

12 Q. Even for those 10 to 20 percent of 10:53
13 patients that didn't have a comorbidity, you still 10:53
14 thought the risks involved with the later gestation 10:53
15 procedural abortions were acceptable; isn't that 10:53
16 true? 10:53

17 MS. PENAN: Objection. Misstates the 10:53
18 witness's testimony. Argumentative. Incomplete 10:53
19 hypothetical. Lacks foundation. Compound. Vague, 10:53
20 ambiguous. 10:54

21 A. When -- when a patient presents for that, 10:54
22 we -- we go over what the risks are. Tell her what 10:54
23 the risks would be of continuing the pregnancy. 10:54
24 And it's up to her if she feels it's acceptable for 10:54
25 her. 10:54

1 BY MR. JONNA: 10:54

2 Q. Right. I'm talking about the ones in 10:54
3 which you determined there is no significant risk. 10:54
4 So the 10 to 20 percent that don't have significant 10:54
5 comorbidities, as a doctor, you would evaluate the 10:54
6 risks to be justified even with the transfusion 10:54
7 rates we described; is that right? 10:54

8 MS. PENAN: Same objections. Plus, asked 10:54
9 and answered. 10:54

10 A. The risk of her having any complications 10:54
11 at 20 weeks is lower than the risk of her having it 10:54
12 at delivery, yes. 10:54

13 BY MR. JONNA: 10:54

14 Q. Okay. Turning back to -- to the exhibit 10:54
15 we are looking at. So are there -- are you aware 10:54
16 of any long-term longitudinal studies of the health 10:54
17 effects of taking mifepristone? 10:54

18 MS. PENAN: Objection. Incomplete 10:54
19 hypothetical. Vague, ambiguous. 10:55

20 A. No, because it's not presumed to have any 10:55
21 health effects long term, but if you feel that it 10:55
22 does, I would like to know what you are worried 10:55
23 about so I can answer that question. 10:55

24 BY MR. JONNA: 10:55

25 Q. Is it true that there are no long-term 10:55

1 longitudinal studies on the safety of mifepristone 10:55

2 and misoprostol? 10:55

3 MS. PENAN: Same objections. 10:55

4 A. There is no long-term safety studies for 10:55

5 most medications because pharmacologically, we 10:55

6 understand that they're there and gone. So I can 10:55

7 say the same thing about many medications. 10:55

8 BY MR. JONNA: 10:55

9 Q. Okay. So the answer is that's true? 10:55

10 MS. PENAN: Objection. Misstates the 10:55

11 witness's testimony. Asked and answered. 10:55

12 A. I answered the question already. 10:55

13 BY MR. JONNA: 10:55

14 Q. I think you answered a different question. 10:55

15 Just to clarify, there are no long-term 10:55

16 longitudinal studies on the safety of mifepristone 10:55

17 and misoprostol; correct? 10:55

18 MS. PENAN: Objection. Same objections. 10:55

19 A. The way the question is asked, no, there 10:55

20 are no long-term safety studies of their use. 10:56

21 BY MR. JONNA: 10:56

22 Q. Okay. Looking at page 9, Section 8.1, it 10:56

23 says "The process of a failed pregnancy termination 10:56

24 could disrupt normal embryo-fetal development and 10:56

25 result in adverse developmental effects. Birth 10:56

1 defects have been reported with a continued 10:56
2 pregnancy after a failed pregnancy termination with 10:56
3 Mifeprex in a regimen with misoprostol. In animal 10:56
4 reproduction studies, increased fetal losses were 10:56
5 observed in mice, rats, and rabbits, and skull 10:56
6 deformities were observed in rabbits." 10:56

7 Do you see that? 10:56

8 A. Yes. 10:56

9 Q. Do you agree with this, that a failed 10:56
10 medical abortion could lead to birth defects? 10:56

11 MS. PENAN: Objection. Incomplete 10:56
12 hypothetical. Lacks foundation. Vague, ambiguous. 10:56
13 The record speaks for itself. 10:56

14 A. Yeah, the statement is there, when you use 10:56
15 mifepristone with misoprostol, birth defects are 10:56
16 known to occur from misoprostol use. 10:56

17 BY MR. JONNA: 10:56

18 Q. Okay. If we scroll down, it discusses the 10:57
19 teratology studies in mice, rats, and rabbits. Do 10:57
20 you see that? 10:57

21 A. Yes. 10:57

22 Q. Do you rely on this animal study in 10:57
23 advising your patients about the risks of medical 10:57
24 abortions? 10:57

25 MS. PENAN: Objection. Incomplete 10:57

1 hypothetical. Lacks foundation. 10:57

2 BY MR. JONNA: 10:57

3 Q. Why not? 10:57

4 (Reporter interruption for clarification.) 10:57

5 A. Yes. I had said "no." So when the FDA 10:57

6 prepares a label, it has sections that it completes 10:57

7 with whatever data is available. It doesn't mean 10:57

8 it necessarily translates to human data. 10:57

9 There is a wide establishment that these 10:57

10 kinds of studies in animals don't always translate, 10:57

11 just like we have abundant data showing mifepristone 10:57

12 is not teratogenic in humans, all right? But the FDA 10:57

13 label will always require this information be 10:57

14 included. 10:57

15 If you look at labels from other regulatory 10:57

16 authorities around the world, they don't always 10:57

17 include all the same information. This is just part 10:58

18 of what the FDA requires to be included. So I don't 10:58

19 use that information. 10:58

20 BY MR. JONNA: 10:58

21 Q. All right. Page 10, Section 12, "Clinical 10:58

22 Pharmacology," it says "The anti-progestational 10:58

23 activity of mifepristone results from competitive 10:58

24 interaction with progesterone at 10:58

25 progesterone-receptor sites. Based on studies with 10:58

1 various oral doses in several animal species 10:58
2 (mouse, rat, rabbit, and monkey), the compound 10:58
3 inhibits the activity of endogenous or exogenous 10:58
4 progesterone." 10:58
5 Do you see that? 10:58
6 A. Yes. 10:58
7 Q. Do you agree with that? 10:58
8 MS. PENAN: Objection. Vague, ambiguous. 10:58
9 Incomplete hypothetical. Lacks foundation. 10:58
10 A. Mostly. I mean, the term "competitive" is 10:58
11 always a vague term, but, yeah, in general, I do. 10:58
12 But how you interpret it can be different based on 10:58
13 your knowledge base. 10:58
14 BY MR. JONNA: 10:58
15 Q. So you believe that's true, even though 10:58
16 it's based on animal studies? 10:58
17 MS. PENAN: Objection. Misstates the 10:58
18 witness's testimony. Asked and answered. 10:58
19 A. That determines how it works, and then you 10:59
20 need human trials to say, you know, "Does it 10:59
21 clinically work?" There's plenty of things that do 10:59
22 something in an animal, and then you go to a human 10:59
23 study and it doesn't work the same. So that's just 10:59
24 part of the entire package, not the basis for the 10:59
25 package. 10:59

1 BY MR. JONNA: 10:59

2 Q. Do you know why the FDA requires animal 10:59

3 studies if they are unreliable? 10:59

4 MS. PENAN: Objection. Incomplete 10:59

5 hypothetical. Lacks foundation. Vague, ambiguous. 10:59

6 A. The FDA requires preclinical studies to 10:59

7 try to get as much information as possible about 10:59

8 safety and toxicity before it's given to humans. 10:59

9 It doesn't necessarily mean it's going to translate 10:59

10 into efficacy. But it's the best models that we 10:59

11 have, and it's what the FDA requires as a starting 10:59

12 point. 10:59

13 There are studies that were done -- there 10:59

14 are products that never got to market because the 10:59

15 animal study said it was fine, and then you start it 10:59

16 in humans and there's problems, or vice versa, where 10:59

17 the animal studies suggested that there was a little 10:59

18 something abnormal, but nothing that would stop its 11:00

19 continuation in humans. It was found to have no 11:00

20 problems. It's just part of the process of how drugs 11:00

21 go through FDA approval. 11:00

22 BY MR. JONNA: 11:00

23 Q. Okay. So turning to page 11, Section 11:00

24 12.3, it says "Mifepristone is rapidly absorbed 11:00

25 after oral ingestion with nonlinear 11:00

1 pharmacokinetics for Cmax after single oral doses 11:00
2 of 200 milligrams and 600 milligrams in healthy 11:00
3 subjects." 11:00

4 Do you see that? 11:00

5 A. Yes. 11:00

6 Q. And you agree with this statement as well? 11:00

7 A. Yes. 11:00

8 MS. PENAN: Objection. Incomplete 11:00
9 hypothetical. Lacks foundation. 11:00

10 BY MR. JONNA: 11:00

11 Q. Underneath that, it says that it has a 11:00
12 peak plasma concentration approximately 90 minutes 11:00
13 after -- oh. We just lost you there, but you are 11:00
14 back. I will repeat it. 11:00

15 It says it has a peak plasma concentration 11:00
16 of approximately 90 minutes after ingestion. Do 11:00
17 you see that? 11:00

18 A. Yes. 11:00

19 Q. And you agree with that statement as well? 11:00

20 A. Yes. 11:01

21 MS. PENAN: Objection. Incomplete 11:01
22 hypothetical. The record speaks for itself. 11:01
23 Vague, ambiguous. 11:01

24 BY MR. JONNA: 11:01

25 Q. Scrolling down, under "Elimination," it 11:01

1 says that "Mifepristone is 50 percent eliminated 11:01
2 between 12 and 72 hours." Do you see that? 11:01
3 A. Yes. 11:01
4 MS. PENAN: Same objections. 11:01
5 BY MR. JONNA: 11:01
6 Q. And you agree with that as well? 11:01
7 A. Yes. 11:01
8 Q. Would you agree that this implies that up 11:01
9 to 50 percent of the mifepristone could be in the 11:01
10 body after 72 hours? 11:01
11 A. Yes. 11:01
12 MS. PENAN: Objection. Incomplete 11:01
13 hypothetical. Vague, ambiguous. Lacks foundation. 11:01
14 BY MR. JONNA: 11:01
15 Q. On page 14, Section 17 there, "Patient 11:01
16 Counseling Information," it says, in highlight 11:01
17 there, "Advise the patient that it is necessary to 11:01
18 complete the treatment schedule, including a 11:01
19 follow-up assessment approximately 7 to 14 days 11:01
20 after taking Mifeprex." 11:01
21 Do you see that? 11:01
22 A. Yes. 11:01
23 Q. And do you advise all of your patients 11:01
24 this way? 11:01
25 A. Yes, and a follow-up assessment can be 11:01

1 done in many different ways. So as we talked about 11:01
2 earlier, already it's on the record. 11:02

3 Q. Okay. It continues saying "Explain that 11:02
4 prolonged heavy vaginal bleeding is not proof of a 11:02
5 complete abortion." Do you see that? 11:02

6 A. Yes. 11:02

7 Q. And do you tell your patients that? 11:02

8 A. Yes. 11:02

9 Q. Do your patients often have prolonged 11:02
10 heavy bleeding? 11:02

11 A. No. 11:02

12 MS. PENAN: Objection. Incomplete 11:02
13 hypothetical. Vague, ambiguous. 11:02

14 BY MR. JONNA: 11:02

15 Q. How -- approximately how often would you 11:02
16 say they have prolonged heavy bleeding? 11:02

17 MS. PENAN: Same objection. Plus, calls 11:02
18 for speculation. 11:02

19 A. In my experience, it's not very common. 11:02
20 The majority of people have bleeding that's heavier 11:02
21 than their regular menses for a day or two, but 11:02
22 typically, it's more like their menses shortly 11:02
23 thereafter. 11:02

24 BY MR. JONNA: 11:02

25 Q. Okay. Page 17 -- sorry. Did I go down 11:02

1 too far? Yeah. 11:02

2 Page 17 in the "Medication Guide," it says 11:03

3 "Mifeprex blocks a hormone needed for your 11:03

4 pregnancy to continue." See that? 11:03

5 A. Yes. 11:03

6 Q. We already discussed that. You agree with 11:03

7 that. That's referring to progesterone; right? 11:03

8 MS. PENAN: Objection. Misstates the 11:03

9 witness's testimony. Incomplete hypothetical. 11:03

10 Vague, ambiguous. 11:03

11 A. Yes, it's referring to progesterone. 11:03

12 BY MR. JONNA: 11:03

13 Q. And it says "You will have bleeding and 11:03

14 cramping that will likely be heavier than your 11:03

15 usual period." 11:03

16 A. Yes. 11:03

17 Q. And that's consistent with your 11:03

18 experience; correct? 11:03

19 A. Yes. 11:03

20 Q. Okay. 11:03

21 MR. JONNA: Let's go off the record. 11:03

22 THE VIDEOGRAPHER: Going off the record at 11:03

23 11:03 a.m. 11:03

24 (Recess taken from 11:03 a.m. to 11:03

25 11:10 a.m.) 11:10

1 THE VIDEOGRAPHER: Back on the record at 11:10
2 11:10 a.m. 11:10
3 BY MR. JONNA: 11:10
4 Q. Okay. I am going to pull up Exhibit 6 11:10
5 now, which is the misoprostol Cytotec label. 11:10
6 (Deposition Exhibit 6 was marked for 11:10
7 identification by the reporter and is 11:10
8 attached hereto.) 11:10
9 BY MR. JONNA: 11:10
10 Q. You've seen this document before, I 11:10
11 assume, Dr. Glidden; right -- I'm sorry, 11:10
12 Dr. Creinin? 11:10
13 A. Yes. 11:10
14 Q. So what -- and I have a problem saying it 11:11
15 wrong. It's misoprostol? 11:11
16 A. Yes, that's correct. 11:11
17 Q. All right. That is probably frustrating 11:11
18 you. 11:11
19 What -- what is misoprostol? 11:11
20 A. It's a prostaglandin E1 analog. 11:11
21 (Reporter interruption for clarification.) 11:11
22 A. Prostaglandin E1 analog. 11:11
23 BY MR. JONNA: 11:11
24 Q. Okay. What does that mean for a simple 11:11
25 person like myself? 11:11

1 A. Prostaglandins are hormones throughout the 11:11
2 body. Women are most familiar with them because 11:11
3 they are released from the lining of the uterus 11:11
4 when they have their period and cause cramping. 11:11
5 But they have effects all over the body. The 11:11
6 misoprostol, for example, is also used because it 11:11
7 protects -- it acts in the lining of the gut, 11:11
8 specifically the stomach, to help protect it from 11:11
9 the impact of nonsteroidal analgesics to cause 11:11
10 ulcers. 11:11

11 So there's prostaglandins in the lungs, 11:11
12 some cause the airways to constrict; some cause the 11:12
13 airways to dilate. So it's -- they are different 11:12
14 types. It's a hormone, and they come in different 11:12
15 types. 11:12

16 So this one is specifically type E with a 11:12
17 subtype of 1, because there's E1s and E2s, they -- 11:12
18 again, how they affect the body. The -- and 11:12
19 "analog" means it's not the naturally occurring 11:12
20 prostaglandin. It's -- it's designed to be more 11:12
21 specific to bind the prostaglandin receptors that 11:12
22 are in more specific areas of the body so that you 11:12
23 have less side effects in other areas. So that's 11:12
24 what a prostaglandin E1 analog is. 11:12

25 Q. Thank you. 11:12

1 What is it used for, generally, 11:12

2 misoprostol? 11:12

3 A. It's -- 11:12

4 MS. PENAN: Objection. Incomplete 11:12

5 hypothetical. Vague, ambiguous. 11:12

6 A. It's FDA-approved for the prevention of 11:12

7 ulcers in people taking nonsteroidal analgesics. 11:12

8 It's very widely used in obstetrics, based on large 11:13

9 clinical trials that look at its use for labor 11:13

10 induction, for labor induction abortion, for 11:13

11 abortion, for miscarriage treatment. 11:13

12 BY MR. JONNA: 11:13

13 Q. Can you briefly describe its role in the 11:13

14 medication abortion protocol? 11:13

15 A. In all -- 11:13

16 MS. PENAN: Objection. Vague, ambiguous. 11:13

17 A. In all of these roles, it works to cause 11:13

18 the uterus to cramp and contract. 11:13

19 BY MR. JONNA: 11:13

20 Q. And so why is it needed in a medication 11:13

21 abortion? 11:13

22 A. Because -- 11:13

23 MS. PENAN: Objection. Lacks foundation. 11:13

24 Calls for speculation. Incomplete hypothetical. 11:13

25 A. Because when mifepristone is used alone, 11:13

1 it has a -- it doesn't work as well as when 11:13
2 mifepristone is combined with a prostaglandin 11:13
3 analog. So the misoprostol will weaken the 11:14
4 attachment of the pregnancy in the uterus and 11:14
5 increase the uterus's sensitivity to natural -- I'm 11:14
6 sorry, increase the uterus's sensitivity to 11:14
7 prostaglandins. It also has some cervical 11:14
8 softening effects. You follow it with misoprostol 11:14
9 to cause the uterus to cramp and contract. It will 11:14
10 then expel that pregnancy at a higher rate than if 11:14
11 you just give them mifepristone alone. 11:14
12 BY MR. JONNA: 11:14
13 Q. Okay. So if we look at page 6 of the -- 11:14
14 of Exhibit 6. 11:14
15 A. Uh-huh. 11:14
16 Q. It says here "Cytotec should not be used 11:14
17 by" -- "should not be taken by pregnant women..." 11:14
18 Do you see that? 11:14
19 A. Uh-huh. Yes. 11:14
20 MS. PENAN: Objection. Misstates the 11:14
21 record. The record speaks for itself. 11:14
22 A. But, yeah, it's an incomplete statement. 11:14
23 You're only picking part of the statement. 11:14
24 BY MR. JONNA: 11:14
25 Q. Right. I was focusing on that because, 11:14

1 you would agree, it's contraindicated for 11:14
2 pregnancy; is that not? 11:14
3 A. No, it's not. 11:14
4 Q. And why is that? 11:14
5 A. Because the complete statement says 11:14
6 "should be not taken -- should not be taken by 11:14
7 pregnant women to reduce the risk of ulcers induced 11:15
8 by nonsteroidal anti-inflammatory drugs." It 11:15
9 doesn't say it should not be taken by pregnant 11:15
10 women because it's used for other indications in 11:15
11 pregnancy. 11:15
12 Q. Okay. And it's used for abortion -- 11:15
13 (Audio glitch.) 11:15
14 (Reporter interruption for clarification.) 11:15
15 MR. JONNA: Yeah, I did hear an echo 11:15
16 there. I don't know where that came from. 11:15
17 Q. Okay. It's used for abortion and 11:15
18 off-label use? 11:15
19 A. Not -- you know, you have to have an FDA 11:15
20 expert chime in because the mifepristone label 11:15
21 states that you should use it. So is it off-label 11:15
22 from the misoprostol label? Yes. Is it on-label 11:15
23 based on the misoprostol label? It's on-label 11:15
24 according to the misoprostol label. 11:15
25 Q. But it -- underwent FDA-approved clinical 11:15

1 trials before coming into use for abortion; isn't 11:15
2 that true? 11:15

3 MS. PENAN: Objection. Asked and 11:15
4 answered. Incomplete hypothetical. Calls for 11:15
5 speculation. Lacks foundation. Vague, ambiguous. 11:16

6 A. No. The drug did go through trial, 11:16
7 mifepristone and misoprostol combined, which is 11:16
8 what's stated in the mifepristone label. 11:16

9 BY MR. JONNA: 11:16

10 Q. But misoprostol, separate from its -- from 11:16
11 what you are describing, misoprostol itself never 11:16
12 went through its own FDA-approved clinical trials 11:16
13 for abortion use; is that true? 11:16

14 MS. PENAN: Objection. Vague, ambiguous. 11:16

15 A. Yeah, I can try and ask you a clarifying 11:16
16 question, but I don't know if I should, and just 11:16
17 have you try to clarify your question. 11:16

18 BY MR. JONNA: 11:16

19 Q. Other than the FDA-approved -- other than 11:16
20 the FDA trials that you are referring to for 11:16
21 mifepristone, are you aware of any other ones for 11:16
22 misoprostol for abortion use? 11:16

23 MS. PENAN: Same objections. 11:16

24 A. You are asking if misoprostol is approved 11:16
25 to be used by itself for abortion? No, there are 11:16

1 no FDA trials for its use by itself for abortion. 11:16

2 BY MR. JONNA: 11:17

3 Q. You've prescribed misoprostol; is that 11:17

4 correct? 11:17

5 MS. PENAN: Objection. Incomplete 11:17

6 hypothetical. 11:17

7 A. Yes. 11:17

8 MS. PENAN: Vague, ambiguous. 11:17

9 A. Yes. 11:17

10 THE WITNESS: Sorry, I didn't wait. I 11:17

11 apologize, Haley. 11:17

12 MS. PENAN: Okay. 11:17

13 A. Yes. 11:17

14 BY MR. JONNA: 11:17

15 Q. What's your understanding of the side 11:17

16 effects of misoprostol? 11:17

17 A. Like all prostaglandins, it causes fever, 11:17

18 chills, nausea, vomiting, diarrhea, and then it's 11:17

19 going to have -- if you are using it in early 11:17

20 pregnancy, it's going to cause a woman to bleed, 11:17

21 and as a result of that, it could cause heavy 11:17

22 bleeding as part of the process of what's going on. 11:17

23 If -- if it's for an abortion, misoprostol can 11:17

24 cause teratogenic effects if the abortion isn't 11:17

25 completed. 11:17

1 Q. You are okay prescribing misoprostol for 11:17
2 medication abortion despite those side effects; is 11:17
3 that true? 11:18

4 MS. PENAN: Objection. Misstates the 11:18
5 witness's testimony. Incomplete hypothetical. 11:18
6 Lacks foundation. Vague, ambiguous. 11:18

7 A. I don't use misoprostol alone for 11:18
8 medication abortion. 11:18

9 BY MR. JONNA: 11:18

10 Q. You are okay prescribing misoprostol with 11:18
11 mifepristone for abortion, despite the side effects 11:18
12 you just described; is that correct? 11:18

13 MS. PENAN: Same objections. Incomplete 11:18
14 hypothetical. Vague, ambiguous. Lacks foundation. 11:18

15 A. When it's used with mifepristone, I have 11:18
16 large trials that allow me to inform the patients 11:18
17 of what to expect and what their rate of side 11:18
18 effects are, so I can properly counsel them. So, 11:18
19 yes, I am comfortable prescribing it because there 11:18
20 is adequate information when used in combination 11:18
21 with mifepristone, to answer your question. 11:18

22 BY MR. JONNA: 11:18

23 Q. You were not an author on an article that 11:18
24 proposed a misoprostol-only abortion protocol; is 11:18
25 that true? 11:18

1 Dr. Creinin, I think you are going to have 11:19
2 to speak up a little bit because I'm not sure if 11:19
3 she's getting these answers. 11:19
4 A. Yes. 11:19
5 Q. Okay. 11:19
6 (Reporter comments.) 11:19
7 BY MR. JONNA: 11:19
8 Q. Have you ever used a misoprostol-only 11:19
9 protocol in your practice? 11:19
10 MS. PENAN: Objection. Asked and 11:20
11 answered. 11:20
12 A. For what indication? 11:20
13 BY MR. JONNA: 11:20
14 Q. For -- for an abortion. 11:20
15 A. For an abortion, no. You said "in my 11:20
16 practice"? No, I have not. 11:20
17 Q. Okay. You were also an author on a study 11:20
18 that looked at administering misoprostol at the 11:20
19 same time as mifepristone, not after; is that true? 11:20
20 A. Yes. 11:20
21 Q. And that protocol does not have FDA 11:20
22 approval; correct? 11:20
23 A. No. It was done under a study. 11:20
24 Q. And so that protocol does not have FDA 11:20
25 approval; correct? 11:20

1	A. No.	11:20
2	MS. PENAN: Objection. Asked and	11:20
3	answered.	11:20
4	BY MR. JONNA:	11:20
5	Q. The answer is yes; right?	11:20
6	A. No.	11:20
7	Q. Okay. Does the protocol have FDA	11:20
8	approval?	11:20
9	A. What -- do you mean FDA approval to be	11:20
10	used clinically?	11:20
11	Q. Yes.	11:20
12	A. No, it's not what's in the label.	11:20
13	Q. Okay.	11:20
14	A. It -- it was a study.	11:20
15	Q. Okay. Have you ever prescribed	11:20
16	misoprostol to a woman who wants to keep her baby?	11:21
17	A. No.	11:21
18	MS. PENAN: Objection. Incomplete	11:21
19	hypothetical. Vague, ambiguous. Lacks foundation.	11:21
20	A. Not for abortion. I have a lot of	11:21
21	patients who have miscarriages and really wanted	11:21
22	the pregnancy.	11:21
23	BY MR. JONNA:	11:21
24	Q. Okay. Have you ever prescribed it to	11:21
25	induce labor?	11:21

1 A. It's used for labor induction. Let me 11:21
2 clarify. Do you mean labor induction in a person 11:21
3 having a delivery or labor induction for an 11:21
4 abortion? 11:21

5 Q. How about just start with for delivery. 11:21

6 A. Misoprostol use for labor induction, I 11:21
7 don't remember if it was commonplace when I was 11:21
8 still doing obstetrics. So I can't answer that off 11:21
9 the top of my head. It's possible that I did 11:21
10 before 1994. 11:21

11 Q. How about to induce labor for an abortion? 11:21

12 A. That's usually in combination with 11:21
13 mifepristone. 11:22

14 Q. Okay. 11:22

15 A. But -- but that's usually done on labor 11:22
16 and delivery, and I'm not on labor and delivery, so 11:22
17 I usually prescribe the mifepristone in our 11:22
18 protocols for our institution. Then whoever is on 11:22
19 labor and delivery, you know, prescribes or starts 11:22
20 the misoprostol. So have I personally? Probably 11:22
21 not. 11:22

22 (Words garbled due to speakers talking 11:22
23 simultaneously.) 11:22

24 A. -- our workflow works. 11:22

25 BY MR. JONNA: 11:22

1 Q. Are there any longitudinal studies 11:22
2 measuring long-term safety impact of a woman taking 11:22
3 misoprostol? 11:22

4 MS. PENAN: Objection. Incomplete 11:22
5 hypothetical. Vague, ambiguous. 11:22

6 A. There may be, related to its indication 11:22
7 for ulcers, but I'm not aware of any off the top of 11:22
8 my head, but they may exist. 11:22

9 BY MR. JONNA: 11:22

10 Q. How would you define "success" for an 11:22
11 abortion? 11:23

12 MS. PENAN: Objection. Vague, ambiguous. 11:23
13 Incomplete hypothetical. 11:23

14 A. Yeah. What -- what type of abortion are 11:23
15 you talking about? 11:23

16 BY MR. JONNA: 11:23

17 Q. Let's start with the medication abortion. 11:23

18 A. Well, the generally accepted definition of 11:23
19 "success" is not needing a procedural intervention. 11:23
20 So that's successful medication abortion. 11:23

21 Q. Okay. What about for a procedural 11:23
22 abortion? 11:23

23 MS. PENAN: Same objections. 11:23

24 A. Completely removing the pregnancy so that 11:23
25 the patient is no longer pregnant. She can have an 11:23

1 incomplete or other things and need another 11:23
2 procedure, but that's part of the -- the adverse 11:23
3 events that can occur. But success for a 11:23
4 procedural abortion, in research and counseling, 11:23
5 typically refers to continuing pregnancy. 11:23
6 BY MR. JONNA: 11:23
7 Q. Did you ever have a successful abortion 11:23
8 where the fetus or embryo is still alive at the 11:23
9 end? 11:24
10 MS. PENAN: Objection. Incomplete 11:24
11 hypothetical. Vague, ambiguous. 11:24
12 A. You have to specify what type of abortion. 11:24
13 BY MR. JONNA: 11:24
14 Q. Either. Any type. Can you have a type of 11:24
15 abortion that could be considered success where 11:24
16 there is a fetus or embryo live at the end? 11:24
17 MS. PENAN: Same objections. 11:24
18 A. By definition, that's impossible. It 11:24
19 can't be successful and still have a continuing 11:24
20 pregnancy. 11:24
21 BY MR. JONNA: 11:24
22 Q. So abortion requires fetal death. Would 11:24
23 you agree? 11:24
24 A. No, I don't agree. 11:24
25 Q. Why is that? 11:24

1 A. Because a fetus refers to something at 11 11:24

2 weeks or greater. And the majority of the 11:24

3 abortions are done earlier gestation. So -- 11:24

4 Q. So an abortion requires either an embryo 11:24

5 to die or a fetus to die? 11:24

6 A. "Die" is your term. I wouldn't use "die" 11:24

7 or "death" as my term. 11:24

8 Q. What term do you use? 11:24

9 A. I would say that the pregnancy is no 11:24

10 longer continuing. 11:24

11 Q. Okay. 11:24

12 All right. I'm going to turn now to the 11:24

13 topic of bleeding following medication abortion. 11:25

14 All right. This is Exhibit 84. It's a 11:25

15 document from Planned Parenthood. Its title is "How 11:25

16 long do you bleed after an abortion?" I just want 11:25

17 to -- 11:25

18 A. Can you go back up, so I can see the date 11:25

19 it was published. Thank you. 11:25

20 (Deposition Exhibit 84 was marked for 11:25

21 identification by the reporter and is 11:25

22 attached hereto.) 11:25

23 BY MR. JONNA: 11:25

24 Q. It was October 4th, 2022. 11:25

25 A. Thank you. 11:25

1 MS. PENAN: And it's now in the chat, 11:25
2 Dr. Creinin, if you would like to click on it. You 11:25
3 can open it and look at the whole thing if you 11:25
4 would like. 11:25

5 THE WITNESS: Okay. 11:25

6 BY MR. JONNA: 11:25

7 Q. I just have a question about this 11:25
8 highlighted section, the one that we are looking 11:25
9 at. It says -- by the way, you served as the 11:25
10 medical director of a Planned Parenthood affiliate; 11:25
11 right? 11:25

12 A. In the past, yes. 11:25

13 Q. Okay. The part that we're looking at on 11:25
14 page 3 says "You'll have very heavy bleeding and 11:25
15 cramping during a medication abortion. For most 11:25
16 people, the cramping and bleeding usually starts 1 11:25
17 to 4 hours after taking misoprostol. It's normal 11:25
18 to see large blood clots up to the size of a lemon 11:26
19 or clumps of tissue during your abortion, like a 11:26
20 really heavy period or miscarriage. But if you 11:26
21 don't have any bleeding within 24 hours after 11:26
22 taking misoprostol, call your nurse, doctor, or 11:26
23 local abortion provider." 11:26

24 Do you see that? 11:26

25 A. Yes. 11:26

1 Q. And do you agree with this, this 11:26
2 description? 11:26

3 MS. PENAN: Objection. Incomplete 11:26
4 hypothetical. Lacks foundation. Vague, ambiguous. 11:26
5 The record speaks for itself. 11:26

6 A. I think if someone was consulting with me 11:26
7 and say, "Would you agree that this is reasonable 11:26
8 to give the patients," I would say that, yes, it's 11:26
9 very reasonable to give the patients as a 11:26
10 description. 11:26

11 BY MR. JONNA: 11:26

12 Q. Okay. Exhibit 85 is a scientific study 11:26
13 that you coauthored. 11:26

14 A. Yes. 11:26

15 (Deposition Exhibit 85 was marked for 11:26
16 identification by the reporter and is 11:26
17 attached hereto.) 11:26

18 BY MR. JONNA: 11:26

19 Q. Do you need me to Zoom in more? Is that 11:26
20 okay? 11:26

21 A. That's fine. 11:26

22 Q. It's titled "Bleeding patterns after 11:26
23 misoprostol versus surgical treatment of early 11:26
24 pregnancy failure: results from a randomized 11:27
25 trial." It's 2007. Is that correct? 11:27

1 the record. Your -- your question is incorrect. 11:27

2 Q. Okay. 11:27

3 A. This was part of a study, and these 11:27

4 clinically important changes were used to identify 11:27

5 possible predictors of adverse bleeding outcomes, 11:28

6 not that they were adverse bleeding outcomes. And 11:28

7 that's exactly what the statement says. 11:28

8 So if you want to provide the correct 11:28

9 statement, it says "To identify possible predictors 11:28

10 of adverse bleeding outcomes, we use logistic 11:28

11 regression to examine associations between 11:28

12 demographic and" -- 11:28

13 (Reporter interruption for clarification.) 11:28

14 A. Yeah, I'm reading it, so it's on the 11:28

15 record that the attorney chose part of the 11:28

16 statement rather than the whole statement. 11:28

17 What this says is, in the study, "To 11:28

18 identify possible predictors of adverse bleeding 11:28

19 outcomes, we use logistic regression to examine 11:28

20 associations between demographic and pregnancy 11:28

21 characteristics and clinically important changes in 11:28

22 hemoglobin level" -- 11:28

23 BY MR. JONNA: 11:28

24 Q. Let me just -- 11:28

25 A. Right. 11:28

1 (Speakers talking simultaneously.) 11:28

2 A. What this says is that we used those to 11:28
3 identify possible predictors, not that by 11:28
4 themselves they result in a significant adverse 11:29
5 outcome. 11:29

6 BY MR. JONNA: 11:29

7 Q. Okay. Let me just clarify. I am focused 11:29
8 on this part of your -- of the article because I 11:29
9 wanted to ask if you agree that those measurements 11:29
10 that I just read are clinically important changes 11:29
11 in hemoglobin levels. Do you agree with that? 11:29

12 A. No. 11:29

13 MS. PENAN: Objection. Asked and 11:29
14 answered. 11:29

15 A. They are clinically important when we are 11:29
16 doing a study to identify possible predictors. 11:29

17 BY MR. JONNA: 11:29

18 Q. Okay. So -- 11:29

19 (Speakers talking simultaneously.) 11:29

20 A. That's what the statement says. 11:29

21 BY MR. JONNA: 11:29

22 Q. All right. So they were only clinically 11:29
23 important for purposes of this study, but they 11:29
24 can't be used for a broader discussion about 11:29
25 changes in the hemoglobin level? 11:29

1 A. They are clinically important to -- for 11:29
2 the purpose of this study to identify possible 11:29
3 predictors of adverse bleeding outcomes. It's 11:29
4 well-established that the outcome of concern is 11:29
5 transfusion or intervention to stop bleeding. 11:29

6 If somebody had a very high hemoglobin, for 11:29
7 example, of 15, and her hemoglobin decreased to 12.5, 11:30
8 her hemoglobin is still normal. It would be a 11:30
9 decrease of 2 1/2, but it's not clinically important. 11:30
10 So this is part of a study to identify possible 11:30
11 predictors. 11:30

12 Q. Okay. Well, I appreciate that 11:30
13 clarification. I certainly just want to get 11:30
14 your -- 11:30

15 A. Yeah, that's fine. 11:30

16 Q. -- accurate position on these issues. 11:30
17 So you said that the outcome of concern is 11:30
18 transfusion. And what else? 11:30

19 A. Or intervention to stop bleeding. 11:30

20 Q. And what does that mean? 11:30

21 A. Usually, in the -- in the case of 11:30
22 medication abortion or miscarriage treatment, it's 11:30
23 a procedure to evacuate the uterus to stop the 11:30
24 bleeding. 11:30

25 Q. Okay. And what -- how many of those 11:30

1 procedures are there? 11:30

2 MS. PENAN: Objection. Vague, ambiguous. 11:30

3 Incomplete hypothetical. Lacks foundation. 11:30

4 A. Yeah. Can you restate the question, what 11:30

5 you are trying to ask? 11:31

6 BY MR. JONNA: 11:31

7 Q. Okay. So you said the outcome of concern 11:31

8 is transfusion or the intervention to stop the 11:31

9 bleeding, and you said that's a procedure to 11:31

10 evacuate the uterus to stop the bleeding. So what 11:31

11 does that refer to? 11:31

12 A. If it's early, it's usually a dilation and 11:31

13 suction curettage. If it's in the situation of 11:31

14 somebody who has a fetal demise at 18 weeks, it 11:31

15 would be a dilation and evacuation. So as it 11:31

16 refers to early miscarriage or early abortion, that 11:31

17 would be a dilation and suction curettage. 11:31

18 Q. Okay. All right. 11:31

19 A. Keep in mind that the -- one of the -- no, 11:31

20 that's okay. I will just -- I'll wait for your 11:31

21 questions. 11:31

22 Q. Okay. Just scrolling down -- by the way, 11:31

23 feel free to, you know, point out context in these 11:31

24 papers. I just -- I'm zeroing in what I'm asking 11:31

25 about, but I'm not suggesting that that's all that 11:31

1 matters. 11:31

2 So, anyway, looking at the highlights here, 11:31

3 the study defines clinically important adverse 11:32

4 bleeding events as participants who experienced 11:32

5 vacuum aspiration because of heavy or prolonged 11:32

6 bleeding, nadir hemoglobin of 8 grams per deciliter, 11:32

7 and/or blood transfusion. Do you see that? 11:32

8 A. Yes. 11:32

9 Q. Do you agree that that's a good 11:32

10 definition? 11:32

11 MS. PENAN: Objection. Incomplete 11:32

12 hypothetical. Vague, ambiguous. 11:32

13 A. We are doing this for a study. I think A 11:32

14 and C are definitely important. We use the nadir 11:32

15 hemoglobin as just an additional marker because 11:32

16 when the blood count gets that low, usually 11:32

17 something else is going on. But the clinically 11:32

18 important ones are A and C. 11:32

19 The other thing, even a few years ago, we 11:32

20 would transfuse commonly for a very low hemoglobin. 11:32

21 It's not done as much anymore. So that's partly of 11:32

22 understanding the time. 11:32

23 BY MR. JONNA: 11:32

24 Q. Okay. 11:32

25 A. So this was published in 2022, but the 11:32

1 study was done much -- long before that. 11:32

2 Q. You -- I think we talked about this 11:33

3 earlier. You are one of the founding members of 11:33

4 the Society of Family Planning; correct? 11:33

5 A. Yes. 11:33

6 Q. And that was in 2005? 11:33

7 A. 2004. 11:33

8 Q. Okay. How would you describe the 11:33

9 reputation of the Society of Family Planning 11:33

10 currently? 11:33

11 MS. PENAN: Objection. Vague, ambiguous. 11:33

12 Incomplete hypothetical. 11:33

13 A. I don't know how to answer. What do you 11:33

14 mean by "reputation" -- 11:33

15 (Speakers talking simultaneously.) 11:33

16 A. -- to who? 11:33

17 BY MR. JONNA: 11:33

18 Q. To you. Do you view it as a credible 11:33

19 organization? 11:33

20 A. Yes. 11:33

21 Q. And -- 11:33

22 A. I don't always -- I don't always agree 11:33

23 with everything, all their statements or whatever, 11:33

24 but that's an individual privilege; right? 11:33

25 Q. Have you had leadership roles in the 11:33

1 organization? 11:33

2 A. Yes. 11:33

3 Q. What kinds? 11:33

4 A. I was vice president at its founding, and 11:33
5 then I was president, and then I was past 11:33
6 president. 11:33

7 Q. Okay. When -- do you currently have any 11:33
8 roles with them? 11:33

9 A. No. 11:33

10 Q. When was the last time that you held one 11:34
11 of those positions? 11:34

12 A. It's in my CV for the exact year, but it 11:34
13 would roughly be around 2012. 11:34

14 Q. Okay. Let me pull up Exhibit 86. This is 11:34
15 the Society of Family Planning's clinical 11:34
16 recommendation for the management of hemorrhage at 11:34
17 the time of abortion. Do you see that? 11:34

18 A. Yes. 11:34

19 (Deposition Exhibit 86 was marked for 11:34
20 identification by the reporter and is 11:34
21 attached hereto.) 11:34

22 BY MR. JONNA: 11:34

23 Q. Do you remember if you've ever seen this 11:34
24 document before? 11:34

25 A. I have. 11:34

1 Q. Okay. The clinical -- let's see here. 11:34
2 Okay. So the clinical recommendation states 11:34
3 "Definitions of postabortion hemorrhage include 11:34
4 greater than 250 milliliters blood loss, greater 11:34
5 than 500 milliliters blood loss, requiring 11:34
6 hospitalization and requiring transfusion. A 11:35
7 clinically relevant definition would include both a 11:35
8 clinical response to excessive bleeding, such as 11:35
9 transfusion or admission, and/or bleeding in excess 11:35
10 of 500 milliliters." 11:35
11 Do you see that? 11:35
12 A. Yes. 11:35
13 Q. Do you agree with this definition of 11:35
14 "hemorrhage"? 11:35
15 MS. PENAN: Objection. Incomplete 11:35
16 hypothetical. 11:35
17 A. My answer is no. 11:35
18 BY MR. JONNA: 11:35
19 Q. Why not? 11:35
20 A. What this statement says is -- it goes 11:35
21 over what studies have used as definitions. We -- 11:35
22 our group has subsequently published a study, 11:35
23 subsequent to this, showing that using the amount 11:35
24 of the loss is not the correct way to define a 11:35
25 clinically relevant definition, and it really is 11:35

1 only based on the clinical response, because people 11:35
2 can lose less than -- more than 500 milliliters and 11:35
3 not need a transfusion; right? So -- or not need 11:35
4 any other intervention or have any issues that 11:35
5 occur after the procedure. 11:35

6 So we've published our data showing that. 11:35
7 So I think subsequent data -- and this is one of the 11:36
8 things about guidelines, is, you know, they come out 11:36
9 at a time, and then there is subsequent data. And 11:36
10 then that's why guidelines, over time, eventually, 11:36
11 because it's a long process, get revised or updated. 11:36
12 But I would say it's just about the clinical 11:36
13 response. 11:36

14 Q. This is not -- 11:36
15 (Speakers talking simultaneously.) 11:36

16 BY MR. JONNA: 11:36

17 Q. Sorry. This is not old data, though, is 11:36
18 it? 11:36

19 A. There's -- 11:36

20 MS. PENAN: Objection. Vague, ambiguous. 11:36

21 BY MR. JONNA: 11:36

22 Q. Sorry. Looking here -- 11:36

23 A. Yes. But there is newer data; right? 11:36

24 Q. Okay. 11:36

25 A. This was -- this was put together over the 11:36

1 year of 2022. So there is newer data that's been 11:36
2 published that shows that -- it's published in 11:36
3 2024. 11:36

4 Q. Right. 11:36

5 A. It was received in -- December 1st, 2022. 11:36
6 Which means all of this was put together primarily 11:36
7 in 2022. The revision had to do with what the 11:36
8 journal was asking for, but the majority of the 11:36
9 data was accumulated prior to December of 2022. 11:36

10 Q. In which journal was this published in? 11:36

11 A. Contraception. 11:37

12 Q. Are you familiar with that journal? 11:37

13 A. I am. 11:37

14 Q. How so? 11:37

15 A. I publish a lot in that journal. It's the 11:37
16 official journal of the Society of Family Planning. 11:37
17 I was also deputy editor for many years on this 11:37
18 journal, and I'm currently on the editorial board. 11:37

19 Q. So you said that there is more recent data 11:37
20 that you think is more instructive on this 11:37
21 question. Can you identify what data you are 11:37
22 referring to? 11:37

23 A. Yeah. That was data from our group 11:37
24 published by Gilbert, is the first author, where we 11:37
25 looked at our outcomes and basically showed that 11:37

1 the amount of blood loss doesn't matter. It's 11:37
2 really the interventions that -- defines clinically 11:37
3 significant bleeding. 11:37

4 Q. Which journal was that published in? 11:37

5 A. Also published in Contraception. 11:37

6 Q. Okay. All right. Would you agree that 11:37
7 not all postabortion hemorrhages are considered 11:38
8 severe hemorrhages? 11:38

9 MS. PENAN: Objection. Incomplete 11:38
10 hypothetical. Vague, ambiguous. 11:38

11 A. The term "postabortion hemorrhage" can be 11:38
12 either subjective, if it's used by a patient or in 11:38
13 a clinical setting, or objective, if used in a 11:38
14 research setting or also in a clinical setting. So 11:38
15 everybody that meets the term of "hemorrhage" may 11:38
16 not meet it in the same way, depending on whether 11:38
17 it's a research setting or a clinical setting. 11:38

18 BY MR. JONNA: 11:38

19 Q. Okay. So just focusing on the research 11:38
20 setting, are there different degrees of hemorrhage? 11:38

21 MS. PENAN: Objection. Vague, ambiguous. 11:38
22 Incomplete hypothetical. 11:38

23 A. In research, we don't classify hemorrhage 11:38
24 as mild, moderate, or severe. It's just 11:39
25 hemorrhage. 11:39

1 BY MR. JONNA: 11:39

2 Q. Okay. How about in clinical practice? 11:39

3 MS. PENAN: Same objections. 11:39

4 A. People will use different adjectives in 11:39
5 their notes. Patients will use different 11:39
6 adjectives. The term "hemorrhage" is vague, even 11:39
7 in research. For example, the FDA uses the medDRA 11:39
8 definitions for hemorrhage -- or for adverse 11:39
9 events, and somebody who just has vaginal bleeding 11:39
10 maps to the term "vaginal hemorrhage" because 11:39
11 that's the term that's used. 11:39

12 So "hemorrhage" just means heavy bleeding. 11:39
13 How heavy can be subjective or objective, and vary 11:39
14 depending on the setting. 11:39

15 BY MR. JONNA: 11:39

16 Q. Okay. Just focusing on your clinical 11:39
17 practice. How do you describe different degrees of 11:39
18 hemorrhage in your clinical practice? 11:39

19 MS. PENAN: Objection. Incomplete 11:39
20 hypothetical. Vague, ambiguous. 11:39

21 A. You know, in clinical practice, you know, 11:39
22 if a patient says to me, "I hemorrhaged," I'm going 11:39
23 to write down "Patient states she hemorrhaged." If 11:39
24 she states, "I have bleeding a little heavier than 11:39
25 a period," I'm going to write down, "Patient had 11:39

1 bleeding a little heavier than a period." 11:40

2 So clinical practice is very 11:40

3 patient-dependent. 11:40

4 BY MR. JONNA: 11:40

5 Q. Right. So setting aside what the patient 11:40

6 describes, when you are evaluating the situation 11:40

7 and there is no patient-provided description, how 11:40

8 do you characterize different degrees of 11:40

9 hemorrhage? 11:40

10 A. It depends -- 11:40

11 MS. PENAN: Same objections. Incomplete 11:40

12 hypothetical. Vague, ambiguous. 11:40

13 BY MR. JONNA: 11:40

14 Q. How do you determine how to characterize 11:40

15 the hemorrhage? 11:40

16 A. It's going to be more -- 11:40

17 MS. PENAN: Same objections. 11:40

18 A. If I determine how heavy the bleeding was 11:40

19 based on how it affects her. Right? If she -- if, 11:40

20 in her world, that bleeding is excessive, then it 11:40

21 counts as excessive; right? Clinical practice is 11:40

22 very -- patients have very subjective views. 11:40

23 You can have patients that have, at 11:40

24 baseline, very heavy bleeding. There's patients that 11:40

25 wear diapers to bed, put towels down to bed with 11:40

1 their normal period. So what's heavy to that person 11:40
2 may not be heavy to others. There's lots of -- 11:40
3 there's studies that show that about 80 percent of 11:40
4 people that think they have -- don't have heavy 11:40
5 periods, actually do qualify as having excessive 11:41
6 menstruation. 11:41

7 So, there is a lot of subjectivity, and so 11:41
8 you go with that in clinical practice. You go with 11:41
9 the subjectivity. You -- I wouldn't tell a patient, 11:41
10 "Well, your bleeding really wasn't that bad." You 11:41
11 know, that's not my -- my position to do that. We 11:41
12 have to go by what she went through. 11:41

13 BY MR. JONNA: 11:41

14 Q. So setting aside the subject -- subjective 11:41
15 components, when you are objectively looking at it, 11:41
16 how would you determine, objectively, whether a 11:41
17 hemorrhage is mild, moderate, or severe? 11:41

18 MS. PENAN: Objection. Incomplete 11:41
19 hypothetical. Vague, ambiguous, and compound. 11:41

20 A. You don't qualify -- we don't qualify a 11:41
21 hemorrhage as mild, moderate, or severe. 11:41

22 BY MR. JONNA: 11:41

23 Q. Okay. 11:41

24 A. People may use those adjectives, and 11:41
25 that's part of writing notes or whatever, but there 11:41

1 is not a qualification for it. 11:41

2 Q. How do you distinguish between heavy 11:41

3 bleeding and hemorrhage? 11:41

4 MS. PENAN: Same objections. 11:41

5 A. They can be used interchangeably, 11:41

6 depending on the situation of a clinical case or 11:41

7 research or the patient -- what the patient says; 11:42

8 right? And you go by -- you have to go with what 11:42

9 -- what's going on from the patient's point of 11:42

10 view. If she has -- you know, again, patients who 11:42

11 have very heavy bleeding and stay at home, and I'll 11:42

12 -- I might write down she had heavy bleeding. 11:42

13 There's patients that have heavy bleeding and feel 11:42

14 it is so heavy that they, you know, need to come to 11:42

15 the office right away. And if she says, "I 11:42

16 hemorrhaged," then I will write down, "Patient 11:42

17 feels she's hemorrhaging." 11:42

18 BY MR. JONNA: 11:42

19 Q. Okay. What if a patient said she thinks 11:42

20 she had very severe bleeding? How would you 11:42

21 characterize that? 11:42

22 A. I -- I would write down that she said she 11:42

23 had very severe bleeding, if that's clinically what 11:42

24 she said. 11:42

25 Q. You wouldn't write down "hemorrhage"? 11:42

1 MS. PENAN: Objection. Asked and 11:42
2 answered. 11:42

3 A. It's possible, I might. You know, it 11:42
4 depends on the situation. But it's always 11:42
5 possible. 11:42

6 BY MR. JONNA: 11:42

7 Q. What -- what would it depend on? 11:42

8 A. What I -- 11:42

9 MS. PENAN: Objection. Calls for 11:42
10 speculation. Incomplete hypothetical. 11:42

11 A. Yeah, you know, I'm just saying, you are 11:42
12 asking if it's theoretically possible. Yeah, I 11:43
13 could possibly write that. I don't, you know... 11:43

14 BY MR. JONNA: 11:43

15 Q. Okay. 11:43

16 A. I don't have, you know, a checklist of 11:43
17 saying, you've got to use this term in this 11:43
18 situation. 11:43

19 Q. Does a hemorrhage occur during every 11:43
20 medication abortion? 11:43

21 MS. PENAN: Objection. Incomplete 11:43
22 hypothetical. Vague, ambiguous. Calls for 11:43
23 speculation. 11:43

24 A. You would have to ask patients how they 11:43
25 feel it occurs. Does she bleed heavier than her 11:43

1 period? Yes. Some people may consider it 11:43

2 hemorrhaging; some people may not. 11:43

3 I have patients who say it's most -- like 11:43

4 on the pain side, "Oh, my God, it was the most severe 11:43

5 pain ever." I have patients who say, "Yeah, the pain 11:43

6 was not a big deal." So everybody comes to the table 11:43

7 with different past experiences, and they interpret 11:43

8 these outcomes differently. 11:43

9 BY MR. JONNA: 11:43

10 Q. Okay. Turning back to Exhibit 86 on 11:43

11 page 4, it says "Counseling prior to medication 11:43

12 abortion is vital to ensure that patients recognize 11:43

13 when heavy bleeding is excessive, defined by many 11:43

14 clinicians as soaking at least two pads per hour 11:44

15 for two consecutive hours." 11:44

16 Do you see that? 11:44

17 A. Yes. 11:44

18 Q. That was a "yes"? 11:44

19 A. Yes. 11:44

20 Q. Do you agree with this definition of 11:44

21 "excessive bleeding"? 11:44

22 MS. PENAN: Objection. Incomplete 11:44

23 hypothetical. Lacks foundation. Vague, ambiguous. 11:44

24 A. That is the point at which we tell 11:44

25 patients, "If it gets that heavy, we want you to 11:44

1 check in with us," because that is on the heavier 11:44
2 side. So, yes, if you want to define "excessive" 11:44
3 in that way. It's not the point at which we tell 11:44
4 patients they need to go to the emergency room, but 11:44
5 that's the point of check-in because they are 11:44
6 bleeding at home. 11:44

7 BY MR. JONNA: 11:44

8 Q. Okay. So this description here is 11:44
9 distinct from what you would consider a hemorrhage; 11:44
10 is that correct? 11:44

11 MS. PENAN: Objection. Misstates the 11:44
12 witness's testimony. Incomplete hypothetical. 11:44
13 Vague, ambiguous. 11:44

14 A. Not necessarily, because she could be 11:44
15 soaking four pads, and that would meet the 11:44
16 definition, and that might also be a hemorrhage. 11:44

17 BY MR. JONNA: 11:44

18 Q. But can there be excessive -- would you 11:44
19 agree, there can be excessive bleeding without a 11:44
20 hemorrhage? 11:45

21 MS. PENAN: Same objections. 11:45

22 A. It depends on how the patient feels about 11:45
23 it. 11:45

24 BY MR. JONNA: 11:45

25 Q. But there could be situations where, 11:45

1 depending on how the patient feels, there can be 11:45
2 excessive bleeding without a hemorrhage, you'd 11:45
3 agree; correct? 11:45

4 MS. PENAN: Objection. Incomplete 11:45
5 hypothetical. Vague, ambiguous. Lacks foundation. 11:45

6 A. I answered -- I answered, and you're 11:45
7 trying to get me to say something that I've already 11:45
8 answered. 11:45

9 BY MR. JONNA: 11:45

10 Q. You haven't answered, actually. 11:45

11 A. I have. I've told you that it depends on 11:45
12 how the patient feels about it. You know, I could 11:45
13 also say, you know, could it be possible that the 11:45
14 sun will come out today? Yeah, you know. It's 11:45
15 okay. Yeah. 11:45

16 Excessive bleeding, hemorrhage, in a 11:45
17 clinical situation, is very dependent on how the 11:45
18 patient feels about it. 11:45

19 Q. All right. 11:45

20 A. So could there be? There could be 11:45
21 anything. So that's an unfair question; right? 11:45
22 Could you wear a red tie tomorrow? Well, yeah, of 11:45
23 course, you could. Right? So I'm always going to 11:45
24 answer yes, you could wear a red tie, because you 11:45
25 could. 11:45

1 Q. Right. Okay. 11:45

2 A. So answering "could there be" is almost -- 11:45

3 just not an effective question. 11:45

4 Q. Okay. Well, I'm trying to understand your 11:45

5 definitions. I'm not trying to put words in your 11:45

6 mouth. 11:46

7 A. I answered the question. 11:46

8 Q. All right. Let's take a look at 11:46

9 Exhibit 92. 11:46

10 (Deposition Exhibit 92 was marked for 11:46

11 identification by the reporter and is 11:46

12 attached hereto.) 11:46

13 BY MR. JONNA: 11:46

14 Q. This is -- I will give you a chance to 11:46

15 skim this. Don't worry. 11:46

16 A. Okay. 11:46

17 Q. Heartbeat International's guidance to 11:46

18 women about how to manage vaginal bleeding. Before 11:46

19 I ask any questions, have -- have you seen this 11:46

20 document before? 11:46

21 A. No. 11:46

22 Q. All right. Take a minute it look at it, 11:46

23 and let me know when you are done. 11:46

24 A. Okay. 11:46

25 Q. Okay. In the second paragraph it says: 11:46

1 "There are certain signs that may indicate possible 11:46
2 problems during your pregnancy. If any of these 11:46
3 occur, call your doctor or go to the nearby 11:46
4 emergency department right away. Heavy vaginal 11:46
5 bleeding, filling two pads in an hour and/or 11:47
6 passing clots the size of a lemon. Severe or 11:47
7 continuing nausea or vomiting. Cramping and/or 11:47
8 back pain. Abdominal pain of any kind, especially 11:47
9 sharp, one-sided or sudden. Faintness. Do not 11:47
10 drive to hospital alone if you have this. Swelling 11:47
11 of your hands or face. Severe headaches. Blurred 11:47
12 vision. Shortness of breath or heart beating fast. 11:47
13 Pain with urination. Chills and/or fever. Leak or 11:47
14 gush of fluid from vagina. Foul-smelling vaginal 11:47
15 discharge." Do you see that? 11:47
16 A. Yes. 11:47
17 Q. Did you know that Heartbeat International 11:47
18 provides this guidance? 11:47
19 A. Did I know before seeing this? No, I did 11:47
20 not. I've never seen this document before. 11:47
21 Q. Would you agree that it's a good idea that 11:47
22 they provide this guidance? 11:47
23 MS. PENAN: Objection. Calls for 11:47
24 speculation. Lacks foundation. Incomplete 11:47
25 hypothetical. Vague, ambiguous. The record speaks 11:47

1 for itself. 11:47

2 A. I don't understand why you want -- what 11:47
3 you are trying to get at by saying "it's a good 11:47
4 idea." If -- if a patient has started a medication 11:47
5 abortion, that's good -- that's information they 11:47
6 already received. 11:48

7 BY MR. JONNA: 11:48

8 Q. So it would be better if Heartbeat didn't 11:48
9 provide this information? 11:48

10 A. No, I didn't say that. 11:48

11 MS. PENAN: Objection. Misstates the 11:48
12 witness's testimony. 11:48

13 A. Yeah. I didn't say. I don't know what 11:48
14 you mean by "is it good." Good for what? I don't 11:48
15 understand. 11:48

16 BY MR. JONNA: 11:48

17 Q. Okay. Is there anything you would add to 11:48
18 this statement if you were -- if you had a chance 11:48
19 to edit it? 11:48

20 A. Well -- 11:48

21 MS. PENAN: Objection. Calls for 11:48
22 speculation. Incomplete hypothetical. 11:48

23 BY MR. JONNA: 11:48

24 Q. I'm not talking about abortion pill 11:48
25 reversal. I'm talking about what we looked at 11:48

1 together. 11:48

2 A. Yeah, that's fine. I can -- I can 11:48

3 definitely answer that. 11:48

4 I think it directs people to overuse the 11:48

5 emergency room. They should have a doctor that's 11:48

6 taking -- that's providing care. So if they are 11:48

7 providing medical care, the answer to providing 11:48

8 medical care isn't always go to an emergency room. 11:48

9 You were asking me earlier about emergency 11:48

10 room rates, and I explained that some people lived 11:48

11 far from the place where they get medication 11:48

12 abortion. And so in those situations, they are told 11:48

13 to go to an emergency room. But we don't tell people 11:48

14 who live close to us to go to an emergency room. So 11:49

15 this is just telling people to use an emergency room; 11:49

16 right? 11:49

17 So you tried to -- you tried to ask me 11:49

18 earlier about, are those emergency room rates really 11:49

19 high. Well, this is the reason they get high, 11:49

20 because people are told to -- to go to the emergency 11:49

21 room instead of having a doctor providing them care 11:49

22 to say, "If you have these problems, you should come 11:49

23 in and see me." 11:49

24 So, for example, the soaking two pads an 11:49

25 hour is not a reason to go to the emergency room, 11:49

1 it's a reason to check in with your doctor. 11:49

2 Q. You see, though, at -- on the top it says 11:49

3 "If any of these occur, call your doctor or go to a 11:49

4 nearby emergency department"; right? 11:49

5 A. Yeah. But it should be call your doc -- 11:49

6 call me, your doctor, who is providing this care if 11:49

7 you have any of these things. And then if 11:49

8 necessary, we'll direct you to go to an emergency 11:49

9 room. 11:49

10 Q. Right. But you do have -- you do 11:49

11 acknowledge that they are also encouraging women to 11:49

12 call their doctor, not just to go to an emergency 11:49

13 room, like you first implied; correct? 11:49

14 A. It says "or." 11:49

15 MS. PENAN: Objection. Asked and 11:49

16 answered. 11:49

17 A. Yeah, it says "or." 11:49

18 BY MR. JONNA: 11:49

19 Q. Right. If they -- 11:50

20 (Speakers talking simultaneously.) 11:50

21 THE REPORTER: One at a time. 11:50

22 BY MR. JONNA: 11:50

23 Q. Sorry about that. That's my fault. I 11:50

24 apologize, Doctor. 11:50

25 A. Yeah -- it says "or." It doesn't say 11:50

1 "Contact us"; right? And then it doesn't say "If 11:50
2 you can't reach us, go to a nearby emergency 11:50
3 department." It just says "or go." 11:50
4 So somebody will just say, "I got 11:50
5 medication from somebody. I don't know who they are, 11:50
6 and I'm just going to go to the emergency room" -- 11:50
7 right? -- or whatever. 11:50
8 So -- so do I agree with it? I think 11:50
9 it's -- these are reasonable instructions, but I 11:50
10 wouldn't start instructing people just to go to an 11:50
11 emergency room. 11:50
12 Q. Okay. Other than that -- 11:50
13 A. Because I would take care of my patients. 11:50
14 Q. Okay. Other than that distinction about 11:50
15 the emergency room, is there anything else in here 11:50
16 that kind of differs from the advice that you -- 11:50
17 MS. PENAN: Objection. Incomplete 11:50
18 hypothetical. Vague, ambiguous. 11:50
19 BY MR. JONNA: 11:50
20 Q. About signs that might indicate a problem? 11:50
21 MS. PENAN: Same objections. 11:50
22 A. Yeah, usually filling two pads in one hour 11:50
23 is not a reason to do anything. You need to do 11:50
24 that for two consecutive hours. Because if 11:50
25 somebody starts to pass the pregnancy, they may 11:51

1 soak three pads in an hour and one pad the next 11:51
2 hour. They've passed the pregnancy and it's going 11:51
3 down. So that's a little bit -- overalarming, but 11:51
4 otherwise, in general, otherwise in general, they 11:51
5 are reasonable. 11:51

6 There are some things on here that are not 11:51
7 related to abortion, per se. The process of the 11:51
8 abortion, like pain with urination, that would -- 11:51
9 you know, if they're worried about a bladder 11:51
10 infection, that's separate, but -- 11:51

11 BY MR. JONNA: 11:51

12 Q. Okay. So if anything, your criticism is 11:51
13 that they are being overly cautious? 11:51

14 MS. PENAN: Objection. Misstates the 11:51
15 witness's testimony. 11:51

16 A. No. I said that they are not taking -- 11:51
17 they are instructing people, rather than calling 11:51
18 the doctor, if you have these problems, to go to an 11:51
19 emergency room without the caveat that it should be 11:51
20 if you can't reach us, that you should go to an 11:51
21 emergency room. 11:51

22 BY MR. JONNA: 11:51

23 Q. Okay. 11:51

24 A. But that's how I provide my care. You are 11:51
25 asking me what I think, and when I provide 11:51

1 medication abortion care, myself and my partners 11:51

2 are available for the patients we provide care to. 11:51

3 Q. Are there any risks that you think they 11:51

4 are not advising women about that they should, when 11:52

5 you look at this -- management of vaginal bleeding? 11:52

6 MS. PENAN: Objection. Incomplete 11:52

7 hypothetical. Vague, ambiguous. 11:52

8 A. I'm reading. 11:52

9 BY MR. JONNA: 11:52

10 Q. Sorry. I meant -- I meant symptoms, not 11:52

11 -- not risks. 11:52

12 A. Yeah, no, I understand what you mean. 11:52

13 Well, I think they -- no, I think this is, 11:52

14 in my short time of looking at this, this is -- to 11:52

15 answer your question, a reasonable list. This is a 11:52

16 reasonable list. 11:52

17 Q. All right. Let me pull up -- Exhibit 93A, 11:52

18 which is the document that RealOptions provides -- 11:52

19 the guidance they provide to women about the risks 11:53

20 of bleeding. I will just give you a chance to look 11:53

21 at that. Let me know when you are done. 11:53

22 (Deposition Exhibit 93A was marked for 11:53

23 identification by the reporter and is 11:53

24 attached hereto.) 11:53

25 BY MR. JONNA: 11:53

1 Q. No, I'm sorry. That's the wrong page. I 11:53
2 was at the wrong page. I apologize. It's right 11:53
3 here? 11:53

4 MS. PENAN: And again, this in the chat, 11:53
5 if you would like to look at the whole document. 11:53

6 A. Okay. What's your question. 11:53

7 BY MR. JONNA: 11:53

8 Q. Just take a minute to read this, the 11:53
9 "Miscarriage Precautions" list, and I can make it 11:53
10 bigger or smaller if you need me to. And then let 11:53
11 me know when you are done. 11:53

12 A. Okay. 11:53

13 Q. Had you seen this document before today? 11:54

14 A. No. 11:54

15 Q. Do you think that these warnings of 11:54
16 miscarriage are sufficient, from your perspective? 11:54

17 MS. PENAN: Objection. Lacks foundation. 11:54
18 Calls for speculation. Incomplete hypothetical. 11:54
19 Vague, ambiguous. Compound. 11:54

20 A. These are not warnings. They are 11:54
21 symptoms. And they are missing things related to 11:54
22 pregnancy symptoms. 11:54

23 BY MR. JONNA: 11:54

24 Q. Like what, what things? 11:54

25 A. Well, people start to develop pregnancy 11:54

1 systems, like nausea, breast tenderness, and then 11:54
2 they go away, or they don't really develop those 11:54
3 symptoms. It could also be symptoms of 11:54
4 miscarriage, but -- what they have listed there 11:54
5 could be symptoms of miscarriage, but that's fine. 11:54
6 Q. Okay. Any other critiques you have of 11:54
7 this document? 11:54
8 MS. PENAN: Same objections. 11:54
9 A. Yeah, they are not critiques. You asked 11:54
10 me my opinion, so... 11:55
11 BY MR. JONNA: 11:55
12 Q. Do you have any other opinions? 11:55
13 A. No. 11:55
14 Q. Okay. 11:55
15 A. Of that section, no. But there is another 11:55
16 section below that's highlighted. Is that part of 11:55
17 your question or just that's symptoms of 11:55
18 miscarriage? 11:55
19 Q. Well, this -- this is a document that's 11:55
20 called "Miscarriage Precautions," and it explains 11:55
21 what a miscarriage is, symptoms of miscarriage. 11:55
22 A. Right. 11:55
23 Q. Causes, future pregnancies, and then it 11:55
24 says "Treatment." So I kind of -- I did want you 11:55
25 to look at the whole document. I'm asking -- 11:55

1 loss" is vague, because some women will spot for 11:57
2 days and days and days, actually all the way until 11:57
3 their next period. So I think it's -- I 11:57
4 personally -- if somebody asked me my opinion, I 11:57
5 would say, "It's too vague. You need to be a 11:57
6 little more specific for a patient to understand 11:57
7 it." That's my opinion. 11:57

8 Q. Okay. But in this case, they are not -- 11:57
9 you don't have that same concern that you had of 11:57
10 the last document, where they are not encouraging 11:57
11 women to first call their obstetrician? 11:57

12 MS. PENAN: Objection. Misstates the 11:57
13 witness's testimony. 11:57

14 BY MR. JONNA: 11:57

15 Q. I don't know if we got your answer. 11:57

16 A. No, but that -- but that assumes that they 11:57
17 have an obstetrician, that everybody has an 11:57
18 obstetrician. But it does say -- so if you don't 11:57
19 have an obstetrician, say, "Go to a nearby 11:57
20 hospital." But -- but this clinic is providing 11:57
21 this, given that they are providing medical care. 11:58
22 So why aren't they -- you know, they now have 11:58
23 established a patient-physician relationship. So 11:58
24 why aren't they saying, "Contact us, we are your 11:58
25 provider"? Right? 11:58

1 Q. Any other comments on the document? 11:58

2 A. Not at this time. 11:58

3 Q. Okay. All right. We are going to look at 11:58

4 some other exhibits now. I'm going to pull up 11:58

5 Exhibit 15, which is the appendix to your -- to 11:58

6 your studies. You've seen this before; correct? 11:58

7 A. Yes. 11:58

8 (Deposition Exhibit 15 was marked for 11:58

9 identification by the reporter and is 11:58

10 attached hereto.) 11:58

11 BY MR. JONNA: 11:58

12 Q. And you reviewed this to prepare for your 11:58

13 deposition; correct? 11:58

14 A. Yes. 11:58

15 Q. Okay. 11:58

16 A. Some of it, but I didn't -- yes. 11:58

17 Q. Do you need me to enlarge that, or can you 11:58

18 see it okay? 11:58

19 A. I can see it fine. 11:58

20 Q. Okay. So -- the three participants that 11:59

21 you listed are listed, I should say, as 11:59

22 hemorrhaging or numbers 8, 10, and 11; is that 11:59

23 correct? 11:59

24 A. Yes. 11:59

25 Q. And number 8 was in the progesterone 11:59

1 group; correct? 11:59

2 A. Yes. 11:59

3 Q. And numbers 10 and 11 were in the placebo 11:59

4 group? 11:59

5 A. Yes. 11:59

6 Q. And number 7 from the placebo group is 11:59

7 also listed as having bleeding and requesting a 11:59

8 D&C; is that correct? 11:59

9 A. Yes. 11:59

10 Q. All right. Let's take a look at 11:59

11 Exhibit 58. 11:59

12 (Deposition Exhibit 58 was marked for 11:59

13 identification by the reporter and is 11:59

14 attached hereto.) 11:59

15 BY MR. JONNA: 11:59

16 Q. This is the progress note for Subject 7. 11:59

17 And at 12:12, it says that "She called in stating 11:59

18 that she's bleeding and has passed a blood clot." 11:59

19 Do you see that? 12:00

20 A. Yes. 12:00

21 Q. And then at 12:35, it says "Now gush of 12:00

22 blood. Wants to come in." Is that what you see? 12:00

23 A. That's what I wrote, yes. 12:00

24 Q. And that's your handwriting; right? 12:00

25 A. Yes. 12:00

1 Q. What does that say between "now" and then 12:00
2 "gush of blood"? 12:00
3 A. With. That's a medical term for "with." 12:00
4 Q. Okay. Now with -- 12:00
5 A. C with a line over it is "with." 12:00
6 Q. Okay. And it said "Wants to come in." 12:00
7 Do you remember if you saw her when she 12:00
8 came in? 12:00
9 A. I would have to look at the records, but I 12:00
10 believe I did. 12:00
11 Q. Did she -- is what she experienced 12:00
12 consistent with a severe hemorrhage? 12:00
13 A. No. 12:00
14 Q. Why not? 12:00
15 A. She didn't describe it that way and she 12:00
16 had a single gush of blood. It wasn't a continuous 12:00
17 bleeding that was -- that was heavy for her. 12:00
18 Q. Okay. Let's take a look at Exhibit 59. 12:01
19 (Deposition Exhibit 59 was marked for 12:01
20 identification by the reporter and is 12:01
21 attached hereto.) 12:01
22 BY MR. JONNA: 12:01
23 Q. This is a progress note for Subject 8, the 12:01
24 progesterone group. And you looked at these 12:01
25 records to prepare for your deposition; correct? 12:01

1 A. Yes. 12:01

2 Q. Okay. If we go to page 2 -- sorry. 12:01

3 Sorry, starting here at 1:09 p.m., it says "PC." 12:01

4 Is that "phone call"? 12:01

5 A. Phone call, uh-huh. 12:01

6 Q. "...from subject regarding heavy bleeding, 12:01

7 soaking through clothes and passing clots." Do you 12:01

8 see that? 12:01

9 A. Yes. 12:01

10 Q. And that's consistent with the guidance 12:01

11 that we saw from that Planned Parenthood document 12:01

12 that warned women what to look out for on the 12:01

13 website, Exhibit 84. Do you recall that? 12:01

14 MS. PENAN: Objection. The record speaks 12:01

15 for itself. Incomplete hypothetical. 12:02

16 BY MR. JONNA: 12:02

17 Q. Yes? 12:02

18 A. I believe it does. And it's consistent 12:02

19 with the instructions we gave patients in the study 12:02

20 as well. 12:02

21 Q. Okay. And there is no -- we'll look at 12:02

22 more records for Subject 8, but there is no 12:02

23 indication here, from what we are looking at, that 12:02

24 she was filling more than two maxi pads for more 12:02

25 than two consecutive hours; is that correct? 12:02

1 MS. PENAN: Objection. The record speaks 12:02
2 for itself. 12:02

3 A. There is nothing documented for that. 12:02
4 There was a document that she is soaking through 12:02
5 her clothes. 12:02

6 BY MR. JONNA: 12:02

7 Q. Okay. And then underneath that line we 12:02
8 just looked at says "Spoke with MD and subject 12:02
9 coming in to be evaluated"; is that correct? 12:02

10 A. Yes. 12:02

11 Q. And this here is not your handwriting; is 12:02
12 that right? 12:02

13 A. No. 12:02

14 Q. That's Courtney Overstreet's handwriting; 12:02
15 right? 12:02

16 A. Yes. 12:02

17 Q. So this person, Courtney, spoke with you, 12:02
18 and you advised Subject 8 to come in to be 12:02
19 evaluated, not to call 911; is that correct? 12:02

20 MS. PENAN: Objection. The record speaks 12:02
21 for itself. 12:03

22 A. Based on her status at that moment in 12:03
23 time, yes. 12:03

24 BY MR. JONNA: 12:03

25 Q. Okay. And there is no -- you don't 12:03

1 disagree that there is no indication in these notes 12:03
2 that you advised Subject 8 to go to the emergency 12:03
3 room. Is that right? 12:03
4 MS. PENAN: Objection. Argumentative. 12:03
5 A. I did not advise her. Just like we talked 12:03
6 about earlier, as her provider, I told her to come 12:03
7 in and see me. 12:03
8 BY MR. JONNA: 12:03
9 Q. Okay. And then there is -- the line after 12:03
10 that is not highlighted, but it says "Needs to go 12:03
11 home and change, and then will come in for 12:03
12 evaluation." Do you see that? 12:03
13 A. Yes. 12:03
14 Q. Do you remember if she said she was going 12:03
15 to drive home and change? 12:03
16 A. I have no idea of whether she was going to 12:03
17 drive home or have someone else drive her. That's 12:03
18 beyond my scope of -- of knowledge based on what's 12:03
19 written here. 12:03
20 Q. At this point in time, if she said she was 12:03
21 going to drive home, you wouldn't have had a 12:03
22 concern? 12:03
23 MS. PENAN: Objection. Misstates the 12:03
24 witness's testimony. Calls for speculation. 12:03
25 Incomplete hypothetical. 12:04

1 A. Yeah. It's -- you are totally 12:04

2 hypothetical. I -- I can't answer that. 12:04

3 BY MR. JONNA: 12:04

4 Q. By the way -- 12:04

5 A. They are still going to do what they want 12:04

6 to do. I have patients that I say, "You should 12:04

7 come to the emergency room right away," and they 12:04

8 say, "Well, I need to go home because of my kids." 12:04

9 "Well, you need to come right away." 12:04

10 And they're like, "Well, I'm going home 12:04

11 first." 12:04

12 So patients still can do whatever they feel 12:04

13 they need to do. 12:04

14 Q. Sure. By the way, all I'm asking for is 12:04

15 what you remember. 12:04

16 A. Right. 12:04

17 Q. And so -- 12:04

18 A. All I remember is Courtney speaking to me 12:04

19 and telling -- and me telling her, while she was on 12:04

20 the phone, "Just tell her to come right in." 12:04

21 Q. Okay. But you don't remember advising her 12:04

22 not to drive; correct? 12:04

23 A. I did not -- I don't remember advising her 12:04

24 not to drive, no. 12:04

25 Q. Okay. 12:04

1 MS. PENAN: Objection. Asked and 12:04
2 answered. 12:04

3 BY MR. JONNA: 12:04

4 Q. If -- if you were certain that she was 12:04
5 experiencing a severe hemorrhage, you would have 12:04
6 told her to call 911 or go to the ER; correct? 12:04

7 MS. PENAN: Objection. Incomplete 12:04
8 hypothetical. Lacks foundation. Calls for 12:04
9 speculation. 12:04

10 A. Not necessarily. It depends if I was -- 12:04
11 you used the term "severe hemorrhage." If she 12:05
12 called me and said, "I'm bleeding heavily, I can't 12:05
13 get up off the floor, I feel faint," I would have 12:05
14 told her to call 911. But those are different 12:05
15 degrees of outcomes of bleeding. 12:05

16 BY MR. JONNA: 12:05

17 Q. Okay. So if we scroll down a few entries, 12:05
18 it said -- it says "Patient in ER. Came by 12:05
19 ambulance." And that's at -- at 3:15 p.m. So 12:05
20 about two hours later. Is that correct? 12:05

21 A. 3:14, yes. 12:05

22 Q. Okay. 12:05

23 All right. So I'm going to show you a 12:05
24 document that may or may not be relevant to you. I 12:05
25 just want to see if this makes any sense to you. 12:05

1 Are you familiar with the Emergency Severity Index? 12:05

2 A. No. 12:05

3 Q. Okay. We'll probably skip through this, 12:05

4 but it's UC Davis -- are you aware of whether UC 12:05

5 Davis uses this index to triage patients in the ER? 12:05

6 A. I don't know. 12:06

7 MS. PENAN: Objection. 12:06

8 BY MR. JONNA: 12:06

9 Q. Okay. Are you familiar with the different 12:06

10 ESI categories? 12:06

11 A. No. 12:06

12 MS. PENAN: Objection. Asked and 12:06

13 answered. 12:06

14 BY MR. JONNA: 12:06

15 Q. Okay. All right. Then I'm going -- are 12:06

16 you aware that there's different -- well, let me 12:06

17 just -- let me just show you something and see if 12:06

18 it refreshes your memory. 12:06

19 All right. This is an overview of the 12:06

20 Emergency Severity Index. I'm not asking you to 12:06

21 study this. I'm just asking you if this rings a bell 12:06

22 or not. 12:06

23 A. No, I've never seen this. 12:06

24 Q. Okay. So whether a -- so the different 12:06

25 triage categories, levels 1, 2, 3, 4, 5 mean 12:06

1 nothing to you? 12:06

2 A. No. 12:06

3 MS. PENAN: Objection. Asked and 12:06

4 answered. 12:06

5 BY MR. JONNA: 12:06

6 Q. Okay. Just confirming. Okay. 12:06

7 All right. So the last question on this: 12:06

8 Do you have any recollection that Category 1 is the 12:06

9 most serious, and then it kind of goes from there? 12:06

10 MS. PENAN: Objection. Asked and 12:06

11 answered. 12:06

12 A. I'm not an emergency room physician, so I 12:06

13 don't use this information. 12:06

14 BY MR. JONNA: 12:06

15 Q. Okay. Fair enough. 12:06

16 I'm going to go to Exhibit 61 now. 12:07

17 (Deposition Exhibit 61 was marked for 12:07

18 identification by the reporter and is 12:07

19 attached hereto.) 12:07

20 THE REPORTER: Counsel, can we get a break 12:07

21 soon? 12:07

22 MR. JONNA: Oh, sure. If the court 12:07

23 reporter wants a break, we take a break right away. 12:07

24 THE REPORTER: Yes, I would like a break. 12:07

25 MR. JONNA: Let's go off the record. 12:07

1 THE VIDEOGRAPHER: Going off the record at 12:07
2 12:07 p.m. 12:07
3 (Recess taken from 12:07 p.m. to 12:07
4 12:42 p.m.) 12:42
5 THE VIDEOGRAPHER: Back on the record at 12:42
6 12:42 p.m. 12:42
7 BY MR. JONNA: 12:42
8 Q. All right. Welcome back, Dr. Creinin. 12:42
9 You understand that you are still under oath; 12:42
10 correct? 12:42
11 A. Yes. 12:42
12 Q. During the break, did you have a chance to 12:42
13 speak to lawyers with the Attorney General's 12:42
14 Office? 12:42
15 A. No. 12:42
16 Q. Have you spoken to them during your 12:42
17 deposition today? 12:42
18 A. No. 12:42
19 Q. You recall that in the Culture of Life 12:42
20 Family Services case, you wrote a declaration, and 12:42
21 you stated that "medication abortion and surgical 12:42
22 abortion are both exceedingly safe." That's your 12:42
23 opinion; correct? 12:43
24 A. Yes. 12:43
25 Q. And just to clarify, does the amount of 12:43

1 bleeding that causes safety concerns, is it the 12:43
2 same in a chemical abortion and a surgical abortion 12:43
3 for you? 12:43

4 MS. PENAN: Objection. Incomplete 12:43
5 hypothetical. Lacks foundation. Vague, ambiguous. 12:43

6 A. Yeah, I would have to -- I'm agreeing 12:43
7 because the question is really vague. I don't 12:43
8 understand what you are saying. 12:43

9 BY MR. JONNA: 12:43

10 Q. We talked earlier about what level of 12:43
11 bleeding causes safety concerns, and I just was 12:43
12 wondering if you -- if your view of that issue is 12:43
13 the same for chemical abortions and surgical 12:43
14 abortions? 12:43

15 MS. PENAN: Same objections. 12:43

16 A. You have to clarify what "chemical 12:43
17 abortions" are. That's not a medical term. 12:43

18 BY MR. JONNA: 12:43

19 Q. Sorry. Medication abortions. 12:43

20 A. All right. . 12:43

21 MS. PENAN: Same objections. 12:43

22 BY MR. JONNA: 12:43

23 Q. Why do you have a problem with that term, 12:43
24 by the way? 12:43

25 A. Because it's not a medical term. 12:43

1 Q. Okay. 12:43

2 A. It's a -- it's a harsh term that's tried 12:43
3 to -- used to characterize a medical treatment that 12:44
4 has an actual medical term. You know, it's like I 12:44
5 could call lawyers something bad, and you wouldn't 12:44
6 like it; right? 12:44

7 Q. Okay. Well -- 12:44

8 A. Because "lawyer" or "attorney" is the 12:44
9 accepted term. 12:44

10 Q. Right. I didn't know "chemical" was a bad 12:44
11 term, but anyway, let's set that aside. 12:44

12 A. It's a slanderous term. 12:44

13 Q. Okay. 12:44

14 A. All right. ? So not used by medical 12:44
15 professionals -- anyway. 12:44

16 Q. Okay. 12:44

17 A. So your question is -- can you repeat the 12:44
18 question? 12:44

19 Q. Does the -- according to you, does the 12:44
20 amount of bleeding that causes safety concerns 12:44
21 change when you're talking about a medication 12:44
22 abortion versus a surgical abortion? 12:44

23 MS. PENAN: Same objections. 12:44

24 A. Yes, because somebody having a medication 12:44
25 abortion is bleeding at home. So her complaints 12:44

1 are coming not in front of me, versus somebody who 12:44
2 I'm doing a procedure on, I can see they are 12:45
3 bleeding, and I can act on it to prevent something 12:45
4 bad from happening, which is why significant 12:45
5 bleeding is also -- it's dependent on what you do. 12:45
6 To be fair, that's the best answer I can 12:45
7 give you, because your question is pretty vague. 12:45
8 BY MR. JONNA: 12:45
9 Q. Okay. I'm going to pull up Exhibit 35. 12:45
10 (Deposition Exhibit 35 was marked for 12:45
11 identification by the reporter and is 12:45
12 attached hereto.) 12:45
13 BY MR. JONNA: 12:45
14 Q. Do you recognize this document? 12:45
15 A. Yes. 12:45
16 Q. What is this? 12:45
17 A. It's the paper we talked about earlier, 12:45
18 related to our study on quantitative blood loss at 12:45
19 the time of dilation and evacuation procedure. 12:45
20 Q. And the title is "Clinical interventions 12:45
21 are more accurate than quantitative measurements 12:45
22 for defining hemorrhage with dilation and 12:45
23 evacuation." Correct? 12:45
24 A. Right. 12:45
25 Q. And it's from 2023; correct? 12:45

1 A. Right. 12:45

2 Q. And you're a coauthor? 12:46

3 A. I'm the senior author, yes. 12:46

4 Q. Okay. On page 2 of the PDF, you wrote 12:46

5 "The Society of Family Planning suggests that a 12:46

6 clinically relevant definition of hemorrhage would 12:46

7 include both a clinical response to excessive 12:46

8 bleeding, such as transfusion or admission and/or 12:46

9 bleeding greater than 500 milliliters." 12:46

10 Do you see that? 12:46

11 A. Yes, I do. 12:46

12 Q. And we looked at those SFP guidelines 12:46

13 before; correct? 12:46

14 A. Yes. 12:46

15 Q. Here, underneath that, it says "No studies 12:46

16 have evaluated the correlation of outcomes or any 12:46

17 specific blood loss measurement to bleeding related 12:46

18 morbidity. A hemorrhage definition should consider 12:46

19 that all interventions are not clinically equal." 12:46

20 Do you see that? 12:46

21 A. Yes. 12:46

22 Q. So did this study look at the UC Davis D&E 12:46

23 procedures from April 2019 to March 2020, to see if 12:47

24 a better hemorrhage definition can be identified? 12:47

25 A. You need to scroll down, so I could agree 12:47

1 with the exact dates. 12:47

2 Yes. 12:47

3 MS. PENAN: Objection. Vague, ambiguous. 12:47

4 BY MR. JONNA: 12:47

5 Q. So these would have been abortions 12:47
6 performed under your supervision; is that correct? 12:47

7 A. No. 12:47

8 MS. PENAN: Objection. Vague, ambiguous. 12:47

9 BY MR. JONNA: 12:47

10 Q. Then under whose supervision? 12:47

11 A. Anybody on our team who provides these 12:47
12 services, including me, but also included other 12:47
13 physicians. 12:47

14 Q. And what proportion would have included 12:47
15 you, approximately? 12:47

16 A. Based on the timing, 15 percent. 12:47

17 Q. Okay. On page 3, you proposed defining 12:47
18 hemorrhage as a true complication reflecting the 12:48
19 need for uterine balloon tamponade, UAE, blood 12:48
20 transfusion, hospitalization, or return to 12:48
21 operating room, which you distinguished from 12:48
22 clinically relevant bleeding. Is that correct? 12:48

23 MS. PENAN: Objection. The record speaks 12:48
24 for itself. 12:48

25 A. In this paper, as it relates to dilation 12:48

1 and evacuation, yes. 12:48

2 BY MR. JONNA: 12:48

3 Q. Okay. So merely bleeding is not enough; 12:48

4 is that correct? 12:48

5 A. As it relates to -- 12:48

6 MS. PENAN: Objection. Misstates the 12:48

7 witness's testimony. Vague, ambiguous. Incomplete 12:48

8 hypothetical. 12:48

9 A. As it relates to dilation and evacuation, 12:48

10 no. Everybody has bleeding. 12:48

11 BY MR. JONNA: 12:48

12 Q. On page 6, you found that the -- that 12:49

13 under the SFP definition, there was a hemorrhage 12:49

14 rate of 77 per 1,000 cases, or 7.7 percent? Is 12:49

15 that correct? 12:49

16 A. That's what's written there. 12:49

17 MS. PENAN: Objection. The record speaks 12:49

18 for itself. 12:49

19 BY MR. JONNA: 12:49

20 Q. And clinically relevant bleeding was 65 12:49

21 per 1,000 cases, or 6.5 percent; is that right? 12:49

22 MS. PENAN: Same objections. 12:49

23 A. Based on what's written there, yes. 12:49

24 BY MR. JONNA: 12:49

25 Q. So if you redefine hemorrhage to be more 12:49

1 than just bleeding, you can get your rate down to 12:49
2 21 per 1,000 cases, or 2.1 percent; would you 12:49
3 agree? 12:49

4 A. For dilation and evacuation, yes. 12:49

5 Q. Do you tell women who get procedural 12:49
6 abortions at UC Davis that there is a 7.7 percent 12:49
7 rate of hemorrhage? 12:49

8 MS. PENAN: Objection. Incomplete 12:49
9 hypothetical. Lacks foundation. Vague, ambiguous. 12:50

10 A. Am I supposed to answer that? 12:50

11 BY MR. JONNA: 12:50

12 Q. Yes. 12:50

13 A. I tell them there's a 2 percent risk. 12:50

14 Q. And why is that? 12:50

15 A. Because of how we define -- how hemorrhage 12:50
16 is defined. It's above. 12:50

17 Q. So during this time, you maintain that 12:50
18 dilation and evacuation was a safe procedure; 12:50
19 correct? 12:50

20 A. Yes. 12:50

21 MS. PENAN: Objection. Vague, ambiguous. 12:50

22 BY MR. JONNA: 12:50

23 Q. You just redefined hemorrhage? 12:50

24 A. You asked if it's a safe procedure. You 12:50
25 asked that earlier. It's a safe procedure compared 12:50

1 to the alternative, which would be continuing the 12:50
2 pregnancy, or if she was having a labor induction 12:50
3 abortion. And again, this reflects our high-risk 12:50
4 population. 12:50

5 Q. Would you -- do you believe that your 12:50
6 definition is accepted in the medical community? 12:50

7 MS. PENAN: Objection. Calls for 12:51
8 speculation. Lacks foundation. Incomplete 12:51
9 hypothetical. Vague, ambiguous. 12:51

10 A. I believe that the discussions I've had 12:51
11 with people in the medical community suggests that 12:51
12 they are moving towards using this rather than just 12:51
13 a number. But you asked me my opinion, and I think 12:51
14 this is the best way to define it, for dilation and 12:51
15 evacuation. 12:51

16 BY MR. JONNA: 12:51

17 Q. Okay. So you said they are moving towards 12:51
18 it, but what -- what would you say is the generally 12:51
19 accepted definition in the medical community 12:51
20 currently? 12:51

21 MS. PENAN: Objection. Misstates the 12:51
22 witness's testimony. Calls for speculation. Lacks 12:51
23 foundation. Incomplete hypothetical. Vague, 12:51
24 ambiguous. 12:51

25 A. I can't answer what the general medical 12:51

1 community does. 12:51

2 BY MR. JONNA: 12:51

3 Q. Okay. So you said that the community is 12:51
4 moving towards it. Is that correct? 12:51

5 A. That is my feeling, but I don't know. I 12:51
6 haven't surveyed what everybody does, and there are 12:51
7 no newer guidelines since this came out. 12:51

8 Q. They are moving towards it from what 12:52
9 position? 12:52

10 A. That I have talked to colleagues who have 12:52
11 said they no longer use the amount as a definition, 12:52
12 but just by the procedures. But there is no 12:52
13 standardized survey to say what people do. You 12:52
14 asked me my opinion. This is my opinion. 12:52

15 Q. What about for medication abortion? 12:52

16 A. This -- all this data refers -- 12:52

17 MS. PENAN: Objection. Sorry. Incomplete 12:52
18 hypothetical. Vague, ambiguous. Lacks foundation. 12:52

19 A. This -- this definition refers to dilation 12:52
20 and evacuation procedures, which are very different 12:52
21 than medication abortion, and relate to people 12:52
22 having procedures where they are right in front of 12:52
23 us. That's different. 12:52

24 BY MR. JONNA: 12:52

25 Q. So do you tell women that even that -- do 12:52

1 you tell them that at least 2.1 percent of women 12:52

2 receive hemorrhages? 12:52

3 A. No -- 12:53

4 MS. PENAN: Objection. Asked and 12:53

5 answered. 12:53

6 A. No. For medication abortion, the relevant 12:53

7 concern for the patient is whether she's going to 12:53

8 need a procedure or whether she's going to need a 12:53

9 transfusion. 12:53

10 BY MR. JONNA: 12:53

11 Q. Right. 12:53

12 A. The type -- the type of procedures that we 12:53

13 sometimes have to do after a D&E to prevent blood 12:53

14 loss are very different. It would be incredibly 12:53

15 rare to need a uterine balloon tamponade or a 12:53

16 uterine artery embolization after a medication 12:53

17 abortion, so rare that it's closer to zero than any 12:53

18 other number. So they are different procedures, 12:53

19 and so there's different definitions. Or different 12:53

20 processes. So they are different definitions. 12:53

21 Q. I'm going to turn back to Exhibit 61. 12:53

22 These are Subject 8's emergency-room medical 12:54

23 records, which I believe you testified that you 12:54

24 looked at before your deposition; correct? 12:54

25 A. Yes. 12:54

1 Q. Do you recall when you looked at these? 12:54

2 A. I'm just keeping all the participants 12:54

3 straight. Subject 8 would be -- at least sometime 12:54

4 this week, one of our meetings this week. 12:54

5 Q. One of your meetings with the lawyers for 12:54

6 the Attorney General's Office? 12:54

7 A. Yes. 12:54

8 Q. And what did they tell you about the 12:54

9 subject 8's medical records? 12:54

10 A. That you would be reviewing them. 12:54

11 Q. Did they tell you what we covered with the 12:54

12 other witnesses? 12:54

13 A. They told me that you questioned the other 12:54

14 witnesses about bleeding. I believe that's what I 12:54

15 can remember, but that's about it. 12:54

16 Q. Did you review -- 12:54

17 A. And we went through the records related to 12:55

18 that. 12:55

19 Q. Did you review these medical records 12:55

20 before that time? In other words, was that the 12:55

21 first time you had seen the emergency room records 12:55

22 for Patient 8? 12:55

23 A. The entire record that you have -- that is 12:55

24 part of this -- 12:55

25 Q. Exhibit? 12:55

1 A. -- document -- exhibit, thank you for 12:55
2 figuring out my word. The entire document, yes. 12:55
3 But I have reviewed parts of it during the study. 12:55
4 Q. Okay. 12:55
5 A. Including my notes and the ultrasound, et 12:55
6 cetera. 12:55
7 Q. All right. Taking a look at page 6 of the 12:55
8 PDF, it says that "Subject 8, who arrived at UC 12:55
9 Davis emergency room on May 31, 2019," her 12:55
10 diagnosis is "complete or unspecified spontaneous 12:55
11 abortion without complication." Do you see that? 12:56
12 A. Yes. 12:56
13 Q. What does that indicate to you? 12:56
14 A. It's a billing code, which, at times, are 12:56
15 not accurate, but it's just a billing code. 12:56
16 Q. Okay. What does that diagnosis mean to 12:56
17 you? 12:56
18 A. It's a billing code. That's what it means 12:56
19 to me. Billing codes don't necessarily match up 12:56
20 with diagnoses. It's a billing code. 12:56
21 Q. It does say "Admission Diagnoses/Reasons 12:56
22 for Visit" above that. Do you see that? 12:56
23 A. Yep, it does, per the ICD-10. And we -- 12:56
24 it's well-established in medical literature that 12:56
25 you can't -- that the codes are not -- don't 12:56

1 necessarily always line up with exactly what 12:56

2 happened. That's just a billing code. 12:56

3 So what they are saying is that she went 12:56

4 through this, and at the end of it, she didn't have a 12:56

5 complication resulting from it. 12:56

6 Q. Is it common practice for US Davis to 12:56

7 provide billing codes that are not accurate? 12:56

8 MS. PENAN: Objection. Calls for 12:57

9 speculation. Lacks foundation. Incomplete 12:57

10 hypothetical. 12:57

11 A. That is the billing code that the billers 12:57

12 felt was closest to what happened, because there 12:57

13 aren't billing codes for every single situation. 12:57

14 There isn't a billing code for a patient who got 12:57

15 mifepristone and then unknown if she got a placebo 12:57

16 or progesterone and then bled and passed the 12:57

17 pregnancy. There isn't a code for it. So this is 12:57

18 the one that they got that was closest to it. 12:57

19 The referral without complications mean -- 12:57

20 with complication, from a billing code, means there's 12:57

21 sequelae from the spontaneous abortion, not that it 12:57

22 occurred -- that there were complications at the 12:57

23 time, but that there's no sequelae. 12:57

24 So in billing nomenclature, with and 12:57

25 without complication, have to do with sequelae. 12:57

1 BY MR. JONNA: 12:57

2 Q. So there is a billing code for abortion 12:57

3 with complication; correct? 12:57

4 A. Yes. 12:57

5 Q. And that billing code wasn't used here; 12:57

6 correct? 12:57

7 A. She had no sequelae after her visit to the 12:57

8 emergency department. 12:57

9 Q. So this wasn't an accurate billing code; 12:57

10 correct? 12:57

11 A. Within the realms of the limitations of 12:57

12 billing codes, that is accurate within the realm of 12:58

13 what's available. 12:58

14 Q. Okay. And you would agree that physicians 12:58

15 are ultimately responsible for the codes, not the 12:58

16 coders; correct? 12:58

17 A. That's not true. 12:58

18 Q. Who is responsible for the codes? 12:58

19 A. The coders and billers. 12:58

20 Q. Okay. So you have no responsibility -- or 12:58

21 the physicians, I should say, have no 12:58

22 responsibilities for the codes? 12:58

23 MS. PENAN: Objection. Misstates the 12:58

24 witness's testimony. Lacks foundation. Incomplete 12:58

25 hypothetical. Vague, ambiguous. 12:58

1 A. To be clear, I don't know what goes on in 12:58
2 the emergency department. I know I can tell you 12:58
3 that in my office, I can put a billing code in, and 12:58
4 if the billers feel it's -- that the chart reflects 12:58
5 something different, they can change it. 12:58
6 Q. Okay. Let's go to page 8, which is page 9 12:58
7 of the PDF. 12:59
8 A. And also, to be clear, that's a diagnosis 12:59
9 code, not a procedure. And so we talked about 12:59
10 billing codes; it's a diagnosis code. 12:59
11 Q. Okay. So looking here on page 9, it 12:59
12 states "Reason for visit, chief complaint, vaginal 12:59
13 bleeding minor." Do you see that? 12:59
14 A. Yes. 12:59
15 Q. And what does that mean to you? 12:59
16 A. That means at the time she presented, her 12:59
17 bleeding was considered minor at the time -- again, 12:59
18 at the time she presented. 12:59
19 Q. And who would have put that description 12:59
20 in? 12:59
21 A. I don't know. 12:59
22 Q. Is that a billing code? 12:59
23 A. No. 12:59
24 Q. Okay. 12:59
25 A. It's a complaint, but I don't know whether 12:59

1 it's the triage nurse, the triage doctor. I don't 12:59
2 know who did it. 12:59
3 Q. And it says "Means of Arrival, Sac Metro 12:59
4 Fire." Do you see that? 12:59
5 A. Yes. 12:59
6 Q. What does that mean? 12:59
7 A. Through ambulance service. 12:59
8 Q. Okay. Underneath, it says "Patient," and 12:59
9 then there is a redaction "for vaginal bleeding for 01:00
10 two hours. Patient reports heavily saturated pad. 01:00
11 Patient passed a couple of clots in the toilet. 01:00
12 Patient 8 weeks pregnant. Patient recently seen 01:00
13 today prior to the bleeding. NAD. VSS. 01:00
14 Miscarriage in January. Patient ambulatory." 01:00
15 What does that refer to, by the way, 01:00
16 "patient ambulatory"? 01:00
17 A. That means she's able to ambulate. 01:00
18 Q. What does that mean? 01:00
19 A. She can move around on her own. 01:00
20 Q. And what does "NAD" means? 01:00
21 A. No acute distress. 01:00
22 Q. What does that mean to you? 01:00
23 A. That at the moment she wasn't in distress. 01:00
24 She was stable, medically stable. 01:00
25 Q. And what does -- what does it indicate to 01:00

1 you that she's ambulatory? 01:00

2 A. That she, at the current time, is not 01:00

3 dizzy or having problems with moving around. 01:00

4 Q. And what does "VSS" mean? 01:00

5 A. Vital signs stable. 01:01

6 Q. What does that indicate to you? 01:01

7 A. That her vital signs were interpreted as 01:01

8 normal by the triage nurse who wrote this. 01:01

9 Q. Is that a good thing? 01:01

10 MS. PENAN: Objection. Vague, ambiguous, 01:01

11 incomplete hypothetical. Lacks foundation. Calls 01:01

12 for speculation. 01:01

13 A. I think everybody wants normal vital 01:01

14 signs. So that would be -- not having normal vital 01:01

15 signs would be worrisome. So by default, it is, to 01:01

16 have good vital signs. Good for you; good for 01:01

17 everybody. 01:01

18 BY MR. JONNA: 01:01

19 Q. And here it says "Patient G8P1A6." Do you 01:01

20 have any idea what that means? 01:01

21 A. That means she's been pregnant eight times 01:01

22 and has had one child, and either an abortion or a 01:01

23 miscarriage six times, or some other pregnancy. 01:01

24 That could be molar pregnancies, ectopic 01:01

25 pregnancies, but some other type of pregnancy six 01:01

1 times. 01:01

2 Q. And would you interpret this statement to 01:01

3 mean patient -- reports heavily saturating one pad? 01:01

4 Because we don't see "pads," plural; correct? 01:01

5 MS. PENAN: Objection. Calls for 01:02

6 speculation. Lacks foundation. 01:02

7 (Speakers talking simultaneously.) 01:02

8 BY MR. JONNA: 01:02

9 Q. You're the doctor; I'm not. I'm asking 01:02

10 how you interpret this. Do you interpret this to 01:02

11 mean saturating one pad? 01:02

12 MS. PENAN: Same objections. 01:02

13 A. There is no number. It just meant she -- 01:02

14 whether she saturated multiple or one, I can't 01:02

15 interpret that. 01:02

16 BY MR. JONNA: 01:02

17 Q. But you would expect if she saturated 01:02

18 multiple, it would say "saturated multiple pads"; 01:02

19 correct? 01:02

20 MS. PENAN: Same objections. 01:02

21 A. I would -- yes, but it doesn't change 01:02

22 anything. 01:02

23 BY MR. JONNA: 01:02

24 Q. Okay. So based on the definitions that we 01:02

25 just discussed of excessive bleeding -- let's just 01:02

1 focus on the Society of Family Planning guidelines, 01:02
2 which I know we talked about. This -- this 01:02
3 description does not qualify as excessive bleeding; 01:02
4 would you agree? 01:02

5 MS. PENAN: Objection. Incomplete 01:02
6 hypothetical. Lacks foundation. Vague, ambiguous. 01:02

7 A. That is one report I have. You know, 01:02
8 that's -- does that mean heavy bleeding? If that 01:03
9 was the only information I had, and there is no 01:03
10 other notes on her, then I would say that she did 01:03
11 not meet criteria for hemorrhage or bleeding, if 01:03
12 that was the only information. Triage nurses are 01:03
13 trying to get quick information. As you know, 01:03
14 emergency rooms are overrun, so they are just 01:03
15 trying to get as quick and little bit of 01:03
16 information as they can to keep moving through, and 01:03
17 triage who needs to be seen immediately and who 01:03
18 doesn't. It just gets back to the no acute 01:03
19 distress and vital signs stable. 01:03

20 BY MR. JONNA: 01:03

21 Q. So, yeah, we'll look at different parts of 01:03
22 the record, and we looked at the -- the notes from 01:03
23 your calls with her. 01:03

24 A. Uh-huh. 01:03

25 Q. I'm just trying to go through the 01:03

1 different components and see what jumps out -- at 01:03
2 you to meet that definition. So -- 01:03
3 A. It just means, at the time she presented, 01:03
4 this is how she was. It doesn't reflect anything 01:03
5 that happened beforehand. As I also said this 01:03
6 morning, there are patients who are bleeding 01:03
7 heavily, go to an emergency room, and by the time 01:03
8 they get there, they are fine. 01:04
9 Q. Right. We actually -- 01:04
10 A. That happens all the time. 01:04
11 Q. But we do what happened beforehand. 01:04
12 Remember, we looked at the notes that you guys took 01:04
13 when you spoke to her. 01:04
14 A. Yeah. And she bled through her clothes. 01:04
15 Exactly. 01:04
16 Q. But you told her to come into the office 01:04
17 and -- 01:04
18 A. Yeah. 01:04
19 Q. -- not to go to the emergency room; right? 01:04
20 A. Yep. 01:04
21 Q. Right. Okay. 01:04
22 Just scrolling through some more. This 01:04
23 report -- so far, you haven't seen any mention of 01:04
24 acute bleeding or anemia; right? 01:04
25 A. No. 01:04

1 Q. That's right? 01:04

2 A. I have not seen that at all so far, based 01:04

3 on the triage note. 01:04

4 Q. All right. Sorry. Too far. 01:04

5 So page 11 of the PDF, we see here 01:04

6 "Positive for vaginal bleeding." Do you see that? 01:05

7 A. Yes. 01:05

8 Q. What does that indicate to you? 01:05

9 A. On the exam, they saw signs of vaginal 01:05

10 bleeding. 01:05

11 Q. Okay. Do you know who would have written 01:05

12 these notes? 01:05

13 A. If you scroll down, I can see who signed 01:05

14 it. And if it's not at the bottom, it would be at 01:05

15 the top, but if you keep going down -- whatever 01:05

16 direction, it's fine. 01:05

17 Q. I'm just trying to get -- 01:05

18 (Speakers talking simultaneously.) 01:05

19 BY MR. JONNA: 01:05

20 Q. Sorry. 01:05

21 A. Keep going. 01:05

22 Q. Going down? 01:05

23 A. Nope, nope, keep going up. It was written 01:05

24 by Dr. Wong. 01:05

25 Q. Okay. So is Dr. Wong one of your 01:05

1 colleagues? 01:05

2 A. No. 01:05

3 Q. Oh, she's in the ER -- ER department; 01:05

4 right? Sorry. 01:05

5 A. He is an emergency-room physician, yes. 01:05

6 Q. So would you expect -- let me strike that 01:06

7 question, actually. 01:06

8 So looking here under "Neurological," it 01:06

9 says "Negative for dizziness" -- how do you pronounce 01:06

10 that, the other term? 01:06

11 A. Syncope. 01:06

12 Q. "...syncope, weakness, lightheadedness, 01:06

13 numbness, and headaches." Do you see that? 01:06

14 A. Yes. 01:06

15 Q. "Psychiatric and Behavioral" says 01:06

16 "Negative for confusion." Do you see that? 01:06

17 A. Yes. 01:06

18 Q. What does that all indicate to you? 01:06

19 A. That she's currently stable and has no 01:06

20 signs of acute anemia. 01:06

21 Q. And those vital signs, do those look 01:06

22 normal to you? 01:06

23 A. Yes. 01:06

24 Q. And you would agree that bleeding through 01:06

25 the clothes is not necessarily hemorrhage. That's 01:06

1 not the same thing. You would agree with that; 01:06
2 correct? 01:06
3 A. No. 01:06
4 MS. PENAN: Objection. Argumentative. 01:06
5 Misstates the witness's testimony. Lacks 01:06
6 foundation. Incomplete hypothetical. Vague, 01:07
7 ambiguous. 01:07
8 A. No, I would not. 01:07
9 BY MR. JONNA: 01:07
10 Q. So you would interpret bleeding through 01:07
11 the clothes to always mean hemorrhage? 01:07
12 A. I think it can. 01:07
13 Q. Right. But it also can't. 01:07
14 MS. PENAN: Objection. Misstates the 01:07
15 witness's testimony. Incomplete hypothetical. 01:07
16 A. Yeah, I think it can. 01:07
17 BY MR. JONNA: 01:07
18 Q. Okay. So turning to page 12 -- oh, you 01:07
19 know, "Cardiovascular," it says "Normal rate, 01:07
20 regular rhythm, and normal heart sounds." Do you 01:07
21 see that? 01:07
22 A. Yes. 01:07
23 Q. What does that indicate? 01:07
24 A. That everything seemed normal under heart 01:07
25 exam, that she wasn't showing any signs of severe 01:07

1 blood loss or other heart problems based on her 01:08
2 heart exam. 01:08

3 Q. Okay. And then under "Skin," it says 01:08
4 "Skin is warm and dry. Capillary refill takes less 01:08
5 than two seconds. No pallor." Do you see that? 01:08

6 A. Yes. 01:08

7 Q. What does that indicate to you? 01:08

8 A. It indicates that she probably has good 01:08
9 blood flow and no signs of -- of acute anemia on 01:08
10 her skin examination. 01:08

11 Q. So this is consistent with someone who is 01:08
12 not experiencing a hemorrhage. You would agree? 01:08

13 MS. PENAN: Objection. Incomplete 01:08
14 hypothetical. Lacks foundation. Vague, ambiguous. 01:08
15 Misstates the witness's testimony. Argumentative. 01:08

16 A. It's consistent with someone who is 01:08
17 clinically stable at the time she is being 01:08
18 examined. 01:08

19 BY MR. JONNA: 01:08

20 Q. Okay. If we go down here, we see, towards 01:08
21 the bottom of PDF page 12, page 11 in the records, 01:08
22 "No vascular flow is seen." Do you see that? 01:08

23 A. Yes. 01:08

24 Q. What does that mean? 01:08

25 A. That means that there is not -- no signs 01:09

1 of blood flowing within the endometrium that you 01:09
2 would see flowing to tissue, like a pregnancy -- 01:09
3 like pregnancy tissue. 01:09

4 Q. Okay. 01:09

5 A. In other words, if you -- the endometrium 01:09
6 was thickened and is looking for signs of whether 01:09
7 that thickness represents just blood and clots 01:09
8 inside the cavity or if it actually represented 01:09
9 tissue. You can use vascular flow to try to tell 01:09
10 if it's tissue, but it doesn't -- it's not 01:09
11 necessarily 100 percent sensitive and specific. 01:09
12 They are just reporting that they turned on the 01:09
13 Doppler, which is part of the ultrasound equipment, 01:09
14 to look for flow in that thickened endometrium and 01:09
15 didn't see any. 01:09

16 Q. Really quick question. Back at Exhibit 01:09
17 59, where it said "Patient" -- "Phone call from 01:09
18 subject regarding heavy bleeding soaking through 01:09
19 clothes and pushing -- and passing clots," do you 01:09
20 see that? 01:09

21 A. Yes. 01:09

22 Q. Do you know if she was wearing a pad at 01:09
23 the time? 01:10

24 A. I know exactly what it says there. 01:10

25 Q. And that's all I'm trying to confirm, what 01:10

1 you recall as you sit here today. 01:10

2 A. Okay. 01:10

3 Q. All right. So here, back to Exhibit 61, 01:10

4 the bottom of page 11, page 12 of the PDF, it says 01:10

5 "Findings likely represent ongoing miscarriage." 01:10

6 Do you see that? What does that indicate to you? 01:10

7 A. That she has been passing tissue and is 01:10

8 continuing to pass tissue. 01:10

9 Q. Okay. 01:10

10 A. Her pregnancy tissue. 01:10

11 Q. So far, you haven't seen anything that 01:10

12 says "findings indicate hemorrhage," do you? 01:10

13 A. An ultrasound -- 01:10

14 MS. PENAN: Objection. Incomplete 01:10

15 hypothetical. Vague, ambiguous. 01:10

16 A. An exam would not be used to indicate 01:10

17 hemorrhage or not. 01:10

18 BY MR. JONNA: 01:10

19 Q. Right. But you haven't seen that in the 01:10

20 records we have looked at so far; correct? No 01:10

21 reference to hemorrhage? 01:11

22 A. No reference -- 01:11

23 MS. PENAN: Objection. Asked and 01:11

24 answered. 01:11

25 A. Yeah, no reference to hemorrhage. Just 01:11

1 from what you've shown me, I have not seen anybody 01:11
2 there use the word "hemorrhage." 01:11
3 BY MR. JONNA: 01:11
4 Q. Okay. 01:11
5 A. That's what you asked me, and I haven't 01:11
6 seen that either. 01:11
7 Q. On the next page, it says "Patient 01:11
8 hemodynamically stable." Do you see that? 01:11
9 A. Yes. 01:11
10 Q. What does that mean? 01:11
11 A. It means her vital signs were stable at 01:11
12 the time of the evaluation. 01:11
13 Q. What does "hemodynamically" mean? 01:11
14 A. Her -- your blood system, and it relates 01:11
15 to the vital signs. And it basically is 01:11
16 suggesting, from the vital signs, that your blood 01:11
17 counts are fine, the way your body is responding. 01:11
18 Q. Would you expect to see stable vital signs 01:11
19 in someone that has -- is stable hemodynamically if 01:11
20 they are currently experiencing a hemorrhage? 01:11
21 MS. PENAN: Objection. Compound. Vague, 01:11
22 ambiguous. Incomplete hypothetical. Calls for 01:11
23 speculation. 01:11
24 A. Yes, you can have stable vital signs in 01:11
25 someone who's currently having hemorrhage. We 01:12

1 already established that she was not at the time 01:12
2 she was being evaluated. But you can, because it 01:12
3 takes time after someone starts to bleed heavily 01:12
4 for the vital signs to change. If they are 01:12
5 otherwise healthy, the body can accommodate the 01:12
6 changes, but only up to a certain point, at which 01:12
7 time you start to see vital sign changes. 01:12

8 So when you see vital sign changes, it's 01:12
9 down the road. It doesn't mean -- so somebody 01:12
10 acutely hemorrhaging can have normal vital signs. 01:12
11 Someone who hemorrhaged before and now is doing okay 01:12
12 can have normal vital signs. 01:12

13 BY MR. JONNA: 01:12

14 Q. Okay. Page -- same page here, it says 01:12
15 "Vital signs are stable, within normal limits." Do 01:12
16 you see that? 01:12

17 A. Yes. 01:12

18 Q. Page 15. This is an -- 01:12

19 MS. PENAN: Objection. The record speaks 01:12
20 for itself. Sorry. 01:12

21 BY MR. JONNA: 01:12

22 Q. Here it says, someone named Zel Sperry 01:12
23 wrote down "Chief Complaints, vaginal bleeding 01:12
24 minor." Do you see that? 01:13

25 A. Yes. 01:13

1 MS. PENAN: Objection. The record speaks 01:13
2 for itself. 01:13

3 BY MR. JONNA: 01:13

4 Q. Page 17. There is a few different 01:13
5 categories here: pulse, capillary refill, 01:13
6 strength. And it says "WDL." Does that mean 01:13
7 "within defined limits"? 01:13

8 MS. PENAN: Objection. Compound. 01:13
9 Incomplete hypothetical. 01:13

10 A. I don't use that term, so I'm going to 01:13
11 guess it does mean something like that, but it's 01:13
12 not a term I'm familiar with. I usually use "WNL," 01:13
13 I'm actually not -- I've never seen W -- WDL, but I 01:13
14 would guess it means "within defined limits." 01:13

15 BY MR. JONNA: 01:13

16 Q. And that's a good thing? 01:13

17 MS. PENAN: Objection. Vague, ambiguous. 01:13
18 Incomplete hypothetical. 01:13

19 A. Yes. 01:13

20 MS. PENAN: Calls for speculation. 01:13

21 A. These -- these exam findings are the same 01:13
22 as the ones you pointed out before. It means that 01:13
23 acutely, at that time, she seems to be fine. 01:14

24 BY MR. JONNA: 01:14

25 Q. Okay. Page 18. We have her CBC with 01:14

1 differential, and it states "Hemoglobin 10.4 grams 01:14
2 per deciliter." Do you see that? 01:14
3 A. Yes. 01:14
4 Q. And how would you characterize that? 01:14
5 A. Low. 01:14
6 MS. PENAN: Objection. Vague, ambiguous. 01:14
7 Incomplete hypothetical. 01:14
8 A. Low. It shows the normal range is 12 to 01:14
9 16. So it's low, but it's not acutely low that I'm 01:14
10 acutely going to worry about the patient. But it's 01:14
11 lower than normal. 01:14
12 BY MR. JONNA: 01:14
13 Q. And Subject 8 did not have a transfusion; 01:14
14 correct? 01:14
15 A. Correct. 01:14
16 Q. Subject 8 did not have a vacuum 01:14
17 aspiration; correct? 01:14
18 A. Correct. 01:14
19 Q. Page 21 of the PDF. This is -- it says 01:15
20 your clinical notes, "Consult by Dr. Creinin." Do 01:15
21 you see that? 01:15
22 A. Yes. 01:15
23 Q. So here you say: "Patient was seen for a 01:15
24 study visit this morning and had no bleeding, and 01:15
25 the ultrasound showed a continuing pregnancy. 01:15

1 Patient states that at about," redacted, "hour to 01:15
2 date, she was at work and felt a small clot come 01:15
3 out into her underwear. She went home and then 01:15
4 about," redacted, "she felt a rush of bleeding and 01:15
5 noted that she soaked through panty liner and 01:15
6 clothes. There was not much liquid blood, mainly 01:15
7 clots. She went to the toilet and passed more 01:15
8 clots into the toilet. Wasn't -- wasn't sure how 01:15
9 much because she didn't look because she did not 01:15
10 want to see POCs. She thinks she may have passed a 01:15
11 small sac-like structure. She called the research 01:15
12 office and was told to come into the office/clinic 01:16
13 to be evaluated. She got scared and called an 01:16
14 ambulance to take her to the hospital. She notes 01:16
15 some amount of dizziness, but that it was present 01:16
16 before the bleeding, about one hour after being 01:16
17 seen in clinic this morning. No dizziness 01:16
18 currently. Has had some cramping for the last two 01:16
19 days, but it has not been terrible. Has had loose 01:16
20 stool, QDx1 x2-3d, and those were the only BMs. No 01:16
21 nausea or vomiting." 01:16
22 Do you see that? 01:16
23 A. Yes. 01:16
24 Q. Is that your description that you inserted 01:16
25 into her medical chart? 01:16

1 A. I would have to look down to see if there 01:16
2 was a resident who wrote that or just me. 01:16
3 Q. Tell me where I should stop. 01:16
4 A. Keep going. All the way to the bottom of 01:16
5 this note. Keep going. 01:16
6 It was written by a resident, and then I 01:17
7 reviewed it. 01:17
8 Q. Okay. So it says "Electronically signed 01:17
9 by Mitchell Creinin, M.D."? 01:17
10 A. Yes. 01:17
11 Q. And so the resident is Mark Evans? 01:17
12 A. Yes. 01:17
13 Q. Okay. 01:17
14 Okay. Before we talk about this note, can 01:17
15 you just tell us what you remember about this visit 01:17
16 with Patient 8 in the ER? 01:17
17 A. Dr. Evans had examined her, and I got 01:17
18 there right near the end of the exam. I'm trying 01:17
19 to remember. I don't remember whether I got 01:17
20 there -- I think she had already had her 01:17
21 ultrasound. That's right. So she, you know, got 01:17
22 triaged, got her ultrasound. I was there when she 01:17
23 came out of the ultrasound exam, and then we did 01:17
24 the pelvic exam after that. And then I -- she had 01:17
25 her daughter with her, and -- who was carrying a 01:18

1 pink backpack. I can remember that. 01:18

2 And then after the ultrasound, the exam, I 01:18
3 talked with her about what our findings were, and 01:18
4 that I felt that she didn't -- that there's still 01:18
5 tissue passing, but that she was passing it on her 01:18
6 own, and that we didn't need to do anything. So 01:18
7 that's what I remember. There's more information 01:18
8 in the exam here. That's what I remember. 01:18

9 Q. Okay. So this reference here that "she 01:18
10 soaked through panty liner and clothes," do you 01:18
11 remember anything more about that statement? 01:18

12 A. What I remember is she -- she bled through 01:18
13 her clothes. She told us that on the phone. She 01:18
14 told us that there. That's what I remember. 01:18

15 Q. So this also says that "She called the 01:19
16 research office and was told to come in to the 01:19
17 office/clinic to be evaluated." And that's 01:19
18 consistent with what you said earlier; correct? 01:19

19 A. Yes. 01:19

20 Q. And when it says here "She got scared and 01:19
21 called an ambulance," do you remember anything 01:19
22 about that? 01:19

23 A. Yes. 01:19

24 Q. What do you remember? 01:19

25 A. That, in her mind, she was bleeding so 01:19

1 heavily that she was scared and called an 01:19
2 ambulance. 01:19

3 Q. Okay. And then looking at the statement 01:19
4 on page 24, this is -- there was a physical exam 01:19
5 and then it says "Speculum exam performed after 01:19
6 ultrasound exam completed." What's a speculum 01:19
7 exam? 01:19

8 A. It's putting a speculum device in the 01:19
9 vagina, so you can see into the vagina and the 01:19
10 cervix. 01:19

11 Q. It says "Initial exam with about 100 cc 01:19
12 clots removed from vagina and noted more remained 01:19
13 in vault and cervix, not visualized before the 01:20
14 patient requested cessation of exam due to pain." 01:20

15 I'm going to stop there. What does "100 01:20
16 cc clots" refer to? 01:20

17 A. So it's 100 milliliters of clots that were 01:20
18 in the vagina. As we talked about earlier, she was 01:20
19 miscarrying, and there was still some tissue. And 01:20
20 part of the ultrasound, you didn't go over, showed 01:20
21 a whole bunch of blood and tissue in her cervix. 01:20
22 So she had about 100 milliliters of blood and clots 01:20
23 in her vagina. And then once that was cleared away 01:20
24 so we could see the whole vagina, it was a little 01:20
25 hard to do because she was so uncomfortable from 01:20

1 the cramping she was having that she was squeezing 01:20
2 her muscles. So we gave her some IV sedation -- 01:20
3 that's what it says -- "later fentanyl," to help 01:20
4 her relax a little to tolerate our exam, because we 01:20
5 wanted to make sure that she didn't need any other 01:20
6 kind of intervention, and that things really were 01:20
7 finishing on their own. 01:20
8 Q. Okay. And then the part you said I 01:21
9 skipped over, I just want to make sure -- 01:21
10 A. On the -- on the ultrasound exam. 01:21
11 Q. Okay. I don't remember what page that one 01:21
12 is now. Let me see. 01:21
13 A. I don't think you passed it yet. I think 01:21
14 it's further up. 01:21
15 Q. Right here. 01:21
16 A. There it is. 01:21
17 Q. What part were you referring to? 01:21
18 A. If you look after the yellow part that 01:21
19 says "No vascular flow is seen," it says 01:21
20 "Heterogeneity is also noted in the endocervical 01:21
21 canal." That means -- basically, it's blood and 01:21
22 clots in the -- in the cervical canal, in the 01:21
23 cervix. 01:21
24 Q. Okay. It doesn't indicate the amount, 01:21
25 though? 01:21

1 A. No. It just says that there is tissue in 01:21
2 there, and it's -- heterogeneity means it's mixed 01:21
3 appearance. Mixed serologic appearance, which 01:22
4 means it's usually blood and clots. 01:22

5 Q. Okay. So then there is a statement here 01:22
6 about vaginal bleeding. It says "IUP visualized in 01:22
7 clinic this morning. No IUP in uterus in ED. 01:22
8 Patient has passed the pregnancy. Hemodynamically 01:22
9 stable. No active bleeding at this point. Pain 01:22
10 well-controlled. Minimal blood/tissue in uterus." 01:22

11 Do you see that? 01:22

12 A. Yes. 01:22

13 Q. What does "IUP" refer to? 01:22

14 A. Intrauterine pregnancy. 01:22

15 Q. And what -- what does "ED" refer to? 01:22

16 A. Emergency department. 01:22

17 Q. Okay. And "minimal blood/tissue in 01:22
18 uterus," what does that refer to? 01:23

19 A. Based on the ultrasound findings, that the 01:23
20 lining, even though it was thickened, is still 01:23
21 nothing that's of concern, that there is a large 01:23
22 amount of tissue still in the uterus. 01:23

23 Q. And then underneath that we see "Rh 01:23
24 Negative." "Recommend Rho D Immune Globulin 15 mcg 01:23
25 1: X1 microgram to prevent Rh alloimmunization." 01:23

1 What does that mean? 01:23

2 A. Good try. That's good, alloimmunization. 01:23

3 Q. Okay. 01:23

4 A. No, at -- at the time, it was recommended 01:23

5 that anybody who was pregnant and had a blood type 01:23

6 that was negative, something negative, O negative, 01:23

7 A negative, whatever it is, that they receive an 01:23

8 immunoglobulin to help prevent problems with future 01:23

9 pregnancies, which that problem is called Rh 01:23

10 alloimmunization. So it has to do with her blood 01:23

11 type, and the fact that she was pregnant and then 01:24

12 passed -- bled and passed the pregnancy. 01:24

13 Q. Is that something that you normally 01:24

14 recommend? 01:24

15 A. At the time, we did. 01:24

16 Q. And not now? 01:24

17 A. Not now. 01:24

18 Q. What's the reason? 01:24

19 A. Because evidence has come out that the 01:24

20 amount of blood mixing in very early pregnancy is 01:24

21 too low to cause Rh alloimmunization. So we don't 01:24

22 need to use that product. It's a blood product 01:24

23 with low resources. Very often there's shortages, 01:24

24 so we save the immunoglobulin for patients who need 01:24

25 it. So it's no longer recommended by most major 01:24

1 medical organizations in early pregnancy for 01:24
2 miscarriage or abortion. 01:24

3 Q. Okay. On the next page, page 26 of the 01:24
4 PDF -- this is another note that you wrote at the 01:24
5 end there. You see your name? 01:24

6 A. Uh-huh. 01:24

7 Q. Yes? 01:24

8 A. Yes. 01:24

9 Q. It says "Attending. Patient known to me. 01:25
10 Is patient in study through FP Research. Patient 01:25
11 planning surgical abortion and received 01:25
12 mifepristone on 5/29/19 as part of the study. She 01:25
13 has been taking progesterone or placebo since 01:25
14 5/30/19, blinded." 01:25

15 I'm just going to stop right here. 01:25

16 So at this point, you didn't know what 01:25
17 group she was in? 01:25

18 I'm sorry. I don't think we heard you. 01:25

19 A. No, I did not know. 01:25

20 Q. Okay. "She had a study follow-up visit 01:25
21 earlier today at which she had no bleeding and 01:25
22 normal pregnancy growth with the pregnancy still 01:25
23 viable. She was scheduled for her next follow-up 01:25
24 visit 6/5/19. She called the research office in 01:25
25 the mid-afternoon, stating she had started bleeding 01:25

1 suddenly at work and had to leave to go home. She 01:25
2 bled through her underwear onto her pants." 01:25
3 Do you see that? 01:25
4 A. Yes. 01:25
5 Q. So those are your words; right? 01:25
6 A. Yes. 01:25
7 Q. And does that refresh your memory about 01:25
8 the bleeding that she described to you? 01:26
9 A. It doesn't refresh my memory. I remember 01:26
10 it. 01:26
11 Q. "We instructed her" -- going on here. "We 01:26
12 instructed her to come into the office. She did 01:26
13 not have an immediate ride and panicked in her 01:26
14 words. She called an ambulance, which brought her 01:26
15 to the ER." 01:26
16 Do you see that? 01:26
17 A. Yes. 01:26
18 Q. What do you remember her saying about 01:26
19 panicking? 01:26
20 A. That she was worried about her amount of 01:26
21 bleeding, didn't feel she could come to the office. 01:26
22 That was her judgment of her status, even though 01:26
23 when she talked to us, we felt she could. So she 01:26
24 did what a lot of women do when they are bleeding 01:26
25 like that, and they are worried, they call an 01:26

1 ambulance. 01:26

2 I would say we see a couple of patients 01:26

3 every day in the emergency department who are having 01:26

4 miscarriages who have the same exact story. They 01:26

5 start bleeding, they get worried about how much it 01:26

6 is, and they call an ambulance and come to the 01:26

7 emergency room. 01:26

8 Q. Okay. It says here "She was in the US 01:26

9 suite when I saw her with Dr. Evans." 01:27

10 What does "US suite" mean? 01:27

11 A. Ultrasound suite. As I said earlier, she 01:27

12 was finishing her ultrasound when I arrived in the 01:27

13 emergency room. 01:27

14 (Speakers talking simultaneously.) 01:27

15 BY MR. JONNA: 01:27

16 Q. Sorry. Continues to say "Her bleeding was 01:27

17 mild to moderate. And the U.S., ultrasound scan, 01:27

18 showed absence of the gestational sac." Do you see 01:27

19 that? 01:27

20 A. Yes. 01:27

21 Q. And what do you mean when you say her 01:27

22 bleeding was mild to moderate? 01:27

23 A. That it was, at the time, in the 01:27

24 ultrasound suite, mild to moderate, as our 01:27

25 estimation of how much bleeding she was having. 01:27

1 Q. But you didn't -- 01:27

2 A. At that current time. 01:27

3 Q. Right. But did you indicate anywhere else 01:27

4 that her bleeding was anything worse than mild to 01:27

5 moderate at some other point? 01:27

6 A. You would have to have me read the whole 01:27

7 chart to see that, but I'm going to guess that 01:27

8 given that she had already passed the pregnancy and 01:27

9 she was slowing down, that at the current time, she 01:27

10 was mild to moderate, and we talked about the exam, 01:27

11 which showed 100 milliliters of blood in her 01:27

12 vagina, that we cleared away, and there was another 01:27

13 50 milliliters there. So that's what we saw at the 01:28

14 time. It was still ongoing, that she had heavier 01:28

15 bleeding earlier in the day. 01:28

16 Q. Is 100 milliliters consistent with 01:28

17 mild-to-moderate bleeding? 01:28

18 A. I -- I would say it's consistent. 01:28

19 Q. We talked earlier about these terms, mild, 01:28

20 moderate, severe, and you said that there is really 01:28

21 no way to define all this stuff, but here you are 01:28

22 using mild to moderate for bleeding. So I'm just 01:28

23 trying to get an idea of how do you -- 01:28

24 A. It's -- 01:28

25 MS. PENAN: Objection. Misstates the 01:28

1 witness's testimony. 01:28

2 BY MR. JONNA: 01:28

3 Q. Let me just finish my question, and then 01:28

4 you can answer. 01:28

5 A. Okay. , thank you. 01:28

6 Q. I'm trying to get an idea, now that we are 01:28

7 looking at this record, so I'm trying to understand 01:28

8 what you mean when you say "mild to moderate" 01:28

9 versus "severe," what's the best way for me to 01:28

10 understand what -- what these different terms mean? 01:28

11 A. It's my objective opinion of what I think 01:28

12 her bleeding looks like. 01:28

13 Q. Okay. So if you -- what would it need to 01:28

14 look like for you to call it severe? 01:28

15 A. Sorry -- 01:28

16 MS. PENAN: Objection. Incomplete 01:28

17 hypothetical. Vague, ambiguous. Calls for 01:28

18 speculation. 01:29

19 A. I said "objective" earlier. It should 01:29

20 have been subjective. That was my subjective 01:29

21 opinion of what her bleeding looked like. 01:29

22 And can you repeat your question? 01:29

23 BY MR. JONNA: 01:29

24 Q. What would her bleeding need to look like 01:29

25 for you to call it severe? 01:29

1 MS. PENAN: Same objections. 01:29

2 A. It varies from patient to patient. I 01:29

3 mean, it's just -- it would be heavier than what I 01:29

4 saw at the time she was there. 01:29

5 BY MR. JONNA: 01:29

6 Q. Okay. So there is no better way to 01:29

7 describe it, other than heavier than what you saw? 01:29

8 A. It's all based on my -- 01:29

9 MS. PENAN: Objection. Asked and 01:29

10 answered. Sorry. 01:29

11 THE WITNESS: That's okay. I apologize. 01:29

12 A. It's also all based on my decades of 01:29

13 experience, and we all look at it, and you get an 01:29

14 idea. You know, somebody can come into the 01:29

15 emergency department with an asthma attack, and 01:29

16 nurses and doctors give their subjective opinion of 01:29

17 how hard they are working to breathe. It's just 01:29

18 subjective. 01:29

19 BY MR. JONNA: 01:29

20 Q. Okay. By the way, we saw -- 01:29

21 (Speakers talking simultaneously.) 01:30

22 MR. JONNA: That's weird. 01:30

23 Q. -- a couple of different narratives that 01:30

24 you wrote in these records. So I'm just trying to 01:30

25 get -- I don't know how doctors write records. Why 01:30

1 were there multiple versions of the -- the notes? 01:30
2 I mean, was it -- is that common? 01:30
3 A. Uh-huh, yes. 01:30
4 MS. PENAN: Objection. Vague, ambiguous. 01:30
5 BY MR. JONNA: 01:30
6 Q. Can you describe that process? 01:30
7 A. Yeah. So there was a note written by the 01:30
8 resident, which I need to cosign, and then I felt I 01:30
9 wanted to write my own notes, since I talked to her 01:30
10 earlier, just for clarification, because I felt I 01:30
11 had a better handle on the story, based on the 01:30
12 interactions from our research office and talking 01:30
13 to her in the emergency room. So it's not uncommon 01:30
14 to cosign a note from the resident, and then for me 01:30
15 to write my own note. That's pretty common for 01:31
16 others as well. 01:31
17 Q. Do you remember what you needed to 01:31
18 clarify? 01:31
19 MS. PENAN: Objection. Misstates the 01:31
20 witness's testimony. Vague, ambiguous. 01:31
21 A. The information in my note is what I 01:31
22 wanted to clarify. 01:31
23 BY MR. JONNA: 01:31
24 Q. Was there anything in particular? 01:31
25 A. Whatever -- 01:31

1 MS. PENAN: Objection. Asked and 01:31
2 answered. 01:31
3 A. Whatever I wrote in my note is what I 01:31
4 wanted to clarify. 01:31
5 BY MR. JONNA: 01:31
6 Q. Okay. So I'm going to scroll down really 01:31
7 quick to page 50. These are the ambulance records, 01:31
8 which -- I think you said you looked at some of 01:31
9 these before the deposition as well; correct? 01:31
10 A. I believe so, but, yes. 01:31
11 Q. Okay. So on the -- on the top here, it 01:31
12 says "How patient was moved to ambulance. 01:32
13 Assisted/walk." Do you see that? 01:32
14 A. Yes. 01:32
15 Q. What does that indicate to you? 01:32
16 MS. PENAN: Objection. Calls for 01:32
17 speculation. The record speaks for itself. 01:32
18 Incomplete hypothetical. 01:32
19 A. That they walked her with assistance, 01:32
20 meaning that she was able to walk, but they -- but 01:32
21 not completely on her own. 01:32
22 BY MR. JONNA: 01:32
23 Q. Is it, in your experience -- can someone 01:32
24 who is experiencing a severe hemorrhage walk on 01:32
25 their own or even with assistance? 01:32

1 MS. PENAN: Objection. Calls for 01:32
2 speculation. Incomplete hypothetical. Lacks 01:32
3 foundation. Vague, ambiguous. 01:32

4 A. Do you mean severe hemorrhage or 01:32
5 hemorrhage? What is your exact question? 01:32

6 BY MR. JONNA: 01:32

7 Q. Let's start with hemorrhage. Is someone 01:32
8 who is experiencing a hemorrhage normally able to 01:32
9 walk, even with assistance? 01:32

10 MS. PENAN: Same objections. 01:32

11 A. Yes. The fact that she needs assistance 01:32
12 is probably a sign that she's going through 01:33
13 something acute. And they can -- as I said 01:33
14 earlier, it takes time for your vital signs and 01:33
15 everything to equilibrate. There's people, when we 01:33
16 are in the operating room, who are just 01:33
17 hemorrhaging right in front of us, and if we check 01:33
18 their blood count and their vital signs, they are 01:33
19 perfectly okay at that moment, and it will take 01:33
20 some time for the vital signs to show a change and 01:33
21 for the blood count to show a change. 01:33

22 So can that happen? As I'm guessing, 01:33
23 because I wasn't there, yes, somebody who had 01:33
24 hemorrhaged or was hemorrhaging could -- could walk 01:33
25 and need assistance. 01:33

1 (Reporter interruption for clarification.) 01:33

2 BY MR. JONNA: 01:33

3 Q. Describe a situation where they are on a 01:33

4 table hemorrhaging. Would that -- if that was -- 01:33

5 in that moment, you would agree that it wouldn't be 01:33

6 possible for someone that's -- not possible. It 01:33

7 wouldn't be common for someone in that situation to 01:33

8 get up and walk. Would you agree? 01:33

9 A. I was talking about -- 01:33

10 MS. PENAN: Objection. Incomplete 01:33

11 hypothetical. Calls for speculation. Vague, 01:33

12 ambiguous. And misstates the witness's testimony. 01:34

13 A. I was talking about if I was doing a 01:34

14 procedure on somebody, if somebody is doing a 01:34

15 procedure on somebody, they should have a speculum 01:34

16 in. So I think it's kind of a moot question. 01:34

17 BY MR. JONNA: 01:34

18 Q. Okay. So when we are talking about a 01:34

19 severe hemorrhage, would you expect those people to 01:34

20 be able to walk on their own or -- or with 01:34

21 assistance when they are -- while they are 01:34

22 experiencing a severe hemorrhage? 01:34

23 MS. PENAN: Objection. Incomplete 01:34

24 hypothetical. Calls for speculation. Vague, 01:34

25 ambiguous. 01:34

1 A. Yes. In my decades of experience, I've 01:34
2 seen people who are actively severely hemorrhaging 01:34
3 who still walk into labor and delivery or walk into 01:34
4 the emergency room or walk into our office. I've 01:34
5 had somebody walk into our office severely 01:34
6 hemorrhaging, who I did an emergency procedure on. 01:34
7 I can remember she wasn't my patient. They just 01:34
8 called me. So, yes, people can do that. 01:34
9 BY MR. JONNA: 01:34
10 Q. Would you expect that an EMT, who's 01:34
11 dealing with someone experiencing a severe 01:34
12 hemorrhage, will allow them to walk? Would that be 01:34
13 your expectation? 01:34
14 MS. PENAN: Objection. Calls for 01:34
15 speculation. Lacks foundation. Incomplete 01:34
16 hypothetical. Vague, ambiguous. 01:34
17 A. Yeah, I don't -- I don't know. But it 01:35
18 sounds like, even from what went on in the 01:35
19 emergency room, that at that moment in time, she 01:35
20 was not experiencing heavy bleeding. But I don't 01:35
21 know for sure because I wasn't there when they were 01:35
22 assisting her to walk. 01:35
23 BY MR. JONNA: 01:35
24 Q. Here on the -- under "Transport Mode," it 01:35
25 says "Nonemergent." Do you see that? 01:35

1 A. Yes. 01:35

2 Q. Under "Response Mode," it says "Emergent." 01:35

3 Do you see that? 01:35

4 A. Yes. 01:35

5 Q. I know you're not an EMT, but would you 01:35

6 agree that means that they -- on the way to pick 01:35

7 her up, they had the sirens on, and when they 01:35

8 picked her up, transporting her, it was no longer 01:35

9 on? 01:35

10 MS. PENAN: Objection. Calls for 01:35

11 speculation. Lacks foundation. Incomplete 01:35

12 hypothetical. Compound. 01:35

13 A. I wouldn't interpret it that way, but I'm 01:35

14 not an EMT, and you would have to ask someone who 01:35

15 is an EMT to confirm that's what it is. It means 01:36

16 that when she called for the ambulance, she was in 01:36

17 the midst of an emergent problem, consistent with 01:36

18 her story. And by the time they got there and 01:36

19 evaluated her, things had calmed down and that they 01:36

20 didn't need to transport her emergently, consistent 01:36

21 with that she had a very heavy bleeding, and at the 01:36

22 time they saw her, that had resolved, or it 01:36

23 wasn't -- I shouldn't say "resolved." It had 01:36

24 lessened. 01:36

25 BY MR. JONNA: 01:36

1 Q. Okay. So just to establish the timeline. 01:36
2 When you saw her, it had lessened or resolved. 01:36
3 When the EMT saw her, it had lessened or resolved. 01:36
4 And when she called you and reported her findings, 01:36
5 it was also not concerning enough that she should 01:36
6 go to the emergency room; correct? 01:36

7 MS. PENAN: Objection. Misstates the 01:36
8 witness's testimony. Compound. Vague, ambiguous. 01:36
9 Calls for speculation. Incomplete hypothetical. 01:36
10 Lacks foundation. 01:36

11 A. In my practice, I could very often get her 01:37
12 in faster than an emergency room. I felt that with 01:37
13 her bleeding that she was describing, she should be 01:37
14 seen right away. It is common, because our office 01:37
15 is set up this way, unlike other offices, that we 01:37
16 can see a patient who is bleeding rather heavily 01:37
17 and take care of her necessary D&C faster than it 01:37
18 could be done in the emergency room. 01:37

19 You go just to the emergency room, by the 01:37
20 time they get everything done and evaluations and 01:37
21 you get through triage and everything, you've been 01:37
22 bleeding for a while, and we can do this much 01:37
23 faster in our specialty practice than, very often, 01:37
24 in the emergency room. So I told her that we 01:37
25 wanted her to come in. 01:37

1 BY MR. JONNA: 01:37

2 Q. Okay. Was -- 01:37

3 A. It was her feeling, based on the amount of 01:37

4 bleeding she was having, that she needed to call an 01:37

5 ambulance. Which is why the response mode is 01:37

6 likely emergent. 01:37

7 Q. Right. Just to establish the timeline. 01:37

8 So when you spoke to her -- sorry, when she spoke 01:37

9 to your research office, you told her to come in 01:37

10 and not to go to the emergency room, as we've 01:38

11 discussed; correct? 01:38

12 A. Correct. 01:38

13 MS. PENAN: Objection. Asked and 01:38

14 answered. 01:38

15 BY MR. JONNA: 01:38

16 Q. The EMT arrived, they determined that the 01:38

17 bleeding had lessened or resolved to the point 01:38

18 where it was no longer emergent; correct? 01:38

19 MS. PENAN: Objection. Calls for 01:38

20 speculation. Lacks foundation. Vague, ambiguous. 01:38

21 A. Based on what you are showing me right 01:38

22 now, that appears to be the situation. We're 01:38

23 interpreting it. 01:38

24 BY MR. JONNA: 01:38

25 Q. And when you saw her at the emergency 01:38

1 room, you determined that the situation had 01:38
2 lessened or resolved to the -- to the effect that 01:38
3 it was -- you called it mild-to-moderate bleeding; 01:38
4 correct? 01:38
5 MS. PENAN: Objection. Asked and 01:38
6 answered. 01:38
7 A. Yes. 01:38
8 BY MR. JONNA: 01:38
9 Q. Okay. When it says here under "Patient 01:38
10 Condition. Complaint, vaginal bleeding, duration, 01:38
11 two hours." Do you see that? 01:38
12 A. Yes. 01:38
13 Q. What -- what, if anything, does that tell 01:38
14 you? 01:38
15 MS. PENAN: Objection. Calls for 01:38
16 speculation. Lacks foundation. Incomplete 01:38
17 hypothetical. Vague, ambiguous. 01:38
18 A. That the history that they obtained from 01:38
19 her is that she had been bleeding for two hours. 01:39
20 BY MR. JONNA: 01:39
21 Q. And what time does it say she arrived 01:39
22 here -- or they arrived? Does it say? Can you 01:39
23 tell? 01:39
24 A. No. 01:39
25 MS. PENAN: Objection. The record speaks 01:39

1 for itself. 01:39

2 BY MR. JONNA: 01:39

3 Q. That's all redacted? 01:39

4 A. I believe so. 01:39

5 Q. Do you know why that's redacted, by the
6 way? 01:39

7 MS. PENAN: Objection. Calls for
8 speculation. 01:39

9 A. Because you -- you could use time, and --
10 I actually think all dates should be redacted, and
11 I'm upset they were not, because anything that you
12 could potentially use to identify the patient based
13 on date and time was supposed to be redacted. 01:39

14 BY MR. JONNA: 01:39

15 Q. How can I tell who the patient is based on
16 a date and time? 01:39

17 A. If you -- we are doing whatever we can to
18 protect the patient. And if you report -- to a
19 reporter that there was a patient that had a
20 pregnancy at this time, and somebody in her family
21 hears it, and they could make the association, then
22 that doesn't protect her confidentiality. 01:40

23 BY MR. JONNA: 01:40

24 Q. Would you be willing to allow us to see
25 the times so that we can determine the time 01:40

1 difference from when she -- when the EMT arrived 01:40

2 and when she called your office? 01:40

3 MS. PENAN: Objection. That's not his 01:40

4 determination to make. 01:40

5 BY MR. JONNA: 01:40

6 Q. Well, I do believe that the nice gentleman 01:40

7 we spoke to at UC Davis was copying you on all the 01:40

8 emails, and I assume you had some say in what 01:40

9 should be produced and what should be redacted; is 01:40

10 that right? 01:40

11 A. Yes, it was ultimately the lawyer's 01:40

12 decision because they did not redact as much as I 01:40

13 would have redacted. 01:40

14 Q. Okay. 01:40

15 A. So what you are getting is what our 01:40

16 attorneys felt was reasonable. 01:40

17 Q. Okay. As you sit here today, do -- do you 01:40

18 have any recollection as to how much time passed 01:40

19 between the time she called your research office 01:41

20 and the time the ambulance arrived? 01:41

21 MS. PENAN: Objection. Calls for 01:41

22 speculation. Lacks foundation. 01:41

23 A. I have no idea. 01:41

24 BY MR. JONNA: 01:41

25 Q. Okay. Page 51 of the PDF. It says that 01:41

1 patient's complaining of vaginal bleeding for the 01:41
2 past two hours. Do you see that? 01:41
3 A. It says "sitting on the toilet, 01:41
4 complaining of vaginal bleeding for the last two 01:41
5 hours -- past two hours." 01:41
6 Q. Okay. "Skin pink, warm, and dry with no 01:41
7 signs of trauma." Do you see that? 01:41
8 A. Yes. 01:41
9 Q. What does that indicate to you? 01:41
10 A. Same as you asked me before. That -- 01:41
11 Q. Right. 01:41
12 A. -- the skin doesn't show any acute signs 01:41
13 of hypo -- hypovolemia or anemia. 01:41
14 Q. The only reason I'm asking you again is 01:41
15 because this is a different time period now. So 01:41
16 this is before she had gone to the hospital. 01:41
17 A. That's fine. You can go ahead. 01:41
18 Q. It says here "Patient is stating she has 01:41
19 gone -- she has only gone through one liner today 01:41
20 for bleeding." Do you see that? 01:42
21 A. Yes. 01:42
22 Q. What does that indicate to you? 01:42
23 A. It means -- 01:42
24 MS. PENAN: Objection. Calls for 01:42
25 speculation. 01:42

1 A. It means from a sanitary protection 01:42
2 standpoint, that she used a liner, that she didn't 01:42
3 have anything else on, but it doesn't necessarily 01:42
4 mean that's all the bleeding that she had. 01:42

5 BY MR. JONNA: 01:42

6 Q. And what's the difference between a liner 01:42
7 and a pad? 01:42

8 MS. PENAN: Objection. Calls for 01:42
9 speculation. 01:42

10 A. A liner is a thin protective, sanitary 01:42
11 protective product that is meant to collect very 01:42
12 small amounts of blood flow, and a pad is meant to 01:42
13 collect more amounts of blood flow. 01:42

14 BY MR. JONNA: 01:42

15 Q. So if you had gone through one liner in a 01:42
16 day, that's a lot less blood than two pads. Is 01:42
17 that correct? 01:42

18 MS. PENAN: Objection. Calls for 01:42
19 speculation. Incomplete hypothetical. Vague, 01:42
20 ambiguous. 01:42

21 A. If all blood was being collected on 01:42
22 sanitary products, that would be correct. But it's 01:42
23 common with patients that are miscarrying or having 01:42
24 a medication abortion or medical treatment for a 01:42
25 miscarriage, they spend a lot of their time 01:43

1 bleeding elsewhere, like on a toilet or in a 01:43
2 bathtub. So you can't use just your statement of 01:43
3 only one liner as indicative of how much bleeding 01:43
4 she had. 01:43
5 BY MR. JONNA: 01:43
6 Q. Is the statement that "She went through 01:43
7 one liner today for bleeding," is that indicative 01:43
8 that she didn't really bleed that much? 01:43
9 MS. PENAN: Objection. Asked and 01:43
10 answered. Misstates the witness's testimony. 01:43
11 Calls for speculation. Lacks foundation. 01:43
12 Incomplete hypothetical. Vague, ambiguous. 01:43
13 A. The answer is no. 01:43
14 BY MR. JONNA: 01:43
15 Q. So it indicates that she actually bled 01:43
16 quite a bit? 01:43
17 A. It doesn't mean anything. It just means 01:43
18 that's all she used from a sanitary protection 01:43
19 standpoint. The other information, like 01:43
20 bleeding -- "I'm bleeding to the point where I just 01:43
21 want -- need to sit on the toilet, or bleeding 01:43
22 through my clothes," also provides some context of 01:43
23 the amount of bleeding someone is having. 01:43
24 Q. Okay. So you wouldn't -- if there was a 01:44
25 lot of bleeding, you wouldn't have expected her to 01:44

1 have gone through multiple liners or multiple pads? 01:44

2 MS. PENAN: Objection. Asked and 01:44

3 answered. 01:44

4 A. If she was wearing sanitary protection, 01:44

5 yes. But she is -- what I interpret this as -- 01:44

6 because you are asking for my interpretation, is 01:44

7 that the only sanitary protection she used during 01:44

8 the day was a liner, that she didn't use anything 01:44

9 else, but she spent a lot of time bleeding through 01:44

10 her clothes and while sitting on a toilet. 01:44

11 BY MR. JONNA: 01:44

12 Q. I'm asking for your -- interpretation 01:44

13 because I know nothing about liners and pads. So 01:44

14 I'm sorry. 01:44

15 A. No, that's okay. 01:44

16 Q. "Patient was assisted to gurney with no 01:44

17 increase in bleeding." Do you see that? 01:44

18 A. Yes. 01:44

19 Q. What does that indicate to you? 01:44

20 A. It means that as they got her up, they 01:44

21 didn't see -- because sometimes when people stand 01:44

22 up, you see more blood come out, and it just means 01:44

23 that they didn't see more blood come out, which 01:44

24 would make sense if she was sitting on the toilet, 01:44

25 that means the blood was already coming out when 01:44

1 they got her up. So as opposed to, for example -- 01:44
2 this is what they are taught -- if you have 01:45
3 somebody laying down, the blood could be collecting 01:45
4 in the vagina. Then in the moment you stand up, 01:45
5 because of gravity, it comes out. But she had been 01:45
6 sitting on a toilet, so I wouldn't necessarily have 01:45
7 expected more to come out. 01:45
8 Q. Okay. That's helpful. I'm going to show 01:45
9 you Exhibit 70 now. 01:45
10 A. Can we take a break? 01:45
11 Q. Oh, yeah, sure, let's take a break. Let's 01:45
12 -- let's go off the record. 01:45
13 THE VIDEOGRAPHER: Going off the record at 01:45
14 1:45 p.m. 01:45
15 (Recess taken from 1:45 p.m. to 1:56 p.m.) 01:45
16 THE VIDEOGRAPHER: Back on the record at 01:56
17 1:56 p.m. 01:56
18 BY MR. JONNA: 01:56
19 Q. Okay. I want to go back briefly to 01:56
20 Exhibit 59. I will pull it up again just to get 01:56
21 your -- to confirm that I'm reading this correctly. 01:56
22 So at 13:09, Subject 8, looking at 01:56
23 Subject 8's records, called your office about the 01:56
24 complaints with heavy bleeding; correct? 01:56
25 A. Yes. 01:56

1 MS. PENAN: Objection. Asked and 01:56
2 answered. 01:56
3 BY MR. JONNA: 01:56
4 Q. And that's 1:09 p.m.? 01:56
5 A. Yes. 01:56
6 Q. Okay. And then there is an entry -- the 01:56
7 entry right below that is from 15:44. 01:56
8 That would be 3:44 p.m.; correct? 01:56
9 A. Yes. 01:56
10 Q. It says, "Phone call to subject regarding 01:56
11 if doing okay and still needing appointment. Left 01:57
12 message requesting callback." 01:57
13 Do you see that? 01:57
14 A. Yes. 01:57
15 Q. Why did your office wait until 3:44 to 01:57
16 follow up with Subject 8 when she called reporting 01:57
17 heavy bleeding at 1:09? 01:57
18 MS. PENAN: Objection. Calls for 01:57
19 speculation. 01:57
20 A. It's really speculating. We have a lot 01:57
21 going on, and it might be then that's when we got 01:57
22 back to her because we didn't -- she didn't show 01:57
23 up. 01:57
24 BY MR. JONNA: 01:57
25 Q. Would you agree that, based on the 01:57

1 description of her bleeding and the fact that you 01:57
2 told her to come in and not to go to the ER, that 01:57
3 you didn't think it was serious enough to follow up 01:57
4 sooner than that? 01:57

5 MS. PENAN: Objection. Misstates the 01:57
6 witness's testimony. Incomplete hypothetical. 01:57
7 Vague, ambiguous. 01:57

8 A. I can't answer that. For all I know, I 01:57
9 mean, it's just as possible that I told somebody to 01:57
10 do it and they got really busy and didn't do it. I 01:58
11 mean -- 01:58

12 BY MR. JONNA: 01:58

13 Q. That's not what you remember happening; 01:58
14 right? 01:58

15 MS. PENAN: Objection. 01:58

16 A. I don't know. 01:58

17 MS. PENAN: Misstates the witness's 01:58
18 testimony. Argumentative. 01:58

19 A. Yeah. That's not what I said. I said, "I 01:58
20 don't know." 01:58

21 BY MR. JONNA: 01:58

22 Q. Right. So I'm not -- again, Doctor, I'm 01:58
23 not asking you to speculate. I'm asking what you 01:58
24 remember. You don't remember telling someone to 01:58
25 call sooner and they ignored you. 01:58

1 You are speculating about that; right? 01:58

2 You don't actually remember that happening? 01:58

3 A. No. 01:58

4 MS. PENAN: Objection. Asked and 01:58
5 answered. 01:58

6 A. I don't remember if I did or did not. I 01:58
7 have no idea. I have no idea. 01:58

8 BY MR. JONNA: 01:58

9 Q. Would you agree that if Subject 8, or 01:58
10 anyone, for that matter, called you reporting 01:58
11 bleeding that you thought was serious, that you 01:58
12 would want to follow up with them if they didn't 01:58
13 show up sooner than what we see here, from 1:09 to 01:58
14 3:14? 01:58

15 MS. PENAN: Objection. Misstates the 01:58
16 witness's testimony. Argumentative. Incomplete 01:58
17 hypothetical. Vague, ambiguous. 01:58

18 A. We wanted her to come in. I don't have 01:58
19 any recollection of whether I told someone, you 01:59
20 know, call if she hasn't come in in this period of 01:59
21 time; or if they told me sooner and I asked them to 01:59
22 call her, and that's when they could get around to 01:59
23 it; or that there was another time they did call 01:59
24 her and it wasn't written down. 01:59

25 It's all speculative. I have no idea. 01:59

1 BY MR. JONNA: 01:59

2 Q. If a patient calls you and reports what 01:59
3 you believe to be a severe hemorrhage, how soon 01:59
4 would you want to see her after you hear that 01:59
5 report? 01:59

6 A. Well, your question refers to "severe 01:59
7 hemorrhage." You keep using that term. 01:59

8 If anybody calls me -- I will talk about 01:59
9 if this patient calls me with this complaint, as 01:59
10 you see here, "heavy bleeding, soaking through her 01:59
11 clothes," I would want her to come in right away. 01:59

12 Q. Okay. 01:59

13 A. But she is still her own boss. She can 01:59
14 choose to go home first. She can choose to decide 01:59
15 that it's slowed down and she's fine. That's her 01:59
16 decision. 01:59

17 So when we didn't see her come back in, we 01:59
18 contacted her again. 02:00

19 Q. If someone's experiencing what you think 02:00
20 could be a severe hemorrhage, you wouldn't want 02:00
21 them to drive to your office, would you? 02:00

22 MS. PENAN: Objection. Calls for 02:00
23 speculation. Incomplete hypothetical. Vague, 02:00
24 ambiguous. 02:00

25 A. I would want them to get to my office as 02:00

1 quickly as they could, and if they were -- if the 02:00
2 person was experiencing heavy bleeding and said, "I 02:00
3 feel fine, and I want to -- you know, I'm going to 02:00
4 do X, Y, or Z," again, they can do what they want. 02:00

5 Not everybody who's heavily bleeding or 02:00
6 hemorrhaging needs an ambulance, but that doesn't 02:00
7 negate the fact that they are experiencing heavy 02:00
8 bleeding or hemorrhage. 02:00

9 BY MR. JONNA: 02:00

10 Q. Right. So can I ask a more general 02:00
11 question? So if a patient called you and reported 02:00
12 what you thought was a potential hemorrhage, would 02:00
13 it be your preference that that patient drive to 02:00
14 your office or go to the emergency room or take an 02:00
15 ambulance? 02:00

16 MS. PENAN: Objection. Incomplete 02:00
17 hypothetical. Calls for speculation. Lacks 02:00
18 foundation. Vague, ambiguous, and asked and 02:00
19 answered. 02:01

20 A. There's a lot of other factors that go 02:01
21 into it, like whether somebody has somebody who can 02:01
22 drive them, how they are feeling in general, what 02:01
23 they are willing to do. I mean, this patient 02:01
24 wanted to go home. 02:01

25 So there's a lot of factors that come into 02:01

1 that play. Every patient is different. So I can't 02:01
2 speculate about a hypothetical patient because 02:01
3 every patient is different. 02:01

4 BY MR. JONNA: 02:01

5 Q. Have you ever had a patient who you 02:01
6 thought was experiencing a hemorrhage that you told 02:01
7 to drive to your office? 02:01

8 A. If she feels she is hemorrhaging, and 02:01
9 based on my discussion with her, I feel she is 02:01
10 stable enough and can get there quickly, I would 02:01
11 tell her to come to my office. 02:01

12 Q. Well, I guess I was more specifically 02:01
13 asking if you remember if that's ever happened. 02:01

14 Have you -- do you remember, through the 02:01
15 course of your career, having a patient who called 02:01
16 you reporting symptoms consistent with a 02:01
17 hemorrhage, and you told them to drive in to your 02:01
18 office? 02:01

19 A. Well -- 02:01

20 MS. PENAN: Objection. Vague, ambiguous, 02:01
21 and incomplete hypothetical, and calls for 02:01
22 speculation. 02:02

23 A. So hemorrhage is the same as very heavy 02:02
24 bleeding. So, yes, I have had people with very 02:02
25 heavy bleeding who I've said, "Just come in right 02:02

1 away, and we will evaluate you." 02:02

2 BY MR. JONNA: 02:02

3 Q. Okay. Do you think -- 02:02

4 A. I've seen more people in my office with 02:02

5 these complaints than I have in the emergency room 02:02

6 because our office is set up to handle this. 02:02

7 Q. So -- 02:02

8 A. Every office is different. 02:02

9 Q. So your opinion is that hemorrhage is the 02:02

10 same as very heavy bleeding? 02:02

11 MS. PENAN: Objection. Misstates the 02:02

12 witness's testimony. Incomplete hypothetical. 02:02

13 Vague, ambiguous. 02:02

14 A. In -- when a patient is describing her 02:02

15 bleeding subjectively, it can be. 02:02

16 Every patient is different. 02:02

17 BY MR. JONNA: 02:02

18 Q. Okay. Okay. Another question about these 02:02

19 ambulance records, and I will move on. 02:03

20 On the top, it says, "Destination 02:03

21 determination, patient's choice." 02:03

22 Do you see that? 02:03

23 A. Yes. 02:03

24 Q. What does that indicate to you? 02:03

25 A. That means -- 02:03

1 MS. PENAN: Objection. Calls for 02:03

2 speculation. Lacks foundation. Incomplete 02:03

3 hypothetical. Vague, ambiguous. 02:03

4 A. That means the patient asked to go to UC 02:03

5 Davis. 02:03

6 BY MR. JONNA: 02:03

7 Q. Okay. And do you have an understanding as 02:03

8 to when an EMT would go where a patient asks versus 02:03

9 where the closest location is? 02:03

10 MS. PENAN: Objection. Calls for 02:03

11 speculation. Lacks foundation. Incomplete 02:03

12 hypothetical. Vague, ambiguous. 02:03

13 A. This could mean lots of things. It could 02:03

14 mean that they are equidistant from two places and 02:03

15 which one do you prefer? It could mean there's a 02:03

16 one-minute difference between the two, which in 02:03

17 this situation, doesn't matter. Even somebody, 02:03

18 necessarily, with a heart attack, you know, which 02:03

19 one does the family prefer. So -- 02:03

20 BY MR. JONNA: 02:03

21 Q. So is it your -- 02:03

22 A. -- it could be any one of those things. 02:03

23 Q. Is it your understanding that in a true 02:03

24 emergency, the EMT would ask the patient where they 02:04

25 would like to go? 02:04

1 MS. PENAN: Objection. Vague, ambiguous. 02:04
2 Calls for speculation. Lacks foundation. 02:04
3 Incomplete hypothetical. 02:04
4 A. Well, we've already established, at the 02:04
5 time that they saw her, whatever had been going on 02:04
6 earlier with her hemorrhaging was resolving. 02:04
7 MR. JONNA: Okay. All right. I would 02:04
8 like to pull up Exhibit 70 now. 02:04
9 (Deposition Exhibit 70 was marked for 02:04
10 identification by the reporter and is 02:04
11 attached hereto.) 02:04
12 BY MR. JONNA: 02:04
13 Q. Exhibit 70 is the investigational agent 02:04
14 disposition record for Subject 8. 02:04
15 A. Uh-huh. 02:04
16 Q. Have you seen these documents before? 02:04
17 A. If I did, it was a long time ago. 02:04
18 Q. And that study on top, "Mife Reversal," 02:04
19 that refers to your study; right? 02:04
20 A. Actually, I have not, because this is a 02:04
21 pharmacy form, not a form from my office. 02:04
22 Q. All right. So under the "Comment," it 02:04
23 says, "Bottle Number 8 not returned to IDS." 02:04
24 Do you see that? 02:05
25 A. Yes. 02:05

1 Q. What does that mean to you? 02:05

2 MS. PENAN: Objection. Calls for 02:05

3 speculation. Lacks foundation. 02:05

4 A. That Bottle Number 8 was not collected by 02:05

5 us from the patient and wasn't returned to IDS, as 02:05

6 the Investigational Drug Service. 02:05

7 BY MR. JONNA: 02:05

8 Q. So Subject 8 did not return her pill 02:05

9 bottle? 02:05

10 A. No. 02:05

11 MS. PENAN: Objection. Calls for 02:05

12 speculation. Lacks foundation. 02:05

13 A. It means Bottle 8 wasn't returned. 02:05

14 BY MR. JONNA: 02:05

15 Q. Right. Bottle 8 for Subject 8? 02:05

16 A. But the others.. 02:05

17 Q. How many bottles -- how many bottles did 02:05

18 the subjects get? 02:05

19 A. Enough to last them through each visit. I 02:05

20 would have to look back at the protocol to be 02:05

21 exactly sure. 02:05

22 Q. Okay. 02:05

23 A. But it is common -- we collect bottles. 02:05

24 It's common. Birth-control pill studies and any 02:05

25 study, we ask them to bring it in, and sometimes 02:05

1 they do; sometimes they don't. 02:05

2 Q. But you want them to bring it in; right? 02:05

3 A. We ask them to bring it in, yes. 02:06

4 Q. Why do you ask them to bring it in? 02:06

5 A. So that we have some sense that they used 02:06

6 the drugs, but to be fair, there's actually 02:06

7 studies, most prominently out of Columbia, that 02:06

8 show that people return empty bottles and never 02:06

9 took the drugs. 02:06

10 So it doesn't really matter, but we do it 02:06

11 to try to be complete. And the more important 02:06

12 thing is when somebody has extra drug at home, we 02:06

13 want to collect it to get it out of circulation. 02:06

14 Q. Do you remember if there was a problem 02:06

15 determining the final pill count for Subject 8? 02:06

16 A. I don't remember there being a problem. 02:06

17 Q. Okay. Do you remember there being a 02:06

18 concern that Subject 8 had not taken her 02:06

19 progesterone? 02:06

20 A. I did call her because she had an outcome 02:06

21 that was different from all the other participants 02:06

22 up to that point, just to really confirm that what 02:06

23 she put on her record, as far as taking the drug, 02:06

24 was real. I had no idea what she had taken or not 02:07

25 taken. 02:07

1 But we had gone through seven subjects with 02:07
2 nothing like this, and now all of sudden, we have it. 02:07
3 And, again, I had no idea what she was taking. I 02:07
4 just wanted to be absolutely sure that she had been 02:07
5 taking her medicine as she indicated. So it wasn't a 02:07
6 problem; it was just me double-checking. 02:07
7 Q. Do you remember when that occurred? 02:07
8 A. It would be in the notes. So -- 02:07
9 Q. Okay. 02:07
10 A. I don't remember when. 02:07
11 Q. All right. Let's take a look at 02:07
12 Exhibit 59, page 1. 02:07
13 This is what you are referring to; right? 02:07
14 A. Uh-huh. 02:07
15 Q. I will just read it. It says, "Phone call 02:07
16 from patient having period now. No problems after 02:07
17 last seen" -- sorry. "No problems" -- 02:07
18 A. -- "with health." 02:07
19 Q. -- "with health." Okay. I'm learning 02:07
20 that now. "States needs birth control. Use 02:07
21 withdrawal. Would like to be seen for birth 02:07
22 control. Wants IUD. States she really did take 02:08
23 her pills as scheduled. I explained that I really 02:08
24 needed to know and would not treat her differently 02:08
25 if she didn't take the meds. She confirmed she 02:08

1 really did take two capsules twice a day." 02:08
2 Did I read that correctly? 02:08
3 A. Yes. 02:08
4 Q. Is this the conversation you were 02:08
5 referring to? 02:08
6 A. Yes. 02:08
7 Q. So, again, just to confirm, you did have 02:08
8 concerns during the study that Subject 8 did not 02:08
9 take her medicine? 02:08
10 A. No idea -- 02:08
11 MS. PENAN: Objection. Misstates the 02:08
12 witness's testimony. 02:08
13 A. Yeah. That's not what I said. 02:08
14 I said I wanted to really confirm it 02:08
15 because it was so different than before, and I had 02:08
16 no idea what she was taking, so whether it was 02:08
17 placebo or progesterone, you know. 02:08
18 It's a double-blind study. So for all I 02:08
19 knew, you know, everybody else got placebo and she 02:08
20 got progesterone, and I didn't know. 02:08
21 When something really different happens, as 02:08
22 an investigator, I wanted to make sure that 02:08
23 everything was confirmed as much as possible. I just 02:08
24 really wanted to make sure she really did take it 02:09
25 because she was -- after going through seven people 02:09

1 where it was, like, yeah, no problem, nothing, no big 02:09
2 deal, and then, boom, this was quite different. 02:09

3 BY MR. JONNA: 02:09

4 Q. Okay. Turning back to your declaration, 02:09
5 which is Exhibit 2, I'm going to go to page 23 02:09
6 here. The paragraph highlighted says: "The first 02:09
7 participant with a hemorrhage was participant 8, 02:09
8 and we had not encountered any complications with 02:09
9 the first seven participants. Participant 8 had 02:09
10 excessive bleeding (more than expected per the 02:09
11 medication abortion instructions) starting on day 3 02:09
12 after her visit earlier in the day, and called an 02:09
13 ambulance to go to the emergency department. I met 02:09
14 her there where an ultrasound examination showed 02:09
15 she had passed the pregnancy. Her bleeding slowed 02:09
16 enough while in the emergency department that I 02:09
17 felt no intervention was necessary. Since this 02:09
18 outcome was within the expected outcomes, we 02:09
19 continued the study as planned. After the study 02:09
20 stopped, we learned this participant was in the 02:10
21 progesterone group." 02:10

22 Do you see that? Yes? 02:10

23 A. I said yes. 02:10

24 Q. Okay. The clause here on line 14 says 02:10
25 "more than expected per the medication abortion 02:10

1 instructions." 02:10

2 Do you see that? 02:10

3 A. Yes. 02:10

4 Q. What document are you referring to 02:10
5 specifically? 02:10

6 A. The instructions we gave every participant 02:10
7 that said if you are soaking more than two pads an 02:10
8 hour for two hours, we want you to call us. 02:10

9 Q. Where did it say that she was soaking more 02:10
10 than two pads per hour? 02:10

11 A. The fact that she was bleeding through her 02:10
12 clothes meant that, subjectively, she felt she was 02:10
13 bleeding at that level. That's her entitlement to 02:10
14 feel that she's bleeding at that level and her 02:10
15 entitlement to call us because she's concerned 02:10
16 about it. 02:10

17 Q. Did she tell you that she bled through one 02:10
18 liner the whole day? 02:10

19 MS. PENAN: Objection. Asked and 02:10
20 answered. 02:10

21 A. That's not what she said, and that's not 02:11
22 even what the record reports. 02:11

23 The record reports that's the only 02:11
24 sanitary product that she used. She bled through 02:11
25 her clothes. She was bleeding on the toilet when 02:11

1 the paramedics got there. 02:11

2 So that's what the records show. 02:11

3 BY MR. JONNA: 02:11

4 Q. So just to be clear, it says "more 02:11

5 than" -- "more than expected per the abortion 02:11

6 instructions," and those instructions said that it 02:11

7 had to be more than two pads per hour. 02:11

8 Is that correct? 02:11

9 A. Yes. 02:11

10 Q. And instead of using that objective 02:11

11 criteria, you instead just used her subjective 02:11

12 complaints to fit her into that criteria; is that 02:11

13 correct? 02:11

14 A. No, that's not correct. 02:11

15 MS. PENAN: Objection. The record speaks 02:11

16 for itself. 02:11

17 A. It's not correct. She felt she was 02:11

18 bleeding at a level that was more than what would 02:11

19 be the two pads an hour. This is true -- this is 02:12

20 true for patients we see clinically. 02:12

21 You know, if you are having diarrhea for 02:12

22 one hour that won't stop, you like -- you want your 02:12

23 doctor to tell you, "Well, keep going until you get 02:12

24 to two hours, because that's our criteria." 02:12

25 If you feel it's really severe, then you 02:12

1 act on it and we act on it. If you feel it's at a 02:12
2 level that's significant enough that would meet -- 02:12
3 that, in your opinion as the patient, you meet the 02:12
4 criteria, then you meet the criteria. 02:12

5 BY MR. JONNA: 02:12

6 Q. When did she say that it was more 02:12
7 significant than two pads per hour? 02:12

8 MS. PENAN: Objection. Misstates the 02:12
9 witness's testimony. Calls for speculation. 02:12
10 Vague, ambiguous. 02:12

11 A. She said she was bleeding through her 02:12
12 clothes and that she -- then, that, to her, was 02:12
13 excessive, and that's a pretty standard pair [as 02:12
14 heard]. 02:12

15 BY MR. JONNA: 02:12

16 Q. Who determined that bleeding through your 02:12
17 clothes is more than two pads per hour? 02:12

18 MS. PENAN: Objection. Calls for 02:13
19 speculation. Lacks foundation. Incomplete 02:13
20 hypothetical. 02:13

21 A. She was bleeding through her clothes. 02:13
22 That's heavier than she expected and we expected. 02:13
23 So we instructed her to come in. I already stated. 02:13

24 BY MR. JONNA: 02:13

25 Q. I could prick my finger and bleed through 02:13

1 my clothes right now, can't I? 02:13

2 MS. PENAN: Objection. Argumentative. 02:13

3 A. Yeah, but you pricking your finger is 02:13

4 different than you bleeding out your vagina. If 02:13

5 you were bleeding really heavily out of your rectum 02:13

6 and it was bleeding through your clothes, I imagine 02:13

7 you would be concerned. 02:13

8 BY MR. JONNA: 02:13

9 Q. So you interpret this statement, "bleeding 02:13

10 through your clothes," to always mean more than two 02:13

11 pads per hour? 02:13

12 MS. PENAN: Objection. Misstates the 02:13

13 witness's testimony. Vague, ambiguous. Calls for 02:13

14 speculation. Lacks foundation. Incomplete 02:13

15 hypothetical. 02:13

16 A. I can't make that determination when you 02:13

17 use the word "always." I can only relate it to 02:13

18 what this patient went through. 02:13

19 BY MR. JONNA: 02:13

20 Q. And in your declaration, instead of 02:14

21 referring to the medication abortion instructions, 02:14

22 why didn't you instead refer to the patient's 02:14

23 subjective assessment? 02:14

24 A. Because that's what I wrote. 02:14

25 Q. Do you think you should have edited it to 02:14

1 refer to her subjective assessment instead? 02:14

2 MS. PENAN: Objection. Argumentative. 02:14

3 A. That's what I wrote. 02:14

4 BY MR. JONNA: 02:14

5 Q. And do you stand by that as you sit here 02:14

6 today? 02:14

7 A. That's what I wrote. 02:14

8 Q. Okay. I know that's what you wrote, but 02:14

9 do you stand by that statement as you sit here 02:14

10 today? 02:14

11 MS. PENAN: Objection. Asked and 02:14

12 answered. 02:14

13 A. That's my expert opinion. 02:14

14 BY MR. JONNA: 02:14

15 Q. What is written here? 02:14

16 A. That's what I just answered you four times 02:14

17 now. 02:14

18 Q. Okay. All right. Going back to 02:14

19 Exhibit 5, I'm going to look at paragraph 5.2, 02:15

20 "Uterine Bleeding." Just if you scan -- I know 02:15

21 you've seen this before. You scan it. Let me know 02:15

22 when you're done. I have a quick question. 02:15

23 A. You can ask your question. 02:15

24 Q. So can you tell me what in here shows that 02:15

25 her bleeding was more than could be expected 02:15

1 pursuant to the medication abortion instructions? 02:15

2 MS. PENAN: Objection. Asked and 02:15

3 answered. 02:15

4 A. This patient was in a study where I have 02:15

5 no idea whether she got placebo or progesterone, 02:15

6 and she was bleeding through her clothes. That's 02:15

7 what I need to know as a clinician. 02:15

8 BY MR. JONNA: 02:16

9 Q. When you -- so it sounds to me like you're 02:16

10 really focusing on the statement "bleeding through 02:16

11 her clothes." 02:16

12 Do you also take into account the other -- 02:16

13 the other statements in the notes, the fact that -- 02:16

14 MS. PENAN: Objection. I'm sorry. 02:16

15 BY MR. JONNA: 02:16

16 Q. Yeah. We looked at a lot of different 02:16

17 records today, which I think some of them you've 02:16

18 seen before; some of them you haven't seen -- the 02:16

19 ambulance records, the ER records. You know, we 02:16

20 have the fact that you told her to come in the 02:16

21 office. 02:16

22 Did you factor all those, or did you just 02:16

23 think about the statement, "soaking through her 02:16

24 clothes"? 02:16

25 MS. PENAN: Objection. Counsel is 02:16

1 testifying. Asked and answered. 02:16

2 A. Yeah, I'm not sure exactly what your 02:16

3 question is after all that. 02:16

4 BY MR. JONNA: 02:16

5 Q. So it sounds to me like your statement in 02:16

6 your declaration, when you are asked to explain the 02:16

7 justification, you focused pretty much exclusively 02:16

8 on the statement that the bleeding was soaking 02:17

9 through her clothes. 02:17

10 Am I -- did I understand you correctly? 02:17

11 MS. PENAN: Objection. Vague, ambiguous. 02:17

12 Confusing. 02:17

13 A. That's part of it. 02:17

14 BY MR. JONNA: 02:17

15 Q. What's the other part of it? 02:17

16 A. She was passing clots. Based on the stuff 02:17

17 you showed me earlier, that she was even sitting on 02:17

18 the toilet bleeding when the paramedics got there, 02:17

19 and that she still was bleeding to the point even 02:17

20 in the emergency room when I said it's slowing 02:17

21 down, she still had you know, blood that was 02:17

22 actively coming out of her vagina. 02:17

23 But this is a process. She had severe 02:17

24 bleeding that we would classify in a study as 02:17

25 hemorrhage, and she passed it on her own. 02:17

1 She was concerned. She called an 02:17
2 ambulance. That's her right to do so. We met her in 02:17
3 the emergency department. We evaluated her and said, 02:17
4 "You got -- got over the hump. There's nothing we 02:17
5 need to do." And luckily, she needed nothing else 02:17
6 done. 02:17

7 Q. So in Section 5.2 -- again, we have seen 02:17
8 this a few times, but it refers to "soaking through 02:18
9 two thick full-size sanitary pads per hour for two 02:18
10 consecutive hours." 02:18

11 Do you see that? 02:18

12 A. I do. 02:18

13 Q. And you didn't know what Subject 8 was 02:18
14 wearing when she told you that she was bleeding 02:18
15 through her clothes; correct? 02:18

16 MS. PENAN: Objection. Asked and 02:18
17 answered. 02:18

18 A. Correct. 02:18

19 BY MR. JONNA: 02:18

20 Q. And you never asked her, as far as you 02:18
21 remember; correct? 02:18

22 A. I didn't -- I don't care. If somebody -- 02:18
23 if a patient of mine calls, bleeding heavily and 02:18
24 worried, whether she's bleeding through her clothes 02:18
25 or not, I'm going to tell her to come in, because 02:18

1 that's the right thing to do for your patient, 02:18
2 because we have -- especially in a study where we 02:18
3 are responsible for her safety, I'm going to tell 02:18
4 her to come in. 02:18

5 Q. You're going to tell her to drive in to 02:18
6 your office; right? 02:18

7 MS. PENAN: Objection. Misstates the 02:18
8 witness's testimony. 02:18

9 A. If the patient seems stable to drive 02:18
10 herself, then we will tell her to drive herself. 02:18
11 It doesn't negate the fact that she experienced 02:18
12 this bleeding. 02:19

13 BY MR. JONNA: 02:19

14 Q. Okay. Back to Exhibit 2 here. On lines 02:19
15 18 and 19, it says that this outcome was within the 02:19
16 expected outcomes. 02:19

17 Do you see that? 02:19

18 A. I do. 02:19

19 Q. Was a severe hemorrhage requiring medical 02:19
20 transport an expected outcome in your study? 02:19

21 A. Having hemorrhage and passing the 02:19
22 pregnancy is part of the risks of the study and the 02:19
23 potential outcomes that were explained to the 02:19
24 patient. 02:19

25 The fact that she went to the emergency 02:19

1 room does not meet the criteria of a serious adverse 02:19
2 event. People go to the emergency room for many 02:19
3 things, and being in the emergency room itself is not 02:19
4 a serious adverse event. 02:19

5 Q. If Subject 8 had a severe hemorrhage 02:20
6 requiring medical transport to the emergency room, 02:20
7 were you ethically required to contact the IRB 02:20
8 right away? 02:20

9 A. No. 02:20

10 MS. PENAN: Objection. Argumentative. 02:20
11 Lacks foundation. 02:20

12 BY MR. JONNA: 02:20

13 Q. Why not? 02:20

14 MS. PENAN: Incomplete hypothetical. 02:20

15 A. Because it doesn't meet the criteria for a 02:20
16 serious adverse event for a study. 02:20

17 BY MR. JONNA: 02:20

18 Q. And you talked about that earlier, but can 02:20
19 you just refresh my memory? What meets that 02:20
20 criteria? 02:20

21 MS. PENAN: Objection. Asked and 02:20
22 answered? 02:20

23 A. Inpatient hospitalization; an intervention 02:20
24 to prevent, for example, inpatient hospitalization 02:20
25 or another severe outcome; teratogenicity or 02:20

1 genetic defects caused as a result of using the 02:20

2 agent; death; life-threatening event. 02:20

3 BY MR. JONNA: 02:20

4 Q. Okay. All right. Let me see here. 02:20

5 So the next paragraph, paragraph 46L, you 02:21

6 say the "The second participant with a hemorrhage 02:21

7 was participant 10 who called an ambulance on day 5 02:21

8 and was brought to our emergency department and 02:21

9 seen by one of my co-investigators." 02:21

10 Do you see that? 02:21

11 A. I see that. 02:21

12 Q. Who was the co-investigator who saw her? 02:21

13 A. I have to ask counsel if I need to provide 02:21

14 that person's name. 02:21

15 Q. Well, I mean, they are all -- as you know, 02:21

16 we have deposed other doctors associated with the 02:21

17 study. So... 02:21

18 THE WITNESS: I have to ask counsel. 02:21

19 Am I required to provide someone's name if 02:21

20 it's someone who has not been deposed or -- 02:21

21 BY MR. JONNA: 02:21

22 Q. So you are declining to -- well, maybe 02:21

23 during a break, you can ask UC Davis' counsel and 02:21

24 let us know. 02:21

25 A. Well, it would be the district attorney. 02:21

1 Q. Yeah, the attorney general -- 02:22

2 (Speakers talking simultaneously.) 02:22

3 BY MR. JONNA: 02:22

4 Q. You understand that's not your counsel, 02:22

5 though; correct? 02:22

6 A. One of the other doctors who was an 02:22

7 investigator on the study that you did not depose. 02:22

8 Q. Okay. Are you aware that Participant 10's 02:22

9 medical records say "Means of Arrival, Ambulatory"? 02:22

10 A. I was made aware of it by the state 02:22

11 attorney generals -- attorneys. 02:22

12 MR. JONNA: This is Exhibit 64, page 5. 02:22

13 (Deposition Exhibit 64 was marked for 02:22

14 identification by the reporter and is 02:22

15 attached hereto.) 02:22

16 BY MR. JONNA: 02:22

17 Q. And you saw this before your deposition 02:22

18 today; correct? 02:22

19 A. Yes. This week. 02:22

20 Q. And "ambulatory" means she brought herself 02:22

21 in. She walked in; correct? 02:23

22 MS. PENAN: Objection. Calls for 02:23

23 speculation. Lacks foundation. Incomplete 02:23

24 hypothetical. 02:23

25 A. That's what I am to presume. 02:23

1 BY MR. JONNA: 02:23

2 Q. Okay. Do you want to explain the 02:23

3 discrepancy? 02:23

4 MS. PENAN: Objection. Argumentative. 02:23

5 A. I was informed by my co-investigator that 02:23

6 she came in by ambulance. 02:23

7 BY MR. JONNA: 02:23

8 Q. Did you have a conversation with your 02:23

9 co-investigator about this after you saw this 02:23

10 record? 02:23

11 A. No, because I saw it this week. 02:23

12 Q. Right. So you didn't speak to that person 02:23

13 after you saw it? 02:23

14 A. That person is no longer with our group. 02:23

15 Q. Okay. Right. So I assume that means you 02:23

16 did not speak to that person. 02:23

17 Is that fair? 02:23

18 MS. PENAN: Objection. Asked and 02:23

19 answered. 02:23

20 A. That's what I said. 02:23

21 BY MR. JONNA: 02:23

22 Q. Okay. All right. Back to Exhibit 2. 02:23

23 Line 27 here, it says, "Because of this 02:23

24 second case, I notified that IRB of these two 02:24

25 hemorrhages, and they reviewed the outcomes to 02:24

1 date. The IRB asked for us to finish follow-up on 02:24
2 all active participants to see if any other 02:24
3 [hemorrhage]" -- "hemorrhages occurred. When no 02:24
4 further hemorrhages occurred, the IRB agreed to 02:24
5 allow us to begin recruitment again." 02:24

6 Do you see that? 02:24

7 A. Yes. 02:24

8 Q. Was there any other reason that you 02:24
9 contacted the IRB? 02:24

10 A. Because the second one met the criteria 02:24
11 for a serious adverse event, because we had to do 02:24
12 an intervention. And also because having two 02:24
13 hemorrhages in the first, really, eight patients 02:24
14 was not what we expected. 02:24

15 And my responsibility in a study like 02:24
16 this is to protect the safety of the participants 02:24
17 when these patients were not -- otherwise at risk, 02:25
18 which is participating in the study. 02:25

19 So the responsible thing to do is to talk 02:25
20 to the Institutional Review Board to let them know 02:25
21 what's going on and keep them up-to-date as part of 02:25
22 my responsibility of protecting their safety. 02:25

23 MR. JONNA: Okay. Taking a look at 02:25
24 Exhibit 63 now. 02:25

25 (Deposition Exhibit 63 was marked for 02:25

1 identification by the reporter and is 02:25
2 attached hereto.) 02:25
3 BY MR. JONNA: 02:25
4 Q. These -- this is Subject 7's reversal log 02:25
5 for visit Number 2 on Study Day 3, and on page -- 02:25
6 this participant -- sorry. Subject 7. 02:25
7 A. Okay. This is the one who had some 02:25
8 bleeding, that didn't want to continue, I believe. 02:25
9 Q. Well, this is the one that actually said 02:25
10 she had severe bleeding, isn't it? 02:25
11 MS. PENAN: Objection. Argumentative. 02:25
12 The record speaks for itself. 02:25
13 A. Yeah. she -- that's her report, that she 02:25
14 reported she had severe bleeding. 02:25
15 BY MR. JONNA: 02:25
16 Q. Right. And you care a lot about the 02:25
17 patient's report. 02:25
18 A. Yes. 02:25
19 Q. In fact, you would use the patient's 02:25
20 report to determine whether to characterize it as a 02:26
21 hemorrhage or not, wouldn't you? 02:26
22 MS. PENAN: Objection. Argumentative. 02:26
23 Counsel is testifying. Misstates the witness's 02:26
24 testimony. Incomplete hypothetical. Vague, 02:26
25 ambiguous. 02:26

1 Q. Okay. So there are objective criteria 02:27
2 that you factor, not just subjective criteria? 02:27

3 A. When I can. Once you go down to the exam, 02:27
4 since you are just focusing on one area. 02:27

5 Q. Well, I'm focusing on what I thought was 02:27
6 the most important here. I will go down, Doctor, 02:27
7 but I'm just -- I thought the patient's subjective 02:27
8 feelings were the most important component. 02:27

9 Did I misunderstand that? 02:27

10 MS. PENAN: Objection. Counsel is 02:27
11 testifying. Misstates the witness's testimony. 02:27
12 Harassing and argumentative. 02:27

13 A. I never said that. 02:27

14 Let me move down to the exam so we can get 02:27
15 a complete picture, rather than what you're just 02:27
16 trying to focus on -- 02:27

17 BY MR. JONNA: 02:27

18 Q. Okay. 02:27

19 A. -- and minimize it. 02:27

20 Q. All right. Well, I'll do that, but before 02:27
21 I do that, I just want to confirm if -- how much 02:27
22 weight -- and how you determine how much weight to 02:27
23 place on a patient's subjective reporting. 02:27

24 MS. PENAN: Objection. Asked and 02:27
25 answered. 02:27

1 were seeing was not severe. Just like the patient 02:28
2 that called before who bled through her clothes, we 02:28
3 told her to come in, but she bled through her 02:28
4 clothes to the point where she passed the 02:28
5 pregnancy. Very different. 02:28
6 BY MR. JONNA: 02:28
7 Q. What does "os" mean? 02:28
8 A. "Os" is the opening of the cervix. 02:28
9 Q. And what does it mean to you, "Blood's 02:28
10 coming from os"? 02:28
11 A. That she's bleeding. When people have 02:29
12 bleeding from their uterus, it has to come through 02:29
13 the cervix. 02:29
14 Q. When it says "blood in vault," what does 02:29
15 that mean? 02:29
16 A. That there was some blood present in the 02:29
17 vagina, which goes along with the blood coming from 02:29
18 her cervix. 02:29
19 Q. You stated that the results were 02:29
20 clinically significant, or someone stated that. 02:29
21 You see that? 02:29
22 A. Yes. 02:29
23 MS. PENAN: Objection. The record speaks 02:29
24 for itself. 02:29
25 BY MR. JONNA: 02:29

1 Q. With respect to the cervix and the vagina; 02:29
2 is that right? 02:29
3 A. Right. 02:29
4 Q. What does "clinically significant" mean? 02:29
5 A. It means, would it be expected in a normal 02:29
6 exam? So it's clinically significant because she's 02:29
7 bleeding. I mean, normally, I would not expect her 02:29
8 to bleed. 02:29
9 Q. Okay. On page 6, it says, "Subject 02:29
10 elected to have D&C in OR." 02:29
11 Do you see that? 02:29
12 A. Yes. 02:29
13 Q. It also says, "Her pregnancy is still 02:29
14 viable." Do you see that? 02:29
15 A. Yes. 02:30
16 Q. How would you describe the difference 02:30
17 between what Subject 7 experienced -- based on your 02:30
18 recollection -- and what Subject 8 experienced? 02:30
19 A. Patient 7 was bleeding, in my estimation, 02:30
20 lightly. She felt it was severe, but it was light. 02:30
21 She didn't complain of bleeding through her clothes 02:30
22 or anything of the nature of what happened with 02:30
23 Patient 8. 02:30
24 Q. Do you recall Patient 8 ever using the 02:30
25 words "severe bleeding," or describing her bleeding 02:30

1 as severe? I think she described it as heavy 02:30

2 bleeding; right? 02:30

3 MS. PENAN: Objection. Asked and 02:30

4 answered. The record speaks for itself. 02:30

5 A. Yeah, I'll have to agree that the record 02:30

6 speaks for itself. You know, this is from years 02:30

7 ago. We wrote down what happened at the time. 02:30

8 BY MR. JONNA: 02:30

9 Q. Okay. All right. I'm going to pull up 02:30

10 Exhibit 65. These are Subject 11's records. And 02:31

11 if you recall, Subject 11 was from the placebo 02:31

12 group. Hemorrhaging required a blood transfusion. 02:31

13 Do you recall that? 02:31

14 (Deposition Exhibit 65 was marked for 02:31

15 identification by the reporter and is 02:31

16 attached hereto.) 02:31

17 A. I just want to make sure it was 8, 10, 11. 02:31

18 Yes. 02:31

19 BY MR. JONNA: 02:31

20 Q. On page 2, it says that "Subject was a 02:31

21 former meth user in a halfway house." 02:31

22 Do you see that? 02:31

23 MS. PENAN: Objection. The record speaks 02:31

24 for itself. 02:31

25 A. That's from 2014. 02:31

1 BY MR. JONNA: 02:31

2 Q. Right. I'm just asking if you see that. 02:31

3 A. Uh-huh. 02:31

4 Q. Yes? 02:31

5 A. Yes. 02:31

6 Q. Okay. What part of this is from 2014, 02:31

7 just to be clear? 02:32

8 A. That record right there. 02:32

9 Q. Okay. Do you know why that's in here? 02:32

10 A. You asked for her -- 02:32

11 MS. PENAN: Objection. Calls for 02:32

12 speculation. 02:32

13 A. You asked for her records. 02:32

14 BY MR. JONNA: 02:32

15 Q. Okay. On page 6 of the PDF, it says, on 02:32

16 the bottom here -- actually, right here, it says, 02:32

17 "Roughly five hours prior to ED arrival, patient 02:32

18 was in a bathtub when she start bleeding and 02:32

19 producing vaginal blood clots." 02:32

20 Do you see that? 02:32

21 A. Yes. 02:32

22 Q. Do you recall having a discussion to 02:32

23 understand why she waited so long to come to the 02:32

24 ER? 02:32

25 MS. PENAN: Objection. Calls for 02:32

1 speculation. Lacks foundation. 02:32

2 A. No. One of my partners took care of this 02:32

3 patient and got all this history. 02:32

4 BY MR. JONNA: 02:33

5 Q. Did you review these records before your 02:33

6 deposition, too? 02:33

7 A. Not these. 02:33

8 Q. So just as you sit here today, do you have 02:33

9 a recollection of this patient -- of hearing that 02:33

10 this patient waited this long to come to the 02:33

11 emergency room after starting bleeding? 02:33

12 A. She started bleeding and passing clots. 02:33

13 It doesn't mean that she was bleeding very heavily 02:33

14 at this point. I can interpret it just as much as 02:33

15 you can. Exactly -- it says what it says. 02:33

16 You know, whether she started to bleed at 02:33

17 five hours and then it got really heavy at one hour 02:33

18 prior to ED arrival, these are things I don't know. 02:33

19 Q. It does say that she was in a bathtub when 02:33

20 she started bleeding and producing vaginal clots. 02:33

21 And then she arrived at the emergency 02:33

22 department five hours later; correct? 02:33

23 A. Right. 02:33

24 MS. PENAN: Objection. The record speaks 02:33

25 for itself. 02:33

1 BY MR. JONNA: 02:33

2 Q. That's not something that you would 02:33

3 recommend, though; right? 02:33

4 A. No, but -- 02:33

5 MS. PENAN: Objection. Incomplete 02:33

6 hypothetical. Lacks foundation. Calls for 02:33

7 speculation. 02:33

8 A. No, but as I said earlier, you can provide 02:33

9 patients with instructions, and whether they follow 02:34

10 it or not is up to them. 02:34

11 BY MR. JONNA: 02:34

12 Q. What does it mean when it says "unable to 02:34

13 perform ROS"? 02:34

14 MS. PENAN: Objection. Calls for 02:34

15 speculation. 02:34

16 A. Review of systems. She was very acute. 02:34

17 So rather than to take time to say, "Did you have 02:34

18 any other symptoms, like, related to your heart or 02:34

19 your lungs or your toes or anything else?" the 02:34

20 person completing this felt that her system was too 02:34

21 acute to worry about those other things. 02:34

22 BY MR. JONNA: 02:34

23 Q. Okay. And you didn't see anything of this 02:34

24 nature in Subject 8's records; right? 02:34

25 A. You -- 02:34

1 MS. PENAN: Objection. The record speaks 02:34
2 for itself. 02:34

3 A. We would have to go through all of 02:34
4 Subject 8's records, but every patient is 02:34
5 different. Subject 8 presented in the emergency 02:34
6 room after her hemorrhage. This person was 02:34
7 presenting while she was hemorrhaging. Very 02:34
8 different scenarios. 02:34

9 BY MR. JONNA: 02:34

10 Q. Okay. I'm just asking if you recall -- in 02:34
11 the records we looked at today, you didn't see 02:34
12 anything like that in Subject 8's records; correct? 02:34

13 MS. PENAN: Objection. Asked and 02:35
14 answered? 02:35

15 A. I can't comment on it because we didn't 02:35
16 look through the entire record to look for that 02:35
17 exactly. 02:35

18 BY MR. JONNA: 02:35

19 Q. Would you agree that the Subject 11's 02:35
20 situation appears to be much more severe? 02:35

21 A. Based on the limited information in front 02:35
22 of me right now, where her pulse is high and they 02:35
23 wrote "Acuity of condition makes it unable to 02:35
24 perform review of symptoms," probably is very 02:35
25 different. But you can also -- yeah. 02:35

1 Q. What does "tachycardic" mean? 02:35

2 A. Fast pulse. 02:35

3 Q. Okay. And then if I scroll down to 02:35

4 page 48 -- actually, I'm sorry -- 49, it says, 02:35

5 "Patient reports heavy vaginal bleeding starting 02:35

6 four hours prior to arrival. The bleeding was 02:35

7 difficult to quantify because she was in tub and 02:35

8 was not wearing a pad. She states that she has 02:36

9 passed multiple clots, but is unsure if she passed 02:36

10 fetal tissue. Reports associated dizziness and 02:36

11 lightheadedness, but specifically denies fever, 02:36

12 chills, chest pain." 02:36

13 Do you see that? 02:36

14 A. Yes. 02:36

15 Q. So we saw five hours earlier, and now we 02:36

16 are seeing four hours. 02:36

17 Would you agree that it's possible she 02:36

18 would not have required a transfusion if she had gone 02:36

19 to the emergency room sooner? 02:36

20 MS. PENAN: Objection. Calls for 02:36

21 speculation. Lacks foundation. Incomplete 02:36

22 hypothetical. 02:36

23 A. It doesn't matter. Patients are who they 02:36

24 are. You know, it's always up to them. It doesn't 02:36

25 matter. You are asking a pointless question. 02:36

1 Do I agree? I don't know. You can't 02:36
2 speculate on how long she's been bleeding like 02:36
3 that. It doesn't matter. This is what happened. 02:36
4 This is when she decided to call. This is part of 02:36
5 the issue. 02:36

6 When we provide medication abortion, you 02:36
7 know, what's the transfusion rate? It's incredibly 02:36
8 low. What I tell patients is -- but when patients 02:36
9 need transfusion is most likely because they didn't 02:37
10 follow the directions. 02:37

11 So do we really tell patients there is no 02:37
12 transfusion risk, or do we tell them this is what 02:37
13 happens? Because people are real-life people. 02:37

14 BY MR. JONNA: 02:37

15 Q. Okay. 02:37

16 A. Right? 02:37

17 Q. So, Doctor, just to be very clear here, I 02:37
18 don't have to tell you the reason why I'm asking a 02:37
19 question, but I did ask you a specific question, 02:37
20 and it's -- you're a very well-credentialed, 02:37
21 experienced doctor, and my question was very 02:37
22 simple. 02:37

23 Is it possible she would not have required 02:37
24 a transfusion if she had gone to the ER sooner? 02:37

25 MS. PENAN: Objection. Calls for 02:37

1 speculation. Lacks foundation. Incomplete 02:37
2 hypothetical. 02:37
3 A. It's possible, yes. 02:37
4 BY MR. JONNA: 02:37
5 Q. Okay. 02:37
6 A. It's also possible she wouldn't have 02:37
7 needed a transfusion if she had decided to quit the 02:37
8 study like the other patient did. Anything's 02:37
9 possible. 02:37
10 Q. Should the fact that she waited four, five 02:37
11 hours to go to the ER have been included in the 02:37
12 study? 02:37
13 MS. PENAN: Objection. Calls -- well.. 02:37
14 A. Should it have been included in the study. 02:38
15 BY MR. JONNA: 02:38
16 Q. Should that fact have been included in the 02:38
17 study? I mean, it seems like a pretty material 02:38
18 fact to me. Would you agree? 02:38
19 MS. PENAN: Objection. Argumentative. 02:38
20 Misstates the witness's testimony. 02:38
21 A. It -- I don't think it matters. This is 02:38
22 what happened. We report the outcomes. 02:38
23 BY MR. JONNA: 02:38
24 Q. So how do you determine -- how do you 02:38
25 determine what facts matter? 02:38

1 MS. PENAN: Objection. Vague, ambiguous. 02:38

2 A. The outcomes. I mean, it's just the 02:38

3 outcomes that we report. 02:38

4 BY MR. JONNA: 02:38

5 Q. Right. 02:38

6 A. Because even the idea that she came in 02:38

7 earlier would be speculative, if she came in. 02:38

8 You are trying to blame the patient, and 02:38

9 that's not appropriate, you know. 02:38

10 BY MR. JONNA: 02:38

11 Q. Okay. What's your understanding of, like, 02:38

12 the main conclusion that you drew from your study? 02:38

13 A. That three people who are real people who 02:38

14 went through this had very, very heavy bleeding to 02:38

15 the point where they needed to present to an 02:38

16 emergency department, and two of them needed 02:38

17 emergent procedure. One of those two needed a 02:39

18 blood transfusion. 02:39

19 Q. And it was -- 02:39

20 A. It's real life of what happened. 02:39

21 Q. And it was -- what was the reason you 02:39

22 thought that happened? 02:39

23 MS. PENAN: Objection. Vague, ambiguous. 02:39

24 Incomplete hypothetical. 02:39

25 BY MR. JONNA: 02:39

1 Q. Not -- I'm not asking you to state 02:39
2 something new today. 02:39

3 In your study, what was the reason you 02:39
4 stated that those bad things happened to those 02:39
5 three people? 02:39

6 MS. PENAN: Objection. The record speaks 02:39
7 for itself. 02:39

8 A. My opinion right now is because they 02:39
9 didn't use misoprostol; right? Because not using 02:39
10 misoprostol, regardless of what you do afterwards, 02:39
11 means your uterus isn't necessarily set up to 02:39
12 contract, and if you start to bleed, especially for 02:39
13 -- if you start to bleed, your uterus may not 02:39
14 contract enough to expel everything and stop the 02:39
15 bleeding. 02:39

16 BY MR. JONNA: 02:39

17 Q. In the case of Subject 11, if she had gone 02:39
18 to the hospital sooner and not needed a 02:39
19 transfusion, that seems like something that should 02:40
20 have been included as a -- as a fact in the study, 02:40
21 that she waited four, five hours? 02:40

22 MS. PENAN: Objection. Misstates the 02:40
23 witness's testimony. Counsel is testifying. 02:40

24 Argumentative. The record speaks for itself. 02:40

25 BY MR. JONNA: 02:40

1 Q. Is that just an inconvenient fact that you 02:40
2 didn't -- that you glossed over, or did you not 02:40
3 know about that till now? 02:40

4 MS. PENAN: Same objections, plus 02:40
5 harassing. 02:40

6 A. That's your opinion. You are entitled to 02:40
7 your opinion. 02:40

8 BY MR. JONNA: 02:40

9 Q. Did you know that she waited four, five 02:40
10 hours to go to the emergency room, before preparing 02:40
11 for this deposition? 02:40

12 A. Before preparing? I don't remember if I 02:40
13 knew that at the time or not. I don't remember. 02:40

14 Q. Is your first report to the IRB in 02:40
15 writing? 02:40

16 A. I don't remember. 02:40

17 Q. We haven't seen it, so presumably if it 02:40
18 was, it would have been included in the documents 02:40
19 that were produced? 02:40

20 MS. PENAN: Objection. Asked and 02:40
21 answered. 02:41

22 A. I don't remember. 02:41

23 BY MR. JONNA: 02:41

24 Q. Looking at Subject 10's records now -- 02:41

25 A. Can we take a break for five minutes, 02:41

1 even? 02:41

2 Q. Sure. 02:41

3 A. Thank you. 02:41

4 THE VIDEOGRAPHER: Going off the record at 02:41

5 2:41 p.m. 02:41

6 (Recess taken from 2:41 p.m. to 2:50 p.m.) 02:41

7 THE VIDEOGRAPHER: Back on the record at 02:50

8 2:50 p.m. 02:50

9 BY MR. JONNA: 02:50

10 Q. All right. I'm going to pull up again 02:50

11 Exhibit 64. These are Subject 10's records. We 02:50

12 looked at the first highlight there. "Means of 02:50

13 arrival, ambulatory," which we agreed that means 02:50

14 she walked in or drove on her own. She didn't take 02:50

15 any ambulance. 02:50

16 Is that correct? 02:50

17 MS. PENAN: Objection. Asked and 02:50

18 answered. Calls for speculation. 02:50

19 A. Yes. 02:50

20 BY MR. JONNA: 02:50

21 Q. It says here that her -- it says under the 02:51

22 "Admission/Diagnoses," "Incomplete spontaneous 02:51

23 abortion with other complications." "Comments: 02:51

24 Vaginal bleeding moderate or pregnancy related." 02:51

25 Do you see that? 02:51

1 A. Yes. 02:51

2 Q. And that's a different ICD code? 02:51

3 MS. PENAN: Objection. The record speaks 02:51
4 for itself. 02:51

5 A. I would have to actually look at the code 02:51
6 from the other one to see if it is. You can have 02:51
7 different descriptions with the same code. So I 02:51
8 don't know if it's exactly a different code. 02:51

9 BY MR. JONNA: 02:51

10 Q. Okay. But it's a different description? 02:51

11 A. Yes. 02:51

12 Q. The other description said "without 02:51
13 complication," and this one says "with other 02:51
14 complications"; correct? 02:51

15 MS. PENAN: Objection. The record speaks 02:51
16 for itself. 02:51

17 BY MR. JONNA: 02:51

18 Q. And this one also says that the vaginal 02:51
19 bleeding is moderate, as opposed to minor; correct? 02:51

20 A. Yes. 02:52

21 MS. PENAN: Objection. The record speaks 02:52
22 for itself. 02:52

23 A. That refers to at the time of 02:52
24 presentation, uh-huh. 02:52

25 BY MR. JONNA: 02:52

1 Q. The triage nurse made the following report 02:52
2 on the bottom: "Care of vaginal bleeding since 02:52
3 0900. Patient took a research 02:52
4 drug/pill/progesterone versus placebo on 26th and 02:52
5 is also taking it every day. Patient is bleeding 02:52
6 bright red blood and clots, soaking one pad within 02:52
7 minutes. Patient appears pale and is dizzy when 02:52
8 standing up." 02:52
9 Do you see that? 02:52
10 A. Yes. 02:52
11 Q. You agree that that description is more 02:52
12 severe than the description we saw for Subject 8 in 02:52
13 the emergency room; correct? 02:52
14 MS. PENAN: Objection. The record speaks 02:52
15 for itself. Vague, ambiguous. Incomplete 02:53
16 hypothetical. Calls for speculation. 02:53
17 A. That is the description of how they were 02:53
18 when they presented to the emergency department. 02:53
19 BY MR. JONNA: 02:53
20 Q. And this description sounds more serious 02:53
21 than the description we read for Subject 8 when she 02:53
22 presented to the emergency department; correct? 02:53
23 MS. PENAN: Same objections. 02:53
24 A. The description sounds more serious than 02:53
25 the other at the time they presented to the 02:53

1 emergency department, which goes along with their 02:53
2 course, which is why the other patient had 02:53
3 completed her process or was completing her 02:53
4 process, and this one was not. 02:53

5 BY MR. JONNA: 02:53

6 Q. Okay. On page 8, it says, "Assumed care 02:53
7 of patient, MD at bedside for pelvic. Labs sent. 02:53
8 Chux pad and mesh underwear changed. Patient 02:53
9 passing large clots." 02:53

10 Do you see that? 02:53

11 A. Yes. 02:53

12 Q. That's also consistent with what we 02:53
13 discussed. This description sounds more serious in 02:53
14 Subject 8; correct? 02:53

15 A. Yes. 02:53

16 MS. PENAN: Same objections. 02:53

17 BY MR. JONNA: 02:53

18 Q. Page 10, it states, under the physical 02:54
19 exam, "Moderate blood from vaginal vault. 4x4 cm 02:54
20 blood clot versus products of conception passed 02:54
21 from cervix. 2x2 blood clot passed from vaginal 02:54
22 vault. Female chaperone present, os open." 02:54

23 What does this indicate to you? 02:54

24 A. She's actively bleeding, actively trying 02:54
25 to pass tissue. The cervix is open, meaning the 02:54

1 uterus is trying to pass the tissue. 02:54

2 Q. Okay. Which wasn't the case for 02:54

3 Subject 8; correct? 02:54

4 MS. PENAN: Objection. Misstates the 02:54

5 witness's testimony. Calls for speculation. Lacks 02:54

6 foundation. 02:54

7 A. At the time the person was in the 02:54

8 emergency room, that exam is different. 02:54

9 BY MR. JONNA: 02:54

10 Q. Okay. Her hemoglobin, on page 12, is 9.6. 02:54

11 Do you see that? 02:54

12 A. Yes. 02:54

13 Q. That's a clinically important change in 02:54

14 hemoglobin, according to you; correct? 02:54

15 MS. PENAN: Objection. Misstates the 02:55

16 witness's testimony. Vague, ambiguous. Lacks 02:55

17 foundation. Incomplete hypothetical. 02:55

18 A. I never said that was a clinically 02:55

19 important change. I don't -- "change" implies 02:55

20 going from one value to another. 02:55

21 Is that a clinically important hemoglobin 02:55

22 in and of itself? It's -- it matches with everything 02:55

23 else going on. It doesn't provide me with any more 02:55

24 information other than she's not so low that -- so 02:55

25 low in her value that she needs a transfusion, but it 02:55

1 goes along with everything else. 02:55

2 BY MR. JONNA: 02:55

3 Q. This is Exhibit 14, which is the study we 02:55

4 have been talking, "Mifepristone Antagonization 02:55

5 With Progesterone to Prevent Medical Abortion"; 02:55

6 correct? 02:55

7 A. Yes. 02:55

8 (Deposition Exhibit 14 was marked for 02:55

9 identification by the reporter and is 02:55

10 attached hereto.) 02:55

11 BY MR. JONNA: 02:55

12 Q. And you're the first author here listed; 02:55

13 right? 02:55

14 A. Yes. 02:55

15 Q. And on the -- can you just confirm, first 02:55

16 of all, the role of Danco Laboratories in the 02:55

17 study? 02:56

18 A. We study drug from them. 02:56

19 THE REPORTER: "Study" what? 02:56

20 A. We purchased study drug from them. 02:56

21 BY MR. JONNA: 02:56

22 Q. Okay. Did they sell it to you at market 02:56

23 rate, or did they give you a discount? 02:56

24 A. Like most -- 02:56

25 MS. PENAN: Objection. Compound. 02:56

1 in the study, and I said they had no role in the 02:57

2 study itself. 02:57

3 BY MR. JONNA: 02:57

4 Q. Did they have any role -- did they have 02:57

5 any role in the way that you communicated the 02:57

6 results of the study? 02:57

7 MS. PENAN: Objection. Vague, ambiguous. 02:57

8 Incomplete hypothetical. Lacks foundation. 02:57

9 A. Representatives from Danco were present at 02:57

10 a conference we held about the study, but they were 02:57

11 -- they had no -- nothing to do with the study 02:57

12 conduct or the manuscript preparation or the 02:57

13 manuscript itself, or the report itself, I should 02:57

14 say. 02:57

15 BY MR. JONNA: 02:57

16 Q. Who invited them to the conference in 02:57

17 Washington, D.C.? 02:57

18 A. I did. 02:58

19 Q. And was that your idea? 02:58

20 A. Yes. 02:58

21 Q. What was the reason for that? 02:58

22 A. In a stakeholders' meeting, you invite 02:58

23 stakeholders so they are aware of what's going on. 02:58

24 Q. How many studies have you been involved in 02:58

25 where you had a stakeholders' meeting that you had 02:58

1 to travel to by airplane? 02:58

2 MS. PENAN: Objection. 02:58

3 THE REPORTER: "You had to" what? Hold 02:58

4 on. I didn't get the last part, "that you had to" 02:58

5 what, at the end? 02:58

6 MR. JONNA: "Travel to by airplane." 02:58

7 MS. PENAN: Objection. Lacks foundation. 02:58

8 Incomplete hypothetical. Assumes facts not in 02:58

9 evidence. 02:58

10 A. I can think of three. 02:58

11 BY MR. JONNA: 02:58

12 Q. Which ones were those? 02:58

13 A. Two related to ulipristal acetate studies 02:58

14 for abortion, and this one. 02:58

15 Q. When were those studies conducted? 02:58

16 A. Ulipristal acetate one was more recently. 02:58

17 It was released within the past year. 02:58

18 Q. What did those studies show, in a 02:58

19 nutshell, or what were they trying to show? 02:59

20 A. That -- 02:59

21 MS. PENAN: Objection. Compound. 02:59

22 A. That study was looking at the use of 02:59

23 ulipristal acetate for medication abortion. 02:59

24 BY MR. JONNA: 02:59

25 Q. What was the conclusion of the study? 02:59

1 A. That they -- that study, which was a 02:59
2 dose-finding study and a small efficacy study, 02:59
3 suggested that ulipristal acetate combined with 02:59
4 misoprostol may be an effective alternative to 02:59
5 mifepristone and misoprostol. 02:59

6 Q. So why are you -- why were -- so let me 02:59
7 just back up for a second. 02:59

8 Is there a reason why you were studying an 02:59
9 alternative to mifepristone? 02:59

10 A. I wasn't studying it. I was just invited 02:59
11 to the meeting. 02:59

12 Q. I see. Is that also -- is that drug also 02:59
13 progesterone receptor blocker? 02:59

14 A. Yes. 02:59

15 Q. Where -- was this meeting also in 03:00
16 Washington, D.C.? 03:00

17 A. One of them was in Washington, D.C. And I 03:00
18 can't remember where the other one was. 03:00

19 Q. What was reason why there was a 03:00
20 stakeholders' meeting for that study, as far as you 03:00
21 know? 03:00

22 MS. PENAN: Objection. Calls for 03:00
23 speculation. Lacks foundation. 03:00

24 A. So that stakeholders would understand what 03:00
25 the data said, and especially -- because abortion 03:00

1 is a hot-topic issue in the United States, to 03:00
2 discuss how -- how it may be handled in the press 03:00
3 and how it may -- and it discusses a group, how it 03:00
4 may impact availability of ulipristal acetate, 03:00
5 which is available as an emergency contraceptive. 03:01
6 BY MR. JONNA: 03:01
7 Q. What were the -- what was the key takeaway 03:01
8 from the stakeholders' meeting, in your opinion? 03:01
9 MS. PENAN: Objection. Calls for 03:01
10 speculation. Vague, ambiguous. 03:01
11 A. The doses studied are higher than what's 03:01
12 used for emergency contraception, and are 03:01
13 consistent with the fact that drugs can be used for 03:01
14 multiple purposes and you use them in multiple 03:01
15 doses, depending on the purpose, just like 03:01
16 mifepristone in super-low doses can be used for 03:01
17 emergency contraception, although it's not 03:01
18 available. 03:01
19 200 milligrams is used for abortion, and 03:01
20 it's used in much higher doses for -- I think it's 03:01
21 adrenal cancer, if I remember correctly. It's a 03:01
22 different medication. 03:01
23 So that was the main message that I can 03:01
24 remember about the study, and that you would have to 03:01
25 wait and see how it might impact availability of the 03:02

1 emergency contraceptive that's available. 03:02

2 So those were the things I can remember. 03:02

3 BY MR. JONNA: 03:02

4 Q. Did you determine which stakeholders to 03:02
5 invite to the meeting for your study that we are 03:02
6 looking at here, mifepristone reversal? 03:02

7 A. I did in collaboration with others that I 03:02
8 invited. As I invited people, I would ask them, is 03:02
9 there anybody I'm missing or that would be 03:02
10 important, and then I decided if it would -- we 03:02
11 would include them if we were able to. 03:02

12 Q. Why did you decide to include ACOG? 03:02

13 MS. PENAN: Objection. Assumes facts not 03:02
14 in evidence. Lacks foundation. 03:02

15 A. As the primary obstetrics and gynecology 03:02
16 organization, medical organization, it would be 03:02
17 important that they be included. 03:02

18 BY MR. JONNA: 03:02

19 Q. Okay. On clinicaltrials.gov, Atheneum 03:03
20 Pharmaceuticals was originally listed as a 03:03
21 collaborator in your study on December 11th, 2018, 03:03
22 but it was removed on December 17th. 03:03

23 Do you know why? 03:03

24 A. Because -- 03:03

25 MS. PENAN: Same objections. 03:03

1 A. I can only speculate that I listed it and 03:03
2 then realized it didn't need to be listed as a 03:03
3 collaborator. 03:03

4 BY MR. JONNA: 03:03

5 Q. Do you have any specific recollection as 03:03
6 to why you made that decision? 03:03

7 A. Because they weren't considered -- 03:03

8 MS. PENAN: Objection. Asked and 03:03
9 answered. 03:03

10 A. Yeah. I don't remember who -- who I 03:03
11 talked to or whatever, but it has to do with the 03:03
12 people in our university who helped us with the 03:03
13 clinicaltrials.gov listings. 03:03

14 BY MR. JONNA: 03:03

15 Q. Okay. Did you, by the way, decide if you 03:03
16 were going to identify that other investigator that 03:03
17 you spoke to? 03:03

18 A. No. I haven't talked to anybody, so -- 03:03

19 Q. Okay. 03:03

20 MS. PENAN: And, Counsel, I would say that 03:04
21 that's a question for Mr. Levine and Dr. Creinin to 03:04
22 discuss. 03:04

23 MR. JONNA: Right. I was just asking if 03:04
24 he discussed that. 03:04

25 Q. Under "Methods" in green, it said, "We 03:04

1 plan to enroll 40 patients in a double-blind 03:04

2 placebo controlled randomized trial." 03:04

3 Do you see that? 03:04

4 A. Yes. 03:04

5 Q. How did you arrive at the number 40? 03:04

6 A. If you keep going later in the paper, it 03:04
7 describes the sample-size calculation. 03:04

8 Q. I'd rather hear from you than read the 03:04
9 paper, so can you just tell me, in a nutshell? 03:04

10 MS. PENAN: Objection. The record speaks 03:04
11 for itself. 03:04

12 A. 40 was determined as the number needed if 03:04
13 progesterone worked as well as claimed by those who 03:04
14 support or promote abortion-pill reversal. So the 03:04
15 study was actually set up to show that it would 03:05
16 work, if it really did work, using two weeks after 03:05
17 treatment as a surrogate marker for continuing 03:05
18 pregnancy. 03:05

19 BY MR. JONNA: 03:05

20 Q. Did you think -- so I assume you thought 03:05
21 40 would be a large-enough number to meaningfully 03:05
22 establish efficacy? 03:05

23 MS. PENAN: Objection. Misstates the 03:05
24 witness's testimony. Argumentative. 03:05

25 A. Yeah, not the word "meaningfully." It 03:05

1 would be what was needed in a single trial to show 03:05
2 that. "Meaningful" implies you need more 03:05
3 information, because efficacy alone is not all the 03:05
4 information that's needed, but it would be the 03:05
5 first step at showing it really is effective. 03:05

6 So the study was set up to show it was 03:05
7 effective. 03:05

8 BY MR. JONNA: 03:05

9 Q. Did you think it was a large-enough number 03:05
10 to establish safety? 03:05

11 MS. PENAN: Same objections. 03:05

12 A. It would be -- safety requires a lot 03:06
13 larger number. So even if you look at FDA studies, 03:06
14 the large size of the FDA studies are driven by the 03:06
15 safety component, not the efficacy component. So 03:06
16 you need a lot more to determine true safety. 03:06

17 But that's why I said this was the first 03:06
18 to say, does it really work as claimed. 03:06

19 BY MR. JONNA: 03:06

20 Q. Did you ever consider the need to enroll 03:06
21 more patients in case people left early for side 03:06
22 effects? 03:06

23 A. We did not -- for this study, we did not 03:06
24 think that that would happen, and that we were 03:06
25 looking at, you know, trying to balance what we had 03:06

1 a budget for, what we could enroll, and we decided 03:06
2 just to go with the 40 that we calculated. 03:06

3 Q. Would you agree that Phase 1 trials of new 03:06
4 medications are often focused primarily on safety? 03:06

5 A. Yes. 03:06

6 Q. So you could have designed a trial without 03:06
7 a control group; is that true? 03:07

8 MS. PENAN: Objection. Vague, ambiguous. 03:07
9 Incomplete hypothetical. Lacks foundation. 03:07

10 A. When you use the word "could," you could 03:07
11 say you could do anything. 03:07

12 BY MR. JONNA: 03:07

13 Q. Okay. Why -- 03:07

14 A. Not all Phase 1 studies don't have a 03:07
15 control group. I've done Phase 1 studies with a 03:07
16 control group. It depends on what questions you 03:07
17 are deciding you want to answer. 03:07

18 Q. Okay. So why did you decide not to design 03:07
19 a trial without a control group? 03:07

20 A. Because there really was no studies out 03:07
21 there that proved anything. I mean, the data still 03:07
22 to this day proves nothing. So even 40, as a first 03:07
23 look, where you have 20 in each group, is still 03:07
24 more than any study that's out there. 03:07

25 So we felt like this was an opportunity to 03:07

1 get comparative safety information. I've done 03:07
2 other early studies, early phase studies, where you 03:07
3 do it as a comparative, and I felt this was the 03:07
4 best design to get the initial information. 03:08
5 Q. Do you think your study helped establish 03:08
6 that an RCT with a control group is not ethical? 03:08
7 THE REPORTER: "Is not" what? 03:08
8 MS. PENAN: Vague, ambiguous. 03:08
9 THE WITNESS: He said "ethical." 03:08
10 THE REPORTER: Yeah. Thank you. 03:08
11 MS. PENAN: Objection. Vague, ambiguous. 03:08
12 Calls for speculation. Lacks foundation. 03:08
13 Incomplete hypothetical. 03:08
14 A. So the question was, do I think a study 03:08
15 with a placebo control group is not ethical? 03:08
16 BY MR. JONNA: 03:08
17 Q. No. Do I think your study established 03:08
18 that an RCT with a control group is not ethical in 03:08
19 this context? 03:08
20 MS. PENAN: Same objections. 03:08
21 A. No, I don't agree. 03:08
22 BY MR. JONNA: 03:08
23 Q. Why not? 03:08
24 A. Because the people that bled were 03:08
25 primarily 56 days or more than 56 days. So I 03:08

1 feel -- I do feel that -- yeah, because there is 03:08
2 really no data out there that doing this at an 03:08
3 earlier gestational age may be a reasonable 03:08
4 approach. Also, the likelihood of heavy bleeding, 03:09
5 even if they were to pass the pregnancy, goes down. 03:09
6 So we chose 44 to 63 days based on the full 03:09
7 gamut of when medication abortion is commonly 03:09
8 performed. At the time, it was still mostly through 03:09
9 63 days. And, also, we didn't want to delay the 03:09
10 people. Since we are delaying by two weeks, didn't 03:09
11 want to delay them significantly out of -- to change 03:09
12 their risks from the surgical procedure. 03:09
13 But I do feel that if it was restricted to 03:09
14 under 56 days, it would be something potentially 03:09
15 reasonable to try again. 03:09
16 Q. Are there any other safety precautions you 03:09
17 could take if you attempted to try the study again? 03:09
18 MS. PENAN: Objection. Vague, ambiguous. 03:09
19 Incomplete hypothetical. Calls for speculation. 03:09
20 A. Not that I can think of at the current 03:09
21 time. 03:09
22 BY MR. JONNA: 03:09
23 Q. Have you ever considered rerunning your 03:09
24 trial without a placebo group? 03:09
25 MS. PENAN: Objection. Incomplete 03:10

1 hypothetical. Calls for speculation. 03:10

2 A. No, no, because there's too many factors 03:10
3 that go into loss. For example, if I see somebody 03:10
4 at six and a half weeks, she may miscarry on her 03:10
5 own; right? Just because she hasn't miscarried yet 03:10
6 doesn't mean she won't. 03:10

7 So there's just other factors that come 03:10
8 into play that -- to get some idea of the 03:10
9 continuation rate with statistical certainty, I would 03:10
10 want to run it with the placebos group. And if you 03:10
11 run it as a single cohort, it doesn't tell me at all 03:10
12 if it's just what would have happened anyway or not. 03:10

13 So that's really the key, is knowing 03:10
14 whether this is just normal background; when you 03:10
15 don't take the misoprostol, it's going to -- that's 03:10
16 what's going to happen or not. 03:11

17 BY MR. JONNA: 03:11

18 Q. Did you screen the women in your study for 03:11
19 hemorrhagic disorder, hemophilia, sickle cell 03:11
20 anemia? 03:11

21 A. We screen them for anything that would be 03:11
22 normally screened for, for medication abortion, as 03:11
23 much as I can remember. So sickle cell anemia is 03:11
24 not an exclusion criteria for mifepristone, but 03:11
25 anemia, significant anemia, is. 03:11

1 And if I remember correctly, we did screen 03:11
2 people for their blood counts. 03:11

3 Q. Did you ask people -- 03:11

4 A. And just like you wouldn't -- for somebody 03:11
5 receiving mifepristone, people who are 03:11
6 anticoagulated or have a coagulopathy would not be 03:11
7 included. 03:11

8 Q. Did you ask them if they were on blood 03:11
9 thinners? 03:11

10 A. Yes. 03:11

11 Q. How about if they were on anticoagulants? 03:11

12 A. Those are the same things. 03:11

13 Q. Okay. So under the "Results" here in 03:11
14 yellow, it says, "We enrolled participants from 03:12
15 February to July, 2019, and stopped enrollment 03:12
16 after 12 patients for safety concerns." 03:12

17 So in six months, you were only able to 03:12
18 recruit 12 women; is that correct? 03:12

19 A. That's what it says there. 03:12

20 Q. So about a fourth of what you needed? 03:12

21 MS. PENAN: Objection. The record speaks 03:12
22 for itself. 03:12

23 A. It's about three and a half times under 03:12
24 what we needed. 03:12

25 BY MR. JONNA: 03:12

1 Q. Did you have more difficulty recruiting 03:12
2 participants than you anticipated? 03:12

3 A. I mean, to be fair, it was a little 03:12
4 harder, but not anything well outside of what we 03:12
5 expected. We were expecting people who were 03:12
6 otherwise healthy, from an abortion standpoint, to 03:12
7 delay their abortion. We expected it would take a 03:12
8 while. 03:12

9 Q. What does "healthy from an abortion 03:12
10 standpoint" mean? 03:12

11 A. They didn't have any reason to -- that 03:13
12 waiting two weeks would increase their risk. So -- 03:13
13 but, you know, there's a -- for people seeking 03:13
14 abortion, they very commonly just want to be done 03:13
15 and move on. So we expected it to be on the slow 03:13
16 side. 03:13

17 So it was a little slower than I would -- 03:13
18 partly because, as a researcher, I always would like 03:13
19 for a study to go faster than you expect. It's 03:13
20 always better to be, you know, more rapid with 03:13
21 enrollment than you think it's going to take. So -- 03:13

22 Q. And you had -- 03:13
23 (Speakers talking simultaneously.) 03:13

24 BY MR. JONNA: 03:13

25 Q. Sorry, go ahead. 03:13

1 A. No, that's it. 03:13

2 Q. You had enrollment sites with the Planned 03:13
3 Parenthood Mar Monte, FPA Women's Health, and UC 03:13
4 Davis itself; is that right? 03:13

5 A. Right. 03:13

6 Q. Do you think it's inherently difficult to 03:13
7 find women who want to have an abortion to take a 03:13
8 pill to induce an abortion, attempt to reverse the 03:13
9 abortion, then complete a surgical abortion if that 03:13
10 abortion fails? 03:14

11 MS. PENAN: Objection. Vague, ambiguous, 03:14
12 compound. Calls for speculation. Lacks 03:14
13 foundation. Incomplete hypothetical. 03:14

14 A. And we didn't do anything like that. We 03:14
15 -- because they weren't taking something to, 03:14
16 quote/unquote, reverse an abortion. They were 03:14
17 being willing to be -- take mifepristone and be 03:14
18 randomized to placebo or progesterone to see if 03:14
19 their pregnancy continued for two weeks. 03:14

20 So, yeah, it's difficult, but we could have 03:14
21 kept going if there weren't safety issues. 03:14

22 BY MR. JONNA: 03:14

23 Q. Right. But turning back to your appendix, 03:14
24 Exhibit 15, so the column here, "Abortions," you 03:14
25 see that? 03:14

1 BY MR. JONNA: 03:15

2 Q. Were you hoping to have a healthier group 03:15
3 of women than this? 03:15

4 MS. PENAN: Objection. Vague, ambiguous. 03:15
5 Calls for speculation. Lacks foundation. 03:15

6 A. I would ask you what criteria you are 03:15
7 using to state that these people are unhealthy. 03:15

8 BY MR. JONNA: 03:15

9 Q. Well, I'm just asking you, as the expert 03:15
10 here, if the number of prior abortions, the BMIs, 03:15
11 if any of these -- you know, the number of 03:16
12 miscarriages, if any of these numbers seem less 03:16
13 than ideal for the study that you wanted to run. 03:16

14 MS. PENAN: Objection. Vague, ambiguous. 03:16
15 Compound. Incomplete hypothetical. Calls for 03:16
16 speculation. 03:16

17 A. No. Just because somebody's had an 03:16
18 abortion before doesn't mean that she is unhealthy. 03:16
19 And when you look at our population, currently over 03:16
20 40 percent of people in the United States are 03:16
21 obese. So the fact we were only at about one-third 03:16
22 at this point, 12 people in, is probably -- and 03:16
23 maybe at the time it was close, but still under 03:16
24 what you would expect for the normal population. 03:16

25 So I don't see anything unhealthy. 03:16

1 BY MR. JONNA: 03:16

2 Q. Okay. Going back to Exhibit 14, page 3, 03:16

3 it says, "Three other patients had severe bleeding, 03:16

4 requiring ambulance transport to an emergency 03:16

5 department." 03:16

6 You see that? 03:16

7 A. Yes. 03:16

8 Q. And we discussed that Subject 10's medical 03:17

9 records stated that she -- her means of arrival 03:17

10 were ambulatory. 03:17

11 Do you recall that? 03:17

12 A. Yes. 03:17

13 MS. PENAN: Objection. The record speaks 03:17

14 for itself. Asked and answered. 03:17

15 BY MR. JONNA: 03:17

16 Q. So that means she didn't arrive at the 03:17

17 hospital by ambulance; correct? 03:17

18 MS. PENAN: Objection. Calls for 03:17

19 speculation. The record speaks for itself. Asked 03:17

20 and answered. 03:17

21 A. Yes, she did not -- according to the 03:17

22 records, she did not arrive by ambulance, although 03:17

23 I was told by my colleague she did. 03:17

24 BY MR. JONNA: 03:17

25 Q. Is that something that you would edit, if 03:17

1 you had the opportunity, in this study? 03:17

2 A. If I was writing it now, I would just say 03:17
3 two of the three arrived by ambulance, but it 03:17
4 doesn't change the outcome. At most, it would be 03:17
5 something that the journal might consider doing a 03:17
6 correction, which is called a "corrigendum," 03:17
7 because it doesn't change the outcomes; it just 03:17
8 clarifies a bit of information. 03:17

9 Whether she arrived by ambulance or by 03:17
10 foot, she still had -- she was still bleeding, had an 03:18
11 incomplete abortion, or required a procedure in the 03:18
12 emergency department. So it doesn't really change 03:18
13 anything from an outcome standpoint. It would just 03:18
14 be a correction. 03:18

15 And I'm going to guess -- so whether the 03:18
16 journal would want to bother with that at this point, 03:18
17 based on the level -- the degree to which it rises, I 03:18
18 don't know. But, yeah, it could be corrected, but 03:18
19 it's just a correction. 03:18

20 Q. Are you going to ask the journal if they 03:18
21 want to correct it? 03:18

22 A. I would have to talk to my coauthors and 03:18
23 decide what we are going to do. 03:18

24 Thank you for asking. 03:18

25 Q. Okay. Lower down in blue, it says, "The 03:18

1 following day she called an ambulance after onset 03:18
2 of heavy vaginal bleeding." 03:18
3 Do you see that? 03:18
4 A. Yes. 03:18
5 Q. Are you -- okay. Well, I guess that's 03:18
6 part of the same -- that's part of the same 03:18
7 statement that would need to be corrected, 03:19
8 presumably, so... 03:19
9 MS. PENAN: Objection. The record speaks 03:19
10 for itself. Vague, ambiguous. Confusing. 03:19
11 BY MR. JONNA: 03:19
12 Q. My question for you is: If it didn't 03:19
13 really matter how she arrived, why did you include 03:19
14 that description in here? 03:19
15 A. I didn't say it didn't matter how she 03:19
16 arrived. 03:19
17 Q. Okay. Well, I thought you said it doesn't 03:19
18 change the conclusions; right? 03:19
19 A. No -- yes, but it doesn't -- I didn't say 03:19
20 it didn't matter. 03:19
21 Q. Okay. So why did you include that fact in 03:19
22 this -- in the description here? 03:19
23 A. Because that was the fact at the time when 03:19
24 -- that I thought all three came by ambulance, 03:19
25 because that is unusual. Even two going by 03:19

1 ambulance is still -- 2 out of 10 is still very 03:19

2 unusual, so... 03:19

3 Q. On the subject of corrections, would you 03:19

4 also take up the issue with the fact that Subject 03:19

5 11 waited four, five hours to go to the emergency 03:20

6 room? Would that be something that you would want 03:20

7 to add to the paper, too? 03:20

8 A. No, because again -- 03:20

9 MS. PENAN: Objection. Incomplete 03:20

10 hypothetical. Vague, ambiguous. 03:20

11 A. No, because how long she waited doesn't 03:20

12 matter. She presented. She's a human. And 03:20

13 whether she waited ten seconds or four hours, 03:20

14 that's up to her. That's part of providing 03:20

15 medication abortion, for example. It's all part of 03:20

16 it. 03:20

17 You know, you tell people to take an 03:20

18 antibiotic four times a day, and sometimes they take 03:20

19 it twice a day, and they still end up in the hospital 03:20

20 because the infection didn't get better, you know. 03:20

21 You don't -- 03:20

22 BY MR. JONNA: 03:20

23 Q. Doesn't that undermine the conclusion that 03:20

24 the dangerous part for her was not taking 03:20

25 misoprostol, as opposed to just waiting at home in 03:20

1 a bathtub, bleeding? 03:20

2 MS. PENAN: Objection. Argumentative. 03:20

3 Misstates the witness's testimony. 03:20

4 A. Because she was judging how much bleeding 03:20

5 she had, and it got to the point where she felt she 03:20

6 needed to do something. That's her -- that's part 03:20

7 of the process. It's part of using humans. We 03:20

8 don't second-guess humans. 03:20

9 BY MR. JONNA: 03:20

10 Q. So I'm just trying to understand, as 03:21

11 someone who's never written a study, I mean, or, 03:21

12 you know, even read that many, to be honest with 03:21

13 you, how do you determine what facts are worth 03:21

14 editing and correcting, and what facts aren't? 03:21

15 To me, the four to five hours seem much 03:21

16 more significant than a lot of other things we are 03:21

17 talking about, but why do you determine that's not a 03:21

18 significant fact versus, like, the mode of 03:21

19 transportation, for example? 03:21

20 MS. PENAN: Objection. Counsel is 03:21

21 testifying. Compound. Vague, ambiguous. 03:21

22 Confusing. 03:21

23 A. How long she had been bleeding for is not 03:21

24 relevant. And, also, you have to fit it within the 03:21

25 word count of the journal. You've got to decide 03:21

1 what facts are most relevant, because otherwise, 03:21
2 every paper would be 10,000 words. So -- 03:21
3 BY MR. JONNA: 03:21
4 Q. It could be one sentence; right? 03:21
5 Patient -- 03:21
6 A. Yeah, but I've already answered -- 03:21
7 MS. PENAN: Same objections, plus asked 03:21
8 and answered. 03:21
9 BY MR. JONNA: 03:21
10 Q. Okay. And then for Subject 8, you also 03:21
11 included her as one of the patients who required 03:22
12 ambulance transport to an emergency department, but 03:22
13 I think we established earlier that, in your view, 03:22
14 she didn't require ambulance transport to an 03:22
15 emergency department. She needed to come to your 03:22
16 office, and she panicked, which is why she later 03:22
17 called the ambulance. So she didn't really require 03:22
18 ambulance transport to an ER. 03:22
19 Wouldn't you agree? 03:22
20 A. No. 03:22
21 MS. PENAN: Objection. Counsel is 03:22
22 testifying. Misstates the witness's testimony. 03:22
23 Compound. Vague, ambiguous. 03:22
24 A. She was bleeding through her clothes. She 03:22
25 had bled through her clothes. She was sitting on a 03:22

1 toilet, bleeding. And, in her opinion, she, in her 03:22
2 state where she was with her support systems there 03:22
3 or not there, or whatever it was, she felt she 03:22
4 required ambulance transport. That's the reality 03:22
5 of what happened. 03:22

6 You don't go back and second-guess. That's 03:22
7 what happened. Right? When we do a study about 03:22
8 pregnancy rates with a birth control pill, I don't 03:22
9 say, "Well, I'm only going to count the ones where I 03:23
10 think the person wasn't using it or was using it 03:23
11 correctly." I mean, part of it is sometimes people 03:23
12 don't use it correctly, and that gets included in the 03:23
13 pregnancy rate because that's the real life of going 03:23
14 through that situation. 03:23

15 BY MR. JONNA: 03:23

16 Q. Okay. 03:23

17 A. This is the real life of the situation. 03:23
18 In her view, she required ambulance transport. So 03:23
19 that is correct. 03:23

20 Q. Okay. And in Patient 7's view, she had 03:23
21 severe bleeding; correct? 03:23

22 MS. PENAN: Objection. Asked and 03:23
23 answered. 03:23

24 A. Yup, she did, and she came in. She came 03:23
25 to the office. If she could have also decided "I'm 03:23

1 worried about this" and gone by ambulance, all 03:23
2 right, and they would have found what we found in 03:23
3 the office, and sent her home. 03:23
4 BY MR. JONNA: 03:23
5 Q. So sometimes the subjective reporting 03:23
6 matters, and objectivity is not required; is that 03:23
7 correct? 03:23
8 MS. PENAN: Objection. Counsel is 03:23
9 testifying. Misstates the witness's testimony. 03:23
10 Vague, ambiguous. Compound. Confusing. 03:24
11 Argumentative. 03:24
12 A. That's not correct. 03:24
13 BY MR. JONNA: 03:24
14 Q. Okay. Looking at the orange -- or the 03:24
15 yellow highlight right here, "The first patient 03:24
16 received progesterone treatment after enrollment at 03:24
17 56 days of gestation. She reported no bleeding at 03:24
18 the first follow-up visit two days post 03:24
19 mifepristone. Shortly after her visit, she started 03:24
20 having brisk bleeding and called an ambulance. 03:24
21 Transvaginal ultrasound examination in the 03:24
22 emergency department found no gestational sac and a 03:24
23 heterogenous endometrial lining of approximately 03:24
24 1.5 cm. Heavy bleeding lasted about three hours 03:24
25 overall, and no intervention was needed." 03:24

1 Do you see that? 03:24

2 A. Yes. 03:24

3 Q. So here, you described the bleeding as 03:24

4 "heavy bleeding"; is that right? 03:24

5 A. Yes. 03:24

6 MS. PENAN: Objection. The record speaks 03:24

7 for itself. Asked and answered. 03:24

8 BY MR. JONNA: 03:24

9 Q. And in the records we looked at, you 03:24

10 described the bleeding as mild to moderate. 03:24

11 MS. PENAN: Objection. Asked and 03:24

12 answered. The record speaks for itself. 03:25

13 A. At the time she was being seen. 03:25

14 BY MR. JONNA: 03:25

15 Q. Is your answer done? 03:25

16 A. Yeah. I said it was mild to moderate at 03:25

17 the time she was being seen. 03:25

18 Q. Okay. And when she arrived at the 03:25

19 emergency room, it was described as minor bleeding; 03:25

20 is that right? 03:25

21 MS. PENAN: Objection. Asked and 03:25

22 answered. The record speaks for itself. 03:25

23 A. Yes. I -- we -- yes, we went over that 03:25

24 earlier. 03:25

25 BY MR. JONNA: 03:25

1 Q. Okay. So scrolling down to page 6 here, 03:25

2 so this chart on the right, this blue chart 03:25

3 represents the progesterone group; is that correct? 03:25

4 A. You have to look at the legend at the 03:25

5 bottom. Thank you. The top one is the placebo. 03:25

6 Q. Do you want to take a look at that one 03:26

7 more time? Progesterone levels in patients -- 03:26

8 A. I'm sorry. Progesterone, yes. The top 03:26

9 one is progesterone. 03:26

10 Q. Okay. So the chart on the right, just to 03:26

11 understand it, it charts progesterone levels in 03:26

12 women across the number of days after mifepristone; 03:26

13 is that correct? 03:26

14 And then there's two lines at the bottom 03:26

15 where the progesterone levels did not significantly 03:26

16 increase. Do you see that? We've highlighted 03:26

17 them, and those are labeled with an asterisk and a 03:26

18 double cross. 03:26

19 Do you see that? 03:26

20 A. Yes. 03:26

21 Q. And those are -- the legend explains what 03:26

22 those are. 03:26

23 Do you see that? 03:26

24 A. Yes. 03:26

25 Q. It says, "An asterisk means hemorrhage, 03:26

1 and a double cross means the woman left the study"; 03:27

2 correct? 03:27

3 A. Yes. 03:27

4 Q. So the woman in the double-cross line left 03:27

5 the study, but the asterisk line, presumably, that 03:27

6 was Subject 8; correct? 03:27

7 A. That would be Subject 8. 03:27

8 Q. Subject 8 didn't really experience 03:27

9 hemorrhage, though; right? 03:27

10 MS. PENAN: Objection. Counsel is 03:27

11 testifying. Misstates the witness's testimony. 03:27

12 Argumentative. Asked and answered. 03:27

13 A. I agree with counsel. We already went 03:27

14 through that. She experienced a hemorrhage. 03:27

15 Counsel with -- the other counsel, it's 03:27

16 crazy; I never said she didn't experience a 03:27

17 hemorrhage. You are trying to put words in my mouth. 03:27

18 BY MR. JONNA: 03:27

19 Q. Why would you classify her bleeding as 03:27

20 hemorrhage? 03:27

21 A. Because she bled -- 03:27

22 MS. PENAN: Objection. Asked and 03:27

23 answered. 03:27

24 A. We went through this earlier. 03:27

25 She bled through her clothes and was 03:27

1 bleeding -- and called an ambulance. That counts 03:27
2 as a hemorrhage. You can look at it any way you 03:28
3 want, but that counts as a hemorrhage. 03:28
4 BY MR. JONNA: 03:28
5 Q. Okay. Anything else? 03:28
6 MS. PENAN: Objection. Asked and 03:28
7 answered. 03:28
8 A. I answered your question. Nothing else. 03:28
9 BY MR. JONNA: 03:28
10 Q. I'm just -- nothing else. Thank you. 03:28
11 All right. Were you surprised that 03:28
12 Subject 8's progesterone levels had such a modest 03:28
13 increase? 03:28
14 MS. PENAN: Objection. Vague, ambiguous. 03:28
15 A. I can't remember. 03:28
16 MS. PENAN: The record speaks for itself. 03:28
17 BY MR. JONNA: 03:28
18 Q. Do you remember if this was one of the 03:28
19 reasons you were concerned whether she took the 03:28
20 progesterone? 03:28
21 A. What I remember -- 03:28
22 MS. PENAN: Same objections. 03:28
23 A. What I remember is: This is the -- I 03:28
24 called her because she had an outcome that was 03:28
25 different than everybody else. That's what I 03:28

1 remember calling her about. 03:28

2 BY MR. JONNA: 03:28

3 Q. So as you sit here today, you don't 03:28

4 remember if this modest increase raised any red 03:28

5 flags for you? 03:29

6 MS. PENAN: Objection. Lacks foundation. 03:29

7 Vague, ambiguous. The record speaks for itself. 03:29

8 A. No, because you can also look at patients 03:29

9 in the lower group where you have something going 03:29

10 up or whatever. No. I called because I wanted -- 03:29

11 she bled, and I wanted to make sure she took all 03:29

12 her meds. 03:29

13 She was the first person to have something 03:29

14 happen very different than everybody else. 03:29

15 BY MR. JONNA: 03:29

16 Q. Would you agree that the change in 03:29

17 Subject 8's progesterone levels, in the range, that 03:29

18 could be explained by natural fluctuation as well? 03:29

19 MS. PENAN: Objection. 03:29

20 BY MR. JONNA: 03:29

21 Q. Let me rephrase the question. 03:29

22 Is it possible that the modest increase we 03:29

23 see here could just be attributed to natural 03:29

24 fluctuation of progesterone levels? 03:29

25 MS. PENAN: Objection. Lacks foundation. 03:29

1 Vague, ambiguous. 03:29

2 A. Your question isn't a complete question. 03:29

3 It's not understandable. 03:29

4 BY MR. JONNA: 03:29

5 Q. Okay. You see the increase in her 03:29

6 progesterone levels is very modest compared to 03:29

7 others. 03:30

8 Do you see that? 03:30

9 A. Yes. 03:30

10 Q. Is it possible that that increase is 03:30

11 attributed only to natural fluctuation of her own 03:30

12 progesterone as opposed to a supplemental 03:30

13 progesterone? 03:30

14 MS. PENAN: Objection. Lacks foundation. 03:30

15 Calls for speculation. Vague, ambiguous. 03:30

16 A. It's also possible she doesn't absorb 03:30

17 well. I mean, that's one of the things you need 03:30

18 to -- when you take an oral medication, it's 03:30

19 possible. It could be a lot of things. 03:30

20 BY MR. JONNA: 03:30

21 Q. Well -- and I'm asking, specifically based 03:30

22 on your training, experience, and knowing a lot 03:30

23 more about progesterone than I do, is it possible 03:30

24 that that rise is attributed to natural 03:30

25 fluctuation? 03:30

1 A. You know -- 03:30

2 MS. PENAN: Same objections, plus asked 03:30

3 and answered. 03:30

4 A. In a participant who says, "I really did 03:30

5 take all my medication," I would say it's much more 03:30

6 likely an absorption issue than any other 03:30

7 hypothesis you want to come up with. 03:30

8 BY MR. JONNA: 03:30

9 Q. Okay. Turning quickly back to Exhibit 15, 03:30

10 looking specifically at Subject 8 -- oops; 03:30

11 it's highlighted here -- she had ten total 03:31

12 pregnancies; is that correct? 03:31

13 MS. PENAN: Objection. The record speaks 03:31

14 for itself. 03:31

15 A. Yes. 03:31

16 BY MR. JONNA: 03:31

17 Q. And one prior delivery, one miscarriage, 03:31

18 and seven prior abortions; is that right? 03:31

19 A. Yes. 03:31

20 MS. PENAN: Same objection. 03:31

21 BY MR. JONNA: 03:31

22 Q. Turning to Exhibit 14, page 5, it says 03:31

23 here on the bottom right, "Blinding for 03:31

24 progesterone capsules is difficult and imperfect; 03:31

25 however, we believe we maintained blinding 03:31

1 because" -- let's see -- "the patients enrolled had 03:31
2 never used progesterone and none looked up the 03:31
3 treatment to identify the drug." 03:31
4 Do you see that? 03:31
5 A. Yes. 03:31
6 Q. And if we scroll up to page 2, it says, 03:31
7 "The Investigational Drug Service could not 03:31
8 over-encapsulate the drugs due to product size." 03:31
9 Do you see that? 03:32
10 A. Yes. 03:32
11 Q. So how did you confirm that no one had 03:32
12 ever used progesterone before? 03:32
13 A. We asked them. 03:32
14 Q. Anything else? 03:32
15 MS. PENAN: Objection. Asked and 03:32
16 answered. 03:32
17 BY MR. JONNA: 03:32
18 Q. How did you confirm -- 03:32
19 (Speakers talking simultaneously.) 03:32
20 THE REPORTER: Go ahead. 03:32
21 MR. JONNA: I'm sorry. I'm sorry. I'm 03:32
22 violating my own rules here. 03:32
23 Q. How do you confirm that they didn't look 03:32
24 it up? 03:32
25 A. We asked them. 03:32

1 Q. Okay. Is it possible that Subject 8 03:32
2 looked it up and decided not to take it because she 03:32
3 wanted an abortion? 03:32

4 MS. PENAN: Objection. Calls for 03:32
5 speculation. Lacks foundation. Incomplete 03:32
6 hypothetical. 03:32

7 A. No. They all wanted -- they all came into 03:32
8 the study wanting a surgical abortion. So odds are 03:32
9 she would have finished the study to get her 03:32
10 surgical abortion at the end. 03:32

11 BY MR. JONNA: 03:32

12 Q. Okay. 03:32

13 A. But since you are using the term "could," 03:32
14 as I said, you could wear a red tie tomorrow. So 03:33
15 "could" is always -- anything is possible. 03:33

16 Q. All right. Looking here, it says, 03:33
17 "Additionally," on page 3, "a research coordinator 03:33
18 independently counted unused study drug to maintain 03:33
19 investigator blinding." 03:33

20 Do you see that? 03:33

21 A. Yes. 03:33

22 Q. Can you just explain to me the difference 03:33
23 between investigator and coordinator? 03:33

24 A. Yeah. Investigator in this situation was 03:33
25 one of the physicians working on the study. 03:33

1 Coordinator is part of the research staff that's 03:33
2 working on the study. 03:33

3 Q. Okay. Do you know if -- well, can you -- 03:33
4 so are all investigators listed on the study? 03:33

5 A. Listed on what? 03:33

6 Q. Are they identified publicly? 03:33

7 A. Just the authors are on the paper, but the 03:33
8 other investigators are not listed. 03:33

9 Q. Okay. How many investigators were there, 03:33
10 approximately? 03:34

11 A. Seven or eight. No, maybe with the 03:34
12 Planned Parenthood, probably -- maybe eight to ten. 03:34

13 Q. How about coordinators? 03:34

14 A. It may have been four or five, maybe more 03:34
15 at that time, but possibly four or five. 03:34

16 Q. Do you know if any of the investigators 03:34
17 had prescribed oral progesterone before? 03:34

18 A. I'm going to presume that all of them 03:34
19 have, but I am presuming -- but given that we all 03:34
20 completed OB/GYN residencies, I'm going to presume 03:34
21 that all of them had prescribed progesterone. 03:34

22 MS. PENAN: Objection. Calls for 03:34
23 speculation. 03:34

24 BY MR. JONNA: 03:34

25 Q. How many times was the counting done? Was 03:34

1 it after every administration? 03:34

2 A. Every administration? No, because that 03:35

3 would require going to their home. 03:35

4 Q. Okay. So how do you -- how often does the 03:35

5 counting take place? 03:35

6 A. At the follow-up visits when patients come 03:35

7 back and bring their drug bottles with them. 03:35

8 Q. Would the coordinators be able to 03:35

9 distinguish between the samples? 03:35

10 MS. PENAN: Objection. Vague, ambiguous. 03:35

11 Confusing. 03:35

12 A. What do you mean by "samples"? 03:35

13 BY MR. JONNA: 03:35

14 Q. The medication. 03:35

15 A. Like, what was placebo -- they saw the 03:35

16 chart. They knew what the patient got. The 03:35

17 investigators did not. So the coordinators were 03:35

18 unblinded, because they would access the chart, and 03:35

19 in the chart was their -- actually, no, that's not 03:35

20 true. It was in the bottles. 03:35

21 So yeah, I'm sorry. I'm confusing with a 03:35

22 different study. 03:36

23 No, I don't -- could they tell the 03:36

24 difference? Possibly, but they don't prescribe 03:36

25 progesterone. They don't -- they wouldn't know the 03:36

1 difference. 03:36

2 Q. Would the investigators be able to 03:36

3 distinguish between the -- 03:36

4 A. If we looked at the drugs, yes, but we 03:36

5 were blinded. We didn't look at the drugs. It's 03:36

6 common -- a common part of blinding is to ensure -- 03:36

7 like, the investigator does some things and the 03:36

8 staff does other things. 03:36

9 Q. Is it common to have investigators that 03:36

10 are not listed as authors? 03:36

11 A. Yes. 03:36

12 Q. Okay. Do you know, during the blinded 03:36

13 phase of the study, did the research investigators 03:36

14 analyze the blood draws for progesterone during the 03:36

15 study? 03:36

16 MS. PENAN: Objection. Vague, ambiguous. 03:36

17 Lacks foundation. Calls for speculation. 03:36

18 A. To be fair, I'm not -- I don't remember if 03:37

19 we got them all or not, you know, during the study. 03:37

20 I don't -- I can't remember. 03:37

21 BY MR. JONNA: 03:37

22 Q. Okay. Going back to Exhibit 14, page 5, 03:37

23 here in green, it says, "Three of 12 patients 03:37

24 enrolled experienced very heavy bleeding resulting 03:37

25 in ambulance transport to an emergency department, 03:37

1 a rate higher than reported with medical abortion, 03:37
2 in which .6 percent of patients may have emergency 03:37
3 department visits. Patients who use mifepristone 03:37
4 for a medical abortion should be advised that not 03:37
5 using misoprostol could result in severe 03:37
6 hemorrhage, even with progesterone treatment." 03:37
7 Do you see that? 03:37
8 A. Yes. 03:37
9 Q. I think I've now understood your position 03:37
10 with Subject 8, so I will skip my question. I will 03:37
11 spare you the repeat question there. 03:38
12 You also wrote that "Women who use 03:38
13 mifepristone should be advised that it could result 03:38
14 in severe hemorrhage, even with progesterone 03:38
15 treatment." 03:38
16 A. Yes. That's what it says. Yes. 03:38
17 Q. Focusing on the part in yellow, though, it 03:38
18 says, "Because of potential dangers for patients 03:38
19 who opt not to use misoprostol after mifepristone 03:38
20 ingestion, any mifepristone antagonization 03:38
21 treatment must be considered experimental." 03:38
22 Do you see that? 03:38
23 A. I do. 03:38
24 Q. But, again, Subject 8 didn't require any 03:38
25 intervention; isn't that correct? 03:38

1 MS. PENAN: Objection. Counsel, 03:38

2 argumentative. 03:38

3 A. What does the fact that Subject 8 didn't 03:38

4 require any intervention mean that this statement 03:38

5 is incorrect? It is correct. 03:38

6 BY MR. JONNA: 03:38

7 Q. It is correct that -- 03:39

8 A. Three people hemorrhaged, and two people 03:39

9 needed D&Cs, and one person needed a transfusion, 03:39

10 out of ten. 03:39

11 Q. Right. So I just asked a very simple 03:39

12 question. Subject 8 did not require any 03:39

13 intervention; correct? 03:39

14 MS. PENAN: Objection. Asked and 03:39

15 answered. 03:39

16 A. When she presented to the emergency 03:39

17 department, she required no intervention in the 03:39

18 emergency department. 03:39

19 BY MR. JONNA: 03:39

20 Q. So you could only conclude that opting to 03:39

21 use neither misoprostol nor progesterone is 03:39

22 experimental; right? 03:39

23 MS. PENAN: Objection. Counsel is 03:39

24 testifying. Misstates the witness's testimony. 03:39

25 Argumentative. Asked and answered. 03:39

1 A. I stand by that statement that's in the 03:39
2 paper that you read. 03:39

3 BY MR. JONNA: 03:39

4 Q. So since none of the women in the 03:39
5 progesterone wing of the study required vacuum 03:39
6 aspiration, transfusion, or other medical 03:39
7 intervention, it's possible that if you ran a 03:39
8 40-person study with just progesterone, you 03:40
9 wouldn't have had any patients who required medical 03:40
10 intervention. 03:40

11 Isn't that true? 03:40

12 MS. PENAN: Objection. Calls for 03:40
13 speculation. Lacks foundation. Incomplete 03:40
14 hypothetical. Argumentative. Misstates the 03:40
15 witness's testimony. 03:40

16 A. Well, if -- if the -- you know, you are 03:40
17 asking about something is possible. It's kind of 03:40
18 like "could." If the first five to six get 03:40
19 through, is it possible that the remainder could 03:40
20 end up also with the same? It's possible. It's 03:40
21 also possible the next 15 could all require 03:40
22 emergency procedures and transfusions. Either one 03:40
23 is possible. 03:40

24 BY MR. JONNA: 03:40

25 Q. And it's also speculation on your part 03:40

1 that Subject 8 would have ever needed the 03:40

2 intervention at any point; correct? 03:40

3 MS. PENAN: Objection. Misstates the 03:40

4 witness's testimony. Calls for speculation. Lacks 03:40

5 foundation. Vague, ambiguous. Confusing. 03:40

6 BY MR. JONNA: 03:40

7 Q. Let me rephrase the question. 03:40

8 We talked about how she didn't need an 03:40

9 intervention when she arrived, and you have no 03:40

10 evidence suggesting that she ever did need an 03:40

11 intervention before she arrived, as well; isn't 03:41

12 that true? 03:41

13 MS. PENAN: Objection. Vague, ambiguous. 03:41

14 Compound. Confusing. Argumentative. Misstates 03:41

15 the witness's testimony. Calls for speculation. 03:41

16 Lacks foundation. 03:41

17 A. I think the facts speak for themselves. 03:41

18 She didn't have an intervention at any point. 03:41

19 BY MR. JONNA: 03:41

20 Q. Let me go up to Exhibit 16, which is the 03:41

21 protocol and SAP, Version 10 from your study. 03:41

22 A. Uh-huh.

23 (Deposition Exhibit 16 was marked for

24 identification by the reporter and is

25 attached hereto.)

1 BY MR. JONNA:

2 Q. You've seen this before? 03:41

3 A. Yes. 03:41

4 Q. On page 6, in orange -- sorry -- yellow 03:41

5 here, it says, "Secondary endpoints: Pathology 03:41

6 changes in trophoblast in a subset of dilation and 03:41

7 curettage specimens." 03:41

8 Do you see that? 03:41

9 A. Yes. 03:41

10 Q. Were there pathology changes in 03:41

11 trophoblast? 03:41

12 MS. PENAN: Objection. Lacks foundation. 03:41

13 Incomplete hypothetical. Vague, ambiguous. 03:41

14 A. To my recollection, there weren't any seen 03:42

15 by the pathologist for the specimens that we 03:42

16 provided to tell -- to see any difference between 03:42

17 those who got progesterone and those who had 03:42

18 placebo. I don't recollect any. 03:42

19 BY MR. JONNA: 03:42

20 Q. Is there any reason why this wasn't 03:42

21 mentioned in the study? 03:42

22 A. Because we didn't have enough patients to 03:42

23 have a meaningful outcome in it. It was a 03:42

24 secondary endpoint that never had -- it really only 03:42

25 matters if we got to full enrollment. 03:42

1 Q. Page 15, it says, "For this study, we 03:42
2 expect bleeding and/or spotting to occur in all 03:42
3 subjects (even though most will not expel the 03:42
4 pregnancy)."

5 Do you see that? 03:42

6 A. I do. 03:42

7 Q. And you advised all the women in the study 03:42
8 of this? 03:42

9 A. We told them we did not expect them to, 03:42
10 but we gave them the same precautions we would 03:42
11 provide for patients getting medication abortion, 03:42
12 because it was possible. 03:42

13 Q. Okay. I'm going to show you Exhibit 21, 03:42
14 which is a -- which is an ACOG statement on your 03:43
15 study that's no longer on their Web page. We got 03:43
16 this from the Wayback Machine, and it's from 03:43
17 July 21, 2022. 03:43

18 And on page 2, ACOG wrote "The 2020 study 03:43
19 intending to evaluate medication abortion reversal in 03:43
20 a controlled IRB-approved setting was ended early due 03:43
21 to safety concerns among the participants receiving 03:43
22 progesterone for abortion pill reversal." 03:43

23 Do you see that? 03:43

24 A. Yes. 03:43

25 (Deposition Exhibit 21 was marked for 03:43

1 identification by the reporter and is 03:43

2 attached hereto.) 03:43

3 BY MR. JONNA: 03:43

4 Q. And that wasn't accurate; correct? 03:43

5 MS. PENAN: Objection. The record speaks 03:43

6 for itself. Argumentative. 03:43

7 A. If you -- if someone asked me my opinion, 03:43

8 I would say that is not accurate as stated. 03:43

9 BY MR. JONNA: 03:43

10 Q. And then ACOG later changed this 03:43

11 statement. 03:43

12 Do you remember that? 03:43

13 A. I don't. 03:43

14 Q. They later changed it, the ending, to say 03:43

15 "due to safety concerns among the participants," 03:44

16 and then they deleted this part. 03:44

17 Do you remember that? 03:44

18 A. I don't. 03:44

19 MS. PENAN: Objection. Asked and 03:44

20 answered. Calls for speculation. Lacks 03:44

21 foundation. Assumes facts not in evidence. The 03:44

22 record speaks for itself. 03:44

23 BY MR. JONNA: 03:44

24 Q. All right. Well, here is the current 03:44

25 statement by ACOG. It says, "It was ended early 03:44

1 due to safety concerns among the participants." 03:44

2 Do you see that? 03:44

3 A. I do. 03:44

4 Q. That's Exhibit 18. 03:44

5 (Deposition Exhibit 18 was marked for 03:44

6 identification by the reporter and is 03:44

7 attached hereto.) 03:44

8 BY MR. JONNA: 03:44

9 Q. Do you remember, now that you've seen 03:44

10 this, the decision to edit the statement? 03:44

11 MS. PENAN: Objection. Calls for 03:44

12 speculation. Lacks foundation. Incomplete -- 03:44

13 yeah, that's it. 03:44

14 A. I talked with so many people about these 03:44

15 things or emailed with so many people. I don't 03:44

16 remember if I talked with them specifically about 03:44

17 that statement or not. I can't tell you. I can't 03:44

18 remember if I did or didn't, but I don't think it 03:44

19 -- whatever. 03:44

20 BY MR. JONNA: 03:44

21 Q. Okay. I'm just asking what you remember. 03:44

22 So you don't remember. 03:44

23 A. Yeah. 03:45

24 Q. Okay. 03:45

25 A. I don't remember if I talked to them about 03:45

1 that or something else. I did talk to them 03:45
2 multiple times, but I don't remember it was 03:45
3 specifically about that. 03:45

4 Q. Do you have any concerns with how this one 03:45
5 is phrased? 03:45

6 A. Not at all. 03:45

7 Q. Okay. And is it your understanding that 03:45
8 ACOG normally issues alerts when they make 03:45
9 corrections to statements like this? 03:45

10 MS. PENAN: Objection. Calls for 03:45
11 speculation. Lacks foundation. Vague, ambiguous. 03:45

12 A. I'm not aware that they do when they do 03:45
13 this, but you would have to ask them. 03:45

14 BY MR. JONNA: 03:45

15 Q. So you don't know why they did not issue a 03:45
16 statement about this correction? 03:45

17 MS. PENAN: Same objections, plus asked 03:45
18 and answered. 03:45

19 A. You would have to ask them if it's their 03:45
20 norm to do that or if it's something, you know, 03:45
21 within their standard operating procedures that 03:45
22 they do. They do updates all of the time, and they 03:45
23 usually send a message out to all the members 03:45
24 within ACOG saying if something's been updated or 03:45
25 changed. So I get those all the time saying, you 03:46

1 know, this committee opinion is now updated, or 03:46

2 something like that. 03:46

3 BY MR. JONNA: 03:46

4 Q. All right. I'm pulling up Exhibit 115, 03:46

5 which is a warning letter sent to you from the -- 03:46

6 well, it's dated June 2nd, 2002. 03:46

7 You recognize this document from Health & 03:46

8 Human Services; correct? 03:46

9 (Deposition Exhibit 115 was marked for 03:46

10 identification by the reporter and is 03:46

11 attached hereto.) 03:46

12 A. Yep, from, June 12, 2002. Yes. 03:46

13 BY MR. JONNA: 03:46

14 Q. And what is this document? 03:46

15 A. It's a 48- -- it's called a "483." It's a 03:46

16 warning letter after an inspection for a study, for 03:46

17 product approval on a study. I was an investigator 03:46

18 at my study site. 03:46

19 Q. Okay. So just to make sure this is an 03:46

20 accurate copy of this, you've seen this before. I 03:46

21 just want to make sure. 03:46

22 A. Yes. 03:47

23 Q. Okay. Have you received any other warning 03:47

24 letters like this? 03:47

25 A. No. 03:47

1 Q. Can you just briefly describe why you 03:47
2 received this warning letter? 03:47

3 A. This was a study of a -- can you scroll 03:47
4 down a little, please? 03:47

5 Q. Sure. 03:47

6 A. Right there. 03:47

7 So this was a study of Lea's Shield, which 03:47
8 was a cervical cap, that the study was sponsored by 03:47
9 CONRAD, which is a -- the Contraceptive Research 03:47
10 and Development program. The protocol or the 03:47
11 sponsor allowed us to choose whether to provide 03:47
12 consent from male participants or to provide an 03:47
13 information sheet, because male -- because the 03:47
14 barrier method would be in the vagina, the question 03:47
15 at hand was whether the man might feel it with his 03:47
16 penis. It's made of silicone. 03:47

17 We chose to do an information sheet. It 03:48
18 was approved by the IRB. Sent an information sheet 03:48
19 home with every participant. And this 483 was citing 03:48
20 me because we didn't consent the male participants. 03:48
21 We only sent home a warning letter -- I'm sorry -- an 03:48
22 information letter, and that's what the citation was 03:48
23 for. 03:48

24 Q. Okay. I'm going to take a quick look at 03:48
25 the second page. So Heading 1 says: "Failure to 03:48

1 ensure that the requirements for obtaining and 03:48
2 documenting informed consent were met." We are 03:48
3 just looking at this paragraph right here. It says 03:48
4 "You also made other important changes to the 03:48
5 informed consent document that are inconsistent 03:48
6 with the sponsor's model consent form. For 03:48
7 example, your consent form states 'Lea 03:49
8 Contraceptive prevents pregnancy when it is used 03:49
9 with spermicidal.' The sponsor's consent form does 03:49
10 not make this statement. Your consent form states, 03:49
11 'The Lea Contraceptive may not protect you against 03:49
12 sexual transmitted diseases.' The sponsor model 03:49
13 form states, 'Lea Contraceptive does not protect.'" 03:49
14 Do you see that? 03:49
15 A. I do. 03:49
16 Q. Did you ever overexaggerate the efficacy 03:49
17 of Lea's Shield? 03:49
18 A. No. 03:49
19 Q. Okay. It also says, "You failed to submit 03:49
20 the sponsor's model consent form." 03:49
21 And then on Number 2, "Failure to conduct 03:49
22 the study in accordance with the investigational 03:50
23 plan." 03:50
24 Do you see that? 03:50
25 A. I do. 03:50

1 Q. It says, "There were no adverse experience 03:50
2 forms completed for the device-related medical 03:50
3 problems experienced by the male partners of the 03:50
4 following female subjects," and then it's redacted, 03:50
5 and then it says, "Problems experienced by the male 03:50
6 partner and reported by female subjects on specific 03:50
7 dates. Between March 3rd, 2000, and March 21, 03:50
8 2000, subject," retracted, "used the study device 03:50
9 nine times and reported that she or her male 03:50
10 partner experienced irritation or discomfort on 03:50
11 each occasion. This information was not recorded 03:50
12 on the appropriate case report forms."

13 Do you see that? 03:50

14 A. Yes. 03:50

15 Q. Was there a reason why the adverse 03:50
16 experiences weren't logged? 03:50

17 MS. PENAN: Objection. Vague, ambiguous. 03:50

18 A. That's the responsibility of my study 03:50
19 staff, but ultimately all the responsibility falls 03:50
20 to me. 03:50

21 BY MR. JONNA: 03:50

22 Q. It also said "You did not" -- under 03:51
23 Number 3, "Failure to maintain complete, accurate, 03:51
24 and current records relating to the investigation." 03:51

25 Do you see that? 03:51

1 BY MR. JONNA: 03:52

2 Q. Have you ever been sued for malpractice? 03:52

3 A. Yes. 03:52

4 Q. Approximately how many times? 03:52

5 A. For clarity, do you mean how many times 03:52

6 have I been named in a lawsuit? 03:52

7 Q. Correct -- well, no. Well, let's start 03:52

8 with that. 03:52

9 How many times have you been named in a 03:52

10 lawsuit? 03:52

11 A. I'm going to guess five or six times. 03:52

12 Q. Did any of those -- 03:52

13 MS. PENAN: So, sorry. 03:52

14 Vague and ambiguous, to that question. 03:52

15 BY MR. JONNA: 03:52

16 Q. Did any of those cases go to trial? 03:52

17 A. No, not that I'm aware of. 03:52

18 Q. Did you report -- did all those cases -- 03:53

19 did any of those cases get dismissed? 03:53

20 A. Yes. 03:53

21 Q. Did you settle some of those cases? 03:53

22 A. I personally never did. Everything I've 03:53

23 ever been named on, I was removed from. 03:53

24 Q. Did your insurance carrier pay money to 03:53

25 get you removed from those cases? 03:53

1 3:54 p.m. 03:54

2 (Recess taken from 3:54 p.m. to 4:02 p.m.) 03:54

3 THE VIDEOGRAPHER: Back on the record at 04:02

4 4:02 p.m. 04:02

5 MR. JONNA: I just want to note for the 04:02

6 record, Dr. Creinin, that we just discussed the 04:02

7 fact that I am about halfway through my outline. 04:02

8 I'm going to make as much progress as I can to ask 04:02

9 you as many questions as I can in this next hour 04:02

10 and a half, because I understand we only have until 04:02

11 5:30. 04:02

12 However, I do have quite a bit more 04:02

13 material, and I'm going to need a second 04:02

14 deposition. So whether that's a full day or less 04:02

15 than a full day, I don't know, but we can discuss 04:02

16 that separately with counsel for the Attorney 04:02

17 General's Office, but -- 04:02

18 MS. PENAN: And I will just say on the 04:02

19 record that we object to that, and that this is the 04:02

20 first we are hearing of it, and that your 04:02

21 deposition of our expert needs to be a reasonable 04:02

22 length, and that two full days is not reasonable, 04:02

23 in our perspective. 04:02

24 And we've been scheduling -- after months 04:03

25 of scheduling, this is the first time that this has 04:03

1 been raised. 04:03

2 MR. JONNA: I will just note that we 04:03
3 noticed this as a deposition that will continue 04:03
4 from day to day as needed, as all expert 04:03
5 depositions are noticed. There's no seven-hour 04:03
6 limit in California. 04:03

7 And, obviously, Dr. Creinin is a pretty 04:03
8 important witness in this case, and a pretty 04:03
9 important expert. So the amount of material that 04:03
10 we need to go over with him is more than your other 04:03
11 witnesses. And even for your other witness, 04:03
12 *Dr. Glitten, we used another three hours on a 04:03
13 second day, as you know, Counsel. 04:03

14 So, anyway, I would hope we could reach an 04:03
15 agreement on a reasonable amount of time to come 04:03
16 back, but I don't want to argue about that right now. 04:03
17 So that can be raised with the court on Tuesday as 04:03
18 well, if that's what you desire. All right. 04:03

19 MS. PENAN: Objection stands. 04:03

20 Please proceed. 04:03

21 BY MR. JONNA: 04:03

22 Q. Okay. Turning back to -- one more 04:03
23 question about the description in your study of the 04:03
24 hemorrhage, and then I will move on to a different 04:04
25 topic. 04:04

1 So one of the paragraphs we didn't look at 04:04
2 is the one I just highlighted right here in orange, 04:04
3 and it says "Severe hemorrhages requiring ambulance 04:04
4 transport to hospital occurred in three patients. 04:04
5 One received progesterone, complete expulsion, no 04:04
6 aspiration; and two received placebo. Aspiration for 04:04
7 both. One required transfusion. We halted 04:04
8 enrollment after the third hemorrhage. No other 04:04
9 significant side effects were reported." 04:04
10 Do you see that? 04:04
11 A. Yes. 04:04
12 Q. What qualifies what Subject 8 experienced 04:04
13 as a severe hemorrhage? 04:04
14 MS. PENAN: Objection. Asked and 04:04
15 answered. 04:04
16 A. I did answer that earlier. This is an 04:04
17 example of abuse, wasting our time as you want to 04:04
18 go longer. That was answered earlier. 04:04
19 BY MR. JONNA: 04:04
20 Q. We talked -- 04:04
21 A. I'm just a little upset by your maneuvers 04:04
22 since you want to now prolong things ridiculously, 04:04
23 but I will answer your question. 04:04
24 Again, she bled through her pants. She 04:04
25 called an ambulance. 04:05

1 Asked and answered. 04:05

2 Q. Right. We talked about that in the 04:05
3 context of the use of the term "hemorrhage," but 04:05
4 I'm just asking what justified calling it a "severe 04:05
5 hemorrhage"?. 04:05

6 MS. PENAN: Same objections. 04:05

7 A. I answered. That was the description we 04:05
8 used in the paper. 04:05

9 BY MR. JONNA: 04:05

10 Q. Okay. Do you think that it's accurate to 04:05
11 lump the three different patients into one category 04:05
12 as all severe hemorrhage patients, 10, 11, and 8? 04:05

13 MS. PENAN: Objection. 04:05

14 A. They all -- 04:05

15 MS. PENAN: Sorry. Asked and answered. 04:05

16 A. They all experienced very heavy bleeding 04:05
17 that, in their opinion, they needed to go to the 04:05
18 emergency room. How they got there really doesn't 04:05
19 matter, as we've discussed earlier. And their 04:05
20 bleeding was outside the realm of most normal 04:05
21 medication abortions. 04:05

22 So that's the terminology we use. 04:05

23 BY MR. JONNA: 04:05

24 Q. What's the difference between hemorrhage 04:06
25 and severe hemorrhage? 04:06

1 incorrectly. 04:06

2 I meant to say -- I'm asking: What's the 04:06
3 difference between a severe hemorrhage and 04:06
4 hemorrhage? 04:07

5 MS. PENAN: Objection. Asked and 04:07
6 answered. 04:07

7 A. Boy, you can get difference answers from 04:07
8 different people. 04:07

9 BY MR. JONNA: 04:07

10 Q. I'm asking you. 04:07

11 A. And it depends on the situation. In some 04:07
12 situations, it might be severe bleeding that 04:07
13 requires intervention. There's -- you know, so you 04:07
14 could argue anybody who hemorrhaged or bled to the 04:07
15 point where something needed to be done, including 04:07
16 going to an ER, could qualify as severe. Some 04:07
17 people might say, "No, that's not severe." 04:07

18 Everybody -- you can have a different 04:07
19 opinion. At the time we wrote this, that was our 04:07
20 opinion. 04:07

21 Q. Okay. So just to be very clear, because I 04:07
22 don't think I got an answer: What is your 04:07
23 definition of "severe hemorrhage" as opposed to 04:07
24 "hemorrhage"? 04:07

25 MS. PENAN: Objection. Asked and 04:07

1 answered. 04:07

2 BY MR. JONNA: 04:07

3 Q. Let's just -- let's just ask this 04:07

4 question: What's your definition of "hemorrhage"? 04:07

5 I will move on after this. Just please 04:07

6 answer these questions. 04:08

7 What is your definition of "hemorrhage"? 04:08

8 MS. PENAN: Objection. Asked and 04:08

9 answered, Counsel. 04:08

10 A. Hemorrhage is heavy bleeding. 04:08

11 BY MR. JONNA: 04:08

12 Q. Okay. What is your definition of "severe 04:08

13 hemorrhage"? 04:08

14 MS. PENAN: Objection. Asked and 04:08

15 answered. 04:08

16 A. Severe heavy bleeding. 04:08

17 BY MR. JONNA: 04:08

18 Q. Okay. Any other qualifiers you want to 04:08

19 include for us before we move on? 04:08

20 MS. PENAN: Objection. Asked and 04:08

21 answered. Argumentative. Harassing. 04:08

22 A. No. 04:08

23 BY MR. JONNA: 04:08

24 Q. And that's heavy bleeding as determined by 04:08

25 the patient or the doctor? 04:08

1 MS. PENAN: Objection. Asked and 04:08
2 answered. 04:08

3 A. It could be either. 04:08

4 BY MR. JONNA: 04:08

5 Q. And who decides which one to go with? 04:08

6 MS. PENAN: Objection. Asked and 04:08
7 answered. Argumentative. Harassing. 04:08

8 A. It depends on what information is 04:08
9 available. 04:08

10 MR. JONNA: Okay. All right. I'm going 04:08
11 to take a look at Exhibit 67. I will go through 04:08
12 this pretty quick. 04:08

13 (Deposition Exhibit 67 was marked for 04:08
14 identification by the reporter and is 04:08
15 attached hereto.) 04:08

16 BY MR. JONNA: 04:08

17 Q. We spoke about this earlier. This is the 04:08
18 mifepristone stakeholders' meeting. 04:09

19 You remember that? 04:09

20 A. Yes. 04:09

21 Q. And this is an email that you sent to a 04:09
22 number of folks, dated December 5, 2019, discussing 04:09
23 talking points, and the subject is "Revised Talking 04:09
24 Points." 04:09

25 Do you see that? 04:09

1 was analyzed. 04:10

2 Q. And unblinded? 04:10

3 A. To do an analysis, I would have to unblind
4 it. 04:10

5 Q. Okay. It says, at the bottom -- or at the
6 top of page 2, I should say, "Of note, I have
7 already been asked about this perceived split in
8 the pro-choice community. So here is a chance for
9 us all to be on the same message." 04:10

10 Do you see that? 04:10

11 A. I do. 04:10

12 Q. What split were you referring to? 04:10

13 A. I said "perceived split," but I am not
14 sure. It -- no, I'm not sure. I really don't. I
15 can't remember at this time, but I could guess, but
16 I really don't know for sure. 04:11

17 Q. I don't want you to guess, but if there's
18 a perceived split about your study or the results
19 of the study or APR in the pro-choice community, if
20 you remember what that is, I would like to hear
21 about that. 04:11

22 A. I think -- 04:11

23 MS. PENAN: Objection. Counsel is
24 testifying. Asked and answered. Calls for
25 speculation. 04:11

1 A. No, I think that -- no. It's actually 04:11
2 good -- it's good we are getting this out. 04:11

3 I do remember now the split was about 04:11
4 whether the study should ever have been done in the 04:11
5 first place. 04:11

6 BY MR. JONNA: 04:11

7 Q. What were the opinions on that? 04:11

8 A. Not to study it, because the data that was 04:11
9 out there was so crappy, why would we do anything 04:11
10 to potentially sell something would work, because I 04:11
11 did set the study up to show that it would work. 04:11

12 And so that was the split, I remember, and 04:11
13 that may be what I was referring to, but there were 04:11
14 a lot of people in the pro-choice community who 04:11
15 were upset I was doing the study because they 04:12
16 didn't want me to potentially show it worked, and 04:12
17 my feeling was I wanted to get at least some data 04:12
18 to see if it may have -- if it may work. 04:12

19 Q. Did you ever get criticism after the fact 04:12
20 from people who said that your study actually did 04:12
21 show it worked? 04:12

22 MS. PENAN: Objection. Vague, ambiguous. 04:12

23 A. But I can't agree with your question 04:12
24 anyway because it didn't show it worked. 04:12

25 BY MR. JONNA: 04:12

1 Q. Well, I'm not saying that you have to 04:12
2 agree with it. 04:12

3 I'm just wondering if anyone criticized 04:12
4 you after the fact because your study did show it 04:12
5 worked? 04:12

6 A. I can't answer -- 04:12

7 MS. PENAN: Objection. 04:12

8 A. -- the question because you're making a 04:12
9 false statement. 04:12

10 BY MR. JONNA: 04:12

11 Q. Did anybody -- I'm not making a statement 04:12
12 at all. 04:12

13 Did anybody talk to you after the fact, 04:12
14 complaining that you did the study, because they 04:12
15 thought it showed that it worked? 04:12

16 MS. PENAN: Objection. Vague, ambiguous. 04:12
17 Misstates the witness's testimony. Argumentative. 04:12
18 Asked and answered. 04:12

19 A. No, because nobody that I talked to who 04:12
20 has any valid scientific background said that it 04:12
21 showed it worked. 04:12

22 BY MR. JONNA: 04:12

23 Q. But you have read that people have claimed 04:12
24 that your study actually shows APR works. 04:12

25 You've read that, haven't you? 04:13

1 It didn't come from the LISTSERV. It came from me 04:14
2 to the LISTSERV. 04:14

3 When you load on the LISTSERV, it loads 04:14
4 that way. You can see it was on behalf of me, so 04:14
5 it came from me. 04:14

6 BY MR. JONNA: 04:14

7 Q. Okay. Do you remember how many people 04:14
8 actually attended the meeting in D.C., 04:14
9 approximately? 04:14

10 A. 20 to 30, maybe. Maybe. 04:15

11 Q. Do you remember approximately how long it 04:15
12 lasted? 04:15

13 A. I would say probably less than this 04:15
14 deposition. Probably, say, six hours. 04:15

15 Q. Who spoke at the meeting besides yourself? 04:15

16 A. Communications experts. And everybody was 04:15
17 given opportunities to talk, but there's some 04:15
18 communications people that talked. 04:15

19 Q. Did any other doctors talk besides you? 04:15

20 A. As far as scheduled to give a talk, not 04:15
21 that I remember, but I don't have any of the agenda 04:15
22 or records in front of me. 04:15

23 Q. Okay. Who paid for the travel, as far as 04:16
24 you remember? 04:16

25 A. The study -- 04:16

1 MS. PENAN: Objection. Vague, ambiguous. 04:16

2 A. With money remaining from the grant. When 04:16

3 I talked to the funder, I said I would like to do 04:16

4 this, and they said that would be fine with them. 04:16

5 BY MR. JONNA: 04:16

6 Q. Is it they paid for the travel, the hotel? 04:16

7 MS. PENAN: Objection. Asked and 04:16

8 answered. 04:16

9 A. I don't remember if they paid for the 04:16

10 travel; I really don't. They did for mine, but I 04:16

11 don't remember if we offered that as part of it, or 04:16

12 just a hotel room or whatever. I don't remember 04:16

13 the details. 04:16

14 BY MR. JONNA: 04:16

15 Q. Did they pay for anyone's time as well? 04:16

16 A. No. They definitely didn't pay for time 04:16

17 as a consulting fee or anything, no. 04:16

18 Q. Okay. All right. I want to show you 04:16

19 Exhibit 69. These are the talking points that were 04:16

20 circulated, and I'm just going to ask you to skim 04:16

21 these. And my question for you: Did you help 04:17

22 create these talking points? 04:17

23 (Deposition Exhibit 69 was marked for 04:17

24 identification by the reporter and is 04:17

25 attached hereto.) 04:17

1 A. I couldn't tell you without skimming them. 04:17

2 I helped to create them. Everybody at the meeting 04:17

3 helped to create them. 04:17

4 BY MR. JONNA: 04:17

5 Q. Okay. The first one that's highlighted in 04:17

6 green says, "The bleeding in these three women was 04:17

7 very brisk and heavy, not typical of what is seen 04:17

8 with medical abortion after the combination of 04:17

9 mifepristone and misoprostol is used." 04:17

10 Do you see that? 04:17

11 A. Yes. 04:17

12 Q. And then underneath that, it says, "All 04:17

13 women except one (in progesterone group, had the 04:17

14 highest baseline progesterone) experienced some 04:17

15 spotting or bleeding." 04:17

16 Do you see that? 04:17

17 A. I do. 04:17

18 Q. What's the point of this sentence? 04:17

19 A. Which sentence? 04:17

20 MS. PENAN: Objection. Vague, ambiguous. 04:17

21 BY MR. JONNA: 04:17

22 Q. This one. 04:17

23 A. You asked me about two. 04:17

24 That is that when -- even when 04:17

25 progesterone is used, people have some spotting and 04:17

1 bleeding. 04:18

2 Q. Okay. 04:18

3 A. Which is something that had not been ever 04:18
4 reported. 04:18

5 Q. And why is it that you think the women 04:18
6 with the highest level of progesterone have no 04:18
7 spotting or bleeding? 04:18

8 MS. PENAN: Objection. Calls for 04:18
9 speculation. Lacks foundation. Incomplete 04:18
10 hypothetical. 04:18

11 A. I have no idea, because that was her 04:18
12 baseline progesterone. 04:18

13 BY MR. JONNA: 04:18

14 Q. Okay. This is a number of do's and don'ts 04:18
15 listed, and my question is: Why did you guys 04:18
16 decide not to discuss certain topics that lead -- 04:19
17 that -- well, let me just leave it at that. 04:19

18 What was the reason for these pointers 04:19
19 about things not to say? What was the point of 04:19
20 half? 04:19

21 A. We had communications experts there, and 04:19
22 that was their advice, so I rely on the experts in 04:19
23 that area. 04:19

24 Q. Right here it says, "When talking about 04:19
25 the use of two pills, don't refer to the FDA label. 04:19

1 Refer to evidence-based treatment or regimen. 04:19
2 Talking about the label could get reporters onto 04:19
3 the subject of the label, and should it be 04:19
4 changed." 04:19
5 Do you see that? 04:19
6 A. I do. 04:19
7 Q. What does that refer to? 04:19
8 MS. PENAN: Objection. Calls for 04:19
9 speculation. 04:19
10 A. What the communications experts suggested, 04:19
11 that we -- how we talk about the use of the 04:19
12 mifepristone and misoprostol. 04:19
13 BY MR. JONNA: 04:19
14 Q. And Danco was also invited to this D.C. 04:19
15 meeting; is that correct? 04:19
16 A. Yes. 04:19
17 MS. PENAN: Objection. Asked and 04:19
18 answered. 04:19
19 A. Yes. 04:19
20 BY MR. JONNA: 04:19
21 Q. Do you see any concerns with that? 04:19
22 A. They are a stakeholder, so I don't see any 04:20
23 concerns with that. 04:20
24 Q. And the grant that you received for the 04:20
25 study was from the Society of Family Planning; 04:20

1 right? 04:20

2 A. Yes. 04:20

3 Q. And it was for how much? 04:20

4 A. I don't remember off the top of my head. 04:20

5 Q. Was it more than \$400,000? 04:20

6 A. Possibly. 04:20

7 Q. And do you think that there is a conflict 04:20

8 of interest with you being one of the founding 04:20

9 members of SFP? 04:20

10 A. Oh, heck, no, not at all. 04:20

11 Q. Okay. 04:20

12 A. I have applied for other grants and not 04:20

13 gotten them. So no. 04:20

14 Q. All right. Turning to the biochemistry of 04:20

15 APR, what's a mechanism of action? 04:20

16 A. I'm sorry. What is your question? 04:20

17 Q. What is a mechanism of action? 04:20

18 A. How something works. 04:20

19 Q. Okay. How is knowing the mechanism of 04:20

20 action of a drug helpful? 04:20

21 MS. PENAN: Objection. Vague, ambiguous. 04:21

22 Lacks foundation. Incomplete hypothetical. 04:21

23 A. You need to know how a drug works to 04:21

24 understand potential side effects to figure out 04:21

25 dosing, other things. I mean, it's kind of a -- 04:21

1 BY MR. JONNA: 04:21

2 Q. What is the -- 04:21

3 A. -- same question. 04:21

4 Q. Yeah. What is the mechanism of action of 04:21
5 progesterone in APR? 04:21

6 A. You may have to -- well, APR doesn't -- 04:21
7 has not been proven. So you're asking what happens 04:21
8 if you give progesterone to somebody who is taking 04:21
9 mifepristone? I mean, what are you asking here? 04:21

10 Q. Is -- yes. Go ahead and answer that 04:21
11 question. 04:21

12 MS. PENAN: I'm going to say objection. 04:21
13 Assumes facts not in evidence. Vague, ambiguous. 04:21
14 Calls for speculation. Lacks foundation. 04:21

15 BY MR. JONNA: 04:21

16 Q. We talked about this earlier. And just to 04:21
17 lay some foundation, describe the mechanism of 04:21
18 action when a woman takes progesterone after taking 04:22
19 mifepristone. 04:22

20 MS. PENAN: Same objections. Plus, 04:22
21 Counsel is testifying. 04:22

22 A. Mifepristone combines very strongly to the 04:22
23 progesterone receptor, stronger than progesterone 04:22
24 itself. If you give more progesterone, there is no 04:22
25 evidence that you will -- you can displace 04:22

1 progesterone. It would be as if I put handcuffs on 04:22
2 you and I pulled hard on your arm; if I pull hard 04:22
3 enough, that handcuff will come off. Well, no, 04:22
4 it's around your wrist really tight; it's just not 04:22
5 going to come off. 04:22

6 So the -- you know, once you -- if you 04:22
7 blocked it, you know, there is no -- there is no 04:22
8 evidence that it would unblock it. 04:22

9 If you gave them at the same time, they 04:22
10 would compete for the receptor. But, you know, 04:22
11 whatever mifepristone is bound to would be more 04:23
12 struck than progesterone itself, but if you are 04:23
13 giving it at a later point when the mifepristone is 04:23
14 already bound to the receptor, it's done what it 04:23
15 needs to do. 04:23

16 BY MR. JONNA: 04:23

17 Q. Progesterone is an agonist; is that right? 04:23

18 A. At what -- in what way? It's an agonist 04:23
19 for what? 04:23

20 Q. Is it characterized as an agonist in this 04:23
21 context? 04:23

22 MS. PENAN: Objection. Vague, ambiguous. 04:23
23 Confusing. 04:23

24 A. Yeah. That's not a valid scientific 04:23
25 question. 04:23

1 BY MR. JONNA: 04:23

2 Q. Does it compete with mifepristone for the 04:23

3 same receptor site on a cell? 04:23

4 MS. PENAN: Objection. Asked and 04:23

5 answered. 04:23

6 A. You can't compete when something is 04:23

7 already bound. You can compete if it's something 04:23

8 that binds weakly and kind of comes off, but if it 04:23

9 binds very strongly, it's bound strongly. 04:23

10 It's not like progesterone comes along, 04:23

11 which has weaker binding, and says, "I'm going to 04:23

12 kick you off the receptor." You can't do that. 04:23

13 BY MR. JONNA: 04:23

14 Q. Is progesterone an agonist at the 04:23

15 progesterone receptor? 04:24

16 A. Yes. 04:24

17 MS. PENAN: Objection. Asked and 04:24

18 answered. 04:24

19 BY MR. JONNA: 04:24

20 Q. Okay. Are you familiar with competitive 04:24

21 binding? 04:24

22 MS. PENAN: Objection. Vague, ambiguous. 04:24

23 Lacks foundation. Incomplete hypothetical. 04:24

24 A. Yes. 04:24

25 BY MR. JONNA: 04:24

1 Q. What does that refer to? 04:24

2 MS. PENAN: Same objections. 04:24

3 A. The different molecules can compete to 04:24

4 bind at the same receptor. 04:24

5 BY MR. JONNA: 04:24

6 Q. Okay. Have you prescribed agonist drugs 04:24

7 to your pregnant patients? 04:24

8 MS. PENAN: Objection. Calls -- lacks 04:24

9 foundation. Incomplete hypothetical. Vague, 04:24

10 ambiguous. Confusing. 04:24

11 A. What type of agonist drug? I mean... 04:24

12 BY MR. JONNA: 04:24

13 Q. Just... 04:24

14 A. I mean, there's -- there's a whole myriad 04:24

15 of pharmacopeia that you could be talking about. 04:24

16 I mean, what are you specifically asking 04:24

17 about? 04:25

18 BY MR. JONNA: 04:25

19 Q. So you have, though; you have prescribed 04:25

20 agonist drugs? 04:25

21 A. That's not what I said. 04:25

22 MS. PENAN: Objection. Misstates the 04:25

23 witness's testimony. Argumentative. 04:25

24 A. I never said that. You said -- you said 04:25

25 have I ever prescribed an agonist drug to a 04:25

1 patient. I said, "What type of agonist drug?" 04:25
2 because there is a whole pharmacopeia of types of 04:25
3 drugs. 04:25
4 BY MR. JONNA: 04:25
5 Q. Any type. 04:25
6 MS. PENAN: Objection. Vague, ambiguous. 04:25
7 Confusing. Lacks foundation. 04:25
8 A. Are you talking about diabetes 04:25
9 medications? Blood pressure medications? Pain 04:25
10 medications? "Any type" is too vague. 04:25
11 BY MR. JONNA: 04:25
12 Q. Okay. What is a ligand? 04:25
13 A. A ligand? 04:25
14 Q. Ligand. 04:25
15 A. A ligand is part of a molecule. 04:25
16 Q. Okay. And a ligand can bind to a receptor 04:25
17 either reversibly or irreversibly; is that true? 04:25
18 MS. PENAN: Objection. Counsel is 04:25
19 testifying. 04:25
20 A. Not really. The ligand is part of a 04:25
21 molecule that can bind, but a ligand itself doesn't 04:25
22 bind. 04:26
23 BY MR. JONNA: 04:26
24 Q. Is an agonist a ligand that binds to a 04:26
25 receptor and activates it? 04:26

1 A. No. 04:26

2 MS. PENAN: Objection. Vague, ambiguous. 04:26

3 Confusing. Lacks foundation. Incomplete 04:26

4 hypothetical. 04:26

5 A. No. You need better scientific experts to 04:26

6 give you this information. That's not how it 04:26

7 works. 04:26

8 BY MR. JONNA: 04:26

9 Q. Okay. How does it work? 04:26

10 A. A molecule binds to a receptor. The 04:26

11 ligands are parts of the molecule that are binding, 04:26

12 but the ligand itself is just part of a molecule. 04:26

13 Q. What is an antagonist? 04:26

14 A. Something that binds -- 04:26

15 MS. PENAN: Objection. Vague, ambiguous. 04:26

16 A. Something that bind -- in this situation 04:26

17 where you are talking about drugs -- because 04:26

18 antagonism can be lots of things. An antagonist is 04:26

19 something that binds to a receptor without 04:26

20 activating it. 04:26

21 BY MR. JONNA: 04:26

22 Q. Okay. How is a competitive antagonist 04:26

23 different from a noncompetitive antagonist? 04:26

24 MS. PENAN: Objection. Vague, ambiguous. 04:27

25 Confusing. Compound. Lacks foundation. 04:27

1 A. I'm not really sure I can answer that 04:27

2 question. I'm just not -- I can't answer that. 04:27

3 Sometimes questions are just out there. So I can't 04:27

4 answer that. 04:27

5 BY MR. JONNA: 04:27

6 Q. Would you agree that the presence of 04:27

7 competing ligands affects the length of time a 04:27

8 ligand will bind with the receptor? 04:27

9 MS. PENAN: Objection. Assumes facts not 04:27

10 in evidence. Vague, ambiguous. Confusing. Lacks 04:27

11 foundation. 04:27

12 A. No, I don't agree with that. 04:27

13 BY MR. JONNA: 04:27

14 Q. Why not? 04:27

15 A. Because it has -- there's a lot that has 04:27

16 to do with the degree of binding and the strength 04:27

17 of the binding. Just because there is a competitor 04:27

18 around doesn't mean it will displace the molecule. 04:27

19 MR. JONNA: Okay. I'm going to pull up 04:27

20 Exhibit 38. 04:27

21 (Deposition Exhibit 38 was marked for 04:27

22 identification by the reporter and is 04:27

23 attached hereto.) 04:28

24 BY MR. JONNA: 04:28

25 Q. This is an article by Barbara Pleuvry, 04:28

1 P-L-E-U-V-R-Y, titled "Receptors, Agonists and 04:28
2 Antagonists." 04:28
3 Do you see that? 04:28
4 A. I do. 04:28
5 Q. There is a -- 04:28
6 A. I need to know what the article is from 04:28
7 and when it was published to see if it's credible. 04:28
8 Q. Okay. 04:28
9 MS. PENAN: Dr. Creinin, it's in the chat, 04:28
10 also. If you want to click through and look at the 04:28
11 whole thing, you are able to. 04:28
12 A. So it's from Anesthesia and Intensive Care 04:28
13 Medicine. All right. That's fine. 04:28
14 BY MR. JONNA: 04:28
15 Q. Okay. I just want to ask about this 04:28
16 definition here and see if you agree with it, the 04:28
17 definition of a "competitive antagonist." 04:28
18 It says, "A competitive or surmountable 04:28
19 antagonist binds reversibly to the same receptor as 04:28
20 an agonist, but occupies the site without 04:28
21 activating the effector mechanism. A competitive 04:28
22 antagonist has zero efficacy. Its action may be 04:28
23 reversed by increasing the concentration of the 04:28
24 agonist." 04:28
25 Do you agree with that statement? 04:29

1 MS. PENAN: Objection. Lacks foundation. 04:29

2 Calls for speculation. Vague, ambiguous. 04:29

3 Incomplete hypothetical. 04:29

4 A. It's very general. In general terms, 04:29

5 that's true, but how it relates specifically to 04:29

6 mifepristone and progesterone may not be as true. 04:29

7 But in general, that's true. 04:29

8 BY MR. JONNA: 04:29

9 Q. Okay. I'm going to show you a video that 04:29

10 actually describes this, and I want to see if you 04:29

11 agree with the characterization in the video. 04:29

12 So it's Exhibit 76. 04:29

13 (Deposition Exhibit 76 was marked for 04:29

14 identification by the reporter and is 04:29

15 attached hereto.) 04:29

16 BY MR. JONNA: 04:29

17 Q. Let me see if I can pull it up here. 04:29

18 A. Can you provide me background on who made 04:29

19 the video, what it's from? 04:29

20 Q. I -- hopefully, that's listed here. Let 04:29

21 me see. It does say the person who's presenting. 04:29

22 It's -- I want to see if this prescription that he 04:29

23 provides for -- now, the title, it says, is 04:30

24 "Agonist Dose-Response Curves in the Presence of 04:30

25 Competitive Antagonist and Noncompetitive 04:30

1 Antagonist," and it's from Pharmapedia, Dr. Steven 04:30
2 Farmer. 04:30
3 Have you heard of him? 04:30
4 A. No. 04:30
5 Q. Okay. I, again -- 04:30
6 A. It's fine. You can show it. 04:30
7 Q. I will play it and see what your reaction 04:30
8 is, and if there's anything that's said here that 04:30
9 you think is not correct, I would be curious to 04:30
10 hear what that is. 04:30
11 So I'm going to press "play." Let me know 04:30
12 if you can hear this. 04:30
13 Can you hear that? 04:30
14 A. Yes, I can. 04:30
15 (Video was played, not reported.) 04:30
16 BY MR. JONNA: 04:34
17 Q. All right. So do you agree with the 04:34
18 depiction in the video, Exhibit 76, of competitive 04:34
19 inhibition? 04:34
20 MS. PENAN: Objection. Lacks foundation. 04:34
21 Compound. Vague, ambiguous. Confusing. 04:34
22 A. Do I agree with it in the sense that 04:35
23 that's generally how things work? Yes, but to know 04:35
24 if it translates to outcomes in humans, you have to 04:35
25 do studies. That's the -- that's all theory of how 04:35

1 things work. Again, it doesn't take into account 04:35
2 degree of binding, et cetera. 04:35

3 So if you have an antagonist that binds 04:35
4 much more strongly than the agonist, you're not going 04:35
5 to get that same type of effect. That's why you need 04:35
6 studies to say, does it really work. It's just all 04:35
7 part of the theory behind a concept without proof of 04:35
8 any effect. 04:35

9 BY MR. JONNA: 04:35

10 Q. Okay. But you don't have any problems 04:35
11 with the way the theory of the concept was 04:35
12 explained in that video? 04:35

13 A. No. Actually, a very nice video. 04:35

14 Q. Okay. I'm going to pull up Exhibit 5 04:35
15 again, which we looked at earlier, which is the 04:35
16 Mifeprex label -- 04:35

17 THE REPORTER: "Which is" what? 04:35

18 MR. JONNA: The Mifeprex label, Exhibit 5, 04:35
19 and we are going to go to page 10. 04:35

20 Under "mechanism of action," it says: "The 04:36
21 anti-progestational activity of mifepristone results 04:36
22 from competitive interaction with progesterone at 04:36
23 progesterone-receptor sites. Based on studies with 04:36
24 various oral doses in several animal species (mouse, 04:36
25 rat, rabbit, and monkey), the compound inhibits the 04:36

1 activity of endogenous or exogenous progesterone..." 04:36

2 Do you see that? 04:36

3 A. Yes. 04:36

4 Q. And you agree with that statement? 04:36

5 MS. PENAN: Objection. Misstates the 04:36

6 witness's testimony. Argumentative. 04:36

7 A. It's what the statement is in the label. 04:36

8 I mean, I can't argue with that. 04:36

9 BY MR. JONNA: 04:36

10 Q. So mifepristone binds to the same receptor 04:36

11 site that progesterone binds to; is that correct? 04:36

12 MS. PENAN: Objection. Asked and 04:36

13 answered. 04:36

14 A. Yes. 04:36

15 BY MR. JONNA: 04:36

16 Q. So mifepristone is a competitive 04:36

17 antagonist of progesterone; is that right? 04:36

18 MS. PENAN: Objection. Asked and 04:36

19 answered. 04:36

20 A. Yes. 04:36

21 MR. JONNA: Okay. Pulling up Exhibit 109 04:36

22 now. 04:37

23 (Deposition Exhibit 109 was marked for 04:37

24 identification by the reporter and is 04:37

25 attached hereto.) 04:37

1 BY MR. JONNA: 04:37

2 Q. This is an article by Emile Baulieu. 04:37

3 A. Etienne-Emile Baulieu and Sheldon Segal. 04:37

4 Q. Yeah. Okay. 04:37

5 "RU 486 and Human Fertility Control." 04:37

6 A. Uh-huh. 04:37

7 Q. Have you seen this before? 04:37

8 A. I believe so. 04:37

9 Q. Okay. 04:37

10 A. But it's been a long time. It's a very 04:37

11 old document. 04:37

12 Q. On page 7, Dr. Baulieu wrote "Acting 04:37

13 reversibly at the molecular level of receptor 04:37

14 binding, RU 486 irreversibly interrupts target cell 04:37

15 integrity if these cells are dependent on the 04:37

16 continuity of progesterone action." 04:37

17 Do you see that? 04:37

18 A. I do. 04:37

19 Q. Do you agree with that statement? 04:37

20 MS. PENAN: Objection. Lacks foundation. 04:37

21 Vague, ambiguous. 04:37

22 A. I don't have any reason not to believe it. 04:37

23 BY MR. JONNA: 04:37

24 Q. Do you agree that mifepristone is a ligand 04:37

25 that binds reversibly to progesterone receptors? 04:38

1 MS. PENAN: Objection. Asked and 04:38
2 answered. 04:38

3 A. By default, anything that doesn't stay 04:38
4 permanently is reversible. I mean, that's just the 04:38
5 default. What that's saying is that it binds 04:38
6 reversibly, which means at some point it's no 04:38
7 longer there, but what it does is irreversible. 04:38

8 That's what that statement says. 04:38

9 BY MR. JONNA: 04:38

10 Q. Okay. Does this happen because 04:38
11 mifepristone binds to the progesterone receptor 04:38
12 through non-covalent bonds? 04:38

13 A. I don't know. 04:38

14 MS. PENAN: Objection. Lacks foundation. 04:38
15 Calls for speculation. Incomplete hypothetical. 04:38
16 Vague, ambiguous. 04:38

17 A. I don't know the type of bonds with which 04:38
18 it binds, and it's irrelevant. 04:38

19 BY MR. JONNA: 04:39

20 Q. Okay. Are non-covalent bonds reversible? 04:39

21 A. I don't know. 04:39

22 MS. PENAN: Objection. Calls for 04:39
23 speculation. Lacks foundation. Incomplete 04:39
24 hypothetical. Vague, ambiguous. 04:39

25 A. I don't know. 04:39

1 BY MR. JONNA: 04:39

2 Q. Would you agree that the activity of a 04:39
3 receptor antagonist can generally be inhibited by 04:39
4 increasing the concentration of a receptor agonist? 04:39

5 MS. PENAN: Objection. Lacks foundation. 04:39
6 Incomplete hypothetical. Vague, ambiguous. 04:39

7 A. You said "generally." So in general 04:39
8 terms, yes, but in specific terms, not always, 04:39
9 because it depends on the binding affinity of the 04:39
10 molecules you are talking about. Half-life, 04:39
11 elimination half-life, all those things come into 04:39
12 play. 04:39

13 So this is all developing theory, and all 04:39
14 your questions are around theory. All this does is 04:39
15 provide theory for why a treatment may or may not be 04:39
16 reasonable, but you don't know if it really works, if 04:39
17 all that theory translates into something that's 04:39
18 clinically effective, unless you do studies, because 04:40
19 all the theory in the world doesn't translate to 04:40
20 clinical outcomes. 04:40

21 BY MR. JONNA: 04:40

22 Q. I'm starting with the theory just to see 04:40
23 what we agree and disagree on, and then we are 04:40
24 going to talk about more specifics. 04:40

25 Can the effect of a competitive antagonist 04:40

1 that blocks an agonist ever be overcome by adding 04:40

2 more agonist? 04:40

3 MS. PENAN: Objection. Lacks foundation. 04:40

4 Calls for speculation. Incomplete hypothetical. 04:40

5 Vague, ambiguous. 04:40

6 A. Yeah. "Ever" is a big term. Can it ever? 04:40

7 For some drugs, yes. But are you talking about any 04:40

8 drug? Are you talking about mifepristone and 04:40

9 progesterone? 04:40

10 I mean, this is why this is going on so 04:40

11 long. Be specific for what you want to know about. 04:40

12 BY MR. JONNA: 04:40

13 Q. Okay. But you are aware that it can 04:40

14 happen for some drugs? 04:40

15 A. Yeah. It doesn't matter for this case. 04:40

16 You are talking specifically about mifepristone and 04:40

17 progesterone, and that's why you are wasting time. 04:40

18 Q. And this could be the case, even if the 04:40

19 antagonist has a greater binding affinity to a 04:40

20 receptor than the agonist; is that true? 04:41

21 A. I don't know. 04:41

22 MS. PENAN: Objection. Lacks foundation. 04:41

23 Incomplete hypothetical. Calls for speculation. 04:41

24 Vague, ambiguous. 04:41

25 A. I don't know, because it depends on the 04:41

1 drugs in question. 04:41

2 BY MR. JONNA: 04:41

3 Q. Okay. Have you ever prescribed drugs that 04:41

4 utilize competitive binding to your patients? 04:41

5 MS. PENAN: Objection. Asked and 04:41

6 answered. Calls for speculation. Lacks 04:41

7 foundation. Incomplete hypothetical. Vague, 04:41

8 ambiguous. 04:41

9 A. Yes. 04:41

10 BY MR. JONNA: 04:41

11 Q. What drugs? 04:41

12 A. Clomiphene, tamoxifen are the two that 04:41

13 come to my mind first. 04:41

14 Q. So can you think of any examples where the 04:41

15 effects of a receptor antagonist are counteracted 04:41

16 by introducing higher instances of the receptor 04:41

17 agonist? 04:41

18 A. We don't -- 04:41

19 MS. PENAN: Objection. Lacks foundation. 04:41

20 Incomplete hypothetical. Vague, ambiguous. 04:41

21 A. We don't -- there is nothing in medicine 04:41

22 that I'm aware of where we purposely prescribe an 04:41

23 antagonist and then purposely prescribe an agonist. 04:42

24 BY MR. JONNA: 04:42

25 Q. Okay. Let me show you Exhibit 19 and get 04:42

1 your reaction to this really quick. 04:42

2 (Deposition Exhibit 19 was marked for 04:42

3 identification by the reporter and is 04:42

4 attached hereto.) 04:42

5 BY MR. JONNA: 04:42

6 Q. So this is a declaration from an expert in 04:42

7 another case, another APR case in Colorado, and I 04:42

8 just have a question about one specific opinion in 04:42

9 this declaration. It's on page 16. I just want to 04:42

10 see -- 04:42

11 A. Yeah, but I'd have to know who the expert 04:42

12 is -- 04:42

13 Q. Oh. 04:42

14 A. -- and what makes them an expert. 04:42

15 Q. It's an expert report of Monique 04:42

16 Wubbenhorst. 04:42

17 A. Yeah. What kind of expert is she? What 04:42

18 does she do? I have no idea what she does. 04:42

19 Q. It says, in paragraph 1, she's a 04:42

20 board-certified obstetrician-gynecologist with 30 04:42

21 years of experience. 04:42

22 I have a question about one -- 04:42

23 A. Wait, wait. I have no idea what her 04:42

24 qualifications are to make these expert opinions. 04:42

25 If you're going to ask me about something, then I 04:42

1 need to know. 04:42

2 Q. Yeah, I'm not -- she's actually -- there 04:42

3 is an example she provides here. It's not a -- 04:43

4 let's see here. Paragraph 16. 04:43

5 MS. PENAN: And, Dr. Creinin, you can open 04:43

6 her declaration from the chat and review it, if you 04:43

7 would like. 04:43

8 BY MR. JONNA: 04:43

9 Q. Paragraph 34. 04:43

10 A. Is it the one at the -- oh, it would be 04:43

11 the newest one. 04:43

12 MS. PENAN: It should be the one at the 04:43

13 bottom. 04:43

14 A. What number of exhibit is this? 19? 04:43

15 MS. PENAN: Yes. 04:43

16 BY MR. JONNA: 04:43

17 Q. Yes. So I just have a question about 04:43

18 paragraph 34. 04:43

19 A. Give me one second, please. 04:43

20 Q. Okay. 04:43

21 A. Thank you. 04:43

22 I would like a moment just to look at her 04:43

23 qualifications. 04:43

24 Okay. 04:44

25 Q. Okay. Can you take a look at paragraph 34 04:44

1 highlighted here, and let me know when you are 04:44

2 done. 04:44

3 A. Yes. 04:45

4 Q. Okay. So paragraph 31 describes 04:45

5 "Counteracting the effects of a receptor antagonist 04:45

6 by introducing higher doses of the receptor agonist 04:45

7 is not a new idea. One widely used example for 04:45

8 emergency medicine is treatment of carbon monoxide 04:45

9 poisoning. In normal respiration, oxygen in the 04:45

10 lungs binds the hemoglobin molecule in red blood 04:45

11 cells in the lungs, and then is carried to tissues 04:45

12 throughout the body. Carbon monoxide causes 04:45

13 hypoxia (low oxygen) because it binds more tightly 04:45

14 to hemoglobin than oxygen. Its affinity for 04:45

15 hemoglobin is more than 200 times that of oxygen. 04:45

16 But when a patient with carbon monoxide poisoning 04:45

17 arrives in the emergency room, she is quickly 04:45

18 treated with high-flow oxygen therapy. That is 04:45

19 because, even though carbon monoxide binds more 04:45

20 tightly to hemoglobin than oxygen, carbon monoxide 04:45

21 binding to the hemoglobin molecule is reversible. 04:45

22 In other words, oxygen can effectively compete 04:45

23 with, and out-compete, carbon monoxide for 04:45

24 hemoglobin binding sites." 04:45

25 Do you see that? 04:45

1 theory. 04:47

2 BY MR. JONNA: 04:47

3 Q. Okay. Well -- 04:47

4 A. And I agree that in theory, this is just 04:47
5 more support that the theory works. 04:47

6 Does it work specifically for progesterone 04:47
7 and mifepristone? I have no idea. 04:47

8 Q. Well, I was just focusing -- we talked -- 04:47

9 MS. PENAN: I would like to just get an 04:47
10 objection on the record that this is completely 04:47
11 irrelevant, and it's especially problematic because 04:47
12 of how long this deposition is going, becoming 04:47
13 unreasonable. 04:47

14 MR. JONNA: It's -- 04:47

15 MS. PENAN: How long have we been on the 04:47
16 record thus far? 04:47

17 MR. JONNA: Counsel, I just want to 04:47
18 continue with this deposition. I mean, I'm not 04:47
19 sure what the point of your statement is right now. 04:47

20 Q. So as far as the -- the reason why I ask 04:47
21 this is because I asked you previously if you are 04:47
22 aware of any examples where the effects of a 04:47
23 receptor antagonist are counteracted by introducing 04:47
24 higher doses of the receptor agonist. 04:47

25 Would you agree -- 04:47

1 (Reporter interruption for clarification.) 04:47

2 BY MR. JONNA: 04:47

3 Q. I asked this question because I previously 04:48
4 asked if you were aware of any examples where the 04:48
5 effects of a receptor antagonist are counteracted 04:48
6 by introducing higher doses of the receptor 04:48
7 agonist. 04:48

8 And I showed you this, and I want to ask 04:48
9 you: Is this an example of that? 04:48

10 A. When you asked me before, I was -- you 04:48
11 were asking specifically about drugs, and I even 04:48
12 commented I'm not aware of times we give drugs that 04:48
13 are antagonists and then purposely give a drug to 04:48
14 counter it. This is an example that did not cross 04:48
15 my mind, but it is an example. 04:48

16 MR. JONNA: Okay. I'm going to pull up 04:48
17 Exhibit 9 now. 04:48

18 (Deposition Exhibit 9 was marked for 04:48
19 identification by the reporter and is 04:48
20 attached hereto.) 04:48

21 BY MR. JONNA: 04:48

22 Q. Exhibit 9 is a study entitled "Effects of 04:48
23 Depot Medroxyprogesterone Acetate Injection Timing 04:48
24 on Medical Abortion Efficacy and Repeat Pregnancy" 04:48
25 by Elizabeth Raymond, et al., published in 2016. 04:49

1 You've seen this before; is that correct? 04:49

2 A. Yes. 04:49

3 Q. This was a randomized trial? 04:49

4 A. Yes. 04:49

5 Q. So pretty good evidence? 04:49

6 MS. PENAN: Objection. Lacks foundation. 04:49

7 BY MR. JONNA: 04:49

8 Q. What is a depot medroxyprogesterone? 04:49

9 A. It is an injectable progestin 04:49

10 contraceptive. 04:49

11 Q. And it's received by injection every three 04:49

12 months? 04:49

13 A. Yes. 04:49

14 Q. And is it referred to as DMPA? 04:49

15 A. Yes. 04:49

16 Q. And progestin is similar to progesterone? 04:49

17 A. No. This is a much higher dose, much more 04:49

18 potent than progesterone. 04:49

19 Q. Okay. 04:49

20 A. It's a different -- you know, when you 04:49

21 give it as an injectable, it sticks around in the 04:49

22 body longer. It has much higher dosing than 04:49

23 progesterone. Even the micronized progesterone 04:49

24 that's in Prometrium, this is like giving sledge 04:49

25 hammers compared to progesterone. 04:50

1 So the effects of this don't necessarily 04:50
2 translate to what you would see with progesterone. 04:50

3 Q. You agree that sometimes progestins can 04:50
4 behave like progesterone? 04:50

5 A. It has nothing to do -- 04:50

6 MS. PENAN: Objection. Misstates the 04:50
7 witness's testimony. Argumentative. Vague, 04:50
8 ambiguous. 04:50

9 A. It has nothing to do with this study. 04:50

10 BY MR. JONNA: 04:50

11 Q. I'm not asking if it has anything to do 04:50
12 with this study. I'm just asking if you agree that 04:50
13 sometimes progestins can behave like progesterone. 04:50

14 MS. PENAN: Same objections, plus lacks 04:50
15 foundation. Incomplete hypothetical. Calls for 04:50
16 speculation. 04:50

17 A. Yeah, progestins will bind to the 04:50
18 progesterone receptor just like progesterone does, 04:50
19 and it will activate the receptor. So in that 04:50
20 sense, they both can do the same thing at the 04:50
21 progesterone receptor. 04:50

22 BY MR. JONNA: 04:50

23 Q. And so this study wanted to look at the 04:50
24 effect of a DMPA injection on the efficacy of 04:50
25 mifepristone; is that right? 04:50

1 MS. PENAN: Objection. The record speaks 04:50
2 for itself. 04:50
3 A. Not entirely. 04:50
4 BY MR. JONNA: 04:50
5 Q. What -- what -- 04:50
6 A. It looked at when -- if you give a 04:50
7 Depo-Provera at the same time as mifepristone, not 04:50
8 24 or 48 hours later; it's if you give it 04:51
9 simultaneously -- 04:51
10 Q. Okay. 04:51
11 A. -- as mifepristone. 04:51
12 Q. The part in green here says, "In a 04:51
13 multinational randomized trial, we assigned women 04:51
14 undergoing medical abortion who wanted depot 04:51
15 medroxyprogesterone acetate to administration 04:51
16 either with mifepristone (Quickstart group) or 04:51
17 after the abortion (Afterstart group)." 04:51
18 Do you see that? 04:51
19 A. Yes. 04:51
20 Q. So, basically, women who received DMPA at 04:51
21 the same time as mifepristone and then women who 04:51
22 received it after; is that correct? 04:51
23 A. So the experimental group was giving it 04:51
24 immediately -- right -- and they are comparing it 04:51
25 to people who got it after the abortion was 04:51

1 complete. 04:51

2 Q. Okay. In yellow, it says, "Ongoing 04:51
3 pregnancy after initial abortion treatment was 04:51
4 significantly more common in the Quickstart group 04:51
5 (8 out of 220 or 3.6 percent) than in the 04:51
6 Afterstart group (2 out of 226 or .9 percent); the 04:51
7 difference was 2.7 percent." 04:51

8 Do you see that? 04:51

9 A. I do. 04:51

10 Q. And the next page -- 04:52

11 MS. PENAN: What is the question? 04:52

12 MR. JONNA: I said, "Do you see that?" 04:52

13 And he said, "I do." 04:52

14 Q. The next page, it says, "Conclusion: 04:52
15 Depot medroxyprogesterone acetate administration 04:52
16 with mifepristone did not appreciably increase the 04:52
17 risk of surgery after medical abortion but did 04:52
18 increase the risk of ongoing pregnancy." 04:52

19 Do you see that? 04:52

20 A. I do. 04:52

21 Q. Do you -- 04:52

22 MS. PENAN: Objection. The record speaks 04:52
23 for itself. 04:52

24 A. What's your question? 04:52

25 BY MR. JONNA: 04:52

1 Q. Do you agree with that? 04:52

2 A. If you go back up, I can look at the data 04:52

3 again and make sure I do agree. 04:52

4 Thank you. 04:52

5 I do agree with it. 04:52

6 Q. And you are aware that ACOG has endorsed 04:52

7 this conclusion and recommends patients who use 04:52

8 DMPA to be counseled that administration of DMPA on 04:53

9 day 1 of the medication abortion regimen may 04:53

10 increase the risk of ongoing pregnancy; correct? 04:53

11 MS. PENAN: Objection. Lacks foundation. 04:53

12 Assumes facts not in evidence. 04:53

13 A. You would have to show me that 04:53

14 recommendation because I'm not aware that ACOG does 04:53

15 recommend it. I think ACOG says be aware that this 04:53

16 can happen, because when you are providing abortion 04:53

17 services, right, you have to take into account 04:53

18 where the -- how far away the patient is. For some 04:53

19 patients, they may be willing to risk a little 04:53

20 higher rate of failure to get their Depo-Provera. 04:53

21 MR. JONNA: All right. This is 04:53

22 Exhibit 25. 04:53

23 (Deposition Exhibit 25 was marked for 04:53

24 identification by the reporter and is 04:53

25 attached hereto.) 04:53

1 BY MR. JONNA: 04:53

2 Q. I'm going to scroll down to page 16. This 04:53
3 is from ACOG. "Patients who select DMPA for 04:53
4 contraception should be counseled that 04:53
5 administration of DMPA on day 1 of the medication 04:53
6 abortion regimen may increase the risk of ongoing 04:53
7 pregnancy." 04:53

8 Do you see that? 04:53

9 A. I see it. It sounds reasonable. 04:53

10 Q. Do you tell your patients that? 04:53

11 A. We don't -- I don't recommend Depo-Provera 04:53
12 on the same day because of this as well as another 04:54
13 study that shows this, even worse outcomes. 04:54

14 Q. Do you think women should be told that 04:54
15 DMPA increases the risk of ongoing pregnancy? 04:54

16 A. Yes. When you administer a very high dose 04:54
17 of a very potent progestin at the same time as 04:54
18 mifepristone, it's -- it can have those effects. 04:54

19 But I can also administer Nexplanon, which 04:54
20 is a progestin, at the same time, and it doesn't have 04:54
21 an effect. So you can't use a different drug in a 04:54
22 different route and a different timing to correlate 04:54
23 with anything related to what's proposed for APR. 04:54
24 It's scientifically invalid. 04:54

25 Q. Okay. This is the study that you 04:54

1 conducted titled "Depot Medroxyprogesterone Acetate 04:54
2 Impact on Mifepristone Action During Medication 04:54
3 Abortion." 04:55
4 Do you see that? 04:55
5 A. I do. 04:55
6 Q. Okay. It's dated 2025; is that right? 04:55
7 A. It is. 04:55
8 Q. And when I asked about your APR studies 04:55
9 earlier today, you didn't mention your DMPA study; 04:55
10 right? 04:55
11 A. I didn't do the study. This is an 04:55
12 analysis. It's not a clinical trial. So I didn't 04:55
13 think you -- and this was about Depo-Provera. I 04:55
14 didn't -- this isn't a study of APR. It's an 04:55
15 analysis. 04:55
16 So if you meant to -- that this would be 04:55
17 one of those, then, yes, it is. But this isn't a 04:55
18 study of APR; it's a study of Depo-Provera. 04:55
19 Q. Under the "Materials and Methods" in the 04:55
20 first page we have highlighted, it says, "In the 04:55
21 secondary analysis of a retrospective study." 04:55
22 Do you see that? 04:55
23 A. I do. 04:55
24 Q. So you basically took data that had 04:55
25 already been analyzed in a study and then 04:55

1 reanalyzed it? 04:55

2 A. Yes. 04:55

3 Q. And why did you do that? 04:55

4 A. First reason was, this is from the 04:55

5 Carroll, et al., paper. Dr. Boris was one of the 04:55

6 authors on that paper. 04:56

7 They didn't use the standardized way of 04:56

8 reporting abortion outcomes, which are the MARE 04:56

9 guidelines. So there are actually guidelines for 04:56

10 the appropriate way to report abortion efficacy 04:56

11 outcomes. 04:56

12 So the first reason was to report those 04:56

13 outcomes based on gestational duration, not just as 04:56

14 one group. And the second reason, then, was to 04:56

15 calculate if -- whatever the effect was of 04:56

16 Depo-Provera on changing the outcome of the 04:56

17 pregnancy, and then estimate using that data if 04:56

18 Depo-Provera was a perfect, quote/unquote, reversing 04:56

19 agent, what would it have done versus what was seen, 04:56

20 to see what the efficacy rate, quote/unquote -- it's 04:56

21 just a calculation -- would be if this really worked. 04:56

22 And this is, again, with giving a drug 04:56

23 that's very high dose at the same time, which is, 04:56

24 again, different than giving it later, giving 04:56

25 something that's less potent later. 04:56

1 Q. Okay. Right here in green, it says, 04:57
2 "These studies, together, show that simultaneous 04:57
3 use of mifepristone and DMPA, a non-natural highly 04:57
4 potent progestogen, may impact medication abortion 04:57
5 outcomes. This information has been interpreted by 04:57
6 proponents of so-called abortion pill reversal as 04:57
7 an indication that progesterone, a natural 04:57
8 progestogen, should be effective to antagonize 04:57
9 mifepristone actions when taken for abortion." 04:57
10 Do you see that? 04:57
11 A. I do. 04:57
12 And I have to, unfortunately, ask for, 04:57
13 like, a three-minute break. 04:57
14 Q. Okay, sure. 04:57
15 A. I'll be right back. 04:57
16 THE VIDEOGRAPHER: Going off the record at 04:57
17 4:57 p.m. 04:57
18 (Recess taken from 4:57 p.m. to 5:01 p.m.) 04:57
19 THE VIDEOGRAPHER: Back on the record at 05:01
20 5:01 p.m. 05:01
21 BY MR. JONNA: 05:01
22 Q. Okay. Turning back to that quote we just 05:01
23 looked at on page 1 of Exhibit -- jeez, I can't 05:01
24 even tell what number this is anymore. 05:02
25 A. Can I add something about the prior study 05:02

1 that you asked me about? 05:02

2 Q. Sure. 05:02

3 A. So the randomized trial, even though it 05:02

4 was randomized, one of the limitations in 05:02

5 interpreting that data is that the overall failure 05:02

6 rate was very high for a medication abortion study. 05:02

7 It was 11 to 12 percent, which is, you know, much 05:02

8 higher than is typically reported where even -- 05:02

9 especially when efficacy is 92 to 97 percent. 05:02

10 So it shows that that randomized trial may 05:02

11 not be totally reflective of the average population 05:02

12 of people receiving medication abortion, which means 05:02

13 the fact that their overall finding of no change in 05:02

14 interventions, versus the findings about continuing 05:02

15 pregnancy, the continuing pregnancy, to me, is the 05:02

16 more important part, which is what you saw with ACOG. 05:03

17 That's what they took away. It's more about the 05:03

18 continuing pregnancy. 05:03

19 So, anyway, I'm sorry that I -- that didn't 05:03

20 come out when we were talking about it. 05:03

21 Q. Okay. Thank you. 05:03

22 So looking back at your study, which is 05:03

23 Exhibit 13, we read that highlighted section in 05:03

24 green there. 05:03

25 A. Yes. 05:03

1 (Deposition Exhibit 13 was marked for 05:03
2 identification by the reporter and is 05:03
3 attached hereto.) 05:03

4 BY MR. JONNA: 05:03

5 Q. I think the last sentence says, "This 05:03
6 information has been interpreted by proponents of 05:03
7 so-called abortion pill reversal as an indication 05:03
8 that progesterone, a natural progestogen, should be 05:03
9 effective to antagonize mifepristone actions when 05:03
10 taken for abortion." 05:03

11 Do you see that? 05:03

12 A. I do. 05:03

13 Q. So was part of your motivation to do this 05:03
14 study to debunk those APR proponents? 05:03

15 MS. PENAN: Objection. Misstates the 05:03
16 witness's testimony. Argumentative. 05:03

17 A. Part of my motivation was to put some 05:03
18 science behind claims that I hear, like when I'm 05:03
19 doing testimonies, or things like -- you mentioned 05:04
20 Colorado earlier. So it was, again, when people 05:04
21 misinterpret science and say, "Well, this means it 05:04
22 must work." Then, again, it's people who don't 05:04
23 understand statistics or don't understand science 05:04
24 trying to mislead or misinterpret. 05:04

25 So part of this was to ensure there was 05:04

1 some solid science out there to help people 05:04

2 understand what the science really shows. 05:04

3 BY MR. JONNA: 05:04

4 Q. But your analysis shows that DMPA does 05:04

5 increase the risk of ongoing pregnancy; correct? 05:04

6 A. It does. 05:04

7 MS. PENAN: Objection. The record speaks 05:04

8 for itself. 05:04

9 A. Yeah. So that's not my study. It's my 05:04

10 analysis. So, yeah. The study; right. 05:04

11 BY MR. JONNA: 05:04

12 Q. So on page 3, it states, "The ongoing 05:04

13 pregnancy rate in patients who did not receive the 05:04

14 DMPA was 1.4 percent." 05:04

15 Do you see that? 05:04

16 A. I do. 05:04

17 Q. And in the DMPA group, the actual ongoing 05:04

18 pregnancy rate was 6.4 percent. 05:04

19 Do you see that? 05:04

20 A. Let me read the sentence. 05:05

21 Yes. 05:05

22 Q. So DMPA decreases the effectiveness of 05:05

23 mifepristone? 05:05

24 MS. PENAN: Objection. Vague. Ambiguous. 05:05

25 Incomplete hypothetical. 05:05

1 Q. Okay. In the next column, you wrote 05:06
2 "Medroxyprogesterone acetate binds the progesterone 05:06
3 receptor with similar affinity as progesterone 05:06
4 itself." Is that correct? 05:06
5 A. Yes. 05:06
6 Q. What is the mechanism of action by which 05:06
7 DMPA decreases the effectiveness of mifepristone? 05:06
8 A. Because -- 05:06
9 MS. PENAN: Objection. Vague, ambiguous. 05:06
10 A. Well, it's theoretical, but most likely 05:06
11 it's because it's being given at the same time as 05:06
12 mifepristone, so that -- and in a very high dose, 05:06
13 so exactly kind of what you were showing in your 05:06
14 video, but the difference is that if I give a lot 05:07
15 of it at the same time before mifepristone can 05:07
16 bind, it prevents mifepristone from binding. 05:07
17 Notice that there still is not an absolute 05:07
18 effect. It's just diminishing it. But I'm giving 05:07
19 it at the same time, versus if I was to give 05:07
20 something less potent, like oral progesterone or 05:07
21 even some other way of giving it, later after 05:07
22 mifepristone is already bound, that's a 05:07
23 differential scenario. 05:07
24 BY MR. JONNA: 05:07
25 Q. Okay. So -- 05:07

1 A. Right. So that's what we calculated, that 05:07
2 if Depo-Provera really did block the ability of 05:07
3 mifepristone to result in ongoing pregnancy, we 05:07
4 would have seen ongoing pregnancy rates of 05:07
5 25 percent. Instead, we only saw 6 percent, which 05:07
6 means at best when Depo-Provera is given at 05:07
7 exact -- at the same time as mifepristone, the 05:07
8 efficacy or the reversibility rate, whatever you 05:07
9 want to call that, is only about a quarter of the 05:07
10 expected rate. So its effect is only about 05:07
11 25 percent. So it would be really hard. 05:08

12 The argument there, then, is, how can you 05:08
13 claim some efficacy when you give a weaker 05:08
14 progestin at a later time when a very highly potent 05:08
15 progestin given at the same time only has 05:08
16 25 percent of the actual effect? 05:08

17 Q. Okay. So just to make sure we are on the 05:08
18 same page, DMPA is able to decrease the 05:08
19 effectiveness of mifepristone by out-competing 05:08
20 mifepristone, at least to some extent; is that 05:08
21 right? 05:08

22 MS. PENAN: Objection. 05:08

23 A. I -- 05:08

24 MS. PENAN: Incomplete hypothetical. 05:08
25 Misstates the witness's testimony. Asked and 05:08

1 answered. 05:08

2 A. I answered that question before. 05:08

3 I started by saying, yes, but Depo-Provera 05:08

4 is being given at the same time as mifepristone in 05:08

5 a very high dose, which is not the same as what 05:08

6 happens with proposed APR. 05:08

7 So you can't use this data to translate in 05:08

8 any way, shape, or form that giving progesterone 05:09

9 after mifepristone administration has efficacy, 05:09

10 especially in the range that is claimed. 05:09

11 BY MR. JONNA: 05:09

12 Q. But your study does support the ability of 05:09

13 a progestin to -- 05:09

14 A. You're asking the same question. 05:09

15 Q. -- increase the ongoing pregnancy rate -- 05:09

16 let me just -- 05:09

17 A. You are asking the same question again. I 05:09

18 already answered it twice. 05:09

19 Q. Your study supports the ability of a 05:09

20 progestin to increase the ongoing pregnancy rate; 05:09

21 correct? 05:09

22 MS. PENAN: Objection. Asked and 05:09

23 answered. 05:09

24 A. No, it does not, not globally. It shows 05:09

25 the potential for a progestin, given very high 05:09

1 doses at the same time as mifepristone, to have 05:09

2 that impact. That's what it says. 05:09

3 BY MR. JONNA: 05:09

4 Q. Okay. In the same column here, you 05:09

5 explain why you think this doesn't support APR. 05:09

6 You wrote, "And generally, rapid absorption of 05:09

7 significant plasma concentrations achieved over the 05:09

8 first 24 hours after DMPA administration are very 05:10

9 different than using a natural oral progestogen 05:10

10 after some time has elapsed following a 05:10

11 mifepristone administration. As such, none of the 05:10

12 outcomes from either of DMPA medication abortion 05:10

13 studies is supportive of this practice, abortion 05:10

14 pill reversal." 05:10

15 Do you see that? 05:10

16 A. I do. 05:10

17 Q. Okay. So you think the effect of DMPA is 05:10

18 different from progesterone based on absorption 05:10

19 rates and time of ingestion; is that right? 05:10

20 A. I said -- 05:10

21 MS. PENAN: Objection. The record speaks 05:10

22 for itself. 05:10

23 A. Yes. 05:10

24 MS. PENAN: Counsel is testifying. 05:10

25 A. You asked me a question I just said the 05:10

1 answer to three times. 05:10

2 BY MR. JONNA: 05:10

3 Q. And for the absorption rates, that's not 05:10

4 based on any human RCTs; is that correct? 05:10

5 A. The absorption rates of what? 05:10

6 Q. What we just described, that the effect of 05:10

7 DMPA is different from progesterone based on 05:10

8 absorption rates. 05:10

9 That's not based on human RCTs, is it? 05:10

10 MS. PENAN: Objection. Vague, ambiguous. 05:10

11 A. Why would you need a randomized control 05:10

12 trial to look at the absorption rate of 05:10

13 Depo-Provera versus progesterone? They are very 05:11

14 well-established absorptions. 05:11

15 (Speakers talking simultaneously.) 05:11

16 BY MR. JONNA: 05:11

17 Q. Okay. Is it based on modeling? 05:11

18 MS. PENAN: Objection. Vague, ambiguous. 05:11

19 Incomplete hypothetical. 05:11

20 A. So the -- 05:11

21 MS. PENAN: Calls for speculation. 05:11

22 A. There is modeling that's been done based 05:11

23 on human studies. That's how you do human studies 05:11

24 and then you create models. That's just the way 05:11

25 it's done. 05:11

1 BY MR. JONNA: 05:11

2 Q. Okay. So just to -- 05:11

3 A. You do pharmacokinetics. 05:11

4 Q. Right. So same question with the time of 05:11
5 ingestion. 05:11

6 That's also not based on human RCTs, is 05:11
7 it? 05:11

8 MS. PENAN: Objection. Asked and 05:11
9 answered. Vague, ambiguous. Confusing. Lacks 05:11
10 foundation. 05:11

11 A. Yeah. 05:11

12 MS. PENAN: Incomplete hypothetical. 05:11

13 A. I would say it's vague. I don't 05:11
14 understand what you are asking. 05:11

15 BY MR. JONNA: 05:11

16 Q. We just said that you think the effect of 05:11
17 DMPA is different from progesterone based on 05:11
18 absorption rates and time of ingestion, and you 05:11
19 just clarified that for the absorption rates, 05:11
20 that's not based on human RCTs. And I'm asking if 05:11
21 that's the same time with the time of ingestion. 05:12

22 MS. PENAN: Objection. Misstates the 05:12
23 witness's testimony. The record speaks for itself. 05:12
24 Asked and answered. Vague, ambiguous. Incomplete 05:12
25 hypothetical. Lacks foundation. 05:12

1 A. Yeah, I still don't understand your 05:12
2 question. Either ask it in a different way or move 05:12
3 on, because that question makes absolutely no 05:12
4 sense. 05:12

5 BY MR. JONNA: 05:12

6 Q. Okay. Do you think that DMPA is different 05:12
7 from progesterone based on the time of ingestion? 05:12
8 You said you -- you said you answered that question 05:12
9 a few times. 05:12

10 A. Yes. 05:12

11 MS. PENAN: Same objections, plus asked 05:12
12 and answered. 05:12

13 A. Yes. 05:12

14 BY MR. JONNA: 05:12

15 Q. Okay. Is that conclusion based on human 05:12
16 RCTs? 05:12

17 A. You don't need a randomized controlled 05:12
18 trial to know that Depo-Provera in these studies 05:12
19 were given at the same as mifepristone, and 05:12
20 progesterone, when it's given for APR, is not. You 05:12
21 don't need a randomized trial to say that. 05:12

22 Q. Okay. So the answer is no? 05:12

23 MS. PENAN: Objection. Misstates the 05:12
24 witness's testimony. It's argumentative. 05:12

25 A. It's a -- it's a pointless question. You 05:12

1 don't need a randomized trial to show that when APR 05:13
2 or so-called APR is provided, it's not given at the 05:13
3 same time as mifepristone. Patients get it 05:13
4 sometime later. 05:13

5 In these studies, Depo-Provera was 05:13
6 administered at the same time as mifepristone. I 05:13
7 don't need to do a randomized trial to say that's 05:13
8 what happens. Your question makes no sense. 05:13

9 BY MR. JONNA: 05:13

10 Q. Okay. Thank you for that. 05:13

11 Would you give a woman progesterone if she 05:13
12 changed her mind within the first hour? 05:13

13 (Reporter interruption for clarification.) 05:13

14 MS. PENAN: Objection. Asked and 05:13
15 answered. 05:13

16 BY MR. JONNA: 05:13

17 Q. Would you give a woman progesterone if she 05:13
18 changed her mind within the first hour? 05:13

19 A. No. 05:13

20 MS. PENAN: Objection. Asked and 05:13
21 answered. 05:13

22 BY MR. JONNA: 05:13

23 Q. Why not? 05:13

24 A. I have to give something that I think has 05:13
25 benefit. 05:13

1 Q. Okay. On page 3 of your study -- let's 05:13
2 see here -- you wrote "In humans, mifepristone 05:14
3 binds to the progesterone receptor approximately 05:14
4 2.5 times more strongly than progesterone itself." 05:14
5 Do you see that? 05:14
6 A. Yes. 05:14
7 Q. And that's part of the reason why you 05:14
8 think APR -- you don't think APR can work; is that 05:14
9 correct? 05:14
10 MS. PENAN: Objection. Misstates the 05:14
11 witness's testimony. Vague, ambiguous. Lacks 05:14
12 foundation. Incomplete hypothetical. 05:14
13 A. That's why -- that's part of why I believe 05:14
14 if somebody is going to claim it works, you need 05:14
15 human trials. 05:14
16 You have presented a lot of stuff that I 05:14
17 have agreed is theory, but there is also 05:14
18 information that would suggest it doesn't work. So 05:14
19 to make claims that it works, you need human 05:14
20 clinical trials of some sort that actually meet the 05:14
21 criteria for clinical trials to show that it does 05:14
22 work, if you are going to make statements that it 05:14
23 does. 05:15
24 BY MR. JONNA: 05:15
25 Q. Does a -- 05:15

1 A. You are misleading patients. 05:15

2 Q. Does mifepristone sometimes fail to cause 05:15
3 an abortion? 05:15

4 A. Yes. 05:15

5 Q. When it fails to cause an abortion, what's 05:15
6 the reason? 05:15

7 MS. PENAN: Objection. Calls for 05:15
8 speculation. Lacks foundation. Incomplete 05:15
9 hypothetical. Vague, ambiguous. 05:15

10 A. Because life is never perfect that 05:15
11 everything works exactly the same way. 05:15

12 BY MR. JONNA: 05:15

13 Q. The reason for the failure has to be that 05:15
14 the progesterone has been able to successfully 05:15
15 attach to progesterone receptor somehow; isn't that 05:15
16 true? 05:15

17 A. No. 05:15

18 MS. PENAN: Objection. Misstates the 05:15
19 witness's testimony. Counsel is testifying. 05:15
20 Argumentative. 05:15

21 BY MR. JONNA: 05:15

22 Q. Why is that not true? 05:15

23 A. It also has to do with absorption. It 05:15
24 could be that she didn't absorb the mifepristone 05:15
25 well. So it doesn't have to be that her natural 05:15

1 progesterone competitively inhibited mifepristone. 05:15

2 It could be just that she didn't absorb it. 05:15

3 We are also looking at actions at the 05:15
4 target organ, which is at the uterus, and you have no 05:15
5 idea -- and, actually, you could argue that probably 05:15
6 every person has slightly different actions at the 05:15
7 target organ, and there is -- life is a bell curve, 05:16
8 and there is always going to be some people at one 05:16
9 end or the other, and it's not going to work exactly 05:16
10 the same as for everybody. 05:16

11 You can be looking at averages when we do a 05:16
12 lot of studies, but there's -- in real life, there's 05:16
13 always somebody at one end -- far end of the curve 05:16
14 and people at the other end of the far end of the 05:16
15 curve. 05:16

16 MR. JONNA: Okay. Exhibit 110 is an 05:16
17 article entitled "Plasma Concentrations and 05:16
18 Receptor Binding of RU 486 and Its Metabolites in 05:16
19 Humans" from 1987. It's a -- Heikinheimo is listed 05:16
20 as the author here, the first one. 05:16

21 (Deposition Exhibit 110 was marked for 05:16
22 identification by the reporter and is 05:16
23 attached hereto.) 05:16

24 BY MR. JONNA: 05:16

25 Q. Do you recognize this study? 05:16

1 A. I do. 05:16

2 Q. Okay. On the first page, in the summary, 05:16

3 it says, "Using Chromosorb chromatography and HPLC, 05:16

4 we measured the plasma concentrations of RU 486, 05:16

5 and" -- I'm not going to try to pronounce these, 05:16

6 but "RU 42633, RU 42838 [sic], an alcoholic 05:17

7 non-demethylated, RU 42698, metabolites up to 72 05:17

8 hours following oral ingestion of 100 milligrams of 05:17

9 RU 486 by five female volunteers." 05:17

10 Do you see that? 05:17

11 A. Yes, I do. 05:17

12 Q. What is a metabolite? 05:17

13 A. It is the breakdown product of the drug as 05:17

14 it goes through metabolism. 05:17

15 Q. And in this study, Heikinheimo didn't test 05:17

16 anything in the human body. 05:17

17 He tested tissue samples in vitro; is that 05:17

18 correct? 05:17

19 MS. PENAN: Objection. The record speaks 05:17

20 for itself. 05:17

21 A. Yes. 05:17

22 MS. PENAN: Lacks foundation. 05:17

23 A. That's the type of study this was. You 05:17

24 know, in early development of drugs, you do 05:17

25 laboratory studies to figure this stuff out so you 05:17

1 understand what happens to drugs. 05:17

2 BY MR. JONNA: 05:17

3 Q. And he included donations of cells from 05:17

4 different people; is that right? 05:18

5 MS. PENAN: Objection. The record speaks 05:18

6 for itself. 05:18

7 A. I would have to read through the study to 05:18

8 know. I can't say it's right or wrong. 05:18

9 BY MR. JONNA: 05:18

10 Q. On page 2 here in green, it says, "Plasma 05:18

11 samples were collected from five healthy female 05:18

12 volunteers after oral ingestion of 100 milligram RU 05:18

13 486 in mid-luteal phase of their cycle. Uteri were 05:18

14 obtained from patients undergoing hysterectomy for 05:18

15 uterine fibroids." And at the end, it says, 05:18

16 "Placentas were obtained from women undergoing 05:18

17 elective Caesarean section." 05:18

18 Do you see that? 05:18

19 A. I do. 05:18

20 Q. Did any of those cells include the 05:18

21 endometrial tissue of a pregnant woman? 05:18

22 MS. PENAN: Objection. The record speaks 05:18

23 for itself. Calls for speculation. Lacks 05:18

24 foundation. Incomplete hypothetical. 05:18

25 A. Nope. This is just an early study trying 05:18

1 to grasp the metabolism. It doesn't -- it's part 05:18

2 of what would then -- it's just -- yes, it's just 05:18

3 an early study trying to understand metabolism. 05:18

4 BY MR. JONNA: 05:18

5 Q. So why is it in this context that you say 05:19

6 binding affinity matters? 05:19

7 MS. PENAN: Objection. The record speaks 05:19

8 for itself. Calls for speculation. Lacks 05:19

9 foundation. 05:19

10 A. I don't -- your question has no relevance 05:19

11 to this. I don't understand your question. 05:19

12 BY MR. JONNA: 05:19

13 Q. Okay. Binding affinity tests are in 05:19

14 vitro; is that correct? 05:19

15 MS. PENAN: Objection. Calls for 05:19

16 speculation. Lacks foundation. 05:19

17 A. Yeah, go ahead. Keep going. I'm still 05:19

18 not understanding what you are trying to -- 05:19

19 BY MR. JONNA: 05:19

20 Q. Are they -- are binding affinity tests in 05:19

21 vitro? 05:19

22 MS. PENAN: Objection. Calls for 05:19

23 speculation. Lacks foundation. 05:19

24 A. You'd have -- you can't do them in vivo. 05:19

25 You can't do a binding affinity test in a live 05:19

1 human. You just can't. You need the tissue. 05:19

2 BY MR. JONNA: 05:19

3 Q. Do you actually know that the binding 05:19

4 affinity translates into effect in a pregnant 05:19

5 woman? 05:19

6 MS. PENAN: Objection. Misstates the 05:19

7 witness's testimony. Calls for speculation. Lacks 05:19

8 foundation. Incomplete hypothetical. Vague, 05:19

9 ambiguous. Confusing. 05:20

10 A. The binding-affinity studies are done 05:20

11 pretty much the same way. So even when you look at 05:20

12 binding affinity of progesterone, that's done in 05:20

13 the same manner, in human tissue. It's not done in 05:20

14 live human tissue or in pregnant women. It's done 05:20

15 in the same way. 05:20

16 BY MR. JONNA: 05:20

17 Q. Do you have any way of knowing that the 05:20

18 binding affinity actually translates into effect in 05:20

19 a pregnant woman? 05:20

20 MS. PENAN: Same objections. 05:20

21 A. You do clinical trials to see what the 05:20

22 effect is. 05:20

23 BY MR. JONNA: 05:20

24 Q. Okay. Isn't it true that Heikinheimo 05:20

25 emphasized that in vitro assays don't necessarily 05:20

1 reflect reality of how a drug works in the body? 05:20

2 MS. PENAN: Objection. The record speaks 05:20

3 for itself. Calls for speculation. Lacks 05:20

4 foundation. Vague, ambiguous. 05:20

5 A. You can't ask me if something is true if 05:20

6 you haven't shown me the statement. 05:20

7 BY MR. JONNA: 05:20

8 Q. Are you aware of whether that's true? 05:20

9 MS. PENAN: Same objections. 05:20

10 A. I don't know. You'd have to show me the 05:20

11 statement. 05:20

12 BY MR. JONNA: 05:20

13 Q. Okay. Let's look at page 5. It states, 05:20

14 "It must be kept in mind the competitive studies 05:21

15 performed at zero minus plus 4 C in cell-free 05:21

16 conditions do not necessarily correctly reflect the 05:21

17 situation at plus 37 C and in the whole organism." 05:21

18 Do you see that? 05:21

19 A. I do. 05:21

20 Q. So you agree with that statement; correct? 05:21

21 MS. PENAN: Objection. Misstates the 05:21

22 witness's testimony. Argumentative. The record 05:21

23 speaks for itself. Lacks foundation. 05:21

24 A. I agree with the statement you just read. 05:21

25 BY MR. JONNA: 05:21

1 Q. And this statement here is that "In 05:21
2 general, the receptor binding ability of a steroid 05:21
3 gives an indication, although not proof, of its 05:21
4 biological activity." 05:21

5 You would agree with that as well? 05:21

6 MS. PENAN: Same objections. 05:21

7 A. That's what I've been saying all along, is 05:21
8 that you have to do clinical trials. These are all 05:21
9 part of understanding the theory behind the drug, 05:21
10 but without clinical trials, you don't know if it 05:21
11 all translates. 05:21

12 So if it translates in your clinical 05:22
13 trials, then it's more likely to be true, but until 05:22
14 you do a human clinical trial, you don't know if your 05:22
15 theories are based -- are supported. 05:22

16 BY MR. JONNA: 05:22

17 Q. Okay. And the blue highlight states, "The 05:22
18 concentrations of the mono-demethylated metabolite 05:22
19 (RU 42633) and hydroxylated alcoholic metabolite 05:22
20 (RU 42698) also reached peak concentrations within 05:22
21 1 to 2 hours, suggesting rapid first-pass 05:22
22 metabolism of RU 486." 05:22

23 Do you see that? 05:22

24 A. I do. 05:22

25 Q. So that means it is actually the 05:22

1 metabolites of mifepristone that are doing much of 05:22

2 the work almost immediately; would you agree? 05:22

3 MS. PENAN: Objection. Counsel is 05:22

4 testifying. Argumentative. 05:22

5 A. Not necessarily. 05:22

6 MS. PENAN: Lacks foundation. 05:22

7 A. Not necessarily, because it depends how 05:22

8 much of the drug is metabolized. In other words, 05:22

9 there is still bioavailability after you go through 05:23

10 metabolism. 05:23

11 You can find metabolites. There are 05:23

12 certain drugs like -- norgestimate is a progestin 05:23

13 where the vast majority of is metabolized in the 05:23

14 first-pass metabolism, and very little of the 05:23

15 norgestimate actually gets through first-pass 05:23

16 metabolism. And norgestimate, in and of itself, is 05:23

17 not active. It's the metabolites that are active. 05:23

18 Mifepristone, on the other hand, does 05:23

19 produce metabolites, but in and of it- -- the 05:23

20 majority of it still gets through first-pass 05:23

21 metabolism. So it's not all metabolized. And in and 05:23

22 of itself, it's still very active. 05:23

23 So what you just said is not true. 05:23

24 BY MR. JONNA: 05:23

25 Q. Do you recall Heikinheimo estimating the 05:23

1 binding affinity of those metabolites? 05:23

2 MS. PENAN: Objection. The document 05:23

3 speaks for itself. Lacks foundation. Calls for 05:23

4 speculation. Incomplete hypothetical. Vague, 05:23

5 ambiguous. 05:23

6 A. If you want to show me, go ahead and show 05:23

7 me. 05:23

8 BY MR. JONNA: 05:23

9 Q. Yeah. It's right here, Table 1. 05:23

10 A. Uh-huh. 05:23

11 Q. So it shows that progesterone has a lower 05:23

12 binding affinity than RU 486; is that right? 05:24

13 A. Correct. 05:24

14 Q. But it's twice as strong as RU 42633; 05:24

15 correct? 05:24

16 A. It's true. 05:24

17 Q. And it's about three times as strong as 05:24

18 RU 42698; correct? 05:24

19 A. That's correct. 05:24

20 Q. And about four times as strong as 05:24

21 RU 42848; is that right? 05:24

22 A. What is four times as strong as? 05:24

23 Q. RU -- 05:24

24 A. RU 486 is about ten times stronger than 05:24

25 42848, and progesterone is about five times 05:24

1 stronger than 42848. 05:24

2 So if mifepristone was metabolized 05:24

3 completely in first-pass metabolism and none of it 05:24

4 remained available, then progesterone would be -- 05:24

5 have a stronger affinity than all of the metabolites, 05:24

6 but that's not the case. 05:24

7 You get metabolites quickly; however, the 05:24

8 majority of the drug is still available. 05:24

9 Q. But mifepristone does have a rapid 05:25

10 first-pass metabolism, according to Heikinheimo, 05:25

11 doesn't it? 05:25

12 MS. PENAN: Objection. The record speaks 05:25

13 for itself. Calls for speculation. Lacks 05:25

14 foundation. Incomplete hypothetical. 05:25

15 A. You are asking a "but" that doesn't 05:25

16 matter. I've already answered that. 05:25

17 It goes through -- it does, based on this, 05:25

18 as you point out, have rapid first-pass metabolism, 05:25

19 but that doesn't mean the drug is completely 05:25

20 metabolized. It means it creates some metabolites, 05:25

21 but the majority of the drug, in its normal form as 05:25

22 mifepristone, gets through the metabolism and still 05:25

23 is active in the body. 05:25

24 That's what it shows in the graph right 05:25

25 next to the table you're showing, that you can see 05:25

1 a significant amount of RU 486 is still present, 05:25
2 and that one of the metabolites is more, but the 05:25
3 other metabolites are significantly less. 05:25

4 So what you would -- what you are trying to 05:25
5 get at, which is false, is that RU 486 is completely 05:25
6 metabolized to just its metabolites and it's not 05:25
7 around anymore, which is not the case. 05:25

8 BY MR. JONNA: 05:25

9 Q. And -- 05:26

10 A. And I want to ask -- as long as you are 05:26
11 showing me this, then let's be complete. 05:26

12 Show me what ORG-2058 is, if you go up to 05:26
13 the methods, because I want to answer that. If you 05:26
14 are going to show this to me, then you've got to do 05:26
15 the whole thing. 05:26

16 There you go. There are chemicals. You've 05:26
17 got to go down. 05:26

18 MS. PENAN: And, Dr. Creinin, this is also 05:26
19 in the chat if you needed to look at the whole 05:26
20 thing. 05:26

21 A. There it is. Stop. Let's see. 05:26

22 What was it? It came from Organon, 05:26
23 progesterone, and cortisol. 05:26

24 So I don't know what the ORG-2058 is, so I 05:26
25 can't comment on it, but there's something that has 05:26

1 even more affinity than that. 05:26

2 So given what it says about it being a -- 05:26

3 having more a -- more Pregnin, my guess is it's 05:26

4 potentially a type of progestin, but I don't know. 05:27

5 If it's a type of progestin, then it lends 05:27

6 even more that synthetic progestins have way more 05:27

7 binding affinity than progesterone. 05:27

8 But anyway, all right. Thank you. 05:27

9 MR. JONNA: Okay. Let's go off the record 05:27

10 for just a minute to talk about the schedule. 05:27

11 THE VIDEOGRAPHER: Going off the record at 05:27

12 5:27 p.m. 05:27

13 (Recess taken from 5:27 p.m. to 5:30 p.m.) 05:27

14 THE VIDEOGRAPHER: Back on the record at 05:30

15 5:30 p.m. 05:30

16 MR. JONNA: Okay. Dr. Creinin, I knew we 05:30

17 had a hard stop today at 5:30. It's 5:30. I'm 05:30

18 going to honor that. 05:30

19 I'm not done. I still have 21 or 22 pages 05:30

20 left of my outline. You know, I probably have 05:30

21 several more hours to go through, but I'm willing 05:30

22 to see if we can condense that and work on an 05:30

23 arrangement to bring you back for less than a full 05:30

24 day. 05:30

25 So we will confer with counsel and see 05:31

1 what we can work out, and if we need to talk to the 05:31
2 judge about it, we will do that. 05:31

3 So I'm not going to make a speech. 05:31
4 Everyone's positions have been stated, so... 05:31

5 MS. PENAN: And I would just like to say 05:31
6 on the record that this is the first that we are 05:31
7 hearing about this. We have been on the record 05:31
8 today -- or we've been here today for nine hours, 05:31
9 which we started early to give counsel more time to 05:31
10 take this deposition. 05:31

11 We agreed to push back this -- past the 05:31
12 close of discovery in order to allow for your 05:31
13 scheduling conflicts, Counsel, for you to take the 05:31
14 deposition of Dr. Creinin. 05:31

15 And he's very busy, and scheduling is -- we 05:31
16 will confer, but it could be a hardship, and you have 05:31
17 not presented any reason to us why this needs to be 05:31
18 such an unreasonably long deposition. 05:31

19 So we will meet and confer, but that is -- 05:31

20 MR. JONNA: All right. Since you made a 05:31
21 speech, I'm just going to say a couple things 05:31
22 really quick. I, obviously -- 05:32

23 MS. PENAN: It wasn't a speech. 05:32

24 MR. JONNA: It should be obvious to 05:32
25 everyone why Dr. Creinin is an important witness in 05:32

1 this case. 05:32

2 We received a number of records from 05:32
3 UC Davis late in the case. That significantly 05:32
4 added to the amount of material we needed to cover 05:32
5 with Dr. Creinin. The importance and relevance of 05:32
6 that study has already been expressed multiple 05:32
7 times, and so that definitely necessitated more 05:32
8 time on the record. 05:32

9 In addition, we never represented this was 05:32
10 going to be a one-day deposition. I simply said I 05:32
11 won't be able to finish at 5:00, and you offered to 05:32
12 make it a little earlier, so we did. We took it a 05:32
13 little earlier. 05:32

14 And it's been noticed as a deposition to 05:32
15 continue from day to day. We have that right under 05:32
16 the Code of Civil Procedure. 05:32

17 And so we are going to -- again, we hope we 05:32
18 can work with you on that, but I don't want to waste 05:32
19 a lot of your time, Dr. Creinin. I have another at 05:32
20 least half a day with you. 05:32

21 So that's where it's at. 05:32

22 We can conclude the deposition now -- or, 05:32
23 you know, for now. 05:33

24 THE VIDEOGRAPHER: Before we just go off 05:33
25 the record, might I get the transcript and video 05:33

1 orders? 05:33

2 Ms. Penan, would you be requesting -- 05:33

3 MS. PENAN: Yes. 05:33

4 THE VIDEOGRAPHER: Both or just the 05:33
5 transcript? 05:33

6 MS. PENAN: Just the transcript, please. 05:33

7 THE VIDEOGRAPHER: Thank you. 05:33

8 And, Mr. Jonna, would you like your video 05:33
9 copy to be synced? 05:33

10 MR. JONNA: Yes, please. 05:33

11 THE VIDEOGRAPHER: Thank you. 05:33

12 MS. PENAN: And I would like to get an 05:33
13 expedited rough transcript. 05:33

14 And when would we be able to get that? 05:33

15 THE VIDEOGRAPHER: We can tell you that 05:33
16 off the record. 05:33

17 MS. PENAN: Okay. Thank you. 05:33

18 THE VIDEOGRAPHER: No problem. 05:33

19 This concludes the video deposition of 05:33
20 Mitchell Creinin. Going off the record at 05:33

21 5:33 p.m. 05:33

22 (Proceedings adjourned at 5:33 p.m.) 05:33

23

24

25

1 STATE OF CALIFORNIA)
2 COUNTY OF LOS ANGELES) ss.

3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

I, GRACE CHUNG, RMR, CRR, CSR No. 6246, a Certified Shorthand Reporter in and for the County of Los Angeles, the State of California, do hereby certify:

That, prior to being examined, the witness named in the foregoing deposition was by me duly sworn to testify the truth, the whole truth, and nothing but the truth;

That said deposition was taken down by me in shorthand at the time and place therein named, and thereafter reduced to typewriting by computer-aided transcription under my direction;

That the dismantling, unsealing, or unbinding of the original transcript will render the reporter's certificate null and void.

I further certify that I am not interested in the event of the action.

In witness whereof, I have hereunto subscribed my name.

Dated October 14, 2025

GRACE CHUNG, CSR NO. 6246
RMR, CRR, CLR