

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@thomasmorsociety.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.*

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(F): DEPOSITIONS**

Judge: Hon. Patrick McKinney  
Dept: 23

Action filed: September 21, 2023

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| <b>APPENDIX OF EVIDENCE<br/>VOLUME V(F): DEPOSITIONS</b> |   |
|--|---|
| <b>No.</b>   | <b>DESCRIPTION:</b>   |
| <b>H.</b>  | Relevant portions of the deposition of the Attorney General’s medical expert, Mitchell Creinin, M.D., volume 2, taken in this action on November 6, 2025.   |
|  | <b>Ex. 2:</b> Expert Declaration of Mitchell Creinin, M.D. (Amended).   |
|  | <b>Ex. 4:</b> Mitchell D. Creinin & Melissa J. Chen, <i>Mifepristone antagonization requires real studies to evaluate safety and efficacy</i> , 100(6) Contraception 427 (2019).  |
|  | <b>Ex. 14:</b> Mitchell D. Creinin, et al., <i>Mifepristone Antagonization with Progesterone to Prevent Medical Abortion</i> , 135(1) Obstet. & Gynecol. 158 (2020).  |
|  | <b>Ex. 15:</b> Appendix 1 to Mitchell D. Creinin, et al., <i>Mifepristone Antagonization with Progesterone to Prevent Medical Abortion</i> , 135(1) Obstet. & Gynecol. 158 (2020).  |
|  | <b>Ex. 16:</b> Protocol for A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion, NCT03774745 (version 10, July 18, 2019).   |
|  | <b>Ex. 24:</b> Amanda Marcotte, <i>The Newest Crisis Pregnancy Offer: “Abortion Reversals,”</i> Slate (Dec. 8, 2014).   |
|  | <b>Ex. 61:</b> Emergency Room Records for Subject Number MR-08 from Mitchell D. Creinin, et al., <i>Mifepristone Antagonization with Progesterone to Prevent Medical Abortion</i> , 135(1) Obstet. & Gynecol. 158 (2020). |
|  | <b>Ex. 67:</b> Email Chain between Mitchell Creinin and Mifepristone Stakeholders (Dec. 4-5, 2019)  |
|  | <b>Ex. 68:</b> Email Chain between Mitchell Creinin and Mifepristone Stakeholders (Dec. 5-9, 2019)  |
|  | <b>Ex. 69:</b> Talking Points for Mifepristone Stakeholders   |
| <b>I.</b>  | Relevant portions of the deposition of the UC Davis Study Co-Author Melissa J. Chen, M.D., volume 2, taken in this action on November 20, 2025.   |
| <b>J.</b>  | Relevant portions of the deposition of Christa Brown, R.N, taken in this action on June 17, 2025.   |

**EXHIBIT H**

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SUPERIOR COURT OF THE STATE OF CALIFORNIA  
COUNTY OF ALAMEDA

THE PEOPLE OF THE STATE OF )  
CALIFORNIA, )  
 )  
Plaintiff, )  
 ) No. 23CV044940  
vs. )  
 )  
HEARTBEAT INTERNATIONAL, )  
INC., and REALOPTIONS, )  
INC., )  
 )  
Defendants. )  
\_\_\_\_\_ )

REMOTE DEPOSITION OF  
MITCHELL D. CREININ, M.D.  
VOLUME II  
PAGES 435 - 585

DATE: Thursday, November 6, 2025  
TIME: 12:59 p.m. - 4:08 p.m.  
ALL PARTIES APPEARING REMOTELY VIA ZOOM

REPORTED BY: Taylor Maldonado, RPR, CSR No. 14482  
JOB NO. J13632231

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VIRTUAL APPEARANCES

FOR THE PLAINTIFF:

CALIFORNIA DEPARTMENT OF JUSTICE  
BY: Hayley Frances Penan, Deputy Attorney General  
Lauren Zweier, Deputy Attorney General  
Erica Connolly, Deputy Attorney General  
1300 I Street, Suite 125  
Sacramento, California 94244  
(916) 210-7785  
hayley.penan@doj.ca.gov

THOMAS MORE SOCIETY  
Peter Breen, pro hac vice  
Chris Galiardo, Attorney at Law  
309 West Washington Street, Suite 1250  
Chicago, IL 60606  
(312) 782-1680  
pbreen@thomasmoresociety.org

FOR THE DEFENDANTS, HEARTBEAT INTERNATIONAL  
AND REALOPTIONS:

LIMANDRI & JONNA LLP  
BY: Paul M. Jonna, Attorney at Law  
P.O. Box 9120  
Rancho Santa Fe, California 92067  
(858) 759-9930  
pjonna@limandri.com

FOR THE DEFENDANTS, REALOPTIONS:

MESSNER REEVES LLP  
BY: Ethan Reimers, Attorney at Law  
611 Anton Boulevard, Suite 450  
Costa Mesa, California 92626  
(949) 335-7916  
ereimers@messner.com

ALSO PRESENT:

Adriel Olvera - Videographer  
Christa Brown  
Danielle White, Attorney at law  
Rebecca Oakley  
Paul Sluis  
Wendy Harrison  
Gillian Hannahs

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INDEX OF EXAMINATIONS

|                               | PAGE |
|-------------------------------|------|
| EXAMINATION BY ATTORNEY JONNA | 442  |
| EXAMINATION BY ATTORNEY PENAN | 578  |

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INDEX OF EXHIBITS

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

| NUMBER     | DESCRIPTION   | PAGE |
|------------|---|------|
| Exhibit 2  | Declaration   | 444  |
| Exhibit 4  | 2019 Creinin Commentary   | 453  |
| Exhibit 8  | The pharmacokinetics of<br>mifepristone in humans<br>reveals insights into<br>differential mechanisms of<br>antiprogestin action        | 468  |
| Exhibit 16 | Protocol and SAP: A<br>Randomized Trial of<br>Mifepristone Antagonization<br>with High-Dose Progesterone<br>to Prevent Medical Abortion | 472  |
| Exhibit 24 | The Newest Crisis Pregnancy<br>Center Offer: Abortion<br>Reversals  | 548  |
| Exhibit 30 | Drug approval package   | 474  |
| Exhibit 55 | Early medical abortion with<br>mifepristone and other<br>agents: Overview and<br>protocol recommendations                               | 463  |
| Exhibit 71 | University of San Francisco<br>Website  | 544  |

|    |             |                               |     |
|----|-------------|-------------------------------|-----|
| 1  | Exhibit 72  | Animal Rule Information       | 478 |
| 2  | Exhibit 77  | Progesterone and              | 498 |
| 3  |             | mifepristone: A pilot         |     |
| 4  |             | prospective single-arm        |     |
| 5  |             | clinical trial for women who  |     |
| 6  |             | have changed their mind after |     |
| 7  |             | commencing medical abortion   |     |
| 8  | Exhibit 93  | Permission to Take Part in a  | 489 |
| 9  |             | Human Research Study          |     |
| 10 | Exhibit 106 | Obstetrics and Gynecology     | 531 |
| 11 |             | UC Davis Health               |     |
| 12 | Exhibit 107 | Use of Negative Control       | 534 |
| 13 |             | Exposure Analysis to Evaluate |     |
| 14 |             | Confounding: An Example of    |     |
| 15 |             | Acetaminophen Exposure and    |     |
| 16 |             | Attention-Deficit/            |     |
| 17 |             | Hyperactivity Disorder in     |     |
| 18 |             | Nurses Health Study II        |     |
| 19 | Exhibit 108 | ACOG - Is it safe to take     | 537 |
| 20 |             | acetaminophen during          |     |
| 21 |             | pregnancy?                    |     |
| 22 | Exhibit 113 | Family planning, population   | 549 |
| 23 |             | growth, and the environment   |     |
| 24 | Exhibit 118 | Stifani Review                | 445 |
| 25 | Exhibit 119 | Rating Evidence in Medical    | 516 |

1  
2  
3  
4  
5  
6  
7  
8  
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10  
11  
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|             |  |     |
|-------------|--|-----|
|             | Literature   |     |
| Exhibit 120 | A Case Series Detailing the<br>Successful Reversal of the<br>Effects of Mifepristone Using<br>Progesterone | 470 |
| Exhibit 121 | Complaint  | 514 |
| Exhibit 122 | Email (Not provided.)  | 571 |

---oOo---

1 PROCEEDINGS

2 ---oOo---

3 THE VIDEOGRAPHER: We are now on the record. 12:59:01PM  
4 Today's date is November 6th, 2025, and the time is 12:59:19PM  
5 12:59 p.m. Pacific time. This is the video deposition, 12:59:27PM  
6 volume number two, of Mitchell D. Creinin, MD, in the 12:59:36PM  
7 matter of The People of the State of California versus 12:59:43PM  
8 Heartbeat International, Inc., et al., filed in the 12:59:48PM  
9 Superior Court of the State of California, County of 12:59:53PM  
10 Alameda, the case number 23CV044940. 12:59:55PM

11 Today's deposition is taking place via web 01:00:08PM  
12 video conference with all participants attending 01:00:11PM  
13 remotely. My name is Adriel Olvera. I'm the 01:00:14PM  
14 videographer representing the Sullivan Group of Court 01:00:22PM  
15 Reporters. 01:00:22PM

16 Counsel on the conference, please identify 01:00:28PM  
17 yourselves and state whom you represent beginning with 01:00:28PM  
18 the questioning attorney. 01:00:29PM

19 ATTORNEY JONNA: Good afternoon. Paul Jonna 01:00:31PM  
20 on behalf of defendants Heartbeat International and 01:00:33PM  
21 RealOptions. 01:00:37PM

22 ATTORNEY PENAN: Good afternoon. Hayley Penan 01:00:38PM  
23 representing the plaintiff People of the State of 01:00:41PM  
24 California. 01:00:43PM

25 ATTORNEY REIMERS: Good afternoon. This is 01:00:46PM

1 Ethan Reimers, co-counsel for RealOptions. 01:00:47PM

2 ATTORNEY CONNOLLY: Good afternoon. Erica 01:00:56PM

3 Connolly, co-counsel for the People of the State of 01:00:59PM

4 California. 01:01:00PM

5 THE VIDEOGRAPHER: Anyone else? Thank you. 01:01:02PM

6 The court reporter will now introduce herself 01:01:05PM

7 and swear in the witness. 01:01:07PM

8 THE COURT REPORTER: Hello. My name is Taylor 01:01:14PM

9 Maldonado. My California CSR number is 14482. Will the 01:01:14PM

10 witness please raise their right hand to be sworn. 01:01:45PM

11 -oOo-

12 MITCHELL D. CREININ, M.D.,

13 having been duly sworn to tell the truth, the whole  
14 truth, and nothing but the truth, testified as follows:

15 -oOo-

16 EXAMINATION 01:01:46PM

17 BY ATTORNEY JONNA: 01:01:46PM

18 Q. Good afternoon, Dr. Creinin. Again, my name 01:01:46PM

19 is Paul Jonna. I represent the defendants. It's good 01:01:50PM

20 to see you again. 01:01:53PM

21 I have already gone through the admonitions of 01:01:54PM

22 a -- of a deposition. 01:01:56PM

23 Do you recall those from our prior deposition? 01:01:57PM

24 A. I do. 01:02:02PM

25 Q. Do you need me to go over any of those today? 01:02:02PM

|    |    |  |            |
|----|----|--|------------|
| 1  | A. | Nope.  | 01:02:05PM |
| 2  | Q. | Okay.  | 01:02:05PM |
| 3  |    | You understand you're still under oath;                  | 01:02:06PM |
| 4  |    | correct?   | 01:02:08PM |
| 5  | A. | I do.  | 01:02:08PM |
| 6  | Q. | What did you do to prepare for your deposition           | 01:02:09PM |
| 7  |    | today, sir?  | 01:02:13PM |
| 8  | A. | Since the last deposition?                               | 01:02:14PM |
| 9  | Q. | Yes.   | 01:02:17PM |
| 10 | A. | Nothing.   | 01:02:18PM |
| 11 | Q. | Did you speak to anyone to prepare for your              | 01:02:19PM |
| 12 |    | deposition today?  | 01:02:22PM |
| 13 | A. | No.  | 01:02:23PM |
| 14 | Q. | Including counsel for the attorney general's             | 01:02:23PM |
| 15 |    | office?  | 01:02:27PM |
| 16 | A. | We did not interact in relation to preparing             | 01:02:27PM |
| 17 |    | for the deposition.                                      | 01:02:31PM |
| 18 | Q. | Did you review any documents to prepare for              | 01:02:32PM |
| 19 |    | this deposition today?                                   | 01:02:37PM |
| 20 | A. | Nothing since the last deposition.                       | 01:02:38PM |
| 21 | Q. | Okay.  | 01:02:41PM |
| 22 |    | It's our goal to conclude the deposition                 | 01:02:43PM |
| 23 |    | within the time allotted of three and a half hours, so   | 01:02:47PM |
| 24 |    | I'll just ask you to please listen carefully to my       | 01:02:50PM |
| 25 |    | question, answer my question specifically, and if I have | 01:02:54PM |

1 follow-up questions, I'll let you know. 01:02:57PM  
2 Does that make sense? 01:02:58PM  
3 A. Yes. 01:02:59PM  
4 Q. All right. 01:03:00PM  
5 I'm going to just jump right back in to 01:03:01PM  
6 Exhibit 2, which is your declaration in this litigation. 01:03:04PM  
7 I'm going to pull that up. Let's see here. Sorry. 01:03:07PM  
8 (Exhibit 2 was marked.) 01:03:07PM  
9 BY ATTORNEY JONNA: 01:03:07PM  
10 Q. Do you see your admitted expert declaration? 01:03:20PM  
11 A. I do not. It just popped up. 01:03:25PM  
12 Q. Do you see it now? 01:03:27PM  
13 A. I do. 01:03:28PM  
14 Q. Okay. All right. 01:03:29PM  
15 I'm going to take to you Page 25, 01:03:31PM  
16 paragraph 47. 01:03:36PM  
17 Does that show up on your screen? 01:03:36PM  
18 A. It does. 01:03:38PM  
19 Q. All right. 01:03:39PM  
20 You state here that, "The authors of the 01:03:41PM  
21 Stifani systematic review concluded that the ongoing 01:03:45PM  
22 pregnancy rate in individuals treated with progesterone 01:03:49PM  
23 after mifepristone is not significantly higher compared 01:03:54PM  
24 to that of individuals receiving mifepristone alone." 01:03:59PM  
25 Do you see that? 01:04:03PM

|    |  |            |
|----|--|------------|
| 1  | A. I do.   | 01:04:04PM |
| 2  | Q. I'm sorry?  | 01:04:07PM |
| 3  | A. I do.   | 01:04:07PM |
| 4  | Q. Okay.   | 01:04:08PM |
| 5  | I'm going to show you Exhibit 118, which is            | 01:04:09PM |
| 6  | the Stifani review.                                    | 01:04:11PM |
| 7  | (Exhibit 118 was marked.)                              | 01:04:11PM |
| 8  | BY ATTORNEY JONNA:                                     | 01:04:11PM |
| 9  | Q. Do you recognize this document?                     | 01:04:13PM |
| 10 | A. I do.   | 01:04:15PM |
| 11 | Q. And I'm going to turn to Table 3.                   | 01:04:15PM |
| 12 | Do you see Table 3?                                    | 01:04:36PM |
| 13 | A. I do.   | 01:04:39PM |
| 14 | Q. And what does Table 3 represent?                    | 01:04:39PM |
| 15 | A. The --  | 01:04:43PM |
| 16 | ATTORNEY PENAN: Objection. Vague.                      | 01:04:43PM |
| 17 | Ambiguous.   | 01:04:45PM |
| 18 | THE WITNESS: The --                                    | 01:04:45PM |
| 19 | ATTORNEY PENAN: Lacks foundation.                      | 01:04:46PM |
| 20 | THE WITNESS: The evidence that they reviewed           | 01:04:49PM |
| 21 | looking at the proportion of pregnant individuals with | 01:04:52PM |
| 22 | continuing pregnancies after taking mifepristone at    | 01:04:56PM |
| 23 | seven weeks gestation or less and at seven to          | 01:04:58PM |
| 24 | eight weeks gestation with or without progesterone.    | 01:05:02PM |
| 25 | ///  |            |

1 BY ATTORNEY JONNA:

01:05:07PM

2 Q. Okay.

01:05:07PM

3 And just focusing on the -- the left column  
4 there, seven weeks of pregnancy or less. And we see  
5 those rates highlighted in yellow, percentage ongoing  
6 pregnancies. And then we see for mifepristone  
7 200 milligrams plus progesterone, it indicates  
8 42 percent; and then mifepristone 200 milligrams alone  
9 indicates 22 percent.

01:05:07PM

01:05:10PM

01:05:13PM

01:05:18PM

01:05:21PM

01:05:26PM

01:05:26PM

10 Do you see that?

01:05:26PM

11 A. I do.

01:05:27PM

12 Q. And you would agree that 42 percent ongoing  
13 pregnancy is significantly higher than 22 percent;  
14 correct?

01:05:28PM

01:05:32PM

01:05:35PM

15 A. You just asked me --

01:05:37PM

16 ATTORNEY PENAN: Objection. Incomplete  
17 hypothetical. Misstates the witness's testimony.  
18 Vague. Ambiguous. Lacks foundation.

01:05:37PM

01:05:40PM

01:05:43PM

19 THE WITNESS: I do not agree. You can ask me  
20 my opinion, but don't tell me I agree or disagree.

01:05:44PM

01:05:47PM

21 BY ATTORNEY JONNA:

01:05:47PM

22 Q. Well, I'm --

01:05:47PM

23 A. We went through this before and it took a lot  
24 of extra time, which is partly why we're here again.

01:05:51PM

01:05:53PM

25 That data does not support, and I do not agree, that the

01:05:57PM

1 42 percent with its confidence interval is greater than 01:06:00PM  
2 the 22 percent with its confidence interval, as the 01:06:05PM  
3 authors of the papers explain, and why those conclusions 01:06:11PM  
4 were derived in the paper. 01:06:13PM

5 Q. You understand that Dr. Stifani did not use 01:06:15PM  
6 Fisher's exact test to determine if there was a 01:06:19PM  
7 statistically significant difference between the two 01:06:22PM  
8 groups; correct? 01:06:25PM

9 ATTORNEY PENAN: Objection. Calls for 01:06:26PM  
10 speculation. Lacks foundation. Vague. Ambiguous. 01:06:27PM  
11 Misstates the witness's testimony. Argumentative. 01:06:29PM

12 THE WITNESS: If you want to take me up to the 01:06:32PM  
13 statistics section, we can spend our time going through 01:06:33PM  
14 the statistics section if you're going to ask me 01:06:37PM  
15 specific questions about the statistics. 01:06:41PM

16 BY ATTORNEY JONNA: 01:06:41PM

17 Q. Well, let me just ask you, as you sit here 01:06:43PM  
18 today, are you aware as to whether or not Dr. Stifani 01:06:46PM  
19 used Fisher's exact test to determine if there was a 01:06:50PM  
20 statistically significant difference between the two 01:06:52PM  
21 different groups? 01:06:55PM

22 A. You're showing me the paper -- 01:06:55PM

23 ATTORNEY PENAN: Objection. Compound. 01:06:58PM

24 THE WITNESS: If you want to discuss the 01:07:00PM  
25 statistics part, then show me the statistics part of the 01:07:01PM

1 paper. 01:07:05PM

2 BY ATTORNEY JONNA: 01:07:05PM

3 Q. I -- I will show you what I intend to show 01:07:05PM

4 you, Doctor. I'm asking you, as you sit here today -- 01:07:09PM

5 A. Then I'm not going to be able to answer the 01:07:09PM

6 question unless you show me the statistics -- 01:07:10PM

7 Q. Okay. 01:07:10PM

8 A. -- parts of the paper. 01:07:11PM

9 Q. So I -- 01:07:11PM

10 A. I can't -- I can't answer your question. 01:07:19PM

11 THE COURT REPORTER: I'm sorry. I -- I can't 01:07:19PM

12 take down two people at the same time. 01:07:19PM

13 ATTORNEY JONNA: Sure. 01:07:19PM

14 BY ATTORNEY JONNA: 01:07:19PM

15 Q. So if your answer is you don't know without 01:07:20PM

16 looking at the paper, that's fine. I'm just asking if 01:07:20PM

17 you know, as you sit here today, whether or not that 01:07:23PM

18 test was -- was conducted. 01:07:27PM

19 A. I don't know off the top of my head the exact 01:07:28PM

20 statistics that were used. If you want me to answer the 01:07:31PM

21 question, then you need to show me that part of the 01:07:34PM

22 paper. 01:07:37PM

23 Q. You do agree, though, that the Fisher's exact 01:07:38PM

24 test is an important way to understand if the difference 01:07:43PM

25 is statistically significant; correct? 01:07:45PM

1           ATTORNEY PENAN:  Objection.  Misstates the           01:07:48PM  
2 witness's testimony.  Argumentative.  Lacks foundation.           01:07:49PM  
3 Incomplete hypothetical.           01:07:52PM

4           THE WITNESS:  In a systematic review, it's not           01:07:54PM  
5 always the correct test.  If you want to show me the           01:07:56PM  
6 statistics part of the paper, I'm happy to go through           01:07:59PM  
7 that with you.           01:08:03PM

8 BY ATTORNEY JONNA:           01:08:03PM

9           Q.  Okay.  And you, in fact, used the Fisher's           01:08:04PM  
10 exact test to show that the results of your 2020 study           01:08:07PM  
11 were not statistically significant; isn't that true?           01:08:10PM

12           A.  I was doing a --           01:08:13PM

13           ATTORNEY PENAN:  Objection.  Lacks foundation.           01:08:15PM

14           THE WITNESS:  I was doing a prospective           01:08:16PM  
15 randomized trial.  This paper is a systematic review.           01:08:18PM  
16 Statistics are not always done the same way and are not           01:08:22PM  
17 appropriate to be done the same way with different types           01:08:25PM  
18 of studies.           01:08:28PM

19 BY ATTORNEY JONNA:           01:08:29PM

20           Q.  Okay.           01:08:29PM

21           So just --           01:08:30PM

22           A.  So if you want to ask me specifics about the           01:08:30PM  
23 statistics of this systematic review, then show me the           01:08:33PM  
24 statistics section.           01:08:37PM

25           Q.  Okay.  Dr. Creinin, I'm specifically asking           01:08:39PM

1 you what I'm asking you, so you cannot tell me what to  
2 ask you.

3 My question to you, sir, is very simply:  
4 Didn't you use the Fisher's exact test to show the  
5 results of your 2020 study were not statistically  
6 significant? And I believe your answer, among many  
7 other things, was yes, you did.

8 Is that true?

9 ATTORNEY PENAN: Objection. Misstates the  
10 witness's testimony. Lacks foundation. Argumentative.  
11 Harassing.

12 THE WITNESS: I --

13 BY ATTORNEY JONNA:

14 Q. If you want --

15 A. -- already answered the question.

16 What is your next question?

17 Q. Okay.

18 So let's just focus on my questions so we can  
19 get through today's deposition. If you want to provide  
20 a speech as to why you don't think the question is  
21 relevant, you can do that at trial. Today I'm asking --

22 ATTORNEY PENAN: Objection. Counsel is  
23 testifying.

24 BY ATTORNEY JONNA:

25 Q. So -- okay.

01:08:42PM

01:08:45PM

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01:09:24PM

01:09:26PM

01:09:27PM

01:09:27PM

1                   Turning back to Exhibit 118, Table 3.                   01:09:28PM  
2                   Assuming that doing a Fisher's exact test for the data           01:09:33PM  
3                   in Table 3, for the first column that we're looking at           01:09:38PM  
4                   here of seven weeks pregnancy or less, showed a P value           01:09:41PM  
5                   of .0355 for these two groups, you would agree that           01:09:44PM  
6                   would show a statistically significant difference;           01:09:48PM  
7                   correct?           01:09:54PM  
8                   ATTORNEY PENAN: Objection. Misstates the           01:09:54PM  
9                   witness's testimony. Argumentative. Calls for           01:09:56PM  
10                  speculation. Lacks foundation. Incomplete           01:09:57PM  
11                  hypothetical.           01:09:57PM  
12                  THE WITNESS: I can't speculate on the           01:09:58PM  
13                  statistics if I --           01:10:00PM  
14                  ATTORNEY PENAN: Vague. Ambiguous.           01:10:02PM  
15                  THE WITNESS: -- haven't done them myself. So           01:10:04PM  
16                  I can't answer a question -- it's asking, you know,           01:10:05PM  
17                  if -- if any test that's done with a P less than .05 and           01:10:08PM  
18                  it's the appropriate test for that type of evaluation,           01:10:14PM  
19                  that would be a significant value, but it has to be the           01:10:18PM  
20                  appropriate test.           01:10:24PM  
21                  BY ATTORNEY JONNA:           01:10:25PM  
22                  Q. Do you have any opinion as to whether that           01:10:26PM  
23                  would be an appropriate test for this?           01:10:28PM  
24                  A. In a systematic review, that's not always the           01:10:29PM  
25                  appropriate test. So I would need to go through the           01:10:32PM

1 statistics section to see what they did and why they did 01:10:35PM  
2 it, which would explain the appropriate testing. 01:10:39PM

3 Q. Do you have an opinion -- kind of switching 01:10:43PM  
4 subjects here. Do you have an opinion, as you sit here 01:10:47PM  
5 today, as to the continuing pregnancy rate for women 01:10:49PM  
6 after taking 200 milligrams of mifepristone alone? 01:10:54PM

7 A. That's a vague question. Can you repeat what 01:11:01PM  
8 you're trying to ask? 01:11:03PM

9 Q. Do you have an opinion, as you sit here today, 01:11:04PM  
10 as to the continuing pregnancy rate for women after 01:11:08PM  
11 taking 200 milligrams of mifepristone alone? 01:11:12PM

12 A. My opinion is that there is incredibly low 01:11:16PM  
13 amounts of data, and the studies that were done to look 01:11:19PM  
14 at that -- that outcome that you're asking the question 01:11:23PM  
15 about were not done with the intention of finding out 01:11:27PM  
16 what the continuing pregnancy rate would be. Those 01:11:31PM  
17 studies were done as part of trying to understand if 01:11:34PM  
18 mifepristone alone would be -- be effective for 01:11:39PM  
19 medication abortion by itself, primarily in women under 01:11:43PM  
20 seven weeks gestation. Very small studies with wide 01:11:47PM  
21 confidence intervals. So I don't know what the exact 01:11:52PM  
22 rate is. I know that a lot of people have tried to 01:11:55PM  
23 approximate it. I think what's important is to take 01:11:58PM  
24 away the limitations of the data. There's one study 01:12:02PM  
25 with approximately 30 people in it that has looked at 01:12:05PM

1 this. That's the Maria study, which, again, was not for 01:12:09PM  
2 that intention. But one small study can't provide you 01:12:14PM  
3 with confirmation of an outcome. 01:12:18PM

4 Q. Okay. I'm going to -- 01:12:21PM

5 A. One of the important things with a systematic 01:12:23PM  
6 review is that the data quality is also considered, 01:12:27PM  
7 given that the data quality for the majority of this is 01:12:30PM  
8 really core, as outlined by the authors, since you're 01:12:33PM  
9 asking about this paper. The relative weight of the 01:12:37PM  
10 data, no matter what the statistics, is considered very 01:12:41PM  
11 limited. 01:12:45PM

12 Q. Okay. 01:12:46PM

13 Turning to Exhibit 4, which is your 2019 01:12:47PM  
14 commentary article, you recognize this; correct? 01:12:53PM

15 A. Uh-huh. I do. 01:12:56PM

16 (Exhibit 4 was marked.) 01:12:59PM

17 Q. On Pages 1 and 2, you have a section titled 01:12:59PM  
18 "Trying to understand efficacy of mifepristone-only 01:13:02PM  
19 treatment." 01:13:05PM

20 Do you see that? 01:13:06PM

21 A. I do. 01:13:07PM

22 Q. And in this section, you discuss trying to 01:13:07PM  
23 figure out how often a pregnancy continues when a woman 01:13:11PM  
24 only takes mifepristone; is that correct? 01:13:15PM

25 A. It is a paraphrase of the section, but yes, 01:13:21PM

1 that's part of it, yes. 01:13:24PM

2 Q. And you discuss the two systematic reviews, 01:13:25PM

3 one by Grossman in 2016 and one by Davenport in 2017; 01:13:30PM

4 correct? 01:13:36PM

5 A. I do. 01:13:36PM

6 Q. And you say that both of these systematic 01:13:37PM

7 reviews have inherent problems; is that right? 01:13:39PM

8 A. I do. 01:13:42PM

9 Q. Does that mean -- 01:13:43PM

10 ATTORNEY PENAN: Objection. The record speaks 01:13:43PM

11 for itself. 01:13:46PM

12 BY ATTORNEY JONNA: 01:13:46PM

13 Q. Does that mean that neither of these reviews 01:13:47PM

14 are reliable? 01:13:48PM

15 ATTORNEY PENAN: Objection. Vague. 01:13:50PM

16 Ambiguous. 01:13:51PM

17 THE WITNESS: In my opinion, both of them have 01:13:51PM

18 issues. And I think anybody who reads a paper needs to 01:13:55PM

19 understand what the limitations are, and I think they 01:13:58PM

20 both do have problems. 01:14:02PM

21 BY ATTORNEY JONNA: 01:14:05PM

22 Q. What's your opinion as to the extent that you 01:14:05PM

23 can rely on the Grossman review despite its limitations? 01:14:08PM

24 ATTORNEY PENAN: Objection. Vague. 01:14:15PM

25 Ambiguous. Lacks foundation. Incomplete hypothetical. 01:14:16PM

1 Confusing.

01:14:19PM

2 THE WITNESS: The issues with the Grossman  
3 review are that they inc- -- they included data about  
4 the -- that -- about half the studies really looked at  
5 the appropriate outcome, and about half did not. So the  
6 data is even more limited. And one of the things about  
7 the Grossman review, it says, "The data is very limited.  
8 This is what's out there." I think it is even more  
9 limited than Grossman led on to state. In other words,  
10 they included some things that I probably would not have  
11 included.

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12 BY ATTORNEY JONNA:

01:15:00PM

13 Q. So what, if anything, can the Grossman review  
14 be useful for?

01:15:01PM

01:15:03PM

15 A. Showing there's an incredibly limited amount  
16 of information available about the impact of  
17 mifepristone by itself on continuing pregnancy rates.

01:15:05PM

01:15:07PM

01:15:12PM

18 Q. Anything else?

01:15:15PM

19 A. That's what I take from it at this point.

01:15:16PM

20 Q. Okay.

01:15:23PM

21 So along with what you just said, in this  
22 paper here you say that -- for Grossman, you said you  
23 looked at 11 studies, but "only six of the included  
24 studies clearly define the outcome of contin-" --  
25 "continuing pregnancy as a viable pregnancy. The other

01:15:24PM

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1 five studies appear to consider retained nonviable 01:15:44PM  
2 gestations in the outcome of continuing pregnancies." 01:15:47PM  
3 Do you see that? 01:15:50PM  
4 A. I do. 01:15:51PM  
5 Q. And this is the problem with the review that 01:15:52PM  
6 you were just discussing; is that right? 01:15:55PM  
7 A. It's what I just said, yes. 01:15:56PM  
8 ATTORNEY PENAN: Objection. Asked and 01:15:58PM  
9 answered. 01:15:59PM  
10 BY ATTORNEY JONNA: 01:15:59PM  
11 Q. On the next page in green, you state that 01:16:00PM  
12 Davenport included 23 non-peer-reviewed reports. 01:16:04PM  
13 Do you see that? 01:16:10PM  
14 A. I do. 01:16:11PM  
15 Q. And in this article, you -- you performed your 01:16:14PM  
16 own review; is that right? 01:16:17PM  
17 ATTORNEY PENAN: Objection. Vague. 01:16:20PM  
18 Ambiguous. 01:16:21PM  
19 THE WITNESS: You're -- 01:16:21PM  
20 ATTORNEY PENAN: Incomplete hypothetical. 01:16:22PM  
21 THE WITNESS: We try to look at the data 01:16:24PM  
22 from -- that both of the reviews included to try to fish 01:16:29PM  
23 out what were the reasonable ones to potentially 01:16:32PM  
24 include. 01:16:36PM  
25 ///

1 BY ATTORNEY JONNA:

01:16:36PM

2 Q. And you limited your analysis to seven  
3 studies, as reflected in Table 1; is that correct?

01:16:36PM

01:16:38PM

4 A. Correct.

01:16:41PM

5 Q. And looking at the ones I've highlighted,  
6 which are the single-dose studies -- now -- you see  
7 those highlights?

01:16:42PM

01:16:46PM

01:16:52PM

8 A. I do.

01:16:53PM

9 Q. So assuming that if you add up the -- both the  
10 600-milligram studies and the 200-milligram study for  
11 Maria, you get 36 continuing viable pregnancies out of  
12 450 total pregnancies. I did the math.

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01:17:02PM

01:17:06PM

01:17:12PM

13 Do you see that?

01:17:15PM

14 A. I can assume your math is correct, that --

01:17:16PM

15 Q. Okay.

01:17:16PM

16 A. -- that that's the yellow highlighted things  
17 there, that that's how they add up, then that's how they  
18 would add up.

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01:17:20PM

01:17:23PM

19 Q. Assuming that's correct and -- and that you  
20 get a survival rate of 8 percent, what does that tell  
21 you?

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01:17:26PM

01:17:29PM

22 ATTORNEY PENAN: Objection. Lacks foundation.  
23 Vague. Ambiguous.

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01:17:33PM

24 THE WITNESS: Well, all of these pregnancies  
25 were less than -- 49 days or less. The followup was

01:17:34PM

01:17:35PM

1 primarily seven days or longer. There was one study 01:17:41PM  
2 that went to 14 days. So it tells me that in a rela- -- 01:17:45PM  
3 in a short interval of primarily one week, but one to 01:17:49PM  
4 two weeks, in very early pregnancies that these authors 01:17:53PM  
5 found, primarily with 600-milligram dose, that there was 01:18:01PM  
6 a low continuing pregnancy rate. There were only 30 01:18:06PM  
7 people treated with the 200-milligram dose and followed 01:18:11PM  
8 for only one week. So it doesn't tell me what a 01:18:15PM  
9 continuing pregnancy would be beyond one week. And even 01:18:17PM  
10 in my study, we felt that a two-week interval would be 01:18:20PM  
11 necessary to even be a -- the beginning of a surrogate 01:18:24PM  
12 marker. So continuing development at one week doesn't 01:18:29PM  
13 tell me anything about overall continuing pregnancy rate 01:18:33PM  
14 in the long run, because that's not what these studies 01:18:36PM  
15 were designed to do. 01:18:39PM

16 BY ATTORNEY JONNA: 01:18:41PM

17 Q. Is it your opinion that you cannot compare the 01:18:41PM  
18 600-milligram doses to the 200-milligram doses? 01:18:44PM

19 A. For the purpose of trying to understand 01:18:49PM  
20 long-term continuing pregnancy, no, you cannot. 01:18:52PM

21 Q. And why is that? 01:18:54PM

22 A. Because they're different doses. 01:18:55PM

23 Q. Okay. 01:18:57PM

24 So in this same paper, you have a section 01:19:05PM  
25 here, Laws Based on No Science. 01:19:14PM

1 Do you see that? 01:19:16PM

2 A. I do. 01:19:16PM

3 Q. And the first sentence says, "Unfortunately, 01:19:17PM

4 in the absence of rigorous evaluation, some lawmakers 01:19:20PM

5 are using case reports as medical gospel in passing law 01:19:25PM

6 stipulating mifepristone antagon- -- antagonization is 01:19:26PM

7 fact." 01:19:31PM

8 Do you see that? 01:19:31PM

9 A. I do. 01:19:32PM

10 Q. Would you agree that the State of California 01:19:32PM

11 was using your incomplete, nonstatistically significant 01:19:34PM

12 study as medical gospel in this case? 01:19:38PM

13 A. I do not. 01:19:41PM

14 ATTORNEY PENAN: Objection. Calls for 01:19:41PM

15 speculation. Lacks foundation. Incomplete 01:19:42PM

16 hypothetical. Vague. Ambiguous. 01:19:43PM

17 BY ATTORNEY JONNA: 01:19:46PM

18 Q. What's the reason you don't -- you think not? 01:19:46PM

19 A. My understanding of the case against your -- 01:19:48PM

20 there are -- the case against Heartbeat International 01:19:53PM

21 has nothing to do with my study. It has to do with 01:19:57PM

22 whether they can advertise a rate of efficacy that has 01:20:00PM

23 not been proven in any medical literature and advertised 01:20:05PM

24 that something is an effective treatment when there 01:20:10PM

25 lacks any studies to prove that it's effective. Doesn't 01:20:14PM

1 say they can't provide it. It just say -- the lawsuit  
2 is about how well that -- if -- that it's effective.  
3 There's nothing about my study that is the basis of the  
4 lawsuit, as far as I can understand.

5 Q. Okay.

6 So your understanding is that your study is  
7 irrelevant to the lawsuit.

8 A. You would have --

9 ATTORNEY PENAN: Objection. Misstates the  
10 witness's testimony. Lacks foundation. Calls for a  
11 legal conclusion.

12 THE WITNESS: You're the person who has been  
13 asking about my study. You haven't asked me one  
14 question about the lawsuit.

15 BY ATTORNEY JONNA:

16 Q. And I'm asking you if it's your understanding  
17 as an expert in this lawsuit that your study's  
18 irrelevant to the attorney general's claims here?

19 A. Irrelevant is something you would have to --

20 ATTORNEY PENAN: Same objection.

21 THE WITNESS: Irrelevant is something you  
22 would have to ask the attorney general. It's not the  
23 cornerstone of the case. And if you want to read me  
24 back your exact question, I'll answer it again.

25 ///

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|    |  |            |
|----|--|------------|
| 1  | BY ATTORNEY JONNA:                                       | 01:21:04PM |
| 2  | Q. Okay.   | 01:21:04PM |
| 3  | Let's --   | 01:21:04PM |
| 4  | A. So you --   | 01:21:04PM |
| 5  | Q. -- look at this --                                    | 01:21:06PM |
| 6  | A. You asked me the question about this part of          | 01:21:07PM |
| 7  | the top under number 3. If the court reporter can read   | 01:21:09PM |
| 8  | back the exact question so I can make sure I have --     | 01:21:11PM |
| 9  | answer it after we've gone through this little bit, I    | 01:21:14PM |
| 10 | would appreciate it.                                     | 01:21:17PM |
| 11 | Q. I asked if you would agree that the State of          | 01:21:18PM |
| 12 | California is using your incomplete, nonstatistically    | 01:21:20PM |
| 13 | significant study as medical gospel in this case?        | 01:21:24PM |
| 14 | A. First of all --                                       | 01:21:28PM |
| 15 | ATTORNEY PENAN: Same objections.                         | 01:21:28PM |
| 16 | THE WITNESS: Yeah. Okay. The answer is                   | 01:21:31PM |
| 17 | "no," because your statement is not factual in any way,  | 01:21:32PM |
| 18 | shape, or form, about how you characterize my study or   | 01:21:35PM |
| 19 | my understanding of the case.                            | 01:21:39PM |
| 20 | BY ATTORNEY JONNA:                                       | 01:21:40PM |
| 21 | Q. Could you complete your study?                        | 01:21:40PM |
| 22 | A. I completed the study because it needed to be         | 01:21:42PM |
| 23 | stopped. That's a reason for calling a -- that --        | 01:21:46PM |
| 24 | that's a reason for calling a study completed. A safety  | 01:21:49PM |
| 25 | event that requires to you stop a study means it's done. | 01:21:54PM |

1 Right? Did I reach the targeted sample size? No. But 01:21:58PM  
2 we completed the study based on stopping rules or the 01:22:02PM  
3 need to stop it for safety indications. 01:22:06PM

4 Q. And you also determined that the -- that the 01:22:09PM  
5 results were not statistically significant; isn't that 01:22:13PM  
6 true? 01:22:16PM

7 A. You're asking a -- 01:22:16PM

8 ATTORNEY PENAN: Objection. Lacks foundation. 01:22:16PM  
9 Incomplete hypothetical. 01:22:19PM

10 THE WITNESS: You're asking a scientifically 01:22:20PM  
11 impossible question. If you set a sample size for a 01:22:23PM  
12 study and you can't achieve that sample size, then you 01:22:26PM  
13 can't appropriately do statistics because you don't have 01:22:29PM  
14 enough people to do the statistics. 01:22:33PM

15 BY ATTORNEY JONNA: 01:22:35PM

16 Q. Okay. 01:22:36PM

17 Looking at the quote here of -- in the same 01:22:36PM  
18 paragraph, it says, "The judge's decision acknowledged 01:22:43PM  
19 that compelling counseling based on the State's 01:22:45PM  
20 viewpoint without credible scientific evidence that 01:22:48PM  
21 treatment was effective interfered with healthcare 01:22:51PM  
22 provider's first amendment rights." 01:22:54PM

23 Do you see that? 01:22:56PM

24 A. I do. 01:22:57PM

25 Q. Do you ever find it ironic that you're now 01:22:57PM

1 helping the State compel doctors to make counseling  
2 decisions based on the State's viewpoint without  
3 credible scientific evidence in violation of the other  
4 side's first amendment rights?

5 ATTORNEY PENAN: Objection. Misstates the  
6 witness's testimony. Lacks foundation. Incomplete  
7 hypothetical. Argumentative. Harassing. Assumes facts  
8 not in evidence. And calls for a legal conclusion.

9 THE WITNESS: My understanding of the case is  
10 it's not compelling them not to offer treatment or not  
11 compelling them to talk in their own office about  
12 something that's off label. My understanding of the  
13 case is that they're saying they can't advertise, which  
14 is false advertisement, of a proven efficacy rate that  
15 has never been proven or advertise that a treatment is  
16 effective when that has never been proven to be  
17 effective.

18 BY ATTORNEY JONNA:

19 Q. I'm going to pull up Exhibit 55, which is a  
20 publication by the National Abortion Federation entitled  
21 "Early medical abortion with mifepristone and other  
22 agents: Overview and protocol recommendations." And  
23 it's dated 2002.

24 (Exhibit 55 was marked.)

25 ///

1 BY ATTORNEY JONNA: 01:24:13PM

2 Q. And it says here that Section 1 was written by 01:24:14PM

3 you, Dr. Mitchell Creinin, and the title here is "Early 01:24:19PM

4 Medical Abortion With Mifepristone and Other Agents." 01:24:26PM

5 Do you see that? 01:24:27PM

6 A. I do. 01:24:27PM

7 Q. Do you recognize this document? 01:24:28PM

8 A. I do. 01:24:30PM

9 Q. If we go to Page 11 of the PDF, 01:24:31PM

10 Section 2(a)(b), which is titled "Pharmacokinetics." 01:24:42PM

11 And then in your discussion about mifepristone, you 01:24:51PM

12 wrote in the yellow highlight there, "Pharmacokinetics 01:24:52PM

13 are similar for daily doses of 100 milligrams or more." 01:24:55PM

14 Do you see that? 01:24:59PM

15 A. I do. 01:24:59PM

16 Q. And you continued in subpart (a), "Over the 01:24:59PM

17 first 72 hours, total serum concentration is similar for 01:25:03PM

18 women administered 200 milligrams or 600 milligrams in a 01:25:08PM

19 single dose." 01:25:08PM

20 Do you see that? 01:25:14PM

21 A. I do. 01:25:14PM

22 Q. And in subpart (b), it says, "Similar peak 01:25:15PM

23 serum concentrations of 2.0 to 2.5 microgram per mL are 01:25:17PM

24 found in women given 100 milligrams, 400 milligrams, 01:25:23PM

25 600 milligrams, and 800 milligrams of mifepristone." 01:25:25PM

1 Do you see that? 01:25:29PM

2 A. I do. 01:25:30PM

3 Q. Do you still agree with this? 01:25:31PM

4 A. I do. 01:25:33PM

5 Q. Okay. 01:25:33PM

6 Scrolling down to Page 19, Conclusions From 01:25:37PM

7 the Literature. You wrote, "As would be expected based 01:25:42PM

8 on mifepristone pharmacokinetics, regimens using 01:25:46PM

9 mifepristone 200 milligrams demonstrate efficacy equal 01:25:50PM

10 to regimens using mifepristone 600 milligrams." 01:25:50PM

11 Do you see that? 01:25:55PM

12 A. I do. 01:25:56PM

13 Q. So it seems like you could compare 01:25:57PM

14 continuing -- continuing pregnancy rates with 01:26:00PM

15 200 milligrams and 600-milligram doses of mifepristone; 01:26:03PM

16 right? 01:26:06PM

17 A. You are incorrect. 01:26:06PM

18 ATTORNEY PENAN: Objection. Lacks foundation. 01:26:08PM

19 Incomplete hypothetical. Vague. Ambiguous. Assumes 01:26:09PM

20 facts not in evidence. 01:26:13PM

21 THE WITNESS: I'll read my -- my response. 01:26:14PM

22 You are incorrect. 01:26:17PM

23 BY ATTORNEY JONNA: 01:26:18PM

24 Q. And why is that? 01:26:18PM

25 A. So pharmacokinetic studies are just part of 01:26:19PM

1 pharmacology when it comes to treatments. There's 01:26:24PM  
2 pharmacokinetics and pharmacodynamics. Pharmacokinetics 01:26:24PM  
3 are just a basis for developing a theory when you're 01:26:31PM  
4 discussing equivalence of doses. So even what it says 01:26:31PM  
5 there, which is "as would be expected based on the 01:26:35PM  
6 pharmacokinetics," you do see equal efficacy, meaning 01:26:35PM  
7 when you do a clinical trial, the outcomes do come out 01:26:42PM  
8 the same. However, it's not a guarantee, and that's why 01:26:44PM  
9 you need to do the clinical trial. So because the data 01:26:48PM  
10 supports that a lower dose than 600 milligrams has 01:26:51PM  
11 similar pharmacokinetics, it would be reasonable to do 01:26:54PM  
12 the studies to show that you do get the same clinical 01:26:56PM  
13 efficacy. And in fact, there were large randomized 01:27:00PM  
14 prospective studies performed by the World Health 01:27:03PM  
15 Organization to show that a 200-milligram and 01:27:08PM  
16 600-milligram dose, when followed by a prostaglandin 01:27:08PM  
17 analog resulted in the same outcomes, which prove that 01:27:14PM  
18 the pharmacokinetics did translate to the same clinical 01:27:15PM  
19 outcome. However, there is also pharmacodynamics, which 01:27:20PM  
20 is what happens at the level of the -- where the drug is 01:27:24PM  
21 working. Right? So because pharmacokinetics cannot 01:27:28PM  
22 necessarily predict exactly what's happening at the 01:27:32PM  
23 organ or at the end-organ level. So there's no way for 01:27:34PM  
24 me to know that 200 milligrams and 600 milligrams are 01:27:38PM  
25 the same when you're looking for a different effect, 01:27:42PM

1 which is whether or not the pregnancy will continue. 01:27:45PM

2 Q. Okay. 01:27:47PM

3 Turning to Page 11, you wrote on the green 01:27:47PM  
4 highlight there that, "Mifepristone binds to the 01:27:55PM  
5 progesterone receptor with an affinity equal to 01:27:58PM  
6 progesterone." 01:28:04PM

7 Do you see that? 01:28:05PM

8 A. I do. 01:28:05PM

9 Q. Do you still agree with that? 01:28:06PM

10 A. I do not. 01:28:07PM

11 Q. And why not? 01:28:08PM

12 A. Because the better data, as I look at it 01:28:09PM  
13 today, is that it has a stronger binding than 01:28:12PM  
14 progesterone. So that was written 23 years ago. 01:28:16PM

15 Q. And what -- 01:28:19PM

16 A. Actually, it was written more than 23 years 01:28:20PM  
17 ago. It was published 23 years ago. 01:28:23PM

18 Q. And what data are you referring to? 01:28:27PM

19 A. I'm sorry. Do you want to -- can you ask the 01:28:29PM  
20 complete question? 01:28:31PM

21 Q. You said that there's better data that causes 01:28:32PM  
22 you not to agree with this statement anymore, so I'm 01:28:35PM  
23 asking you what data that is. 01:28:36PM

24 A. I'm drawing a blank. We talked about it last 01:28:37PM  
25 time. I'm happy to look through my statement to get the 01:28:40PM

1 exact author's data. I want to say it's Heikinheimo,  
2 but I would have to double-check.

3 Q. Okay. All right.

4 I'm going to pull up Exhibit 8.

5 (Exhibit 8 was marked.)

6 BY ATTORNEY JONNA:

7 Q. This is a -- a different study by Heikinheimo.  
8 We looked at one last time. This one's titled "The  
9 pharmacokinetics of mifepristone in humans reveals  
10 insights into differential mechanisms of antiprogestin  
11 action." It's dated 2003.

12 Have you seen this study before?

13 A. I believe I have.

14 Q. On Page 2 in highlight there, it says, "Peak  
15 concentrations rise according to the dose of  
16 mifepristone within the dose range of 2 to  
17 25 milligrams; however, at higher doses of 100 to  
18 800 milligrams, values do not differ significantly, most  
19 likely as a result of saturation of the serum binding  
20 capacities of mifepristone."

21 Do you see that?

22 A. I do.

23 Q. Do you agree with that statement?

24 A. I have no reason to argue --

25 ATTORNEY PENAN: Objection. Lacks foundation.

01:28:44PM

01:28:50PM

01:28:51PM

01:28:53PM

01:29:00PM

01:29:02PM

01:29:02PM

01:29:07PM

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01:29:15PM

01:29:17PM

01:29:19PM

01:29:21PM

01:29:26PM

01:29:30PM

01:29:32PM

01:29:37PM

01:29:41PM

01:29:41PM

01:29:41PM

01:29:41PM

01:29:41PM

01:29:49PM

01:29:49PM

1 Incomplete hypothetical. 01:29:50PM

2 THE WITNESS: I have no reason to argue with 01:29:52PM

3 their findings. 01:29:54PM

4 BY ATTORNEY JONNA: 01:29:55PM

5 Q. Okay. 01:29:57PM

6 On Page 1 in yellow it says, "The results of 01:29:57PM

7 preliminary studies have suggested that even a 01:30:04PM

8 100-milligram dose of mifepristone might be equally 01:30:07PM

9 effective." 01:30:09PM

10 Do you see that? 01:30:10PM

11 A. I do. 01:30:11PM

12 Q. And you have no reason to dispute that 01:30:12PM

13 conclusion either? 01:30:15PM

14 A. I think it's unclear -- 01:30:16PM

15 ATTORNEY PENAN: Same objections. 01:30:17PM

16 THE WITNESS: I think it's unclear the way you 01:30:18PM

17 stated it, because earlier in that same paragraph it 01:30:20PM

18 talks about "effective" as being part of a regimen with 01:30:24PM

19 coadministration of a prostaglandin; right? So when 01:30:30PM

20 they're talking about efficacy here, they're talking 01:30:34PM

21 about a lower dose being effective when combined with a 01:30:37PM

22 prostaglandin -- or, I would say, prostaglandin 01:30:43PM

23 analog -- for its use for abortion. So it doesn't mean 01:30:46PM

24 that that dose -- that different doses don't have 01:30:49PM

25 different effects when you were looking at mifepristone 01:30:53PM

1 alone and the potential for continuing pregnancy. 01:30:54PM

2 BY ATTORNEY JONNA: 01:30:57PM

3 Q. I'm going to pull up Exhibit 120. This is the 01:30:57PM

4 2018 Delgado study, which I presume you've seen before; 01:31:04PM

5 correct? 01:31:09PM

6 (Exhibit 120 was marked.) 01:31:09PM

7 THE WITNESS: Yes. 01:31:09PM

8 BY ATTORNEY JONNA: 01:31:09PM

9 Q. I'm going to -- 01:31:09PM

10 A. Although it's not a study. 01:31:10PM

11 Q. Okay. What is it, then? 01:31:12PM

12 A. It's a report, at best. 01:31:13PM

13 Q. Okay. 01:31:16PM

14 I'm going to turn your attention to Page 8 of 01:31:17PM

15 the PDF, Table 2. 01:31:21PM

16 A. Uh-huh. 01:31:23PM

17 Q. Which shows the reversal percentage stratified 01:31:24PM

18 by the gestational age. 01:31:31PM

19 Do you see that? 01:31:34PM

20 A. I do. 01:31:35PM

21 Q. And as you would expect, it's lowest at five 01:31:35PM

22 weeks, 25 percent reversal rate. 01:31:38PM

23 Do you see that? 01:31:41PM

24 A. I do. 01:31:41PM

25 Q. And it's the highest at nine weeks, 77 percent 01:31:42PM

1 reversal rate. 01:31:45PM

2 Do you see that? 01:31:47PM

3 A. That's what they report in that table. 01:31:47PM

4 ATTORNEY PENAN: Objection. The document 01:31:50PM  
5 speaks for itself. 01:31:51PM

6 BY ATTORNEY JONNA: 01:31:51PM

7 Q. And the studies that you've cited in your 01:31:54PM  
8 commentary article, they mostly include women up to 01:31:54PM  
9 seven weeks gestation; is that correct? 01:31:55PM

10 A. Yes. 01:31:58PM

11 Q. So if we limit the 2018 Delgado study to women 01:31:58PM  
12 of seven weeks or less, then we have 291 women total -- 01:32:04PM  
13 you know, 102 plus 113 plus 76 -- and 121 reversals -- 01:32:11PM  
14 50 plus 52 plus 19 -- for a 41.5 percent reversal rate. 01:32:18PM

15 Do you see that? 01:32:25PM

16 A. I see what you're referring to. 01:32:26PM

17 Q. Which is better than the 8 percent rate that 01:32:28PM  
18 we calculated today from your commentary article; is 01:32:30PM  
19 that -- is that right? 01:32:34PM

20 A. Well, if you're -- 01:32:35PM

21 ATTORNEY PENAN: Objection. Lacks foundation. 01:32:35PM  
22 Incomplete hypothetical. Calls for speculation. Vague. 01:32:37PM  
23 Ambiguous. 01:32:40PM

24 THE WITNESS: If you're -- 01:32:40PM

25 ATTORNEY PENAN: The document speaks for 01:32:41PM

1       itself. 01:32:42PM

2               THE WITNESS:  If you're asking if 41 percent 01:32:43PM

3       is higher than 8 percent, which I believe are the 01:32:45PM

4       numbers you quoted, yes, 41 percent is a number that's 01:32:48PM

5       higher than 8 percent. 01:32:48PM

6       BY ATTORNEY JONNA: 01:32:51PM

7               Q.  Okay. 01:32:51PM

8               Okay.  I'm going to pull up Exhibit 16, which 01:32:51PM

9       is the protocol for your mifepristone reversal study. 01:32:58PM

10              (Exhibit 16 was marked.) 01:32:58PM

11       BY ATTORNEY JONNA: 01:32:58PM

12              Q.  And on Page 6 in blue it says, "The primary 01:33:01PM

13       endpoint continuing pregnancy with presence of 01:33:07PM

14       gestational cardiac activity after two weeks of study 01:33:09PM

15       treatment." 01:33:13PM

16              Do you see that? 01:33:13PM

17              A.  I do. 01:33:14PM

18              Q.  And so you were only planning to track women 01:33:14PM

19       for -- for two weeks, not for ten weeks; is that 01:33:18PM

20       correct? 01:33:21PM

21              A.  That's correct. 01:33:21PM

22              ATTORNEY PENAN:  Objection.  Asked and 01:33:22PM

23       answered.  The record speaks for itself. 01:33:23PM

24       BY ATTORNEY JONNA: 01:33:25PM

25              Q.  And you agree that we know if mifepristone has 01:33:25PM

1 been successful in terminating a pregnancy within two  
2 weeks; is that correct?

3 ATTORNEY PENAN: Objection. Misstates the  
4 witness's testimony.

5 THE WITNESS: Your -- your question is  
6 incorrect. I don't know if mifepristone is effective  
7 within two weeks. That is a surrogate marker we chose  
8 as an outcome point for this study. I don't -- that  
9 doesn't guarantee whether somebody will lose the  
10 pregnancy later or not. I mean, it's just that's the  
11 outcome we chose for the study because the population we  
12 were enrolling were people who desire an abortion, and  
13 we were trying to do the -- when you do an initial  
14 evaluation of a new treatment, you're not -- you're not  
15 looking at the outcome itself; you're looking at a  
16 surrogate of the outcome, and we chose two weeks of  
17 continuing as a surrogate of the potential for the  
18 pregnancy to be a continuing pregnancy beyond.

19 BY ATTORNEY JONNA:

20 Q. Why did you choose two weeks?

21 A. Because the patients were seeking abortion,  
22 and my goal was not to delay their abortion much longer  
23 than -- that -- in the way that would increase their  
24 risks from having their procedure.

25 Q. Okay.

1 Pulling up Exhibit 30. This is the FDA 01:34:41PM  
2 pharmacology review for mifepristone. 01:34:50PM  
3 Have you seen this document before? 01:34:52PM  
4 (Exhibit 30 was marked.) 01:34:52PM  
5 THE WITNESS: I may have. I can't -- if 01:34:56PM  
6 there's a specific area that may look familiar to me, I 01:34:59PM  
7 can tell you -- 01:35:02PM  
8 BY ATTORNEY JONNA: 01:35:02PM  
9 Q. Okay. 01:35:02PM  
10 A. -- if I've seen the document. I have not -- I 01:35:05PM  
11 am not necessarily familiar with every single part of 01:35:07PM  
12 it. 01:35:10PM  
13 Q. Okay. 01:35:11PM  
14 I'm going to turn your attention to Page 6. 01:35:11PM  
15 It says, "This is a pharmacology review of NDA." 01:35:14PM  
16 "NDA" means new drug application; is that 01:35:20PM  
17 right? 01:35:24PM  
18 A. It does. 01:35:24PM  
19 Q. And if we go to Page 21, which is Page 16 of 01:35:25PM  
20 the document, it says at the bottom, "Combination of RU 01:35:32PM  
21 38486 and progesterone: Outcome of gestation in rats." 01:35:40PM  
22 Do you see that? 01:35:43PM  
23 A. I do. 01:35:44PM  
24 Q. And on the next page, it has a section that 01:35:45PM  
25 says, "Combination of RU 38486 and progesterone: 01:35:48PM

1 Outcome of gestation in rabbits." 01:35:58PM  
2 Do you see that? 01:35:58PM  
3 A. I do. 01:35:59PM  
4 Q. And at the end of these sections it says, 01:36:00PM  
5 "Thus, the abortifacient activity of RU 486 is 01:36:03PM  
6 antagonized by progesterone, allowing for normal 01:36:07PM  
7 pregnancy and delivery." 01:36:09PM  
8 Do you see that? 01:36:10PM  
9 A. I do. 01:36:11PM  
10 Q. And have you seen this conclusion by the FDA 01:36:11PM  
11 before today? 01:36:15PM  
12 A. Yes. 01:36:16PM  
13 Q. In what context? 01:36:16PM  
14 A. In looking at this document. 01:36:19PM  
15 Q. To prepare for this deposition or before -- 01:36:20PM  
16 before this litigation? 01:36:24PM  
17 A. I have seen it multiple times in the past, and 01:36:25PM  
18 I may have seen it as well in preparing for the 01:36:29PM  
19 deposition, but I -- I have seen it multiple times. I 01:36:34PM  
20 don't remember all the times I've seen it. 01:36:38PM  
21 Q. So if -- 01:36:40PM  
22 ATTORNEY PENAN: Also asked and answered 01:36:40PM  
23 during the first part of this deposition, Counselor. 01:36:45PM  
24 THE WITNESS: Yeah. I believe that you 01:36:48PM  
25 actually did go over this in the prior session, but if 01:36:49PM

1 you want to go over it again, we can use our time doing 01:36:51PM

2 so. 01:36:55PM

3 BY ATTORNEY JONNA: 01:36:55PM

4 Q. So, first of all, I'm not sure that's correct. 01:36:55PM

5 But in any event, would you agree that the FDA 01:36:58PM

6 here relied on animal studies to come to a conclusion 01:37:01PM

7 about the effect of supplemental progesterone on 01:37:04PM

8 mifepristone? 01:37:09PM

9 A. These conclusions refer to the animal studies. 01:37:09PM

10 Q. To come to a conclusion about the effect of 01:37:12PM

11 supplemental progesterone on mifepristone; correct? 01:37:19PM

12 A. These conclusions are -- 01:37:20PM

13 ATTORNEY PENAN: Objection. Asked and 01:37:20PM

14 answered. Calls for speculation. Lacks foundation. 01:37:22PM

15 Incomplete hypothetical. Vague. Ambiguous. 01:37:24PM

16 THE WITNESS: These conclusions are about the 01:37:27PM

17 animal studies, which are required for all drugs that 01:37:29PM

18 are tested. And we know that animal studies don't 01:37:32PM

19 always translate into human effects, especially for 01:37:36PM

20 reproductive hormones. So these conclusions are from 01:37:39PM

21 the animal studies. 01:37:44PM

22 BY ATTORNEY JONNA: 01:37:46PM

23 Q. Do you think the FDA was wrong to rely on 01:37:46PM

24 animal studies here? 01:37:52PM

25 A. We discuss -- 01:37:52PM

1           ATTORNEY PENAN:  Objection.  The document           01:37:53PM  
2  speaks for itself.  Calls for speculation.  Lacks           01:37:54PM  
3  foundation.  Incomplete hypothetical.  Misstates the           01:37:57PM  
4  document.  And asked and answered.                           01:38:00PM

5           THE WITNESS:  The FDA requires animal studies           01:38:02PM  
6  as part of their preclinical testing before it's studied           01:38:05PM  
7  in humans.  It's -- they are never wrong to use animal           01:38:08PM  
8  studies to ensure that they kind of have a basic           01:38:11PM  
9  understanding of the drug and what can happen in the           01:38:14PM  
10 animals before it's given to humans.  However, it's very           01:38:19PM  
11 common for sometimes things not to work out exactly the           01:38:23PM  
12 same way.  This is just part of what's required by the           01:38:26PM  
13 FDA for preclinical testing.                                   01:38:29PM

14 BY ATTORNEY JONNA:   01:38:29PM

15           Q.  Have you ever referred to this pharmacology           01:38:34PM  
16 review in any of your studies?                                   01:38:36PM

17           A.  I --   01:38:39PM

18           ATTORNEY PENAN:  Objection.  Calls for           01:38:39PM  
19 speculation.  Lacks foundation.                                   01:38:40PM

20           THE WITNESS:  I don't believe so.                   01:38:42PM

21 BY ATTORNEY JONNA:   01:38:43PM

22           Q.  And why is that?                                   01:38:44PM

23           A.  It's a preclinical nonhuman study.  It doesn't           01:38:45PM  
24 prove anything when it's used in humans.  It's just part           01:38:50PM  
25 of the information the FDA requires prior to using the           01:38:54PM

1 drug in humans and seeing its effects. 01:38:59PM

2 Q. Okay. 01:39:02PM

3 I'm going to pull up Exhibit 72. This is a 01:39:03PM

4 document titled "Animal Rule Information" from the FDA 01:39:11PM

5 website, and I'm going to ask you about certain sections 01:39:16PM

6 of this. 01:39:18PM

7 Have you ever seen this section from the FDA 01:39:19PM

8 website before? 01:39:21PM

9 (Exhibit 72 was marked.) 01:39:21PM

10 THE WITNESS: I have not. 01:39:22PM

11 BY ATTORNEY JONNA: 01:39:22PM

12 Q. You are aware that, under certain 01:39:23PM

13 circumstances, the FDA approve drugs solely based on 01:39:25PM

14 animal studies; correct? 01:39:29PM

15 A. I -- 01:39:30PM

16 ATTORNEY PENAN: Objection. Argumentative. 01:39:30PM

17 Misstates the witness's testimony. Assumes facts not in 01:39:33PM

18 evidence. Vague. Ambiguous. 01:39:37PM

19 THE WITNESS: Again -- 01:39:37PM

20 ATTORNEY PENAN: Lacks foundation. 01:39:38PM

21 THE WITNESS: -- I'm not aware. And if you 01:39:39PM

22 believe that's true, then I would also ask -- I would 01:39:39PM

23 ask that you tell us what drugs those are. 01:39:41PM

24 BY ATTORNEY JONNA: 01:39:43PM

25 Q. Okay. 01:39:43PM

1           Let's take a look at Page 2 of the document, 01:39:43PM  
2           and I've highlighted here in green. And we'll just read 01:39:46PM  
3           it into the record. "The animal rule can be used only 01:39:49PM  
4           in limited circumstances. It applies only to drugs and 01:39:52PM  
5           biological products that are intended to ameliorate or 01:39:55PM  
6           prevent serious or life-threatening conditions caused by 01:40:00PM  
7           exposure to lethal or permanently disabling toxic 01:40:03PM  
8           chemical, biological, radiological, or nuclear (CBRN) 01:40:07PM  
9           substances when it has not been feasible to study the 01:40:13PM  
10          product's effectiveness in field trials after accidental 01:40:16PM  
11          or hostile exposure to a CBRN substance, and it would 01:40:20PM  
12          not be ethical to deliberately expose healthy human 01:40:25PM  
13          volunteers to a lethal or permanently disabling toxic 01:40:29PM  
14          CBRN substance. And when the investigational product 01:40:36PM  
15          cannot be proved for the proposed indication through 01:40:41PM  
16          other existing regulatory pathways, the product safety 01:40:41PM  
17          must still be demonstrated in humans."

18                   Do you see that? 01:40:46PM

19           A.    I do. 01:40:47PM

20           Q.    You do agree that mifepristone threatens the 01:40:49PM  
21          continuation of a pregnancy; correct? 01:40:50PM

22                   ATTORNEY PENAN: Objection. Argumentative. 01:40:52PM  
23          Misstates the witness's testimony. Lacks foundation. 01:40:54PM  
24          Incomplete hypothetical. Vague. Ambiguous. 01:40:54PM

25                   THE WITNESS: I don't like the word 01:40:56PM

1 "threatens." But does mifepristone impact the potential 01:40:58PM  
2 for the pregnancy to continue? I can say that, yes. 01:41:04PM

3 BY ATTORNEY JONNA: 01:41:06PM

4 Q. And I think you testified last time that 01:41:07PM  
5 embryos don't die. 01:41:10PM

6 You said you -- you don't like to use that 01:41:11PM  
7 terminology; is that correct? 01:41:14PM

8 ATTORNEY PENAN: Objection. Misstates the 01:41:16PM  
9 witness's testimony. 01:41:18PM

10 THE WITNESS: If I -- I would have to have 01:41:18PM  
11 that read back to me if I used those words, but it 01:41:21PM  
12 sounds like something I would say. 01:41:24PM

13 BY ATTORNEY JONNA: 01:41:25PM

14 Q. You do agree that reasonable people, including 01:41:27PM  
15 other OB/GYNs have different opinions of when human life 01:41:30PM  
16 begins, different opinions than yours; correct? 01:41:34PM

17 ATTORNEY PENAN: Objection. Calls for 01:41:37PM  
18 speculation. Lacks foundation. Incomplete 01:41:39PM  
19 hypothetical. Vague. Ambiguous. Argumentative. 01:41:40PM

20 THE WITNESS: There are a lot of people all 01:41:44PM  
21 over the world who have their theories about when life 01:41:45PM  
22 begins. 01:41:48PM

23 BY ATTORNEY JONNA: 01:41:48PM

24 Q. Would you agree that reasonable people can 01:41:49PM  
25 disagree on that, or is it your opinion that there can 01:41:51PM

1 be no reasonable disagreement on that issue? 01:41:54PM

2 ATTORNEY PENAN: Same objections. Plus 01:41:58PM

3 harassing. 01:41:59PM

4 THE WITNESS: I don't see why reasonable 01:42:00PM

5 people can't have different opinions. 01:42:01PM

6 BY ATTORNEY JONNA: 01:42:04PM

7 Q. So for those people, would you agree that it 01:42:04PM

8 would be reasonable for them to rely on the animal study 01:42:07PM

9 rule in the context of APR? 01:42:10PM

10 A. I don't think -- 01:42:12PM

11 ATTORNEY PENAN: Same objections. 01:42:13PM

12 THE WITNESS: I don't think this rule applies. 01:42:15PM

13 BY ATTORNEY JONNA: 01:42:17PM

14 Q. And why -- 01:42:17PM

15 A. Based on what you read to me. 01:42:17PM

16 Q. Well, we're going to look more carefully at 01:42:19PM

17 this, but what's your reason for saying that right now? 01:42:21PM

18 A. Well, if you're going to say we're going to 01:42:24PM

19 look more carefully, then I'm going to withhold any 01:42:25PM

20 answer until you tell me what you want to look at more 01:42:27PM

21 carefully. 01:42:29PM

22 Q. Okay. 01:42:30PM

23 Let's look at Page -- yeah. Here. The yellow 01:42:30PM

24 highlights here. So the -- let's just go through what 01:42:38PM

25 the rule provides. "FDA will rely on the evidence from 01:42:40PM

1 studies in animals to provide substantial evidence of 01:42:44PM  
2 the effectiveness of these products only when" -- and 01:42:47PM  
3 there's four elements there. For -- for number one, 01:42:50PM  
4 "there is a reasonably well-understood 01:42:52PM  
5 pathophysiological mechanism of the toxicity of the 01:42:56PM  
6 substance and its prevention or substantial reduction by 01:43:01PM  
7 the product." 01:43:02PM

8 Do you see that? 01:43:03PM

9 A. I do. 01:43:04PM

10 Q. And we talked a lot about the theory of APR 01:43:04PM  
11 last time, and I believe you agree that there is 01:43:08PM  
12 evidence that APR is biological plausible; correct? 01:43:11PM

13 ATTORNEY PENAN: Objection. Misstates the 01:43:15PM  
14 witness's testimony. 01:43:16PM

15 THE WITNESS: I believe I said that it would 01:43:18PM  
16 be re- -- that the theories give it biologic 01:43:21PM  
17 plausibility, but you need studies to see if the 01:43:25PM  
18 theories bear out in humans. 01:43:28PM

19 BY ATTORNEY JONNA: 01:43:32PM

20 Q. Okay. 01:43:32PM

21 For point two, the -- it says "the effect is 01:43:32PM  
22 demonstrated in more than one animal species, expected 01:43:35PM  
23 to react with a responsive predictive for humans, unless 01:43:39PM  
24 the effect is demonstrated in a single animal species 01:43:44PM  
25 that represents a sufficiently well-characterized animal 01:43:45PM

1 model for predicting the response in humans." 01:43:49PM

2 Do you see that? 01:43:52PM

3 A. I see that. 01:43:53PM

4 Q. And you recall that the FDA tested both in 01:43:54PM  
5 rabbits and in rats. And in rats, it was the Yamabe 01:43:58PM  
6 study from 1989 and the Camilleri study from 2023. 01:44:04PM

7 Do you recall that? 01:44:10PM

8 A. I do. 01:44:12PM

9 Q. For point three, it says, "the animal study 01:44:13PM  
10 end point is clearly related to the desired benefit in 01:44:15PM  
11 humans, generally the enhancement of survival or 01:44:20PM  
12 prevention of major morbidity." 01:44:20PM

13 Do you see that? 01:44:25PM

14 A. I do. 01:44:25PM

15 Q. And in the APR context, the end point of 01:44:27PM  
16 greater surviving pregnancies in the animal studies is 01:44:28PM  
17 clearly related to the desired benefit in humans of 01:44:32PM  
18 increasing surviving pregnancy rates. 01:44:35PM

19 Would you agree? 01:44:39PM

20 ATTORNEY PENAN: Objection. Lacks foundation. 01:44:39PM

21 Incomplete hypothetical. Vague. Ambiguous. 01:44:40PM

22 Argumentative. 01:44:41PM

23 THE WITNESS: I -- I'm reading through all 01:44:47PM

24 four points. So if you want to -- I can -- do you want 01:44:48PM

25 me to ask me about all four of them but you need all 01:44:51PM

1 four, that's fine, but I wouldn't ask me about each  
2 individual one.

3 BY ATTORNEY JONNA:

4 Q. Okay.

5 A. Because you need every one. Okay?

6 Q. Right.

7 So do you dispute the statement I just  
8 presented to you for point three?

9 A. I just said --

10 ATTORNEY PENAN: Same objections.

11 THE WITNESS: I just said that the F --  
12 according to this, because I'm reading through this,  
13 since this is the first time I'm seeing this, is that  
14 the FDA requires all four of these points.

15 BY ATTORNEY JONNA:

16 Q. Right.

17 And I was just going through --

18 A. And I -- and I don't think -- I don't think  
19 all four of these points exist.

20 Q. Okay.

21 Well, let's just --

22 A. So...

23 Q. Let's look at point four before we hear your  
24 thoughts on that. "The data or information on the  
25 kinetics and pharmacodynamics of the product or other

01:44:56PM

01:44:57PM

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01:44:58PM

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01:45:29PM

1 relevant data or information in animals and humans 01:45:32PM  
2 allows selection of an effective dose in humans." 01:45:36PM  
3 Do you see that? 01:45:40PM  
4 A. I do. 01:45:41PM  
5 Q. And in the APR context, I know you take issue 01:45:41PM  
6 with the Delgado study, but you do acknowledge that it 01:45:44PM  
7 includes data about different doses of progesterone 01:45:46PM  
8 after mifepristone used in humans; correct? 01:45:50PM  
9 A. I do -- 01:45:50PM  
10 ATTORNEY PENAN: Objection. Misstates the 01:45:53PM  
11 witness's testimony. Argumentative. Lacks foundation. 01:45:54PM  
12 A. I do not. 01:45:58PM  
13 BY ATTORNEY JONNA: 01:45:58PM  
14 Q. And why is that? 01:46:00PM  
15 A. Because there's no value in that work. It has 01:46:01PM  
16 zero research value. There -- it is a paper that claims 01:46:04PM  
17 to be one thing; is another. In scientific literature, 01:46:14PM  
18 we consider it fraudulent. So there is nothing from it 01:46:14PM  
19 that can be used. 01:46:17PM  
20 I also find it interesting that you're trying 01:46:18PM  
21 to argue that we should be able to use animal models, 01:46:21PM  
22 and there -- but human studies have been attempted. So 01:46:24PM  
23 you can't have it both ways. You can't now go back and 01:46:33PM  
24 say, "Well, there -- we should just be able to 01:46:35PM  
25 approve -- have it approved based on animal studies 01:46:36PM

1 based on this FDA criteria," which doesn't apply here, 01:46:39PM  
2 "but we've done human studies also." You can't have it 01:46:41PM  
3 both ways. All right? So because you're saying this is 01:46:44PM  
4 an exception that the FDA applies saying, "You don't 01:46:46PM  
5 need human studies." But yet, all along, people who are 01:46:50PM  
6 promoting APR have been trying to promote the human data 01:46:53PM  
7 they have as human studies. So it doesn't work both 01:46:59PM  
8 ways. 01:47:02PM

9 The biggest thing here is that the animal 01:47:02PM  
10 response for reproductive hormones is known not to 01:47:06PM  
11 always correlate -- in fact, very commonly not correlate 01:47:10PM  
12 directly -- with what's seen in humans. So you can't 01:47:15PM  
13 necessarily say the response that's seen in animals is 01:47:19PM  
14 predictive of what's seen in humans for reproductive 01:47:21PM  
15 hormones. 01:47:26PM

16 So number two doesn't hold up. So for that 01:47:27PM  
17 reason, the four of these together don't hold up. 01:47:29PM

18 Q. Okay. 01:47:33PM

19 Any other reasons you don't think the 01:47:34PM  
20 animal -- 01:47:36PM

21 A. I only need one of them. That's fine. 01:47:37PM

22 Q. So the rule doesn't apply. Okay. 01:47:39PM

23 All right. Let's go back to Exhibit 4, which 01:47:43PM  
24 is your commentary article again. On Page 2, Section 2, 01:47:46PM  
25 which is highlighted in yellow, you have a section 01:47:53PM

1 titled "Trying to Understand Harm." 01:47:57PM

2 Do you see that? 01:48:00PM

3 A. Yes. 01:48:00PM

4 Q. And you wrote on the top here, "Among eight 01:48:01PM  
5 studies that used a single dose of mifepristone, 01:48:05PM  
6 200 milligrams or 600 milligrams, no cases of hemorrhage 01:48:08PM  
7 or transfusion occurred. Though these studies were 01:48:12PM  
8 limited to women 49 days gestation or less, since 01:48:14PM  
9 medical abortion is available through 70 days, what are 01:48:19PM  
10 the risks when mifepristone is used without misoprostol 01:48:23PM  
11 beyond 49 days?" 01:48:32PM

12 Do you see that? 01:48:32PM

13 A. I do. 01:48:33PM

14 Q. And if you recall, all the women who 01:48:33PM  
15 experienced what you called "severe bleeding" in your 01:48:33PM  
16 mifepristone reversal study, subjects 8, 10, and 11 were 01:48:34PM  
17 past seven weeks. 01:48:37PM

18 Do you recall that? 01:48:38PM

19 A. I do. 01:48:39PM

20 Q. So would these eight studies where no 01:48:39PM  
21 hemorrhage or transfusion occurred support the inference 01:48:43PM  
22 that taking mifepristone without misoprostol is safe at 01:48:47PM  
23 seven weeks or less? 01:48:47PM

24 A. It does not. 01:48:57PM

25 ATTORNEY PENAN: Objection. Lacks foundation. 01:48:57PM

1 Incomplete hypothetical. Calls for speculation. 01:48:57PM  
2 BY ATTORNEY JONNA: 01:48:58PM  
3 Q. And why is that? 01:48:59PM  
4 A. It supports the theory, not an inference. 01:48:59PM  
5 There's a difference. 01:49:04PM  
6 Q. Okay. 01:49:06PM  
7 A. All right. 01:49:06PM  
8 Q. So you -- 01:49:07PM  
9 A. Inference means you don't want to make a 01:49:07PM  
10 conclusion from it. Theories mean that it supports the 01:49:10PM  
11 rationale for finding out if it's true. 01:49:14PM  
12 Q. Okay. 01:49:16PM  
13 So you do agree that it supports that theory? 01:49:17PM  
14 A. It supports -- 01:49:21PM  
15 ATTORNEY PENAN: Objection. Misstates the 01:49:21PM  
16 witness's testimony. 01:49:22PM  
17 THE WITNESS: It supports the theory that at 01:49:23PM  
18 an earlier gestational age doing a study may be safer, 01:49:26PM  
19 but it doesn't in any way support the theory that it 01:49:33PM  
20 would work. 01:49:36PM  
21 BY ATTORNEY JONNA: 01:49:36PM  
22 Q. Okay. 01:49:36PM  
23 Going back to your expert declaration, 01:49:36PM  
24 Exhibit 2. I'm going turn your attention to Page 10, 01:49:39PM  
25 paragraph 28. You wrote, "Studies from infertility 01:49:42PM

1 populations have shown an association of high-dose 01:49:46PM  
2 progesterone use with an increased likelihood of thyroid 01:49:50PM  
3 cancer diagnosis." 01:49:53PM  
4 Do you see that? 01:49:54PM  
5 A. I do. 01:49:54PM  
6 Q. So is it your position that thyroid cancer is 01:49:55PM  
7 a risk for APR? 01:49:58PM  
8 ATTORNEY PENAN: Objection. Misstates the 01:50:00PM  
9 witness's testimony. Calls for speculation. Lacks 01:50:01PM  
10 foundation. Incomplete hypothetical. 01:50:04PM  
11 THE WITNESS: It's a potential risk. 01:50:06PM  
12 BY ATTORNEY JONNA: 01:50:09PM  
13 Q. Okay. 01:50:09PM  
14 I'm going to pull up Exhibit 93. 01:50:09PM  
15 (Exhibit 93 was marked.) 01:50:09PM  
16 BY ATTORNEY JONNA: 01:50:09PM  
17 Q. Which is a document titled "Permission to Take 01:50:17PM  
18 Part in a Human Research Study." 01:50:20PM  
19 Do you recognize this document? 01:50:21PM  
20 A. I do. 01:50:23PM  
21 Q. And this document was provided to subjects as 01:50:24PM  
22 part of the informed consent process for your study; 01:50:27PM  
23 correct? 01:50:30PM  
24 A. Yes. 01:50:30PM  
25 Q. And you approved this document; correct? 01:50:31PM



1 Q. So in the section here, "What are the risks?" 01:51:39PM  
2 I'll give you a chance to look at it, but you 01:51:50PM  
3 don't inform women that they may be experiencing a 01:51:52PM  
4 higher rate of thyroid cancer based on taking 01:51:56PM  
5 progesterone for your study; is that correct? 01:51:57PM  
6 A. That's correct. 01:51:58PM  
7 Q. And you would have told them about it if you 01:52:00PM  
8 thought it was a significant risk; is that correct? 01:52:04PM  
9 A. At the time of this -- 01:52:07PM  
10 ATTORNEY PENAN: Objection. Misstates the 01:52:07PM  
11 witness's testimony. Lass -- lacks foundation. 01:52:08PM  
12 Incomplete hypothetical. Calls for speculation. 01:52:10PM  
13 THE WITNESS: At the time of the study. And 01:52:13PM  
14 also the -- the use was for a short period of time, for 01:52:22PM  
15 up to two weeks, as opposed to much longer. It's used 01:52:26PM  
16 in infertility populations. But, again, the study was 01:52:30PM  
17 done before the 2022 publication. 01:52:34PM  
18 BY ATTORNEY JONNA: 01:52:37PM  
19 Q. Okay. 01:52:38PM  
20 On the same document, the yellow highlight 01:52:38PM  
21 there says, "Birth defects with a continuing pregnancy." 01:52:42PM  
22 Do you see that? 01:52:46PM  
23 A. Yes. 01:52:46PM  
24 Q. And then you state, "The information" -- 01:52:47PM  
25 sorry. I'm going to just bring -- make this bigger. 01:52:49PM

1 "This information is only important if you choose to not 01:52:52PM  
2 have a surgical abortion after completing the study and 01:52:55PM  
3 you have not passed the pregnancy while taking the 01:52:58PM  
4 medications. The two drugs used in this study, 01:53:01PM  
5 mifepristone and progesterone, are not known to cause 01:53:03PM  
6 birth defects." 01:53:07PM  
7 Do you see that? 01:53:07PM  
8 A. I do. 01:53:07PM  
9 Q. And what evidence is that statement based on? 01:53:09PM  
10 A. Published studies that look at this 01:53:12PM  
11 information. 01:53:18PM  
12 Q. So I assume you agree that APR does not pose a 01:53:19PM  
13 risk of increased birth defects; correct? 01:53:24PM  
14 ATTORNEY PENAN: Objection. Misstates the 01:53:28PM  
15 witness's testimony. Argumentative. Lacks foundation. 01:53:31PM  
16 Incomplete hypothetical. 01:53:33PM  
17 THE WITNESS: If someone was to give 01:53:35PM  
18 progesterone in an attempt to use what's called APR, I 01:53:36PM  
19 would not have a concern that the progesterone would 01:53:41PM  
20 cause birth defects. 01:53:43PM  
21 BY ATTORNEY JONNA: 01:53:45PM  
22 Q. Okay. 01:53:45PM  
23 Did you know that, during this litigation, 01:53:45PM  
24 Heartbeat released its internal deidentified APR patient 01:53:56PM  
25 data? 01:54:02PM

1 A. I'm not aware. 01:54:03PM

2 Q. Well, if you -- assuming for the sake of 01:54:04PM

3 this -- these series of questions that they did and that 01:54:11PM

4 there were about 8,800 entries and that only three -- 01:54:14PM

5 there were only three records of women needing 01:54:21PM

6 transfusions, and two of those three didn't take any of 01:54:24PM

7 their progesterone, and there were only 11 hospital 01:54:28PM

8 admissions and 88 ER visits, assuming that's what the 01:54:31PM

9 data shows, would you agree that those figures indicate 01:54:37PM

10 that the APR protocol is safe? 01:54:39PM

11 ATTORNEY PENAN: Objection. Compound. Vague. 01:54:42PM

12 Ambiguous. Confusing. Calls for speculation. Lacks 01:54:43PM

13 foundation. Incomplete hypothetical. Assumes facts not 01:54:49PM

14 in evidence. 01:54:52PM

15 THE WITNESS: I can't make any conclusions 01:54:53PM

16 without actually seeing the data and seeing it in a 01:54:56PM

17 report that would allow me to understand how the data 01:54:57PM

18 was obtained, how patients were followed. I have no 01:55:03PM

19 idea if that's -- if it's concrete data. If you want to 01:55:04PM

20 say it -- if there was a hypothetical of somebody saying 01:55:07PM

21 all this, I mean, it's all -- that's all -- to me, it's 01:55:09PM

22 all a hypothetical because I haven't seen it. I don't 01:55:15PM

23 know what it means. 01:55:18PM

24 BY ATTORNEY JONNA: 01:55:19PM

25 Q. Okay. Well, that's -- does it sound like data 01:55:20PM

1 that you'd want to look at as part of your expert 01:55:22PM

2 testimony in this case? 01:55:28PM

3 ATTORNEY PENAN: Same objections. 01:55:29PM

4 THE WITNESS: I mean, anybody can -- you know, 01:55:30PM

5 that's why data is usually done -- accumulated in a 01:55:32PM

6 scientific manner. You know, and it isn't just released 01:55:35PM

7 to say, "Hey, we did this. Aren't we great?" You know, 01:55:40PM

8 you've got -- if you're going to have data, it's got to 01:55:41PM

9 be collected appropriately and analyzed appropriately 01:55:43PM

10 and go through peer review for it to be considered 01:55:47PM

11 something of value; otherwise, anybody could just say 01:55:52PM

12 anything. So I have -- 01:55:57PM

13 BY ATTORNEY JONNA: 01:55:57PM

14 Q. Are you -- 01:55:57PM

15 A. -- no idea. I can't make any conclusions 01:55:58PM

16 about it. 01:55:59PM

17 Q. Are you aware that there was testimony in 01:56:00PM

18 this -- in this lawsuit about how the data was 01:56:02PM

19 collected? 01:56:04PM

20 A. I'm not aware. 01:56:04PM

21 ATTORNEY PENAN: Same objections. 01:56:05PM

22 BY ATTORNEY JONNA: 01:56:06PM

23 Q. Is that something that you would want to 01:56:06PM

24 review and -- as part of forming your opinions in this 01:56:09PM

25 case? The data and how it's collected and what it 01:56:12PM

1 shows, would that be relevant at all to your opinions in  
2 this lawsuit?

3 A. My opinions are based on what's available  
4 currently, so. . .

5 Q. Right.

6 And if there was currently available data,  
7 would 8,800-plus entries and testimony about how that  
8 data was gathered, would that be relevant at all to your  
9 expert testimony in this case?

10 ATTORNEY PENAN: Same objection.

11 THE WITNESS: I mean, the information would be  
12 important to understand. But how much value it has just  
13 as testimony, testimony itself is not enough for -- to  
14 make a scientific conclusion.

15 BY ATTORNEY JONNA:

16 Q. Right.

17 But you said that the data -- you'd want to  
18 know how the --

19 A. You asked -- you asked the question --

20 Q. I'm sorry.

21 A. -- and I answered it.

22 Q. Let me just finish my question, sir. I'm  
23 sorry.

24 You said you would want to know how the data  
25 was collected; is that correct?

01:56:18PM

01:56:21PM

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01:57:00PM

01:57:00PM

01:57:02PM

01:57:02PM

01:57:02PM

01:57:02PM

01:57:06PM

1 A. Yes. 01:57:07PM

2 Q. And how would the data need to be collected 01:57:07PM

3 for the statistics to show safety? 01:57:09PM

4 A. Well, if you're going to collect -- well, I 01:57:13PM

5 would want to know whether they were using a de-identify 01:57:16PM

6 database that patients agreed to be part of. You know, 01:57:18PM

7 was it collected ethically? Were patients being 01:57:22PM

8 enrolled prospectively? And if they were, then is that 01:57:26PM

9 really, again, ethical? Were they being put into a 01:57:29PM

10 study without being -- knowing they were put into a 01:57:33PM

11 study? This all has to do with, you know, fraudulent 01:57:36PM

12 data. So I would want to know all something things. 01:57:37PM

13 Q. But you're not going to be able to provide any 01:57:42PM

14 opinions in this case about any of that because you 01:57:44PM

15 haven't reviewed the data; correct? 01:57:45PM

16 A. Correct. 01:57:47PM

17 ATTORNEY PENAN: Objection. It's 01:57:47PM

18 argumentative. 01:57:48PM

19 BY ATTORNEY JONNA: 01:57:51PM

20 Q. And the -- if, in fact, the data showed what I 01:57:51PM

21 represented -- three women out of 88 entries needing 01:57:54PM

22 transfusions, 11 hospital admissions, and 88 ER 01:57:58PM

23 visits -- just looking at those figures alone, I'm sure 01:58:00PM

24 you would agree that that indicates that the protocol is 01:58:03PM

25 safe; correct? 01:58:06PM

1 A. Yeah. But you have -- 01:58:07PM

2 ATTORNEY PENAN: Objection. Argumentative. 01:58:07PM

3 Harassing. Asked and answered. Calls for speculation. 01:58:09PM

4 Lacks foundation. Incomplete hypothetical. Vague. 01:58:12PM

5 Ambiguous. Compound. 01:58:14PM

6 THE WITNESS: The -- I think the lawsuit is 01:58:16PM

7 about claims of efficacy, and you're just talking about 01:58:19PM

8 safe. 01:58:22PM

9 BY ATTORNEY JONNA: 01:58:23PM

10 Q. Right. 01:58:23PM

11 And I'm not -- 01:58:23PM

12 A. So I'm -- 01:58:23PM

13 Q. Sorry. That's just not my question. 01:58:24PM

14 My question was -- I'm not asking you to tell 01:58:26PM

15 me what the lawsuit is about. I'm asking a specific 01:58:28PM

16 question. 01:58:31PM

17 A. If those numbers are real, then it potentially 01:58:32PM

18 could be safe, but I'd need to look at the numbers, not 01:58:37PM

19 just hear you roll them off. 01:58:39PM

20 Q. Okay. 01:58:41PM

21 Is it your understanding that, during a normal 01:58:42PM

22 medication abortion, about one in 1,000 women will need 01:58:43PM

23 a transfusion? 01:58:47PM

24 ATTORNEY PENAN: Objection. Lacks foundation. 01:58:50PM

25 Incomplete hypothetical. 01:58:53PM

1 THE WITNESS: It's my understanding that it's 01:58:54PM  
2 less than that. 01:58:56PM  
3 BY ATTORNEY JONNA: 01:58:57PM  
4 Q. What is -- what is the number, then? 01:58:57PM  
5 A. Less than one in 1,000. 01:58:59PM  
6 Q. Okay. 01:59:03PM  
7 And that's as specific as you can be? 01:59:03PM  
8 A. That's as specific as I can be, because her 01:59:06PM  
9 risk is going to be dependent on how far along she is in 01:59:08PM  
10 the pregnancy, and her access to other care, et cetera. 01:59:12PM  
11 Q. All right. 01:59:15PM  
12 I'm going to pull up Exhibit 77, which is a 01:59:17PM  
13 study titled "Progesterone and mifepristone: A pilot 01:59:24PM  
14 prospective single-arm clinical trial for women who have 01:59:30PM  
15 changed their mind after commencing medical abortion," 01:59:34PM  
16 dated 2023. 01:59:34PM  
17 (Exhibit 77 was marked.) 01:59:34PM  
18 BY ATTORNEY JONNA: 01:59:34PM  
19 Q. Do you see that? 01:59:35PM  
20 A. I do. 01:59:36PM  
21 Q. You've reviewed this before; correct? 01:59:36PM  
22 A. I have. 01:59:38PM  
23 Q. And this study tracks six women who attempted 01:59:38PM  
24 APR; right? 01:59:42PM  
25 A. It does. 01:59:42PM

1 Q. And there were five out of six successful 01:59:43PM  
2 reversals; correct? 01:59:47PM  
3 A. There were five out of six that have 01:59:48PM  
4 continuing pregnancies. 01:59:50PM  
5 Q. And you noted in your declaration that the -- 01:59:51PM  
6 that the one woman who lost her pregnancy, that she made 01:59:54PM  
7 two ER visits. 01:59:57PM  
8 Do you recall that? 01:59:58PM  
9 A. I do. 01:59:59PM  
10 Q. And -- but you also recall that she did not 01:59:59PM  
11 require any intervention; correct? 02:00:01PM  
12 A. I do. 02:00:03PM  
13 Q. And so you would agree that that means that 02:00:04PM  
14 she didn't suffer a serious adverse bleeding event; 02:00:08PM  
15 correct? 02:00:12PM  
16 ATTORNEY PENAN: Objection. Argumentative. 02:00:12PM  
17 Lacks foundation. Incomplete hypothetical. Vague. 02:00:15PM  
18 Ambiguous. 02:00:18PM  
19 THE WITNESS: Based on the information that 02:00:19PM  
20 was provided in the paper, she would not qualify. 02:00:21PM  
21 BY ATTORNEY JONNA: 02:00:24PM  
22 Q. As suffering a serious adverse bleeding event; 02:00:24PM  
23 correct? 02:00:29PM  
24 A. Correct. 02:00:29PM  
25 Q. And you would also agree that this study 02:00:29PM

1 provides at least some evidence that APR is safe; 02:00:32PM

2 correct? 02:00:32PM

3 ATTORNEY PENAN: Objection. Argumentative. 02:00:37PM

4 Misstate's the witness's testimony. Lacks foundation. 02:00:39PM

5 Calls for speculation. Incomplete hypothetical. 02:00:40PM

6 THE WITNESS: No. It's only six people. 02:00:43PM

7 BY ATTORNEY JONNA: 02:00:43PM

8 Q. So it provides zero evidence. 02:00:45PM

9 A. It provides nothing more than if it wasn't 02:00:47PM

10 published. It's six -- 02:00:50PM

11 Q. So -- 02:00:50PM

12 A. -- people. 02:00:50PM

13 Q. So it's completely irrelevant? 02:00:50PM

14 A. It's irrelevant. 02:00:52PM

15 Q. Okay. 02:00:54PM

16 A. It's also a horrible publication. But we -- 02:00:57PM

17 if you want to ask me about what's wrong with it, I can 02:00:59PM

18 tell you. Because you're just trying to tell me the 02:01:03PM

19 things you think are good. It's -- it's horrible. This 02:01:05PM

20 is another example of baloney publications on this 02:01:08PM

21 topic. 02:01:12PM

22 Q. Okay. 02:01:12PM

23 Is "baloney publications," is that a term of 02:01:12PM

24 art in the scientific community? 02:01:15PM

25 ATTORNEY PENAN: Objection. Argumentative. 02:01:18PM

1 BY ATTORNEY JONNA: 02:01:21PM  
2 Q. Let's talk about health risks for 02:01:22PM  
3 mifepristone. 02:01:25PM  
4 Can -- can women experience excessive bleeding 02:01:25PM  
5 after only taking mifepristone? 02:01:29PM  
6 ATTORNEY PENAN: Objection. Vague. 02:01:32PM  
7 Ambiguous. Incomplete hypothetical. 02:01:36PM  
8 THE WITNESS: Yes. 02:01:38PM  
9 BY ATTORNEY JONNA: 02:01:38PM  
10 Q. And in those cases, what would those be caused 02:01:39PM  
11 by? 02:01:43PM  
12 A. The pregnancy -- 02:01:43PM  
13 ATTORNEY PENAN: Objection. Vague. 02:01:43PM  
14 Ambiguous. Incomplete hypothetical. Calls for 02:01:45PM  
15 speculation. 02:01:48PM  
16 THE WITNESS: The pregnancy beginning to 02:01:48PM  
17 detach or detaching. 02:01:50PM  
18 BY ATTORNEY JONNA: 02:01:52PM  
19 Q. Okay. 02:01:53PM  
20 And can women experience excessive bleeding 02:01:53PM  
21 after taking misoprostol? 02:01:57PM  
22 A. Yes. 02:01:59PM  
23 ATTORNEY PENAN: Objection. Incomplete 02:02:01PM  
24 hypothetical. 02:02:02PM  
25 ///

1 BY ATTORNEY JONNA: 02:02:02PM

2 Q. And what would that be caused by? 02:02:04PM

3 A. Incomplete -- 02:02:05PM

4 ATTORNEY PENAN: Objection. Calls for 02:02:08PM  
5 speculation. Incomplete hypothetical. 02:02:09PM

6 THE WITNESS: Incomplete passage of the 02:02:12PM  
7 pregnancy tissue or the beginning of passage without it 02:02:13PM  
8 coming out. 02:02:16PM

9 BY ATTORNEY JONNA: 02:02:16PM

10 Q. And how do you treat excessive bleeding in 02:02:16PM  
11 your medication abortion patients? 02:02:19PM

12 A. If it's -- 02:02:22PM

13 ATTORNEY PENAN: Objection. Incomplete 02:02:23PM  
14 hypothetical. Calls for speculation. Lacks foundation. 02:02:25PM

15 THE WITNESS: If -- 02:02:25PM

16 ATTORNEY PENAN: Vague. 02:02:29PM

17 THE WITNESS: If it's -- 02:02:29PM

18 ATTORNEY PENAN: Ambiguous. 02:02:29PM

19 THE WITNESS: -- acutely excessive and the 02:02:30PM  
20 patient is in need of having the bleeding stop 02:02:33PM  
21 immediately, that's typically stopped with a suction 02:02:36PM  
22 aspiration of the uterus. 02:02:40PM

23 BY ATTORNEY JONNA: 02:02:42PM

24 Q. And is that a -- 02:02:49PM

25 ATTORNEY PENAN: Counsel, we've been going for 02:02:52PM

1 a little over an hour. Could we take a break soon? 02:02:53PM  
2 ATTORNEY JONNA: Yes. Let me just finish this 02:02:57PM  
3 line of questions, and we'll take a break. 02:02:57PM  
4 BY ATTORNEY JONNA: 02:02:57PM  
5 Q. And is that an effective treatment for 02:02:59PM  
6 excessive bleeding? 02:03:02PM  
7 A. Yes. 02:03:04PM  
8 Q. And it's well understood? 02:03:04PM  
9 A. Yes. 02:03:08PM  
10 ATTORNEY PENAN: Objection. Vague. 02:03:08PM  
11 Ambiguous. 02:03:09PM  
12 BY ATTORNEY JONNA: 02:03:10PM  
13 Q. And so you would agree that the risks of 02:03:10PM  
14 bleeding from APR can be addressed in these same 02:03:12PM  
15 effective and well understood ways; correct? 02:03:15PM  
16 ATTORNEY PENAN: Objection. Vague. 02:03:18PM  
17 Ambiguous. Incomplete hypothetical. Lacks foundation. 02:03:20PM  
18 Calls for speculation. 02:03:24PM  
19 THE WITNESS: Hypothetically, yes. 02:03:26PM  
20 ATTORNEY JONNA: Okay. Let's go off the 02:03:29PM  
21 record. 02:03:30PM  
22 THE VIDEOGRAPHER: Off the record at 2:03 p.m. 02:03:35PM  
23 (Off the record: 2:03 p.m. to 2:12 p.m.) 02:10:47PM  
24 THE VIDEOGRAPHER: We are back on the record 02:12:39PM  
25 at 2:12 p.m. 02:12:42PM

1 BY ATTORNEY JONNA: 02:12:44PM

2 Q. Okay. 02:12:44PM

3 Just wanted to make sure I understood your -- 02:12:45PM

4 what is your understanding of what APR refers to? More 02:12:53PM

5 of a foundational question. I just want to make sure 02:12:53PM

6 we're on the same page. What is your understanding of 02:13:00PM

7 what that term refers to? 02:13:00PM

8 ATTORNEY PENAN: Objection. Incomplete 02:13:03PM

9 hypothetical. Lacks foundation. 02:13:03PM

10 THE WITNESS: The theory that using high doses 02:13:10PM

11 of progesterone administered by various people in 02:13:11PM

12 different ways will increase the likelihood that someone 02:13:20PM

13 who took mifepristone will have a continuing pregnancy, 02:13:24PM

14 as compared to whether she had not taken anything. 02:13:25PM

15 Well, that's a comparative. But APR is the use of 02:13:29PM

16 progesterone in somebody who has taken mifepristone, 02:13:32PM

17 with the theory that it will increase the likelihood a 02:13:36PM

18 pregnancy will continue. 02:13:36PM

19 BY ATTORNEY JONNA: 02:13:36PM

20 Q. Okay. 02:13:36PM

21 So you agree that not taking misoprostol is 02:13:42PM

22 part of what the defendants call "APR"; correct? 02:13:45PM

23 ATTORNEY PENAN: Objection. Argumentative. 02:13:50PM

24 Misstates the witness's testimony. Lacks foundation. 02:13:52PM

25 Calls for speculation. Incomplete hypothetical. 02:13:54PM

1 THE WITNESS: Well, if you're not -- if you're 02:14:02PM  
2 only using mifepristone and then you're taking 02:14:04PM  
3 progesterone and not completing the medication abortion 02:14:08PM  
4 regimen, then that would mean you're not using 02:14:11PM  
5 misoprostol. 02:14:14PM  
6 BY ATTORNEY JONNA: 02:14:15PM  
7 Q. And that's one of the reasons why you argue 02:14:15PM  
8 that APR might be unsafe; is that correct? Not 02:14:17PM  
9 taking -- 02:14:20PM  
10 ATTORNEY PENAN: Objection. Mis- -- 02:14:21PM  
11 BY ATTORNEY JONNA: 02:14:21PM  
12 Q. -- not taking misoprostol. 02:14:22PM  
13 ATTORNEY PENAN: Objection. Misstate's the 02:14:24PM  
14 witness's testimony. Lacks foundation. Calls for 02:14:27PM  
15 speculation. Incomplete hypothetical. 02:14:29PM  
16 THE WITNESS: Yeah. Can you -- if I -- where 02:14:30PM  
17 do you quote me that I said it was unsafe? 02:14:33PM  
18 BY ATTORNEY JONNA: 02:14:35PM  
19 Q. Do you -- okay. Let's just back up. 02:14:43PM  
20 Do you believe that APR is unsafe? 02:14:44PM  
21 A. I would ask you to define what you mean by 02:14:46PM  
22 "safe," because safety can mean lots of things. 02:14:46PM  
23 Q. And I'm asking you as the expert in this case 02:14:48PM  
24 who presumably has some opinions on this. I'm not going 02:14:51PM  
25 to define the word "safe" for you. 02:14:54PM



1 Whether it's safe for everybody or not, I don't know 02:16:18PM  
2 because the data doesn't exist. If it doesn't work, 02:16:21PM  
3 then, in a sense, you get risk without benefit. So 02:16:29PM  
4 that's part of the definition of safety. If you get no 02:16:29PM  
5 benefit, but you get risk, that's not safe. 02:16:34PM

6 Safety can also mean: Is it going to cause 02:16:35PM  
7 terrible side effects; is it going to increase the 02:16:40PM  
8 likelihood of her having bleeding? There's lots of 02:16:43PM  
9 different ways you can define "safe." Safety -- 02:16:46PM

10 BY ATTORNEY JONNA: 02:16:46PM

11 Q. Okay. 02:16:46PM

12 A. -- also includes that it has to have efficacy, 02:16:48PM  
13 because then you only get risk without efficacy. 02:16:50PM

14 Q. Right. 02:16:50PM

15 Let me -- 02:16:50PM

16 A. I don't have that data -- 02:16:50PM

17 Q. Let me re- -- sure. 02:16:57PM

18 A. -- for everybody who could be treated because 02:16:58PM  
19 medication abortion is provided through ten weeks 02:16:59PM  
20 gestation. 02:17:03PM

21 Q. Let me rephrase my question. I just -- this 02:17:04PM  
22 is kind of -- this is a foundational question, actually. 02:17:06PM

23 So is one of the concerns that you have with 02:17:09PM  
24 APR the fact that women are taking mifepristone and not 02:17:11PM  
25 taking misoprostol during a medication abortion? 02:17:15PM

1 ATTORNEY PENAN: Same objections. 02:17:22PM

2 THE WITNESS: Well, what do you mean -- a 02:17:25PM

3 concern for what? I mean, I know you're trying to 02:17:26PM

4 reword your question. What are my concerns? Like, is 02:17:28PM

5 my concern that somebody could experience bleeding? 02:17:30PM

6 Yes. Because she's not taking misoprostol. And I don't 02:17:34PM

7 know if progesterone is going to make that worse or 02:17:43PM

8 better or anything. I have no idea. 02:17:44PM

9 BY ATTORNEY JONNA: 02:17:44PM

10 Q. Okay. 02:17:44PM

11 And misoprostol is used with mifepristone in 02:17:44PM

12 order to increase the chances of a complete abortion. 02:17:49PM

13 That's why you give it; correct? 02:17:52PM

14 ATTORNEY PENAN: Objection. Argumentative. 02:17:53PM

15 THE WITNESS: The two together are highly 02:17:55PM

16 effective for abortion, yes. 02:17:58PM

17 BY ATTORNEY JONNA: 02:18:00PM

18 Q. So misoprostol after mifepristone makes 02:18:00PM

19 continuing pregnancy less likely; correct? 02:18:13PM

20 ATTORNEY PENAN: Objection. 02:18:14PM

21 THE WITNESS: It makes continuing pregnancy 02:18:15PM

22 less likely, because the likelihood that the pregnancy 02:18:17PM

23 will still be in her uterus is lower. 02:18:19PM

24 BY ATTORNEY JONNA: 02:18:19PM

25 Q. So not taking misoprostol makes continuing 02:18:22PM

1 pregnancy more likely; correct? 02:18:26PM

2 A. Potentially. That hasn't been well studied. 02:18:29PM  
3 I mean, that was the point of all those systematic 02:18:29PM  
4 reviews is they don't apply across all medication 02:18:37PM  
5 abortion. They only looked at things through seven 02:18:39PM  
6 days. Continuation -- you know, you can argue -- I 02:18:43PM  
7 mean, well, continuation for one day or three days or 02:18:46PM  
8 seven days or 14 or -- or six months. It depends what 02:18:50PM  
9 you're looking at. 02:18:51PM

10 Q. Is -- if -- 02:18:51PM

11 A. So I think you're doing a lot of twisting this 02:18:53PM  
12 stuff, and I've answered the question. If you don't 02:18:55PM  
13 take misoprostol, you're not finishing the regimen. The 02:18:58PM  
14 two together are what's used to cause medication 02:19:04PM  
15 abortion. If I tell the patient who's six weeks, 02:19:06PM  
16 "There's a 98-percent chance this is going to work to 02:19:07PM  
17 completely evacuate your uterus," that's the combination 02:19:11PM  
18 of the two drugs. So you can't have a -- she's going to 02:19:15PM  
19 have a very low rate of continuing pregnancy if there's 02:19:18PM  
20 a 98-percent chance her uterus will be emptied by the 02:19:21PM  
21 two drugs. 02:19:24PM

22 Q. If a patient came to you and -- and regretted 02:19:24PM  
23 taking mifepristone and wanted to continue her 02:19:24PM  
24 pregnancy, would you tell her to take misoprostol? 02:19:31PM

25 A. No. 02:19:31PM

1 Q. Okay. 02:19:31PM

2 So when you talk about the efficacy of APR 02:19:37PM

3 being unproven, is it fair to say that you're focused on 02:19:40PM

4 the efficacy of the progesterone in the protocol? 02:19:44PM

5 ATTORNEY PENAN: Objection. Misstates the 02:19:52PM

6 witness's testimony. Vague. Ambiguous. Lacks 02:19:55PM

7 foundation. Calls for speculation. 02:19:58PM

8 THE WITNESS: Well, the treatment that's 02:19:59PM

9 provided is progesterone; right? So somebody's -- if 02:19:59PM

10 you assume that the only people who are being provided 02:20:03PM

11 APR are people who have taken mifepristone, the 02:20:05PM

12 treatment or the intervention is progesterone. 02:20:08PM

13 BY ATTORNEY JONNA: 02:20:10PM

14 Q. Right. 02:20:11PM

15 Because there's no doubt in the science that 02:20:11PM

16 not taking misoprostol will increase the chances of 02:20:13PM

17 continuing pregnancy; correct? 02:20:13PM

18 ATTORNEY PENAN: Objection. Confusing. 02:20:25PM

19 THE WITNESS: Yeah. You've asked this before, 02:20:28PM

20 and now you're just trying to ask it again a different 02:20:28PM

21 way. If you don't take the misoprostol, there's a 02:20:29PM

22 higher likelihood the pregnancy will still be in the 02:20:34PM

23 uterus. The proportion that are -- that are 02:20:35PM

24 continuing -- it depends whether you mean continuing 02:20:37PM

25 three days, seven days -- I mean, I can answer the same 02:20:38PM

1 way again. You're asking the same question over and  
2 over. Okay?

3 BY ATTORNEY JONNA:

4 Q. What --

5 A. I answered it already.

6 Q. And when you make efficacy arguments about  
7 progesterone after mifepristone, you're comparing it  
8 against watchful waiting or expected management; is that  
9 correct?

10 A. That's what you would be comparing it against,  
11 because if somebody has taken mifepristone and says,  
12 "I've decided I don't want to continue my pregnancy,"  
13 then her options are to not do anything and see what  
14 happens or to do something. And that something has  
15 never -- there's nothing that's been proven to be of any  
16 benefit. So whether -- whatever she does, it's the --  
17 you do nothing or you do whatever.

18 Q. So for -- for a woman who changed her mind  
19 after taking mifepristone, if there is a risk that not  
20 taking misoprostol will potentially increase the rate of  
21 hemorrhage or D&C or transfusion, that has to be balanced  
22 against the known benefit that a pregnancy is more  
23 likely to continue; would you agree?

24 A. I'm not clear what you're asking. You're  
25 being -- you're -- you're twist -- you're -- you're --

1 I -- can you re-ask the question because your questions  
2 are really twisted.

3 Q. For a woman who changed her mind after taking  
4 mifepristone, if there is a risk that not taking  
5 misoprostol will potentially increase the rate of  
6 hemorrhage or D&C or transfusion, that would have to be  
7 balanced against the known benefit that a pregnancy is  
8 more likely to continue.

9 Would you agree?

10 A. If she doesn't take the misoprostol?

11 ATTORNEY PENAN: Objection.

12 THE WITNESS: I -- again, I'm -- you're using  
13 a lot of double negatives and things. It's just hard to  
14 understand.

15 BY ATTORNEY JONNA:

16 Q. Okay.

17 A. Are you -- you know, again, I feel like you're  
18 asking the same things over and over in different ways  
19 trying to get a different answer. And that's why it's  
20 all very confusing.

21 Q. Okay.

22 Since APR includes not taking misoprostol --

23 A. Uh-huh.

24 Q. -- then I'm sure you would agree that APR is  
25 clearly more effective for maintaining a pregnancy than

1 continuing the abortion pill protocol and taking 02:22:51PM  
2 misoprostol; is that correct? 02:22:54PM  
3 A. No. I was -- 02:22:55PM  
4 ATTORNEY PENAN: Objection. 02:22:56PM  
5 THE WITNESS: No. That was -- 02:22:56PM  
6 ATTORNEY PENAN: Incomplete hypothetical. 02:22:56PM  
7 Lacks foundation. Vague. Ambiguous. 02:22:57PM  
8 THE WITNESS: APR is not just not taking the 02:23:00PM  
9 misoprostol. APR is not taking the misoprostol and 02:23:04PM  
10 administering progesterone. 02:23:06PM  
11 BY ATTORNEY JONNA: 02:23:09PM  
12 Q. Right. 02:23:09PM  
13 But we did agree earlier that APR also 02:23:09PM  
14 includes not taking misoprostol; correct? 02:23:12PM  
15 ATTORNEY PENAN: Objection. Misstates the 02:23:16PM  
16 witness's testimony. Incomplete hypothetical. 02:23:17PM  
17 THE WITNESS: I'll -- I'll try to simplify 02:23:25PM  
18 this. I -- based on what I -- what it appears you're 02:23:26PM  
19 asking. If a woman takes mifepristone and doesn't take 02:23:29PM  
20 misoprostol, there's a higher likelihood the pregnancy 02:23:30PM  
21 will continue than if she took misoprostol. 02:23:33PM  
22 BY ATTORNEY JONNA: 02:23:33PM  
23 Q. Okay. 02:23:37PM  
24 Turning back to your study, it didn't 02:23:38PM  
25 include -- your -- your mifepristone study. It did not 02:23:40PM

1 include any participants who took misoprostol; correct? 02:23:44PM  
2 A. Correct. 02:23:49PM  
3 Q. And there was no misoprostol control group; 02:23:49PM  
4 right? 02:23:52PM  
5 A. No. 02:23:53PM  
6 Q. Okay. 02:23:53PM  
7 I'm going pull up Exhibit 121. 02:23:55PM  
8 Have you seen the attorney general's complaint 02:24:07PM  
9 in this lawsuit? 02:24:10PM  
10 (Exhibit 121 was marked.) 02:24:10PM  
11 THE WITNESS: Yes. 02:24:11PM  
12 BY ATTORNEY JONNA: 02:24:11PM  
13 Q. Okay. I'm going to go to Page 8, paragraph 02:24:26PM  
14 31, which quotes the AMA Journal of Ethics saying that 02:24:29PM  
15 "case series are ranked lower than other study designs 02:24:30PM  
16 because of associated bias, lack of random sampling, the 02:24:36PM  
17 absence of controls or a comparison group, and 02:24:39PM  
18 heterogeneity of subjects." 02:24:41PM  
19 Do you see that? 02:24:41PM  
20 A. I do. 02:24:41PM  
21 Q. Do you agree with that statement from the AMA 02:24:45PM  
22 Journal of Ethics? 02:24:48PM  
23 A. I do. 02:24:50PM  
24 Q. The next sentence says, "Because case series 02:24:51PM  
25 provide only weak scientific evidence, they are not 02:24:54PM

1 commonly used to make changes in how medications are  
2 used."

3 Do you see that?

4 A. I do.

5 Q. Do you agree with that statement?

6 A. I do.

7 Q. Why is it that case series are only weak  
8 scientific evidence?

9 A. Because they only -- a case series is  
10 observational, meaning that it can't prove cause and  
11 effect. And a case series is only a few patients. So  
12 what you're basically saying is, "We did -- we have  
13 something that was done in a few patients, and this is  
14 what we found." There's no way you can make any  
15 conclusion. It would be like saying, "I flipped a coin  
16 three times and it came up heads three times in a row;  
17 therefore, forever it will come up three times in a  
18 row." It's just too small a sample. And there's no  
19 proof that, in a case series, that association you find  
20 is, as I said, causative.

21 An example I like to give when I'm teaching  
22 medical students is, if I look across the street and see  
23 ten blond teenagers all with purple shoelaces, does that  
24 mean that being blond causes you to have purple  
25 shoelaces? Or is it just an association? And it -- as

1 you can easily understand, it's just an association. 02:25:58PM

2 It's not cause and effect. 02:26:01PM

3 So a small case series has no way to prove 02:26:02PM  
4 anything, other than to help with the theory that 02:26:06PM  
5 something might be useful in an extenuating circumstance 02:26:09PM  
6 or as a new treatment, but that further study is needed. 02:26:13PM  
7 It just is part of creating a theory. 02:26:17PM

8 Q. Okay. 02:26:21PM

9 I'm going to pull up Exhibit 119, which is 02:26:22PM  
10 titled "Rating Evidence in Medical Literature," which is 02:26:31PM  
11 a document the attorney general has used in this lawsuit 02:26:34PM  
12 to explain how it evaluates the credibility of medical 02:26:38PM  
13 evidence. 02:26:40PM

14 Are you aware of that? 02:26:41PM

15 (Exhibit 119 was marked.) 02:26:41PM

16 THE WITNESS: Yes. 02:26:42PM

17 BY ATTORNEY JONNA: 02:26:42PM

18 Q. Page 1. It states that there's this 02:26:47PM  
19 definition provided for evidence-based medicine which 02:26:51PM  
20 includes "conscientious, explicit, and judicious use of 02:26:55PM  
21 current best evidence in making decisions about the care 02:27:01PM  
22 of individual patients." 02:27:02PM

23 Do you see that? 02:27:03PM

24 A. I do. 02:27:04PM

25 Q. So this document essentially advises doctors 02:27:04PM

1 to use the best available evidence in making decisions; 02:27:08PM  
2 correct? 02:27:10PM  
3 A. Yes. 02:27:10PM  
4 ATTORNEY PENAN: Objection. The record speaks 02:27:12PM  
5 for itself. Calls for speculation. Lacks foundation. 02:27:13PM  
6 BY ATTORNEY JONNA: 02:27:20PM  
7 Q. It doesn't tell doctors that they can't 02:27:21PM  
8 recommend a treatment if they lack randomized clinical 02:27:21PM  
9 trials showing safety and efficacy; correct? 02:27:23PM  
10 A. It does not -- 02:27:23PM  
11 ATTORNEY PENAN: Same objection. Plus 02:27:25PM  
12 compound. Vague. Ambiguous. Confusing. 02:27:26PM  
13 ATTORNEY JONNA: Did the court reporter get 02:27:26PM  
14 the answer? 02:27:26PM  
15 THE WITNESS: It does not. 02:27:33PM  
16 BY ATTORNEY JONNA: 02:27:33PM  
17 Q. Okay. 02:27:33PM  
18 On Page 2, I want to show you this table here. 02:27:35PM  
19 Just take a look at this. 02:27:35PM  
20 My question is, do you agree with the rating 02:27:46PM  
21 of evidence presented in this table? 02:27:48PM  
22 A. For the most part in looking at it quickly, 02:27:49PM  
23 yes. Those are pretty standard grades. 02:28:07PM  
24 Q. Do you see that level of evidence 1b is a 02:28:11PM  
25 prospective cohort study with good followup? 02:28:14PM



1 deficiencies.

02:29:12PM

2 Q. I simply asked if he had good followup. So --  
3 and you said --

02:29:14PM

02:29:17PM

4 A. You didn't simp- -- you did not simply ask --  
5 you asked if Glidden -- if I was aware that Glidden  
6 stated that.

02:29:17PM

02:29:19PM

02:29:22PM

7 Q. I previously asked if you were aware that  
8 Glidden called it a prospective cohort study. And then  
9 I asked if Turner had good followup in the study. So I  
10 think you've answered those questions. Moving on.

02:29:23PM

02:29:25PM

02:29:29PM

02:29:33PM

11 Dr. Delgado's study was a retrospective cohort  
12 study; correct?

02:29:35PM

02:29:37PM

13 A. No, it was not.

02:29:38PM

14 Q. Why is that?

02:29:39PM

15 A. It wasn't anything. It clai- -- the title  
16 said "case series." The body of it said "retrospective  
17 cohort study." The methods describe a "prospective  
18 clinical trial." So it's nothing. It's fraudulent.

02:29:40PM

02:29:45PM

02:29:49PM

02:29:52PM

19 Q. And what makes it fraudulent again?

02:29:56PM

20 A. Because those three things. You can't -- you  
21 can't say it's one thing -- you can't say it's three  
22 different things. You can't. Basically, you --  
23 everything has to fit through. It's called "internal  
24 consistency." And there's no internal consistency in  
25 the way the data was collected compared to how the study

02:29:56PM

02:29:59PM

02:30:03PM

02:30:07PM

02:30:09PM

02:30:13PM

1 was described, how it went initially to the IRB, and the 02:30:15PM  
2 IRB said, "You can't describe it that way. That's not 02:30:17PM  
3 how we approved it." And then you change what you 02:30:19PM  
4 said -- you said to the IRB. And then the title says 02:30:22PM  
5 something completely different. The title says it's a 02:30:25PM  
6 case series. There's nothing in the reporting that 02:30:27PM  
7 reports it as a case series. There's standardized 02:30:30PM  
8 reporting mechanisms for all studies in the EQUATOR 02:30:33PM  
9 Network that say, "This is how you report a study if 02:30:34PM  
10 you're calling it a 'case series' or a 'cohort study' or 02:30:36PM  
11 a 'randomized trial.'" And it doesn't follow anything. 02:30:40PM  
12 It's just a -- it's just medical nothing. 02:30:44PM

13 Q. But you don't have any evidence that 02:30:52PM  
14 Dr. Delgado manipulated data or that he left out 02:30:55PM  
15 material information in his study; correct? 02:30:59PM

16 ATTORNEY PENAN: Objection. Calls for 02:31:01PM  
17 speculation. Compound. Lacks foundation. Incomplete 02:31:03PM  
18 hypothetical. 02:31:05PM

19 THE WITNESS: For your -- to directly answer 02:31:07PM  
20 your question? No. 02:31:10PM

21 BY ATTORNEY JONNA: 02:31:10PM

22 Q. Okay. 02:31:10PM

23 That -- that would certainly rise to the level 02:31:14PM  
24 of fraud in a study, though; right? 02:31:16PM

25 A. Everything the way it's written describes 02:31:20PM

1 something that isn't a study. 02:31:22PM

2 BY ATTORNEY JONNA: 02:31:22PM

3 Q. Okay. 02:31:23PM

4 A. Right? So if -- 02:31:25PM

5 Q. So -- 02:31:25PM

6 A. If everything that's described in there 02:31:26PM  
7 doesn't match up, it's by definition not of any 02:31:27PM  
8 scientific value. You can't have -- you can't have a 02:31:32PM  
9 study titled a "case control," describe it as a 02:31:38PM  
10 "retrospective cohort study," and then describe in your 02:31:41PM  
11 methodologies a prospective trial. 02:31:44PM

12 Q. Okay. 02:31:44PM

13 A. We recruited patients prospectively through a 02:31:46PM  
14 single recruitment center, told them where to go. 02:31:48PM  
15 Patients were consented ahead of time. That's a 02:31:52PM  
16 prospective study. Without IRB approval; right? So 02:31:54PM  
17 everything about it would not be acceptable to any 02:32:00PM  
18 reputable medical journal. 02:32:02PM

19 Q. So you would characterize his study as Level 02:32:04PM  
20 2b evidence or Level 4 evidence? 02:32:09PM

21 A. I wouldn't characterize it -- 02:32:09PM

22 ATTORNEY PENAN: Objection. Asked and 02:32:12PM  
23 answered. 02:32:12PM

24 THE WITNESS: I wouldn't characterize it, 02:32:12PM  
25 because it doesn't rise to the level of a study. You 02:32:15PM

1 can't give a grade to something that doesn't have 02:32:17PM  
2 internal consistency to meet the criteria for any type 02:32:20PM  
3 of study. 02:32:25PM  
4 BY ATTORNEY JONNA: 02:32:25PM  
5 Q. Okay. 02:32:25PM  
6 What -- how about Delgado's 2012 case series? 02:32:27PM  
7 Would you agree that that would qualify as Level 4 02:32:30PM  
8 evidence showing a positive result? 02:32:33PM  
9 A. Yes. Not a positive -- it's just Level 4 02:32:35PM  
10 evidence. The type of result, whether it's positive or 02:32:39PM  
11 negative, is -- is not -- is irrelevant. It's a case 02:32:41PM  
12 series. 02:32:44PM  
13 Q. And what about -- 02:32:44PM  
14 A. It's -- 02:32:44PM  
15 Q. I'm sorry. Go ahead. 02:32:45PM  
16 A. Go ahead. No. That's it. 02:32:47PM  
17 Q. What about Turner's 2017 case series? That's 02:32:48PM  
18 also Level 4 evidence? 02:32:51PM  
19 A. Yes. 02:32:52PM  
20 Q. Are you aware that there's also bench research 02:32:53PM  
21 showing that the action of mifepristone can be 02:32:59PM  
22 antagonized by progesterone in vitro? 02:33:02PM  
23 ATTORNEY PENAN: Objection. Calls for 02:33:06PM  
24 speculation. Incomplete hypothetical. Lacks 02:33:09PM  
25 foundation. Vague. Ambiguous. 02:33:10PM

1 THE WITNESS: Yeah. But, again, any research 02:33:11PM  
2 like that doesn't bear out to have any clinical utility. 02:33:13PM  
3 It's just part of creating a theory. 02:33:18PM  
4 BY ATTORNEY JONNA: 02:33:20PM  
5 Q. Right. I'm not asking that, sir. I'm just 02:33:20PM  
6 asking if you're aware that there is bench research 02:33:22PM  
7 showing that the action of mifepristone can be 02:33:26PM  
8 antagonized by progesterone in vitro. Yes or no? 02:33:29PM  
9 ATTORNEY PENAN: Objection. Asked and 02:33:31PM  
10 answered. Argumentative. Harassing. 02:33:35PM  
11 THE WITNESS: Yes. 02:33:35PM  
12 BY ATTORNEY JONNA: 02:33:35PM  
13 Q. And that would be Level 5 evidence on this 02:33:35PM  
14 chart; correct? 02:33:37PM  
15 A. Yes. 02:33:37PM  
16 Q. All right. 02:33:38PM  
17 Looking at Page 3. And how the article 02:33:41PM  
18 characterizes case series and case ris- -- reports, 02:33:49PM  
19 it's -- in referring to these it says, "While these 02:33:52PM  
20 studies do not meet criteria necessary for achieving 02:33:55PM  
21 higher evidence level status, they are quite common in 02:33:59PM  
22 reporting outcomes in surgical specialties." 02:34:02PM  
23 Do you see that? 02:34:04PM  
24 A. I do. 02:34:04PM  
25 Q. So it's acceptable to use Level 3 and Level 4 02:34:05PM

1 evidence in surgery, which can be very high risk. So 02:34:11PM  
2 I'm sure you would also agree that Level 3 and Level 4 02:34:11PM  
3 evidence can also be relied on in the APR context; 02:34:15PM  
4 correct? 02:34:18PM

5 A. That's not what this says -- 02:34:21PM

6 ATTORNEY PENAN: Objection. Incomplete 02:34:21PM  
7 hypothetical. Lacks foundation. Calls for speculation. 02:34:22PM  
8 Vague. Ambiguous. Compound. And misstates the 02:34:25PM  
9 witness's testimony. 02:34:27PM

10 THE WITNESS: It doesn't say that at all here. 02:34:30PM

11 BY ATTORNEY JONNA: 02:34:33PM

12 Q. Okay. 02:34:33PM

13 What do you mean by that? 02:34:33PM

14 A. What this says is that, in surgical 02:34:34PM  
15 specialties, it's common for people to describe case 02:34:39PM  
16 reports. That's all it says. 02:34:42PM

17 Q. Do you believe that Level 3 and Level 4 02:34:44PM  
18 evidence can be relied on in the APR context? 02:34:49PM

19 A. No. 02:34:52PM

20 Q. Why not? 02:34:52PM

21 A. Because I'm doing a human intervention. 02:34:54PM

22 Q. Okay. 02:34:59PM

23 I'm going to show you a quote on Page 5. At 02:35:11PM  
24 the top there. "One must be careful not to adopt an 02:35:17PM  
25 inflexible approach of only applying recommendations of 02:35:20PM

1 greater strength. The practice of evidence-based 02:35:24PM  
2 medicine is not cookbook medicine, and, therefore, the 02:35:27PM  
3 basis for patient care decisions should not be 02:35:29PM  
4 restricted to randomized trials or meta analyses. These 02:35:33PM  
5 are uncommon diseases and -- and complex pathologies 02:35:38PM  
6 that cannot be investigated with study designs that 02:35:44PM  
7 achieve levels of evidence higher than 3 or 4." 02:35:44PM  
8 Do you see that? 02:35:46PM  
9 A. I do. 02:35:46PM  
10 Q. Do you agree with that statement? 02:35:46PM  
11 A. I do. 02:35:48PM  
12 Q. Do you agree that the basis for patient care 02:35:49PM  
13 decisions should not be restricted to randomized trial? 02:35:50PM  
14 A. I do. 02:35:51PM  
15 ATTORNEY PENAN: Objection. Asked and 02:35:52PM  
16 answered. 02:35:53PM  
17 BY ATTORNEY JONNA: 02:35:53PM  
18 Q. And with respect to the reference to "uncommon 02:35:54PM  
19 diseases," you do agree that it's uncommon for a woman 02:35:57PM  
20 to change her mind after taking mifepristone; correct? 02:36:00PM  
21 A. I do. 02:36:02PM  
22 ATTORNEY PENAN: Objection. Incomplete 02:36:04PM  
23 hypothetical. Lacks foundation. 02:36:05PM  
24 BY ATTORNEY JONNA: 02:36:06PM  
25 Q. Looking at your declaration again, Exhibit 2, 02:36:07PM

1 Page 12. You state here in yellow, "A retrospective 02:36:12PM  
2 cohort study describes individuals with shared exposure 02:36:21PM  
3 identified from past data and describes their outcomes." 02:36:25PM  
4 Do you see that? 02:36:30PM  
5 A. Yes, I do. 02:36:31PM  
6 Q. And isn't it true that a group of women 02:36:32PM  
7 receiving progesterone after taking mifepristone could 02:36:34PM  
8 form a cohort for purposes of a cohort study? 02:36:38PM  
9 ATTORNEY PENAN: Objection. Incomplete 02:36:41PM  
10 hypothetical. Vague. Ambiguous. 02:36:42PM  
11 THE WITNESS: They could, but there's yet one 02:36:45PM  
12 to be published. 02:36:47PM  
13 BY ATTORNEY JONNA: 02:36:47PM  
14 Q. Okay. 02:36:47PM  
15 And Delgado's study analyzed a group of women 02:36:49PM  
16 who had been exposed to mifepristone and progesterone to 02:36:55PM  
17 describe their outcomes of whether or not their 02:36:56PM  
18 pregnancies continued; isn't that correct? 02:36:57PM  
19 ATTORNEY PENAN: Objection. Argumentative. 02:37:01PM  
20 Misstates the witness's testimony. Lacks foundation. 02:37:03PM  
21 Incomplete hypothetical. 02:37:07PM  
22 THE WITNESS: It's not. It's -- I've already 02:37:09PM  
23 answered that you can't rely anything -- that it's -- by 02:37:11PM  
24 the title, a case series; in the text, a retrospective 02:37:13PM  
25 cohort; in the description of the methodologies, a 02:37:18PM

1 prospective trial.

02:37:23PM

2 BY ATTORNEY JONNA:

02:37:23PM

3 Q. So I --

02:37:23PM

4 A. So I can't --

02:37:22PM

5 Q. -- understand --

02:37:24PM

6 A. -- agree with your statement -- so I can't

02:37:22PM

7 agree to your statement.

02:37:22PM

8 Q. Right.

02:37:22PM

9 I understand that's your ultimate conclusion.

02:37:24PM

10 I'm actually asking a much, much more specific question.

02:37:26PM

11 Setting aside that conclusion, you do agree,

02:37:29PM

12 though, that the study analyzed a group of women who had

02:37:32PM

13 been exposed to mifepristone and progesterone to

02:37:36PM

14 describe their outcomes of whether or not their

02:37:40PM

15 pregnancies continued; correct?

02:37:43PM

16 A. I don't agree with --

02:37:45PM

17 ATTORNEY PENAN: Same objections. Plus

02:37:45PM

18 argumentative.

02:37:47PM

19 THE WITNESS: I've -- I've already answered

02:37:48PM

20 this.

02:37:49PM

21 BY ATTORNEY JONNA:

02:37:49PM

22 Q. So you dispute --

02:37:50PM

23 A. And I -- I do not agree because it's -- I

02:37:51PM

24 can't call it a study. You can't rely on anything in

02:37:52PM

25 it. You just can't.

02:37:55PM

1 Q. Okay. Do you -- 02:37:55PM  
2 A. So I can't answer your question. 02:37:57PM  
3 Q. Okay. Let me -- let me ask it this way, then. 02:37:59PM  
4 Would you agree that Delgado attempted to 02:38:01PM  
5 study and analyze a group of women who had been exposed 02:38:05PM  
6 to mifepristone and progesterone to describe their 02:38:09PM  
7 outcomes of whether or not their pregnancies continued? 02:38:11PM  
8 A. No. 02:38:14PM  
9 ATTORNEY PENAN: Same objection. 02:38:15PM  
10 BY ATTORNEY JONNA: 02:38:15PM  
11 Q. Why not? 02:38:15PM  
12 ATTORNEY PENAN: Plus compound. Vague. 02:38:16PM  
13 THE WITNESS: Because -- 02:38:16PM  
14 ATTORNEY PENAN: Ambiguous. 02:38:17PM  
15 THE WITNESS: -- he performed a prospective 02:38:20PM  
16 study and tried to describe it as a retrospective cohort 02:38:23PM  
17 and then -- tried to then describe it as a case series. 02:38:26PM  
18 And it doesn't follow any reporting criteria, any way, 02:38:30PM  
19 shape, or form, for any of those. So I can't agree to 02:38:33PM  
20 any statement you're trying to get me to agree to 02:38:37PM  
21 because it doesn't fit. 02:38:40PM  
22 BY ATTORNEY JONNA: 02:38:40PM  
23 Q. I'm just asking if you will agree to 02:38:43PM  
24 foundational -- 02:38:45PM  
25 A. And I won't. 02:38:46PM

1 Q. One second, sir. I'm sorry. I'm sorry. You 02:38:47PM  
2 have to let me finish -- 02:38:49PM  
3 A. I won't. I've already -- 02:38:50PM  
4 Q. -- my question. 02:38:50PM  
5 A. -- answered this. 02:38:51PM  
6 Q. There is a court reporter trying to take down 02:38:52PM  
7 what we're saying, sir. Please -- 02:38:54PM  
8 A. Okay. 02:38:54PM  
9 Q. -- wait for me to finish my question, and then 02:38:57PM  
10 you can provide your answer. 02:38:58PM  
11 A. Thank you. 02:38:59PM  
12 Q. I am not asking about whether you -- I -- I 02:39:00PM  
13 understand. You think it's not a study. I understand 02:39:01PM  
14 you think its fraudulent. I understand all of that. 02:39:04PM  
15 My question is just about whether you would 02:39:07PM  
16 agree to what the study -- how the study was reported to 02:39:09PM  
17 be conducted and -- and whether you would agree that 02:39:13PM  
18 Dr. Delgado was trying to analyze women who had been 02:39:16PM  
19 exposed to mifepristone and progesterone, to describe 02:39:20PM  
20 their outcomes of whether or not their pregnancies 02:39:23PM  
21 continued. 02:39:26PM  
22 ATTORNEY PENAN: Objection. Calls for 02:39:27PM  
23 speculation. Lacks foundation. Incomplete 02:39:28PM  
24 hypothetical. 02:39:30PM  
25 THE WITNESS: That's a different question than 02:39:32PM

1 you asked before. Was Dr. Delgado trying to put 02:39:34PM  
2 together some data on this? That's basically -- I 02:39:39PM  
3 believe he was, and I have no idea what he was doing or 02:39:42PM  
4 how he was doing it. And I don't believe there's 02:39:45PM  
5 anything I can conclude from it. 02:39:47PM  
6 BY ATTORNEY JONNA: 02:39:49PM  
7 Q. Have you ever spoken to Dr. Delgado about his 02:39:51PM  
8 study? 02:39:56PM  
9 A. I have not. 02:39:56PM  
10 Q. Why not? 02:39:57PM  
11 A. I have -- why not? Because I haven't. 02:39:58PM  
12 Q. Do you have any reason to question his 02:40:00PM  
13 character or his integrity? 02:40:05PM  
14 ATTORNEY PENAN: Objection. Compound. 02:40:07PM  
15 THE WITNESS: As a -- as a scientist, I think 02:40:13PM  
16 anybody who would turn that out has no scientific 02:40:15PM  
17 integrity. It's garbage. 02:40:18PM  
18 BY ATTORNEY JONNA: 02:40:22PM  
19 Q. Okay. 02:40:23PM  
20 And you are aware that the Delgado study 02:40:23PM  
21 analyzed data from 547 patients; correct? 02:40:29PM  
22 A. It wasn't a study -- 02:40:33PM  
23 ATTORNEY PENAN: Objection. Asked and 02:40:33PM  
24 answered. Argumentative. The document -- 02:40:34PM  
25 THE WITNESS: And it -- 02:40:34PM

1           ATTORNEY PENAN: -- speaks for itself. 02:40:37PM

2           THE WITNESS: And it include -- sorry. I 02:40:38PM

3 apologize for over-speaking the -- the attorney. 02:40:39PM

4           It wasn't a study, number one. Number two, it 02:40:43PM

5 only analyzed 547 and left out people that should have 02:40:46PM

6 been analyzed if somebody knew what they were doing. So 02:40:50PM

7 it selectively analyzed some of the people. So it's why 02:40:53PM

8 I said, it's just -- it doesn't follow any way, shape, 02:40:57PM

9 or form science the way it should be evaluated. 02:41:01PM

10 BY ATTORNEY JONNA: 02:41:05PM

11           Q. Okay. 02:41:05PM

12           A. So it's not a study. 02:41:04PM

13           Q. I'm going to pull up Exhibit 106, which is the 02:41:05PM

14 OB/GYN website -- sorry -- home page on the UC Davis 02:41:07PM

15 hospital website. 02:41:13PM

16           A. Yup. 02:41:13PM

17                   (Exhibit 106 was marked.) 02:41:13PM

18 BY ATTORNEY JONNA: 02:41:13PM

19           Q. Have you seen this before? 02:41:15PM

20           A. Yes. 02:41:15PM

21           Q. And are you aware that, in response to the 02:41:21PM

22 FDA's recent announcement that use of Tylenol during 02:41:23PM

23 pregnancy is associated with increased risks of ADHD and 02:41:29PM

24 autism, the UC Davis OB/GYN department displayed on its 02:41:32PM

25 website the claim that Tylenol is established as safe to 02:41:35PM

1 use during pregnancy? 02:41:38PM

2 A. I am. 02:41:39PM

3 ATTORNEY PENAN: Objection. Calls for 02:41:40PM

4 speculation. Lacks foundation. Incomplete 02:41:42PM

5 hypothetical. Outside the scope of the witness's 02:41:43PM

6 designation. 02:41:46PM

7 BY ATTORNEY JONNA: 02:41:47PM

8 Q. Is it misleading to say that Tylenol is safe 02:41:47PM

9 to use during pregnancy when the FDA cautions its use 02:41:51PM

10 and cites two large studies that show an association 02:41:53PM

11 with Tylenol use during pregnancy and increased rates of 02:41:55PM

12 autism? 02:41:59PM

13 A. (Inaudible) -- 02:42:00PM

14 ATTORNEY PENAN: Same objections. Plus 02:42:00PM

15 compound. Vague. Ambiguous. And calls for a legal 02:42:02PM

16 conclusion. 02:42:04PM

17 THE WITNESS: If you want to get into the 02:42:05PM

18 politics of the current FDA, I'm happy to do so, which 02:42:07PM

19 is filled with people who don't know -- at the top who 02:42:11PM

20 don't know how to interpret science. Every major 02:42:15PM

21 medical organization has come out against what the FDA 02:42:19PM

22 is trying to do here. The -- the -- Tylenol is not the 02:42:24PM

23 cause of autism. Tylenol used during pregnancy is not. 02:42:27PM

24 The evidence is overly clear that it does not. 02:42:32PM

25 ///

1 BY ATTORNEY JONNA: 02:42:35PM

2 Q. Have very large studies ruled out that Tylenol 02:42:36PM

3 does not increase the rate of autism? 02:42:39PM

4 A. It's -- 02:42:44PM

5 ATTORNEY PENAN: Same objections. 02:42:44PM

6 THE WITNESS: The abundance of the data 02:42:47PM

7 supports that it is safer to use than not use. And the 02:42:49PM

8 associations that are seen in the two studies quoted by 02:42:54PM

9 the FDA are associations that are confounded 02:42:58PM

10 tremendously and aren't supported by other studies, 02:43:02PM

11 which is why studies are done. 02:43:08PM

12 BY ATTORNEY JONNA: 02:43:10PM

13 Q. Right. 02:43:10PM

14 So my question was simply: Have large studies 02:43:12PM

15 ruled out that Tylenol does not increase the rate of 02:43:13PM

16 autism? 02:43:15PM

17 ATTORNEY PENAN: Same objections. 02:43:16PM

18 THE WITNESS: I can't answer that as I sit 02:43:18PM

19 here right now. 02:43:20PM

20 BY ATTORNEY JONNA: 02:43:21PM

21 Q. Have large studies been conducted to make sure 02:43:22PM

22 that Tylenol doesn't -- actually increase -- let me -- 02:43:25PM

23 let me rephrase the question. 02:43:30PM

24 Have large studies been conducted to make sure 02:43:31PM

25 that Tylenol doesn't increase the rate of ADHD? 02:43:34PM

1           ATTORNEY PENAN: Same objections. 02:43:34PM

2           THE WITNESS: I -- the studies I'm aware of 02:43:42PM

3 show that, when appropriately controlled for, Tylenol 02:43:44PM

4 use in pregnancy does not increase the risk of autism or 02:43:47PM

5 any other neurodevelopmental disorder. 02:43:50PM

6 BY ATTORNEY JONNA: 02:43:50PM

7           Q. You do agree that having large studies on 02:43:55PM

8 these topics would be a good idea, though, before making 02:43:57PM

9 safety claims; correct? 02:44:00PM

10           ATTORNEY PENAN: Same objections. Plus 02:44:02PM

11 argumentative. 02:44:03PM

12           THE WITNESS: There has to be a biologic 02:44:04PM

13 rationale, and it would be helpful to have studies, yes. 02:44:13PM

14 BY ATTORNEY JONNA: 02:44:18PM

15           Q. All right. 02:44:18PM

16 I'm going to pull up Exhibit 107, which is one 02:44:18PM

17 of the studies that the FDA cited. And it -- 02:44:22PM

18 Have you seen this document before, by the 02:44:29PM

19 way? 02:44:31PM

20           A. I have not. 02:44:32PM

21 (Exhibit 107 was marked.) 02:44:32PM

22 BY ATTORNEY JONNA: 02:44:32PM

23           Q. So it apparently looked at 8,856 children 02:44:33PM

24 born, and it claimed on the first page, "Our NCE 02:44:38PM

25 negative control exposure analysis suggested that only 02:44:45PM

1 acetaminophen used at the time of pregnancy was 02:44:49PM

2 associated with childhood ADHD." 02:44:50PM

3 Do you see that? 02:44:53PM

4 A. I do. 02:44:54PM

5 Q. And it continues to say, "Our findings 02:44:55PM

6 corroborate those of previous reports suggesting that 02:44:58PM

7 prenatal acetaminophen exposure may influence 02:45:02PM

8 neurodevelopment." 02:45:02PM

9 Do you see that? 02:45:02PM

10 A. I do. 02:45:02PM

11 Q. So in the face of a study with 8,856 children 02:45:07PM

12 found an increased risk of ADHD associated with Tylenol 02:45:07PM

13 exposure during pregnancy, UC Davis makes a blanket 02:45:13PM

14 statement that Tylenol is safe during pregnancy; is that 02:45:16PM

15 right? 02:45:20PM

16 ATTORNEY PENAN: Objection. Lacks foundation. 02:45:20PM

17 Incomplete hypothetical. Outside the scope of the 02:45:20PM

18 witness's designation. Assumes facts not in evidence. 02:45:23PM

19 THE WITNESS: So I get my information from the 02:45:26PM

20 experts in this area. So you're asking me to be an 02:45:28PM

21 expert in an area I'm not. My understanding of the 02:45:31PM

22 study is based on the reading I have done, as well as 02:45:34PM

23 the expertise of the colleagues in my department, is 02:45:37PM

24 that the best evidence is -- and the American College of 02:45:41PM

25 OB/GYN, I should add -- is that the best evidence is 02:45:45PM

1 that it likely does not influence neurodevelopment and 02:45:48PM  
2 that we do know there are influences on neurodevelopment 02:45:55PM  
3 from uncontrolled fevers in a woman during pregnancy. 02:45:55PM  
4 The other option when somebody has fever in pregnancy is 02:45:59PM  
5 a nonsteroidal analgesic, which we know has a direct 02:46:03PM  
6 impact on the fetus and can cause harm to fetal kidneys 02:46:07PM  
7 and the fetal heart. So you're facing somebody where 02:46:09PM  
8 you're -- have a fever which will cause damage, in and 02:46:12PM  
9 of itself versus, the treatments. 02:46:15PM  
10 One of -- the problems with these is that 02:46:18PM  
11 the -- with these studies and that's the high -- the 02:46:21PM  
12 highly cited problems is: Is it the acetaminophen or 02:46:23PM  
13 the reason the person took the acetaminophen? And the 02:46:27PM  
14 other studies that are out there corroborate the idea 02:46:31PM  
15 that it's most likely the reason she took the 02:46:34PM  
16 acetaminophen and not the acetaminophen itself. 02:46:36PM  
17 However, just like when it comes to family 02:46:38PM  
18 planning issues, the other people in my department cede 02:46:42PM  
19 to those of us that are the subspecialists in this area 02:46:44PM  
20 and have the expertise, I cede to my colleagues who have 02:46:46PM  
21 the expertise in this area, which is where that 02:46:48PM  
22 statement comes from; not from me. 02:46:51PM  
23 BY ATTORNEY JONNA: 02:46:53PM  
24 Q. Okay. 02:46:53PM  
25 Pulling up Exhibit 108. 02:46:54PM

1 (Exhibit 108 was marked.) 02:47:01PM  
2 BY ATTORNEY JONNA: 02:47:01PM  
3 Q. UC Davis directly references the ACOG 02:47:02PM  
4 statement on Tylenol, which here -- we look here. It 02:47:06PM  
5 says, "This has not been proven by science. The highest 02:47:09PM  
6 quality research studies show there is no evidence that 02:47:10PM  
7 acetaminophen causes autism." 02:47:13PM  
8 Do you see that? 02:47:16PM  
9 A. I do. 02:47:16PM  
10 Q. Do you think it's misleading to say "there is 02:47:17PM  
11 no evidence"? 02:47:19PM  
12 ATTORNEY PENAN: Objection. Calls for 02:47:20PM  
13 speculation. Lacks foundation. Incomplete 02:47:23PM  
14 hypothetical. Vague. Ambiguous. Calls for a legal 02:47:25PM  
15 conclusion. And outside the scope of the witness's 02:47:27PM  
16 designation. 02:47:31PM  
17 THE WITNESS: I think the full sentence there 02:47:31PM  
18 is "the highest quality research studies." 02:47:35PM  
19 BY ATTORNEY JONNA: 02:47:38PM  
20 Q. So does the -- does the absence of evidence 02:47:38PM  
21 that it causes ADHD make it safe? 02:47:41PM  
22 ATTORNEY PENAN: Same objections. 02:47:44PM  
23 THE WITNESS: I think you're asking me 02:47:45PM  
24 questions outside of my expertise area. 02:47:46PM  
25 ///

1 BY ATTORNEY JONNA: 02:47:49PM

2 Q. Okay. 02:47:49PM

3 Focusing on your expertise, and -- how do you 02:47:49PM

4 determine what constitutes the highest qual- -- who 02:47:53PM

5 determines, I should say, what constitutes the highest 02:47:57PM

6 quality research? 02:47:59PM

7 ATTORNEY PENAN: Objection. Vague. 02:48:02PM

8 Ambiguous. Lacks foundation. Incomplete hypothetical. 02:48:04PM

9 Calls for speculation. 02:48:04PM

10 THE WITNESS: The highest quality research is 02:48:07PM

11 determined by the type of study it is as well as how 02:48:10PM

12 well the -- the study controls for confounders and other 02:48:13PM

13 variables, if it's a -- a database study like the ones 02:48:17PM

14 you're describing. But there's lots of other things 02:48:21PM

15 that go into quality. That's why there's grade -- the 02:48:25PM

16 grade system to describe the quality. 02:48:25PM

17 BY ATTORNEY JONNA: 02:48:25PM

18 Q. Could -- would you agree that reasonable 02:48:28PM

19 scientific researchers can disagree about what the 02:48:30PM

20 "highest quality research" means? 02:48:34PM

21 ATTORNEY PENAN: Objection. Calls for 02:48:36PM

22 speculation. Lacks foundation. Incomplete 02:48:38PM

23 hypothetical. Vague. Ambiguous. 02:48:41PM

24 THE WITNESS: In general, the grade system is 02:48:43PM

25 pretty straightforward. So I think, you know, you 02:48:44PM

1 might -- somebody may argue a 2a or 2b or something like 02:48:48PM  
2 that, but in general it's not that hard to tell what -- 02:48:51PM  
3 whether something meets the criteria. 02:48:56PM

4 The one thing the grade system doesn't take 02:48:58PM  
5 into account -- the grade system just describes the type 02:49:01PM  
6 of study. The other quality factors that can be 02:49:04PM  
7 measured, though, are size, generalizability. Like, if 02:49:07PM  
8 you look at just a white population. You know, it's not 02:49:10PM  
9 necessarily generalizable to other populations. Those 02:49:13PM  
10 things all come into play as well. 02:49:16PM

11 So there's the grade system about the type of 02:49:18PM  
12 study, and then there's other factors that relate to 02:49:21PM  
13 generalizability. 02:49:22PM

14 BY ATTORNEY JONNA: 02:49:24PM

15 Q. But you don't have any problems with UC Davis 02:49:24PM  
16 taking positions inconsistent with the FDA in this 02:49:27PM  
17 context; correct? 02:49:31PM

18 ATTORNEY PENAN: Objection. Misstates the 02:49:32PM  
19 witness's testimony. Calls for speculation. Lacks 02:49:36PM  
20 foundation. Incomplete hypothetical. Vague. 02:49:38PM  
21 Ambiguous. Argumentative. 02:49:38PM

22 THE WITNESS: I have a problem with the FDA 02:49:41PM  
23 taking a position that's completely opposite of every 02:49:43PM  
24 major medical organization of the world. 02:49:50PM

25 ///

1 BY ATTORNEY JONNA: 02:49:52PM

2 Q. And what's -- what's your problem with that? 02:49:52PM

3 A. Because it's not based in good science, which 02:49:54PM  
4 is what the responsibility of the FDA is right now. 02:49:58PM

5 Q. So you know better than the FDA? 02:49:58PM

6 A. I think under -- 02:49:59PM

7 ATTORNEY PENAN: Objection. Argumentative. 02:49:59PM  
8 Harassing. 02:50:01PM

9 THE WITNESS: I think in the current 02:50:03PM  
10 administration, the FDA is -- is not working as well as 02:50:07PM  
11 it should. 02:50:10PM

12 BY ATTORNEY JONNA: 02:50:11PM

13 Q. What -- what do you mean by that? 02:50:16PM

14 A. In the Trump administration under Kennedy as 02:50:16PM  
15 the head of DHHS, the FDA is not working the way it 02:50:20PM  
16 should. 02:50:21PM

17 Q. And what do you -- what do you attribute that 02:50:22PM  
18 to? 02:50:25PM

19 A. The people in charge. 02:50:25PM

20 Q. And what's wrong with the people in charge? 02:50:27PM

21 A. They don't know what they're doing. 02:50:29PM

22 Q. And how do you know that they don't know what 02:50:30PM  
23 they're doing? 02:50:33PM

24 A. Every major medical organization -- every -- 02:50:33PM  
25 of -- has demon- -- has come out in -- in opposition to 02:50:44PM

1 this ill-conceived and poorly based statement. 02:50:51PM

2 Q. Do you believe that other medical 02:51:00PM

3 organizations should have the right to object to the 02:51:03PM

4 FDA's position on this issue? 02:51:08PM

5 ATTORNEY PENAN: Objection. Incomplete 02:51:10PM

6 hypothetical. Calls for speculation. Lacks foundation. 02:51:11PM

7 Outside the scope of the witness's designation. 02:51:16PM

8 THE WITNESS: I think there's a difference if 02:51:19PM

9 you have one group who has a special interest that wants 02:51:20PM

10 to try to come out against something versus every 02:51:29PM

11 medical organization. I think there's a difference. 02:51:32PM

12 BY ATTORNEY JONNA: 02:51:32PM

13 Q. Which group has a special interest? What are 02:51:35PM

14 you referring to? 02:51:37PM

15 A. No. I'm -- you just asked -- 02:51:38PM

16 ATTORNEY PENAN: Objection. 02:51:38PM

17 THE WITNESS: -- me a hypothetical. 02:51:40PM

18 Can I -- go ahead. Finish your objection. 02:51:47PM

19 ATTORNEY PENAN: Objection. Outside the scope 02:51:47PM

20 of the witness's designation. Calls for speculation. 02:51:47PM

21 Lacks foundation. Incomplete hypothetical. Vague. 02:51:48PM

22 Ambiguous. Confusing. 02:51:52PM

23 THE WITNESS: You just asked me a 02:51:56PM

24 hypothetical. So the -- you responded in your 02:51:58PM

25 hypothetical was that if there was one organization that 02:52:00PM

1 has some special interest that tries to make everything 02:52:00PM  
2 change, but everybody else says, "Look, the evidence is 02:52:04PM  
3 really clear," that's not the same as every major 02:52:07PM  
4 medical organization saying, "This is very clear." 02:52:11PM  
5 BY ATTORNEY JONNA: 02:52:14PM  
6 Q. So your understanding is that every major 02:52:14PM  
7 medical organization disagrees with the FDA's statement 02:52:17PM  
8 on Tylenol and pregnancy? 02:52:20PM  
9 A. That is my understanding. And all of this is 02:52:25PM  
10 hypothetical in a sense, because this is outside of my 02:52:28PM  
11 area. If you have major medical organizations that all 02:52:31PM  
12 agree, based on the science, and you have somebody out 02:52:33PM  
13 there who is saying, "Well, we just don't want to 02:52:36PM  
14 agree," that's different. Then everybody's saying, 02:52:39PM  
15 "Yup. We all agree this is kind of not right." 02:52:43PM  
16 Q. How many medical organizations are you aware 02:52:47PM  
17 of internationally that disagree with ACOG's position on 02:52:51PM  
18 APR? 02:52:58PM  
19 A. Other than the associations related to 02:52:58PM  
20 pro-life organizations, I'm not aware of any. 02:53:03PM  
21 Q. And how many of those associated with pro-life 02:53:05PM  
22 organizations are you aware of? 02:53:11PM  
23 A. I don't -- I don't count them. 02:53:13PM  
24 Q. More than one, though; right? 02:53:15PM  
25 A. Yes. There's more than one pro-life 02:53:17PM

1 organization. 02:53:23PM

2 Q. They don't count to you, though. 02:53:23PM

3 ATTORNEY PENAN: Objection. Misstates the 02:53:23PM

4 witness's testimony. 02:53:23PM

5 THE WITNESS: They are -- they are bound to 02:53:25PM

6 uphold science in the same way, and they demonstrate 02:53:27PM

7 they don't when they try to do statistical analyses on 02:53:30PM

8 ten people or three people. That's not science. So if 02:53:35PM

9 they're not going to do science right, then -- then 02:53:36PM

10 they're misinterpreting data, very similar to how the 02:53:39PM

11 FDA currently is. 02:53:43PM

12 BY ATTORNEY JONNA: 02:53:43PM

13 Q. They did statistical analysis on ten people? 02:53:45PM

14 Is that what you said? 02:53:48PM

15 A. If they want to try to do that kind of stuff, 02:53:49PM

16 then that's not science. 02:53:53PM

17 Q. That sounds like what you did, though, doesn't 02:53:54PM

18 it? 02:53:56PM

19 A. No. I -- 02:53:56PM

20 ATTORNEY PENAN: Objection. Argumentative. 02:53:56PM

21 THE WITNESS: No. What I did is said that the 02:53:59PM

22 numbers weren't enough to make any conclusion. What 02:54:02PM

23 anti-choice groups have done is say, "See? Look. You 02:54:05PM

24 got these numbers, and it proves our point." So no. 02:54:07PM

25 I -- I -- I think you're the one who's incorrect there. 02:54:11PM

1 BY ATTORNEY JONNA: 02:54:14PM

2 Q. Are you aware that progestogens are used in 02:54:14PM

3 gender-affirming care? 02:54:20PM

4 ATTORNEY PENAN: Objection. Outside the 02:54:22PM

5 witness's designation. 02:54:23PM

6 THE WITNESS: I'm aware, but it's not my area 02:54:25PM

7 of expertise. 02:54:27PM

8 BY ATTORNEY JONNA: 02:54:28PM

9 Q. Are you aware that UC San Francisco prescribes 02:54:28PM

10 progesterone for gender-affirming care? 02:54:33PM

11 A. I -- 02:54:36PM

12 ATTORNEY PENAN: Objection. Calls for 02:54:36PM

13 speculation. Lacks foundation. Incomplete 02:54:36PM

14 hypothetical. And outside the scope of the witness's 02:54:39PM

15 designation. 02:54:41PM

16 THE WITNESS: I don't know what the doctors at 02:54:42PM

17 UCSF prescribe for gender-affirming care. That's 02:54:44PM

18 outside my area of expertise. 02:54:49PM

19 BY ATTORNEY JONNA: 02:54:51PM

20 Q. I'm going to pull up Exhibit 71. 02:54:51PM

21 (Exhibit 71 was marked.) 02:55:06PM

22 BY ATTORNEY JONNA: 02:55:06PM

23 Q. Sorry. This is from their website. I'm going 02:55:06PM

24 to turn your attention to Page 3, which states, "The 02:55:08PM

25 general approach of therapy is to combine an estrogen 02:55:15PM

1 with an androgen blocker and, in some cases, a 02:55:18PM  
2 progestogen." 02:55:22PM  
3 Do you see that? 02:55:22PM  
4 A. I do. 02:55:23PM  
5 Q. In the context of feminizing hormone therapy. 02:55:23PM  
6 Do you see that? 02:55:27PM  
7 A. I do. 02:55:28PM  
8 Q. And if you go to Page 6, they state that, 02:55:28PM  
9 "There are no well-designed studies of the role of 02:55:35PM  
10 progestogens in feminizing hormone regimens." 02:55:39PM  
11 Do you see that? 02:55:44PM  
12 A. I do. 02:55:44PM  
13 ATTORNEY PENAN: Objection. Calls for 02:55:44PM  
14 speculation. Lacks foundation. Incomplete 02:55:46PM  
15 hypothetical. Outside the -- 02:55:47PM  
16 BY ATTORNEY JONNA: 02:55:47PM  
17 Q. So -- 02:55:47PM  
18 ATTORNEY PENAN: -- scope of the witness's 02:55:48PM  
19 designation. 02:55:49PM  
20 BY ATTORNEY JONNA: 02:55:50PM  
21 Q. So in your view, for this reason, should 02:55:51PM  
22 progesterone not be used in gender-affirming care? 02:55:54PM  
23 ATTORNEY PENAN: Objection. Calls for 02:55:57PM  
24 speculation. Lacks foundation. Incomplete 02:55:57PM  
25 hypothetical. Outside the scope of the witness's 02:56:00PM

1 designation. 02:56:03PM

2 THE WITNESS: I have no expertise in this 02:56:03PM

3 area, so I can't make any judgment. 02:56:05PM

4 BY ATTORNEY JONNA: 02:56:07PM

5 Q. So you have no opinion one way or the other? 02:56:07PM

6 A. Not my area of -- 02:56:11PM

7 ATTORNEY PENAN: Same objections. Plus asked 02:56:11PM

8 and answered. 02:56:13PM

9 BY ATTORNEY JONNA: 02:56:14PM

10 Q. It continues by saying that, "There's no 02:56:18PM

11 evidence to suggest that using progestins in the setting 02:56:20PM

12 of transgender care are harmful." 02:56:25PM

13 Do you see that? 02:56:27PM

14 A. I do. 02:56:28PM

15 ATTORNEY PENAN: Same objections. 02:56:29PM

16 BY ATTORNEY JONNA: 02:56:29PM

17 Q. As an expert researcher with significant 02:56:30PM

18 experience researching and conducting studies, in your 02:56:35PM

19 view, is that a good enough reason for the use of 02:56:37PM

20 progestogens in gender-affirming care? 02:56:41PM

21 ATTORNEY PENAN: Objection. Calls for 02:56:43PM

22 speculation. Lacks foundation. Incomplete 02:56:45PM

23 hypothetical. Vague. Ambiguous. And outside the scope 02:56:46PM

24 of the witness's designation. 02:56:49PM

25 THE WITNESS: I can't comment on this. It's 02:56:51PM

1 outside of my area of expertise. I don't treat patients 02:56:53PM

2 for gender-affirming care. 02:56:58PM

3 BY ATTORNEY JONNA: 02:56:59PM

4 Q. Would it affect your opinions if WPATH 02:57:04PM

5 standards for gender-affirming care stated that there is 02:57:09PM

6 a risk of VTE from progesterone use in trans women? 02:57:11PM

7 ATTORNEY PENAN: Objection. Calls for 02:57:17PM

8 speculation. Lacks foundation. Incomplete 02:57:18PM

9 hypothetical. And outside the scope of the witness's 02:57:20PM

10 designation. 02:57:23PM

11 THE WITNESS: I can't speculate on it because 02:57:24PM

12 I don't know what their -- the WPATH guidelines say. 02:57:26PM

13 And it's outside my area of expertise. 02:57:30PM

14 ATTORNEY JONNA: Okay. Go off the record. 02:57:34PM

15 Can we go off the record, please? 02:57:49PM

16 THE VIDEOGRAPHER: One moment. We are off the 02:57:57PM

17 record at 2:57 p.m. 02:57:59PM

18 (Off the record: 2:57 p.m. to 3:11 p.m.) 03:11:09PM

19 THE VIDEOGRAPHER: We are back on the record 03:11:09PM

20 at 3:11 p.m. 03:11:11PM

21 BY ATTORNEY JONNA: 03:11:14PM

22 Q. All right. 03:11:14PM

23 I'm going to pull up Exhibit 24, which is an 03:11:15PM

24 article from Slate magazine, 2014, entitled "The Newest 03:11:18PM

25 Crisis Pregnancy Center Offer: 'Abortion Reversals.'" 03:11:23PM

1 Do you see that? 03:11:26PM  
2 (Exhibit 24 was marked.) 03:11:26PM  
3 THE WITNESS: I do. 03:11:27PM  
4 BY ATTORNEY JONNA: 03:11:27PM  
5 Q. Have you seen this article before? 03:11:27PM  
6 A. Probably. 03:11:30PM  
7 Q. It interviews Dr. Grossman. And on Page 3, it 03:11:31PM  
8 states, "Grossman says that the progesterone probably 03:11:38PM  
9 won't hurt a woman if she's under medical supervision, 03:11:40PM  
10 but he's concerned that the advertising of this 03:11:44PM  
11 procedure could mislead the public about the prevalence 03:11:46PM  
12 of abortion regret." 03:11:47PM  
13 Do you see that? 03:11:49PM  
14 A. I do. 03:11:49PM  
15 Q. Do you agree that promoting abortion pill 03:11:50PM  
16 reversal would mislead the public as to the prevalence 03:11:53PM  
17 of abortion regret? 03:11:57PM  
18 A. I believe it's possible -- 03:12:00PM  
19 ATTORNEY PENAN: Objection. Calls -- 03:12:01PM  
20 objection calls for speculation. Incomplete 03:12:02PM  
21 hypothetical. Lacks foundation. 03:12:03PM  
22 THE WITNESS: I believe the statement is 03:12:06PM  
23 correct as stated. It could mislead the public about 03:12:07PM  
24 prevalence of abortion regret. 03:12:11PM  
25 ///

1 BY ATTORNEY JONNA: 03:12:13PM

2 Q. And do you agree with his -- the earlier part 03:12:14PM

3 of that statement that "progesterone probably won't hurt 03:12:19PM

4 a woman if she's under medical supervision"? 03:12:22PM

5 A. I do. 03:12:25PM

6 Q. Okay. 03:12:26PM

7 I'm going to pull up Exhibit 113 now. 03:12:27PM

8 (Exhibit 113 was marked.) 03:12:27PM

9 BY ATTORNEY JONNA: 03:12:27PM

10 Q. This is a commen- -- excuse me -- this is a 03:12:55PM

11 commentary article you wrote titled "Family planning, 03:13:01PM

12 population growth, and the environment" from 2020. 03:13:03PM

13 Do you see that? 03:13:03PM

14 A. I do. 03:13:04PM

15 Q. And on Page 1, you stated, "Family planning is 03:13:05PM

16 the most humane and viable strategy for human survival." 03:13:07PM

17 Do you see that? 03:13:12PM

18 A. I do. 03:13:13PM

19 Q. Is your belief that family planning is the 03:13:13PM

20 most humane and viable strategy for human survival 03:13:17PM

21 validated by double-blind placebo controlled randomized 03:13:21PM

22 control trials? 03:13:26PM

23 ATTORNEY PENAN: Objection. Incomplete 03:13:27PM

24 hypothetical. Vague. Ambiguous. Confusing. 03:13:28PM

25 Argumentative. 03:13:32PM

1 THE WITNESS: If you scroll to the top, it's a 03:13:35PM  
2 commentary. These are my opinions. 03:13:40PM  
3 BY ATTORNEY JONNA: 03:13:43PM  
4 Q. So the answer is "no"? 03:13:43PM  
5 ATTORNEY PENAN: Objection. Argumentative. 03:13:44PM  
6 Misstates the witness's testimony. 03:13:46PM  
7 BY ATTORNEY JONNA: 03:13:49PM  
8 Q. So you -- your opinion is that the most humane 03:13:50PM  
9 and viable strategy for human survival involves 03:13:52PM  
10 terminating pregnancies? 03:13:56PM  
11 A. No. Family -- 03:13:57PM  
12 ATTORNEY PENAN: Objection. Misstates the 03:13:57PM  
13 witness's testimony. Lacks foundation. Argumentative. 03:13:58PM  
14 Harassing. 03:14:01PM  
15 THE WITNESS: Family planning is contraception 03:14:03PM  
16 and abortion. It allows people to have pregnancies and 03:14:06PM  
17 be pregnant and have children when they want to. 03:14:09PM  
18 BY ATTORNEY JONNA: 03:14:09PM  
19 Q. So your opinion is that the most humane and 03:14:14PM  
20 viable strategy for human survival includes terminating 03:14:17PM  
21 pregnancies; correct? 03:14:21PM  
22 ATTORNEY PENAN: Objection. Misstates the 03:14:23PM  
23 witness's testimony. Incomplete hypothetical. 03:14:25PM  
24 Argumentative. 03:14:27PM  
25 THE WITNESS: When a person doesn't want to be 03:14:28PM

1 pregnant, it is humane for her to not be forced to  
2 continue a pregnancy.

3 BY ATTORNEY JONNA:

4 Q. And that's a part of what you think is the  
5 right strategy for human survival; correct?

6 ATTORNEY PENAN: Objection. Misstates the  
7 witness's testimony. Lacks foundation. Outside the  
8 scope of the witness's designation.

9 THE WITNESS: If you scroll to the top again,  
10 the title of this piece is "Population growth and the  
11 environment." One of the unfortunate parts of the world  
12 we live in is that, in the 1970s, we -- as a world, we  
13 passed the ability of the earth to provide for everybody  
14 on earth. The biggest part of our carbon footprint  
15 issue right now is that we have more users than the  
16 earth can handle, so that the earth is not able to  
17 recreate what we need on a yearly basis. So we're using  
18 more of the earth's resources and affecting the  
19 environment on a yearly basis than the earth can  
20 regenerate or provide. So the biggest problem, in my  
21 opinion, along with my coauthor -- one of the biggest  
22 problems is the amount of pop- -- the population on the  
23 earth. The more users there are, the more we use up the  
24 earth, and the more the earth can't provide appropriate  
25 food and environmental sustainability for us to survive

1 as a people. Will this affect us in 1,000 years, in 03:16:09PM  
2 10,000 years? Who knows? But the -- environmental 03:16:15PM  
3 science had demonstrated that this is one of the biggest 03:16:19PM  
4 problems we have. 03:16:22PM

5 So family planning, which is part of people 03:16:23PM  
6 controlling if and when they have children based on what 03:16:25PM  
7 they want, is a big part of the -- I don't want to say 03:16:28PM  
8 "solution," but of the answers to this problem that 03:16:36PM  
9 we've been dealing with for 50 years. 03:16:38PM

10 BY ATTORNEY JONNA: 03:16:42PM

11 Q. And how do you define "family planning" again? 03:16:42PM

12 ATTORNEY PENAN: Objection. Asked and 03:16:45PM  
13 answered. 03:16:47PM

14 THE WITNESS: Family planning is contraception 03:16:47PM  
15 and abortion as used by people to have children or be 03:16:50PM  
16 pregnant when they desire, or not have children when 03:16:55PM  
17 they don't desire. 03:16:59PM

18 BY ATTORNEY JONNA: 03:17:01PM

19 Q. All right. 03:17:01PM

20 Page 2, here in purple you wrote, "Both rich 03:17:02PM  
21 and poor nations have a responsibility to limit family 03:17:06PM  
22 size. In future population growth, the world cannot 03:17:09PM  
23 sustain unchecked consumption in rich nations nor high 03:17:13PM  
24 fertility in poor nations." 03:17:17PM

25 Do you see that? 03:17:19PM

1           A.    I do. 03:17:19PM

2           Q.    What does it mean for a nation to limit family 03:17:21PM  
3 size? 03:17:25PM

4           A.    It has a -- 03:17:26PM

5           ATTORNEY PENAN:  Objection.  Outside the scope 03:17:26PM  
6 of the witness's designation.  The record speaks for 03:17:28PM  
7 itself. 03:17:31PM

8           THE WITNESS:  It has a responsibility to do 03:17:31PM  
9 so, meaning if -- if people desire to have limited 03:17:33PM  
10 family size, that they -- the nations should enable that 03:17:36PM  
11 so that people can have their own destiny, meaning that 03:17:41PM  
12 one of the biggest -- because if you read through the 03:17:45PM  
13 parts that are before it, what it really describes is 03:17:48PM  
14 the fact that we have poor nations with high fertility 03:17:52PM  
15 rates because there -- people are not given the 03:17:56PM  
16 resources to control their fertility in a way they 03:17:58PM  
17 desire.  And when we looked at rich nations, they 03:18:01PM  
18 consume environmental basics, like large use of fuels at 03:18:04PM  
19 rates that far exceed the poor nations so that both the 03:18:15PM  
20 rich nations and the poor nations are contributing to 03:18:21PM  
21 the environmental impact problem.  So that poor and rich 03:18:24PM  
22 nations both have this responsibility to allow people to 03:18:28PM  
23 limit their family size and population growth in ways 03:18:32PM  
24 that they want to. 03:18:35PM

25           The problems are that we live in a world where 03:18:37PM

1 countries are not allowing people to do that, by not  
2 providing contraception widely or by limiting abortion  
3 when it's desired. You have large foundations like the  
4 Gates Foundation that has to pay for highly effective  
5 contraceptives to get to poor nations, because the  
6 nations themselves aren't -- aren't able to provide  
7 them. And people want them. This is what that  
8 statement is about.

9 BY ATTORNEY JONNA:

10 Q. Just to clarify one point you just made --  
11 it's kind of subtle, but important -- you say that rich  
12 and poor nations should allow families to limit family  
13 size, but here, when I'm reading this text, it said  
14 "rich and poor nations have a responsibility to limit  
15 family size." I just want to make sure I understand  
16 what you're saying. You're envisioning that nations  
17 have a responsibility to limit family size, not making  
18 sure families can limit family size.

19 What -- what is the -- what are you advocating  
20 for when you say "nations have a responsibility to limit  
21 family size"?

22 ATTORNEY PENAN: Objection. Misstates the  
23 witness's testimony. Lacks foundation. Incomplete  
24 hypothetical. And outside the scope of the witness's  
25 designation.

1 THE WITNESS: It's -- you're highlighting one 03:19:48PM  
2 part of all the rest of it, and I already answered it, 03:19:50PM  
3 that nations have a responsibility to allow their -- 03:19:53PM  
4 allow families to limit their growth as they want. 03:19:56PM  
5 Because it's well established that the high fertility in 03:20:00PM  
6 poor nations is not necessarily what the majority of 03:20:04PM  
7 people there want. And we already do that in our 03:20:06PM  
8 country, where we make contraceptives available. It's 03:20:12PM  
9 one of the -- you know, it took years of fighting to 03:20:16PM  
10 have the Affordable Care Act, which allows wider 03:20:19PM  
11 contraceptive availability, you know, which is in line 03:20:24PM  
12 with other developed countries, to allow people to limit 03:20:24PM  
13 the family size in the way they want, if they want. 03:20:28PM  
14 Right? Not everybody wants to limit their size. But 03:20:32PM  
15 there's a responsibility for the rich and poor nations 03:20:35PM  
16 to enable families to have their ability to control 03:20:38PM  
17 their fertility if they want to. 03:20:42PM  
18 BY ATTORNEY JONNA: 03:20:46PM  
19 Q. Yeah. So I think you've said like four or 03:20:46PM  
20 five times now something different than what we're 03:20:48PM  
21 looking at. 03:20:50PM  
22 You said that they should allow families to 03:20:51PM  
23 limit. 03:20:53PM  
24 A. No. You're -- 03:20:54PM  
25 Q. Here you wrote -- 03:20:54PM

1 A. You're trying to -- 03:20:54PM

2 Q. Here you wrote -- sorry, sir. I listened to 03:20:55PM

3 you for -- 03:20:56PM

4 A. I stopped. 03:20:57PM

5 Q. I listened to you provide a very long answer 03:20:58PM

6 to a very short question. 03:21:01PM

7 You keep on saying that nations should allow 03:21:03PM

8 families to limit their size. In this document, though, 03:21:06PM

9 I don't see the word "allow." I see that "nations have 03:21:07PM

10 a responsibility to limit family size." 03:21:10PM

11 Do you see the -- a difference in those two 03:21:14PM

12 concepts? 03:21:15PM

13 ATTORNEY PENAN: Objection. Asked and 03:21:17PM

14 answered. The document speaks for itself. Lacks 03:21:18PM

15 foundation. Incomplete hypothetical. And outside the 03:21:21PM

16 scope of the witness's designation. 03:21:23PM

17 THE WITNESS: And I will say again. You're 03:21:25PM

18 picking one sentence out of a flow of words and a flow 03:21:26PM

19 of sentences, and you're not getting the answer out of 03:21:31PM

20 me that you want. I answered the question. 03:21:33PM

21 BY ATTORNEY JONNA: 03:21:35PM

22 Q. Are you in favor of China's one-child policy? 03:21:36PM

23 ATTORNEY PENAN: Objection. Outside the scope 03:21:41PM

24 of the witness's designation. 03:21:44PM

25 THE WITNESS: I'm -- I'm get -- can I ask? I 03:21:57PM

1 need to answer that? 03:21:59PM  
2 BY ATTORNEY JONNA: 03:21:59PM  
3 Q. Yes. 03:22:02PM  
4 A. No. I'm not in favor of China's one-child 03:22:03PM  
5 policy. 03:22:03PM  
6 Q. Why not? 03:22:03PM  
7 A. Because that is, I think, an overly drastic 03:22:05PM  
8 means of -- of dealing with their out of control 03:22:07PM  
9 population growth. I think there's other ways to do it. 03:22:10PM  
10 You know, their one-child policy has now been mostly 03:22:14PM  
11 reneged. But I -- I think just saying to somebody, "You 03:22:17PM  
12 can't have children," is not the right way to deal with 03:22:25PM  
13 the problems around population growth in their country. 03:22:27PM  
14 Q. Is there a -- 03:22:31PM  
15 A. That's just my -- that's just my -- my 03:22:32PM  
16 opinion. I'm not a Chinese diplomat or a Chinese 03:22:35PM  
17 government official. 03:22:39PM  
18 Q. Do you think that the size -- family size 03:22:40PM  
19 should be regulated by law? 03:22:44PM  
20 A. No. 03:22:46PM  
21 ATTORNEY PENAN: Objection. Outside the scope 03:22:46PM  
22 of the witness's designation. Calls for speculation. 03:22:48PM  
23 Lacks foundation. Calls for a legal conclusion. 03:22:50PM  
24 BY ATTORNEY JONNA: 03:22:50PM  
25 Q. It's your -- 03:22:50PM

1 A. No. 03:22:57PM

2 Q. It's your opinion that poor people having too 03:22:57PM  
3 many children is the cause of rising nationalism, war, 03:23:01PM  
4 famine, and migration of displaced people; is that 03:23:03PM  
5 correct? 03:23:04PM

6 ATTORNEY PENAN: Objection. Misstates the 03:23:04PM  
7 witness's testimony. Outside the scope of the witness's 03:23:09PM  
8 designation. Lacks foundation. Incomplete 03:23:11PM  
9 hypothetical. Compound. 03:23:13PM

10 THE WITNESS: No. I never said that. And I 03:23:14PM  
11 don't appreciate you putting -- trying to put words into 03:23:16PM  
12 my mouth. 03:23:19PM

13 BY ATTORNEY JONNA: 03:23:19PM

14 Q. Is denying women information about the 03:23:32PM  
15 possibility of reversing their abortion consistent with 03:23:34PM  
16 your goal of limiting family size among poor people? 03:23:37PM

17 ATTORNEY PENAN: Objection. Misstates the 03:23:41PM  
18 witness's testimony. Lacks foundation. Incomplete 03:23:42PM  
19 hypothetical. 03:23:53PM

20 THE WITNESS: No. I -- that's. . . 03:23:53PM

21 Can you ask the question again to be sure -- 03:23:55PM

22 BY ATTORNEY JONNA: 03:23:55PM

23 Q. Is -- 03:23:55PM

24 A. -- I'm getting my yes or no correct? This is 03:23:57PM  
25 ridiculous. Go ahead. 03:23:59PM

1 Q. Is -- is denying women information about the 03:24:00PM  
2 possibility of reversing their abortion consistent with 03:24:04PM  
3 your goal of limiting family size among poor people? 03:24:05PM  
4 A. No, because I don't -- 03:24:07PM  
5 ATTORNEY PENAN: Again, objection. Calls for 03:24:08PM  
6 speculation. Vague. Ambiguous. Confusing. Misstates 03:24:12PM  
7 the witness's testimony. Asked and answered. 03:24:15PM  
8 THE WITNESS: No. 03:24:18PM  
9 BY ATTORNEY JONNA: 03:24:20PM  
10 Q. And why is that? 03:24:21PM  
11 A. Because you're -- APR is a theoretical. 03:24:22PM  
12 That's all it is. So you're not denying women anything. 03:24:35PM  
13 I can make up any theoretical. I could go down the same 03:24:39PM  
14 path and say -- we'll use your Tylenol from earlier. 03:24:43PM  
15 "Tylenol will stop the effects of mifepristone." I 03:24:47PM  
16 could try to create a couple of patient -- I could give 03:24:51PM  
17 it to a couple of patients and publish that their 03:24:53PM  
18 pregnancies continued and say, "See?" It's 03:24:56PM  
19 theoretically possible. Anything is theoretical. But 03:24:59PM  
20 no, none of your statements are correct. 03:25:03PM  
21 Q. Is teaching that abortion is safe and 03:25:05PM  
22 effective consistent with your goal of limiting family 03:25:07PM  
23 size for poor people? 03:25:10PM  
24 A. I don't have a goal -- 03:25:14PM  
25 ATTORNEY PENAN: Objection. 03:25:14PM

1 THE WITNESS: -- of limiting size -- 03:25:15PM  
2 ATTORNEY PENAN: Misstates the witness's -- 03:25:15PM  
3 THE WITNESS: -- for poor people. 03:25:16PM  
4 ATTORNEY PENAN: Sorry. Can I get my 03:25:18PM  
5 objection on the record? 03:25:18PM  
6 THE WITNESS: Please. 03:25:18PM  
7 ATTORNEY PENAN: Objection. Misstates the 03:25:18PM  
8 witness's testimony. Compound. Vague. Ambiguous. 03:25:19PM  
9 Lacks foundation. Incomplete hypothetical. 03:25:23PM  
10 Thanks. 03:25:26PM  
11 THE WITNESS: Do I need to answer it again? 03:25:33PM  
12 BY ATTORNEY JONNA: 03:25:33PM  
13 Q. Yes. What's your answer? 03:25:35PM  
14 A. I don't have a goal of limiting family size 03:25:36PM  
15 for poor people or limit -- or -- if that was the exact 03:25:37PM  
16 question. 03:25:40PM  
17 Q. You have a goal for rich and poor nations 03:25:41PM  
18 limiting family size in future population growth; 03:25:44PM  
19 correct? 03:25:49PM  
20 A. No. 03:25:51PM  
21 ATTORNEY PENAN: Objection. Misstates the 03:25:51PM  
22 witness's testimony. 03:25:53PM  
23 BY ATTORNEY JONNA: 03:25:53PM  
24 Q. You stated, "Both rich and poor nations" -- 03:25:54PM  
25 A. You know what? If you want to keep asking 03:25:56PM

1 questions about this, why don't you read the whole  
2 statement, because you're selecting out two sentences  
3 from a whole piece that builds to that and trying to  
4 twist all of this. It's reprehensible.

5 Q. What's the -- how am I trying to twist it?  
6 What do you -- what do you mean by that? I'm reading --  
7 I'm reading quotes from your article. You stated that,  
8 "Rich and poor nations have a responsibility to limit  
9 family size and future population" --

10 A. Read all the stuff before it. Why don't you  
11 read it all in context. Go up a couple paragraphs and  
12 just read the whole thing if you want to get it on  
13 record. So it's all on context.

14 Q. I'm not going to read the whole thing in the  
15 record.

16 A. Well, that's your choice. That's your choice.  
17 You're trying to -- you're taking one thing out of  
18 context from the whole greater paragraph and then  
19 constantly asking me, "Don't you agree that this is what  
20 you're trying to do," when I've never said that. So  
21 if --

22 Q. Okay.

23 A. If you want to keep asking the same thing,  
24 I'll keep saying "no," and then -- or you can move on.  
25 Your choice.

1 Q. What part of it have I taken out of context? 03:26:56PM  
2 A. Well, why don't we read the whole thing? 03:27:00PM  
3 Q. If you want to -- 03:27:03PM  
4 A. Go ahead. 03:27:03PM  
5 Q. Go ahead and skim the whole document. I'm not 03:27:05PM  
6 going to read it. If you want to skim it and let me 03:27:07PM  
7 know when you're done, you can tell me what I've taken 03:27:11PM  
8 out of context. You have a copy in your chat, so you 03:27:12PM  
9 can scroll through it and let me know when you're done. 03:27:14PM  
10 A. All right. 03:27:18PM  
11 So this paragraph that you're taking the 03:27:55PM  
12 sentence out of the middle of is talking about how we 03:27:57PM  
13 will look back at this time when we are dealing with 03:28:00PM  
14 intense population growth and the impact it has on 03:28:06PM  
15 biology. 03:28:15PM  
16 If you go two paragraphs up, it talks about 03:28:16PM  
17 that we see a world of finite resources under 03:28:18PM  
18 significant stress at our current population under siege 03:28:21PM  
19 by a global economic policy that assumes human ingenuity 03:28:24PM  
20 will continue to provide for any number of humans. 03:28:27PM  
21 Right? 03:28:27PM  
22 So the paragraph that you're bringing these 03:28:31PM  
23 statements out of talks about that the history of our 03:28:33PM  
24 era will be the story of how the minority of earth's 03:28:36PM  
25 inhabitants living in rich nations, we either share or 03:28:40PM

1 deny our finite resources the majority of inhabitants 03:28:44PM  
2 living in poor nations, meaning that the rich will take 03:28:49PM  
3 advantage of being rich and continue to allow the poor 03:28:54PM  
4 to be even poorer. The unrelenting pressure of future 03:28:56PM  
5 population growth only intensifies every environmental 03:29:01PM  
6 and social challenge. 03:29:04PM  
7 I go -- we go on to say, "Unfortunately, the 03:29:05PM  
8 politics of population growth and income inequality 03:29:08PM  
9 often interfere with discussion of population policies. 03:29:12PM  
10 For this reason, many in" -- and this -- "policies" 03:29:16PM  
11 refer to the fact that there are countries that try to 03:29:18PM  
12 force their population to have children when they don't 03:29:24PM  
13 want to, and that comes from earlier in this piece. 03:29:30PM  
14 "For this reason, many environmental and social justice 03:29:33PM  
15 advocates hesitate to prioritize family planicy (sic) -- 03:29:39PM  
16 family planning as a policy objective, and that's 03:29:41PM  
17 because of the politics in those countries." 03:29:45PM  
18 The piece goes on. "This thinking fails to 03:29:48PM  
19 consider our fragile and interconnected earth." The 03:29:51PM  
20 statement you're making, "Both rich and poor nations 03:29:53PM  
21 have a responsibility to limit family size and future 03:29:55PM  
22 population growth as it relates to our fragile earth. 03:29:57PM  
23 The world cannot sustain unchecked consumption in rich 03:30:02PM  
24 nations, nor high fertility in poor nations," meaning we 03:30:05PM  
25 are basically using up our earth in multiple ways, 03:30:08PM

1 either the high consumption from the wealthy or the high 03:30:11PM  
2 population, which is concentrated more in poor nations. 03:30:15PM  
3 "While social justice efforts to reduce 03:30:20PM  
4 inequality must continue, it is naive to consider that 03:30:24PM  
5 increasing population does not exacerbate the problem of 03:30:26PM  
6 wealth disparity." 03:30:30PM  
7 And I can go on, but that's what you're 03:30:31PM  
8 reading in context of we're talking about the impact on 03:30:33PM  
9 the environment and the role that family planning plays. 03:30:36PM  
10 Q. Okay. 03:30:43PM  
11 ATTORNEY JONNA: Let's go off the record for a 03:30:43PM  
12 minute. Can we go off the record, please, 03:30:44PM  
13 Mr. Videographer? 03:31:06PM  
14 THE VIDEOGRAPHER: Yeah. One second. We are 03:31:06PM  
15 off the record at 3:31 p.m. 03:31:07PM  
16 (Off the record: 3:31 p.m. to 3:47 p.m.) 03:47:33PM  
17 THE VIDEOGRAPHER: We are back on the record 03:47:33PM  
18 at 3:47 p.m. 03:47:47PM  
19 BY ATTORNEY JONNA: 03:47:50PM  
20 Q. All right. Dr. Creinin, thank you for your 03:47:50PM  
21 patience. I'm going to try to, you know, wrap up my 03:47:53PM  
22 questioning in this last segment here. 03:47:56PM  
23 So just to clarify a few points. It's your 03:47:58PM  
24 position -- and I think we've talked about this in the 03:48:03PM  
25 past -- that medication abortion is safe; is that 03:48:07PM

1 correct? 03:48:09PM

2 A. Yes. 03:48:10PM

3 Q. And that's your sworn testimony as you sit 03:48:10PM

4 here under oath; correct? 03:48:14PM

5 A. Yes. 03:48:16PM

6 ATTORNEY PENAN: Objection. Asked and 03:48:16PM

7 answered. 03:48:22PM

8 BY ATTORNEY JONNA: 03:48:22PM

9 Q. And your sworn testimony today -- is it your 03:48:23PM

10 sworn testimony today that medication abortion is safer 03:48:24PM

11 than penicillin? 03:48:32PM

12 ATTORNEY PENAN: Objection. Misstates the 03:48:34PM

13 witness's testimony. Lacks foundation. Incomplete 03:48:35PM

14 hypothetical. 03:48:36PM

15 THE WITNESS: I don't have a basis for making 03:48:37PM

16 that comparison. 03:48:42PM

17 BY ATTORNEY JONNA: 03:48:43PM

18 Q. But you do understand the risk profile of 03:48:44PM

19 medication abortion; correct? 03:48:48PM

20 A. Yes. 03:48:51PM

21 Q. Do you understand the risks of penicillin? 03:48:51PM

22 A. For the most part. But I also understand the 03:48:54PM

23 risk profile for medication abortion in the context that 03:49:00PM

24 it's administered. There's different contexts in which 03:49:00PM

25 penicillin can be administered. 03:49:03PM

1 Q. Would it be false to say medication abortion 03:49:05PM  
2 is safer than penicillin? 03:49:12PM

3 A. I can't answer that question. 03:49:15PM

4 ATTORNEY PENAN: Objection. Vague. 03:49:15PM

5 Ambiguous. Incomplete hypothetical. Lacks foundation. 03:49:17PM

6 Calls for speculation. Outside the scope of the 03:49:18PM

7 witness's designation. 03:49:19PM

8 BY ATTORNEY JONNA: 03:49:21PM

9 Q. Your answer? I'm sorry? 03:49:21PM

10 A. I can't answer that question. It -- it always 03:49:22PM

11 depends on the context in which it's administered. And 03:49:25PM

12 also, it's the op- -- when you're looking at the safety 03:49:30PM

13 of something, you're comparing it to what the option is. 03:49:34PM

14 Right? So if somebody has a penicillin allergy and they 03:49:37PM

15 have a -- an infection that penicillin is the only 03:49:42PM

16 option, it has dangers that it doesn't have if somebody 03:49:44PM

17 doesn't have a penicillin allergy? 03:49:44PM

18 When somebody is pregnant and is seeking 03:49:47PM

19 abortion, mifepristone and medication abortion is safer 03:49:49PM

20 than continuing the pregnancy. So it's all in context. 03:49:54PM

21 Q. So -- so you wouldn't be -- 03:49:58PM

22 A. You're trying to compare an apple and an 03:50:00PM

23 orange. 03:50:03PM

24 Q. Okay. 03:50:04PM

25 So you wouldn't be comfortable saying under 03:50:04PM

1 oath that medication abortion is safer than penicillin; 03:50:07PM  
2 correct? 03:50:07PM  
3 A. I can't -- 03:50:07PM  
4 ATTORNEY PENAN: Objection. Misstates the 03:50:12PM  
5 witness's testimony. Incomplete hypothetical. 03:50:13PM  
6 THE WITNESS: That's not what I said. I said 03:50:16PM  
7 I just can't make that comparison. It's -- you're 03:50:17PM  
8 asking me to make a comparison that can't be made. 03:50:19PM  
9 BY ATTORNEY JONNA: 03:50:19PM  
10 Q. Can -- would you be comfortable saying under 03:50:23PM  
11 oath that medication abortion is safer than Tylenol? 03:50:25PM  
12 ATTORNEY PENAN: Objection. Lacks foundation. 03:50:28PM  
13 Incomplete hypothetical. Calls for speculation. 03:50:30PM  
14 THE WITNESS: It's the -- I -- I give the same 03:50:34PM  
15 answer. You know, it's -- you're looking at medication 03:50:35PM  
16 abortion, you're only -- you're comparing it to what the 03:50:38PM  
17 other option is. Tylenol is given for something 03:50:40PM  
18 completely different. That's a just a false way of 03:50:43PM  
19 looking at things. I can't answer that question. 03:50:46PM  
20 BY ATTORNEY JONNA: 03:50:48PM  
21 Q. Well, just to help you answer that question, 03:50:52PM  
22 the complaint in this case, which I'm sure you read as 03:50:58PM  
23 you said earlier, says the following: "The standard 03:51:02PM  
24 medication abortion regimen -- regime (sic) consisting 03:51:07PM  
25 of two medications, mifepristone and misopro- -- 03:51:11PM

1 misoprostol has been proven to be incredibly safe, safer  
2 than penicillin, Viagra, and even some over-the-counter  
3 drugs like Tylenol."

4 Do you see that?

5 A. I do.

6 Q. And can you confirm for us under oath that  
7 that statement is true?

03:51:27PM

03:51:27PM

8 ATTORNEY PENAN: Objection. Calls for  
9 speculation. Lacks foundation. Incomplete  
10 hypothetical.

03:51:29PM

03:51:32PM

03:51:34PM

11 THE WITNESS: I'm not an expert to discuss  
12 those things. If you want to ask the district -- or the  
13 state attorney about those statements, that's fine. But  
14 I'm not that expert.

03:51:35PM

03:51:41PM

03:51:45PM

03:51:49PM

15 BY ATTORNEY JONNA:

03:51:51PM

16 Q. So I'm just asking you as their expert whether  
17 you stand by that statement under oath today.

03:51:51PM

03:51:53PM

18 ATTORNEY PENAN: Objection. Same objections.  
19 And asked and answered.

03:51:58PM

03:52:00PM

20 THE WITNESS: I answered the question.  
21 It's -- I answered the question already.

03:52:01PM

03:52:07PM

22 BY ATTORNEY JONNA:

03:52:08PM

23 Q. And you can't -- you're not comfortable  
24 confirming that that's an accurate statement; correct?

03:52:10PM

03:52:13PM

25 A. I answered the question.

03:52:15PM

1           ATTORNEY PENAN: Same objections. Outside the 03:52:16PM  
2 scope of the witness's designation. Asked and answered. 03:52:18PM  
3 BY ATTORNEY JONNA: 03:52:26PM  
4           Q. You also can't swear under oath today that APR 03:52:26PM  
5 doesn't work. 03:52:31PM  
6           We've already talked about that; correct? 03:52:31PM  
7           A. I could -- yes. I -- 03:52:34PM  
8           ATTORNEY PENAN: Objection. Misstates the 03:52:34PM  
9 witness's testimony. 03:52:35PM  
10           THE WITNESS: I could also swear under oath 03:52:36PM  
11 that I have no proof that it does work. 03:52:39PM  
12 BY ATTORNEY JONNA: 03:52:41PM  
13           Q. That wasn't my question. So -- 03:52:42PM  
14           A. And just -- 03:52:43PM  
15           Q. -- please -- 03:52:43PM  
16           A. But that's my answer. 03:52:43PM  
17           Q. Right. And that's -- 03:52:45PM  
18           A. That's my answer. 03:52:45PM  
19           Q. -- my question to you as the expert for the 03:52:45PM  
20 attorney general. 03:52:48PM  
21           Can you swear under oath that APR does not 03:52:48PM  
22 work? 03:52:52PM  
23           A. And what I said was -- 03:52:52PM  
24           ATTORNEY PENAN: Objection. Asked and 03:52:52PM  
25 answered. 03:52:55PM

|    |   |            |
|----|---|------------|
| 1  | BY ATTORNEY JONNA:                                    | 03:52:55PM |
| 2  | Q. "Yes" or "no," sir?                                | 03:52:55PM |
| 3  | A. No. I can answer anyway I want.                    | 03:52:57PM |
| 4  | ATTORNEY PENAN: Objection.                            | 03:52:57PM |
| 5  | THE WITNESS: My answer is yes, but I can also         | 03:52:58PM |
| 6  | say that I have no evidence that it does work. And    | 03:53:01PM |
| 7  | that's what I said before.                            | 03:53:04PM |
| 8  | BY ATTORNEY JONNA:                                    | 03:53:04PM |
| 9  | Q. Your answer is "no" or "yes"? Let me make          | 03:53:06PM |
| 10 | sure you understood the question.                     | 03:53:06PM |
| 11 | Can you swear under oath that APR does not            | 03:53:08PM |
| 12 | work?   | 03:53:11PM |
| 13 | ATTORNEY PENAN: Objection. Asked and                  | 03:53:11PM |
| 14 | answered. Argumentative. Harassing.                   | 03:53:15PM |
| 15 | THE WITNESS: I'll make it clear. I cannot             | 03:53:17PM |
| 16 | swear under oath. I can swear -- okay. There is --    | 03:53:19PM |
| 17 | there is no evidence that APR works, and there is no  | 03:53:24PM |
| 18 | evidence that it does (sic) work. So what I can swear | 03:53:28PM |
| 19 | under oath is both of those.                          | 03:53:31PM |
| 20 | BY ATTORNEY JONNA:                                    | 03:53:34PM |
| 21 | Q. Okay.  | 03:53:38PM |
| 22 | Can you swear under oath that APR is unsafe?          | 03:53:38PM |
| 23 | ATTORNEY PENAN: Objection. Asked and                  | 03:53:44PM |
| 24 | answered.   | 03:53:47PM |
| 25 | THE WITNESS: We went through this before.             | 03:53:47PM |

1 "Safety" is how you define it. But if -- if you want to 03:53:49PM  
2 talk about side effects, giving progesterone is unlikely 03:53:55PM  
3 to cause significant side effects. If there is no 03:53:59PM  
4 benefit to the treatment, there is a potential for 03:54:03PM  
5 something long-term that could be a problem. Right? So 03:54:06PM  
6 depends how you, again, define "safety." We went 03:54:10PM  
7 through this before. You're asking the same questions 03:54:14PM  
8 as before. 03:54:17PM

9 BY ATTORNEY JONNA: 03:54:18PM

10 Q. Okay. 03:54:18PM

11 And just pulling up an email that was produced 03:54:18PM  
12 by UC Davis here. It's dated September 30th, 2019. I 03:54:23PM  
13 will mark this as Exhibit 122. 03:54:30PM

14 (Exhibit 122 was marked.) 03:54:35PM

15 BY ATTORNEY JONNA: 03:54:35PM

16 Q. And it's to an individual by the name Cait 03:54:36PM  
17 Desilets. C-A-I-T. Last name is D-E-S-I-L-E-T-S. 03:54:36PM

18 Take a look at that email; let me know when 03:54:36PM  
19 you're done reviewing it. 03:54:59PM

20 A. It's not pulled up. 03:54:59PM

21 Q. What do you see on your -- on your share 03:55:01PM  
22 screen right now, then? 03:55:02PM

23 ATTORNEY PENAN: The complaint. 03:55:03PM

24 THE WITNESS: Part of the last complaint. 03:55:04PM

25 Yeah. Part of the complaint. 03:55:05PM

|    |   |            |
|----|---|------------|
| 1  | BY ATTORNEY JONNA:                              | 03:55:05PM |
| 2  | Q. Let me -- let me see here. Hold on.          | 03:55:06PM |
| 3  | Do you see the email now? Do you see the        | 03:55:15PM |
| 4  | email?  | 03:55:21PM |
| 5  | A. Yes, I -- yes.                               | 03:55:21PM |
| 6  | Q. Okay.  | 03:55:21PM |
| 7  | Take a look at it. Let me know when you're      | 03:55:22PM |
| 8  | done reading it.                                | 03:55:25PM |
| 9  | ATTORNEY PENAN: Could you make it a little      | 03:55:28PM |
| 10 | bigger?   | 03:55:29PM |
| 11 | ATTORNEY JONNA: Sure.                           | 03:55:30PM |
| 12 | ATTORNEY PENAN: Thank you.                      | 03:55:31PM |
| 13 | THE WITNESS: From 2019?                         | 03:55:38PM |
| 14 | BY ATTORNEY JONNA:                              | 03:55:38PM |
| 15 | Q. That's correct.                              | 03:55:40PM |
| 16 | A. Okay. What's your question?                  | 03:56:03PM |
| 17 | Q. Looking at point three, you tell this -- who | 03:56:04PM |
| 18 | is this person, by the way? Do you recall?      | 03:56:09PM |
| 19 | A. I have no idea.                              | 03:56:12PM |
| 20 | Q. That's your email address at the top,        | 03:56:13PM |
| 21 | mdcreinin@ucdavis.edu?                          | 03:56:13PM |
| 22 | A. Yes.   | 03:56:13PM |
| 23 | Q. And this was produced by UC Davis. And       | 03:56:18PM |
| 24 | there's the Bates stamp: UCD_CREININ2835.       | 03:56:23PM |
| 25 | Do you see that?                                | 03:56:24PM |

1 A. I do. 03:56:25PM

2 Q. So this was produced from your email account 03:56:25PM

3 in this litigation; correct? 03:56:29PM

4 A. That's what you're telling me. 03:56:31PM

5 Q. Okay. 03:56:33PM

6 And so the statement here under point three, 03:56:34PM

7 "Note that claims about progesterone being safe are 03:56:39PM

8 true, but that is not the safety issue here." 03:56:43PM

9 Do you see that?

10 A. I do.

11 Q. And do you recall what you meant when you made

12 this statement here?

13 A. It's very similar to the questions you've just

14 been asking me. Progesterone may be safe, but the 03:56:54PM

15 safety issue here is about not using misoprostol. 03:56:56PM

16 Q. Okay. 03:56:56PM

17 And then when you say, "Also note that 03:57:08PM

18 mifepristone is not teratogenic," what do you mean by 03:57:08PM

19 that? 03:57:08PM

20 A. That mifepristone does not cause genetic -- is 03:57:08PM

21 not known to cause any genetic anomalies for -- 03:57:11PM

22 Q. And neither is -- neither is progesterone; 03:57:15PM

23 correct? 03:57:17PM

24 A. Correct. 03:57:17PM

25 Q. So there is no evidence that the -- any 03:57:18PM

1 component of the APR protocol can cause birth defects;  
2 is that correct?

3 ATTORNEY PENAN: Objection. Vague.  
4 Ambiguous. Compound. Lacks foundation. Incomplete  
5 hypothetical.

6 THE WITNESS: If you're referring specifically  
7 to somebody is given progesterone, will it cause birth  
8 defects, progesterone is not known to cause birth  
9 defects.

10 BY ATTORNEY JONNA:

11 Q. And neither is mifepristone; correct?

12 A. That is correct.

13 Q. And there's no evidence that providing  
14 progesterone after mifepristone causes birth defects  
15 either; correct?

16 A. I just said -- I just answered that. Yes,  
17 there is no evidence.

18 Q. I -- do you see the next email here that I  
19 pulled up from July 5th, 2018? Does that show up for  
20 you?

21 A. It does.

22 Q. This is an email from you to Beverly Winikoff  
23 dated July 2018.

24 If you could take a look at this and let me  
25 know when you've had a chance --

1           A.    Can you make it bigger, please?           03:58:37PM

2           Q.    Sure.           03:58:37PM

3           A.    Thank you.    Okay.           03:58:37PM

4           Q.    So just looking at the sentence that I           03:59:08PM

5 highlighted here, the first one: "I don't think a           03:59:10PM

6 one-week window is fair enough to say with certainty           03:59:12PM

7 that there is no impact from the mifepristone alone, so           03:59:15PM

8 really want to wait the two weeks."           03:59:18PM

9                    Do you see that?           03:59:21PM

10          A.    I do.           03:59:22PM

11          Q.    And what -- why do you want to wait the two           03:59:22PM

12 weeks?           03:59:24PM

13          A.    That was about the design of my study, and           03:59:24PM

14 we -- it's actually what we talked about earlier, in           03:59:27PM

15 that if you just waited one week, I don't know for           03:59:30PM

16 certain that looking at an outcome one week after           03:59:33PM

17 mifepristone plus progesterone versus mifepristone           03:59:36PM

18 from -- plus placebo, that I would know for certain that           03:59:40PM

19 there was an -- I'll take a step back.           03:59:47PM

20                    I designed the study -- and we went over this           03:59:50PM

21 at the last deposition -- with the aim of actually           03:59:53PM

22 showing it worked.    So if I used only a one-week window,           03:59:55PM

23 it's possible that in the mifepristone and placebo           03:59:59PM

24 group, if progesterone really worked, that mifepristone           04:00:04PM

25 and placebo at one week, we may not have seen a           04:00:07PM

1 difference. It could be that I needed longer than a 04:00:11PM  
2 week for the pregnancy that had mifepristone and placebo 04:00:14PM  
3 to be lost. I wanted to give it a full two weeks to 04:00:18PM  
4 make -- to minimize that chance of -- of getting a wrong 04:00:22PM  
5 outcome. Two weeks was about the fullest extent I was 04:00:27PM  
6 willing to go in these patients. I didn't -- 04:00:31PM

7 The questions probably centered around the 04:00:32PM  
8 idea of "why -- why can't you just wait one week versus 04:00:36PM  
9 two weeks?" So I wanted to make sure that I wasn't 04:00:39PM  
10 under calling -- if -- if progesterone worked, for 04:00:43PM  
11 example, that one week wasn't long enough to see the 04:00:46PM  
12 effects of mifepristone by itself, then I would have 04:00:51PM  
13 shown that it didn't work, compared to mifepristone 04:00:54PM  
14 plac- -- plus placebo. So I wanted to give it the full 04:00:59PM  
15 two weeks to give it a better chance to really show if 04:01:03PM  
16 it worked. 04:01:06PM

17 Q. Okay. 04:01:08PM

18 And in the second highlighted statement here, 04:01:08PM  
19 "Of course, there can always be compliance issues as 04:01:10PM  
20 compared to women who want to stop the abortion, but we 04:01:17PM  
21 are measuring progesterone levels during the two weeks 04:01:19PM  
22 which will give us some idea of compliance." 04:01:22PM

23 Do you see that? 04:01:26PM

24 A. I do. 04:01:26PM

25 Q. Was progesterone monitoring used in your study 04:01:27PM

1 to get an idea of compliance to the protocol? 04:01:29PM

2 A. It was done so that we could get some idea, 04:01:32PM  
3 but we also know that, because it's not done daily, you 04:01:35PM  
4 could have theoretically have people who didn't take it 04:01:39PM  
5 and did take it the day that they were getting tested. 04:01:42PM  
6 I mean, that's why it's "some idea of compliance." We 04:01:46PM  
7 see the same in studies using other hormones where 04:01:46PM  
8 people -- we have evidence -- we can find other evidence 04:01:50PM  
9 to say, "Yeah. They took it right before they came in, 04:01:53PM  
10 but they didn't." So it's just a way of trying to 04:01:55PM  
11 check, but it doesn't guarantee it. It also could -- 04:01:56PM  
12 there is other reasons to get progesterone to give us 04:01:59PM  
13 some ideas about what the effects were from taking the 04:02:03PM  
14 drug. And as we talked about last time, you can still 04:02:06PM  
15 have compliant people that don't absorb, which is why I 04:02:09PM  
16 said "some idea of compliance." But that was probably 04:02:14PM  
17 answering a question that she had in -- in the email. 04:02:17PM

18 But it's not unusual to monitor levels just to 04:02:19PM  
19 get some idea. But there's people who -- I've -- I've 04:02:22PM  
20 done studies before where the -- because of the effects, 04:02:26PM  
21 I know they're compliant, but you don't get any level. 04:02:30PM  
22 So you have things where you can -- for example, if you 04:02:34PM  
23 can tell that ovulation isn't occurring but I can't find 04:02:36PM  
24 the drug, you know, sometimes you just -- it's not a 04:02:41PM  
25 perfect system, but you're trying to get some idea. 04:02:43PM

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CERTIFICATE OF REPORTER

I, TAYLOR M. MALDONADO, a Certified Shorthand Reporter, holding a valid and current license issued by the State of California, CSR No. 14482, duly authorized to administer oaths, do hereby certify:

That the witness in the foregoing deposition was administered an oath to testify to the whole truth in the within-entitled cause.

That said deposition was taken down by me in shorthand at the time and place therein stated and thereafter transcribed into typewriting, by computer, under my direction and supervision.

Should the signature of the witness not be affixed to the deposition, the witness shall not have availed himself/herself of the opportunity to sign or the signature has been waived.

I further certify that I am neither counsel for nor related to any party in the foregoing deposition and caption named nor in any way interested in the outcome thereof.

DATED: 11/21/2025



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TAYLOR M. MALDONADO, RPR, CSR NO. 14482

1 ROB BONTA  
 Attorney General of California  
 2 NELI N. PALMA (SBN: 203374)  
 Senior Assistant Attorney General  
 3 KARLI EISENBERG (SBN: 281923)  
 KATHLEEN BOERGERS (SBN: 213530)  
 4 Supervising Deputy Attorneys General  
 ERICA CONNOLLY (SBN: 288822)  
 5 HAYLEY PENAN (SBN: 313693)  
 LAUREN ZWEIER (SBN: 291361)  
 6 Deputy Attorneys General  
 1300 I Street, Suite 125  
 7 P.O. Box 944255  
 Sacramento, CA 94244-2550  
 8 Telephone: (916) 210-7785  
 Fax: (916) 324-5567  
 9 E-mail: Hayley.Penan@doj.ca.gov  
*Attorneys for Plaintiff*  
 10 *People of the State of California*

11 SUPERIOR COURT OF THE STATE OF CALIFORNIA

12 COUNTY OF ALAMEDA

15 **THE PEOPLE OF THE STATE OF**  
 16 **CALIFORNIA,**

17 Plaintiff,

18 v.

19 **HEARTBEAT INTERNATIONAL, INC.,**  
 20 **REALOPTIONS, DOES 1-100,**  
 21 **INCLUSIVE,**

22 Defendant.

*Exempt from Filing Fees Pursuant to Gov.  
 Code § 6103*

Case No. 23CV044940

**AMENDED EXPERT DECLARATION  
 OF DR. MITCHELL D. CREININ, M.D.**

Dept: 23  
 Judge: Hon. Michael M. Markman  
 Action Filed: September 21, 2023

23 I, Mitchell D. Creinin, M.D., declare and state as follows:

- 24 1. I have been retained as an expert by counsel for Plaintiff in connection with the above-  
 25 captioned litigation. I am over 18 years of age and competent to make this declaration.  
 26 I submit this declaration in support of the Plaintiff's case.
- 27 2. I have knowledge of the matters stated herein, have cited relevant literature and other  
 28 sources concerning these matters, and could and would so testify if called as a witness.

1 **Background**

- 2 3. I am a medical doctor and am board-certified in the specialty of Obstetrics &  
3 Gynecology by the American Board of Obstetrics and Gynecology. I received this  
4 certification in 1989 and have maintained active certification continuously for the past  
5 36 years. I am board-certified in the subspecialty of Complex Family Planning, one of  
6 the five board recognized subspecialties by the American Board of Obstetrics and  
7 Gynecology. I received my subspecialty board certification in 2022, the first year this  
8 certification was offered. I have continued to maintain active subspecialty  
9 certification.
- 10 4. I earned my Doctor of Medicine from Northwestern University School of Medicine in  
11 Chicago in 1988. I completed an Obstetrics and Gynecology residency from 1988  
12 through 1992 at the University of California, San Francisco (UCSF). I then completed  
13 two fellowships at UCSF during the academic year of 1992 to 1993. The first was a  
14 Family Planning fellowship in the Department of Obstetrics and Gynecology and the  
15 second was a Clinical Research fellowship from the Departments of Medicine and  
16 Epidemiology and Biostatistics. The coursework for this second fellowship was  
17 predecessor for what is known today as a Master of Science degree.
- 18 5. I am licensed to practice medicine in the State of California. I held an active license in  
19 California from 1989 through 1995, moved out of state, and then returned in 2011; I  
20 have maintained an active California license from 2011 until the present. I held a  
21 medical license to practice medicine in Pennsylvania from 1994 through 2012. I also  
22 held an active medical license to practice medicine in Hawaii from 1991 through  
23 1993.
- 24 6. Prior to moving back to California, I was employed by the University of  
25 Pittsburgh/Magee-Womens Hospital. I was recruited by the Department of Obstetrics,  
26 Gynecology, and Reproductive Sciences to start a Family Planning program in 1994.  
27 While at the University of Pittsburgh from 1994 through 2011, I held positions in the  
28 Department as the Director of Family Planning, Director of Family Planning Research,

1 and Director of Gynecologic Specialties. I also served as Director of the Family  
2 Planning fellowship, which I started at the University of Pittsburgh as the second  
3 fellowship in the country, training 14 family planning subspecialists during my tenure.  
4 I progressed through the academic ranks at the University of Pittsburgh based on my  
5 academic achievements which included research grants, publications, presentations at  
6 scientific meetings, clinical care, and national and international recognition, reaching  
7 the rank of Professor in 2003. My expertise included secondary appointments at the  
8 University of Pittsburgh Graduate School of Public Health, where I served as a mentor  
9 to Master of Public Health students and taught courses on epidemiology and clinic  
10 research design, and at the University of Pittsburgh Clinical and Translational Science  
11 Institute. While at the University of Pittsburgh, I served on the Institutional Review  
12 Board from 2006 through 2011.

13 7. I am currently employed full time as an obstetrician-gynecologist and Complex  
14 Family Planning Specialist by University of California, Davis Health (UC Davis). I  
15 have been employed by UC Davis continuously since June 2011. I hold an academic  
16 position as a Distinguished Professor with tenure. I was recruited to UC Davis to be  
17 Chair of the Department of Obstetrics and Gynecology, a position I held from 2011  
18 through 2014. In 2014, I returned to spending more time on my research and clinical  
19 specialty, stepping down as chair. I served as Director of Family Planning from 2014  
20 through 2022. I established a Family Planning fellowship at UC Davis as well, for  
21 which I have been the director since its inception in 2014, training 12 family planning  
22 subspecialists to date. I have served on the Institutional Review Board from 2017 to  
23 the present.

24 8. I am a Fellow of the American College of Obstetricians and Gynecologists (ACOG),  
25 the premier professional membership organization for obstetricians/gynecologists. I  
26 have been a fellow continuously since 1990.

- 1 9. I was a founding member and served as President of the Society of Family Planning,  
2 the premier academic organization for the subspecialty addressing clinical care and  
3 research for contraception, abortion, and early pregnancy care.
- 4 10. I am a clinical expert in the provision of abortion, having provided care for over 5,000  
5 patients as an integral component of my practice. I provided advanced gestational  
6 duration procedures in an operating room setting through 2023 and have provided  
7 office-based procedure and medication abortion since 1986 and continue to do so  
8 today. I also provide a wide spectrum of gynecologic care in my practice but still  
9 focus mostly on family planning related care.
- 10 11. At UC Davis, I provide clinical and lecture-based training to medical students,  
11 residents, and fellows primarily in Obstetrics and Gynecology but also in Family  
12 Medicine and Emergency Medicine among other specialties. I teach on topics related  
13 to abortion, miscarriage, ectopic pregnancy, and contraception.
- 14 12. I am invited to lecture all over the world on topics related to abortion and  
15 contraception. In the last few years alone, besides local and national meetings in the  
16 U.S., I have lectured at the Mexican Congress of Obstetrics and Gynecology, the  
17 Royal Australian and New Zealand College of Obstetricians and Gynaecologists  
18 Annual Scientific Meeting, the European Society of Gynecology, the International  
19 Federation of Gynecology and Obstetrics Congress, and the Belgian Royal Academy  
20 of Medicine.
- 21 13. I have spent my entire professional career conducting medical and scientific research  
22 related to human reproduction and gynecology, including research on human subjects.  
23 I have received funding for research from the NIH, USAID, CDC, WHO, foundations,  
24 professional organizations, and industry. I have served as study principal investigator  
25 and data center coordinator for numerous multicenter studies. I have served as  
26 principal investigator at my study site for numerous multicenter studies. I have also  
27 served as a mentor or co-investigator for many other human clinical trials. Overall, I  
28 have served as a study principal investigator for 30 funded human clinical trials, a

1 study site principal investigator for 94 funded human clinical trials, and a co-  
2 investigator for 48 funded human clinical trials. I have published 282 peer-reviewed  
3 manuscripts, written 31 books or book chapters primarily related to abortion and  
4 contraception, and presented more than 275 scientific abstracts at professional  
5 meetings.

6 14. I am a national and international expert on medication abortion and hormones, having  
7 spent my entire career learning, researching, and teaching on the subjects. I researched  
8 medication abortion methodologies including methotrexate and misoprostol,  
9 misoprostol alone, and mifepristone and misoprostol, including studies that are the  
10 basis for national and international guidelines on effective and safe provision of  
11 medication abortion.

12 15. I serve on the editorial board of *Contraception*, the premier subspecialty scientific  
13 journal related to family planning and reproductive health. I previously served as a  
14 Deputy Editor from 2013 through 2022. I serve as a peer-reviewer for numerous  
15 highly respected medical journals including *New England Journal of Medicine*, *JAMA*,  
16 *Lancet*, *Obstetrics and Gynecology*, and *American Journal of Obstetrics and*  
17 *Gynecology*.

18 16. I have provided consultative services for Danco Laboratories since 2002. As a small  
19 pharmaceutical company without a full-time medical division, Danco contracts with a  
20 few experts to be available to provide consultation to medical professionals who  
21 contact the company with medical questions about their product, which is a  
22 requirement for them as a company. I get paid \$300/month for this service and have  
23 been paid the same amount for the duration of my service.

24 17. A true and correct copy of my current Curriculum Vitae is attached.

25 **Prostaglandins, mifepristone, and methotrexate**

26 18. Prostaglandins are found naturally throughout the body. Many different types of  
27 natural prostaglandins exist and have different effects in different tissues. For  
28 example, some prostaglandins will affect the airways by dilating them (Prostaglandin

1 E) and some will cause airway constriction (Prostaglandin F). In the uterus, all  
2 prostaglandins cause the myometrium to contract. Women who have intense cramping  
3 with periods have significant prostaglandin release or heightened sensitivity to  
4 prostaglandins, resulting in significant cramps and pain. Commonly used medications  
5 for uterine cramping, like ibuprofen, are prostaglandin synthetase inhibitors, meaning  
6 they work to prevent the synthesis of prostaglandins. For this reason, they work better  
7 when taken before compared to after pain starts.

8 19. Prostaglandins were studied for late first trimester and second trimester abortion in the  
9 early 1970s but, because of their actions throughout the body, caused significant side  
10 effects that were felt to be intolerable as an abortion treatment, including high rates of  
11 fever, nausea, vomiting, and diarrhea (all known side effects of prostaglandins).  
12 Through the 1970s and 1980s, newer prostaglandin analogues became available that  
13 were more specific for the type of prostaglandin receptor thereby causing more effects  
14 in target tissue and less systemic side effects. An example of a prostaglandin analogue  
15 is misoprostol, which is a PGE<sub>1</sub> analogue. In humans, this analogue is found most  
16 specifically in the gastrointestinal tract and myometrium.<sup>1</sup> Thus, compared to natural  
17 prostaglandins and early prostaglandin analogues used in the 1970s, a newer  
18 prostaglandin analogue, like misoprostol, could be used for abortion with the potential  
19 for less side effects.

20 20. Mifepristone is a progesterone-receptor antagonist, known as an anti-progestin.  
21 Mifepristone is considered a type of progestin (specifically, an anti-progestin) because  
22 it is a synthetic (non-naturally occurring) progestogen. Because it blocks rather than  
23 activating the progesterone receptor, mifepristone is called an anti-progestin. In  
24 humans, mifepristone binds more strongly to the progesterone receptor than  
25 progesterone itself, approximately 2-3 times stronger.<sup>2</sup>

26 <sup>1</sup> Markovič T, Jakopin Ž, Dolenc MS, Mlinarič-Raščan I. Structural features of subtype-  
27 selective EP receptor modulators. *Drug Discov Today*. 2017;22(1):57-71.

28 <sup>2</sup> Heikinheimo O, Kontula K, Croxatto H, et al. Plasma concentrations and receptor  
binding of RU 486 and its metabolites in humans. *J Steroid Biochem*. 1987;26(2):279–284.

1 21. Mifepristone has rapid actions within the reproductive system to effect abortion as  
2 proven by large clinical trials with a dosing interval between mifepristone and  
3 misoprostol of 15 minutes or less having high clinical efficacy.<sup>3</sup> Mifepristone has a  
4 long elimination half-life of 24-48 hours, meaning it stays in the circulation and active  
5 for a long time.<sup>4</sup> In general, the elimination half-life of progesterone is less than one  
6 hour. However, the elimination half-life of oral micronized progesterone (the available  
7 oral prescription medication that consists of progesterone in refined peanut oil in a  
8 capsule form) may be as long as 5-10 hours with peak levels reached 1-3 hours after  
9 administration.<sup>5</sup> There is no pharmacokinetic or pharmacodynamic basis to support  
10 that progesterone will do anything to antagonize the effects of mifepristone. Thus,  
11 only prospective human clinical trials can prove any such outcome.

12 22. Mifepristone works in early pregnancy by blocking progesterone from binding to the  
13 progesterone receptor and by acting directly on the corpus luteum, the source of  
14 progesterone during early pregnancy.<sup>6</sup> This means that mifepristone is blocking  
15 peripheral actions of progesterone in the trophoblast (invading pregnancy tissue that  
16 develops into the placenta) as well as directly affecting the source of progesterone  
17 production. To understand progesterone levels, they generally peak after ovulation in  
18 the 3-10 ng/mL range and then increase early in the first trimester when pregnancy is  
19 present. In early pregnancy, progesterone is being initially supplied by the corpus  
20 luteum in the ovary, until approximately 7 weeks after which the trophoblast is

21  
22 <sup>3</sup> Creinin MD, Schreiber CA, Bednarek P, Lintu H, Wagner MS, Meyn LA; Medical  
23 Abortion at the Same Time (MAST) Study Trial Group. Mifepristone and misoprostol  
24 administered simultaneously versus 24 hours apart for abortion: a randomized controlled trial.  
25 *Obstet Gynecol.* 2007;109(4):885-94.

26 <sup>4</sup> Heikinheimo O, Kekkonen R, Lähtenmäki P. The pharmacokinetics of mifepristone in  
27 humans reveal insights into differential mechanisms of antiprogesterin action. *Contraception.*  
28 2003;68(6):421-6.

<sup>5</sup> Pickar JH, Bon C, Amadio JM, Mirkin S, Bernick B. Pharmacokinetics of the first  
combination 17 $\beta$ -estradiol/progesterone capsule in clinical development for menopausal hormone  
therapy. *Menopause.* 2015;22(12):1308-16.

<sup>6</sup> Niinimäki M, Ruokonen A, Tapanainen JS, Järvelä IY. Effect of mifepristone on the  
corpus luteum in early pregnancy. *Ultrasound Obstet Gynecol.* 2009;34(4):448-53.

1 providing progesterone to support itself. Progesterone levels are higher in the 5<sup>th</sup> week,  
2 declining slightly from the 5<sup>th</sup> to the 7<sup>th</sup> week (as ovarian production wanes) with  
3 median values of 22 ng/mL at 5 weeks, 19 ng/mL at 6 weeks and 7 weeks. Values then  
4 increase after 7 weeks with median levels of 22-24 ng/mL through 11 weeks  
5 duration.<sup>7</sup> Increasing progesterone levels artificially to counteract the decline in  
6 progesterone that results from direct action on trophoblast does not change  
7 mifepristone's strong and prolonged binding to the progesterone receptor.

8 23. Blocking progesterone in early pregnancy has multiple effects in the reproductive  
9 tract. The effects likely vary with time since mifepristone intake and the relative  
10 importance of each is unknown. These effects include an increase in uterine sensitivity  
11 to prostaglandins, an increase in prostaglandins present in the myometrium,  
12 endometrial necrosis, and cervical softening.<sup>8</sup> The effects related to prostaglandins is  
13 important as to why a combination of mifepristone and a prostaglandin analogue (i.e.,  
14 misoprostol) is highly effective for uterine evacuation.

15 24. Initial studies of mifepristone for abortion looked at different doses and regimens,  
16 including single day and multiple day protocols. None of the treatments appeared to be  
17 effective enough for clinical use. Taking advantage of the increased sensitivity to  
18 prostaglandins, researchers thought of adding prostaglandin analogues after  
19 mifepristone and found the combination highly effective, leading to the regimens in  
20 use today. Multiple studies have shown that prostaglandin analogues alone like  
21 misoprostol are effective and safe for abortion; however, the combination of  
22 mifepristone and an analogue, specifically misoprostol, is more effective, works more  
23 quickly, is more cost effective, and results in fewer procedural interventions than  
24 misoprostol alone.

25  
26 <sup>7</sup> Ku CW, Zhang X, Zhang VR, Allen JC, Tan NS, Østbye T, Tan TC. Gestational age-  
27 specific normative values and determinants of serum progesterone through the first trimester of  
pregnancy. *Sci Rep.* 2021;11(1):4161.

28 <sup>8</sup> Fiala C, Gemzel-Danielsson K. Review of medical abortion using mifepristone in  
combination with a prostaglandin analogue. *Contraception.* 2006;74(1):66-86.

1 25. Methotrexate is a dihydrofolate reductase inhibitor, which means it blocks an enzyme  
2 (dihydrofolate reductase) that is vital for cell reproduction (RNA and DNA synthesis).  
3 Methotrexate is used for various indications including cancer (in high doses),  
4 rheumatoid arthritis, psoriasis, lupus, multiple sclerosis, eczema, and ectopic  
5 pregnancy. Methotrexate is a mainstay of medical treatment for ectopic pregnancy and  
6 works on trophoblastic tissue by inhibiting syncytialization of cytotrophoblast.<sup>9</sup> When  
7 early trophoblast (cytotrophoblast) invades in the uterus, tube or elsewhere, the cells  
8 fuse to form giant cells called syncytiotrophoblast. Methotrexate prevents the fusing  
9 or continued invasion. It appears that methotrexate does not destroy  
10 syncytiotrophoblast but, rather, prevents its formation. The syncytiotrophoblast is  
11 important because this is the site of hormone production, including hCG and  
12 progesterone. Once a significant amount of trophoblast is present, methotrexate would  
13 be expected to be less effective. We see this clinically with ectopic pregnancy in  
14 which methotrexate treatment is less effective with higher hCG levels, which reflects  
15 greater implantation (more syncytiotrophoblast). Similarly, in studies that used  
16 methotrexate with misoprostol for abortion, efficacy decreased after 7 weeks  
17 gestation, in line with the actions of methotrexate.

### 18 **Progesterone in pregnancy**

19 26. Progesterone is available in vaginal gels (4%, 45 mg per applicator and 8%, 90 mg per  
20 applicator), vaginal inserts (100 mg), and oral micronized capsules (100 mg and 200  
21 mg). The capsules are approved for oral use but are also delivered vaginally.  
22 Progesterone intramuscular injections are not standardly used in pregnancy-related  
23 health care today and only used in assisted reproductive technologies in specific  
24 circumstances (e.g., some patients with polycystic ovarian syndrome or  
25 perimenopause). Oral micronized progesterone, unlike other progesterone treatments,  
26 is contraindicated in patients with peanut allergy.

27 \_\_\_\_\_  
28 <sup>9</sup> Creinin MD, Stewart-Akers AM, DeLoia JA. Methotrexate effects on trophoblast and  
the corpus luteum in early pregnancy. Am J Obstet Gynecol. 1998;179(3 Pt 1):604-9.

1 27. Progesterone is used in an established pregnancy in very specific circumstances. Large  
2 clinical trials demonstrate when there is and is not benefit.

3 28. The most common use of progesterone is during assisted reproductive technologies,  
4 like in vitro fertilization. In these circumstances, patients use drugs that shut down  
5 their own system and the physician provides all of the hormones necessary to support  
6 the pregnancy. This artificial situation is not directly applicable outside of this  
7 indication. However, data from this population demonstrates potential risks of high  
8 progesterone exposure. In medicine, risks are balanced with benefits so any risk is  
9 weighed against the known benefit (and, as a corollary, if benefit is not proven, then  
10 there is only risk; nothing is risk-free). Studies from infertility populations have shown  
11 an association of high-dose progesterone use with an increased likelihood of thyroid  
12 cancer diagnosis.<sup>10</sup>

13 29. Progesterone use during pregnancy has been studied for patients with prior pregnancy  
14 loss or recurrent pregnancy loss based on the hypothesis that they may not have  
15 enough of their own progesterone or the receptors do not respond well to  
16 progesterone. Large clinical trials have demonstrated no benefit of progesterone  
17 except in very specific circumstances; in other words, progesterone does not have  
18 benefit universally and, even then, the benefit is limited. For patients with prior  
19 miscarriages, treating with very high doses of progesterone (400 mg vaginally twice  
20 daily through 16 weeks gestation) has no benefit unless the patient has had 3 or more  
21 losses. In such cases, the birth rate is only increased by 3%. Progesterone does show  
22 some marginal benefit when a patient has had a prior miscarriage and has bleeding in  
23 early pregnancy. With one prior loss, the birth rate is improved from 70% to 75% with  
24 progesterone use. With three prior losses, there is more benefit, increasing the birth  
25

---

26 <sup>10</sup> Hannibal CG, Jensen A, Sharif H, Kjaer SK. Risk of thyroid cancer after exposure to  
27 fertility drugs: results from a large Danish cohort study. *Hum Reprod.* 2008;23(2):451-6.  
28 Lindquist S, Kjær SK, Albieri V, Frederiksen K, Hansen T, Nøhr B, Jensen A. Fertility drugs and  
incidence of thyroid cancer in a Danish nationwide cohort of 146 024 infertile women. *Hum  
Reprod.* 2022;37(4):838-47.

1 rate from 57% to 72%. The benefit is marked (albeit still limited) only in a  
2 subpopulation of women who have had 3 or more miscarriages and have bleeding.<sup>11</sup>

3 30. Progesterone use during pregnancy has been studied for preterm labor prevention.  
4 Again, as a general treatment in patients with a history of preterm labor, vaginal  
5 progesterone had no proven benefit.<sup>12</sup> However, in women with a shortened cervix  
6 and a prior preterm birth, vaginal progesterone may have some benefit.<sup>13</sup>

7 31. Overall, progesterone use in pregnancy is likely safe for most patients when evaluated  
8 first by a clinician and when there are proven benefits. Large clinical trials and  
9 systematic reviews with thousands of participants show that progesterone is not a  
10 magical treatment for all patients with a history of miscarriage or preterm delivery and  
11 that only specific subpopulations demonstrate proven benefit (and commonly just  
12 marginal benefit).

### 13 **Study designs and reporting**

14 32. Pre-clinical studies are designed to provide information that support human studies  
15 and do not provide evidence of any human effects but, rather, simply support inquiry  
16 into human disease when humans have not been studied. Animal studies are pre-  
17 clinical and, for hormones and reproductive tract effects, are known not to correlate

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19  
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21 \_\_\_\_\_  
22 <sup>11</sup> Coomarasamy A, Williams H, Truchanowicz E, Seed PT, Small R, Quenby S, et al. A  
23 randomized trial of progesterone in women with recurrent miscarriages. *N Engl J Med*  
2015;373:2141-8. Coomarasamy A, Devall AJ, Brosens JJ, Quenby S, Stephenson MD, Sierra S,  
24 et al. Micronized vaginal progesterone to prevent miscarriage: a critical evaluation of randomized  
25 evidence. *Am J Obstet Gynecol* 2020;223:167-76.

26 <sup>12</sup> Conde-Agudelo A, Romero R. Vaginal progesterone does not prevent recurrent preterm  
27 birth in women with a singleton gestation, a history of spontaneous preterm birth, and a  
28 midtrimester cervical length >25 mm. *Am J Obstet Gynecol.* 2022;227(6):923-926. Nelson DB,  
Lafferty A, Venkatraman C, McDonald JG, Eckert KM, McIntire DD, et al. Association of  
vaginal progesterone treatment with prevention of recurrent preterm birth. *JAMA Netw Open*  
2022;5:e2237600.

<sup>13</sup> ACOG. Updated Clinical Guidance for the Use of Progesterone Supplementation for the  
Prevention of Recurrent Preterm Birth. *Obstetrics & Gynecology* 141(6):1234.

1 with human findings.<sup>14</sup> As such, animal studies are not considered proof of human  
2 effects.<sup>15</sup>

3 33. Human studies are observational or interventional. In observational studies,  
4 researchers do not assign participants to an intervention. Interventional studies assign  
5 participants to an intervention which can be random or not random. Observational  
6 studies include case reports/series, cross-sectional studies, case-control studies, and  
7 cohort studies. Observational studies cannot determine causality but can, depending on  
8 the type of observational study, suggest an association. Interventional studies, when  
9 controlled, can determine a relationship between an intervention and an outcome.  
10 Examples of interventional studies include pre-post design (before-after study), single-  
11 arm interventions, cross-over studies, non-randomized controlled trials, and  
12 randomized trials.

13 34. Case reports and case series are the lowest level of observational studies. A case report  
14 provides a detailed report of the diagnosis, treatment, and follow-up of an individual  
15 patient. Case reports also contain some demographic information about the patient (for  
16 example, age, gender, ethnic origin). A case series is a group or series of case reports  
17 involving patients who were given similar treatment usually with 3-10 or more  
18 patients.<sup>16</sup> Reports of case series contain detailed information about the individual  
19 patients, which is why large numbers of patients are not reported as a case series. This  
20 includes demographic information and information on diagnosis, treatment, response  
21 to treatment, and follow-up after treatment  
22 (<https://www.cancer.gov/publications/dictionaries/cancer-terms/def/case-series>). A  
23 case series is different than a retrospective cohort study. A case series includes  
24 individuals with a specific disease or condition and relies on detailed clinical  
25 information from a single source. A retrospective cohort study describes individuals

26 <sup>14</sup> Stanczyk FZ. All progestins are not created equal. *Steroids* 2003;68:879-90.

27 <sup>15</sup> Bracken MB. Why animal studies are often poor predictors of human reactions to  
28 exposure. *J R Soc Med.* 2009;102(3):120-2.

<sup>16</sup> Nissen T, Wynn R. *BMC Res Notes* 2014;7:264.

1 with shared exposure identified from past data and describes their outcomes. Because  
2 a case series includes detailed individual patient information, a large cohort cannot be  
3 summarized in a case series; rather, a retrospective cohort study would be appropriate.  
4 Simply, case reports and case series generate hypotheses about possible cause and  
5 effect that require larger observational studies to confirm a possible association and  
6 interventional studies to prove a cause and effect.

7 35. Structured tools for reporting human research exist on the EQUATOR network  
8 (<https://www.equator-network.org/>). Such guidelines ensure that study reports include  
9 all necessary information to ensure reliability and promote transparent and accurate  
10 reporting. These guidelines ensure that the manuscript is understandable by the reader,  
11 could be replicated by another researcher, and the authors make appropriate  
12 conclusions about the ability to use the information for clinical decision making.  
13 Guidelines include checklists to present a clear list of reporting items that should be  
14 included. Examples include CONSORT for randomized trials, STROBE for  
15 observational studies, and CARE for case reports.

16 **“Abortion Pill Reversal” concept**

17 36. The concept of abortion pill reversal (APR) is that high doses of progesterone,  
18 administered orally, intramuscularly, or vaginally, will reverse the effects of  
19 mifepristone taken by a patient who has started a medication abortion (taken  
20 mifepristone). Conceptually, the idea may have merit but that just means that  
21 appropriate studies are needed to prove clinical efficacy, safety, and benefit.

22 37. Off-label prescribing, per the FDA requires two principles. First, the patient has to be  
23 informed that the treatment is off label. Second, adequate research has to be available  
24 to support efficacy and safety of the treatment. Without the latter, use should occur  
25 under research protocols.

26 38. Prescribing standards include the need to tell the patient how effective the treatment  
27 will be, expected side effects and complications, appropriate follow-up, and  
28 alternatives. For example, medication abortion with mifepristone and misoprostol is

1 FDA-approved through 70 days gestation. The label clearly delineates a difference in  
2 efficacy rates with advancing gestation, the rate of side effects and complications, and  
3 necessary follow-up.

4 39. APR lacks information on efficacy overall (see points that follow) but also, in theory,  
5 across different gestational durations, time since mifepristone intake, and rate of side  
6 effects and complications. How can any patient be counseled appropriately without  
7 information about efficacy rates at 6 weeks vs. 9 weeks gestation or if she took  
8 mifepristone 10 minutes ago or 70 hours ago? As a theoretical example, if  
9 progesterone treatment had no effect if the patient was more than 8 weeks gestation  
10 and took mifepristone more than 24 hours ago, that is important. Perhaps taking  
11 progesterone in that situation would make outcomes worse. Maybe outcomes vary by  
12 parity or weight? It is possible that patients who start progesterone more than 48 hours  
13 after mifepristone use would have a continuing pregnancy regardless since they had  
14 not passed the pregnancy in the first 48 hours. We have no idea, so counseling is not  
15 possible. Without evidence of efficacy, side effects, or complications (see next  
16 section), how can a treatment be advertised which leads consumers to believe it is an  
17 effective, proven therapy?

18 **“Abortion Pill Reversal” relevant studies**

19 40. To develop hypotheses about the idea of APR without a controlled study, the  
20 likelihood that pregnancies will continue or abort after mifepristone-only treatment  
21 must be known. Early studies evaluating mifepristone alone are inadequate to estimate  
22 how effective mifepristone is when used alone for medication abortion. Medication  
23 abortion is currently provided across a wide gestational duration range (up to 10  
24 weeks), and these early studies were designed to figure out potential mifepristone  
25 regimens in very early gestation (generally up to 7 weeks duration), had small  
26 numbers, and allowed only a short time before intervention was provided if treatment  
27  
28

1 did not work. Various attempts to synthesize this data<sup>17</sup> are fraught with inadequacies,  
2 as I have summarized in a previous publication.<sup>18</sup> Of note, these small mifepristone-  
3 only studies did include cases with complications, including hemorrhage and  
4 transfusion. As such, there is reason to assume that use of mifepristone without  
5 misoprostol (when progesterone is provided) could result in the same, and providers  
6 need to know this information to counsel patients appropriately just like they do for  
7 transfusion rates with medication abortion.

8 41. The relevant original APR literature includes two small case series, a small  
9 randomized trial that was discontinued prematurely due to safety concerns (my study),  
10 and a pilot study discontinued early because of the inability to recruit subjects. The  
11 largest report, entitled a case series, doesn't truly meet the criteria for a case series; in  
12 fact, it does not meet the criteria for a study of any type. Lastly, a systematic review  
13 that followed appropriate scientific rules for performing and reporting a systematic  
14 review has been published. I will review each of these reports in detail in the order  
15 they were reported.

16 42. Case series #1: Delgado G, Davenport ML. Progesterone use to reverse the effects of  
17 mifepristone. *Ann Pharmacother.* 2012;46(12):e36. This case series included seven  
18 women (one lost to follow-up) who received progesterone after taking mifepristone.  
19 The progesterone route of administration and dosage varied among the six women  
20 included in the case series, including intramuscular progesterone in oil in different  
21 regimens and combined with oral or vaginal progesterone. Four of the six women had  
22 continuing pregnancies. Five of the six women were 7-11 weeks gestation and one  
23 was unknown. The reporting was adequate in that details of every patient were

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25 <sup>17</sup> Grossman D, White K, Harris L, Reeves M, Blumenthal PD, Winikoff B, Grimes DA.  
26 Continuing pregnancy after mifepristone and "reversal" of first-trimester medical abortion: a  
27 systematic review. *Contraception.* 2015;92(3):206-11. Davenport M, Delgado G, Harrison MP,  
28 Khau V. Embryo Survival after Mifepristone: A Systematic Review of the Literature. *Issues  
Law Med.* 2017;32(1):3-18.

<sup>18</sup> Creinin MD, Chen MJ. Mifepristone antagonization requires real studies to evaluate  
safety and efficacy. *Contraception.* 2019;100(6):427-9.

1 described. However, the authors made clinical recommendations based on the report.  
2 As noted earlier, clinical recommendations are not scientifically justified by a  
3 retrospective case series involving six patients. A case series can do nothing more than  
4 conclude that a treatment may have some effect yet to be determined or confirmed.

5 43. Case series #2: Garratt D, Turner JV. Progesterone for preventing pregnancy  
6 termination after initiation of medical abortion with mifepristone. *Eur J Contracept*  
7 *Reprod Health Care*. 2017;22(6):472-5. This case series included three women who  
8 received progesterone after taking mifepristone at 6-8.5 weeks duration. Progesterone  
9 was administered vaginally for approximately two weeks. Two of the three women  
10 had continuing pregnancies. The criteria for the reports were adequate in that details of  
11 every patient were described. One of the authors' comments in the manuscript was,  
12 "[t]here is currently no definitive evidence for the success of using progesterone to  
13 prevent the abortifacient effect of mifepristone." Yet, they then conclude that "[w]here  
14 the possible benefit is so great, the low risk of harm from using progesterone as well  
15 as the lack of teratogenicity of mifepristone supports this indication." However, the  
16 limit of a case series, especially one with three patients, is that no conclusions can be  
17 made about cause and effect. A case series only supports the concept and creates  
18 hypotheses that need to be further evaluated.

19 44. Large report called a "case series": Delgado G, Condly SJ, Davenport M,  
20 Tinnakornsrisuphap T, Mack J, Khauv V, Zhou PS. A case series detailing the  
21 successful reversal of the effects of mifepristone using progesterone. *Issues Law Med*.  
22 2018;33(1):21-31. This work with 754 patients (but only 547 analyzed) is heavily  
23 relied upon by APR advocates. Yet, it lacks any qualities of a study such that it cannot  
24 be considered science or evidence to any extent.

25 a. The report was published in *Issues in Law and Medicine*, a journal that is not  
26 scientifically reputable and that is not known for publishing peer-reviewed  
27 research used by clinicians or for clinically relevant data. It is published by the  
28 National Legal Center for the Medically Dependent & Disabled, Inc. It has a clear

1 policy rather than scientific focus, describing itself as providing “technical and  
2 informational assistance to attorneys, health care professionals, educators and  
3 administrators on legal, medical, and ethical issues rising from health care  
4 decisions” (<https://issuesinlawandmedicine.com/about/>). Of note is that  
5 “attorneys” are listed first; medical journals are typically aimed at medical  
6 professionals first and foremost.

- 7 b. This report was initially published as a prospective study with Institutional Review  
8 Board (IRB) approval, then withdrawn at the request of the IRB  
9 ([https://retractionwatch.com/2018/07/17/study-claiming-abortion-reversal-is-safe-  
10 and-effective-temporarily-withdrawn-for-ethical-issues/](https://retractionwatch.com/2018/07/17/study-claiming-abortion-reversal-is-safe-and-effective-temporarily-withdrawn-for-ethical-issues/)). The IRB noted that the  
11 report inferred that the IRB had reviewed and approved a prospective study when,  
12 in fact, the IRB application was for a retrospective analysis of de-identified data.
- 13 c. The withdrawn report was then re-published by the same journal without otherwise  
14 changing the analysis, results, or conclusions—further indicating that this  
15 publication is not in a reputable scientific journal. A reputable journal would not  
16 retract and then republish an article with this kind of methodological and ethical  
17 flaw. As someone who spent many years as the editor of a medical journal, it is  
18 unheard of in the field of medical research to withdraw a paper, rewrite the  
19 methods section to a completely different study design, and then republish the rest  
20 of the paper unaltered in the same journal. Reputable journals would have  
21 considered the paper fraudulent, especially when the IRB asked for withdrawal,  
22 and would not have then published the report.
- 23 d. As a retrospective analysis, the study design only allows the potential to determine  
24 associations and not cause and effect (see paragraph 33). The authors attempt to  
25 use a “control” based on their assumptions related to what proportion of  
26 pregnancies would have continued based on flawed evaluations of mifepristone  
27 alone studies (see paragraph 40). Thus, as an observational “study,” even if the  
28 study was valid, the findings are not proof of efficacy or safety.

- 1 e. The authors call the report a “retrospective analysis” and a “case series” in the  
2 same report. The title calls this a case series. The text calls this a “retrospective  
3 analysis.” The report is definitely not a case series as a case series requires detailed  
4 reporting of details on every patient, which is not done here. The methods sections  
5 states that “women gave informed consent for treatment...” Thus, data was  
6 collected prospectively. This text means the authors describe experimenting on  
7 patients (getting informed consent) and collecting the data prospectively without  
8 IRB approval to do so and without clinical trial registration. Recruitment,  
9 treatment, and data collection were actively managed prospectively via a central  
10 telephone hotline to refer patients to 325 different collaborators throughout the  
11 world. The collaborators obtained consent and collected information on the  
12 patients. These actions describe a prospective study, not a retrospective study and  
13 certainly not a case series. The report is written in a haphazard manner not  
14 following any standard reporting guidelines. Thus, the authors performed a  
15 prospective study unethically, tried to call it a case series and then also call it a  
16 retrospective analysis (which is what the IRB approval is for). These points alone  
17 demonstrate the inability to call this work science or use it to make any  
18 conclusions.
- 19 f. The authors do not report the outcomes for all patients; they only report the full  
20 outcomes for those with continuing pregnancies. For the approximately 50% for  
21 which the pregnancy did not continue, the authors fail to report what happened,  
22 including whether any adverse events occurred. The reported safety data only  
23 described preterm delivery and birth defects for pregnancies in which the  
24 mifepristone was unsuccessful in terminating the pregnancy. No other pregnancy  
25 complications were tracked for those who had successful pregnancies. Importantly,  
26 the report authors did not report any adverse effects, side effects, or details of what  
27 happened to the pregnant women in the report for whom the pregnancy did not  
28 continue, leaving more questions than answers about the safety of the treatment.

1 This incomplete reporting does not meet the criteria of a case series or  
2 retrospective analysis, again demonstrating this report is selective and incomplete.

3 g. The treatment used was described as “high-dose” progesterone but included  
4 multiple different treatments which are not all equal in dosing or progesterone  
5 exposure. These regimens included progesterone in oil intramuscularly,  
6 micronized progesterone orally, micronized progesterone capsules administered  
7 vaginally, compounded micronized progesterone vaginal suppositories,  
8 progesterone vaginal gel, and progesterone vaginal suppositories. The doses for  
9 almost all of the routes are not reported. Also, the outcomes for all of these dosing  
10 methods are not reported. These multiple regimens make it almost impossible to  
11 draw definitive conclusions and, therefore, at most, could only mean the data could  
12 generate information to potentially support further study (not conclude cause and  
13 effect).

14 h. The report only included 547 (72.5%) of the 754 patients treated with  
15 progesterone; again, as a case series, the outcomes for all patients would be  
16 reported. The report excluded 207 patients, including those who had already taken  
17 misoprostol before the progesterone, those with whom the collaborators lost  
18 contact, and 57 who chose to complete the medication abortion or obtain a surgical  
19 abortion (which are inappropriate to exclude as that is an outcome). Excluding  
20 patients who received the treatment once the outcome is known skews the results  
21 and is scientifically fraudulent.

22 i. The report fails to account for the gestational duration of all included in the report  
23 (only 409 people). Since the success rate of medication abortion decreases (and  
24 continuing pregnancy increases) as gestational duration increases, failing to  
25 account for this variable makes it impossible to determine whether, for example,  
26 the patients in the higher success rate groups like the high dose oral progesterone  
27 group had a larger proportion of pregnant patients with higher gestational  
28 durations, which would make the mifepristone less likely to be successful in the

1 absence of any progesterone treatment. Ultimately, this likely underestimates the  
2 true rate of continuing pregnancy and overestimates any effectiveness of APR.

3 j. Even if these flaws did not exist, the reported success rates of 64-68%  
4 effectiveness based on the report are misleading; the report had an overall  
5 “reversal” rate of 48% but reported a 64% rate for a subset of those that received  
6 intramuscular injections and 68% (only 31 patients) for those in the high-dose oral  
7 subgroup. Thus, unqualified statements that APR has a 64-68% success rate,  
8 without acknowledging the 48% overall rate reported or clarifying the subset of  
9 patients to which the higher rate applied are misleading, lending even less  
10 credibility to the report. Note that the 68% rate is in a subset of 31 patients from an  
11 observational study (although I claim this report does not even qualify as a study).  
12 Since conclusions cannot be made from observational studies, a report of  
13 outcomes based on 31 patients is not sufficient evidence to prove cause and effect  
14 efficacy and safety.

15 45. Randomized Controlled Trial: Creinin MD, Hou MY, Dalton L, Steward R, Chen MJ.  
16 Mifepristone Antagonization With Progesterone to Prevent Medical Abortion: A  
17 Randomized Controlled Trial. *Obstet Gynecol.* 2020;135(1):158-65.

18 a. My study was the first pragmatic attempt to conduct a human scientific  
19 investigation of the concept of APR. I wanted to do this study because of the lack  
20 of science in this area at a time when state legislators, with the backing of  
21 conservative anti-choice groups, were pushing the concept of APR into law,  
22 mandating abortion patients be told about APR as a proven medical option should  
23 they take mifepristone and change their mind. As an established researcher, I knew  
24 that good science was needed to understand more than observational studies could  
25 provide. I felt, as an abortion provider, that I wanted to know if APR might  
26 actually work because I wanted my patients to be able to get care from me and  
27 people who understood this field. That being said, when I set out to answer this  
28

1 question, I had never met a patient in over 30 years of practice who contacted me  
2 stating she changed her mind.

- 3 b. I obtained funding as any researcher would do – I submitted a grant proposal to an  
4 open call for medication abortion research from the Society of Family Planning.  
5 As with any grant funding, the funder contracts with the recipient (which is the  
6 University) with stipulations in the contract about independence and data  
7 ownership such that I was a funded, independent researcher for this project.
- 8 c. As for any human prospective study, I obtained IRB approval and registered the  
9 study on a human trials registry before the first patient was recruited.
- 10 d. I approached the study in the same manner in which all drug development is  
11 approached when initial human clinical trials (phase 1) are designed. Phase 1  
12 studies are primarily focused on safety and to gauge potential efficacy by a  
13 surrogate marker in a population not at risk for the outcome. For example, a Phase  
14 1 study of a new oral contraceptive pill would involve testing in a population not at  
15 risk for pregnancy (not heterosexually active or using permanent contraception) to  
16 see if the product is safe and does it do what it is supposed to do (e.g., prevent  
17 ovulation) such that inference about potential efficacy could be evaluated. These  
18 studies zero in on a dose that is potentially effective and safe, allowing progression  
19 to phase 2 studies that are larger, refine the dose further, and could eventually  
20 include small efficacy trials in patients at risk.
- 21 e. Accordingly, I planned to recruit patients at 6-9 weeks gestation who were  
22 planning a procedural abortion to volunteer to delay their abortion by 2 weeks (a  
23 time frame that would not increase the risk of their procedure). The 2-week  
24 outcome was the surrogate marker of pregnancy continuation (if the patient was  
25 still pregnant and embryonic cardiac activity was still present). In this way, the  
26 outcome of the treatment would not matter as the patients all desired abortion.
- 27 f. The study design was a double-blind randomized trial in which the investigational  
28 drug service at UC Davis prepared a randomization plan and provided treatment in

1 a bottle for patients to use. The sample size was calculated in advance to be large  
2 enough, with full enrollment, to have statistical power to establish a 68%  
3 continuing pregnancy rate with progesterone vs. 25% with placebo, as claimed by  
4 Delgado and colleagues. Thus, this small, randomized trial, if fully enrolled, would  
5 be large enough to provide preliminary efficacy data in line with APR claims. The  
6 calculated and planned sample was 40 participants with 20 per group.

- 7 g. At enrollment, all patients had a continuing pregnancy established by ultrasound  
8 prior to receiving mifepristone 200 mg. Patient were then given a container with  
9 their treatment which was either progesterone or similar appearing placebo  
10 capsules. None of the participants had ever used progesterone in the past.  
11 Participants were instructed to start their treatment 24 hours after the mifepristone  
12 and were called by the study team to confirm drug initiation. Treatment was the  
13 same doses (or number of placebo capsules) as described in the oral progesterone  
14 regimen in the 2018 Delgado report.<sup>19</sup> Follow-up visits were planned at 3, 7, and  
15 15 days after mifepristone administration with plans for a procedural abortion at  
16 the last visit for participants who had not passed the pregnancy. All participants  
17 received the same medication abortion instructions we used clinically so they  
18 would be prepared for bleeding and cramping should they start to pass the  
19 pregnancy.
- 20 h. We enrolled 12 participants over 6 months after which the study was stopped due  
21 to safety signals. The treatment used was unknown to the participants and  
22 investigators until the study was stopped. Interestingly, only two of the  
23 participants thought they used progesterone (only one was correct).
- 24 i. Two participants withdrew from the study, one in each group. One had worsening  
25 nausea and vomiting of pregnancy, was not taking all of the treatment as per the  
26 protocol, and wanted to have her procedural abortion so she would feel better

27 <sup>19</sup> Delgado G, Condly SJ, Davenport M, Tinnakornsriruphap T, Mack J, Khau V, Zhou  
28 PS. A case series detailing the successful reversal of the effects of mifepristone using  
progesterone. *Issues Law Med.* 2018;33(1):21-31.

1 (progesterone group). The other, who had a prior medication abortion, became  
2 worried about bleeding that started two days after mifepristone use and wanted a  
3 procedure (placebo group).

4 j. Of the remaining 10 participants, four of five in the progesterone group and two of  
5 five in the placebo group had continuing pregnancies at two weeks. Three  
6 participants had hemorrhages during follow-up that required emergency room  
7 visits; these participants were 56-, 60-, and 60-days gestation at enrollment. Only  
8 one other participant was that far in pregnancy, a participant at 61 days in the  
9 placebo group who had a continuing pregnancy at two weeks. The course related  
10 to the participants with hemorrhage explains why the study was stopped and, also,  
11 the importance of proper study conduct and oversight.

12 k. The first participant with a hemorrhage was participant 8 and we had not  
13 encountered any complications with the first seven participants. Participant 8 had  
14 excessive bleeding (more than expected per the medication abortion instructions)  
15 starting on day 3 after her visit earlier in the day and called an ambulance to go to  
16 the emergency department. I met her there where an ultrasound examination  
17 showed she had passed the pregnancy. Her bleeding slowed enough while in the  
18 emergency department that I felt no intervention was necessary. Since this  
19 outcome was within the expected outcomes, we continued the study as planned.  
20 After the study stopped, we learned this participant was in the progesterone group.

21 l. The second participant with a hemorrhage was participant 10 who called an  
22 ambulance on day 5 and was brought to our emergency department and seen by  
23 one of my co-investigators. An ultrasound examination showed the pregnancy had  
24 expelled but there was still significant tissue in her uterus and an urgent aspiration  
25 procedure was performed in the emergency department to stop the bleeding; no  
26 transfusion was needed. After the study stopped, we learned this participant was in  
27 the placebo group. Because of this second case, I notified the IRB of these two  
28 hemorrhages and they reviewed the outcomes to date. The IRB asked for us to

1 finish follow-up on all active participants to see if any other hemorrhages  
2 occurred. When no further hemorrhages occurred, the IRB agreed to allow us to  
3 begin recruitment again.

4 m. We enrolled two more participants (numbers 11 and 12) and participant 11 called  
5 an ambulance on day 6, was brought to our emergency department, and seen by  
6 one of my co-investigators. The patient was hypotensive (very low blood  
7 pressure). An ultrasound examination showed the pregnancy was still in her uterus  
8 and an emergent aspiration procedure was performed in the emergency department  
9 to stop the bleeding and a transfusion was needed. After the study stopped, we  
10 learned this participant was in the placebo group. I let the IRB know immediately  
11 and told the IRB I would complete follow-up on the one enrolled participant and  
12 then stop the study due to these three hemorrhages (with unknown treatment when  
13 the decision was made).

14 n. Because the study could not reach its full sample, it lacks the ability to provide any  
15 statistical efficacy comparison of the groups. For example, if we did statistics on  
16 the enrolled sample with the five participants who did not withdraw early, the  
17 differences in outcomes are statistically not different with a probability that the  
18 outcomes are the same of 48% (4/5 [80%, 95% confidence interval 45-100%] vs  
19 2/5 [40%, 95% confidence interval 0-83%],  $p=0.52$ , Fisher's exact test), or roughly  
20 50/50 chance. Thus, any claims that this data supports APR are wrong.

21 o. The analysis showed minimal systemic side effects from progesterone treatment  
22 but adverse safety events occurred such that, in line with Phase 1 studies,  
23 prospective studies in a population at risk could not be safely performed. Given  
24 that the report by Delgado did not include what happened to the 50% of people  
25 who did not have continuing pregnancy, this study raises concerns about what  
26 information we can accurately share about progesterone treatment. We obviously  
27 do not have enough information to validate efficacy or safety claims.  
28

- 1 46. Scoping review: DeBeasi PLC. Mifepristone Antagonization with Progesterone to  
2 Avert Medication Abortion: A Scoping Review. *Linacre Q.* 2023;90(4):395-407. This  
3 scoping review was published in a bioethics journal and the official journal of the  
4 Catholic Medical Association. A scoping review is a narrative review without any  
5 consideration of study strengths and weaknesses or data quality as is done with a  
6 systematic review (see paragraph 47). The weakness of the included studies have been  
7 described above. The authors make conclusions based on these weak observational  
8 studies/reports although such work cannot be used to draw definitive conclusions. As  
9 such, this summary work offers no scientifically important information.
- 10 47. Systematic review: Stifani BM, Lavelanet AF. Reversal of medication abortion with  
11 progesterone: a systematic review. *BMJ Sex Reprod Health.* 2024;50(1):43-52.  
12 Briefly, the authors performed a systematic review of available data using appropriate  
13 methodology, using PRISMA guidelines and fully describing their search  
14 methodologies, analyses, and outcomes per the guidelines. The authors rated the  
15 quality of the evidence from the reports cited above in points 42, 43, and 44 as low  
16 quality but included them anyway because of the limited evidence available. The  
17 authors concluded that “the ongoing pregnancy rate in individuals treated with  
18 progesterone after mifepristone is not significantly higher compared to that of  
19 individuals receiving mifepristone alone.”
- 20 48. Pilot prospective trial: Turner JV, Garratt D, McLindon LA, Barwick A, Spark MJ.  
21 Progesterone after mifepristone: A pilot prospective single arm clinical trial for  
22 women who have changed their mind after commencing medical abortion. *J Obstet*  
23 *Gynaecol Res.* 2024;50(2):182-189. This prospective trial included IRB approval and  
24 human clinical trial registration prior to study initiation. The trial registration  
25 ([https://anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN1262000](https://anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12620000596909)  
26 [0596909](https://anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=ACTRN12620000596909)) indicated a plan to enroll 52 participants over 19 months, ending in January  
27 2022. The registration was not updated after the 6<sup>th</sup> participant was recruited and  
28 completed the study in approximately September 2021, which is the duty of the

1 authors for any human clinical trial registration. The sample size in the paper indicates  
2 26 participants rather than 52, an error the journal did not catch. Thus, the sample size  
3 was manipulated after trial registration. The authors do not state in their discussion  
4 why they stopped the study early. This study enrolled women 18-45 years old in  
5 Australia who reported mifepristone intake in the prior 72 hours. Participants received  
6 oral progesterone for 19 days with pregnancy continuation assessed at 14 days. Over 9  
7 months, the telehealth study received 9 calls and enrolled 6 participants. The authors  
8 state that perhaps the low recruitment was because patients would go elsewhere online  
9 for APR rather than their study and do not assume that, possibly, the need for such  
10 treatment is not what they assume. The participants were 5.5-10 weeks gestation with  
11 3 of the 6 at 9-10 weeks. One treatment was initiated 4 days after mifepristone intake  
12 and the others on days 1-3. Five of the six pregnancies continued for two weeks. The  
13 one participant that passed the pregnancy had two emergency department visits. The  
14 authors reported no significant side effects from progesterone treatment. The authors  
15 conclude “As a pilot trial, the study was limited to a small number of participants  
16 which did not enable statistical assessment of whether progesterone taken after  
17 mifepristone ingestion increased the rate of pregnancy viability” and “Larger clinical  
18 trials are required to determine the clinical effectiveness of progesterone-after-  
19 mifepristone.”

20 **“Abortion Pill Reversal” additional data and information**

21 49. Proponents of APR have recently used data published on the impact of depo-  
22 medroxyprogesterone acetate (DMPA) injectable contraception provided at the same  
23 time as mifepristone in patients having a medication abortion as evidence of the  
24 virtues of APR. For clarity, the impact of DMPA and the contraceptive implant, both  
25 progestin-only contraceptive methods, have been studied when used simultaneously  
26 with mifepristone in patients having a medication abortion compared to waiting until  
27 after the abortion.  
28

- 1 a. Implant: Studies have shown no impact of the implant on medication abortion  
2 outcomes even though this progestin is started simultaneously with mifepristone  
3 and continues to provide increasing levels of hormone over the 3 days after  
4 placement.<sup>20</sup>
- 5 b. DMPA: DMPA use is associated with higher rates of continuing pregnancy and,  
6 possibly, increased likelihood of medication abortion failure.<sup>21</sup> Still, the overall  
7 continuing pregnancy rate when DMPA is administered with mifepristone is low.

8 50. A recent secondary analysis I published<sup>22</sup> re-evaluated the Carroll et al study<sup>23</sup> to  
9 estimate the actual impact of DMPA on mifepristone.

- 10 a. DMPA is a much more potent progestogen than progesterone, is rapidly absorbed  
11 when administered intramuscularly, and is present in the blood at high  
12 concentrations for weeks.
- 13 b. We first analyzed the impact of DMPA varied by gestational duration, which was  
14 not performed in the initial publication.
- 15 c. Second, we used the outcomes in those patients that did and did not use DMPA to  
16 calculate the expected continuing pregnancy rate if DMPA had a 100% effect to  
17 antagonize mifepristone. Based on the continuing pregnancy rate with  
18 simultaneous DMPA and mifepristone use, only 25% of the hypothesized

19 \_\_\_\_\_  
20 <sup>20</sup> Raymond EG, Weaver MA, Tan Y, Louie KS, Bousiéguéz M, Lugo-Hernández EM, et  
21 al. Effect of Immediate Compared With Delayed Insertion of Etonogestrel Implants on Medical  
22 Abortion Efficacy and Repeat Pregnancy: A Randomized Controlled Trial. *Obstet Gynecol*  
2016;127:306–2. Carroll AL, Strauss AM, Philipps NM, Kaczmarczik KD, Shakur Z, Ramirez  
G, Klc TR, Tessier KM, Boraas CM. Efficacy of medication abortion with concurrent initiation of  
progestin contraceptives: A retrospective cohort study. *Contraception*. 2024;140:110536.

23 <sup>21</sup> Raymond EG, Weaver MA, Louie KS, Tan Y, Bousiéguéz M, Aranguré-Peraza AG, et  
24 al. Effects of Depot Medroxyprogesterone Acetate Injection Timing on Medical Abortion  
25 Efficacy and Repeat Pregnancy: A Randomized Controlled Trial. *Obstet Gynecol* 2016;128:739–  
45. Carroll AL, Strauss AM, Philipps NM, Kaczmarczik KD, Shakur Z, Ramirez G, Klc TR,  
Tessier KM, Boraas CM. Efficacy of medication abortion with concurrent initiation of progestin  
contraceptives: A retrospective cohort study. *Contraception*. 2024;140:110536.

26 <sup>22</sup> Creinin MD, Boraas CM. Depomedroxyprogesterone acetate impact on mifepristone  
27 action during medication abortion. *Eur J Contracept Reprod Health Care*. 2025:1-5.

28 <sup>23</sup> Carroll AL, Strauss AM, Philipps NM, Kaczmarczik KD, Shakur Z, Ramirez G, Klc  
TR, Tessier KM, Boraas CM. Efficacy of medication abortion with concurrent initiation of  
progestin contraceptives: A retrospective cohort study. *Contraception*. 2024;140:110536.

1 continuing pregnancy rate was realized. This 25% rate is much less than the >60%  
2 rate quoted by APR advocates with a less potent treatment delayed some time after  
3 mifepristone administration.

4 d. We concluded, based on this information, that outcomes with other progestin  
5 therapies cannot be related to each other given the variable effects of the implant  
6 and DMPA, and that at most, a 25% effect is seen with DMPA simultaneous use  
7 implying that the claims of APR advocates are inexact and likely not real. This  
8 finding lays strong doubt to any evidence of a “calculated” effect of APR in the  
9 68% range.

10 51. Lastly, APR advocates have claimed for years that high numbers of patients seek their  
11 services. This claim is vague and no published literature supports such claims.  
12 Ironically, the most recently published pilot study enrolled 6 people from all of  
13 Australia over 9 months, demonstrating the rarity of this request. The fact is that there  
14 is no evidence that using progesterone has any benefit over doing nothing. As I stated  
15 earlier, when there is no proven benefit and potential risks, the benefit does not  
16 outweigh the risk. Observational studies that claim an association are not proof of  
17 cause and effect, especially when the observational studies are not scientifically sound.  
18 Propaganda that claims to be science is still propaganda.

19 **Summary**

20 52. Decades of research and real-life clinical use have confirmed the high efficacy and  
21 safety of mifepristone and misoprostol for medication abortion. The science is  
22 consistent across studies in various populations. Medication abortion with  
23 mifepristone and misoprostol is an example of a well-studied treatment with  
24 appropriate data available to fully inform clinicians and patients about efficacy at  
25 different gestational durations, adverse events, and complications. APR is an unproven  
26 treatment, supported only by hypothesis and weak observational studies that do not  
27 prove cause and effect. The only randomized trial done to date could not be completed  
28 due to safety concerns related to not providing misoprostol and was not large enough

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statistically to make any conclusions. In a data free zone, advertising about proven efficacy is not supported by science. APR is a concept in line with recommendations to use hydroxychloroquine and ivermectin for COVID-19. To those that peddled these ideas, it seemed reasonable and sound. However, appropriately performed studies showed no benefit. Perhaps, someday, evidence may exist that proves APR efficacy and safety. However, that someday is not now.

I declare under penalty of perjury that the foregoing is true and correct and that this declaration was executed on June 23, 2025, in Sacramento, California.

  
\_\_\_\_\_  
Dr. Mitchell D. Creinin, M.D.

## PROOF OF ELECTRONIC SERVICE

**Case Name:** People v. Heartbeat Int'l, Inc., et al.  
**Case Number:** 23CV044940  
**Party Represented:** People of the State of California

### Declaration of Electronic Service

1. I am at least 18 years of age and not a party to this matter.
2. I am employed in the Office of the Attorney General of the State of California. My business address is 300 South Spring Street, Suite 1702, Los Angeles, CA 90013-1230, Los Angeles County.
3. My electronic service address is [Cheryll.Tran@doj.ca.gov](mailto:Cheryll.Tran@doj.ca.gov).
4. On June 24, 2025, I electronically served the following document[s]:

### AMENDED EXPERT DECLARATION OF DR. MITCHELL D. CREININ, M.D.

5. I electronically served the aforementioned document[s] by emailing them to the following individual[s]:

Paul Jonna  
Jeff Trissell  
Kathy Denworth  
Brian McPherson  
LiMandri & Jonna LLP  
[pjonna@limandri.com](mailto:pjonna@limandri.com)  
[jtrissell@limandri.com](mailto:jtrissell@limandri.com)  
[kdenworth@limandri.com](mailto:kdenworth@limandri.com)  
[bmcperson@limandri.com](mailto:bmcperson@limandri.com)  
*Attorneys for Heartbeat International &  
RealOptions*

Andrew Hollins  
Ethan Reimers  
Sabrina Johnson  
Claudia Scherz  
[ahollins@messner.com](mailto:ahollins@messner.com)  
[ereimers@messner.com](mailto:ereimers@messner.com)  
[mroccalendar@messner.com](mailto:mroccalendar@messner.com)  
[sjohnson@messner.com](mailto:sjohnson@messner.com)  
[cscherz@messner.com](mailto:cscherz@messner.com)  
*Attorneys for RealOptions*

I declare under penalty of perjury under the laws of the State of California and the United States of America that the foregoing is true and correct, and that this declaration was executed on June 24, 2025.

\_\_\_\_\_  
Cheryll Tran  
Declarant

\_\_\_\_\_  
/s/ Cheryll Tran  
Signature



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Commentary

## Mifepristone antagonization requires real studies to evaluate safety and efficacy

Mitchell D. Creinin\*, Melissa J. Chen

Department of Obstetrics and Gynecology, University of California, Davis, Sacramento, CA, USA

EXHIBIT  
4

The modern era of medical abortion treatment evolved with the development of mifepristone, a progesterone-receptor antagonist with an affinity for the receptor greater than progesterone itself [1]. Early studies of modern medical abortion regimens evaluated mifepristone alone, primarily at very early gestations. Continued research demonstrated that adding a prostaglandin analogue within a few days after mifepristone significantly improved the efficacy of the treatment [2]. The current FDA-approved regimen of mifepristone 200 mg with misoprostol treatment 24–48 h later is effective through 70 days gestation [3]. Ongoing pregnancy as a reason for treatment failure increases 10-fold from 0.3% at less than 49 days gestation to approximately 3% at 64–70 days' gestation [3–5]. While most women with an ongoing pregnancy opt for further treatment, such as surgical aspiration, some decide to continue the pregnancy. Recent UK data show that among 2673 women having a medical abortion from 9 to 10 weeks' gestation, 90 women had ongoing pregnancies after treatment of whom 9 (10%) opted to continue the pregnancy [6]. Thus, even following treatment, some women do change their mind.

The non-medical terms “abortion reversal,” “medical abortion reversal” and “abortion pill reversal” have been used to describe a purported treatment first published as a case series in the *Annals of Pharmacotherapy* in December 2012 [7]. However, medical abortion cannot be “reversed,” which would imply putting a pregnancy back in the uterus. Conceptually, the goal of progesterone proponents is mifepristone antagonization with high doses of progesterone; two small case reports and one large case series have been published about such treatment [7–9]. Commentaries in the *American Journal of Obstetrics and Gynecology* and *New England Journal of Medicine* have outlined the numerous scientific and ethical problems with these reports, including lack of control groups, no confirmation of mifepristone ingestion, failure to establish viability prior to progesterone treatment, and providing experimental treatment without patient consent or institutional review board oversight [10,11]. Within the reproductive rights community, some may even argue that mifepristone antagonization is conceptually impossible and potentially harmful to women.

We see a parallel issue in second trimester surgical abortion, with women requesting osmotic dilator removal in less than 1%

of procedures [12]. Even when providers have reviewed all pregnancy options prior to dilator placement, counsel patients that dilator placement is the start of the procedure, and confirm with patients that they are absolutely clear in their decision before proceeding, a small minority of women do change their mind. The best information we have about what happens after dilator removal is a small case series of 12 women, which demonstrated pregnancy loss in 50% and complications in 66% of women [12]. Still, when requested, patient autonomy requires dilator removal.

What should we do for the small fraction of women who change their mind after taking mifepristone? Is recommending expectant management or progesterone treatment the better choice? To answer this question, we need to understand what happens when mifepristone is taken without misoprostol, if mifepristone antagonization with progesterone works (including the appropriate progesterone route, dose and duration) for all or just for specific gestational age ranges, and what safety concerns are present in both scenarios.

### 1. Trying to understand efficacy of mifepristone-only treatment

Two competing systematic reviews, both of which have inherent problems, attempted to establish the continuing pregnancy rate after mifepristone-only treatment to provide a base rate for comparison with attempted mifepristone antagonization [13,14].

First, Grossman et al [13] found 11 publications with 17 treatment groups meeting criteria to be included in the review. Continuing pregnancy rates ranged from 0 to 36% when patients were assessed generally 1–2 weeks after mifepristone ingestion. Overall, the review included 1092 women with an intrauterine pregnancy; continuing pregnancies occurred in 193 (18%) after mifepristone alone. Of note, all but one of the studies included women at 49 days gestation or less. Only six of the included studies clearly defined the outcome of continuing pregnancy as a viable pregnancy [15–20]. The other five studies appeared to consider retained non-viable gestations in the outcome of continuing pregnancies [21–25].

In 2017, Davenport, Delgado and colleagues [14] published a second review as a rebuttal to the review from Grossman et al. This review included 12 publications with 16 treatment groups; seven publications [15–20,25] had been considered acceptable for inclusion in the analysis by Grossman et al. These authors report a

\* Corresponding author: 4860 Y Street, Suite 2500, Sacramento, CA 95817, USA.  
E-mail address: [mdcreinin@ucdavis.edu](mailto:mdcreinin@ucdavis.edu) (M.D. Creinin).

slightly lower combined continuing pregnancy rate of 13%. While this review excluded four studies that did not clearly define a continuing pregnancy as a viable pregnancy [18–21], it did include three reports of published meeting proceedings that were not peer-reviewed. Only one published study (by Vervest and Haspels [26]) in the Davenport et al review was not included in the Grossman et al review.

In our own re-evaluation of the peer-reviewed studies included in both reviews, only seven studies clearly define continuing viable pregnancy rates after mifepristone alone (Table 1). We excluded non-peer-reviewed meeting proceedings, three studies that considered an increasing hCG as evidence of continuing pregnancy as this could represent viable or non-viable gestations [21,24,25], and two studies without any definition of continuing pregnancies in the text [22,23]. The studies in Table 1 include 550 women who received a wide range of mifepristone dosing, the majority (n = 468, 88%) of whom were enrolled in studies with an upper gestational age limit of 49 days or less. Among the four studies using a single mifepristone dose, only one had a study arm with 200 mg, the dose used in contemporary clinical practice. The continuing pregnancy rate was higher with 200 mg (7/30 [23%, 95% confidence interval 8–38%]) than 600 mg (29/420 [7%, 95% confidence interval 4–9%]), p = .006 (Fisher exact test) [17–20]. However, the number of women (n = 30) is too little for this statistical comparison to be considered precise [17].

## 2. Trying to understand harm

Because we have inadequate data to determine the continuing pregnancy rate after mifepristone alone, we cannot be certain if mifepristone antagonization is effective. Some argue that since progesterone might be effective, is there any harm in offering such treatment to the rare patient who does change her mind? We do not know that answer either. Whereas the first two published case series included only eight women at 10 weeks or less gestation [7,8], a single large series analyzed 547 women treated in various ways by 325 different providers with “high-dose” progesterone, including progesterone in oil intramuscularly, micronized progesterone orally, micronized progesterone capsules administered vaginally, compounded micronized progesterone vaginal suppositories, progesterone vaginal gel, and progesterone vaginal suppositories [9]. The authors reported continuing pregnancy in 261 (48%) but did not report any adverse events, side effects, or details of what happened to the approximately 50% of women for whom the treatment did not “work.”

In contrast, mifepristone-only studies for abortion did report complications, including hemorrhage and transfusion [15,16,26].

Among eight studies that used a single dose of mifepristone 200 mg or 600 mg, no cases of hemorrhage or transfusion occurred, though these studies were limited to women 49 days gestation or less [17–20,22–25]. Since medical abortion is available through 70 days [3], what are the risks when mifepristone is used without misoprostol beyond 49 days? These unanswered questions underscore that the published case series of progesterone use for mifepristone antagonization are reports and not clinical trials.

## 3. Laws based on no science

Unfortunately, in the absence of rigorous evaluations, some lawmakers are using case reports as medical gospel and passing laws stipulating mifepristone antagonization as fact. These laws mandate that women who receive mifepristone be informed that it may be possible to reverse the effects of mifepristone if they change their minds. In 2015, Arkansas implemented the first mandatory abortion reversal counseling. Other states that soon followed included Arizona (later repealed in 2016), South Dakota, Utah, and Idaho. In 2019, Arkansas updated its law to clarify the information provided to patients, and four states (Oklahoma, Kentucky, Nebraska, and North Dakota) enacted new laws. Kansas also passed such a law that the governor vetoed. A federal judge recently blocked the North Dakota law following a lawsuit from plaintiffs that included the American Medical Association. The judge’s decision acknowledged that compelling counseling based on the State’s viewpoint without credible scientific evidence that the treatment was effective interfered with health care providers’ first-amendment rights. Similarly, when Louisiana was considering such a law in 2017, a Louisiana Department of Health report in April 2017 found “neither sufficient evidence nor a scientific basis to conclude that the effects of an abortion induced with drugs or chemicals can be reversed” [27]. Still, states continue to introduce bills to create similar laws. These laws interfere with our duty to counsel women about both efficacy and safety, and put providers in the position of counseling about unproven assurances without any mention of potential harms. In 2015 and reiterated in August 2017, the American Congress of Obstetricians and Gynecologists publicly opposed laws mandating reversal information as lacking scientific standing [28].

## 4. So, what do we do now?

Abortion providers can either continue to dismiss the concept of mifepristone antagonization or can work to help patients find answers. Choosing the latter option is a proactive stance towards

**Table 1**

Studies reporting the proportion of continuing viable pregnancies after mifepristone alone for medical abortion\*

| First author     | Year published | Mifepristone dose  | Duration of treatment | Number | Gestational age limit (days) | Follow-up (days after mifepristone) | Complete abortion | Continuing viable pregnancy rate |
|------------------|----------------|--------------------|-----------------------|--------|------------------------------|-------------------------------------|-------------------|----------------------------------|
| Kovacs [15]      | 1984           | 25 mg twice daily  | 4 days                | 18     | 42                           | 14                                  | 12 (67%)          | 2 (11% [0–26%])                  |
|                  |                | 50 mg twice daily  | 4 days                | 10     | 42                           | 14                                  | 5 (50%)           | 1 (10% [0–29%])                  |
|                  |                | 100 mg twice daily | 4 days                | 8      | 42                           | 14                                  | 5 (63%)           | 0                                |
| Cameron [16]†    | 1986           | 150 mg daily       | 4 days                | 20     | 56                           | 14                                  | 12 (60%)          | 5 (25% [11–47%])                 |
| Vervest [26]     | 1985           | 100–200 mg daily   | 4 days                | 35     | 55                           | 14                                  | 25 (71%)          | 0                                |
|                  |                | 200 mg daily       | 4 days                | 9      | 56–70                        | 14                                  | 3 (33%)           | 0                                |
| Maria [17]‡      | 1988           | 200 mg             | Single dose           | 30     | 49                           | 7                                   | 19 (63%)          | 7 (23% [12–41%])                 |
|                  |                | 600 mg             | Single dose           | 174    | 49                           | 7                                   | 147 (84%)         | 4 (2% [0.1–5%])                  |
| Maria [18]‡      | 1988           | 600 mg             | Single dose           | 149    | 42                           | 7                                   | 131 (88%)         | 14 (9% [5–14%])                  |
| Carol [19]       | 1989           | 600 mg             | Single dose           | 50     | 39                           | NR                                  | 40 (80%)          | 6 (12% [6–24%])                  |
| Ylikorkala [20]‡ | 1989           | 600 mg             | Single dose           | 47     | 43                           | 14                                  | 33 (70%)          | 5 (11% [5–23%])                  |

NR: not reported.

Data presented as n (%) or n (% [95% confidence interval]).

\* All studies except Vervest et al [26] included in systematic review by Grossman et al [13]; all studies included in Davenport et al [14].

† Gestational age determination included ultrasound examination.

providing evidence-based care to patients seeking medical abortion, especially to the very few who may change their mind.

If a woman uses mifepristone and then returns to the same provider's office 24 hours later stating she has changed her mind, what should that provider tell her? Is progesterone itself harmful – likely not based on widespread use within obstetrics. Does progesterone actually work for mifepristone antagonization – we don't know and can only tell our patient that the existing reports in the literature are inadequate to answer that question. Is NOT using misoprostol harmful, especially if the patient is beyond 49 days gestation – we also do not know that answer. If one believes that progesterone treatment cannot antagonize mifepristone, then the safety of not using misoprostol after starting a mifepristone-misoprostol regimen is the real question. Using progesterone for mifepristone antagonization means not using misoprostol as prescribed. Currently, the rare patient who changes her mind is potentially going to a website to get an experimental treatment rather than returning to the clinician providing her abortion services. The answers can only be found in properly conducted clinical trials that can inform evidence-based decision making and not in poorly conceived laws based on no science. For FDA approval, new treatments go through safety testing before efficacy testing. It is incumbent upon the medical community to conduct proper research on mifepristone antagonization that evaluates the efficacy and safety of providing progesterone and not using misoprostol.

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#### Conflicts of interest

Dr. Creinin is a consultant for Danco Laboratories to provide medical advice to clinicians who contact the company with questions related to mifepristone use.

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Original Research

# Mifepristone Antagonization With Progesterone to Prevent Medical Abortion

## A Randomized Controlled Trial

Mitchell D. Creinin, MD, Melody Y. Hou, MD, MPH, Laura Dalton, DO, MBA, Rachel Steward, MD, MSc, and Melissa J. Chen, MD, MPH

**OBJECTIVE:** To estimate the efficacy and safety of mifepristone antagonization with high-dose oral progesterone.

**METHODS:** We planned to enroll 40 patients in a double-blind, placebo-controlled, randomized trial. We enrolled patients at 44–63 days of gestation with ultrasound-confirmed gestational cardiac activity who were planning surgical abortion. Participants ingested mifepristone 200 mg and initiated oral progesterone 400 mg or placebo 24 hours later twice daily for 3 days, then once daily until their planned surgical abortion 14–16 days after enrollment. Follow-up visits were scheduled  $3 \pm 1$ ,  $7 \pm 1$ , and  $15 \pm 1$  days after mifepristone intake with ultrasonography and blood testing for human chorionic gonadotropin and progesterone. Participants exited from the study when they had their surgical abortion or earlier for gestational cardiac activity absence, gestational sac expulsion, or medically indicated suction aspiration. We assessed

the primary outcome of continued gestational cardiac activity at approximately 2 weeks ( $15 \pm 1$  day), side effects after drug ingestion, and safety outcomes including hemorrhage and emergent treatment.

**RESULTS:** We enrolled participants from February to July 2019 and stopped enrollment after 12 patients for safety concerns. Mean gestational age was 52.5 days. Two (one per group) voluntarily discontinued 3 days after mifepristone ingestion for subjective symptoms (nausea and vomiting, bleeding). Among the remaining 10 patients (five per group), gestational cardiac activity continued for 2 weeks in four in the progesterone group and two in the placebo group. One patient in the placebo group had no gestational cardiac activity 3 days after mifepristone use. Severe hemorrhage requiring ambulance transport to hospital occurred in three patients; one received progesterone (complete expulsion, no aspiration) and two received placebo (aspiration for both, one required transfusion). We halted enrollment after the third hemorrhage. No other significant side effects were reported.

**CONCLUSION:** We could not estimate the efficacy of progesterone for mifepristone antagonization due to safety concerns when mifepristone is administered without subsequent prostaglandin analogue treatment. Patients in early pregnancy who use only mifepristone may be at high risk of significant hemorrhage.

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From the Department of Obstetrics and Gynecology, University of California, Davis, Sacramento, Planned Parenthood Mar Monte, San Jose, and FPA Women's Health, Sacramento, California.

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Each author has confirmed compliance with the journal's requirements for authorship.

Corresponding author: Mitchell D. Creinin, MD, University of California, Davis, Sacramento, CA; email: mdcrein@ucdavis.edu.

### Financial Disclosure

Mitchell D. Creinin is a consultant for Danco Laboratories, providing medical consultation for clinicians that contact Danco with questions regarding mifepristone. Laura Dalton is an employee of Planned Parenthood. The other author did not report any potential conflicts of interest.

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In the United States, approximately 862,000 abortions occur per year, of which almost 40% occur using medical abortion.<sup>1</sup> The treatment approved by the U.S. Food and Drug Administration for medical abortion is a combination of mifepristone and miso-



prostaglandin through 70 days of gestation.<sup>2</sup> Mifepristone acts as a competitive progesterone receptor antagonist and promotes decidual necrosis to weaken implantation, enhances uterine sensitivity to prostaglandins, and softens the cervix.<sup>3</sup> Accordingly, mifepristone has some activity to induce abortion when used alone. However, overall efficacy is generally 80% or less, and these studies typically included patients at less than 49 days of gestation.<sup>4</sup> Medical abortion efficacy is improved significantly with the addition of a prostaglandin analogue.<sup>4</sup> Mifepristone followed in 24–48 hours by misoprostol is 96–97% effective through 70 days of gestation; however, as gestation advances from 49 to 70 days, complete abortion rate decreases and continuing pregnancy rate increases.<sup>2</sup> Approximately 0.3% of patients at 49 days of gestation or less experience a continuing pregnancy compared with 3.1% of patients at 64–70 days.<sup>2</sup> A recent U.K. study of patients who initiated medical abortion at 64–70 days found that 9 of 89 (10%) patients with continuing pregnancies detected at follow-up opted to continue the pregnancy.<sup>5</sup>

Case series have reported that some patients may change their minds about terminating their pregnancies after ingesting mifepristone and before misoprostol treatment.<sup>6–8</sup> Although an exact proportion is unknown, the best estimate is that fewer than 0.005% of patients who use mifepristone choose to continue their pregnancies.<sup>9</sup> Because mifepristone binds strongly to the progesterone receptor and has a long half-life,<sup>4</sup> some scientists believe that this action is potentially irreversible. However, others have questioned this theory and believe that providing high doses of progesterone may antagonize the effects of mifepristone when administered for abortion.<sup>6</sup>

No clinical trials have been performed to adequately study antagonizing mifepristone with progesterone treatment. Case series reported to date have significant limitations, including using investigational treatment (high-dose progesterone) after mifepristone ingestion without consenting patients for this experiment; incomplete reporting of outcomes; use of varying progesterone doses, routes and durations; and lack of control groups to understand true efficacy.<sup>6–8</sup> The largest case series (547 patients evaluated) reported a 48% continuing pregnancy rate using various progesterone regimens, with the highest rates (64–68%) using various intramuscular or oral treatments.<sup>8</sup> To address these issues, we conducted a double-blind placebo-controlled randomized trial to evaluate continuing pregnancy rates, safety, and side effects of

high-dose oral progesterone in patients who used mifepristone during early pregnancy.

## METHODS

We conducted this randomized, double-blind, placebo-controlled trial at the University of California, Davis Medical Center. We approached patients who had completed counseling and consent for a surgical abortion and were 63 days of gestation or less about study participation. Inclusion criteria were 18 years or older, English-speaking, singleton pregnancy, and willingness to delay the abortion by approximately 2 weeks. Exclusion criteria were medical contraindications to medical abortion per the mifepristone U.S. Food and Drug Administration label,<sup>2</sup> an allergy to mifepristone or progesterone, or a peanut allergy (on-label contraindication to oral progesterone). The University of California, Davis, Institutional Review Board approved this study and all participants gave written study consent before beginning any study procedures.

The screening visit included obtaining study consent, recording demographic information, soliciting baseline pregnancy symptoms (subjectively rated as none, mild, moderate or severe), and inquiring whether they had used mifepristone or progesterone previously. Patients for whom transvaginal ultrasonography demonstrated gestational cardiac activity and a gestational age 44–63 days of gestation based on Goldstein and Wolfson's criteria<sup>10</sup> could enroll that day. Patients who were at less than 44 days of gestation at screening returned for enrollment, at which time transvaginal ultrasonography was repeated to confirm gestational cardiac activity and gestational age.

Enrolled participants had blood drawn for human chorionic gonadotropin (hCG) and progesterone levels, then swallowed mifepristone 200 mg in front of an investigator. Study treatment (progesterone or placebo) was prepared by the University of California, Davis Investigational Drug Service by placing 38 capsules of progesterone 200 mg or similar-appearing placebo capsules in opaque pill containers. The Investigational Drug Service could not over-encapsulate the drugs due to product size. The Investigational Drug Service performed the randomization allocation using a computer-generated random sequence in blocks of four, sequentially numbered the containers, and maintained the randomization log to ensure drug allocation concealment until study completion. Participants were instructed to start study treatment 24 hours after mifepristone ingestion by taking two capsules twice daily for 3 days, then two



capsules once daily until the study exit visit. We chose this dosing regimen because it was the most effective option previously described in a case series of mifepristone antagonization.<sup>8</sup> Participants received a diary to document any side effects and capsule intake. Participants also received the standard medical abortion bleeding and side effect instructions distributed to medical abortion patients at the University of California, Davis.

Research staff contacted participants 24 hours after mifepristone administration to confirm the start of study treatment. Follow-up visits were scheduled 3 ( $\pm 1$ ), 7 ( $\pm 1$ ), and 15 ( $\pm 1$ ) days after mifepristone intake. Each visit included diary review, assessment of symptoms or drug side effects, ultrasonography to establish presence or absence of gestational cardiac activity, and blood testing for hCG and progesterone. Additionally, a research coordinator independently counted unused study drug to maintain investigator blinding. The patient's planned surgical abortion was scheduled concurrent with her last study visit. Participants exited from the study when they had their surgical abortion, or earlier for gestational cardiac activity absence, gestational sac expulsion, or medically indicated suction aspiration. At the final visit, participants were asked whether they knew what treatment they received or looked up the capsules online for identification.

The primary outcome was continuing pregnancy with presence of gestational cardiac activity after approximately 2 weeks ( $15 \pm 1$  days). Secondary outcomes included expulsion rates over 2 weeks, change in hCG and progesterone levels during treatment, study drug side effects, and safety outcomes (eg, hemorrhage, emergency department visit, emergent suction aspiration). Safety evaluations (adverse events review) were performed by the principal investigator after each patient completed the study and at research review meetings every 2 weeks by the primary study team. The principal investigator was responsible for continued safety oversight and decisions to stop the study for safety reasons.

We estimated a 68% continuing pregnancy rate with oral progesterone treatment based on a report using the same dosing after mifepristone administration in early pregnancy, stating that 68% of patients had pregnancies that continued to 20 weeks of gestation or more.<sup>8</sup> We also estimated that only 25% of patients receiving placebo would have continuing pregnancies.<sup>11</sup> Using 80% power and  $\alpha = 0.05$ , 20 participants per group were required.

We performed an intention-to-treat analysis, using Fisher exact test or  $\chi^2$  test as indicated, *t* test

for continuous variables and Mann-Whitney *U* for comparing median values.

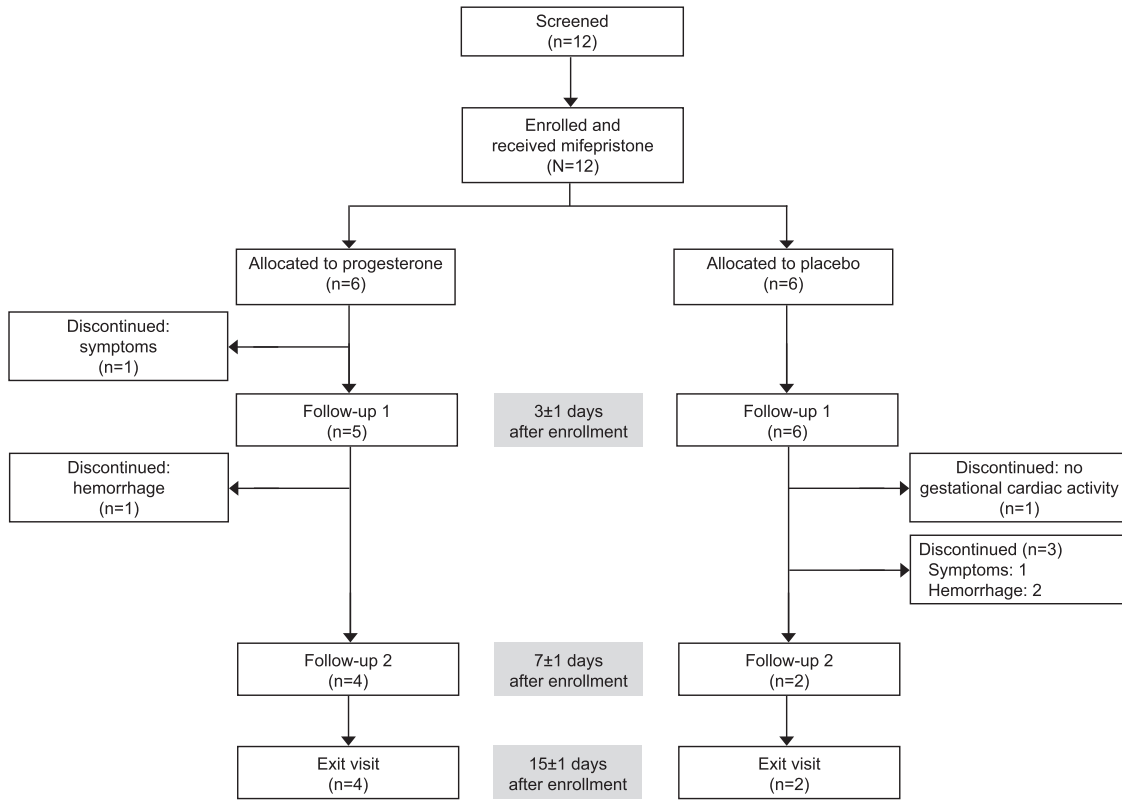
## RESULTS

We enrolled 12 patients from February 2019 to July 2019 (Fig. 1). Patient characteristics are presented in Table 1. Two patients exited the study voluntarily related to side effects; both underwent suction aspiration 3 days after mifepristone administration. The first patient, in the placebo group, was 48 days at enrollment and had a prior medical abortion. She had increased anxiety about bleeding that started 2 days after mifepristone use and requested a suction aspiration. The second patient, in the progesterone group, had three prior pregnancies and mild nausea and vomiting at baseline. She had developed increasing nausea and vomiting after enrolling, resulting in dehydration that required intravenous fluids as an outpatient. She took only two of her four treatment doses before requesting a suction aspiration.

Overall, four of six patients in the progesterone group and two of six patients in the placebo group had continuing pregnancies at 2 weeks. Excluding the two patients who did not finish treatment, these rates are four of five and two of five, respectively. A detailed listing of individual patient characteristics and outcomes is included in Appendix 1, available online at <http://links.lww.com/AOG/B658>.

Four pregnancies did not continue, including one patient at 48 days in the placebo group who had no gestational cardiac activity 3 days after mifepristone use and had an uneventful suction aspiration. Three other patients had severe bleeding requiring ambulance transport to an emergency department. The first patient received progesterone treatment after enrollment at 56 days of gestation. She reported no bleeding at the first follow-up visit 2 days postmifepristone. Shortly after her visit, she started having brisk bleeding and called an ambulance. Transvaginal ultrasound examination in the emergency department found no gestational sac and a heterogenous endometrial lining of approximately 1.5 cm. Heavy bleeding lasted about 3 hours overall, and no intervention was needed. The second patient received placebo and enrolled at 60 days of gestation. She noted new mild bleeding at a follow-up visit 2 days after mifepristone use. The following day, she called an ambulance after onset of heavy vaginal bleeding. In the emergency department, a study physician found significant heterogenous material in the uterine cavity on ultrasound examination with continued brisk bleeding, so a suction





**Fig. 1.** Participant flowchart of patients who received mifepristone 200 mg followed by progesterone for up to 2 weeks. *Creinin. Mifepristone Antagonization. Obstet Gynecol 2019.*

aspiration was performed. Pathology demonstrated normal chorionic villi. The third patient also received placebo and enrolled at 60 days of gestation. She noted new mild spotting at a follow-up visit 2 days after mifepristone use. The following day, she called an ambulance after experiencing hemorrhage. In the emergency department, a study physician evaluated the patient, who had significant brisk bleeding, hypotension, and tachycardia. Transvaginal ultrasound examination showed that the gestational sac was still in the uterine cavity, so an emergent suction aspiration was performed. This patient's hemoglobin level decreased in the emergency department from 9.2 to 7.5 g/dL, and she received a 1-unit transfusion of packed red blood cells. At safety contacts 2 and 4 weeks later, the patient reported no issues. We stopped enrollment for safety reasons after the third patient required emergent evaluation and a transfusion.

Baseline and follow-up serum hCG and progesterone levels are presented in Figures 2 and 3, respectively. Median baseline hCG and progesterone levels for the progesterone group were 76,776 milli-international units/mL (range 21,062–126,647 milli-international

units/mL) and 12.4 ng/mL (range 10.5–24.0 ng/mL), respectively. Median baseline hCG and progesterone levels for the placebo group were 153,908 milli-international units/mL (range 25,450–246,638 milli-international units/mL) and 16.3 ng/mL (range 11.2–18.9 ng/mL), respectively. In the progesterone group, progesterone levels increased 240–1,010% within a few days of starting treatment among patients with continuing gestational cardiac activity at 2 weeks; the one patient with hemorrhage demonstrated an increase of only 45% despite being adherent to study drug instructions.

Table 2 describes side effects related to pregnancy or treatment. One patient in the progesterone group noted the onset of severe nausea and vomiting shortly after mifepristone intake that preceded progesterone treatment; otherwise, no appreciable differences in development of new severe side effects were identified between treatment groups. All patients experienced some spotting (n=8) or bleeding (n=9) during treatment, except for the patient with the highest baseline progesterone level (24.1 ng/mL).

Only two participants believed they received progesterone, of whom one did (continuing



**Table 1. Characteristics at Enrollment for Patients Receiving Mifepristone and Randomized to Progesterone or Placebo Treatment**

| Characteristic                | Total (N=12)     | Progesterone (n=6) | Placebo (n=6)    |
|-------------------------------|------------------|--------------------|------------------|
| Age (y)                       | 27.3 (20.9–39.6) | 29.8 (24.6–39.6)   | 24.1 (20.9–33.8) |
| Gestational age (d)           | 52.5 (47–61)     | 49.5 (47–56)       | 55 (48–61)       |
| BMI (kg/m <sup>2</sup> )      | 24.6 (19.0–52.3) | 24.8 (19.0–36.4)   | 24.6 (22.7–52.3) |
| Obese (30.0 or higher)        | 4 (33)           | 2 (33)             | 2 (33)           |
| Race                          |                  |                    |                  |
| White                         | 3 (25)           | 0                  | 3 (50)           |
| Black or African American     | 5 (42)           | 4 (67)             | 1 (17)           |
| Asian                         | 4 (33)           | 2 (33)             | 2 (33)           |
| Ethnicity                     |                  |                    |                  |
| Hispanic or Latina            | 2 (17)           | 1 (17)             | 1 (17)           |
| Marital status                |                  |                    |                  |
| Never married                 | 7 (58)           | 3 (50)             | 4 (67)           |
| Married                       | 2 (17)           | 1 (17)             | 1 (17)           |
| Divorced or separated         | 3 (25)           | 2 (33)             | 1 (17)           |
| Education level               |                  |                    |                  |
| High school graduate          | 2 (17)           | 0                  | 2 (33)           |
| Some college                  | 9 (75)           | 5 (83)             | 4 (67)           |
| College graduate              | 1 (8)            | 1 (17)             | 0                |
| Gravidity                     | 4 (1–12)         | 4.5 (1–10)         | 3.5 (1–12)       |
| More than 3 prior pregnancies | 7 (58)           | 4 (67)             | 3 (33)           |
| Parity                        | 1 (0–6)          | 1.5 (0–6)          | 0.5 (0–3)        |
| Nulliparous                   | 4 (33)           | 1 (17)             | 3 (33)           |
| Prior abortion                | 9 (75)           | 4 (67)             | 5 (83)           |
| More than 3 prior abortions   | 4 (33)           | 2 (33)             | 2 (33)           |
| Past mifepristone use         | 4 (733)          | 1 (17)             | 3 (33)           |
| Prior progesterone use        | 0                | 0                  | 0                |

BMI, body mass index.  
Data are median (range) or n (%).

pregnancy at 2 weeks) and one did not (hemorrhage requiring emergent aspiration). The remaining 10 patients were evenly split between placebo and unsure. None of the patients looked on the internet to identify the study capsules they received.

## DISCUSSION

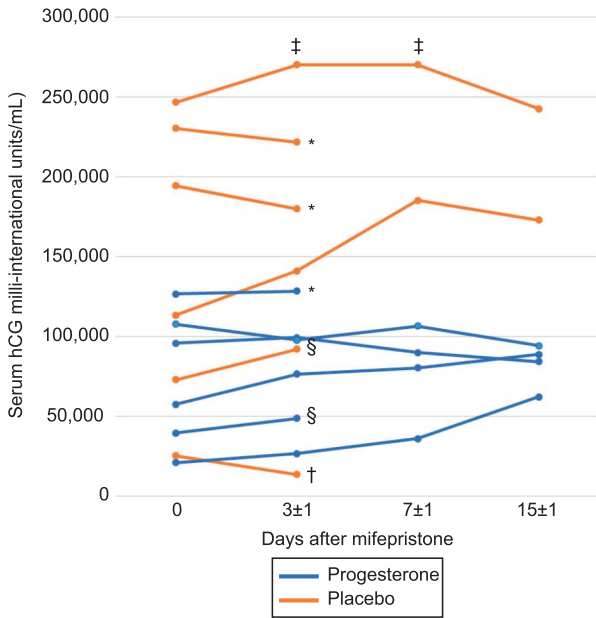
Although the study sample size was powered to demonstrate a difference in continuing pregnancy rates between progesterone and placebo treatment after mifepristone ingestion, we could not evaluate this outcome owing to stopping enrollment for safety reasons. However, we can make a few global and important conclusions from this very small, randomized trial. First, patients who receive high-dose oral progesterone treatment do not experience side effects that are noticeably different than placebo. Although patients using progesterone did report worsening of some pregnancy symptoms such as vomiting and tiredness, these issues were rarely severe.

Second and most important are the lessons about treatment safety. Providing treatment in any medical

situation requires a full understanding of the potential benefits and risks. Previous case series reports do not describe outcomes for the one third or more patients without continuing pregnancies after progesterone treatment.<sup>8</sup> Three of 12 patients enrolled experienced very heavy bleeding resulting in ambulance transport to an emergency department, a rate higher than reported with medical abortion, in which 0.6% of patients may have emergency department visits.<sup>12</sup> Patients who use mifepristone for a medical abortion should be advised that not using misoprostol could result in severe hemorrhage, even with progesterone treatment. We stopped the study because of these complications and, thus, could not quantify the full extent of this risk. Because of the potential dangers for patients who opt not to use misoprostol after mifepristone ingestion, any mifepristone antagonization treatment must be considered experimental.

The study has multiple limitations, primarily the inability to safely reach the enrollment goal to fully assess the primary outcome. Additionally, blinding for progesterone capsules is difficult and imperfect; however, we believe we maintained blinding because the





**Fig. 2.** Serum human chorionic gonadotropin (hCG) levels in patients who received mifepristone 200 mg followed by progesterone for up to 2 weeks. \*Participants experiencing hemorrhage. †Participant experienced loss of gestational cardiac activity. ‡Value greater than 270,000 (upper limit of hCG test). §Discontinued related to side effects.

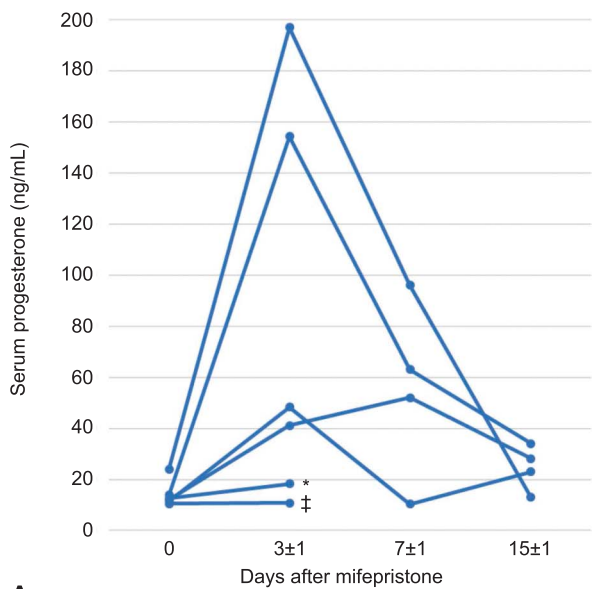
*Creinin. Mifepristone Antagonization. Obstet Gynecol 2019.*

patients enrolled had never used progesterone and none looked up the treatment to identify the drug. Of note, the variability in progesterone level among patients in the progesterone group may be explained by differential oral absorption of progesterone.<sup>13</sup> Although one may postulate another route of progesterone administration might affect the outcome, the case reports in the literature suggest similar continuing pregnancy rates after oral and intramuscular treatment.<sup>8</sup>

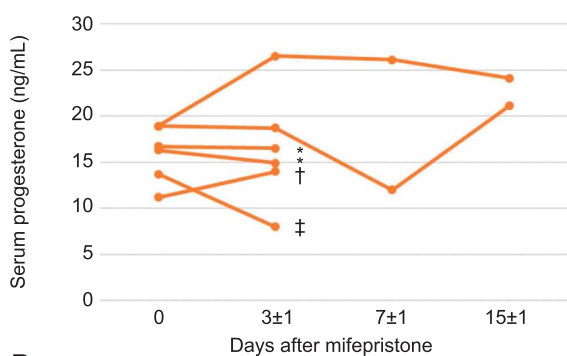
Our study established outcomes at 2 weeks as a surrogate for ongoing pregnancy; as such, it does not capture those who may still experience pregnancy loss more than 2 weeks after mifepristone exposure.<sup>14</sup> Accordingly, the outcomes described may not reflect the ultimate rate of pregnancies that continue past 20 weeks of gestation. Progesterone levels declined from high peaks to levels near baseline with continued treatment for 2 weeks. These findings raise two opposing questions: First, if progesterone can prevent medical abortion after mifepristone, is treatment necessary for more than 2 weeks? The case report from which the oral progesterone regimen for this study was based used the treatment through the “end of the first trimester.”<sup>8</sup> Second, do those treated with placebo just expel the pregnancy earlier than those who receive proges-

terone but no overall long-term difference in continuing pregnancy exists?

The context of this study is the question of whether a patient who has taken mifepristone 200 mg for a medical abortion and decides not to proceed with misoprostol treatment will be less likely to expel the pregnancy if she receives high-dose progesterone as compared with no treatment. Although mifepristone can cause abortion when used by itself in early pregnancy, the exact rate is not clear because studies were small and limited primarily to pregnancies of 49 days or less. Medical abortion today is used through 70 days of gestation. Additionally, a background rate of pregnancy loss is present regardless of mifepristone treatment. In patients with gestational



**A**



**B**

**Fig. 3.** Progesterone levels in patients who received mifepristone 200 mg followed by progesterone (A) or placebo (B) for up to 2 weeks. \*Participants experiencing hemorrhage. †Participant experienced loss of gestational cardiac activity. ‡Discontinued related to side effects.

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**Table 2. Side Effects\* Noted During Follow-up of Patients in Early Pregnancy Receiving Mifepristone and Randomized to Progesterone or Placebo Treatment for Up to 2 Weeks**

|              | Reported at Baseline |               | Increased From Baseline <sup>†</sup> |               | Increased to Severe During Follow-up <sup>†</sup> |               |
|--------------|----------------------|---------------|--------------------------------------|---------------|---|---------------|
|              | Progesterone (n=6)   | Placebo (n=6) | Progesterone (n=6)                   | Placebo (n=6) | Progesterone (n=6)                                | Placebo (n=6) |
| Nausea       | 4 (67)               | 5 (83)        | 2 (33)                               | 2 (33)        | 2 (33)  | 1 (17)        |
| Vomiting     | 2 (33)               | 3 (50)        | 4 (67)                               | 0             | 2 (33)  | 0             |
| Mastalgia    | 4 (67)               | 5 (83)        | 1 (17)                               | 0             | 0   | 0             |
| Tiredness    | 5 (83)               | 4 (67)        | 3 (50)                               | 0             | 0   | 1 (17)        |
| Mood changes | 4 (67)               | 5 (83)        | 0                                    | 0             | 1 (17)  | 0             |
| Reflux       | 2 (33)               | 2 (33)        | 1 (17)                               | 0             | 0   | 0             |
| Dizziness    | 2 (33)               | 1 (17)        | 0                                    | 0             | 0   | 0             |
| Bleeding     | 0                    | 0             | 4 (67)                               | 4 (67)        | 1 (17)  | 3 (50)        |
| Spotting     | 1 (17)               | 1 (17)        | 3 (50)                               | 4 (67)        | 0   | 0             |
| Cramping     | 3 (50)               | 2 (33)        | 4 (67)                               | 5 (83)        | 0   | 0             |

Data are n (%).

\* Subjectively assessed by participant as none, mild, moderate, or severe.

<sup>†</sup> At any time during follow-up.

cardiac activity demonstrated by ultrasonography at 6–10 weeks, 13.4% will spontaneously have an early pregnancy loss.<sup>15</sup>

This study, although small, provides important insight into the safety of mifepristone antagonization with progesterone during early pregnancy. We should not dismiss mifepristone antagonization as impossible; fully understanding outcomes will serve as the best means to accurately inform our patients, the medical community, and legislators. Existing literature before this study is comprised of case reports and series, which are not evidence of efficacy and do not address safety.<sup>6–8</sup> This level of evidence is inadequate to support or refute the benefits and risks of any treatment. Unfortunately, legislators often fail to understand differences in levels of evidence and some states now require physicians who provide medical abortion to counsel patients that the actions of mifepristone can be reversed if they change their mind. In 2015, Arkansas implemented mandatory abortion-reversal counseling, followed by Arizona (later repealed in 2016), South Dakota, Utah, Idaho, and, most recently, North Dakota. Several other states have introduced and passed legislation, although some was vetoed by the governors. Abortion is no different than any other medical treatment when considering clinical practice guidelines; laws should not mandate counseling or provision of any treatment when we do not fully understand treatment efficacy (including best route of administration, dose, and duration) and safety.

The dilemma that has been created around mifepristone antagonization exists only because of the void in high-quality research addressing the issue. For now, such a treatment is experimental and should be offered only in institutional review board–approved human clinical trials to ensure proper oversight.

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### Authors' Data Sharing Statement

Will individual participant data be available (including data dictionaries)? *Yes*.

What data in particular will be shared? *Data included with the submission in Appendix 1, available online at <http://links.lww.com/AOG/B658>.*

What other documents will be available? *No*.

When will data be available (start and end dates)? *With publication*.

By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? *In Appendix 1, <http://links.lww.com/AOG/B658>.*

### PEER REVIEW HISTORY

Received September 5, 2019. Received in revised form October 9, 2019. Accepted October 17, 2019. Peer reviews are available at <http://links.lww.com/AOG/B659>.

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rev 12/2019



**Appendix 1. Individual Patient Characteristics at Enrollment and Outcomes for Women Receiving Mifepristone 200 mg and Randomized to Progesterone or Placebo Treatment**

| Subject Number | Study group* (years) | Age (years) | Gestational Age (days) | Race  | Ethnicity    | Education            | Marital Status | Smoking | Alcohol | Marijuana Use | Drug Use | Total Pregnancies | Vaginal Delivery | Cesarean Delivery | Miscarriages | Abortions | Weight (kg) | BMI (kg/m <sup>2</sup> ) |
|----------------|----------------------|-------------|------------------------|-------|--------------|----------------------|----------------|---------|---------|---------------|----------|-------------------|------------------|-------------------|--------------|-----------|-------------|--------------------------|
| 1              | Progesterone         | 24.6        | 53                     | Asian | Not Hispanic | Some college         | Never married  | Never   | Never   | Never         | Never    | 1                 | 0                | 0                 | 0            | 0         | 84.2        | 32.9                     |
| 2              | Progesterone         | 30.9        | 50                     | Black | Not Hispanic | Some college         | Separated      | Never   | Current | Current       | Never    | 8                 | 3                | 0                 | 0            | 4         | 68.9        | 23.8                     |
| 3              | Placebo              | 20.9        | 50                     | Asian | Not Hispanic | Some college         | Never married  | Never   | Never   | Never         | Never    | 1                 | 0                | 0                 | 0            | 0         | 61.8        | 24.1                     |
| 4              | Placebo              | 22.6        | 48                     | White | Hispanic     | Some college         | Married        | Current | Current | Current       | Current  | 2                 | 0                | 0                 | 0            | 1         | 152.0       | 52.3                     |
| 5              | Progesterone         | 39.6        | 49                     | Black | Not Hispanic | Some college         | Never married  | Current | Never   | Never         | Never    | 5                 | 2                | 0                 | 0            | 2         | 51.8        | 19.0                     |
| 6              | Placebo              | 24.8        | 61                     | Asian | Not Hispanic | Some college         | Never married  | Never   | Current | Current       | Never    | 3                 | 0                | 0                 | 1            | 1         | 66.7        | 24.4                     |
| 7              | Placebo              | 23.5        | 48                     | White | Not Hispanic | High School graduate | Never married  | Former  | Never   | Current       | Never    | 7                 | 0                | 1                 | 0            | 5         | 71.8        | 22.7                     |
| 8              | Progesterone         | 27.7        | 56                     | Black | Not Hispanic | Some college         | Never married  | Never   | Current | Never         | Never    | 10                | 1                | 0                 | 1            | 7         | 100.8       | 36.4                     |
| 9              | Progesterone         | 31.9        | 47                     | Asian | Not Hispanic | College graduate     | Married        | Never   | Never   | Never         | Never    | 4                 | 0                | 2                 | 1            | 0         | 66.0        | 25.8                     |
| 10             | Placebo              | 27.0        | 60                     | Black | Not Hispanic | High School graduate | Never married  | Never   | Current | Current       | Never    | 4                 | 2                | 0                 | 0            | 1         | 63.5        | 24.8                     |
| 11             | Placebo              | 33.8        | 60                     | White | Not Hispanic | Some college         | Separated      | Current | Former  | Former        | Former   | 12                | 6                | 0                 | 0            | 5         | 105.5       | 34.3                     |
| 12             | Progesterone         | 28.6        | 48                     | Black | Hispanic     | Some college         | Divorced       | Never   | Current | Current       | Never    | 3                 | 1                | 0                 | 0            | 1         | 53.8        | 19.7                     |

| Subject Number | hCG (mIU/ml) | Progesterone (ng/ml) | Exit Study Day* | FINAL OUTCOME    |  | Reason for Hospital visit |
|----------------|--------------|----------------------|-----------------|------------------|--|---------------------------|
|                |              |                      |                 | Hospital visit   | Reason for Hospital visit                      |                           |
| 1              | 95,870       | 12.1                 | 17              | No               | N/A  | N/A                       |
| 2              | 57,681       | 11.5                 | 16              | No               | N/A  | N/A                       |
| 3              | 113,431      | 18.9                 | 16              | No               | N/A  | N/A                       |
| 4              | 25,450       | 13.7                 | 4               | No               | N/A  | N/A                       |
| 5              | 107,780      | 24.1                 | 16              | No               | N/A  | N/A                       |
| 6              | 246,638      | 18.9                 | 16              | No               | N/A  | N/A                       |
| 7              | 73,018       | 11.2                 | 4               | No               | N/A  | N/A                       |
| 8              | 126,647      | 12.6                 | 3               | Yes (ER), Day 3  | Hemorrhage, hemoglobin 10.4 gm/dL              |                           |
| 9              | 39,660       | 10.5                 | 4               | Yes (L&D), Day 3 | Dehydration, nausea, vomiting                  |                           |
| 10             | 230,220      | 16.3                 | 5               | Yes (ER), Day 5  | Hemorrhage, hemoglobin 9.6 gm/dL               |                           |
| 11             | 194,384      | 16.7                 | 6               | Yes (ER), Day 6  | Hemorrhage, hemoglobin change 9.2 to 7.5 gm/dL |                           |
| 12             | 21,062       | 13.9                 | 15              | No               | N/A  | N/A                       |

BMI: body mass index; GCA: gestational cardiac activity; ER: emergency room; L&D: labor and delivery; N/A: not applicable

\* Initiated on study day 2 (24 hours after mifepristone ingestion)

† Day 1: day of mifepristone administration

Creinin MD, Hou MY, Dalton L, Steward R, Chen MJ. Mifepristone antagonization with progesterone to prevent medical abortion: a randomized controlled trial. *Obstet Gynecol* 2020;135.

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**A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

NCT03774745

Protocol and SAP date: July 18, 2019 (version 10)

# PROTOCOL TITLE: **A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

## **1) Protocol Title**

Title: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion

## **2) Objectives**

Research questions:

1. Does high dose oral progesterone treatment increase the continuing pregnancy rate in women 44-63 days gestation exposed to mifepristone without misoprostol treatment?
2. If oral progesterone may be of benefit, do some characteristics of the pregnancy (e.g., gestational age) or patient (e.g. parity) potentially impact the outcome?
3. If oral progesterone may be of benefit, what sample size would be needed to validate such an outcome for various gestational age ranges in a prospective placebo-controlled randomized trial?
4. How long does it take to recruit women seeking surgical abortion to participate in a double-blind randomized trial evaluating oral progesterone for antagonization of mifepristone treatment for abortion?

Hypothesis: High-dose oral progesterone initiated 18-24 hours after mifepristone 200 mg in early pregnancy will result in more continuing pregnancies after 2 weeks of treatment than placebo.

## **3) Background**

Medical abortion commonly refers to early pregnancy termination (usually before 10 weeks' gestation) performed without primary surgical intervention and resulting from the use of abortion-inducing medications (1). The use of medications to cause abortion has been around for almost 70 years but the modern era of medical abortion treatment evolved with the development of mifepristone (1), a progesterone-receptor blocker with an affinity for the receptor greater than progesterone itself (2).

Early research into modern medical abortion regimens took a leap forward with the discovery that adding a prostaglandin analogue within a few days after mifepristone significantly improved the efficacy of the treatment (3). In the late 1980s, France, China, Switzerland and the UK became the first countries to make medical abortion treatment clinically available, with regimens using mifepristone 600 mg followed 36-48 hours later by a prostaglandin analogue, restricted to use up to 49 days gestation.

Today, our understanding of the agents available and used for medical abortion have advanced the regimen to permit use of a lower dose of mifepristone than originally approved (200 mg) with misoprostol, a prostaglandin analogue that is inexpensive and stable at room temperature, through 70 days' gestation. The advance in gestational age

## PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion

has nothing to do with mifepristone and is entirely related to the route and dose of the prostaglandin analogue. The latest data available (from 2014) estimates that 31% of all outpatient abortions in the United States are estimated to occur using medications, with the abortion almost exclusively occurring in the privacy of women’s homes (4).

Medical abortion with mifepristone and misoprostol is highly effective; however, the risk of continuing pregnancy is still present, especially as gestation advances (5-7). While most women opt for further treatment in these scenarios, such as surgical aspiration, there are some who decide to continue the pregnancy. In an abstract presented at the 2018 National Abortion Federation meeting, data from BPAS in the UK show that among 2,673 women having a medical abortion from 9-10 weeks’ gestation, 90 women had ongoing pregnancies after treatment of whom 9 (10%) opted to continue the pregnancy (Jennifer Hsia, MD, MPH; personal communication, poster abstract, NAF 2018). Thus, even following treatment, some women do change their mind.

Legislators began to focus on women who change their mind after mifepristone administration following release of a report of “medical abortion reversal” in which women received high dose progesterone to antagonize the effects of mifepristone. This first report, published in *Annals of Pharmacotherapy* in December 2012 by Delgado and Davenport (8), described seven patients treated by “[s]ix physicians in the US trained in NaProTECHNOLOGY protocols at the Pope Paul VI Institute.” Of the seven patients, one was lost to follow-up, four had continuing pregnancies and delivered healthy newborns, and two had miscarriages. Treatment varied between patients but primarily consisted of Progesterone 200 mg in oil intramuscularly with or without oral micronized progesterone. Four of the six reported women were 8 weeks’ gestation or less, one was an unknown gestation and the other woman was reportedly 11 weeks when she received mifepristone. Thus, of the women with follow-up who were possibly within the current medical abortion treatment limits of 10 weeks, 3 of 5 (60%) had continuing pregnancies. Following this report, two literature reviews attempted to synthesize information on continuing pregnancy rates following mifepristone treatment. Grossman et al (9) found

| Studies reporting the proportion of women with continuing pregnancies following administration of mifepristone alone for medical abortion |  |                  |                       |   |                   |   |
|---|--|------------------|-----------------------|---|-------------------|---|
| Study   | Mifepristone oral dose                 | N                | Gestational age limit | Follow-up visit (number of days after mifepristone) | Complete abortion | Continuing pregnancy at follow-up visit (%; 95% C |
| Birgerson 1988 [9]  | 10, 25 or 50 mg twice daily for 7 days | 153              | 49 days               | 8–10 days   | 67%               | 27% (20–34%)                                      |
| Cameron 1986 [8]  | 150 mg daily for 4 days                | 20               | 56 days               | 14 days   | 60%               | 25% (11–47%)                                      |
| Carol 1989 [17]   | 600 mg (single dose)                   | 50               | 39 days               | NS  | 80%               | 12% (6–24%)                                       |
| Grimes 1988 [10]  | 600 mg (single dose)                   | 50               | 49 days               | 14 days   | 88%               | 10% (4–21%)                                       |
| Kovacs 1984 [11]  | 25–100 mg twice daily for 4 days       | 36 <sup>a</sup>  | 42 days               | 14 days   | 61%               | 8% (3–22%)  |
| Maria 1988a [16]  | 600 mg (single dose)                   | 149 <sup>a</sup> | 42 days               | 7 days  | 88%               | 9% (6–15%)  |
| Maria 1988b [18]  | 600 mg (single dose)                   | 174              | 49 days               | 7 days  | 84%               | 11% (8–17%)                                       |
| Maria 1988b [18]  | 200 mg (single dose)                   | 30               | 49 days               | 7 days  | 63%               | 23% (12–41%)                                      |
| Somell 1990 [12]  | 600 mg (single dose)                   | 70               | 42 days               | 7 days  | 80%               | 17% (10–28%)                                      |
| Swahn 1989 [13]   | 25 mg twice daily for 4 days           | 14               | 49 days               | 14 days   | 57%               | 36% (16–61%)                                      |
| Ylikorkala 1989 [14]  | 600 mg (single dose)                   | 47 <sup>b</sup>  | 43 days               | 14 days   | 70%               | 11% (5–23%)                                       |
| Zheng 1989 [15]   | 600 mg (single dose)                   | 204              | 42 days               | 7 days  | 65%               | 31% (25–38%)                                      |
| Zheng 1989 [15]   | 600 mg (single dose)                   | 95               | 49 days               | 7 days  | 53%               | 46% (37–56%)                                      |

NS, not specified.  
<sup>a</sup> One additional participant was later found to have an ectopic and is excluded from the total here.  
<sup>b</sup> Three additional participants had a missed abortion at time of treatment and are excluded from the total here.

13 studies meeting appropriate criteria to be included in the review with continuing

**PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

pregnancy rates ranging from 8% to 46% when patients were assessed generally 1-2 weeks after mifepristone ingestion. Of note, the studies with the lowest rates of continuing pregnancies typically included women earlier in gestation.

Another review was published in 2017 by Davenport, Delgado and colleagues (10) openly as a rebuttal to the review from Grossman et al (9). This review, published in a journal not indexed in Pubmed, included only three of the same papers meeting inclusion criteria for the analysis by Grossman et al and excluded four of the papers included by Grossman et al stating that these studies did not always use ultrasound to designate if a viable pregnancy was present. These authors report a mean percentage of continuing pregnancies of only 12.6%, with most studies using mifepristone 600 mg or more. Recently, two additional case series have been published. The first is an Australian description of 3 women (at 43 days, approximately 53 days, and 61 days gestation) who initiated treatment with progesterone vaginally for 14 days at 28, 3.5, and 31 hours, respectively, after ingesting mifepristone (11). The first two women had continuing pregnancies and delivered healthy newborns, and the third woman experienced a miscarriage on the day she initiated progesterone treatment.

The second is a report from Dr. Delgado’s abortionreversalpill.com network (12). Published again in the same journal not indexed in Pubmed, this case series includes 754 women treated in

various ways by 325 different providers with “high-dose” progesterone, including progesterone in oil intramuscularly,

| Gesta-tional Age | Total | Reversal | Reversal Failure | Reversal % | P value | 95% Confidence Intervals |
|------------------|-------|----------|------------------|------------|---------|--------------------------|
| 5 weeks          | 76    | 19       | 57               | 25%        | 0.5     | 0.15-0.35                |
| 6 weeks          | 113   | 52       | 61               | 46%        | <0.001  | 0.37-0.55                |
| 7 weeks          | 102   | 50       | 52               | 49%        | <0.001  | 0.39-0.59                |
| 8 weeks          | 88    | 54       | 34               | 61%        | <0.001  | 0.51-0.72                |
| 9 weeks          | 30    | 23       | 7                | 77%        | <0.001  | 0.62-0.92                |

micronized progesterone orally, micronized progesterone capsules administered vaginally, compounded micronized progesterone vaginal suppositories, progesterone vaginal gel, and progesterone vaginal suppositories. The authors defined successful treatment as viability post 20 weeks’ gestation. They excluded 207 women from analysis, including those who received treatment >72 hours post-mifepristone or in whom misoprostol had been used (n=38), were lost to follow-up at <20 weeks’ gestation (n=112), or who opted to complete the abortion (changed mind again, n=57). Of 547 women in the analysis, treatment was successful in 261 (48%) women including 257 births and 4 women LTFU after 20 weeks. Subgroups with the highest success rates included 31 women treated with high-dose oral progesterone 400 mg twice daily for 3 days followed by 400 mg daily until end of “first trimester” (68%) and 125 women who received progesterone in oil IM initially or exclusively (64%). Notably, efficacy was higher with more advanced gestational age. The authors estimated that 25% of women would have continued the pregnancy even without treatment; that statistic implies no

## **PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

treatment effect for woman earlier than 6 weeks gestation and an overall effect size of any treatment to be 23%.

The dilemma that has been created around medical abortion reversal only exists because of the void in high-quality research addressing the issue; basic concepts need to be addressed to begin to understand if medical abortion reversal is actually possible. These case series reports (8,11,12) lack control groups, and the reports by Delgado and colleagues (8,12) involved experimental treatment without consent or oversight. Unfortunately, even without such trials, conservative lawmakers are using these case reports as medical gospel and passing laws stipulating reversal as fact. In 2015, Arkansas implemented mandatory abortion reversal counseling followed by Arizona (later repealed in 2016), South Dakota, and Utah. The Idaho governor signed such a counseling law on March 20, 2018, which went into effect on July 1, 2018. Numerous other states have initiated bills to create similar laws that have not passed. Conversely, Louisiana Department of Health report in April 2017 found “neither sufficient evidence nor a scientific basis to conclude that the effects of an abortion induced with drugs or chemicals can be reversed” (13). In 2015 and reiterated in August 2017, the American Congress of Obstetrics and Gynecology publicly stood against laws mandating reversal information as lacking scientific standing (14).

In this study, we propose a double-blind randomized trial to evaluate the potential impact of progesterone treatment on early pregnancies exposed to mifepristone. This study is also a first step to understanding if large studies evaluating mifepristone antagonization with high-dose progesterone are indicated and if placebo-controlled randomized trials can be successfully completed when evaluating this question.

### **4) Inclusion and Exclusion Criteria**

#### Inclusion Criteria

1. Pregnant females 18 years and older at enrollment.
2. Seeking surgical abortion at 44-63 days gestation on Study day 1.
3. Have received counseling and signed informed consent per UCD standard procedures for surgical abortion.
4. Singleton pregnancy
5. Presence of embryonic gestational cardiac activity on transvaginal ultrasonography.
6. English-speaking
7. Willing to sign informed consent and follow study protocol.
8. Willing to experience potential expulsion of the pregnancy with mifepristone treatment.

#### Exclusion Criteria

1. Medical contraindications to medical abortion.
  - a. Poorly controlled hypertension (systolic BP >160 or diastolic BP >95)
  - b. Significant anemia – known recent hemoglobin <9.5 gm/dL

**PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

- c. Clinically significant cardiovascular disease (angina, valvular disease, arrhythmia, or congestive heart failure)
  - d. Breastfeeding
  - e. Coagulopathy or therapeutic coagulation
  - f. Ultrasound evidence of molar or ectopic pregnancy
  - g. Chronic systemic corticosteroid use
  - h. Adrenal disease
  - i. Sickle cell anemia with frequent/recent crises
  - j. Glaucoma
2. IUD in place during conception, even if removed.
  3. Peanut allergy.
  4. Known intolerance of mifepristone or progesterone.
  5. Any other condition, that in the opinion of the clinician, would contraindicate mifepristone, progesterone or medical abortion.

Pregnant women will be included in this research. This study evaluates effect of high-dose progesterone on initiation of medical abortion and only pregnant women can have an abortion. Potential subjects must have gone through appropriate informed consent for surgical abortion per the standard of care within the UCD Department of Obstetrics and Gynecology prior to consent and screening for this research trial.

## **5) Study Timelines**

Subject participation: approximately 15-17 days

Study timeline

- Duration of enrollment: 11 months (Anticipate Feb 2019 through Dec 2019)
- Completion of primary analysis: 2 months after completion of follow-up (Anticipate Feb 2020)

## **6) Study Endpoints**

Primary endpoint: continuing pregnancy with presence of gestational cardiac activity after two weeks of study treatment

Secondary endpoints:

- Expulsion rates over two weeks following mifepristone treatment
- Pathology changes in trophoblast in a subset of dilation and curettage specimens
- Change in hCG and progesterone levels during treatment
- Tolerability of treatment
  - Ability to continue treatment for two weeks
  - Adverse events (side effects) related to progesterone or placebo after mifepristone including but not limited to nausea, vomiting, headache, mood changes, cramping, vaginal spotting, vaginal bleeding

## PROTOCOL TITLE: **A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

- Safety outcomes: adverse events related to medical safety (e.g., hemorrhage, emergency department visits, emergent dilation and curettage procedures)

Study enrollment, outcomes and safety events will be reviewed continuously by the investigative team and in formal Family Planning Research meetings approximately twice monthly to monitor for events that would indicate safety issues.

### **7) Procedures Involved**

Design: Double-blind placebo-controlled study of the effects of oral micronized progesterone on the viability of early pregnancies treated with mifepristone.

Study Treatment: Subjects will receive mifepristone 200 mg on Study day 1. Intervention treatment of micronized progesterone 200 mg capsules or placebo in a labeled container will be started on Study day 2.

- The UCD Investigational Drug Service (IDS) will supply sequentially numbered containers containing study drug or placebo and labeled specifically for this study.
  - The IDS will prepare a randomization table for the two treatment groups and will maintain the blinding of the randomization from the study team and patients.
  - The IDS will prepare study drug and placebo to ensure blinding.
  - Each study container will contain 38 capsules.
- Dosing schedule is based on the oral dosing regimen using micronized progesterone 200 mg capsules described by Delgado and colleagues (12):
  - Study day 2-4: Two capsules orally twice daily.
  - Study days 5 through 15, 16 or 17: Two capsules orally once daily.
- Progesterone dosing comparison to dosing for approved indication:
  - Dosing for the first 3 days is double the recommended daily dose when progesterone is used orally as treatment for inducing menses in women with secondary amenorrhea (400 mg once daily for 10 days), consistent with a “high” dose initial treatment.

Recruitment:

- Potential participants will be recruited through Planned Parenthood Mar Monte (PPMM), Family Planning Associates (FPA), and the UCD Family Planning clinic.
- Women who call in to either site seeking surgical abortion or who are seen at both sites with an estimated gestational age <63 days will be informed of the study.
- Women who are interested in the study will be given a referral number to the UC Davis Family Planning Research Office.

## PROTOCOL TITLE: **A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

### Methodology:

#### *Clinical Visit Procedures:*

An initial clinical visit at UCD will be required to evaluate for medical eligibility for abortion, obtain UCD consent for surgical abortion, perform transvaginal ultrasonography to confirm gestational dating (using criteria of Goldstein and Wolfson [16]) and presence of gestational cardiac activity, and confirm blood type/Rh-factor. This visit is standard care for women seeking abortion services.

#### *Study Procedures:*

- Screening visit
  - On the same day as the clinical visit or at another visit if desired, women <63 days gestation who have completed the consent process for surgical abortion will be seen in the UCD Family Planning Research office for study consent and evaluation.
  - After obtaining informed study consent, demographic information and pertinent medical history will be obtained.
- Enrollment visit
  - This visit may occur on the same day as screening if the subject is between 44 and 63 days gestation with a viable pregnancy (embryo present with gestational cardiac activity); otherwise, subject will be scheduled to return for enrollment visit when she is  $\geq 44$  days.
  - Subjects having an enrollment visit on a separate day from screening will have a transvaginal ultrasound repeated to confirm an embryo is present with gestational cardiac activity
    - If gestational cardiac activity not present, study physician to determine if enrollment visit should be rescheduled (if viability still possible) or if subject should be referred for clinical care of early pregnancy loss
  - Procedures
    - Confirm study eligibility
    - Two 5 mL tubes of blood will be obtained for baseline serum hCG and progesterone level.
    - Subjects will be questioned about baseline symptoms related to pregnancy (e.g., nausea, headache, mood changes).
    - Subjects will receive mifepristone 200 mg orally once all study entry criteria are confirmed (Study day 1).
    - Subjects will receive study treatment with dispensation of the next sequentially numbered study drug container. Subjects will be instructed as follows:
      - Begin study treatment on day 2, 18-24 hours after mifepristone administration (with the goal of being as close to 24 hours as possible).
      - Take the second dose on day 2 12 hours later or at bedtime (if going to bed less than 12 hours after the first dose).

**PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

- On days 3 and 4, take the study treatments about 12 hours apart, one dose in the morning and one in the evening.
- On day 5 through the end of the study, take the study treatment in the morning, at about the same time every day.
- Subjects will be provided with:
  - A daily diary to mark down use of the study drug, adverse effects, and bleeding. The diary will also include information on baseline pregnancy symptoms (present when she started the study). Subjects will be instructed to mark down any adverse effects (e.g., nausea, headache, mood changes) on the back of the diary; for any pregnancy symptom present at baseline, the subject will be instructed only to mark down if this symptom becomes worse than baseline.
  - An information sheet with study office phone numbers and instructions related to expected bleeding and cramping should the pregnancy expel after mifepristone treatment.
- Study day 2: the study site will contact the subject by phone around the time that study treatment is supposed to be started.
- Follow-up Visits: schedule on study days 4 ( $\pm 1$  day) and 8 ( $\pm 1$  day) at UCD Family Planning Research office.
  - Diary will be reviewed.
  - Study drug container will be reviewed and remaining drug counted by study staff.
  - The subject will be asked if she is tolerating the treatment and willing to continue study participation.
  - Two 5 mL tubes of blood will be obtained for serum hCG and progesterone level.
  - Ultrasonography will be performed to evaluate for presence of the gestational sac, interval growth and presence of gestational cardiac activity; the exam should preferentially be performed vaginally unless the gestational age or subject anatomy requires abdominal sonography for clearer visualization.
    - If gestational cardiac activity is absent, the visit will be considered an exit visit.
      - Collect remaining study drug and diary.
      - Refer subject to the original referral source (PPMM, FPA or the UCD Family Planning clinic) for completion of follow-up care; a patient from PPMM or FPA can request to complete care at UCD.
        - Referrals for PPMM-referred subjects returning to PPMM will be made to the Sacramento B Street Clinic.
        - Referrals for FPA-referred subjects returning to FPA will be made to the Sacramento Clinic.

**PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

- The subject will be exited from the study after a final outcome is determined by the clinical team.
- If the pregnancy is expelled, the visit will be considered an exit visit.
  - Collect remaining study drug and diary.
  - Refer subject to the original referral location (PPMM Sacramento B Street Clinic, FPA Sacramento Clinic or the UCD Family Planning clinic) for completion of follow-up care; a patient from PPMM or FPA can request to complete care at UCD.
    - Referrals for PPMM-referred subjects returning to PPMM will be made to the Sacramento B Street Clinic.
    - Referrals for FPA-referred subjects returning to FPA will be made to the Sacramento Clinic.
  - The subject will be exited from the study after a final outcome is determined by the clinical team.
- If the subject is continuing in the study, she will be reminded of the correct timing of study treatment intake, to fill out her diary daily, and to bring her diary and study drug with her to the next visit.
- Study exit visit: schedule for study day 15-17
  - Scheduled exit visits (study day 15-17) should occur through the original referral source (PPMM, FPA or the UCD Family Planning clinic) but a patient from PPMM or FPA can request to complete care at UCD.
    - Visits for PPMM-referred subjects returning to PPMM will occur at the Sacramento B Street Clinic.
    - Visits for FPA-referred subjects returning to FPA will occur at the FPA Sacramento Clinic.
  - Diary will be reviewed and collected from the participant.
  - Study drug container will be collected and remaining drug counted by study staff.
  - Two 5 mL tubes of blood will be obtained for serum hCG and progesterone level.
  - Ultrasonography will be performed to evaluate for presence of the gestational sac, interval growth and presence of gestational cardiac activity; the exam should preferentially be performed vaginally unless the gestational age or subject anatomy requires abdominal sonography for clearer visualization.
  - A surgical abortion will be performed through routine care if pregnancy has not passed and patient desires.
- If a subject desires to exit the study early (have a surgical abortion prior to Day 15-17), the exit visit procedures should be performed on the day of the surgical abortion.

**PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

- Unscheduled visits: to occur if the subject has any medical concerns or experiences heavy bleeding which may indicate loss of viability or passage of pregnancy
  - Diary will be reviewed.
  - Study drug container will be reviewed and remaining drug counted by study staff.
  - Ultrasonography will be performed to evaluate for presence of the gestational sac, interval growth and presence of gestational cardiac activity; the exam should preferentially be performed vaginally unless the gestational age or subject anatomy requires abdominal sonography for clearer visualization.
    - If gestational cardiac activity is absent
      - Two 5 mL tubes of blood will be obtained for serum hCG and progesterone level.
      - Collect remaining study drug and diary
      - Refer subject to the original referral source (PPMM, FPA or the UCD Family Planning clinic) for completion of care; a patient from PPMM can request to complete care at UCD.
        - Referrals for PPMM-referred subjects returning to PPMM will be made to the Sacramento B Street Clinic.
        - Referrals for FPA-referred subjects returning to FPA will be made to the Sacramento Clinic.
      - The subject will be exited from the study after a final outcome is determined by the clinical team.
    - If the pregnancy is expelled
      - Two 5 mL tubes of blood will be obtained for serum hCG and progesterone level.
      - Collect remaining study drug and diary
      - Refer subject to the original referral source (PPMM, FPA or the UCD Family Planning clinic) for completion of follow-up care; a patient from PPMM can request to complete care at UCD.
        - Referrals for PPMM-referred subjects returning to PPMM will be made to the Sacramento B Street Clinic.
        - Referrals for FPA-referred subjects returning to FPA will be made to the Sacramento Clinic.
      - The subject will be exited from the study after a final outcome is determined by the clinical team.
- Specimen from surgical abortion procedures at UCD will be collected and submitted to the UCD pathology department for research examination for effects of mifepristone or progesterone on the trophoblast or embryonic tissue.
- Copies of clinical visits for completion of abortion or follow-up care after pregnancy expulsion will be obtained from the referral site.

## PROTOCOL TITLE: **A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

- The UCD Family Planning specialists will be available on call 24 hours/day, 7 days/week for any study participant with a question or medical issue.

A total of 40 mL of blood will be obtained over 2 weeks for laboratory testing.

### *Subject compensation:*

Subject compensation for time and effort will be issued through UCD.

## **8) Data and/or Specimen Management and Confidentiality**

### Sample size:

- Delgado and colleagues estimate the oral progesterone regimen in this study has an efficacy of 68% (10) and that about 25% of women will expel the pregnancy after mifepristone 200 mg treatment alone, (10,12) implying an effect size of ~43%.
  - Sample size needed for Effect1=68%, Effect2=25%, Alpha=0.05, Beta=0.20: 20 per group.
  - Sample size needed for Effect1=70%, Effect2=25%, Alpha=0.05, Beta=0.20: 18 per group.
- We plan a convenience sample of 40 women (approximately 20 per group) which is enough to answer the primary question of efficacy proposed by Delgado and colleagues.
  - Should no obvious benefit be observed then a larger trial would not be indicated.
  - If some benefit is present, then a sample size could be estimated for a larger trial with considerations of sample size estimates for different gestational age ranges.
  - Importantly, if we cannot feasibly recruit from this population, then a larger study would also need to consider alternative mechanisms for enrollment.
- Recruitment: expect 36 subjects from PPMM and FPA (competitive enrollment) and 4 subjects from UCD.

### Data Analysis Plan:

We will include all women randomized and perform intent-to-treat analysis with no apparent exclusions. In addition, a second analysis will be conducted with a per-protocol population, excluding women who do not report ingesting the study medication per protocol. Evaluations will include primary outcome (continuing pregnancy), expulsion rates, adverse effects, and treatment continuation rates.

At time of enrollment, we will collect baseline demographic data, including age, race, ethnicity, education level, and medical history (including obstetric and gynecologic history).

## **PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

Fisher's Exact Testing will be used to compare outcomes and baseline characteristics in the two groups.

While not powered to detect a statistically significant difference among the two groups for secondary outcomes, exploratory analyses will be performed to identify possible trends and areas of interest for a subsequent larger trial. Chi square and Fisher's Exact Tests will be utilized to compare dichotomous variables as appropriate.

### Data Management Plan:

Participants will be assigned a unique study number for use on source documents and participant study charts. Each participant will be assigned a file to be kept in a locked cabinet of a locked research-only office. Participant files will contain signed consent forms, study allocation number, and paper copies of data collection forms. Identifiers will include name and medical record number. Data from participants' study charts will be entered into a study database without any identifying information. Only password-protected, institutionally secured UCD computers will be used for data entry and analysis. Data will be reviewed by the principal investigator and research coordinator to ensure accuracy and completeness.

Participants will be given standard contact information for all clinical and study-related questions at any time. Our division has a dedicated phone line for Family Planning research subjects that is covered by research personnel during the day (who have close access to an assigned Family Planning physician) and forwarded to the on call Family Planning specialist physician at night. All Family Planning attendings and fellows will be trained as study personnel.

### Confidentiality

All research and clinical activities will be conducted in private spaces (clinical exam rooms, preoperative center, or operating room). All research staff will be trained on protocol prior to study initiation and be up-to-date on CITI training.

### Specimen Transport Plan

Blood specimens will be submitted to the UCD clinical laboratory for testing. Some study exit visits will occur at the PPMM Sacramento B Street Clinic and FPA Sacramento Clinic. Blood obtained at PPMM and FPA visits will be collected by study personnel who will be present at the visit and transported to the UCD clinical and pathologic laboratory for testing. No pathologic specimens will be obtained at PPMM or FPA.

## **9) Data and/or Specimen Banking**

No specimens will be banked.

## **PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

The research database will be banked indefinitely for the purpose of future research questions and will contain only de-identified information as above. The database will be maintained on the UCD server in a file with limited access to Family Planning research team. The data can be used for analyses as approved through this IRB submission; other evaluations will require a separate IRB submission to review the de-identified data.

### **10) Provisions to Monitor the Data to Ensure the Safety of Subjects**

- Safety data will be collected throughout the study through diaries of potential medication side effects.
- Adverse event (AE): adverse experience such as symptom, physical exam finding, or worsening of a preexisting condition that has a temporal association with research participation. Causal relationship with study treatment is not necessary to designate an AE.
- Serious adverse event (SAE): adverse event that requires hospitalization, causes significant disability, causes a birth defect, is life threatening or results in death.
- AEs will be logged and reviewed by an investigator for study drug relationship
- Any SAE will be reported to the principal investigator. The participant will be managed medically as indicated. All source data will be reviewed. Physician investigators will assess for causality or relatedness of the adverse experience to the study.
- SAEs will be summarized at annual IRB renewal submission. SAEs that are unanticipated and thought to be related to the study (thereby placing research subjects at higher risk of harm than originally thought) will be reported to the IRB by the principal investigator within five days of becoming aware of the event.
- The study will be reviewed approximately twice monthly at the Family Planning division research meeting, which includes all research staff. Any concerns regarding individual or trends in AEs will prompt further review of the study and consideration of study termination.
- Study allocation will remain concealed except in a scenario in which revealing allocation is clinically important for the participant's management

### **11) Withdrawal of Subjects**

Participants may elect to discontinue the study for any reason. Participants will be withdrawn from the study pending investigator review of AE that warrants removal or any SAE (see Section 10).

### **12) Risks to Subjects**

#### **1. Mifepristone side effects:**

*The mifepristone label does not provide side effects for mifepristone alone; side effects are provided for the combination of mifepristone and misoprostol. The data,*

**PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

*especially as it relates to bleeding, does not reflect just mifepristone use. Data on mifepristone side effects are taken from reference #19.*

|               |     |
|---------------|-----|
| Nausea        | 39% |
| Cramping      | 27% |
| Headache      | 20% |
| Dizziness     | 20% |
| Warmth/chills | 19% |
| Vomiting      | 14% |
| Spotting      | 9%  |
| Diarrhea      | 7%  |

For this study, we expect bleeding and/or spotting to occur in all subjects (even though most will not expel the pregnancy).

2. Progesterone side effects:

*From the Prometrium label – use in premenopausal women at 400 mg/day*

|                                 |     |
|---------------------------------|-----|
| Dizziness                       | 24% |
| Abdominal Pain (Cramping)       | 20% |
| Headache                        | 16% |
| Breast Pain                     | 16% |
| Infection Viral                 | 12% |
| Musculoskeletal Pain            | 12% |
| Fatigue                         | 8%  |
| Abdominal Distention (Bloating) | 8%  |
| Diarrhea                        | 8%  |
| Nausea                          | 8%  |
| Back Pain                       | 8%  |
| Irritability                    | 8%  |
| Coughing                        | 8%  |

3. Teratogenicity: if women decide to continue the pregnancy after receiving one or both study treatments, mifepristone and progesterone are not considered teratogens. Teratogenicity with standard medical abortion treatment is related to misoprostol, which is not being used in this study.

4. Pregnancy expulsion: few women expel the pregnancy with mifepristone 200 mg treatment in medical abortion studies. However, few studies follow women for up to 2 weeks. We do not know the spontaneous expulsion rate with this treatment but expect the rate may be around 30%; Delgado and colleagues estimate the oral progesterone regimen in this study has an efficacy of 68% (10) meaning that at least ~30% will expel the pregnancy, even with progesterone treatment.

If pregnancy expulsion occurs, the woman will experience bleeding and cramping. The cramping can be very strong for several hours and is typically treated with NSAIDs. Subjects will be made aware that if they need stronger pain medication they can contact the physician on call. Initial bleeding may be similar to, or greater than, a

## **PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

heavy period and may include blood clots and tissue. Within a few hours bleeding is usually equal to or less than a typical menses. After passing the pregnancy, bleeding or spotting can be expected for an average of 9-16 days and may last for up to 30 days.

Approximately 1-5% of women may experience very heavy bleeding, which is soaking through more than two sanitary pads per hour for two hours in a row.

In 1% of women or less, a suction aspiration (surgical abortion) to stop the bleeding may be indicated. Very rarely (less than 1/1,000 women), the amount of blood loss may be life-threatening and a blood transfusion may be necessary.

In 1-5% of women, incomplete expulsion may occur which would also necessitate a suction aspiration (surgical abortion). In less than 1% of women, a uterine infection could occur from incomplete abortion.

5. Phlebotomy: Temporary discomfort from the needle stick, bleeding at the needle puncture site and bruising may occur. Very rarely (1% or less), fainting may occur.
6. Vaginal ultrasound: Temporary discomfort similar to a pelvic examination may occur.
7. Delay in surgical abortion: A delay of up to 2 weeks in the gestational age range for this study does not incur increased surgical risk.
8. Privacy: There is a risk that protected health information could become known to someone not involved in this study. A unique study number will be assigned and study records will remain in a locked cabinet of a locked research-only office.

### **13) Potential Benefits to Subjects**

There is no direct benefit of study participation for the subject.

### **14) Multi-Site Research**

The UCD study site oversees the study which will also have study procedures performed at PPMM Sacramento B Street Clinic and FPA Sacramento Clinic. Study procedures will only include referral, obtaining specimens (e.g., phlebotomy), and sending copies of medical records to the UCD study site. Thus, no staff at the PPMM Sacramento B Street Clinic or FPA Sacramento Clinic will be considered study personnel. The site physicians and staff coordinators at PPMM Sacramento B Street Clinic and FPA Sacramento Clinic will work administratively with the UCD study physicians and coordinator to ensure the following:

- The site conducts the study appropriately.

## **PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

- The PPMM and FPA co-investigators and site coordinators have the most current version of the protocol.
- Planned Parenthood Federation of America (PPFA) approval is obtained before the PPMM site begins to refer subjects.
- All modifications are communicated to PPMM and FPA.

Initial communication with the each study site will include an all-staff meeting to inform staff of the study, entry criteria and plan. The purpose of this meeting is to ensure adequate knowledge of staff about the study for referral of study subjects.

Continued communication with the PPMM and FPA site investigators and coordinators will occur routinely through e-mail and monthly through planned conference calls. Issues with recruitment, specimen collection and study progress will be discussed.

### **15) Sharing of Results with Subjects**

Study results will not be shared with subjects or their primary physicians. Outcomes for PPMM Sacramento B Street Clinic patients who expel the pregnancy during the two-week treatment period will be shared with the PPMM Sacramento B Street Clinic study team. Outcomes for FPA Sacramento Clinic patients who expel the pregnancy during the two-week treatment period will be shared with the FPA Sacramento Clinic study team.

### **16) Provisions to Protect the Privacy Interests of Subjects**

All conversations during enrollment and clinical care will be in private clinic spaces as per usual practice. During screening, research staff will review that the study is voluntary and that demographic questions can be skipped. Remaining aspects of the enrollment visit are clinically necessary and will be treated similarly to a standard clinical visit. It will be reinforced that study participation or declination will not change the patient's medical care.

Baseline history questions and pre-operative interview ensure medically safe abortion procedures and give providers information about offering additional social support to women who may benefit. We interview all women to confirm they are making an autonomous decision to terminate a pregnancy and are not being coerced. As Family Planning specialists, our physicians are trained to provide appropriate and thoughtful care to women seeking abortions and there are no deviations in interview practices from standard clinical care for the research described here.

Electronic medical records will only be accessed, added, or reviewed when clinically necessary. Participants will be notified of this and research staff will review and sign an institutional HIPAA release to grant this access.

**PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

**17) Compensation for Research-Related Injury**

The University of California, Davis Health System will provide care needed to treat injuries directly resulting from taking part in this research. Insurance or third party payers may be billed, if appropriate, for the costs of the care subjects received. Subjects may be responsible for some of the costs. The University of California, Davis does not plan to compensate subjects for injuries.

**18) Economic Burden to Subjects**

The subject is responsible for costs related to abortion care. The subject will not be responsible for any costs related to study participation. Study participation requires additional visits to the UCD Ambulatory Care Center and may incur transportation cost or additional time away from work.

**19) Drugs or Devices**

I confirm that all investigational drugs will be received by the Investigational Drug Service (IDS). The IDS will store, handle, and administer those drugs so that they will be used only on subjects and be used only by authorized investigators.

**20) [ClinicalTrials.gov](https://clinicaltrials.gov) Registration**

**Section 1: NIH Funded Studies**

If yes to BOTH, the study must be registered on [Clinicaltrials.gov](https://clinicaltrials.gov).

| Yes                      |   |
|--------------------------|---|
| <input type="checkbox"/> | This study is funded by the <a href="https://www.nih.gov">NIH</a> . (If this study is not funded by NIH, go to Section 2.)  |
| <input type="checkbox"/> | One or more human subjects will be prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. |

**Section 2: Studies subject to FDA jurisdiction**

If yes to ANY the study must be registered on [Clinicaltrials.gov](https://clinicaltrials.gov).

| Yes                      |   |
|--------------------------|---|
| <input type="checkbox"/> | This is a prospective clinical study of health outcomes in human subjects that compares an intervention with an FDA-regulated device against a control. This is not a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes. |
| <input type="checkbox"/> | This is a pediatric postmarket surveillance of a device as required under section 522 of the Federal Food, Drug, and Cosmetic Act.  |

**PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

|                          |  |
|--------------------------|--|
| <input type="checkbox"/> | This is a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act. |
|--------------------------|--|

To view a flowchart describing applicable clinical trials subject to FDA jurisdiction click [here](#).

**Section 3: Publishing the results**

If yes to BOTH the study must be registered on Clinicaltrials.gov.

|                                     |   |
|-------------------------------------|---|
| <b>Yes</b>                          |   |
| <input checked="" type="checkbox"/> | This study prospectively assigns people or a group of people to an intervention, with or without concurrent comparison or control groups, to study the cause-and-effect relationship between a health-related intervention <i>and</i> a health outcome. |
| <input checked="" type="checkbox"/> | The PI has access to and control over all the data from the clinical trial and has the right to publish the results of the trial and plans to publish the results in a journal that follows the <a href="#">ICMJE recommendations</a> .                 |

This requirement includes studies of behavioral interventions.

**Section 4: Registration on Clinicaltrials.gov is not required**

|                          |  |
|--------------------------|--|
| <b>Yes</b>               |  |
| <input type="checkbox"/> | I have read sections 1-3 above and registration on clinicaltrials.gov is not required for this research. |

**21) Criteria for 10 Year Approval**

N/A.

**22) References**

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**PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

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**PROTOCOL TITLE: A Randomized Trial of Mifepristone Antagonization with High-Dose Progesterone to Prevent Medical Abortion**

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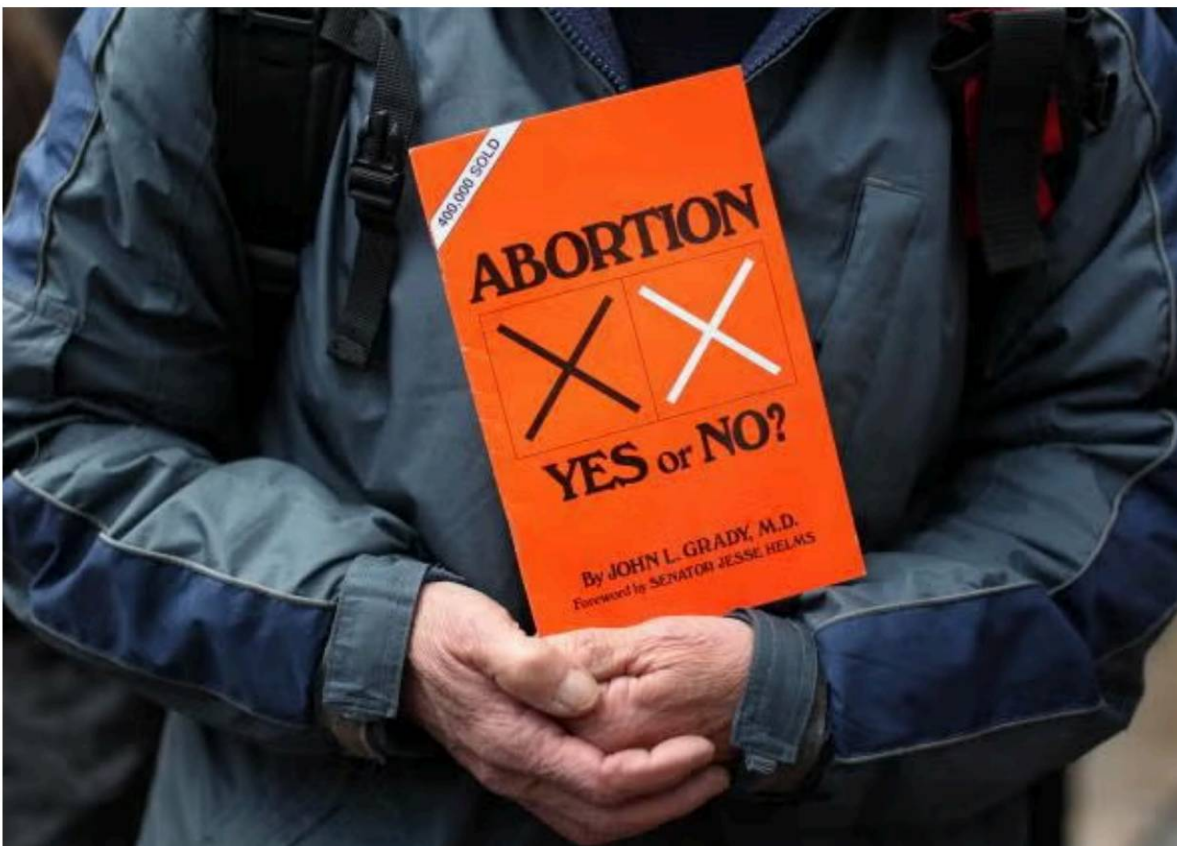
WONDERING WHAT NEW CONSTITUTIONAL CRISIS AWAITS

THE XX FACTOR

## The Newest Crisis Pregnancy Center Offer: “Abortion Reversals”

BY AMANDA MARCOTTE

DEC 08, 2014 • 5:25 PM



Abortion reversals, pitched to the mostly mythical woman who says not yes or no but “maybe so.”

Photo by Peter Muhly/AFP/Getty Images

In order to justify the crush of medically unnecessary regulations on abortion clinics in recent years, it’s become common for anti-choicers to pose as the protectors of women’s health. Considering how much more dangerous childbirth is than abortion, this has always been a farcical claim, but now it appears some anti-choice activists are taking it a step further and actively encouraging women to take what could be a very serious risk to their health. Elizabeth Kulze at *Vocativ* reports that a crisis pregnancy center in Iowa (called the Women’s Choice Center, one of the more obnoxious examples of anti-choice centers trying

to trick you into thinking they provide abortion) is offering “abortion reversals” to women who are halfway through a medication abortion.

Medication abortions are typically done with two pill doses in the first 63 days of pregnancy. The first, a dose of mifepristone you take at the doctor’s office, blocks progesterone receptors and helps soften up the cervix and promote uterine contractions. The second pill, misoprostol, causes the uterus to expel its contents. Misoprostol can work on its own—many black-market abortion pills are just misoprostol—but, according to the American Congress of Obstetricians and Gynecologists, taking the mifepristone improves the likelihood of a safe, complete abortion.

My Roommate Refused the Lottery Ticket I Bought Her. That Might’ve Been the Biggest Mistake Re

“Abortion reversal” is a procedure—I hate to even use that word when it’s really more an experiment—in which progesterone is injected into a patient after she has taken mifepristone in an effort to reverse its effects. It was developed by an anti-abortion doctor named George Delgado. In 2012 in the *Annals of Pharmacotherapy*, Delgado claimed to have injected progesterone into six women to reverse the effects of mifepristone, which resulted in four of those women giving birth. In a 2014 presentation to the American Association of Pro-Life Obstetricians and Gynecologists, he claimed 30 more live births. But, outside of the 2012 paper about the six women, there’s no real information available on the safety or efficacy of this largely untested procedure.

Delgado's website, [Abortion Pill Reversal](#), doesn't offer much in the way of helpful information either. The single "success story" is [little more than one of those fables](#) of Christian redemption for sinful behavior. "Rhonda and Gary were both 18, in love, and in college. Like many in our society, they did not think that having sex prior to marriage carried any consequences or could hurt them in any way," it reads. After a swipe at contraception use and another swipe at the idea of letting young women make their own choices, you get the priest intervening and the young woman being saved from the dangers of sex and independent thinking, all through the power of a progesterone injection after taking mifepristone. "They had recommitted themselves to their faith and were now trusting that God would guide them every step of the way," Delgado writes. Readers who are skeptical that having a baby at 18 with your first real boyfriend is the key to happiness may not be convinced. But that hasn't stopped [several other crisis pregnancy centers](#) from directing visitors to their web sites to Delgado's.

Looking for more information, I talked to Dr. Daniel Grossman, a vice president for research at [Ibis Reproductive Health](#) and a fellow at the ACOG, who sounded a note of caution about this procedure in a phone interview. In the "exceedingly rare" case in which a woman might take one pill and then decide she wants the pregnancy after all, there's no research to show that progesterone shots will help her save it, he explained. Mifepristone "by itself is not an effective abortion regimen," he said, and so many women who just take the first pill will not miscarry if they simply don't take the second. If he had a patient who changed her mind halfway through, he explained, he would recommend doing nothing and monitoring the pregnancy to make sure it's continuing normally.

Grossman says that the progesterone probably won't hurt a woman if she's under medical supervision, but he's concerned that the advertising of this procedure could mislead the public about the prevalence of abortion regret. "In my experience caring for women seeking abortion, they don't go into this lightly. They're very clear about their decision usually when they walk into the clinic and especially after they've gotten counseling," he told me, noting that research shows "regret after an abortion is really rare."

Even the Women's Choice Center director Vicki Tyler told *Vocativ* that, although they are offering the procedure, so far they have not performed any.

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# SLATEGROUP

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**Health Information Management Department - UC Davis Health  
Declaration of Custodian of the Legal Medical Record and/or Radiology Images**

August 6, 2025

I, Seema Prakash, a UC Davis Health Release of Information Analyst, attests to the following:

I am the duly authorized UC Davis Health Custodian of the Legal Medical Record and Radiology; and have the authority to certify medical records/radiology images.

Attached to this affidavit is a true copy of the legal medical records and/or radiology images requested in the subpoena duces tecum, patient authorization or other appropriate legal document.

The medical records and/or radiology images attached belong to **Subject Number MR-08** a UC Davis Health patient. The records and/or radiology images were prepared by the UC Davis Health personnel in the ordinary course of business at or near the time of the act, condition, or event reference therein.

The method used to prepare the attached medical records was photocopying and/or scanning the documents from the patient's original medical hard copy chart and/or printing records from the patient's electronic medical record; or by duplicating the original radiology images and transferring the patient's electronic radiology images to CD. The records and/or radiology images disclosed are pursuant to this authorization/subpoena.

Pursuant to Evidence Code section 1560[e], the records and/or radiology images described in the subpoena duces tecum, patient authorization, or other legal document, were delivered to the requesting party or his/her designee by electronic delivery or for copying; or the records were made available to the In-house Certified Professional Photocopier for transmittal and processing to the requestor.

I declare under penalty of perjury, pursuant to the laws of the State of California that the foregoing statements are true and correct.



Seema Prakash  
Release of Information Unit  
Health Information Management Department  
UC Davis Health  
<http://him.ucdavis.edu>  
Phone 916-734-5205  
Fax 916-734-2126

Release ID: 407327741

Patient

XXXXXX

Active Coverages as of 5/31/2019

XXXXXX

Problem List as of 5/31/2019

Problems last reviewed by Stewart, Daniel R, DO on 5/31/2019  
No problems documented.

Immunizations as of 5/31/2019

Immunizations never marked as reviewed

**RHO(D) Immune Globulin**

Given by: Sherwood, Erica, RN  
Site: Left Anterolateral fat of thigh  
VIS Publish Date: N/A  
Manufacturer: Grifols Therape

Date: 5/31/2019  
Route: Intramuscular  
Lot number: D2MAC00023

Dose: 50 mcg  
NDC: 13533-661-60

**Rho D Immune Globulin mini inj clinic**

Given by: Burnett, Jody, LVN  
Site: Left Ventrogluteal  
VIS Publish Date: NA  
Manufacturer: Other

Date: 1/17/2019  
Route: Intramuscular  
Lot number: D2MAA00013

Dose: 50 mcg  
CVX code: 157  
Expiration date: 3/14/2019

Medication List

Medications

ⓘ This report is for documentation purposes only. The patient should not follow medication instructions within. For accurate instructions regarding medications, the patient should instead consult their physician or after visit summary.

Current Medications

**acetaminophen (TYLENOL) 325 mg Capsule**

Instructions: Indications: prn headaches

Entered by: Creinin, Mitchell, MD

Entered on: 5/29/2019

**Doxycycline (MONODOX) 100 mg capsule**

## Patient (continued)

### Medication List (continued)

Authorized by: Chen, Melissa Joy, MD  
Start date: 9/23/2019  
Refill: No refills remaining

Ordered on: 9/23/2019  
Quantity: 4 capsule

#### Doxycycline (MONODOX) 100 mg capsule

Authorized by: Mastey, Namrata, MD  
Start date: 2/6/2020  
Refill: No refills remaining

Ordered on: 2/6/2020  
Quantity: 4 capsule

#### Doxycycline (MONODOX) 100 mg capsule

Authorized by: Melo, Juliana, MD  
Start date: 10/29/2020  
Refill: No refills remaining

Ordered on: 10/29/2020  
Quantity: 4 capsule

### Advance Care Planning

#### Plan

##### Patient Capacity

The patient has full capacity. There is no history of patient status change.

##### Current Code Status

| Date Active | Code Status | Order ID | Comments | User | Context |
|-------------|-------------|----------|----------|------|---------|
| Prior       |             |          |          |      |         |

##### Health Care Agents

There are no Health Care Agents on file.

05/31/2019 - Appointment in UC Davis Medical Center Ultrasound

Visit Information

Appointment Information

US OB 1ST TRIMESTER< 14 WEEKS Completed  
5/31/2019 [REDACTED]

| Time       | Provider       | Department | Length |
|------------|----------------|------------|--------|
| [REDACTED] | US MH (ROOM 2) | HOSP US    | 40 min |

Referral Provider: TURNIPSEED, SAMUEL D Arrival Time: [REDACTED]  
Enc Form Number: [REDACTED]

History

|              |           |            |                                |     |
|--------------|-----------|------------|--------------------------------|-----|
| Made On:     | 5/31/2019 | [REDACTED] | By: Grisham, Darin             | RIS |
| Checked In:  | 5/31/2019 | [REDACTED] | By: Popescu, Sequoia, Rad Tech | ES  |
| Changed:     | 5/31/2019 | [REDACTED] | By: Popescu, Sequoia, Rad Tech | RIS |
| EOD Status:  | 6/6/2019  | [REDACTED] | By: Epic, Cadence Two          | ES  |
| Checked Out: | 7/18/2019 | [REDACTED] | By: User, Epic                 | AR  |

Changes

|                      |   |   |
|----------------------|---|---|
| 5/31/2019 [REDACTED] | <p>Old Appointment:<br/>Visit Type: US OB 1ST TRIMESTER&lt; 14 WEEKS<br/>Provider: US MH (ROOM 1)<br/>Dept: HOSP US [100001134]<br/>Date: 5/31/2019<br/>Time: [REDACTED]<br/>Length: 40</p> | <p>New Appointment:<br/>Visit Type: US OB 1ST TRIMESTER&lt; 14 WEEKS<br/>Provider: US MH (ROOM 2)<br/>Dept: HOSP US [100001134]<br/>Date: 5/31/2019<br/>Time: [REDACTED]<br/>Length: 40</p> |
|----------------------|---|---|

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05/31/2019 - Appointment in UC Davis Medical Center Ultrasound (continued)

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Case XXXXX

---

**Surgery Information**

---

**General Information**

---

|  |                      |                |
|--|----------------------|----------------|
| Date: 5/31/2019                          | Time:                | Status: Posted |
| Location: ZZZ Radiology (Don't Schedule) | Room:                | Service:       |
| Patient class:                           | Case classification: |                |

**Diagnosis Information**

---

No post-op diagnosis codes associated with the log.

**Clinical Documentation**

---

**Case Tracking Events**

---

No case tracking events recorded

**Event Tracking**

---

No event timings documented

**Patient Preparation**

---

None

05/31/2019 - Appointment in UC Davis Medical Center Ultrasound (continued)

Coding Summary

XXXXXX

Admission Information

|                    |                     |                     |                               |                     |                             |
|--------------------|---------------------|---------------------|-------------------------------|---------------------|-----------------------------|
| Arrival Date/Time: | 05/31/2019          | Admit Date/Time:    | 05/31/2019                    | IP Adm. Date/Time:  |                             |
| Admission Type:    | Emergency Admission | Point of Origin:    | Emergency Room                | Admit Category:     |                             |
| Means of Arrival:  | Sac Metro Fire      | Primary Service:    | Emergency Medicine            | Secondary Service:  |                             |
| Transfer Source:   |                     | Service Area:       |                               | Unit:               |                             |
| Admit Provider:    | US MH (ROOM 2)      | Attending Provider: | Wong, Andrew<br>Cheng-Wei, MD | Referring Provider: | Turnipseed, Samuel<br>D, MD |

Discharge Information

| Discharge Date/Time | Discharge Disposition                               | Discharge Destination | Discharge Provider | Unit                               |
|---------------------|---|-----------------------|--------------------|------------------------------------|
| 05/31/2019          | Discharged To Home Or Self Care (Routine Discharge) | None                  | None               | UC Davis Medical Center Ultrasound |

Admission Diagnoses / Reasons for Visit (ICD-10-CM)

| Code  | Description   | Comments         |
|-------|---|------------------|
| O03.9 | Complete or unspecified spontaneous abortion without complication | vaginal bleeding |

Final Diagnoses (ICD-10-CM)

| Code              | Description   | POA | CC | HAC | Affects DRG |
|-------------------|---|-----|----|-----|-------------|
| O03.9 [Principal] | Complete or unspecified spontaneous abortion without complication |     |    |     |             |

CPT®/HCPCS Codes

| Code         | Modifiers | Date       | Qty | Performing Provider        | APC | Exp Reimb | Px Event |
|--------------|-----------|------------|-----|----------------------------|-----|-----------|----------|
| 99285 (CPT®) | 25        | 05/31/2019 | 1   | Wong, Andrew Cheng-Wei, MD |     |           |          |

05/31/2019 - Appointment in UC Davis Medical Center Ultrasound

Visit Information

Appointment Information

US OB 1ST TRIMESTER< 14 WEEKS  
5/31/2019 [REDACTED] Canceled

| Time       | Provider            | Department | Length |
|------------|---------------------|------------|--------|
| [REDACTED] | US MH (ER PORTABLE) | HOSP US    | 40 min |

Referral Provider: TURNIPSEED, SAMUEL D      Enc Form Number: [REDACTED]

History

|             |                     |            |     |                          |     |
|-------------|---------------------|------------|-----|--------------------------|-----|
| Made On:    | 5/31/2019           | [REDACTED] | By: | Yabuki, Erin, Technician | RIS |
| Checked In: | 5/31/2019           | [REDACTED] | By: | Yabuki, Erin, Technician | ES  |
| Can. Chkln: | 5/31/2019           | [REDACTED] | By: | Yabuki, Erin, Technician | ES  |
| Canceled:   | 5/31/2019           | [REDACTED] | By: | Yabuki, Erin, Technician | ES  |
| Cancel Rsn: | Cancelled by Clinic |            |     |                          |     |

Coding Summary

XXXXXXXXXX

Admission Information

|                    |                     |                     |                            |                       |                    |                          |
|--------------------|---------------------|---------------------|----------------------------|-----------------------|--------------------|--------------------------|
| Arrival Date/Time: | Admission Type:     | Emergency Admission | Admit Date/Time:           | 05/31/2019 [REDACTED] | IP Adm. Date/Time: |                          |
| Means of Arrival:  | Sac Metro Fire      | Primary Service:    | Emergency Medicine         | Point of Origin:      | Emergency Room     | Admit Category:          |
| Transfer Source:   |                     | Service Area:       |                            | Secondary Service:    |                    |                          |
| Admit Provider:    | US MH (ER PORTABLE) | Attending Provider: | Wong, Andrew Cheng-Wei, MD | Unit:                 |                    | Referring Provider:      |
|                    |                     |                     |                            |                       |                    | Turnipseed, Samuel D, MD |

Discharge Information

| Discharge Date/Time   | Discharge Disposition                               | Discharge Destination | Discharge Provider | Unit                               |
|-----------------------|---|-----------------------|--------------------|------------------------------------|
| 05/31/2019 [REDACTED] | Discharged To Home Or Self Care (Routine Discharge) | None                  | None               | UC Davis Medical Center Ultrasound |

Admission Diagnoses / Reasons for Visit (ICD-10-CM)

| Code  | Description   | Comments         |
|-------|---|------------------|
| O03.9 | Complete or unspecified spontaneous abortion without complication | vaginal bleeding |

Final Diagnoses (ICD-10-CM)

| Code              | Description   | POA | CC | HAC | Affects DRG |
|-------------------|---|-----|----|-----|-------------|
| O03.9 [Principal] | Complete or unspecified spontaneous abortion without complication |     |    |     |             |

05/31/2019 - Appointment in UC Davis Medical Center Ultrasound (continued)

Coding Summary (continued)

CPT®/HCPCS Codes

| Code         | Modifiers | Date       | Qty | Performing Provider        | APC | Exp Reimb | Px Event |
|--------------|-----------|------------|-----|----------------------------|-----|-----------|----------|
| 99285 (CPT®) | 25        | 05/31/2019 | 1   | Wong, Andrew Cheng-Wei, MD |     |           |          |

05/31/2019 - ED in EMERGENCY - PAVILION

## Visit Information

### Admission Information

|                    |                       |                     |                            |                     |                      |
|--------------------|-----------------------|---------------------|----------------------------|---------------------|----------------------|
| Arrival Date/Time: | 05/31/2019 [REDACTED] | Admit Date/Time:    | 05/31/2019 [REDACTED]      | IP Adm. Date/Time:  |                      |
| Admission Type:    | Emergency Admission   | Point of Origin:    | Emergency Room             | Admit Category:     |                      |
| Means of Arrival:  | Sac Metro Fire        | Primary Service:    | Emergency Medicine         | Secondary Service:  | N/A                  |
| Transfer Source:   |                       | Service Area:       | UCDHS SERVICE AREA         | Unit:               | EMERGENCY - PAVILION |
| Admit Provider:    |                       | Attending Provider: | Wong, Andrew Cheng-Wei, MD | Referring Provider: |                      |

### ED Disposition

| ED Disposition | Condition | User                  | Date/Time                   | Comment |
|----------------|-----------|-----------------------|-----------------------------|---------|
| Home           | --        | Stewart, Daniel R, DO | Fri May 31, 2019 [REDACTED] | --      |

### Discharge Information

|                                      |  |                |
|--------------------------------------|--|----------------|
| Date/Time: 05/31/2019 [REDACTED]     | Disposition: Discharged To Home Or Self Care (Routine Discharge) | Destination: — |
| Provider: Wong, Andrew Cheng-Wei, MD | Unit: EMERGENCY - PAVILION                                       |                |

### Follow-up Information

| Follow up With       | Specialties          | Details   | Why   | Contact Info  |
|----------------------|----------------------|-----------|---|---|
| OB/GYN ACC           |                      | In 2 days | Follow up with OB in 2 days   | 4860 Y Street, Suite # 2500<br>Sacramento California 95817                  |
| EMERGENCY - PAVILION | Emergency Department |           | abdominal pain, fever, increased bleeding, vomitng, loss of consciousness or any new concerning symptoms. | 2315 Stockton Boulevard<br>Sacramento California 95817-2201<br>916-734-3790 |

## Reason for Visit

### Chief Complaint

- Vaginal Bleeding Minor

### Visit Diagnosis

- Complete abortion (primary) [O03.9]

## ED Notes

### ED Triage Note by Sperry, Zel, RN at 5/31/2019 [REDACTED]

|                            |                                      |                                  |
|----------------------------|--------------------------------------|----------------------------------|
| Author: Sperry, Zel        | Service: —                           | Author Type: .NURSE: (RN or LVN) |
| Filed: 05/31/19 [REDACTED] | Date of Service: 05/31/19 [REDACTED] | Status: Addendum                 |
| Editor: Sperry, Zel        |                                      |                                  |

Pt [REDACTED] for vaginal bleeding for 2 hours. Pt reports heavily saturating pad. Pt passed a couple clots in the toilet. Pt 8 weeks pregnant. Pt recently seen today prior to the bleeding. NAD. VSS. Pt G8P1A6. Misscariage in January. Pt ambulatory. NAD. Pt reports active bleeding. VSS. No other medical complaints per pt

Electronically signed by Sperry, Zel at 05/31/19 [REDACTED]

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

ED Notes (continued)

ED Nursing Note by Sherwood, Erica, RN at 5/31/2019

Author: Sherwood, Erica, RN  
Filed: 05/31/19  
Editor: Sherwood, Erica, RN (.NURSE: (RN or LVN))

Service: —  
Date of Service: 05/31/19

Author Type: .NURSE: (RN or LVN)  
Status: Addendum

Assumed pt care, pt for vag bleeding, was seen this am with confirmed 8wks3days pregnancy, bleeding started after appt, passed clots at home, most recent miscarriage was in January

Electronically signed by Sherwood, Erica, RN at 05/31/19

ED Provider Notes by Wong, Andrew Cheng-Wei, MD at 5/31/2019

Author: Wong, Andrew Cheng-Wei, MD  
Filed: 05/31/19  
Editor: Wong, Andrew Cheng-Wei, MD (\*PHYSICIAN: FACULTY)

Service: Emergency Medicine  
Date of Service: 05/31/19

Author Type: \*PHYSICIAN: FACULTY  
Status: Addendum

EMERGENCY DEPARTMENT PHYSICIAN NOTE - XXXXX

Date of Service: 5/31/2019 Patient's PCP: Center, Wellspace Arden-Arcade  
Community Health  
Note Started: 5/31/2019 DOB: XXXXX

History

Chief Complaint

Patient presents with

- Vaginal Bleeding Minor

The history provided by the patient.

Interpreter used: No

XXXXX a yr old female, who has a past medical history of Obesity., presenting to the ED with a chief complaint of vaginal bleeding that began today. Passed clots no LOC or abdominal pains. VB was intermittent. No modifying factors.

Took Mifepristone on 5/29 for abortion on study of progesterone vs placebo. G10P1. LMP 4/3. 8 weeks 3 days.

A full history, including past medical, social, and family history (as detailed in this note), was reviewed and updated as necessary.

HISTORY:

Past Medical History

- Obesity

Past Surgical History:

No date: Dilation and curettage

No Known Allergies

Current Outpatient Medications:

- acetaminophen (TYLENOL) 325 mg Capsule, Indications: prn headaches
- Doxycycline (MONODOX) 100 mg capsule, Take 2

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

## ED Notes (continued)

### Social History

#### Tobacco Use

- Smoking status: Never Smoker
- Smokeless tobacco: Never Used

#### Substance Use Topics

- Alcohol use: Yes
  - Alcohol/week: 0.6 - 1.2 oz
  - Types: 1 - 2 Glasses of wine per week
  - Frequency: 2-4 times a month
  - Drinks per session: 1 or 2
- Drug use: Never

### Social History

#### Social History Narrative

- Not on file

#### Review of Systems

#### Review of Systems

Constitutional: Negative for activity change, appetite change, chills, diaphoresis and fever.

Eyes: Negative for visual disturbance.

Respiratory: Negative for cough and shortness of breath.

Cardiovascular: Negative for chest pain and leg swelling.

Gastrointestinal: Negative for abdominal distention, abdominal pain, blood in stool, constipation, diarrhea, nausea and vomiting.

Genitourinary: Positive for **vaginal bleeding**. Negative for dysuria, flank pain, hematuria and vaginal discharge.

Musculoskeletal: Negative for back pain, neck pain and neck stiffness.

Skin: Negative for rash.

Neurological: Negative for dizziness, syncope, weakness, light-headedness, numbness and headaches.

Psychiatric/Behavioral: Negative for confusion.

All other systems reviewed and are negative.

#### Physical Exam

#### TRIAGE VITAL SIGNS:

Temp: 36.4 °C (97.5 °F) (05/31/19 [REDACTED])

Temp src: Oral (05/31/19 [REDACTED])

Pulse: 97 (05/31/19 [REDACTED])

BP: 125/79 (05/31/19 [REDACTED])

Resp: 15 (05/31/19 [REDACTED])

SpO2: 100 % (05/31/19 [REDACTED])

Weight: (not recorded)

#### Physical Exam

Constitutional: She is oriented to person, place, and time. She appears well-developed and well-nourished.

capsules night before procedure with dinner and take two capsules the night after procedure with dinner.

- Ibuprofen (MOTRIN) 800 mg Tablet, Take 1 tablet by mouth every 8 hours if needed for pain. take with food

#### Family History

| Problem | Relation | Age of Onset |
|---------|----------|--------------|
|---------|----------|--------------|

- |                     |                         |  |
|---------------------|-------------------------|--|
| • Cancer<br>ovarian | Mother                  |  |
| • No Known Problems | Father                  |  |
| • Cancer<br>ovarian | Maternal<br>Grandmother |  |



05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**ED Notes (continued)**

performed if clinically indicated. Final Report Electronically Signed By: Simran Sekhon, M.D. on 5/31/2019

**Consults:** A Consult was obtained from the OB service to evaluate for vaginal bleeding. They recommend discharge.

**Chart Review:** I reviewed the patient's prior medical records. Pertinent information that is relevant to this encounter had mifepristone on 5/29.

**PATIENT SUMMARY**

Patient is a -year-old female presenting with vaginal bleeding 8 weeks pregnant. With medical assisted abortion. Patient hemodynamically stable. No abdominal tenderness to palpation. Beta-hCG elevated however downtrending. Pelvic ultrasound with no products of conception and uterus. Consulted obstetrics who recommended Cytotec and RhoGam. Patient received Toradol and fentanyl for pain. Discharged with Motrin and Tylenol prescriptions. Patient follow-up with OB in clinic. Stable at time of discharge and agreeable with plan.

**LAST VITAL SIGNS:**

Temp: 36.4 °C (97.5 °F) (05/31/19 )  
Temp src: Oral (05/31/19 )  
Pulse: 97 (05/31/19 )  
BP: 125/79 (05/31/19 )  
Resp: 15 (05/31/19 )  
SpO2: 100 % (05/31/19 )  
Weight: (not recorded)

**Clinical Impression:**

|                      |               |
|----------------------|---------------|
|                      | ICD-10-<br>CM |
| 1. Complete abortion | O03.9         |
| 2. vaginal bleeding  |               |

**Disposition:** Admit

**PATIENT'S GENERAL CONDITION:**

Fair: Vital signs are stable and within normal limits. Patient is conscious but may be uncomfortable. Indicators are favorable.

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**ED Notes (continued)**

Electronically signed by: Daniel R Stewart, DO, Resident

This patient was seen, evaluated, and care plan was developed with the resident. I agree with the findings and plan as outlined in our combined note. Andrew Cheng-Wei Wong, MD

Electronically signed by: Andrew Cheng-Wei Wong, MD, Attending Physician

Electronically signed by Wong, Andrew Cheng-Wei, MD at 05/31/19 [REDACTED]

**ED Nursing Note by Sherwood, Erica, RN at 5/31/2019 [REDACTED]**

Author: Sherwood, Erica, RN

Service: —

Author Type: .NURSE: (RN or LVN)

Filed: 05/31/19 [REDACTED]

Date of Service: 05/31/19 [REDACTED]

Status: Signed

Editor: Sherwood, Erica, RN (.NURSE: (RN or LVN))

Pt to US

Electronically signed by Sherwood, Erica, RN at 05/31/19 [REDACTED]

**ED Nursing Note by Sherwood, Erica, RN at 5/31/2019 [REDACTED]**

Author: Sherwood, Erica, RN

Service: —

Author Type: .NURSE: (RN or LVN)

Filed: 05/31/19 [REDACTED]

Date of Service: 05/31/19 [REDACTED]

Status: Signed

Editor: Sherwood, Erica, RN (.NURSE: (RN or LVN))

Pt returned from US

Electronically signed by Sherwood, Erica, RN at 05/31/19 [REDACTED]

**ED Nursing Note by Sherwood, Erica, RN at 5/31/2019 [REDACTED]**

Author: Sherwood, Erica, RN

Service: —

Author Type: .NURSE: (RN or LVN)

Filed: 05/31/19 [REDACTED]

Date of Service: 05/31/19 [REDACTED]

Status: Signed

Editor: Sherwood, Erica, RN (.NURSE: (RN or LVN))

Urine cup provided, pt reports she just went in US and doesn't know if she'll be able to provide a sample, research team at bedside talking with pt

Electronically signed by Sherwood, Erica, RN at 05/31/19 [REDACTED]

**ED Nursing Note by Kunce, Kristi at 5/31/2019 [REDACTED]**

Author: Kunce, Kristi

Service: —

Author Type: .NURSE: (RN or LVN)

Filed: 05/31/19 [REDACTED]

Date of Service: 05/31/19 [REDACTED]

Status: Signed

Editor: Kunce, Kristi (.NURSE: (RN or LVN))

Accompanied OB MD for pelvic exam. Pt tolerated well.

Electronically signed by Kunce, Kristi at 05/31/19 [REDACTED]

**ED Nursing Note by Kunce, Kristi at 5/31/2019 [REDACTED]**



05/31/2019 - ED in EMERGENCY - PAVILION (continued)

ED Care Timeline (continued)

|      |   |  |                               |
|------|---|--|-------------------------------|
| ████ | Triage Dispo  | <b>Additional Patient Info</b><br>Referred In?: No<br><b>High Risk Discharge</b><br>Admitted From: Home<br><b>Triage Dispo</b><br>Triage Category: 3_Emergent<br>Destination: RC Treat<br>Current Location: Waiting<br><b>Other flowsheet entries</b><br>Preferred language: English<br>Interpreter needed: No | Sperry, Zel                   |
| ████ | Triage Completed                                    |  | Sperry, Zel                   |
| ████ | Orders Placed                                       | Lab - BETA HCG QUANT, PREGNANCY; CBC WITH DIFFERENTIAL;<br>URINALYSIS-COMPLETE; ED HCV SCREEN WITH REFLEX<br>Imaging - US OB 1ST TRIMESTER<14WKS<br>Blood Bank - TYPE AND SCREEN   | Wong, Andrew<br>Cheng-Wei, MD |
| ████ | Triage Dispo  | <b>Triage Dispo</b><br>Destination: C Pod  | Sperry, Zel                   |
| ████ | Patient roomed in ED                                | To room ED DECON   | Sperry, Zel                   |
| ████ | Med Rec Acuity Score                                | <b>Other flowsheet entries</b><br>Med Rec Acuity Score: 0  | Epic, Batchq                  |
| ████ | Print Label for BETA HCG QUANT, PREGNANCY Completed | BETA HCG QUANT, PREGNANCY - Type: <b>BLOOD</b> ; Source: <b>BLOOD, VENOUS</b>  | Vivar, Andrea, CPT            |
| ████ | Print Label for CBC WITH DIFFERENTIAL Completed     | CBC WITH DIFFERENTIAL - Type: <b>BLOOD</b> ; Source: <b>BLOOD, VENOUS</b>  | Vivar, Andrea, CPT            |
| ████ | Print Label for ED HCV SCREEN WITH REFLEX Completed | ED HCV SCREEN WITH REFLEX - Type: <b>BLOOD</b> ; Source: <b>BLOOD, VENOUS</b>  | Vivar, Andrea, CPT            |
| ████ | Print Label for TYPE AND SCREEN Completed           | TYPE AND SCREEN - Type: <b>BLOOD</b> ; Source: <b>BLOOD, VENOUS</b>  | Vivar, Andrea, CPT            |
| ████ | Patient transferred                                 | From room ED DECON to room ED ROOM E5  | Johnson, Alyssa, RN           |
| ████ | Placed in treatment bed                             |  | Johnson, Alyssa, RN           |
| ████ | Assign Resident                                     | Stewart, Daniel R, DO assigned as ED PGY3  | Stewart, Daniel R, DO         |
| ████ | MD Eval (Door to Doc)                               |  | Stewart, Daniel R, DO         |
| ████ | DATA VALIDATE                                       | <b>Vitals</b><br>BP: 131/74 (Device Time: █████) )<br>MAP cuff: 90 (Device Time: █████) )  | Sherwood, Erica, RN           |
| ████ | Custom Formula Data                                 | <b>Relevant Labs and Vitals</b><br>Temp (in Celsius): 36.9   | Sherwood, Erica, RN           |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

ED Care Timeline (continued)

|   |  |  |                             |
|---|--|--|-----------------------------|
| █ | <b>ED Vitals</b>                                   | <b>Vitals</b><br>Restart Vitals Timer: Yes<br>Temp: 36.9 °C (98.4 °F)<br>Temp (Celsius): 36.9 C<br>Temp src: Oral<br>Pulse: 94<br>Resp: 18<br>SpO2: 98 %<br>Device (Oxygen Therapy): room air<br>Restart Vitals Timer? (Automatic): Yes<br><b>Pain</b><br>Presence of Pain: denies pain/discomfort | Sherwood, Erica, RN         |
| █ | <b>Assign Attending</b>                            | Wong, Andrew Cheng-Wei, MD assigned as Attending   | Wong, Andrew Cheng-Wei, MD  |
| █ | <b>Orders Placed</b>                               | Physician Consult - OBSTETRICS AND GYNECOLOGY CONSULT  | Stewart, Daniel R, DO       |
| █ | <b>Collect BETA HCG QUANT, PREGNANCY Completed</b> | BETA HCG QUANT, PREGNANCY - Type: <b>BLOOD</b> ; Source: <b>BLOOD, VENOUS</b>  | Sherwood, Erica, RN         |
| █ | <b>Collect CBC WITH DIFFERENTIAL Completed</b>     | CBC WITH DIFFERENTIAL - Type: <b>BLOOD</b> ; Source: <b>BLOOD, VENOUS</b>  | Sherwood, Erica, RN         |
| █ | <b>Collect ED HCV SCREEN WITH REFLEX Completed</b> | ED HCV SCREEN WITH REFLEX - Type: <b>BLOOD</b> ; Source: <b>BLOOD, VENOUS</b>  | Sherwood, Erica, RN         |
| █ | <b>Collect TYPE AND SCREEN Completed</b>           | TYPE AND SCREEN - Type: <b>BLOOD</b> ; Source: <b>BLOOD, VENOUS</b>  | Sherwood, Erica, RN         |
| █ | <b>Specimens Collected</b>                         | BETA HCG QUANT, PREGNANCY - ID: <b>19P-151CP2100</b> Type: <b>BLOOD</b><br>TYPE AND SCREEN - ID: <b>19B-151BB0114</b> Type: <b>BLOOD</b><br>CBC WITH DIFFERENTIAL - ID: <b>19P-151HP0906</b> Type: <b>BLOOD</b><br>ED HCV SCREEN WITH REFLEX - ID: <b>19S-151SC0826</b> Type: <b>BLOOD</b>         | Sherwood, Erica, RN         |
| █ | <b>Rad Ordered</b>                                 | US OB 1ST TRIMESTER<14WKS  | McKinney, Sequoia, Rad Tech |
| █ | <b>Orders Acknowledged</b>                         | New - BETA HCG QUANT, PREGNANCY; TYPE AND SCREEN; CBC WITH DIFFERENTIAL; US OB 1ST TRIMESTER<14WKS; URINALYSIS-COMplete; ED HCV SCREEN WITH REFLEX; OBSTETRICS AND GYNECOLOGY CONSULT  | Sherwood, Erica, RN         |
| █ | <b>Team Member Assigned</b>                        | Sherwood, Erica, RN assigned as ED Triage Nurse  | Sherwood, Erica, RN         |
| █ | <b>Assign Nurse</b>                                | Kunce, Kristi assigned as ED Nurse   | Kunce, Kristi               |
| █ | <b>Custom Formula Data</b>                         | <b>Other flowsheet entries</b><br>Calculated row for use by alert logic - not for staff use or review (PECARN TBI-KT): 15  | Sherwood, Erica, RN         |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

ED Care Timeline (continued)



**INITIAL RN  
ASSESSMENT**

**Initial RN Assessment**

Initial RN Assessment Started?: yes

Sherwood, Erica,  
RN

**Airway**

Airway Patent?: Yes

**Breathing**

Breathing: Spontaneous; Symmetrical

Trachea: Midline

Lung Sounds: Right: Clear

Lung Sounds: Left: Clear

**Circulation**

Circulation: Cap. Refill <3 Sec.; Warm; Dry

**Neuro**

AVPU:: Alert

Glasgow Coma Scale: Adult

Best Eye Response: 4-->(E4) spontaneous

Best Verbal Response: 5-->(V5) oriented

Best Motor Response: 6-->(M6) obeys commands

Glasgow Coma Scale Score: 15

**Pupils**

Pupil Size Right: 3 mm

Pupil Reaction Right: equal

Pupil Size Left: 3 mm

Pupil Reaction Left: equal

**Cognitive/Perceptual/Neuro**

Cognitive/Neuro/Behavioral WDL: WDL

**Sleep/Rest/Relaxation**

Sleep/Rest/Relaxation: awake

**Coping**

Observed Emotional State: anxious

Verbalized Emotional State: anxiety

**Pulses**

Pulses assessment: WDL

**Capillary Refill**

Cap refill assessment: WDL

**Strength**

Strength assessment: WDL

**Sensation**

Sensation assessment: WDL

**Chest Pain?**

Chest Pain?: No

**Edema**

Edema assessment: WDL

**Respiratory assessment**

Respiratory assessment: WDL

Trachea: Midline

**Pulm Secretions**

Pulmonary secretions assessment: WDL

**Gastrointestinal**

GI Assessment: WDL

**Urine**

Urine assessment: (UTA not yet observed)

**Skin**

Skin assessment: WDL

Head of Bed (HOB) Positioning: HOB at 30 degrees

Body Position: supine

Patch/Ointment present? (Admit/ED): No

**Head to Toe Assessment**

Head to Toe: WDL Except

G/U: Vaginal Bleeding; No Trauma (8wks 3 days pregnant)

**Compliance Documentation**

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

ED Care Timeline (continued)

ID band: On  
Recently been threatened/injured?: No  
**Falls assessment**  
Falls Risk:: Adult  
**Adult ED Falls Assessment**  
History of falls?: No  
Risk for falls?: No  
**Other flowsheet entries**  
(RETIRED SPR19) Allergy band: N/A

|        |  |   |                               |
|--------|--|---|-------------------------------|
| ██████ | Orders Discontinued                          | TYPE AND SCREEN (05/31/19 ██████)   | Interface, Beaker 886331      |
| ██████ | Collect TYPE AND SCREEN Discontinued         | TYPE AND SCREEN   | Interface, Beaker 886331      |
| ██████ | Print Label for TYPE AND SCREEN Discontinued | TYPE AND SCREEN   | Interface, Beaker 886331      |
| ██████ | CBC WITH DIFFERENTIAL Resulted               | Abnormal Result Collected: 5/31/2019 ██████ Last updated: 5/31/2019 ██████<br>Status: <b>Final result</b> White Blood Cell Count: <b>5.7 K/MM3</b> [Ref Range: 4.5 - 11.0] Red Blood Cell Count: <b>4.60 M/MM3</b> [Ref Range: 3.70 - 5.50]<br>Hemoglobin: <b>10.4 g/dL</b> ▾ [Ref Range: 12.0 - 16.0] Hematocrit: <b>32.2 %</b> ▾ [Ref Range: 34.0 - 46.0] MCV: <b>70.0 fL</b> ▾ [Ref Range: 80.0 - 100.0] MCH: <b>22.7 pg</b> ▾ [Ref Range: 27.0 - 33.0] MCHC: <b>32.4 %</b> [Ref Range: 32.0 - 36.0] RDW: <b>18.9 %</b> ^ [Ref Range: 0.0 - 14.7] MPV: <b>7.2 fL</b> [Ref Range: 6.8 - 10.0] Platelet Count: <b>362 K/MM3</b> [Ref Range: 130 - 400] Neutrophils % Auto: <b>63.6 %</b><br>Lymphocytes % Auto: <b>27.8 %</b> Monocytes % Auto: <b>6.1 %</b> Eosinophils % Auto: <b>1.7 %</b> Basophils % Auto: <b>0.8 %</b> Neutrophils Abs Auto: <b>3.6 K/MM3</b> [Ref Range: 1.8 - 7.7] Lymphocytes Abs Auto: <b>1.6 K/MM3</b> [Ref Range: 1.0 - 4.8] Monocytes Abs Auto: <b>0.4 K/MM3</b> [Ref Range: 0.1 - 0.8] Eosinophils Abs Auto: <b>0.1 K/MM3</b> [Ref Range: 0.0 - 0.5] Basophils Abs Auto: <b>0.0 K/MM3</b> [Ref Range: 0.0 - 0.2] | Rivera Pallares, Joel, C.L.S  |
| ██████ | Rad Reported                                 | US OB 1ST TRIMESTER<14WKS   | McKinney, Sequoia, Rad Tech   |
| ██████ | BETA HCG QUANT, PREGNANCY Resulted           | Abnormal Result Collected: 5/31/2019 ██████ Last updated: 5/31/2019 ██████<br>Status: <b>Final result</b> Beta HCG Serum: <b>90,596.5 mIU/mL</b> ^ [Ref Range: 0.0 - 0.6]   | Interface, Beaker 886351      |
| ██████ | Orders Placed                                | Medications - Rho D Immune Globulin (HYPERRHO) "mini-dose" Injection 50 mcg   | Stewart, Daniel R, DO         |
| ██████ | Orders Acknowledged                          | New - Rho D Immune Globulin (HYPERRHO) "mini-dose" Injection 50 mcg   | Sherwood, Erica, RN           |
| ██████ | Orders Placed                                | Medications - Misoprostol (CYTOTEC) Tablet 800 mcg  | Evans, Mark W, MD             |
| ██████ | Orders Acknowledged                          | New - Misoprostol (CYTOTEC) Tablet 800 mcg  | Sherwood, Erica, RN           |
| ██████ | Registration Completed                       |   | Skibby, Kelly                 |
| ██████ | Order Performed                              | US OB 1ST TRIMESTER<14WKS - ID: ██████  |                               |
| ██████ | US OB 1ST TRIMESTER<14WKS Resulted           | Collected: 5/31/2019 ██████ Last updated: 5/31/2019 ██████ Status: <b>Final</b>   | Interface Radiant, Ib Results |
| ██████ | Rad Resulted                                 | US OB 1ST TRIMESTER<14WKS   | Interface Radiant, Ib Results |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

ED Care Timeline (continued)

|      |                                       |   |                       |
|------|---------------------------------------|---|-----------------------|
| ████ | <b>DATA VALIDATE</b>                  | <b>Vitals</b><br>BP: 112/63 (Device Time: █████ )<br>Pulse: 102 (Device Time: █████ )<br>SpO2: 100 % (Device Time: █████ )<br>MAP cuff: 79 (Device Time: █████ )  | Sherwood, Erica, RN   |
| ████ | <b>Custom Formula Data</b>            | <b>Relevant Labs and Vitals</b><br>Temp (in Celsius): 37  | Sherwood, Erica, RN   |
| ████ | <b>ED Vitals</b>                      | <b>Vitals</b><br>Restart Vitals Timer: Yes<br>Temp: 37 °C (98.6 °F)<br>Temp (Celsius): 37 C<br>Temp src: Oral<br>Resp: 17<br>Device (Oxygen Therapy): room air<br>Restart Vitals Timer? (Automatic): Yes<br><b>Pain</b><br>Presence of Pain: denies pain/discomfort | Sherwood, Erica, RN   |
| ████ | <b>Orders Placed</b>                  | Medications - Fentanyl (SUBLIMAZE) Injection 50 mcg   | Stewart, Daniel R, DO |
| ████ | <b>Orders Acknowledged</b>            | New - Fentanyl (SUBLIMAZE) Injection 50 mcg   | Kunce, Kristi         |
| ████ | <b>Medication Given</b>               | Fentanyl (SUBLIMAZE) Injection 50 mcg - Dose: 50 mcg ; Route: IV ; Scheduled Time: █████  | Kunce, Kristi         |
| ████ | <b>Medication Given</b>               | Rho D Immune Globulin (HYPERRHO) "mini-dose" Injection 50 mcg - Dose: 50 mcg ; Route: IM ; Site: Left anterior thigh ; Scheduled Time: █████  | Sherwood, Erica, RN   |
| ████ | <b>Medication Given</b>               | Misoprostol (CYTOTEC) Tablet 800 mcg - Dose: 800 mcg ; Route: BUCCAL ; Scheduled Time: █████  | Sherwood, Erica, RN   |
| ████ | <b>Med Rec Acuity Score</b>           | <b>Other flowsheet entries</b><br>Med Rec Acuity Score: 0   | Epic, Batchq          |
| ████ | <b>Orders Completed</b>               | OBSTETRICS AND GYNECOLOGY CONSULT   | Creinin, Mitchell, MD |
| ████ | <b>Discharge Disposition Selected</b> | ED Disposition set to Home  | Stewart, Daniel R, DO |
| ████ | <b>ED PTA Meds Reconciled</b>         |   | Stewart, Daniel R, DO |
| ████ | <b>Allergies Reviewed</b>             |   | Stewart, Daniel R, DO |
| ████ | <b>History Reviewed</b>               | Sections Reviewed: Obstetric, Medical, Surgical, Family, Tobacco, Alcohol, Drug Use, Sexual Activity, Social Documentation, Socioeconomic   | Stewart, Daniel R, DO |
| ████ | <b>Home Medications Reviewed</b>      |   | Stewart, Daniel R, DO |
| ████ | <b>Social Drivers</b>                 | <b>Alcohol Use</b><br>Q1: How often do you have a drink containing alcohol?: 2-4 times a month (Data migrated from History)<br>Q2: How many drinks containing alcohol do you have on a typical day when you are drinking?: 1 or 2 (Data migrated from History)      | Stewart, Daniel R, DO |
| ████ | <b>AVS Printed</b>                    | Acknowledgement of Treatment  | Stewart, Daniel R, DO |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

ED Care Timeline (continued)

|        |                         |   |  |
|--------|-------------------------|---|--|
| ██████ | AVS Printed             | ED After Visit Summary  | Stewart, Daniel R, DO  |
| ██████ | AVS Printed             | Acknowledgement of Treatment<br>ED After Visit Summary  | Stewart, Daniel R, DO  |
| ██████ | Orders Placed           | Medications - Ketorolac (TORADOL) Injection 15 mg   | Stewart, Daniel R, DO  |
| ██████ | Discharge Orders Placed | Medications - Ibuprofen (MOTRIN) 600 mg Tablet; Acetaminophen (TYLENOL EXTRA STRENGTH) 500 mg Tablet  | Stewart, Daniel R, DO  |
| ██████ | Orders Acknowledged     | New - Ketorolac (TORADOL) Injection 15 mg   | Kunce, Kristi  |
| ██████ | Medication Given        | Ketorolac (TORADOL) Injection 15 mg - Dose: 15 mg ; Route: IV ; Scheduled Time: ██████  | Kunce, Kristi  |
| ██████ | DATA VALIDATE           | Vitals<br>BP: 99/86 (Device Time: ██████ )<br>MAP cuff: 92 (Device Time: ██████)  | Kunce, Kristi  |
| ██████ | Custom Formula Data     | Relevant Labs and Vitals<br>Temp (in Celsius): 36.9   | Kunce, Kristi  |
| ██████ | ED Vitals               | Vitals<br>Restart Vitals Timer: Yes<br>Temp: 36.9 °C (98.4 °F)<br>Temp (Celsius): 36.9 C<br>Temp src: Oral<br>Pulse: 84<br>Resp: 15<br>SpO2: 100 %<br>Device (Oxygen Therapy): room air<br>Restart Vitals Timer? (Automatic): Yes<br><b>Pain</b><br>Presence of Pain: complains of pain/discomfort<br>(0-10) Pain Rating: Rest: 8<br><b>Pain</b><br>(RETIRED SPR19) Preferred Pain Scale: number (Numeric Rating Pain Scale)<br><b>Pain</b><br>(RETIRED SPR19) Pain Body Location: abdomen<br>(RETIRED SPR19) Quality: cramping | Kunce, Kristi  |
| ██████ | ED Provider Notes       | Note originally filed at this time  | Stewart, Daniel R, DO; Cosigned by Wong, Andrew<br>Chenq-Wei, MD |
| ██████ | Patient discharged      |   | Kunce, Kristi  |

Clinical Notes

Consults by Creinin, Mitchell, MD at 5/31/2019 ██████

Author: Creinin, Mitchell, MD  
Filed: 06/01/19 ██████  
Editor: Creinin, Mitchell, MD (\*PHYSICIAN: FACULTY)

Service: (A) GYN  
Date of Service: 05/31/19 ██████

Author Type: \*PHYSICIAN: FACULTY  
Status: Addendum

OBSTETRICS & GYNECOLOGY CONSULT HISTORY & PHYSICAL

Date of 5/31/2019

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ARMSTR0507

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Clinical Notes (continued)

Service:

**CHIEF COMPLAINT:** Vaginal bleeding

**HISTORY OF PRESENT ILLNESS:** XXXXX a [redacted] yr G10P1081 AA female with no significant PMH who presents with vaginal bleeding. She has an unwanted pregnancy and is currently in a clinical trial in the OB/GYN Department. She received mifepristone 200 mg at 8w0d on 5/29/19 at [redacted] and has been taking either progesterone or placebo (blinded) since 5/30/19.

Patient was seen for a study visit this morning and had no bleeding and the US showed a continuing pregnancy. Patient states that at about [redacted] h today, she was at work and felt a small clot come out into her underwear. She went home and then about [redacted] she felt a "rush" of bleeding and noted that she soaked through panty liner and clothes. There was not much liquid blood, mainly clots. She went to the toilet and passed more clots into the toilet, but wasn't sure how much because she didn't look because she did not want to see POCs. She thinks she may have passed a small sac like structure. She called the research office and was told to come in to the office/clinic to be evaluated. She got scared and called an ambulance to take her to the hospital. She notes some amount of dizziness, but that it was present before the bleeding (about 1 hour after being seen in clinic this morning). No dizziness currently. Has had some cramping for the last 2 days, but it has not been terrible. Has had loose stool QDx1 x2-3d and those were the only BMs. No nausea or vomiting.

**ROS:** Denies any other symptoms currently.

**HISTORY:**

**Medical History:**

**Past Medical History:**

| Diagnosis | Date |
|-----------|------|
| • Obesity | 2015 |

**Surgical History:**

**Past Surgical History:**

| Procedure  | Laterality | Date |
|--|------------|------|
| • DILATION AND CURETTAGE<br><i>elective 1st tri abortion X 7</i> |            |      |

**Obstetrics History:**

**OB History**

| Gravida | Para | Term    | Preterm  | AB          | Living |
|---------|------|---------|----------|-------------|--------|
| 10      | 1    | 1       |          | 8           | 1      |
| SAB     | TAB  | Ectopic | Multiple | Live Births |        |
| 1       | 7    |         |          | 1           |        |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**Clinical Notes (continued)**

| #  | Outcome                               | Date     | GA    | Lbr Len/2nd | Weight | Sex | Delivery  | Anes | PTL Lv |
|----|---------------------------------------|----------|-------|-------------|--------|-----|-----------|------|--------|
| 10 | Current                               |          |       |             |        |     |           |      |        |
| 9  | SAB                                   | 01/13/19 | 11w0d |             |        |     | SAB       |      |        |
|    | Birth Comments: spontaneous expulsion |          |       |             |        |     |           |      |        |
| 8  | TAB                                   | 2018     |       |             |        |     |           |      |        |
|    | Birth Comments: D&C, uncomplicated    |          |       |             |        |     |           |      |        |
| 7  | TAB                                   | 2017     |       |             |        |     |           |      |        |
|    | Birth Comments: D&C, uncomplicated    |          |       |             |        |     |           |      |        |
| 6  | TAB                                   | 2016     |       |             |        |     |           |      |        |
|    | Birth Comments: D&C, uncomplicated    |          |       |             |        |     |           |      |        |
| 5  | TAB                                   | 2015     |       |             |        |     |           |      |        |
|    | Birth Comments: D&C, uncomplicated    |          |       |             |        |     |           |      |        |
| 4  | TAB                                   | 2014     |       |             |        |     |           |      |        |
|    | Birth Comments: D&C, uncomplicated    |          |       |             |        |     |           |      |        |
| 3  | TAB                                   | 2013     |       |             |        |     |           |      |        |
|    | Birth Comments: D&C, uncomplicated    |          |       |             |        |     |           |      |        |
| 2  | TAB                                   | 2012     |       |             |        |     |           |      |        |
|    | Birth Comments: D&C, uncomplicated    |          |       |             |        |     |           |      |        |
| 1  | Term                                  | 11/06/11 |       |             |        | F   | Vag-Spont |      | LIV    |

**Obstetric Comments**

Regular, monthly periods  
Last STI screening 2 years ago 2016, no new partners

**Social History:**  
**Social History**

**Tobacco Use**

- Smoking status: Never Smoker
- Smokeless tobacco: Never Used

**Substance Use Topics**

- Alcohol use: Yes
  - Alcohol/week: 0.6 - 1.2 oz
  - Types: 1 - 2 Glasses of wine per week
  - Frequency: 2-4 times a month
  - Drinks per session: 1 or 2
- Drug use: Never

**Family History:**  
**Family History**

| Problem             | Relation | Name | Age of Onset |
|---------------------|----------|------|--------------|
| • Cancer<br>ovarian | Mother   |      |              |
| • No Known Problems | Father   |      |              |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Clinical Notes (continued)

- Cancer Maternal  
ovarian Grandmother

**VITAL SIGNS:**

Vital Signs (Last Recorded):

Temp: 36.9 °C (98.4 °F) (05/31/19 [REDACTED]) Temp src: Oral

Pulse: 84 | BP: 99/86 | Resp: 15 | SpO2: 100 %

There is no height or weight on file to calculate BMI. | |

**PHYSICAL EXAM:**

All portions of breast &/or pelvic examination chaperoned by Kristi Kunce, RN.

**General:** Alert, well appearing, well groomed female in no apparent distress

**HEENT:** Atraumatic; normocephalic; external ocular movements grossly intact.

**CV:** Normal rate, regular rhythm, no murmurs, rubs, or gallops

**Pulm:** Clear to auscultation bilaterally, no wheezes, rales, or rhonchi

**Abdomen:** Obese, soft, nontender.

**Extremities:** Warm, well-perfused. No calf swelling/tenderness.

**Derm:** No rashes on exposed skin; without abnormal acne or hirsutism

**Psychiatric:** Normal orientation, mood and affect, but with an appropriate amount of anxiety

**Neuro:** Grossly normal. Moves all extremities equally.

**Pelvic:**

**Vulva/Perineum:** Grossly normal, with small amount of blood noted.

**Speculum exam (performed after ultrasound exam completed):** Initial exam with about 100 cc clots removed from vagina and noted more remained in vault and cervix not visualized before patient requested cessation of exam due to pain. Patient noted that she felt her pelvic floor muscles contracting during that exam. Subsequently offered pain medication to complete exam. After fentanyl 50 mcg x1, exam continued with significantly improved tolerance. A total of about 50 cc clots removed from vagina this exam. Cervix visualized and normal appearing. Ring forceps used to remove two small clots emerging from os. Once cleared, only a very small amount of dark blood mixed with mucus noted to be emerging from os but no active flow noted.

**LAB TESTS/STUDIES**

I personally reviewed the following:

Results for orders placed or performed during the hospital encounter of 05/31/19

**BETA HCG QUANT, PREGNANCY Status: Abnormal**

| Result         | Value        | Status |
|----------------|--------------|--------|
| Beta HCG Serum | 90,596.5 (H) | Final  |

**CBC WITH DIFFERENTIAL Status: Abnormal**

| Result                 | Value    | Status |
|------------------------|----------|--------|
| White Blood Cell Count | 5.7      | Final  |
| Red Blood Cell Count   | 4.60     | Final  |
| Hemoglobin             | 10.4 (L) | Final  |
| Hematocrit             | 32.2 (L) | Final  |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Clinical Notes (continued)

|                     |          |       |
|---------------------|----------|-------|
| MCV                 | 70.0 (L) | Final |
| MCH                 | 22.7 (L) | Final |
| MCHC                | 32.4     | Final |
| RDW                 | 18.9 (H) | Final |
| MPV                 | 7.2      | Final |
| Platelet Count      | 362      | Final |
| Neutrophils % Auto  | 63.6     | Final |
| Lymphocytes % Auto  | 27.8     | Final |
| Monocytes % Auto    | 6.1      | Final |
| Eosinophil % Auto   | 1.7      | Final |
| Basophils % Auto    | 0.8      | Final |
| Neutrophil Abs Auto | 3.6      | Final |
| Lymphocyte Abs Auto | 1.6      | Final |
| Monocytes Abs Auto  | 0.4      | Final |
| Eosinophil Abs Auto | 0.1      | Final |
| Basophils Abs Auto  | 0.0      | Final |

Transabdominal and Transvaginal Ultrasound 5/31/2019:

FINDINGS:

No intrauterine pregnancy is noted.

The endometrium is 1.5 cm in thickness and demonstrates heterogeneity. No vascular flow is seen. Heterogeneity is also noted in the endocervical canal.

The ovaries only visualized on the transabdominal portion of the exam and appear unremarkable. No adnexal masses seen.

There is no free fluid.

IMPRESSION:

1. No intrauterine pregnancy is seen.
2. Heterogenous material is noted in the endometrial cavity and endocervical canal.
3. In the setting of patient passing clots and tissue, findings likely represent ongoing miscarriage.
4. Please correlate with serum beta-hCG levels and an follow-up ultrasound can be performed if clinically indicated.

ASSESSMENT & PLAN:

XXXXX a ■■■ yr G10P1081 AA female 2d s/p mifepristoneat 8w0d as part of a clinical trial who presents with vaginal bleeding, found to have no POCs in uterus on ultrasound.

**# Vaginal bleeding:** IUP visualized in clinic this morning. No IUP in uterus in ED. Patient has passed the pregnancy. Hemodynamically stable. No active bleeding at this time. Pain well-controlled. Minimal blood/tissue in uterus.

- Misoprostol 800 mcg Buccal x1

- Routine medications for pain control subsequently, e.g. NSAIDs &/or acetaminophen.

**# Rh Negative:** Recommend Rho D Immune Globulin 50 mcg IM x1 ("Micrhogam") to prevent Rh alloimmunization.

**# Clinical trial:** will follow-up with study staff as needed. Dr. Creinin did discuss with patient.

**# Dispo:** To home with standard bleeding/infection return precautions.

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Clinical Notes (continued)

**# Follow-up:** Family Planning division of Ob/Gyn Dept. Will contact patient for follow up. This has been discussed with patient.

This patient was evaluated and staffed with Dr. Creinin.  
The above plan was discussed with the ED team.

*Electronically Signed By:*  
Mark Evans, MD, MSPH  
PGY-2, Obstetrics & Gynecology  
UC Davis Medical Center  
Pager: 816-1937  
PI# 24294

### ATTENDING

I saw and evaluated the patient with Dr. Evans.  
I have reviewed the patient's medical history, the resident's physical examination findings, the patient's diagnosis, and the treatment plan.  
I discussed the patient's care with Dr. Evans.  
We developed the treatment plan together. I agree with Dr. Evans' findings and plan as documented in the note above.

*Electronically signed by:*  
Mitchell Creinin, MD  
Obstetrics & Gynecology  
Pager 816-0727  
PI# 11824

Electronically signed by Creinin, Mitchell, MD at 06/01/19 [REDACTED]

#### Consults by Creinin, Mitchell, MD at 5/31/2019 1711

Author: Creinin, Mitchell, MD

Service: (A) GYN

Author Type: \*PHYSICIAN: FACULTY

Filed: 05/31/19 [REDACTED]

Date of Service: 05/31/19 [REDACTED]

Status: Addendum

Editor: Creinin, Mitchell, MD (\*PHYSICIAN: FACULTY)

Consult Orders

1. OBSTETRICS AND GYNECOLOGY CONSULT [REDACTED] ordered by Stewart, Daniel R, DO at 05/31/19 [REDACTED]

### OBSTETRICS & GYNECOLOGY BRIEF CONSULT NOTE

Date & time of 5/31/2019 [REDACTED]

Service:

**CHIEF COMPLAINT:** Vaginal bleeding

**REASON FOR CONSULT:** Evaluate vaginal bleeding

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Clinical Notes (continued)

**ASSESSMENT & PLAN:**

XXXXX a [REDACTED] yr G10P1081 AA female with vaginal bleeding that began today at [REDACTED]. Has been seen and evaluated by gynecology team. Evaluation ongoing. Patient hemodynamically stable. Will follow-up ultrasound when complete. Per my review of the first few images on ultrasound while at bedside, it appears the patient has passed the pregnancy.

Full consult note to follow.

This patient is being discussed with Dr. Creinin.

*Electronically Signed By:*

Mark Evans, MD, MSPH  
PGY-2, Obstetrics & Gynecology  
UC Davis Medical Center  
Pager: 816-1937  
PI# 24294

**ATTENDING**

Patient known to me - is patient in study through FP Research. Patient planning surgical abortion and received mifepristone on 5/29/19 as part of the study. She has been taking progesterone or placebo since 5/30/19 (blinded). She had a study follow-up visit earlier today at which she had no bleeding and normal pregnancy growth with the pregnancy still viable. She was scheduled for her next follow-up visit 6/5/19. She called the research office in the mid-afternoon stating she had started bleeding suddenly at work and had to leave to go home. She bled through her underwear onto her pants. We instructed her to come into the office. She did not have an immediate ride and "panicked" in her words; she called an ambulance which brought her to the ER. She was in the US suite when I saw her with Dr. Evans. Her bleeding was mild to moderate and the US scan showed absence of the gestational sac. Patient will go back to the ER and Dr. Evans will do a speculum exam to ensure no tissue is in the os. Patient will need Microgham. Will decide if misoprostol is indicated to ensure complete expulsion. Patient told no further study visits or clinical visits needed.

Full consult note to follow. Our research office will call the patient on 6/3/19 to check on status.

Mitchell Creinin, MD

Electronically signed by Creinin, Mitchell, MD at 05/31/19 [REDACTED]

**Discharge Instructions by Evans, Mark W, MD at 5/31/2019 [REDACTED]**

Author: Evans, Mark W, MD

Service: —

Author Type: \*PHYSICIAN: RESIDENT

Filed: 05/31/19 [REDACTED]

Date of Service: 05/31/19 [REDACTED]

Status: Edited

Editor: Evans, Mark W, MD (\*PHYSICIAN: RESIDENT)

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Clinical Notes (continued)

Ob/Gyn Phone Number: 916-734-6900

Thank you for choosing UC Davis Medical Center for your emergency health care needs. It has been our privilege to take care of you today. You have been treated for vaginal bleeding and discharged home. Please take all medicines that are prescribed to you as directed. It is crucial, if you have a primary care physician, to follow up with him or her in the time frame recommended as many health conditions that seem self-limited initially may actually worsen over time. If you do not have a primary care physician, we will outline the various resources available for you to find one.

If at any time you feel that your condition is worsening, call your doctor or return to the emergency department for reevaluation.

Please realize that the results of some studies that you had done during your stay with us (such as xrays and cultures) are only preliminarily resulted. Results of these studies may change as more information becomes available or as the studies are reevaluated by other members of our health care team in the next few days. We will attempt to contact you with any important changes or additions to the studies that were obtained today.

### MEDICATIONS

1. Resume all home medications as directed.
2. Start new discharge medications as directed.
3. Do not drive or operate machinery while taking narcotic pain medications.
4. You may have been prescribed a pain medicine(s) that contains Tylenol (acetaminophen). If you are taking other Tylenol containing medicines at home, **be sure NOT to exceed 4 gram's (4000 milligrams) of Tylenol per day.**

Electronically signed by Evans, Mark W, MD at 05/31/19 [REDACTED]

### Labs

#### URINALYSIS-COMPLETE (Discontinued) [REDACTED] 1

Electronically signed by: Sperry, Zel on 05/31/19 [REDACTED]  
Ordering user: Sperry, Zel 05/31/19 [REDACTED]  
Authorized by: Wong, Andrew Cheng-Wei, MD  
Frequency: STAT ONCE 05/31/19 [REDACTED] - 1 occurrence  
Quantity: 1

Status: Discontinued

Ordering provider: Wong, Andrew Cheng-Wei, MD  
Ordering mode: ED Triage Protocol  
Class: Inpatient Normal  
Instance released by: Sperry, Zel, RN (auto-released) 5/31/2019 [REDACTED]

Discontinued by: Interface, Incoming Scheduling 06/01/19 [REDACTED] [Patient Discharged]

#### Specimen Information

| ID | Type  | Source | Collected By |
|----|-------|--------|--------------|
| —  | URINE | —      | —            |

#### BETA HCG QUANT, PREGNANCY (Final result) [REDACTED] 1

Electronically signed by: Sperry, Zel on 05/31/19 [REDACTED]  
Ordering user: Sperry, Zel 05/31/19 [REDACTED]  
Authorized by: Wong, Andrew Cheng-Wei, MD  
Frequency: STAT ONCE 05/31/19 [REDACTED] 1 occurrence  
Quantity: 1  
Instance released by: Sperry, Zel, RN (auto-released) 5/31/2019 [REDACTED]

Status: Completed

Ordering provider: Wong, Andrew Cheng-Wei, MD  
Ordering mode: ED Triage Protocol  
Class: Inpatient Normal  
Lab status: Final result

#### Specimen Information

| ID | Type | Source | Collected By |
|----|------|--------|--------------|
|----|------|--------|--------------|

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Labs (continued)

19P-151CP2100 BLOOD BLOOD, VENOUS Sherwood, Erica, RN 05/31/19

BETA HCG QUANT, PREGNANCY [REDACTED] (Abnormal) Resulted: 05/31/19 [REDACTED], Result status: Final result

Ordering provider: Wong, Andrew Cheng-Wei, MD 05/31/19 Order status: Completed

Filed by: Interface, Beaker 886351 05/31/19 [REDACTED] Collected by: Sherwood, Erica, RN 05/31/19 1652

Resulting lab: UCDHS MAIN LAB

CLIA number: [REDACTED]

Narrative:

The reference interval for post-menopausal females is 0.1 - 11.6 mIU/mL.

Components

| Component      | Value    | Reference Range  | Flag | Lab    |
|----------------|----------|------------------|------|--------|
| Beta HCG Serum | 90,596.5 | 0.0 - 0.6 mIU/mL | H ^  | PAVLAB |

Testing Performed By

| Lab - Abbreviation | Name           | Director              | Address   | Valid Date Range                          |
|--------------------|----------------|-----------------------|---|---|
| 102 - PAVLAB       | UCDHS MAIN LAB | Lydia P. Howell, M.D. | 2315 Stockton Boulevard<br>Sacramento CA 95817-2201 | 04/15/14 [REDACTED] - 07/01/23 [REDACTED] |

TYPE AND SCREEN (Discontinued) [REDACTED]

Electronically signed by: Sperry, Zel on 05/31/19 [REDACTED]  
Ordering user: Sperry, Zel 05/31/19 [REDACTED]  
Authorized by: Wong, Andrew Cheng-Wei, MD  
Frequency: STAT ONCE 05/31/19 [REDACTED] - 1 occurrence  
Quantity: 1

Status: Discontinued

Ordering provider: Wong, Andrew Cheng-Wei, MD  
Ordering mode: ED Triage Protocol  
Class: Inpatient Normal  
Instance released by: Sperry, Zel, RN (auto-released) 5/31/2019

Discontinued by: Interface, Beaker 886331 05/31/19 [REDACTED] [Other (Duplicate, please refer to T&S 19B-151BB0059)]

Specimen Information

| ID            | Type  | Source        | Collected By                            |
|---------------|-------|---------------|---|
| 19B-151BB0114 | BLOOD | BLOOD, VENOUS | Sherwood, Erica, RN 05/31/19 [REDACTED] |

TYPE AND SCREEN [216881859]

Result status: In process

Ordering provider: Wong, Andrew Cheng-Wei, MD 05/31/19 Order status: Canceled

Discontinued by: Interface, Beaker 886331 05/31/19 [REDACTED] [Other (Duplicate, please refer to T&S 19B-151BB0059)] Filed by: Interface, Beaker 886331 05/31/19 [REDACTED]

Collected by: Sherwood, Erica, RN 05/31/19 [REDACTED] lab: UCDHS BLOOD BANK LAB

CLIA number: [REDACTED]

Testing Performed By

| Lab - Abbreviation | Name                 | Director              | Address   | Valid Date Range                          |
|--------------------|----------------------|-----------------------|---|---|
| 1230000001 - BB    | UCDHS BLOOD BANK LAB | Lydia P. Howell, M.D. | 2315 Stockton Boulevard<br>Sacramento CA 95817-2201 | 11/07/16 [REDACTED] - 07/01/23 [REDACTED] |

CBC WITH DIFFERENTIAL (Final result) [REDACTED]

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**Labs (continued)**

Electronically signed by: **Sperry, Zel on 05/31/19** [REDACTED] Status: **Completed**  
 Ordering user: **Sperry, Zel 05/31/19** [REDACTED] Ordering provider: **Wong, Andrew Cheng-Wei, MD**  
 Authorized by: **Wong, Andrew Cheng-Wei, MD** Ordering mode: **ED Triage Protocol**  
 Frequency: **STAT ONCE 05/31/19** [REDACTED] - 1 occurrence Class: **Inpatient Normal**  
 Quantity: 1 Lab status: **Final result**  
 Instance released by: **Sperry, Zel, RN (auto-released) 5/31/2019** [REDACTED]

**Specimen Information**

| ID            | Type  | Source           | Collected By                               |
|---------------|-------|------------------|--|
| 19P-151HP0906 | BLOOD | BLOOD,<br>VENOUS | Sherwood, Erica, RN 05/31/19<br>[REDACTED] |

**CBC WITH DIFFERENTIAL** [REDACTED] (Abnormal)

Resulted: 05/31/19 [REDACTED] Result status: Final result

Ordering provider: **Wong, Andrew Cheng-Wei, MD 05/31/19** [REDACTED] Order status: **Completed**  
 Filed by: **Rivera Pallares, Joel, C.L.S 05/31/19** [REDACTED] Collected by: **Sherwood, Erica, RN 05/31/19** [REDACTED]  
 Resulting lab: **UCDHS MAIN LAB** CLIA number: [REDACTED]

**Components**

| Component              | Value | Reference Range      | Flag | Lab    |
|------------------------|-------|----------------------|------|--------|
| White Blood Cell Count | 5.7   | 4.5 - 11.0 K/MM3     | —    | PAVLAB |
| Red Blood Cell Count   | 4.60  | 3.70 - 5.50<br>M/MM3 | —    | PAVLAB |
| Hemoglobin             | 10.4  | 12.0 - 16.0 g/dL     | L v  | PAVLAB |
| Hematocrit             | 32.2  | 34.0 - 46.0 %        | L v  | PAVLAB |
| MCV                    | 70.0  | 80.0 - 100.0 fL      | L v  | PAVLAB |
| MCH                    | 22.7  | 27.0 - 33.0 pg       | L v  | PAVLAB |
| MCHC                   | 32.4  | 32.0 - 36.0 %        | —    | PAVLAB |
| RDW                    | 18.9  | 0.0 - 14.7 %         | H ^  | PAVLAB |
| MPV                    | 7.2   | 6.8 - 10.0 fL        | —    | PAVLAB |
| Platelet Count         | 362   | 130 - 400 K/MM3      | —    | PAVLAB |
| Neutrophils % Auto     | 63.6  | %                    | —    | PAVLAB |
| Lymphocytes % Auto     | 27.8  | %                    | —    | PAVLAB |
| Monocytes % Auto       | 6.1   | %                    | —    | PAVLAB |
| Eosinophils % Auto     | 1.7   | %                    | —    | PAVLAB |
| Basophils % Auto       | 0.8   | %                    | —    | PAVLAB |
| Neutrophils Abs Auto   | 3.6   | 1.8 - 7.7 K/MM3      | —    | PAVLAB |
| Lymphocytes Abs Auto   | 1.6   | 1.0 - 4.8 K/MM3      | —    | PAVLAB |
| Monocytes Abs Auto     | 0.4   | 0.1 - 0.8 K/MM3      | —    | PAVLAB |
| Eosinophils Abs Auto   | 0.1   | 0.0 - 0.5 K/MM3      | —    | PAVLAB |
| Basophils Abs Auto     | 0.0   | 0.0 - 0.2 K/MM3      | —    | PAVLAB |

**Testing Performed By**

| Lab - Abbreviation | Name           | Director                 | Address  | Valid Date Range                          |
|--------------------|----------------|--------------------------|--|---|
| 102 - PAVLAB       | UCDHS MAIN LAB | Lydia P. Howell,<br>M.D. | 2315 Stockton<br>Boulevard<br>Sacramento CA 95817-<br>2201 | 04/15/14 [REDACTED] - 07/01/23 [REDACTED] |

**ED HCV SCREEN WITH REFLEX (Final result)** [REDACTED]

Electronically signed by: **Sperry, Zel on 05/31/19** [REDACTED] Status: **Completed**  
 Ordering user: **Sperry, Zel 05/31/19** [REDACTED] Ordering provider: **Wong, Andrew Cheng-Wei, MD**  
 Authorized by: **Wong, Andrew Cheng-Wei, MD** Ordering mode: **ED Triage Protocol**  
 Frequency: **Routine ONCE 05/31/19** [REDACTED] - 1 occurrence Class: **Inpatient Normal**

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**Labs (continued)**

Quantity: 1 Lab status: Final result  
Instance released by: Sperry, Zel, RN (auto-released) 5/31/2019 [REDACTED]

**Specimen Information**

| ID            | Type  | Source           | Collected By                               |
|---------------|-------|------------------|--|
| 19S-151SC0826 | BLOOD | BLOOD,<br>VENOUS | Sherwood, Erica, RN 05/31/19<br>[REDACTED] |

**ED HCV SCREEN WITH REFLEX [REDACTED] (Normal)** Resulted: 05/31/19 [REDACTED], Result status: Final result

Ordering provider: Wong, Andrew Cheng-Wei, MD 05/31/19 Order status: Completed

Filed by: Dhahan, Gurdev, C.L.S 05/31/19 [REDACTED] Collected by: Sherwood, Erica, RN 05/31/19 [REDACTED]

Resulting lab: UCDHS SPECIALTY TESTING CTR CLIA number: [REDACTED]

Narrative:

No antibodies to HCV detected; a nonreactive result does not exclude the possibility of exposure to HCV.

**Components**

| Component             | Value       | Reference Range | Flag | Lab    |
|-----------------------|-------------|-----------------|------|--------|
| Hepatitis C Ab Screen | Nonreactive | Nonreactive     | —    | STCLAB |

**Testing Performed By**

| Lab - Abbreviation | Name                        | Director              | Address   | Valid Date Range                          |
|--------------------|-----------------------------|-----------------------|---|---|
| 129 - STCLAB       | UCDHS SPECIALTY TESTING CTR | Lydia P. Howell, M.D. | 3740 Business Drive<br>Sacramento CA 95820-2164 | 04/15/14 [REDACTED] - 07/01/23 [REDACTED] |

**Imaging**

**US OB 1ST TRIMESTER<14WKS (Final result) [REDACTED]**

Electronically signed by: Sperry, Zel on 05/31/19 [REDACTED] Status: Completed

This order may be acted on in another encounter.

Ordering user: Sperry, Zel 05/31/19 [REDACTED] Ordering provider: Wong, Andrew Cheng-Wei, MD

Authorized by: Wong, Andrew Cheng-Wei, MD Ordering mode: ED Triage Protocol

Frequency: STAT ONCE 05/31/19 [REDACTED] - 1 occurrence Class: Inpatient Normal

Quantity: 1 Lab status: Final result

Instance released by: Sperry, Zel, RN (auto-released) 5/31/2019 [REDACTED]

**Questionnaire**

| Question  | Answer  |
|---|---|
| Patient is high-risk, Maternal Fetal Medicine to interpret? | No  |
| Pager #:  | If you have questions, please contact Internal Triage at (916) 703-6576 |
| Date of patient's last menstrual period:                    | Patient's last menstrual period was 04/03/2019.                         |

Order comments: Indication: Patient in Emergency Department with positive UPT and Abdominal Pain or Vaginal Bleeding

**End Exam Questions**

|  | Answer | Comment |
|--|--------|---------|
| Was the exam explained to the patient?                 |        |         |
| Are images available in PACS?                          | Yes    |         |
| Was this exam performed portably?                      |        |         |
| Where was the exam performed?                          |        |         |
| Should this exam be reviewed for limited or no charge? |        |         |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Imaging (continued)

**US OB 1ST TRIMESTER<14WKS [216881863]**

Resulted: 05/31/19 [REDACTED] Result status: Final result

Ordering provider: Wong, Andrew Cheng-Wei, MD 05/31/19 [REDACTED]

Order status: Completed

Resulted by: Sekhon, Simran, MD

Filed by: Interface Radiant, Ib Results 05/31/19 [REDACTED]

Performed: 05/31/19 [REDACTED] - 05/31/19 [REDACTED]

Accession number: [REDACTED]

Resulting lab: IDX

Narrative:

US OB 1ST TRIMESTER<14WKS

EXAM DATE: 5/31/2019 [REDACTED]

COMPARISON: None

INDICATION: Indication: Patient in Emergency Department with positive UPT and Abdominal Pain or Vaginal Bleeding

TECHNIQUE: Real-time transabdominal ultrasound scanning of the female pelvis was performed by the sonographer. Endovaginal ultrasound was performed to obtain better imaging of the pelvic organs. Representative static images and video clips are submitted for review.

FINDINGS:

No intrauterine pregnancy is noted.

The endometrium is 1.5 cm in thickness and demonstrates heterogeneity. No vascular flow is seen. Heterogeneity is also noted in the endocervical canal.

The ovaries only visualized on the transabdominal portion of the exam and appear unremarkable. No adnexal masses seen. There is no free fluid.

IMPRESSION:

1. No intrauterine pregnancy is seen.
2. Heterogenous material is noted in the endometrial cavity and endocervical canal.
3. In the setting of patient passing clots and tissue, findings likely represent ongoing miscarriage.
4. Please correlate with serum beta-hCG levels and an follow-up ultrasound can be performed if clinically indicated.

Final Report Electronically Signed By: Simran Sekhon, M.D. on 5/31/2019 [REDACTED]

Testing Performed By

| Lab - Abbreviation | Name | Director | Address | Valid Date Range              |
|--------------------|------|----------|---------|-------------------------------|
| 51 - Unknown       | IDX  | Unknown  | Unknown | 10/16/05 [REDACTED] - Present |

Signed

Electronically signed by Sekhon, Simran, MD on 5/31/19 at [REDACTED]

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**Treatment Team**

| Provider                         | Service | Role               | Provider Team | Specialty             | From                | To                  |
|----------------------------------|---------|--------------------|---------------|-----------------------|---------------------|---------------------|
| Wong, Andrew<br>Cheng-Wei,<br>MD | —       | Attending          | —             | EMERGENCY<br>MEDICINE | 05/31/19 [REDACTED] | 05/31/19 [REDACTED] |
| Kunce, Kristi,<br>RN             | —       | ED Nurse           | —             | —                     | 05/31/19 [REDACTED] | —                   |
| Sherwood,<br>Erica, RN           | —       | ED Triage<br>Nurse | —             | —                     | 05/31/19 [REDACTED] | —                   |
| Stewart, Daniel<br>R, DO         | —       | ED PGY3            | —             | EMERGENCY<br>MEDICINE | 05/31/19 [REDACTED] | —                   |

**Events**

**ED Arrival at 5/31/2019 [REDACTED]**

Unit: EMERGENCY - PAVILION

**Admission at 5/31/2019 [REDACTED]**

Unit: EMERGENCY - PAVILION  
Patient class: Emergency

Room: ED DECON

Bed: EDDCON

**ED Roomed at 5/31/2019 [REDACTED]**

Unit: EMERGENCY - PAVILION  
Patient class: Emergency

Room: ED DECON

Bed: EDDCON

**Transfer In at 5/31/2019 [REDACTED]**

Unit: EMERGENCY - PAVILION  
Patient class: Emergency

Room: ED ROOM E5

Bed: E05

**ED Transfer at 5/31/2019 [REDACTED]**

Unit: EMERGENCY - PAVILION  
Patient class: Emergency

Room: ED ROOM E5

Bed: E05

**Discharge at 5/31/2019 [REDACTED]**

Unit: EMERGENCY - PAVILION  
Patient class: Emergency

Room: ED ROOM E5

Bed: E05

**Discharge at 5/31/2019 [REDACTED]**

Unit: EMERGENCY - PAVILION  
Patient class: Emergency

Room: ED ROOM E5

Bed: E05

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Case XXXXX

## Surgery Information

### General Information

|  |                      |                |
|--|----------------------|----------------|
| Date: 5/31/2019                          | Time:                | Status: Posted |
| Location: ZZZ Radiology (Don't Schedule) | Room:                | Service:       |
| Patient class:                           | Case classification: |                |

### Diagnosis Information

No post-op diagnosis codes associated with the log.

## Clinical Documentation

### Case Tracking Events

No case tracking events recorded

### Event Tracking

No event timings documented

### Patient Preparation

None

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Medication Administrations

**Fentanyl (SUBLIMAZE) Injection 50 mcg [REDACTED]**

Ordering Provider: Stewart, Daniel R, DO  
 Ordered On: 05/31/19 [REDACTED]  
 Ordered Dose (Remaining/Total): 50 mcg (0/1)  
 Frequency: ONE TIME ONLY  
 Admin Instructions: IV: IV push (undiluted) over 2 minutes

Status: Completed (Past End Date/Time)  
 Starts/Ends: 05/31/19 [REDACTED] - 05/31/19 [REDACTED]  
 Route: IV  
 Ordered Rate/Order Duration: — / —

| Timestamps                         | Action | Dose   | Route | Other Information  |
|------------------------------------|--------|--------|-------|--|
| Performed 05/31/19 [REDACTED]      | Given  | 50 mcg | IV    | Performed by: Kunce, Kristi<br>Scanned Package: 0409-9094-12 |
| Documented:<br>05/31/19 [REDACTED] |        |        |       |  |

**Ketorolac (TORADOL) Injection 15 mg [REDACTED]**

Ordering Provider: Stewart, Daniel R, DO  
 Ordered On: 05/31/19 [REDACTED]  
 Ordered Dose (Remaining/Total): 15 mg (0/1)  
 Frequency: ONE TIME ONLY  
 Admin Instructions: Maximum of 5 days of therapy.

Status: Completed (Past End Date/Time)  
 Starts/Ends: 05/31/19 [REDACTED] - 05/31/19 [REDACTED]  
 Route: IV  
 Ordered Rate/Order Duration: — / —  
 IV: IV push (undiluted) over minimum of 15 seconds.

| Timestamps                         | Action | Dose  | Route | Other Information   |
|------------------------------------|--------|-------|-------|---|
| Performed 05/31/19 [REDACTED]      | Given  | 15 mg | IV    | Performed by: Kuncce, Kristi<br>Scanned Package: 0409-3793-19 |
| Documented:<br>05/31/19 [REDACTED] |        |       |       |   |

**Misoprostol (CYTOTEC) Tablet 800 mcg [REDACTED]**

Ordering Provider: Evans, Mark W, MD  
 Ordered On: 05/31/19 [REDACTED]  
 Ordered Dose (Remaining/Total): 800 mcg (0/1)  
 Frequency: ONE TIME ONLY  
 Admin Instructions: For oral administration, take with food. For vaginal administration, the tablet dosage form is placed deep in the posterior fornix next to the cervix.

Status: Completed (Past End Date/Time)  
 Starts/Ends: 05/31/19 [REDACTED] - 05/31/19 [REDACTED]  
 Route: BUCCAL  
 Ordered Rate/Order Duration: — / —

| Timestamps                         | Action | Dose    | Route  | Other Information   |
|------------------------------------|--------|---------|--------|---|
| Performed 05/31/19 [REDACTED]      | Given  | 800 mcg | BUCCAL | Performed by: Sherwood, Erica, RN<br>Scanned Package: 68084-041-11,<br>68084-041-11, 68084-041-11, 68084-041-11 |
| Documented:<br>05/31/19 [REDACTED] |        |         |        |   |

**Rho D Immune Globulin (HYPERRHO) "mini-dose" Injection 50 mcg [REDACTED]**

Ordering Provider: Stewart, Daniel R, DO  
 Ordered On: 05/31/19 [REDACTED]  
 Ordered Dose (Remaining/Total): 50 mcg (0/1)  
 Frequency: ONE TIME ONLY  
 Admin Instructions: Each single dose syringe of HyperRHO Mini-Dose equals approximately 250 units or 50 micrograms of Rho(D) antibody.

Status: Completed (Past End Date/Time)  
 Starts/Ends: 05/31/19 [REDACTED] - 05/31/19 [REDACTED]  
 Route: IM  
 Ordered Rate/Order Duration: — / —

| Timestamps | Action | Dose | Route / Site | Other Information |
|------------|--------|------|--------------|-------------------|
|------------|--------|------|--------------|-------------------|

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

### Medication Administrations (continued)

Performed 05/31/19 Given 50 mcg IM Performed by: Sherwood, Erica, RN  
 [REDACTED] Left anterior thigh Scanned Package: 13533-661-60  
 Documented:  
 05/31/19 [REDACTED]

### Immunizations Given

Immunizations never marked as reviewed

#### RHO(D) Immune Globulin

Given by: Sherwood, Erica, RN Date: 5/31/2019 [REDACTED] Dose: 50 mcg  
 Site: Left Anterolateral fat of thigh Route: Intramuscular NDC: 13533-661-60  
 VIS Publish Date: N/A  
 Manufacturer: Grifols Therape Lot number: D2MAC00023

### Other Orders

#### Medications

#### Rho D Immune Globulin (HYPERRHO) "mini-dose" Injection 50 mcg (Completed) [REDACTED] 1

Electronically signed by: Stewart, Daniel R, DO on 05/31/19 [REDACTED] Status: Completed  
 Ordering user: Stewart, Daniel R, DO 05/31/19 [REDACTED] Ordering provider: Stewart, Daniel R, DO  
 Authorized by: Stewart, Daniel R, DO Ordering mode: Standard  
 Frequency: Urgent ONCE 05/31/19 [REDACTED] - 1 occurrence Class: Inpatient Normal  
 Acknowledged: Sherwood, Erica, RN 05/31/19 [REDACTED] for Placing Order  
 Admin instructions: Each single dose syringe of HyperRHO Mini-Dose equals approximately 250 units or 50 micrograms of Rho(D) antibody.  
 Package: 13533-661-06

#### Medication Detail

| Medication  | Ordered Dose | Frequency     | Start                | End                  |
|---|--------------|---------------|----------------------|----------------------|
| Rho D Immune Globulin (HYPERRHO) "mini-dose" Injection 50 mcg (Completed) | 50 mcg       | ONE TIME ONLY | 5/31/2019 [REDACTED] | 5/31/2019 [REDACTED] |

Route: IM  
 Admin Amount: 50 mcg

#### Admin Instructions

Each single dose syringe of HyperRHO Mini-Dose equals approximately 250 units or 50 micrograms of Rho(D) antibody.

Class: Inpatient Normal  
 Last Admin Time: 05/31/19 [REDACTED]  
 Number of Expected Doses: 1

#### E-Prescribing Detail

##### Hospital Medication Detail

|   | Dose   | Frequency     |
|---|--------|---------------|
| Rho D Immune Globulin (HYPERRHO) "mini-dose" Injection 50 mcg | 50 mcg | ONE TIME ONLY |

Admin Instructions: Each single dose syringe of HyperRHO Mini-Dose equals approximately 250 units or 50 micrograms of Rho(D) antibody.  
 Class: Inpatient Normal  
 Route: IM

#### Order Info

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Other Orders (continued)

| Date and Time        | Department           | Electronically Signed By/Authorizing |
|----------------------|----------------------|--------------------------------------|
| 5/31/2019 [REDACTED] | EMERGENCY - PAVILION | Stewart, Daniel R                    |

**Misoprostol (CYTOTEC) Tablet 800 mcg (Completed) [REDACTED]**

Status: **Completed**

Electronically signed by: **Evans, Mark W, MD on 05/31/19 [REDACTED]**  
 Ordering user: Evans, Mark W, MD 05/31/19 [REDACTED]      Ordering provider: Evans, Mark W, MD  
 Authorized by: Evans, Mark W, MD      Ordering mode: Standard  
 Frequency: ONCE 05/31/19 [REDACTED] - 1 occurrence      Class: Inpatient Normal  
 Acknowledged: Sherwood, Erica, RN 05/31/19 [REDACTED] for Placing Order  
 Admin instructions: For oral administration, take with food. For vaginal administration, the tablet dosage form is placed deep in the posterior fornix next to the cervix.  
 Package: 68084-041-01

**Medication Detail**

| Medication                                       | Ordered Dose | Frequency     | Start                | End                  |
|--|--------------|---------------|----------------------|----------------------|
| Misoprostol (CYTOTEC) Tablet 800 mcg (Completed) | 800 mcg      | ONE TIME ONLY | 5/31/2019 [REDACTED] | 5/31/2019 [REDACTED] |

Route: BUCCAL  
 Admin Amount: 4 tablet (4 x 200 mcg tablet)

**Admin Instructions**

For oral administration, take with food. For vaginal administration, the tablet dosage form is placed deep in the posterior fornix next to the cervix.

Class: Inpatient Normal  
 Last Admin Time: 05/31/19 [REDACTED]  
 Number of Expected Doses: 1

**E-Prescribing Detail**

**Hospital Medication Detail**

|                                      | Dose    | Frequency     |
|--------------------------------------|---------|---------------|
| Misoprostol (CYTOTEC) Tablet 800 mcg | 800 mcg | ONE TIME ONLY |

Admin Instructions: For oral administration, take with food. For vaginal administration, the tablet dosage form is placed deep in the posterior fornix next to the cervix.  
 Class: Inpatient Normal  
 Route: BUCCAL

**Order Info**

| Date and Time        | Department           | Electronically Signed By/Authorizing |
|----------------------|----------------------|--------------------------------------|
| 5/31/2019 [REDACTED] | EMERGENCY - PAVILION | Evans, Mark W                        |

**Fentanyl (SUBLIMAZE) Injection 50 mcg (Completed) [REDACTED]**

Status: **Completed**

Electronically signed by: **Stewart, Daniel R, DO on 05/31/19 [REDACTED]**  
 Ordering user: Stewart, Daniel R, DO 05/31/19 [REDACTED]      Ordering provider: Stewart, Daniel R, DO  
 Authorized by: Stewart, Daniel R, DO      Ordering mode: Standard  
 Frequency: ONCE 05/31/19 [REDACTED] - 1 occurrence      Class: Inpatient Normal  
 Acknowledged: Kunce, Kristi 05/31/19 [REDACTED] for Placing Order  
 Admin instructions: IV: IV push (undiluted) over 2 minutes  
 Package: 0409-9094-22

**Medication Detail**

| Medication | Ordered Dose | Frequency | Start | End |
|------------|--------------|-----------|-------|-----|
|------------|--------------|-----------|-------|-----|

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**Other Orders (continued)**

|   |        |               |                      |                      |
|---|--------|---------------|----------------------|----------------------|
| <b>Fentanyl (SUBLIMAZE) Injection 50 mcg</b><br>(Completed) | 50 mcg | ONE TIME ONLY | 5/31/2019 [REDACTED] | 5/31/2019 [REDACTED] |
|---|--------|---------------|----------------------|----------------------|

Route: IV  
Admin Amount: 1 mL = 50 mcg of 50 mcg/mL  
Volume: 2 mL

**Admin Instructions**

IV: IV push (undiluted) over 2 minutes

Class: Inpatient Normal  
Last Admin Time: 05/31/19 [REDACTED]  
Number of Expected Doses: 1

**E-Prescribing Detail**

**Hospital Medication Detail**

|  | Dose   | Frequency     |
|--|--------|---------------|
| <b>Fentanyl (SUBLIMAZE) Injection 50 mcg</b><br>Admin Instructions: IV: IV push (undiluted) over 2 minutes<br>Class: Inpatient Normal<br>Route: IV | 50 mcg | ONE TIME ONLY |

**Order Info**

| Date and Time        | Department           | Electronically Signed By/Authorizing |
|----------------------|----------------------|--------------------------------------|
| 5/31/2019 [REDACTED] | EMERGENCY - PAVILION | Stewart, Daniel R                    |

**Ketorolac (TORADOL) Injection 15 mg (Completed) [REDACTED]**

Electronically signed by: **Stewart, Daniel R, DO** on 05/31/19 [REDACTED] Status: **Completed**  
 Ordering user: Stewart, Daniel R, DO 05/31/19 [REDACTED] Ordering provider: Stewart, Daniel R, DO  
 Authorized by: Stewart, Daniel R, DO Ordering mode: Standard  
 Frequency: ONCE 05/31/19 [REDACTED] - 1 occurrence Class: Inpatient Normal  
 Acknowledged: Kunce, Kristi 05/31/19 [REDACTED] for Placing Order  
 Admin instructions: Maximum of 5 days of therapy.  
 IV: IV push (undiluted) over minimum of 15 seconds.  
 Package: 0409-3793-01

**Medication Detail**

| Medication  | Ordered Dose | Frequency     | Start                | End                  |
|---|--------------|---------------|----------------------|----------------------|
| <b>Ketorolac (TORADOL) Injection 15 mg</b><br>(Completed) | 15 mg        | ONE TIME ONLY | 5/31/2019 [REDACTED] | 5/31/2019 [REDACTED] |

Route: IV  
Admin Amount: 1 mL = 15 mg of 15 mg/mL  
**Admin Instructions**  
Maximum of 5 days of therapy.  
IV: IV push (undiluted) over minimum of 15 seconds.

Class: Inpatient Normal  
Last Admin Time: 05/31/19 [REDACTED]  
Number of Expected Doses: 1

**E-Prescribing Detail**

**Hospital Medication Detail**

|  | Dose  | Frequency     |
|--|-------|---------------|
| <b>Ketorolac (TORADOL) Injection 15 mg</b> | 15 mg | ONE TIME ONLY |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**Other Orders (continued)**

Admin Instructions: Maximum of 5 days of therapy.  
IV: IV push (undiluted) over minimum of 15 seconds.  
Class: Inpatient Normal  
Route: IV

**Order Info**

| Date and Time        | Department           | Electronically Signed By/Authorizing |
|----------------------|----------------------|--------------------------------------|
| 5/31/2019 [REDACTED] | EMERGENCY - PAVILION | Stewart, Daniel R                    |

**Ibuprofen (MOTRIN) 600 mg Tablet (Expired) [REDACTED]**

Electronically signed by: **Stewart, Daniel R, DO on 05/31/19 [REDACTED]** Status: **Expired**  
 Ordering user: Stewart, Daniel R, DO 05/31/19 [REDACTED] Ordering provider: Stewart, Daniel R, DO  
 Authorized by: Stewart, Daniel R, DO Ordering mode: Standard  
 Frequency: Routine Q6H PRN 05/31/19 - 5 days Class: Print  
 Admin instructions: take with food

**Medication Detail**

| Medication                                 | Quantity  | Refills | Start     | End      |
|--|-----------|---------|-----------|----------|
| Ibuprofen (MOTRIN) 600 mg Tablet (Expired) | 30 tablet | 0       | 5/31/2019 | 6/5/2019 |

Sig: Take 1 tablet by mouth every 6 hours if needed. take with food  
 Route: ORAL  
 Class: Print

**E-Prescribing Detail**

**Outpatient Medication Detail**

**Ibuprofen (MOTRIN) 600 mg Tablet**

Sig: Take 1 tablet by mouth every 6 hours if needed.  
 take with food  
 Class: Print  
 Route: ORAL

**Order Info**

| Date and Time        | Department           | Electronically Signed By/Authorizing |
|----------------------|----------------------|--------------------------------------|
| 5/31/2019 [REDACTED] | EMERGENCY - PAVILION | Stewart, Daniel R                    |

**Acetaminophen (TYLENOL EXTRA STRENGTH) 500 mg Tablet (Expired) [REDACTED]**

Electronically signed by: **Stewart, Daniel R, DO on 05/31/19 [REDACTED]** Status: **Expired**  
 Ordering user: Stewart, Daniel R, DO 05/31/19 [REDACTED] Ordering provider: Stewart, Daniel R, DO  
 Authorized by: Stewart, Daniel R, DO Ordering mode: Standard  
 PRN reasons: pain Class: Print  
 Frequency: Routine Q8H PRN 05/31/19 - 5 days

**Medication Detail**

| Medication   | Quantity  | Refills | Start     | End      |
|--|-----------|---------|-----------|----------|
| Acetaminophen (TYLENOL EXTRA STRENGTH) 500 mg Tablet (Expired) | 30 tablet | 0       | 5/31/2019 | 6/5/2019 |

Sig: Take 2 tablets by mouth every 8 hours if needed for pain.  
 Route: ORAL  
 PRN Reason(s): pain  
 Class: Print

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Other Orders (continued)

E-Prescribing Detail

Outpatient Medication Detail

Acetaminophen (TYLENOL EXTRA STRENGTH) 500 mg Tablet

Sig: Take 2 tablets by mouth every 8 hours if needed for pain.

Class: Print

Route: ORAL

Order Info

| Date and Time        | Department           | Electronically Signed By/Authorizing |
|----------------------|----------------------|--------------------------------------|
| 5/31/2019 [REDACTED] | EMERGENCY - PAVILION | Stewart, Daniel R                    |

Physician Consult

OBSTETRICS AND GYNECOLOGY CONSULT (Completed) [REDACTED] 1

Electronically signed by: Stewart, Daniel R, DO on 05/31/19 [REDACTED] Status: Completed  
 Ordering user: Stewart, Daniel R, DO 05/31/19 [REDACTED] Ordering provider: Stewart, Daniel R, DO  
 Authorized by: Wong, Andrew Cheng-Wei, MD Ordering mode: Standard  
 Frequency: Routine ONCE 05/31/19 [REDACTED] - 1 occurrence Class: Inpatient Normal  
 Quantity: 1 Instance released by: Stewart, Daniel R, DO (auto-released) 5/31/2019 [REDACTED]

Questionnaire

| Question              | Answer                                      |
|-----------------------|---|
| Clinical Indications: | vaginal bleeding.enrolled in research study |

Order Info

| Date and Time        | Department           | Electronically Signed By | Authorizing            |
|----------------------|----------------------|--------------------------|------------------------|
| 5/31/2019 [REDACTED] | EMERGENCY - PAVILION | Stewart, Daniel R        | Wong, Andrew Cheng-Wei |

Flowsheets

Custom Formula Data

| Row Name | 05/31/19 [REDACTED] | 05/31/19 [REDACTED] | 05/31/19 [REDACTED] | 05/31/19 1628 | 05/31/19 [REDACTED] |
|----------|---------------------|---------------------|---------------------|---------------|---------------------|
|----------|---------------------|---------------------|---------------------|---------------|---------------------|

Relevant Labs and Vitals

|                   |          |        |   |          |          |
|-------------------|----------|--------|---|----------|----------|
| Temp (in Celsius) | 36.9 -KK | 37 -ES | — | 36.9 -ES | 36.4 -ZS |
|-------------------|----------|--------|---|----------|----------|

OTHER

|   |   |   |        |   |   |
|---|---|---|--------|---|---|
| Calculated row for use by alert logic - not for staff use or review (PECARN TBI-KT) | — | — | 15 -ES | — | — |
|---|---|---|--------|---|---|

DATA VALIDATE

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

Flowsheets (continued)

| Row Name      | 05/31/19  | 05/31/19   | 05/31/19   |
|---------------|-----------|------------|------------|
| <b>Vitals</b> |           |            |            |
| BP            | 99/86 -KK | 112/63 -ES | 131/74 -ES |
| Pulse         | —         | 102 -ES    | —          |
| SpO2          | —         | 100 % -ES  | —          |
| MAP cuff      | 92 -KK    | 79 -ES     | 90 -ES     |

ED Vitals

| Row Name                             | 05/31/19                                   | 05/31/19                   | 05/31/19                   |
|--------------------------------------|--|----------------------------|----------------------------|
| <b>Vitals</b>                        |  |                            |                            |
| Restart Vitals Timer                 | Yes -KK                                    | Yes -ES                    | Yes -ES                    |
| Temp                                 | 36.9 °C (98.4 °F) -<br>KK                  | 37 °C (98.6 °F) -ES        | 36.9 °C (98.4 °F) -<br>ES  |
| Temp (Celsius)                       | 36.9 C -KK                                 | 37 C -ES                   | 36.9 C -ES                 |
| Temp src                             | Oral -KK                                   | Oral -ES                   | Oral -ES                   |
| Pulse                                | 84 -KK                                     | —                          | 94 -ES                     |
| Resp                                 | 15 -KK                                     | 17 -ES                     | 18 -ES                     |
| SpO2                                 | 100 % -KK                                  | —                          | 98 % -ES                   |
| Device (Oxygen Therapy)              | room air -KK                               | room air -ES               | room air -ES               |
| Restart Vitals Timer? (Automatic)    | Yes -KK                                    | Yes -ES                    | Yes -ES                    |
| <b>Pain</b>                          |  |                            |                            |
| Presence of Pain                     | complains of pain/discomfort -KK           | denies pain/discomfort -ES | denies pain/discomfort -ES |
| (0-10) Pain Rating: Rest             | 8 -KK                                      | —                          | —                          |
| <b>Pain</b>                          |  |                            |                            |
| (RETIRED SPR19) Quality              | cramping -KK                               | —                          | —                          |
| (RETIRED SPR19) Pain Body Location   | abdomen -KK                                | —                          | —                          |
| <b>Pain</b>                          |  |                            |                            |
| (RETIRED SPR19) Preferred Pain Scale | number (Numeric Rating Pain Scale) -<br>KK | —                          | —                          |

INITIAL RN ASSESSMENT

| Row Name                       | 05/31/19                    |
|--------------------------------|-----------------------------|
| <b>Initial RN Assessment</b>   |                             |
| Initial RN Assessment Started? | yes -ES                     |
| <b>Airway</b>                  |                             |
| Airway Patent?                 | Yes -ES                     |
| <b>Breathing</b>               |                             |
| Breathing                      | Spontaneous;Symmetrical -ES |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**Flowsheets (continued)**

|                                    |                                     |
|------------------------------------|-------------------------------------|
| Trachea                            | Midline -ES                         |
| Lung Sounds:<br>Right              | Clear -ES                           |
| Lung Sounds:<br>Left               | Clear -ES                           |
| <b>Circulation</b>                 |                                     |
| Circulation                        | Cap. Refill <3<br>Sec.;Warm;Dry -ES |
| <b>Neuro</b>                       |                                     |
| AVPU:                              | Alert -ES                           |
| Glasgow Coma<br>Scale              | Adult -ES                           |
| Best Eye<br>Response               | 4-->(E4)<br>spontaneous -ES         |
| Best Verbal<br>Response            | 5-->(V5) oriented -<br>ES           |
| Best Motor<br>Response             | 6-->(M6) obeys<br>commands -ES      |
| Glasgow Coma<br>Scale Score        | 15 -ES                              |
| <b>Pupils</b>                      |                                     |
| Pupil Size Right                   | 3 mm -ES                            |
| Pupil Reaction<br>Right            | equal -ES                           |
| Pupil Size Left                    | 3 mm -ES                            |
| Pupil Reaction<br>Left             | equal -ES                           |
| <b>Cognitive/Perceptual/Neuro</b>  |                                     |
| Cognitive/Neuro/<br>Behavioral WDL | WDL -ES                             |
| <b>Sleep/Rest/Relaxation</b>       |                                     |
| Sleep/Rest/Relax<br>ation          | awake -ES                           |
| <b>Coping</b>                      |                                     |
| Observed<br>Emotional State        | anxious -ES                         |
| Verbalized<br>Emotional State      | anxiety -ES                         |
| <b>Pulses</b>                      |                                     |
| Pulses<br>assessment               | WDL -ES                             |
| <b>Capillary Refill</b>            |                                     |
| Cap refill<br>assessment           | WDL -ES                             |
| <b>Strength</b>                    |                                     |
| Strength<br>assessment             | WDL -ES                             |
| <b>Sensation</b>                   |                                     |
| Sensation<br>assessment            | WDL -ES                             |
| <b>Chest Pain?</b>                 |                                     |
| Chest Pain ?                       | No -ES                              |
| <b>Edema</b>                       |                                     |
| Edema                              | WDL -ES                             |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**Flowsheets (continued)**

assessment

**Respiratory assessment**

Respiratory assessment WDL -ES

**Pulm Secretions**

Pulmonary secretions assessment WDL -ES

**Gastrointestinal**

GI Assessment WDL -ES

**Urine**

Urine assessment  UTA not yet observed -ES

**Skin**

Skin assessment WDL -ES


Head of Bed (HOB) Positioning HOB at 30 degrees -ES

Body Position supine -ES

Patch/Ointment present? (Admit/ED) No -ES

**Head to Toe Assessment**

Head to Toe WDL Except -ES

G/U Vaginal Bleeding:No Trauma  8wks 3 days pregnant -ES

**Compliance Documentation**

ID band On -ES

Recently been threatened/injured? No -ES

(RETIRED SPR19) Allergy band N/A -ES

**Falls assessment**

Falls Risk: Adult -ES

**Adult ED Falls Assessment**

History of falls? No -ES

Risk for falls? No -ES

**Med Rec Acuity Score**


| Row Name             | 05/31/19 | 05/31/19 |
|----------------------|----------|----------|
| OTHER                |          |          |
| Med Rec Acuity Score | 0 -BE    | 0 -BE    |


**Social Drivers**

| Row Name         | 05/31/19          |
|------------------|-------------------|
| Alcohol Use      |                   |
| Q1: How often do | 2-4 times a month |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**Flowsheets (continued)**

you have a drink containing alcohol?  Data migrated from History -DS

Q2: How many drinks containing alcohol do you have on a typical day when you are drinking? **1 or 2**  Data migrated from History -DS

**Suicide Violence Screen/Restraints**

| Row Name             | 05/31/19 |
|----------------------|----------|
| <b>OTHER</b>         |          |
| Suicide Risk Present | No -ZS   |

**Triage Dispo**

| Row Name                       | 05/31/19  | 05/31/19     |
|--------------------------------|-----------|--------------|
| <b>Additional Patient Info</b> |           |              |
| Referred In?                   | —         | No -ZS       |
| Interpreter needed             | —         | No -ZS       |
| Preferred language             | —         | English -ZS  |
| <b>High Risk Discharge</b>     |           |              |
| Admitted From                  | —         | Home -ZS     |
| <b>Triage Dispo</b>            |           |              |
| Triage Category                | —         | 3 Yellow -ZS |
| Destination                    | C Pod -ZS | RC Treat -ZS |
| Current Location               | —         | Waiting -ZS  |

**Triage Vitals**

| Row Name                          | 05/31/19              |
|-----------------------------------|-----------------------|
| <b>Triage Vitals</b>              |                       |
| BP                                | 125/79 -ZS            |
| Pulse                             | 97 -ZS                |
| Resp                              | 15 -ZS                |
| Temp                              | 36.4 °C (97.5 °F) -ZS |
| Temp (Celsius)                    | 36.4 C -ZS            |
| Temp src                          | Oral -ZS              |
| SpO2                              | 100 % -ZS             |
| Restart Vitals Timer? (Automatic) | Yes -ZS               |
| <b>Pain</b>                       |                       |
| (0-10) Pain Rating: Rest          | 8 -ZS                 |
| <b>Pain</b>                       |                       |
| (RETIRED SPR19) Pain              | abdomen -ZS           |

05/31/2019 - ED in EMERGENCY - PAVILION (continued)

**Flowsheets (continued)**

Body Location

**Pain**

(RETIRED number (Numeric  
SPR19) Rating Pain Scale) -  
Preferred Pain ZS  
Scale

**User Key**

(r) = Recorded By, (t) = Taken By, (c) = Cosigned By

| Initials | Name                  | Provider Type        | Discipline        |
|----------|-----------------------|----------------------|-------------------|
| BE       | Epic, Batchq          | —                    | —                 |
| KK       | Kunce, Kristi         | .NURSE: (RN or LVN)  | Interdisciplinary |
| ES       | Sherwood, Erica, RN   | .NURSE: (RN or LVN)  | nurse             |
| ZS       | Sperry, Zel           | .NURSE: (RN or LVN)  | nurse             |
| DS       | Stewart, Daniel R, DO | *PHYSICIAN: RESIDENT | Interdisciplinary |

**Coding Summary**

XXXXXX

**Admission Information**

|                                     |  |                            |
|-------------------------------------|--|----------------------------|
| Arrival Date/Time: 05/31/2019       | Admit Date/Time: 05/31/2019                    | IP Adm. Date/Time:         |
| Admission Type: Emergency Admission | Point of Origin: Emergency Room                | Admit Category:            |
| Means of Arrival: Sac Metro Fire    | Primary Service: Emergency Medicine            | Secondary Service:         |
| Transfer Source:                    | Service Area: UCDHS SERVICE AREA               | Unit: EMERGENCY - PAVILION |
| Admit Provider:                     | Attending Provider: Wong, Andrew Cheng-Wei, MD | Referring Provider:        |

**Discharge Information**

| Discharge Date/Time | Discharge Disposition                               | Discharge Destination | Discharge Provider         | Unit                 |
|---------------------|---|-----------------------|----------------------------|----------------------|
| 05/31/2019          | Discharged To Home Or Self Care (Routine Discharge) | None                  | Wong, Andrew Cheng-Wei, MD | EMERGENCY - PAVILION |

**Admission Diagnoses / Reasons for Visit (ICD-10-CM)**

| Code  | Description   | Comments         |
|-------|---|------------------|
| O03.9 | Complete or unspecified spontaneous abortion without complication | vaginal bleeding |

**Final Diagnoses (ICD-10-CM)**

| Code              | Description   | POA | CC | HAC | Affects DRG |
|-------------------|---|-----|----|-----|-------------|
| O03.9 [Principal] | Complete or unspecified spontaneous abortion without complication |     |    |     |             |

**CPT®/HCPCS Codes**

| Code         | Modifiers | Date       | Qty | Performing Provider        | APC | Exp Reimb | Px Event |
|--------------|-----------|------------|-----|----------------------------|-----|-----------|----------|
| 99285 (CPT®) | 25        | 05/31/2019 | 1   | Wong, Andrew Cheng-Wei, MD |     |           |          |

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05/31/2019 - ED in EMERGENCY - PAVILION (continued)

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Coding Summary (continued)

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XXXXXX

# UC DAVIS HEALTH

**Acknowledgement of Emergency Treatment**  
5/31/2019

XXXXXX

### Emergency Department Visit Information

#### Arrival Information

Arrival

5/31/2019

Means of Arrival

Sac Metro Fire

Escorted By

#### You were seen by:

Wong, Andrew Cheng-Wei, MD

#### Your diagnosis was:

Complete abortion - Primary

Comments

#### Acknowledgement of Receipt

I acknowledge receipt of instructions indicated above. I understand that I have had emergency treatment only, and that I may be released before all of my medical problems are known or treated. I will arrange follow-up care as instructed above.

If my condition appears worse, I will contact my physician or return to the Emergency Department.

XXXXXX

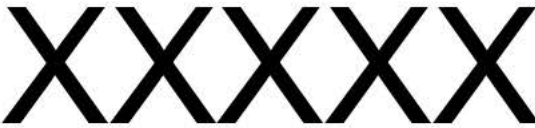
Patient Signature

Provider Signature

Date:

#### \*\*\*Important Note\*\*\*

A full version of the After Visit Summary report is available in EMR in the Chart Review activity.



**NON-MEDICARE OUTPATIENT  
OBSERVATION NOTICE**

Patient Name:

Medical Record Number:

Date:

You are receiving this written notice because:

- You were or are receiving observation service during your hospital stay.
- Your observation service is considered an outpatient status provided by and ordered by your physician.

Observation services may affect coverage and payment of your care after you leave the hospital:

- While on observation status, your care is being provided on an outpatient basis which may affect your health care reimbursement. Check with your Health Plan for any deductibles or co-pays that may apply. The phone number or website is usually found on your insurance card.
- If you are uninsured, please ask to see a hospital financial counselor to discuss your options.
- If you have any questions about your outpatient observation status, you may call the case management department @ 916-889-6887.

Please sign below to show you received this notice.



Signature of Patient or Representative

Date / Time

Please also print your name if you are the representative for the patient.



**ACKNOWLEDGEMENT OF RECEIPT:  
NOTICE OF PRIVACY PRACTICES**

The UC Davis Health System Notice of Privacy Practices provides information about how we may use and disclose protected health information about you.

In addition to the copy we are providing you, copies of the current notice are available by accessing our Web site at <http://www.ucdmc.ucdavis.edu/compliance/> and may be obtained throughout UC Davis Health System.

I acknowledge that I have received the Notice of Privacy Practices.



Signature of Patient or Patient's Representative

Date

Print Name

Relationship to Patient

Interpreter (If applicable)

**Written Acknowledgement Not Obtained**

Please document your efforts to obtain acknowledgment and reason it was not obtained.

- Notice of Privacy Practices Given – Patient Unable to Sign
- Notice of Privacy Practices Given – Patient Declined to Sign
- Notice of Privacy Practices Mailed to Patient – Awaiting Signature
- Other Reason Patient Did Not Sign \_\_\_\_\_

Signature of UC Davis Health System Representative

Date

Print Name

Department



XXXXXX



Metro Fire PCR

Patient Information

XXXXXXXXXX

Response Times & Units

EMS Unit Call Sign: M101      Primary Role of Unit: Ground Transport      1st on Scene: Yes      Other BLS/ALS Agency on Scene: None

Metro Fire Engine/Truck on Scene: E101      Transporting Unit #: M101

Unit En Route: 05/31/2019 [REDACTED]      At Patient: 05/31/2019 [REDACTED]      In Service: 05/31/2019 [REDACTED]

Dispatched: 05/31/2019 [REDACTED]      At Scene: 05/31/2019 [REDACTED]      Depart: 05/31/2019 [REDACTED]      Wall Time - APOT: 05/31/2019 [REDACTED]

Total Mileage: 7.3

Call Type/Location/Disposition

Incident Address: [REDACTED]

Location: Private Residence / Apartment      Response: 911 Response (Scene)

Call Type: Pregnancy/Childbirth/Miscarriage      Resp. Mode: Emergent (Immediate Response)

Disposition: Treated/Transported      Transport Mode: Non-Emergent

Destination: University Of California, Davis Medical Center - UCD      Dest. Determ.: Patient's Choice

# of Patients at Scene: Single

How Patient Was Moved to Ambulance: Assisted/Walk

Past Medical History

Medical History: OB - Miscarriage

Other Past Medical History: G8P1A6

Patient Medications

| Patient Medications | Dosage | Route |
|---------------------|--------|-------|
| None                |        |       |

Medication Allergies

Medication Allergies: No Known Drug Allergy

Patient Condition

Chief Complaint

| Complaint Type  | Complaint        | Duration |
|-----------------|------------------|----------|
| Chief (Primary) | Vaginal bleeding | 2 Hours  |

Date/Time of Symptom Onset: 05/31/2019 [REDACTED]      Primary Symptom: Abnormal uterine and vaginal bleeding

Alcohol/Drug Use: Patient Denies Alcohol/Drug Use

Possible Injury: No      Cardiac Arrest: No

Provider Impression

Primary Impression: Vaginal Bleeding

Protocols Used

| Protocols Used            | Protocol Age Category |
|---------------------------|-----------------------|
| General Medical Complaint | Adult                 |

XXXXXXXXXX

Assessment

Assessment Summary

05/31/2019 [REDACTED]

| Location | Description      | Detailed Findings     | Details |
|----------|------------------|-----------------------|---------|
| Eye      | Bilateral:       | Reactive              |         |
|          | Left:            | Reactive              |         |
|          | Right:           | Reactive              |         |
| Pelvis   | Bleeding-Vaginal | Bleeding Uncontrolled |         |

Normal Findings

Skin ; Mental Status ; Neurological ; Head ; Face ; Eye ( ) ; Neck ; Shoulder ( Shoulder-Left, Shoulder-Right ) ; Chest/Lungs ; Abdomen ( Generalized, Left Lower Quadrant, Left Upper Quadrant, Periumbilical, Right Lower Quadrant, Right Upper Quadrant, Epigastric ) ; Back/Spine ( Back-General, Cervical-Left, Cervical-Midline, Cervical-Right, Crush Injury, Lumbar-Left, Lumbar-Midline, Lumbar-Right, Sacral-Left, Sacral-Midline, Sacral-

Printed: 05/31/2019 [REDACTED]

XXXXXX

Unit ID: M101

XXXXX

Right, Thoracic-Left, Thoracic-Midline, Thoracic-Right ) ;

Not Done

Vitals Signs

| PTA | Time | GCS | Systolic | Diastolic | Pulse | Vitals Resp | Effort | SpO2 | Qualified   | Crew                      |
|-----|------|-----|----------|-----------|-------|-------------|--------|------|-------------|---------------------------|
| No  |      | 15  | 100      |           | 90    | 20          | Normal |      |             | Fritz, Kyle (P32850)      |
| No  |      | 15  | 150      | 80        | 100   | 20          | Normal | 98   | At Room Air | Majestic, Jordan (P35629) |
| No  |      | 15  | 126      | 74        | 94    | 16          | Normal | 99   | At Room Air | Majestic, Jordan (P35629) |

Narrative

ATF pt sitting on toilet A/Ox4 GCS 15 complaining of vaginal bleeding for the past 2 hours. Pt stated 8 weeks 3 days pregnant confirmed by ultrasound this morning. Bleeding began after Ob/GYN appointment this morning and no issues were found from appointment. Pt G8P1A6 with last miscarriage in January 2019. Skin pink, warm and dry with no signs of trauma. Blood clots present in toilet, with pt stating she has only gone through 1 liner today for bleeding. Pt was assisted to gurney with no increase in bleeding. En route Pt stating that she feels like she is still bleeding, with associated cramping that comes and goes. No secondary complaints. TXP to UCD without incident. Care to Er Rn with full report. End.

Base Hospital Contact & Pre Arrival Alerts

Was a Base Hospital No Contacted?:

Unit Personnel

| Crew Member               | Level of Certification | Role  |
|---------------------------|------------------------|---|
| Huckaby, Adam (P27478)    | EMT-Paramedic          | First Responder   |
| Sahaydak, Julian (P29525) | EMT-Paramedic          | First Responder   |
| Fritz, Kyle (P32850)      | EMT-Paramedic          | First Responder   |
| Getreu, Tyler (P34642)    | EMT-Paramedic          | First Responder   |
| Dupray, Nicholas (P33402) | EMT-Paramedic          | Driver/Pilot - Transport; Driver/Pilot-Response                           |
| Majestic, Jordan (P35629) | EMT-Paramedic          | Primary Patient Caregiver - Transport; Primary Patient Caregiver-At Scene |

Signatures

Type of Person Signing: Healthcare Provider

Signature Reason: Ambulance Patient Offload Time

Printed Name: Erica Rn

Signature Date:

Signature Status: Signed

*Erica Shwood*

Type of Person Signing: EMS Primary Care Provider (for this event)

Signature Reason: EMS Provider

Printed Name: Jordan Majestic

Signature Date: 05/31/2019

Signature Status: Signed

*JM*

XXXXXXXX

Type of Person Signing: Patient

Signature Reason: Permission to Transport; Permission to Treat; HIPAA Acknowledgement/Release; Release for Billing

Printed Name: Ericnikkia Delk

Signature Date: 05/31/2019

Signature Status: Signed

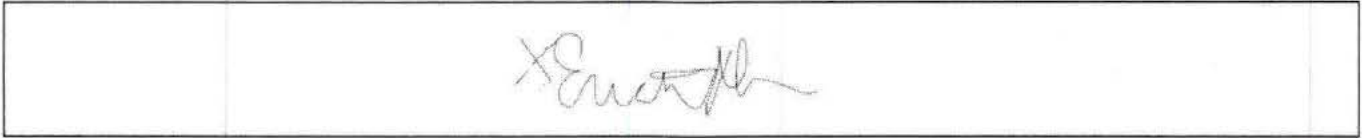


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Attachments

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Modified By: Jordan Majestic  
Modified On: 05/31/2019

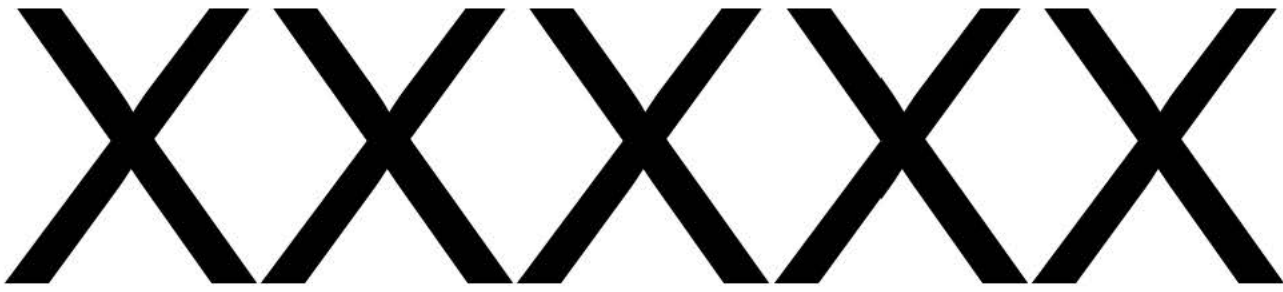
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Unit ID: M101

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TERMS AND CONDITIONS OF SERVICE

1. UCDH (UCDH) is part of the University of California and is comprised of the UCDH Medical Center, its hospital-based clinics, the Primary Care Network clinics, the UCDH Medical Group, and the UC Davis School of Medicine.

2. MEDICAL CONSENT: I consent to any medical treatments or procedures, X-ray examinations, drawing blood for tests, medications, injections, telehealth services, taking of medical photographs, videotaping, laboratory procedures, and hospital services (except for those which require special consent) rendered to me under the general and special instructions of the attending physicians, or other physicians of UCDH assisting in my care.

3. ADMISSION TO THE HOSPITAL: I also consent to my admission to UCDH Medical Center if this is deemed necessary for my care. All of the terms and conditions of this agreement shall also apply to such admission.

4. TEACHING, RESEARCH AND HEALTHCARE INSTITUTION: The University of California, including UCDH, is a teaching, research and healthcare institution. I understand that medical residents, medical students, students of ancillary health care professions (e.g., nursing, x-ray, rehabilitation therapy), post-graduate fellows, and other trainees may observe, examine, treat or otherwise participate in my care at the request and under the supervision of my health care provider as part of the University's medical education programs. I understand that my health information may be used and shared with researchers who engage in research, teaching and study related to my treatment, health condition, specimens and/or medical or physical status. Additionally, as a result, potentially commercially useful products may be developed and I understand that I will have no ownership rights in those products. Any use of my medical information and/or specimens by UCDH or other institutions will be in accordance with state and federal law, including all laws and regulations governing confidentiality of patient records.

5. RELEASE OF INFORMATION: UCDH will obtain my written authorization to release information about my medical treatment, except in those circumstances when UCDH is permitted or required by law to release information (see UCDH's Notice of Privacy Practices for a description of the specific circumstances under which UCDH may release this information). For example, UCDH may release a copy of my patient record to other health care providers, health plans and government agencies. Additionally, I understand that if I am diagnosed with cancer, a reportable disease in California, UCDH is required by law to report my diagnosis to the State Department of Health Services.

6. PERSONAL VALUABLES: UCDH maintains fireproof safes for the safekeeping of money and valuables. UCDH shall not be liable for the loss of or damage to any money, documents, jewelry, glasses, dentures, furs or other articles of unusual value and shall not be liable for loss or damage to any personal property, unless deposited in UCDH's safe or locked storeroom. The liability for loss of any personal property deposited with UCDH shall be no more than \$500.00.

7. USE AND DISCLOSURE OF MEDICAL INFORMATION: The California Information Practices Act requires UCDH to provide the following information to individuals who supply information about themselves: As a patient of UCDH, you will be asked to submit information about yourself, such as your address and phone number, Social Security number, insurance information, medical history and treatment, and other personal information. The principal purpose for requesting this information is to ensure accurate identification, continuity of medical care, and payment for such care.

University policy, California and federal law and regulations authorize the maintenance of this information. Furnishing all information requested is mandatory unless otherwise noted. Failure to provide such information may affect your medical care and/or insurance benefits and coverage. The information you provide may be disclosed to others, however, you have the right to review your



TERMS AND CONDITIONS OF SERVICE

medical information and the right to request restriction of access to your medical information, as described in the Notice of Privacy Practices. If you would like your agent under a durable power of attorney for health care or your next of kin to receive a copy of your rights and responsibilities as a patient of UCDH (Notice of Privacy Practices & Patient Rights and Responsibilities Notice), please contact the Health Information Management Department at (916) 734-5205.

8. FINANCIAL AGREEMENT: I agree to pay The Regents of the University of California for professional, hospital and clinic services, including UCDH physician services, in accordance with the Charge Master in effect on the date of service. I also agree to pay for other professional services provided by other physicians at UCDH. Should the account be referred to an attorney or collection agency for collection, I agree to be responsible for all collection fees (attorney's fees, costs and collection expenses) in addition to any other amounts due. Unpaid accounts referred to outside agencies for collection also bear interest at the then current legal rate.

9. ASSIGNMENT OF BENEFITS (INCLUDING MEDICARE BENEFITS): I authorize and direct the payment to UCDH of any insurance benefits including hospital insurance and unemployment compensation disability benefits otherwise payable to or on my behalf for UCDH services, including emergency services, at a rate not to exceed those in the Charge Master in effect on the date of service. I understand that I am financially responsible for charges not paid pursuant to this agreement. I further agree that any credit balance resulting from payment of insurance or other sources may be applied to any other account owed to UCDH by me.

10. NOTICE TO CONSUMERS

Medical doctors are licensed and regulated by the Medical Board of California. For information or complaints regarding medical doctors, you may contact the Medical Board of California at (800) 633-2322 and/or online at www.mbc.ca.gov.

Physician Assistants are licensed and regulated by the Physician Assistant Committee. For information or complaints regarding physician assistants, you may contact the Physician Assistant Committee at (916) 561-8780 and/or online at www.pac.ca.gov.

I have read, agreed to and received a copy of this Terms and Conditions of Service.

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Signature of Patient

or Signature of Patient's Representative

Relationship of Representative to Patient

Signature of Interpreter

Signature of Witness (required if patient unable to sign)

05-31-19 Date of Signing

For office use only: EXCEPTIONAL SIGNATURE REQUIREMENTS ARE REFERENCED BELOW. Please check the appropriate box(es).
[ ] PATIENT IS LEGALLY INCOMPETENT TO SIGN: The court approved guardian or conservator, the agent under an Advance Directive, or family member or other appropriate surrogate must sign as "Patient's Representative."
[ ] PATIENT IS PHYSICALLY INCAPABLE OF SIGNING: The patient should give verbal consent, witnessed by a UCDH employee. The Patient's Representative should sign in witness of the patient having given verbal consent. The UCDH employee witness shall also sign.

## Sarah M Behrendt

---

**From:** Kelly C. Cleland <kcleland@Princeton.EDU>  
**Sent:** Thursday, December 5, 2019 9:12 AM  
**To:** Mitchell D Creinin  
**Subject:** RE: Mifepristone Stakeholders - revised talking points

**Importance:** High

**Follow Up Flag:** Follow up  
**Flag Status:** Completed

**Categories:** Green Category

Hi Mitch,

I just got off the phone with Kirsten and some people from Conway – Conway is working with ACN on revised talking points that they are going to circulate later this afternoon. They want to get something out before the article and NPR story with the assumption that people are going to start getting phone calls right away. The challenge is that people will of course want to see the article before they talk to media.

Can we send the article out to the mife coalition along with the talking points in a couple of hours? I know it's embargoed until 5 but it seems important for folks to have access to the article along with the messages. They can send with an embargo stamp so people know not to share widely.

Please

Kelly Cleland, MPA MPH (she/her)  
218 Wallace Hall  
Princeton, NJ 08544  
609.258.1395  
[kcleland@princeton.edu](mailto:kcleland@princeton.edu)

<http://americansocietyforec.org/>  
[www.not-2-late.com](http://www.not-2-late.com)

EXHIBIT  
67

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**From:** Mitchell D Creinin <mdcreinin@ucdavis.edu>

**Sent:** Thursday, December 5, 2019 11:26 AM

**To:** Abigail Long - Danco (ALong@earlyoptionpill.com) <along@earlyoptionpill.com>; Alice Mark <amark@prochoice.org>; Autumn Katz <AKatz@reprorights.org>; abeck@aclu.org; adennis@societyfp.org; Angel Foster <Angel.Foster@uottawa.ca>; Callie Langton <clangton@stbfoundation.org>; Dean, Gillian <gillian.dean@PPFA.ORG>; Carolyn Westhoff (clw3@columbia.edu) <clw3@columbia.edu>; jgirdish@prh.org; Grossman, Daniel <daniel.grossman@ucsf.edu>; Schreiber, Courtney <Courtney.Schreiber@uphs.upenn.edu>; Jenny O'Donnell <jodonnell@societyfp.org>; Kirsten Moore <Kirsten.Moore@emaaproject.org>; White, Kari <kariwhite@utexas.edu>; jennifer@abortioncarenetwork.org; Kelly C. Cleland <kcleland@Princeton.EDU>; Shiri Hickman <shickman@acog.org>; Clark, Liz <elizabeth.clark@PPFA.ORG>; Melissa Joy Chen <mejchen@ucdavis.edu>; jennifer@prh.org; Courtney Overstreet <cboverstreet@ucdavis.edu>; lorilrfps@sbcglobal.net; Tracy Weitz - Susan Thompson Buffett Foundation (tweitz@stbfoundation.org) <tracy.weitz@gmail.com>; sophia@stateinnovation.org; mchristin@acog.org

**Cc:** Rebecca Starr Saeteurn <rssaeteurn@ucdavis.edu>

**Subject:** Re: Mifepristone Stakeholders - revised talking points

With some additional comments from our comms experts.

A medical journal listserv has the paper listed so we have already started getting a lot of requests, including from Europe. I know that some of you will get requests for comments as well. Based on some additional feedback, I will be sending this information to the FP fellowship and Ryan Program listservs around 4 pm today (Eastern).

Of note, I have already been asked about this perceived split in the pro-choice community...so here is a chance for us all to be on the same message.

Thank you all again!

Mitch

Mitchell Creinin, MD  
Professor  
Director of Family Planning  
Department of Obstetrics and Gynecology  
University of California Davis Health  
4860 Y Street, Suite 2500  
Sacramento, CA 95817  
[mdcreinin@ucdavis.edu](mailto:mdcreinin@ucdavis.edu)  
Assistant: 916-734-6670  
Direct: 916-734-6963  
916-734-6031

---

**From:** Mitchell D Creinin <[mdcreinin@ucdavis.edu](mailto:mdcreinin@ucdavis.edu)>

**Sent:** Wednesday, December 4, 2019 7:40 PM

**To:** Abigail Long - Danco ([ALong@earlyoptionpill.com](mailto:ALong@earlyoptionpill.com)) <[along@earlyoptionpill.com](mailto:along@earlyoptionpill.com)>; Alice Mark <[amark@prochoice.org](mailto:amark@prochoice.org)>; Autumn Katz <[AKatz@reprorights.org](mailto:AKatz@reprorights.org)>; [abeck@aclu.org](mailto:abeck@aclu.org) <[abeck@aclu.org](mailto:abeck@aclu.org)>; [adennis@societyfp.org](mailto:adennis@societyfp.org) <[adennis@societyfp.org](mailto:adennis@societyfp.org)>; Angel Foster <[Angel.Foster@uottawa.ca](mailto:Angel.Foster@uottawa.ca)>; Callie Langton <[clangton@stbfoundation.org](mailto:clangton@stbfoundation.org)>; Dean, Gillian <[gillian.dean@PPFA.ORG](mailto:gillian.dean@PPFA.ORG)>; Carolyn Westhoff ([clw3@columbia.edu](mailto:clw3@columbia.edu)) <[clw3@columbia.edu](mailto:clw3@columbia.edu)>; [jgirdish@prh.org](mailto:jgirdish@prh.org) <[jgirdish@prh.org](mailto:jgirdish@prh.org)>; Grossman, Daniel <[daniel.grossman@ucsf.edu](mailto:daniel.grossman@ucsf.edu)>; Schreiber, Courtney <[Courtney.Schreiber@uphs.upenn.edu](mailto:Courtney.Schreiber@uphs.upenn.edu)>; Jenny O'Donnell <[jodonnell@societyfp.org](mailto:jodonnell@societyfp.org)>; Kirsten Moore <[Kirsten.Moore@emaaproject.org](mailto:Kirsten.Moore@emaaproject.org)>; White, Kari <[kariwhite@utexas.edu](mailto:kariwhite@utexas.edu)>; [jennifer@abortioncarenetwork.org](mailto:jennifer@abortioncarenetwork.org) <[jennifer@abortioncarenetwork.org](mailto:jennifer@abortioncarenetwork.org)>; Kelly C. Cleland <[kcleland@Princeton.EDU](mailto:kcleland@Princeton.EDU)>; Shiri Hickman <[shickman@acog.org](mailto:shickman@acog.org)>; Clark, Liz <[elizabeth.clark@ppfa.org](mailto:elizabeth.clark@ppfa.org)>; Melissa Joy Chen <[meichen@ucdavis.edu](mailto:meichen@ucdavis.edu)>; [jennifer@prh.org](mailto:jennifer@prh.org) <[jennifer@prh.org](mailto:jennifer@prh.org)>; Courtney Overstreet <[cboverstreet@ucdavis.edu](mailto:cboverstreet@ucdavis.edu)>; [lorilrfps@sbcglobal.net](mailto:lorilrfps@sbcglobal.net) <[lorilrfps@sbcglobal.net](mailto:lorilrfps@sbcglobal.net)>; Tracy Weitz - Susan Thompson Buffett Foundation ([tweitz@stbfoundation.org](mailto:tweitz@stbfoundation.org)) <[tracy.weitz@gmail.com](mailto:tracy.weitz@gmail.com)>; [sophia@stateinnovation.org](mailto:sophia@stateinnovation.org) <[sophia@stateinnovation.org](mailto:sophia@stateinnovation.org)>; [mchristin@acog.org](mailto:mchristin@acog.org) <[mchristin@acog.org](mailto:mchristin@acog.org)>

**Cc:** Rebecca Starr Saeteurn <[rssaeteurn@ucdavis.edu](mailto:rssaeteurn@ucdavis.edu)>

**Subject:** Mifepristone Stakeholders Follow-up materials

Thank you everyone for participating in this meeting. I have received tons of positive feedback about how helpful it was for us all to come together to consider how to frame both stopping medical abortion combination treatment and the study results. I especially want to thank Autumn and Marc for presenting information on the current legal picture as part of the meeting.

I have attached a summary of the talking points we discussed today. I had my interview this evening with NPR (Mara Gordon) who plans to run the piece at 5 pm on 12/5/19 without any anti-choice interviews. Excellent! Importantly, I want to let everyone know that the talking points were immensely helpful. If you see something that you consider to be wrong or something I missed, let me know.

I would appreciate if you (especially the comms experts) would disperse this information within your groups/experts. The document includes study highlights, background information on medical abortion and stopping medical abortion combination treatment, and other thoughts to have in the back pocket during an interview. Again, these worked really well for me tonight.

Enclosed are the following:

1. Talking point summary from the meeting
2. Mife coalition talking points related to mife reversal legislation
3. Study manuscript (embargoed until 5 pm Eastern time on 12/5/19)

Please follow-up with my amazing assistant, Rebecca Saeteurn, with your expenses, including parking at the hotel. She is cc'd on this email.

Again, I am truly appreciative that so many of you took time out of your busy schedules to come together to find a common voice. I look forward to continuing to work together in the future.

Happy holidays to all.

Mitch

Mitchell Creinin, MD  
Professor  
Director of Family Planning  
Department of Obstetrics and Gynecology  
University of California Davis Health  
4860 Y Street, Suite 2500  
Sacramento, CA 95817

[mdcreinin@ucdavis.edu](mailto:mdcreinin@ucdavis.edu)

📞 Assistant: 916-734-6670

📞 Direct: 916-734-6963

📞 916-734-6031



Please consider the environment before you print this page.

## Sarah M Behrendt

---

**From:** Mitchell D Creinin  
**Sent:** Monday, December 9, 2019 9:04 AM  
**To:** Catherine D Cansino  
**Subject:** Re: Important study released today - talking points if you get an interview request

**Follow Up Flag:** Follow up  
**Flag Status:** Completed

**Categories:** Green Category

Cat-  
I think it is best if I do not write it. Many in AAPLOG think I am very biased, obviously. It might be best to not even come from our institution. I did send out through the listserv talking points so there already is a summary of the issues to discuss.

I think one of the biggest non-communicated issues has been the failure of the largest case series to actually be a complete case report. As we know, a case series reports the outcomes of all of the persons treated. In the Delgado report of ~750 women, they only provide a "success" rate and outcomes for those who had a delivery. The analysis only include ~550 women in the final calculations. They provide no details of outcomes (adverse events especially) in the ~50% of these 550 women who did not have continuing pregnancies.

Another ironic decision for their calculations is removal of 57 women who changed their mind and had an abortion. Outcome of treatment should include these women - maybe they changed their mind because of symptoms. Interesting how they enrolled women who supposedly changed their mind about having a medical abortion but would not include in their analysis women who then changed their mind again! I guess women are only allowed to change their mind in the direction they prefer.

If you feel that I should write something or if you want to do it, let me know. Happy to discuss (discussing this has been a huge part of my day every day for the last week!).

Thanks.

Mitch

Mitchell Creinin, MD  
Professor  
Director of Family Planning  
Department of Obstetrics and Gynecology  
University of California Davis Health  
4860 Y Street, Suite 2500  
Sacramento, CA 95817  
[mdcreinin@ucdavis.edu](mailto:mdcreinin@ucdavis.edu)  
Assistant: 916-734-6670  
Direct: 916-734-6963  
916-734-6031

EXHIBIT  
68

**From:** Catherine D Cansino <cansino@UCDAVIS.EDU>  
**Sent:** Thursday, December 5, 2019 11:13 AM  
**To:** Mitchell D Creinin <mdcreinin@ucdavis.edu>  
**Subject:** Re: Important study released today - talking points if you get an interview request

Thank you for sharing this info. Would be great to write a commentary on OB.Gyn.News where I'm on the Editorial Advisory Board. Would you like to write it, or one of the Fellows, or I can author too if you prefer. Would love to get ahead of this and offer this opportunity to our Editor-in-Chief. Do let me know

Cat

---

**From:** Fellowship in Family Planning <FPFELLOWSHIP@LISTSRV.UCSF.EDU> on behalf of Mitchell D Creinin <mdcreinin@UCDAVIS.EDU>  
**Sent:** Thursday, December 5, 2019 10:26:04 AM  
**To:** FPFELLOWSHIP@LISTSRV.UCSF.EDU <FPFELLOWSHIP@LISTSRV.UCSF.EDU>  
**Subject:** Important study released today - talking points if you get an interview request

Hello all.

I am sending this to you because, at 5 pm Eastern, a study regarding mifepristone "reversal" is being released that may get a lot of media requests from our community. The manuscript, appendix and talking points are attached with this email. In addition, a toolkit related to mifepristone "reversal" is also attached.




PLEASE ABIDE BY THE EMBARGO AND DO NOT TALK TO ANY JOURNALISTS UNTIL AFTER 5 pm. Some journals have found I would about the paper through a listserv they have and have started calling some organizations to try to get a copy of the paper. Please do not send it to anyone to honor the journals and embargo.

The talking points come from a meeting held in DC with an incredible mix of lawyers, state level advocates, researchers, comms experts, funders and other key opinion leaders to go over the findings and develop points that would be important for our community to rally around.

It is important we continue to speak with one voice on this topic. If anyone gets a media request and wants to talk with me, please feel free to reach out.

Thank you all for your continued commitment to the women we serve.

Mitch

Mitchell Creinin, MD  
Professor  
Director of Family Planning  
Department of Obstetrics and Gynecology  
University of California Davis Health  
4860 Y Street, Suite 2500  
Sacramento, CA 95817  
[mdcreinin@ucdavis.edu](mailto:mdcreinin@ucdavis.edu)  
 Assistant: 916-734-6670  
 Direct: 916-734-6963  
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## Mifepristone reversal study talking points

## STUDY

- Performed at UC Davis
- Planned to enroll 40 women in a RCT – women took mifepristone 200 mg and then randomized to start high-dose oral progesterone or placebo 24 hours later – and to use the drugs until study completion.
- Participants followed for up to two weeks.
- Study stopped after 12 enrolled (6 in each group) for safety concerns, due to hemorrhage requiring ER transport in 3 women, 2 of whom had an emergency D&C and one of whom received a blood transfusion.
- Four women in the study were 56 days (8 weeks or more). The three women who hemorrhaged were all 56 days or more. The one other subject, who received placebo, had an ongoing pregnancy at 2 weeks.
- The bleeding in these three women was very brisk and heavy – not typical of what is seen with medical abortion after the combination of mifepristone and misoprostol is used.
- All women except one (in progesterone group, had the highest baseline progesterone) experienced some spotting or bleeding.
- All hemorrhages occurred more than 48 hours after using mifepristone.
- No evidence of severe side effects from progesterone.
- Continuing pregnancy rates at 2 weeks: 4/6 for progesterone treatment and 2/6 for placebo.

## MEDICAL ABORTION - BACKGROUND

- Medical abortion is a **combination regimen** of two drugs, mifepristone and misoprostol.
- Mifepristone, the first drug, is followed in evidence-based abortion care by misoprostol 24-48 hours later. The misoprostol is given buccally or vaginally in most evidence-based regimens.
- Medical abortion is used for pregnancies through 70 days gestation (10 weeks).
- Available studies from early testing with mifepristone alone (not in a combination with misoprostol) were performed primarily in women 49 days gestation (7 weeks or less).
- More than 4 million U.S. women have used the combined drug regimen over the past 20 years with well proven efficacy and safety.
- Medical abortion in the U.S. is very safe – less than 1% (0.6%) of women have an ER visit after medical abortion treatment.

## MEDICAL ABORTION “REVERSAL” – BACKGROUND

- “Abortion reversal” is a term that anti-abortion extremists use to describe a medically unproven protocol in which a high dose of progesterone is given after the first medications used in the two-drug regimen for medical abortion.

- Unproven treatment that some people think will halt the medical abortion process – uses high doses of progesterone after a woman has taken mifepristone as part of the two-drug combination regimen for medical abortion.
- Only case series in the literature, which is the lowest level of evidence. Case series cannot prove cause and effect, only report what happened.
- Largest series reports on ~550 women, which was only 75% of the women supposedly treated. Used various treatments of progesterone with overall continuing pregnancy rate of ~50%. Two regimens had the highest rates of continuing pregnancy (~67%), including an oral regimen that was also used in the RCT.
- No case series reports the outcomes (including safety outcomes) for the ~50% of women who did not have a continuing pregnancy.
- The American Congress of Obstetricians and Gynecologists (ACOG) does not recommend the practice, stating that “claims of medication abortion reversal are not supported by the body of scientific evidence, and this approach is not recommended in ACOG’s clinical guidance on medication abortion.”

#### TAKE AWAYS (TALKING POINTS) – STUDY

- The study raises serious safety concerns about not completing the evidence-based medical abortion **combination** regimen. Mifepristone is not intended to be used without follow-up misoprostol treatment. It is even more concerning that states are passing laws to encourage women to participate in an unmonitored experiment. When a study is monitored, as this one was, we have the ability to stop if safety concerns arise.
- The authors took the question seriously, tried to find a preliminary answer through a rigorous, prospective RCT with IRB approval, and had to stop the study early because of the concern that it is bad for patients to not complete the 2-drug medical abortion regimen. We care about our patients and want them to make their decisions before they initiate treatment. Legislators are encouraging women to make their decisions after they initiate treatment, which we have always know is bad medicine.
- Other corroborating data:
  - Relevant data from miscarriage studies shows that women who choose expectant management have higher hemorrhage, emergency D&C and transfusion rates than women who receive medical management with regimens that include misoprostol.
  - Early studies of mifepristone and misoprostol using lower doses of misoprostol orally had similar bleeding issues in women at gestational ages of 56 days or more.

#### OTHER TALKING POINTS

- Patients deserve medically accurate information
- Abortion providers want to give the best and safest care to women.
- We do this research because abortion providers want to give the best and safest care to women; when anyone tries to force experimental treatment on our patients, we want to do appropriate research to study unproven claims.

- Improving patient safety, the patient experience and standards of care is why we do research – it is ethical work.
- People who seek abortion care arrive at a thoughtful decision about what is best for them, their families, and their futures; we trust them to be the experts in their own lives.
- Abortion care providers want patients to make informed decisions. They spend time discussing all medically proven options with patients and supporting whatever decision they make.

#### DOS and DON'TS

- Always talk about medical abortion as a **combination** treatment. The importance here is that mifepristone is not dangerous because it is not designed to be used by itself. Medical abortion is a **combination** of mifepristone and misoprostol and advocating that women not complete the regimen is the potential danger.
- When talking about the use of two pills, don't refer to the "FDA label" - refer to evidence-based treatment or regimen. Talking about the label could get reporters onto the subject of the label and should it be changed.
- Try not to use "reversal" during interviews. Medicines to stop abortion or medicines to halt the abortion process is better. It is OK to tell reporters up front that "abortion reversal" is not a medical term or a real thing, so we should be specific and call it what it is: taking progesterone after the first step of a two-drug **combination** regimen for medical abortion.
- Don't go into the weeds about the differences this study versus Delgado's study. Instead call Delgado's research "an unethical experiment" and quickly move on to your point.

**EXHIBIT I**

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF ALAMEDA

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| THE PEOPLE OF THE STATE OF | ) |                |
| CALIFORNIA,                | ) |                |
|                            | ) |                |
| Plaintiffs,                | ) |                |
|                            | ) | No. 23CV044940 |
| vs.                        | ) |                |
|                            | ) |                |
| HEARTBEAT INTERNATIONAL,   | ) |                |
| INC., and REALOPTIONS,     | ) |                |
| INC.,                      | ) |                |
|                            | ) |                |
| Defendants.                | ) |                |
| _____                      | ) |                |

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MELISSA J. CHEN, M.D.  
VOLUME II  
PAGES 121 - 205

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TIME: 10:01 a.m. - 11:56 a.m.  
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REPORTED BY: Taylor Maldonado, RPR, CSR No. 14482  
JOB NO. J13809707

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Taylor Maldonado. My California CSR number is 14482.  
Will the witness please raise their right hand to be  
sworn.

-oOo-

MELISSA J. CHEN, M.D.,

having been duly sworn to tell the truth, the whole  
truth, and nothing but the truth, testified as follows:

-oOo-

EXAMINATION

BY ATTORNEY MCPHERSON:

Q. Good morning, Dr. Chen.

Do you understand that this is a continuation  
of -- of your deposition that -- that we -- that we  
began but we're not able to finish?

A. Yes.

Q. Okay.

And you understand that, during the remainder  
of the time, you're under the same oath that you were  
during the first part of your deposition?

A. Yes.

Q. Is there any reason why can't give your best  
testimony today?

A. No.

Q. Okay.

You're not under the influence of any drugs,

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ATTORNEY PENAN: Same objections. Plus vague, ambiguous, and compound.

THE WITNESS: I would say that if someone were to just take mifepristone alone, that it is not -- like, I -- I wouldn't believe that it is as effective in, you know, causing the pregnancy to pass as if they were to take mifepristone and misoprostol.

BY ATTORNEY MCPHERSON:

Q. Okay.

And honing in more specifically on surviving pregnancies, because I know there -- there's a distinction here; right? There's a distinction between pregnancies that haven't fully passed and pregnancies that are -- that are still viable; right?

A. Correct.

Q. Do -- do you believe that a woman in the scenario we just discussed would be more likely to have a viable pregnancy if she didn't take misoprostol?

ATTORNEY PENAN: Objection. Calls for speculation. Lacks foundation. Incomplete hypothetical. Vague. Ambiguous. Compound. And calls for an expert opinion.

THE WITNESS: So if -- if someone just takes mifepristone and doesn't take misoprostol, I would think that they would be more likely to have an ongoing

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pregnancy than if they took mifepristone and  
misoprostol. That being said, there are -- you know,  
medication abortion is also not 100 percent, so there  
are still ongoing pregnancies even after taking  
misoprostol.  
BY ATTORNEY MCPHERSON:  
Q. Okay. And so -- so although the -- the --  
there may be some pregnancies that survive following  
mifepristone and misoprostol, there -- there's going to  
be more surviving pregnancies if it's just mifepristone  
without the misoprostol.  
Is that -- is that -- is that your position?  
ATTORNEY PENAN: Same objections.  
THE WITNESS: Yes.  
BY ATTORNEY MCPHERSON:  
Q. Okay.  
Do you believe that abortion pill reversal is  
potentially dangerous because abortion pill reversal  
involves not taking misoprostol after taking  
mifepristone?  
ATTORNEY PENAN: Objection. Calls for  
speculation. Lacks foundation. Incomplete  
hypothetical. Vague. Ambiguous. Compound. Calls for  
an expert opinion.  
THE WITNESS: I think what -- what we had

10:53:41AM 1 concluded was that there is a risk of hemorrhage if just  
10:53:48AM 2 the mifepristone is taken and not the misoprostol, if  
10:53:54AM 3 the process for, you know, passage of the pregnancy has  
10:53:58AM 4 started.

10:54:10AM 5 BY ATTORNEY MCPHERSON:

10:54:10AM 6 Q. And it's your understanding, right, that  
10:54:12AM 7 that's what abortion pill reversal practitioners  
10:54:16AM 8 recommend; right? They -- they recommend women to not  
10:54:19AM 9 take misoprostol if they want to reverse their abortion.

10:54:24AM 10 ATTORNEY PENAN: Objection. Calls for  
10:54:26AM 11 speculation. Lacks foundation. Incomplete  
10:54:26AM 12 hypothetical. Vague. Ambiguous. Compound. Assumes  
10:54:30AM 13 facts not in evidence. And calls for an expert opinion.

10:54:35AM 14 THE WITNESS: I mean, I don't -- I don't know  
10:54:38AM 15 exactly what the people who are practicing abortion pill  
10:54:41AM 16 reversal are counseling to their patients about not  
10:54:47AM 17 taking misoprostol or, you know, taking other  
10:54:52AM 18 medications or things like that. Yeah. I'll just stop  
10:54:59AM 19 there.

10:54:59AM 20 BY ATTORNEY MCPHERSON:

10:55:00AM 21 Q. Okay.

10:55:00AM 22 I'm going to go back to, really quickly, the  
10:55:38AM 23 attorney general's complaint. And this is -- this is,  
10:55:44AM 24 again, Exhibit 121. And we're going to go, again, to  
10:55:51AM 25 Page 12 of the complaint. And I want to direct your

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CERTIFICATE OF REPORTER

I, TAYLOR M. MALDONADO, a Certified Shorthand Reporter, holding a valid and current license issued by the State of California, CSR No. 14482, duly authorized to administer oaths, do hereby certify:

That the witness in the foregoing deposition was administered an oath to testify to the whole truth in the within-entitled cause.

That said deposition was taken down by me in shorthand at the time and place therein stated and thereafter transcribed into typewriting, by computer, under my direction and supervision.

Should the signature of the witness not be affixed to the deposition, the witness shall not have availed himself/herself of the opportunity to sign or the signature has been waived.

I further certify that I am neither counsel for nor related to any party in the foregoing deposition and caption named nor in any way interested in the outcome thereof.

DATED: 12/05/2025



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TAYLOR M. MALDONADO, RPR, CSR NO. 14482

**EXHIBIT J**

1 SUPERIOR COURT OF THE STATE OF CALIFORNIA

2 COUNTY OF ALAMEDA

3  
4 THE PEOPLE OF THE )  
STATE OF CALIFORNIA, )

5 )  
6 PLAINTIFF, )

7 vs. )

Case No. 23CV044940

8 HEARTBEAT )  
INTERNATIONAL, INC., )  
9 REALOPTIONS, DOES 1- )  
100, INCLUSIVE, )

JUDGE MICHAEL M. MARKMAN

11 DEFENDANT. )

12 DEPOSITION OF

13 CHRISTA BROWN

14  
15  
16 June 17, 2025

17 12:35 p.m.

18  
19 Remote Proceeding  
20 Columbus, Ohio

21  
22  
23  
24 WILLIAM CISAR, CER, CDR  
Esquire Deposition Solutions  
25 Notary Commission No. 2024-RE-884892

1                   This is Ethan Reimers on behalf of  
2 RealOptions.

3                   MS. PENAN: Hi. This is Hayley Penan, also on  
4 behalf of the People of the State of California.

5                   THE REPORTER: Okay. Absent any objection at  
6 this time, counsel and the witness agree to my remote  
7 administration of the oath to this witness and that the  
8 final transcript may be used for all purposes allowed by  
9 the California Code of Civil Procedure. Hearing no  
10 objection, this shall constitute agreement and  
11 stipulation of such, and I will now swear in the  
12 witness.

13                   Ms. Brown, please raise your right hand.

14   CHRISTA BROWN,  
15           having first been duly sworn, testified as follows:

16                   THE REPORTER: Thank you.

17                   You may proceed.

18   EXAMINATION

19           BY MS. ZWEIER:

20           Q.    Good morning, Ms. Brown. Thanks for appearing  
21 today.

22           A.    Good morning.

23           Q.    My name -- my name is Lauren Zweier, and I'm a  
24 deputy attorney general in the California Department of  
25 Justice. Can you state and spell your name for the

1 progesterone, does it?

2 MR. JONNA: Objection. The document speaks  
3 for itself.

4 THE WITNESS: So that's it -- the -- on -- on  
5 1A, it says, "Initial studies have shown APR may have a  
6 64 to 68 percent success rate," and that is accurate.

7 BY MS. ZWEIER:

8 Q. Do you know what the success rate is for  
9 vaginal administration of progesterone?

10 A. I don't -- I don't recall that off the top of  
11 my head, but I know that that's rarely used unless the  
12 woman has -- if she's not able to tolerate the oral  
13 progesterone. For example, if she has hyperemesis,  
14 she's vomiting repeatedly, some of our prescribers will  
15 use vaginal progesterone as a -- as -- to substitute  
16 instead of the oral if she's not able to, you know,  
17 maintain the oral progesterone.

18 Q. Uh-huh. Okay.

19 A. But the vast majority of the cases are oral  
20 progesterone.

21 Q. Okay. And I'm going to direct you to the next  
22 page. This one's titled "Explanation of Side Effects of  
23 Progesterone."

24 Is this information that's also relayed to  
25 callers on the call?

1                   Can you see the page that says, "Consent for  
2 Patients Who Took Methotrexate"?

3           A.    Yes.

4           Q.    It has the Bates label Heartbeat 189?

5           A.    Yes.

6           Q.    And this is the consent to callers who took  
7 methotrexate?

8           A.    Yes.

9           Q.    And I noticed that in the Policies and  
10 Procedures document, which was Exhibit 2, it didn't  
11 include an information sheet or talking points on what  
12 should be said to callers who have taken methotrexate.

13                   Do you know what's said to those callers?

14           A.    It -- I believe that that's included in the  
15 step-by-step guide, and what is explained to them is  
16 exactly what's on this consent.  So it's -- like I said  
17 before, it's -- it's sort of reiterating what's going to  
18 be on the consent, and that -- what methotrexate is,  
19 what our program was intended for, and what treatment  
20 may be available to her.  And of course we can't confirm  
21 that because we are connecting her with a prescriber who  
22 assumes her care, and that is at the discretion of that  
23 provider of what type of care they will offer her.  But  
24 we want her to have an explanation, which is why we send  
25 the consent.

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CERTIFICATE OF REPORTER

I, WILLIAM CISAR, a Digital Reporter and Notary Public within and for the State of Ohio do hereby certify:

That the foregoing witness whose examination is hereinbefore set forth was duly sworn and that said testimony was accurately captured with annotations by me during the proceeding.

I further certify that I am not related to any of the parties to this action by blood or marriage and that I am not interested in the outcome of this matter, financial or otherwise.

IN WITNESS THEREOF, I have hereunto set my hand this 18th day of June 2025.



---

WILLIAM CISAR, CER, CDR  
Notary Commission Ohio No. 2024-RE-884892  
Commission Expires: December 15, 2029

CERTIFICATE OF TRANSCRIPTIONIST

I, SANDRA REDAVID, Legal Transcriptionist do hereby certify:

That the foregoing is a complete and true transcription of the original digital audio recording of the testimony and proceedings captured in the above-entitled matter. As the transcriptionist, I have reviewed and transcribed the entirety of the original digital audio recording of the proceeding to ensure a verbatim record to the best of my ability.

I further certify that I am neither attorney for nor a relative or employee of any of the parties to the action; further, that I am not a relative or employee of any attorney employed by the parties hereto, nor financially or otherwise interested in the outcome of this matter.

IN WITNESS THEREOF, I have hereunto set my hand this 18th day of June 2025.

**SANDRA REDAVID**

\_\_\_\_\_  
SANDRA REDAVID