NO.23-35294

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

State of Washington, et al,
Plaintiffs-Appellees,

v.

United States Food and Drug Administration, et al.,
Defendants-Appellees,

v.

State of Idaho, et al,
Movants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

No. 1:23-cv-03026-TOR
The Honorable Thomas O. Rice

CORRECTED SECOND SUPPLEMENTAL EXCERPTS OF RECORD INDEX VOLUME

ROBERT W. FERGUSON
Attorney General

Emma Grunberg, WSBA 54659
Tera M. Heintz, WSBA 54921
Deputy Solicitor Generals
Andrew Hughes, WSBA 49515
Lauryn K. Fraas, WSBA 53238
Kristin Beneski, WSB 45478
Assistant Attorneys General

Noah Guzzo Purcell, WSBA 43492
Solicitor General
Colleen M. Melody, WSBA 42275
Civil Rights Division Chief
800 Fifth Avenue, Suite 2000
Seattle, WA 98104
Emma.Grunberg@atg.wa.gov
Andrew.Hughes@atg.wa.gov
206-521-3222

Table of Contents

Volume 1 of 2

Document	Date Filed	Docket number	Second Supplemental Excerpt Page
Amended Index of Administrative Record for Washington et al. v. FDA et. al.	4/12/24	150	2-51
Order Granting in Part Plaintiffs' Motion to Supplement the Administrative Record	3/8/24	146	52-72
Plaintiff States' Reply in Support of Motion to Supplement the Administrative Record	2/9/24	141	73-91
Defendants' Response in Opposition to Plaintiff States' Motion to Supplement the Administrative Record	2/2/24	139	92-107
Plaintiff States' Motion to Supplement the Administrative Record	1/19/24	133	108-26
Reply in Support of Plaintiffs-Intervenors' Motion to Intervene	4/19/23	103	127-39
Declarations in Support of Plaintiff States' Motion for Preliminary Injunction	2/24/23	4	140-44
Exhibits	2/24/23	4-1	145-272

Volume 2 of 2

Document	Date Filed	Docket number	Second Supplemental Excerpt Page
Exhibits	2/24/23	4-1	274-531

NO.23-35294

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

State of Washington, et al,
Plaintiffs-Appellees,

v.

United States Food and Drug Administration, et al.,
Defendants-Appellees,

v.

State of Idaho, et al,
Movants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

No. 1:23-cv-03026-TOR
The Honorable Thomas O. Rice

SECOND SUPPLEMENTAL EXCERPTS OF RECORD
VOLUME 1 OF 2

ROBERT W. FERGUSON
Attorney General

Emma Grunberg, WSBA 54659
Tera M. Heintz, WSBA 54921
Deputy Solicitor Generals
Andrew Hughes, WSBA 49515
Lauryn K. Fraas, WSBA 53238
Kristin Beneski, WSB 45478
Assistant Attorneys General

Noah Guzzo Purcell, WSBA 43492
Solicitor General
Colleen M. Melody, WSBA 42275
Civil Rights Division Chief
800 Fifth Avenue, Suite 2000
Seattle, WA 98104
Emma.Grunberg@atg.wa.gov
Andrew.Hughes@atg.wa.gov
206-521-3222

U.S. FOOD & DRUG ADMINISTRATION

CERTIFICATE

Pursuant to the provisions of Rule 44 of the Federal Rules of Civil Procedure, I hereby certify that Robert Herrell, Lead Regulatory Counsel, Division of Information Disclosure Policy, Office of Regulatory Policy, Center for Drug Evaluation and Research, United States Food and Drug Administration, whose Declaration is attached, has custody of the records relating to human drugs on file with the United States Food and Drug Administration.

In witness whereof, I have, pursuant to the provisions of Title 42, United States Code, Section 3505, and FDA Staff Manual Guide 1410.23, hereto set my hand and caused the seal of the Department of Health and Human Services to be affixed this 12th day of April, 2024.

Howard R. Philips

Howard R. Philips
Director
Division of Information Disclosure Policy
Center for Drug Evaluation and Research

By Direction of the Secretary of
Health and Human Services

DECLARATION OF ROBERT HERRELL

Robert Herrell declares as follows.

1. I am a Lead Regulatory Counsel in the Division of Information Disclosure Policy, Office of Regulatory Policy, Center for Drug Evaluation and Research, United States Food and Drug Administration ("FDA").

2. In this capacity, I have custody of certain records relating to human drugs on file with FDA.

3. Attached is a copy of the index of administrative record documents and other materials relating to *Washington, et al. v. FDA, et al.,* No. 23-cv-03026-TOR (E.D. Wash.), added pursuant to the court's March 8, 2024 order.

4. Copies of documents listed in the attached index are part of the official records of FDA.

I declare under penalty of perjury that the forgoing is true and correct.

Executed on: April 12, 2024

Robert R. Herrell -S

Digitally signed by Robert R. Herrell -S
Date: 2024.04.12 08:24:28 -04'00'

Robert Herrell

Amended Index of Administrative Record for
Washington et al. v. FDA et al.,
No. 23-cv-03026-TOR (E.D. Wash.)

Description	Date	Bates Number
I. Pre-2019 Documents		
Danco Group letter to CDER re: NDA 20-687, distribution plan	Jan. 21, 2000	FDA 0001-0002
Letter from CDER to Sandra P. Arnold, Population Council re: Approval (Sept. 28, 2000)	Sept. 28, 2000	FDA 0003-0005
Approved Labeling Text	Sept. 28, 2000	FDA 0006-0017
Approvable letter	Sept. 18, 1996	FDA 0018-0027
Letter from CDER to Sandra P. Arnold, Population Council re: additional information (Feb. 18, 2000)	Feb. 18, 2000	FDA 0028-0034
Medical Reviews	multiple	FDA 0035-0077
Chemistry Reviews	multiple	FDA 0078-0089
Environmental Assessment and Finding of No Significant Impact	multiple	FDA 0090-0111
Pharmacology Reviews	multiple	FDA 0112-0142
Statistical Reviews	multiple	FDA 0143-0158
Clinical Pharmacology and Biopharmaceutics Reviews	multiple	FDA 0159-0222
Summary review memo	Sept. 28, 2000	FDA 0223-0230
Final deemed REMS Review	dated June 3, 2011; signed June 6, 2011	FDA 0231-0257
REMS approved June 8, 2011	June 8, 2011	FDA 0258-0268
FDA Supplemental Approval letter	June 8, 2011	FDA 1281-1284
Korlym Label	Feb. 17, 2012	FDA 0269-0291
Korlym Risk Assessment and Risk Mitigation Review	Jan. 27, 2012	FDA 0292-0306
Korlym Summary Review	Feb. 17, 2012	FDA 0307-0330
Review of Year 1 REMS Assessment Report	Aug. 1, 2012	FDA 0331-0341
October 2013 REMS Review	dated Oct. 10, 2013; signed Oct. 17, 2013	FDA 0342-0360
Review of Year 4 REMS Assessment Report	Oct. 13, 2015	FDA 0361-0370
Approval package index and approval letter for Supp. 20	Mar. 29, 2016	FDA 0371-0381
March 2016 printed labeling	Mar. 29, 2016	FDA 0382-0402
March 2016 REMS	Mar. 29, 2016	FDA 0403-0411
Supp. 20 summary review	Mar. 29, 2016	FDA 0412-0439
Supp. 20 cross discipline team leader review	Mar. 29, 2016	FDA 0440-0526
Supp. 20 medical review	Mar. 29, 2016	FDA 0527-0634
Supp. 20 chemistry reviews	multiple	FDA 0635-0644
Supp. 20 pharmacology review	multiple	FDA 0645-0649

Description	Date	Bates Number
Supp. 20 statistical review	multiple	FDA 0650-0653
Supp. 20 clinical pharmacology and biopharmaceutics reviews	multiple	FDA 0654-0672
Supp. 20 risk assessment and risk mitigation reviews	Mar. 29, 2016	FDA 0673-0709
Supp. 20 misc. reviews	multiple	FDA 0710-0792
Supp. 20 administrative and correspondence	multiple	FDA 0793-0846
Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2017	Dec. 31, 2017	FDA 0847-0848
Mifeprex (mifepristone) information	Feb. 5, 2018	FDA 0849-0851
Questions and Answers on Mifeprex	Mar. 29, 2016	FDA 0852-0855
FDA-2002-P-0364		
Citizen Petition Denial from FDA	Mar. 29, 2016	FDA 0856-0888
Citizen Petition from the Am. Ass'n of Pro Life Obstetricians and Gynecologists, the Christian Medical Ass'n, and Concerned Women for America, FDA-2002-P-0364	Aug. 20, 2002	FDA 0889-0983
Tab A: Selected Bibliography to Citizen Petition	undated	FDA 0984-0988
Tab B: Statistics Used in Petition	undated	FDA 0989-0993
Tab C: NDAs Approved Under Subpart H	Aug. 8, 2002	FDA 0994-1003
Tab D	multiple	FDA 1004-1027
Tab E: David Willman, *The New FDA; How a New Policy Led to Seven Deadly Drugs; Medicine: Once a wary watchdog, the U.S. Food and Drug Administration set out to become a 'partner' of the pharmaceutical industry. Today, the American public has more remedies, but some are proving lethal*, L.A. Times, Dec. 20, 2000	Dec. 20, 2000	FDA 1028-1063
Tab F: *RU-486 Action Date is Sept 30; Allen Named Reproductive Division Director*, 62 The Pink Sheet 14, June 12, 2000	June 12, 2000	FDA 1064-1066
Tab G: Rachel Zimmerman, *Clash Between Pharmacia and FDA May Hinder the Use of RU-486*, Wall St. J., Oct. 18, 2000, at B1	Oct. 18, 2000	FDA 1067-1070
Tab H: Dennis F. Thompson, Editorial, *Surrogate End Points, Skepticism, and the CAST Study*, 36 Annals of Pharmacotherapy 170 (Jan. 2002)	Jan. 2002	FDA 1071-1073
Tab I: Mitchell D. Creinin, *Early Medical Abortion with Mifepristone or Methotrexate: Overview and Protocol Recommendations*, Nat'l Abortion Fed'n (2000)	multiple	FDA 1074-1118
Tab J: Ralph W. Hale, M.D. & Stanley Zinberg, M.D., Editorial, *Use of Misoprostol in Pregnancy*, 344 New Eng. J. Med. 59 (2001)	Jan. 4, 2001	FDA 1119-1121

Description	Date	Bates Number
Tab K: Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 Va. L. Rev. 1753, 1775, 1853-1855 (Nov. 1996)	Nov. 1996	FDA 1122-1127
Tab L: Mitchell D. Creinin, MD & Heather Jerald, BS, *Success rates and estimation of gestational age for medical abortion vary with transvaginal ultrasonic criteria*, 180 Am. J. Obstetrics & Gynecology 35-41 (1999)	Jan. 1999	FDA 1128-1142
Tab M: Sheryl Gay Stolberg, *F.D.A. Adds Hurdles in Approval of Abortion Pill,* N.Y. Times (Jun. 8, 2000)	June 8, 2000	FDA 1143-1145
Tab N: Beth Kruse et al., Management of side effects and complications in medical abortion, 183 Am. J. Obstetrics & Gynecology S65 (Aug. 2000)	Aug. 2000	FDA 1146-1161
Tab O: ACOG Practice Bulletin, *Clinical Management Guidelines for Obstetrician-Gynecologists,* No. 26 (Apr. 2001)	Apr. 2001	FDA 1162-1175
Tab P: Elizabeth Aubeny, M.D. et al., *Termination of Early Pregnancy (Up to and After 63 Days of Amenorrhea) With Mifepristone (RU-486) and Increasing Doses of Misoprostol*, 40 Int'l J. Fertility (Supp. 2) 85-91 (1995)	1995	FDA 1176-1180
Tab Q: Carol Jeuzaltis, *Doctor's abortion-drug technique draws fire*, Chi. Trib., Sept. 12, 1994, at 1	Sept. 12, 1994	FDA 1181-1183
Tab R: Denise Gellene, RU-486 Abortion Pill Hasn't Caught on in U.S. (May 31, 2001), http://www.latimes.com	May 31, 2001	FDA 1184-1189
Tab S: Susan Okie, *Physicians Sent Abortion Pill Alert, Six Women Using RU-486 Taken Ill, and Two Died, Letter Says*, Wash. Post, Apr. 18, 2002, at A02	Apr. 18, 2002	FDA 1190-1193
Tab T: Claudette Hajaj Gonzalez et al., *Congenital abnormalities in Brazillian children associated with misoprostol misuse in first trimester of pregnancy*, 351 Lancet 1624-27 (May 30, 1998)	May 30, 1998	FDA 1194-1198
Tab U: Salim Daya, MB, MSc, *Accuracy of gestational age estimation by means of fetal crown-rump length measurement*, 168 Am. J. Obstetrics & Gynecology 903 (Mar. 1993); Ivar K. Rossavik, M.D., Ph.D. et al., *Conceptual age and ultrasound measurements of gestational sac and crown-rump length in in vitro fertilization pregnancies,* 49 Fertility & Sterility 1012 (June 1988)	multiple	FDA 1199-1211
Tab V: Ieda M. Orioli & Eduardo E. Catilla, *Epidemiological assessment of misoprostol*	Apr. 2000	FDA 1212-1215

Description	Date	Bates Number
teratogenicity, 107 Brit. J. Obstetrics & Gynaecology 519 (Apr. 2000)		
Tab W: F.R. Vargas et al., *Prenatal Exposure to Misoprostol and Vascular Disruption Defects: A Case-Control Study*, 95 Am. J. Med. Genetics 302 (July 2000)	July 12, 2000	FDA 1216-1221
Tab X: Marc Kaufman & Ceci Connolly, *U.S. Backs Pediatric Tests In Reversal on Drug Safety*, Wash. Post, Apr. 20, 2002, at A03	Apr. 20, 2002	FDA 1222-1224
Tab Y: William J. Eaton, *Path Cleared for Abortion Pill Use Medicine: French maker of RU-486 gives patent rights to a nonprofit group. Testing, FDA approval are required to meet goal of licensing drug in U.S. by 1996*, L.A. Times, May 17, 1994, at A1	May 17, 1994	FDA 1225-1228
Tab Z: Sharon Bernstein, *Sunday Report; Persistence Brought Abortion Pill to U.S.; Two feminist activists culled nonprofit organizations and dedicated individuals to do the work that no pharmaceutical company was willing to tackle*, L.A. Times, Nov. 5, 2000, at A1	Nov. 5, 2000	FDA 1229-1236
Megan Greenberg, RN et al., *Barriers and Enablers to Becoming Abortion Providers: The Reproductive Health Program*, 44 Family Med. 493 (July/Aug. 2012)	July/Aug. 2012	FDA 1237-1244
Letter from Kelly Blanchard, President, Ibis Reproductive Health et al., to Robert M. Califf, M.D., Deputy Commissioner for Medical Products and Tobacco and Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research (Nov. 3, 2015)	Nov. 3, 2015	FDA 1245-1253
Letter from Advancing New Standards in Reproductive Health (ANSIRH) et al., to Stephen Ostroff, M.D., Acting Commissioner of Food and Drugs, Robert M. Califf, M.D., Deputy Commissioner for Medical Products and Tobacco, and Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research (Feb. 4, 2016)	Feb. 4, 2016	FDA 1254-1262
Letter from Hal C. Lawrence, III, M.D., FACOG, Executive Vice President and CEO, ACOG, to Robert M. Califf, M.D., Deputy Commissioner for Medical Products and Tobacco, and Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research (Nov. 4, 2015)	Nov. 4, 2015	FDA 1263-1264
Letter from Janet Woodcock, M.D., Director, Center for Drug Evaluation and Research, to Jessica Arons, J.D.,	Feb. 25, 2016	FDA 1265

Description	Date	Bates Number
President and Chief Executive Officer, Reproductive Health Technologies Project (Feb. 25, 2016)		
Medical Officer's Review	Jan. 27, 2000	FDA 1266-1280
Misoprostol 2002 label		FDA 1285-1295
Misoprostol 2012 label		FDA 1296-1309
Misoprostol 2018 label		FDA 1310-1323
II. Citizen Petition Docket FDA-2019-P-1534		
Citizen Petition from American Association of Pro-Life Obstetricians and Gynecologists and American College of Pediatricians	3/31/2019	2019 CP 000001-027
Exhibit A: Current and Requested Language (from Mifeprex Label and Risk Evaluation and Mitigation Strategy)		2019 CP 000028-038
Exhibit B: List of Attached References and Sources		2019 CP 000039-043
Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2017, RCM # 2007-525, NDA 20-687		FDA 0847-0848
Mifeprex 2000 label		FDA 0006-0017
Mifeprex 2016 label		FDA 0382-0402
Mifeprex Medication Guide (*in same document as Mifeprex 2016 label*)		FDA 0382-0402
Mifeprex 2016 Risk Evaluation and Mitigation Strategy (REMS)		FDA 0403-0411
Mifeprex Prescriber Agreement Form (*in same document as REMS – 2016)*		FDA 0403-0411
Ala. Code § 26-23E-7		2019 CP 000044
U.S. Gov't Accountability Office, GAO-18-292, U.S. Food & Drug Admin., *Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts* (2018)		2019 CP 000045-078
Am. Coll. of Obstetricians & Gynecologists, Prac. Bull. No. 143, *Medical Management of First-Trimester Abortion*, 123 Obstetrics & Gynecology 676-92 (Mar. 2014, reaffirmed 2016)		2019 CP 000079-113
Am. Coll. of Obstetricians & Gynecologists, Prac. Bul. No. 181, *Prevention of Rh D Alloimmunization* (Aug. 2017)		2019 CP 000114-127
Aid Access, *How do you know if you have abortion complications?*		2019 CP 000128-130
Miriam Arain et al., *Maturation of the adolescent brain*, 9 Neuropsychiatric Disease & Treatment 449-61 (2013)		2019 CP 000131-143

Description	Date	Bates Number
David M. Aronoff et al., *Misoprostol impairs female reproductive tract innate immunity against clostridium sordellii*, 180 J. Immunol. 8222-30 (2008)		2019 CP 000144-164
M. Antonia Biggs et al., *Support for and interest in alternative models of medication abortion provision among a national probability sample of U.S. women*, 99 Contraception 118-24 (2018)		2019 CP 000165-171
Isabelle Carlsson et al., *Complications Related to Induced Abortion: a Combined Retrospective and Longitudinal Follow-up Study*, 18 BMC Women's Health 158 (2018)		2019 CP 000172-180
Melissa J. Chen & Mitchell D. Creinin, *Mifepristone with buccal misoprostol for medical abortion: A systematic review*, 126 Obstetrics & Gynecology 12–21 (2015)		2019 CP 000181-190
Council for International Organizations of Medical Sciences, *training manual on medicine safety*		No longer available
Megan K. Donovan, *Self-Managed Medication Abortion: Expanding the Available Options for U.S. Abortion Care*, 21 Guttmacher Policy Rev. 41-47 (2018)		2019 CP 000191-197
Peter M. Doubilet et al., *Diagnostic criteria for nonviable pregnancy early in the first trimester*, 369 N. Eng. J. Med.1443–51 (2013)		2019 CP 000198-206
Lv Fang et al., *Repeated Abortion Affects Subsequent Pregnancy Outcomes in BALB/c Mice*, 7 PLoS ONE e48384 (2012)		2019 CP 000207-216
Mary Fjerstad et al., *Rates of Serious Infection after Changes in Regimens for Medical Abortion*, 361 N. Eng. J. Med. 145-51 (2009)		2019 CP 000217-225
Margaret M. Gary & Donna J. Harrison, *Analysis of severe adverse events related to the use of mifepristone as an abortifacient*, 40 Annals of Pharmacotherapy 191-97 (2006)		2019 CP 000226-232
Daniel Grossman, *American women should have access to abortion pills before they need them*, L.A. Times (Nov. 21, 2018)		2019 CP 000233-241
Daniel Grossman, *Research Protocol: Alternative Provision of Medication Abortion via Pharmacy Dispensing*, Version #:1.3 (July 17, 2018)		2019 CP 000242-250
Affidavit of Donna Harrison, *Okla. Coalition for Reproductive Justice v. Cline*, Case No. CV-2014-1886 (D. Ct. Okla. Feb. 24, 2015)		2019 CP 000251-291

Description	Date	Bates Number
Testimony of Donna Harrison & Michael J. Norton before the Iowa Board of Medicine (Aug. 21, 2013)		2019 CP 000292-312
Maowen Hu et al., *Impact of New Society of Radiologists in Ultrasound Early First-Trimester Diagnostic Criteria for Nonviable Pregnancy*, 33 J. Ultrasound Med. 1585–88 (2014)		2019 CP 000313-316
Rachel Jones et al., *Which Abortion Patients Have Had a Prior Abortion? Findings from the 2014 U.S. Abortion Patient Survey*, 27 J. Women's Health 58-63 (2014)		2019 CP 000317-322
Claire Lampen, *Webcam Abortion Services Offer Crucial Access—So What's Stopping them?* Gizmodo (Apr. 17, 2018)		2019 CP 000323-330
Patricia A. Lohr et al., *Oral Mifepristone and buccal misoprostol administered simultaneously for abortion: a pilot study*, 76 Contraception 215-20 (2007)		2019 CP 000331-336
Kelsey Lynd et al., *Simplified Medical Abortion Using a Semi-Quantitative Pregnancy Test for Home-Based Follow-up*, 121 Int'l J. Gynaecology & Obstetrics 144-48 (2013)		2019 CP 000337-351
Maarit J. Mentula et al., *Immediate Adverse Events after Second Trimester Medical Termination of Pregnancy: Results of a Nationwide Registry Study*, 26 Human Reprod. 927-32 (2011)		2019 CP 000352-357
Ralph P. Miech, *Pathopharmacology of excessive hemorrhage in mifepristone abortions*, 41 Annals of Pharmacotherapy 2002-07 (2007)		2019 CP 000358-363
Ralph P. Miech, *Pathophysiology of mifepristone-induced septic shock due to Clostridium sordellii*, 39 Annals of Pharmacotherapy 39 1483-87 (2005)		2019 CP 000364-369
Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 3679 N. Eng. J. Med. 790-94 (2017)		2019 CP 000370-374
Maarit Niinimaki et al., *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795-804 (2009)		2019 CP 000375-385
Planned Parenthood Releases New Educational Video on Telemedicine Abortion (Feb. 6, 2018)		2019 CP 000386-388

Description	Date	Bates Number
Elizabeth G. Raymond et al., *Increasing Access to Abortion with Telemedicine*, 176 JAMA Internal Med. 585-86 (2016)		2019 CP 000389-390
Elizabeth G. Raymond et al., *Low-sensitivity Urine Pregnancy Testing to Assess Medical Abortion Outcome: A Systematic Review*, Contraception (2018)		2019 CP 000391-396
Elizabeth G. Raymond et al., *Self-assessment of Medical Abortion Outcome Using Symptoms and Home Pregnancy Testing*, 97 Contraception 324-28 (2018)		2019 CP 000397-401
Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 N. Eng. J. Med. 2161-70 (2018)		2019 CP 000402-411
SIA Legal Team, *Self-Induced Abortion and the Law: What Emergency Room Staff Need to Know* (2018)		2019 CP 000412-415
Karen Fung Kee Fung & Erica Eason, SOGC Clinical Practice Guidelines: *Prevention of Rh Alloimmunization* (No. 133, Sept. 2003)		2019 CP 000416-424
Esther M. Sternberg et al., *Inflammatory mediator-induced hypothalamic-pituitary5 adrenal axis activation is defective in streptococcal cell wall arthritis-susceptible Lewis rats*, 86 Proc. Nat'l Acad. Sci. USA 2374-78 (1989)		2019 CP 000425-429
Molly Walker, *Mifepristone: Better for Managing Early Miscarriage*, Medpage Today (June 6, 2018)		2019 CP 000430-432
World Health Organization, *Safe Abortion: Technical and Policy Guidance for Health Systems* 45 and 39 (Section 2.2.2.1 Medication for pain) (2d ed. 2012)		2019 CP 000433-566
Gynuity Health Projects, *Medical Abortion*		2019 CP 000567-571
Gynuity Health Projects, *Exploring the Role of At-home Semi-Quantitative Pregnancy Tests for Medical Abortion Follow-up* (2015)		2019 CP 000572-579
Gynuity Health Projects, *De-Medicalizing Mifepristone Medical Abortion* (2007)		2019 CP 000580-585
TelAbortion: The Telemedicine Abortion Study: FAQs		No longer available
Acknowledgment Letter from U.S. Food & Drug Admin. to American Association of Pro-Life Obstetricians & Gynecologists and American College of Pediatricians	4/1/2019	2019 CP 000586-587

Description	Date	Bates Number
Interim Response Letter from U.S. Food & Drug Admin. to American Association of Pro-Life Obstetricians & Gynecologists and American College of Pediatricians	9/26/2019	2019 CP 000588-589
Comment from NARAL Pro-Choice Maryland	9/26/2019	2019 CP 000590-591
Citizen Petition Consult re: Prescriber Certification and Adverse Event Reporting	12/16/2021	2019 CP 000592-598
Citizen Petition Consult re: Actions Requested by Petitioners	12/16/2021	2019 CP 000599-627
Citizen Petition Response Letter from U.S. Food & Drug Admin. to American Association of Pro-Life Obstetricians & Gynecologists and American College of Pediatricians	12/16/2021	2019 CP 000628-668
Identification of Drug and Biological Products Deemed to Have Risk Evaluation and Mitigation Strategies for Purposes of the Food and Drug Administration Amendments Act of 2007, 73 Fed. Reg. 16313 (Mar. 27, 2008)		2019 CP 000669-670
Ctr. for Drug Evaluation & Res., Application Number 020687Orig1s020, Clinical Review (Mar. 29, 2016)		FDA 0527-0634
1999 Medical Officer's Review		FDA 0035-0077
Maarit J. Mentula et al., *Immediate Adverse Events after Second Trimester Medical Termination of Pregnancy: Results of a Nationwide Registry Study*, 26 Human Reprod. 927-32 (2011)		2019 CP 000352-357
2016 Cross-Discipline Team Leader Review		FDA 0440-0526
Am. Coll. of Obstetricians & Gynecologists, Prac. Bull. No. 143, *Medical Management of First-Trimester Abortion*, 123 Obstetrics & Gynecology 676-92 (Mar. 2014, reaffirmed 2016)		2019 CP 000079-113
Irving M. Spitz et al., *Early pregnancy termination with mifepristone and misoprostol in the United States*, 338 N. Eng. J. Med. 1241-47 (1998)		2021 REMS 000177-183
Melissa J. Chen & Mitchell D. Creinin, *Mifepristone with buccal misoprostol for medical abortion: A systematic review*, 126 Obstetrics & Gynecology 12–21 (2015)		2019 CP 000181-190
Claudia Diaz Olavarrieta et al., *Nurse versus Physician-provision of Early Medical Abortion in Mexico: A Randomized Controlled Non-Inferiority Trial,* 93 Bull. World Health Organ. 249-58 (2015)		2019 CP 000671-680
H. Kopp Kallner et al., *The efficacy, safety and acceptability of medical termination of pregnancy provided by standard care by doctors or by nurse-midwives: a randomised controlled equivalence trial*, 122 BJOG 510-17 (2015)		2019 CP 000681-688

Description	Date	Bates Number
I.K. Warriner et al., *Can midlevel health-care providers administer early medical abortion as safely and effectively as doctors? A randomized controlled equivalence trial in Nepal*, 377 Lancet 1155-61 (2011)		2019 CP 000689-695
Mahesh Puri et al., *The role of auxiliary nurse-midwives and community health volunteers in expanding access to medical abortion in rural Nepal*, 22 Reprod. Health Matters 94-103 (2015)		2019 CP 000696-706
R-M Renner et al., *Who can provide effective and safe termination of pregnancy care? A systematic review*, 120 BJOG 23-31 (2013)		2019 CP 000707-715
S. Barnard et al., *Doctors or mid-level providers for abortion (Review)*, Cochran Database of Systematic Revs. (2015)		2019 CP 000716-754
Shireen J. Jejeebhoy et al., *Feasibility of expanding the medication abortion provider based in India to include avurvedic physicians and nurses*., 38 Int'l Perspectives on Sexual & Reprod. Health 133-42 (2012)		2019 CP 000755-765
N. Baiju et al., *Effectiveness, safety and acceptability of self-assessment of the outcome of first-trimester medical abortion: a systematic review and meta-analysis*, 126 BJOG 1536-44 (2019)		2019 CP 000766-774
World Health Organization, *Safe Abortion: Technical and Policy Guidance for Health Systems* 45 and 39 (Section 2.2.2.1 Medication for pain) (2d ed. 2012)		2019 CP 000433-566
Isabelle Carlsson et al., *Complications Related to Induced Abortion: a Combined Retrospective and Longitudinal Follow-up Study*, 18 BMC Women's Health 158 (2018)		2019 CP 000172-180
Patricia A. Lohr et al., *Oral Mifepristone and buccal misoprostol administered simultaneously for abortion: a pilot study*, 76 Contraception 215-20 (2007)		2019 CP 000331-336
Courtney A. Schreiber et al., *A pilot study of mifepristone and misoprostol administered at the same time for abortion in women with gestation from 50 to 63 days,* 71 Contraception 447–50 (2005)		2019 CP 000775-778
Amitasrigowri S. Murthy et al., *A pilot study of mifepristone and misoprostol administered at the same time for abortion up to 49 days gestation*, 71 Contraception 333-36 (2005)		2019 CP 000779-782
Elizabeth G. Raymond et al., *First-trimester medical abortion with mifepristone 200 mg and*		2021 REMS 000626-637

Description	Date	Bates Number
misoprostol: a systematic review, 87 Contraception 26-37 (2013)		
Melissa J. Chen & Mitchell D. Creinin, *Mifepristone with buccal misoprostol for medical abortion: A systematic review*, 126 Obstetrics & Gynecology 12–21 (2015)		2019 CP 000181-190
Beverly Winikoff et al., *Two Distinct Oral Routes of Misoprostol in Mifepristone Medical Abortion*, 112 Obstetrics & Gynecology 1303-10 (2008)		2019 CP 000783-790
RhoGAM injections: payment levels vary among insurers, OBG Management 72 (2002)		2019 CP 000791-792
Maarit Niinimaki et al., *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795-804 (2009)		2019 CP 000375-385
Warning Letter from Ctr. for Drug Evaluation & Res., U.S. Food & Drug Admin., to Aidaccess.org (Mar. 8, 2019)		2021 REMS 000051-054
Daniel Grossman et al., *Medication Abortion with Pharmacist Dispensing of Mifepristone*, 137 Obstetrics & Gynecology 613-22 (2021)		2021 REMS 000772-781
Corinne H. Rocca et al., *Effectiveness and safety of early medication abortion provided in pharmacies by auxiliary nurse-midwives: A non-inferiority study in Nepal*, 13 PLoS ONE 1-12 (2018)		2021 REMS 001629-1640
Ellen R. Wiebe et al., *Comparing telemedicine to in-clinic medication abortions induced with mifepristone and misoprostol*, Contraception: X 1-4 (2020)		2021 REMS 001641-1644
Daniel Grossman et al., *Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment*, 107 Contraception 36-41 (2022)		2021 REMS 001623-1628
Ushma D. Upadhyay et al., *Safety and Efficacy of Telehealth Medication Abortion in the US During the COVID-19 Pandemic*, 4 JAMA Network Open 1-3 (2021)		2021 REMS 001655-1657
Paul Hyland et al., *A Direct-to-Patient Telemedicine Abortion Service in Australia: Retrospective Analysis of the First 18 Months*, 58 Aust. New Zeal. J. Obstetrics & Gynecology 335-40 (2018)		2021 REMS 001015-1020
Holly A. Anger et al., *Clinical and service delivery implications of omitting ultrasound before medication abortion provided via direct-to-patient telemedicine and mail in the U.S.*, 104 Contraception 659-65 (2021)		2021 REMS 001658-1664

Description	Date	Bates Number
Elizabeth Raymond et al., *TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States*, 100 Contraception 173-77 (2019)		2021 ED 000112-116
John Joseph Reynolds-Wright et al., *Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during COVID-19 pandemic*, 47 BMJ Sex. Reprod. Health 246-51 (2021)		2021 ED 000444-449
M. Endler et al., *Safety and acceptability of medical abortion through telemedicine after 9 weeks of gestation: a population-based cohort study*, BJOG 609-18 (2019)		2021 REMS 001693-1702
Hannah Norten et al., *10-year evaluation of the use of medical abortion through telemedicine: a retrospective cohort study*, BJOG (2021)		2021 REMS 001684-1692
Abigail R.A. Aiken et al., *Self reported outcomes and adverse events after medical abortion through online telemedicine: population based study in the Republic of Ireland and Northern Ireland*. 357 BMJ (2017)		2021 REMS 001665-1683
Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43-48 (2021)		2021 ED 000117-122
Courtney Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, 104 Contraception 49-53 (2021)		2021 ED 000439-443
Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. Obstetrics & Gynecology 1464-74 (2021)		2021 ED 000085-095
Elizabeth G. Raymond et al., Commentary: *No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond*, 101 Contraception 361-66 (2020)		2021 ED 000469-474
AMA, Patient Physician Relationships, Opinion 1.1.1		2019 CP 000793
AMA, Ethical Practice in Telemedicine, Opinion 1.2.12		2019 CP 000794-795
Council for International Organizations of Medical Sciences, *Guidelines for Preparing Core Clinical Safety Information on Drugs* (2d ed. 1999)		2019 CP 000796-896
Maarit Niinimaki et al., *Immediate Complications After Medical Compared With Surgical*		2019 CP 000375-385

Description	Date	Bates Number
Termination of Pregnancy, 114 Obstetrics & Gynecology 795-804 (2009)		
Luu Doan Ireland et al., *Medical Compared with Surgical Abortion for Effective Pregnancy Termination in the Frist Trimester*, 126 Obstetrics & Gynecology 22-28 (2015)		2019 CP 000897-903
Rachel Jones et al., *Which Abortion Patients Have Had a Prior Abortion? Findings from the 2014 U.S. Abortion Patient Survey*, 27 J. Women's Health 58-63 (2014)		2019 CP 000317-322
III. Citizen Petition Docket FDA-2022-P-3209		
Citizen Petition from Students for Life of America	12/13/2022	2022 CP 000001-067
Acknowledgment Letter from U.S. Food & Drug Admin.	12/14/2022	2022 CP 000068
Citizen Response Letter from U.S. Food & Drug Admin. to Students for Life of America	1/3/2023	2022 CP 000069-070
IV. FDA's April 2021 Enforcement Discretion Decision		
Letter from Maureen G. Phipps, Chief Executive Officer, American College of Obstetricians and Gynecologists and Judette Louis, President, Society for Maternal-Fetal Medicine, to Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin. re: Docket Number: FDA-2020-D-1106; Policy for Certain REMS Requirements During the Covid-19 Public Health Emergency Guidance for Industry and Health Care Professionals	4/20/2020	2021 ED 000001-003
Am. Coll. of Obstetricians & Gynecologists, Committee Opinion No. 798, *Implementing telehealth in practice*, 135 Obstetrics & Gynecology e73-e79 (2020)		2021 ED 000004-010
Am. Coll. of Obstetricians & Gynecologists, *Position Statement: Improving Access to Mifepristone for Reproductive Health Indications* (June 2018)		2021 ED 000011-013
Kelly Cleland & Nicole Smith, *Aligning mifepristone regulation with evidence: driving policy change using 15 years of excellent safety data*, 92 Contraception 179-81 (2015)		2021 ED 000014-016
Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 3679 N. Eng. J. Med. 790-94 (2017)		2019 CP 000370-374
Li Ping Song et al., *Early medical abortion with self-administered low-dose mifepristone in combination with misoprostol*, 44 *J. Obstet. Gynaecology Res.* 1705-11 (2018)		2021 ED 000017-023

Description	Date	Bates Number
Am. Coll. of Obstetricians & Gynecologists et al., *Joint Statement on Abortion Access During the COVID-19 Outbreak* (Mar. 18, 2020)		2021 ED 000024-026
Ushma D. Upadhyay et al., *Interest in self-administration of subcutaneous depot medroxyprogesterone acetate in the United States*, 94 Contraception 303-13 (2016)		2021 ED 000027-037
Julia E. Kohn et al., *Increased 1-year continuation of DMPA among women randomized to self-administration: results from a randomized controlled trial at Planned Parenthood*, 97 Contraception 198-204 (2018)		2021 ED 000038-044
Holly M. Burke et al., *Effect of self-administration versus provider-administered injection of subcutaneous depot medroxyprogesterone acetate on continuation rates in Malawi: a randomised controlled trial*, 6 Lancet Glob Health 568-e578 (2018)		2021 ED 000045-055
Memorandum to Janet Woodcock, Director, Ctr. for Drug Evaluation & Res. re: In-Person Dispensing Requirement in Mifepristone REMS Program During the COVID-19 Public Health Emergency Reference: NDA # 020687	6/10/2020	2021 ED 000056-060
CDC Guidance: *Outpatient and Ambulatory Care Settings: Responding to Community Transmission of COVID-19 in the United States* (2019)		2021 ED 000061-064
Memorandum to Janet Woodcock, Director, Ctr. for Drug Evaluation & Res. re: In-Person Dispensing Requirement in Mifepristone REMS Program During the COVID-19 Public Health Emergency Reference: NDA # 020687	6/10/2020	2021 ED 000065-070
Letter from Janet Woodcock, Acting Commissioner, U.S. Food & Drug Admin. to Maureen Phipps, Chief Executive Officer, American College of Obstetricians and Gynecologists, Judette Louis, President, Society for Maternal-Fetal Medicine, Matt Granato, Chief Executive Officer, Society for Maternal-Fetal Medicine	3/19/2021	2021 ED 000071-072
Letter from Multiple Health Care Providers to Janet Woodcock, Director, Ctr. for Drug Evaluation & Res. re: Request Regarding Restrictions on Mifepristone	3/23/2021	2021 ED 000073-077
Isabel R. Fulcher et al., *State and Federal Abortion Restrictions Increase Risk of COVID-19 Exposure by Mandating Unnecessary Clinic Visits*, 102 Contraception 385-91 (2020)		2021 ED 000078-084
Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. Obstetrics & Gynecology 1464-74 (2021)		2021 ED 000085-095
Ushma D. Upadhyay et al., *Adoption of No-test and Telehealth Medication Abortion Care Among*		2021 ED 000096-100

Description	Date	Bates Number
Independent Abortion Providers in Response to COVID-19, Contraception X (2020)		
Pam Belluck, *Abortion by Telemedicine: A Growing Option as Access to Clinics Wanes*, N.Y. Times (Apr. 28, 2020)		2021 ED 000101-111
Elizabeth Raymond et al., *TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States*, 100 Contraception 173-77 (2019)		2021 ED 000112-116
Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43-48 (2021)		2021 ED 000117-122
American Association of Family Physicians, *Misoprostol Alone Is Associated with a High Rate of Successful First-trimester Abortion*, 100 American Family Physician (2019)		2021 ED 000123-125
Nat'l Acads. of Scis., Eng'g & Med., *The Safety & Quality of Abortion Care in the United States* (2018)		2021 ED 000126-348
The White House, *Executive Order on Advancing Racial Equity and Support for Underserved Communities through the Federal Government* (Jan. 20, 2021)		2021 ED 000349-354
The White House, *Executive Order on Establishment of the White House Gender Policy Council* (Mar. 8, 2021)		2021 ED 000355-360
Letter from Maureen Phipps, Chief Executive Officer, American College of Obstetricians and Gynecologists, William Grobman, President, Society for Maternal-Fetal Medicine, to Janet Woodcock, Acting Commissioner, U.S. Food & Drug Admin.	3/25/2021	2021 ED 000361-362
Royal C. of Obstetricians & Gynaecologists, *Coronavirus (COVID-19) infection and abortion care* (July 2020)		2021 ED 000363-404
Royal C. of Obstetricians & Gynaecologists, *RCOG/FSRH Welcome Government's Decision to Reinstate Telemedicine for Abortion Care* (Mar. 2020)		2021 ED 000405-409
Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. Obstetrics & Gynecology 1464-74 (2021)		2021 ED 000085-095
Information request from U.S. Food & Drug Admin. to NDA mifepristone applicant	4/1/2021	2021 ED 000410-411
Information request from U.S. Food & Drug Admin. to NDA mifepristone applicant	4/5/2021	2021 ED 000412
Information request from U.S. Food & Drug Admin. to ANDA mifepristone applicant	4/7/2021	2021 ED 000413-415

Description	Date	Bates Number
Response from NDA mifepristone applicant to 4/1/2021 and 4/5/2021 information requests	4/7/2021	2021 ED 000416-420
Response from ANDA mifepristone applicant to 4/7/2021 information request	4/9/2021	2021 ED 000421-423
Memorandum: Mifepristone; All Adverse Events. NDA 020687 and ANDA 091178. #2007-525. April 12, 2021	4/12/2021	2021 ED 000424-433
Memorandum to Patrizia Cavazzoni, Director, Ctr. for Drug Evaluation & Res. re: In-Person Dispensing Requirement in Mifepristone REMS Program During the COVID-19 Public Health Emergency Reference: NDA # 020687	4/12/2021	2021 ED 000434-438
Memorandum: Mifepristone; All Adverse Events. NDA 020687 and ANDA 091178. #2007-525. April 12, 2021		2021 ED 000424-433
Courtney Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, 104 Contraception 49-53 (2021)		2021 ED 000439-443
Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43-48 (2021)		2021 ED 000117-122
Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. of Obstetrics & Gynecology 1464-74 (2021)		2021 ED 000085-095
John Joseph Reynolds-Wright et al., *Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during COVID-19 pandemic*, 47 BMJ Sex. Reprod. Health 246-51 (2021)		2021 ED 000444-449
CDC's guidance on *Healthcare Facilities: Managing Operations During the COVID-19 Pandemic*		2021 ED 000450-455
Memorandum to Patrizia Cavazzoni, Director, Ctr. for Drug Evaluation & Res. re: In-Person Dispensing Requirement in Mifepristone REMS Program During the COVID-19 Public Health Emergency Reference: NDA # 020687	4/12/2021	2021 ED 000456-465
Beatrice L. Brown et al., *Ensuring Safe Access to Mifepristone During the Pandemic and Beyond*, 174 Annals of Internal Med. 105-06 (2021)		2021 ED 000466-468
Elizabeth G. Raymond et al., Commentary: *No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond*, 101 Contraception 361-66 (2020)		2021 ED 000469-474

Description	Date	Bates Number
Christina Fuleihan, *American College of Obstetricians and Gynecologists v. United States Food & Drug Administration: Restricted Access to Medical Abortion Threatens Reproductive Rights during the COVID-19 Pandemic*, 46 Am. J. L. & Med. 507-17 (2020)		2021 ED 000475-486
Caroline Moreau et al., *Abortion regulation in Europe in the era of COVID-19: a spectrum of policy responses*, 47 BMJ Sex Reprod. Health (2020)		2021 ED 000487-494
Katherine Gambir et al., *Effectiveness, safety and acceptability of medical abortion at home versus in the clinic: a systematic review and meta-analysis in response to COVID-19*. 5 BMJ Global Health (2020)		2021 ED 000495-506
Isabel R. Fulcher et al., *State and Federal Abortion Restrictions Increase Risk of COVID-19 Exposure by Mandating Unnecessary Clinic Visits*, 102 Contraception 385-91 (2020)		2021 ED 000078-084
Ushma D. Upadhyay et al., *Adoption of No-test and Telehealth Medication Abortion Care Among Independent Abortion Providers in Response to COVID-19*, Contraception X (2020)		2021 ED 000096-100
Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43-48 (2021)		2021 ED 000117-122
John Joseph Reynolds-Wright et al., *Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during COVID-19 pandemic*, 47 BMJ Sex. Reprod. Health 246-51 (2021)		2021 ED 000444-449
Courtney Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, 104 Contraception 49-53 (2021)		2021 ED 000439-443
Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. Obstetrics & Gynecology 1464-74 (2021)		2021 ED 000085-095
Memorandum from Patrizia Cavazzoni, Director, Ctr. for Drug Evaluation & Res. to Janet Woodcock, Acting Commissioner re: In-Person Dispensing Requirement in Mifepristone REMS Program During the COVID-19 Public Health Emergency Reference: NDA # 020687	4/12/2021	2021 ED 000507-508
Memorandum from Janet Woodcock, Acting Commissioner, to Patrizia Cavazzoni, Director, Ctr. for Drug Evaluation & Res. re: In-Person Dispensing Requirement in Mifepristone REMS Program During	4/12/2021	2021 ED 000509

Description	Date	Bates Number
the COVID-19 Public Health Emergency Reference: NDA # 020687		
Letter from Janet Woodcock, Acting Commissioner, U.S. Food & Drug Admin. to Maureen G. Phipps, Chief Executive Officer, American College of Obstetricians and Gynecologists and William Grobman, President, Society for Maternal-Fetal Medicine	4/12/2021	2021 ED 000510-511
Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43-48 (2021)		2021 ED 000117-122
Courtney Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, 104 Contraception 49-53 (2021)		2021 ED 000439-443
Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. Obstetrics & Gynecology 1464-74 (2021)		2021 ED 000085-095
John Joseph Reynolds-Wright et al., *Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during COVID-19 pandemic*, 47 BMJ Sex. Reprod. Health 246-51 (2021)		2021 ED 000444-449
U.S. Food & Drug Admin. General Advice Letter for ANDA 091178 (Apr. 12, 2021)	4/12/2021	2021 ED 000512-514
U.S. Food & Drug Admin. General Advice Letter for NDA 20687 (Apr. 12, 2021)	4/12/2021	2021 ED 000515-517
V. 2021 REMS Review		
Letter from Affiliated Medical Services et al., to Janet Woodcock, Director, Ctr. for Drug Evaluation & Res., U.S. Food & Drug Admin. re: Request Regarding Covid-19	3/27/2020	2021 REMS 000001-005
Am. Coll. of Obstetricians & Gynecologists et al., *Joint Statement on Abortion Access During the COVID-19 Outbreak* (Mar. 18, 2020)		2021 REMS 000006-008
Am. Coll. of Obstetricians & Gynecologists et al., *Joint Statement on Elective Surgeries* (Mar. 16, 2020)		2021 REMS 000009-011
U.S. Food & Drug Admin., *Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency: Guidance for Industry and Health Care Professionals* (Mar. 2020)		2021 REMS 000012-019
Nat'l Acads. of Scis., Eng'g & Med., *The Safety & Quality of Abortion Care in the United States* (The Nat'l Acads. Press 2018)		2021 ED 000126-348

Description	Date	Bates Number
Margit Endler et al., *Telemedicine for Medical Abortion: A Systematic Review*, 126 Brit. J. Obstetrics & Gynecology 1094-1102 (2019)		2021 REMS 000020-028
Ctr. for Drug Evaluation & Res., Application Number 020687Orig1s020, Clinical Review (Mar. 29, 2016)		FDA 0527-0634
Danco Labs., LLC, *Mifeprex Effectiveness & Advantages*		2021 REMS 000029-034
Letter from state attorneys general to Alex Azar, Secretary, U.S. Dep't of Health & Human Servs., and Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin.	3/30/2020	2021 REMS 000035-040
U.S. Food & Drug Admin., *Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency: Guidance for Industry and Health Care Professionals* (Mar. 2020)		2021 REMS 000012-019
Sabrina Tavernise, *Texas and Ohio Include Abortion as Medical Procedures That Must Be Delayed*, N.Y. Times, Mar. 23, 2020		2021 REMS 000041
Am. Coll. of Obstetricians & Gynecologists, *Position Statement: Improving Access to Mifepristone for Reproductive Health Indications* (June 2018)		2021 ED 000011-013
Letter from American Academy of Family Physicians to Dr. Norman Sharpless, Acting Commissioner, U.S. Food & Drug Admin. (June 20, 2019)		2021 REMS 000042
American Medical Association, *Supporting Access to Mifepristone (Mifeprex) H-100.948*		2021 REMS 000043
Letter from 500 Women Scientists et al., to Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin.	4/6/2020	2021 REMS 000044-048
Dep't of Health & Social Care and The Rt. Hon. Matt Hancock MP, *Temporary approval of home use for both stages of early medical abortion* (Mar. 30, 2020)		2021 REMS 000049-050
Nat'l Acads. of Scis., Eng'g & Med., *The Safety & Quality of Abortion Care in the United States* (The Nat'l Acads. Press 2018)		2021 ED 000126-348
U.S. Food & Drug Admin., *Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency: Guidance for Industry and Health Care Professionals* (Mar. 2020)		2021 REMS 000012-019
Warning Letter from Ctr. for Drug Evaluation & Res., U.S. Food & Drug Admin., to Aidaccess.org (Mar. 8, 2019)		2021 REMS 000051-054

Description	Date	Bates Number
Letter from P.D. Parker to Dr. Janet Woodcock, Director, Ctr. for Drug Evaluation & Res., U.S. Food & Drug Admin. re: Request Regarding COVID-19, Docket: FDA-2020-D-1106	4/10/2020	2021 REMS 000055-056
Letter from Elaine Reed to Dr. Janet Woodcock, Director, Ctr. For Drug Evaluation & Res., U.S. Food & Drug Admin. re: Request Regarding COVID-19, Docket: FDA-2020-D-1106	4/10/2020	2021 REMS 000057-058
Letter from Senators Elizabeth Warren, Patty Murray, and Tammy Baldwin to Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin.	4/14/2020	2021 REMS 000059-063
Deena Beasley, *U.S. hospitals, patients cancel elective surgery as coronavirus spreads*, Reuters, Mar. 16, 2020		2021 REMS 000064-068
U.S. Food & Drug Admin., *Policy for Certain REMS Requirements During the COVID-19 Public Health Emergency: Guidance for Industry and Health Care Professionals* (Mar. 2020)		2021 REMS 000012-019
Michelle J. Bayefsky et al., *Abortion during the COVID-19 Pandemic – Ensuring Access to an Essential Health Service*, 382 N. Eng. J. Med. e47(1)-(3) (2020)		2021 REMS 000069-071
Guttmacher Inst., *Medication Abortion* (Nov. 2019)		2021 REMS 000072-083
ANSIRH, University of California, San Francisco, *Analysis of Medication Abortion Risk and the FDA report "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018,"* Issue Brief, April 2019		2021 REMS 000084-085
Nat'l Acads. of Scis., Eng'g & Med., *The Safety & Quality of Abortion Care in the United States* (The Nat'l Acads. Press 2018)		2021 ED 000126-348
Melissa J. Chen & Mitchell D. Creinin, *Mifepristone with buccal misoprostol for medical abortion: A systematic review*, 126 Obstetrics & Gynecology 12–21 (2015)		2019 CP 000181-190
Am. Med. Ass'n House of Delegates, *Ending the Risk Evaluation and Mitigation Strategy (REMS) policy on mifepristone (Mifeprex)*, Policy H-100.948 (2018)		2021 REMS 000086-156
American Academy of Family Physicians, *FPs Tackle Primary Care Spending, Other Weighty Topics*, Oct. 12, 2018		2021 REMS 000157-162
Am. Coll. of Obstetricians & Gynecologists, *ACOG Statement on Medication Abortion* (Mar. 30, 2016)		2021 REMS 000163-165

Description	Date	Bates Number
Jane E. Henney & Helene D. Gayle, *Time to Reevaluate U.S. Mifepristone Restrictions*, 381 N. Eng. J. Med. 597-98 (2019)		2021 REMS 000166-167
Sarah Raifman et al., *Medication Abortion: Potential for Improved Patient Access Through Pharmacies*, 58 J. Am. Pharmacists Ass'n 377-81 (2018)		2021 REMS 000168-172
Letter from Am. Ctr. for Law and Justice to Alex Azar, Secretary, U.S. Dep't of Health & Human Servs., and Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin.	4/14/2020	2021 REMS 000173-176
Irving M. Spitz, et al., *Early Pregnancy Termination with Mifepristone and Misoprostol in the United States,* 338 N. Eng. J. Med. 1241-47 (1998)		2021 REMS 000177-183
Letter from Christian Med. & Dental Ass'ns to Alex Azar, Secretary, U.S. Dep't of Health & Human Servs., and Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin.	4/20/2020	2021 REMS 000184-185
Ctrs. for Disease Control & Prevention, *Current Trends Ectopic Pregnancy -- United States, 1990-1992*, 44 Morbidity & Mortality Weekly Report 46-48 (1995)		2021 REMS 000186-189
Courtney A. Kerestes et al., *Abortion providers' experiences and views on self-managed medication abortion: an exploratory study*, 100 Contraception 160-64 (2019)		2021 REMS 000190-194
Letter from Melissa Duxbury, President, New Hampshire Acad. of Fam. Physicians to Dr. Janet Woodcock, Director, Ctr. for Drug Evaluation & Res., U.S. Food & Drug Admin. re: Request Regarding COVID-19, Docket: FDA-2020-D-1106	4/22/2020	2021 REMS 000195-196
Letter from state legislators to Alex Azar, Secretary, U.S. Dep't of Health & Human Servs. and Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin. re: Maintaining Safety Regulations of Mifepristone's Current REMS	4/28/2020	2021 REMS 000197-209
Letter from Women's Health Public Health Advocates to Dr. Janet Woodcock, Director, Ctr. for Drug Evaluation & Res., U.S. Food & Drug Admin. re: Request Regarding COVID-19, Docket: FDA-2020-D-1106	4/28/2020	2021 REMS 000210-223
Letter from U.S. Food & Drug Admin. to Hector Balderas, Attorney General of New Mexico	5/19/2020	2021 REMS 000224
Letter from Alice Huling, Campaign for Accountability to Dr. Janet Woodcock, Director, Ctr. for Drug Evaluation & Res., U.S. Food & Drug Admin. re:	5/20/2020	2021 REMS 000225-228

Description	Date	Bates Number
Referral of Unlawful Prescription of Dangerous Abortion Pill Reversal		
George Delgado & Mary L. Davenport, *Progesterone Use to Reverse the Effects of Mifepristone*, 46 Annals of Pharmacotherapy e36 (2012)		2021 REMS 000229-232
George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33 Issues Law & Med. 3-14 (2018)		2021 REMS 000233-244
Daniel Grossman & Kari White, *Abortion "Reversal" – Legislating Without Evidence*, 379 N. Eng. J. Med. 1401-03 (2018)		2021 REMS 000245-250
Mitchell D. Creinin et al., *Mifepristone Antagonization With Progesterone to Prevent Medical Abortion*, 135 Obstetrics & Gynecology 158-65 (2020)		2021 REMS 000251-258
Brief for the States of N.Y. et al. as Amici Curiae in Support of Plaintiffs' Mot. for a Preliminary Injunction, *Am. College of Obstetricians & Gynecologists v. FDA*, No. 8:20cv01320 (D. Md.)	6/3/2020	2021 REMS 000259-280
Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics & Gynecology 296-303 (2011)		2021 REMS 000281-288
Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2017*, Guttmacher Inst. (2019)		2021 REMS 000289-312
Jill Barr-Walker et al., *Experiences of women who travel for abortion: A mixed methods systematic review*, PLoS ONE 1-26 (2019)		2021 REMS 000313-338
Liza Fuentes & Jenna Jerman, *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, 28 J. Women's Health 1623-31 (2019)		2021 REMS 000339-347
Am. Med. Ass'n House of Delegates, *Ending the Risk Evaluation and Mitigation Strategy (REMS) policy on mifepristone (Mifeprex)*, Policy H-100.948 (2018)		2021 REMS 000086-156
Email from Live Action et al. to Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin.	7/28/2020	2021 REMS 000348-352
Letter from U.S. Senator Ted Cruz et al. to Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin.	9/1/2020	2021 REMS 000353-358
Letter from U.S. Congressman Michael C. Burgess et al. to Dr. Norman Sharpless, Acting Commissioner, U.S. Food & Drug Admin. (May 10, 2018)		2021 REMS 000359-366
Kevin Murphy, *Abortion-Drug Dealer Pleads Guilty, Linked to Grand Rapids Man Accused of Poisoning Pregnant Woman's Drink*, Wis. Rapids Trib. (Mar. 5, 2020)		2021 REMS 000367-369

Description	Date	Bates Number
Chelsea Conaboy, *She Started Selling Abortion Pills Online. Then the Feds Showed Up*, Mother Jones (Mar. 2019)		2021 REM 000370-372
Letter from U.S. Senator Cindy Hyde-Smith et al. to Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin. (Apr. 14, 2020)		2021 REMS 000373-383
Emily Bazelon, *The Dawn of the Post-Clinic Abortion*, N.Y. Times (Aug. 28, 2014)		2021 REMS 000384-392
Judicial Watch, Inc., *A Judicial Watch Special Report: The Clinton RU-486 Files* (2006)		2021 REMS 000393-456
Erica Hellerstein, *The Rise of the DIY Abortion in Texas*, Atlantic (June 27, 2014)		2021 REMS 0457-476
Live Action, *Abortion Pill Exposed*		2021 REMS 000477-561
Maarit Niinimaki et al., *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795-804 (2009)		2019 CP 000375-385
Letter from Maryland General Assembly Members to Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin.	10/6/2020	2021 REMS 000562-564
Am. Coll. of Obstetricians & Gynecologists, *Position Statement: Improving Access to Mifepristone for Reproductive Health Indications* (June 2018)		2021 ED 000011-013
Letter from Am. Academy of Family Practitioners to Dr. Norman Sharpless, Acting Commissioner, U.S. Food & Drug Admin. (June 20, 2019)		2021 REMS 000565
Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2017*, Guttmacher Inst. (2019)		2021 REMS 000289-312
Letter from David Rosman, President, Massachusetts Medical Society, to Dr. Stephen Hahn, Commissioner, U.S. Food & Drug Admin.	10/7/2020	2021 REMS 000566-567
Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 N. Eng. J. Med 2161-70 (2018)		2021 REMS 000568-577
Am. Coll. of Obstetricians & Gynecologists, Prac. Bull. No. 200, *Early Pregnancy Loss*, 132 Obstetrics & Gynecology e197-e207 (2018)		2021 REMS 000578-588
Letter from U.S. Congressman Robert E. Latta et al. to Dr. Janet Woodcock, Acting Commissioner, U.S. Food & Drug Admin.	4/22/2021	2021 REMS 000589-600

Description	Date	Bates Number
Kathi A. Aultman et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36 Issues in Law & Med. 3-27 (2021)		2021 REMS 000601-625
Elizabeth G. Raymond et al., *First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review*, 87 Contraception, 26-37 (2013)		2021 REMS 000626-637
Ea Mulligan & Hayley Messenger, *Mifepristone in South Australia, the first 1343 tablets*, 40 Aust. Fam. Physician. 342-45 (2011)		2021 REMS 000638-642
Maarit Niinimaki et al., *Immediate Complications After Medical Compared With Surgical Termination of Pregnancy*, 114 Obstetrics & Gynecology 795-804 (2009)		2019 CP 000375-385
Joint Motion and Order to Stay Case Pending Agency Review *Chelius v. Becerra*, 17-cv-0493 (D. Haw. May 7, 2021) ECF Nos. 148, 149	5/7/2021	2021 REMS 000643-650
U.S. Food & Drug Admin., Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2021	6/30/2021	2021 REMS 000651-652
Information request sent by U.S. Food & Drug Admin. to NDA mifepristone applicant	6/30/2021	2021 REMS 000653-655
Information request sent by U.S. Food & Drug Admin. to ANDA mifepristone applicant	6/30/2021	2021 REMS 000656-658
Information request sent by U.S. Food & Drug Admin. to NDA mifepristone applicant	7/15/2021	2021 REMS 000659-663
Information request sent by U.S. Food & Drug Admin. to ANDA mifepristone applicant	7/15/2021	2021 REMS 000664-667
Letter from Gillian Dean, Senior Director of Medical Services, Planned Parenthood to U.S. Food & Drug Admin. re: FDA Review of Mifepristone	7/28/2021	2021 REMS 000668-679
Planned Parenthood Federation of America, *The Irreplaceable Role of Planned Parenthood Health Centers* (Jan. 2020)		2021 REMS 000680-682
Danco Labs., LLC, *Mifeprex: Effectiveness & Advantages*		2021 REMS 000029-034
U.S. Food & Drug Admin., *Questions and Answers on Mifeprex,* at Q12 (Apr. 2019)		2021 REMS 000683-685
Guttmacher Inst., *Evidence You Can Use: Medication Abortion* (Feb. 2021)		No longer available
Nat'l Acads. of Scis., Eng'g & Med., *The Safety & Quality of Abortion Care in the United States* (The Nat'l Acads. Press 2018)		2021 ED 000126-348
ANSIRH, University of California, San Francisco, *Analysis of Medication Abortion Risk and the FDA report "Mifepristone U.S. Post-Marketing Adverse*		2021 REMS 000084-085

Description	Date	Bates Number
Events Summary through 12/31/2018," Issue Brief, April 2019		
Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175-83 (2015)		2021 REMS 000686-694
Elizabeth G. Raymond et al., *First-trimester medical abortion with mifepristone 200 mg and misoprostol: a systematic review*, 87 Contraception 26-37 (2013)		2021 REMS 000626-637
Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215-19 (2012)		2021 REMS 000695-699
Emily E. Petersen et al., *Vital Signs: Pregnancy-Related Deaths, United States, 2011–2015, and Strategies for Prevention, 13 States, 2013–2017*, 68 Morbidity & Mortality Weekly Report 423-29 (2019)		2021 REMS 000700-706
A. P. Mollhajee et al., *Pregnancy Intention and Its Relationship to Birth and Maternal Outcomes*, 109 Obstetrics & Gynecology 678-86 (2007)		2021 REMS 000707-715
Jessica D. Gipson et al., *The Effects of Unintended Pregnancy on Infant, Child, and Parental Health: A Review of the Literature*, 39 Stud. Fam. Plan. 18-38 (2008)		2021 REMS 000716-737
World Health Org., *Safe Abortion: Technical and Policy Guidance for Health Systems* (2d. ed. 2012)		2021 REMS 000738-747
Am. Coll. of Obstetricians & Gynecologists & Soc'y of Family Planning, Prac. Bull. No. 225, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 1 (Oct. 2020)		2021 REMS 000748-764
Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person*, 130 Obstetrics & Gynecology 778-82 (2017)		2021 REMS 000765-769
ANSIRH, *Safety and Effectiveness of First-Trimester Medication Abortion in the United States* (Aug. 2016)		2021 REMS 000770-771
Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43-48 (2021)		2021 ED 000117-122
Daniel Grossman et al., *Medication Abortion with Pharmacist Dispensing of Mifepristone*, 137 Obstetrics & Gynecology 613-22 (2021)		2021 REMS 000772-781
Elizabeth G. Raymond et al., Commentary: *No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond,* 101 Contraception 361-66 (2020)		2021 ED 000469-474

Description	Date	Bates Number
Nat'l Abortion Fed'n, *2020 Clinical Policy Guidelines for Abortion Care*, at 15 Standard 6.6 (2020)		2021 REMS 000782-845
Elizabeth G. Raymond & Hillary Bracken, *Early Medical Abortion Without Prior Ultrasound*, 92 Contraception 212-14 (2015)		2021 REMS 000846-848
Elizabeth Raymond et al., *Simplified Medical Abortion Screening: A Demonstration Project*, 97 Contraception 292-96 (2018)		2021 REMS 000849-853
Bliss Kaneshiro et al., *Expanding Medical Abortion: Can Medical Abortion Be Effectively Provided Without the Routine Use of Ultrasound?*, 83 Contraception 194-201 (2011)		2021 REMS 000854-861
Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. Obstetrics & Gynecology 1464-74 (2021)		2021 ED 000085-095
Diane Greene Foster et al., *Attitudes and Decision Making Among Women Seeking Abortions at One U.S. Clinic*, 44 Perspectives Sexual & Reprod. Health 117-24 (2012)		2021 REMS 000862-869
Julia E. Kohn et al., *Medication Abortion Provided Through Telemedicine in Four U.S. States*, 134 Obstetrics & Gynecology 343-50 (2019)		2021 REMS 000870-877
Kate Grindlay & Daniel Grossman, *Telemedicine Provision of Medical Abortion in Alaska: Through the Provider's Lens*, 23 J. Telemedicine & Telecare 680-85 (2016)		2021 REMS 000878-883
Daniel A. Grossman et al., *Changes in Service Delivery Patterns After Introduction of Telemedicine Provision of Medical Abortion in Iowa*, 103 Am. J. Pub. Health 73-78 (2013)		2021 REMS 000884-889
Sara Daniel et al., *Characteristics of Patients Using Telemedicine Compared With In-Person Visits for State-Mandated Informed Consent Before Abortion in Utah*, 99 Contraception 316 (2020)		2021 REMS 000890
Katherine Ehrenreich et al., *Women's Experiences Using Telemedicine to Attend Abortion Information Visits in Utah: A Qualitative Study*, 29 Women's Health Issues 407-13 (2019)		2021 REMS 000891-897
Shelly Kaller et al., *Pre-Abortion Informed Consent Through Telemedicine vs. in Person: Differences in Patient Demographics and Visit Satisfaction*, 31 Women's Health Issues 227-35 (2021)		2021 REMS 000898-906
Am. Coll. of Obstetricians & Gynecologists, Comm. Op. No. 518: *Intimate Partner Violence*, Comm. On Health Care for Underserved Women (Feb. 2012)		2021 REMS 000907-912

Description	Date	Bates Number
Neha A. Deshpande & Annie Lewis-O'Connor, *Screening for Intimate Partner Violence During Pregnancy*, 6 Obstetrics & Gynecology 141-48 (2013)		2021 REMS 000913-920
Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2017*, Guttmacher Inst. (2019)		2021 REMS 000289-312
Debra B. Stulberg et al., *Abortion Provision Among Practicing Obstetrician-Gynecologists*, 118 Obstetrics & Gynecology 609-14 (2011)		2021 REMS 000921-931
Eve Espey et al., *Abortion Education in Medical Schools: A National Survey*, 192 Am. J. Obstetrics & Gynecology 640-43 (2005)		2021 REMS 000932-935
Alison Block et al., *Postgraduate Experiences with an Advanced Reproductive Health and Abortion Training and Leadership Program*, 49 Fam. Med. 706-13 (2017)		2021 REMS 000936-943
Information request sent by U.S. Food & Drug Admin. to ANDA mifepristone applicant	8/5/2021	2021 REMS 000944-946
Information request sent by U.S. Food & Drug Admin. to NDA mifepristone applicant	8/5/2021	2021 REMS 000947-949
Letter from the Society of Family Planning Board of Directors to U.S. Food & Drug Admin. re: US Food and Drug Administration's review of the risk evaluation and mitigation strategy for mifepristone	8/11/2021	2021 REMS 000950-955
Laura Schummers et al., *Do medication abortion complications increase when mifepristone is available without regulations restricting practice? A population-based study using linked health administrative data from Canada*, 47 BMJ Sex. Reprod. Health 2-3 (2021)		2021 REMS 000956-957
Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175-83 (2015)		2021 REMS 000686-694
Nathalie Kapp & Patricia A. Lohr, *Modern methods to induce abortion: Safety, efficacy and choice*, 63 Best Pract. Res. Clin. Obstetrics & Gynaecology 37-44 (2020)		2021 REMS 000958-965
Daniel Grossman et al., *Induced abortion provision among a national sample of obstetrician-gynecologists*, 133 Obstetrics & Gynecology 477-83 (2019)		2021 REMS 000966-972
Silpa Srinivasulu et al., *US clinicians' perspectives on how mifepristone regulations affect access to medication abortion and early pregnancy loss care in primary care*, 104 Contraception 92-97 (2021)		2021 REMS 000973-978
Danielle Calloway et al., *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States*, 104 Contraception 24-28 (2021)		2021 REMS 000979-983

Description	Date	Bates Number
Sarah Munro et al., *Perspectives among Canadian physicians on factors influencing implementation of mifepristone medical abortion: A national qualitative study*, 18 Ann. Fam. Med. 413-21 (2020)		2021 REMS 000984-992
Kayla N. Rasmussen et al., *Expanding access to medication abortion through pharmacy dispensing of mifepristone: Primary care perspectives from Illinois*, 104 Contraception 98-103 (2021)		2021 REMS 000993-998
Daniel Grossman et al., *Medication Abortion with Pharmacist Dispensing of Mifepristone*, 137 Obstetrics & Gynecology 613-22 (2021)		2021 REMS 000772-781
Beverly Winikoff et al., *Extending outpatient medical abortion services through 70 days of gestational age*, 120 Obstetrics & Gynecology 1070-76 (2012)		2021 REMS 000999-1005
Melissa J. Chen & Mitchell D. Creinin, *Mifepristone with buccal misoprostol for medical abortion: A systematic review*, 126 Obstetrics & Gynecology 12–21 (2015)		2019 CP 000181-190
Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43-48 (2021)		2021 ED 000117-122
Kelly Cleland et al., *Significant adverse events and outcomes after medical abortion*, 121 Obstetrics & Gynecology 166-71 (2013)		2021 REMS 001006-1014
Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. Obstetrics & Gynecology 1464-74 (2021)		2021 ED 000085-095
Paul Hyland et al., *A Direct-to-Patient Telemedicine Abortion Service in Australia: Retrospective Analysis of the First 18 Months*, 58 Aust. New Zeal. J. Obstetrics & Gynecology 335-40 (2018)		2021 REMS 001015-1020
Nat'l Acads. of Scis., Eng'g & Med., *The Safety & Quality of Abortion Care in the United States* (The Nat'l Acads. Press 2018)		2021 ED 000126-348
Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215-19 (2012)		2021 REMS 000695-699
Linda A. Bartlett et al., *Risk factors for legal induced abortion-related mortality in the United States*, 103 Obstetrics & Gynecology 729-37 (2004)		2021 REMS 001021-1029
Rachel K. Jones & Jenna Jerman, *Time to appointment and delays in accessing care among U.S. abortion patients*, Guttmacher Inst. (2016)		2021 REMS 001030-1051

Description	Date	Bates Number
Diana Greene Foster & Katrina Kimport, *Who seeks abortions at or after 20 weeks?*, 45 Perspectives Sex. & Reprod. Health 210-18 (2013)		2021 REMS 001052-1060
Gretchen Ely et al., *Access to abortion services in Tennessee: Does distance traveled and geographic location influence return for a second appointment as required by the mandatory waiting period policy?*, 44 Health & Social Work 13-21 (2019)		2021 REMS 001061-1070
Information request sent by U.S. Food & Drug Admin. to NDA mifepristone applicant	8/17/2021	2021 REMS 001071
Information request sent by U.S. Food & Drug Admin. to ANDA mifepristone applicant	8/19/2021	2021 REMS 001072
Response to 8/5/21 information request from ANDA mifepristone applicant	8/26/2021	2021 REMS 001073-1079
Response to 8/5/2021 information request from NDA mifepristone applicant	8/27/2021	2021 REMS 001080-1142
Information request sent by U.S. Food & Drug Admin. to NDA mifepristone applicant	9/2/2021	2021 REMS 001143-1144
Response to 9/2/2021 information request from NDA mifepristone applicant	9/9/2021	2021 REMS 001145-1148
Information request sent by U.S. Food & Drug Admin. to NDA mifepristone applicant	9/15/2021	2021 REMS 001149-1150
Information request sent by U.S. Food & Drug Admin. to ANDA mifepristone applicant	9/15/2021	2021 REMS 001151-1152
Response to 9/15/2021 information request from NDA mifepristone applicant	9/20/2021	2021 REMS 001153-1155
Response to 9/15/2021 information request from ANDA mifepristone applicant	9/23/2021	2021 REMS 001156-1158
Letter from Dr. Graham Chelius, The Society of Family Planning, The California Academy of Family Physicians to Dr. Janet Woodcock, Acting Commissioner, U.S. Food & Drug Admin. re: Evidence Supporting Elimination of the Mifepristone REMS	9/29/2021	2021 REMS 001159-1167
Am. Med. Ass'n House of Delegates, *Ending the Risk Evaluation and Mitigation Strategy (REMS) policy on mifepristone (Mifeprex)*, Policy H-100.948, (2018)		2021 REMS 000086-156
Am. Coll. of Obstetricians & Gynecologists, *Position Statement: Improving Access to Mifepristone for Reproductive Health Indications* (June 2018)		2021 ED 000011-013
Cong. of Delegates, Am. Acad. of Fam. Physicians, *Resolution No. 506 (CoSponsored C) Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization on Mifepristone* (May 24, 2018)		2021 REMS 001168-1171

Description	Date	Bates Number
Letter from Janet Woodcock, M.D., Acting Commissioner, U.S. Food & Drug Admin., to Maureen Phipps, Chief Executive Officer, American College of Obstetricians and Gynecologists, William Grobman, President, Society for Maternal-Fetal Medicine (Apr. 12, 2021)		2021 ED 000510-511
Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. Obstetrics & Gynecology 1464-74 (2021)		2021 ED 000085-095
Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43-48 (2021)		2021 ED 000117-122
Kelly Cleland et al., *Significant adverse events and outcomes after medical abortion*, 121 Obstetrics & Gynecology 166-71 (2013)		2021 REMS 001006-1014
Laura Schummers et al., *Do Medication Abortion Complications Increase When Restrictive Risk Evaluation and Mitigation Strategy Regulations are Removed? A Population-Based Study Using Single-Payer Linked Health Administrative Data*, 102 Contraception 273-304 (2020)		2021 REMS 001172
Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175-83 (2015)		2021 REMS 000686-694
Nathalie Kapp & Patricia A. Lohr, *Modern methods to induce abortion: Safety, efficacy and choice*, 63 Best Pract. Res. Clin. Obstetrics & Gynaecology 37-44 (2020)		2021 REMS 000958-965
Sara Daniel et al., *Obstetrician-Gynecologist Willingness to Provide Medication Abortion with Removal of the In-Person Dispensing Requirement for Mifepristone*, 104 Contraception 73-76 (2021)		2021 REMS 001173-1176
Liza Fuentes & Jenna Jerman, *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, 28 J. Women's Health 1623-31 (2019)		2021 REMS 000339-347
Jonathan M. Bearak et al., *Disparities and Change Over Time in Distance Women Would Need to Travel to Have an Abortion in the USA: A Spatial Analysis*, 2 Lancet Pub. Health e493-e500 (2017)		2021 REMS 001177-1184

Description	Date	Bates Number
Alice F. Cartwright et al., *Identifying National Availability of Abortion Care and Distance from Major US Cities: Systematic Online Search*, 20 J. Med. Internet Res. e186 (2018)		2021 REMS 001185-1197
Jenna Jerman et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, Guttmacher Inst. (2016)		2021 REMS 001198-1226
Jill Barr-Walker et al., *Experiences of women who travel for abortion: A mixed methods systematic review*, PLoS ONE 1-26 (2019)		2021 REMS 000313-338
Daniel Grossman et al., *Change in Distance to Nearest Facility and Abortion in Texas, 2012 to 2014*, 317 JAMA Network 437–38 (2017)		2021 REMS 001227-1229
Sharon A. Dobie et al., *Abortion Services in Rural Washington State, 1983–1984 to 1993–1994: Availability and Outcomes*, 31 Fam. Plan. Persp. 241-45 (1999)		2021 REMS 001230-1234
Robert W. Brown et al., *Provider Availability, Race, and Abortion Demand*, 67 Southern Eco. J. 656-71 (2001)		2021 REMS 001235-1250
James D. Shelton et al., *Abortion Utilization: Does Travel Distance Matter?*, 8 Fam. Plan. Persp. 260–62 (1976)		2021 REMS 001251-1254
Alison H. Norris et al., *Abortion Access in Ohio's Changing Legislative Context, 2010–2018*, 110 Am. J. Pub. Health 1228-34 (2020)		2021 REMS 001255-1261
Ushma D. Upadhyay et al., *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, 104 Am. J. Pub. Health 1687-94 (2014)		2021 REMS 001262-1269
U.S. Food & Drug Admin., *Opioid Medications* (2021)		2021 REMS 001813-001816
U.S. Food & Drug Admin., Ctr. For Drug Eval. & Res., *Labeling* (Jeuveau) (2019)		2021 REMS 001817-001830
U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Labeling* (Propecia) (2012)		2021 REMS 001831-001848
U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Labeling* (NuvaRing) (2013)		2021 REMS 001849-001884
U.S. Food & Drug Admin., Ctr. for Drug Eval. & Res., *Labeling* (Coumadin) (2011)		2021 REMS 001885-001920
Appendix		2021 REMS 001921-002050

Description	Date	Bates Number
Letter from ACOG to U.S. Food & Drug Admin.	10/6/2021	2021 REMS 002051-002052
Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 N. Eng. J. Med. 2161-70 (2018)		2019 CP 000402-411
Carolyn L. Westhoff, *A better medical regimen for the management of miscarriage*, 378 N. Eng. J. Med. 2232-33 (2018)		2023 SUPP 000069-070
Am. Coll. of Obstetricians & Gynecologists, *Position Statement: Improving Access to Mifepristone for Reproductive Health Indications* (June 2018)		2021 ED 000011-013
Kelly Cleland & Nicole Smith, *Aligning mifepristone regulation with evidence: driving policy change using 15 years of excellent safety data*, 92 Contraception 179-81 (2015)		2021 ED 000014-016
Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 3679 N. Eng. J. Med. 790-94 (2017)		2019 CP 000370-374
Li Ping Song et al., *Early medical abortion with self-administered low-dose mifepristone in combination with misoprostol*, 44 J. Obstet. Gynaecology Res. 1705-11 (2018)		2021 ED 000017-023
FDA mission statement		2021 REMS 002053-002057
ACOG Practice Bulletin No. 225		2021 REMS 000748-764
Daniel Grossman et al., *Induced abortion provision among a national sample of obstetrician-gynecologists*, 133 Obstetrics & Gynecology 477-83 (2019)		2021 REMS 000966-972
Am. Coll. of Obstetricians & Gynecologists et al., *Joint Statement on Abortion Access During the COVID-19 Outbreak* (Mar. 18, 2020)		2021 ED 000024-026
Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43-48 (2021)		2021 ED 000117-122
Courtney Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, 104 Contraception 49-53 (2021)		2021 ED 000439-443
Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. Obstetrics & Gynecology 1464-74 (2021)		2021 ED 000085-095

Description	Date	Bates Number
Response to 6/30/2021 information request by NDA mifepristone applicant	10/8/2021	2021 REMS 001270-1273
Response to 8/5/2021 information request by NDA mifepristone applicant	10/8/2021	2021 REMS 001274-1290
Response to 6/30/2021 information request by ANDA mifepristone applicant	10/11/2021	2021 REMS 001291-1299
Additional response to 8/5/2021 information request by ANDA mifepristone applicant	10/12/2021	2021 REMS 1300-1308
Response to 8/19/2021 information request by ANDA mifepristone applicant	10/13/2021	2021 REMS 001309-1310
Information request sent by U.S. Food & Drug Admin. to ANDA mifepristone applicant	10/15/2021	2021 REMS 001311
Response to 6/30/2021 information request and follow-up response to 10/12/2021 submission by ANDA mifepristone applicant	10/16/2021	2021 REMS 001312-1321
Response to 8/19/2021 information request by ANDA mifepristone applicant	10/18/2021	2021 REMS 001322-1324
Information request sent by U.S. Food & Drug Admin. to NDA mifepristone applicant	10/22/2021	2021 REMS 001325-1326
Information request sent by U.S. Food & Drug Admin. to ANDA mifepristone applicant	10/22/2021	2021 REMS 001327-1328
Response to 10/22/2021 information request from NDA mifepristone applicant	10/26/2021	2021 REMS 001329-1332
Information request sent by U.S. Food & Drug Admin. to ANDA mifepristone applicant	10/26-27/2021	2021 REMS 001333-1337
Response to 10/22/2021 and 10/27/2021 information requests from ANDA mifepristone applicant	10/29/2021	2021 REMS 001338-1342
U.S. Food & Drug Admin. Meeting Minutes and slides	11/2/2021	2021 REMS 001343-1379
Information request sent by U.S. Food & Drug Admin. to NDA mifepristone applicant	11/6/2021	2021 REMS 001380-1382
Information request sent by U.S. Food & Drug Admin. to ANDA mifepristone applicant	11/6/2021	2021 REMS 001383-1384
Response to 9/2/2021 and 11/6/2021 information requests by NDA mifepristone applicant	11/9/2021	2021 REMS 001385-1387
Response to 11/6/2021 information request by ANDA mifepristone applicant	11/9/2021	2021 REMS 001388-1389
Memorandum: Mifepristone and All Adverse Events. NDA 020687 and ANDA 091178. RCM # 2007-525	12/16/2021	2021 REMS 001390-1401
Am. Coll. of Obstetricians & Gynecologists v. FDA, 472 F. Supp. 3d 183 (D. Md. July 13, 2020), order clarified, 2020 WL 8167535 (D. Md. Aug. 19, 2020)		2021 REMS 001402-1440

Description	Date	Bates Number
FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578 (Jan. 12, 2021)		2021 REMS 001441-1446
U.S. Food & Drug Admin., Questions and Answers on Mifeprex; Question and Answer #14. Content current as of date: April 13, 2021		2021 REMS 001446a-1446e
Memorandum: Mifepristone; All Adverse Events. NDA 020687 and ANDA 091178. #2007-525. April 12, 2021		2021 ED 000424-433
Xavier Becerra, Secretary, U.S. Dep't of Health & Human Servs., *Renewal of Determination That a Public Health Emergency Exists* (Oct. 15, 2021)		2021 REMS 001447
Mifeprex (mifepristone) [package insert]. New York, NY: Danco Laboratories, LLC; April 2019		2021 REMS 001448-1466
Mifepristone [package insert]. Las Vegas, NV: GenBioPro, Inc.; February 2019		2021 REMS 001467-1484
Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2021. NDA 020687 and ANDA 091178. RCM # 2007-525. Finalized September 24, 2021		2021 REMS 001485-1487
Am. Coll. of Obstetricians & Gynecologists & Soc'y of Family Planning, Prac. Bull. No. 225, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 1 (Oct. 2020)		2021 REMS 000748-764
Nat'l Abortion Fed'n, *2020 Clinical Policy Guidelines for Abortion Care*, at 15 Standard 6.6 (2020)		2021 REMS 000782-845
Am. Coll. of Obstetricians & Gynecologists, Prac. Bull. No. 196, *Thromboembolism in Pregnancy,* 132 Obstetrics & Gynecology e1-e17 (2018)		2021 REMS 001488-1504
U.S. Food & Drug Admin. REMS Memo	12/16/2021	2021 REMS 001505-1508
Review of the one-year REMS assessment report for the Mifepristone REMS Program	12/16/2021	2021 REMS 001509-1532
Memorandum: Mifepristone; All Adverse Events. NDA 020687 and ANDA 091178. #2007-525. April 12, 2021		2021 ED 000424-433
Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2018. NDA 020687. RCM # 2007-525. Finalized October 30, 2018.		2021 REMS 001533-1535
Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2018. NDA 020687. RCM # 2007-525. Finalized March 8, 2019.		2021 REMS001536-1538
Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2019. NDA 020687. RCM # 2007-525. Finalized November 19, 2019.		2021 REMS 001539-1541
Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2019. NDA 020687 and		2021 REMS 001542-1544

Description	Date	Bates Number
ANDA 091178. RCM # 2007-525. Finalized March 19, 2020		
Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2020. NDA 020687 and ANDA 091178. RCM # 2007-525. Finalized October 6, 2020		2021 REMS 001545-1547
Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2020. NDA 020687 and ANDA 091178. RCM # 2007-525. Finalized March 16, 2021		2021 REMS 001548-1550
Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2021. NDA 020687 and ANDA 091178. RCM # 2007-525. Finalized September 24, 2021		2021 REMS 001485-1487
Memorandum: Mifepristone and All Adverse Events. NDA 020687 and ANDA 091178. RCM # 2007-525. Finalized December 16, 2021		2021 REMS 001390-1401
Franz Hanschmidt et al., *Abortion Stigma: A Systematic Review*, 48 Perspectives Sexual & Reproductive Health 169-77 (2016)		2021 REMS 001551-1560
REMS Modification Rationale Review	12/16/2021	2021 REMS 001561-1609
NDA approval letter Mifeprex (NDA 020687) dated September 28, 2000		FDA 0003-0005
Am. Coll. of Obstetricians & Gynecologists, Prac. Bull. No. 191, *Tubal Ectopic Pregnancy* (Feb. 2018)		2021 REMS 001610-1622
Review of the one-year REMS assessment report for the Mifepristone REMS Program, December 16, 2021		2021 REMS 001509-1532
Ctr. for Drug Evaluation & Res., Application Number 020687Orig1s020, Clinical Review (Mar. 29, 2016)		FDA 0527-0634
Review of proposed REMS modifications to Mifeprex (Mar. 29, 2016)		FDA 0673-0709
Summary of Regulatory Action for Mifeprex (Mar. 29, 2016)		FDA 0412-0439
U.S. Food & Drug Admin. General Advice Letter for NDA 20687 (Apr. 12, 2021)		2021 ED 000515-517
U.S. Food & Drug Admin. General Advice Letter for ANDA 091178, (Apr. 12, 2021)		2021 ED 000512-514
Response to 9/2/2021 information request from NDA mifepristone applicant (Sept. 9, 2021)		2021 REMS 001145-1148
Response to 6/30/2021 information request from NDA mifepristone applicant (Oct. 8, 2021)		2021 REMS 001270-1273

Description	Date	Bates Number
Memorandum: Mifepristone; All Adverse Events. NDA 020687 and ANDA 091178. #2007-525 April 12, 2021		2021 ED 000424-433
Memorandum: Mifepristone and All Adverse Events. NDA 020687 and ANDA 091178. RCM # 2007-525. Finalized December 16, 2021.		2021 REMS 001390-1401
Daniel Grossman et al., *Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment*, 107 Contraception 36-41 (2022)		2021 REMS 001623-1628
Daniel Grossman et al., *Medication Abortion with Pharmacist Dispensing of Mifepristone*, 137 Obstetrics & Gynecology 613-22 (2021)		2021 REMS 000772-781
Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43-48 (2021)		2021 ED 000117-122
Courtney Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, 104 Contraception 49-53 (2021)		2021 ED 000439-443
Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG: Int'l J. Obstetrics & Gynecology 1464-74 (2021)		2021 ED 000085-095
Corinne H. Rocca et al., *Effectiveness and safety of early medication abortion provided in pharmacies by auxiliary nurse-midwives: A non-inferiority study in Nepal*, 13 PLoS ONE 1-12 (2018)		2021 REMS 001629-1640
Ellen R. Wiebe et al., *Comparing telemedicine to in-clinic medication abortions induced with mifepristone and misoprostol*, Contraception: X 1-4 (2020)		2021 REMS 001641-1644
Nat'l Abortion Fed'n, *2020 Clinical Policy Guidelines for Abortion Care*, at 15 Standard 6.6 (2020)		2021 REMS 000782-845
Am. Coll. of Obstetricians & Gynecologists & Soc'y of Family Planning, Prac. Bull. No. 225, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 1 (Oct. 2020)		2021 REMS 000748-764
Heide E. Jones et al., *First trimester medication abortion practice in the United States and Canada*, 12 PLoS ONE 1-10 (2017)		2021 REMS 001645-1654
Daniel Grossman et al., *Induced abortion provision among a national sample of obstetrician-gynecologists*, 133 Obstetrics & Gynecology 477-83 (2019)		2021 REMS 000966-972

Description	Date	Bates Number
Sara Daniel et al., *Obstetrician-Gynecologist Willingness to Provide Medication Abortion with Removal of the In-Person Dispensing Requirement for Mifepristone*, 104 Contraception 73-76 (2021)		2021 REMS 001173-1176
Review of the one-year REMS assessment report for the Mifepristone REMS Program, Dec. 16, 2021.		2021 REMS 001509-1532
Ushma D. Upadhyay et al., *Safety and Efficacy of Telehealth Medication Abortion in the US During the COVID-19 Pandemic*, 4 JAMA Network Open 1-3 (2021)		2021 REMS 001655-1657
Paul Hyland et al., *A Direct-to-Patient Telemedicine Abortion Service in Australia: Retrospective Analysis of the First 18 Months*, 58 Aust. New Zeal. J. Obstetrics & Gynaecology 335-40 (2018)		2021 REMS 001015-1020
Elizabeth Raymond et al., *TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States*, 100 Contraception 173-77 (2019)		2021 ED 000112-116
Holly A. Anger et al., *Clinical and service delivery implications of omitting ultrasound before medication abortion provided via direct-to-patient telemedicine and mail in the U.S.*, 104 Contraception 659-65 (2021)		2021 REMS 001658-1664
John Joseph Reynolds-Wright et al., *Telemedicine medical abortion at home under 12 weeks' gestation: a prospective observational cohort study during COVID-19 pandemic*, 47 BMJ Sex. Reprod. Health 246-51 (2021)		2021 ED 000444-449
Abigail R.A. Aiken et al., *Self reported outcomes and adverse events after medical abortion through online telemedicine: population based study in the Republic of Ireland and Northern Ireland*. 357 BMJ (2017)		2021 REMS 001665-1683
Hannah Norten et al., *10-year evaluation of the use of medical abortion through telemedicine: a retrospective cohort study*, BJOG (2021)		2021 REMS 001684-1692
M. Endler et al., *Safety and acceptability of medical abortion through telemedicine after 9 weeks of gestation: a population-based cohort study*, BJOG 609-18 (2019)		2021 REMS 001693-1702
Elizabeth G. Raymond et al., Commentary: *No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond,* 101 Contraception 361-66 (2020)		2021 ED 000469-474
Alice Mark et al., *The future of abortion is now: Mifepristone by mail and in-clinic abortion access in the United States*, 104 Contraception 38-42 (2021)		2021 REMS 001703-1708

Description	Date	Bates Number
Danielle Martin et al., *Canada's universal health care system: achieving its potential*, 391 Lancet 1718-35 (2018)		2021 REMS 001709-1726
Am. Coll. of Obstetricians & Gynecologists, *Position Statement: Improving Access to Mifepristone for Reproductive Health Indications* (June 2018)		2021 ED 000011-013
Am. Med. Ass'n House of Delegates, *Ending the Risk Evaluation and Mitigation Strategy (REMS) policy on mifepristone (Mifeprex)*, Policy H-100.948, (2018)		2021 REMS 000086-156
Cong. Of Delegates, Am. Acad. Of Fam. Physicians, *Resolution No. 506 (CoSponsored C) Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization of Mifepristone* (May 24, 2018)		2021 REMS 001168-1171
Laura Schummers et al., *Do Medication Abortion Complications Increase When Restrictive Risk Evaluation and Mitigation Strategy Regulations are Removed? A Population-Based Study Using Single-Payer Linked Health Administrative Data*, 102 Contraception 273-304 (2020)		2021 REMS 001172
Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175-83 (2015)		2021 REMS 000686-694
Nathalie Kapp & Patricia A. Lohr, *Modern methods to induce abortion: Safety, efficacy and choice*, 63 Best Pract. Res. Clin. Obstetrics & Gynaecology 37-44 (2020)		2021 REMS 000958-965
Liza Fuentes & Jenna Jerman, *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, 28 J. Women's Health 1623-31 (2019)		2021 REMS 000339-347
Jonathan M. Bearak et al., *Disparities and Change Over Time in Distance Women Would Need to Travel to Have an Abortion in the USA: A Spatial Analysis*, 2 Lancet Pub. Health e493-e500 (2017)		2021 REMS 001177-1184
Alice F. Cartwright et al., *Identifying National Availability of Abortion Care and Distance from Major US Cities: Systematic Online Search*, 20 J. Med. Internet Res. e186 (2018)		2021 REMS 001185-1197
Jill Barr-Walker et al., *Experiences of women who travel for abortion: A mixed methods systematic review*, PLoS ONE 1-26 (2019)		2021 REMS 000313-338
Grossman, D. et al., *Change in Distance to Nearest Facility and Abortion in Texas, 2012 to 2014*, 317 JAMA Network 437–38 (2017)		2021 REMS 001227-1229

Description	Date	Bates Number
Sharon A. Dobie et al., *Abortion Services in Rural Washington State, 1983–1984 to 1993–1994: Availability and Outcomes*, 31 Fam. Plan. Persp. 241-45 (1999)		2021 REMS 001230-1234
James D. Shelton et al., *Abortion Utilization: Does Travel Distance Matter?*, 8 Fam. Plan. Persp. 260–62 (1976)		2021 REMS 001251-1254
Alison H. Norris et al., *Abortion Access in Ohio's Changing Legislative Context, 2010–2018*, 110 Am. J. Pub. Health 1228-34 (2020)		2021 REMS 001255-1261
Ushma D. Upadhyay et al., *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, 104 Am. J. Pub. Health 1687-94 (2014)		2021 REMS 001262-1269
Ctrs. for Disease Control & Prevention, *Surveillance summaries 2018*, 69 Morbidity & Mortality Weekly Report (2020)		2021 REMS 001727-1774
Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2017*, Guttmacher Inst. (2019)		2021 REMS 000289-312
Guttmacher Inst., *Induced Abortion in the United States* (2019)		2021 REMS 001775-1777
University of Minnesota Healthy Youth Dev. Prevention Rsch Ctr, *2019 Minnesota Adolescent Sexual Health Report* 3 (2019)		2021 REMS 001778-1783
Jenna Jerman et al., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, Guttmacher Inst. (2016)		2021 REMS 001198-1226
Sarah C.M. Roberts et al., *Out-of-pocket costs and insurance coverage for abortion in the United States*, 24 Women's Health Issues e211-18 (2014)		2021 REMS 001784-1791
Nicole E. Johns et al., *Distance traveled for Medicaid-covered abortion care in California*, 17 BMC Health Servs. Res. 287 (2017)		2021 REMS 001792-1802
Beverly Winikoff et al., *Extending outpatient medical abortion services through 70 days of gestational age*, 120 Obstetrics & Gynecology 1070-76 (2012)		2021 REMS 000999-1005
Melissa J. Chen & Mitchell D. Creinin, *Mifepristone with buccal misoprostol for medical abortion: A systematic review*, 126 Obstetrics & Gynecology 12–21 (2015)		2019 CP 000181-190
Laura Schummers et al., *Do medication abortion complications increase when mifepristone is available without regulations restricting practice? A population-based study using linked health*		2021 REMS 000956-957

Description	Date	Bates Number
administrative data from Canada, 47 BMJ Sex. Reprod. Health. 2-3 (2021)		
Silpa Srinivasulu et al., *US clinicians' perspectives on how mifepristone regulations affect access to medication abortion and early pregnancy loss care in primary care*, 104 Contraception 92-97 (2021)		2021 REMS 000973-978
Danielle Calloway et al., *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States*, 104 Contraception 24-28 (2021)		2021 REMS 000979-983
Kayla N. Rasmussen et al., *Expanding access to medication abortion through pharmacy dispensing of mifepristone: Primary care perspectives from Illinois*, 104 Contraception 98-103 (2021)		2021 REMS 000993-998
Kelly Cleland et al., *Significant adverse events and outcomes after medical abortion*, 121 Obstetrics & Gynecology 166-71 (2013)		2021 REMS 001006-1014
Nat'l Acads. of Scis., Eng'g & Med., *The Safety & Quality of Abortion Care in the United States* (The Nat'l Acads. Press 2018)		2021 ED 000126-348
Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstetrics & Gynecology 215-19 (2012)		2021 REMS 000695-699
Beverly Winikoff et al., *Extending outpatient medical abortion services through 70 days of gestational age*, 120 Obstetrics & Gynecology 1070-76 (2012)		2021 REMS 000999-1005
Rachel K. Jones & Jenna Jerman, *Time to appointment and delays in accessing care among U.S. abortion patients*, Guttmacher Inst. (2016)		2021 REMS 001030-1051
Diana Greene Foster & Katrina Kimport, *Who seeks abortions at or after 20 weeks?*, 45 Perspectives Sex. & Reprod. Health 210-18 (2013)		2021 REMS 001052-1060
Gretchen Ely et al., *Access to abortion services in Tennessee: Does distance traveled and geographic location influence return for a second appointment as required by the mandatory waiting period policy?* 44 Health & Social Work 13-21 (2019)		2021 REMS 001061-1070
Sarah Munro et al., *Perspectives among Canadian physicians on factors influencing implementation of mifepristone medical abortion: A national qualitative study*, 18 Ann. Fam. Med. 413-21 (2020)		2021 REMS 000984-992
Letter from U.S. Food & Drug Admin. to Danco Laboratories, LLC re: REMS Modification Notification	12/16/2021	2021 REMS 001803-1807
Letter from U.S. Food & Drug Admin. to GenBioPro, Inc. re: REMS Modification Notification	12/16/2021	2021 REMS 001808-1811

Description	Date	Bates Number
Letter from U.S. Food & Drug Admin. to Dr. Graham Chelius, The Society of Family Planning, The California Academy of Family Physician	12/16/2021	2021 REMS 001812
Mifepristone REMS	4/2019	2021 REMS 002058-002065
Mifepristone REMS	5/2021	2021 REMS 002066-002073
VI. January 3, 2023 Approval of Mifepristone REMS Modifications		
NDA Type A Meeting Request	3/11/2022	2023 SUPP 000001-012
Letter from U.S. Food & Drug Admin. to mifepristone applicant granting Type A Meeting Request	3/16/2022	2023 SUPP 000013-015
Meeting request - written responses	4/8/2022	2023 SUPP 000016-022
NDA mifepristone applicant request for extension to submit REMS Modification application	4/13/2022	2023 SUPP 000023-025
ANDA mifepristone applicant request for extension to submit REMS Modification application	4/13/2022	2023 SUPP 000026-027
Letter from U.S. Food & Drug Admin. to NDA mifepristone applicant granting an extension until 6/30/22	4/15/2022	2023 SUPP 000028-029
Letter from U.S. Food & Drug Admin. to ANDA mifepristone applicant granting an extension until 6/30/22	4/15/2022	2023 SUPP 000030-031
Letter from Maureen G. Phipps, Chief Executive Officer, Am. College of Obstetricians & Gynecologists and James L. Madara, Chief Executive Officer, Am. Med. Ass'n to Dr. Robert Califf, Commissioner, U.S. Food & Drug Admin. re: actions related to mifepristone	6/21/2022	2023 SUPP 000032-037
Am. Coll. of Obstetricians & Gynecologists, *Position Statement: Improving Access to Mifepristone for Reproductive Health Indications* (June 2018)		2021 ED 000011-013
Kelly Cleland & Nicole Smith, *Aligning mifepristone regulation with evidence: driving policy change using 15 years of excellent safety data*, 92 Contraception 179-81 (2015)		2021 ED 000014-016
Mifeprex REMS Study Group, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 3679 N. Eng. J. Med. 790-94 (2017)		2019 CP 000370-374
Li Ping Song et al., *Early medical abortion with self-administered low-dose mifepristone in combination with misoprostol*, 44 J. Obstet. Gynaecology Res. 1705-11 (2018)		2021 ED 000017-023

Description	Date	Bates Number
Am. Coll. of Obstetricians & Gynecologists, Prac. Bull. No. 150, *Early pregnancy loss*, 125 Obstetrics & Gynecology 1258-67 (2015)		2023 SUPP 000038-046
Stephanie J. Ventura, et al., *Estimated pregnancy rates and rates of pregnancy outcomes for the United States, 1990-2008*, 60 Nat'l Vital Statistics Rep. 1-21 (2012)		2023 SUPP 000047-068
Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 N. Eng. J. Med. 2161-70 (2018)		2019 CP 000402-411
Carolyn L. Westhoff, *A better medical regimen for the management of miscarriage*, 378 N. Eng. J. Med. 2232-33 (2018)		2023 SUPP 000069-070
Am. Coll. of Obstetricians & Gynecologists & Soc'y of Family Planning, Prac. Bull. No. 225, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 1 (Oct. 2020)		2021 REMS 000748-764
Daniel Grossman et al., *Induced abortion provision among a national sample of obstetrician-gynecologists*, 133 Obstetrics & Gynecology 477-83 (2019)		2021 REMS 000966-972
Am. Coll. of Obstetricians & Gynecologists et al., *Joint Statement on Abortion Access During the COVID-19 Outbreak* (Mar. 18, 2020)		2021 ED 000024-026
Courtney Kerestes et al., *Provision of medication abortion in Hawai'i during COVID-19: Practical experience with multiple care delivery models*, 104 Contraception 49-53 (2021)		2021 ED 000439-443
Am. Coll. of Obstetricians & Gynecologists, Prac. Bull. No. 135, *Second-trimester abortion*, 121 Obstetrics & Gynecology 1394-406 (2013)		2023 SUPP 000071-083
Guttmacher Inst., *Medication Abortion* (updated version—July 2023)		2023 SUPP 000084-087
World Health Organization, *Medical management of abortion* (WHO 2018)		2023 SUPP 000088-159
Dinna Abbas et al., *Outpatient medical abortion is safe and effective through 70 days gestation*, 92 Contraception 197-99 (2015)		2023 SUPP 000160-162
Melissa J. Chen & Mitchell D. Creinin, *Mifepristone with buccal misoprostol for medical abortion: A systematic review*, 126 Obstetrics & Gynecology 12–21 (2015)		2019 CP 000181-190
Ilana G. Dzuba et al., *A non-inferiority study of outpatient mifepristone-misoprostol medical abortion at 64-70 days and 71-77 days of gestation*, 101 Contraception 302-08 (2020)		2023 SUPP 000163-169

Description	Date	Bates Number
Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 JAMA Internal Medicine 482–91 (2022)		2023 SUPP 000170-179
Donna L. Hoyert, *Maternal mortality rates in the United States, 2020*, Nat'l Center for Health Statistics (Feb. 2022)		2023 SUPP 000180-184
Amy N. Addante et al., *The association between state-level abortion restrictions and maternal mortality in the United States, 1995-2017*, 104 Contraception 496-501 (2021)		2023 SUPP 000185-190
Summer Sherburne Hawkins et al., *Impact of State-Level Changes on Maternal Mortality: A Population-Based, Quasi-Experimental Study*, 58 Am. J. Preventive Med. 165-74 (2020)		2023 SUPP 000191-200
Nisha Verma & Scott A. Shainker, *Maternal mortality, abortion access, and optimizing care in an increasingly restrictive United States: A review of the current climate*, 44 Seminars in Perinatology 1-9 (2020)		2023 SUPP 000201-209
Guttmacher Inst., *Medicaid Coverage of Abortion* (Feb. 2021)		2023 SUPP 000210-218
Amanda Jean Stevenson, *The Pregnancy-Related Mortality Impact of a Total Abortion Ban in the United States: A Research Note on Increased Deaths Due to Remaining Pregnant*, 58 Demography 2019-28 (2021)		2023 SUPP 000219-228
M. Antonia Biggs et al., *Women's Mental Health and Well-being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study*, 74 JAMA Psychiatry 169-78 (2017)		2023 SUPP 000229-238
N.I. Gavin et al., *Perinatal depression: a systematic review of prevalence and incidence*, 106 Obstetrics & Gynecology 1071-83 (2005)		2023 SUPP 000239-251
Am. Coll. of Obstetricians & Gynecologists, Committee Opinion No. 586: *Health disparities in rural women*, 123 Obstetrics & Gynecology 384-88 (2014)		2023 SUPP 000252-256
NDA – supplemental application submission	6/22/2022	2023 SUPP 000257-350
ANDA – supplemental application submission	6/22/2022	2023 SUPP 000351-439
Information request sent to ANDA mifepristone applicant	7/22/2022	2023 SUPP 000440-445
Information request sent to NDA mifepristone applicant	7/22/2022	2023 SUPP 000446-450

Description	Date	Bates Number
NDA amendment responding to 7/22/2022 information request	8/26/2022	2023 SUPP 000451-478
ANDA amendment responding to 7/22/2022 information request	8/26/2022	2023 SUPP 000479-503
Teleconference with mifepristone applicants and U.S. Food & Drug Admin. (no minutes prepared)	9/19/2022	---
Information requests from U.S. Food & Drug Admin. and responses from mifepristone applicants	9/22-23/2022	2023 SUPP 000504-506
Information requests sent to NDA and ANDA mifepristone applicants	9/27/2022 9/29/2022	2023 SUPP 000507-516
Email from NDA and ANDA mifepristone applicants regarding 10/6/22 teleconference and 9/27/22 information request from U.S. Food & Drug Admin.	10/4/2022	2023 SUPP 000517-533
Teleconference with NDA and ANDA mifepristone applicants and U.S. Food & Drug Admin. discussing 9/29/2022 information request	10/6/2022	2023 SUPP 000534-538
NDA amendment	10/19/2022	2023 SUPP 000539-560
ANDA amendment	10/19/2022	2023 SUPP 000561-578
Teleconference with NDA and ANDA mifepristone applicants and U.S. Food & Drug Admin.	10/25/2022	2023 SUPP 000579-582
Review of NDA and ANDA mifepristone applicants' 10/19/22 amendments	11/23/2022	2023 SUPP 000583-587
Information request sent to NDA and ANDA mifepristone applicants	11/23/2022	2023 SUPP 000588-590
NDA amendment	11/30/2022	2023 SUPP 000591-609
ANDA amendment	11/30/2022	2023 SUPP 000610-621
Teleconference with NDA and ANDA mifepristone applicants and U.S. Food & Drug Admin.	12/1/2022	2023 SUPP 000622-625
Review of proposed Major REMS Modification	12/5/2022	2023 SUPP 000626-629
Information request sent to NDA and ANDA mifepristone applicants	12/5/2022	2023 SUPP 000630-633
Teleconference with NDA and ANDA mifepristone applicants and U.S. Food & Drug Admin. to discuss 12/5/2022 information request	12/7/2022	2023 SUPP 000634-637
Review of Proposed Major REMS Modification: Draft REMS Assessment Plan Comments	12/8/2022	2023 SUPP 000638-641
NDA amendment	12/8/2022	2023 SUPP 000642-734
ANDA amendment	12/8/2022	2023 SUPP 000735-834

Description	Date	Bates Number
Review of NDA and ANDA mifepristone applicants' 12/8/22 amendments	12/14/2022	2023 SUPP 000835-839
Information request sent to NDA and ANDA mifepristone applicants (discussed at 12/15/22 teleconferences between U.S. Food & Drug Admin. and applicants)	12/14/2022	2023 SUPP 000840-843
Teleconferences with NDA and ANDA mifepristone applicants and U.S. Food & Drug Admin.	12/15/2022 (9 AM)	2023 SUPP 000844-847
Teleconference with NDA and ANDA mifepristone applicants and U.S. Food & Drug Admin.	12/15/2022 (5 PM)	2023 SUPP 000848-851
NDA amendment	12/16/2022	2023 SUPP 000852-945
ANDA amendment	12/16/2022	2023 SUPP 000946-1039
U.S. Food & Drug Admin. Memorandum re adverse events from 10/1/21 – 12/3/22	12/22/2022	2023 SUPP 001040-1051
Mifeprex (mifepristone) [package insert]. New York, NY: Danco Laboratories, LLC; April 2019		2021 REMS 001448-1466
Mifepristone [package insert]. Las Vegas, NV: GenBioPro, Inc.; February 2019		2021 REMS 001467-1484
U.S. Food & Drug Admin., Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022 (finalized Nov. 9, 2022)		2023 SUPP 001052-1053
Am. Coll. of Obstetricians & Gynecologists & Soc'y of Family Planning, Prac. Bull. No. 225, *Medication Abortion Up to 70 Days of Gestation*, 136 Obstetrics & Gynecology 1 (Oct. 2020)		2021 REMS 000748-764
Nat'l Abortion Fed'n, *2020 Clinical Policy Guidelines for Abortion Care*, at 15 Standard 6.6 (2020)		2021 REMS 000782-845
Memorandum: Mifepristone and All Adverse Events. NDA 020687 and ANDA 091178. RCM # 2007-525. Finalized December 16, 2021		2021 REMS 001390-1401
Review of Supplemental Drug Applications Proposing Modifications to the Mifepristone REMS Program	12/23/2022	2023 SUPP 001054-1055
U.S. Dep't of Justice, Office of Legal Counsel, Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions	12/23/2022	2023 SUPP 001056-1076
Memorandum to File re: Referenced Publications	12/30/2022	2023 SUPP 001077-1080
James Studnicki et al., *A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999–2015*, 8 Health Servs. Research & Managerial Epidemiology 1-11 (2021)		2023 SUPP 001081-1091

Description	Date	Bates Number
J. Studnicki et al., *A Post Hoc Exploratory Analysis: Induced Abortion Complications Mistaken for Miscarriage in the Emergency Room are a Risk Factor for Hospitalization*, 9 Health Serv. Research & Managerial Epidemiology 1-4 (2022)		2023 SUPP 001092-1095
Katherine A. Rafferty & Tessa Longbons, *#AbortionChangesYou: A Case Study to Understand the Communicative Tensions in Women's Medication Abortion Narratives*, 36 Health Comm.1485-94 (2020)		2023 SUPP 001096-1106
Kathi A. Aultman et al., *Deaths and Severe Adverse Events after the use of Mifepristone as an Abortifacient from September 2000 to February 2019*, 36 Issues in Law & Med. 3-27 (2021)		2021 REMS 000601-625
Christina A. Cirucci et al., *Mifepristone Adverse Events Identified by Planned Parenthood in 2009 and 2010 Compared to Those in the FDA Adverse Event Reporting System and Those Obtained Through the Freedom of Information Act*, 8 Health Servs. Research & Managerial Epidemiology 1-5 (2021)		2023 SUPP 001107-1111
Joint Summary Review	1/3/2023	2023 SUPP 0001112-1150
Nat'l Abortion Federation, *2020 Violence and Disruption Statistics* (Dec. 16, 2021)		2023 SUPP 001151-1159
Amanda Musa, *Wyoming Authorities Search for a Suspect Believed to Have Set an Abortion Clinic on Fire*, CNN WIRE (June 11, 2022)		2023 SUPP 001160-1162
Ctr. for Drug Evaluation & Res., Application Number 020687Orig1s020, Clinical Review (Mar. 29, 2016)		FDA 0527-0634
Summary of Regulatory Action for Mifeprex (Mar. 29, 2016)		FDA 0412-0439
REMS Review for mifepristone, NDA 020687 (Mar. 29, 2016)		FDA 0684-0697
REMS Review for mifepristone, NDA 020687 (Mar. 29, 2016)		FDA 0698-0709
Approval Letter for SE-20 Efficacy Supplement for mifepristone, NDA 020687 (Mar. 29, 2016)		FDA 0374-0381
REMS Review for mifepristone, NDA 020687 (Feb. 22, 2018)		2023 SUPP 001163-1179
Approval Letter for SE-22 REMS Supplement for mifepristone, NDA 020687 (Apr. 11, 2019)		2023 SUPP 001180-1186
Am. Coll. of Obstetricians & Gynecologists v. FDA, 472 F. Supp. 3d 183 (D. Md. July 13, 2020), order clarified, 2020 WL 8167535 (D. Md. Aug. 19, 2020)		2021 REMS 001402-1440
FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578 (Jan. 12, 2021)		2021 REMS 001441-1446

Description	Date	Bates Number
REMS Modification Rationale Review for mifepristone, NDA 020687 (Dec. 16, 2021)		2021 REMS 001561-1609
Letter from U.S. Food & Drug Admin. to NDA mifepristone applicant granting an extension until 6/30/22 (Apr. 15, 2022)		2023 SUPP 000030-031
U.S. Food & Drug Admin., *Format and Content of a REMS Document: Guidance for Industry* (Oct. 2017)		2023 SUPP 001187-1220
Daniel Grossman et al., *Mail-order pharmacy dispensing of mifepristone for medication abortion after in-person clinical assessment*, 107 Contraception 36-41 (2022)		2021 REMS 001623-1628
NDA Labeling Review	1/3/2023	2023 SUPP 001221-1225
REMS Modification Notification letter (Dec. 16, 2021)		2021 REMS 001803-1807
REMS memorandum (Dec. 16, 2021)		2021 REMS 001561-1609
ANDA Labeling Review	1/3/2023	2023 SUPP 001226-1258
Memorandum to File re: AIM Study	1/3/2023	2023 SUPP 001259-1261
Ning Liu & Joel G. Ray, *Short-term Adverse Outcomes After Mifepristone–Misoprostol Versus Procedural Induced Abortion: A population-based propensity-weighted study*, 176 Annals Internal Med. 145-53 (2023)		2023 SUPP 001262-1273
Danco Laboratories, LLC Approval Package for Application Number 020687Orig1s025	1/3/2023	2023 SUPP 001274-1447
Letter from U.S. Food & Drug Admin. to Danco Laboratories, LLC re: Supplement Approval NDA 020687/S-025	1/3/2023	2023 SUPP 001448-1460
Letter from U.S. Food & Drug Admin. to GenBioPro, Inc. re: Supplemental Approval ANDA 091178-S004	1/3/2023	2023 SUPP 001461-1465
Mifepristone Tablets, 200 mg, Single Shared System Risk Evaluation and Mitigation Strategy (REMS) Supporting Document	1/2023	2023 SUPP 001466-1470
Mifeprex 2023 Labeling and Medication Guide	1/2023	2023 SUPP 001471-1489
Mifepristone 2023 Labeling and Medication Guide	1/2023	2023 SUPP 001490-001509
Mifepristone Patient Agreement Form (Danco and GenBioPro)	1/2023	2023 SUPP 001510
Mifeprex Pharmacy Agreement Form (Danco)	1/2023	2023 SUPP 001511-1512
Mifepristone Pharmacy Agreement Form (GenBioPro)	1/2023	2023 SUPP 001513

Description	Date	Bates Number
Mifeprex Prescriber Agreement Form (Danco)	1/2023	2023 SUPP 001514-1515
Mifepristone Prescriber Agreement Form (GenBioPro)	1/2023	2023 SUPP 001516-1517
VII. Citizen Petition Docket FDA-2022-P-2425		
Citizen Petition from American College of Obstetricians and Gynecologists	10/4/2022	2022 CP 000071-000098
Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. Med. 57-67 (2022)		2022 CP 000099-000109
Citizen Response Letter from U.S. Food & Drug Admin. to American College of Obstetricians and Gynecologists	1/3/2023	2022 CP 000110-000113

FILED IN THE
U.S. DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

Mar 08, 2024

SEAN F. McAVOY, CLERK

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, STATE OF OREGON, STATE OF ARIZONA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, STATE OF ILLINOIS, ATTORNEY GENERAL OF MICHIGAN, STATE OF NEVADA, STATE OF NEW MEXICO, STATE OF RHODE ISLAND, STATE OF VERMONT, DISTRICT OF COLUMBIA, STATE OF HAWAII, STATE OF MAINE, STATE OF MARYLAND, STATE OF MINNESOTA, and COMMONWEALTH OF PENNSYLVANIA, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs, UNITED STATES DEPARTMENT OF HEALTH AND	NO. 1:23-CV-3026-TOR ORDER GRANTING IN PART PLAINTIFFS' MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD

HUMAN SERVICES, and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

Defendants.

BEFORE THE COURT is Plaintiff States' Motion to Supplement the Administrative Record (ECF No. 133). The matter was submitted for consideration without oral argument. The Court has reviewed the record and files herein, and is fully informed. For the reasons discussed below, Plaintiff States' Motion to Supplement the Administrative Record (ECF No. 133) is **GRANTED IN PART**.

BACKGROUND

This case concerns federal regulation of mifepristone, a drug used to assist with the termination of early intrauterine pregnancy. The motion pending before the Court arises out of Plaintiffs' request to complete and/or supplement the administrative record. *See* ECF No. 133. For purposes of contextualizing the parties' arguments, the Court reviews the underlying facts and procedural history of the litigation.

In 2000, the United States Food and Drug Administration (FDA), an agency within the United States Department of Health and Human Services (HHS), approved the distribution of mifepristone under Subpart H of the Food, Drug, and

Cosmetic Act (FDCA). ECF No. 35 at 23-24, ¶ 87.[1] Under Subpart H, FDA imposed certain restrictions on the prescription and distribution of mifepristone to assure safe use. *Id.*; *see also* 21 C.F.R. § 314.520(a) (2023) ("If FDA concludes that a drug product shown to be effective can be safely used only if distribution or use is restricted, FDA will require such postmarketing restrictions as are needed to assure safe use of the drug product."). These restrictions included, *inter alia*:

> (1) an "in-person dispensation requirement," under which the drug could only be administered and dispensed in a hospital, clinic, or medical office, by or under the supervision of a physician-provider;
>
> (2) a "prescriber certification requirement," under which providers could not prescribe the drug without first attesting to their clinical abilities and agreeing to various reporting requirements in a signed form retained by the manufacturer; and
>
> (3) a "patient agreement form requirement," under which prescribers and patients were required to review and sign a form which included information about the mifepristone regimen and risks, and under which the prescriber was required to (a) retain one copy of the form in the patient's medical record and (b) provide the patient with one separate copy.

[1] Mifepristone was approved for distribution under the brand name "Mifeprex." ECF No. 35 at 2, ¶ 2. A generic version was also approved in 2019. *Id.* at 32, ¶ 103. Mifepristone is used in a two-dose regimen with misoprostol, a separate FDA-approved drug, to terminate a pregnancy. *Id.* at 21, ¶ 82.

ECF No. 35 at 23-24, ¶ 87.[2]

Through the Food and Drug Administration Amendments Act (FDAAA) of 2007, Congress replaced Subpart H with the Risk Evaluation and Mitigation Strategies (REMS) statute. ECF Nos. 35 at 25, ¶ 89; 51 at 6-7; *see also* 21 U.S.C. § 355-1(a)(1) (authorizing the Secretary of FDA to require a REMS when "necessary to ensure that the benefits of the drug outweigh the risks of the drug"). The statute lists six factors for FDA to consider in deciding whether a REMS is necessary. *See* 21 U.S.C. § 355-1(A)-(F). Additionally, Congress licensed FDA to require that a REMS include certain "elements to assure safe use" (ETASU). 21 U.S.C. § 355-1(f). ETASU are required upon a determination by the Secretary that the drug has been proven effective, "but is associated with a serious adverse drug experience," and therefore can only be approved with certain restrictions in place to mitigate the "serious specific risk[s]" of the drug. *Id.*

[2] Related restrictions included, for instance, that the regimen could only be administered within a 49-day gestational period, and that both mifepristone and misoprostol must be administered under medical supervision over the course of two separate, in-person office visits and one in-person follow-up visit. ECF No. 51-5 at 4. These restrictions were later amended to extend the gestational period to 70 days and to require only one in-person visit. *Id.* at 4-5.

With the enactment of the FDAAA, Congress determined that all drugs previously approved pursuant to Subpart H would be deemed to have a REMS in place, with any restrictions under Subpart H qualifying as ETASU. ECF No. 51 at 8 (citing Pub. L. 110-85, tit. IX, § 909(b)(1)). Thus, mifepristone was subject to a qualifying REMS, and the three above-mentioned Subpart H restrictions on its distribution remained in place as ETASU. *Id.*; *see also* ECF No. 35 at 25, ¶ 89.

Since 2007, FDA has occasionally reevaluated the necessity of a REMS and ETASU for mifepristone.[3] ECF No. 51 at 9. In 2016, the agency notably concluded that "known serious risks occur rarely" and predicted that because "the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low." ECF No. 35 at 30, ¶ 100. As a result, FDA made several changes to the REMS, including updating the prescriber agreement and allowing non-physician health care providers who meet certification requirements to dispense the drug. ECF No. 51-5 at 4-5.

On May 7, 2021, FDA announced it would undertake a full review of the mifepristone REMS. ECF No. 35 at 32-33, ¶¶ 104-105. In a December 16, 2021 letter addressing a citizen petition brought by the American Association of Pro-

[3] As of 2019, the REMS and ETASU apply to both Mifeprex and the generic version of mifepristone. ECF No. 35 at 32, ¶ 103.

Life Obstetricians and Gynecologists and American College of Pediatricians, FDA advised that it was making several changes to the REMS, including (1) suspending the in-person dispensation requirement[4] and (2) promulgating a new pharmacy certification requirement, under which pharmacies may dispense mifepristone upon the condition that they first obtain special certification from drug sponsors.[5] ECF No. 1-13 at 2-5. Both the prescriber certification requirement and the patient agreement requirement remained in force. ECF No. 35 at 37, ¶ 116; 39 at ¶ 121. As a result of this review, FDA issued an updated mifepristone REMS on January 3, 2023. *See* ECF No. 1-13.

On February 23, 2023, Plaintiffs, comprised of seventeen States and the District of Columbia, sued Defendants in this Court challenging FDA's

---

[4] Due to the COVID-19 public health emergency, FDA had previously been enjoined from enforcing the in-person dispensation requirement by a federal court in Maryland. *See Am. Coll. Of Obstetricians & Gynecologists v. U.S. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020). The United States Supreme Court granted the FDA's request for a stay of the injunction in January 2021. *FDA v. Am. Coll. Of Obstetricians & Gynecologists*, 141 S.Ct. 578 (2021).

[5] The prior REMS required that mifepristone could only be dispensed by a provider in a healthcare clinic. ECF No. 35 at 38, ¶ 118.

promulgation of the 2023 REMS as unlawful under the Administrative Procedure Act (APA) and U.S. Constitution. ECF Nos. 1; 35 at 88-90 (amended complaint). Plaintiffs asked the Court to issue a preliminary injunction (1) "affirming FDA's original conclusion that mifepristone is safe and effective," (2) enjoining any actions by Defendants to remove mifepristone from the market, and (3) enjoining the January 2023 REMS and ETASU—or any REMS and ETASU—from taking effect. ECF Nos. 3 at 5; 60 at 10. On April 7, 2023, the Court preliminarily enjoined Defendants from altering the status or rights of the parties under the operative REMS. *See* ECF No. 80; *see also Washington v. United States Food & Drug Admin.*, 668 F. Supp. 3d 1125, 1143 (E.D. Wash. 2023), *opinion clarified*, 669 F. Supp. 3d 1057.

Plaintiffs now move to supplement the record, claiming that in the course of designating the administrative record Defendants have intentionally omitted (1) a 2022 citizen petition by the American College of Obstetricians and Gynecologists (ACOG) and 48 other organizations; (2) a letter by FDA to the ACOG denying the citizen petition; (3) documents and studies cited within the ACOG citizen petition; and (4) the "Turnaway Study," a longitudinal study on abortion access. ECF No. 133 at 5. Plaintiffs claim that FDA considered these materials in the course of deciding whether to promulgate the 2023 REMS, or that, alternatively, supplementation of these extra-record documents is appropriate. *Id.*

DISCUSSION

I. Extra-Record Evidence

The APA empowers the judiciary to review and set aside agency action that is "arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). Judicial review of agency action is necessarily circumscribed: a court "may uphold agency action only on the grounds that the agency invoked when it took the action." *Michigan v. EPA*, 576 U.S. 743, 758 (2015) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)); *Florida Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) ("The reviewing court is not generally empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry.").

To deter *de novo* judicial review and *post hoc* justifications for administrative action, the APA instructs courts to review "the whole record or those parts of it cited by a party." 5 U.S.C. § 706; *see Dep't of Com. v. New York*, 588 U.S. ----, 139 S.Ct. 2551, 2573 (2019) (explaining that "a court is ordinarily limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record . . . [because] judicial inquiry into 'executive motivation' represents 'a substantial intrusion' into the workings of another branch of Government") (quoting *Arlington Heights v. Metro. Hous. Dev. Corp.*, 429 U.S. 252, 268, n.18 (1977)). The "whole" administrative record "consists of all

documents and materials directly or indirectly considered by agency decision-makers and includes evidence contrary to the agency's position." *Thompson v. U.S. Dep't of Lab.*, 885 F.2d 551, 555 (9th Cir. 1989) (internal quotations and citations omitted) (emphasis omitted). Absent "clear evidence to the contrary," the agency's designation of the administrative record is entitled "to a presumption of completeness." *In re United States*, 875 F.3d 1200, 1206 (9th Cir.), *vacated on other grounds*, 583 U.S. 29 (2017); *see also Walter O. Boswell Mem. Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) ("If a court is to review an agency's action fairly, it should have before it neither more nor less information than did the agency when it made its decision.").

Of course, exceptions exist to this general rule. *Thompson*, 885 F.2d at 555 ("The whole administrative record . . . is not necessarily those documents that the *agency* has compiled and submitted as 'the' administrative record.") (internal quotations and citations omitted) (emphasis in original). Where a party identifies "omitted materials with sufficient specificity" and "reasonable, non-speculative grounds for the belief that the documents were considered by the agency and not included in the record," the court may order the agency to complete the record. *Oceana, Inc. v. Pritzker*, No. 16-cv-06784-LHK (SVK), 2017 WL 2670733 at *2 (N.D. Cal. June 21, 2017) (internal quotations and citations omitted); *see also Xerces Soc'y for Invertebrate Conservation v. Shea*, --- F. Supp. 3d ----, 2023 WL

4941221, at *5 (D. Or. July 17, 2023). It is insufficient for a party to merely assert that the missing "documents were relevant, were before or in front of the agency[,] and not included in the record." *Xerces Soc'y*, 2023 WL 4941221 at *5; *see, e.g.*, *S.F. Bay Conservation & Dev. Comm'n v. United States Army Corps of Eng'rs*, No. 16-cv-05420-RS(JCS), 2018 WL 3846002 at *4 (N.D. Cal. Aug. 13, 2018) ("The fact that the documents might be relevant to the [Corps'] decisions does not establish that the Corps actually considered them, either directly or indirectly."). A plaintiff may "also rebut the presumption of completeness by showing that the agency applied the wrong standard in compiling the record," such as where the agency excludes documents because "they did not 'form the basis' for the agency's determination [as opposed to the indirect versus direct consideration standard]." *Oceana, Inc.*, 2017 WL 2670733 at *2 (internal citation omitted).

Alternatively, in narrow circumstances, supplementation of extra-record evidence may be appropriate where:

> [A]dmission of that evidence (1) is necessary to determine whether the agency has considered all relevant factors and has explained its decision, (2) is necessary to determine whether the agency has relied on documents not in the record, (3) when supplementing the record is necessary to explain technical terms or complex subject matter, or (4) when plaintiffs make a showing of agency bad faith.

San Luis & Delta-Mendota Water Auth. v. Locke, 776 F.3d 971, 992 (9th Cir. 2014) (internal quotations and citations omitted); *accord Lands Council v. Powell*,

395 F.3d 1019, 1030 (9th Cir. 2005). Parties seeking to supplement the administrative record bear a "heavy burden to show that the additional materials sought are necessary to adequately review the [agency's] decision." *Fence Creek Cattle Co. v. U.S. Forest Serv.*, 602 F.3d 1125, 1131 (9th Cir. 2010).

Here, Plaintiffs assert that supplementation is warranted because it is "necessary to determine whether the agency has considered all relevant factors and has explained its decision." *San Luis.*, 776 F.3d at 992. Of the four factors, this variable is the most exacting. *Id.* at 993. The Ninth Circuit has warned that "the exception does not permit district courts to use extra-record evidence to judge the wisdom of the agency's action" or to "question[ ] the agency's scientific analyses or conclusions," but instead is intended "only to help the court understand whether the agency complied with the APA's requirement that the agency's decision be neither arbitrary nor capricious." *Id.* at 993. Therefore, a court may supplement the record when the agency entirely "fails to consider a general subject matter," but should stay its hand when "the record contains sufficient information to explain how the agency used the information before it and why it reached its decision." *ForestKeeper v. La Price*, 270 F. Supp. 3d 1182, 1228 (E.D. Cal. 2017) (internal quotations and citations omitted) (cleaned up). Documents post-dating the agency decision may not be included within the record. *Southwest Ctr. for Biological Diversity v. U.S. Forest Serv.*, 100 F.3d 1443, 1450 (9th Cir. 1996).

Bearing these legal principles in mind, the Court turns to the substance of Plaintiffs' arguments.

II. Citizen Petition, Denial Letter & References

Plaintiffs request that (1) the 2022 citizen petition by the ACOG, (2) FDA's letter to the ACOG denying the citizen petition, and (3) all sources cited within the petition be included within the administrative record. ECF No. 133 at 7.

Plaintiffs submit that this Court has already found the petition and denial letter were "before" FDA at the time of its decision. ECF No. 133 at 6. Specifically, in resolving whether Plaintiffs had exhausted their administrative remedies in its prior Order entering a preliminary injunction, this Court wrote:

> In 2020, fifteen Plaintiff States asked FDA to eliminate the REMS patient agreement and certification requirements as "onerous and medically unnecessary" and received a form response from FDA. In 2021, FDA conducted a "full review" of REMS, including information about comparator drugs with mifepristone. *In 2022, the ACOG and other medical and professional healthcare organizations petitioned FDA, in part, to eliminate the REMS as medically unnecessary and unduly burdensome for uses of mifepristone, primarily for miscarriage management*.
>
> Based on the information and requests already put forth before FDA, FDA cannot credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition. Thus, the Court finds that administrative exhaustion through a citizen petition on the January 2023 REMS would be futile.

Washington, 668 F. Supp. 3d at 1139 (emphasis added).

Plaintiffs also contend that FDA considered the petition because of the denial letter itself. ECF No. 133 at 7-8. Plaintiffs state that the petition was denied on the same day that the 2023 REMS were promulgated, thereby evincing that the petition was directly considered by FDA in reaching a decision. *Id.* at 9.

For its part, FDA protests that neither its denial letter nor this Court's prior Order suffice to show it considered the citizen petition in promulgating the 2023 REMS. ECF No. 139 at 8-9. FDA further insists that the petition is irrelevant to the REMS, as the petition advocated for the unauthorized use of mifepristone for miscarriage management, whereas the 2023 REMS dealt with the authorized use of mifepristone for termination of early intrauterine pregnancy. *Id.* at 14.

The Court agrees with Plaintiffs that the ACOG citizen petition and denial letter should be included within the administrative record. To be clear, the Court's earlier determination on the issue of exhaustion called for the application of a different legal standard than the one at issue here. For these purposes, however, Plaintiffs have sufficiently identified specific documents (that is, the petition and letter) and reasonable, non-speculative grounds for their belief that those materials were considered by FDA in the course of its decision-making process. *Oceana, Inc.*, 2017 WL 2670733 at *2. Chief among those reasons were the facts that the denial letter was conspicuously issued on the same day the 2023 REMS were

promulgated and the fact that the amended REMS addresses issues within the same subject matter as the petition.

Regarding FDA's argument that the citizen petition is irrelevant, the Court agrees that the primary "thesis" of the petition was that miscarriage management should be added as an indication to the drug's label and that FDA should eliminate or modify the REMS for that purpose. However, the petition also advanced a secondary argument that the REMS should be done away with entirely, including with respect to the use of mifepristone for termination of early pregnancy. *See* ECF No. 61-1 at 13 (recommending "that the Patient Agreement Form be removed entirely because it is medically unnecessary and repetitive of informed consent"); 16 (arguing that early "research suggests that the pharmacy requirement is unnecessary to ensure that mifepristone's benefits outweigh its risks and unduly burden access"); 18 (discussing a New England Journal of Medicine study on the effect of removing all restrictions on mifepristone prescriptions for abortion in Canada). Therefore, Plaintiffs have demonstrated to the Court's satisfaction that the 2022 ACOG citizen petition and denial letter were "before" FDA at the time it promulgated the 2023 REMS and that FDA directly or indirectly considered such evidence in amending the REMS. [6]

[6] FDA also implies, but does not explicitly argue, that the petition was not "before" it at the time of its decision, because it rendered its decision on the 2023

Plaintiffs also request that FDA be ordered to produce the 52 documents and studies cited *within* the citizen petition. ECF No. 133 at 8. Plaintiffs argue that the cited works should be disclosed primarily for consistency, because FDA has produced the references of other record-produced documents. *Id.* Alternatively, Plaintiffs claim that supplementation is appropriate because it will help the Court evaluate whether FDA "failed to consider an important aspect of the problem": whether lifting the REMS and ETASU would impact mifepristone's safety profile. *Id.* at 9-11; ECF No. 141 at 10.

Plaintiffs have not met their burden to show the record is incomplete with respect to the citations within the citizen petition. Even if the Court were to say those documents were "before" FDA, Plaintiffs have not offered any evidence

---

REMS when it ruled on the December 16, 2021 citizen petition brought by the American Association of Pro-Life Obstetricians and Gynecologists and American College of Pediatricians. *See* ECF No. 139 at 6. The Court declines to engage with this argument, as the amended REMS were not promulgated until January 2023, and other materials within the designated record also post-date the December 16, 2021 letter. *See FTC v. Standard Oil Co. of Cal.*, 449 U.S. 232, 239-31 (1980) (listing factors for the court to consider in determining the finality of agency action).

suggesting the documents were considered directly or indirectly by the agency. The fact that the agency elected to include other, referenced documents as part of the administrative record is not dispositive of whether the specific references within the citizen petition were considered.

On the whole, Plaintiffs' alternate claim that the citations should be supplemented because FDA failed to consider a general subject matter also fails. Plaintiffs correctly point out that the underlying Order on Plaintiffs' motion for a preliminary injunction held that FDA failed to assess whether mifepristone qualifies for REMS and ETASU based on the statutory criteria. *Washington*, 668 F. Supp. 3d at 1141. However, Plaintiffs were not specific about the content of the citations, many of which seem to concern mifepristone's safety profile with respect to miscarriages rather than abortion. *See, e.g.*, 61-1 at 22-28, ¶¶ 5-7, 11-19, 23-29, 32, 45. It seems that allowing supplementation with respect to these citations would serve more as a vehicle for the Court to rely upon extra-record evidence to" judge the wisdom of [FDA's] action" than it would assist the Court with understanding whether FDA acted arbitrarily and capriciously in promulgating the 2023 REMS. *San Luis*, 776 F.3d at 993; *see also Save the Colorado v. United States Dep't of Interior*, 517 F. Supp. 3d 890, 898-99 (D. Ariz. 2021) (declining to allow supplementation of documents referenced within a produced document and reasoning that "[r]equiring such a sweeping application of what was indirectly

before the agency would undermine the value of judicial review"). The Court finds that Plaintiffs have not met their heavy burden to show that the majority of these references should be included within the administrative record.

There is one exception. The citizen petition cited and discussed at some length a 2022 study by the New England Journal of Medicine on Canada's deregulation of mifepristone. ECF No. 61-1 at 18. The study concluded that lifting restrictions on the drug in Canada did not impact its safety profile. ECF No. 61-1 at 18. In their motion, Plaintiffs press that the record needs to be supplemented with this specific study because it will show FDA overlooked evidence showing eliminating the REMS would not impact the safety of mifepristone. ECF No. 141 at 10-11.

The Court agrees that this evidence is relevant and may assist the Court with understanding whether, in fact, FDA acted arbitrarily and capriciously in promulgating REMS and ETASU for mifepristone. *See* 21 U.S.C. § 355-1(a)(1)(E) ("[T]he Secretary shall consider . . . [t]he seriousness of any known or potential adverse events that may be related to the drug and the background incidence of such events in the population likely to use the drug."). FDA attempts to rebut these arguments by asserting that it did consider evidence relating to Canada's experience. ECF No. 139 at 13. But as Plaintiffs mention, the study cited by Defendants in their 2021 review was limited in scope: it merely compared

the outcomes of telemedicine versus in-person visits for medication abortion in Canada. ECF No. 141 at 11. The 2022 New England study, by contrast, goes directly to Plaintiffs' arguments that the REMS and ETASU should have been eliminated entirely. Admission of this evidence will assist the Court with "develop[ing] a background against which it can evaluate the integrity of [FDA's] analysis." *San Luis*, 776 F.3d at 993. Accordingly, FDA shall produce the citizen petition, denial letter, and New England Journal of Medicine Study on Canada's deregulation of mifepristone.

III. Turnaway Study

As a final matter, Plaintiffs request that the Court order FDA to include the Turnaway Study (Study) with the administrative record. The Study is a longitudinal survey which evaluates and compares "women's psychological well-being 5 years after receiving or being denied an abortion." ECF No. 135 at 7. Plaintiffs argue that the Study should be included because it is cited throughout the produced record (by Plaintiffs' count, up to 35 times), including in a 2016 letter sent by the study's author, Advancing New Standards in Reproductive Health (ANSIRH), to FDA. ECF No. 133 at 5. Plaintiffs contend that this means the Study was "before" FDA, or that, alternatively, supplementation is required. *Id.* at 9, 11. Specifically, Plaintiffs press that inclusion of the Study is necessary because it again will highlight FDA's failure to consider an important aspect of the

problem; that is, whether the REMS and ETASU restrictions create "undu[e] burdens[ ] on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas." 21 U.S.C. § 355-1(f)(2)(C)(ii).

FDA offers several counterarguments. First, FDA argues that it is unclear what version of the Study Plaintiffs are referring to, writing, "As far as the agency can tell, the Turnaway Study is not a discrete document, but was a multi-year longitudinal study, data from which has been reported at various points in multiple publication." ECF No. 139 at 10. Second, FDA notes that several of the Turnaway publications are included within the administrative record. *Id.* Third, the agency reiterates that the mere citation of documents within a record document does not make the cited document part of the administrative record. *Id.* Separately, regarding Plaintiffs' arguments that the Study should be supplemented if it is not part of the completed record, FDA protests that it *did* include data similar to the Study's findings, which showed that most women who seek abortions are in difficult financial situations and that receiving an abortion improves mental health outcomes for women who desire the procedure. *Id.* at 13-14.

The Court agrees with FDA. As to the issue of completion, Plaintiffs' reply fails to squarely address FDA's concern over which version of the Study is at issue. This runs afoul of the requirement that a party asserting that the record is

incomplete must identify the missing material with specificity. *Save the Colorado*, 517 F. Supp. 3d at 901 (declining to include broad categories of documents which the plaintiff sought to supplement the record with but failed to individually identify). Although the fact that the Study was discussed multiple times in different record documents might give rise to the inference that the agency indirectly considered it, the Court has no way of knowing which version(s) of the Study were discussed in those references. Thus, the Court cannot confidently conclude that the Study was "before" FDA.

The Court also declines to supplement the record with the Study. As mentioned, the exceptions to the general rule against supplementing extra-record evidence are narrowly construed. Unlike the conclusions of the New England Study regarding the propriety of full deregulation and the effect it would have on the safety profile of the drug, which were not identified anywhere within the record by FDA, here the agency noted numerous places in the record where it examined data related to the mental health impacts of abortion on women and the impact of receiving a wanted abortion on low-income women, including in ANSIRH's letter to FDA. ECF No. 139 at 14; *see also* ECF No. 142-1. The Study would be repetitive of these findings, and other reported documents which discuss the Study's findings.

//

ACCORDINGLY, IT IS HEREBY ORDERED:

Plaintiffs' Motion to Supplement the Administrative Record (ECF No. 133) is **GRANTED IN PART**. As set forth herein, the 2022 ACOG citizen petition, letter denying the 2022 ACOG citizen petition, and New England Journal of Medicine study on Canada's deregulation of mifepristone discussed in the citizen petition shall be produced forthwith as part of the Administrative Record.

The District Court Executive is directed to enter this Order and furnish copies to counsel, including those attorneys who have not signed up for electronic filing and service. *See* Gen Order No. 100-04-1.

DATED March 8, 2024.

THOMAS O. RICE
United States District Judge

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

NO. 1:23-cv-03026-TOR

PLAINTIFF STATES' REPLY IN SUPPORT OF MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD

02/20/2024
Without Oral Argument

I. INTRODUCTION

This Court has already ruled that the formal citizen petition submitted in 2022 by ACOG and 48 other organizations was "before FDA" in connection with its decision to impose the 2023 mifepristone REMS. This petition, ECF No. 61-1, provides evidence showing that each REMS element is medically unnecessary and unduly burdensome, and asks FDA to lift the REMS entirely. FDA's insistence that it "did not consider" this citizen petition—which FDA denied on the very same day it re-imposed a REMS on mifepristone—conflicts with this Court's prior ruling, ECF No. 80 at 16-17, and contradicts FDA's own contemporaneous admission that it "carefully considered" the petition. Tellingly, FDA fails to even address this compelling evidence that it did, in fact, consider the petition. Similarly, the record is incomplete without—at a minimum—the Turnaway Study report cited in the letter to FDA from the Turnaway Study's author.

Alternatively, even if FDA turned a blind eye to these materials when it re-imposed a REMS on mifepristone, they should still be added to the record because they will demonstrate that FDA failed to consider major issues it was statutorily obligated to consider: that the REMS restrictions do not make mifepristone safer, are inconsistent with the regulation of riskier drugs, and are unduly burdensome.

II. ARGUMENT

A. ACOG's Citizen Petition Was "Before FDA," as the Court Has Ruled

As discussed at length in the Plaintiff States' Motion, this Court previously ruled that ACOG's 2022 citizen petition to lift the mifepristone REMS was "before

FDA" in connection with FDA's decision to impose the current REMS, such that it would be futile to submit yet another citizen petition seeking the same relief. ECF No. 133 at 3-4, 7-8 (citing ECF No. 80 at 16-17). Moreover, FDA denied ACOG's petition on the very same day it imposed the current REMS, which is compelling evidence that the agency directly or at least indirectly considered the petition in connection with the action it took that day. Unable to deny the Court's prior ruling or its own prior acknowledgement that it "carefully considered" the petition, FDA's Opposition simply ignores both.

Instead, the agency insists that it "did not consider" ACOG's petition in connection with its decision to impose the current REMS. ECF No. 139 at 5. To support this contention, FDA claims that it actually decided to impose the 2023 mifepristone REMS all the way back in 2021, and that ACOG's 2022 citizen petition was received "after FDA's 2021 determination" to re-impose a REMS. *Id.* at 6. FDA's suggestion that documents received after 2021 somehow did not or could not inform its 2023 agency action is belied by FDA's own produced record, which includes numerous documents that post-date 2021. One such document is a June 21, 2022, letter to FDA from ACOG and the American Medical Association, which is part of the produced record along with 28 documents that are cited in that letter. *See* ECF No. 127 at 41-44 (Index listing 2023 SUPP 000032-037 with 28 sub-listings). FDA's inclusion of these post-2021 documents in the record demonstrates that the agency either directly or indirectly considered them. *See* ECF No. 139 at 7 (conceding that, at a minimum, the record "designated" by the agency

consists of documents the agency "directly or indirectly considered"). Since FDA admittedly considered ACOG's post-2021 letter, its suggestion that it somehow could not have considered ACOG's post-2021 citizen petition falls flat.

FDA next pivots and resurrects an unsuccessful argument it made at the preliminary injunction stage, claiming that it did not consider ACOG's petition in connection with its decision to re-impose a REMS because the petition was focused, in part, on the use of mifepristone for miscarriage management. *See* ECF No. 139 at 6-7; ECF No. 51 at 18-19. But as the Plaintiff States previously explained, ACOG's petition in fact asked FDA to eliminate the REMS as medically unnecessary and unduly burdensome for *all* uses of the drug—which is the "gold standard" for both abortion and miscarriage management—and cited evidence to support removing the REMS entirely. ECF No. 60 at 4 (citing ECF No. 61-1); ECF No. 61-7 at 3; *see also* ECF No. 3 at 12 (summarizing the petition's requests that the three elements of the current REMS are "medically unnecessary," "redundant," provide "no benefit to patient safety," and are unduly burdensome). Appropriately accounting for the ACOG petition as a whole, including this and other specific information that was "before FDA" as of January 2023, the Court concluded that it would be futile to require the Plaintiff States to submit yet another citizen petition asking FDA to remove the mifepristone REMS. ECF No. 80 at 16-17.

Against this Court's prior findings, a different court's passing comment that ACOG's citizen petition is "not directly relevant" to the mifepristone REMS cannot salvage FDA's efforts to suppress the petition. *See* ECF No. 139 at 8-9.

This comment is pulled out of context by FDA, because the Western District of Virginia's conclusion was the same as this Court's—that further exhaustion would be futile, "as FDA has demonstrated by its past actions and prior findings that it will not grant the relief sought by Plaintiffs." *Whole Woman's Health All. v. U.S. Food & Drug Admin.*, No. 3:23-cv-00019, 2023 WL 5401885, at *6-7 (W.D. Va. Aug. 21, 2023) ("agree[ing] with" this Court's similar conclusion). Moreover, to the extent the district court's comment in *Whole Woman's Health* was based on an overly narrow reading of ACOG's petition, that cannot overcome this Court's own prior conclusion that ACOG's petition and its supporting studies were "already put forth before FDA[.]" ECF No. 80 at 16-17.

Further, as previously noted, FDA admitted on January 3, 2023, that it had "carefully considered" ACOG's citizen petition. ECF No. 133 at 2, 8-9 (quoting ECF No. 1-20 at 2). This admission means that FDA necessarily directly considered the petition's request to remove the REMS entirely and the supporting evidence of the same—not just the request to add an additional indication to the mifepristone label. *See* ECF No. 61-1 at 12-17 (discussing each REMS element in turn, seeking the removal of each, and concluding that "Existing Data Demonstrate that a Removal of All REMS Requirements Will Not Harm Patient Safety"). FDA does not dispute that its denial letter acknowledged "careful[] consider[ation]" of ACOG's citizen petition, nor could it: FDA acknowledges that ECF No. 1-20 is its own denial letter. ECF No. 139 at 6-7. Nor is it plausible for FDA to now claim that the ACOG petition is entirely unrelated to the current REMS when FDA

denied the petition's request to remove the REMS on the *very same day* it imposed the current REMS. *See* ECF No. 133 at 2, 8-9. Notably, FDA offers no explanation for the telling timing of its two closely related actions taken by the *same* office within FDA (the Center for Drug Evaluation and Research) concerning the *same* REMS program for the *same* drug on the *same* day. Because there is no dispute that FDA considered ACOG's petition at the very same time it was imposing the 2023 REMS, the petition is part of the record. *See Ctr. for Food Safety v. EPA*, No. 23-cv-02714-SI, 2023 WL 8813528, at *3 (N.D. Cal. Dec. 19, 2023) ("materials provided to an agency during a decision-making process related to the subject matter of that decision" are properly part of the administrative record).

Last but certainly not least, the fact that ACOG's citizen petition is properly part of the administrative record compels the conclusion that the documents cited therein are also properly part of the record. FDA's only argument for excluding these documents is that it did not consider the petition itself. ECF No. 139 at 8-9 (arguing that it should not be "surprising" that the "ACOG Citizen Petition documents" were not included because the petition supposedly was limited to the miscarriage indication and not the REMS program). Indeed, FDA admits that it *does* consider "references" cited in "letters" directed to it. *Id.* at 11 n.3. The produced record confirms this: throughout, citizen petitions, letters, and other direct communications to FDA are routinely accompanied by the documents cited within those communications. *See, e.g.*, ECF No. 127 at 7-10 (Index listing 2019 CP 000001-027 with 52 sub-listings); *id.* at 15-16 (Index listing 2021 ED 000001-

003 with nine sub-listings); *id.* at 16-17 (Index listing 2021 ED 000073-077 with 10 sub-listings); *id.* at 17 (Index listing 2021 ED 000361-362 with three sub-listings); *id.* at 17-18 (Index listing 2021 ED 000434-438 with six sub-listings). This pattern repeats throughout the 46-page Index of the produced administrative record. *See generally id.* FDA claims that it does not consider "the references cited within the references" in letters it receives, ECF No. 139 at 11 n.3, but the materials at issue here—studies directly cited in the ACOG petition—fall squarely within the former category that FDA *concedes* are appropriately part of the record. Because the ACOG citizen petition was before FDA when it decided to re-impose the REMS—and because the evidence cited therein (including but not limited to the 2022 study in the New England Journal of Medicine on Canada's successful elimination of their REMS-like restrictions on mifepristone, *see* ECF No. 61-1 at 18, 29 n.52) is directly relevant to the petition's request to lift the REMS entirely, the documents cited in the petition are properly part of the record.

In sum, FDA's assertion that "Plaintiffs have not provided *any* evidence" that the agency considered the ACOG citizen petition, ECF No. 139 at 8, is simply untrue. (1) This Court's prior ruling, which was based on (2) the formal citizen petition citing evidence that supports removal of the REMS entirely, which (3) FDA admittedly "carefully considered" and responded to and that (4) FDA denied on the very same day it re-imposed a REMS, all demonstrate that FDA directly or indirectly considered the citizen petition—and the documents cited therein—in connection with the challenged agency action.

B. The Turnaway Study Is Cited and Discussed in a Letter to FDA

As discussed above, FDA concedes, and the produced record confirms, that it *does* consider information cited in "letters" directed to it. And as discussed in the Plaintiff States' Motion, the Turnaway Study was cited and discussed in a letter to FDA signed by the study's author, Advancing New Standards in Reproductive Health (ANSIRH). ECF No. 133 at 9; ECF No. 1-9; ECF No. 35 ¶ 95 & n.19. The Turnaway Study's data—including the findings that being denied an abortion results in worse health, family, and financial outcomes—are what provide the evidentiary basis for the summaries and references found throughout the produced record. *See* ECF No. 133 at 5; ECF No. 135 ¶ 6.c (listing 35 places the Turnaway Study is cited in the administrative record). While the Turnaway Study's data is undoubtedly relied upon by numerous studies given its groundbreaking significance, *see* ECF No. 139 at 10, this is no basis for FDA's refusal to complete the record. *Contra id.* At a minimum, the Turnaway Study report cited in the ANSIRH letter to FDA was before the agency and should be added to the record. ECF No. 1-9; Second Beneski Decl. ¶¶ 4, 5 & Exs. B, C.

And regardless of whether the record is completed or supplemented in this way, FDA effectively admits it *knows* that unduly restricting access to mifepristone harms the underserved patient populations it is statutorily required to consider. *See* ECF No. 139 at 13-14. On the merits, FDA will have to explain why it nevertheless retained a medically unnecessary and harmful REMS with ETASU to artificially restrict the availability of this extraordinarily safe medication.

C. Evidence of FDA Ignoring Key Factors Is Highly Relevant

Because the materials at issue were demonstrably before FDA, the Court need not determine whether "supplementation" as opposed to "completion" of the record is necessary. But the supplementation standard is satisfied here, too.

This is not an effort to "pad the record" with evidence of some minor point that FDA missed. *Contra* ECF No. 139 at 13. This case is about FDA ignoring *major* aspects of the problem in making a decision that failed to follow the law and cannot be reconciled with mifepristone's outstanding safety record, particularly as compared with other medications not burdened with a REMS. At the preliminary injunction stage, the Plaintiff States argued that a REMS with ETASU for mifepristone is unjustifiable under the statutory limits Congress placed on FDA's authority. *See* ECF No. 80 at 18-20. In response to this argument, this Court noted FDA "d[id] not address whether mifepristone qualifies for ETASU, asserting it need *only* determine whether modifications [to the existing REMS program] are appropriate under 21 U.S.C. § 355-1(g)(4)(B)." *Id.* at 20 (emphasis added). The Court rejected FDA's crabbed view of its statutory obligations, ruling that "it would be contrary to the plain language of the statute that the agency need not consider arguments that mifepristone's REMS and ETASU should be removed in whole or in part based on criteria under 21 U.S.C. § 355-1(a)(1), (f)(1)." *Id.* at 21.

On the merits, the Plaintiff States will argue that FDA failed to consider the fundamental issue of whether mifepristone meets the statutory criteria for a REMS with ETASU *at all*. They will further argue that the particular ETASU that FDA

imposed are medically unnecessary, do not conform to the restrictions on similar or more dangerous drugs, and are unduly burdensome, especially for underserved patient populations, and that they therefore fail the statutory test and are arbitrary and capricious. *See* ECF No. 80 at 19-20 (quoting 21 U.S.C. § 355-1(f)(2)(C)-(D)). The missing documents at issue will support these arguments, which go to whether FDA meaningfully *considered* these issues, not FDA's weighing of the evidence. *See id.* at 21 ("It is not the Court's role to review the scientific evidence and decide whether mifepristone's benefits outweigh its risks without REMS and/or ETASU. . . . However, based on the present record, FDA did not assess *whether* mifepristone qualifies for REMS and ETASU . . ." (emphasis added)).

The missing documents show, among other things, that FDA disregarded evidence—such as the 2022 Canada study—showing that lifting the REMS would not impact mifepristone's safety profile, and that FDA failed to grapple with the impacts of the unnecessary and discriminatory REMS on underserved patients. Whether the REMS is "necessary to ensure that the benefits of the drug outweigh the risks" (i.e., whether it produces different safety outcomes than normal prescribing) and whether it is "unduly burdensome" are central questions that FDA is not at liberty to ignore. 21 U.S.C. § 355-1(a)(1), 21 U.S.C. § 355-1(f)(2)(C)-(D). Thus, the request for supplementation fits comfortably within even the narrower standard adopted by some district courts: the missing documents do not reflect mere "nuanced points" or "specific hypotheses/ conclusions," but show that FDA overlooked "a general subject matter that is subject to the agency's decision[.]"

E.g., *Nw. Env't Advocs. v. U.S. Fish & Wildlife Serv.*, No. 3:18-cv-01420-AC, 2019 WL 6977406, at *7 (D. Or. Dec. 20, 2019); *see* ECF No. 139 at 12-13.

Next, and contrary to FDA's argument, its consideration of "Canada's experience" with one aspect of mifepristone prescribing does not absolve FDA from considering studies before it that bear on other REMS restrictions. *Contra* ECF No. 139 at 13. FDA points to its 2021 REMS Modification Rationale Review, in which it discussed a 2020 Canadian study that compared outcomes of telemedicine versus in-clinic visits for medication abortion. ECF No. 140-1 at 26-27 & 43 n.7. But FDA's consideration of this single 2020 study on telemedicine cannot somehow justify its complete failure to consider a *different* Canadian study, published in 2022, demonstrating that provider certification, a patient agreement form, and pharmacy certification do nothing to increase mifepristone's safety. ECF No. 61-1 at 18 (discussing a 2022 study after "Canada removed all restrictions on prescribing mifepristone for abortion, thereby allowing it to be prescribed and dispensed like any other drug").

Finally, FDA's suggestion that the Plaintiff States "request a new agency action," ECF No. 139 at 14, is disingenuous. This Court already found that filing another citizen petition to seek a different outcome would be futile. The instant Motion is limited to documents of which FDA was well aware when it imposed the current REMS, and which are necessary to resolve this case.

III. CONCLUSION

The Plaintiff States' Motion should be granted.

DATED this 9th day of February 2024.

ROBERT W. FERGUSON
Attorney General

/s/ Kristin Beneski
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744
Noah.Purcell@atg.wa.gov
Kristin.Beneski@atg.wa.gov
Colleen.Melody@atg.wa.gov
Andrew.Hughes@atg.wa.gov
Lauryn.Fraas@atg.wa.gov
Tera.Heintz@atg.wa.gov
Attorneys for Plaintiff State of Washington

ELLEN F. ROSENBLUM
Attorney General of Oregon

/s/ Carla A. Scott
SANDER MARCUS HULL, WSBA #35986
CARLA A. SCOTT, WSBA #39947
Senior Assistant Attorneys General
YOUNGWOO JOH, OSB #164105
Assistant Attorney General
Trial Attorneys
Tel: (971) 673-1880
Fax: (971) 673-5000
marcus.hull@doj.state.or.us
carla.a.scott@doj.state.or.us
youngwoo.joh@doj.state.or.us

Attorneys for State of Oregon

KRIS MAYES
Attorney General of Arizona

/s/ Daniel C. Barr
Daniel C. Barr (Arizona No. 010149)
Chief Deputy Attorney General
Luci D. Davis (Arizona No. 35347)
Office of the Attorney General of Arizona
2005 N. Central Ave.
Phoenix, AZ 85004-1592
Phone: (602) 542-8080
Email: Daniel.Barr@azag.gov
Luci.Davis@azag.gov
Attorneys for Plaintiff State of Arizona

PHILIP J. WEISER
Attorney General of Colorado

/s/ Eric Olson
ERIC OLSON, CO #36414
Solicitor General
MICHAEL MCMASTER, CO #42368
Assistant Solicitor General
Office of the Attorney General
Colorado Department of Law
1300 Broadway, 10th Floor
Denver, CO 80203
Phone: (720) 508-6000
Attorneys for Plaintiff State of Colorado

WILLIAM TONG
Attorney General of Connecticut

/s/ Joshua Perry
Joshua Perry
Solicitor General
Office of the Connecticut Attorney General
165 Capitol Ave, Hartford, CT 06106
Joshua.perry@ct.gov
(860) 808-5372
Fax: (860) 808-5387

Attorney for Plaintiff State of Connecticut

KATHLEEN JENNINGS
Attorney General of Delaware

/s/ Vanessa L. Kassab
VANESSA L. KASSAB
Deputy Attorney General
Delaware Department of Justice
820 N. French Street
Wilmington, DE 19801
302-683-8899
vanessa.kassab@delaware.gov
Attorney for Plaintiff State of Delaware

KWAME RAOUL
Attorney General of Illinois

/s/ Caitlyn G. McEllis
Caitlyn G. McEllis (6306561)
Senior Policy Counsel
Office of the Illinois Attorney General
115 South LaSalle Street
Chicago, IL 60603
Phone: (312) 793-2394
Caitlyn.McEllis@ilag.gov
Attorney for Plaintiff State of Illinois

DANA NESSEL
Attorney General of Michigan

/s/ Stephanie M. Service
Stephanie M. Service (P73305)
Assistant Attorney General
Michigan Department of Attorney General
Health, Education & Family
Services Division
P.O. Box 30758
Lansing, MI 48909
(517) 335-7603
ServiceS3@michigan.gov
Attorney for Plaintiff Attorney General of Michigan

AARON D. FORD
Attorney General of Nevada

/s/ Heidi Parry Stern
Heidi Parry Stern (Bar. No. 8873)
Solicitor General
Office of the Nevada Attorney General
555 E. Washington Ave., Ste. 3900
Las Vegas, NV 89101
HStern@ag.nv.gov
Attorney for Plaintiff State of Nevada

RAÚL TORREZ
Attorney General of New Mexico

/s/ Aletheia Allen
Aletheia Allen
Solicitor General
Executive Office
State of New Mexico Department of Justice
201 Third St. NW, Suite 300
Albuquerque, NM 87102
505-527-2776
AAllen@nmag.gov
Attorney for Plaintiff State of New Mexico

PETER F. NERONHA
Attorney General of Rhode Island

/s/ Julia C. Harvey
JULIA C. HARVEY #10529
Special Assistant Attorney General
150 S. Main Street
Providence, RI 02903
(401) 274-4400 x2103
Attorney for Plaintiff State of Rhode Island

CHARITY R. CLARK
Attorney General of Vermont

/s/ Douglas Keehn
DOUGLAS KEEHN

Assistant Attorney General
109 State Street
Montpelier, VT 05609-1001
(802) 793-3892
douglas.keehn@vermont.gov
Attorney for Plaintiff State of Vermont

BRIAN L. SCHWALB
Attorney General for the District of Columbia
JENNIFER C. JONES
Deputy Attorney General
Public Advocacy Division
WILLIAM STEPHENS
Assistant Deputy Attorney General
Public Advocacy Division

/s/ Nicole S. Hill
NICOLE S. HILL
Assistant Attorney General
Office of the Attorney General for the
District of Columbia
400 Sixth Street, N.W.
Washington, D.C. 20001
(202) 727-4171
nicole.hill@dc.gov
Attorneys for Plaintiff District of Columbia

ANNE E. LOPEZ
Attorney General

/s/ Erin N. Lau
Erin N. Lau 009887
465 South King St., Room 200
Honolulu, Hawaii 96813
Erin.N.Lau@hawaii.gov
Counsel for the State of Hawaii

AARON M. FREY
Attorney General

/s/ Halliday Moncure
Halliday Moncure, Bar No. 4559
Assistant Attorney General

Office of the Maine Attorney General
6 State House Station
Augusta, ME 04333-0006
(207) 626-8800
halliday.moncure@maine.gov

ANTHONY G. BROWN
Attorney General of Maryland

/s/ Joshua M. Segal
JOSHUA M. SEGAL*
Assistant Attorney General
Office of the Attorney General of Maryland
200 Saint Paul Place, 20th Floor
Baltimore, Maryland 21202
(410) 576-6446
jsegal@oag.state.md.us
Attorney for Plaintiff State of Maryland

KEITH ELLISON
Attorney General
State of Minnesota

/s/ Liz Kramer
LIZ KRAMER (#0325089)
Solicitor General
JENNIFER OLSON (#0391356)
Assistant Attorney General
445 Minnesota Street, Suite 1400
St. Paul, Minnesota 55101-2131
(651) 757-1010 (Voice)
(651) 282-5832 (Fax)
liz.kramer@ag.state.mn.us
jennifer.olson@ag.state.mn.us
Attorneys for Plaintiff State of Minnesota

MICHELLE A. HENRY
Attorney General of Pennsylvania

/s/ Elizabeth P. Lester-Abdalla
ELIZABETH P. LESTER-ABDALLA*
(Pa Bar No. 327276)
Deputy Attorney General

1600 Arch Street, Suite 300
Philadelphia, PA 19103
(215) 560-2980
elester-abdalla@attorneygeneral.gov
Attorney for the Commonwealth of Pennsylvania

**Pro hac vice admission pending*

CERTIFICATE OF SERVICE

I hereby certify that on February 9th, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

DATED this 9th day of February 2024, at Seattle, Washington.

/s/ Kristin Beneski
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

ARUN G. RAO
Deputy Assistant Attorney General

AMANDA N. LISKAMM
Director

JAMES W. HARLOW
Acting Assistant Director

NOAH T. KATZEN
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 305-2428
(202) 514-8742 (fax)
Noah.T.Katzen@usdoj.gov

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, *et al.*, Plaintiffs, v. U.S. FOOD AND DRUG ADMINISTRATION, *et al.*, Defendants.	No. 1:23-cv-03026 DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFF STATES' MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD

TABLE OF CONTENTS

INTRODUCTION 1
BACKGROUND 1
ARGUMENT 3
I. Plaintiffs Have Not Shown The Record Is Incomplete 3
II. The Court Should Not Consider Extra-Record Material 7
CONCLUSION 10

TABLE OF AUTHORITIES

Cases

Audubon Soc'y of Portland v. Zinke,
Case No. 1:17-cv-00069-CL, 2017 WL 6376464 (D. Or. Dec. 12, 2017) 6

Blue Mountains Biodiversity Project v. Jeffries,
72 F.4th 991 (9th Cir. 2023) 3, 4, 7, 8

City of L.A. v. Dickson,
No. 19-71581, 2021 WL 2850586 (9th Cir. Jul. 8, 2021) 3

Conservation Cong. v. U.S. Forest Serv.,
No. 2:13-cv-01922-TLN-CMK, 2016 WL 10637090 (E.D. Cal. Oct. 12, 2016) ..4

Cook Inletkeeper v. EPA,
400 F. App'x 239 (9th Cir. 2010) 9

Ctr. for Biological Diversity v. Jewell,
No. CV-12-02296-PHX-DGC, 2014 WL 116408 (D. Ariz. Jan. 13, 2014) 8, 9

Detroit Int'l Bridge Co. v. Gov't of Canada,
No. CV 10-476 (RMC), 2016 WL 10749142 (D.D.C. Apr. 25, 2016).....4

Fence Creek Cattle Co. v. U.S. Forest Serv.,
602 F.3d 1125 (9th Cir. 2010).....8

Lands Council v. Powell,
395 F.3d 1019 (9th Cir. 2005) 8

Nw. Env't Advocs. v. U.S. Fish & Wildlife Serv.,
No. 3:18-CV-01420-AC, 2019 WL 6977406 (D. Or. Dec. 20, 2019).....8

Organic Pastures Dairy Co. v. Sebelius,
No. 1:12-CV-02019-SAB, 2013 WL 4648548 (E.D. Cal. Aug. 29, 2013) 8,9

Safari Club Int'l v. Jewell,
No. CV-16-00094-TUC-JGZ, 2016 WL 7785452
(D. Ariz. July 7, 2016)..... 5, 7, 10

Save the Colorado v. U.S. Dep't of the Interior,
517 F. Supp. 3d 890 (D. Ariz. 2021) 7

Whole Woman's Health All. v. FDA,
No. 3:23-CV-00019, 2023 WL 5401885 (W.D. Va. Aug. 21, 2023).....5

WildEarth Guardians v. U.S. Fish & Wildlife Serv.,
No. CV-13-00151-TUC-RCC, 2015 WL 13567455 (D. Ariz. Sept. 28, 2015).....9

Statutes

5 U.S.C. § 706 4

Regulations

21 C.F.R. § 10.25(a) 10
21 C.F.R. § 10.45(f) 10

INTRODUCTION

Plaintiffs challenge the Food and Drug Administration's January 2023 approval of modifications to the Risk Evaluation and Mitigation Strategy (REMS) for mifepristone for early termination of pregnancy (the Mifepristone REMS Program). On September 1, 2023, FDA produced the administrative record, tallying over 6,000 pages, for this challenged action. Now, Plaintiffs move to supplement the administrative record, ECF No. 133 (Mot.), with (1) documents relating to a citizen petition that FDA did not consider in connection with the challenged agency action and (2) an unspecified document or documents relating to a study, data from which is discussed in various record materials. The Court should deny the motion.[1]

BACKGROUND

On May 7, 2021, FDA announced a review of the Mifepristone REMS Program. Katzen Decl. Ex. 1, 2021 REMS 001568. That review encompassed

[1] The plaintiffs in another challenge to the same agency action have moved to complete or supplement the administrative record with the same citizen petition materials. *Chelius, et al. v. Becerra, et al.*, Civ. No. 1:17-00593-JAO-RT, ECF No. 198 (D. Haw. Nov. 30, 2023). Defendants have opposed that motion, *id.*, ECF No. 202, which will be argued on March 8, 2024, *id.*, ECF No. 201.

"multiple sources of information," including literature published between March 29, 2016 (the date of the last major REMS modification) and July 26, 2021. Katzen Decl. Ex. 1, 2021 REMS 001570.

On December 16, 2021, FDA concluded that the Mifepristone REMS Program should be retained but modified. Katzen Decl. Ex. 2, 2019 CP 000634. FDA accordingly directed mifepristone's sponsors to submit supplemental applications proposing the modifications that FDA had determined were necessary. Katzen Decl. Ex. 2, 2019 CP 000634; Katzen Decl. Ex. 3, 2021 REMS 001803-07; Katzen Decl. Ex. 4, 2021 REMS 001808-11. The sponsors did so in 2022, and FDA approved the applications on January 3, 2023 (the January 2023 REMS Modification). Katzen Decl. Ex. 5, 2023 SUPP 001119-28; Katzen Decl. Ex. 6, 2023 SUPP 001448-60; Katzen Decl. Ex. 7, 2023 SUPP 001461-65.

On October 22, 2022—after FDA's 2021 determination—the American College of Obstetricians and Gynecologists (ACOG) and 48 other organizations submitted a citizen petition requesting that FDA ask one of the sponsors of mifepristone to submit a supplemental application "to add miscarriage management as an indication to the mifepristone label and to modify the REMS so that it does not unduly burden its use for miscarriage management." ECF No. 61-1, at 2; *see id.* at 1. FDA denied that petition, explaining that the sponsors of mifepristone decide whether to seek approval for a new indication. ECF No. 1-20,

at 3. And "[b]ecause the management of miscarriage is not a currently approved indication for mifepristone," FDA explained, "it would be premature for FDA to consider the impact that the addition of this indication would have, if any, on the Mifepristone REMS Program so that it is not unduly burdensome for that use." *Id.* at 4.

ARGUMENT

Although Plaintiffs style their motion as one solely to "supplement" the administrative record, in substance they ask this Court to order FDA to either complete or supplement the administrative record. *See City of L.A. v. Dickson*, No. 19-71581, 2021 WL 2850586, at *1 n.2 (9th Cir. Jul. 8, 2021) (noting the different standards for completing and supplementing the administrative record). Neither course is appropriate here.

I. Plaintiffs Have Not Shown The Record Is Incomplete

In an Administrative Procedure Act case, review is ordinarily limited to the administrative record consisting of "all documents and materials directly or indirectly considered by the agency decision-makers" in reaching the particular decision under review. *Blue Mountains Biodiversity Project v. Jeffries*, 72 F.4th 991, 996 (9th Cir. 2023) (internal quotation marks omitted). Courts "presume that an agency properly designated the [a]dministrative [r]ecord" absent "clear evidence to the contrary." *Id.* at 997 (quotations omitted).

Plaintiffs have not provided *any* evidence, let alone clear evidence, that FDA considered the ACOG Citizen Petition documents or documents beyond those in the record from the "Turnaway Study," either directly or indirectly, in connection with the January 2023 REMS Modification. Plaintiffs argue that the ACOG Citizen Petition was "before" the agency in the sense of being in FDA's files prior to the January 2023 REMS Modification. Mot. 6-8. But the mere "fact that the agency possessed the documents prior to the [challenged] decision does not mean that they were 'before the agency' for purposes of judicial review under … 5 U.S.C. § 706." *Detroit Int'l Bridge Co. v. Gov't of Canada*, No. CV 10-476 (RMC), 2016 WL 10749142, at *2 (D.D.C. Apr. 25, 2016); *see Conservation Cong. v. U.S. Forest Serv.*, No. 2:13-cv-01922-TLN-CMK, 2016 WL 10637090, at *2 (E.D. Cal. Oct. 12, 2016) (holding that plaintiffs "cannot succeed simply by showing that the agencies were aware of [a document] or had [it] somewhere in their possession"). Rather, to be "before" the agency, the documents must have been directly or indirectly considered by the decisionmaker in taking *the challenged agency action*. *Blue Mountains Biodiversity Project*, 72 F.4th at 996. The documents covered by Plaintiffs' motion were not.

Nor should it be surprising that the ACOG Citizen Petition documents were not considered by the agency in connection with the January 2023 REMS Modification. As another court considering similar claims observed, the ACOG

Citizen Petition is "not directly relevant" to that agency action. *Whole Woman's Health All. v. FDA*, No. 3:23-CV-00019, 2023 WL 5401885, at *6 (W.D. Va. Aug. 21, 2023). Whereas the ACOG Citizen Petition pertained to an unapproved use of mifepristone for miscarriage management,[2] the January 2023 REMS Modification (and the preceding 2021 review) pertained to mifepristone's approved use for termination of early pregnancy. *See* Katzen Decl. Ex. 1, 2021 REMS 001571 (noting that FDA's review excluded data related to miscarriages because those data were "not applicable to the approved indication"). And ven if these documents were relevant, that alone would not be a basis to deem the produced record incomplete. *See Safari Club Int'l v. Jewell*, No. CV-16-00094-TUC-JGZ, 2016 WL 7785452, at *2 (D. Ariz. July 7, 2016).

Even further afield is Plaintiffs' contention that the mere *citation* of studies by other documents in the record or by the ACOG Citizen Petition means those studies should be part of the record. Mot. 7, 8. For example, Plaintiffs argue that the "Turnaway Study" is part of the record because it was cited in various record

[2] Although certain statements in the ACOG Citizen Petition were phrased broadly and not expressly limited to the use of mifepristone for miscarriage management, those statements were made in support of arguments that unambiguously concerned that unapproved use. *E.g.*, ECF No. 61-1, at 12.

documents. Mot. 8; ECF 135 at 2, ¶ 6.c. But they do not show that the produced record excludes any document that FDA directly or indirectly considered. To begin with, it is not even clear what "Turnaway Study" documents Plaintiffs are referring to. *See Audubon Soc'y of Portland v. Zinke*, Case No. 1:17-cv-00069-CL, 2017 WL 6376464, at *4 (D. Or. Dec. 12, 2017) (requiring moving party to "identify the materials alleged omitted from the record with sufficient specificity, as opposed to merely proffering broad categories of documents … that are likely to exist") (internal quotation marks omitted). As far as the agency can tell, the Turnaway Study is not a discrete document, but was a multi-year longitudinal study, data from which has been reported at various points in multiple publications. *See* Katzen Decl. Ex. 9, The Turnaway Study, https://perma.cc/J49Q-KFNW (reporting publication of "more than fifty scientific papers in the peer-reviewed journals using data from the Turnaway Study"). And several of those publications—the ones FDA considered—*are* included in the administrative record. *See, e.g.*, ECF No. 135, Ex. A, 2023 SUPP 000229 ("This study presents data from the Turnaway Study …").

That aside, the mere citation of documents in a record document does not, by itself, make the cited documents part of the administrative record. To be "indirectly considered," documents must be "so heavily relied on in [subordinates'] recommendation[s]" or in other materials directly considered by the decision maker "that the decision maker" can be said to have "constructively considered

them." *Safari Club*, 2016 WL 7785452, at *2 (quotations omitted). Consistent with that standard, courts "have rejected the argument that if a document considered by the agency decision-maker refers to other documents, those underlying documents must be included in the record." *Save the Colorado v. U.S. Dep't of the Interior*, 517 F. Supp. 3d 890, 898 (D. Ariz. 2021). To hold that being cited within a record document by itself establishes that the cited document is part of the record would "stretch the chain of indirect causation to its breaking point," *id.*, and create an infinite recursion: if a study cited in a record document becomes part of the record for that reason alone, so would all studies cited in that study, all studies cited in those studies, and so on.[3]

II. The Court Should Not Consider Extra-Record Material

Plaintiffs' alternative request to supplement the record with extra-record material also lacks merit. Courts "place a thumb on the scale against supplementation" of the record. *Blue Mountains Biodiversity Project*, 72 F.4th at

[3] Plaintiffs attempt to wave the problem away by suggesting that the produced record contains similarly cited material. Mot. 7. Not so. In connection with the January 2023 REMS Modification, FDA considered Dr. Chelius' and the States' letters and their references. But the record does not contain the equivalent of what Plaintiffs ask for: the references cited within the references to those letters.

998. If supplementation were routine, "it would be obvious that the federal courts would be proceeding, in effect, de novo rather than with the proper deference to agency processes, expertise, and decision-making." *Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005). Thus, to justify departing from the record-review rule, Plaintiffs must meet a "heavy burden to show that the additional materials sought are necessary to adequately review the [agency]'s decision." *Fence Creek Cattle Co. v. U.S. Forest Serv.*, 602 F.3d 1125, 1131 (9th Cir. 2010).

Plaintiffs claim (Mot. 8-10) the documents are "necessary to determine whether the agency has considered all relevant factors and has explained its decision." *Lands Council*, 395 F.3d at 1030 (internal quotation marks omitted). But this exception to the record-review rule is "narrowly construed and applied," *id.*, to prevent plaintiffs from "driv[ing] a truck through what is supposed to be a narrow exception to the record review rule," *Nw. Env't Advocs. v. U.S. Fish & Wildlife Serv.*, No. 3:18-CV-01420-AC, 2019 WL 6977406, at* 9 (D. Or. Dec. 20, 2019) (quotations omitted). It applies only when the agency "fail[ed] to consider a general subject matter that is demonstrably relevant to the outcome of the agency's decision, not when specific hypotheses and/or conclusions are omitted from consideration." *Ctr. for Biological Diversity v. Jewell*, No. CV-12-02296-PHX-DGC, 2014 WL 116408, at *2 (D. Ariz. Jan. 13, 2014) (quotations omitted); *see Organic Pastures Dairy Co. v. Sebelius*, No. 1:12-CV-02019-SAB, 2013 WL

4648548, at *5 (E.D. Cal. Aug. 29, 2013). It cannot be used "merely to bolster the record or supply background information." *Ctr. for Biological Diversity*, 2014 WL 116408, at *1.

Plaintiffs have not met their heavy burden to show the exception applies. The record spans more than 6,000 pages, including the detailed, 49-page REMS Modification Rationale Review, Katzen Decl. Ex. 1, and "contains sufficient information to explain how the [agency used the information before it] and why it reached its decision," *WildEarth Guardians v. U.S. Fish & Wildlife Serv.*, No. CV-13-00151-TUC-RCC, 2015 WL 13567455, at *3 (D. Ariz. Sept. 28, 2015) (quoting *Cook Inletkeeper v. EPA*, 400 F. App'x 239, 240–41 (9th Cir. 2010)).

Far from identifying any general subject matter that FDA failed to consider, Plaintiffs impermissibly seek to pad the record with additional evidence on specific issues. Moreover, the record shows that FDA considered those issues. Plaintiffs argue, for example, that the ACOG Citizen Petition documents show, based on data from Canada, that the Mifepristone REMS Program could be eliminated without an increase in complications or adverse events. Mot. 9-10. But the record reflects that FDA *did consider* evidence relating to Canada's experience. Katzen Decl. Ex. 1, 2021 REMS 001585–86. So, too, for the Turnaway Study, which, Plaintiffs say, shows that most women who seek abortions have "difficult financial situations" and that obtaining wanted abortions improves mental health. Mot. 10. The existing

record addresses these points. *See* Katzen Decl. Ex. 10, FDA 1255 (reporting that most abortion patients have "difficult financial situations"); Katzen Decl. Ex. 8, 2021 REMS 001198-226 (reporting low income for most abortion patients); ECF No. 135, Ex. A, 2023 SUPP 000229-238 (reporting positive mental health effects of wanted abortion).

Unable to explain why the record is inadequate, Plaintiffs argue that FDA "should have considered" the Turnaway Study and the studies cited in the ACOG Citizen Petition because they are allegedly relevant. Mot. 10. But "courts have expressly rejected the use of the 'relevant factors' test as grounds for the admission of extra-record evidence where the plaintiff argues that the new evidence *should* have been considered by the agency." *Safari Club Int'l*, 2016 WL 7785452, at *5 (emphasis in original). Plaintiffs can, of course, request a new agency action based on that evidence. *See* 21 C.F.R. § 10.45(f) ("An interested person who wishes to rely upon information or views not included in the administrative record shall submit them to the Commissioner with a new petition to modify the action under § 10.25(a)."). But the Court should not consider that extra-record evidence in reviewing the agency action challenged here.

CONCLUSION

For the foregoing reasons, the Court should deny Plaintiff States' Motion to Supplement the Administrative Record.

February 2, 2024

JAMES W. HARLOW
Acting Assistant Director

/s/ Noah T. Katzen
NOAH T. KATZEN
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, DC 20044-0386
(202) 305-2428
(202) 514-8742 (fax)
Noah.T.Katzen@usdoj.gov

Counsel for Defendants

CERTIFICATE OF SERVICE

I hereby certify that, on February 2, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Noah T. Katzen
NOAH T. KATZEN

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026-TOR PLAINTIFF STATES' MOTION TO SUPPLEMENT THE ADMINISTRATIVE RECORD 02/20/2024 Without Oral Argument

I. INTRODUCTION

This case is about whether the Food and Drug Administration (FDA) acted arbitrarily, capriciously, or contrary to law when it decided—against the overwhelming weight of the evidence before it and the professional medical consensus—to restrict access to mifepristone by re-imposing a set of burdensome and unnecessary restrictions known as a Risk Evaluation and Mitigation Strategy (REMS). The REMS includes Elements to Assure Safe Use (ETASU), mandatory restrictions meant to be reserved in rare cases for exceptionally dangerous drugs. Despite mifepristone's extraordinarily strong safety record, FDA irrationally and unlawfully singled this medication out for the most onerous form of restrictions.

To facilitate meaningful judicial review under the Administrative Procedure Act (APA), FDA must submit the *whole* administrative record—i.e., all materials that were before FDA when it decided to impose the REMS, including evidence that contradicts FDA's position. Here, however, FDA has submitted an incomplete record. To begin, glaringly absent is a key document that this Court has already found was "before FDA": a 2022 citizen petition filed by the American College of Obstetricians and Gynecologists (ACOG) and 48 other signatories, formally asking FDA to lift the REMS based on abundant evidence that these restrictions are unnecessary and impede access to an essential medication. ECF No. 80 at 17. After "carefully consider[ing]" ACOG's citizen petition, FDA denied it on the very same day that it imposed the current REMS: January 3, 2023. ECF No. 1-20 at 2. FDA's denial letter is missing from the record, too.

Additionally, the produced record excludes the Turnaway Study, a landmark study on abortion access that is cited at least 35 times within the produced record, including in a 2016 letter to FDA signed by the very entity that conducted the study. This study was before FDA and was—or should have been—considered.

The Plaintiff States therefore request that the Court order FDA to supplement the filed record to include the ACOG citizen petition and the documents cited therein, FDA's letter denying the ACOG citizen petition, and the Turnaway Study.

II. BACKGROUND

A. The Court's Preliminary Injunction Ruling

This lawsuit alleges, *inter alia*, that the mifepristone REMS is contrary to law, exceeds FDA's statutory authority, and is arbitrary and capricious. ECF No. 35 at 88-89. In April 2023, this Court preliminarily enjoined FDA from altering the status quo and rights as it relates to the availability of mifepristone in the Plaintiff States under the current REMS. ECF No. 80. In its order, the Court addressed the States' argument that they were not required to petition FDA before filing suit because they and others had already done so, and recognized that:

> In 2020, fifteen Plaintiff States asked FDA to eliminate the REMS patient agreement and certification requirements as "onerous and medically unnecessary" and received a form response from FDA. ECF No. 60 at 5. In 2021, FDA conducted a "full review" of REMS, including information about comparator drugs with mifepristone. ECF No. 60 at 7. In 2022, the ACOG and other medical and professional healthcare access organizations petitioned FDA to, in part, eliminate the REMS as medically unnecessary and unduly burdensome for uses of mifepristone, primarily for miscarriage

management. ECF Nos. 35 at 47, ¶ 139; 60 at 4; 61-1. FDA rejected ACOG's citizen petition. ECF No. 35 at 51, ¶ 144.

Id. at 16-17. Thus, the Court concluded: "Based on the information and requests already put forth before FDA, FDA cannot credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition." *Id.*

As to the merits, the Court explained that FDA may impose a REMS if it "determines, after considering six factors, it is 'necessary to ensure that the benefits of the drug outweigh the risks of the drug.'" *Id.* at 18–19 (quoting 21 U.S.C. § 355-1(a)(1)). "Moreover, a REMS may include . . . [ETASU] due to a drug's 'inherent toxicity or potential harmfulness' if the drug has 'been shown to be effective, but is associated with a serious adverse drug experience, [and] can be approved only if, or would be withdrawn unless, such elements are required as part of such strategy to mitigate a specific serious risk listed in the labeling of the drug.'" *Id.* at 19 (quoting 21 U.S.C. § 355-1(f)(1)(A)).

Based on the record at that stage, the Court found, *inter alia*, that "FDA did not assess whether mifepristone qualifies for REMS and ETASU based on the criteria set forth" in the governing statutes. *Id.* at 21. Thus, "it appears FDA failed to consider an important aspect of the problem." *Id.* (citing *Turtle Island Restoration Network v. U.S. Dep't of Com.*, 878 F.3d 725, 732 (9th Cir. 2017)). Further, responding to FDA's contention that it "need only determine whether modifications are appropriate" without addressing whether mifepristone actually qualifies for ETASU, the Court found that "it would be contrary to the plain

language of the statute that the agency need not consider arguments that mifepristone's REMS and ETASU should be removed in whole or part" based on statutorily-established criteria. *Id.* at 20-21.

B. FDA's Production of the Administrative Record

On September 1, 2023, FDA notified the Plaintiff States that its production of the administrative record was complete, and filed an Index of the same. ECF No. 127; Beneski Decl. ¶ 3. The produced record consists of approximately 5,099 pages, and includes some of the documents that the Court recognized were "before FDA" when it decided to impose the current REMS restrictions. *See* ECF No. 80 at 16-17; Williams Decl. ¶ 5. However, the produced record did not include the 2022 citizen petition filed by ACOG and 48 other organizations (ECF No. 61-1), or FDA's January 3, 2023, letter denying the petition (ECF No. 1-20). *Id.* ¶ 6. Nor did it include the Turnaway Study, a landmark study that is cited at least 35 times within the produced record, including in a 2016 letter to FDA signed by the entity that conducted the study and 29 other organizations. *Id.*; *see* ECF No. 1-9 at 3; ECF No. 35 ¶ 95 & n.19.

After comprehensively reviewing the produced record, in December 2023, the Plaintiff States advised FDA that these and other documents were missing, and requested that FDA supplement the record accordingly. Beneski Decl. ¶ 4. FDA agreed to add some of the missing documents to the record, but refused to add the 2022 ACOG citizen petition, the documents cited therein, the denial letter, or the Turnaway Study. *Id.* ¶ 5.

III. ARGUMENT

A. Legal Standard

Judicial review of an agency decision "is based on the administrative record and the basis for the agency's decision must come from the record." *Ass'n of Irritated Residents v. E.P.A.*, 790 F.3d 934, 942 (9th Cir. 2015). Judicial review is based on "the whole record[.]" 5 U.S.C. § 706. The "whole" record consists of "all documents and materials directly or *indirectly* considered by agency decision-makers and includes evidence contrary to the agency's position." *Thompson v. U.S. Dep't of Lab.*, 885 F.2d 551, 555 (9th Cir. 1989). "[T]he whole record is not necessarily those documents that the agency has compiled and submitted as 'the' administrative record; the court must look to all the evidence that was before the decision-making body[.]" *Pub. Power Council v. Johnson*, 674 F.2d 791, 794 (9th Cir. 1982) (internal quotation marks omitted). "An incomplete record must be viewed as a fictional account of the actual decisionmaking process." *Portland Audubon Soc'y v. Endangered Species Comm.*, 984 F.2d 1534, 1548 (9th Cir. 1993) (citation and internal quotation marks omitted).

Moreover, supplementation is also appropriate when, *inter alia*, "necessary to determine if the agency has considered all factors and explained its decision[.]" *Fence Creek Cattle Co. v. U.S. Forest Serv.*, 602 F.3d 1125, 1131 (9th Cir. 2010); *accord Lands Council v. Powell*, 395 F.3d 1019, 1030 (9th Cir. 2005). Because "[a]n agency's action may be arbitrary and capricious if it can be shown that 'the agency . . . entirely failed to consider an important aspect of the problem, [or]

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

offered an explanation for its decision that runs counter to the evidence before the agency,' . . . documents that were *not* relied upon by a decisionmaker, or evidence relating to such documents and their non-consideration, have been held to be necessary elements of an administrative record." *Trout Unlimited v. Lohn*, No. C05-1128C, 2006 WL 1207901, at *3 (W.D. Wash. May 4, 2006) (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983)).

B. ACOG's Citizen Petition Was Before FDA When It Imposed the REMS

This Court has already recognized that ACOG's 2022 citizen petition, which asked FDA to remove the REMS as medically unnecessary and unduly burdensome, was "before FDA" when FDA decided to re-impose a REMS with ETASU on mifepristone in 2023. ECF No. 80 at 17. As the Court concluded: "Based on the information and requests already put forth before FDA"—specifically including the 2022 petition filed by "ACOG and other medical and professional healthcare access organizations" (ECF No. 61-1)—"FDA cannot credibly argue that its decision on the Mifepristone REMS Program would change upon another citizen petition." ECF No. 80 at 17.

For the same reason, FDA also cannot credibly argue that ACOG's citizen petition was somehow not before the agency when it made its decision. To be sure, FDA denied the petition. *See id.*; ECF No. 1-20 at 2. But FDA's disagreement with ACOG does not justify excluding ACOG's petition from the record. To the contrary, "the court must look to all the evidence that was before" FDA when it made its decision, *Pub. Power Council*, 674 F.2d at 794, which "includes evidence

contrary to the agency's position." *Thompson*, 885 F.2d at 555. FDA's "careful[] consider[ation]" of ACOG's petition, ECF No. 1-20 at 2—not its rejection of ACOG's request—is dispositive. The petition was undoubtedly before the agency, and the record should be supplemented accordingly.

Additionally, the record should be supplemented to include the 52 studies and other documents ACOG cited in its petition to support its request to remove the REMS. Just as the petition itself was "before the decision-making body," so too were the materials cited in the petition—in the same way that cases cited in a legal brief are before the court. The produced record itself confirms this by including studies and other documents that are cited within record documents. For example, the filed record includes the 2020 letter to FDA submitted by 15 Plaintiff States, along with the five documents cited therein. *See* ECF No. 127 at 20-21 (Index listing 2021 REMS 000035-040 with five sub-listings). Similarly, the filed record includes a 2021 letter from Dr. Graham Chelius to Acting FDA Commissioner Dr. Janet Woodcock, along with the 22 documents cited therein. *See id.* at 31-33 (Index listing 2021 REMS 001159-1167 with 22 sub-listings). The 52 citations within the ACOG citizen petition provide the evidentiary support for the signatories' request to lift the REMS, and that evidence was "before FDA" just as the petition itself was.

Finally, this Court has also recognized that FDA "rejected ACOG's citizen petition." ECF No. 80 at 17. FDA's January 3, 2023 letter denying ACOG's request to lift the REMS—which was issued on the very same day the FDA imposed the

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

current REMS—confirms that FDA in fact "carefully considered" ACOG's petition. ECF No. 1-20 at 2. While the filing of a formal citizen petition with the FDA is enough, on its own, to establish that the petition was "before FDA," the denial letter leaves no doubt that the petition was directly considered. But the denial letter, too, is missing from the filed administrative record.

The ACOG citizen petition, the documents cited therein, and the denial letter are all part of the "whole" administrative record. Supplementation is warranted.

C. The Turnaway Study Was Before FDA

The Turnaway Study, a prospective longitudinal study conducted by Advancing New Standards in Reproductive Health (ANSRH), examined the effects on people's lives of being denied a wanted abortion. ECF No. 1-9 at 3. This landmark study, which examines the consequences of restricting abortion access for people's health and well-being, is cited extensively throughout the produced record, appearing in at least 35 citing references. Williams Decl. ¶ 6.c. Among them is a letter to FDA from 30 signatories, including ANSRH itself, citing the Turnaway Study as evidence in urging FDA to lift the REMS. *Id.*; ECF No. 1-9; ECF No. 35 ¶ 95 & n.19. For the same reasons discussed above, the Turnaway Study was therefore before FDA when it imposed the REMS.

D. The Missing Documents Are Necessary for Judicial Review

Even if the Court were to reconsider its prior conclusion that ACOG's citizen petition was "before FDA" and find that FDA did not "directly" or even "indirectly" consider the petition and the related documents, the Court should still

supplement the record to include these and the other missing documents because they will help in evaluating the Plaintiff States' APA claims—including whether FDA "considered all factors and explained its decision[.]" *Fence Creek Cattle Co.*, 602 F.3d at 1131. "[D]ocuments which may demonstrate that the Government ignored relevant factors" in an APA case "are appropriately part of the administrative record[.]" *High Sierra Hikers Ass'n v. U.S. Dep't of the Interior*, No. C-09-4621 JCS, 2011 WL 2531138, at *9 (N.D. Cal. June 24, 2011); *Lands Council*, 395 F.3d at 1030 ("extra-record evidence" should be admitted when "necessary to determine whether the agency has considered all relevant factors and has explained its decision" (citation and internal quotation marks omitted)).

Here, the Plaintiff States will argue—as the Court has already preliminarily found—that FDA "failed to consider an important aspect of the problem" and failed to "consider arguments that mifepristone's REMS and ETASU should be removed in whole or in part . . . ." ECF No. 80 at 20-21. ACOG's citizen petition cited extensive evidence that the mifepristone REMS is unnecessary for safety or risk management, that it imposes burdens that disincentivize prescribing, dispensing, and accessing the medication, and that removing the restrictions would not harm patient safety. *See generally* ECF No. 61-1. As one key example, ACOG's petition cited a study published in the New England Journal of Medicine that, as ACOG explained, demonstrated "no increase in complications from mifepristone use" after Canada "removed all restrictions on prescribing mifepristone for abortion, thereby allowing it to be prescribed and dispensed like

any other drug . . . .” *Id.* at 18 & 29 n.52. This study examined data from the 10-month period in Canada when mifepristone was distributed under “REMS-like restrictions” and the 28-month period when it was distributed without such restrictions, and found “no difference” in the rates of complications or serious adverse events. *Id.* FDA was made aware of this study through ACOG’s citizen petition and should have considered it before imposing the REMS in 2023.

Likewise, the Turnaway Study, which is cited throughout the produced record, shows that “the majority of people who seek abortion care are already in difficult financial situations,” meaning the unnecessary REMS restrictions have disproportionate impacts on these patients. ECF No. 1-9 at 3-4. And as a study within the record concludes based on Turnaway Study data, “women receiving wanted abortions had similar or better mental health outcomes than those who were denied a wanted abortion.” Williams Decl. Ex. A at 9. FDA should have considered these findings, and their implications for particularly vulnerable patient populations, in light of the statutory requirement that ETASU must not be “unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas,” and must “minimize the burden on the health care delivery system . . . .” 21 U.S.C. §§ 355-1(f)(2)(C)-(D).

Because FDA’s decision to ignore these materials is integral to the Plaintiff States’ claims, supplementation is warranted for this independent reason.

IV. CONCLUSION

The Plaintiff States’ motion to supplement the record should be granted.

DATED this 19th day of January 2024.

ROBERT W. FERGUSON
Attorney General

/s/ Kristin Beneski
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744
Noah.Purcell@atg.wa.gov
Kristin.Beneski@atg.wa.gov
Colleen.Melody@atg.wa.gov
Andrew.Hughes@atg.wa.gov
Lauryn.Fraas@atg.wa.gov
Tera.Heintz@atg.wa.gov
Attorneys for Plaintiff State of Washington

ELLEN F. ROSENBLUM
Attorney General of Oregon

/s/ Carla A. Scott
SANDER MARCUS HULL, WSBA #35986
CARLA A. SCOTT, WSBA #39947
Senior Assistant Attorneys General
YOUNGWOO JOH, OSB #164105
Assistant Attorney General
Trial Attorneys
Tel: (971) 673-1880
Fax: (971) 673-5000
marcus.hull@doj.state.or.us
carla.a.scott@doj.state.or.us
youngwoo.joh@doj.state.or.us

Attorneys for State of Oregon

KRIS MAYES
Attorney General of Arizona

/s/ Daniel C. Barr
Daniel C. Barr (Arizona No. 010149)
Chief Deputy Attorney General
Luci D. Davis (Arizona No. 35347)
Office of the Attorney General of Arizona
2005 N. Central Ave.
Phoenix, AZ 85004-1592
Phone: (602) 542-8080
Email: Daniel.Barr@azag.gov
Luci.Davis@azag.gov
Attorneys for Plaintiff State of Arizona

PHILIP J. WEISER
Attorney General of Colorado

/s/ Eric Olson
ERIC OLSON, CO #36414
Solicitor General
MICHAEL MCMASTER, CO #42368
Assistant Solicitor General
Office of the Attorney General
Colorado Department of Law
1300 Broadway, 10th Floor
Denver, CO 80203
Phone: (720) 508-6000
Attorneys for Plaintiff State of Colorado

WILLIAM TONG
Attorney General of Connecticut

/s/ Joshua Perry
Joshua Perry
Solicitor General
Office of the Connecticut Attorney General
165 Capitol Ave, Hartford, CT 06106
Joshua.perry@ct.gov
(860) 808-5372
Fax: (860) 808-5387

Attorney for Plaintiff State of Connecticut

KATHLEEN JENNINGS
Attorney General of Delaware

/s/ Vanessa L. Kassab
VANESSA L. KASSAB
Deputy Attorney General
Delaware Department of Justice
820 N. French Street
Wilmington, DE 19801
302-683-8899
vanessa.kassab@delaware.gov
Attorney for Plaintiff State of Delaware

KWAME RAOUL
Attorney General of Illinois

/s/ Caitlyn G. McEllis
Caitlyn G. McEllis (6306561)
Senior Policy Counsel
Office of the Illinois Attorney General
115 South LaSalle Street
Chicago, IL 60603
Phone: (312) 793-2394
Caitlyn.McEllis@ilag.gov
Attorney for Plaintiff State of Illinois

DANA NESSEL
Attorney General of Michigan

/s/ Stephanie M. Service
Stephanie M. Service (P73305)
Assistant Attorney General
Michigan Department of Attorney General
Health, Education & Family
Services Division
P.O. Box 30758
Lansing, MI 48909
(517) 335-7603
ServiceS3@michigan.gov
Attorney for Plaintiff Attorney General of Michigan

AARON D. FORD
Attorney General of Nevada

/s/ Heidi Parry Stern
Heidi Parry Stern (Bar. No. 8873)
Solicitor General
Office of the Nevada Attorney General
555 E. Washington Ave., Ste. 3900
Las Vegas, NV 89101
HStern@ag.nv.gov
Attorney for Plaintiff State of Nevada

RAÚL TORREZ
Attorney General of New Mexico

/s/ Aletheia Allen
Aletheia Allen
Solicitor General
Executive Office
State of New Mexico Department of Justice
201 Third St. NW, Suite 300
Albuquerque, NM 87102
505-527-2776
AAllen@nmag.gov
Attorney for Plaintiff State of New Mexico

PETER F. NERONHA
Attorney General of Rhode Island

/s/ Julia C. Harvey
JULIA C. HARVEY #10529
Special Assistant Attorney General
150 S. Main Street
Providence, RI 02903
(401) 274-4400 x2103
Attorney for Plaintiff State of Rhode Island

CHARITY R. CLARK
Attorney General of Vermont

/s/ Douglas Keehn
DOUGLAS KEEHN

Assistant Attorney General
109 State Street
Montpelier, VT 05609-1001
(802) 793-3892
douglas.keehn@vermont.gov
Attorney for Plaintiff State of Vermont

BRIAN L. SCHWALB
Attorney General for the District of Columbia
JENNIFER C. JONES
Deputy Attorney General
Public Advocacy Division
WILLIAM STEPHENS
Assistant Deputy Attorney General
Public Advocacy Division

/s/ Nicole S. Hill
NICOLE S. HILL
Assistant Attorney General
Office of the Attorney General for the
District of Columbia
400 Sixth Street, N.W.
Washington, D.C. 20001
(202) 727-4171
nicole.hill@dc.gov
Attorneys for Plaintiff District of Columbia

ANNE E. LOPEZ
Attorney General

/s/ Erin N. Lau
Erin N. Lau 009887
465 South King St., Room 200
Honolulu, Hawaii 96813
Erin.N.Lau@hawaii.gov
Counsel for the State of Hawaii

AARON M. FREY
Attorney General

/s/ Halliday Moncure
Halliday Moncure, Bar No. 4559
Assistant Attorney General

Office of the Maine Attorney General
6 State House Station
Augusta, ME 04333-0006
(207) 626-8800
halliday.moncure@maine.gov

ANTHONY G. BROWN
Attorney General of Maryland

/s/ Joshua M. Segal
JOSHUA M. SEGAL
Assistant Attorney General
Office of the Attorney General of Maryland
200 Saint Paul Place, 20th Floor
Baltimore, Maryland 21202
(410) 576-6427
jsegal@oag.state.md.us
Attorney for Plaintiff State of Maryland

KEITH ELLISON
Attorney General
State of Minnesota

/s/ Liz Kramer
LIZ KRAMER (#0325089)
Solicitor General
JENNIFER OLSON (#0391356)
Assistant Attorney General
445 Minnesota Street, Suite 1400
St. Paul, Minnesota 55101-2131
(651) 757-1010 (Voice)
(651) 282-5832 (Fax)
liz.kramer@ag.state.mn.us
jennifer.olson@ag.state.mn.us
Attorneys for Plaintiff State of Minnesota

MICHELLE A. HENRY
Attorney General of Pennsylvania

/s/ Jill M. Graziano
JILL M. GRAZIANO (Pa Bar No. 82725)
Chief Counsel to the Attorney General
1000 Madison Ave., Ste. 310

Norristown, PA 19403
jgraziano@attorneygeneral.gov
(484) 460-1330
Attorney for the Commonwealth of Pennsylvania

CERTIFICATE OF SERVICE

I hereby certify that on January 19, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice.

DATED this 19th day of January 2024, at Seattle, Washington.

/s/ Kristin Beneski
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

RAÚL R. LABRADOR
Attorney General
DAVID M.S. DEWHIRST (ID #12141)
Chief Deputy Attorney General
THEODORE J. WOLD (CA #289177)
Solicitor General
LINCOLN DAVIS WILSON (WA #53764)
Deputy Attorney General
Chief, Civil Litigation and Constitutional Defense Division
JOSHUA N. TURNER (MN #0400279)
Deputy Solicitor General
Office of the Attorney General
P.O. Box 83720
Boise, Idaho 83720-0010
Tel: (208) 334-2400
Fax: (208) 854-8071

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al.,

Plaintiffs,
v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.

Defendants,

STATE OF IDAHO; STATE OF IOWA; STATE OF MONTANA; STATE OF NEBRASKA; STATE OF SOUTH CAROLINA; STATE OF TEXAS; STATE OF UTAH,

Plaintiffs-Intervenors,

Case No. 1:23-cv-03026

REPLY IN SUPPORT OF PLAINTIFFS-INTERVENORS' MOTION TO INTERVENE

State Intervenors' Motion is a routine example of Rule 24 intervention. State Intervenors assert the same claims against the FDA as Plaintiffs, dispute the same agency action, challenge the same REMS, allege many of the same harms, and seek—in part—the same relief. In opposition, the FDA and Plaintiffs rely on arguments this Court has already rejected and on basic misunderstandings of the law. They seek to impose heightened burdens that flout the Ninth Circuit's instruction that Rule 24 is construed "broadly in favor of proposed intervenors." *Wilderness Soc. v. U.S. Forest Service*, 630 F.3d 1173, 1179 (9th Cir. 2011). As this Court has recognized, such a slanted view must be rejected. *Jordan v. Nationstar Mortg., LLC*, No. 2:14-CV-0175-TOR, 2016 WL 7494297, at *2 (E.D. Wash. Oct. 14, 2016) (describing Rule 24 as a "liberal policy" whose "requirements are broadly interpreted in favor of intervention"). Intervention here is well supported; it will cause the existing parties no prejudice; and it will "prevent or simplify future litigation involving related issues." *See United States v. City of Los Angeles*, 288 F.3d 391, 397 (9th Cir. 2002).

ARGUMENT

I. State Intervenors Have Standing To Intervene.

The FDA assumes State Intervenors must separately establish standing and are asserting injuries that belong only to their citizens. It is incorrect on both counts.

Separate Standing Not Required. The FDA begins with a fundamental misstep by arguing that the State Intervenors must show standing. That is not required because the Court has already found Plaintiffs have standing to challenge the 2023 mifepristone REMS under the APA. *See Massachusetts v. EPA*, 549 U.S. 497, 518 (2007) ("Only one of the petitioners needs to have standing to permit us to consider

the petition for review."). The FDA's position is at odds with Ninth Circuit precedent that "once the court determines that one of the plaintiffs has standing, it need not decide the standing of the others." *Leonard v. Clark*, 12 F.3d 885, 888 (9th Cir. 1993).

This standing rule makes sense. Article III limits a court's power to decide "Cases" or "Controversies." *Town of Chester, N.Y. v. Laroe Ests., Inc.*, 581 U.S. 433, 438 (2017). Once one plaintiff presents the court with a case or controversy, Article III imposes no further barrier on judicial power to reach the dispute. *Id.* Standing relates to a federal court's power over disputes; it has nothing to do with a court's power over litigants, which is instead a question of personal jurisdiction. This Court has established its jurisdiction to hear the dispute over the 2023 REMS.

The FDA thinks this rule inapplicable because State Intervenors seek different relief from that sought by Plaintiffs. Dkt. #92 at 5. But Plaintiffs' Amended Complaint contradicts the FDA: they too have brought APA claims to "hold unlawful and set aside" the 2023 REMS and otherwise invalidate it. Dkt. #35 at ¶¶ 257-66. That is the same relief State Intervenors seek—no more, no less. Dkt. #76-1 at ¶¶ 97-107.

It's true that Plaintiffs seek additional relief, but all that matters is that the Court has found they have standing to seek the relief State Intervenors also seek. The Supreme Court has made this point clear: "an intervenor of right must demonstrate Article III standing when it seeks additional relief beyond that which the plaintiff requests." *Town of Chester*, 581 U.S. at 439. State Intervenors are not seeking "additional" relief "beyond" the relief already sought by Plaintiffs.

For this reason, the FDA misplaces reliance on *Oregon Prescription Drug Monitoring Program v. U.S. DEA*, 860 F.3d 1228 (9th Cir. 2017), where the intervenors

sought different relief on different legal grounds from the original plaintiff's complaint. *Id.* at 1234. Plaintiffs and State Intervenors, by contrast, pray for the same relief on the same legal grounds. That Plaintiffs seek to go further than State Intervenors is of no moment. And the FDA cannot unilaterally recharacterize the baseline relief Plaintiffs have prayed for in their Amended Complaint. Plaintiffs' Amended Complaint is "the best evidence of the relief [they] seek[]." *See Town of Chester*, 581 U.S. at 440. This Court has already found that Plaintiffs "claim that the 2023 REMS violated the Administrative Procedures Act." Dkt. #80 at 10. So do State Intervenors.

The State Intervenors Have Independent Standing. In any event, State Intervenors have shown their own standing. The FDA confuses distinct concepts of standing by arguing that State Intervenors are asserting *parens patriae* standing on behalf of their citizens. But that isn't so. State Intervenors assert their own sovereign and quasi-sovereign interests, which is very different than what *Mellon* bars. *See Kentucky v. Biden*, 23 F.4th 585, 596-99 (6th Cir. 2022) (explaining the difference); *Oregon v. Legal Servs.*, 552 F.3d 965, 971 (9th Cir. 2009) (drawing same distinction).

Those "sovereign-and-quasi-sovereign-interest theories" do not rest "on impermissible notions of third-party standing in which a state asserts in a purely vicarious manner the interests of its citizens." *Id.* They instead assert classic state interests that entitle them to "special solicitude" for standing purposes. *Massachusetts*, 549 U.S. at 520. The Ninth Circuit has also recognized that States can bring APA claims to vindicate these interests. *See Natl. Res. Defense v. U.S.*, 542 F.3d 1235, 1249 n.8 (9th Cir. 2008). The FDA ignores this binding precedent.

In this case, State Intervenors "may so sue . . . to vindicate [their] own sovereign and quasi-sovereign interests against the United States." *Id.* at 596. The 2023 REMS deregulate mifepristone and make it more likely for State Intervenors' citizens to unlawfully or improperly obtain the drug. Dkt. #76-1 at ¶¶ 46-52. Plaintiffs' Amended Complaint confirms as much, alleging that eliminating mifepristone's REMS will reduce the risk of criminal and civil enforcement by bordering States, like Idaho and Texas. Dkt. #35 at ¶¶ 130, 185. And deregulation will lead directly to citizen harm. Dkt. #76-1 at ¶¶ 41-51. State Intervenors' sovereign and quasi-sovereign interests provide them with standing. *See Massachusetts*, 549 U.S. at 520; *California v. Trump*, 963 F.3d 926, 936 (9th Cir. 2020) ("[A] state may sue to assert its quasi-sovereign interests in the health and well-being . . . of its residents in general.").

State Intervenors also have alleged direct harm to their own economic interests traceable directly to the 2023 REMS, which alone provides standing. *Hinojos v. Kohl's Corp.*, 718 F.3d 1098, 1104 n.4 (9th Cir. 2013). For example, Idaho alleges that "[t]he increased risk to Idaho women and unborn children [from the REMS] will [cause] it to incur additional medical care expenses, including emergency care, some of which is borne by Idaho through Medicaid expenditures." Dkt. #76-1 at ¶ 54. Plaintiffs asserted the same economic harms tied to the 2023 REMS, and this Court held such harms conferred standing. Dkt. #80 at 13-14. The result cannot be any different here.

The FDA ignores that track record and tries again. It argues that State Intervenors haven't shown that their allegations of economic harms are beyond speculative. But it does so based on caselaw addressing standing at the summary judgment stage, which does not apply here. *See, e.g., Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 412

(2013) ("[A]t the summary judgment stage, such a party can no longer rest on mere allegations." (cleaned up)); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992) (same). And the FDA's squabbling over what certain studies actually show or deference to its own "reasoned conclusion" proves the point. *See* Dkt. #92 at 10. "At the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice" because courts "presum[e] that general allegations embrace those specific facts that are necessary to support the claim." *Lujan*, 504 U.S. at 561. The FDA's dispute over the merits of State Intervenors' alleged injuries is for another day. *Maya v. Centex Corp.*, 658 F.3d 1060, 1068 (9th Cir. 2011). At this early stage, "allegations of economic injury suffice," full stop. *Hinojos*, 718 F.3d at 1104 n.4.

The FDA's final effort is to label State Intervenors' injuries "unadorned speculation" and "merely incidental." Dkt. #92 at 11. Neither characterization holds up. This Court has already found that there is "a reasonably probable threat to [State] economic interests in the form of unrecoverable costs that are fairly traceable to the 2023 REMS." Dkt. #80 at 14. Similarly, State Intervenors allege the 2023 REMS removed necessary safeguards to protect women, which increases the medical expenses State Intervenors incur. *See* Dkt. #76-1 at ¶¶ 24-26, 29-30, 37-38, 41-44, 47-51, and 53-54.

The FDA relies on *Arizona v. Biden*, 40 F.4th 375 (6th Cir. 2022), but this case is nothing like it. The States' allegations in *Arizona* relied on contingent and speculative assumptions about how a Guidance document would impact noncitizen criminal activity. *Id.* at 383. As the court explained well, "[t]hat the National Government decides to remove or detain person A over person B does not establish that it will pursue fewer people." *Id.* Here, in contrast, State Intervenors and Plaintiffs have both

alleged that the 2023 REMS directly result in adverse health outcomes and that States will foot the bill for some of the increased medical expenses.

The Ninth Circuit in *California v. Azar* recently affirmed a nearly identical theory of standing. 911 F.3d 558 (9th Cir. 2018). Like the FDA does here, the agency in *Azar* argued that the economic injuries were too speculative. But the Ninth Circuit held that "the states have shown that the threat to their economic interest is reasonably probable." *Id.* at 573. True, a causal chain was involved, but "[j]ust because a causal chain links the states to the harm does not foreclose standing." *Id.* at 571.

State Intervenors need only generally allege injuries, and their generally alleged injuries are entitled to special solicitude. *California*, 963 F.3d at 936. At this stage, State Intervenors allege "a quintessential injury-in-fact." *Maya*, 658 F.3d at 1069.

II. State Intervenors Have A Right To Intervene.

Plaintiffs try a different approach from the FDA, but their arguments fare no better. Their Rule 24 analysis cannot be squared with Ninth Circuit precedent. State Intervenors have shown each of the four factors are met here.

Timeliness. State Intervenors filed their Motion to Intervene exactly three weeks after Plaintiffs filed their Amended Complaint, just five weeks after Plaintiffs commenced this action, and before the FDA answered or this Court issued any scheduling order. Yet Plaintiffs contend that State Intervenors' Motion is untimely. *See* Dkt. #93 at 8-9. Tellingly, they cite no case finding that a motion to intervene filed within five weeks of case commencement is untimely. That's because caselaw uniformly says the opposite. *See, e.g., Kalbers v. US DOJ*, 22 F.4th 816, 822 (9th Cir. 2021) (intervention timely when filed "just a few weeks" after intervenor learned of

need to intervene); *Los Angeles*, 288 F.3d at 398 (intervention timely when "filed only approximately one and half months after the suit was filed"). Nor does the Court's entry of a preliminary injunction make State Intervenors' Motion untimely. *BNSF Ry. Co. v. Tri-City & Olympia R.R. Co. LLC*, 2010 WL 11527085, at *1 (E.D. Wash. Mar. 8, 2010) (allowing intervention "although a preliminary injunction is in place").

Notably, Plaintiffs have not claimed they would be prejudiced by State Intervenors' entry, which "is the most important consideration in deciding whether a motion for intervention is untimely." *Smith v. L.A. Unified Sch. Dist.*, 830 F.3d 843, 857 (9th Cir. 2016). State Intervenors moved to intervene swiftly when they learned that this litigation implicated their interests. In fact, State Intervenors acted more quickly than Plaintiffs, who've argued that "[t]aking seven weeks to assemble a multi-state coalition and gather evidence following this final agency action hardly evinces a 'lack of urgency.'" Dkt. #60 at 17. State Intervenors motion is just as timely.

Protectable Interest. Plaintiffs are just plain wrong that State Intervenors lack an interest "protectable under some law" that is related to "the claims at issue." *Wilderness Soc*, 630 F.3d at 1176. It is not plausible that, as Plaintiffs suggest, the only valid State interest in the mifepristone REMS is the one that seeks to invalidate it. State Intervenors also have an interest in safe mifepristone REMS, an interest that is legally protected by the APA. And State Intervenors' interest is related to Plaintiffs' claims, which also challenge the mifepristone REMS. Nothing more is needed to satisfy this factor. *Calif. Dep't of Toxic Substances Control v. Jim Dobbas, Inc.*, 54 F.4th 1078, 1092 (9th Cir. 2022) (reversing and finding protectable interest).

Plaintiffs only dispute that State Intervenors' interests are unrelated to their claims. Dkt. #93 at 4. They characterize State Intervenors' interest as "solely" concerning the in-person dispensing requirement, but that is not the case. State Intervenors have a broader interest in ensuring lawful and safe mifepristone REMS. Dkt. #76-1 at ¶¶ 1, 17-27. This case shares a direct relationship with that interest because it challenges the same 2023 REMS at issue in State Intervenors' Complaint. Even if State Intervenors' interest were "solely" about the in-person dispensing requirement, Plaintiffs are wrong that such an interest is unrelated to their claims. They seek to invalidate the 2023 REMS, which, as the Court noted, may be inconsistent with other further relief they seek, but Plaintiffs are entitled to plead inconsistent relief. *Oki America, Inc. v. Microtech International, Inc.*, 872 F.2d 312, 314 (9th Cir. 1989).

Nor does the ability to regulate medication abortion defeat State Intervenors' interests here. State Intervenors are not asserting an interest based on a connection between their laws and the mifepristone REMS, which was the case in *ACOG v. FDA*, 467 F. Supp. 3d 282 (D. Md. 2020). State Intervenors have a right to vindicate their interests under the APA, which are squarely at issue here. Because "resolution of the plaintiff's claims actually will affect [State Intervenors]," the relationship requirement is satisfied. *See Donnelly v. Glickman*, 159 F.3d 405, 410 (9th Cir. 1998)

Impairment of Interest. Once an intervenor demonstrates a protectable interest, courts have "little difficulty concluding that the disposition of the case may, as a practical matter, affect it." *Citizens for Balanced Use v. Montana Wilderness Ass'n*, 647 F.3d 893, 898 (9th Cir. 2011). Plaintiffs' goal of eliminating mifepristone's REMS would apply to mifepristone's availability nationally. And even were it confined to

Plaintiffs' borders, State Intervenors' interests would still be impaired. As Plaintiffs admit, eliminating the REMS impacts State Intervenors' ability to enforce its laws and the safeguards available to protect their citizens. Dkt. #35 at ¶¶ 130, 185.

Plaintiffs' principal response is that State Intervenors can assert their interests in a separate lawsuit. Dkt. #93 at 6-7. But this view discounts the effect of judgment here and at the Ninth Circuit. *See United States v. Oregon*, 839 F.2d 635, 639 (9th Cir. 1988) (citing precedents "recognizing practical limitations on the ability of intervention applicants to protect interests in the subject of the litigation after court-ordered equitable remedies are in place"). The impairment "analysis focuses on the *future* effect pending litigation will have on the intervenors' interests." *Klamath Siskiyou Wildlands Ctr. v. U.S. BLM*, 2019 WL 6749411, at *2 (D. Or. Dec. 11, 2019). Here, it isn't difficult to see that a future decision from this Court or the Ninth Circuit may impair or impede State Intervenors' interest. In the Ninth Circuit, "such a stare decisis effect is an important [impairment] consideration." *Oregon*, 839 F.2d at 638.

Plaintiffs' go-file-your-own-lawsuit answer also disregards Rule 24's well-recognized purpose to promote the "efficient resolution of issues." *Wilderness Soc.*, 630 F.3d at 1179. This is why Rule 24 is liberally construed "in favor of intervention." *Id.* Intervention exists to "prevent or simplify future litigation involving related issues." *City of Los Angeles*, 288 F.3d at 398. But Plaintiffs turn this purpose on its head and ask this Court to deny intervention so that litigation can be multiplied. That disrespects constrained judicial resources and ignores Rule 24's primary purpose.

Inadequate Representation. Plaintiffs do not dispute that they do not adequately represent State Intervenors' interests. And that's true. There is an obvious

misalignment of interests. Still, they contend that the "FDA adequately represents" State Intervenors' interests. They do not say how the FDA is a fit representative to advance State Intervenors' claims against itself. Nor has the FDA claimed that it would do so. It seems too obvious to have to say much more, but a party who an intervenor proposes to sue will not adequately represent the intervenors' interests. State Intervenors need only show that representation of their "interest may be inadequate—a 'minimal' burden." *See Kalbers*, 22 F.4th at 828. They've done so.

III. State Intervenors May Permissively Intervene.

Both the FDA and Plaintiffs oppose permissive intervention on the same grounds as they oppose intervention as of right. Their arguments are addressed above and won't be rehashed here. One final point bears mention. State Intervenors' participation in this case will not "unduly delay or prejudice the adjudication of the original parties' rights." Fed. R. Civ. P. 24(b)(3). Neither the FDA nor Plaintiffs have argued that intervention here will prejudice their rights. Plaintiffs baldly assert that intervention will "unduly delay" this case, but their assertion is based on the erroneous belief that State Intervenors seek to advance "tangential claims." Dkt. #93 at 11. State Intervenors will instead provide the Court with an unrepresented perspective and so "will significantly contribute to full development of the underlying factual issues in the suit and to the just and equitable adjudication of the legal questions presented." *Spangler v. Pasadena City Bd. of Educ.*, 552 F.2d 1326, 1329 (9th Cir. 1977).

CONCLUSION

State Intervenors request the Court grant their Motion to Intervene.

Dated: April 19, 2023

/s/ Lincoln Davis Wilson

LINCOLN DAVIS WILSON (#53764)
Deputy Attorney General
Chief, Civil Litigation and
Constitutional Defense Division
Office of the Attorney General
P.O. Box 83720
Boise, Idaho 83720-0010
Tel: (208) 334-2400
Fax: (208) 854-8071
Lincoln.Wilson@ag.idaho.gov

CERTIFICATE OF SERVICE

I hereby certify that, on April 19, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ Lincoln Davis Wilson
LINCOLN DAVIS WILSON (WA #53764)

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON; STATE OF OREGON; STATE OF ARIZONA; STATE OF COLORADO; STATE OF CONNECTICUT; STATE OF DELAWARE; STATE OF ILLINOIS; ATTORNEY GENERAL OF MICHIGAN; STATE OF NEVADA; STATE OF NEW MEXICO; STATE OF RHODE ISLAND; and STATE OF VERMONT, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs; UNITED STATES	NO. 1:23-cv-03026 DECLARATIONS IN SUPPORT OF PLAINTIFF STATES' MOTION FOR PRELIMINARY INJUNCTION 03/27/2023 With Oral Argument at time and location to be determined by Court

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

Defendants.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Table of Contents
Declarations in Support of Plaintiffs' Motion for Preliminary Injunction

Exhibit	Declarant
1	Declaration of Susan E. Birch
2	Declaration of Connie Cantrell
3	Declaration of Alyssa Colwill, M.D., M.C.R.
4	Declaration of Sumona DasGupta
5	Declaration of Paul Dillon
6	Declaration of Donald Downing R PH.
7	Declaration of Dr. Charissa Fotinos
8	Declaration of Emily M. Godfrey, M.D., M.P.H.
9	Declaration of Marji Gold, MD
10	Declaration of Cynthia Harris
11	Declaration of Sunday Henry, M.D., Gordon Hedenstrom, R.PH. and Joel Schwartzkopf
12	Declaration or Elizabeth Janiak, SCD, MSC, MA
13	Declaration of Judy Lazarus
14	Declaration of Mark D. Nichols, M.D.
15	Declaration of Sarah W. Prager, MD, MAS
16	Declaration of Brian Reed
17	Declaration of Samantha Rolland
18	Declaration of Grace Shih, MD, MAS
19	Declaration of Angad Singh, M.D.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

CERTIFICATE OF SERVICE

I hereby certify that on February 24th, 2023, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF System, which in turn automatically generated a Notice of Electronic Filing (NEF) to all parties in the case who are registered users of the CM/ECF system. The NEF for the foregoing specifically identifies recipients of electronic notice. I hereby certify that I have mailed by United States Postal Service, and sent via electronic mail, the document to the following non-CM/ECF participants:

United States Food and Drug Administration
Chief Counsel, Food and Drug Administration
ATTENTION: LITIGATION
White Oak Building 31, Room 4544
10903 New Hampshire Ave., Silver Spring, MD 20993-0002
OC-OCC-FDA-Litigation-Mailbox@fda.hhs.gov

Robert M. Califf, Commissioner
Chief Counsel, Food and Drug Administration
ATTENTION: LITIGATION
White Oak Building 31, Room 4544
10903 New Hampshire Ave., Silver Spring, MD 20993-0002
OC-OCC-FDA-Litigation-Mailbox@fda.hhs.gov

I hereby certify that I have mailed by United States Postal Service the document to the following non-CM/ECF participants:

Department of Health and Human Services
c/o General Counsel
200 Independence Avenue, S.W.
Washington, D.C. 20201

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Xavier Becerra, Secretary
c/o General Counsel
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

I hereby certify that I have caused the document to be served by hand-delivery to the following non-CM/ECF participants:

U.S. Attorney Vanessa R. Waldref
United States Attorney's Office
Eastern District of Washington
920 W. Riverside Avenue, Suite 340
Spokane, WA 99201

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 24th day of February 2023, at Seattle, Washington.

/s/ Kristin Beneski
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Exhibit 1

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF SUSAN E. BIRCH

I, Susan E. Birch, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am the Director of the Washington State Health Care Authority (HCA) who oversees efforts to transform the health care system, helping ensure Washington residents have access to better health and better care at a lower cost.

3. HCA is the designated single state agency responsible for administering Washington's Medicaid program. HCA operates Apple Health, Washington State's Medicaid program. Apple Health provides free or low-cost health care for income-qualified individuals.

4. People who move to Washington with the intent to live here have access to Apple Health with no waiting period, if they meet the income eligibility requirements. A person does not need to live in the state for a specific period of time prior to applying for or receiving Apple Health coverage.

5. Washington State funds medication abortions for Apple Health clients in need of that health care. Unlike most other health care services provided through the Medicaid program, Washington receives no reimbursement for any portion of the cost of abortion services from the federal government. Washington State pays the entire cost of medication abortions provided through Apple Health.

6. Data available to the Health Care Authority suggest that between state fiscal years 2015 and 2022, Apple Health clients received over 32,000

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

medication abortions. The average cost to Washington State of each of those medication abortions provided to Apple Health clients was about $340.

7. Washington State also funds surgical abortions for Apple Health clients who need that health care. These services are also entirely funded by the State with no federal match.

8. Based on available data, the Health Care Authority has seen an average 5% year-over-year decrease between state fiscal years 2015 and 2022 in the number of patients receiving surgical abortion care in Washington State through Apple Health.

9. Data available to the Health Care Authority suggest that between state fiscal years 2015 and 2022, Apple Health clients received over 42,000 surgical abortions. The average cost to Washington State of each of those surgical abortions provided to Apple Health clients was about $610.

10. Any limits on the availability of medication abortion in Washington State is highly likely to cause an increase in the rate of surgical abortion for Apple Health insureds. The corresponding increase in costs resulting from the more-expensive surgical procedure would be borne by Washington State. I anticipate these increased rates of surgical abortion if there are barriers to access based on drug availability, limits on who may prescribe abortion medication, restrictions on where prescriptions may be filled, or other obstacles to patients' access to care.

11. The Health Care Authority also oversees the School Employee Benefits Board (SEBB) and the Public Employees Benefits Board (PEBB) which develop benefit plans, including health care coverage, for eligible public and school employees, retirees, and dependents.

12. The Health Care Authority has seen that between state fiscal years 2017 and 2022 PEBB members received over 1,100 medication abortions; between fiscal years 2021 and 2022 SEBB members received over 250 medication abortions. The average cost to Washington State of each medication abortion provided to PEBB and SEBB members ranges between $510 and $650.

13. The Health Care Authority has seen an average 3% year-over-year decrease between state fiscal years 2017 and 2022 in the number of members seeking surgical abortion care in Washington State through the PEBB Program.

14. The Health Care Authority has seen that between state fiscal years 2017 and 2022 PEBB members received over 800 surgical abortions; between fiscal years 2021 and 2022 SEBB members received over 150 surgical abortions. The average cost to Washington State of each surgical abortion provided to PEBB and SEBB members was approximately $1,500.

15. Apple Health, SEBB, and PEBB also cover insureds who require management of pregnancy loss and miscarriage. I am aware that the same drugs prescribed for elective medication abortions are also prescribed to treat patients experiencing pregnancy loss. Just as with medication abortion, I anticipate

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

increased rates of surgery to manage pregnancy loss if there are barriers to accessing the currently used drug regimen.

16. Although difficult to quantify with precision, there is no question that the cost impacts to the State of Washington from any further restriction of the availability of abortion medication would be significant. In the Apple Health Program alone, for example, assuming each of the 32,000 medication abortions between 2015 and 2022 had been surgical abortions, the resulting increased cost to the State would have been more than $8.6 million dollars. In the PEBB and SEBB programs, assuming each of the 1,350 medication abortions between fiscal years 2017 and 2022 had been surgical abortions, the resulting increased costs to the State could have been more than $1 million.

17. A decrease in the availability of mifepristone would also likely lead to increased costs to the State related to maternity care and childbirth, since a decrease in the availability or effectiveness of medication abortion is likely to lead to an increase in unwanted pregnancies being carried to term by insureds of Apple Health, SEBB, and PEBB.

18. In fiscal year 2021, on average for each delivery, the State paid about $11,200 for prenatal care and delivery for Apple Health clients.

I declare under penalty of perjury under the laws of the State of

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Washington and the United States of America that the foregoing is true and correct.

DATED this 21 day of February, 2023, at [Olympia], [WA].

Susan E. Birch
Director

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Exhibit 2

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF CONNIE CANTRELL

I, Connie Cantrell, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am the Executive Director of Cedar River Clinics, an organization that provides direct patient services, including birth control and abortion, and works to preserve and ensure access to reproductive and sexual healthcare. As Executive Director, I am responsible for an organization with four clinic locations and a telemedicine program in Washington State. I have served in this role since 2017. Before that, I spent about a decade as Cedar River Clinic's Director of Operations and served for approximately 14 years as a Clinic Manager in Cedar River's Yakima clinic. I have also held the role of Certified Health Assistant, and Surgical Tech, and briefly served as a volunteer when I first joined Cedar River Clinics in 1992. All told, I have been with Cedar River Clinics for more than thirty years.

3. Early in my career at Cedar River Clinics, I received training as a Certified Health Care Assistant. I worked under the supervision of Attending Physicians to provide direct patient care for patients seeking abortions, including providing patient counseling, pre and post abortion care, and assisting in abortion procedures. I am also familiar with medication abortions.

4. Cedar River Clinics has locations in Renton, Seattle, Tacoma, and Yakima. Our reproductive health care clinics offer first and second trimester

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

abortions, birth control, STI testing and treatment, cancer screenings, annual exams, and more. We have a LGBTQ wellness program which includes gender affirming care for transgender/non-binary patients. We offer both in-clinic and telemedicine services and are a member of the Reproductive and Sexual Health Program with the Washington Department of Health.

5. Cedar River Clinic was founded in Yakima in 1979 with subsequent locations being added when provider owners retired or wanted to close. Expanding abortion access is one of our priorities but we had to make the difficult decision to close our Yakima clinic in 2010. However, after hearing from patients traveling to us from Eastern Washington about the increasing wait times, we did a community needs assessment which led to our decision to reopen our Yakima location. Due to COVID, we expedited to begin our reopening as a telemedicine satellite site and last year, we opened for in-person care. Due to the reversal of *Roe v. Wade*, we expedited the plans to further expand the clinical space in Yakima so we can reopened fully to offer abortion procedures in March of 2023.

6. When the Yakima clinic resumes providing surgical abortions in March 2023, it will be only one of a small handful of full-service abortion clinics in Eastern Washington.

The Impact of *Dobbs*

7. For nearly 45 years, Cedar River Clinics had been providing first and second trimester abortion to individuals from across Washington State and

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

those traveling from out of state or internationally. Many of those patients had to travel due to restrictive laws. Since the *Dobbs v. Jackson Women's Health Organization* decision in June 2022 and subsequent abortion bans, Cedar River Clinics are experiencing a rising tide in the volume of individuals coming to Washington from other states to seek an abortion. It is not limited to our region; we are serving patients from across the country especially the South and Midwest who are being impacted by the abortion bans in their states.

8. Based on my own and my staff's observation, in the post-*Dobbs* landscape, it has also been harder for individuals to understand their options when seeking abortion care. There is significant confusion among individuals, especially individuals traveling to Washington from states criminalizing abortion or restricting abortion access, regarding what is legal and what consequences they may face in their home jurisdiction. At Cedar River Clinics, we make it a priority to educate patients and inform them of their rights. Because of *Dobbs* we are seeing an increasing need to devote resources to patient education, reassurance, and outreach.

9. We have also seen an escalation in protesters since *Dobbs*. This includes protesters blocking patients from driving up to our clinics and harassing staff, patients, and their support people at the clinic entrance. In addition to the mental and emotional burden this imposes, this means clinics need to devote more resources to managing this issue and provide security.

The Importance of Mifepristone

10. Mifepristone is one of a two-drug regimen that is the standard of care for medication abortions and miscarriage management. Medication abortions have become increasingly prevalent in Washington in the last several years. Cedar River Clinics offers medication abortion in-clinic and through telemedicine. Today, medication abortions make up approximately 40% of all the abortions Cedar River Clinics perform.

11. If mifepristone is removed from the market, it will have a devastating impact on individuals trying to access abortion. If patients are unable to access mifepristone, their options may only be a misoprostol-only abortion or surgical abortion. Returning to a one-drug, misoprostol-only protocol for medication abortion and miscarriage management will harm patients. Misoprostol is less effective and has more severe side effects. Moreover, misoprostol-only abortions typically require more doses over a longer period of time, and thus take longer to complete than abortions using a combination of mifepristone and misoprostol.

12. Surgical abortion will be the other option for patients who do not have access to mifepristone. There are a multitude of reasons why a patient may prefer a medication abortion to surgery including personal preference and matters of privacy and safety. Medication abortion offers greater privacy for patients, some of whom may fear being seen by community members or by an abuser if

forced to visit a known abortion clinic. Patients often prefer not to face protesters. Other individuals may not have the ability to travel to a clinic location for a variety of reasons, including being unable to take time away from work, childcare concerns, or to afford the cost of transportation. Although we subsidize care and abortion funds help as much as possible, the cost of surgical abortion is also prohibitive for many patients.

13. Clinics would also very likely see a higher number of second trimester surgical abortion cases if mifepristone is removed from the market. Arranging time off work, arranging childcare, and making travel plans for a surgical abortion takes time and could push some abortions into the second trimester.

14. For clinics themselves, surgical abortions require more time, money, and resources for staff, and to subsidize patient care. This means clinics would serve fewer individuals and abortion would become less accessible for all.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 21 day of February, 2023, at Seattle, WA.

Connie Cantrell

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Exhibit 3

ELLEN F. ROSENBLUM
Attorney General
SANDER MARCUS HULL WSBA #35986
Senior Assistant Attorney General
YOUNGWOO JOH, OSB # 164105*
Assistant Attorney General
Oregon Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
Telephone: (503) 947-4700
Email: marcus.hull@doj.state.or.us
youngwoo.joh@doj.state.or.us
Attorneys for State of Oregon

**Application for pro hac vice admission forthcoming*

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

Defendants.

NO. 1:23-cv-03026

DECLARATION OF ALYSSA COLWILL, M.D., M.C.R.

I, Alyssa Colwill, hereby declare:

1. I am over the age of 18, am competent to testify as to the matters in this declaration, and make this declaration based on my personal knowledge.

2. I make this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. I received my Doctor of Medicine from the Chicago Medical School at Rosalind Franklin University of Medicine and Science in 2012. I completed my residency in Obstetrics and Gynecology at the Hospital of the University of Pennsylvania in 2016. From 2016 to 2018, I was a Family Planning Fellow at the Oregon Health & Science University, and in 2018 I received a Masters of Clinical Research from OHSU.

4. Since completing my fellowship, I am an Assistant Professor in the Department of Obstetrics and Gynecology at OHSU. I am also board-certified by the American Board of Obstetrics and Gynecology, with a sub-specialization in Complex Family Planning. I am currently the Clinical Lead for the Complex Family Planning division at OHSU.

5. I have been licensed to practice medicine in the State of Oregon since 2016, license no. MD176540. I have also been licensed to practice medicine in the State of Washington since 2022, license no. MD61311123.

6. I am currently a medical provider at OHSU, in the Department of Obstetrics and Gynecology. As part of OHSU's Complex Family Planning

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (503) 947-4791

division, I regularly see patients who seek pregnancy-related healthcare on a regular basis, including those seeking miscarriage management and termination of pregnancy via medication or procedural abortions.

7. In a typical month, I see about 35 patients seeking miscarriage management care or medication or procedural abortion. In the course of my career, I have supervised about 3000 medication-based treatments for miscarriage management or abortion. Of that number, about three-quarters involved the prescription and use of mifepristone.

8. Attached as **Exhibit A** is a copy of my current curriculum vitae.

9. I am familiar with the drug mifepristone. I have personally administered mifepristone in several clinical trials. Mifepristone is one of a two-drug regimen prescribed for medication abortions and miscarriage management. The drug is also used for the purpose of inducing delivery in the event of a second- or third-trimester loss. It is also used for procedural abortions after the first trimester.

10. For gestation of up to 70 days, the standard of care for medication abortion involves one dose of mifepristone and one dose of misoprostol. A patient first takes mifepristone, which blocks the hormone progesterone, which is necessary to support the maintenance of a pregnancy. Between 24 and 48 hours later, the patient takes misoprostol, which causes cramping and bleeding to expel the contents of the uterus.

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (503) 947-4791

11. The use of mifepristone in combination with misoprostol is widely considered in the field of obstetrics and gynecology to be the gold standard for medical management of miscarriages and medication abortions. That has been the case since the early 2000s, when peer-reviewed studies demonstrated that the use of mifepristone and misoprostol together is both safer and more effective than the use of misoprostol alone.[1]

12. The prescription and use of mifepristone with misoprostol is the standard of care for medication abortion in the State of Oregon and has been since the early 2000's.[2] The use of mifepristone for miscarriage management became standard of care in 2019 after a randomized trial showed improved outcomes compared to using misoprostol alone.[3] In the past twenty years, nearly all medication abortions have been via the two-drug regimen of mifepristone and misoprostol.

---

[1] Medication abortion up to 70 days of gestation. ACOG Practice Bulletin No. 225. American College of Obstetricians and Gynecologists. Obstet Gynecol 2020;136:e31-4.

[2] Medication abortion up to 70 days of gestation, *supra* n.1.

[3] Early pregnancy loss. ACOG Practice Bulletin No. 200. American College of Obstetricians and Gynecologists. Obstet Gynecol 2018;132:e197-207; Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. Mifepristone pretreatment for the medical management of early pregnancy loss. N Engl J Med 2018;378:2161–70.

13. Mifepristone is also used for procedural abortion and in obstetrical complications. Mifepristone is also used for Cushing's syndrome. However, innovation and treatment with mifepristone has been limited due to REMS restrictions.

14. Although misoprostol can be prescribed alone for miscarriage management or medication abortions, it requires more frequent doses, with increased undesirable patient side effects, including nausea, cramping, bleeding, and flu-like symptoms.

15. Mifepristone is one of a small number of medications that the FDA subjects to a Risk Evaluation and Mitigation Strategy (REMS). The REMS impose restrictions on how a drug may be prescribed and used.

16. REMS are typically applied to inherently dangerous drugs, such as opioids.

17. Mifepristone, however, is extremely safe. In fact, its safety and efficacy is well documented in medical literature. The FDA's own publications on mifepristone show that the drug is safe and effective, demonstrating no scientific basis for subjecting the drug to REMS restrictions.

18. The REMS for mifepristone require certifications for prescribers (such as providers) and pharmacies. It further requires that mifepristone be dispensed by or under the supervision of a certified prescriber, or by certified pharmacies for prescriptions issued by certified prescribers. The REMS also

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (503) 947-4791

require the use of certification forms for the pharmacy and prescriber (or provider), as well as a patient-agreement form. It also requires the National Drug Code and lot number from each dispensed package of mifepristone be recorded in a patient's record.

19. Additionally, for a certified pharmacy to fulfill a prescription for mifepristone, that pharmacy must be registered with the mifepristone manufacturer as being in a prescription-fulfillment relationship with the specific provider. In other words, each individual provider must *separately* contact each individual pharmacy for that pharmacy to be allowed to fulfill the provider's prescription.

20. Those certification requirements are onerous and impede access to mifepristone without sound medical justification. For example, if a patient in rural Oregon obtains a mifepristone prescription from a certified provider, but that provider does not have a registered relationship with the patient's nearest certified pharmacy, that patient cannot fulfill their prescription at that pharmacy in person.

21. Although recent changes to FDA rules do allow the mailing of mifepristone, that does not meaningfully mitigate the reduced access caused by the mifepristone REMS. For one, I am not aware of any retail pharmacies that are yet certified by the FDA for mailing mifepristone. And second, the mailing

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (503) 947-4791

of important medication can add another two or three days to the time it takes for a patient to receive crucial and time-sensitive care.

22. Further, many rural providers do not have the volume of patient care to justify the onerous steps to register as a certified provider required by the mifepristone REMS. As a result, they frequently refer patients out to other providers, such as OHSU. In 2022, for example, I received referrals weekly from rural providers for miscarriage management or medication abortion. That means that the patient must see a second provider for something that, but for the mifepristone REMS, their original provider could have handled more expeditiously and safely.

23. In short, the mifepristone REMS effectively reduces the number of providers available to a patient without a medically sound reason for its imposition. In addition to reducing patient choice, it also increases the patient-load of the providers who are certified. That also increases the average wait time for healthcare for conditions in which time is of the essence.

24. Combined with the time needed to establish healthcare with a new provider, that can delay treatment or adversely affect patient health. For example, those time sensitive delays can prevent a patient from being eligible for a medication abortion, limiting the patient's option to a procedural abortion. A patient diagnosed with a miscarriage may end up having unpredictable bleeding while awaiting treatment. In addition, a patient is more likely to have

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (503) 947-4791

an incomplete miscarriage and require further interventions while trying to obtain care.

25. In my experience, those delays do often contribute to patients losing healthcare options or experiencing adverse health effects.

26. The mifepristone REMS does not enhance patient safety, because its requirements are redundant with what healthcare providers already do. For example, the provider certification form requires the provider to certify that they can accurately date a pregnancy, diagnose an ectopic pregnancy, and treat complications that may arise or refer to someone who could. But medical providers qualified to provide a medication abortion are necessarily trained in pregnancy dating, ectopic risk factors, and care coordination.

27. The Patient Agreement Forms required by the REMS also can cause patient confusion and distress. For example, the form requires the patient to declare they "have decided to take mifepristone and misoprostol *to end my pregnancy*." But mifepristone is not just used for medication abortion; it is also the standard of care for medically managing miscarriage. Second, the form requires the patient to declare they "will take the misoprostol tablets 24 to 48 hours after I take mifepristone." But emerging medical evidence suggests that misoprostol may sometimes be appropriately taken fewer than 24 hours after taking mifepristone, and sometimes even concurrently. Thus, for those patients whose doctors direct them to take misoprostol fewer than 24 hours after

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (503) 947-4791

mifepristone, the Patient Agreement Form is contrary to their doctor's advice and may lead to confusion. And, as I noted above, the Patient Agreement Form can also cause additional patient stress as the form causes some to worry that the medication is actually more dangerous than it is. The Patient Agreement Form can also make counseling more difficult, especially in circumstances requiring a translator.

28. When patients in early pregnancy contact OHSU for miscarriage or abortion care, OHSU staff schedules them for either an in-person or telehealth consultation with a provider in the department of Obstetrics and Gynecology. For my consultations, I begin each visit by reviewing the patient's medical history and symptoms to determine what types of abortions for which the patient is eligible. I then discuss with the patient the risks, benefits, and alternatives for each kind of abortion care for which they are eligible (informed consent). Lastly, I answer any questions they have so that they are able to make an informed decision.

29. Those procedures are consistent with the training and direction I have received from OHSU's Department of Obstetrics and Gynecology.

30. If those patients are eligible for, and choose, a medication abortion, we proceed with the visit for that care.

31. I discuss the medication abortion process and discuss the Patient Agreement Form with the patient. After the patient answers my questions, I ask

whether they consent to a medication abortion. If they do, I confirm that consent in their medical record and sign a paper consent form.

32. I then go over the instructions for how and when to take their medication, what the follow-up process is, what they should do if they experience any of the (very rare) serious complications associated with mifepristone or misoprostol, and I answer any additional questions they may have.

33. I am also required by the REMS to review and have the patient sign the Patient Agreement Form. The Patient Agreement Form is duplicative of the information contained in the FDA's Medication Guide, which is dispensed to the patient with the medication.

34. I also prescribe mifepristone (with misoprostol) to patients who are experiencing a miscarriage. Under the REMS, I am required to sign the same Patient Agreement Form as I am for patients receiving mifepristone for a medication abortion. That is confusing and often distressing for patients, because the form does not describe circumstances that apply to patients for miscarriage management.

35. I have had patients, who were already undergoing the traumatizing experience of a miscarriage, become deeply upset, confused, or distressed at having to sign a form about medication abortion.

36. I recently had a patient who was experiencing a miscarriage for a pregnancy that she very much wanted. I counseled her on the availability of mifepristone for miscarriage management. The patient was already dealing with the anguish of losing her pregnancy. Upon reviewing the Patient Agreement Form that she had to sign, the patient was emotionally distressed and deeply upset at the form's requirement that she attest that she was *deciding* to end her pregnancy that she had lost.

37. As with any other medical procedure, I discuss risks and benefits, explain the treatment, and obtain informed consent for the prescription of mifepristone for miscarriage management or medication abortion. The Patient Agreement Form is duplicative of that counseling.

38. In the consent-process alone, the additional paperwork and procedure required by the mifepristone REMS adds at least 2-3 minutes of required provider-time per patient. According to data collected by the Oregon Health Authority, 4,240 patients in 2021 obtained medication abortions. That amounts to approximately 140 to 210 provider hours spent in 2021 on a medically unjustified hurdle to mifepristone access—provider hours that could have been spent providing care to other patients. That does not account for the administrative costs in time and money to obtain certification and to register prescription-fulfillment relationships with mifepristone manufacturers.

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (503) 947-4791

39. With a conservative estimate about 30-minutes per patient visit, that is an additional 280 to 420 patients who could have been provided healthcare in 2021. That additional patient capacity would certainly have been appreciated, as healthcare demand across the state exceeds providers' availability. At OHSU's Department of Obstetrics and Gynecology alone, there is a six-month waiting period for new patients.

40. Attached as **Exhibit B** is a copy of the OHA data describing the 4,240 patients who obtained medication abortions in 2021. Notably, because those statistics are for only induced termination of pregnancies, they do not include cases of miscarriage management in which a non-viable pregnancy was diagnosed. Nor do they account for a significant portion of other circumstances in which a provider would need to review the mifepristone Patient Agreement Form with a patient. Thus, the above estimates almost certainly significantly underestimate the amount of provider time spent by Oregon providers on the REMS requirements in 2021.

41. The 2023 changes to the REMS requirements do not change the above time estimates, because they continue to require the same Patient Agreement Form.

42. To my knowledge, not one of my patients has experienced a fatal infection or death caused by mifepristone prescribed for miscarriage management or medication abortion. It is among the safest drugs I prescribe.

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (503) 947-4791

43. Based on my experience, professional judgment, and the best available medical science, mifepristone is significantly safer than, for example, acetaminophen and Viagra, neither of which have any REMS restrictions. Acetaminophen toxicity is the second most common cause of liver transplant worldwide and is responsible for 65,000 emergency department visits, 2,600 hospitalizations, and 500 deaths per year in the United States.[4] Reports to the FDA have shown that Viagra was associated with 522 deaths after 13 months on the market.[5] In comparison, mifepristone has been associated with 28 deaths out of 5.6 million medication abortion cases from September 2000 to June 2022.[6]

---

[4] Agrawal S, Khazaeni B. Acetaminophen Toxicity. [Updated 2022 Aug 1]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2022 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK441917/.

[5] Al Ibrahim AH, Ghallab KQ, Alhumaid FI, Almahfoudh HH, Almadan AJ, Al Eid MA, AlMishqab MH, Alsaffar MF, Aljamea JH. A Systematic Review of Sildenafil Mortality Through the Years. Cureus. 2022 Dec 4;14(12):e32179. doi: 10.7759/cureus.32179. PMID: 36474651; PMCID: PMC9719720.

[6] U.S. Food and Drug Administration. Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022. Available at: https://www.fda.gov/media/164331/download.

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (503) 947-4791

44. In sum, the REMS restrictions on mifepristone are not medically justified, they impose additional burdens and stresses on patients, and they reduce access to essential reproductive healthcare, especially for those living in rural areas or with limited access to healthcare services.

I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED on February 23, 2023.

Alyssa Colwill, MD, MCR
Alyssa Colwill, MD, MCR (Feb 23, 2023 15:44 PST)

Alyssa Colwill, M.D., M.C.R.

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (503) 947-4791

EXHIBIT A

CURRICULUM VITAE
OREGON HEALTH SCIENCE UNIVERSIT

NAME Alyssa Co elli Col ill **DATE**

I. PRESENT POSITION AND ADDRESS

Academic Rank	Assistant Professor
Department Di ision	Obstetrics and Gynecology
Professional Address	3181 SW Sam Jackson Park Road UHN 50 Portland, Oregon 97239
E Mail Address	colwill@ohsu.edu

II. EDUCATION

Undergraduate and Graduate Include ear Degree and Institution

September 2004 – May 2008	University of Minnesota – Twin Cities Major: Bachelor of Science in Nutritional Science; Minor: Biology, Music Summa Cum Laude, Dean's List, High Distinction

Postgraduate Include ear Degree and Institution

August 2008 – June 2012	Doctor of Medicine, M.D. Rosalind Franklin University of Medicine and Science – Chicago Medical School
June 2012 – June 2016	Internship & Residency Hospital of the University of Pennsylvania Obstetrics and Gynecology
March 2015	Clinical Elective Botswana UPenn Partnership Gaborone, Botswana, Africa
July 2016 – June 2018	Family Planning Fellowship Oregon Health & Science University
July 2016 – June 2018	Masters of Clinical Research, M.C.R. Oregon Health & Science University
September/November 2017, April 2018	Clinical Elective Kampot & Phnom Pehn, Cambodia, Asia

Certification Include Board Number Date and Recertification

American Board of Obstetrics and Gynecology - Board Certified 11/12/19 (Exp 12/31/23)
American Board of Obstetrics and Gynecology, Complex Family Planning Subspecialist – Board Certified 7/25/2022

Licenses Include State Date Status Number and Rene al Date
March 29th, 2016 State of Oregon, Active Status, MD176540. Up to date with all renewals
August 4th, 2022 State of Washington, Active Status, MD61311123. Up to date with all renewals.

III. PROFESSIONAL E PERIENCE

Academic Include ear Position and Institution

2016 – 2018 Instructor and Family Planning Fellow, Oregon Health & Science University
2016 – present Consultant Ob/Gyn for the Oregon Zoo
2018 – present Assistant Professor, Oregon Health & Science University
2021 – present Director of the Kenneth J. Ryan Residency Training Program
2022 – present Complex Family Planning Clinical Lead

IV. SCHOLARSHIP

Area s of Research Scholarly Interest Family Planning ith specific interests in analgesia for medical abortion immediate postpartum intrauterine de ice placement impro ing orkflo utili ing implementation science uality and safety non tubal ectopic pregnancies

Grants and Contracts
SFPRFSS20-18 (Colwill) 10/2020-9/2022
Society of Family Planning Research Fund 114,693.06
Salary Support Grant
Role: PI

SFPRF17-16 (Colwill) 2/2017-6/2018
Society of Family Planning Research Fund 91,020
Opioid Analgesia for Medical Abortion: A Randomized Controlled Trial
Role: PI

Foundation for Women & Girls with Blood Disorders (FWGBD) 2/2022 – exp 1/2023
Bleeding in Carriers of Hemophilia A: 35,000
The Role of von Willebrand Factor, Platelet Function and Endometrial Tissue Expression of FVIII
Role: Co-Investigator

Ob/Gyn Mission Support Award (Colwill) 7/1/2022 – present
OHSU Ob/Gyn Department 50,000
Oregon's Oasis: Creating a Visiting Residency Rotation for Ob/Gyn Residents Residing in Abortion Deserts
Role: PI

Publications Creati e Work

Peer-reviewed
Liberty, Abigail MD, MSPH; Samuelson Bannow, Bethany MD; Matteson, Kristen MD, MPH; Edelman, Alison MD, MPH; **Col ill Alyssa MD MCR**. Menstrual Technology Innovations and the Implications for Heavy Menstrual Bleeding. Obstetrics & Gynecology ():10.1097/AOG.0000000000005126, February 15, 2023. DOI: 10.1097/AOG.0000000000005126

Liberty A, Nacev E, Doshi U, **Col ill AC**. Medical management of hepatic ectopic pregnancy with systemic methotrexate, MRI and serial HCG monitoring. J Case Rep Images Obstet Gynecol 2023;9(1):1-6.

Han L, Alton K, **Col ill AC**, Jensen J, McCrimmon S, Darney B. Willingness to Use Cannabis for Gynecological Conditions: A National Survey. Journal of Women s Health, Vol. 30, No. 3, March 2021: 438-444.

Reid JA, Bayer LL, Edelman AB, **Col ill AC**. Controversies in family planning: Management of cesarean-scar ectopic pregnancy. Contraception. 2020 Dec 23:S0010-7824(20)30459-5. doi: 10.1016/j.contraception.2020.12.006. Epub ahead of print. PMID: 33359510.

Col ill AC, Alton K, Bednarek P, Bayer L, Jensen J, Garg B, Beardsworth K, Edelman A. Cannabinoids for Pain Control during Medical Abortion: A Randomized Controlled Trial. Obstet Gynecol. 135(6):1289-1295, June 2020.

Col ill AC Bayer L, Bednarek P, Garg B, Jensen J, Edelman A. Response to Letter. Obstet Gynecol. 135(6):1486, June 2020.

Col ill AC Bayer L, Bednarek P, Garg B, Jensen J, Edelman A. Opioid Analgesia for Medical Abortion: A Randomized Controlled Trial. Obstet Gynecol. 134(6):1163-1170, December 2019.

Alton, K, Han, L, McCrimmon, S, Darney, B, **Col ill AC**, Jensen, J. Patterns of and Attitudes Towards Cannabis Use in Women's Health. Obstet Gynecol. 133:172, May 2019.

Lee DD, **Col ill AC**, Teel J, Srinivas SK. Safe passage: Improving the transition of care between triage and labor and delivery. uality Management in Health Care. 2018 Oct/Dec; 27(4): 223-228.

Col ill AC, Schreiber CA, Sammel MD, Sonalkar S. Six-week Retention Rate of Immediate Post-placental Intrauterine Devices: A Retrospective Study of the Impact of Mode of Delivery. *ontraception*. 2018.

O Rourke K, Teel J, Nicholls E, Lee DD, **Col ill AC**, Srinivas SK. Improving Staff Communication and Transitions of Care between Obstetric Triage and Labor and Delivery. *stet necol Neonatal N rs* 2017.

Abstracts

Col ill A, Lee D, O'Rourke K, Romanos A, Teel J, Srinivas S. Improving handoffs between triage and labor and delivery at a university hospital: A pilot study. *BM al Saf* 24:736; 2015.

In ited Lectures Conference Presentations or Professorships

International and National

Six Week Retention of Intrauterine Devices Placed after Placental Delivery: A Retrospective Study. Poster Presentation at: American College of Obstetricians and Gynecologists Annual Meeting; May 16th, 2016; Washington, D.C.

Improving Handoffs Between Triage and Labor and Delivery at a University Hospital: A Pilot Study. Oral and Poster Presentation at: Institute for Healthcare Improvement; December 6-9th, 2015; Orlando, FL.

Opioid Analgesia for Medical Abortion: A Randomized Controlled Trial. PowerPoint Presentation at: Fellowship in Family Planning Annual Meeting; May 6th, 2017; San Diego, CA.

Is M&M Enough Using uality & Safety Strategies to Improve Patient-Centered Care. Powerpoint Presentation at the University of Hawaii; September 27th, 2017; Honolulu, HI.

Is M&M Enough Using uality & Safety Strategies to Improve Patient-Centered Care. Powerpoint Presentation at the Pacific Northwest Joint Family Planning Fellowship Symposium, University of British Columbia; February 2nd, 2018; Vancouver, British Columbia, Canada.

Laparoscopic Gravid Hysterectomy for Morbidly Adherent Placenta. Poster Presentation at American Society for Reproductive Medicine Scientific Congress and Expo, Virtual Congress; October 17th, 2020.

Mifepristone for Early Pregnancy Loss. Powerpoint Presentation for Vancouver Clinic Staff. March 3rd, 2021.

Dreaming of Wearing White Pants Workup and Management of Abnormal Uterine Bleeding. Lecture at Contraceptive Technology, Virtual Meeting; September 24th, 2021.

Abortion Access: Crucial for Reducing Disparities in Maternal Mortality. 2021 Oregon Perinatal Collaborative Virtual Summit; October 15th, 2021.

Management of Heavy Menstrual Bleeding with Hematologic Disorders. Pacific Northwest Conference, Virtual Meeting; October 21st, 2021.

Dream of Wearing White Pants Workup and Management of Heavy Menstrual Bleeding. Primary Care Review, Virtual Meeting; January, 2022.

Abortion Access: Crucial for Reducing Disparities in Maternal Mortality. Ob/Gyn Grand Rounds presentation at University of Washington. April 20th, 2022; Seattle, Washington.

Reproductive Healthcare Access: Crucial for Reducing Disparities in Maternal Mortality. Ob/Gyn Grand Rounds presentation at Creighton St Joseph's. May 13th, 2022; Phoenix, Arizona.

Allies for Equity Summit: Hunger and Reproductive Justice. Panelist. Hosted by the Oregon Food Bank. October 20th, 2022.

Comprehensive Reproductive Care in the Post-Roe Era. Pacific Northwest Update in Obstetrics & Gynecology. October 21st, 2022.

Abortion Access in a Post-Roe Environment. Oregon Perinatal Collaborative Summit, Virtual Meeting. October 28th, 2022.

Institutional

Second Trimester Abortion. Grand Rounds presentation at Oregon Health & Science University; September 29th, 2017; Portland, Oregon.

D&E Breakdown Barriers. Presentation to OR staff at Oregon Health & Science University; December 17, 2018; Portland, Oregon.

Abortion Access: Crucial for Reducing Disparities in Maternal Mortality. Family Medicine Grand Rounds presentation at Oregon Health & Science University. December 15th, 2021; Portland, Oregon.

OHSU Preparedness: The Impact of Upcoming Abortion Restrictions. Department of Medicine Grand Rounds at Oregon Health & Science University. June 21st, 2022; Portland, Oregon.

Reproductive Care in a Post-Roe Era. Department of Obstetrics & Gynecology Grand Rounds at Oregon Health & Science University. September 23rd, 2022; Portland, Oregon.

Abnormal Uterine Bleeding Evaluation and Treatment. Women's Health Hematology Consortium. Oregon Health & Science University. October 28th, 2022; Portland, Oregon.

Interviews:

What Americans Can Expect if Abortion Pills Become Their Only Safe Option. April 12th, 2022.
https://fivethirtyeight.com/features/what-americans-can-expect-if-abortion-pills-become-their-only-safe-option/

Changes to Abortion Laws Mean Ob-Gyns Have Less Opportunities to Learn Procedures. October 6th, 2022.

https://www.npr.org/2022/10/06/1127307423/changes-to-abortion-laws-mean-ob-gyns-have-less-opportunities-to-learn-procedure

OHSU Now: Visiting Resident to Receive Abortion Care Training. November 16th, 2022. https://news.ohsu.edu/2022/11/16/ohsu-welcomes-first-out-of-state-obgyn-resident-to-receive-training-in-abortion-care

KGW8 Visiting Resident for Abortion Training November 16th-17th, 2022 https://muckrack.com/broadcast/savedclips/view/l6J4wx1ira

OHSU Now: OHSU study finds significant gaps in menstrual research and clinical care. February 15th, 2023. https://news.ohsu.edu/2023/02/15/ohsu-study-finds-significant-gaps-in-menstrual-research-and-clinical-care

V. SERVICE

Membership in Professional Societies

2020 – present	FWGBD
2016 – present	Society of Family Planning
2012 – present	ACOG
2012 – 2016	Obstetrical Society of Philadelphia

Committees

Departmental

2022 – present	HASTE Reproductive Justice Committee Member
2020 – 2021	HASTE Ally Committee Member
2016 - present	OHSU Gynecology uality Education Committee Member
2021 – present	Chair of Clinical Competency for Complex Family Planning Fellowship

Institutional

2018 – present	School of Medicine Faculty Council Committee Member

Workshops

5/2021: Intersectional Allyship for Racial Justice: A Workshop for White Allies (Equity in the Center)

VI. TEACHING OHSU Educators Portfolio

Classroom Teaching

Nurse-Midwifery Curriculum
- "Contraception for Women with Chronic Medical Conditions" (November 2017)

Ob/Gyn Resident uality and Safety Curriculum
- "Using uality & Safety Strategies to Improve Patient-Centered Care" (September 2017)

Ob/Gyn Resident Curriculum
- "First Trimester Ultrasound" (August 2017, October 2017)

Third year medical student Ob/Gyn Clerkship curriculum
- "Contraception" (April 2017, July 2017, August 2017, December 2017, February 2018, March 2018, April 2018, May 2018)

Physician Assistant Curriculum
- "Ectopic and Other Early Pregnancy Risks" (April 2018)
- "Contraception" (April 2017)

Medical Students for Choice LARC Training

"LARC Insertion Training" (October 2016)

uality and Safety Review

"Gynecology Monthly Review and uality Improvement" (October 2015, June 2016)

"Obstetrics Monthly Review and uality Improvement" (December 2015)

"Gynecology Oncology Morbidity and Mortality Review" (January 2015)

Maternal Mortality

Botswana UPenn Partnership: Reviewing Maternal Morbidity (May 2015)

IUD Insertion Training (March 2014)

Methotrexate & Ovarian Reserve after Treatment of Ectopic Pregnancy (March 2014)

Pain Management with IUD Insertion (July 2013)

Nexplanon Trainer 2022- present

Curriculum De elopment

Emergency Department D&C Policy update (6/2020)
Family Planning Elective Medical Student Curriculum Development (6/2020)
Nontubal Ectopic Pregnancy Guidelines (2019)
Pregnancy of Unknown Location guidelines (2018)
Fetal Burial Guidelines (2017)

Honors and A ards for Education and Ser ice

Oregon Health Science Uni ersity

Institutional

2020 OHSU Continuing Professional Development Clinical Star Award
2018 Golden Rose Award

Departmental

2022 APGO Excellence in Medical Student Teaching Award
2021 Resident Research Award Mentor
2020 Gynecology Medical Student Educator Teaching Award
2018 OHSU Fellow Teaching Award

Hospital of the Uni ersity of Pennsyl ania

Departmental

2014 Sharon Youcha, M.D. Compassionate Patient Care Award
2013 Intern's Midwifery Award
2012 Dean's Award, Gold Humanism in Medicine Honor Society Member

Institutional

2016 Penn Pearls Teaching Award, Resident Teaching Award for Excellence in Resident Education

Rosalind Franklin Uni ersity Chicago Medical School

2011 Medical Students for Choice Reproductive Health Externship Scholarship
2010 Female Student Leadership Award

EXHIBIT B

Center for Health Statistics

Oregon Health Authority

Induced Termination of Pregnancy in Oregon, 2015-2021

1. **Select a topic and year** to display from the drop-down menus. **Hover** over any number or line **for more information**.
2. You can **select a category** to graph over time **by clicking on a header or number** in the table below.
   Hold Ctrl and click, or click and drag, to select more than one item. Click the item again to reset.

Select a topic: Method of termination by length of gestation

Select a year: 2021

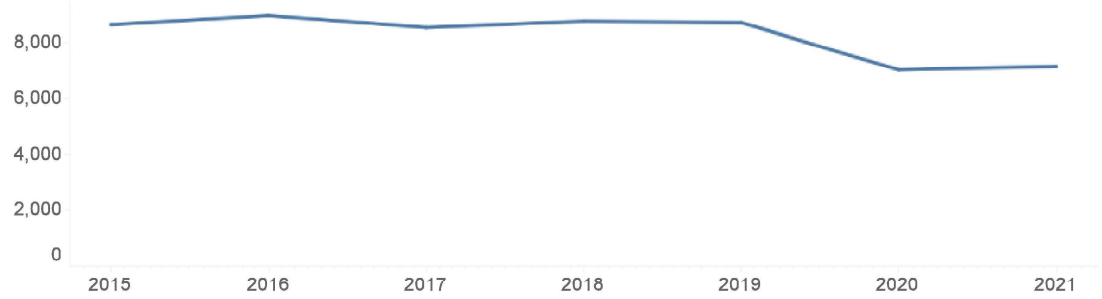
Total Oregon occurrence abortions in 2021: 7,109

Navigate to historical counts and rates dashboard

Method of termination by length of gestation, 2021 Oregon occurrence abortions

Graph now showing:

All methods
All gestations



		Total	<9 weeks	9-12 weeks	13-16 weeks	17-20 weeks	21-22 weeks	23+ weeks	Unknown
Total		**7,109**	**5,076**	**1,233**	**461**	**205**	**73**	**59**	**2**
Medical (non-surgical)	**Total**	**4,246**	**3,663**	**538**	**8**	**8**	**8**	**19**	**2**
	Medication	**4,240**	3,663	538	8	4	7	18	2
	Vaginal prostaglandin	**6**	–	–	–	4	1	1	–
Surgical	**Total**	**2,857**	**1,413**	**694**	**452**	**197**	**65**	**36**	**–**
	Suction curettage	**1,666**	1,032	475	158	1	–	–	–
	Dilation & evacuation	**920**	194	146	284	196	64	36	–
	Sharp curettage	**266**	183	72	10	–	1	–	–
	Hysterotomy/Hysterectomy	**5**	4	1	–	–	–	–	–
Other method	**Total**	**6**	–	**1**	**1**	–	–	**4**	–
	Other method	**6**	–	1	1	–	–	4	–

Notes:

A dash (–) means the quantity is zero.

Declaration of Dr. Alyssa Colwill - 2.23.23

Final Audit Report 2023-02-23

Created:	2023-02-23
By:	Jason Lohman (jason.lohman@doj.state.or.us)
Status:	Signed
Transaction ID:	CBJCHBCAABAAcUQ2IxtD8zG7g5JdEClQoQs9S-vHZjnz

"Declaration of Dr. Alyssa Colwill - 2.23.23" History

Document created by Jason Lohman (jason.lohman@doj.state.or.us)
2023-02-23 - 11:36:06 PM GMT

Document emailed to colwill@ohsu.edu for signature
2023-02-23 - 11:36:35 PM GMT

Email viewed by colwill@ohsu.edu
2023-02-23 - 11:37:30 PM GMT

Signer colwill@ohsu.edu entered name at signing as Alyssa Colwill, MD, MCR
2023-02-23 - 11:44:12 PM GMT

Document e-signed by Alyssa Colwill, MD, MCR (colwill@ohsu.edu)
Signature Date: 2023-02-23 - 11:44:14 PM GMT - Time Source: server

Agreement completed.
2023-02-23 - 11:44:14 PM GMT

Adobe Acrobat Sign

Exhibit 4

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF SUMONA DASGUPTA

I, Sumona DasGupta, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am the Director, Pharmacy Business & Strategic Development for the University of Washington (UW) Medical Center & Harborview Medical Center. I have held this position for a year. In this role, I oversee all business development in the pharmacy department across multiple hospitals including an academic medical center, level 1 trauma center, primary care network, and community hospital. This role oversees the 340B program,[1] expansion of pharmacy services through partnerships with stakeholders, and is focused on creating pharmacy programs that increase value to our patients. Prior to holding this position, I served as the Assistant Director for Pharmacy Audit and Compliance from 2013–2022. In that role, I oversaw all compliance functions in the pharmacy department, regulatory affairs including rule and legislation development and operational execution. Prior to joining UW Medicine, I served as the Compliance Officer for a public hospital district in King County, and as a

---

[1] Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients.

lawyer at K&L Gates in their healthcare practice with a focus on mergers and acquisitions. My credentials include a JD and a CHC (Certified in Healthcare Compliance), and I currently serve on the national board of 340B Health.

UW Pharmacies

3. UW Medicine currently has 11 outpatient pharmacies at its medical centers and clinics in Washington. In 2022, these pharmacies dispensed over 600,000 prescriptions. In addition, UW Medicine also has inpatient pharmacies at the University of Washington Center – Montlake and Northwest, and Harborview Medical Center. The inpatient pharmacies provide pharmacist clinical services and drugs to patients at UW Medicine.

4. UW Medicine also has a mail order pharmacy system that is a URAC-accredited specialty pharmacy,[2] the Eastside Specialty Mail Order Pharmacy (ESC mail order pharmacy). This mail order pharmacy only supports UW Medicine patients, and prescriptions written by UW Medicine providers.

The New Mifepristone REMS Requirement Requiring Certified Pharmacies

5. I am familiar with the FDA's Risk Evaluation and Mitigation Strategy (REMS) on dispensing mifepristone, which was last modified on January 3, 2023 (2023 REMS).

---

[2] URAC is the nation's largest independent healthcare accreditation organization and establishes quality standards for the entire healthcare industry.

6. Under the 2023 REMS, mifepristone may only be dispensed by or under the supervision of a certified provider or by a certified pharmacy. The 2023 REMS establishes an onerous certification process for pharmacies that choose to dispense mifepristone and imposes an array of requirements on certified pharmacies.

7. Certified pharmacies must designate an authorized representative to implement the certification process and ensure compliance and oversee the implementation with the 2023 REMS on behalf of the pharmacy.

8. The 2023 REMS imposes several obligations on certified pharmacies. For every mifepristone prescription it fills, a certified pharmacy must confirm that the prescriber is a certified prescriber by confirming that the requisite Prescriber Agreement Form is on file with the pharmacy or was received with the prescription. Failure by pharmacy staff to complete this verification could result in a citation against the pharmacy.

9. The 2023 REMS requires that the certified pharmacy can receive the Prescriber Agreement Forms by email and fax.

10. The 2023 REMS requires that mifepristone is delivered to the patient within 4 calendar days after the date the pharmacy receives the prescription. Complying with this deadline, requires the ESC mail order pharmacy to mail the prescription the next calendar day by 2pm to ensure it is

delivered in time. The pharmacy may be unable to meet this deadline if the Prescriber Agreement Form is delayed or not accompanied with the prescription.

11. If there is a delay beyond the 4 calendar days, the certified pharmacy must confirm with the prescriber the appropriateness of dispensing mifepristone, and document the prescriber's decision, which may delay the patient receiving the medication in a timely manner. Also, in the event of a drug shortage, this requirement could lead to significant delays. The requirement of delivery to the patient within 4 calendar days was not required in the prior REMS.

12. The 2023 REMS also requires pharmacies to record the National Drug Code (NDC) and lot number for each package of mifepristone dispensed. Information for the lot number is unique for each drug product and requires that the lot number be documented by an individual user in a free text field associated with dispensing the prescription. Without an IT system to automate this system, it makes compliance extremely difficult to guarantee.

13. Due to new restrictions under the 2023 REMS, we can no longer purchase mifepristone through our normal wholesalers. Consequently, the 2023 REMS has necessitated the execution of new contracts, new accounts, and new purchase orders through a new wholesaler for the certified pharmacy to access the drug.

14. Under the 2023 REMS, UW pharmacies are required to track and report patient deaths to the prescriber, who must then notify GenBioPro, Inc. as

required by the Prescriber Agreement Form. This is an unusual requirement—pharmacies do not typically have any role in ensuring that a prescriber notify a manufacturer about adverse events. Although deaths associated with mifepristone are extremely unlikely, the pharmacy has nonetheless had to develop a workflow to manage cases where it is notified of an associated death of a patient.

15. To date, my team has spent approximately 80 to 100 hours working on the implementation of the 2023 REMS. Implementation tasks have included developing new IT systems for dispensing mifepristone in compliance with the REMS, creating systems to manage the prescribing of mifepristone, creating electronic storage of Prescriber Agreement forms, training all pharmacy staff, designing a patient package, identifying new distribution channels from which to purchase the drug, and creating billing workflows specifically for insurance carriers that do not cover mifepristone.

16. Building out the infrastructure to implement the 2023 REMS has been very burdensome. We have had to create an entirely separate process for dispensing mifepristone. Without our sophisticated IT teams, I do not know how we would have managed implementation of these requirements. For smaller independent pharmacies or community hospitals with less sophisticated IT systems, the operational hurdles associated with the amended 2023 REMS may present insurmountable barriers to dispensing mifepristone.

17. In addition to the work that has already been done to implement the 2023 REMS, workgroups are still engaging in development, training and implementation. Additional pharmacy personnel involved in procuring, counseling, dispensing, handling mail orders, and auditing will all require training.

18. Implementing the 2023 REMS has been very costly for UW. Workgroup members have devoted long hours to implementation work.

19. The 2023 REMS also imposes additional audits on certified pharmacies, including one within six months of the first purchase of mifepristone and annually thereafter. All certified pharmacies are required to comply with audits carried out by the Mifepristone Sponsors or a third party acting on behalf of the Mifepristone Sponsors to ensure that all processes and procedures are in place and are being followed. A negative audit result can have a serious impact on a pharmacy and compromise its ability to continue dispensing mifepristone. These additional compliance requirements may also discourage smaller pharmacies from participating in the REMS program which means that patients will have fewer options to obtain mifepristone compared to other drugs.

20. I spoke with GenBioPro in December 2022 about the anticipated burdens the 2023 REMS would create. I shared UW's concerns about the Prescriber Agreement Forms and Certified Pharmacy Agreements and noted the potential for delays to patients resulting from the REMS. We also noted our

concerns around auditing and explained that it would be difficult to ensure that all the requirements were met before dispensing the drug.

21. The 2023 REMS for mifepristone are different from other REMS that I have encountered. Typically, REMS are issued for a specific drug, rather than for a specific medical condition. Although we have seen some REMS that only apply to women, due to potential harms to a fetus, most REMS apply whenever a drug is dispensed. In contrast, the 2023 REMS for mifepristone is only applicable, based on the REMS materials, where the 200-milligram drug is being used for purposes of a medication abortion.

22. Mifepristone at 200 mg. is also used in UW clinics off-label as part of standard practice protocols for miscarriage management. The REMS materials, including the required agreements, refer only to the use of mifepristone for the purpose of terminating an intrauterine pregnancy, which can cause confusion when mifepristone is used for miscarriage management. The FDA has not indicated that it will exercise discretion enforcement under the REMS for use of mifepristone for miscarriage management. Consequently, providers need to review with their patients who have suffered a miscarriage a Patient Agreement Form stating that they have "decided to end a pregnancy." Without clarity for when the REMS do and does not apply to the certified pharmacy, it will be difficult to ensure REMS compliance.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 21 day of February, 2023, at Seattle, Washington.

Sumona DasGupta

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Exhibit 5

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF PAUL DILLON IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

I, Paul Dillon, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am the Vice President for Public Affairs of Planned Parenthood of Greater Washington and Northern Idaho (PPGWNI). I have worked for PPGWNI since 2015, and have been in my current role since 2018.

3. In my role as Vice President of Public Affairs for PPGWNI, I am responsible for managing outreach in support of PPGWNI's mission to providing exceptional health care services, honest education and fearless advocacy. I represent PPGWNI in the communities we serve and within the affiliate as an executive leader.

A. Access to Abortion in Washington

4. PPGWNI operates 11 clinics throughout central and eastern Washington, with locations in Spokane, Spokane Valley, Pullman, Walla Walla, Moses Lake, Sunnyside, Pasco, Kennewick, Wenatchee, Yakima, and Ellensburg. Each clinic offers medication abortions. Procedural abortions are only available at our clinics in Spokane, Kennewick, and Yakima.

5. Washington has a strong legacy of protecting abortion rights. But rights aren't rights without access. In central and eastern Washington access to abortion is quite limited.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

6. Of the 20 central and eastern Washington counties within PPGWNI's territory, only nine have abortion providers to my knowledge.[1] Because a majority of counties do not have abortion providers, and because those that do have only very few abortion providers, many pregnant people in central and eastern Washington have to travel a long way for medical care. For example, if someone lives in Republic, Washington, their nearest clinic providing abortion care is PPGWNI's clinic in Spokane, approximately three to three-and-a-half hours away.

7. PPGWNI's clinics are all located in medically underserved communities. PPGWNI sees a high percentage of patients on Medicaid. In central Washington in particular, PPGWNI serves a large population of monolingual Spanish-speakers, many of whom are migrant farmworkers. Access to abortion care is still very limited for these and other populations PPGWNI serves.

B. The Impacts of *Dobbs*

8. The Supreme Court's *Dobbs* decision overturning *Roe v. Wade* has created significant barriers for PPGWNI's efforts to provide abortion care, even as abortion remains legal in Washington.

---

[1]The 11 central and eastern Washington counties without abortion providers to my knowledge are: Klickitat, Okanogan, Douglas, Ferry, Stevens, Pend Oreille, Adams, Lincoln, Columbia, Garfield, and Asotin Counties.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

9. With three of our clinics (Spokane, Spokane Valley, and Pullman) so close to the border, PPGWNI has long seen patients from Idaho. But since *Dobbs*, we have seen a significant increase in out-of-state patients.

10. In January 2023, PPGWNI saw an increase of 25% in total abortion patient visits compared to January 2022. We saw a 75% increase in Idaho patients from January 2023 compared to January 2022. This includes a 36% increase for procedural abortion patient visits and 90% increase for medication abortion visits from Idaho.

11. Our clinics in Pullman and Kennewick saw the biggest changes. In our Pullman clinic, we now have an outright majority of patients—53% in 2022 and likely higher in 2023—coming from Idaho. This is up from 39% in 2021.

12. Further, with the closure of PPGWNI's Boise clinic, we have started to see an influx of out-of-state patients at our Kennewick and Walla Walla clinics. These clinics have not historically treated many out-of-state patients, but they are now the closest clinics for many people in southern Idaho.

13. Since *Dobbs*, We have also started to see patients come from as far away as Texas and Florida.

14. This increase in patient volume has led to longer wait times to see providers in PPGWNI's clinics including up to three weeks for smaller sites like Wenatchee and Walla Walla. These longer wait times can have serious repercussions because abortion is a time-sensitive service. In many cases, a

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

three-week wait may put someone past the point where a medication abortion is possible.

C. The Importance of Mifepristone

15. As I noted above, all of PPGWNI's clinics provide medication abortions using mifepristone. Mifepristone is a very important medicine for PPGWNI's patients and providers.

16. Lack of access to mifepristone has negative consequences for patients seeking abortion as well as providers.

17. When patients are not able to access mifepristone, their options are misoprostol-only abortions or procedural abortions.

18. Based on many conversations with PPGWNI providers, I am aware that misoprostol-only medication abortions lead to more severe side-effects like bleeding, cramping, flu-like symptoms, and nausea. Moreover, misoprostol-only abortions typically require more doses of misoprostol over a longer period of time, and thus take longer to complete than mifepristone/misoprostol abortions. This means that a patient undergoing a misoprostol-only abortion is likely to spend additional days in discomfort and cramping until their abortion is complete.

19. Procedural abortion is the other option for patients who do not have access to mifepristone. For patients who, for whatever reason, are unable to obtain mifepristone within the first 10 weeks of pregnancy, procedural abortion

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

may be their only option. While procedural abortion is extremely safe and effective, it has several disadvantages compared to medication abortions.

20. Unlike mifepristone, which is available at each of PPGWNI's 11 clinics, including via telehealth appointments, and can be mailed to patients in Washington, PPGWNI can only provide procedural abortions at three of its locations. Consequently, patients who need procedural abortions, but live far away from PPGWNI's clinics that provide it, may face significant travel barriers. And due to the lesser availability, patients requiring procedural abortions generally face longer wait times for appointments, which can lead to significant stress and other complications.

21. Procedural abortion is also considerably more expensive—both for PPGWNI and patients. Medication abortion costs $700. For procedural care, if gestation is 19 weeks to 21 weeks, the cost can range between $1,450–$1,850. Beyond the cost of the procedure itself, patients undergoing procedural abortions often have to pay for things like travel and lodging, neither of which is necessary for a patient who simply receives mifepristone in the mail.

22. Furthermore, medication abortions are simply preferable to many patients. A patient undergoing a procedural abortion must come into the clinic, undergo a medical procedure, spend time in the recovery room, etc. By contrast, a patient undergoing a medication abortion can be in the comfort and safety of

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

home, in a supportive environment, with Netflix and a heating pad, if they so choose.

D. The 2023 Mifepristone REMS

23. While we were grateful for the removal of the in-person requirement with the FDA's recent updates to REMS for mifepristone, it still created an unnecessary pharmacy certification requirement that it does not impose for other, equally or less safe, medications. This creates additional barriers to access for patients who are travelling to our health centers from out of state and need time-sensitive care. Unfortunately, the updated REMS also retains longstanding requirements that providers be specially certified in order to prescribe mifepristone and that patients sign a special form in order to receive their prescription, a challenge at a time of provider shortages throughout central and eastern Washington. Permanently removing the REMS in its entirety is critical to reducing the disproportionate harms of abortion restrictions.

E. Threats to Abortion Providers

24. Abortion remains highly stigmatized throughout much of the area PPGWNI serves. PPGWNI clinics—including our providers and patients—have been subject to violence and harassment.

25. In 1996, PPGWNI's Spokane Valley clinic was bombed by anti-abortion extremists. In 2015, an arsonist set fire to PPGWNI's clinic in

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Pullman. In 2020, PPGWNI's Spokane clinic received a bomb threat. In 2021, PPGWNI's Spokane Valley clinic had its windows smashed.

26. PPGWNI providers and patients are also subject to routine harassment and intimidation from anti-abortion activists at our clinics. Recently, protestors associated with the "Church at Planned Parenthood" have gathered at PPGWNI clinics in an effort to disrupt clinic operations. These protesters have yelled at and verbally harassed patients, and have frequently interfered with clinic operations, including by blocking driveways and sidewalks. One group member in Yakima followed a PPGWNI provider to their home.

27. In 2021, a judge on the Spokane County Superior Court concluded that the group violated a Washington law prohibiting interference with health facilities and permanently enjoined the group from interfering with PPGWNI's clinic operations. Earlier this year the Court ordered the group to pay $110,000 in damages to PPGWNI, as well as attorneys' fees. Even so, the group has continued its protests and communicated to us that they intend to come back even harder.

28. This is part of a pattern since *Dobbs*, in which PPGWNI has seen protests intensify. According to our security data, protest activity post-*Dobbs* is 50% higher than it was in 2021.

29. We have also seen these efforts to disrupt our operations spread to clinics where they did not previously occur. For example, we did not normally

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

have protests at our Wenatchee clinic, but since *Dobbs*, we have seen regular protests there.

30. In addition to the harassment and violence, PPGWNI routinely faces cybersecurity threats from hackers trying to obtain information about patients and providers. Most commonly, we receive phishing emails that seek to obtain patient records and provider addresses. Because of the heightened risk of cybersecurity attacks, every PPGWNI staff member has to undergo annual IT security training.

31. Due to these various threats to PPGWNI's clinics, providers, and patients, we have had to devote considerable resources to security and patient privacy.

32. All PPGWNI clinics have security cameras and employ security guards to be on-site whenever the clinics are open. Clinics have locking vestibules known as "man traps" to ensure unauthorized people cannot enter the clinics. The clinics are also now equipped with bulletproof glass, following the incident in Spokane Valley in which the clinic's windows were smashed.

33. PPGWNI also maintains rigorous standards around patient privacy. We prohibit filming or recording equipment on site, maintain secure waiting areas and a rigorous check-in process, require providers to badge in and escort patients, etc. Nonetheless, we still face issues with protesters trying to film patients and providers, record license plates, and otherwise harass patients and providers.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 17th day of February 2023, at Spokane, Washington.

Paul Dillon

PAUL DILLON
Vice President of Public Affairs
Planned Parenthood of Greater
Washington and Northern Idaho

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Exhibit 6

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF DONALD DOWNING R PH.

I, Donald Downing R. PH, declare as follows:

1. I am a Clinical Professor at the University of Washington School of Pharmacy. I am a licensed pharmacist in the State of Washington, License number, PH00009898. I make this declaration based on my personal knowledge, my training, and experience as a licensed pharmacist. All opinions expressed herein are to a reasonable degree of medical certainty more probably than not true.

2. I am familiar with the practice of pharmacy in the State of Washington because of my position as a licensed pharmacist in this state since 1975 and for my education and training. I owned and operated two community pharmacies for thirteen years providing post-surgical care, home infusion services, and other clinical services. I also collaborated to start up several Washington State tribal health care clinics. I provided care at those clinics for years and I continue consult with tribes on health care issues.

3. I currently practice as a Clinical Professor at the University of Washington School of Pharmacy and serve as the co-director of its Community and Global Health Engagement Program. Since 1996, I have taught classes at the University of Washington School of Pharmacy to pharmacy students on many aspects of pharmacy, including pharmacy practice, law and ethics, reproductive health, and more. I have worked separately as a pharmacy consultant, assisting a number of pharmacies in many areas of pharmacy management. All of my work

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

has enabled me to obtain an expertise in the regulatory and practical environment affecting pharmacists filling prescriptions in the State of Washington.

4. Pharmacy practice and management related to reproductive care is my specific specialty. I have provided over 400 sexual and reproductive health related talks and certificate trainings and have worked to enable pharmacists to be active participants in sexual and reproductive health care service. In 2014, the American Society for Emergency Contraception and the International Consortium for Emergency Contraception presented me with the Felicia Stewart Award for lifetime achievement in efforts to increase access to emergency contraception. In 2020, I was awarded the Bowl of Hygeia for these and other community service endeavors.

5. I currently am working on developing models of care for contraception and emergency contraception. I am also involved at the design stage of research to study strategies to reduce barriers to pharmacy participation in the prescription and dispensing of mediation abortion. This latter study is in its initial stage of proposal and methods-development, though initial reception to the proposal indicates that it will receive broad-based funding support.

6. I am familiar with the amended Risk Evaluation and Mitigation Strategy (REMS) on dispensing mifepristone, which took effect on January 3, 2023.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

7. I am aware that under the January 2023 REMS only a certified pharmacy may dispense mifepristone.

8. To become a certified pharmacy, a pharmacy must agree to comply with a number of strict requirements for dispensing mifepristone. Pharmacies are, among other things, required to:

a. verify that the prescription it receives was written by a specially certified provider by confirming their completed Prescriber Agreement Form was received with the prescription or is on file with the pharmacy,

b. ensure delivery of the medication within four calendar days of receiving the prescription or comply with the additional requirement of confirming with the prescribing provider the appropriateness of prescribing the drug after four days,

c. designate an authorized representative to carry out the certification process, training of their staff, oversight, and implementation,

d. comply with various recordkeeping requirements, and

e. comply with audits.

9. As the co-Director of the University of Washington's School of Pharmacy Community and Global Health Engagement Program, I maintain routine contact with pharmacies in the State of Washington. I have spoken to a

number of pharmacists in the State of Washington who would like to dispense mifepristone at their pharmacies but who are hesitant to do so because of the increased burden of becoming and operating as a certified pharmacy under the amended REMS. The REMS create additional administrative requirements beyond what is required for the vast majority of prescription drugs.

10. For a number of years, the community pharmacy industry nationwide has suffered from staff shortages primarily due to pharmacy benefit management organizations who have severely undermined the financial sustainability of large and small pharmacies alike. Staffing shortages and below-cost prescription compensation have caused many pharmacies to operate at an administrative deficit when they are filling prescriptions for an increasing number of drugs. As a result, each year the number of pharmacies operating in Washington State has been decreasing. The mifepristone REMS require pharmacies to take on extraordinary administrative tasks such as verifying that the provider is specially certified, providing additional training, and increased recordkeeping at a time when they are already under-staffed. The REMS will increase pharmacy workloads, as pharmacies will also be required to troubleshoot situations that arise in real time. For example, a patient could come to the pharmacy with a prescription but without having the required provider form. If the provider was not one that the pharmacy had not previously verified, then the pharmacy would need to take the additional step of verifying the provider and

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

obtaining their mifepristone provider agreement form before the pharmacy could fill the prescription. Without adequate staff to take on this additional task, the pharmacy will need to delay dispensing this time sensitive medication. Because the timeframe for medication abortion is time-limited, and because the REMS require the pharmacy to fill the prescription within four calendar days, the administrative burden is an urgent one.

11. Small chain and family-owned pharmacies are the most heavily impacted by the January 2023 REMS. These pharmacies most often serve rural communities and lower populated areas. These smaller pharmacies are often ill equipped to meet the additional burden that the REMS create, because they are not large enough to absorb the extra staffing, training, administrative, and recordkeeping burdens of the REMS—all of which the pharmacy must undertake without compensation.

12. Less mifepristone availability at pharmacies because of the REMS will inevitably increase the likelihood that patients who live in rural and lower populated areas will need to travel long distances to find a certified pharmacy who carries mifepristone.

13. Compliance with the REMS will also pose increased exposure to potential legal liability for pharmacies and pharmacists. The REMS, in effect, require the pharmacies to police the enforcement of their terms by requiring the pharmacies to be the ones to ensure that the prescription that they have in front

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

of them meets the various requirements of the REMS. The REMS do this by requiring pharmacies to verify the prescriber's certification in the mifepristone REMS program. In addition, with the increasing number of states across the United States that have banned distribution of mifepristone, pharmacy administrators must also factor into their operating costs the potential of having to face legal action initiated because of potential violation—or alleged violation—of out-of-state laws.

14. For most pharmacies in Washington, mifepristone will account for a very small part of their overall business, yet will account for a much larger part of their overall workload, giving these pharmacies very little return for their work. Because REMS require pharmacies to spend additional time with patients, additional time checking with prescribing providers, additional time with recordkeeping and compliance, as well as increase potential legal liabilities, pharmacies (and especially business leaders making decisions on behalf of pharmacies) are hesitant to invest in providing a service that is subject to such extensive, and unusual, regulation. The cost-benefit analysis will cause many pharmacies to conclude that dispensing this drug is not worth the increased burden, thereby decreasing availability of the drug in Washington State.

15. If the FDA had not placed these REMS on mifepristone, pharmacies in Washington State could dispense mifepristone in the same manner in which it

dispenses other drugs and many more pharmacies would likely choose to dispense mifepristone.

16. REMS are usually imposed on drugs that require more than the usual safeguards because of potential harm that the drug can cause. The imposition of the REMS on mifepristone does not fit this usual rule. There are numerous studies that confirm both the safety and the efficacy of mifepristone. Indeed, the restrictions placed on mifepristone by the FDA can actually increase risk to patients who would otherwise be able to quickly and safely terminate their pregnancies and are now faced with additional delay and lack of availability.

17. In my nearly fifty years as a pharmacist, pharmacy owner, professor, and reproductive-health specialist, I have routinely found that pharmacists in Washington State go to great lengths to provide high-quality reproductive medications to their patients. Nonetheless, the January 2023 mifepristone REMS present a series of burdens for pharmacies that are stigmatizing, administratively burdensome, confusing, expensive, and legally risky. The REMS will cause Washington pharmacies to opt out of dispensing mifepristone when they otherwise would dispense it if the drug did not carry a REMS. The decision not to become specially certified to dispense mifepristone will be made more often by smaller pharmacies, which are themselves more likely to serve rural, minority, or poor communities.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 20th day of February, 2023, at Seattle, Washington.

Donald Downing R. PH

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Exhibit 7

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF DR. CHARISSA FOTINOS

I, Charissa Fotinos, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am the Medicaid Director of the Washington State Health Care Authority (HCA). HCA is the designated single state agency responsible for administering Washington's Medicaid program, known as Apple Health.

3. In this position I have primary responsibility for ensuring HCA offers high-quality, cost-effective care to Apple Health clients while adhering to federal Medicaid requirements.

4. The HCA operates Apple Health, Washington State's Medicaid program. Apple Health provides free or low-cost health care for income-qualified individuals. Pregnant individuals at or below 193 percent of the Federal Poverty Level are eligible for Apple Health.

5. The HCA also oversees the School Employee Benefits Board (SEBB) and the Public Employees Benefits Board (PEBB) which develop benefit plans, including health care coverage, for eligible public and school employees, retirees, and dependents.

6. Medication abortion is a common method for pregnant people in Washington to terminate a pregnancy within the first ten weeks of pregnancy. I am aware that, since 2000, the U.S. Food and Drug Administration has approved

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

a protocol for the medical termination of a pregnancy that involves taking mifepristone, followed by misoprostol.

7. Washington State funds medication abortions for Apple Health clients in need of that health care.

8. Based on available data, between state fiscal years 2015 and 2022, Washington State has seen an average 10% year-over-year increase in the number of patients seeking medication abortion care through Apple Health.

9. Based on available data, between state fiscal years 2017 and 2022, Washington State has seen an average 8% year-over-year increase in the number of patients seeking medication abortion care through the PEBB program.

10. Any limits on the availability of medication abortion in Washington State is highly likely to cause an increase in the number of surgical abortions for persons insured by Apple Health, SEBB, and PEBB. The corresponding increase in costs resulting from the more-expensive surgical procedure would be borne by Washington State. I anticipate these increased rates of surgical abortion due to the fact that misoprostol alone is not as effective in terminating a pregnancy as the two medications combined. With fewer completed abortions from misoprostol alone, there would be an expected increase in the number of surgical abortions.

11. Additional factors that could lead to an increase in costs for Apple Health, SEBB, and PEBB would be due to an increase in the number of visits for

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

abortion related complications. The risk of excessive bleeding is higher after an abortion with misoprostol alone compared to the combination treatment. This could result in an increase in the number of office visits, emergency department visits and the need for additional interventions to treat excessive bleeding.

12. Additional costs could occur if misoprostol alone did not result in the termination of the pregnancy and the decision was made to continue the pregnancy. Misoprostol use early in pregnancy has been associated with an increased risk of facial and limb birth defects that increase the costs of care for the infant. Additionally, all these circumstances are likely to increase the amount of anxiety, stress and disruption experienced by the birth parents and any later caregivers. While specific costs are hard to quantify, an increase in visits and treatment for behavioral health conditions is likely.

13. I am aware that the same two-drug protocol described above for use in medication abortion is also used to treat people experiencing pregnancy loss (commonly referred to as miscarriage). Mifepristone, followed by misoprostol, has been shown to be safe and effective in the management of missed miscarriage in early pregnancy.

14. Any limits on the availability of mifepristone to treat missed miscarriage in Washington State is highly likely to cause an increase in the number of surgical interventions for persons insured by Apple Health, SEBB, and PEBB. The corresponding increase in costs resulting from the more-expensive

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

surgical procedure would be borne by Washington State. I anticipate these increased rates of surgical intervention due to the fact that misoprostol alone is not as effective in treating miscarriage as the two medications combined. With fewer successful treatments from misoprostol alone, there would be an expected increase in the number of surgical procedures needed to treat pregnancy loss.

15. Additional factors that could lead to an increase in costs for Apple Health, SEBB, and PEBB would be due to an increase in the number of visits for missed miscarriage-related complications. As with the abortion context, use of misoprostol alone to treat miscarriage could result in an increase in the number of office visits, emergency department visits and the need for additional interventions to treat excessive bleeding.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 21st day of February, 2023, at Olympia, WA.

Charissa Fotinos MD, MSc

Dr. Charissa Fotinos
Medicaid Director

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Exhibit 8

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF EMILY M. GODFREY, M.D., M.P.H.

I, Emily Godfrey, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am an Associate Professor with tenure in the Department of Family Medicine and in the Department of Obstetrics and Gynecology Division of Family Planning at the University of Washington (UW). I am board-certified in Family Medicine and have been practicing medicine since 2000. I completed a fellowship in Complex Family Planning and a Master of Public Health degree at the University of Rochester in 2003.

3. I am licensed to practice medicine in the state of Washington. Previously, I was licensed to practice in the states of Illinois and New York.

4. I obtained my undergraduate degree at the University of Wisconsin with a B.S. in English Literature. I received my medical degree from the Medical College of Wisconsin and completed my residency in family medicine at West Suburban Hospital in Oak Park, Illinois. My CV is attached as Exhibit A.

5. Throughout my 20+ year career in medicine, my research has been primarily focused on contraception and abortion care in primary care. I have received over $4 million in federal funds, non-profit foundation and industry grants to support my research. I have published over 50 peer-reviewed articles in medical and public health journals. Additionally, I have published 32 other publications, including national and international guidelines, book chapters,

editorials, curricula, videos and research tools, including a video featured by UW Medicine about medication abortion.[1]

6. I founded the University of Washington's Access, Delivered initiative, which consists of a provider toolkit that offers a step-by-step guideline for initiating telehealth medication abortion service within primary care practices.[2] The Access, Delivered provider toolkit has been downloaded by over 2,000 providers and healthcare organizations interested in innovating their own services.

7. I currently run the UW Department of Family Medicine Women's Health Research and Scholarship Lab where we mentor undergraduate, medical, public and family medicine students and residents on topics related to contraception and abortion. I have received several awards for research mentoring over the course of my career.

My Practice

8. I have been at UW since 2012, where I practice full-spectrum family medicine and conduct research related to women's health. I see patients at a UW

---

[1] UW Medicine, *Here's How Abortion Pills Work – and Why We Need Them* (Aug. 17, 2022) available at https://rightasrain.uwmedicine.org/well/health/medication-abortion.

[2] UW Medicine, *Access, Delivered* available at https://familymedicine.uw.edu/accessdelivered/.

Medicine primary care clinic where I provide preventive care and treat acute and chronic health needs in infants, children, adolescents and adults. At this clinic, I also provide maternity care and women's health office-based procedures, including uterine ultrasound, contraceptive device insertions and removals, and first-trimester uterine aspiration. I teach and supervise general primary care, obstetrical care and reproductive health procedures to medical students, residents and fellows in family medicine. A routine and active part of my practice is treating patients seeking medication abortion. I prescribe mifepristone for abortion care approximately 2-3 times a month and am fully familiar with the FDA's risk evaluation and mitigation strategy (REMS) on dispensing mifepristone. I have safely prescribed mifepristone since it was first FDA approved in January 2000. During these two decades, I have counseled and prescribed mifepristone to at least one thousand patients in various clinical settings, including high-volume family planning and primary care clinics in New York, Illinois and Washington.

9. Over the course of my career, I have taught and supervised hundreds of residents, fellows and attending physicians on medication abortion assessment and prescribing in obstetrics/gynecology, internal medicine and family medicine.

10. When a patient comes to the clinic seeking medication abortion, we will generally begin the visit by reviewing the patient's medical history and symptoms. If they are eligible for medication abortion, I will discuss the risks

and benefits and answer any questions they may have. As a doctor of Family Medicine, my duty is to ensure they receive and understand the information they need to then make an informed decision about their care.

11. If they decide to have a medication abortion, I explain both of the medications to them: mifepristone and misoprostol. I explain how the medications work and how they should take them. I also discuss the potential side effects and what they should expect to happen. I also explain what the patient should do if they start to experience any significant side effects, and then answer any questions the patient has. Finally, I will ask the patient if they consent to the abortion and if they do, at that time I will record their consent in their medical chart. Because it is required by the REMS, I will also have the patient review and sign the Patient Agreement Form in front of me. I will then dispense the medication by hand to the patient along with the Mifeprex Medication Guide. I generally encourage patients to follow up with me in one week and give them the clinic pager number where they can call and get immediate assistance with any urgent medication questions.

12. In order to remain compliant, I have patients review and sign the Patient Agreement Form as required by the FDA REMS. However, after counseling the patient myself and recording their verbal consent in the medical chart, I do not believe the Patient Agreement Form provides any benefit at all to the patient. If anything, this formal and redundant step harms the patient

experience. An overemphasis on reviewing disclosure materials can make mifepristone sound like a scary and unsafe pill. But this is far from the truth. In fact, mifepristone is incredibly safe. It is probably one of the safest pills that people can be prescribed to take because it is highly targeted. Unlike chemotherapy or antibiotics, which can cause adverse effects while they are working to help patients, mifepristone works to inhibit just glucocorticoid and progesterone receptors and is in the blood system for less than 24-hours. Additionally, unlike other drugs I routinely prescribe to patients, such as oxycodone for chronic pain or amphetamine-dextroamphetamine for attention-deficit/hyperactivity disorder, mifepristone is not addictive and is taken only as a single dose. Aside from being incredibly safe, mifepristone is also very effective.

13. It is vitally important to note that mifepristone is a much needed medication not only for people who are seeking pregnancy termination, but also for people who are seeking to use medications for miscarriage management. Evidence demonstrates that treatment for miscarriage with mifepristone and misoprostol is better than treatment for miscarriage with misoprostol alone.[3] I prescribe mifepristone for miscarriage care to approximately one patient a month.

---

[3] Schreiber, C. A., Creinin, M. D., Atrio, J., Sonalkar, S., Ratcliffe, S. J., & Barnhart, K. T., *Mifepristone pretreatment for the medical management of early pregnancy loss*, New England Journal of Medicine*, 378(23), 2161-2170* (2018).

14. The counseling I conduct around mifepristone for miscarriage management is very similar to the counseling for medication abortion. Per the mifepristone distributor, my patients experiencing a miscarriage also have to sign the FDA's Patient Agreement Form in front of me. I have had miscarriage patients who have been very reluctant to sign the Patient Agreement Form because it is not targeted at their care and they do not want to sign a form meant for abortion provision. Some find it confusing and others are upset by it. In those instances, the Patient Agreement Form makes patient counseling much harder. Removing the REMS program from mifepristone would allow me to provide better care for my patients who need mifepristone for miscarriage management.

The REMS Discourage Family Medicine Doctors from Prescribing Mifepristone

15. Family medicine doctors have the highest number of office visits of any medical specialty in the U.S., with more than 200 million annually and serve as key access points for almost 70% of patients in the United States. All but 6% of U.S. counties have family physicians, and historically, family medicine doctors have provided a disproportionately greater share of obstetrical care in rural areas compared to obstetricians or midwives.[4] They are often the only

---

[4] Patterson, DG, Andrilla, CHA, Garberson, LA, *The Supply and Rural-Urban Distribution of the Obstetrical Care Workforce in the U.S*, Policy Brief #168, Seattle, WA, WWAMI Rural Health Research Center, University of

source of care, reproductive or otherwise, for adolescents and for patients in underserved and rural areas.[5] During these visits, family physicians deliver a broad range of acute, chronic, and preventive medical services for patients across all ages and genders, including gynecological, obstetrical, and other reproductive health services. Family medicine doctors value continuity of care throughout the patient's life.

16. Because continuity of care is the crux of family medicine, all family physicians are required to obtain prenatal and obstetrical skills during their residency training. Carrying a pregnancy to childbirth is 30 times more dangerous for the pregnant person than having an abortion, which is why first trimester abortion care, especially with the use of medications, is within the scope of

---

Washington (June 2020); Larson, EH, Andrilla, CHA, Garberson, LA, *Supply and Distribution of the Primary Care Workforce in Rural America*, Policy Brief #167, Seattle, WA, WWAMI Rural Health Research Center, University of Washington (June 2020).

[5] *The Distribution of the U.S. Primary Care Workforce, Primary Care Workforce Facts and Stats, No. 3*, Agency for Healthcare Research and Quality, *available at* https://www.ahrq.gov/research/findings/factsheets/primary/pcwork3/index.html (last accessed Feb. 21, 2023).

practice for family medicine doctors.[6] The Accreditation Council for Graduate Medical Education requires that family medicine residents have 100 hours or 125 patient encounters in gynecological care, which should include family planning, miscarriage management, contraceptive services and options counseling for unplanned pregnancy. The American Academy of Family Physicians (AAFP) has more specific, competency-based guidelines, which include training to care for people who are pregnant, to provide comprehensive contraceptive method counseling and pregnancy options counseling, to evaluate gestational age and to perform women's health office-based procedures such as endometrial biopsy, subdermal and intrauterine contraceptive device insertions and removals. Further, the Society of Teachers of Family Medicine group on Hospital and Procedural Training issued a consensus statement that during residency, every family medicine resident should be exposed and given the opportunity to train to

---

[6] Raymond EG, Grimes DA, *The comparative safety of legal induced abortion and childbirth in the United States,* Obstetrics and Gynecology119:215-9 (2012); Hoyert, D, Minino, A, *Maternal mortality in the United States: Changes in coding, publication, and data release, 2018*. Hyattsville, MD: National Center for Health Statistics (2020); Zane, S, Creanga, AA, Berg, CJ, et al, *Abortion-Related Mortality in the United States: 1998-2010*, Obstetrics and gynecology 126:258-65 (2015).

competence for independent provision of first-trimester aspiration abortion.[7] The National Academies of Sciences, Engineering, and Medicine issued evidence-based guidelines in 2018 for the safety and quality of abortion care in the United States, noting family medicine doctors routinely provide safe and effective medication and aspiration abortions.[8]

17. The mifepristone REMS is and continues to be a roadblock that keeps family medicine providers from integrating mifepristone into their regular practice.[9] When mifepristone was approved in 2000, one in three generalist doctors said they were planning to prescribe mifepristone in their practices.[10] Yet

---

[7] Herbitter, C, Bennett, A, Schubert, FD, Bennett, IM, Gold, M, *Management of early pregnancy failure and induced abortion by family medicine educators*, J Am Board Fam Med 26:751-8 (2013).

[8] National Academies of Sciences, Engineering, and Medicine, *The Safety and Quality of Abortion Care in the United States* (2018), available at: https://nap.nationalacademies.org/catalog/24950/the-safety-and-quality-of-abortion-care-in-the-united-states.

[9] Raymond, EG, Blanchard, K, Blumenthal, PD, et al, *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, N Engl J Med 376:790-4 (2017).

[10] Sheryl Gay Stolberg, *F.D.A. Adds Hurdles in Approval of Abortion Pill,* New York Times, Jun. 8, 2020, available at https://archive.nytimes.com/www.nytimes.com/library/national/science/health/0

research suggests that today, less than 5% of family medicine doctors actually offer early abortion services in their primary care practices, primarily due to the additional burdens and complications of ordering, storing and distributing mifepristone under REMS.[11] The negative impact of this means that many patients are not able to turn to their own, existing primary care physician or even another physician in their community for medication abortion.

18. The January 2023 FDA REMS update has permanently removed the "on-site" dispensing requirement of mifepristone, only to replace it with a different, complicated process requiring pharmacy certification. In this scenario, only special "registered" retail pharmacies can dispense mifepristone directly to patients who, in turn, have to have a prescription prescribed from a "certified" prescriber. It has been well documented that requiring a signed Prescriber

---

60800hth-abortion-drug.html; National Survey of Women's Health Care Providers on Medical Abortion, *Will 1999 Be the Year for Mifepristone (RU-486)? And, an Update on Women's Other Options for Very Early Abortion*, Kaiser Family Foundation, Aug. 31, 1998, available at https://www.kff.org/womens-health-policy/will-1999-be-the-year-for-mifepristone/.

[11] Patel, P, Narayana, S, Summit, A, Gold, M, Morgan, ZJ, Peterson, LE, et al, *Abortion provision among recently graduated family physicians*, Fam Med. 52:724-9 (2020).

Agreement discourages many family medicine doctors from prescribing mifepristone.[12] There are multiple reasons for this. For one, certification requires that prescribers be ready to "provide surgical intervention" or "have made plans to provide such care through others" in the rare case that uterine aspiration is needed. In my experience, this stipulation has impeded many family physicians from prescribing mifepristone, since obtaining additional surgical aspiration training is not feasible for many practicing family physicians. And even if training were feasible, uterine aspiration procedures require that primary care clinics purchase additional expensive equipment and instruments that can be burdensome to store and maintain, especially if they are rarely used. Additionally,

---

[12] Greenberg, M., Herbitter, C., Gawinski, B. A., Fletcher, J., & Gold, M, *Barriers and enablers to becoming abortion providers*, Family medicine, 44(7), 493 (2012); Calloway, D., Stulberg, D. B., & Janiak, E., *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States*, Contraception, 104(1), 24-28 (2021); Godfrey, E. M., Fiastro, A. E., Jacob-Files, E. A., Coeytaux, F. M., Wells, E. S., Ruben, M. R., ... & Bennett, I. M, *Factors associated with successful implementation of telehealth abortion in 4 United States clinical practice settings*, Contraception, 104(1), 82-91 (2021); Bennett, I., Aguirre, A. C., Burg, J., Finkel, M. L., Wolff, E., Bowman, K., & Fleischman, J., *Initiating abortion training in residency programs: issues and obstacles*, FAMILY MEDICINE-KANSAS CITY-, 38(5), 330 (2006).

community-based OB/GYNs are often unwilling to serve as a backup, especially if abortion is stigmatized in their communities. Another reason is that the existence of the REMS makes medication abortion appear different from other primary care services, and lends to misperceptions about the complexity and safety of medication abortion provision.[13] This also makes many providers reluctant to add it to their practice.

19. Another example of how REMS blocks access to care is that the Prescriber Agreement certification requires that providers are "able to assure patients access to medical facilities equipped to provide blood transfusions." Such a stipulation is unnecessary, especially since the risk from massive hemorrhage for a first trimester medication abortion is incredibly rare, occurring at about 1 per 1000 prescriptions of mifepristone.[14] These data are aligned with my personal experience of prescribing mifepristone for more than 20 years in which only one of my patients to whom I prescribed mifepristone received a blood transfusion. Family medicine providers are often the only providers for

---

[13] Brown, B. L., Wood, S. F., & Sarpatwari, A., *Ensuring safe access to mifepristone during the pandemic and beyond,* Annals of internal medicine, 174(1), 105-106 (2021).

[14] Creinin, MD, Grossman, DA, *Medication Abortion Up to 70 Days of Gestation*, ACOG Practice Bulletin Number 225, Obstetrics & Gynecology 136(4):e31-e47 (Oct. 2020).

patients in vast rural areas where access to transfusion services may be hours away. Such stipulations serve as unnecessary barriers to care. When family medicine doctors cannot serve their patients living in rural or remote areas of the U.S., these patients are forced to travel to distant, or unfamiliar urban centers for their care, which causes them additional expenses, time away from home, and add the burden of finding coverage for work, childcare, elder care and other in-community responsibilities. Notably doctors are not required to sign such a certification before prescribing other medications that also carries a high risk for needing a blood transfusion, such as warfarin (used to prevent blood clots).

20. The REMS Prescriber Agreement also makes it so that a provider has to affirmatively "opt-in" in order to prescribe mifepristone. This, too, erects a big hurdle in the area of family medicine, as many individual family medicine providers work within larger health systems (like UW Medicine). Because of all of the stipulations on the Prescriber Agreement Form, and despite mifepristone's incredibly safe record and family medicine's training in obstetrical care, the decision to provide medication abortions can get bogged down within a larger healthcare system that cannot feasibly accommodate all of the extra steps required to meet REMS. Often those responsible for this decision are not healthcare providers themselves and erroneously see it as taking on too much legal or administrative liability. Without support from the larger institution, it is unlikely an individual provider will initiate medication abortion services in their

clinical setting.[15] In fact, a research study I conducted on the implementation of medication abortion via telemedicine among 21 primary care providers suggests primary care providers working in larger clinics had more difficulty implementing medication abortion because of REMS. For example, having to safely and responsibly dispense mifepristone from the clinic when no other prescribed drugs are dispensed this way requires that the clinician take on the role of "pharmacist," which is not what they are trained to do. Dispensing a drug in the middle of a clinical session also essentially disrupts the clinic flow of a large busy primary care practice, putting the provider behind schedule. Even with the mail-order pharmacy option to deliver mifepristone, large health systems can't readily contract with these entities without layers of bureaucratic approval and changes in contractual policies. Because of these barriers, our study clinic champions were told that implementing medication abortion took away from other essential services offered by primary care.[16] This similar sentiment was

---

[15] Summit, AK, Lague, I, Dettmann, M, Gold, M, *Barriers to and enablers of abortion provision for family physicians trained in abortion during residency*, Perspect Sex Reprod Health 52:151-9 (2020).

[16] Godfrey, E. M., Fiastro, A. E., Jacob-Files, E. A., Coeytaux, F. M., Wells, E. S., Ruben, M. R., & Bennett, I. M., *Factors associated with successful implementation of telehealth abortion in 4 United States clinical practice settings*, Contraception, 104(1), 82-91 (2021).

noted in a different study with primary care providers practicing medicine in the Midwest.[17]

21. Medication abortion via telehealth appointments can be safely provided with similar efficacy and no increased risk of significant adverse events. Evidence suggests that licensed family medicine providers can safely prescribe medication abortion pills and serve an entire state through telemedicine.[18] Based on my own research I conducted that will be published in the near future, my findings show that telemedicine abortion care also reduces concerns about patients having to walk through protestor activity and face congested waiting rooms of abortion clinics. Telemedicine may also lower direct and indirect costs of care for patients, including the costs associated with travel, lost wages and childcare, as well as the cost of the service itself, all of which are known barriers to timely abortion services.[19]

---

[17] Calloway, D., Stulberg, D. B., & Janiak, E., *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States*, Contraception, 104(1), 24-28 (2021).

[18] Godfrey, E. M., Thayer, E. K., Fiastro, A. E., Aiken, A. R., & Gomperts, R., *Family medicine provision of online medication abortion in three US states during COVID-19*, Contraception, 104(1), 54-60 (2021).

[19] Margo, J, McCloskey, L, Gupte, G, Zurek, M, Bhakta, S, Feinberg, E, *Women's Pathways to Abortion Care in South Carolina: A Qualitative Study of*

22. It is important that family medicine providers are empowered to offer medication abortion services via telemedicine to their patients in their own practices. The US COVID-19 Public Health Emergency (PHE) led to sustained changes in healthcare delivery, expanding telehealth for a variety of services, including in primary care.[20] Through my own research, family medicine providers have indicated that it is easy to include a medication abortion consultation via telemedicine, especially when the primary care office already has telemedicine in place for other types of consultations. As I stated above, my own research showed that REMS requirements, such as signing the Patient Agreement Form, and dispensing and shipping mifepristone to patients impede family medicine providers, especially those working in large health systems from readily implementing telehealth medication abortion.[21] As such, stand-alone,

---

Obstacles and Supports, Perspectives on Sexual and Reproductive Health 48:199-207 (2016).

[20] Cortez, C et al., *Changes in Short-term, Long-term, and Preventive Care Delivery in US Office-Based and Telemedicine Visits During the COVID-19 Pandemic*, JAMA Health Forum, Jun. 9, 2021, available at https://jamanetwork.com/journals/jama-health-forum/fullarticle/2781917.

[21] Fiastro, A. E., Sanan, S., Jacob-Files, E., Wells, E., Coeytaux, F., Ruben, M. R. & Godfrey, E. M., *Remote delivery in reproductive health care: operation*

online medication abortion entities such as Hey Jane, Choix, Aid Access, Abortion on Demand, etc. can more readily implement REMS. These online options are increasingly popular for patients seeking abortion services and serve as an important access point for patients, given the hostile political climate for abortion care access for millions of Americans.

23. Despite clear advantages of telemedicine abortion for some, it is not necessarily a good option for everyone. This is particularly true for individuals with limited access to technology, including limited broadband access; individuals with privacy or security concerns; and individuals with lack of experience with or knowledge of telemedicine. Plus, through a research study my team recently completed that evaluated sociodemographics between almost 1,700 patients seeking in-clinic versus online medication abortion services, we found that younger individuals (less than 25 years), non-English speakers and those with at least one chronic medical issue were less likely to choose telemedicine and seek in-clinic services instead. These findings suggest the need to have both telemedicine and in-clinic medication abortion options to meet patient preferences. Further, since evidence suggests that close to 70% of female patients aged 18-44 years seen by family physicians have two or more chronic medical or mental health conditions, these study findings demonstrate the critically

---

of direct-to-patient telehealth medication abortion services in diverse settings, The Annals of Family Medicine 20(4), 336-342 (2022).

important role family medicine physicians have in providing comprehensive family planning services, including early abortion care, to medically complex patients of reproductive age.[22]

24. I also find that a certain number of patients want to meet with and be treated by their own primary care physician—particularly on issues as sensitive as pregnancy, abortion, and miscarriage.[23] This finding was also evident in my own research study. Patients prefer to see their own primary care provider because they experience undue concern and stress at having to be referred to another provider or told to make a telehealth appointment with an unknown provider. Given that many family medicine doctors value continuity of care and generally handle all aspects of maternal care, carving out medication abortion for differential treatment makes no sense and only stigmatizes the service further.

25. Plus, when abortion care is included in primary care, a family medicine provider knows the patients' histories, can readily access the medical

---

[22] Hsiao, CJ, Cherry, DK, Beatty, PC, Rechtsteiner, EA, *National Ambulatory Medical Care Survey: 2007 summary*, National health statistics reports 1-32 (2010).

[23] Rubin, S. E., Godfrey, E. M., Shapiro, M., & Gold, M, *Urban female patients' perceptions of the family medicine clinic as a site for abortion care*, Contraception, 80(2), 174-179 (2009).

record, and have already established trust with their patients. This often allows for a much better patient experience.

26. I am also concerned about the updated January 2023 REMS requirement that requires certified mifepristone prescribes to "submit the form to each certified pharmacy in which you intend to submit Mifeprex prescriptions." Such a requirement is onerous, burdensome and completely unnecessary. In a busy primary care practice that serves hundreds of patients daily, it is impractical to expect every single primary care provider to submit a form to each certified pharmacy in the clinic's catchment area. There may be potentially hundreds of pharmacies in which patients who seek care from primary care would want to pick up their prescriptions. To track which pharmacies are "certified" or not, and whether clinicians have "submitted" their form to each potential "certified" pharmacy is out of the scope of any mainstream clinic or provider.

27. Additionally, I am aware from conversations with colleagues and other providers that many have serious safety concerns about becoming a "certified prescriber" of a medication that some states have moved to criminalize and that is drawing so much media attention. This fear makes sense. As a family medicine doctor who is also an abortion-care provider, I have closely followed the increased violence against abortion care providers in recent years—and especially since the *Dobbs* decision. While I continue to identify as an abortion care provider and being a "certified prescriber" of mifepristone, many other

family medicine doctors are not, and I can understand that concern. While certified pharmacies must attest to confidentiality measures, there is still a fear that an antiabortion employee at a local drug store or pharmacy may obtain that list and disclose the names of community-based providers who have signed a FDA Prescriber Agreement Form to protestors or those who threaten to harm abortion providers. This is a fear that the FDA has continued to ignore by continuing to require providers to become certified in order to prescribe mifepristone.

The REMS Makes It More Difficult for Patients to Access Mifepristone

28. Abortion care necessarily has a specific time window, and receiving care within that window creates urgency. Based on research I conducted with 30 patients who recently sought medication abortion at a high-volume clinic in Washington State, I was saddened to hear just about every study participant describe how they first went to their regular OB/GYN or family medicine provider only to find out that they could only confirm that the patient was pregnant. Some of their providers referred the patient to the closest clinic that offers abortion services, only to be shocked to find out there was at least a 2-3 week wait. Such news left many of these desperate participants to search online to quickly find another provider who could provide those services. No one plans an unplanned pregnancy. And thus, to make patients frantically search for a legitimate place for care at a moment when they face unexpected health

challenges is both cruel and inhumane. Research shows that early medication abortion options provide women and pregnant persons greater autonomy over decision-making.[24] Allowing family medicine providers and primary care providers to prescribe mifepristone the way they prescribe other types of drugs—directly to the pharmacy of the patient's choice without any registration or certification—allows for dignified care.

29. Unfortunately, the personal choice to seek abortion care is still stigmatized in many communities. Many people do not want to be seen going into a clinic (like a Planned Parenthood) that is known to their neighbors and others as a place that provides abortion services. Research I have been involved with and the patients I have seen in my clinic suggests that patients prefer obtaining abortion care in primary care rather than abortion clinics due to reasons of trust, privacy, and continuity of care.[25]

---

[24] LaRoche, K. J., & Foster, A. M, *"It gives you autonomy over your own choices": A qualitative study of Canadian abortion patients' experiences with mifepristone and misoprostol*, Contraception, 102(1), 61-65 (2020).

[25] Logsdon, MB, Handler, A, Godfrey, EM, *Women's preferences for the location of abortion services: A pilot study in two Chicago clinics*, Matern Child Health J. 16:212-6 (2012); Wu, JP, Godfrey, EM, Prine, L, Andersen, KL, MacNaughton, H, Gold, M, *Women's satisfaction with abortion care in academic*

30. While the availability of medication abortion through telehealth appointments can help mitigate these stressors, the FDA's misguided decision to continue to require providers to become "certified providers" in order to prescribe mifepristone will continue to limit the number of providers available to staff such telehealth appointments and, in turn, limit the overall number of appointments available to patients. Moreover, as discussed above, telehealth appointments may not be appropriate for all patients for various reasons. For these patients, the REMS can have a devastating impact.

31. If a patient delays in finding a "certified provider," they may miss the very limited window in which to have a safe and effective medication abortion. This can cause more pregnant patients to delay care, and ultimately increase the need for second-trimester and surgical abortions, both of which have increased complication rates as compared to medication abortions.[26] These types of abortion are also more expensive and may put abortion out of the reach of some patients.

---

family medicine centers, Fam Med.47:98-106 (2015); Summit, AK, Casey, LM, Bennett, AH, Karasz, A, Gold, M, *"I don't want to go anywhere else": Patient experiences of abortion in family medicine*, Fam Med. 48:30-4 (2016).

[26] Upadhyay, UD, Desai, S, Zlidar, V, et al, *Incidence of emergency department visits and complications after abortion,* Obstetrics and Gynecology125:175-83 (2015).

32. These harms will also be felt more intensely by patients in rural or medically underserved areas within Washington State, where there are already very few options for abortion care, and those patients may not have the financial means nor the family support needed to travel to a city that does have providers who can provide the care they need. First trimester medication abortion with mifepristone that can be taken at home or in the place of the patient's choosing has the potential to address abortion service disparities and health access inequities, particularly among disadvantaged populations. Tragically, the current guidelines still unduly require patients to sign redundant and unnecessarily frightening forms that impede access to care.

Implementation of the REMS at UW

33. In addition to my patient clinic work and research work at UW, I have also been participating in a workgroup at UW charged with implementing the amended mifepristone REMS issued by the FDA on January 3, 2023.

34. I have been involved in numerous planning meetings on the implementation of the REMS, including managing how the REMS impacts workflows for providers and pharmacy staff.

35. I estimate that I spend 4 to 5% of my full-time equivalent working on issues related to implementation of the REMS, including updating clinic protocols, creating clinic work-flow documents, working with colleagues to figure out a system to ensures every provider in the UW Primary Care Clinics

who wants to prescribe mifepristone signs a Provider Agreement Form, and collating training materials to ensure other providers in the UW Primary Care Clinics are aware of how to assess and manage patient seeking medication abortion. I am also helping our Epic information technology team with changes to the Smartset, ensuring that patients who seek telehealth medication abortion can readily sign the Patient Agreement Form. I am helping to test and pilot these updates to make certain that our systems are in place for proper signatures from patients before prescriptions of mifepristone are sent to the pharmacy. I am helping to inform UW Medicine to create a website in which patients can get information about medication abortion, read the patient agreement form, and read the Mifeprex Medication Guide ahead of their appointments. My time spent on discussing, explaining, following and testing/piloting REMS implementation is time that I could have spent seeing more patients, training more residents, or working on important research.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 22nd day of February, 2023, at Seattle, Washington.

Emily M Godfrey

Emily Godfrey, M.D., M.P.H.

Exhibit A

Curriculum Vitae

Emily Maria Godfrey, MD, MPH
University of Washington
Department of Family Medicine
Box 354982
Seattle, WA 98105
(206) 685-4895
godfreye@uw.edu
Pronouns: she/her/hers

1. Personal Data

Place of birth: Chicago, Illinois
Citizenship: USA

2. Education

1991	B.S., with Honors, English Literature, University of Wisconsin, Madison, WI
1997	M.D., Medical College of Wisconsin, Milwaukee, WI
2003	M.P.H, Research Design, University of Rochester School of Medicine and Dentistry, Rochester, NY

3. Postgraduate Training

1997-2000	Internship/Residency: Family Medicine, West Suburban Medical Center, Oak Park, IL
2000-2002	Fellow, Family Planning, University of Rochester, Rochester, NY
2003-2004	Fellow, Faculty Development, Stroger Hospital of Cook County, Department of Family Medicine, Chicago, IL
2010-2012	Family Planning Epidemiology and Public Health Fellowship, Centers for Disease Control and Prevention, Atlanta GA
2016-2017	Certificate Program in Patient Safety and Quality, University of Washington, Seattle, WA

4. Faculty Positions Held

2000-2003	Clinical Instructor in Family Medicine, University of Rochester, Rochester, NY
2004-2005	Visiting Assistant Professor, Family Medicine, University of Illinois, Chicago, IL
2005-2011	Assistant Professor (tenure track), Family Medicine, University of Illinois College of Medicine, Chicago, IL
2005-2011	Affiliate Assistant Professor, Community Health Sciences, University of Illinois School of Public Health, Chicago, IL
2010-2012	Assistant Research Professor, Obstetrics and Gynecology, University of North Carolina, Chapel Hill, NC
2011-2012	Associate Professor (tenured), Family Medicine, University of Illinois College of Medicine, Chicago, IL
2012-	Associate Professor (tenured), Family Medicine, University of Washington School of Medicine, Seattle, WA
2013-2017	Adjunct Associate Professor, Obstetrics and Gynecology, University of Washington School of Medicine, Seattle, WA

2017- Associate Professor, Obstetrics and Gynecology, University of Washington School of Medicine, Seattle, WA

5. Hospital Positions Held

2000-2003 Family Medicine Physician, Highland Hospital, Rochester, NY

2001-2003 Emergency Medicine Physician, Highland Hospital Emergency Department, Rochester, NY

2002-2003 Attending Physician, Unity Health System Walk-in Care Clinic, Unity Hospital, Rochester, NY

2003-2012 Attending Physician, Departments of Family Medicine and Obstetrics and Gynecology, Stroger Hospital of Cook County, Chicago, IL

2004-2012 Attending Physician, Department of Family Medicine, University of Illinois Medical Center, Chicago, IL

2006-2012 Family Planning RHEDI Residency Director, Department of Family Medicine, University of Illinois, Chicago, IL

2013- Attending Physician, Departments of Family Medicine and Obstetrics and Gynecology, University of Washington Medical Center, Seattle WA

6. Honors and Awards

1995 Standing Ovation Award for diligent efforts on behalf of domestic violence education, Medical College of Wisconsin

1996 Standing Ovation Award for leadership shown through Physicians for Social Responsibility, Medical College of Wisconsin

2001-2002 Wyeth-Ayerst New Leaders Award

2002 Best Abstract Presentation, Association of Reproductive Health Professionals National Conference, La Jolla, CA (Title "Coping with abortion: Assessing women's well being from patients' and providers' perspectives.")

2004 Association of Reproductive Health Professionals Member of the Year Award

2005 Berlex Foundation Junior Faculty Development Workshop Award

2006 IL House of Representatives Sarah Feigenholtz Pro-Choice Leadership Award, Given to 11 physicians in IL who have made remarkable advances in providing reproductive health services to IL women

2006 **Grant Generating Project** Research Fellowship Award, University of Missouri Dept. of Family Medicine

2007 National Center of Excellence in Women's Health AHRQ Workshop Travel Award

2008 Faculty Mentoring Award, University of Illinois College of Medicine

2009 Association of American Medical Colleges Early Career Women Faculty Professional Development Seminar

2011 The Linda K. Gunzburger Faculty Award for Excellence in Scholarship, University of Illinois Department of Family Medicine

2014 Best Conference Lecture, Contraceptive Technology National Conference

2015 Patient Safety Heroes Award, University of Washington Medical Center

2015 Midcareer Mentoring Award, Society of Family Planning

2017-2019 PCORI Ambassador Scholarship recipient Travel Award

2021 The UW Dept of Family Medicine Clinical Excellence Award -provided to the UWNC Northgate Repro Clinic (faculty/staff)

7. Board Certification

2000 Family Medicine, American Board of Family Medicine (ABFM)
2007, 2014 Recertification, ABFM

8. Licensure to Practice

1999-2012 Illinois (#036101057)
2000-2007 New York (#217837)
2012-pres Washington (#MD60303537)

9. Diversity, Equity and Inclusion Activities

2002-pres **Physician who includes comprehensive family planning services in primary care practice**. Unplanned pregnancies are most common among people with low incomes, or with jobs that do not provide health care coverage, which disproportionally affect women of color. Women and gender diverse individuals affected by racism and poverty have fewer options for high-quality contraception and other health care services. As a result, persons without adequate access to care are more likely to seek abortion services. My research and clinical focus on the inclusion of early abortion care in primary care helps to bring equity and justice in our community and our world.

2019-pres **Co-founder and lead mentor, UW Department of Family Medicine Women's Health Research and Scholarship Lab**. I mentor minority students and residents interested in pursuing a project related to women's health, either as the sole mentor or as a dyad team with a clinician-educator faculty member. To date, all undergraduate students were either African American or Asian American. Of the 10 medical students mentored, 9 were minority students (5 Asian-American, 1 African American and 2 Latinx). Our dyad faculty team mentored three Asian-American primary care residents.

2019-pres **Faculty member, search committee, Department of Family Medicine Reproductive Health Fellowship,** with emphasis on underrepresented minority recruitment**.**

2021-pres **Signed, Sealed, Delivered and Fleeing Oppression**: These two grant projects include a **community advisory board** aimed at including members from underrepresented minority communities.

10. Professional Organizations

1997-pres Member, American Academy of Family Physicians
2000-pres Member, National Abortion Federation
2000-2017 Member, Association of Reproductive Health Professionals
2003-2017 Member, Society of Teachers of Family Medicine
2004-pres Member, North American Primary Care Research Group
2004-2010 Member, IL Academy of Family Physicians
2004-pres Member, Physicians for Reproductive Health (formally Physicians for Reproductive Choice and Health)
2002-2006 Member, American Medical Women's Association
2006-pres Fellow, Society of Family Planning
2013-pres Fellow, American Academy of Family Physicians
2016-2020 Founder/Board Chair, Cystic Fibrosis Reproductive and Sexual Health Collaborative (cfreshc.org)

11. Teaching Responsibilities

Undergraduate student courses:

2014-2020 Course Director, Independent Study in Clinical Research Trials for undergraduate students. Developed curriculum with associated readings and videos. Work with 1-2 students independently per quarter.

2014-2018 Advisor, Alpha Epsilon Delta (AED) (Pre-med honor society). Undergraduate students contact me to shadow me in clinic and hospital rounds.

Medical student/PA student courses:

2007-2010 Director, "Independent Study Research Course" in Family Medicine. University of Illinois College of Medicine. Created independent research course in which learners think critically about a research question related to women's health, develop data collection design and write a final project paper.

2007-2009 Seminar developer, "I think I might be pregnant: A primer on contraception, abortion and options counseling for medical students." University of Illinois College of Medicine. Created and provided 2nd year medical student lecture, small-group case-based tutorial and selected required readings (~150 students annually).

Resident courses:

2006-2011 Co-Director (~50% responsible), "Values Clarification: An Interactive Workshop." UIC Department of Family Medicine. Co-developed with Behavioral Scientists. Co-lead a 2.5-hour annual resident workshop presented to first-year Family Medicine residents during their mid-year orientation week.

2006-2011 Co-Director (~50% responsible), "Options Counseling Skills. UIC Department of Family Medicine. Co-developed and led a 1.5-hour biannual case-based resident workshop presented to all Family Medicine residents during their required didactic teaching time.

2013 Instructor, "Systematic Reviews: The Foundation of Evidence-based Practice." UW Department of Family Medicine Workshop. Developed and co-presented two 3-hour workshops for all faculty and residents, collaborated with UW Health Sciences librarians.

Graduate Student courses:

2004-2010 Course Director, "Family Planning – Policies and Practices" (CHSC 594), UIC School of Public Health. Developed and led a 3-credit graduate-level course focusing on the interventions and the impact of family planning from the public health perspective. Organized syllabus and readings, arranged for guest lectures, presented lectures, facilitated fieldwork experiences and led discussions.

2018, 2019 MEDEX annual GYN exam proctor.

Faculty level courses:

2007- Implanon Training: Instruction on placement and removal of implantable contraception (Conducted sessions for faculty and residents in 2007-2010, 2013-2021)

2013 Instructor, "Systematic Reviews: The Foundation of Evidence-based Practice." UW Department of Family Medicine Workshop. Developed and co-presented two 3-hour workshops for all faculty and residents, collaborated with UW Health Sciences librarians.

International teaching:

2012 Visual inspection of the cervix with acetic acid (VIA). Training of local nurses and midwives in rural Senegal. In conjunction with Peace Care, Chicago, IL and Peace Corps volunteers based in Senegal (Feb 2012).

Research Trainees:

Undergraduate Students:

AY15 Mentor, Niveda Shikar (UW Senior). Completed literature review of video use for counseling in the healthcare setting. Also learned about IRB applications, recruitment strategies, data collection; helped complete source documents for ACCCUSS study. Presented at the UW Undergraduate Research Symposium, 2015.

AY15-18 Mentor, Tatiana Josephy BS, (UW post-bachelor/pre-med student). Helped to develop a contraceptive registry for women with complex medical conditions. Submitted PCORI P2P successfully funded June 2016.

AY15 Mentor, Hae (Angel) Lee (UW Freshman/Sophomore, Quarters). Learned about systematic review and meta-analysis methodology. Assisted with literature search related to contraceptive exposure and birth defects. Presented at the UW Undergraduate Research Symposium, 2015. Currently an engineer in California.

AY15-16 Mentor, Savannah Burr (UW Junior/Senior, Neuroscience). Completed term paper and research project related to how teens and young adults can maintain confidentiality when on parent or guardian insurance plans. Presented at UW Undergraduate Research Symposium, 2016. Admitted to UW Physical Therapy School in 2017. Currently a physical therapist at Seattle Children's Hospital.

AY20-21 Mentor, Sajal Sanan (UW Senior, Microbiology). Analyzed data for the project entitled, *Comparison of completeness and timeliness of Paper, Text and Smartphone App Bleeding Diaries*. Presented as the 2019 NAPCRG National Conference (Toronto, Canada). **Awarded travel funds by the UW Mary Gates Foundation (2019), stipend from the Cambridge Reproductive Health Consultants for participation on the Access, Delivered project manuscript (2021), and WA State Society Daughters of the American Revolution Evans' Medical School Scholarship (2021).** Currently UW School of Medicine student Class of 2025.

Master of Public Health Students:

AY14 MPH Committee Member, Leah Torres MD, Family Planning Fellow and MPH candidate, RCT of focused contraceptive counseling and case management versus usual care in women postpartum from a preterm birth. Currently an OB/GYN practicing in Alabama.

AY14 Co-mentor, Arahadana Thaparahana, UW MPH student, survey study evaluating factors associated with acceptance of contraception after abortion in Nepal. 2014.

AY15-16 Supervisor, Alison Ojanen-Goldsmith, MSW, UW MPH student. Completed a practicum on evaluating family planning services in primary care and types of clinicians who have completed CME related to CDC family planning guidance. Currently the Director of Research for Planned Parenthood MN.

AY19-20 Supervisor, Erin Thayer. MPH student. Research Coordinator for the PCORI Eugene Washington Award to build patient-centered outcomes research (PCOR) in the cystic fibrosis community and determining best platforms for online PCOR collaborations. Presented as the 2019 NAPCRG National Conference (Toronto, Canada). Awarded travel funds by UW Graduate and Professional Student Senate (2019), stipend from the Cambridge Reproductive Health Consultants for participation on the Access, Delivered project manuscript (2021). Currently a data analyst for the Department of Family Medicine at University of Southern California, and continues to be a consultant for UW Access Delivered project.

AY22 MPH Committee Member, Linda Guijosa, MPH Candidate, Executive Master of Public Health Degree Program UW School of Public Health.

AY22 Mentor/Supervisor, Brittany Rattiliff MPH Candidate (2020-2022), Executive Master of Public Health Degree Program UW School of Public Health. Project: Engagement of members from underrepresented communities regarding abortion care and access. **Awarded project funds by UW Department of Family Medicine JEDI Committee**. Abstract accepted to the 2022 Association of Clinicians for the Underserved (ACU).

Medical Students:

AY10-12 Research mentor, Anita Bordioloi, MD candidate, Retrospective review of medical abortion in the student health care clinic setting. (2009-2012). Study published in Journal of American College Health, 2012.

AY15 Medical Student Research Training Program (MSRTP) Mentor, Michael Nguyen , MD candidate, Systematic review on strategies to disseminate family planning guidelines into primary care, Summer 2014.

AY17 Grant application mentor, Ryann Milne-Price, MD/MPH Candidate, Reproductive Health Education in Family Medicine (RHEDI) successful grant application for Western Montana Family Medicine Residency Program.

AY20 Co-faculty mentor (2019, 2020), Suzette Guzman, University of Chicago medical student. Investigating faith-based family medicine residency programs and family planning training. Abstract accepted as student poster at the 2020 NAPCRG conference. **Awarded the Student Scholarship Award for 2021 STFM Medical Education Conference (virtual).**

AY21 Faculty mentor, Anh Nguyen (UW I^3 Program). Investigating family planning training in family medicine and internal medicine residency programs. **Project abstract accepted as oral presentation at the 2021 Western Medical Research Conference, and as a poster at the 2021 Society of General Internal Medicine.**

AY21 Faculty mentor, Madison Miller (UW I^3 Program). Investigating controversial public health topics in mainstream media and use of university affiliation. **Project abstract accepted as poster to the 2021 Society of Teachers of Family Medicine Conference (Virtual). Received a 2021 UW Medical Student Conference Travel Award.**

AY21 Faculty mentor, Ramya Kommidi (New York Institute of Technology College of Osteopathic Medicine) Mentored student on Access, Delivered project during the 3-week AMSA "Reproductive Health Mentorship Sprint."

AY21 Mentor, L'Oreal Kennedy (UW 2nd year medical student). Seattle Children's: Antiracism starts at the top. **Successfully submitted Letter to the Editor, Seattle Times, January 8, 2021.**

AY21 Faculty mentor, Isabella (Bella) V. Stokes (UW 2nd year medical student). Assisted with the Access Delivered project. **AAFP Family Medicine Leads Emerging Leader Institute Awardee, 2021 Scholar.** FM Leads Institute (WWAMI Abortion Project) was the **Winner of the 2022 UW DFM Department Fair & Scholarship Forum Best Visual Presentation.**

AY21 Mentor, Tatiana Josephy (University of Chicago, 4th year medical student). First author of two published papers in 2021 related to (1) utilizing a smart-phone app for research participants to report bleeding and other associated symptoms during contraception use and (2) describing the establishment of a contraceptive registry that combines clinical outcomes with contraceptive survey data.

AY22 Faculty mentor, Nikeeta Shah (Western University of the Health Sciences, 4th year medical student). Communication needs of patients accessing online medication abortion services. **Abstract accepted as student oral presentation at the 2021 NAPCRG conference (virtual).**

Residents:

AY15-16 Mentor, Alyce Sutko MD, MPH, UW Department of Family Medicine PGY-3, "Contraceptive Adherence among women with hypertension in primary care." STFM submission.

AY18 Mentor, Elise Gelston MD, MPH, UW Department of Family Medicine PGY-2. "Preserved female sexual function and quality of life after Copper IUD placement." UW DFM Scholarship Forum (2019) – **voted honorable mention**.

AY19-20 Mentor, Viet Nguyen MD, UW Department of Family Medicine PGY-3. Phleboliths mistaken for intraperitoneal TCu380A IUD in the presence of missing strings: A case report. **Successfully published in BMJ Case Reports, March 2021**.

AY20 Mentor, Nina Tan MD, UW Department of Internal Medicine, PGY-2. Advancing Access to Medication Abortion in Primary Care: Conducting a Needs Assessment for Family Planning Training Among Internal Medicine Primary Care Residency Programs. **Successfully funded grant application to the Society of Family Planning Emerging Scholars Award, July 2020**.

AY21 Mentor, Monica Agarwal MD, UW Department of Family Medicine PGY-3. The Trump Administration is systematically undermining women's reproductive rights. **Successfully published as an Op-Ed on Kevin, MD, September 14, 2020.**

Fellows:

AY13 Mentor, Lisa Callegari MD, UW Post-doctoral fellow in HSRD at Puget Sound VA. I was a supervisor for Lisa's MPH practicum on doing a systematic review on reproductive life planning tools.

AY15 Co-mentor, Lyndsey Benson MD, MS, UW Family Planning Fellow in Obstetrics and Gynecology. Provided advice and reviewing her project on heterosexual anal intercourse. FFP-funded project.

AY16 Co-mentor, Ying Zhang MD, UW NRSA Fellow in Family Medicine. Mentored practicum project evaluating reproductive health services among Somali refugee populations in Seattle, AAFP Foundation funded project.

AY17 Co-mentor, Traci Kazmerski, MD Boston Children's Hospital Pediatric Health Services Research Fellow in the Division of Pulmonary and Respiratory Diseases. Mentored on sexual and reproductive health Career Research Award to the Cystic Fibrosis Foundation. Mentored on CF Reproductive and Sexual Health Collaborative submission to the North American CF Conference, November 2017. **Fellow abstract was selected as semi-finalist for the Junior Investigators Best Abstract in Clinical Research**.

AY18 Co-mentor, Rebecca Taub MD, UW Family Planning Fellow in Obstetrics and Gynecology. Mentoring on QI skills as a participant of the project funded through the UW Patient Safety Innovations Program.

Faculty:

AY14-15 Co-mentor, Lois Thetford PA, UW Department of Family Medicine, MEDEX faculty, "How important is contraception in the health seeking behavior of homeless youth?" Study for publication.

AY15	Mentor, Brandi Shah MD, MPH, Attending physician, PAC Med, Enhancing teenage sexual-reproductive health care in primary care settings. Submitted for RWJ award, not funded. Currently a student health provider at the University of Alabama.
AY20-pres	Mentor, Alexa Lindley MD, MPH. UW Department of Family Medicine, Residency Section faculty. We initiated the **DFM Women's Health Research and Scholarship Lab**, a dyad mentorship model intended to support and empower FM residents and UW medical students. The goal of this program is to help residents, Residency Section and Research Section faculty meet their scholarship milestones, while focusing on coaching and guiding the learner to pick a project related to women's health that they are passionate about and develop scholarship skills that are important to them. This program was presented at the UWDFM Residency Scholarship and Research teaching session. A manuscript describing this program has been accepted for publication in Medical Education.
AY21-pres	Mentor, Kim Kardonsky, MD UW Department of Family Medicine. Enhancing family planning services in primary care: A systematic Review. Currently working on manuscript for publication.

12. Editorial Responsibilities

2017-2018	Editor, Primary Care--Clinics in Office Practice: Women's Health

13. Special International and National Responsibilities

2006-2007	Consultant, Midwest Professional Research and Educational Services, Milwaukee WI. Developed IUD training program for mid-level providers.
2005-2012	Governance Board Member, Association of Reproductive Health Professionals
2008	Consultant, **World Health Organization (WHO) Special Programme of Research, Development, and Research Training in Human Reproduction,** Geneva Switzerland.
2006-pres	Speaker, Merck Pharmaceuticals. Provide educational session on HPV vaccine and etonorgestrel birth control implant
2006-pres	Curriculum Advisory Committee member, TEACH Early Abortion Training Curriculum, UCSF Bixby Center for Global Reproductive Health: San Francisco, CA.
2009	Discussant, Non-contraceptive use of the levonorgestrel intrauterine system in a managed care setting. 46th Annual Conference of the Association of Reproductive Health Professionals and Society of Family Planning, October, Los Angeles, CA.
2009-2012	Abstract Reviewer, Association of Reproductive Health Professionals Annual Meeting.
2010-2015	Abstract Reviewer, **Society of Family Planning Scientific Review Committee**.
2011	Clinical Advisor, Quick Reference Guide for clinicians: Choosing a Birth Control Method, Association of Reproductive Health Professionals.
2011-2012	Co-chair, Scientific Committee, Association of Reproductive Health Professionals Annual Meeting.
2011	Member, Male Clinical Services for Title X Family Planning Guideline Revision, Health and Human Services, Office of Population Affairs Expert Panel.
2011	Member, Community Outreach for Title X Family Planning Guideline Revision, Health and Human Services, Office of Population Affairs Expert Panel.
2012-2015	Member, **Centers for Disease Control and Prevention (CDC)**, Women's Clinical Services for Title X Family Planning Guideline Revision, Health and Human Services, Office of Population Affairs Expert Panel.
2012	Member, National Meeting Planning Committee, Association of Reproductive Health Professionals Annual Meeting.
2012-2020	*Ad hoc* reviewer, National Fellowship in Family Planning Fellow Grant Program

2013-2017	Guideline Committee Member, **World Health Organization (WHO)** Guideline on sexuality counseling for health care providers
2014-2017	Member, **Society of Family Planning** Education Committee
2014-pres	Member, **Centers for Disease Control and Prevention (CDC)** *US Medical Eligibility Criteria for Contraceptive Use* (US MEC) and *US Selected Practice Recommendations for Contraceptive Use* (US SPR) Expert Working Group.
2014-pres	Member, Upstream USA National Medical Advisory Committee.
2015, 2017	*Ad hoc* reviewer, **Society of Family Planning Research Fund**.
2012-2018	Site Visit Evaluator, Complex Family Planning Fellowship in Family Medicine (Albert Einstein/Montefiore Department of Family and Social Medicine and UCSF Department of Family and Community Medicine)
2016	Z-CAN Proctor, **Centers for Disease Control and Prevention (CDC)** Public Health Emergency Response to Zika, September 2016, Puerto Rico
2016	Moderator, Vulnerable Populations oral sessions, 2016 NAPCRG Annual Meeting.
2017-2022	Member, **North American Primary Care Research Group (NAPCRG)** Program Committee
2017-pres	Council member, **North American Primary Care Research Group (NAPCRG) PaCE (Patient and Clinician Engagement) Program**. My work in this group is featured in the PaCE Video.
2017-pres	Abstract reviewer, **Patient-Centered Outcomes Research Institute (PCORI)** Ambassador Program
2016-2020	**Founding Chair**, Cystic Fibrosis Reproductive and Sexual Health Collaborative (CFReSHC)
2018	Moderator, Abortion Provision: Maintaining scope of practice for primary care providers alongside family planning specialists. North American Forum on Family Planning 2018 Annual Conference.
2021-pres	Member, **Robert Graham Center** Patient and Clinician Engagement (PaCE) Advisory Committee
2023-pres	**Vice Chair**, NAPCRG Program Committee

14. Special Local Responsibilities

2013, 2016	Nominee Reviewer, Liu Bie Ju Award for Excellence in Women's Health, University of Washington Medical Student Poster Sessions.
2013-pres	*Ad hoc* reviewer, Pilot grant applications, UW Institute of Translational Health Science Center.
2013-pres	Faculty, UWNC Northgate Repro Health Clinic, UW Dept of Family Medicine
2014-2015	**Chair**, UW Department of Family Medicine Annual Fair Planning Committee
2014	Member, UW Department of Family Medicine Industry Committee
2015	Member, UW Department of Family Medicine Research Section Incentives Committee
2015-2016	Co-Director, National Research Service Award (NRSA) in the UW Department of Family Medicine
2017-2019	**Standing Member**, UW Royalty Research Fund Review Committee
2019	Assistant Director, Reproductive Health & Advocacy Fellowship Program, UW Dept of Family Medicine
2017-pres	MEDEX Proctor – supervise and teach primary care physical exam and summative clinical reasoning skills to MEDEX students
2019-2021	Member, Medical Student Research Training Program Committee, UW School of Medicine
2020-pres	Faculty, Reproductive Health & Advocacy Fellowship Program, UW Dept of Family Medicine

15. **Clinical Activities:** I currently spend 15% FTE providing clinical services: 10% FTE is dedicated to my own primary care practice and 5% as a faculty member for the UW Northgate Reproductive Health Clinic, a service that was awarded the 2021 UW Department of Family Medicine Clinical Excellence Award.

    Between 2013 and 2018, I took call several times a month and served as the Family Medicine Service (which included Labor and Delivery) hospital attending 3-4 weeks annually, had my own primary care practice one day a week and saw patients weekly in the Reproductive Health Clinic. I also saw patients and precepted residents at the King County/NeighborCare OB clinic in Columbia City. Until 2020, through my joint appointment in the UW Department of OB/GYN, I provided weekly clinical care and supervising OB/GYN, internal medicine and family medicine residents and medical students in the Family Planning Clinic at the Roosevelt Women's Health Care Clinic.

16. **Research Funding**

Current

2023-2024	Evaluate potential delays in access to abortion services in Washington state following the U.S. Supreme Court decision (Balkus/Godfrey – Co-PI) UW Population Health Initiative Tier 2 pilot grant (Autumn 2022) A multi-disciplinary team with a WA state community partner will develop a system to efficiently extract and summarize electronic medical records data to evaluate potential delays in abortion access in WA state Annual Direct Costs: $95,000
2022-2023	Fleeing oppression: Seeking abortion services in permissive states (Godfrey – PI) Society of Family Planning Research Fund (SFPRF16-IAA4) Uses an integrated theoretical framework to study patient-centered access to abortion service health care in WA state Annual Direct Costs: $50,000
2022-2023	Pragmatic Evaluation of Adaptive Treatment Regimens in the Post-CFTR Modulator Era: the RELIEVE Project (Szczesniak/Gifford -PI) Cystic Fibrosis Foundation This study seeks to understand the decision-making process of discontinuing treatment therapies among individuals with cystic fibrosis in the era of highly effective modulator therapy Annual Direct Costs: $51,192 Role: Patient/Stakeholder engagement content expert
2020-2023	Access, Delivered (Godfrey – PI) UW Medicine Family Planning Fund – Anonymous donation Studies the implementation of novel telemedicine and mifepristone by mail abortion services in primary care and independent reproductive health clinics. Total funding: $510,000
2020-2023	MENstrual Symptom Tracking to Understand and Assess (women) Living with CF (MENSTRUAL) (Godfrey/Sufian – Co-PI) Cystic Fibrosis Foundation (CFF) (GODFRE20A0) This is a nation-wide longitudinal cohort study that uses a daily menstrual tracking app to assess whether CF-related symptoms are menstrually related. Annual Direct Costs: $80,000
2019-2023	Assessment of contraceptive safety and effectiveness in Cystic Fibrosis (Godfrey/Aitken – Co-PI) Cystic Fibrosis Foundation (CFF) (GODFRE19A0)

This is a multi-site retrospective cohort study that examines the safety and effectiveness of contraception among women with cystic fibrosis by linking self-respondent contraceptive data with clinical data from the CFF Patient Registry.
Annual Direct Costs: $350,000

Completed

2021-2022 Access to and acceptability of telemedicine medication abortion in primary care (Srinivasulu/Godfrey – Co-PI)
Society of Family Planning Research Fund (SFPRF15-MSD4)
Studies patients' experiences and accessibility of receiving telemedicine medication abortion services and pill delivery innovated by a large, urban primary care health system during the COVID-19 pandemic.
Annual Direct Costs: $80,000

2021-2022 Signed, Sealed, Delivered: Patient experiences of telehealth medication abortion services at the Cedar River Clinics (Godfrey – PI)
Society of Family Planning Research Fund (SFPRF15-MSD2)
Compares how medication abortion services offered by telemedicine shifts the accessibility of abortion care to patients.
Annual Direct Costs: $80,000

2018-2021 Building Online Research Partnerships to Improve Sexual and Reproductive Health for Women with Cystic Fibrosis (Godfrey – PI)
Patient-Centered Outcomes Research Institute (PCORI) (UWASH-10569)
The overall goal of this engagement award is to build capacity for patient-centered outcomes research within the Cystic Fibrosis patient, research and clinical community.
Total funding: $393,000

2015-2019 Anticipatory Counseling on LNG IUS Continuation, Utilization, and Satisfaction: A Pilot Study (Godfrey-PI)
Bayer Pharmaceuticals Investigator-Initiated Grant (# WH-2014-018)
This goal of this study is to test an anticipatory counseling intervention among new LNG using video technology.
Total funding: $293,118

2016-2018 Building a National Contraceptive Registry for Multiple Complex Medical Conditions: Improving contraceptive care for women through engagement (Godfrey – PI)
Society of Family Planning Research Fund (SFPRF10-II2)
The goal of this planning grant is to build a proof-of-concept contraceptive registry for women with cystic fibrosis, and with plans to add additional medical conditions.
Annual Direct Costs: $50,000

2016-2018 Advancing reproductive health wellness between patients with Cystic Fibrosis, healthcare providers and researchers (Godfrey – PI)
Patient-Centered Outcomes Research Institute (PCORI) (5140022)
Funding to form a patient-driven task force to address reproductive health-related concerns and to develop comparative effectiveness research questions related to reproductive life span care for patients with cystic fibrosis.
Annual Direct Costs: $40,000

2017-2018 Improving efficiency and effective contraceptive counseling in UW primary care and women's health clinics (Godfrey – PI)
UWM Patient Safety Innovation Program
The goal of this project is the increase patient satisfaction and reduce clinician counseling time in the UW-affiliated primary care and women's health clinics using a novel anticipatory video for the hormonal IUD.
Total funding: $50,000

2015-2017 Translating evidence-based family planning research into primary care clinical settings (Godfrey – PI)
Society of Family Planning Research Fund Mid-Career Award (SFPRF9-MC1)
This goal of this study is to study how family planning guidelines are best implemented into primary care.
Total funding: $80,000

2015-2018 A multi-center, double-blinded, randomized, phase IV 6-month pilot study to compare bleeding patterns, satisfaction and quality of life among new Copper 380A IUD users treated with naproxen sodium (440 mg twice daily) versus placebo (Godfrey - PI)
Teva Pharmaceuticals Investigator-Initiated Grant (DR304-WH-60191)
This goal of this study is to test the effectiveness of naproxen as treatment for heavy or prolonged menstrual bleeding with copper IUD use.
Total funding: $174,058

2015-2016 A Study Measuring Core Body Temperature Using Tempu-Ring in Women of Childbearing Age (Webster – PI)
Prima Temp, Inc. (PT-001)
This study is a proof-of-concept to test body temperature using vaginal ring technology.
Total funding: $34,694
Role: Site PI

2015-2016 Phase III, Single Arm, Clinical Trial To Study The Contraceptive Efficacy And Safety Of The MK-8342B (etonogestrel + 17β-estradiol) Vaginal Ring In Healthy Women 18 Years Of Age And Older, At Risk For Pregnancy (Fox – PI)
Merck, Sharp and Dohme Corp. (MK-8342B-061-0035)
This study is a Phase III trial to test the efficacy of etonogestrel + 17β-estradiol contraceptive vaginal ring among women at risk of pregnancy.
Total funding: $97,784
Role: Site PI

2013-2015 How well are contraceptive guidelines followed? (Godfrey – PI)
University of Washington Institute of Translational Health Sciences (UL 1 RR 025014)
Small Pilot Project Grant
Total costs: $15,000 (research support only)

2013-2015 CDC Intergovernmental Personnel Agreement (IPA) (#1303027)
Funds the development of national and global evidence-based contraceptive guidelines.
Total funded: $85,165

2006-2010 University of Illinois at Chicago, Family Planning Training Grant for Family Medicine (Godfrey – PI)
RHEDI Program
To train Family Medicine residents in the provision of contraception and early abortion services.
Annual Direct Funding: $120,000

2008-2010 Women's Abortion Experiences in the Family Medicine Setting (Wu – PI)
IPAS
To explore women's experiences of receiving abortion care in a primary care setting
Total funding: $30,000 (research support only)
Role: Co-Investigator

2008-2009 Acceptability of the Nuvaring among College and Graduate Students (Gilliam – PI)
Organon, Inc (Investigator Initiated Project)
Randomized trial to compare oral contraceptive pills to the Nuvaring among university students.
Total funding: $18,900 (research support only)
Role: Co-Investigator

2007-2009 Intrauterine Contraception for Adolescents aged 14 to 18: A pilot, multicenter, randomized controlled trial of Levonorgestrel-releasing intrauterine system compared to

Copper T 380A (Memmel – PI)
Anonymous foundation
To assess continuation, expulsions, pregnancies, and satisfaction among teens assigned to one of two forms of intrauterine devices approved by the United States FDA.
Total funding: $69,466
Role: Co-Investigator

2006-2007 Integration of Early Abortion Services in Primary Care: Acceptability Survey of Family Medicine in Two Clinical Settings (Rubin - PI)
Center for Reproductive Health Education in Family Medicine
To determine the acceptability of early abortion services within primary care by women of reproductive age.
Total funding: $6,200 (research support only)
Role: Co-Investigator

2001-2003 Factors Influencing Contraception Use in Women Aged 35 and Over (Godfrey – PI)
Anonymous foundation
To determine barriers to contraceptive use by women aged 35 years and older.
Total funding: $10,500 (research support only)

Completed Consultant Work

2018-2020 Sexual and Reproductive Health in Adult Women with CF (Kazmerski – PI)
Cystic Fibrosis Foundation Career Development Award
This survey study identifies the general and disease-specific SRH concerns, care utilization, and preferences of adult women with CF. Findings will also characterize the perceived effects of sex hormones over the female life course.

17. Bibliography

a) ***Refereed Journals*** *(∞=corresponding author)*

1. **Godfrey EM,** Mawson J, Stanwood N, Fielding S, Schaff E. Low-dose mifepristone for contraception: A weekly vs. planned post-coital randomized pilot study. *Contraception*. 2004;70 (1):41-46. PMID: 15208051.
2. **Godfrey EM**, Anderson A, Fielding S, Meyn L, Creinin M. Clinical utility of urine pregnancy tests to determine medical abortion outcome is limited. *Contraception*. 2007;75 (5):378-82. PMID: 17434020.
3. Rubin SE, **Godfrey E**, Gold M. Patient attitudes toward early abortion services in the Family Medicine clinic. *J Am Board Fam Med*. 2008;21 (2):162-164. PMID: 18343866.
4. Patel A, Rashid S, **Godfrey EM,** Panchel H. Prevalence of Chlamydia trachomatis and Neisseria gonorrhea genital infections in a publicly funded pregnancy termination clinic: Empiric vs. indicated treatment? *Contraception*. 2008;78 (4):328-331. PMID: 18847583.
5. Von Hertzen H, **Godfrey EM**. Emergency Contraception: The State of the Art. Reproductive BioMedicine Online; 2009 Vol. 18 Suppl.1. 28–31. PMID: 19281661.
6. **Godfrey EM**, Leeman L, Lossy P. Early pregnancy loss needn't require a trip to the hospital. Journal of Family Practice. 2009; 58(11): 585-590. PMID: 19891936.
7. Rubin SE, **Godfrey EM,** Shapiro M, Gold M. Urban female patients' perceptions of the family medicine clinic as a site for abortion care. *Contraception*. 2009;80(2):174-179. PMID: 19631794.
8. **Godfrey EM**, Wheat SG, Cyrier R, Wong W, Trussell J, Schwarz EB. Contraceptive needs of women seeking care from a publicly-funded sexually transmitted infection clinic. *Contraception*. 2010;82(5):543-548. PMID: 21074018.
9. Dada OA, **Godfrey EM**∞, Piaggio G, von Hertzen H. A randomized, double-blind non-inferiority study to compare two regimens of levonorgestrel for emergency contraception in Nigeria. *Contraception*. 2010;82(3):373-378 PMID: 20851232.

10. Wu SC, **Godfrey EM**∞, Wojdyla D, Dong J, Cong J, Wang C, von Hertzen H. Copper T380A intrauterine device for emergency contraception: A prospective multicentre cohort clinical trial. Br J Obstet Gynaecol. 2010 Sept 1;117(10):1205-1210. PMID: 20618314.
11. Wu S, Dong J, Cong J, Wang C, von Hertzen H, **Godfrey EM∞.** A multicenter randomized double-blind trial of gestrinone (R2323) and mifepristone for emergency contraception. *Obstet Gynecol*. 2010;115(4):740-744. PMID: 20308833.
12. Gilliam ML, Neustadt A, Kozloski M, Mistretta S, Tilmon S, **Godfrey EM**. Comparison of adherence and acceptability of the contraceptive ring and pills among students: A randomized controlled trial. *Obstet Gynecol.* 2010;115(3):503-510. PMID: 20177280.
13. **Godfrey EM**, Rubin SE, Smith E, Gold M. Women's perspectives of abortion in primary care. *J Womens Health.* 2010;19(3):1-6.
14. Panchel H, **Godfrey EM**∞, Patel A. Buccal misoprostol for cervical ripening prior to first trimester abortion. *Contraception*. 2010;81(2):161-164. PMID: 20103456.
15. **Godfrey EM**, Memmel L, Neustadt A, Shah M, Nicosia A, Moorthie M, Gilliam M. Intrauterine contraception for adolescents aged 14 to 18: A pilot, multi-center randomized controlled trial of Levonorgestrel-releasing intrauterine system compared to the Copper T 380A. *Contraception.* 2010;81(2):123-127. PMID: 20103449.
16. **Godfrey EM**, Chin NP, Fielding SL, Fiscella K, Dozier A. Contraceptive methods and use by women aged 35 and over: A qualitative study of perspectives. *BMC Women's Health*. 2011;11(5):1-9. PMID: 21324194.
17. **Godfrey EM**, Bordoloi A, Moorthie M, Pela E. Medication abortion within a student health care clinic: A review of the first 46 consecutive cases. *J American Coll Health* 2012; 60(2):178-183. PMID: 22316416.
18. Logsdon M, Handler A, **Godfrey EM**∞. Women's Preferences for the Location of Abortion Services: A Pilot Study in Two Chicago Clinics. *Matern Child Health* 2012; 16(1):212-216. PMID: 21107667.
19. Lind C, **Godfrey EM**, Rankin K, Handler A. Likelihood of Emergency Contraception Use Among African-American Women at Risk of Adverse Birth Outcomes. *Maternal Child Health* 2013 Aug 31, PMID: 23996273.
20. Turok DK, **Godfrey EM,** Wojdyla D, Dermish A, Torres L, Wu SC. Copper T380 intrauterine device for emergency contraception: highly effective at any time in the menstrual cycle. *Hum Reprod* 2013 28(10): p. 2672-6. PMID: 23945595.
21. **Godfrey EM**, Folger SG, Jeng G, Jamieson DJ, Curtis KM. Treatment of bleeding irregularities in women with copper-containing IUDs: A systematic review. *Contraception* 2013 87 (5): 549-566. PMID: 23199413.
22. Rodriguez MI, **Godfrey EM**, Warden M, Curtis KM. Prevention and management of nausea and vomiting with emergency contraception: A systematic review. *Contraception* 2013 87 (5): 583-589. PMID: 23121827.
23. **Godfrey EM**, Whiteman MK, Curtis KM. Treatment of unscheduled bleeding in women using extended or continuous use combined hormonal contraception: A systematic review. *Contraception* 2013 87 (5): 567-575. PMID: 23044386.
24. Callegari LS, Darney BG, **Godfrey EM**, Sementi O, Dunsmoor-Su R, Prager SW, Evidence-Based Selection of Candidates for the Levonorgestrel Intrauterine Device (IUD). *J Am Board Fam Med*, 2014. 27(1): p. 26-33. PMID: 24390883.
25. **Godfrey EM**, Tepper NK, Curtis KM, Moskosky S, Gavin L. Developing Federal recommendations for providing quality family planning services: Clinical services for women. *Am J Prev Med.* 2015;49 (2S1):S6-S13. PMID: 26190848.
26. Wu JP, **Godfrey EM**, Prine L, Anderson KL, MacNaughton H, Gold M. Women's Satisfaction with Abortion care in academic family medicine centers. *Fam Med*. 2015 Feb;47 (2):98-106. PMID: 25646981.
27. **Godfrey EM**. Helping clinicians prevent pregnancy among sexually active adolescents: U.S. Medical Eligibility Criteria for Contraceptive Use and U.S. Selected Practice Recommendations

for Contraceptive Use. *J Pediatr Adolesc Gynecol*. 2015;28: 209-214. PMID: 26026219. Selected as the August 2015 most highlighted journal article.

28. **Godfrey EM**, Zapata LB, Cox CM, Curtis KM, Marchbanks PA. Unintended pregnancy risk and contraceptive use among women 45-50 years old: Massachusetts, 2006, 2008, and 2010. *Am. J. Obstet. Gynecol.* Jun 2016;214(6):712 e711-718. PMID: 26694134.
29. Hoopes A, Simmons KB, **Godfrey EM**, Sucato G. 2016 updates to US Medical Eligibility Criteria for Contraceptive Use and Selected Practice Recommendations for Contraceptive Use: Highlights for adolescent patients, *J. Pediatr. Adolesc. Gynecol.* Apr 2017; 30(2):149-155. PMID: 28167141.
30. Heltshe S, **Godfrey EM,** Josephy T, Aitken ML, Taylor-Cousar JL. Pregnancy Incidence among cystic fibrosis women in the era of CFTR modulators, *J. of Cyst. Fibros*. Nov 2017; 16(6):687-694. PMID: 28190780.
31. Amico JR, Cheng TL, **Godfrey EM**. Providing Abortion Services in the Primary Care Setting. In Primary Care Clinic Office Practice, *Primary Care* Dec 2018; 45(4):599-605. PMID: 30401344.
32. Torres LN, Turok DK, Clark EAS, Sanders J, **Godfrey EM**. Increasing intrauterine device and implant use among those at risk of a subsequent preterm birth: A randomized, controlled trial of postpartum contraceptive counseling, *Women's Health Issues*, 28 (5): 393-400, 2018. PMID: 30227936.
33. Gilmore K, Ojanen-Goldsmith A, Callegari LS, **Godfrey EM**. The first 6 months: developing a user-informed anticipatory counselling video about the levonorgestrel intrauterine system, *BMJ Sexual & Reproductive Health* Oct 2018; 44:233-234. PMID: 29934403.
34. Tepper NK, **Godfrey EM**, Folger SG, Whiteman MK, Marchbanks PA, Curtis KM. Hormonal contraceptive use among women of older reproductive age: considering risks and benefits, *J Women's Health.*2018; 27(4):413-17, PMID: 29634450.
35. **Godfrey EM**, West II, Holmes J, Keppel GA, Baldwin LM. Use of an electronic health record data sharing system for identifying current contraceptive use within the WWAMI region Practice and Research Network, *Contraception* Dec 2018; 98(6): 476-481, PMID: 29936151.
36. Zhang Y, McCoy EE, Scego R, Phillips W, **Godfrey EM**. A qualitative exploration of Somali refugee women's experiences with family planning in the U.S., *J. Immigr Minor Health.* 2019; 2020 Feb;22(1):66-73, PMID: 30941615.
37. **Godfrey EM**, Mody S, Schwartz M, Taylor-Cousar J, Jain R, Heltshe S, Sufian S, Josephy T, Aitken ML. Contraceptive use among women with cystic fibrosis: A pilot study linking reproductive health questions to the Cystic Fibrosis foundation National Patient Registry, *Contraception* Jun 2020; 101(6): 420-426. PMID: 32109430.
38. **Godfrey EM**, Kazmerski TM, Brown, G, Thayer EK, Mentch L, Pam M, Al Achkar M. Educational needs and preferences for patient-centered outcomes research in the cystic fibrosis community: Mixed-methods study, *JMIR Form Res 2021;5(3) e24302*. PMID: 33661127.
39. Thayer EK, Pam M, Al Achkar M, Mentch L, Brown G, Kazmerski TM, **Godfrey EM**∞. Best practices for virtual engagement of patient-centered outcomes research teams during and after the COVID-19 pandemic: Qualitative Study, *J Particip Med* 2021;13(1) e24966. PMID: 33646964.
40. Nguyen VP, Lindley AR, Mansoori B, **Godfrey EM**∞. Phleboliths mistaken for intraperitoneal TCu380A IUD in the presence of missing strings: A case report. *BMJ Case Reports* 2021; 14:e237838. PMID: 33753376.
41. **Godfrey EM**, Fiastro AE, Jacob-Files EA, Coeytaux FM, Wells ES, Ruben MR, Sanan SS, Bennett IM. Factors associated with successful implementation of telehealth abortion in four United States clinical practice settings. *Contraceptio*n Jul 2021; 104(1):82-91. PMID: 33932401.

42. **Godfrey EM**, Thayer EK, Fiastro A, Aiken ARA, Gomperts R. Family medicine provision of online medication abortion in three states during COVID-19. *Contraception* Jul 2021; 104(1):54-60. PMID: 33939985.
43. McClintock AH, Nguyen A, Tan N, **Godfrey EM**. Faith-Based and Federal Government-Affiliated Training Sites for Primary Care: Implications for the provision of women's health services. *J Gen Intern Med.* May 5, 2021, PMID: 33954885.
44. **Godfrey EM,** Thayer EK, Mentch L, Brown G, Pam M, Kazmerski TM, Al Achkar A. Development and evaluation of a virtual patient-centered outcomes research training program for the cystic fibrosis community. *Res Involv Engagem*,7,86. Dec 4 2021. https://doi.org/10.1186/s40900-021-00328-4.
45. Josephy T, Loeffler DR, Pam M, **Godfrey EM**. A model for building a national contraceptive registry for women with complex medical conditions. *J Amer Med Informatics Assoc*, Jan 2022; 29(2):348-353, PMID: 34679174.
46. Josephy T, Sanan S, Thayer E, **Godfrey EM**∞. Comparison of completeness and timeliness of paper, text and smartphone app bleeding diaries. *Matern Child Hlth J*, Jan 23 2022. Doi: 10.1007/s10995-021-03362-6.
47. Stransky O, Pam M, Ladores S, Birru Talabi M, Borrero S, **Godfrey E**, Roe A, Sawicki G, Zuckerwise L, Mentch L, Deal A, O'Leary R, Taylor-Cousar J, Jain R, Kazmerski T. Engaging stakeholders in the development of a reproductive goals decision aid for women with cystic fibrosis. *J Patient Exp*, 9 Feb 2022. Doi: 10.1177/23743735221077527.
48. Fiastro A, Sanan S, Jacob-Files E, Wells E, Coeytaux F, Ruben M, Bennett IM, **Godfrey EM**. Remote delivery of reproductive healthcare: a case study using telehealth medication abortion services operating in diverse healthcare. *Ann Fam Med*, Jul 2022; 20(4):336-42. DOI: https://doi.org/10.1370/afm.2821.
49. Kazmerski TM, Stransky OM, Lavage D, Taylor-Cousar JL, Sawicki GS, Ladores SL, **Godfrey EM**, Aitken ML, Fields A, Sufian S, Jain M, Barto TL, Billings J, Hadjiliadis D, Jain R. Sexual and reproductive health experiences and care of adult women with cystic fibrosis. *J Cyst Fibros*, Oct 2022. DOI: https://doi.org/10.1016/j.jcf.2022.09.013
50. Miller M, Lindley A, West J, Thayer EK, **Godfrey EM**∞. Lower use of academic affiliation by university faculty who study abortion in top U.S. newspapers. *J Commun Healthc* DOI: 10.1080/17538068.2022.2150166
51. Lindley A, **Godfrey EM**, McClintock AH. Supporting Women in Academia: A Dyad Mentorship Model. Medical Education (in press Feb 2023).

b) Collaborative Authorship

1. U.S. Selected Practice Recommendations for Contraceptive Use, 2013: adapted from the World Health Organization selected practice recommendations for contraceptive use, 2nd edition. (**EM Godfrey** CDC presenter and author) *MMWR Recomm Rep*, 2013. 62 (RR-05): p. 1-60.
2. Gavin L, Moskosky S, Carter M, Curtis K, Glass E, **Godfrey EM**, Marcell A, Mautone-Smith N, Pazol K, Tepper N, Zapata L. Providing Family Planning Services: Recommendations of CDC and U.S. Office of Population Affairs. *MMWR Recomm Rep*. 2014 Apr 25;63 (RR-04):1-54. PMID: 24759690.
3. NEJM Knowledge+ Family Medicine Board Review. Authored 9 questions with other UW DFM faculty in Obstetrics Management for comprehensive lifelong learning product from NEJM Group, 2015 (available at: http://knowledgeplus.nejm.org/our-products/family-medicine-board-review/).
4. World Health Organization. Brief Sexuality-Related Communication: Recommendations for a public health approach. (**EM Godfrey**, Guideline Development Group Member) 2015 (available at: http://www.who.int/reproductivehealth/publications/sexual_health/sexuality-related-communication/en/).

c) Peer-reviewed Curricula

1. **Godfrey EM,** Lossy P, Leeman L. New approaches for management of 1st trimester pregnancy complications in the Family Medicine residency setting. Family Medicine Digital Resources Library; 2006. Available from: http://www.fmdrl.org/630.
2. **Godfrey EM**, Devens M. Options counseling for precepting faculty slide presentation. Family Medicine Digital Resources Library; 2008. Available from: http://www.fmdrl.org/1787.
3. **Godfrey EM.** Resource list for implementing a basic course in early obstetrical ultrasound in the Family Medicine residency program. Family Medicine Digital Resources Library; 2008. Available from: http://www.fmdrl.org/1841.

d) Book Chapters

1. Leeman L, **Godfrey EM.** Pregnancy Termination: First Trimester Suction Aspiration. In *Pfenninger and Fowler's Procedures for Primary Care*, 3rd Edition, Ed. JL Pfenninger, GC Fowler. Philadelpia: Elsevier, 2011.
2. **Godfrey EM**, Kottke M. Contraception: Oral Contraception. In *Practical Pediatric and Adolescent Gynecology*, 1st Ed. PJ Adams Hillard. Oxford:Wiley-Blackwell, 2013.
3. **Godfrey EM**, Dehlendorf C. Integrating sexual and reproductive healthcare training into family medicine. In *Medical Education in Sexual and Reproductive Health: A systems approach in family planning and abortion*, 1st Ed. U Landy, PD Darney and J Steinauer eds. Cambridge University Press, 2021.

e) Published Books, Videos, Software

1. **Godfrey EM**, Gilmore K, Callegari L. Hormonal IUD Anticipatory Guidance Video. University of Washington, May 2017.
2. Fiastro A, Wells E, Coeytaux F, **Godfrey E**. ACCESS, DELIVERED: A Toolkit for Providers Offering Medication Abortion. University of Washington ResearchWorks. https://doi.org/10.6069/gad7-z583. Published 2021. Impact: highlighted in Ms. Magazine How Telemedicine Startups Are Revolutionizing Abortion Health Care in the U.S., November 16, 2020.
3. **Godfrey EM**, Pam M, Rattiliff B, Ruben M, Al Achkar M, & Training Manual Community Advisory Board. Patient-Centered Outcomes Research Training Manual: Helping researchers initiate and maintain patient-engaged research teams (Cystic Fibrosis case study). University of Washington Department of Family Medicine, 2021. https://doi.org/10.6069/Y2BV-YW94.
4. **Godfrey EM,** Al Achkar, M., Thayer, E., Ruben, M., Rattiliff, B., Pam, M., Mentch, L., Brown, G., & Kazmerski, T. Workspace for Online Patient Engagement in Research. University of Washington Department of Family Medicine, 2022. https://doi.org/10.6069/VGZR-6N29.

f) Other Publications

1. **Godfrey EM,** Schaff EA. 200 mg mifepristone plus gemeprost was as effective as 600 mg for termination of pregnancy at 57-63 days gestation (commentary). *Evidence-based Obstet Gynecol*. 2003;3 (4):196-97.
2. **Godfrey EM,** Stanwood NL. Termination of early pregnancy with vaginal misoprostol alone is not as effective as with mifepristone plus misoprostol (commentary). *Evidence-based Obstet Gynecol.* 2005;5 (1):18-19.
3. Shulman LP, Bateman LH, Creinin MD, Cullins VE, Doyle LL, **Godfrey E**, Murphy P, Rodriguez P, Spear SJ, Steward FH, Thomas MA, Westhoff CL, Worthington S. Surrogate markers, emboldened and boxed warnings, and an expanding culture of misinformation: Evidence-based clinical science should guide FDA decision making about product labeling (editorial). *Contraception*. 2006;73 (5):440-42.
4. **Godfrey EM,** Schaff EA. Low-dose mifepristone and two regimens of levonorgestrel for emergency contraception: A WHO multicentre randomised trial, and randomized double-blind comparison of two single

doses of mifepristone for emergency contraception (commentary). *Evidence-based Obstet Gynecol.* 2006;6 (1):24-26.

5. **Godfrey EM,** Spear SJ. Issues with the patch: Addressing the risks vs. benefits. (review) *Female Patient.* 2007; 32(Nov).
6. **Godfrey EM**. Chicago protects infants by banning BPA (letter). Chicago Tribune, May 28, 2009. Accessed at http://www.chicagotribune.com/news/opinion/letters/chi-090528godfrey_briefs,0,6633295.story.
7. Jordan B, **Godfrey EM**, Espey E. Improving patient care and reducing unintended pregnancy: Translating new guidelines into effective practice. (editorial) *Contraception*. 2010; 82 (1):1-2.
8. **Godfrey EM**. Parental notification is harmful to girls (letter). Chicago Tribune, May 14, 2010. Accessed at http://www.chicagotribune.com/news/opinion/letters/chi-100514godfrey_briefs,0,7756596.story.
9. **Godfrey EM**. Strategies to expand contraception coverage: another tool in the box. (commentary) *Contraception*. 2011; 84(4):339-341.
10. Folger SG, Jamieson D, **Godfrey EM,** Zapata LB, Curtis KM. Evidence-based guidance on selected practice recommendations: Identification of research gaps. (commentary) *Contraception* 2013;87(5): 517-523.
11. Sufian S, Mentch L and **Godfrey EM**. Women with CF are Helping Guide Reproductive and Sexual Health Research. *CF Roundtable: A newsletter for adults who have Cystic Fibrosis*, Summer 2017; 27(3): 16-17, 28.
12. Harper D, **Godfrey EM**. Optimizing Women's Health in Primary Care Preface. *Primary Care* Dec 2018; 45(4):VIII-IX.
13. Mentch L, Pam M, **Godfrey E**. Patient-Centered Outcomes Research: A new approach for the CF community. *CF Roundtable: A newsletter for adults who have Cystic Fibrosis*, Summer 2020.
14. Agarwal M, Lindley A, **Godfrey E**. The Trump Administration is systematically undermining women's reproductive rights. Kevin MD Blog-Post, September 14, 2020.
15. **Godfrey E**. Abortion is a health care issue, not a legal one—Allow pills by mail. The Seattle Times Op-Ed, May 25, 2021.
16. **Godfrey EM**. Yes, its easier to get birth control than it was in the 1970s - but women still need abortion care. The Conversation, January 18, 2022.
17. Riley T, Zia Y**, Godfrey E**. Our bodily autonomy is a human right, abortion is essential healthcare. The Seattle Times Op-Ed, May 10, 2022.
18. **Godfrey EM**, McClintock A. How primary care is poised to support reproductive health and abortion in the post-Roe era. The Conversation, August 11, 2022.

g) Manuscripts Submitted

1. **Godfrey EM**, Schwartz MR, Hinckley-Stukovsky KD, Woodward D, Magaret AS, Aitken ML. Electronic survey piloting process as a model for developing and testing past contraceptive use and pregnancy history: Cystic fibrosis case study. Submitted to *JMIR Formative Research* (Feb 9, 2023).
2. Riley T, **Godfrey EM,** Angelini E, Zia Y, Balkus JE. Demand for medication abortion among public university students in Washington. Submitted to *J. Coll Health* (Jan, 2023).
3. **Godfrey EM**, Fiastro AE, Ruben MR, Young, EV, Bennett IM, Jacob-Files E. Patient perspectives regarding provider communication during telemedicine versus in-clinic abortion. Resubmitted to *Obstet Gynecol* (Feb 16, 2023).
4. Fiastro AE**,** Zheng Z, Ruben MR, Gipson J, **Godfrey EM**. Patient characteristics associated with receiving telehealth versus in-clinic medication abortion services from a high-volume reproductive health clinic. Resubmitted to *JAMA Open*, Feb 15 2023.
5. Fiastro AE**,** Young EV, Jacob-Files E, Ruben MR, Coeytaux FM, Bennett IM, **Godfrey EM**. Advanced provision of medication for induced abortion: A qualitative study of patient perspectives. Submitted to *Contraception* on Dec 9, 2022.

6. Sufian S, Mueller R, Ruben MR, Brown G, Schwind EL, Walker P, Mody S, Caldwell K, **Godfrey EM**. Understanding the complex embodiment of women with chronic illness: the case of cystic fibrosis. Submitted to *Sociology and Health* on Jan 29, 2023.

h) Published Abstracts (last 5 years)

1. **Godfrey EM**, Gilmore KC, Benson L. A novel anticipatory counseling video for new levonorgestrel intrauterine system (LNG-IUS) uses: a multicenter randomized controlled pilot study. Poster presented at the 2017 North American Forum for Family Planning. *Contraception.* 2017;96(4):280.
2. Kazmerski TM, Josephy T, Sufian S, Gilmore KC, Jain R, Ladores SL, Mody S, Heltshe S, **Godfrey EM.** Advancing comprehensive care through the interdisciplinary cystic fibrosis reproductive and sexual health collaborative. *Pediatr Pulmonol*. 2017;52(47): S481.
3. Kazmerski TM, Ladores SL, Jain R, Mody S, Pam M, Brown G, Sufian S, Mentch L, Berhalter-Tumiel L, Gilmore KC, **Godfrey EM**. The Cystic Fibrosis Reproductive & Sexual Health Collaborative: Next steps in building a sustainable partnership. *Pediatr Pulmonol*. Sep 2018;53: 412-412.
4. **Godfrey EM,** Mody S, Gilmore KC, Schwartz M, Taylor-Cousar JL, Jain R, Aitken ML, Heltshe S, Sufian S. Contraception, pregnancy and modulator use among reproductive-aged women with cystic fibrosis. *Pediatr Pulmonol*. Sep 2018;53: 420-420.
5. **Godfrey EM,** Kazmerski TM, Thayer E, Brown G, Mentch L, Pam M, Al-Achkar M. Determining the needs and content of a patient-centered outcomes research training program for the cystic fibrosis community. *Pediatr Pulmonol*. Sep 2019; 54(S2):462.
6. **Godfrey EM**, Thayer E, Mentch L, Al-Achkar M, Kazmerski TM, Brown G, Pam M. Developing an effective training program to build patient-centered outcomes research (PCOR) capacity within the cystic fibrosis community. *Pediatr Pulmonol*. Sep 2019; 54(S2):209.
7. **Godfrey EM**, Schwartz M, Thayer E, Woodward D, Stukovsky KH, Aitken ML. Collecting contraceptive history among women with cystic fibrosis: Pilot testing survey questions. *Pediatr Pulmonol*. Oct 2020 vol 55(S2):S329.
8. Kazmerski TM, Stransky OM, Taylor-Cousar JL, Sawicki GS, Ladores SL, **Godfrey EM**, Aitken ML, Sufian S, Jain M, Barto TL, Billins J, Hadjiliadis D, Jain R. Sexual and reproductive health care utilization and preferences of adult women with cystic fibrosis. *Pediatr Pulmonol*. Oct 2020; 55 S95.
9. Kazmerski TM, Stransky OM, Taylor-Cousar JL, Sawicki GS, Ladores SL, Godfrey EM, Aitken ML, Sufian S, Jain M, Barto TL, Billings J, Hadjiliadis D, Jain R. Sexual and reproductive health behaviors and experiences of adult women with cystic fibrosis. *Pediatr Pulmonol*. Oct 2020; 55:S91.
10. Nguyen AN, Tan N, **Godfrey E**, McClintock AH. Faith-based and federal government-affiliated training sites for primary care: Implications for Women's health services. *J Investig Med*. Jan 2021; 69(1):244.
11. Ruben M, **Godfrey E**, Rattiliff B, Brown G, Caldwell K, Mody S, Langfelder-Schwind E, Walker P, Sufian S. Factors contributing to success retention of people with cystic fibrosis in a 3-month daily symptom-tracking study. *J Cyst Fibros* 21S2 (2022): S18**.**
12. Mody S, Sufian S, Ruben M, Caldwell K, Walter P, Langfelder-Schwind E, Brown G, **Godfrey E**. Feasibility of using a modified menstrual tracking app to correlate menstrual cycles and cystic fibrosis symptoms in women with CF: Early findings of the MENSTRUAL study**.** *J Cyst Fibros* 21S2 (2022): S14**.**
13. **Godfrey EM**, Fiastro A, Ruben M, Young E, Bennett IM, Jacob-Files E. Determining best communication practices in telemedicine abortion care: Qualitative study of patient perspectives. *Ann Fam Med*. Jan 2023, 21 (Supp 1) 4114. DOI: https://doi.org/10.1370/afm.21.s1.4114

18. Invited Lectures

Invited National and International Lectures

2001 "Medical abortion: Indications for use." 8th Annual Medical Students for Choice National Meeting, April, Chicago, IL

2002 "Medical abortion." 9th Annual Medical Students for Choice National Meeting, April, San Jose, CA

2002 "Treatment of spontaneous abortion with misoprostol." Annual Meeting of the Nicaraguan Society of Obstetricians and Gynecologists, July, Managua, Nicaragua.

2002 "The uses of medications in spontaneous abortion: Misoprostol." International Family Planning Leadership Program at the University of California, San Francisco Center for Reproductive Health and Policy, September, San Francisco, CA

2004 "Advanced gynecological procedures." 32nd Annual Conference of the American Association of Physician Assistants, June, Las Vegas, NV.

2005 "Update on intrauterine contraception: Lecture and workshop." 17th Annual Meeting of Contraceptive Technology, April, Washington DC

2005 **"**Manual vacuum aspiration workshop." Planned Parenthood Federation of America, June, Philadelphia, PA.

2005 "IUD insertion workshop." Contraceptive Technology: Quest for Excellence, October, Atlanta, GA.

2005 **Plenary talk** "Menstrual suppression and flexible contraceptive options." Contraceptive Technology: Quest for Excellence, October, Atlanta, GA.

2006 "Manual vacuum aspiration workshop." Nurse Practitioner Meeting of the Planned Parenthood Federation of America, February, Philadelphia, PA.

2006 "Medical Students for Choice provider panel." Annual Meeting of the American Medical Students Association National Conference, April, Chicago, IL.

2006 "Options for managing early pregnancy loss: Focus on manual vacuum aspiration workshop." Annual Meeting of the Association of Reproductive Health Professionals, September, La Jolla, CA.

2007 "Management of early pregnancy failure in the outpatient or emergency department setting." Association of Reproductive Health Professionals National Webinar Series, April 11 and July 11

2008 "Options for therapeutic abortion: Manual vacuum aspiration and medication management." Association of Reproductive Health Professionals National Webinar Series, March 12.

2008 **Presenter and Panelist**, Junior faculty career development and research panel. Association of Reproductive Health Professionals 45th Annual Conference, Washington DC.

2008 **Presenter and Panelist**, Psychosocial components of complication management. Panel Discussion for the 2nd Annual Psychosocial Conference for the Fellowship in Family Planning. San Francisco, CA.

2010 "Medical management of early pregnancy loss." Association of Reproductive Health Professionals National Webinar Series, January 11.

2010 "Medical management of early pregnancy loss." Annual Conference of the Association of Reproductive Health Professionals/Society of Family Planning, September, Atlanta, GA.

2010 **Presenter and Panelist**, "How Research Guides Clinical Practice." Annual Conference of the Association of Reproductive Health Professionals/Society of Family Planning, September, Atlanta, GA.

2011 "The United States Medical Eligibility Criteria and World-wide Updates for Contraception Use in Adolescents." 25th Annual Meeting of the North American Society for Pediatric and Adolescent Gynecology, April, Chicago, IL

2011 "Contraceptive Update: CDC Medical Eligibility Criteria for Women with Certain Characteristics and Medical Conditions." Association of Reproductive Health Professionals National Webinar Series, May.

2011 **Presenter and Panelist**, "The Impact of Chronic Medical conditions on Reproductive Health Module." 48th Annual Conference of the Association of Reproductive Health Professionals, September, Las Vegas, NV.

2011 **Presenter and Panelist,** "Contraceptives for Women with Chronic Conditions: A panel presentation." North American Forum on Family Planning, October, Washington, DC.
2011 "Contraception Updates from the CDC." Contraceptive Technology: Quest for Excellence, November, Atlanta, GA.
2011 "Using Society of Family Planning and Centers for Disease Control and Prevention Guidelines to Improve Patient Care." Medical Students for Choice Annual Meeting, November, Baltimore, MD.
2012 "The New U.S. Selected Practice Recommendations: Practical Applications for Contraceptive Management." Contraceptive Technology Annual Conferences, March, San Francisco, CA and Boston, MA.
2012 "Male Patients in the Family Planning Clinic: Clinical Cases." Contraceptive Technology Annual Conferences, March, San Francisco, CA and Boston, MA.
2013 "Update on the New U.S. Selected Practice Recommendations." Contraceptive Technology Annual Conference, March, San Francisco, CA.
2013 "Contraceptive cases utilizing the new U.S. Selected Practice Recommendations for Contraceptive Use." Contraceptive Technology Annual Conference, March, San Francisco, CA.
2014 **Plenary**, "Highlights of the U.S. Selected Practice Recommendations (SPR)." Contraceptive Technology Annual Conference, March/April. San Francisco, CA and Boston, MA.
2014 "Utilizing the New U.S. Selected Practice Recommendations for Contraceptive Management: Interesting cases." Contraceptive Technology Annual Conference, San Francisco, CA and Boston, MA.
2016 "Evidence-based Family Planning Care: Incorporating National Guidelines into Your Practice." Contraceptive Technology Annual Conference, March/April. San Francisco CA and Boston, MA.
2017 **Feature Presentation**, "Just Out! The updated 2016 contraceptive guidelines from the Centers for Disease Control and Prevention." Society of Adolescent Health and Medicine National Conference, March. New Orleans, LA.
2018 **"**Vision and Persistence: A clinician's journey to patient engaged research, Northern New England Clinical & Translational Research Network (NNE-CTR), June 10, Portland, ME.
2019 Creating a relationship with your women's healthcare provider. Cystic Fibrosis Reproductive and Sexual Health Collaborative (VIRTUAL).
2020 Contraceptive care for patients with cystic fibrosis. Cystic Fibrosis Reproductive and Sexual Health Collaborative (VIRTUAL).
2020 **Presenter and Panelist, "**Virtual Engagement. Presented with patient-partner at the June 24 PCORI Engagement Award Lunch and Learn**.**
2020 "Contraception in the era of CFTR modulators." Presented with clinician- and patient- partners at the July 22 CFRI Townhall.
2020 **Keynote Speaker**, "Best Practices for Virtual PCOR Engagement." NAPCRG Patient and Clinician Engagement (PaCE) Preconference, November 19.
2020 **Presenter and Panelist,** "Access, Delivered Project" through the Introduction to the Changing Landscape of Medication Abortion. at Reproductive Health Access Project (RHAP)-sponsored event. (virtual event), October and December.
2021 **Presenter,** "CF Symptoms and the Menstrual Cycle." North American Cystic Fibrosis Conference Hot Topics and Trends in Clinical Research (virtual event), November 5
2021 **Presenter and Panelist, "**Navigating PCORI as a Family Planning Researcher." Society of Family Planning (virtual event), November 9.
2022 **Presenter and Panelist, "**Better Health NOW**:** Online Public Launch of Primary Care Collaborative to address health inequities and lack of access to whole-person care." Primary Care Collaborative (virtual event), March 29.
2022 **Presenter and Panelist,** "World Contraception Day Webinar" Upstream USA (virtual event), September 26.

2022 **Presenter and Panelist,** "NAPCRG Diamonds – Patient and Clinician Session" 2022 NAPCRG Annual Conference, Phoenix AZ, Nov. 22.

Invited Regional Lectures

2002 **Grand Rounds**, University of Wisconsin-Madison Dept. of Family Medicine "Medical abortion regimens." July, Madison, WI.

2002 **Grand Rounds**, Medical College of Ohio Dept. of Obstetrics and Gynecology. "Medical abortion basics." December, Toledo, OH.

2003 **Grand Rounds**, Stroger Hospital of Cook County Dept. of Obstetrics and Gynecology "Medical abortion basics." June, Chicago, IL.

2004 "Update on intrauterine contraception." Workshop presented at the Nurse Practitioner Regional Conference, September, Chicago, IL.

2004 **Grand Rounds**, Swedish American Hospital Dept. of Obstetrics and Gynecology, "Update on intrauterine contraceptive methods." December, Rockford, IL.

2005 **Grand Rounds**, Illinois Masonic Medical Center Medical abortion from the primary care perspective. Grand Rounds lecture presented to the Department of Family Medicine, , Chicago, IL.

2005 "Update on intrauterine contraception." Workshop presented to the Knoxville Public Health Department, Knoxville, TN.

2005 "Manual vacuum aspiration: Practicing with papayas." Workshop presented to public health students, Abortion Access Project National Meeting, Chicago, IL.

2005 **Grand Rounds**, "Manual vacuum aspiration". Grand Rounds lecture presented to the Department of Obstetrics and Gynecology, Stroger Hospital of Cook County, Chicago, IL.

2006 **Grand Rounds**, Menstrual suppression and flexible contraceptive options. Grand Rounds lecture presented to the Department of Family Medicine, University of New Mexico, Albuquerque, NM.

2006 **Grand Rounds**, Update on intrauterine contraception: How the OB/GYN can play a role. Grand Rounds lecture presented to the Department of Obstetrics and Gynecology, Rush Medical College, Chicago, IL.

2006 "Medical abortion from a public health perspective." Lecture presented to medical students, Northwestern University Medical Students for Choice and American Medical Student Association, Chicago, IL.

2007 **Panelist**, "Abortion providers: Safety panel". Roundtable presented at the 1st Annual Meeting of the Psychosocial Conference for the Fellowship in Family Planning. San Francisco, CA.

2007 "Intrauterine device skills seminar". Workshop, tutorial and patient training presented for Region V Title X Nurse Practice Clinicians Meeting, South Bend, IN.

2007 **Grand Rounds,** "Cases in contraception." Grand Rounds lecture presented to the Department of Family Medicine, UIC-Rockford, Rockford, IL.

2009 **Presenter and Panelist**, "The Gaping Hole in the Closing Gap: Women in Academic Medicine." American Medical Women's Association Region 6 Conference and Research Symposium, Chicago, IL.

2010 "Providing in non-urban settings." Lecture-Discussion presented at Midwest Region 5 Medical Students for Choice Conference, Chicago, IL.

2010 "Office-based miscarriage management." Midwest Access Project Reproductive Health Seminar Series for Family Medicine Physicians, Chicago, IL.

2013 "Combined Hormonal Contraceptives and Perimenopause: Management Strategies for a Smoother Transition." University of Washington Department of Obstetrics and Gynecology Women's Health Care Update CME Course, Seattle, WA.

2013 "Adolescent Women's Healthcare: STIs, contraception and pregnancy." Washington Academy of Family Physicians 64th Annual Scientific Assembly, Cle Elum, WA.

2013 "Contraceptive Updates and Recommendations." University of Washington Maternal Child Health Public Health Webinar, Seattle, WA.

2013 "Reproductive Sexual Health (STDs, Contraception and Unplanned Pregnancy): Using clinical cases and guideline tools." University of Washington Department of Family Medicine 41st Annual Advances in Family Practice and Primary Care CME Course, Seattle, WA.

2013 "Venous Thromboembolism: Is there a risk with progestins?" Advance Practice in Primary and Acute Care 36th Annual CME Course, Seattle, WA.

2013 "Contraception for Women with Medical Conditions". University of Washington Department of Family Medicine 41st Annual Advances in Family Practice and Primary Care CME Course, Seattle, WA.

2013 "Contraceptive Updates and Recommendations from the CDC." Planned Parenthood Great Northwest Clinical Advisory Meeting, Seattle, WA.

2014 "Contraceptive-Antiretroviral Drug Interactions: Issues to consider when prescribing contraceptives to HIV+ patients." Northwest AIDS Education and Training Center Clinical Update, Seattle, WA.

2014 "Complex Contraceptive Cases: Guidance from the CDC". University of Washington Department of Family Medicine 42nd Annual Advances in Family Practice and Primary Care CME Course, Seattle, WA.

2015 "Complex Contraception: Using National Guidance to Find Answers." University of Washington Department of Family Medicine 43rd Annual Advances in Family Practice and Primary Care CME Course, Seattle, WA.

2015 "Contraceptive Dilemmas: Finding Solutions Using the US Medical Eligibility Criteria and Selected Practice Recommendations." Advanced Practice in Primary and Acute Care 38th Annual CME Course, Seattle, WA.

2016 "How well are contraceptive guidelines followed?" WWAMI-region Practice and Research Network Annual Meeting, Seattle, WA.

2016 "Updates on the United States Medical Eligibility Criteria for Contraceptive Use and the Selected Practice Recommendations for Contraceptive Use." Advanced Practice in Primary and Acute Care 39th Annual CME Course, Seattle, WA.

2017 "Treatment of Menopausal Symptoms." Current Concepts in Drug Therapy CME Course, University of Washington Department of Medicine, Seattle, WA.

2017 "Treatment of Menopausal Symptoms." University of Washington Department of Family Medicine 45th Annual Advances in Family Practice and Primary Care CME Course, Seattle, WA.

2017 "Demystifying contraception for the medically complex patient." Advanced Practice in Primary and Acute Care 40th Annual CME Course, Seattle, WA.

2018 "What to expect when you don't want to expect: Development of anticipatory counseling video for hormone IUD users." UW Friday Harbor Lab, Friday Harbor, WA.

2018 "Advances in Contraception: Uses in Young Women and Perimenopausal Women." Advanced Practice in Primary and Acute Care 41st Annual CME Course, Seattle, WA.

2020 **Presenter and Panelist**, "Engaging our communities in research." Pacific Northwest Family Planning Symposium, Honolulu, HI.

2020 "Contraception across the gender spectrum." Advanced Practice in Primary and Acute Care 43rd Annual CME Course, (VIRTUAL).

2021 "Depo-medroxyprogesterone acetate (DMPA) and Bone Health" University of New Mexico Dept. of Obstetrics and Gynecology ECHO Project, Jan. 11 (VIRTUAL).

2021 "Access, Delivered: A toolkit for providers to implement telehealth medication abortion services." UW WWAMI Region Practice-based Research Network Annual Conference, New Investigator Session Mar. 4 (VIRTUAL).

2022 **Presenter and Panelist** "Family medicine and medication abortion." King County Academy of Family Physicians, Nov. 3 (VIRTUAL).

Invited Local Lectures

2004 "Clinical update on the copper T IUD." University of Chicago Obstetrics and Gynecology Residency, November, Chicago, IL.

2006 "Flexible contraceptive options." Lecture presented to Obstetrics and Gynecology residents, University of Chicago, Chicago, IL.

2008 "Public health importance of family planning." Lecture presented to 1st and 2nd year medical students for the Family Planning Elective. University of Chicago Pritzker School of Medicine, Chicago, IL.

2008 "Long-term progestin contraceptive methods." Workshop lecture presented to residents in the Department of Obstetric and Gynecology, Loyola University of Chicago, Chicago, IL.

2010 **Grand Rounds**, University of Illinois at Chicago Dept. of Family Medicine. "The United States CDC Medical Eligibility Criteria for Women with Medical Conditions." Chicago, IL.

2010 "Physician decision making regarding morally/bioethically controversial procedures." Northwestern University Medical School Profession of Medicine course for 2nd year medical students, Chicago, IL.

2010 "Understanding the US Medical Eligibility Criteria for Women with Medical Conditions from a Public Health Perspective." Emory University School of Public Health, Atlanta, GA.

2011 "Using the US Medical Eligibility Criteria for Contraception Use for Women with Medical Conditions." Emory University School of Medicine, Department of Gynecology and Obstetrics Family Planning lecture series, Atlanta, GA.

2011 "Understanding the US Medical Eligibility Criteria for Women with Medical Conditions from a Public Health Perspective." Emory University School of Public Health, Atlanta, GA.

2011 **Grand Rounds**, Emory University School of Medicine, Dept of Gynecology and Obstetrics, "Updates from the CDC: Translating Research to Practice for Contraceptive Use." Atlanta, GA.

2012 "Contraception: Using U.S.-based Guidelines to Help Prevent Unplanned Pregnancy." Emergency Medicine Resident Lecture. Veterans Administration Hospital, Atlanta, GA.

2012 "Contraception Basics for Internal Medicine." Internal Medicine Resident Lecture. Veterans Administration Hospital, Atlanta, GA.

2013 "Breaking Bad News: Fetal Anomalies and Fetal Demise." University of Washington Department of Radiology Fellowship Seminar, Seattle, WA.

2014 "CDC Family Planning Guidance." UW Center for Research in Reproduction and Contraception, Seattle, WA.

2015 "Anticipatory Counseling on LNG IUS Continuation, Utilization and Satisfaction ACCCUSS Study." University of Washington Department of Obstetrics and Gynecology Faculty Research Seminar, Seattle, WA.

2015 "Developing quality, evidence-based family planning tools and guidelines." University of Washington Department of Global Health spring course GH 490/590,

Seattle, WA.

2015 "Hormonal and non-hormonal Contraceptive Lecture", University of Washington MEDEX Program, Seattle WA.

2017 "Zika: CDC Emergency Relief Efforts in Puerto Rico and what the Seattle family physician needs to know," UW Department of Family Medicine Grand Rounds, Seattle, WA.

2017 "Zika and women of reproductive age-mastering intervention on the global stage," UW Department of Obstetrics and Gynecology Resident Seminar, Seattle, WA.

2017 "Case study of Zika." UW Global Health Department, Global Perspectives in Reproductive Health Course, Seattle, WA.

2019 "Patient-centered outcomes research." UW Dept. of Family Medicine Residency lecture, Seattle WA.

2019 "Best practices for online engagement for patient-centered outcomes research teams: work in progress". UW Dept. of Family Medicine Research Section seminar, Seattle, WA.

2020 "A Stepwise Process to Strengthen Surveys Asking About Prior Contraceptive Use." UW Dept. of Family Medicine Research Section seminar (VIRTUAL)

2021 "Upstream USA: Implementing comprehensive contraceptive care into primary care." UWNC Clinic Chief Meeting Jan. 13 (VIRTUAL).

2021 "Scholarship mentorship in residency: a triad model." UW Dept. of Family Medicine Residency Program, Feb. 22, 2021. Presented with colleague Dr. Alexa Lindley. (VIRTUAL).

2021 "The Updated 2016 Contraceptive Guidelines from the Centers for Disease Control and Prevention (CDC)." UW Complex Family Planning Fellowship, Dept of Obstetrics and Gynecology, Mar. 9 (VIRTUAL).

2022 "Clinical operations of providing telehealth medication abortion services for family medicine clinicians working in diverse settings." Research Seminar, Dept of Family Medicine, Jan. 4 (VIRTUAL).

2022 **Presenter and Panelist**"Impact of shifts in U.S. law and policy on health care practice and health services research." HSPop fall seminar, UW School of Public Health, Nov. 16 (VIRTUAL)

2023 "I definitely felt at greater ease:" Patient perspectives of telemedicine versus in-clinic abortion care. Research Seminar, Dept of Family Medicine, Jan. 3 (VIRTUAL).

NO.23-35294

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

State of Washington, et al,
Plaintiffs-Appellees,

v.

United States Food and Drug Administration, et al.,
Defendants-Appellees,

v.

State of Idaho, et al,
Movants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF WASHINGTON

No. 1:23-cv-03026-TOR
The Honorable Thomas O. Rice

SECOND SUPPLEMENTAL EXCERPTS OF RECORD
VOLUME 2 OF 2

ROBERT W. FERGUSON
Attorney General

Emma Grunberg, WSBA 54659
Tera M. Heintz, WSBA 54921
Deputy Solicitor Generals
Andrew Hughes, WSBA 49515
Lauryn K. Fraas, WSBA 53238
Kristin Beneski, WSB 45478
Assistant Attorneys General

Noah Guzzo Purcell, WSBA 43492
Solicitor General
Colleen M. Melody, WSBA 42275
Civil Rights Division Chief
800 Fifth Avenue, Suite 2000
Seattle, WA 98104
Emma.Grunberg@atg.wa.gov
Andrew.Hughes@atg.wa.gov
206-521-3222

Exhibit 9

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al.,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION, et al.,

Defendants.

NO. 1:23-cv-03026

DECLARATION OF MARJI GOLD, MD

I, Marji Gold, declares as follows:

1. I am over the age of 18. I make this declaration based on my own personal knowledge and am competent to testify as to the matters herein.

A. Background and Qualifications

2. I am a Board-Certified family physician in the Bronx, New York. I am also a professor in the Department of Family and Social Medicine at Albert Einstein College of Medicine.

3. I hold degrees from Sarah Lawrence College and NYU Medical School.

4. I underwent special training in abortion care and reproductive health care in the early 1980s, and have been performing abortions for approximately 40 years.

5. I have been performing medical abortions since 1995, when I was a site director for the mifepristone clinical trials in the United States that ultimately led to the FDA's approval of mifepristone.

6. Since the FDA approved mifepristone in 2000, I have been offering patients medication abortion with mifepristone and misoprostol as part of my regular clinical role.

7. A copy of my curriculum vitae is attached hereto as Exhibit A.

8. I submit this declaration in support of Plaintiff's Motion for Preliminary Injunction. I do so only in my individual capacity, not on behalf of any institution with which I am affiliated.

9. I have been retained as an expert in this matter, and am being compensated at a rate of $500 per hour.

B. Expert Opinions

1. Mifepristone's safety and efficacy is remarkable

10. Mifepristone is one the safest, most effective medications currently prescribed in the United States. Since the initial clinical trials that I worked on in 1995, study after study has confirmed that mifepristone, when used as part of a regimen with misoprostol, is over 95% effective in successfully completing an abortion, with a rate of major adverse events of less than .6%.[1]

11. Mifepristone is safer than acetaminophen (Tylenol®), sildenafil (Viagra®), or just about any other commonly used medicine.

12. The most common side effects associated with medication abortions using mifepristone are nausea, cramping, and bleeding. But these are not really

---

[1] *See, e.g.*, Ushma D. Upadhyay, et al., *Outcomes and Safety of History-Based Screening for Medication Abortion A Retrospective Multicenter Cohort Study*, JAMA INTERN MED. 2022;182(5):482-491; ACOG Practice Bulletin 225; VOL.136, NO. 4, October 2020

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

side effects: they are expected because that is how the medicine works. Once mifepristone stops the pregnancy from developing, misoprostol stimulates uterine contractions, which expel the pregnancy from the uterus. This process is very similar to a miscarriage.

2. The January 2023 REMS cannot be justified by any medical or safety concerns

13. The U.S. Food and Drug Administration ("FDA") has imposed a Risk Evaluation and Mitigation Strategy ("REMS") on mifepristone. The current REMS, which went into effect in January 2023, requires that clinicians must sign a "Provider Agreement" form before they dispense or prescribe mifepristone, that pharmacists must sign a form certifying that they will dispense the medication subject to various monitoring and recordkeeping requirements, and that patients sign a Patient Agreement form. After signing the Provider Agreement, a clinician is considered certified, and similarly, after a pharmacy completes the Pharmacy Agreement form, it is considered a certified pharmacy. The REMS also state that mifepristone can only be dispensed to patients in clinic by or under the supervision of a certified prescriber, or by certified pharmacies for prescriptions issued by certified prescribers. Those updates went into effect on January 3, 2023.

14. From a medical and safety standpoint, these conditions are totally unnecessary. Mifepristone is extremely safe and effective, and there is no basis

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

for imposing burdensome conditions on mifepristone that are not required for countless other, more dangerous and less effective drugs.

3. Rather than improving patient safety, the January 2023 REMS impedes access to mifepristone and decreases patient safety

15. The January 2023 REMS fails to improve patient safety. In fact, the January 2023 REMS has the contrary effect of decreasing patient safety by making access to mifepristone more difficult, and thus increasing the time that the patient has to wait for the abortion. Generally speaking, mifepristone in combination with misoprostol is safest and most effective when used earlier in pregnancy, with the risks increasing as the pregnancy proceeds.

16. For instance, the requirement of the January 2023 REMS that the prescriber be certified delays patients' access to mifepristone in cases where the patient's regular physician has not completed the certification paperwork. These patients will have to locate a physician who *is* certified, and that delay can decrease patient safety as stated above. The patient may also need to miss days from work and/or school, and lose income.

17. Additionally, well-founded fears of harassment and violence deter providers and institutions from becoming certified. Historically, providers and institutions have been concerned about the risks associated with being on a list of abortion providers, for fear that such a list could easily be leaked, or its security otherwise compromised. It can be very dangerous to be publicly known as an

abortion provider. In the late 1980s, for example, there were a lot of shootings of doctors and clinic staff at abortion clinics and in their homes. The high-volume abortion clinics in which I worked during that time had offered bulletproof vests for the doctors to wear. In addition, many clinics that offer abortion care have been damaged by arson; many have had to close. Harassment of abortion providers is a reality that I have personally had to contend with, and continues to impact many clinicians on a regular basis.

18. In the current hostile environment surrounding abortion care, which includes states passing bills that empower ordinary citizens to sue anyone they deem has "aided and abetted" a person seeking an abortion, clinicians may be reluctant to become certified and thus be identified as a person who prescribes mifepristone. Since the REMS requires certified prescribers to send their signed forms to *each* certified pharmacy at which they intend to prescribe, clinicians who wish to provide this care have reason to be concerned that an anti-abortion staff or pharmacist at a pharmacy might leak the confidential list and expose them to possible violence and/or civil or criminal liability. These concerns may be greater in communities with outspoken anti-abortion members, and thus decrease patient access to care.

19. Clinicians who hold medical licenses in multiple states, especially those with very restrictive and punitive abortion laws, may feel that they are likely to face criminal prosecution or litigation in those states, even if they live

and work in a state like Washington or New York, where I live, that protects abortion services and clinicians who provide abortion care. These clinicians may be reluctant to sign the certification form even in their supportive home state. I get similar questions from the family medicine residents and students that I train, especially those who come from very restrictive states and plan to return there to work after completing their training; they wonder if "being on the mifepristone list" will put them at risk of harassment, violence, and/or prosecution if they return home to be closer to their families. By fostering these sorts of fears, the REMS certification requirement discourages providers from prescribing mifepristone, and therefore makes it more difficult for patients to obtain it.

20. Additionally, the requirement of the January 2023 REMS that the prescriber be certified is redundant because providers are already engaged in the practices the certification requires. That is, providers already screen for fetal age, for ectopic pregnancies, and counsel patients for every medication abortion, in accordance with standard medical practice.

21. In addition, clinicians who might want to be able to offer medication abortion to their patients might see the REMS-mandated certification as an indication that mifepristone is actually more dangerous than it is, and different from the other medications that we offer patients on a regular basis. These clinicians might decide not to offer this care, thus decreasing the abortion-providing workforce and creating yet another barrier to abortion access.

22. The January 2023 REMS requirement that patients sign a specific form (the "Patient Agreement") in order to be treated with mifepristone has the effect of making abortion or miscarriage treatment look entirely different from any other common medical treatment. Patients don't need to sign an agreement for insulin, or blood pressure medications, or asthma medication, to name a few, to be prescribed to their preferred pharmacy; having to sign a form makes mifepristone seem more dangerous than it actually is, and may deter patients from choosing their preferred treatment for abortion. This process undermines patient autonomy. Additionally, at many clinics that serve low-income communities of color, including the clinic where I practice, the Patient Agreement form is not available electronically and only available in paper form. Thus, patients have to physically come to the office to sign the form, even though they are otherwise permitted to see a doctor remotely and receive the prescription by mail or dispensed at a pharmacy—which is a much more convenient and accessible option for many patients.

23. The Patient Agreement form requirement for mifepristone does not make sense from a medical or safety standpoint given that standard treatments or drugs with higher risks (such as insulin or acetaminophen [Tylenol®], for example) do not require a Patient Agreement form.

24. The January 2023 REMS requirement that pharmacies must be certified in order to dispense mifepristone is another requirement that impedes

access to mifepristone. As a provider/prescriber, I find this requirement burdensome because I (or my patients) need to call around to multiple pharmacies to locate one that is certified to dispense mifepristone. This requirement of the January 2023 REMS results in mifepristone being more difficult for patients to obtain. No other drug is burdened by this same requirement that the pharmacy must be specially certified.

25. Additionally, the requirement of the January 2023 REMS that the pharmacy be certified is redundant because pharmacists are already engaged in the practices the certification requires. Pharmacists routinely check with patients about drug allergies, confirm that they are not taking other medications that might interact with mifepristone, and advise patients on the prescriber's instructions for use of the medicine, in accordance with standard pharmacist practice.

26. When I was working on the mifepristone clinical trials, and when mifepristone was subsequently approved by the FDA, there was great hope that abortion care would become widely available for everyone who needed it. Mifepristone, in theory, made it possible for family physicians, as well as other primary care clinicians, to provide abortion care as part of their routine primary care practice.

27. Without any scientific or medical basis, the REMS has consistently frustrated that hope and kept abortion care beyond the reach of many patients, especially those from low-income communities of color, and other groups that

that are routinely marginalized from care. The primary care physicians who serve these communities are also disappointed that they cannot offer this routine medical service to patients in accordance with standard medical practice without becoming certified. As a result of the REMS restrictions, medication abortion has been largely relegated to specialized abortion clinics.

I declare under penalty of perjury under the laws of the State of Washington and the United States that the foregoing is true and correct.

DATED this 21st day of February, 2023, at Bronx, New York.

Marji Gold, MD

Exhibit A

Marji Gold, M.D. Curriculum Vitae

EDUCATION

1969 Sarah Lawrence College, Bronxville, New York B.A.

1973 New York University School of Medicine, New York, N.Y. M.D.

POST-GRADUATE TRAINING

Montefiore Medical Center

7/73-6/76 Internship/Residency in Family Medicine

7/75-6/76 Chief Resident in Family Medicine

1982 Special training in performing first trimester abortions

7/85-7/88 Fellowship in Faculty Development in Family Medicine: Research project in collaboration with the AECOM DRTC evaluating the impact of educational intervention on provider behavior in the treatment of type II diabetics at the Montefiore Family Health Center

Institute for Urban Family Health

8/83-7/85 Faculty Development Program

PROFESSIONAL EXPERIENCE

Montefiore Medical Center

1976-present Family Medicine Residency Program
A: Ambulatory community health center practice (at the MMG-2 Family Health Center), including prenatal and postpartum care, full child and adult health care, routine women's health care
B: Supervision and teaching of residents, medical students, and nurse practitioners at the ambulatory care site, **8 hours/week**
C: Coordinator of women's health curriculum for family medicine residents
D. Faculty advisor for "centering pregnancy" project for prenatal care at FHC
E. Advising residents (1-2/year) on social medicine projects
F. Advising/preparing residents for presentations – local and STFM

1982-present Family Medicine Residency Program Trainer in first trimester abortion procedures

2003-2022 Director, RHEDI/Center for Reproductive Health Education in Family Medicine – grant funded ($1,000,000/year)

Oversee all aspects of program providing funding and technical assistance to family medicine residency programs seeking to integrate abortion and family planning training into the required curriculum. Coordinate evaluation and funding of active programs, and work with faculty at additional programs to assist them with curriculum development and implementation strategy.
Supervise and train fellows, residents, and medical students in the twice-weekly reproductive health session at the Family Health Center
Develop and present r=departmental grand rounds 1-2 times/year
Oversee the women's health rotation for the family medicine residents
Mentor family medicine residents (3-5/year) in project development and implementation, preparation for presentations, and overall career plans
Oversee and coordinate program for free LARC devices for FHC and WB

Albert Einstein College of Medicine

1992-93 Development of curriculum for family medicine clerkship and cases for problem-based learning (PBL) seminars

1993-2005 PBL seminar leader for family medicine clerkship

1993-2005 Facilitator for special topic seminars ("Breastfeeding Promotion" and "Counseling for Reproductive Choice") during each rotation in the family medicine clerkship

1993-2004 Faculty advisor for community project (Barriers to Emergency Contraception)
Includes meetings with students during each rotation in the family medicine clerkship to help plan their project, assessing the progress of the project, reading and commenting on their final reports

1998-2004 Family medicine clerkship site director

1992- 2012 Faculty for 1st year AECOM student on ICM/Generalist Mentorship Pathway

2002-present Director of 4th year clinical elective "Reproductive Health" at FHC

2006-presdent Course leader for Reproductive Health unit in Research-Based Advocacy Course

2003-present Faculty Advisor, Medical Students for Choice
Includes shadowing in clinical sessions, presentations at local and regional meetings, one-on-one career advice **15 hours/month**

2004-present Faculty Mentor AMWA
Includes dinners with students, student visits to the FHC, discussions about future plans and "surviving" medical school

1994-2001; 2002-2005
Director, HRSA-funded Faculty development Fellowship
Included weekly meetings with the fellowship group, reviewing components of successful adult education, developing and practicing presentations with feedback from the group, developing, implementing, and evaluating an educational intervention project, as well as one-on-one meetings to develop career plans

2002-present Director, Fellowship in Family Planning (grant-funded $800,00 year)
Lead weekly meetings with the fellowship group, review components of successful adult education in reproductive health care, help fellows build skills in developing and practicing presentations with feedback from the group, developing, implementing, and evaluating a research project, writing for publication, as well as one-on-one meetings to develop career plans. **Time with fellows for clinical supervision and mentoring: 15 hours/week**

2004-Present: Director, RHEDI 9grant-fiunded, ab out $1,000,000 annually). National director of programs to incorporate abortion training into family medicine residency programs.

2004-present: Director, Reproductive Health Clinic at Family Health Center. **Time with residents for direct supervision: 10 hours/week**

Planned Parenthood/NYC

1993-present Abortion trainer in CTI (Clinician Training Initiative) program for family physicians

FACULTY APPOINTMENTS

Professor, Family and Social Medicine, Albert Einstein College of Medicine

Assistant Professor, Epidemiology and Population Health, Albert Einstein College of Medicine

RECENT GRANTS

2015-17 NYC DOH Quality Improvement Network for Contraceptive Access (QINCA): NYC Hospital Learning Collaborative co-PI

2017-19 Interest in and acceptability of medication abortion provision at a state university PI

2018-20 What Will it Take? Expanding Medical Abortion Access with Family Physicians PI

2019-21 How does a chatbot fit into abortion care? Assessing common questions asked to the Carafem mobile platform and patient motivation for use PI

2020-22 Quality Improvement Network for Contraceptive Access (QINCA) 2.0: NYC Health Care Facility Learning Collaborative co-PI

SPECIAL AWARDS

1998 STFM Regional Meeting – first place award for seminar presentation "Helping Patients and Families with End-of-Life Decisions"

1998 DFSM Teaching Award

2000-03 Medicine as a Profession Fellowship, sponsored by Open Society Institute Project to integrate reproductive health services and training into family medicine residency programs in underserved urban communities

2003 STFM Innovative Teaching Award presented at national meeting, Atlanta, GA

2005 STFM Regional Meeting, Third Place award for seminar presentation "Designing and Implementing a Competency and Patient-Centered Curriculum in Women's Health/Gynecology", Vanita Kumar, MD, Marji Gold, MD

2006 Membership in Davidoff Society – For Excellence in Medical Student Teaching

2014 Faculty Mentoring Award – Society for Family Planning

PROFESSIONAL SOCIETY MEMBERSHIP

American Academy of Family Physicians (AAFP)
Society of Teachers of Family Medicine (STFM)
Board Member – National Abortion Federation (NAF)

BOARD CERTIFICATION

Diplomate, American Board of Family Medicine

AECOM/MONTEFIORE COMMUNITY SERVICE

AECOM Division of Education – until 12/04

AECOM Committee on Appointments (Professor Level) 1998-2001

DFSM Division of Education – until 12/14

DFSM Leadership Group – until 12/14

DFSM Recruitment Committee/ad hoc faculty - current member

DFSM Committee Against Racism

DFSM Diversity & Inclusion Task Force

DFSM Committee on Appointments - Chair

PROFESSIONAL ORGANIZATION LEADERSHIP ACTIVITIES

Society of Teachers of Family Medicine
Member, Collaborative for Abortion Training and Access
Member, Collaborative on Minority Health
Member, Collaborative on Women's Health

2002-2010 -Society of Family Planning
Member at-large, Board of Directors

2012-present Board Member – National Abortion Federation (NAF)

2012-present – Editorial Board of Contraception

OTHER PROFESSIONAL ACTIVITIES

1992- Peer reviewer for Journal of Family Practice

1993- Peer reviewer for Family Medicine

1994 **Invited participant for National Cancer Institute** Symposium
Review of multicultural materials for patient education

1994,1998 **Invited workshop participant for Wellstart International**
"Integrating Lactation Management in Medical School and Residency Curricula"

1994-2001 Primary Investigator for Montefiore for the US collaborative ARM trial of q mifepristone/misoprostol in the US

2002- Peer reviewer for Families, Systems, and Health

2003- Peer reviewer for Annals of Family Medicine

2010- Peer reviewer for Contraception

SELECTED OUTSIDE PRESENTATIONS

1987 STFM regional Meeting, Cambridge, Mass., October 11-13
workshop "Working Women with Young Children"

1988 STFM National Meeting, Baltimore, Md., April 23-27
workshop "Breastfeeding: Improving our Support Skills"
workshop "Working Women with Young Children"

1989 STFM: Family in Family Medicine Meeting, Amelia Island, Fla.
and National Meeting, Denver, Colo., April 30-May 3
workshop "Non-Traditional Families: Dealing with Stereotypes"

1989 STFM Regional Meeting, Hershey, Pa., Oct. 11-13
workshop "Learning to Listen to Ourselves: The Impact of Language"

1990 STFM: Family in Family Medicine Meeting, Amelia Island, Fla.
and National Meeting, Seattle, Wash. May 5-9
workshop "Learning to Listen to Ourselves: The Impact of Language"

1990 STFM Regional Meeting, New York, N.Y. Oct. 25-27
workshop "Should Boys Play with Dolls?: A Family Physician looks at Sex-Role Stereotypes

1991 STFM: Family in Family Medicine, Amelia Island, Fla.
workshop "Should Boys Play with Dolls?: A Family Physician looks at Sex-Role Stereotypes

1992 STFM Regional Meeting, Lancaster, Pa. Oct., 2-4
"Collaboration with Midwives: Another Look at the Family Physician's Role in Maternity Care"

1994 STFM National Meeting, Atlanta, Ga., April 30-May 4
and STFM Regional Meeting, Philadelphia, Pa., Oct. 28-30

Invited presentation "Choices Counseling: Helping Women Decide About Abortion"

1995 STFM Regional and National Meetings
“Developing an Advisor-Advisee Relationship”

1997 STFM National Meeting, Boston, Mass.

“Stories from long-term relationships with patients”

1998 STFM Regional Meeting, New Brunswick, New Jersey
“Helping Patients and Families with End-of-Life Decisions”

1999 STFM Regional Meeting
"New Choices in Early Pregnancy Interruption"

2000 National Abortion Federation
Invited facilitator
"Incorporating teaching of early abortion techniques into residency education"

2000 STFM National Meeting
"New Choices in Early Pregnancy Interruption"
Breakfast Table - "Supporting Breastfeeding - Overcoming Obstacles"

2000 STFM Regional Meeting
"The Visit Before the Morning After: Teaching about Emergency Contraception"
"What's the Point in PowerPoint?"

2000 STFM/AAFP Conference on Patient Education 11/00
"Counseling patients for early pregnancy termination"

2001 STFM Regional Meeting, Mystic, Conn.
"Can the Umass Gnome Teach Abortions?"
"Can We Really Do *That* in Family Medicine?"
"Using Health Care Maintenance Forms for Teaching"

2001 STFM/AAFP Patient Education Conference, Seattle, Wash.
"Update on Integration of Medical Abortion into Family Medicine"
"Talking to Patients about Emergency Contraception"

2002 STFM Families and Health Conference, San Diego, Calif. (Seminar)
STFM National Meeting, San Francisco, Calif. (Poster)
"The Visit Before the Morning After: Teaching about Emergency Contraception"

2002 STFM Regional Meeting, Cleveland, Ohio
"Defining Competencies for Pregnancy Prevention"

2002 APHA National Meeting, Philadelphia, PA
"Barriers to Medical Abortion in Community Settings.

2002 **Invited speaker** "Update in Women's Reproductive Health Care"
Presented at Updates in Family Medicine, San Francisco, Calif.

2003 National Abortion Federation, Seattle, Wash.
Invited Presentation "Evaluation of "sono-as-needed" protocol for medical abortion in a community practice"

2004 **Invited Grand Rounds Speaker** Beth Israel Medical Center, NY,NY

Breastfeeding Support in the Family Medicine practice, Joon Lee, MD, Marji Gold, MD

2004 Annual National Abortion Federation Meeting, New Orleans, LA
Invited Presentation "Sono as Needed: Implementing Medical Abortions at Community Health Centers" – Marji Gold, M.D., Ruth Lesnewski, M.D., Tanya Panton, M.D.

"3rd Annual Family Practice Roundtable: Abortion Care in a Family Medicine Setting" – Marji Gold, M.D., Linda Prine, M.D.

2004 STFM Annual Conference, Toronto, Ontario, Canada,
"Medical Abortion Cases" Roundtable – Nikki Colodny, Marji Gold, M.D., Susan Hadley, M.D., Vanita Kumar, M.D., Ruth Lesnewski, M.D., Linda Prine, M.D., M.D., Max Yarowsky, M.D.

"Teaching Residents Across the Abortion Divide" – Marji Gold, M.D., William Toffler, M.D., Daniel Vinson, M.D., MSPH

2004 World Health Conference of Family Doctors (WONCA), Orlando, Florida, "Using the Manual Vacuum Aspiration Syringe for Incomplete and Spontaneous Abortion, Endometrial Biopsy and Early Pregnancy Termination in Primary Care Outpatient Settings" – Marji Gold, M.D., Linda Prine, M.D.

2004 STFM Northeast Regional Meeting, Rye Brook, New York,
"Centering Pregnancy: A New Approach to group Prenatal Visits" –David Walker MD , Evia Nano, MD, Marji Gold, MD

"The Visit Before the Morning After: Providing Advanced Prescription for Emergency Contraception" Vanita Kumar MD, Louisa Hann MD, Marji Gold, MD

2004 STFM/AAFP Patient Education Conference, San Francisco, CA
"Improving Access To Emergency Contraception- A Collaborative Approach To Patient Education And Systems Change" Louisa Hann MD, Marji Gold, MD

2005 STFM Conference on Families and Health, Amelia Island, FL
"The Reflective Practitioner Group: Integrative training for residents learning early abortion" – Marji Gold, M.D., Barbara Gawinski, PhD.

2005-19 Annual National Abortion Federation, Montreal, Canada
"4rd Annual Family Practice Luncheon Roundtable: Abortion Care in a Family Medicine Setting" – Marji Gold, M.D., Linda Prine, M.D

2005 STFM National Meeting, New Orleans, LA

Invited Facilitator "Balancing Work and Life", Women's Theme Day Roundtable, Marji Gold, MD

"Improving Women's Health: The Reproductive Health Initiative (RHI) Model Curriculum", Marji Gold, MD, Jen Hurlburt

"Skills for Procedure Training: Faculty Development in Reproductive Health" – Marji Gold, M.D., Suzan Goodman, M.D., Linda Prine, M.D., Larry Leeman, M.D.

2005 NAPCRG Montreal Canada
"How Do You Train Family Medicine Residents to Be Abortion Providers?" (poster) Christine Dehlendorf, Dahlia Brahmi, David Engel, Kevin Grumbach, Carole Joffe, Marji Gold

2005 STFM Regional Meeting, Hershey, PA
"Designing and Implementing a Competency and Patient-Centered Curriculum in Women's Health/Gynecology", Vanita Kumar, MD, Marji Gold, MD

"Learning to Listen to Ourselves: Teaching Women-Centered Language in Reproductive Health", Louisa Hann, MD, Vanita Kumar, MD, Marji Gold, MD

2005 **Invited Grand Rounds Speaker**
Group Health Cooperative Family Practice Residency, Seattle, WA
"Integration of Medication Abortion into a Primary Care Setting," - Marji Gold, M.D

2005 **Invited Grand Rounds Speaker**
Swedish Family Medicine Residency Program, Providence Campus , Seattle, WA
"Integration of Medication Abortion into a Primary Setting," Seattle, WA – Marji Gold, M.D

2005 **Invited Grand Rounds Speaker**
UCSF/SFGH Family & Community Medicine Residency Program, San Francisco, CA "Integration of Medication Abortion into a Primary Care Setting," San Francisco, CA- Marji Gold, M.D

2005 **Invited Grand Rounds Speaker**
Dept. of Family Medicine, University at Buffalo "Integration of Medication Abortion into a Primary Care Setting," Buffalo, NY- Marji Gold, M.D

2005 **Invited Grand Rounds Speaker**
Dept. of Family Medicine, University of Massachusetts, Worcester, MA, "Timely Initiation of Contraception – and What if it Isn't?"

2005 **Invited Grand Rounds Speaker**
UMDNJ Robert W. Johnson Family Medicine Residency Program, New Brunswick, NJ "Integration of Medication Abortion into a Primary Care Setting," - Marji Gold, M.D, Justine Wu, MD

2006 National Abortion Federation Annual Meeting San Francisco, CA
Research presentation "How Do You Train Family Medicine Residents to Be Abortion Providers?" Christine Dehlendorf MD, Dahlia Brahmi MD, Marji Gold MD

Breakfast session – "Training Issues in Abortion Care"
Marji Gold MD and Eve Espey MD

"5th Annual Family Practice Luncheon Roundtable: Update on Abortion Training in Family Medicine", Linda Prine MD, Vanita Kumar MD, Marji Gold MD

Research Poster - "Reproductive Health Beliefs of Indo-Caribbeans" Kamini Geer MD, Marji Gold, MD

Research Poster – "Integration of early abortion services into primary care: an acceptability survey of female patients", Susan Rubin, MD, Marji Gold, MD

2006 STFM National Meeting, San Francisco, CA
Invited Presentation Preconference – Celebrating Women in Family Medicine
"The Feminization of Medicine: A SWOT Analysis", Marji Gold, MD

Breakfast Table – "Narratives of Choice: Pregnancy Options Decision Making" Cori Blum MD, Marji Gold MD

Workshop: "Writing a proposal for funding to integrate abortion and family planning into your residency curriculum" Marji Gold MD

Research Poster - "Reproductive Health Beliefs of Indo-Caribbeans" Kamini Geer MD , Marji Gold MD

Research Poster - "Integration of early abortion services into primary care: an acceptability survey of female patients" Susan Rubin MD, Emily Godfrey, MD, Marji Gold, MD

2006 **Invited Grand Rounds** Columbia-Presbyterian Family Medicine Residency Program, NY, NY
"Taking Phone Calls from Medication Abortion Patients", Marji Gold, MD, Yael Swica, MD

2006 **Invited Speaker** UCSF/SFGH Family & Community Medicine Residency Program/Primary Care Internal Medicine
"The Politicization of Reproductive Health" Marji Gold MD, Carole Joffe PhD, Christine Dehlendorf, MD

2006 **Invited Grand Rounds Speaker** OHSU (Portland, Oregon) Department of Family Medicine "Medication Abortion in Family Medicine" Teresa Gipson MD, Marji Gold MD

2006 **Invited Workshop Presentation** Family Medicine Residency of Idaho, Boise, Idaho
"MVA for Miscarriage Management/Using Papayas to Teach Hands-On Skills" Marji Gold MD

2006 STFM Regional Meeting Boston (Danvers) MA
"Cinema and the Speculum: Using Popular Film Clips to Teach Patient-Centered Language and Behavior During Pelvic Exams" Sayantani DasGupta, MD, Marji Gold, MD

"Contraceptive Risk, It's all Relative: Helping Patients Understand Risk and Contraceptive Choices", Vanita Kumar, MD, Marji Gold, MD

Research Presentation "Integration of early abortion services into primary care: an acceptability survey of female patients" Susan Rubin, MD, Marji Gold MD

"Timely Initiation of Contraception" Emily Jackson, MD, Adjoa Duker, MD, Marji Gold, MD

2006 **Invited Grand Rounds Speaker** Dept. of Family Medicine, Lehigh Valley Medical Center, Allentown, PA
"Timely Initiation of Contraception – and What if it Isn't?"

2006 AAFP/STFM Conference on Patient Education/Quality Improvement, Denver, CO.
"Cervical cancer screening and contraception across the lifecycle", Joquetta Paige, MD, Marji Gold, MD

"Learning to Listen to Ourselves: Using Patient-Centered Language to Improve Reproductive Health Care" Joquetta Paige, MD, Marji Gold, MD

2006 **Invited Keynote Speaker** Medical Students for Choice Regional Conference Bronx, NY

"Integrating Abortion Care into Routine Office Practice – or Where Will You Work as a Pro-Choice Doctor" Marji Gold, MD

2007 National Abortion Federation Annual Meeting, Boston, MA 4/07

"Cross-Discipline Collaboration for Abortion Training", Marji Gold, MD, Larry Leeman, MD, Eve Espey, MD

2007 Society of Teachers of Family Medicine, National Meeting, Chicago, IL 5/07

"Learning to Listen to Ourselves: Teaching Patient-centered Language in Reproductive Health" Marji Gold, MD; Vanita Kumar, MD; Justine Wu, MD

"Teaching Women's Reproductive Health Care", Linda Prine, MD; Marji Gold, MD; Suzan Goodman, MD, MPH; Monique Thiry-Zaragoza, MD; Debra Stulberg, MD; Christine Delendorf, MD; Susan Rubin, MD; Susan Hadley,, MD; Vanita Kumar, MD; Peter Sawires, MA; Kristin Moore , MPA

"Cinema and the Speculum: Using Popular Film Clips to Teach Patient-centered Language and Behavior", Marji Gold, MD, Emily Jackson MD

"Skills for Procedure Training—Faculty Development in IUD Insertion", Linda Prine, MD; Julie Sicilia-May, MD; Ginger Gillespie, MD; Vanita Kumar, MD; Marji Gold, MD

2007 Association of Reproductive Health Professionals National Meeting Minneapolis, MN 9/07

"Availability of Emergency Contraception From US College Student Health Centers" (research poster), Kathleen Devine MD, Evelyn Hessing MD, Marji Gold MD

2007 Society of Teachers of Family Medicine, Northeast Regional Meeting, Pittsburgh, PA 10/07

Third Prize for Outstanding Presentation "Language matters: woman-centered talk as a fundamental skill during pelvic exams", Marji Gold, MD, Lucy Candib, MD, Sara Shields, MD

"Addressing Contraceptive Needs of Adolescent Females by Providing More Effective Teen Friendly Family Planning Services ", Adjoa Duker MD, Marji Gold MD

Does Cervical Cancer Screening Impede Access To Contraceptives? An Assessment Of Knowledge And Behaviors Among Family Physicians (poster)
Joquetta Paige MD, Marji Gold MD

Universal Voluntary Screening Of Adolescents In A School-Based Clinic

For
Gonorrhea And Chlamydia (poster)
Margaret Rosenberg MD, Marji Gold MD, Mayris Webber PhD, David Appel MD

2007 National Primary Care Research Group National Meeting, Vancouver BC, 10/07

Changing the Face of Reproductive Health: Discussions of Pregnancy and Contraception With Men (poster)
Emily Jackson, MD; Marji Gold

Early Abortion Services Within Primary Care: Factors Predicting Acceptability From Patients at Two Abortion Clinics (poster)
Emily Godfrey, MD, MPH; Susan Rubin; Erica Smith; Marji Gold

Integration of Early Abortion Services Into the Family Medicine Clinic: Acceptability Survey of Female Patients (presentation)
Susan Rubin, MD, MPH; Emily Godfrey; Marji Gold

Acceptance of Early Abortion Services in Primary Care Settings: A Comparison of Abortion Clinic and Family Medicine Patients in Chicago (presentation)
Erica Smith; Emily Godfrey; Susan Rubin; Marji Gold

2007 **Invited Speaker** Doctors for a Women's Choice for Abortion – Celebration of 40 years of Legal abortion in the United Kingdom, London, UK 10/07
"Training the next generation of abortion providers in the United States", Marji Gold, MD

2008 Society of Teachers of Family Medicine Annual Meeting, Baltimore, MD, 4/30-5/4

Women in Family Medicine (pre-conference workshop)
Marji Gold MD

Reproductive Health and Sexual Health Needs of Men
Emily Jackson MD, Marji Gold MD

Addressing the Health Issues of Lesbians and WSW (Women who Have Sex with Women)
Tara Stein MD, Silvia Amesty MD, Emily Jackson MD, Marji Gold MD

Family Medicine Patient Preferences in Early Abortion: A Survey of Chicago and New York Patients
Emily Godfrey MD MPH, Susan Rubin MD, Erica Smith BA, Marji Gold MD

IUDS: What You Need to Know

Marissa Harris MD, Emily Jackson MD, Marji Gold MD

2008 Society of Teachers of Family Medicine North East Regional Conference, Baltimore, MD

Teaching systems-based practice: building upon residents' experiences with training in multiple settings
Cara Herbitter MPH, Marji Gold MD

Improving Our Approach to Screening for STIs in Adolescents
Meg Rosenberg MD, Marji Gold MD

Why Good Docs Make Bad Presentations and How You Can Avoid Their Fate
Marissa Harris MD, Tara Stein MD, Marji Gold MD

Contraception In Adolescents: An Update On Improving Continuation
Adjoa Duker MD, Marji Gold MD

First Prize for Best Seminar: Language Matters: Woman-Centered Talk during Pelvic Exams" – Sara Shields MD, Lucy Candib MD, Marji Gold MD (First Prize for Best Seminar at the Meeting)

A Discussion about PAP Testing Before IUD Insertion in the Absence of Clear Guidelines
Tara Stein MD, Marji Gold MD

NYC Women's Health Free Clinic: A Model for Expanding Reproductive Health Services and Training
Honor MacNaughton MD, Elizabeth McCormick MD, Natasha Kelly DO, Vanessa Batista MSIV

What is the Extent of Family Planning Training in Family Medicine Programs?
Cara Herbitter MPH, Marji Gold MD, Megan Greenberg

Incorporation of Reproductive Attitudes and Beliefs of Specific Cultural Groups in Delivery of Family Planning Services
Marissa Harris MD, Marji Gold MD

2008 North American Primary Care Research Group, Rio Grande, Puerto Rico

Abortion Training at Multiple Sites: An Unexpected Curriculum for Teaching Systems-Based Practice
Cara Herbitter MPH, Vanita Kumar MD, Alison Karasz MD, Marji Gold MD

What is the Extent of Family Planning Training in Family Medicine Programs?

Jessica Dalby MD, Crystal Query, Cara Herbitter MD, Megan Greenberg, Marji Gold

Reproductive Attitudes of a Convenience Sample of Reproductive Ages West-Indian Women Residing in New York City
Marissa Harris MD, Marji Gold MD

Providers' Attitudes about PAP Smears, Colposcopy, and the Intrauterine Device
Tara Stein MD, Marji Gold MD

Men's Attitudes Toward Contraception, Pregnancy and Abortion: A Qualitative Study
Emily Jackson MD, Marissa Harris MD, Marji Gold MD

2009 National Abortion Federation Annual Meeting, Portland, OR

Improving Reproductive Health Education for Family Medicine Residents
Crystal Query MD, Marji Gold MD, Cara Herbitter MPH, Megan Greenberg BA

2009 Society of Teachers of Family Medicine Annual Meeting, Denver, CO

Strategies for Teaching Residents Pregnancy Options Counseling
Cara Herbitter MPH, Vanita Kumar MD, Alison Karasz PhD, Marji Gold MD

Is Pap Screening a Barrier to IUD Insertion: a Review of the Current Guidelines
Tara Stein MD, Marji Gold MD

Improving Reproductive Health Education for Family Medicine Residents
Marji Gold MD, Cara Herbitter MPH, Megan Greenberg BA

2009 Association of Reproductive Health Professionals National Meeting, Los Angeles, CA

US Family Physicians' Knowledge, Attitude and Practice with Intrauterine Contraception
Susan Rubin MD, Marji Gold MD

What is the Extent of Family Planning Training in Family Medicine Residencies?
Marji Gold MD, Cara Herbitter MPH, Megan Greenberg BA

2009 The Society of Teachers of Family Medicine North East Regional Conference, Rye Brook, NY

Strategies to Increase IUD Training in Family Medicine Residencies

Marji Gold MD, Linda Prine MD, Megan Greenberg BA

Perceived Barriers to Contraception in an Underserved Population
Sharon Bennattabou MD, Marji Gold MD

RHP: Outcomes of a Unique Abortion Training Program
Megan Greenberg BA, Cara Herbitter MPH, Barbara Gawinski PhD, Marji Gold MD

Barriers to Access to Reproductive Health Care in Family Medicine
Marji Gold MD

2009 North American Primary Care Research Group, Montreal, Quebec

Reproductive Health Program: Outcomes of a Unique Abortion Training
Megan Greenberg BA, Jason Fletcher PhD, Cara Herbitter MPH, Marji Gold MD

2010 National Abortion Federation Annual Meeting, Philadelphia, PA

Passing the Torch – Educating Medical Students & Training Residents
Larry Leeman MD, Eve Espey MD, Marji Gold MD

2010 Society of Teachers of Family Medicine Annual Meeting, Vancouver, BC

Conversations About Abortion Self-induction: Promoting Women-centered Care and Policy
Marji Gold, MD; Christine Dehlendorf, MD; Dan Grossman, MD; Melanie Pena, MPH; Kelly Blanchard, MPH

The Reproductive Health Program at the University of Rochester: What Can We Learn From Trainees?
Barbara Gawinski, PhD; Megan Greenberg, BA; Cara Herbitter, MPH; Marji Gold, MD; Jason Fletcher, MA, MS, PhD

Medical Students as Patients: An Experiential Learning Project About Emergency Contraception and Patient-centered Care
Cara Herbitter, MPH; Jason Fletcher, PhD; Alice Fornari, EdD, RD; Leslie Boden, MSUP; Marji Gold, MD

Addressing the Health Needs of Transgender Patients
Cara Herbitter, MPH; Nicole Kirchen, MD, MPH; Tara Stein, MD; Marji Gold, MD

Strategies to Increase IUD Training in Family Medicine Residencies
Marji Gold, MD; Megan Greenberg, BA; Cara Herbitter, MPH; Linda Prine, MD; Jason Fletcher, PhD

Uncertainty In Clinical Decision Making: Embracing the Challenges for Educators and Learners
Ellen Tattelman, MD; Marji Gold, MD; Margaret Rosenberg, MD

Reproductive Attitudes and Health Beliefs of West-Indian Women In New York City
Marissa Harris MD, MPH, Cara Herbitter MPH, Marji Gold MD

Language Matters: Woman-centered Talk During Pelvic Exams
Sara Shields, MD, MS; Lucy Candib, MD; Marji Gold, MD

Perceived Barriers to Reproductive Health Care in a Homeless Population
Arati Karnik, MD; Sharon Phillips, MD; Andrea Littleton, MD; Marji Gold, MD

2010 Association of Reproductive Health Professionals National Meeting, Atlanta GA

The Reproductive Health Program: Outcomes of a Unique Abortion Training Program (poster)
Megan Greenberg, Cara Herbitter MPH, Barbara Gawinski PhD, Jason Fletcher PhD, Marji Gold MD

2010 Family Medicine Education Consortium North East Regional Conference, Hershey PA

Preventing Unwanted Teen Pregnancy: The Importance of offering IUDs in a School Health Setting (Breakfast Discussion)
Tara Stein MD, MPH, Marji Gold MD

Women's Abortion Experiences in Family Medicine: A Multi-Site, Cross-Sectional Survey
Justine Wu MD, MPH, Emily Godfrey MD,MPH, Linda Prine MD, Honor MacNaughton MD, Marji Gold MD

Medication Abortion: Frequently Asked Questions / Simplifying Medical Abortion: Home-Use of Mifepristone
Kohar Der Simonian MD, Lindsay Faucette MD, Victor Sta. Ana MD, Honor MacNaughton MD / Marji Gold MD, Linda Prine MD, Sarah Miller MD, Sharon Phillips MD

Students as Patients and Teachers: An Evaluation of an Experiential Emergency Contraception Project (Poster)
Cara Herbitter MPH, Jason Fletcher PhD, Leslie Boden MSUP,Alice Fornari EdD, RD, Marji Gold MD

2010 North American Primary Care Research Group Annual Meeting, Seattle, WA

Ambivalence About Pregnancy Planning: A Qualitative Study of Providers And The Women They Counsel
Sarah Miller, MD, Marji Gold, MD; Shama Samant, BS; Alison Kliegman, BA

The Reproductive Experiences of Homeless Women: A Mixed-Methods Study
Sharon Phillips, MD, Marji Gold, MD

Students As Patients And Teachers: An Evaluation of an Experiential Emergency Contraception Project
Cara Herbitter, MPH, Jason Fletcher, PhD; Alice Fornari, EdD, RD; Leslie Boden, MSUP; Marji Gold, MD

Evaluating Primary Care Access In Different Healthcare Systems: Comparison, Collaboration, And Research Capacity Building
Sarah Lesko, MD, MPH, Jennifer Devoe, MD, DPhil; Shabnam Asghari, MD, MPH, PhD; Barry Saver, MD, MPH; Catherine Drouin, PhD; George Freeman, MD; Marji Gold, MD; Emily Marshall, MD; Trudy Singzon, MD, MPH; Marshall Godwin, MD, Msc, FCFP

2011 Society of Teachers of Family Medicine Annual Meeting, New Orleans, LA

An Evaluation of an IUD Initiative at Family Medicine Residency Programs (poster)
Cara Herbitter, MPH; Jason Fletcher, PhD; Finn Schubert, BA; Megan Greenberg, BA; Marji Gold, MD

Integrating Abortion Training Into Family Medicine Residencies: Critical Factors and Useful Practices
Marji Gold, MD; Finn Schubert, BA; Cara Herbitter, MPH

Changing Conversations About Abortion in Family Medicine
Cara Herbitter, MPH; Marji Gold, MD; Finn Schubert, BA; Sarah Stumbar, MPH

Uterine Aspiration and Intrauterine Device Placement Using a Papaya Model and Patient-Centered Communication
Sarah Miller, MD; Sharon Phillips, MD; Leah Rothman, DO; Rachel Roth, DO; Marji Gold, MD; Linda Prine, MD; Dana Schonberg, MD

Women's Abortion Experiences in Family Medicine: A Multi-site, Cross-sectional Survey
Justine Wu, MD, MPH; Emily Godfrey, MD, MPH; Honor McNaughton, MD; Linda Prine, MD; Kathryn Anderson-Clark, PhD; Marji Gold, MD

Uncertainty in Clinical Decision Making: Embracing the Challenges for Educators and Learners
Ellen Tattelman, MD; Margaret Rosenberg, MD; Marji Gold, MD

Perspectives On Reproductive Healthcare Access Among Homeless Girls Living In Family Shelters In The Bronx
Lin-Fan Wang; April Wilson; Sharon Phillips; Andrea Littleton; Marji Gold

2011 Family Medicine Education Consortium North East Regional Conference, Danvers, MA

Countering Misinformation from Crisis Pregnancy Centers: Issues for Resident and Patient Education (poster)
Marji Gold MD, Dana Schonberg MD, Lin-Fan Wang MD, Finn Schubert BA,
Cara Herbitter MPH

An Evaluation of an IUD Initiative at Family Medicine Residency Programs
Cara Herbitter MPH, CPH, Jason Fletcher PhD, Finn Schubert BA, Megan Greenberg RN, Marji Gold MD

Patient-Centered Papaya Workshop
Sarah B. Miller MD, MPH, Lucia McLendon MD, Ginger Gillespie MD, Marji Gold MD, Linda Prine MD, Julie A. Johnston MD, Catherine Romanos MD, Marjorie Affell MD, MPH

Taking the Training Wheels Off: Abortion Training as a Paradigm for Involving
Trainees in Procedural Care
Sarah Miller MD, MPH, Zowie Barnes MD, Honor MacNaughton MD, Tara Stein MD, MPH, Sharon Phillips MD, MPH, Marji Gold MD

2011 North American Primary Care Research Group Annual Meeting – Banff, Canada, Nov. 2011

Pregnancy Ambivalence: A Qualitative Study of Providers and the Women They Counsel (poster)
Sarah Miller MD MPH, Ariana Bennett, MPH

Contraceptive Needs of Women Incarcerated at Rikers Island Jail Complex (poster)
Dana Schonberg MD, Marji Gold MD, Ariana Bennett, MPH

Women's Abortion Experiences in Family Medicine: A Multi-site, Cross-sectional Survey (poster)
Justine Wu MD MPH, Emily Godfrey MD MPH, Honor MacNaughton MD, Linda Prine MD, Kathryn Andersen-Clark PhD, Marji Gold MD

Acceptability of Home Use of Mifepristone for Medical Abortion (poster)
Marji Gold MD, Finn Schubert, Cara Herbitter MPH, Yael Swica MD MA, Erica Chong MPH

An Evaluation of an IUD Initiative at Family Medicine Residency Programs
Cara Herbitter MPH, Jason Fletcher PhD, Finn Schubert, Megan Greenberg RN, Ariana Bennett MPH, Marji Gold MD

2012 National Abortion Federation Annual Meeting – Vancouver, Canada, April 2012

Contraceptive Needs of Women Incarcerated at Rikers Island Jail Complex (poster)
Dana Schonberg MD, Marji Gold MD, Ariana Bennett MPH

A Review of Abortion, Family Planning, and Miscarriage Management Content in Family Medicine Textbooks (poster)
Sarp Aksel, Marji Gold MD, Finn Schubert, Ariana Bennett MPH, Cara Herbitter MPH

Training the Next Generation of Providers
Larry Leeman MD, Marji Gold, MD

11th Annual Family Medicine Luncheon
Marji Gold MD, Linda Prine, MD

2012 STFM Annual Spring Meeting – Seattle, WA, April 2012

Countering Misinformation From Crisis Pregnancy Centers: Issues for Resident and Patient Education
Marji Gold MD, Dana Schonberg MD, Lin-Fan Wang MD, Finn Schubert, Cara Herbitter MPH

Working Part Time in Academic Family Medicine: A Panel Discussion
Sarina Schrager MD MS, University of Wisconsin; Tracy Juliao PhD, St John Hospital Family Practice, Farmington Hills, MI; Marji Gold MD, Albert Einstein College of Medicine; Mari Egan MD MHPE, University of Chicago; Cheryl Seymour MD, Maine Dartmouth Family Medicine Residency, Augusta, ME

Representations of Abortion in Pop Culture: Helping Learners Develop Media Awareness and Teaching Skills
Marji Gold MD, Dana Schonberg MD, Lin-Fan Wang MD, Cara Herbitter MPH, Finn Schubert, Ariana Bennett MPH

Mystery in Medicine: Comfort With the Unknown
Ellen Tattelman MD, Margaret Rosenberg MD, Marji Gold MD

Contraceptive Needs of Women Incarcerated at Rikers Island Jail Complex
Dana Schonberg MD, Ariana Bennett MPH, Marji Gold MD

Ambivalence About Pregnancy Planning: A Qualitative Study of Providers and the Women They Counsel
Sarah Miller MD, Ariana Bennett MPH, Marji Gold MD

Advocacy for Reproductive Health: Successes and Challenges
Sharon Phillips, MD MPH; Dana Schonberg MD, Lin-Fan Wang MD, Marji Gold MD

2012 Family Medicine Education Consortium Northeast Regional Meeting 2012 – Cleveland, OH, September 2012

Physicians as Advocates for Reproductive Health
Lin-Fan Wang MD, Dana Schonberg MD, Jennifer Amico MD, Marji Gold MD

Pregnancy Options Counseling Training as a Paradigm for Teaching Trainees about Counseling Patients
Dana Schonberg MD, Lin-Fan Wang MD, Tara Stein MD, Marji Gold MD

A Review of Abortion, Family Planning, and Miscarriage Management Content in Family Medicine Textbooks (poster)
Sarp Aksel, Marji Gold MD, Finn Schubert, Ariana Bennett MPH, Cara Herbitter MPH

Addressing the Health Needs of Transgender Patients
Cara Herbitter MPH, Finn Schubert, Ariana Bennett MPH, Marji Gold MD

Representations of Abortion in Pop Culture: Helping Learners Develop Media Awareness and Teaching Skills
Marji Gold MD, Dana Schonberg MD, Lin-Fan Wang MD, Cara Herbitter MPH, Finn Schubert, Ariana Bennett MPH

Menopause and Beyond: Women's Sexual Health and Experiences
Alice S. Teich MD, Lin-Fan Wang MD, Marji Gold MD

2013 National Abortion Federation Annual Meeting – April 2013

Pre-Conference: Training the Next Generation: Integration of Abortion into Clinician Education
Marji Gold MD

2013 STFM Annual Spring Meeting – Baltimore, MD, April 2013

Management of EPF and Abortion by FM Educators (poster)
Cara Herbitter MPH, Ariana Bennett MPH, Finn Schubert BA, Iana Bennett MD PhD, Marji Gold MD

Eliciting Patient Understandings about Treatment Risk: Birth Control as Paradigm

Alice Teich MD, Dana Schonberg MD, Carol Mendez, Finn Schubert MD, Marji Gold MD

Perspective of Cambodian and Chinese Female Adolescents and Mothers about Sexual and Reproductive Health
Lin-Fan Wang MD, Ariana Bennett MPH, Marji Gold MD

Simplifying Medical Abortion
Marji Gold MD, Ariana Bennett MPH, Dana Schonberg MD, Lin-Fan Wang MD, Tara Stein MD

Sexual and Reproductive Health Professionalism Seminar
Carol Mendez MD, Marji Gold MD, Cara Herbitter MPH, Sarah Miller MD

Reproductive Health Legislative Updates
Lin-Fan Wang MD, Marji Gold MD, Jennifer Amico MD

2013 Family Medicine Education Consortium Northeast Regional Meeting 2013– Philadelphia, PA, November 2013

Eliciting Patient Understandings about Treatment Risk: Birth Control as Paradigm
Jennifer Amico MD, Bhavik Kumar MD, Ariana Bennett MD, Marji Gold MD

Enhancing Postpartum Contraception
Bhavik Kumar MD, Jennifer Amico MD, Marji Gold MD

Management of Early Pregnancy Failure and Induced Abortion by Family Medicine Educators (poster)
Ariana Bennett MPH, Cara Herbitter MPH CPH, Finn Schubert BA, Ian Bennett MD PhD, Marji Gold MD

Professionalism in Matters of Sexual Health
Ariana Bennett MPH, Cara Herbitter MPH CPH, Finn Schubert BA, Ian Bennett MD PhD, Marji Gold MD

Representations of Reproductive Health Topics in Popular Magazines: Helping Learners Develop Media Awareness and teaching Skills (poster)
Ariana Bennett MPH, Finn Schubert BA, Steph Herold MPH, Cortney Taylor, Marji Gold MD

Professional Disagreement
Dana Schonberg MD MPH, Jennifer Amico MD, Bhavik Kumar MD, Marji Gold MD

Increasing Teen Access to IUDs by Expanding Our Network of training
Tara Stein MD MPH, Ariana Bennett MPH, Marji Gold MD

Full Access to Reproductive Healthcare under the ACA: Educating Learners to Eliminate Barriers to Care
Finn Schubert BA, Aleza Summit MPH, Bhavik Kumar MD, Ariana Bennett MPH, Marji Gold MD

2013 Medical Students for Choice Annual Conference on Family Planning- Denver, CO November 2013

Social Contexts of Women's Decisions about Abortion Methods
Finn Schubert BA, Marji Gold MD

2013 North American Primary Care Research Group-Ottawa, Ontario, CA November 2013

How Patients Choose and Experience Early Abortion Care in the Family Medicine Setting (Poster)
Aleza Summit MPH, Ariana Bennett MPH, Cara Herbitter MPH CPH, Alison Karasz PhD, Marji Gold MD

Under-Recognized Factors in Pregnancy in a Primary Care Population: Reproductive Coercion, Transactional Sex, Violence, and Ambivalence (Poster)
Sharon Phillips MD MPH, Ariana Benntt MPH, Laura Krinsky, Marji Gold

Physicians' and Patients' Experiences with Early Elective IUD Removals (Poster)
Jennifer Amico MD, Ariana Bennett MPH, Alison Karasz PhD, Marji Gold MD

A Study of Teen Access to and Acceptability of Intrauterine Devices (IUDs) (Poster)
Tara Stein MD MPH, Ariana Bennett MPH, Steph Herold MPH, Marji Gold MD

2014 National Abortion Federation Annual Meeting- San Francisco, CA April, 2014

Providing Abortion in Family Medicine as an Approach to Reduce Stigma and Anti-abortion Harassment
Linda Prine MD, Marji Gold MD

2014 Society of Teachers of Family Medicine Annual Spring Conference- San Antonio, TX May 2014

Best Practices for Educating Residents About Transgender Health Topics (Poster)
Finn Schubert BA, Zil Goldstein MD, Marji Gold MD, Ariana Bennett MPH

The Future of Family Planning in Texas: Are Family Physicians Ready?

(Poster)
Bhavik Kumar MD, Arthur E. Blank MD, Marji Gold MD
Representations of Reproductive Health Topics in Popular Magazines: Helping Learners Develop Media Awareness/Teaching Skills (Poster)
Ariana Bennett MPH, Finn Schubert BA, Steph Herold MPH, Cortney Taylor, Marji Gold

Patient and Physician Experiences with Early Elective IUD Removals
Jennifer Amico MD, Ariana Bennett MPH, Marji Gold MD

Training Family Medicine Residents in a School-Based Health Center to Provide IUDs On-Site to Teens
Tara Stein MD MPH, Marji Gold MD, Ariana Bennett MPH

Addressing Stigmatized Health Care in Family Medicine Education
Ariana Bennett MPH, Finn Schubert BA, Aleza Summit MPH, Ellen Tattelman MD, Linda Prine MD, Marji Gold MD

eLearning for Pregnancy Loss: New Strategies to Teach Miscarriage Management in Family Medicine Settings
Robin Wallace MD, Grace Shih MD, Marji Gold MD

Understanding the Impact of Incarceration on Our Patients and Families
Dana Schonberg MD MPH, Lauren Casey BA, Ariana Bennett MPH, Marji Gold MD

Values Clarification Around Patients' Sexual Decision-Making
Evelyn Figueroa MD, Finn Schubert BA, Ariana Bennett, Aleza Summit, Marji Gold MD

Breaking Down Barriers: Exploring Health Disparities in Contraception Care
Georgie Broomfield MD, Venis Wilder MD, Bhavik Kumar MD, Linda Prine MD, Marji Gold MD

Gynecological Teaching Associates as a Model for Teaching Patient-Centered Women's Health Care
Marji Gold MD, Jennifer Amico MD, Aleza Summit MPH

2014 Family Medicine Education Consortium- Arlington, VA October 2014

Addressing Stigmatized Health Care in Family Medicine
Hilary Rosenstein MD, Ariana Bennett MPH, Ellen Tattelman MD, Marji Gold MD

Miscarriage Management Workshop
Sara Baird MD, Lily Pike MD, Linda Prine MD, Honor MacNaughton MD

Understanding Early Aspiration Abortion in the Family Medicine Setting

Bhavik Kumar MD, Ariana Bennett MPH

Promoting Breastfeeding for Women/Babies Seen in Urban Community Health Centers
Joyce Roberts MD, Marji Gold MD, Aimee Mankodi MD, Laura Tavarez

Breaking down Barriers: Exploring Health Disparities in Contraception Care
Bhavik Kumar MD, Venis Wilder MD, Georgie Bromfield MD, Linda Prine MD, Marji Gold MD

Gynecological Teaching Associates as a Model for Teaching Patient-Centered Women's Health Care
Aleza Summit MPH, Tara Stein MD, MPH

Point of Care Screening for Abdominal Aortic Aneurysm
Linda Prine MD, Brian Ross MD, Chandra Singh MD

Values Clarification around Patients' Sexual Health Decision-Making
Finn Schubert BA, Evelyn Figueroa MD, Aleza Summit MPH, Ariana Bennett MPH, Marji Gold MD

Addressing Reproductive Needs through a Patient-Centered Lens: Looking Beyond the Unintended/Intended Dichotomy
Sarah Miller MD, MPH, Aleza Summit MPH, Ariana Bennett MPH, Marji Gold MD

LARC Provision in Family Medicine: From Enhanced Residency Training to Post-Residency Practice (Poster)
Finn Schubert BA, Tara Stein MD, MPH, Marji Gold MD

Understanding the Impact of Incarceration on Our Patients and Families
Dana Schonberg MD, MPH, Lauren Casey BA, Ariana Bennett MPH

2014 North American Primary Care Research Group- New York, NY November 2014

LARC Provision in Family Medicine: From Enhanced Residency Training to Post-Residency
Practice
Finn Schubert BA, Tara Stein MD, MPH, Marji Gold MD

Women's and Providers' Experiences with Early Elective IUD Removal
Jennifer Amico, MD, Ariana Bennett, MPH; Alison Karasz, PhD, Marji Gold MD

Contraception in Jail: What Do Women Want? A Qualitative Study

Dana Schonberg, MD, MPH, Ariana Bennett, MPH, Alison Karasz, PhD, Marji Gold, MD

2014 Medical Students for Choice Annual Conference- Atlanta, GA November 2014

Non-judgmental Contraceptive Counseling at the Time of an Abortion
Marji Gold MD, Lauren Casey BA

2015 Society of Teachers of Family Medicine- Orlando, FL April 2015

Developing Patient-Centered Teams: The Role of Sharing Stories About Patients and Patient Care
Ariana Bennett MPH, Marji Gold MD

Enhanced Reproductive Health Training for Family Medicine Residents
Aleza Summit MPH, Finn Schubert, Marji Gold MD

Breastfeeding Promotion in Urban Communities
Aimee Mankodi MD, Marji Gold MD, Joyce Robert, Laura Tavarez

Strategies to Improve Clinical and Didactic Education about IUDs and Contraceptive Implants in Family Medicine Residencies
Finn Schubert, Tara Stein MD, Erica Bishop, Marji Gold MD

Looking Beyond the “Intended” Versus “unintended” Pregnancy: Addressing
Reproductive Needs Through a Patient-Centered Lens
Sarah Miller MD MPH, Aleza Summit MPH, Carolyn Pierce MD, Ariana Bennett MPH, Marji Gold MD

What Patients Value about Early Abortion Care in the Family Medicine Setting: Key Implications for Family Medicine Learners
Aleza Summit MPH, Lauren Casey, Alison Karasz PhD, Marji Gold MD

2015 National Abortion Federation- Baltimore, MD April 2015

Using Family Doctors to Increase the Abortion Provider Workforce in the Context of Stigma
Linda Prine MD, Marji Gold MD

2015 Family Medicine Education Consortium- Danvers, MA October 2015

Using Patient-Centered Language During Genitourinary (GU) Exams

Bhavik Kumar MD MPH, Alison Paul MD, Sara Sheilds MD, Navid Roder MD, Marji Gold MD

What Patients Value about Early Abortion Care in the Family Medicine Setting: Key Implications for Family Medicine Learners (Poster)
Aleza Summit MPH, Lauren Casey, Ariana Bennett MPH, Alison Karasz PhD, Marji Gold MD

Addressing the Needs of Patients Who Have Visited Crisis Pregnancy Centers
Lauren Casey, Marji Gold MD

Enhanced Reproductive Health Training for Family Medicine Residents
Aleza Summit MPH, Finn Schubert, Marji Gold MD

Pregnancy and Obesity: Offering respectful Reproductive Health Care to All Women in the Face of Stigma
Aleza Summit MPH, Hilary Rosenstein MD, Marji Gold MD

Providing Patient-Centered Contraceptive Counseling in the Context of Abortion Care
Hannah Helmy PhD MPH, Alison Paul MD, Marji Gold MD

Conversations about Reproductive Coercion in Family Medicine Education
Hilary Rosenstein MD, Sharon Phillips MD MPH, Ariana Bennett MPH, Marji Gold MD

Developing Patient-Centered Team: The Role of Sharing Stories about Patients and Patient Care
Ariana Bennett MPH, Marji Gold MD

2015 North American Primary Care Research Group- Cancun Mexico October 2015

Access to the Copper IUD as Emergency Contraception in Nine U.S. Cities
Finn Schubert, MPH; Erica Bishop; Marji Gold, MD

The Future of Family Planning in Texas: Are Family Physicians Ready?
Bhavik Kumar, MD; Ariana Bennett, MPH; Arthur Blank, PhD; Marji Gold, MD

Women's Experiences With Early Elective IUD Removal
Jennifer Amico, MPH, MD; Ariana Bennett, MPH; Marji Gold, MD; Alison Karasz, PhD

Patient Preferences for Contraceptive Counseling After Abortion
Aleza Summit, MPH; Lauren Casey, BA; Ariana Bennett, MPH; Alison Karasz, PhD; Marji
Gold, MD

Developing Patient-Centered Teams: The Role of Sharing Stories About Patients and Patient Care
Ariana Bennett, MPH; Jane Hassinger; Lisa Martin; Lisa Harris; Marji Gold, MD

2015 Medical Students For Choice- Philadelphia, PA November 2015

Women Seeking Multiple Abortions: Provider Perspectives
Lauren Casey, Marji Gold MD

Provider Panel
Cheryl Chastine MD, Lin Fan Wang MD, Marji Gold MD

2016 North American Primary Care Research Group

Evaluation of Video-based Curriculum Tool for Improving Education about

Long-Acting Reversible Contraception in Family Medicine Residencies

Integration of Onsite LARC services into school-based health centers

“You can’t give this job away”: Being a leader in abortion care

2016 Medical Students For Choice- Tucson AZ, November 2016

Contraceptive Counseling at the Time of Abortion: Provider Perspectives
Rory Woodard, Marji Gold MD

2016 STFM Annual Meeting

The Copper IUD as Post-Coital Contraception: Addressing Access and Knowledge Gaps Erica Bishop, Marji Gold

Providers' Experiences with Early Elective IUD Removal
Jenn Amico, Ari Bennett, Alison Karasz, Marji Gold

Conversations About Reproductive Coercion in Family Medicine Training Hilary Rosenstein, MD; Ariana Bennett, MPH; Sharon Phillips, MD, MPH; Marji Gold, MD

Pregnancy and Obesity: Offering respectful reproductive health care to all women in the face of weight stigma Aleza Summit, Hilary Rosenstein, Marji Gold

Video-based Learning Tool for Improving Education about Long-acting Reversible Contraception in Family Medicine Residencies Aleza Summit, Hannah Helmy, Miranda Dettmann, Marji Gold

Patient-centered contraceptive counseling in the context of abortion care Aleza Summit, Marji Gold, Allison Paul, Hannah Helmy, Lauren Casey

Is there a doctor in the house? A guide to challenging phone calls, for residents and preceptors Alison Paul, Kamini Geer, Marji Gold

2018 Invited Presentation on Medical Abortion; Irish Academy of General Practitioners

PUBLICATIONS

1990 Marji Gold, M.D., "Nurse-Practitioners as Teachers of Family Medicine Residents: In-Hospital Post-partum Rounds", Journal of the American Academy of Nurse Practitioners, April-June 1990 2(2): 79-82

1992 Book Review of Women, Work, and Health published in Family Systems Medicine Vol. 10 No. 2

1994 **Invited contribution**
Marji Gold, M.D., "Improving Skills to Support Breast-Feeding" The Female Patient Vol. 19 No. 9

1995 **Invited Editorial**
Marji Gold, M.D., "Abortion Training in Family Medicine", Family Medicine v. 28, #4: 287-88

1995 **Invited publication**
Marji Gold, M.D., A Curriculum for Teaching First-Trimester Abortion published by Clinician Training Initiative of Planned Parenthood/NYC

1997 Marji Gold, MD, Denise Luks, Pharm.D, Matthew Anderson, MD, "Medical Options for Early Pregnancy Termination", American Family Physician, v.56 #2 pp. 533-8

Denise Luks-Golger, Pharm.D, Marji Gold, MD, Matthew Anderson, MD, "Mifepristone (RU-486): A Promising Alternative to Surgical Abortion", Pharmacy and Therapeutics, v. 22 #1

1998 Gold, Marji; Dyche, Larry; Fulchon, Celestine; Gooding, Anne; and Massad, Robert: "Orientation to Social Medicine and the Bronx: An Adult-Learner, Value-Driven Educational Experience," Teaching and Learning in Medicine 10(2):101-108

2002 Bonuck, K; Arno, P; Memmott, M; Freeman, K; *Gold, M*, McKee, D: "Breast-Feeding Promotion Interventions: Good Public Health and Economic Sense", Journal of Perinatology v. 2: 278-81

Prine, L; Lesnewski, R; Gold, M; "Outcomes of Medical Abortion in Community Family Medicine Practices" Annals of Family Medicine 2003

Lesnewski R, Prine L, Bregman R, Gold M: Benefits of integrating medical abortion into a family medicine residency practice. AMWA Connections, 2003, Sept-Oct; 25(4)

Lesnewski R, Prine L, Gold M: Abortion training as an integral part of residency training. Family Medicine 2003, June; 35(6): 386-387.

Prine L, Lesnewski R, Berley N, Gold M: Medical abortion outcomes in four family practices. Journal of the American Board of Family Practice 2003, July-Aug, 16(4): 290-295

2004 Alison Karasz, PhD, Nicole Tan Kirchen, MD, Marji Gold, MD "The Visit Before the Morning After: Barriers to Pre-prescribing Emergency Contraception", Annals Of Family Medicine Vol. 2, No. 4 July/August 2004

2005 Lesnewski, R., Prine, L., Gold, M., Letter to the Editor re: Safety of and Contraindications for Use of Intrauterine Devices, American Family Physician,
Oct. 2005, 72 (8)

"Medical Education for Social Justice: Paulo Freire Revisited" Alice Fornari, EdD, Kamini Geer, MD, Louisa Hahn, MD, Vanita Kumar, MD, Hyun Joon Lee, MD, Susan Rubin, MD and Marji Gold, MD, Journal of Medical Humanities, 12/06 27:245–251

2007 Wesley Clark MPH, Tanya Panton MD, Louisa Hann MD, Marji Gold MD "Medication abortion employing routine sequential

measurements of serum hCG and sonography only when indicated", Contraception 75 (2007) 131– 135

Wesley H Clark MPH, Marji Gold MD, Daniel Grossman MD, Beverly Winikoff MD, MPH "Can mifepristone medical abortion be simplified? A review of the evidence and questions for future research" Contraception 75 (2007) 245– 250

Christine Dehlendorf, MD, Dalia Brahmi, MD, David Engel, MD, Kevin Grumbach, MD, Carole Joffe PhD; Marji Gold, MD "Integrating Abortion Training into Family Medicine Residency Programs" Family Medicine 2007;39(5):337-42

Dalia Brahmi, MD; Christine Dehlendorf, MD, David Engel, MD; Kevin Grumbach, MD; Carole Joffe PhD; Marji Gold, MD "A Descriptive Analysis of Abortion Training in Family Medicine Residency Programs – Resident Perspectives" Family Medicine 2007;39(6):399-403

Rubin, Susan MD, Godfrey, Emily, MD, Gold, Marji, MD, "Patient Attitudes Toward Early Abortion Services in the Family Medicine Clinic", Research Letter, Journal of the American Board of Family Medicine, *in press*

Invited Book Chapter "Sexual Assault and Abuse" in Gynecology for the Primary Care Physician, Emily Jackson, Joquetta D. Paige, Dalia Brahmi, Adjoa B. Duker, and Marji Gold

Invited Book Chapter "Abortion and Miscarriage" in Gynecology for the Primary Care Physician, Kamini Geer and Marji Gold

2008 Rubin SE, Godfrey E, Gold M. Patient Attitudes Toward Early Abortion Services in the Family Medicine Clinic. The Journal of the American Board of Family Medicine. 2008;21(2):162 -164.

Sobota M, Warkol R, Gold M, et al. An intervention to improve advance emergency contraceptive prescribing practices among academic primary care physicians. Contraception. 2008;78(2):131-135.

2009 Lyus RJ, Gianutsos P, Gold M. First trimester procedural abortion in family medicine. J Am Board Fam Med. 2009 Mar-Apr;22(2):169-74. Erratum in: J Am Board Fam Med. 2009 Nov-Dec;22(6):712. PubMed PMID: 19264940.

Kershnar, R., C. Hooper, M. Gold, E. R. Norwitz, and J. L. Illuzzi. "Adolescent Medicine: Attitudes, Training, and Experience of Pediatric, Family Medicine, and Obstetrics-Gynecology Residents." Yale Journal of Biological Medicine 82.4 (2009): 129-41. Print.

Sampson O, Navarro SK, Khan A, Hearst N, Raine TR, Gold M, Miller S, de Bocanegra HT. Barriers to adolescents' getting emergency contraception through pharmacy access in California: differences by language and region. Perspect Sex Reprod Health. 2009 Jun;41(2):110-8. PubMed PMID: 19493220.

Rubin SE, Godfrey EM, Shapiro M, Gold M. Urban female patients' perceptions of the family medicine clinic as a site for abortion care. Contraception. 2009 Aug;80(2):174-9. Epub 2009 Mar 18. PubMed PMID: 19631794.

2010 Kumar V, Herbitter C, Karasz A, Gold M. Being in the room: reflections on pregnancy options counseling during abortion training. Fam Med. 2010 Jan;42(1):41-6. PubMed PMID: 20063222.

Godfrey EM, Rubin SE, Smith EJ, Khare MM, Gold M. Women's preference for receiving abortion in primary care settings. J Womens Health (Larchmt). 2010 Mar;19(3):547-53. PubMed PMID: 20156084.

Herbitter C, Kumar V, Karasz A, Gold M. Abortion training at multiple sites: an unexpected curriculum for teaching systems-based practice. Teach Learn Med. 2010 Apr;22(2):102-6. PubMed PMID: 20614374.

Rubin SE, Fletcher J, Stein T, Gold M, Segall-Gutierrez P. Underuse of the IUD in contraceptive care and training. Fam Med. 2010 Jun;42(6):387-8. PubMed PMID:20526899.

Grossman D, Holt K, Peña M, Lara D, Veatch M, Córdova D, Gold M, Winikoff B, Blanchard K. Self-induction of abortion among women in the United States. Reprod Health Matters. 2010 Nov;18(36):136-46. PubMed PMID: 21111358.

Invited Book Chapter: " Contraceptive Counseling" in Shields SG, Candib LM. Women-Centered Care in Pregnancy and Childbirth. Radcliffe Publishing; 2010.

2011 Jackson E, Karasz A, Gold M. Family formation in the inner city: low-income men's perception of their role in unplanned conception and pregnancy prevention. J Health Care Poor Underserved. 2011 Feb;22(1):71-82. PubMed PMID: 21317507.

Fornari A, Fletcher J, Herbitter C, Boden L, Gold M. Students as patients and teachers: evaluation of an experiential emergency contraception project. Fam Med. 2011 Mar;43(3):172-8. PubMed PMID: 21380949.

Rubin SE, Fletcher J, Stein T, Segall-Gutierrez P, Gold M. Determinants of intrauterine contraception provision among US family physicians: a

national survey of knowledge, attitudes and practice. Contraception. 2011 May;83(5):472-8. Epub 2010 Dec 3. PubMed PMID: 21477692.

Herbitter C, Greenberg M, Fletcher J, Query C, Dalby J, Gold M. Family Planning Training in US Family Medicine Residencies. Fam Med. 2011 Sep;43(8):574-81. PubMed PMID: 21918937.

Leighton L, Miller S, Phillips S, Schonberg D, Gold M. Meeting women's needs in the PCMH: stories from practice. Fam Med. 2011 Nov-Dec;43(10):743-4. PubMed PMID: 22076720.

Miller, Sarah, Sharon Phillips, Dana Schonberg, Marji Gold, Rachel Rosenheck, and Penina Segall-Gutierrez. "Obesity and the Combined Oral Contraceptive Pill: Efficacy and Effects." Expert Review of Obstetrics & Gynecology 6.5 (2011): 477-80. Print.

2012 Greenberg M, Herbitter C, Gawinski BA, Fletcher J, Gold M. Barriers and enablers to becoming abortion providers: The Reproductive Health Program. Fam Med 2012;44(7):493-500.

Kohn JE, Hacker JG, Rousselle MA, Gold M. Knowledge and Likelihood to Recommend Intrauterine Devices for Adolescents Among School-based Health Center Providers. Journal of Adolescent Health. 2012;51(4):319–324.

Page C, Stumbar S, Gold M. Attitudes and preferences toward the provision of medication abortion in an urban academic internal medicine practice. J Gen Intern Med. 2012;27(6):647–652.

2013 Amico, Jennifer, Lin-Fan Wang, Ariana Bennett, and Marji Gold. "Pregnancy Options Counseling Training as a Paradigm for Teaching Trainees about Counseling Patients." Contraception 88.2 (2013): 305. Print.

Bracken, Hilary, Nguyen Thi Nhu Ngic, Erika Banks, Pau Blumenthal, Richard Derman, Ashiesha Patel, Marji Gold, and Beverly Winikoff. "Misoprostol for Treatment of Intrauterine Fetal Death at 14-28 Weeks of

Pregnancy." *American Journal of Obstetrics and Gynecology* 208.1 (2013): 562-63. Print.

Goodman, S., G. Shih, M. Hawkins, S. Feierabend, P. Lossy, N. J. Waxman, M. Gold, and C. Dehlendorf. "A Long-Term Evaluation of a Required Rotation With Opt-out Provisions for Family Medicine Residents." Family Medicine 45.3 (2013): 180-86. Print.

Guiahi, Maryann, Sahnah Lim, Corey Westover, Marji Gold, and Carolyn L. Westoff. "Enablers and Barriers to Abortion Training." *Journal of Graduate Medical Education* 5.2 (2013): 238-43. Print.

Herbitter, Cara, Ariana Bennett, Finn D. Schubert, Ian M. Bennett, and Marji Gold. "Management of Early Pregnancy Failure and Induced Abortion by Family Medicine Educators." *Journal of the American Board of Family Medicine* 26.6 (2013): 751-58.

Kottenstette, Jennifer B., Marji Gold, Helen Bellanca, Nadine Peacock, Andrea McGlynn, and Debra Stulberg. "Pregnancy Intentions, Reproductive Life Plans, and Preconception Care: Finding the Intersection of Finding the Intersection of Public Health, Clinical Care, and Real LIfe." *Contraception* 88.2 (2013): 303. Print.

Swica, Y., E. Chong, T. Middleton, L. Prine, M. Gold, C. A. Schreiber, and B. Winkoff. "Acceptability of Home Use of Mifepristone for Medical Abortion." *Contraception* 88.1 (2013): 122-27. Web.

2014 Schonberg, Dana, Lin-Fan Wang, Ariana Bennett, Marji Gold, Emily Jackson. “The Accuracy of Using Last Menstrual Period to Determine Gestational Age for First Trimester Medication Abortion: A Systematic Review.” *Contraception* 90 (2014): 480-7. Print.

2015 Bennett, Ariana, Alison Karasz, Marji Gold. “Developing Patient-Centered Teams: The Role of Sharing Stories about Patients and Patient Care.” *Families, Systems, and Health* 33.3 (2015): 203-212. Print.

Schubert, Finn D., Sarp Askel, Ariana Bennett, Nancy R. Glassman, Marji Gold. “A Review of Contraception and Abortion Content in Family Medicine Textbooks.” *Family Medicine* 44.7 (2015):524-528. Print.

Schubert, Finn D., Cara Herbitter, Jason Fletcher, Marji Gold. “IUD Knowledge and Experience Among Family Medicine Residents.” *Family Medicine* 47.6 (2015): 474-7. Print.

Summit, Aleza, Lauren M.J. Casey, Ariana H. Bennett MPH, Alison Karasz PhD, Marji Gold MD. “‘I don’t want to go anywhere else”: Patient Experiences of Abortion in Family Medicine.” *Family Medicine* 48.1(2016):27-31.

Schonberg D, Bennett AH, Sufrin C, Karasz A, Gold M. What Women Want: A Qualitative Study of Contraception in Jail. American journal of public health. 2015;105 (11):2269-2274.

2016 Phillips SJ, Bennett AH, Hacker MR, Gold M. Reproductive coercion: an under-recognized challenge for primary care patients. Family Practice, 2016.

Bennett, Ariana, Alison Karasz, Marji Gold. "Developing Patient-Centered Teams: The Role of Sharing Stories about Patients and Patient Care." *Families, Systems, and Health.* 33:3 (2015): 203-212

Schonberg, Dana, Lin-Fan Wang, Ariana Bennett, Marji Gold, Emily Jackson. "The Accuracy of Using Last Menstrual Period to Determine Gestational Age for First Trimester Medication Abortion: A Systematic Review." *Contraception* 90 (2014): 480-7. PMID 25152258

Schubert, Finn D., Sarp Askel, Ariana Bennett, Nancy R. Glassman, Marji Gold. "A Review of Contraception and Abortion Content in Family Medicine Textbooks." *Family Medicine.* 47:7 (2015):524-8.

Schubert, Finn D., Cara Herbitter, Jason Fletcher, Marji Gold. "IUD Knowledge and Experience Among Family Medicine Residents." *Family Medicine*. 47:6 (2015): 474-7. PMID 26039766

Summit, Aleza, Lauren M.J. Casey, Ariana H. Bennett MPH, Alison Karasz PhD, Marji Gold MD. "'I don't want to go anywhere else": Patient Experiences of Abortion in Family Medicine." *Family Medicine.* 2016;48(1):30-4

Jennifer R. *Amico*, Ariana H. Bennett, Alison Karasz, Marji Gold, "'She just told me to leave it': Women's experiences discussing early elective IUD removal" *Contraception*, Volume 94, Issue 4, October 2016, Pages 357-361

Finn D. Schubert, Erica S. Bishop, Marji Gold Access to the copper IUD as post-coital contraception: results from a mystery caller study *Contraception*, Volume 94, Issue 5, November 2016, Pages 561-566

2017 Amico JR, Bennett AH, Karasz A, Gold M. "I wish they could hold on a little longer": Providers' experiences with requests for early IUD removal. *Contraception* 2017;96(2):106-110

2019 Gold M. Commentary response for "Larc provision by family physicians: low but on the rise". Journal of the American Board of Family Medicine. 2019;32(1):4-5. doi: 10.3122/jabfm.2019.01.180347.

Gold MG. From reproductive rights to reproductive justice. Social Medicine. 2019;12(2):84-92.

Sumathi Narayana, MD | Dana Schonberg, MD, MPH | Zoey Thill, MD, MPP, MPH | Jennifer Amico, MD, MPH | Allison Paul, MD, MPH | Marji Gold, Family Doctors and the Criminalization of Abortion Care
Fam Med. 2019;51(10):803-805

2020 Gold, M et al. Commentary: No-test medication abortion: A sample protocol for increasing access during a pandemic and beyond **Contraception,** Volume 101, Issue 6, June 2020, Pages 361-366

Summitt, A; Lague, I; Gold, M Barriers to and Enablers of Abortion Provision for Family Physicians Trained in Abortion During Residency Perspectives on Asexual and Reproductive Health October 2020 Vol 52:3 pages 151-159

2022 Ushma D. Upadhyay, PhD, MPH; Elizabeth G. Raymond, MD, MPH; Leah R. Koenig, MSPH; Leah Coplon, CNM, MPH; Marji Gold, MD; et al. Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study JAMA Intern Med. 2022;182(5):482-491.

2023 Koenig, Leah, et al. Mailing abortion pills does not delay care: a cohort study comparing mailed to in-person dispensing of abortion medications in the United States **Contraception,** ***in press***

.

Exhibit 10

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF CYNTHIA HARRIS

I, Cynthia Harris, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I have worked in the Sexual and Reproductive Health field for almost 30 years - 7 years at the clinic level and 22 years at the state level. I have been the manager of the Sexual and Reproductive Health Program at the Washington State Department of Health for 10 years.

3. As manager of the Department of Health's Sexual and Reproductive Health Program, my responsibilities are to ensure access within available funding to contraceptive services, STI testing, STI treatment and other sexual and reproductive health services including abortion through contracts with providers throughout Washington State.

4. The most-recent year for which the Washington State Department of Health has finalized abortion-care data is 2021. In 2021, there were 15,968 abortions among Washington residents, out of 100,340 reported pregnancies. In addition to abortions among Washington residents, 998 abortions were provided to non-residents who traveled from out of state. Non-residents seeking abortion care in Washington came from 41 states, as well as Guam and Canada, with the majority coming from Idaho (406), Oregon (330), and Alaska (51).

5. In 2021, 59% of the abortions provided in Washington were medication abortions.

6. The total number of Washington facilities that reported providing abortions in 2021 is 46. Of those facilities, 37 provided five or more abortions.

7. DOH's Sexual and Reproductive Health Program contracts with 6 agencies that have 34 of the 46 clinics that provide abortions in Washington. These contracts are part of DOH's public health mission to improve equitable access to affordable, quality abortion care services for low-income and underserved patients in Washington. The six agencies DOH contracts with are: Planned Parenthood Great Northwest, Hawai'i, Alaska, Indiana, Kentucky; Planned Parenthood of Greater Washington and North Idaho; Planned Parenthood Columbia Willamette; Mount Baker Planned Parenthood; Cedar River Clinics; and Equinox Primary Care.

8. Of the 34 DOH-contracted abortion clinics, 22 are located in western Washington and 12 are located in eastern Washington (east of the Cascade Mountains). Of the 12 contracted clinics in eastern Washington, 11 are operated by Planned Parenthood Greater Washington Northern Idaho, and one is operated by Cedar River Clinics. Outside of these two important partners, DOH has not located providers with the resources, capacity, and willingness to provide abortion care services in the eastern part of the State.

9. All of the 34 DOH-contracted registered abortion clinics in Washington provide medication abortions, with 31 offering medication abortions via telehealth.

10. Twelve of the 34 DOH-contracted registered abortion clinics also provide procedural abortions. Of these 12 clinics that provide procedural abortions, 9 are in western Washington, all located on the I-5 corridor. Three DOH contracted abortion clinics provide procedural abortions in eastern Washington, with one clinic in Kennewick, one clinic in Spokane, and one clinic in Yakima. An additional procedural abortion site will open in Yakima in March 2023.

11. Exhibit 1 is a map showing the 20 out of Washington's 39 counties that have registered abortion clinics that contract with DOH. Abortion service access points are saturated on the western side of the state while sites in the eastern and southern parts of Washington are most likely to serve patients from Idaho and Oregon respectively based on geographic location. Clinics offering both medication and procedural abortion are located further away from each other in eastern Washington, which can cause residents of those counties to travel longer distances to access care, especially depending on appointment availability.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

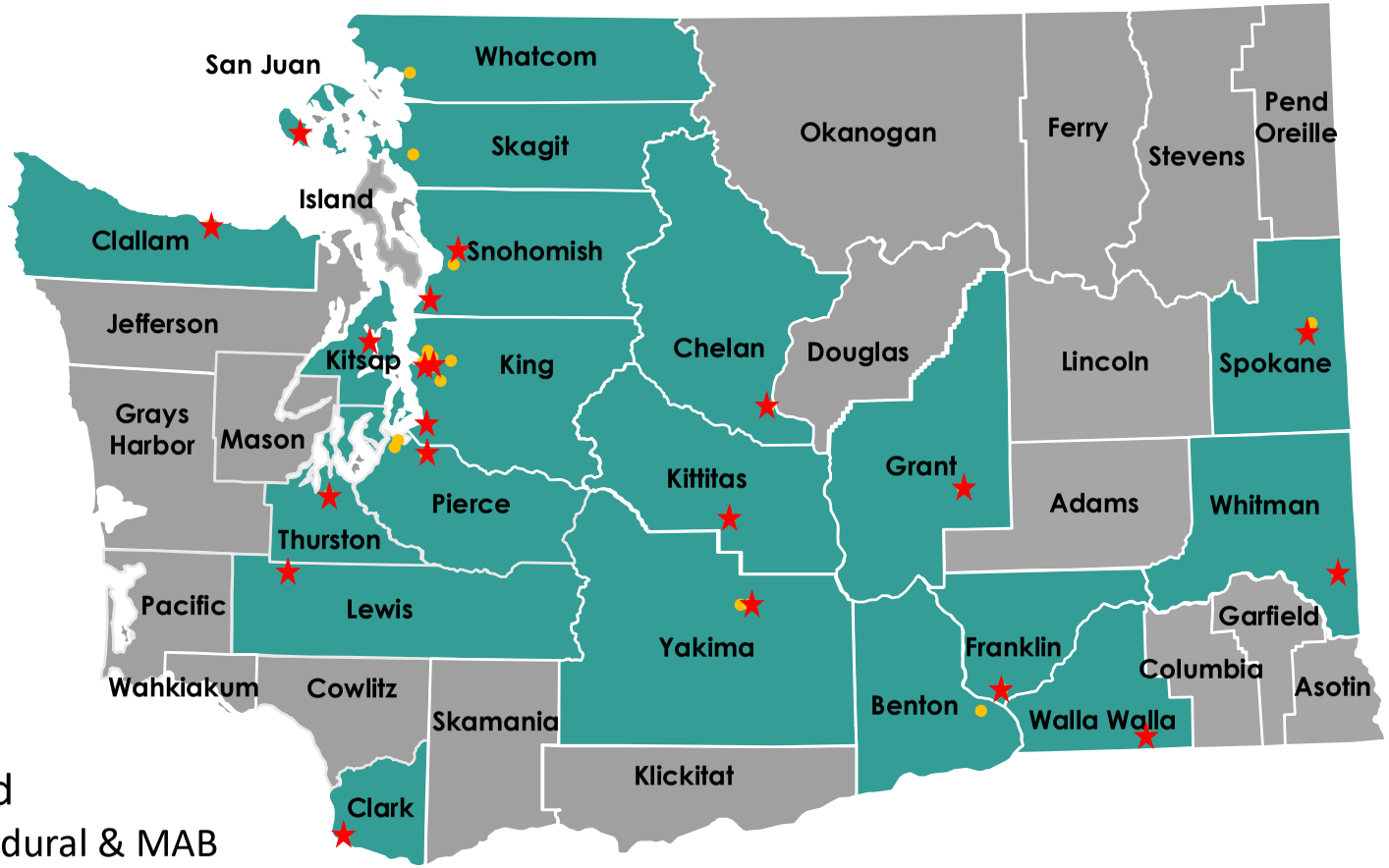
DATED this 21st day of February, 2023, at Mabton, Washington.

Cynthia Harris

CYNTHIA HARRIS

Exhibit A

Washington State Sexual & Reproductive Network Abortion Service Sites



2-SSER-329

Case 1:23-cv-03026 ECF No. 4-1 filed 02/24/23 PageID.781 Page 184 of 386

Exhibit 11

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF SUNDAY HENRY, M.D., GORDON HEDENSTROM, R.PH., AND JOEL SCHWARTZKOPF

Sunday Henry, Gordon Hedenstrom and Joel Schwartzkopf declare as follows:

1. I, Sunday Henry, am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge. I am a board certified family physician and Director of Medical Services at Cougar Health Services. I have provided healthcare services in rural Idaho and Washington State since 2008. I have a Bachelor degree from the University of Idaho, and received my medical degree from Creighton University School of Medicine. I completed a family medicine residency at the Family Medicine Residency of Idaho and completed a fellowship in Primary Care Sports Medicine thereafter. I am also the WSU Head Team Physician.

I, Gordon Hedenstrom, am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge. I am a board certified pharmacist and Pharmacy Director at Cougar Health Services. I have provided pharmacy services in Idaho and Washington including rural eastern Washington over the past 25 years. I received degrees in both Pharmacy and Business Administration from Washington State University. I have served in multiple healthcare positions including Branch Manager, Direction of Regional Operations and most recently, for the past 8 years, as Director of Pharmacy at CHS.

I, Joel Schwartzkopf, am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge. I serve the students of WSU Pullman as the Assistant Vice Chancellor for Student Health and Wellbeing and as the Executive Director of Cougar Health Services. I received my Master of Physician Assistant Studies from the University of Nebraska Medical Center, my Master of Business Administration from Colorado State University, and my Bachelor of Science in Emergency Medical Services from Creighton University.

2. We are submitting this declaration in support of the State of Washington's motion for preliminary injunction.

3. Cougar Health Services (CHS) is a medical center located on the WSU Pullman Campus in Pullman, Washington. As an Accreditation Association for Ambulatory Health Care (AAAHC) accredited facility, CHS offers comprehensive services for preventative, on-going, and acute health needs. Our board-certified providers care for more than 10,000 individual WSU Pullman students each year in a variety of specialties, from sports medicine to gynecology to mental health. CHS pharmacy is a full-service pharmacy located inside the medical clinic on the WSU Pullman Campus.

4. CHS provides gynecological and sexual healthcare for WSU students on our Pullman campus. These services include birth control prescriptions, placement of intrauterine devices and birth control implants, and

counseling on various methods of birth control; emergency contraception/Plan B; sexually transmitted infection testing, treatment and prevention; confirmation of pregnancy and episodic medical care for women who are pregnant.

5. CHS does not offer any type of abortion services for its students, including medication abortion. Instead, it refers students to other providers, including Planned Parenthood, whose closest clinics are in Pullman and Spokane. This referral process is time-sensitive and often creates an undue amount of stress for the student while they are attempting to access services.

6. We are familiar with mifepristone and the associated Risk Evaluation and Mitigation Strategy (REMS) program requirements when used for medication abortion, including the most recent January 2023 REMS. In our opinion, the REMS program requirements act as a barrier to the ability of WSU students to receive comprehensive reproductive health care services in a rural area.

7. In particular, CHS does not have any providers that are registered prescribers for mifepristone under the REMS program requirements and the CHS pharmacy is not an authorized pharmacy under the REMS program requirements.

8. Given the limited availability of reproductive health care services in this rural area, the requirements imposed by the January 2023 REMS act to further limit access to comprehensive reproductive health care services to patients in this community.

(337 of 533)

Case: 23-35294, 06/27/2024, ID: 12893962, DktEntry: 71-3, Page 63 of 259

We declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 21 day of February, 2023, at Pullman, Washington.

Sunday Henry MD
Sunday Henry, MD

Gordon Hedenstrom R.Ph.
Gordon Hedenstrom, R.PH.

Joel Schwartzkopf

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Exhibit 12

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF ELIZABETH JANIAK, SCD, MSC, MA

I, Elizabeth Janiak, ScD, MSc, MA declare as follows:

1. I am over the age of 18. I make this declaration based on my own personal knowledge and am competent to testify as to the matters herein.

A. Background and Qualifications

2. I am an interdisciplinary researcher with expertise in sociology, epidemiology, and health systems research.

3. I am an Assistant Professor of Obstetrics, Gynecology and Reproductive Biology at Brigham and Women's Hospital / Harvard Medical School, and of Social and Behavioral Sciences at the Harvard T.H. Chan School of Public Health.

4. I graduated with a BA from Harvard College and earned an MA in American Studies from New York University. I completed an MSc in Society, Human Development, and Health and ScD in Social and Behavioral Sciences, both from the Harvard T.H. Chan School of Public Health. I received postdoctoral training at Brigham and Women's Hospital. I am a former recipient of the Society of Family Planning Research Fund's Junior Investigator Award.

5. My research explores how public policy and health system characteristics affect the availability and quality of contraceptive and abortion care in the United States. My research utilizes both qualitative and quantitative methods, particularly survey research, analysis of administrative data, and

person-centered qualitative methods such as in-depth interviews and focus groups.

6. A copy of my curriculum vitae is attached hereto as Exhibit A.

7. I submit this declaration in support of Plaintiff's Motion for Preliminary Injunction. I do so only in my individual capacity, not on behalf of any institution with which I am affiliated.

8. I have been retained as an expert in this matter, and am being compensated at a rate of $165 per hour.

B. Expert Opinions

9. The U.S. Food and Drug Administration ("FDA") submits mifepristone, a medication used for early abortion and miscarriage care, to a Risk Evaluation and Mitigation Strategy ("REMS") that, among other things, requires that mifepristone be dispensed by or under the supervision of a certified prescriber, or by certified pharmacies for prescriptions issued by certified prescribers, and the use of Prescriber (or Provider) and Patient Agreement forms. Updates permitting dispensing by certified pharmacies went into effect on January 3, 2023.

1. Mifepristone's safety and efficacy have been established by robust empirical evidence.

10. According to the National Academies of Sciences, Engineering and Medicine's landmark report, *The Safety and Quality of Abortion Care in the*

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

United States, quality abortion care should be safe, effective, patient-centered, timely, efficient, and equitable.[1]

11. Based on my review of literature, I know that "mifepristone has been shown to have an excellent safety profile" and that "[a]bortion with mifepristone is safe and effective."[2] For example, contemporary evidence-based medication abortion protocols using mifepristone and misoprostol have an efficacy rate of 97%.[3]

---

[1] *The Safety and Quality of Abortion Care in the United States.* National Academies of Sciences, Engineering, and Medicine; Health and Medicine Division; Board on Health Care Services; Board on Population Health and Public Health Practice; Committee on Reproductive Health Services: Assessing the Safety and Quality of Abortion Care in the U.S. Washington (DC): National Academies Press (US); 2018 Mar 16.

[2] Calloway D, Stulberg DB, Janiak E. *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States.* Contraception. 2021 July; 104(1):24-28.

[3] Chen M, Creinin MD. *Mifepristone with Buccal Misoprostol for Medical Abortion: a Systematic Review*. Obstet Gynecol 2015;126(1):12-21.

12. Some individuals in need of pregnancy termination prefer medical treatment to procedural intervention such as manual vacuum aspiration.[4] Ensuring access to both procedural and medication abortion options is key to patient-centeredness of abortion care.

2. The REMS have historically impeded access to mifepristone, impairing the timeliness, efficiency, and equity of abortion care.

13. The regulatory regimes imposed by the FDA on mifepristone have consistently impeded access to this safe and effective treatment. In 2000, initial approval mandated use of a restricted distribution system. In 2007, HR3580 authorized the FDA to establish the REMS program, and a REMS program for mifepristone was imposed in 2011.

14. The advent of mifepristone held great potential to expand access to abortion services because a wide array of clinicians is well-qualified to prescribe the drug, including specialist and generalist obstetrician-gynecologists, as well as appropriately trained primary care physicians, family and women's health nurse practitioners, pediatricians, and physician assistants. Because primary care clinicians (n>300,000) vastly outnumber obstetrician-gynecologists (n=approx. 43,000) in the United States, and they are more likely

---

[4]Ho PC. *Women's perceptions on medical abortion*. Contraception. 2006;74(1):11-5.

to practice in underserved and rural communities, integration of mifepristone into primary care settings in particular could improve abortion care timeliness, efficiency, and equity in the United States.[5]

15. The REMS program has impeded widespread provision of mifepristone by generalist obstetrician-gynecologists and by primary care clinicians. In studies among obstetrician-gynecologists in Massachusetts and Alabama, my colleagues and I found that the REMS program constitutes a major barrier to mifepristone use for generalist obstetrician-gynecologists.[6] Further, my research original qualitative research with primary care clinicians

---

[5] Association of American Medical Colleges. [Internet.] Physician Specialty Data Report. Accessed 19 February 2023. Accessible at: https://www.aamc.org/data-reports/workforce/interactive-data/number-people-active-physician-specialty-2021.

[6] Neill S, Goldberg AB, Janiak E. "Medication Management of Early Pregnancy Loss: The Impact of the US Food and Drug Administration Risk Evaluation and Mitigation Strategy [A289]." Obstet Gynecol 2022 139 (2022): 83S; Mokashi M, Boulineaux C, Janiak E, Boozer M, Neill S. “There’s only one use for it”: Stigma as a Barrier to Mifepristone Use for Early Pregnancy Loss in Alabama. [A31]. Obstet Gynecol 2022 139 (2022): 9S-10S.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

in Illinois and several New England states found that individuals trained in and motivated to provide abortion care consistently cite the REMS as a major barrier.[7] Another recent nationwide study similarly concluded that the REMS program impedes mifepristone provision among trained clinicians who desire to integrate abortion services into their scope of practice.[8]

16. In my original research study, primary care clinicians specifically reported that being able to prescribe mifepristone in a manner similar to other drugs, for dispensing at a retail pharmacy, would facilitate provision of medication abortion.[9]

---

[7]Calloway *supra* note 2; Lee CM, Johns SL, Stulberg DB, Allen RH, Janiak E. *Barriers to abortion provision in primary care in New England, 2019-2020: A qualitative study*. Contraception. 2023; 117:39-44.

[8] Razon N, Wulf S, Perez C, McNeil S, Maldonado L, et al. *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics*. Contraception 2022;109(5):19-24.

[9] Rasmussen KN, Janiak E, Cottrill AA, Stulberg DB. *Expanding access to medication abortion through pharmacy dispensing of mifepristone: Primary care perspectives from Illinois*. Contraception. 2021; 104(1):98-103.

3. The January 2023 REMS program continues to impede access to mifepristone

17. The January 2023 REMS program for mifepristone continues to impede access by continuing burdensome requirements from prior REMS and adding additional burdensome requirements for pharmacies.

18. The January 2023 REMS requirement that prescribers register with the drug manufacturer (the "Prescriber Agreement") impedes access to mifepristone in multiple ways.

19. Mifepristone (plus adjunctive misoprostol) is a safe, effective, efficient and patient-centered intervention for miscarriage management as well as abortion.[10] However, the association of mifepristone with abortion can make it difficult to use for any indication.[11]

---

[10] Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*. N Engl J Med 2018;378:2161-70; Chu JJ, Devall AJ, Beeson LE, Hardy P, Cheed V, et al. *Mifepristone and misoprostol versus misoprostol alone for the management of missed miscarriage (MifeMiso): a randomised, double-blind, placebo-controlled trial.* Lancet. 2020; 396(10253): 770–778.

[11] Mokashi *supra* note 6.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

20. By effectively requiring prescribers to register as potential abortion providers, and send those registrations to any pharmacies who may dispense mifepristone, the REMS program creates fear and stigmatization among prescribers. Given a history and ongoing practice of terroristic violence against abortion providers in the United States, individuals logically fear that the registration process mandated by the REMS could put them and their practices at risk.[12]

21. There is no need for a prescriber agreement to ensure safe dispensing of mifepristone, as has been demonstrated by data from Canada. Though Canadian regulations briefly included REMS-like restrictions including provider self-certification and dispensing restrictions, all such regulations were quickly removed after introduction of mifepristone in 2017. Canadian data demonstrate an excellent safety profile for normally prescribed mifepristone with no provider self-certification, including significantly lower rates of documented complications (0.69%) than found in most clinical trials of mifepristone.[13]

---

[12] Cohen DS, Connon K. *Living in the Crosshairs: The Untold Stories of Anti-Abortion Terrorism.* Oxford University Press: 2015.

[13] Schummers L, Darling EK, Dunn S, McGrail K, Gayowsky A, et al. *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada.* N Engl J Med 2022;386:57-67.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

22. The January 2023 REMS requirement that patients sign a specific form (the "Patient Agreement") stating the drug will be used for a medication abortion is another requirement that impedes access to mifepristone. The Patient Agreement's statement that mifepristone will be used for a medication abortion results in unnecessary confusion for patients given the evidence base that mifepristone is also effective for both early pregnancy loss treatment and cervical preparation prior to dilation and evacuation procedures.[14] Patients should not be mandated to sign a form that may contradict their own treatment plan.

23. The January 2023 REMS requirement that pharmacies must be certified by the manufacturer in order to dispense mifepristone is another requirement that impedes access to mifepristone. Based on my review of literature, there is no evidence that a pharmacy should have to be specially certified to dispense mifepristone and it is irrefutably clear that mifepristone can be safely prescribed through the typical avenues.[15] While conferring no benefit

---

[14] Goldberg AB, Fortin JA, Drey EA, Dean G, Lichtenberg ES, et al. *Cervical Preparation Before Dilation and Evacuation Using Adjunctive Misoprostol or Mifepristone Compared With Overnight Osmotic Dilators Alone: A Randomized Controlled Trial*. Obstet Gynecol. 2015;126(3):599-609..

[15] Schummers *supra* note 13; Grossman D, Baba CF, Kaller S, Biggs MA, Raifman S, et al. *Medication Abortion with Pharmacist Dispensing of Mifepristone*. Obstet Gynecol. 2021;137(4):613-622.

to patient safety, the pharmacy certification requirement does burden pharmacists and prescribers, impeding their ability to offer mifepristone. By compelling pharmacies to become certified and to verify that all prescriptions they fill are from a certified prescriber specifically registered as a mifepristone provider, the REMS program creates administrative hurdles that may be difficult or impossible for some pharmacies to negotiate.

4. The 2023 REMS program for mifepristone perpetuates, health inequities by race/ethnicity, gender, geography, age, and other factors.

24. People who receive abortion care in specialty reproductive health clinics or via telemedicine are overwhelmingly very satisfied with their care.[16] Nonetheless, according to research conducted in both abortion specialty clinic

---

[16] Tilles C, Denny A, Cansino C, Creinin MD. *Factors influencing women's satisfaction with surgical abortion.* Contraception. 2016;93(2):164-9; Meurice ME, Whitehouse KC, Blaylock R, Chang JJ, Lohr PA. *Client satisfaction and experience of telemedicine and home use of mifepristone and misoprostol for abortion up to 10 weeks' gestation at British Pregnancy Advisory Service: A cross-sectional evaluation*. Contraception. 2021;104(1):61-66.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

settings and primary care settings, a majority of patients would prefer to receive abortion care in their usual site of care or from a known provider.[17]

25. Preference for receiving abortion care within a system where one is an established patient may be driven by a variety of factors, including a pre-existing, trusting relationship between patient and provider. Individuals who experience high distrust of medical settings, including people who identify as Black, Indigenous, or People of Color (BIPOC), may particularly benefit from integration of abortion services into settings where their trust as patients has already been earned. Moreover, individuals with unique clinical and social needs—such as individuals who do not speak English, persons with disabilities, trans, nonbinary, and gender nonconforming (TGNC) patients, and adolescents—may benefit from tailored models of care. For all patients, choice of care setting is paramount to patient-centeredness, a key attribute of quality abortion care.[18]

26. By preventing trained and willing clinicians from integrating mifepristone into their scope of practice, the 2023 REMS program eliminates or

---

[17] Godfrey EM, Rubin SE, Smith EJ, Khare MM, Gold M. *Women's preference for receiving abortion in primary care settings*. J Womens Health (Larchmt). 2010;19(3):547-53; Rubin SE, Godfrey E, Gold M. *Patient attitudes toward early abortion services in the family medicine clinic*. J Am Board Fam Med. 2008;21(2):162-4.

[18] National Academies *supra* note 1.

limits choice of abortion care setting for many. The burdens of lack of choice fall disproportionately on individuals who lack geographic access to abortion care providers, even in states where abortion remains broadly legal—as in many areas in the US Midwest and South, and rural locations.[19]

5. The ability to access mifepristone via specially certified mail order pharmacies does not resolve access barriers imposed by the 2023 REMS program nor ameliorate its impacts on health inequities.

27. Mailing mifepristone is a safe and effective service delivery model that may improve access to care for some patients.[20] However, mailed mifepristone is not a viable alternative to pharmacy dispensing for all individuals. In particular, people experiencing intimate partner violence (IPV) may not be able to safely receive abortion medications via mail. Reproductive coercion (RC) is a form of IPV that can include the behavior of coercing an individual to

---

[19] Jones RK, Kirstein M, Philbin J. *Abortion incidence and service availability in the United States, 2020*. Perspect Sex Reprod Health. 2022;54(4):128-141.

[20] ARA Aiken ARA, Lohr PA, Lord J, Ghosh N, Starling J. *Effectiveness, safety and acceptability of no-test medical abortion (termination of pregnancy) provided via telemedicine: a national cohort study*. BJOG 2021;128:1464-74.

continue a pregnancy against their will. While estimates of the prevalence of RC vary widely, a recent study found 1 in 6 obstetrics and gynecology patients have experienced RC.[21]

28. Other populations who may not be able to safely receive mifepristone via mail include young people who must keep their pregnancy private from family members. My research has found that though large majorities of young people involve parents and other adult relatives in abortion decisions and care-seeking, some individuals fear a pregnancy disclosure could precipitate abuse, loss of housing, or withholding of financial resources.[22]

29. Mailed mifepristone is also not a substitute for pharmacy dispensing for individuals experiencing housing insecurity and homelessness. While the prevalence of homelessness among abortion patients specifically is not

---

[21] Clark LE, Allen RH, Goyal V, Raker C, Gottlieb AS. *Reproductive coercion and co-occurring intimate partner violence in obstetrics and gynecology patients*. Am J Obstet Gynecol. 2014;210(1):42.e1-8.

[22] Tantoco NK, Goldberg AB, Sabino J, Janiak E. *"They would be disappointed": an analysis of minors' motivations for seeking judicial bypass of Massachusetts' parental consent requirement for abortion.* [Abstract.] Contraception 2017;96(4):276.

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

well documented, prior research found 1 in 8 abortion patients had moved multiple times in the prior year.[23] Abortion patients in the United States are disproportionately low-income and vulnerable to disruptive life events that threaten housing stability.

6. Conclusion

30. To improve reproductive health care quality and equity, policies and health systems should endeavor to make abortion services available to patients in a wide variety of settings that can meet their diverse and unique needs. It is my expert opinion that removing the Patient Agreement Form, the Prescriber and Provider Agreements, and the pharmacy certification requirement currently imposed by the January 2023 REMS will significantly improve public health in the United States.

---

[23] Jones RK, Frohwirth L, Moore AM. *More than poverty: disruptive events among women having abortions in the USA*. J Fam Plann Reprod Health Care. 2013;39(1):36-43.

I declare under penalty of perjury under the laws of the State of Washington and the United States that the foregoing is true and correct.

DATED this 21st day of February, 2023, at Boston, Massachusetts.

Elizabeth Janiak, ScD, MSc, MA

Exhibit A

Elizabeth Janiak, ScD
ejaniak@bwh.harvard.edu | 617-525-9686
Abbreviated Curriculum Vitae / NIH Biosketch Hybrid

Education and Training

INSTITUTION AND LOCATION	DEGREE	DATE	FIELD OF STUDY
Harvard College, Cambridge, MA	BA	06/2003	Comparative Study of Religion
New York University, New York, NY	MA	05/2007	American Studies
Harvard School of Public Health, Boston, MA	MSc	05/2011	Society, Human Development, and Health
Harvard T.H. Chan School of Public Health, Boston, MA	ScD	05/2016	Social and Behavioral Sciences
Brigham and Women's Hospital / Harvard Medical School, Boston, MA	Postdoctoral Research Fellowship	06/2017	Obstetrics, Gynecology and Reproductive Biology

Faculty Appointments

2017-2019	Instructor, Department of Obstetrics, Gynecology and Reproductive Biology, Brigham and Women's Hospital and Harvard Medical School
2017-2019	Instructor, Division of Women's Health, Department of Medicine, Brigham and Women's Hospital and Harvard Medical School
2017-	Lecturer, Women's and Gender Studies, Massachusetts Institute of Technology
2018-2021	Instructor,Social and Behavioral Sciences, Harvard T.H. Chan School of Public Health
2019-	Assistant Professor, Department of Obstetrics, Gynecology and Reproductive Biology, Brigham and Women's Hospital and Harvard Medical School
2022-	Assistant Professor of Social and Behavioral Sciences, Harvard T.H. Chan School of Public Health

Personal Statement
I am an interdisciplinary social science researcher studying the impact of public policy and social determinants of health on access to and quality of abortion and contraceptive care in the United States. Broadly, my research explores how dynamics of social inequality affect just and equitable reproductive healthcare access. My methodological expertise includes qualitative research, causal inference for observational data sets, and survey design. I use an intersectional approach to analyze how inequities in reproductive health outcomes according to race, gender, sexual orientation, geography, dis/ability, and socioeconomic class are produced. I also design and evaluate structured interventions to improve reproductive health care quality. I am particularly interested in the role of social stigma and conscious and unconscious bias in shaping health outcomes. Ongoing and recent projects that I would like to highlight include:

R21 HD103977
Janiak (PI)
07/2021-06/2023
National Institute for Child Health and Human Development, *Birth Control to Improve Birth Spacing (BIBS)*
Sequential mixed-methods study of drivers of postpartum contraceptive use.

R01 AA030529
Hall and Welsh (MPIs); Janiak Role: Site PI, co-investigator
09/2022-08/2027
National Institute on Alcohol Abuse and Alcoholism, *Improving alcohol and substance use care access, outcomes, and equity during the reproductive years: A Type 1 Hybrid Trial in Family Planning Clinics*

Irving Harris Foundation and Large Anonymous Donor
Janiak and Stulberg (Co-PIs)
01/2019-12/2024
Expanding Access to Mifepristone in Primary Care Settings
Mixed-methods implementation science and efficacy study of two interventions to identify and ameliorate barriers to evidence- based use of mifepristone for abortion and miscarriage care.

Massachusetts Executive Office of Health and Human Services
White (PI), Janiak Role: Site PI, co-investigator
10/2018-09/2023
Partners in Contraceptive Choice and Knowledge (PICCK)
Research and evaluation embedded in a technical assistance program for Massachusetts birth hospitals to improve quality and scope of contraceptive care.

Selected Citations (chronological order):

a. **Janiak E,** Goldberg AB. Eliminating the phrase “elective abortion”: why language matters. Contraception, 2016;93(2):89-92.
b. Mallampati D, Simon MA, **Janiak E**. Evolving state-based contraceptive and abortion policy. JAMA 2017;317(24):2481-2482.
c. Smith BEY, Bartz D, Goldberg AB, **Janiak E**. "Without any indication": stigma and a hidden curriculum within medical students' discussion of elective abortion. Soc Sci Med. 2018;10(214):26-34.
d. **Janiak E**, Fulcher IR, Cottrill AA, Tantoco N, Mason AH, Fortin J, Sabino J, Goldberg AB. Massachusetts' Parental Consent Law and Procedural Timing Among Adolescents Undergoing Abortion. Obstet Gynecol. 2019;133(5):978-986.
e. Calloway D, Stulberg DB, **Janiak E**. Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States. Contraception. 2021;104(1):24-28.
f. Fulcher IR, Onwuzurike C, Goldberg AB, Cottrill AA, Fortin J, **Janiak E**. The impact of the COVID-19 pandemic on abortion care utilization and disparities by age. Am J Obstet Gynecol. 2022;226(6):819.e1-819.e15
g. Ravi K, **Janiak E**. Adverse pregnancy outcomes: biological essentialism versus embodied biology. Lancet. 2022 05 28; 399(10340):2013-2014.

B. Positions, Scientific Appointments, and Honors

Positions and Non-faculty Scientific Appointments

2007-	Member, Abortion Access Steering Committee, Massachusetts Department of Public Health
2007-2009	Case Manager, Massachusetts Abortion Access Program at Planned Parenthood League of Massachusetts
2011-	Member, American Public Health Association
2011-2014	Member, Association of Reproductive Health Professionals
2013-2017	Junior Fellow, Society of Family Planning
2014-2017	Junior Fellows Committee, Society of Family Planning
2016-	Director of Social Science Research, Planned Parenthood League of Massachusetts
2017	Co-chair, Trainee Grant Review Committee, Society of Family Planning Research Fund
2017-2021	Elected Faculty Representative in Population Health, Research Oversight Committee, Brigham Research Institute, Brigham and Women’s Hospital
2018-	Full Fellow, Society of Family Planning
2019-2020	Member, Annual Meeting Committee, Society of Family Planning Research Fund
2020	Grant Reviewer, Fellowship in Complex Family Planning
2021	Grant Reviewer, Robert Wood Johnson Foundation, Health Data for Action grants
2016-	*Ad hoc* Reviewer (selected): *American Journal of Public Health, Contraception, Health Equity, Historical Methods, Journal of Health and Social Behavior, Perspectives on Sexual and Reproductive Health, PLoS ONE, Social Science and Medicine – Population Health*
2023-	Associate Editor, *Contraception and Reproductive Medicine*

Honors

1999-2002	John Harvard Scholarship for Academic Distinction
2003	Graduated *summa cum laude,* Harvard College, Cambridge, MA
2003	Elected *Phi beta kappa,* Alpha Iota of Massachusetts, Harvard College, Cambridge, MA
2004-2007	MacCracken Fellow, tuition, stipend, and research grant, New York University, New York, NY
2009-2010	Lowney Memorial Scholarship, Planned Parenthood League of Massachusetts, Boston, MA
2009-2011	Pforzheimer Public Service Fund tuition grant, Harvard School of Public Health, Boston, MA
2012-2013	Seiden Denny Scholarship and Stipend, for excellence in maternal and child health, Harvard School of Public Health, Boston, MA
2013-2014	Institutional Tuition Grant, Harvard School of Public Health, Boston, MA
2013	Population, Reproductive, and Sexual Health Section Student Scholarship, for outstanding commitment to sexual and reproductive health, American Public Health Association Annual Meeting, Boston, MA
2014-2015	Junior Investigator Award, Society of Family Planning Research Fund, SFPRF8-JI1
2014-2016	Maternal and Child Health/Children, Youth, and Families Interdepartmental Concentration Award, tuition grant and stipend, Harvard T.H. Chan School of Public Health, Boston, MA
2018-2021	Eleanor and Miles Shore 50th Anniversary Award for Scholars in Medicine, salary and research support, Harvard Medical School

C. Contribution to Science

a. Analyzing how social norms and attitudes affect access to and experiences of reproductive health care. To explore the mechanisms through which *interpersonal and individual level* barriers to reproductive health care operate, I have developed a body of research grounded in behavioral theory. This includes both qualitative studies to probe how stigma affects health care professionals and patients, as well as quantitative studies using validated psychometric scales. My research highlights how social norms drive interest in and ability to obtain reproductive health services, affecting care-seeking behavior and driving experiences of interpersonal discrimination in health care settings. However, social norms and their relative impact on access to care are profoundly shaped by intersecting dynamics of power and oppression related to gender identity, racial and ethnic identity, and socioeconomic position.

   a. **Janiak E**, Freeman S, Maurer R, Berkman LF, Goldberg AB, Bartz D. Relationship of job role and clinic type to perceived stigma and occupational stress among abortion workers. Contraception 2018;98(6):517-521.
   b. Smith BEY, Bartz D, Goldberg AB, **Janiak E**. "Without any indication": stigma and a hidden curriculum within medical students' discussion of elective abortion. Soc Sci Med. 2018;10(214):26-34.
   c. Agénor M, Cottrill AA, Kay E, **Janiak EF**, Gordon AR, Potter J. Contraceptive Beliefs, Decision Making and Care Experiences Among Transmasculine Young Adults: A Qualitative Analysis. Perspect Sex Reprod Health. 2020;52(1):7-14.
   d. **Janiak E**, Braaten KP, Cottrill AA, Fulcher IR, Goldberg AB, Agénor M. Gender diversity among aspiration-abortion patients. Contraception. 2021;103(6):426-427.
   e. Merz AA, **Janiak E**, Mokashi M, Allen RH, Jackson C, Berkowitz L, Steinauer J, Bartz D. "We're called upon to be nonjudgmental": A qualitative exploration of US medical students' discussions of abortion as a reflection of their professionalism. Contraception. 2022;106(2):57-63.

b. Illuminating how health systems characteristics affect reproductive health care quality. My body of work at the *health systems level* focuses on understanding drivers of care quality across domains of timeliness, safety, and patient-centeredness. Using survey data and a variety of administrative sources including the electronic medical record (EMR), paper-based medical charts, and on-the-shelf data from case management programs, my research has found that patients face multiple barriers to quality care including gaps in physician knowledge and inconsistent access to high-quality referrals. These gaps in quality often fall disproportionately on individuals using public insurance and individuals who identify as people of color.

   a. Holt K, **Janiak E**, McCormick MC, Lieberman E, Dehlendorf C, Kajeepeta S, et al. Pregnancy options counseling and abortion referrals among United States primary care physicians: results from a national survey. Family Medicine. 2017;49(7):527-536.

b. Ho S, **Janiak E.** Impact of a case management programme for women seeking later second-trimester abortion: the case of the Massachusetts Access Program. BMJ Sex Reprod Health. 2018 Jul 14.
c. Maistrellis E, **Janiak E**, Hammel R, Hurwitz S, Delli-Bovi L, Bartz D. Demographic, Clinical, and Counseling Factors Associated with the Selection of Pregnancy Termination Method in the Second Trimester for Fetal and Pregnancy Anomalies. Women's Health Issues. 2019; 29(4):349-355.
d. **Janiak E**, Clark J, Bartz D, Langer A, Gottlieb B. Barriers and Pathways to Providing Long-Acting Reversible Contraceptives in Massachusetts Community Health Centers: A Qualitative Exploration. Perspect Sex Reprod Health. 2018;50(3):111-118.
e. Cottrill AA, Fulcher IR, Goldberg AB, Sabino J, Fortin J, **Janiak E**. Time Trends in Massachusetts Adolescents' Postabortion Contraceptive Uptake. J Adolesc Health. 2021; 68(2):364-369.

c. Describing how policy-level factors influence access to reproductive health care. I have conducted original research to understand how *state and federal laws and regulations* impact access to reproductive healthcare, including through modeling studies, EMR analyses, and qualitative research. Additionally, I have published policy analyses in high-impact journals such as *JAMA*. My research has found that it is imperative to understand the interplay of federal and state policies to correctly characterize their combined influence on health care access and health outcomes.
a. **Janiak E**, O'Donnell J, Holt K. Proposed Title X Regulatory Changes: Silencing Health Care Providers and Undermining Quality of Care. Womens Health Issues. 2018; 28(6):477-479.
b. Foley O, **Janiak E**, Dutton C. Women's decision making for postpartum sterilization: does the Medicaid waiting period add value? Contraception. 2018;98(4):312-316.
c. **Janiak E**, Fulcher IR, Cottrill AA, Tantoco N, Mason AH, Fortin J, Sabino J, Goldberg AB. Massachusetts' Parental Consent Law and Procedural Timing Among Adolescents Undergoing Abortion. Obstet Gynecol. 2019;133(5):978-986.
d. Fulcher IR, Neill S, Bharadwa S, Goldberg AB, **Janiak E**. State and federal abortion restrictions increase risk of COVID-19 exposure by mandating unnecessary clinic visits. Contraception. 2020; 102(6):385-391.
e. **Janiak E**, Belizaire C, Liu J, Fulcher IR. The association of U.S. state-level abortion restrictions with medication abortion service delivery innovations during the early COVID-19 pandemic. Contraception. 2022;113(9):26-29.

Link to full list of publications (41 indexed publications as of January 2023):
http://www.ncbi.nlm.nih.gov/pubmed/?term=janiak+e

D. Contribution to Teaching

a. Reproductive Health, Rights, and Justice course design (2018). Created novel course for the Harvard Chan School's Women, Gender, and Health scholarly concentration. Course compares and contrasts perspectives on reproduction from biomedical, human rights, and reproductive justice paradigms, drawing on historial, epidemiological, and sociological literature. Original course, unique within the school, approved by faculty committee, full departmental faculty, and schoolwide curriculum committee through rigorous multistep process.
b. Anti-Racism in OB/GYN: from Knowledge to Action course design (2020). Created a lecture series on anti-racist knowledge and practices for faculty and trainees in BWH Obstetrics and Gynecology. Course includes speakers of national renown and covers foundational knowledge and skill-building in the realms of research, care delivery, and advocacy.

E. Selected Additional Funding, 2017-present

Fellowship in Complex Family Planning Grant
Janiak (PI); Trainee PI: Sara Neill, MD, MPH
07/2019-06/2021
Mifepristone use among Massachusetts obstetrician-gynecologists

Mixed-methods exploration of barriers to and facilitators of mifepristone use for early pregnancy loss and abortion among generalist OB/GYNs.

SFPRF12-II4, Society of Family Planning Research Fund
Janiak (PI)
10/2017-05/2021
Abortion Stigma Reduction at the Population Level: Development of a Mass Media Intervention
Public health researchers and practitioners have partnered to improve population health by combating stigma around myriad health issues. Our study uses this approach to develop evidence-based messaging and to test its efficacy in reducing abortion stigma.

SFPRF11-01, Society of Family Planning Research Fund
Braaten (PI); Role: Co-investigator
10/2017-09/2020
Understanding and Addressing the Needs of Abortion Patients Who Use Opioids: A Mixed-Methods Study
This mixed-methods study explored abortion experiences and care quality among women who use opioids, with a focus on pain management, post-abortion contraceptive needs, and stigma reduction.

Brigham Care Redesign Incubator Start-Up Program
Janiak (Co-PI with Candace Feldman, MD, ScD)
01/2017-12/2018
Screening to Understand Pregnancy Preferences and Offer Referrals and Treatment (SUPPORT)
Intervention uses reproductive life planning screening question and referral pathways to contraceptive and preconception care to address disparities in health outcomes for women with systemic rheumatic disease.

SFPRF10-1, Society of Family Planning Research Fund
Janiak (PI)
10/2016-09/2018
Describing the impact of parental involvement laws for minors seeking abortion care: the case of Massachusetts
Retrospective review of clinical records and legal referral information for over 2,000 minors seeking abortion.

F. Selected Invited Lectures and Abstracts, 2017-present

2017 “Hospital Culture and Abortion Stigma: How Institutional Policies and Climate Affect Patient Care” (invited presentation) North American Forum on Family Planning, Atlanta, GA
2017 “State-level Abortion Restrictions: History, Trends, and Evidence of Impact” (Grand Rounds) Department of Obstetrics and Gynecology, Beth Israel Deaconess Medical Center
2018 “Abortion Care for Individuals who Use Opioids” (Lecture) Abortion Seminar, University of California San Francisco
2018 “A Clinical Pathway Model for Effective Referrals for Long-Acting Reversible Contraception” (invited roundtable) American Public Health Association Annual Meeting, San Diego, CA
2018 “Improving Reproductive Health Care for Women with Systemic Rheumatic Disease” (Grand Rounds) Division of Rheumatology, BWH
2018 “Geographies of Inequality: State-level Abortion Restrictions in the United States” (lecture) Willows Reproductive Health Speaker Series, Dept of Global Health and Population, Harvard Chan School
2020 “Intersectionality: a Practical Primer for Reproductive Health Research” (Grand Rounds) Department of Obstetrics and Gynecology, BWH
2021 “Contraceptive autonomy among pregnancy-capable individuals with disabilities” (lecture) Disability and Disparities Seminar, Lurie Institute for Disability Policy, Brandeis University
2021 “Public Health Implications of Texas Senate Bill Eight’s Abortion Ban” (panel) Boston College Law School
2022 “Geographies of Inequality: How Increasing Abortion Restrictions Affect Population Health in the United States” (lecture) Course: Advancing Women’s Health: A 2022 Update / Department of Medicine, BWH
2022 “Reproductive Autonomy and Abortion” (lecture series) University of Global Health Equity, Kigali, Rwanda

Exhibit 13

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF JUDY LAZARUS

I, Judy Lazarus, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am a Certified Nurse-Midwife with Neighborcare Health, where I am a clinician in full scope practice. I am a Doctor of Nursing Practice (DNP), Advanced Registered Nurse Practitioner (ARNP), and Fellow of the American College of Nurse-Midwives (FACNM).

3. In addition to my full scope clinical practice, I was a midwifery educator at the University of Washington in the School of Nursing, Department of Child, Family, and Population Health Nursing for 20 years. I retired from teaching in [2020]. During my teaching career, I served as Chair of the American College of Nurse-Midwives Preceptor Development and Support Committee for the Clinical and Academic Educators Committee.

4. Neighborcare Health's mission is to provide comprehensive health care to families and individuals who have difficulty accessing care; respond with sensitivity to the needs of our culturally diverse patients; and advocate and work with others to improve the overall health status of the communities we serve. As an organization, our values are social justice, cultural sensitivity, community, and excellent care and service to our patients and community.

5. Neighborcare Health serves communities and patients who are underserved by the larger health care system and who face barriers to accessing

high-quality health care. In 2021, 80% of the patients Neighborcare Health served were individuals living at or below the federal poverty level. The same year, 73% of our patients were either insured by Medicaid or uninsured. Our patients are racially and ethnically diverse, with approximately 89% of our midwifery patients self-identifying as members of a minority racial or ethnic group. In 2021, we served 27% of our patients in a language other than English.

6. Neighborcare Health operates clinics, mostly in greater Seattle and King County area. We operate 12 medical clinics, 7 dental clinics, 14 school-based health centers, 3 homeless and housing clinics, and 5 pharmacies.

7. Neighborcare Health is a federally qualified health center (FQHC), a federal designation applicable to community-based health organizations that qualify for federal funding in order to provide primary care and preventive care services to individuals regardless of their ability to pay. FQHCs like Neighborcare Health are a critical part of the nation's health care safety net.

8. Federal law does not permit FQHCs to use federal funds, either directly or indirectly, to provide abortion services. Accordingly, Neighborcare Health provides no abortion services at any of its clinics or locations.

9. Neighborcare Health routinely treats patients who are experiencing early pregnancy loss, sometimes referred to as miscarriage. Early pregnancy loss is common and occurs in approximately one out of every 10 known pregnancies.

10. Mifepristone is a drug that is safe and effective for use in treating early pregnancy loss that occurs up to 12 weeks gestation. Using a two-drug regimen, which is the gold-standard of care, a patient experiencing early pregnancy loss is prescribed one dose of mifepristone and one dose of misoprostol. A patient first takes mifepristone, which blocks the hormone progesterone, a hormone necessary to maintain the interior of the uterus. Between 24 and 48 hours later, the patient then takes misoprostol, which causes cramping and bleeding to expel the contents of the uterus. This process completes the miscarriage.

11. Decades of evidence demonstrate that use of mifepristone, followed by misoprostol, to treat early pregnancy loss is both safe and effective.

12. While misoprostol can be used alone for the medical management of early pregnancy loss, a combination of misoprostol and mifepristone has been proven to be much more effective in the management of early pregnancy loss. When used alone, misoprostol has a rate of 67% for complete expulsion of pregnancy products two days after the medication is taken. The addition of mifepristone to medical management of early pregnancy loss increases the rate of completion after two days up to 84%. A 2018 randomized controlled trial comparing mifepristone and misoprostol to misoprostol alone, confirmed that the combination is more efficacious with a 25% increase in completion of the expulsion of products of conception. In addition, the study noted that the

combination was associated with a 37% decreased risk of the need for uterine aspiration to complete treatment. Reports of adverse events were rare in both groups and experiences of bleeding intensity, pain, and adverse events were the same in the combination group as with misoprostol alone.

13. The availability of mifepristone to treat early pregnancy loss has advantages for patients and health care providers. For patients, use of mifepristone to treat early pregnancy loss allows them to be at home, in a setting under their control, when they experience cramping, bleeding, and the passing of the uterine contents. The procedural alternative of evacuation requires a patient to come to a clinic and undergo a vaginal procedure. For many patients, the evacuation procedure is experienced as traumatic and invasive, and co-occurs at a time of pregnancy loss that may already be traumatic for patients.

14. For clinics, use of mifepristone to treat early pregnancy loss frees clinic space, equipment, providers, and staff to treat patients and conditions that cannot be treated outside the clinical setting. For organizations like ours committed to treating as many patients in need of care as possible, the use of mifepristone to treat early pregnancy loss has clear upsides for patient access and health equity.

15. I am familiar with the amended Risk Evaluation and Mitigation Strategy (REMS) on prescribing and dispensing mifepristone, which took effect on January 3, 2023.

16. The REMS includes requirements that mifepristone be dispensed by or under the supervision of a certified prescribers. Practitioners must sign a Prescriber Agreement form to become certified by the drug's manufacturer. Requiring providers to be specially certified will reduce the number of providers who will be able to prescribe mifepristone to treat early pregnancy loss. For example, family practice doctors who treat early pregnancy loss a couple of times a year are less likely to be able to devote the time to getting credentialed to prescribe mifepristone. This may mean that a patient experiencing early pregnancy loss will need to see someone other than their usual, trusted provider at a time when they may already be experiencing significant trauma. Simply put, when a medication is harder than usual to prescribe—even when it is the evidence-based standard of care—fewer providers will be able to prescribe it, even if they would like to.

17. The REMS also includes a requirement that mifepristone be dispensed only by specially certified pharmacies. This is a significant practical obstacle for community pharmacies and the patients who use them. Because of the REMS, fewer pharmacies will become certified, and patients will have to search farther to find a specially certified pharmacy. For patients like ours, many of whom do not own a car, do not speak English, or have work schedules or family obligations that do not allow them to spend time during the day searching for a specially certified pharmacy, this barrier imposed by the REMS means that

they would be less likely to be able to get a mifepristone prescription filled, even if their provider prescribed it.

18. The REMS also require a patient receiving mifepristone to sign a Patient Agreement Form. The form states near the top "I have decided to take mifepristone and misoprostol to end my pregnancy." Patients experiencing early pregnancy loss do not "decide" to end their pregnancies, and this language is an inaccurate and harmful REMS requirement, given how commonly mifepristone is prescribed for early pregnancy loss. In my own practice, if Neighborcare Health develops the ability to prescribe and dispense mifepristone, I will need to spend significant time counseling patients regarding the language on this form, and how it relates to the use of mifepristone for early pregnancy loss.

19. Notwithstanding Neighborcare Health's commitment to delivering evidence-based, high-quality health care, we are currently unable because of the REMS to offer mifepristone to treat early pregnancy loss. If mifepristone did not carry a REMS, I am confident that Neighborcare Health providers would already be prescribing mifepristone and working to help our patients access it.

20. In partnership with one of my colleagues in Neighborcare Health's clinical midwifery practice, Jessica Burke-Lazarus, I have been working on a care delivery proposal that would allow Neighborcare Health to prescribe and dispense mifepristone to treat early pregnancy loss. Because of the heightened training, compliance, recordkeeping, and other requirements of the mifepristone

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

REMS, it will take months of work before Neighborcare Health will be able to make a final decision about whether it will be able to offer mifepristone consistent with the REMS, while meeting all of our other legal and patient-care standards. Even if our proposal is approved, it will take significant work to develop and implement the administrative and compliance systems that would be necessary to comply with the REMS. All of this time would be better devoted to serving Neighborcare Health's patients and working to reduce health disparities for the diverse communities we serve.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 21st day of February, 2023, at Seattle, WA.

Judy Lazarus
DNP, CNM, ARNP, FACNM

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

Exhibit 14

ELLEN F. ROSENBLUM
Attorney General
SANDER MARCUS HULL #35986
Senior Assistant Attorney General
YOUNGWOO JOH, OSB # 164105 (*pro hac vice* forthcoming)
Assistant Attorney General
Oregon Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
Telephone: (503) 947-4700
Email: marcus.hull@doj.state.or.us
youngwoo.joh@doj.state.or.us
Attorney for State of Oregon

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON *et al.*,

Plaintiffs,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, in his official capacity as Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services,

Defendants.

NO. _____

DECLARATION OF MARK D. NICHOLS, M.D.

(In support of Motion for Preliminary Injunction)

I, Mark D. Nichols, hereby declare:

1. I am over the age of 18, am competent to testify as to the matters in this declaration, and make this declaration based on my personal knowledge.

2. I make this declaration in support of Plaintiffs' Motion for Preliminary Injunction.

3. I have over 40 years of experience as a medical provider in the field of obstetrics and gynecology. Additionally, I have performed medical research and published peer-reviewed papers in the field of family planning, with a particular focus on surgical and medication abortion, emergency contraception, and hormonal contraception.

4. I received my Doctor of Medicine from the University of California, Davis in 1979. I completed my residency in obstetrics and gynecology at the Oregon Health & Science University in 1983. Since completing my residency, I have been an assistant professor, associate professor, and professor at OHSU. Since 2022, I have held the title of Emeritus Professor at OHSU.

5. I am board-certified by the American Board of Obstetrics and Gynecology, and I am an Elected Fellow of the American College of Obstetrics and Gynecology. I have also held numerous elected and appointed positions in professional organizations dedicated to family planning.

6. I have been licensed to practice medicine in Oregon since 1981, under license no. MD12638. From 1988 to 2013, I was the Chief of the Division of General Gynecology and Obstetrics at OHSU. Since 1988, I have been a director, co-director, and Director Emeritus of the Family Planning Fellowship at OHSU.

7. From 1994 to 2011, I was the Medical Director of Planned Parenthood Columbia Willamette Affiliate. I have also been a family planning consultant for the Oregon Health Authority, a consultant for Medecins sans Frontieres, Safe Abortion Care, and a consultant, visiting professor, and obstetrician for various family planning programs and services in other countries.

8. I have authored or co-authored 68 peer-reviewed published papers in the field of obstetrics and gynecology. Of those papers, 22 relate to contraception, 32 relate to abortion care generally, 9 relate to medication abortion with mifepristone and misoprostol, including 6 addressing the medical outcomes of medication abortion.

9. As a medical provider in the Department of Obstetrics and Gynecology at OHSU, my practice included the full range of obstetric and gynecologic care including office visits, prenatal care, delivering babies and performing gynecologic surgery. As part of my practice, I regularly prescribed medications for miscarriage care and for medication abortions. Those medications included mifepristone. I also supervised the use and prescription of medication for miscarriage management and medication abortions by other medical professionals in the Department, including by other physicians, nurse practitioners, midwives, physicians' assistants, and residents.

10. Since 2022, I have been retired from my position as a medical provider at OHSU, but I continue to work with Planned Parenthood, including

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (971) 673-5000

to provide medication abortion services. I also work with the Lilith Clinic in Portland to provide, among other things, medication abortion services.

11. As a medical provider at Planned Parenthood and the Lilith Clinic, I continue to prescribe and supervise the use and prescription of mifepristone for miscarriage management and medication abortion purposes.

12. In my career, I have supervised several thousand medication abortions, nearly all of which were effected through the prescription of mifepristone with misoprostol.

13. Attached as **Exhibit A** is a copy of my current curriculum vitae.

14. I have particular expertise with the drug mifepristone. I was the principal investigator of the Population Council funded clinical trial for the Portland site. This work led to the FDA's approval of mifepristone. From 1994 to 2000, I studied the medical outcomes of medication abortion via mifepristone through both clinical studies and closely following the medical literature on this topic.

15. As an obstetrician and gynecologist, I prescribed mifepristone for my patients and have done so since 1999, after it was approved by the U.S. Food & Drug Administration.

16. Mifepristone is one of a two-drug regimen prescribed for medication abortions and miscarriage management. The drug is also used for the purpose of inducing delivery in the event of a second- or third-trimester loss.

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (971) 673-5000

17. For gestation of up to 70 days, the standard of care of medication abortion with the two-drug regimen involves one dose of mifepristone and one dose of misoprostol. A patient first takes mifepristone, which terminates a pregnancy by blocking the hormone progesterone. Progesterone is necessary for the maintenance of a pregnancy. Between 24 and 48 hours later, the patient takes misoprostol, which causes cramping and bleeding to expel the contents of the uterus.

18. The use of mifepristone in combination with misoprostol is widely considered in the field of obstetrics and gynecology to be the gold standard for medical management of miscarriages and medication abortions. That has been the case since the early 2000s, when peer-reviewed studies demonstrated that the use of mifepristone and misoprostol together is both safer and more effective than the use of misoprostol alone.

19. The prescription and use of mifepristone with misoprostol is the standard of care for miscarriage management and medication abortion in the State of Oregon and has been since 2018 after the publication by Schreiber.[1] Since the FDA approval of mifepristone, all medication abortions that I have provided have been via the two-drug regimen of mifepristone and misoprostol.

---

[1] Schreiber CA, Creinin MD, Atrio J, Sonalkar S, Ratcliffe SJ, Barnhart KT. Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss. N Engl J Med. 2018 Jun 7;378(23):2161-2170.

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (971) 673-5000

20. Although misoprostol can be prescribed alone for miscarriage management or medication abortions, it has a lower success rate and requires higher and more frequent doses, with increased undesirable patient side effects, including nausea, cramping, bleeding, and flu-like symptoms.

21. Mifepristone is one of a small number of medications that the FDA subjects to a Risk Evaluation and Mitigation Strategy (REMS). The REMS impose restrictions on how a drug may be prescribed and used.

22. REMS are typically applied to inherently dangerous drugs, such as opioids.

23. Mifepristone, however, is extremely safe. In fact, the medical literature contains a vast number of high quality, peer reviewed research papers that document the safety and efficacy of the use of mifepristone. For example, a 2022 study conducted by Schummers *et al.* documented 84,000 patient experiences with mifepristone/misoprostol abortion with exceptionally low rates of complications.[2] That study showed a 0.04 percent incidence of severe complications (hospitalization, sepsis, transfusion, or surgery).

24. I have also personally studied its safety and efficacy in the clinical trial that led to FDA's approval. The FDA's own publications on mifepristone

---

[2] Schummers L, Darling EK, Dunn S, McGrail K, Gayowsky A, Law MR, Laba TL, Kaczorowski J, Norman WV. Abortion Safety and Use with Normally Prescribed Mifepristone in Canada. N Engl J Med. 2022 Jan 6;386(1):57-67.

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (971) 673-5000

show that the drug is safe and effective, demonstrating no scientific basis for subjecting the drug to REMS restrictions.

25. The REMS for mifepristone require certifications for prescribers (such as providers) and pharmacies. It further requires that mifepristone be dispensed by or under the supervision of a certified prescriber, or by certified pharmacies for prescriptions issued by certified prescribers. The REMS also require the use of certification forms for the pharmacy and prescriber (or provider), as well as a patient-agreement form.

26. The mifepristone REMS does not enhance patient safety, because its requirements are redundant with what healthcare providers already do. For example, the provider certification form requires the provider to certify that they can accurately date a pregnancy, diagnose an ectopic pregnancy, and treat complications that may arise or refer to someone who could. But medical providers qualified to provide a medication abortion are necessarily trained in pregnancy dating, ectopic risk factors, and care coordination.

27. The Patient Agreement Forms required by the REMS also can cause patient confusion, concern, and emotional distress. For example, the form requires the patient to declare they "have decided to take mifepristone and misoprostol *to end my pregnancy*." But mifepristone is not just used for medication abortion; it is also the standard of care for medically managing miscarriage. Second, the form requires the patient to declare they "will take the misoprostol tablets 24 to 48 hours after I take mifepristone." But emerging

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (971) 673-5000

medical evidence suggests that misoprostol may sometimes be appropriately taken fewer than 24 hours after taking mifepristone, and sometimes even concurrently. Thus, for those patients whose doctors direct them to take misoprostol fewer than 24 hours after mifepristone, the Patient Agreement Form is contrary to their doctor's advice and may lead to confusion. And, as I noted above, the Patient Agreement Form can also cause additional patient stress as the form causes some to worry that the medication is actually more dangerous than it is. The Patient Agreement Form makes counseling more difficult, especially in circumstances requiring a translator.

28. In my practice, I have seen patients for miscarriage and abortion care through my services at OHSU, Planned Parenthood, and the Lilith Clinic. When patients in early pregnancy contact those clinics seeking abortion care, their staff schedules them for either an in-person or telehealth consultation. For my consultations, I begin each visit by reviewing the patient's medical history and symptoms to determine what types of abortions for which the patient is eligible. I then discuss with the patient the risks, benefits, and alternatives for each kind of abortion care for which they are eligible. Lastly, I answer any questions they have so that they are able to make an informed decision.

29. If they are eligible for, and choose, a medication abortion, we proceed with the visit for that care.

30. I discuss the medication abortion process and discuss the Patient Agreement Form with the patient. After the patient answers my questions, I ask

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (971) 673-5000

whether they consent to a medication abortion. If they do, I confirm that consent in their medical record.

31. I then go over the instructions for how and when to take their medications, what the follow-up process is, what they should do if they experience any of the (very rare) serious complications associated with mifepristone or misoprostol, and I answer any additional questions they may have.

32. I am also required by the REMS to review and have the patient sign the Patient Agreement Form. The Patient Agreement Form is duplicative of the information contained in the FDA's Medication Guide, which is dispensed to the patient with the medication.

33. I also prescribe mifepristone (with misoprostol) to patients who are experiencing a miscarriage. Under the REMS, I am required to sign the same Patient Agreement Form as I am for patients receiving mifepristone for a medication abortion. That is confusing and often distressing for patients. I have had patients, who were already undergoing the traumatizing experience of a miscarriage, become upset at having to sign a form about medication abortion despite my explaining the regulatory requirements.

34. As with any other medical procedure, I discuss risks and benefits, alternatives, explain the treatment, and obtain informed consent for the prescription of mifepristone for miscarriage management or medication abortion. The Patient Agreement Form is duplicative of that counseling.

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (971) 673-5000

35. A frequent response from patients when we review the Patient Agreement Form is a look of concern on their face. Some expressed concern, assuming that the additional process was because mifepristone was inherently risky. I frequently need to explain to patients that it is an FDA-required process, and that the medical literature is replete with documentation of mifepristone's safety.

36. I am not aware of any other similar medication that requires these additional, duplicative, and onerous hurdles to receiving a prescription. Based on my experience, professional judgment, and the best available medical science, mifepristone is significantly safer than medications like Tylenol, Viagra, and penicillin, none of which have any REMS restrictions. More people die annually from those medications in the United States than from using mifepristone, yet none of those medications require patients to sign a specific consent form or undergo the counseling required by the mifepristone REMS.

37. I am not aware of any one of my several thousands of medication abortion patients experiencing a serious adverse reaction or death caused by mifepristone. It is among the safest drugs I have ever prescribed.

//

//

//

//

//

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (971) 673-5000

38. In sum, the REMS restrictions on mifepristone are not medically justified, they impose additional burdens and stresses on patients and providers, and they reduce access to essential reproductive healthcare, especially for those living in rural areas or with limited access to healthcare services.

I declare under penalty of perjury that the foregoing is true and correct.

EXECUTED on February 22, 2023.

mark nichols
mark nichols (Feb 22, 2023 17:03 CST)
Mark. D. Nichols, M.D.

Department of Justice
1162 Court Street NE
Salem, OR 97301-4096
(503) 947-4700 / Fax: (971) 673-5000

Declaration of Dr. Mark Nichols

Final Audit Report 2023-02-22

Created:	2023-02-22
By:	Jason Lohman (jason.lohman@doj.state.or.us)
Status:	Signed
Transaction ID:	CBJCHBCAABAA0F8Tz1inxKdjzf-3fJGvysGc_0xRsBmy

"Declaration of Dr. Mark Nichols" History

Document created by Jason Lohman (jason.lohman@doj.state.or.us)
2023-02-22 - 11:01:50 PM GMT

Document emailed to mark nichols (mdnicholsmd@gmail.com) for signature
2023-02-22 - 11:02:33 PM GMT

Email viewed by mark nichols (mdnicholsmd@gmail.com)
2023-02-22 - 11:03:26 PM GMT

Document e-signed by mark nichols (mdnicholsmd@gmail.com)
Signature Date: 2023-02-22 - 11:03:51 PM GMT - Time Source: server

Agreement completed.
2023-02-22 - 11:03:51 PM GMT

Adobe Acrobat Sign

EXHIBIT A

1

CURRICULUM VITAE
OREGON HEALTH & SCIENCE UNIVERSITY

NAME	Mark D. Nichols, MD	DATE	February 22, 2023
Academic Rank:	Emeritus Professor		
Department/Division:	Obstetrics and Gynecology		
Professional Address:	3181 SW Sam Jackson Park Road - UHN 50		
E-Mail Address:	nicholsm@ohsu.edu		

I. EDUCATION

Undergraduate and Graduate (Include Year, Degree, and Institution):

1975 Bachelor of Science in Biological Sciences, University of California, Davis

Postgraduate (Include Year, Degree, and Institution):

1979 Doctor of Medicine, University of California, Davis
1979-1983 Internship and Residency
Department of Obstetrics and Gynecology
Oregon Health Sciences University
1990 Research Fellow
Margaret Pyke Center, Middlesex Hospital
University College, London, England
(January - July)
July, 1996 Advanced Cardiac Life Support Provider Course
American Heart Association
Portland OR (Recertified in biannually, last in April, 2020)

Certification (Include Board, Number, Date, and Recertification):

American Board of Obstetrics and Gynecology, December 1985
Elected Fellow American College of Obstetrics and Gynecology, September 1986

Licenses (Include State, Date, Status, Number, and Renewal Date):

April 11, 1981 State of Oregon, License No. 12638, biannually renewed,
Sept. 2010 Zambia, Temporary Medical License

II. PROFESSIONAL EXPERIENCE

Academic (Include Year, Position, and Institution):

1983 - 1993 Assistant Professor, Oregon Health Sciences University
1993 - 2003 Associate Professor, Oregon Health & Science University
2003 – 2022 Professor, Oregon Health & Science University
2022 – present Emeritus Professor, Oregon Health & Science University

Administrative (Include Year, Position, and Institution):

1983 - 1995 Assistant Director, Residency Training Program, Oregon Health Sciences University, Department of Obstetrics and Gynecology
1988 - 2013 Chief, Division of General Gynecology and Obstetrics, Department of Obstetrics and Gynecology, Oregon Health & Science University, Portland OR
2001 - 2010 Director, Family Planning Fellowship, Oregon Health & Science University, Portland OR

2010 - 2013 Co- Director, Family Planning Fellowship, Oregon Health & Science University, Portland OR
2013 – present Director Emeritus, Family Planning Fellowship, Oregon Health & Science University, Portland OR

Other (Include Year, Position, and Institution):
1994 Interim Medical Director, Planned Parenthood Columbia Willamette Affiliate
1994 - 2011 Medical Director, Planned Parenthood Columbia Willamette Affiliate
2011 - 2013 Co-Medical Director, Planned Parenthood Columbia Willamette Affiliate
1997 - 2001 Family Planning Consultant, Oregon Health Division
2022 Consultant, Medecins Sans Frontieres, Safe Abortion Care

International Work
2010 Consultant, Population Services International, Zambia
2010 Member, Surgical Team mission to Gimbie Hospital, Ethiopia
2012 Consultant, Population Services International, Nigeria
2014 Consultant, Population Services International, Tanzania
2014 Visiting Professor, Mekelle University, Ethiopia
2015 Obstetrician, Medecins Sans Frontieres, South Sudan
2015 Consultant, Laos Nutrition Institute, Vientiane, Laos
2016 Visiting Professor, Mekelle University, Ethiopia
2017 Obstetrician, Medecins Sans Frontieres, South Sudan
2018 Consultant, Population Services International, Vietnam

III. SCHOLARSHIP

Area(s) of Research/Scholarly Interest:

Family planning with particular interest in surgical and medical abortion, emergency contraception, hormonal contraception, and training fellows, residents and medical students in family planning.

Grants and Contracts:

1. R W Johnson Pharmaceutical, “A Double Blind Placebo Controlled Safety and Efficacy Study of Antocin™ for the Prolongation of Gestation,” November 1994 - July 1997, $138,654. PI: Jeff Jensen, MD, Sub PI: Mark Nichols, MD

2. The Population Council, Inc., RU-486, “Evaluation of the Efficacy, Safety and Acceptability of Mifepristone and Misoprostol in Inducing Abortion in Pregnant Women with Amenorrhea of up to 63 Days,” November 1994 - December 1995 - $209,800. PI: Mark Nichols, MD

3. Wyeth-Ayerst Laboratories and University Hospital Consortium, “Norplant Observational Cohort,” June 1995 - June 2003, $275,000. PI: Mark Nichols, MD

4. Wyeth-Ayerst Laboratories, “A Multi center, Open-Label, Randomized, Comparative Study to Evaluate the Effects of Alesse™ and Loestrin FE 1/20® on Clinical and Biomedical Measures of Androgenicity,” November 1996 - June 1997, $16,920. PI: Mark Nichols, MD

5. Parke-Davis, “A Randomized, Double Blind, Active-Controlled, Parallel Group, Multi-center Study Assessing Menstrual Cycle Control and Ovulation Suppression Associated with Vaginal Administration of Five Dose Combinations of Norethindrone Acetate and Ethinyl Estradiol,” December 1996 - March 1997, $86,689. PI: Leon Speroff, MD, Sub PI: Mark Nichols, MD

6. Pharmacia & Upjohn, "Cyclo Provera™ Contraceptive Injection: A Comparative Study of Safety, Patient Acceptability and Efficacy to Ortho-Novum® 7/7/7, 28 Tablets," June 1997 - June 1999, $92,556. PI: Mark Nichols

7. Organon, "An Open Label, Multi center, Randomized, Comparative Safety, Efficacy, Cycle Control, and Quality of Life Study of CTR 25, Alesse™, and Ortho Tri-Cyclen®," April 1998 - July 1999, $76,310. PI: Kenneth Burry, MD, Sub PI: Mark Nichols, MD

8. John Hopkins University, "Comparing Acceptability of Manual vs Electrical Vacuum Aspiration for First Trimester Induced Abortion," $37,310. June 2000 – July 2001. PI: Mark Nichols, MD

9. Pharmacia Co. "Phase III Study of DMPA Injection (DMPA-SC) in Women with Endometriosis in the US and Canada" $42,480. January 2000 - January 2001. PI: Mark Nichols

10. Galen Holdings "A Multi-center, Randomized Controlled Double-Blind Study to Determine Efficacy in the Relief of Hot Flushes in Women Receiving Oral Estradiol" $23,527. Sept. 2001 – Aug. 2002. PI: Leon Speroff, MD, Sub-PI: Mark Nichols, MD

11. Organon-Thebes "A Multinational, Multi-center, Randomized Controlled Trial, to Assess the Endometrial Histological Profile Following Treatment with Tibolone (ORG 0D14) Versus Conjugated Estrogen (CE) Plus Medroxyprogesterone Acetate (MPA) in Postmenopausal Women" $138,000. PI: Jeffrey Jensen, MD, Sub PI: Mark Nichols, MD

12. Pfizer Care "A Randomized, Double Blind, Multi-Center, 24 Week Study to Assess Cumulative Amenorrhea in Postmenopausal Women Taking Femhrt® and Prempro®". $37,275. PI: Leon Speroff, MD, Sub-PI: Mark Nichols, MD

13. Buffett Foundation Grant. "Intrauterine Lidocaine Infusion for Pain Management in First Trimester Abortions" $48,000. June 2002 – June 2003 PI: Alison Edelman, MD Sub PI: Mark Nichols, MD

14. Buffett Foundation Grant. "Continuous Oral Contraceptive Pills: Are Bleeding Patterns Dependent on the Hormone Chosen?" $51,000. PI: Alison Edelman, MD Sub PI: Mark Nichols, MD

Publications/Creative Work:

Peer-reviewed

1. **Nichols, M.** Diagnosing Breast Disease, *West. J. Med*., 148:324, 1988.

2. Novy MJ, Haymond J, **Nichols M.** Shirodkar Cerclage in a Multifactorial Approach to the Patient with Advanced Cervical Changes, *AJOG*, 162:1412-20, 1990.

3. **Nichols MD.** Review of Vulvar Ulcers, *Postgraduate Obstet. Gynecol.*, 11(No. 7):1991.

4. **Nichols M,** Robinson GER, Bounds W, Johnson J, Upward E, Newman B, Guillebaud J. Effect of Four Combined Oral Contraceptives on Blood Pressure in the Pill-Free Interval, *Contraception*, 47:367-76, 1993.

5. Thurmond A, Weinstein A, Jones M, Jensen J, **Nichols M.** Localization of Contraceptive Implant Capsules for Removal, *Radiology*, 193:580-581, 1994.

6. Carp H, Jayaram A, Vadhera R, **Nichols M,** Morton M. Epidural Anesthesia for Cesarean Delivery and Vaginal

Birth After Maternal Fontan Repair: Report of Two Cases, *Anesth Analg*, 78:1190-2, 1994.

7. **Nichols M.** Curriculum Change in an OB/GYN Residency Program and It's Impact on Pregnancy in Residency, *AJOG*, 170:1658-65, 1994.

8. Winikoff B, Ellertson C, Elul B, Sivin I; for the Mifepristone Clinical Trials Group. Acceptability and Feasibility of Early Pregnancy Termination by Mifepristone-Misoprostol. Results of Large Multi center Trial in the United States, *Arch Fam Med*, 7:360-6, 1998. (Member of the Mifepristone Clinical Trials Group)

9. Spitz IM, Bardin CW, Benton L, Robbins A. Early Pregnancy Termination with Mifepristone and Misoprostol in the United States, *New Eng J Med*, 338:1241-7, 1998. (Cited as Principal Investigator)

10. Jensen JT, Astley SJ, Morgan E, **Nichols MD.** Outcomes of Suction Curettage and Mifepristone Abortion in the United States, *Contraception*, 59(3):153-9, 1999.

11. Kaunitz AM, Garceau RJ, Cormie MA, Lunelle Study Group (Member). Comparative Safety, Efficacy and Cycle Control of LUNELLE Monthly Contraceptive Injection (Medroxyprogesterone Acetate and Estradiol Cypionate Injectable Suspension) and Ortho-Novum 7/7/7 Oral Contraceptive (Norethindrone/Ethinyl Estradiol Triphasic), *Contraception*, 60:179-187, 1999.

12. Thorneycroft IH, Stanczyk FZ, Bradshaw KD, Ballagh SA, **Nichols M,** Weber ME. Effect of Low-dose Oral Contraceptives on Androgenic Markers and Acne, *Contraception*, 60:255-62, 1999.

13. Paul M, Schaff E, **Nichols M.** The Roles of Clinical Assessment, Human Chorionic Gonadotropin Assays, and Ultrasonography in Medical Abortion Practice, *Am J Obstet Gynecol,* 183(2):S34-S43, 2000.

14. Borgatta L, Burnhill M, Haskell S, **Nichols M,** Leonhardt K. Instituting Medical Abortion Services: Changes in Outcome and Acceptability Related to Provider Experience, *JAMWA*, 55:173-6, 2000.

15. Westhoff C, Dasmahapatra R, Winikoff B, Clarke S, and the Mifepristone Clinical Trials Group. Predictors of analgesia use during supervised medical abortion. *Contraception* 2000;61:225-229 (Member of the Mifepristone Clinical Trials Group)

16. Bird ST, Harvery SM, **Nichols M.** Comparing the Acceptability of Manual Vacuum Aspiration and Electric Vacuum Aspiration as Methods of Early Abortion. *JAMWA* 56: 124-126;2001

17. Edelman AT, **Nichols MD**, Jensen J. Comparison of pain and time of procedures with two first-trimester abortion techniques performed by residents and faculty *Am J Obstet Gynecol* 184:1564-7;2001

18. **Nichols M,** Edelman A. RU 486 for Primary Care Providers. *Primary Care Reports* , 7:89-95;2001

19. Phair N, Jensen J, **Nichols M.** Paracervical block and elective abortion: The effect of waiting between injection and procedure pain. *Am J. Obstet. Gynecol.* 186:1304-7;2002

20. **Nichols M,** Morgan E, Jensen J. Comparing bimanual pelvic examination to ultrasound measurements for the assessment of gestational age in the first trimester of pregnancy. *Journal Repro Med* 50:825-8;2002

21. Kwiecien M, Edelman A, **Nichols MD,** Jensen JT. Bleeding patterns and patient acceptability of standard or continuous dosing regimens of a low dose oral contraceptive: a randomized trial. *Contraception* 67:9-13;2003

22. Edelman A, Jensen J, Nelson E, and **Nichols M**. Cannula fracture in first trimester abortion: a case report and

survey of National Abortion Federation providers. *Contraception* 67:49-51;2003

23. Bird ST, Harvey SM, Beckman LJ, **Nichols MD**, Rogers K, and Blumenthal PD. Similarities in Women's Perceptions and Acceptability of Manual Vacuum Aspiration and Electric Vacuum Aspiration for First Trimester Abortion. *Contraception* 67:207-212;2003.

24. Picardo CM, **Nichols MD**, Edelman AE, Jensen JT. Attitudes and information sources of the risks and benefits of oral contraception. *JAMWA* 58:112-116;2003

25. Edelman A.B., Jensen J.T., Lee D.M., Nichols M.D. Successful medical abortion of a pregnancy within a non-communicating rudimentary uterine horn. *AJOG* 189:886-7;2003

26. Emmons S, Adams KE, Cain JM, **Nichols M.** The impact of perceived gender bias on obstetric and gynecology skills acquisition by third year medical students. *Academic Medicine*, 79:1-7;2004

27. Edelman A, **Nichols M,** Leclair C, Astley S, Shy K, and Jensen JT**.** Intrauterine Lidocaine Infusion for Pain Management in First-Trimester Abortions *Obstet. Gynecol.* 103:1267-127;2004

28. Smits AK, Clark EC, **Nichols MD**, Saultz JW. Factors Influencing Cessation of Maternity Care in Oregon. *Family Medicine* 36:87-92;2004

29. Cwiak CA, Edelman AB, Hatcher RA, Zieman M, **Nichols MD**, Jensen JT, Emmons SL, and Khan IM. Teaching contraception: An interactive presentation using *Managing Contraception. AJOG* 191:1788-92;2004

30. Harvey S M, **Nichols MD**. Development and Evaluation of the Abortion Attributes Questionnaire. *Journal of Social Issues*. 61:95-107;2005

31. Edelman A.B., Jensen J.T., Lee D.M., **Nichols M.D.,** Buckmaster J, Goetsch, M. Cervical preparation using laminaria with adjunctive buccal misoprostol prior to second trimester dilation and evacuation procedures: a randomized clinical trial, *AJOG* 194:425-30;2006

32. Emmons SL. Adams KE. **Nichols** M. Cain J. The impact of perceived gender bias on obstetrics and gynecology skills acquisition by third-year medical students. *Academic Medicine* 79:326-32;2004

33. Emmons SL. **Nichols M.** Schulkin J. James KE. Cain JM. The influence of physician gender on practice satisfaction among obstetrician gynecologists. *American Journal of Obstetrics & Gynecology.* 194:1728-38; 2006

34. Edelman AB. Gallo MF. Jensen JT. **Nichols MD.** Schulz KF. Grimes DA. Continuous or extended cycle vs. cyclic use of combined oral contraceptives for contraception. *Cochrane Database of Systematic Reviews. (3):CD004695, 2005.*

35. Edelman A.B., Jensen J.T., **Nichols M.D.** Continuous Oral Contraceptives: Are Bleeding Patterns Dependent on the Hormones Given? *Obsterics & Gynecology* 107:657-65, 2006

36. Edelman, Alison MD, MPH; Nichols, **Mark D. MD**; Leclair, Catherine MD; Jensen, Jeffrey T. MD, MPH. Four Percent Intrauterine Lidocaine Infusion for Pain Management in First-Trimester Abortions. *Obstetrics & Gynecology* 107:269-275;2006.

37. Edelman A, M.F. Gallo MF, **Nichols MD**, Jensen JT, Schulz K, and Grimes DA. Continuous versus cyclic use of combined oral contraceptives for contraception: systematic Cochrane review of randomized controlled trials.

Hum. Reprod. 2006 21: 573-578.

38. **Nichols M,** Carter J, and Fylstra D. A comparative study of hysteroscopic sterilization performed in-office versus a hospital operating room. *Journal of Minimally Invasive Gynecology* 13:447-50, 2006.

39. Edelman A, Lew R, Cwiak C, **Nichols M,** Jensen J. Acceptability of contraceptive-induced amenorrhea in an racially diverse group of U.S. women. Contraception 2007;75:450-453.

40. Kaskowitz A., Carlson N., **Nichols M.,** Edelman A., Jensen J. Online Availability of Hormonal Contraceptives Without a Health Care Examination: Effect of Knowledge and Health Care Screening. *Contraception.* 76:273-7;2007

41. Munks EB, Edelman AB, Jensen JT, **Nichols MD,** Burry K and Patton P. IVF Patients' Attitudes Toward Multifetal Pregnancy Reduction. *Journal of Repro Med* 52:635;2007

42. Bednarek PH, **Nichols MD**, Carlson N, Edelman AB, Creinin MD, Truitt S, Jensen JT. Effect of "Observed Start" versus traditional "Sunday Start" on hormonal contraceptive continuation rates after medical abortion. *Contraception* 78:26-30,2008

43. Kaneshiro B, Jensen JT, Carlson N, **Nichols M,** Edelman A. The Association of Body Mass Index and Unintended Pregnancy in the US: Results from Cycle 6 of the National Survey of Family Growth. *Contraception* 77(4):234-8, 2008 Apr

44. Singh RH, Ghanem KG, Burke AE, **Nichols MD,** Rogers K, Blumenthal PD. Predictors and perception of pain in women undergoing first trimester surgical abortion. *Contraception* 78(2):155-161;2008

45. Michelle M. Isley, Alison Edelman, Bliss Kaneshiro, Dawn Peters, **Mark D. Nichols,** and Jeffrey T. Jensen. Sex education and contraceptive use at coital debut in the U.S.: Results from cycle 6 of the National Survey of Family Growth. Accepted in *JAMA*

46. Kaneshiro B. Jensen JT. Carlson NE. Harvey SM. **Nichols MD**. Edelman AB. Body mass index and sexual behavior. *Obstetrics & Gynecology.* 112(3):586-92, 2008 Sep.

47. Stanek AM, Bednarek PH, **Nichols MD,** Jensen JT, Edelman AB. Barriers associated with the failure to return for intrauterine device insertion following first-trimester abortion. *Contraception.* 79:216-20, 2009

48. Kraemer DF, Yend, P, **Nichols, M.** An economic comparison of female sterilization of hysteroscopic tubal occlusion with laparoscopic bilateral tubal ligation. *Contraception* 80: 254–260, 2009

49. Renner RM. Jensen JT. Nichols MD. Edelman A. Pain control in first trimester surgical abortion.*Cochrane Database of Systematic Reviews.* (2):CD006712, 2009.

50. Kaneshiro B, Jensen JT, Carlson N, **Nichols M**, Edelman A. Treatment of Unscheduled Bleeding in Continuous Oral Contraceptive Users With Doxycycline: A Randomized Controlled Trial. *Obstet Gynecol.* 115(6):1141-9, 2010 Jun

51. Renner RM. Jensen JT. **Nichols MD**. Edelman AB Pain control in first-trimester surgical abortion: a systematic review of randomized controlled trials. *Contraception*. 81(5):372-88, 2010 May.

52. Isley M, Edelman A,. Kaneshiro B,. Peters,D. **Nichols,** M, Jensen, JT. Sex education and contraceptive use at coital debut in the United States: results from Cycle 6 of the National Survey of Family Growth. *Contraception*.

82(3):236-42, 2010 Sep

53. Kaneshiro B, Bednarek P, Isley M, Jensen J, **Nichols M,** Edelman A. Blood loss at the time of first-trimester surgical abortion in anticoagulated women. Contraception 2011; 83:431-435.

54. Renner RM, **Nichols M,** Jensen JT, Hong L, Edelman AB. Paracervical block for pain control in first-trimester surgical abortion: a randomized controlled trial. Obstet Gynecol 2012; 119: 1030-1037.

55. Kaneshiro B**,** Edelman AB, Carlson N**, Nichols M,** Jensen JT. A randomized controlled trial of subantimicrobial doxycycline to prevent unscheduled bleeding with continuous oral contraceptive pill use. Contraception.2012; 85: 351-358.

56. Isley MM, Jensen JT, **Nichols MD,** Lehman A, Bednarek P, Edelman A. Intrauterine lidocaine infusion for pain management during outpatient transcervical tubal sterilization: a randomized controlled trial. Contraception 2012; 85: 275-281.

57. Kaneshiro B, Edelman A, Carlson N**, Nichols M,** Jensen J. Unscheduled bleeding with continuous oral contraceptive pills: a comparison of progestin dose. *Contraception accepted 2011, available epub*

58. Bayer LL; Jensen JT; Li H; **Nichols MD**; Bednarek PH. Adolescent experience with intrauterine device insertion and use: a retrospective cohort study. *Contraception. 86(5):443-51, 2012 Nov.*

59. Micks EA; Edelman AB; Renner RM; Fu R; Lambert WE; Bednarek PH; **Nichols MD;** Beckley EH; Jensen JT. Hydrocodone–Acetaminophen for Pain Control in First-Trimester Surgical Abortion: A Randomized Controlled Trial. O*bstetrics & Gynecology. 120(5):1060-9, 2012 Nov.*

60. Goldthwaite LM; Baldwin MK; Page J; Micks EA; **Nichols MD**; Edelman AB; Bednarek PH.Comparison of interventions for pain control with tenaculum placement: a randomized clinical trial. *Contraception. 89(3):229-33, 2014 Mar.*

61. Krashin JW; Edelman AB; **Nichols MD**; Allen AJ; Caughey AB; Rodriguez MI. Prohibiting consent: what are the costs of denying permanent contraception concurrent with abortion care?. *American Journal of Obstetrics & Gynecology. 211(1):76.e1-76.e10, 2014 Jul.*

62. Bayer LL; Edelman AB; Fu R; Lambert WE; **Nichols MD**; Bednarek PH; Miller K; Jensen JT. An Evaluation of Oral Midazolam for Anxiety and Pain in First-Trimester Surgical Abortion: A Randomized Controlled Trial.*Obstetrics & Gynecology. 126(1):37-46, 2015 Jul.*

63. Micks E, Edelman A, Botha R, Bednarek P, **Nichols M**, Jensen J. The effect of sevoflurane on interventions for blood loss during dilation and evacuation procedures at 18–24 weeks of gestation: a randomized controlled trial. Contraception 91 (2015) 488–494

64. Baldwin MK, Edelman AB, Lim JY, **Nichols MD**, Bednarek, PH,, Jensen JT. Intrauterine device placement at 3 versus 6 weeks postpartum: a randomized trial. *Contraception 93 (2016) 356–363*

65. Renner R-M, Edelman AB, **Nichols MD**, Jensen JT, Lim JY, Bednarek PH Refining paracervical block techniques for pain control in first trimester surgical abortion: a randomized controlled noninferiority trial. *Contraception 94 (2016) 461–466*

66. Patil E, Darney B, Orme-Evans K, Beckley E, Bergander L, **Nichols M**, Bednarek PH. Aspiration Abortion With Immediate Intrauterine Device Insertion: Comparing Outcomes of Advanced Practice Clinicians and Physicians.

Journal of Midwifery & Women's Health. 61(3):325-330, March 2016

67. Bayer LL, Edelman AB, Fu R, Lambert WE, **Nichols MD**, Bednarek PH, Miller K, Jensen JT. An Evaluation of Oral Midazolam for Anxiety and Pain in First-Trimester Surgical Abortion. A Randomized Controlled Trial. *Obstet Gynecol 2015;126:37–46*

Non-peer-reviewed

1. Nichols MD. Formal Discussant. An Obstetric and Gynecologic Clerkship's Influence on a Medical Community, *Am J Obstet Gynecol*, 176:1363-8, 1997.

2. Nichols, MD. Formal Discussant. Real-time Ultrasonographically Guided Removal of Nonpalpable and Intramuscular Norplant Capsules, *Am J Obstet Gynecol*, 178:1185-93, 1998.

3. Nichols, MD. Formal Discussant. Cytologic evaluation of non-bloody breast cyst fluid. *Am J Obstet Gynecol, Am J Obstet Gynecol*, 182:1300-5, 2000

4. Nichols, MD. Letter to the Editor, "Fewer Abortions would be needed". *Oregonian*, June 15, 2001

5. Nichols, MD. Methotrexate for management of a pregnancy in a non-communicating uterine horn. Letter to the editor. *Journal Repro Med* 50:878-9;2002

6. Nichols, MD. Clinical Trials Report, *Current Women's Health Reports*, 2:407-408;2002

7. Reeves MF; Blumenthal PD; Jones RK; **Nichols MD**; Saporta VA. New research at the 2014 National Abortion Federation Annual Meeting: continuously improving abortion care. *Contraception. 89(5):339-40, 2014 May.*

8. Reeves MF; Blumenthal PD; Jones RK; **Nichols MD**; Saporta VA. New research at the 2015 National Abortion Federation Annual Meeting: putting research into practice.*Contraception. 91(5):359, 2015 May.*

9. Darney P; Creinin MD; **Nichols M;** Gilliam M; Westhoff CL; Tenth anniversary of the Society for Family Planning. *Contraception. 92(4):279-81, 2015 Oct.*

Publications (submitted)

Chapters

1. Nichols M. "Faculty Ownership". In: *Teaching and Evaluating Clinical Skills*, 1995, APGO.

2. Nichols M, Halvorson-Boyd G, Goldstein R, Gevirtz D and Healow D. "Pain Management" in *Management of Unintended and Abnormal Pregnancy.* Wiley –Blackwell, 2009

Abstracts

1. Thulin PC, Carter JH, Nichols MD, Kurth M, Nutt JG. Menstrual-cycle Related Changes in Parkinson's Disease, *Neurology*, 46:A376, 1996.

2. Fossum GT, Thomas M, Wise R, Nichols M, Sinofsky F, Pasquale S. Preliminary Evaluation of a New Instrument Design for the Removal of Norplant Capsules.

3. Bird ST, Harvey SM, Nichols MD. Women's Acceptability of Manual Vacuum Aspiration (MVA: An Exploratory Study of Abortion Patients in Portland, Oregon.

4. Romm J, Nichols M. The Men's Group: Discussion Group for Male OB/GYN Residents, International Society of Psychosomatic Obstetrics and Gynecology, June 1998, Washington DC.

5. Stanczyk FZ, Bradshaw KD, Ballagh BA, Nichols MD, Thorneycroft, LH. Effect of Oral Contraceptive Progestins on Production of Ovarian, Adrenal and Peripheral Androgens, European Society of Contraception, June 1998, Prague.

6. Sheryl Thornbird PhD, Marie Harvey DrPH, Linda Beckman,PhD, Mark Nichols, MD, Paul Blumenthal. MD. Men's involvement in abortion: Perceptions of women having abortions in three U.S. cities Population, Family Planning, and Reproductive Health section of the 130th Annual APHA Meeting, Philadelphia, PA November, 2002.

7. Singh RH, Nichols MD, Rogers K, Ghanem KG, & Blumenthal Pd. Subjective predictors of pain in women undergoing electrical vacuum aspiration (eva) versus manual vacuum aspiration (mva) for first trimester abortion. Assoc. of Reproductive Health Professionals Annual meeting, Tampa FL, Sept. 2005

8. Edelman A, Nichols M, Leclair C, & Jensen JT. 4% intrauterine lidocaine infusion for pain management in first trimester abortions. Assoc. of Reproductive Health Professionals Annual meeting, Tampa FL, Sept. 2005.

9. Drath E, Nichols M, & Edelman A. Ultrasound, Twin Gestation, and Abortion Decision Making: Patients and Providers. NASPOG Annual Scientific Meeting, February, 2006, Hawaii

10. Bednarek P, Nichols M, Edelman A, Jensen JT, Truitt S, Creinin MD. Effect of observed start compared with Sunday start on contraceptive continuation after medical abortion. *Obstet Gynecol* 2007, supp 57S.

Audio Presentations

1. "RU-486," Audio-Digest Obstetrics and Gynecology, Vol. 41, No. 8, April 19, 1994

2. "Family Planning/STD Case Consultation," Center for Health Training, June 7, 1999

3. "Legal and Medical Implications of the Federal Abortion Ban" Podcast from Lewis & Clark Law School, Portland, OR Jan. 2006

Posters

1. Nichols MD, Kirk EP. Resident Retreat: A Stress Reducer and Morale Booster, CREOG and APGO Meeting, March 1991, Orlando, FL

2. Thomas L, Nichols MD. Ultrasound Evaluation of the Post Mifepristone Abortion Patient, Pacific Coast Obstetrical and Gynecological Society, Sunriver OR, 1996

3. Edelman A, Nichols MD. Comparison of Resident and Faculty Performed Abortions using Two Different Abortion Techniques, District VIII Meeting, American College of Obstetricians and Gynecologists, Anchorage AK, August 2000

4. Edelman A, Nichols MD. Comparison of Resident and Faculty Performed Abortions using Two Different Abortion Techniques, District VIII Meeting, American College of Obstetricians and Gynecologists, Anchorage AK, August 2000.

5. Phair N, Jensen J, Nichols M. Paracervical block and elective abortion: The effect of waiting between injection and procedure pain, PCOGS Annual meeting, Ashland OR, October, 2001. Received award as best poster of the meeting.

6. Lew R, Edelman A, Cwiak C, Jensen J, Nichols M. Acceptability of Contraceptive-Induced Amenorrhea in American Women, ACOG Annual Clinical Meeting, San Francisco, May 2005.

7. Koontz, Edelman A, Jensen J, Nichols M. Continuous Oral Contraceptives: Are Bleeding Patterns Dependent on the Hormones Given? ACOG Annual Clinical Meeting, San Francisco, May 2005.

8. Paula Bednarek, MD, Mark Nichols, MD, Alison Edelman, MD, MPH, Jeffrey T. Jensen, MD, MPH, Sarah Truitt, MD, Mitchell D. Creinin, MD. Effect of "Observed Start" versus "Sunday Start" on hormonal contraception continuation after medical abortion. ACOG Annual Clinical Meeting, SanDiego, May 2007

Invited Lectures, Conference Presentations or Professorships (since promotion to Associate Professor):

Local (Selected)

1. "IUD Review," Grand Rounds, Kaiser Sunnyside Hospital, Department of Obstetrics and Gynecology, January 1993.

2. "Breast Disease for the Gynecologist," Langley Memorial Lectures, Portland OR, February 1993.

3. "Second Trimester Abortion Technique," Grand Rounds, Bess Kaiser Hospital, Obstetrics and Gynecology Department, April 1993.

4. "RU-486," City Club of Portland, July 1994.

5. "Circumcision Review," Grand Rounds, OHSU, Department of Obstetrics and Gynecology, June 1995.

6. "Abortion" and "Breast Disease," OHSU, Nursing School Advanced Gynecology Course, October 1995.

7. "Emergency Management of Vaginal Bleeding," St. Vincent Hospital, January 1996.

8. "Trauma in Pregnancy," OHSU, Emergency Medicine Residents, September 1996.

9. "Contraception Review," OHSU, Internal Medicine Residents, January 1997.

10. "Management of Miscarriages," OHSU, Student Health Service, January 1997.

11. "Contraception and World Population," Portland State University Population Control Class, January 1997.

12. "Emergency contraception: Coca-Cola to Mifepristone," Grand Rounds, OHSU, Department of Obstetrics and Gynecology, April 1997.

13. "First Trimester Bleeding," OHSU, Emergency Medicine Residents, June 1997.

14. "Approach to Dysfunctional Uterine Bleeding," Grand Rounds, OHSU, Internal Medicine Department, March 1998.

15. "Medical Abortion Review," Kaiser Grand Rounds, Clackamas OR, December 1998.

16. "Update on Emergency Contraception and Medical Abortion," Grand Rounds, OHSU, Department of Obstetrics and Gynecology, January 1999.

17. "Emergency Contraception," OHSU, School of Nursing, Graduate Program, January 1999.

18. "Emergency Contraception," Planned Parenthood, Columbia/Willamette Affiliate, Portland OR, March 1999.

19. "Emergency Contraception," Mt. Hood Medical Center, OB/GYN and Pediatrics Department Meeting, June 1999.

20. "Abnormal Uterine Bleeding," Grand Rounds, OHSU, Department of Obstetrics and Gynecology, July 1999.

21. "Medical Abortion Review," St. Vincent Medical Center Ob/Gyn Dept., Portland OR, October 1999.

22. Norplant/IUD Training, Clinicians from Lane, Linn, Josephine, Tillamook, Marion, Coos, Polk, Lincoln, Malheur, Douglas, Washington, Multnomah and Klamath Counties and Planned Parenthood, Portland OR, November 1999.

23. "Review of Emergency Contraception," Tuality Hospital, Hillsboro OR, March 2000.

24. "Wedge Issues of Choice," NARAL Leadership Training, Unitarian Church, Portland OR, April 2000.

25. "Emergency Contraception" Emanuel Hospital, Ob/Gyn Department, June 2000

26. "Emergency Contraception" Center for Women's Health, OHSU, September 2000

27. "Mifepristone: FDA Approval and Review," OHSU, Grand Rounds, Department of Obstetrics and Gynecology, October 2000.

28. "RU486," OB/GYN Department Educational Conference, Providence St. Vincent Medical Center, Portland OR, March 2001.

29. "Review of Emergency Contraception". Pediatric Department, Emanuel Hospital, Portland, OR, February, 2002

30. "Contraceptive Update: What's New?" OHSU, Grand Rounds, Department of Obstetrics and Gynecology, March 2002.

31. "Women seeking abortion care. Are they discriminated against?" Reed College VOX course, Portland, OR, March, 2002.

32. "Update in Contraception" Lorenzen Women's Physician Forum, Portland, OR, November 2002

33. "Update in Contraception" Grand Rounds, Good Samaritan Hospital, Portland, OR, February 2003

34. "Becoming an abortion provider" Reed Vox seminar, Reed College, Portland, OR, April, 2003

35. "Planned Parenthood Update" SW Washington Medical Center, Ob/Gyn Department Grand Rounds, Vancouver, WA, June, 2003

36. "Update on Contraception", Student Health Center, OHSU, November 2003

37. "IUD Review", Legacy Hospital CNM Department, Portland, OR February 2004

38. "Oral Contraceptive Update", St. Vincent Medical Center, Resident teaching conference, Portland, OR, March 2004

39. "Essure device for female sterilization", SW Washington Med. Center, Ob/Gyn dept. Grand Rounds, Vancouver, WA, Jan. 2005

40. "Transcervical Female Sterilization", East Portland Rotary Club, Portland, OR Jan. 2005

41. "Legal and Medical Implications of the Federal Abortion Ban" Lewis & Clark Law School, Portland, OR Jan. 2006

42. "Pain Management of Gynecologic Procedures" Grand Rounds, OHSU Ob/Gyn department, Portland, OR Oct. 2008

43. "Management of Breech Presentation" Grand Rounds, OHSU Ob/Gyn department, Portland, OR Sept 2009

44. "Alternatives to Hysterectomy" Brown Bag Lecture, OHSU, Portland, OR October 2009

45. "Pain management for gynecologic procedures", Grand Rounds Dept of Anesthesiology, OHSU, September 2010.

Regional

1. "Norplant Review and Insertion Training," Washington Academy of Family Practice Review Course, Spokane WA, April 1993.

2. "Gynecology for the Primary Care Provider: Preventive Health Care," Primary Care Conference, Sunriver OR, June 1993.

3. "Contraception for Patients with Chronic Health Problems," Nurse Practitioners of Oregon, September 1995.

4. "RU-486 Review," Ashbury Memorial Lectureship, Guest Speaker, Corvallis OR, November 1995.

5. "Common Gynecologic Problems and the Internist," 3rd Annual Internal Medicine Review Course, April 1996.

6. "Contraceptive Update," Family Planning Conference, Eugene OR, September 1996.

7. "Gynecological Procedures," 28th Annual Family Practice Review, Portland OR, February 1997.

8. "Contraception," 28th Annual Family Practice Review, Portland OR, February 1997.

9. "Family Planning," Reproductive Health Conference 1997, Portland OR, March 1997.

10. "Elective Abortions: RU-486 and Methotrexate," Reproductive Health Conference, Portland OR, March 1997.

11. “Medical Abortion,” 5th Annual Oregon Section ACOG Update in Obstetrics, Gynecology, and Primary Care, Bend OR, April 1997.

12. “Hormonal Contraception for Females: Recommendations and Guidelines,” Endocrine Conference, Ashland OR, August 1997.

13. “Emergency Contraception: From Coca-Cola to Mifepristone,” 21st Annual Pacific NW Review of OB-GYN, Portland OR, October 1997.

14. “Office Gynecology,” 29th Annual Family Practice Review, Portland OR, February 1998.

15. “IUD Insertion Technique,” Roseburg OR, March 1998.

16. “Office Gynecology,” 5th Annual Internal Medicine Review, Portland, April 1998.

17. “Contraceptive Overview,” Planned Parenthood, Eugene OR, November 1998.

18. “Emergency Contraception,” 30th Annual Family Practice Review, Portland OR, February 1999.

19. “Gynecologic Procedures,” 30th Annual Family Practice Review, Portland OR, February 1999.

20. “Emergency Contraception,” Oregon Section, ACOG 6th Annual Meeting, Sunriver OR, April 1999.

21. “Emergency Contraception: New Innovations,” Center for Health Training, 28th Annual Clinical Update, Portland OR, April 1999.

22. “Emergency Contraception,” Sacred Heart Medical Center, 1st Annual Primary Care Conference, Eugene OR, May 1999.

23. “Update in Contraception,” Sacred Heart Medical Center, 1st Annual Primary Care Conference, Eugene OR, May 1999.

24. “ Laparoscopic Tubal Ligation Techniques,” 23rd Annual Pacific NW Review of OB-GYN, Portland OR, October 1999.

25. “Impact of Religious Hospital Mergers on Training Residents in Abortion Care.” Toward Rational Living Conference, Portland OR, November 1999.

26. “Gynecology: Office Procedures,” 31st Annual Family Practice Review, Portland, February 2000.

27. “RU486 in OB/GYN,” Women’s Health Care Symposium, Eugene OR, September 2000.

28. “Savvy About Sex,” Martha Browning Bryant Memorial Lecture, Oregon Chapter of The American College of Nurse-Midwives, October 2000.

29. “Emergency Contraception,” Institute of Women’s Health and Integrative Medicine, October 2000.

30. “Update on Pap Smears” Family Practice OB Ski and Women’s Health Conference, Bend OR, January 2001.

31. “Gynecological Skills Workshop”, Family Practice OB Ski and Women’s Health Conference, Bend OR, January

2001.

32. “Gynecology: Office Procedures,” 32nd Annual Family Practice Review, OHSU, February 2001.

33. “Dysfunctional Uterine Bleeding,” 8th Annual Internal Medicine Review, April 2001.

34. “Sonohysterography or SIS (Saline Infusion Sonography),” 8th Annual Oregon ACOG Update in Obstetrics and Gynecology, Bend OR, April 2001.

35. “Where are we with RU-486" Oregon Nurses Association/Nurse Practitioners of Oregon, 24th Annual Meeting, Eugene, OR Sept. 2001

36. “Pharmacology of Oral Contraceptives”, OHSU with 4 remote sites, Nurse Practitioner curriculum, Oct. 2001

37. “Laparoscopic Supracervical Hysterectomy: Making the Recovery Even Faster”. 25th Annual Pacific Northwest Review Conference, Portland OR, November 2001

38. “Review of Emergency Contraception”, Oregon Pharmacology Association, Nov. 2001

39. “Intrauterine contraception” Nurse Practitioner Training Course, Portland, OR, Jan. 2002

40. “What's new in contraception?” Montana section ACOG Annual Meeting, Big Sky, MT, Feb. 2002

41. “RU-486 in Ob/Gyn”, Montana section ACOG Annual Meeting, Big Sky, MT, Feb. 2002

42. “Review of Emergency Contraception”, Montana section ACOG Annual Meeting, Big Sky, MT, Feb. 2002

43. "What's New in Contraception", 33rd Annual Family Practice Review, Portland, February, 2002

44. "Gynecologic Procedures" 33rd Annual Family Practice Review, Portland, February, 2002

45. “Update on Contraception” Good Samaritan Hospital, Corvallis, OR, March 2002

46. “RU-486 in Ob/Gyn” Good Samaritan Hospital, Corvallis, OR, May, 2002

47. “Labor Inductions” OAFP Women’s Health Conference, Bend, OR, Jan. 2003

48. “The new IUD”OAFP Women’s Health Conference, Bend, OR, Jan. 2003

49. “Update in Contraception” Reproductive Health Conference, Portland, OR, March 2003

50. “IUD training” Reproductive Health Conference, Portland, OR, March 2003

51. “Essure Device for Tubal Sterilization” 10th Annual Oregon ACOG Update in Obstetrics and Gynecology, Bend OR, April 2003.

52. “Update on Contraception for the New Millenium” Women’s Health Care Symposium, Eugene, OR, May 2003

53. “Trans-Cervical Sterilization: A review of the Essure device” 27th Annual Pacific NW Review of OB-GYN, Portland OR, October 2003.

54. “Medical Abortion Review” National Abortion Federation Course, Portland, OR, October, 2003

55. "What's New in Contraception", 35th Annual Family Practice Review, Portland, February, 2004

56. "Gynecologic Procedures" 35th Annual Family Practice Review, Portland, February, 2004

57. “IUD Training” Center for Health Training, Portland, OR October, 2004

58. “Why Women Wait”. Western Regional meeting of Medical Students for Choice, Portland, October, 2004

59. “MVA Training Sessions” Western Regional meeting of Medical Students for Choice, Portland, October, 2004

60. “Ultrasound in Medical Abortion” Sponsored by NAF , Portland, OR, November, 2004

61. "Gynecologic Procedures" 36th Annual Family Practice Review, Portland, February, 2005

62. "Contraceptive Update" 36th Annual Family Practice Review, Portland, February, 2005

63. “Alternatives to Hysterectomy” 36th Annual Family Practice Review, Portland, February, 2005

64. “Looking in the Future: New Contraceptive Methods” Reproductive Health Conference, Portland, OR, March 2005

65. “Shortage of Abortion Providers in the U.S.” Students for Choice conference, Willamette University, Jan. 2006

66. "Gynecology Procedures" 37th Annual Family Practice Review, Portland, February, 2006

67. “Review of Medical Abortion” Pacific Northwest Review Course, Portland, OR October, 2006

68. “Implanon training” Sponsored by Implanon, Portland, OR March, 2007

69. “Review of Contraceptive Implants” Reproductive Health 2007, Portland, OR March 2007

70. “Management of Early Pregnancy Failure”, Nurse Practitioners of Oregon annual meeting, Hood River, OR Oct. 2008

71. “Medical Abortion”, Nurse Practitioners of Oregon annual meeting, Hood River, OR Oct. 2008

72. “ Addressing the abortion provider shortage” Western regional meeting, Medical Students for Choice, Portland, OR, April 2009

National

1. “IUD Review,” Grand Rounds, University of Maryland, Obstetrics and Gynecology Department, February 1993.

2. “IUD Review,” Grand Rounds, Pennsylvania Hospital, Obstetrics and Gynecology Department, May 1993.

3. “IUD Review,” Grand Rounds, Maricopa County, Obstetrics and Gynecology Department, June 1993.

4. “OB/GYN Review Course,” Loma Linda University, Guest Faculty, Yosemite CA, April 1995.

5. “Incorporating Abortion Training Into the Ob/Gyn Residency Curriculum,” National Abortion Federation Conference, Baltimore MD, November 1998

6. “Second Trimester Abortion Technique” and “Abortion Providers Panel: Incorporating Abortion Care Into Your Practice,” Medical Students for Choice, 6th Annual Meeting, Atlanta, GA, April 1999.

7. “Fine Needle Aspiration for the Evaluation of Breast Masses,” National Medical Committee Planned Parenthood Federation of America, Dallas TX, Sept. 1999.

8. “Parenteral Estrogen and Progestin Contraceptive: a Review,” Risk Management Seminar, National Abortion Federation, Denver CO, Sept. 1999.

9. “Faculty Models” National Abortion Federation Resident Training Workshop, New Orleans LA, February 2000.

10. “Building Support in Your Department & Negotiating the Contract: From a Residency Program Perspective,” National Abortion Federation Resident Training Workshop, New Orleans LA, February 2000.

11. “Background/Historical Context,” “Medications: Mifepristone, Misoprostol and Methotrexate,” “Protocol,” “Patient Management,” National Abortion Federation & Planned Parenthood Federation of America “Mifepristone 2000," Pleasant Hill CA, March 2000.

12. “Required Training in Abortion” Training in Abortion: The Next Level, Washington DC, October 2000

13. "Family Planning Fellowships and Planned Parenthood”, PPFA National Medical Committee, Washington DC, December, 2001

14. "Evidence Based Regimen for mifepristone abortions" National Abortion Federation Annual Meeting, San Jose, CA, April 2002

15. “Faculty Models” National Abortion Federation Residency Training Workshop, Phoenix, AZ, December 2002

16. “The Who-What-When-How of Training” National Abortion Federation Residency Training Workshop, Phoenix, AZ, December 2002

17. “Gender Discrimination in Obstetrics and Gynecology: the Impact on recruiting men and retaining women” APGO Faculty Development Seminar, Kapalua, Maui, January 2003

18. “Clinical Issues in First Trimester Abortion”, Medical Students for Choice, Annual Meeting, Seattle, WA, April 2003

19. “Clinical Issues in Second Trimester Abortion”, Medical Students for Choice, Annual Meeting, Seattle, WA, April 2003

20. “Medical Student and Resident Education in Abortion” National Abortion Federation, Annual Meeting, Seattle, WA, April 2003

21. "The Who-What-When-How of Training”, National Abortion Federation Residency Training Workshop, Chicago, March, 2004

22. “Alternatives to Hysterectomy” Medica Symposia Conference, Maui, Hawaii, December, 2004

23. “Contraceptive Options for Women over 40” Medica Symposia Conference, Maui, Hawaii, December, 2004

24. “Gynecologic Procedures” Medica Symposia Conference, Maui, Hawaii, December, 2004

25. “Workup and Management of Postmenopausal Bleeding” Medica Symposia Conference, Maui, Hawaii, December, 2004

26. “Transcervical Female Sterilization”, PPFA Medical Directors Conference, Steamboat Springs, CO, March, 2005

27. “Multi-site Studies”, Family Planning Fellowship Directors Meeting, San Francisco, CA, May, 2005

28. “Infections in Medical Abortion” Annual Meeting of the National Abortion Federation, San Francisco, CA April, 2006

29. “Technique of IUD insertion to minimize perforation risk” PPFA teleconference, November 2006

30. “Requiring abortion training in Ob/Gyn residency: Does it effect recruitment?” 34th Annual national meeting of the North American Society for Psychosocial Obstetrics and Gynecology, Portland, OR February 2007

31. “First Trimester Abortion Technique”, Medical Students For Choice National Meeting, Tampa, FL, March 2007

32. “Review of Essure Procedures”, ASRM, Washington DC, October 2007

33. “Abortion training in Ob/Gyn Residencies” Medical Students for Choice National Meeting, Minneapolis, MN, April 2008

34. “OHSU Feticide Policy” Family Planning Fellowship Annual meeting, New Orleans, LA, May 2008

35. “Balancing Life and Work Panel” ARHP annual meeting, Washington DC, Sept 2008

36. “Update on pain management in surgical abortion”. National Abortion Federation annual meeting, Portland, OR, April, 2009.

37. “Management of the non-lethal anomaly”. National Abortion Federation annual meeting, Portland, OR, April, 2009.

38. “Pain Management of Gynecologic Procedures” Grand Rounds, Northwestern University, Ob/Gyn department, Chicago, IL May 2009

39. “Essure Review”, American Society of Reproductive Medicine annual meeting, Atlanta GA, October 2009

40. “Issues in second trimester abortion”, MSFC annual meeting, Salt Lake City, UT, November 2009

41. “Practitioners Perspective Panel”, MSFC annual meeting, Salt Lake City, UT, November 2009

42. “Abortion Panel”, MEDC meeting, Salt Lake City, UT, March 2010

43. “IUD Review”, Grand Rounds, University of Utah Department Ob/Gyn, Salt Lake City, UT, March 2010

44. “Hysteroscopic Sterilization Review” MEDC annual meeting, Las Vegas, NV, March 2011

45. "Patient Safety in Abortion Care", MEDC annual meeting, Las Vegas, NV, March 2011

46. "Pain management in gyn procedures" Grand Rounds, Dept Ob/Gyn, Wayne State University, Detroit MI, March 2011

47. "Values clarification workshop" Residents, Dept Ob/Gyn, Wayne State University, Detroit MI, March 2011

International

1. "Background/Historical Context," "Medications: Mifepristone, Misoprostol and Methotrexate," "Protocol," "Patient Management," National Abortion Federation & Planned Parenthood Federation of America "Mifepristone 2000," Vancouver BC. September 2000

2. "IUD Review", Grand Rounds, Ob/Gyn Department, University of Zambia, Lusaka, Zambia, September 2010

3. "Contraception Review" Hospital Staff Meeting, Gimbie Adventist Hospital, Gimbie Ethiopia, November 2010

4. "Post abortion IUCDs to reduce subsequent pregnancies" International Family Planning Conference, November 2011, Dakar, Senegal

5. "Update on USA contraception research" Shanghai Institute of Planned Parenthood Research, October 2013

IV. SERVICE

Membership in Professional Societies:

Oregon Medical Association, 1983 - present

American College of Obstetrics and Gynecology, Oregon Section, 1983-present

Multnomah County Medical Society, 1983 - present

Association of Reproductive Health Professionals, 1983 - present

Association of Professors in Gynecology and Obstetrics, 1983 - 1993

American Fertility Society, Elected 1984

National Abortion Federation 1996 - present

National Abortion Rights Action League, 1987 - present

Pacific Northwest Obstetrical and Gynecological Society, 1989 - present

Pacific Coast Obstetrical and Gynecological Society, 1993 – present

Society of Family Planning, 2005 - present

Appointed or Elected Positions in Professional Societies:

American College of Obstetrics and Gynecology, Oregon Section
- Advisory Committee Member, 1984-1987
- Program Coordinator, 1984-1987
- Vice Chair, 1997-2000
- Chair, 2000-2003
- Program Chair, Annual Meeting, April 1998
- Program Chair, Annual Meeting, April 1999
- Program Chair, Annual Meeting, April 2000
- Program Chair, Annual Meeting, April 2001
- Program Chair, Annual Meeting, April 2002
- Program Chair, Annual Meeting, April 2003

American College of Obstetrics and Gynecology, District VIII
- Advisory Council member, 1997-2003
- Junior Fellow Advisor, 2000-2003

Association of Reproductive Health Professionals
- Program Planning Committee, 1998
- Co-Chair, Planning Committee, 2009

National Abortion Federation
- Co-Chair, Risk Management Seminar, 1999
- Co-Chair of Scientific Session at NAF National Meeting
  - Atlanta GA, April 1998
  - Vancouver BC, April 1999
  - Pittsburgh PA, April 2000
  - St. Louis MO, April 2001
  - San Jose, CA, April 2002
  - Seattle, WA, April 2003
  - New Orleans, LA, April 2004
  - Montreal, Canada, April 2005
  - San Francisco, CA, April 2006
  - Boston, MA, April 2007
  - Minneapolis, MN, April 2008
  - Portland, OR, April 2009
  - Philadelphia, PA, April 2010
  - Chicago, IL, April 2011
  - Vancouver BC, April 2012

Pacific Coast Obstetrical and Gynecological Society
- Program Chair, 1998 meeting
- Member program committee, 1997-2003
- Program Chair, 2001 meeting

Society for Family Planning
- President Elect, 2007-2009
- Chair Scientific Committee, 2007-2009
- President, 2009-2011

Immediate Past President, 2011-2013

Editorial and Ad Hoc Review Activities:

Member, Editorial Board

Contraception 2014 - 2018

Journal Reviewer Experience

American Journal of Obstetrics and Gynecology
Obstetrics and Gynecology
Journal of American Women's Association (JAMWA)
British Journal of Obstetrics and Gynecology
New England Journal of Medicine
International Journal of Obstetrics and Gynecology
Contraception

Section Editor

Current Women's Health Reports, General Gynecologic Issues Section, 2001, 2002, and 2003

Committees:
International/National

Norplant Training in the Community, Panel Member, Dallas, Texas, April 1996

Planned Parenthood Federation of America
National Medical Committee, April 1996 - 2002
Primary Care Subcommittee, April 1996 - 2002
Nominating Committee for National Medical Committee, 1997, 1999
Chair, Nominating Committee for National Medical Committee, 2001
Member, National Board of Directors, 2017-2023
Secretary, National Board of Directors, 2018-2021
Chair, Federation Governance Committee, 2019-2022
Co-chair, Accreditation and Quality Committee, 2021-2025

National Abortion Federation
Planning Committee, Risk Management Seminar, Denver CO, September 1999

American College of Obstetrics and Gynecology,
Oregon Section
Advisory Committee Member, 1984-1987

District VIII
Advisory Committee 2000-2003
Junior Fellow Advisor 2000-2003

Association of Reproductive Health Professionals
Program Planning Committee, 1998, 2008

Regional

Pacific Coast Obstetrical and Gynecological Society, 1993 - present
Member program committee, 1997-2003

Institutional

OHSU School of Medicine
Grievance Committee, September 1985 - June 1989
Joint Conference Committee on Graduate Medical Education, January 1987 - 1994
Student Health Advisory Committee, January 1988 - June 1994
Curriculum Review Task Force, Transition to Residency Course, February 1991 - 1993
Faculty Council, August 1991 - June 1997
Faculty Senate, June 1994- June 1996
Search Committee for Director for Maternal Fetal Medicine Division, 1998
Promotion and Tenure, October 1996 - 2002
Women's Health Student Interest Group, Faculty Advisor, 1998 - 2010
Medical Students for Choice, OHSU Chapter, Faculty Advisor, 1998 - 2010
School of Medicine Awards Committee, 2002-2007
Faculty Practice Plan Board of Directors, elected member, 2009-2012

Departmental

Executive Committee 1988-2013
Promotion and Tenure Committee 1995-2005
Clinical Care Committee 1999-2007
Education Committee 1999-2013
Combined Education Committee 1983-1995

Hospital

Medical Records Committee, September 1983 - 1987
Ambulatory Care Committee, July 1987 - July 1990
Operating Room Committee, 1988 - 1992
University Medical Group
Finance Committee, April 1993 - April 1997
Clinical Practice Committee, May 1994 - April 1997
Board of Directors, Specialty Care Representative, March 1998 - 2001
Compensation Committee, 1998
Board of Directors, 1998 - 2001
IPCO Advisory Board, 1995 - 1998
University Hospital North, Ambulatory Surgery Move Task Force, March 1997 - June 1998
Surgical Services Committee, 1998 - 2003
Ambulatory Surgery Management Group, 2000 - 2003.

Local, State, National Recognition for Clinical Excellence:

Selected as one of the "Top-Rated Physicians in America", in Guide to Top Doctors, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012
Named as one of the "Best Doctors for Women-coast to coast", *Ladies Home Journal*, April, 2002
Selected as one of "Our Best Doctors" by Portland physicians, *Portland Monthly*: 2004, 2005, 2006, 2007, 2008,

2009, 2010, 2011, 2013
"Pioneer and Leader Award", for introduction of Essure in PPFA, September 2004

Clinical Care Awards:

Rose Awards: numerous

Community Service:

Birth Home, Board of Directors, Portland OR, 1982 - 1987
Planned Parenthood Columbia Willamette
Medical Committee, April 1984 - 2013
Chairman Medical Committee, June 1991 - 1994
Board of Directors, July 1991 – 1994
Portland Feminist Women's Health Center, Medical Advisor, 1983 - 1987
Oregon State Health Division
Out of Hospital Birth Task Force, September 1985 - November 1987
Direct Entry Midwifery, Board of Directors, 1993 - 1999
Family Planning Consultant, April 1997 - 2013
Teen Pregnancy Prevention Task Group Member, December 1996 - 1998
Region X Chlamydia Project Member, February 1997 - 1999
Population Services International
Advisory Committee on Emergency Contraception Promotion Project 2000-2001

V. TEACHING (OHSU Educator's Portfolio):

Overview of your Role as an Educator:

Almost all of my clinical activities occur with a learner present. I see patients at the Center for Women's Health with third year medical students, provide care at Planned Parenthood with Ob/Gyn residents and Family Planning fellows, perform surgery and deliver babies with medical students and residents. My philosophy of teaching is to allow learners to perform to their abilities and to encourage assumption of increasing responsibility as skills and knowledge grow. I believe that learning occurs best when individuals are given autonomy (commensurate with their training) to provide medical care. I attempt to foster this type of learning by providing feedback during and after the learners care for patients. In surgery, that occurs while directing every action of the learners. In the clinic setting, the learners have more independence to develop their skills without step by step direction.

Scholarship of Teaching:

Curriculum Development

I developed the program objectives for the Family Planning Fellowship. This document was submitted to the Buffett Foundation, and we received approval as a training site.

Educational Conference Presentations

See "Invited Lectures, Conference Presentations or Professorships:" (above)

Classroom Teaching (Since 1995, and not cited in Local Presentations above)

Principles of Clinical Medicine,

"Obstetric Physical Examination", 1995, 1996, 1997, 1998, 2000, 2001, 2002, 2003, 2004, 2005
Pelvic/GU Examination Instructor, 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010

Gross Anatomy Class – MS I Course:
Instructor 2001, 2003, 2004

Physician Assistant Curriculum
"Breast Disease" 1999, 2001
"Contraception" 1999, 2001
"Ectopic Pregnancy" 2003, 2004, 2005, 2006, 2007

Human Growth and Development - MS II Course
"Contraception, Abortion, and Sterilization" 1995-2012
"Female Infertility" 1995-2001
"Abnormal Menstrual Cycles" 1995-2004
"Panel: Population Growth", 1995-1998

Pediatric Resident Noon Conference Series
"Contraception for Adolescents," 1996, 1998, 2000, 2003
"Evaluation and Management of Abnormal Bleeding in Adolescents," 2000, 2002

Internal Medicine Resident Noon Conference Series
"Contraception Review", 2004

Students for Reproductive Choice Elective
"Surgical Abortion Technique" 1997-2007

Women's Health Care Nurse Practitioner Curriculum
"Abortion Review" 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003
"Benign Breast Disease" 1995, 1996, 1997, 1998, 1999, 2000, 2001, 2002, 2003
"Oral Contraceptives and Emergency Contraception" 2002, 2003

Nurse-Midwifery Curriculum
"Shoulder Dystocia" 1995-2016
"Breech Presentation" 2006, 2008, 2010, 2012, 2014, 2016

Family Practice Resident Noon conference
"Contraception Update" 2003
"Medical Abortion" 2003

Endocrinology Fellows Noon Conference
"Contraceptive Review" 2005

Women's Health Interest Group
"Management of Breech Presentation" 2010

Education Grants and Contracts:

Fellowship in Family Planning, funded by the Buffett Foundation. This pays for the salary of two fellows (R5 & R6) and 10% of the faculty of the fellowship director, (split evenly with the assistant fellowship director)

Effectiveness of Educational Activity:

Evaluations from teaching activities are available.

Mentorship:

Served on the MPH thesis committee for Kim Goldsmith, 2003-2004.
Served as mentor of numerous residents for their research projects including Lisa Thomas, Alison Edelman, Neva Phair, Carla Picardo, Marni Kwiecen, Liz Morgan, Gary Burgoine, Stephanie Koontz, Gina Allison, Emily Drath

Service and Membership of Educational Committees:

Steering Committee for the Human Growth and Development Course, SOM, OHSU, 1995-2002
Course Development Committee, Transition to Internship, SOM, OHSU, 1998
Member, Thesis Advisor for Kim Goldsmith, candidate for MPH, 2003

Honors and Awards for Education:

Outstanding Teaching Award, presented by graduating chief residents, OB/GYN Department at OHSU, June 1992.

APGO/CREOG National Faculty Award, presented for excellence in teaching to one faculty member in the Ob/Gyn Dept. at OHSU each year, June 1993.

Excellence in Basic Sciences Teaching MSII Curriculum, OHSU, School of Medicine, 1994-1995.

Teaching Excellence Award, OHSU, School of Medicine, 1999-2000

J. David Bristow Award, OHSU, School of Medicine, Senior Class recognition to "one faculty member who exemplifies the ideals of the true physician as he/she conducts clinical practice with patients and colleagues", June 2001.

APGO/CREOG National Faculty Award, presented for excellence in teaching to one faculty member each year, June 2001

Planned Parenthood Federation of America, Affiliate Excellence Award given to one affiliate in the country for outstanding clinical teaching and research, 2003

Chosen as Faculty Marshal, OHSU School of Medicine Commencement Ceremony, June, 2004

Teaching Excellence Award, OHSU, School of Medicine, 2003-2004

Medical Students for Choice Faculty Mentor Award, presented at MSFC National meeting, Philadelphia, March, 2005

J. David Bristow Award, OHSU, School of Medicine, Senior Class recognition to "one faculty member who exemplifies the ideals of the true physician as he/she conducts clinical practice with patients and colleagues", June 2007.

The Leonard Tow Humanism in Medicine Award, June 2007

25

Chosen as Faculty Marshal, OHSU School of Medicine Commencement Ceremony, June, 2008

Outstanding Teacher Award, presented by graduating chief residents, OB/GYN Department at OHSU, June 2009.

Medical Students for Choice Faculty Mentor Award, presented at MSFC National meeting, Salt Lake City, UT, October 2009.

Robert Hatcher Family Planning Mentor Award, Society of Family Planning, 2015

Mark Nichols Award created to honor the top graduating medical student at OHSU going into an Ob/Gyn Residency, 2016

Exhibit 15

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF SARAH W. PRAGER, MD, MAS, IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, Sarah W. Prager, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am a professor of Obstetrics and Gynecology at the University of Washington (UW). I am the Director of the Family Planning Division and Complex Family Planning Fellowship. I am board-certified in Obstetrics and Gynecology and Complex Family Planning with the American Board of Obstetrics and Gynecology. I have clinical practices at UW Medical Center and the Cedar River Clinic in Renton.

3. I received my Master of Advanced Studies in Clinical Research from the University of California, San Francisco in 2006, my medical degree from the University of Texas Southwestern Medical School in 2000, and my BA from Princeton University in 1993. I currently chair the Clinical Policies Committee for the National Abortion Federation and I co-authored the Early Pregnancy Loss Practice Bulletin for the American College of Obstetricians and Gynecologists (ACOG). I have co-authored six topics on early pregnancy loss for UpToDate. I am a Fellow of the American College of Obstetricians and Gynecologists (FACOG), was the Chair of the Washington Section of ACOG, and am currently the Secretary of District VIII for ACOG, as well as the co-Chair of the Abortion Access and Training Working Group. A copy of my CV is attached hereto as Exhibit A.

4. In my practice, I provide the full spectrum of general obstetrics and gynecological care. My special clinical focus is complex family planning and helping pregnant people navigate their needs around abortion, contraception, and miscarriage. As part of my practice, I regularly prescribe medications for miscarriage care and for medication abortions, including mifepristone. I also supervise the use of medication for miscarriage care and medication abortions by other medical professionals at the UW Medical Center, including by other physicians, nurse practitioners, midwives, physicians' assistants, and residents.

5. I submit this declaration in support of Plaintiff's Motion for Preliminary Injunction.

Mifepristone

6. I am familiar with the drug mifepristone. As an OB/GYN, I prescribe mifepristone for my patients and have done so since approximately 2000, after it was approved by the FDA and once I was in residency.

7. Mifepristone is one of a two-drug regimen prescribed for medication abortions and miscarriage care. The drug is also used for purposes of induction in cases of second- and third-trimester loss.

8. The two-drug regimen for medication abortion up to 70 days involves one dose of mifepristone and one dose of misoprostol. A patient first takes mifepristone, which terminates a pregnancy by blocking the hormone progesterone, which is necessary for the maintenance of a pregnancy. Between

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

24 and 48 hours later, the patient then takes misoprostol, which causes cramping and bleeding to expel the contents of the uterus. This process is similar to a miscarriage.

9. The use of mifepristone in combination with the drug misoprostol is considered the gold standard in the medical management of miscarriage and medication abortions. This has been the case since the early 2000s, when peer-reviewed studies demonstrated that use of the two-drug regimen is both safer and more effective than use of a one-drug regimen of misoprostol alone.[1] Although it

---

[1] Bygdeman, M., Swahn, M.L., *Progesterone receptor blockage. Effect on uterine contractility and early pregnancy*, Contraception 32:45-51(1985); Blanchard, K., Winikoff, B., Ellertson, C., *Misoprostol used alone for the termination of early pregnancy*, Contraception 59:209-217 (1999); Cameron, I.T., Michie, A.F., Baird, D.T., *Therapeutic abortion in early pregnancy with antiprogestogen RU 486 alone or in combination with prostaglandin analogue (gemeprost)*, Contraception 34(5):459-468 (1986); Jain, J.K., Dutton, C., Harwood, B., Meckstroth, K.R., Mishell, D.R., *A prospective randomized, double-blinded, placebo-controlled trial comparing mifepristone and vaginal misoprostol to vaginal misoprostol alone for elective termination of early pregnancy,* Human Reproduction 17(6):1477-1482; (2002); Swahn, M.L., Ugocsai, G., Bygdeman, M., Kovacs, L., Belsey, E.M., Van Look, P.F.A., *Effect of oral prostaglandin E2 on uterine contractility and outcome of treatment in*

is possible to prescribe misoprostol alone for the medical management of miscarriages and for medication abortions, it requires higher and more frequent doses, with increased undesirable patient side effects, such as nausea, cramping, bleeding, and flu-like symptoms.

Treatment for Medication Abortion

10. When patients in early pregnancy contact my office seeking abortion care, my staff schedules them for either an in-person or telehealth consultation with me. I begin each visit by reviewing the patient's medical history and symptoms to determine the kinds of abortion for which they are eligible. I then discuss with my patient the risks, benefits and alternatives for each kind of abortion care for which they are eligible and answer any questions they may have to ensure that they have the information they need to make an informed decision about their care.

11. If they are eligible for, and choose, a medication abortion, we proceed with the visit for such care.

12. I discuss the medication abortion process and discuss the Patient Agreement Form with the patient. After answering any questions, I ask whether

---

women receiving RU 486 (mifepristone) for termination of early pregnancy, Human Reproduction 4(1):21-28 (1989); Zheng, S.R., *RU486 (mifepristone): clinical trials in China*, Acta Obstet Gynecol Scand Suppl 149:19-23 (1989).

they consent to a medication abortion, and if they do, I confirm that consent in their medical record.

13. I then go over again the instructions for how and when to take their medication, what the follow-up process is, what they should do if they experience any of the (very rare) serious complications associated with mifepristone or misoprostol, and answer any questions they may have.

14. In the course of the visit, I also have to review and have the patient sign the Patient Agreement Form. The Patient Agreement Form is duplicative of the information contained in the FDA's Medication Guide, which is dispensed to the patient with the medication.

15. I also prescribe mifepristone, in combination with the drug misoprostol, to patients who are experiencing a miscarriage. Using this two-drug regimen to manage miscarriage is the gold standard for miscarriage management and has been the basic standard of care at UW for approximately five years.[2]

16. Under the REMS, the patients I treat for miscarriage management are required to sign the same Patient Agreement Form as patients receiving mifepristone for a medication abortion. This is confusing and often distressing

---

[2] *See* Schreiber, C.A., Creinin, M.D., Atrio, J., Sonalkar, S., Ratcliffe, S.J., Barnhart, K.T., *Mifepristone pretreatment for the medical management of early pregnancy loss*, N Engl J Med 378(23):2161–70 (2018).

for patients. I have had patients who have been upset at having to sign a form about medical abortion when they are, in fact, experiencing a miscarriage.

17. The way that I counsel patients regarding taking mifepristone for medication abortion or miscarriage management—discussing risks and benefits, explaining the treatment, and obtaining patient consent—is essentially the same as how I or any other medical provider counsels a patient on any medical procedure. This is absolutely standard practice in medicine, taught in medical schools and residences, and reinforced through practice. The Patient Agreement Form is duplicative of the counseling I already do and is completely unnecessary.

18. The Patient Agreement Form can also make counseling *more* difficult in many circumstances. Some patients, for instance, are confused as to why I am asking them to sign an agreement form for a drug that I am explaining to them is very safe. In those instances, the Patient Agreement Form acts to unnecessarily heighten patient worry and stress. When I am treating patients who are non-English speakers, the Patient Agreement Form creates an item that must be explained and worked through with the translator and creates additional burden as well as confusion.

19. Further, in a post-*Roe* era in which there is increasing criminalization of abortion and general chaos of abortion laws across the country, I have growing concern about the Patient Agreement Form for my out-of-state patients. While I recognize that my treatment notes will always be part of my

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

patients' medical charts, the fact that I am required to have patients affirmatively sign a document (that must be given to them and placed in their medical chart) stating that they are choosing to have a medication abortion creates an additional and unnecessary risk to patients that has no grounding in medicine or science.

20. In the course of my medical career, I have counseled and treated hundreds, if not thousands, of patients with mifepristone for medication abortion or miscarriage management. I am not aware of any of those patients experiencing a serious adverse reaction or death. It is among the safest drugs I prescribe my patients.

The REMS Cannot be Justified by any Medical or Safety Concerns

21. Mifepristone is one of a small number of medications that the FDA subjects to a Risk Evaluation and Mitigation Strategy (REMS).

22. The REMS require that mifepristone be dispensed by or under the supervision of a certified prescriber, or by certified pharmacies for prescriptions issued by certified prescribers, and the use of Pharmacy, Prescriber (or Provider) and Patient Agreement forms. Those updates went into effect on January 3, 2023.

23. REMS are typically applied to inherently dangerous drugs like opioids. Mifepristone, however, is extremely safe. Indeed, the FDA's own publications reviewing the safety and efficacy of mifepristone show that there is no scientific need for mifepristone to be subject to a REMS.

24. Mifepristone is safer for patients than acetaminophen (Tylenol), for example. Studies show that less than one percent of patients who take mifepristone for abortion care require hospitalization for adverse events or complications. And as I noted above, I am not aware of any of the hundreds (if not thousands) of patients I have treated with mifepristone over the last 23 years having had a serious adverse drug event or death. By contrast, acetaminophen is the most common cause of liver transplantation in the United States, and is responsible for 56,000 emergency room visits, 2,600 hospitalizations, and 500 deaths per year in the United States. [3] But no REMS apply to the use of acetaminophen, and it can be obtained without a prescription at pharmacies and many other stores.

25. Furthermore, mifepristone is prescribed in some endocrinological (non-gynecological) situations at higher doses, including for conditions like Cushing's Disease. There are no REMS associated with those uses of mifepristone.

26. Because of mifepristone's superior safety profile, leading medical organizations including the American College of Obstetricians and

---

[3] Suneil Agrawai and Babek Khazaeni, *Acetaminophen Toxicity*, National Library of Medicine (Aug. 1, 2022) *available at* https://www.ncbi.nlm.nih.gov/books/NBK441917/#:~:text=It%20is%20responsible%20for%2056%2C000,is%20contained%20in%20combined%20products.

Gynecologists (ACOG), the American Academy of Family Physicians (AAFP), and the American Medical Association (AMA) have called for the removal of the mifepristone REMS. In 2016, ACOG concluded "that a Risk Evaluation and Mitigation Strategy (REMS) is no longer necessary for mifepristone, given its history of safe use. The REMS requirement is inconsistent with requirements for other drugs with similar or greater risks, especially in light of the significant benefit that mifepristone provides to patients."[4]

27. In 2018 AAFP similarly concluded that "the REMS restrictions are not based on scientific evidence"; are overly burdensome on practitioners and impede patient access to care, particularly "for patients who might prefer to go to their own physician and for rural patients who have no other access points beyond their local physician"; cause "delays in care, thereby increasing second-trimester and surgical abortions, both of which have increased complication rates"; and create "a barrier to safe and effective off-label uses of mifepristone, such as for anti-corticoid treatment of Cushing's disease, term labor induction, and miscarriage management[.]"[5]

---

[4] *ACOG Statement on Medication Abortion*, https://www.acog.org/news/news-releases/2016/03/acog-statement-on-medication-abortion.

[5] Am. Acad. of Family Phys. 2018 Congress of Delegates, *Resolution No. 506 (Co-Sponsored C) – Removing Risk Evaluation and Mitigation Strategy*

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

28. In 2021, the AMA urged the FDA to "eliminate the requirement for patients to sign a form to get the drug" and "lift the requirement that prescribers acquire a certification from the manufacturer," noting that "[b]arriers to accessing mifepristone do not make care safer, are not based on medical evidence, and create barriers to patient access to essential reproductive health care."[6]

29. The mifepristone REMS do nothing to enhance patient safety because they are redundant to what healthcare providers already do anyway. The provider certification form, for example, requires the provider to certify that they can accurately date a pregnancy, diagnose an ectopic pregnancy, and treat complications that may arise or refer to someone who could. But any provider who might provide a medication abortion—including obstetricians, gynecologists, family physicians, primary care physicians, and certified nurse midwives—are already extensively trained in pregnancy dating, ectopic risk

---

(REMS) Categorization on Mifepristone, *available at* https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-No.-506-REMS.pdf.

[6]Letter to Robert Califf, MD (Jun. 21, 2022), *available at* https://searchlf.ama-assn.org/letter/documentDownload?uri=/unstructured/binary/letter/LETTERS/lfdr.zip/2022-6-21-Joint-ACOG-AMA-Letter-to-FDA-re-Mifepristone.pdf.

factors, and care coordination. The provider certification thus does not provide any additional patient safety.

30. Similarly, as I discussed above, the Patient Agreement Form is duplicative of information that providers are already required to provide patients, and therefore contributes nothing to enhancing patient knowledge or improving patient care.

31. In fact, the Patient Agreement Form can cause patient confusion for multiple reasons. First, the Patient Agreement Form requires the patient to declare they "have decided to take mifepristone and misoprostol *to end my pregnancy*." But mifepristone is not just used for medication abortion; it is also the standard of care for medically managing miscarriage. Second, the Patient Agreement Form requires the patient to declare they "will take the misoprostol tablets 24 to 48 hours after I take mifepristone." But emerging medical evidence suggests that misoprostol may sometimes be appropriately taken fewer than 24 hours after taking mifepristone, and sometimes even concurrently. Accordingly, for those patients whose doctors direct misoprostol be taken fewer than 24 hours after mifepristone, the Patient Agreement Form is contrary to their doctor's advice and may lead to confusion. And, as I noted above, the Patient Agreement Form can also cause additional patient stress as the form causes some to worry that the medication is actually more dangerous than it is. The Patient Agreement

Form can also make counseling a patient more difficult, particularly in situations in which a translator is being used.

Burdens and Harms of Complying with January 2023 REMS for Mifepristone

32. In addition to not being justified by science and not providing any benefits to patient safety, the REMS conditions impose substantial burdens and harms on health care practitioners.

33. As the Director of the Family Planning Division and Family Planning Fellowship at UW, part of my responsibilities have been to lead, strategize and operationalize UW's compliance with the FDA's recently-updated REMS on dispensing mifepristone.

34. Based on this work, I have seen firsthand how implementing the REMS into patient care creates a substantial burden to medical professionals and health care facilities, which will continue to impede access to safe, legal abortion care and effective miscarriage management for all Washingtonians.

35. UW has organized a workgroup to work through the exceedingly complicated problem of integrating the 2023 REMS requirements into patient care at UW Medicine. The workgroup is multidisciplinary, including approximately twenty professionals, including those responsible for regulatory compliance, information technology specialists, clinicians, pharmacists, University management, and legal personnel. The workgroup has been meeting

for 4 or 5 months, and the group has expended hundreds of hours on implementing the REMS. This includes creating and instituting the dual signature Patient Agreement form, and implementing a system for confirming the proper certifications at the provider and pharmacy level. The IT team has had to determine how to build out the process; figure out what the Patient and Prescriber Agreement forms look like and how to integrate them into UW systems; determine how to keep track of and where to house a list of certified prescribers, and how pharmacies can access the list in order to confirm prescriber certification before filling the prescription. Once that process is in place, there will need to be training and education to all providers and other involved personnel on how to use the new system.

36. Despite the workgroup's progress, significant work remains to be done to implement all the requirements of the 2023 REMS. I have spent approximately 20-40 hours on this work, which includes significant intersecting efforts with the entire workgroup. I estimate that other members of the workgroup have similarly averaged 20-40 hours in this work. I cannot imagine many smaller medical organizations, community hospitals, or local pharmacies will be able to devote such intensive resources to comply with these new regulatory demands.

37. The harms from the REMS extend beyond the difficulties in complying with the requirements. The REMS implicitly discourage providers from using mifepristone for miscarriage care and medication abortions. As noted

above, REMS are generally only placed on dangerous drugs liked opioids and the existence of the REMS coupled with the provider certification creates a disincentive to prescribe a very safe medication. It also creates additional burdens. Whereas under the prior REMS, a single supervisory physician (like me) could obtain certification from the manufacturer and then oversee use of mifepristone by numerous other medical professionals in the same medical system, the new REMS require each individual provider to obtain certification if they will be prescribing via telehealth to a certified pharmacy. This part of REMS compliance has created a huge amount of additional work at UW as it takes time to identify the prescribers who need to complete a Provider Agreement; ensure that they review and sign it; and then ensure that it is given to the UW certified pharmacy.

38. Given the increasingly threatening and hostile environment surrounding abortion care—including threats of prosecution of abortion-care providers by other states and harassment and violence by anti-abortion activists—medical professionals are understandably hesitant to become certified and to identify as prescribing medication abortions. The REMS compound these fears, as certified prescribers must send their certification to each certified pharmacy at which they intend to prescribe. While pharmacies are required to keep these lists confidential, fears of a potential leak act as a significant deterrent to many doctors being willing to prescribe mifepristone—particularly in

communities where there may be greater threats of anti-abortion violence, further burdening patient access to care.

39. These fears are particularly acute for doctors who hold medical licenses in multiple states, where abortion laws differ from Washington's. These providers fear that they may open themselves up to criminal prosecution or litigation in those states for providing abortion care in Washington. The same is true for some of our residents who come from states where abortion is now illegal and who plan to eventually practice medicine in those states. The REMS does not account for the growing number of threats and other types of targeted intimidation experienced by many abortion providers. Nor does the REMS consider the ever-increasing burden on patient access to abortion care.

40. Currently, almost half of all OB-GYN residents are training in states where abortion is now illegal or severely restricted. These residents now cannot get routine training in life-saving abortion care within their training programs, and are seeking that training elsewhere. Washington State has an obligation first to the clinicians training here, but also to clinicians who cannot access training elsewhere. The additional burden of the REMS makes operationalizing this training for out-of-state clinicians even more difficult.

41. Based on my professional experience and medical training, there is no scientific or medical basis for the mifepristone REMS program. The FDA's

decision to nevertheless continue placing these unnecessary and burdensome restrictions on a safe and effective drug, clearly demonstrates that the mifepristone REMS program is not needed to protect patients—but is instead intended to limit patient's access to medication abortion.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 20th day of February, 2023, at Istanbul, Turkey.[7]

Sarah Prager
Sarah W. Prager, MD, MAS

[7] I live and work in Washington, but I am signing this declaration while traveling abroad.

Exhibit A

CURRICULUM VITAE
SARAH PRAGER, M.D., M.A.S.

PERSONAL DATA

Place of Birth	New York City, New York
Citizenship	United States of America

EDUCATION

B.A.	Princeton University Princeton, New Jersey *Summa Cum Laude*	1989 – 1993
M.D.	University of Texas Southwestern Medical School Dallas, Texas	1996 – 2000
M.A.S.	University of California, San Francisco San Francisco, California	2004 – 2006

POSTGRADUATE TRAINING

Internship and Residency	Fletcher Allen Health Care University of Vermont Burlington, Vermont	2000 – 2004
Family Planning Fellowship	University of California, San Francisco San Francisco, California	2004 – 2006
Teaching Scholars Program	University of Washington Medical Center Seattle, Washington	2009 – 2010
Exxcellence in Family Planning Research Course	The Foundation for Exxcellence in Women's Health Care	1/31 - 2/6, 2014
Medical Education Research Certificate (MERC) Program	University of Washington Medical Center Seattle, Washington	2015 - 2017

FACULTY POSITIONS HELD

Clinical Fellow	University of California, San Francisco San Francisco General Hospital San Francisco, California	2004 – 2006
Assistant Professor	University of Washington Department of Obstetrics and Gynecology	2006 – 2012
Adjunct Assistant Professor	University of Washington Department of Health Systems And Population Health	2007 – 2012
Adjunct Associate Professor	University of Washington Department of Health Systems And Population Health	2012 – 2018
Associate Professor	University of Washington Department of Obstetrics and Gynecology	2012 - 2018
Affiliate Faculty	Center for Excellence in Maternal and Child Health Epidemiology Department University of Washington	2016 - present
Professor	University of Washington Department of Obstetrics and Gynecology	2018 - present
Adjunct Professor	University of Washington Department of Health Systems And Population Health	2018 - present
Professor	St. Paul Hospital and Millennium Medical College Department of Obstetrics and Gynecology Addis Ababa, Ethiopia	2019 - present

HOSPITAL/MEDICAL POSITIONS HELD

Physician, Reproductive Health Services	Cedar River Clinic Renton, Washington	2006 – present
Family Planning Clinic Director	Harborview Medical Center Women's Clinic Seattle, Washington	2007 – 2010

Last Updated: 2/14/2023

Family Planning Ryan Residency Program Director, 2007-2013 Associate Director, 2013-present	University of Washington Department of Obstetrics and Gynecology Seattle, Washington	2007 – present
Family Planning Clinic Director	University of Washington Family Planning Clinic in the Women's Health Care Center Seattle, Washington	2010 – present
Family Planning Division Director	University of Washington Department of Obstetrics and Gynecology Seattle, Washington	2013 - present
Fellowship in Family Planning Director	University of Washington Department of Obstetrics and Gynecology Seattle, Washington	2013 - present
Title X Director	Cedar River Clinics Washington	2017 – present
Fellowship in Family Planning Director	St. Paul Hospital and Millennium Medical College Department of Obstetrics and Gynecology Addis Ababa, Ethiopia	2019 - present

HONORS AND AWARDS

Merit Scholarship	University of Texas Southwestern Medical School	1996 – 2000
Outstanding Teacher Award	Fletcher Allen Health Care University of Vermont Burlington, Vermont	2003
Organon Research Award	Fletcher Allen Health Care University of Vermont Burlington, Vermont	2004
"Golden Eddy" Award for Outstanding Patient Education	University of Washington Seattle, Washington	2010
Faculty Research Mentoring Award	University of Washington Seattle, Washington	2011
Mentor of the Year Award District VIII	American Congress of Obstetricians and Gynecologists	2012

Last Updated: 2/14/2023

Excellence in Resident Education	University of Washington Seattle, Washington	2008, 2009, 2011, 2016
Nominated for UW Medicine Mentoring Award	University of Washington Seattle, Washington	2016
Women of Courage Honoree	University of Washington Women's Center Seattle, Washington	2017

BOARD CERTIFICATION

Obstetrics and Gynecology American Board of Obstetrics and Gynecology	2005 – present
Complex Family Planning American Board of Obstetrics and Gynecology	2022 - present

CURRENT LICENSURE

State of Washington; Physician and Surgeon	2006 – present

DIVERSITY, EQUITY AND INCLUSION ACTIVITIES

Member	Society of Family Planning DEI Working Group	2019 - 2022
Member	UW OBGYN Department DEI Committee Subcommittee on Culture and Policy	2020 - present
Small Group Facilitator	UW White Caucus Group Sessions held throughout the Summer of 2020 for interested UW faculty and staff	Summer 2020
Small Group Co-Facilitator	From Ally to Antiracist Course conducted for UW faculty/staff 4 weekly sessions in January, 2021. Continued monthly meetings for small group participants	Jan - June, 2021
Small Group Co-Facilitator	White Antiracist Group Course conducted for UW faculty/staff 6 monthly sessions from July - December, 2021. Extended by participant request	2021 - present
Facilitator	UW Complex Family Planning Division DEI Caucuses	2020 - 2021

Member	National Abortion Federation DEI Committee	2021 - present
Co-Facilitator	UW White Antiracist Group (WAG) UWMC-led group with new sessions every 6 months.	2021 - present

PROFESSIONAL ORGANIZATIONS

Member	Medical Students for Choice	1996 – present
Member	Planned Parenthood Federation of America	2000 – present
Member	American Congress of Obstetricians and Gynecologists (ACOG)	2000 – present
Member	National Abortion Federation	2004 – present
Member	Physicians for Reproductive Health	2004 – present
Member	Society for Family Planning	2006 – present
Member	Association of Reproductive Health Professionals	2006 – 2018
Member	Seattle Gynecology Society	2008 – present
Member	Washington State Medical Association	2008 – present
Member	European Society for Contraception And Reproductive Health	2009 – present
Member	Ethiopian Society of Obstetricians and Gynecologists (ESOG)	2019 - present

TEACHING RESPONSIBILITIES

Curricula

International Curricula

Curriculum Development for the following courses: 2005 – 2006
Ectopic Pregnancy, Hydatidiform Mole, Spontaneous Abortion,
Vertex Presentation, Vertex Delivery Mechanism.
Hue Medical Facility, Vietnam/University of California, San Francisco

Curriculum Consultant 2009 – present
Immediate Postpartum IUD Insertion Training
Population Services International, Washington, D.C.

Curriculum Development 2019 - present
Fellowship in Family Planning
St. Paul Hospital Millennium Medical College
Addis Ababa, Ethiopia

Creation and Administration, Oral and Written Boards 2020 - present
Fellowship in Family Planning
St. Paul Hospital Millennium Medical College
Addis Ababa, Ethiopia

National Curricula

Content Creator and Lead Educator 2014 - present
Inserting Long Acting Reversible Contraception (LARC) Immediately After Childbirth. eLearning Course, Independent Study, 2014.
http://www.cardeaservices.org/resourcecenter/inserting-long-acting-reversible-contraception-larc-immediately-after-childbirth.

Curriculum Director and Lead Educator 2008 – present
Training, Education and Advocacy in Miscarriage Management (TEAMM)
https://www.miscarriagemanagement.org/

Member 2017 - present
Ryan Program Curriculum Advisory Committee
https://www.innovating-education.org/category/early-pregnancy-loss/

ACOG Curricula

Course Director May 2008
Hands-On Office-Based Gynecologic Procedures
ACOG Annual Clinical Meeting, New Orleans, Louisiana

Course Co-Director 2010 and 2011
Family Planning 2011: Contraceptive Challenges, Controversies and Evidence
ACOG Annual Clinical Meeting, San Francisco, California and Washington, D.C.

Fellow Curriculum

Fellowship and Curriculum Director 2014 – present

Fellowship in Family Planning
University of Washington Medical Center, Seattle, Washington

Fellowship Director 2019 – present
Fellowship in Family Planning
St. Paul Hospital and Millennium Medical College, Addis Ababa, Ethiopia

Resident Curricula

Program and Curriculum Director 2007 – 2013
Associate Director 2013 - present
Ryan Residency Training Program in Family Planning
University of Washington Medical Center, Seattle, Washington

Global Health Curriculum Committee 2009 – 2014
Global Health Curriculum in Women's Health
Obstetrics and Gynecology Residency Program
University of Washington, Seattle, Washington

Medical School Curricula

Course Director 2007 – 2018
OB 550 Elective: Voluntary Pregnancy Termination
University of Washington School of Medicine, Seattle, Washington

Medical Student Lecturer 2008 – present
HuBio 565 Lifecycles: Contraception and Abortion (4 hours)
University of Washington School of Medicine, Seattle, Washington

Course Co-Director (with Vicki Mendiratta and Michael Fialkow) 2011 – present
OB 505 Elective: OB GYN Preceptorship
University of Washington School of Medicine, Seattle, Washington

Department of Global Health Curriculum

Advisor and contributor 2014 – 2019
Global Perspectives in Reproductive Health
Graduate: GH 590/Undergraduate: GH 490
University of Washington School of Medicine, Seattle, Washington

<u>Formal Teaching of Residents</u>

Harborview Resident Lecture Series 2006 – 2010
Lectures for residents and medical students: Contraceptive Overview, Intrauterine Contraception, Surgical and Medical Abortion, Management of First Trimester Loss
Harborview Medical Center, Seattle, Washington

Resident Didactic Sessions 2007 – present

Yearly:

1. Values Clarification Exercise/Professionalism in Medicine: Exploring how to provide medical care in the face of personal judgements/differences of opinion
2. Papaya Workshop: Uterine aspiration simulation
3. IUD insertion training: simulation on a plastic uterine model
4. Nexplanon insertion and removal training: simulation on fake arms

Every other year:

5. Contraceptive Conundrums: Challenging cases for contraceptive management.
6. Hormonal Contraception Overview
7. Long Acting Reversible Contraception
8. Medical Abortion
9. First and Second Trimester Abortion
10. Miscarriage Management

Faculty, Staff and Resident Teaching

Nexplanon Training: 2007 - present
Instruction on placement and removal of implantable contraception (Annual sessions)

International Teaching

Immediate Postpartum IUD February 2009
Insertion Training for Midwives and Ob/Gyns
University Teaching Hospital, Lusaka, Zambia

Immediate Postpartum IUD November 2010
Insertion Training for Midwives and Ob/Gyns
Mulago National Referral Hospital, Kampala, Uganda

Other Medical Student Teaching

Medical Student Teaching 2006 – 2019
Papaya Workshops: Instruction on uterine procedure skills
University of Washington School of Medicine, Seattle, Washington

Medical Student Precepting 2007 – present
Precept third year medical students during the Obstetrics and Gynecology clerkship
University of Washington School of Medicine, Seattle, Washington

Medical Student Teaching 2007 – present
Faculty Observer for the Pelvic Exam Module
University of Washington School of Medicine, Seattle, Washington

Medical Student Core Lectures 2007 – 2014
Contraception and abortion overview lecture to medical students on the Ob/Gyn rotation
University of Washington School of Medicine, Seattle, Washington

Medical Student Teaching 2010 - 2019

IUD Insertion Workshops: Instruction on insertion of all available methods of IUDs
University of Washington School of Medicine, Seattle, Washington

Formal Mentoring

Faculty

Alyssa Stephenson-Famy, MD 2011 – present
Career Mentor, Clinician Educator Track

Elizabeth Micks, MD, MPH 2012 – 2022
"Cervicovaginal immune response to vaginally-administered hormonal contraception"
Career Mentor

Lyndsey Benson, MD, MS 2016 - present
Early Pregnancy Loss Management in the Emergency Department
Complex Family Planning Faculty, University of Washington, Seattle, Washington

Lauren Owens, MD, MPH 2022 - present
Career Mentor, Clinician Educator Track, Associate Fellowship Director, CFP
Complex Family Planning Faculty, University of Washington, Seattle, WA

Graduate Students

Kristen Upson, MPH 2007 -2009
"Factors associated with contraceptive non-use among U.S. women ages 35-44 years at risk of unwanted pregnancy". Published 2010
Health Services Research, School of Public Health, University of Washington, Seattle, Washington

Blair Darney, MPH, PhD 2007 – 2012
"The Family Medicine Residency Training Initiative in Miscarriage Management (RTI-MM): Impact on Practice in Washington State". Published 2013
Health Services Research, School of Public Health, University of Washington, Seattle, Washington

Lisa Callegari, MD 2011 – 2013
"Factors associated with lack of effective contraception among obese women in the United States" Published 2014
Health Services Research, School of Public Health, Health Services
Obstetrics and Gynecology Faculty, University of Washington, Seattle, Washington

Kelly Gilmore 2012 – 2014
"Providing long-acting reversible contraception services in Seattle school-based health centers: key themes for facilitating implementation" Published 2015
Health Services Research, School of Public Health
University of Washington, Seattle, Washington

Last Updated: 2/14/2023

Catherine Wright, MPH, PhDc 2013 – present
"Pregnancy Loss and Cardiovascular Disease: Associations and Underlying Genetic Factors".
PhD Program in Epidemiology, School of Public Health,
University of Washington, Seattle, Washington

Alison Ojanen-Goldsmith, MPH, MSW 2013 – present
"Beyond the Clinic: Preferences, Motivations and Experiences with Alternative Abortion Care".
Manuscript preparation in process
Health Services Research, School of Public Health
University of Washington, Seattle, Washington.

Robin Supplee, ARNP, CNM, MPH 2015 – 2018
"Influence of Interdepartmental Training on the Practice of Miscarriage Management"
Manuscript preparation in process
Health Services Research, School of Public Health
University of Washington, Seattle, Washington

Catherine Henley, MPH, PhDc 2019 - 2022
"Contraceptive Use and Associated Sexual Behaviors Among Latina Adolescents Aged 18-19 in the United States"
PhD Program in Epidemiology, School of Public Health,
University of Washington, Seattle, Washington

Genevieve Taylor, MPH 2020 - 2021
" COVID-19 and Sexual and Reproductive Health Services in King County, Washington"
MPH Program in Epidemiology, school of Public Health
University of Washington, Seattle, Washington

Fellows

Annie Hoopes 2012 – 2015
"Knowledge and Acceptability of Long-Acting Reversible Contraception Among Adolescent Women Receiving School-Based Primary Care Services" Published 2016
Health Services Research, School of Public Health
Adolescent Medicine Fellow, University of Washington, Seattle, Washington

Lyndsey Benson, MD, MS 2014 - 2016
"Heterosexual Anal Intercourse: Perception and Practices" Manuscript published
Family Planning Fellow, University of Washington, Seattle, Washington

Liz Harrington, MD, MPH 2015 – 2018
"Mobile phone SMS dialogue with women and their male partners (Mobile WACh XY) and postpartum contraceptive uptake in Kenya: A randomized controlled trial"
Family Planning Fellow, University of Washington, Seattle, Washington

Lauren Owens, MD, MPH 2016 - 2018
"Understanding and meeting family planning needs of women who inject drugs"
Family Planning Fellow, University of Washington, Seattle, Washington

Last Updated: 2/14/2023

Rebecca Taub, MD, MPH 2017 - 2019
"The effects of testosterone on ovulatory function in transmasculine individuals"
Family Planning Fellow, University of Washington, Seattle, Washington

Aishat Olatunde, MD, MS 2019 - 2021
"Comprehensive Early Pregnancy Loss Management in the Emergency Department"
Complex Family Planning Fellow, University of Washington, Seattle, Washington

Ferid Abbas Abubeker, MD MPH 2019 - 2021
"Medical termination for pregnancy in early first trimester (≤ 63 days) using combination of mifepristone and misoprostol or misoprostol alone: a systematic review"
Family Planning Fellow, St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

Tesfaye Hurisa Tufa, MD, MPH 2019 - 2021
"Drugs used to induce fetal demise prior to an abortion: a systematic review"
Family Planning Fellow, St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

Lemi Tolu, MD, MPH 2019 - 2021
"Intra-cardiac lidocaine administration to induce fetal demise before late second-trimester abortion: Retrospective review"
Family Planning Fellow, St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

Mekdes Daba Feyssa, MD, MPH 2019 - present
"COVID-19 and pregnancy: Information for health professionals"
Family Planning Fellow, St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

Abraham Fessehaye 2020 - present
"Foley catheter for cervical preparation prior to second trimester dilation and evacuation: a supply-based alternative for surgical abortion"
Family Planning Fellow, St. Paul's Hospital Millennium Medical College, Addis Ababa, Ethiopia

Jennifer Chin, MD, MS 2020 - 2022
"Ketamine versus fentanyl for surgical abortions: a randomized noninferiority trial"
Complex Family Planning Fellow, University of Washington, Seattle, Washington

Alexandria Wells, MD, MBs 2022 - present
"Opinions and Usage of Family Planning Methods Pre and Post Dobbs"
Complex Family Planning Fellow, University of Washington, Seattle, Washington

Residents

Olivia Sementi 2008 - 2011
"Evidence-Based Selection of Candidates for the Levonorgestrel Intrauterine Device (IUD)"
Published 2014
Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Anna Altshuler, MD 2009 – 2013

Last Updated: 2/14/2023

"How We Form Beliefs About Abortion: Social Media-Based Online Survey"
Published 2014
Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Carly Ingalls, MD 2013 – 2016
"Is Obesity an Independent Risk Factor for Abortion Complications?" Published 2016
Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Jordie Stevens, MD 2013 – 2020
"Leukocytosis, Fever and Bacteremia During Cervical Preparation with Osmotic Dilators for Dilation and Evacuation" Manuscript accepted for publication 2020
Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Kavita Vinekar, MD 2014 - 2019
"Differences in estimated blood loss with use of general anesthesia versus monitored anesthesia care for dilation and evacuation procedures" Manuscript submitted
Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Carlie Field, MD 2015 – 2019
"Simulation training in intrauterine contraception during pre-clinical years of medical school: A hands-on approach to improve awareness, enhance skills, and promote interest"
Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Kristin Lilja 2016 – 2019
"Urban versus rural access to emergency contraception in Washington"
Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Emily Unger 2019 - 2022
"Guidelines for Medication and Surgical Abortion in the First and Second trimester
Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Lauren MacNeill 2020 - present
"Abortion Training at the University of Washington OBGYN Residency Program: Resident Perspectives and Program Challenges"
Obstetrics and Gynecology Resident, University of Washington, Seattle, Washington

Medical Students

Tiana Nizamic 2012 - 2015
"Use of the Levonorgestrel-Releasing Intrauterine System in Transplant Patients"
Published 2014
University of Washington Medical School, Seattle, Washington

Malica Mantrala 2012 – 2015
"Safety of the Levonorgestrel Intrauterine System for Adolescents with Developmental Disabilities" Published 2014
University of Washington Medical School, Seattle, Washington

Last Updated: 2/14/2023

Quyen Vu 2013 – 2016
"Efficacy and Safety of Long-Acting Reversible Contraception in Women With Cardiovascular Conditions" Published 2016
University of Washington Medical School, Seattle, Washington

Benjamin Lang 2014 – 2017
"Use of the levonorgestrel intrauterine device in women with type II diabetes mellitus
University of Washington Medical School, Seattle, Washington

Other Mentorship Activities

Faculty mentor for Medical Students for Choice 2006 - 2018

Faculty mentor for OBGYN Interest Group 2008 - 2019

American Medical Student Association 2021-present
Reproductive Health Mentor

EDITORIAL ACTIVITIES

Ad hoc reviewer for Ongoing
Archives of Gynecology and Obstetrics
American Journal of Obstetrics and Gynecology
Contraception
European Journal of Public Health
Global Health: Science and Practice Journal
International Journal of Gynecology and Obstetrics
Jama – Archives
Journal of Adolescent Health
Journal of Women's Health
Medical Decision Making
Obstetrics and Gynecology
Perspectives in Sexual and Reproductive Health

SPECIAL NATIONAL RESPONSIBILITIES

Medical Students for Choice 1996 – 1998
Chapter Founder and President; University of Texas Southwestern Medical School

Medical Students for Choice 1999 – 2000
Regional Coordinator; Texas, Oklahoma and Louisiana

ACOG: Junior Fellow Vice-Chair and Chair, Vermont Section 2001 – 2003

ACOG: Junior Fellow Vice-Chair and Chair, District I 2003 – 2004

Last Updated: 2/14/2023

SARAH PRAGER, M.D., M.A.S.

ACOG: Committee on Gynecologic Practice	2004 – 2006
ACOG: CREOG Education Committee	2007 – 2010
CDC: Working Group: Selected Practice Recommendations for Contraception Use	2010 – 2013
CDC: Working Group: Updating the Medical Eligibility Criteria for Contraception Use and the Selected Practice Recommendations for Contraception Use	2015 – 2016
ACOG: Committee on Health Care for Underserved Women Vice-Chair of the Committee Chair of the Committee	2011 – 2018 2014 – 2016 2016 – 2018
National Abortion Federation: Member, Board of Directors Chair, Committee on Clinical and Procedural Guidelines	2017 – present 2018 - present
ACOG: Scientific Co-Chair, District VIII and IX Annual District Meeting Planned the meeting, October 4-6, 2019, Maui, Hawaii.	2017-2018
ACOG: Abortion Access and Training Working Group Co-chair	2019 - current
ACOG: Secretary, District VIII	2022 - current
Society of Family Planning Member, Clinical Affairs Subcommittee Write and/or review clinical guidelines on family planning topics Member, Education Committee Write items for question bank for preparation for written boards Curate Complex Family Planning (CFP) fellowship curriculum Create/collate educational materials for CFP curriculum	 2019 - 2022 2022 - current

SPECIAL LOCAL RESPONSIBILITIES

ACOG:	
Secretary, District VIII, Washington Section	2009 – 2012
Treasurer, District VIII, Washington Section	2012 - 2013
Young Physician at Large for District VIII	2013 – 2015
Vice Chair, District VIII, Washington Section	2013 – 2016
Chair, District VIII, Washington Section	2016 - 2019
Legislative Chair, Washington Section	2019 - 2021
University of Washington Department of OBGYN Co-director of the Clinician Educators Working Group	2012 – present
Washington State Hospital Association	2013 - 2014

Last Updated: 2/14/2023

Safe Deliveries Roadmap Postpartum Advisory Group: Member
Safe Deliveries Roadmap Prepregnancy Advisory Group: Member
Safe Deliveries Roadmap Steering Committee: Member

University of Washington Faculty Council on Women in Academia
Member 2014 – 2016
Vice Chair 2016 - 2019

Center for Leadership and Innovation in Medical Education (CLIME) 2015 – 2019
Co-lead, Membership Core

Seattle King County Public Health 2016 – 2019
Family Planning Access and Quality Committee: Member

Washington State Department of Health 2017 - 2020
Maternal Mortality Review Panel: Member

Upstream USA 2018 - present
Washington Advisory Committee Member

University of Washington Medical Center 2021 - present
Council on Appointments and Promotion

SPECIAL INTERNATIONAL RESPONSIBILITIES

Evaluation of Family Planning Services: Focus on IUD insertion January 2010
Nepal

Evaluation of Family Planning Services: Focus on Implant insertion November 2012
Zimbabwe

Population Services International May 2014
Evaluation of Family Planning Services: Focus on Implant insertion
Zambia

Population Services International May 2015
Evaluation of Family Planning Services: Focus on LARC
Pakistan

St. Paul Institute for Reproductive Health and Rights (SPIRHR) 2021 - present
Advisor to the Board (Cannot serve on Board as non-Ethiopian)
Help guide clinical, research, advocacy and educational efforts in Ethiopia

FUNDING HISTORY

Current

Last Updated: 2/14/2023

Strengthening the Family Planning and Abortion Training Program at St. Paul Hospital and Millennium Medical College (Prager)
Anonymous Foundation
Principal Investigator
2020 - 2023 (Extension)
$202,602

Training, Education, and Advocacy in Miscarriage Management (Prager)
Washington State Department of Health, HED23409-1
Principal Investigator
07/01/2021 – 06/30/2023
$193,648

Fellowship in Family Planning (Prager)
Anonymous Foundation
Director
07/01/2014 – 06/30/2023 (Extension)
$2,337,851

Past

HPV status of LEEP negative specimens (Wegner)
University Health Center College of Medicine Research Committee
Co-Investigator
2003 – 2004
$9,000

Immediate Initiation of Oral Contraceptive Pills after Therapeutic Abortion, Immediate Initiation of Transdermal Hormonal Contraception after Therapeutic Abortion (Prager)
Anonymous Foundation
Principal Investigator
2005 – 2008
$70,440

Comparison of Oral and Patch Hormonal Contraception on Metabolic, Thrombotic and Vascular Response (Knopp)
Ortho McNeil Pharmaceuticals, NCT0043997
Co-Investigator
2006 – 2010
$761,500

Ryan Residency Training Program in Family Planning (Prager)
Anonymous Foundation
Principal Investigator
2006 – 2009
$869,953

Last Updated: 2/14/2023

University of Washington, Family Medicine Training, Resident Training Initiative in Miscarriage Management Program (Prager)
Washington State Department of Health, N17270
Principal Investigator
2008 – 2009
$448,071

Miscarriage Management Training Initiative (Prager)
Abortion Access Project
Principal Investigator
2009 – 2013
$777,648

Interferon Pathway Targeting by Depo-Provera in Women (Prager)
Society of Family Planning, SFP5-13
Principal Investigator
2011 – 2013 (Extension)
$12,497

Formation of Abortion Attitudes (Prager)
Society of Family Planning Research Fund, SFPRF6 – T8
Principal Investigator
2012 – 2013
$5,000

Early Pregnancy Loss (Steinauer)
University of California, San Francisco
Co-Investigator
2015 - 2016
$17,106

Nanofiber MPT Development (Woodrow)
Bill and Melinda Gates Foundation, 66-9897
Co-Investigator
2015 - 2017

Injectable Microspheres for fertility Regulation by Endocrine Enhancement (iMFree): A Longer-Acting Injectable Contraceptive (Ratner)
FHI 360, OPP1055878 AM02
Co-Investigator
2016 - 2017
$559,003

Training, Education, and Advocacy in Miscarriage Management (Prager)
Washington State Department of Health, N18447, HED23409
Principal Investigator
07/01/2010 – 06/30/2021 (Extension)
$1,070,308

Last Updated: 2/14/2023

Effects of contraceptive ring on vaginal microbiota, HIV shedding & local immunity (Marrazzo)
National Institute of Health, 1 R01 HD077872-01
Co-Investigator
2014 – 2019
$376,729

Training, Education and Advocacy in Miscarriage Management (Prager)
Anonymous Foundation
Principal Investigator
2013 – 2021 (Extension)
$1,237,250

Exploring stakeholder perspectives and creating community dialogue on the practice and security of community-based and self-provided abortion care: A community-based participatory research project (Prager, Ojanen-Goldsmith)
Society of Family Planning Research Fund, A122100
Co-Principal Investigator
2017 – 2021
$150,000

BIBLIOGRAPHY

Peer Reviewed Journal Articles

1. **Prager S**, Darney, PD. The levonorgestrel intrauterine system in nulliparous women. Contraception 2007; vol 75, Issue 6: S12-S15. PMID: 17531602.
2. **Prager SW**, Steinauer JE, Foster SD, Darney PD, Drey EA. Risk factors for repeat elective abortion. Am J Obstet Gynecol 2007; 197:575.e1-575.e6. PMID: 17904511.
3. **Prager SW**, Oyer DJ. Second-trimester surgical abortion. Clin Obstet Gynecol. 2009 Jun;52(2):179-87. doi: 10.1097/GRF.0b013e3181a2b43a. Review. PMID: 19407524.
4. Lyus R, Lohr P, **Prager S**; Board of the Society of Family Planning. Use of Mirena LNG-IUS and ParaGard CuT380A intrauterine devices in nulliparous women. Contraception, May 2010; 81(5): 367- 371. PMID: 20399942.
5. Upson K, Reed SD, **Prager SW**, Schiff MA. Factors associated with contraceptive non-use among U.S. women ages 35-44 years at risk of unwanted pregnancy. Contraception May 2010; 81(5):427-434. PMID: 20399950.
6. **Prager S**, Lyus R, Lohr P. Reply: Use of Mirena™ LNG-IUS and ParaGard™ CuT380A intrauterine devices for nulliparous women. Contraception, February, 2011; 83(2): 186-187. PMID: 21237345.
7. Lyus R, Lohr P, **Prager S**. The Dalkon Shield and pelvic infection. Contraception, July, 2011; 84(1): 108-109.
8. **Prager S,** Gupta P, Chilambwe J, Vwalika B, Neukom J, Siamwanza N, Eber M, Blumenthal PD. Feasibility of training Zambian nurse-midwives to perform postplacental and postpartum insertions of intrauterine devices. International Journal of Obstetrics and Gynecology; 2012 Jun;117(3):243-7. PMID: 22445950.

Last Updated: 2/14/2023

9. Peterson SE, Nelson JL, Guthrie KA, Gadi VK, Aydelotte TM, Oyer DJ, **Prager SW**, Gammill HS. Prospective assessment of fetal-maternal cell transfer in miscarriage and pregnancy termination. Hum Reprod. 2012 Sep;27(9):2607-12. PMID: PMC3415291.
10. Darney BG, Weaver MR, Stevens NG, Kimball J, **Prager SW**. The Family Medicine Residency Training Initiative in Miscarriage Management: Impact on practice in Washington State. Fam Med 2013 Feb;45:102-8. PMCID: PMC3774008.
11. Darney BG, Weaver MR, VanDerhei D, Stevens NG, **Prager SW**. “One of those areas that people avoid” a qualitative study of implementation in miscarriage management. BMC Health Services Research 2013, April;13:123. PMCID: PMC3637834.
12. Darney BGD, VanDerhei D, Weaver MR, Stevens NG, **Prager SW**. "We have to what?": Lessons learned about engaging support staff in an interprofessional intervention to implement MVA for management of spontaneous abortion. Contraception. 2013 Aug;88: 221-225. PMCID: PMC4085572.
13. Darney, B. G., M. Weaver, S. G. Sosa-Rubi, D. Walker, E. Mori, **S. Prager** and E. Gakidou (2013). "The Oportunidades Conditional Cash Transfer Program: Effects on Pregnancy and Contraceptive Use Among Young Rural Women in Mexico." International Perspectives on Sexual and Reproductive Health. Dec;**39**(4): 205-214. PMCID: PMC4096692.
14. Steinauer JE, Sokoloff A, Roberts EM, Drey EA, Dehlendorf CE, **Prager SW**. Immediate versus delayed initiation of the contraceptive patch after abortion: a randomized trial. Contraception. 2014 Jan;89(1):42-7. PMID: 24176251.
15. Callegari LS, Darney BG, Sementi O, Godfrey EM, Dunsmoor-Su R, **Prager SW**. Evidence-Based Selection of Candidates for the Levonorgestrel Intrauterine Device (IUD). J Am Board Fam Med 2014 Jan-Feb;27(1):26-33. PMC4049525.
16. Callegari LS, Nelson KM, Arterburn DE, **Prager SW**, Schiff MA, Schwarz EB. Factors associated with lack of effective contraception among obese women in the United States. Contraception. 2014 Sep;90(3):265-71. PMID: 24950888.
17. Amies Oelschlager AME, Micks EA, Debiec KE, Nizamic T, Mantrala MD, **Prager SW**. Long Acting Reversible Contraception in Adolescents with Cardiovascular Conditions. J Ped and Adolesc Gynecol (2014) Dec(6):353-5. PMID: 25256877.
18. **Prager S**. Committee on Healthcare for Underserved Women. Committee Opinion No. 615. Access to contraception. Obstet Gynecol 2015 Jan;125(1):250–5. PMID: 25560140
19. Altshuler AL, Gerns Storey HL, **Prager SW**. Exploring abortion attitudes of US adolescents and young adults using social media. Contraception. 2015 Mar;91(3):226-33. PMID: 25537853.
20. **Prager SW,** Dalton VK, Allen RH. Committee on Practice Bulletins – Gynecology. ACOG Practice Bulletin no. 150: Early Pregnancy Loss. Obstet Gynecol. 2015 May;125:1258–67. PMID: 25932865
21. Gilmore K, Hoopes AJ, Cady J, Amies Oelschlager AM, **Prager S**, Vander Stoep A. Providing long-acting reversible contraception services in Seattle school-based health centers: key themes for facilitating implementation. J Adolesc Health. 2015 Jun;56(6):658-65. PMID: 26003582.
22. Vuilleumier PH, **Prager SW**. Is birthing pain the trigger of postpartum depression? Trends in Anaesthesia and Critical Care. 2015 Jun;5(4)101-103.
23. Vu Q, Micks E, McCoy E, **Prager S**. Efficacy and Safety of Long-Acting Reversible Contraception in Women With Cardiovascular Conditions. Am J Cardiol. 2016 Jan 15;117(2):302-4. PMID: 26679424.

Last Updated: 2/14/2023

24. Hoopes AJ, Ahrens KR, Gilmore K, Cady J, Haaland WL, Amies Oelschlager AM, **Prager S**. Knowledge and Acceptability of Long-Acting Reversible Contraception Among Adolescent Women Receiving School-Based Primary Care Services. J Prim Care Community Health. 2016 Jul;7(3):165-70. PMID: 27067583.
25. Blumenthal PD, Chakraborty NM, **Prager S**, Gupta P, Lerma K, Vwalika B. Programmatic experience of post-partum IUD use in Zambia: an observational study on continuation and satisfaction. Eur J Contracept Reprod Health Care. 2016 Jul 1:1-5. PMID: 27367825.
26. Benson LS, Micks EA, Ingalls C, **Prager SW**. Safety of Outpatient Surgical Abortion for Obese Patients in the First and Second Trimesters. Obstet Gynecol. Nov, 2016;128(5):1065-1070. PMID: 27741198
27. Owens L., **Prager S**. Operationalizing 17a-Hydroxyprogesterone Caproate to Prevent Recurrent Preterm Birth: Definitions, Barriers, and Next Steps. Obstet Gynecol. (2017) May;129(5):945. PMID: 28426603
28. Lohr PA, Lyus R, **Prager S**. Use of intrauterine devices in nulliparous women. Contraception. 2017 June;95(6):529-537. PMID: 27591814
29. **Prager S**. Committee on Health Care for Underserved Women. Committee Opinion No 707: Access to Emergency Contraception. Obstet Gynecol. 2017 Jul;130(1): e48-e52. PMID: 28644339
30. Kelly E Quinley, MD, Deborah Chong, MD, **Sarah Prager, MD MAS**, Charlotte Page Wills MD, Arun Nagdev, MD, Sara Kennedy, MD MPH. Manual uterine aspiration: adding to the emergency physician stabilization toolkit. Annals of Emergency Medicine. 2017 Dec 13. PMID: 29248332.
31. Lang B, Josephy T, Micks E, **Prager S**. Use of the levonorgestrel-releasing intrauterine device in women with type II diabetes mellitis. Clinical Diabetes 2018 Apr; cd170028. DOI: https://doi.org/10.2337/cd17-0028
32. Bonnie Crouthamel, Melissa Schiff, Anne-Marie Amies Oelschlager, **Sarah Prager**, Kate Debiec. Bits and Pieces: A Crowd-Sourced Series of 54 Cases of Fractured Hormonal Implants. Journal of Pediatric and Adolescent Gynecology. April 2018 Vol. 31, Issue 2, p 128-131. DOI: https://doi.org/10.1016/j.jpag.2017.10.002
33. **Prager S**, Sufrin C. ACOG Committee Opinion No. 729: Importance of Social Determinants of Health and Cultural Awareness in the Delivery of Reproductive Health Care. Obstet Gynecol. 2018 Jun;131(6):1163. doi: 10.1097/AOG.0000000000002661. PMID: 29794659
34. **Prager, Sarah W. MD MAS**, Averbach, Sarah MD MAS, Roberts, Elizabeth M. MD, Okeigwe, Ijeoma, MD, MPH, Sokoloff, Abby MPH, Drey, Eleanor A. MD, EdM, Steinauer, Jody E. MD, MAS. Immediate initiation of oral contraceptive pills after surgical abortion: a randomized controlled trial. J Reprod Med 2019;64:15-20
35. Meyerowitz EA, **Prager S**, Stout K, et al. Endocarditis following IUD insertion in a patient with tetralogy of Fallot. BMJ Case Reports CP Feb 2019;12:bcr-2018-227962.
36. Benson LS, Gilmore KC, Micks EA, McCoy E, **Prager SW**. Perceptions of Anal Intercourse Among Heterosexual Women: A Pilot Qualitative Study. Sex Med. Jun. 2019;7(2):198-206. doi: 10.1016/j.esxm.2018.12.003. https://www.ncbi.nlm.nih.gov/pubmed/30833227
37. Field C, Benson LS, Stephenson-Famy A, **Prager S**. Intrauterine device training workshop for preclinical medical students. *MedEdPORTAL*. 2019;15:10841. https://doi.org/10.15766/mep_2374-8265.10841
38. Taub RL, Adriane Ellis S, Neal-Perry G, Magaret AS, **Prager SW**, Micks EA. The effect of testosterone on ovulatory function in transmasculine individuals. Am J Obstet Gynecol. 2020 Feb 7. pii: S0002-9378(20)30134-4. doi: 10.1016/j.ajog.2020.01.059.

Last Updated: 2/14/2023

39. Mark A, Grossman D, Foster AM, **Prager SW,** Winikoff B. When Patients Change Their Minds After Starting an Abortion: Guidance from the National Abortion Federation's Clinical Policies Committee. Contraception. Volume 101, Issue 5, May 2020, Pages 283-285. https://doi.org/10.1016/j.contraception.2020.01.016. PMID: 32035097
40. Lyndsey S. Benson, MD, MS, **Sarah W. Prager, MD, MAS**. Evidence-based management of early pregnancy loss. OBG Management. Vol. 32, No. 7, July, 2020. Pages 26-33. MDedge.com/obgyn.
41. Abubeker, FA. Fessehaye, A. Feyssa, MD. **Prager, S**. Bucket-handle uterine rupture during second-trimester medication abortion, a rare form of rupture of the lower uterine segment and vaginal fornix: a case report. Contraception X 2 (2020) 100025. https://doi.org/10.1016/j.conx.2020.100025.
42. Owens L. Gilmore K. Terplan M. **Prager S**. Micks E. Providing reproductive health services for women who inject drugs: a pilot program. Harm Reduction Journal. (2020) 17:47. https://doi.org/10.1186/s12954-020-00395-y.
43. Lemi Belay, MD, Tesfaye Hurisa, MD, Ferid Abbas, MD, Mekdes Daba, MD, MPH, Biruck Abebe, MD, Balkachew Nigatu, MD, **Sarah Prager, MD, MAS**. Effects of COVID-19 Pandemic on Safe Abortion and Contraceptive Services and Mitigation Measures: A Case Study from a Tertiary Facility in Ethiopia. Ethiopian Journal of Reproductive Health (EJRH) July, 2020 Volume 12, No. 3. https://ejrh.org/index.php/ejrh/article/view/418/131
44. Tolu LB, Tufa TH, Abas F, Kahn C, MacAfee L, **Prager S**, Bell JD. Intra-cardiac lidocaine administration to induce fetal demise before late second-trimester abortion: Retrospective review. Int J Gynaecol Obstet. 2020 Oct 12;. doi: 10.1002/ijgo.13419. PubMed PMID: 33043458.
45. Tufa TH, **Prager S**, Lavelanet AF, Kim C. Drugs used to induce fetal demise prior to abortion: a systematic review. Contracept X. 2020;2:100046. doi: 10.1016/j.conx.2020.100046. eCollection 2020. PubMed PMID: 33294839; PubMed Central PMCID: PMC7689273.
46. Mindaye ET, Kassahun M, **Prager S**, Tufa TH. Adult case of giant sacrococcygeal teratoma: case report. BMC Surg. 2020 Nov 24;20(1):295. doi: 10.1186/s12893-020-00962-x. PubMed PMID: 33234106; PubMed Central PMCID: PMC7687728.
47. Benson LS, Stevens J, Micks EA, **Prager SW**. Leukocytosis during cervical preparation with osmotic dilators for dilation and evacuation. SAGE Open Med. 2021 Jan 12;9:2050312120986731. doi: 10.1177/2050312120986731. PMID: 33489232; PMCID: PMC7809630.
48. Tufa TH, **Prager S**, Wondafrash M, Mohammed S, Byl N, Bell J (2021) Comparison of surgical versus medical termination of pregnancy between 13-20 weeks of gestation in Ethiopia: A quasi-experimental study. PLoS ONE 16(4): e0249529. https://doi.org/10.1371/journal.pone.0249529
49. Ferid A. Abubeker, Tesfaye H. Tufa, Matiyas A. Shiferaw, Mekdes D. Feyssa, Wondimu Gudu, Delayehu Bekele, **Sarah Prager**. Successful dilation and evacuation for second trimester conjoined twin: A case report and systematic review of the literature. *J Med Case Reports* 15:298 (2021). https://doi.org/10.1186/s13256-021-02815-4
50. Tolu LB, Tufa TH, Abubeker FA, Daba, M, **Prager S**. (2021) Can We Safely Stop Administering Anti-D Immune Globulin to First Trimester Rh-Negative Mothers Undergoing Abortion? A Systematic Review and Meta-Analysis. Annals Gynecol Obstet 5(1):118- 124. DOI: 10.36959/468/477
51. Jade M. Shorter, Helen Pymar, **Sarah Prager**, Arden McAllister, Courtney A. Schreiber, Early pregnancy care in North America: A proposal for high-value care that can level health

disparities. Contraception. Volume 104, Issue 2, 2021, Pages 128-131. ISSN 0010-7824, https://doi.org/10.1016/j.contraception.2021.04.015.

52. Anna K Cardall, Janet C Jacobson, **Sarah Prager,** Anne N Flynn, Jennefer Russo. Medical management of ectopic pregnancy in a family planning clinic: A case series. Contraception, 2022. ISSN 0010-7824, https://doi.org/10.1016/j.contraception.2021.11.010.
53. Mark A, Roberts R, Foster AM, **Prager SW**, Ryan R, Winikoff B. "Who is driving you home today?" Escort policy as a barrier to abortion access. Contraception. 2022 Jan 11:S0010-7824(21)00498-4. doi: 10.1016/j.contraception.2021.12.012. PMID: 35031304.
54. Tufa TH, Abubeker FA, **Prager S**, Tolu LB, Grentzer J, Surur F, Bell JD. The role of advanced training in family planning and reproductive health in a low-income country; the experience of Ethiopia. Contraception. 2022 Feb 22:S0010-7824(22)00034-8. DOI:https://doi.org/10.1016/j.contraception.2022.02.002. PMID: 35217091
55. Erin E McCoy, Amanda KH Weidner, Lyndsey S Benson, Blair G Darney & **Sarah W Prager.** (2022) Practice change following an interdepartmental training on early pregnancy loss management in the emergency department. Cogent Public Health, 9:1, 2052402, DOI: 10.1080/27707571.2022.2052402. https://doi.org/10.1080/27707571.2022.2052402
56. Sarah Horvath MD, MSHP, Vinita Goyal MD, MPH, Sarah Traxler MD, MSHP, **Sarah Prager MD, MAS**. Society of Family Planning committee consensus on Rh testing in early pregnancy, Contraception (2022), doi: https://doi.org/10.1016/j.contraception.2022.07.002
57. Jennifer Chin, MD, Madeline McGrath, BA, Erica Lokken, PhD, Carlos Delgado Upegui, MD, **Sarah Prager, MD, MAS**, Elizabeth Micks, MD, MPH. Ketamine Compared With Fentanyl for Surgical Abortion: A Randomized Controlled Trial. Obstet Gynecol 2022;00:1-9. DOI: 10.1097/ACOG.0000000000004903
58. Abraham Fessehaye Sium, Tesfaye H. Tufa, Jaclyn M. Grentzer, **Sarah Prager.** Effectiveness of intracardiac lidocaine and intra-amniotic digoxin at inducing fetal demise before second trimester abortion past 20 weeks at a tertiary Hospital in Ethiopia: a retrospective review. Contraception: X, 4 (2022) 100082 ISSN 2590-1516, https://doi.org/10.1016/j.conx.2022.100082. (https://www.sciencedirect.com/science/article/pii/S2590151622000119)
59. Abraham Fessehaye Sium, **Sarah Prager**, Mekdes Wolderufael, Ferid A. Abubeker, Tesfaye H. Tufa, Jaclyn M. Grentzer. Foley catheter for cervical preparation prior to second trimester dilation and evacuation: A supply-based alternative for surgical abortion: A case series. Contraception: X 4 (2022) 100085. https://doi.org/10.1016/j.conx.2022.100085.

Book Chapters

1. **Prager S**, Steinauer J. Hormonal Contraception. In: Lewis V, ed. Reproductive Endocrinology and Infertility Austin: Landes Bioscience, 2007:65-83.
2. **Prager S,** Oyer D. Second-Trimester Surgical Abortion. In: Clinical Obstetrics And Gynecology, 52(2):179-187, June 2009.
3. Micks E, **Prager S**. Short-acting progestin methods of contraception. In Jenson J, Creinin M et al (Ed). *Speroff & Darney's Clinical Guide for Contraception*. Sixth edition. 2020. Philadelphia: Wolters Kluwer.
4. **Sarah Prager** and Erin McCoy. The Role of Early Pregnancy Loss Care in Ensuring Competence in Uterine Evacuation. In: Advancing Women's Health Through Medical Education: A Systems Approach in Family Planning and Abortion. Cambridge University Press. 2021. DOI: 10.1017/9781108884709

Last Updated: 2/14/2023

5. David Turok and **Sarah Prager**. Academic Family Planning and Sexual and Reproductive Health Collaborations: Training and Advocacy with Community Partners. In: Advancing Women's Health Through Medical Education: A Systems Approach in Family Planning and Abortion. Cambridge University Press. 2021. DOI: 10.1017/9781108884709

Published Books, Videos, Software, etc.

Prager S. (Faculty Collaborator). Inserting Long Acting Reversible Contraception (LARC) Immediately After Childbirth. eLearning Course, Independent Study, 2014. http://www.cardeaservices.org/resourcecenter/inserting-long-acting-reversible-contraception-larc-immediately-after-childbirth.

Other Publications

1. **Prager S**, Darney P. Can the levonorgestrel-releasing intrauterine system (Mirena®) be used in nulliparous women? Gynaecol Forum 2006; 11:7-9.
2. **Prager S**, There is no post-abortion syndrome. Guest Columnist, Seattle Post-Intelligencer July 9, 2007.
3. **Prager S,** The pill does not induce abortion. Letter to the Editor, Seattle Post-Intelligencer, Nov. 24, 2007.
4. CREOG Educational Objectives Ninth Edition (Co-authored with CREOG Education Committee) 2010.
5. Micks E, **Prager S**. Plan A: postabortion contraception. Clin Obstet Gynecol. 2014 Dec;57(4):751-62. PMID: 25254920.
6. **Prager SW,** McCoy EE. Immediate Postpartum Intrauterine Contraception Insertion. Obstet Gynecol Clin North Am. 2015 Dec;42(4):569-82. PMID: 26598300.
7. **Prager S**, Micks E, Dalton VK. Pregnancy loss (miscarriage): Assessment, counseling and choice of treatment. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed March 30, 2019.
8. Alice Mark, Angel M. Foster, Daniel Grossman, **Sarah W. Prager**, Matthew Reeves, Cristina Villarreal Velásquez, Beverly Winikoff. Foregoing Rh testing and anti-D immunoglobulin for women presenting for early abortion: a recommendation from the National Abortion Federation's Clinical Policies Committee. Contraception. May 2019 Volume 99, Issue 5, Pages 265–266. DOI: https://doi.org/10.1016/j.contraception.2019.02.008
9. Mahlet Yigeremu, **Sarah W. Prager**, Sofanit Haile. Maintaining SRH Services during the COVID-19 Pandemic. COVID-19 Pregnancy and Women's Health for Health Care Professionals. May 06, 2020, Ethiopian Society of Obstetricians and Gynecologists. http://www.esog-eth.org/images/Update-2020/COVID-19_FOR_PROVIDERS-_ESOG_VERSION_01_1.pdf.
10. **Prager S**, Micks E, Dalton VK. Pregnancy loss (miscarriage): Management techniques. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed Nov. 20, 2020.
11. **Sarah Prager.** The Impact of COVID-19 on Abortion Education. BMJ Sexual and Reproductive Health Blog. Posted January 24, 2021. https://blogs.bmj.com/bmjsrh/2021/01/24/the-impact-of-covid-19-on-abortion-education/
12. **Prager S**, Micks E, Dalton VK. Pregnancy loss (miscarriage): Terminology, risk factors, and etiology. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Last updated: Sept. 24, 2021. Accessed October 6, 2021.

Last Updated: 2/14/2023

SARAH PRAGER, M.D., M.A.S.

13. **Prager S**, Micks E, Dalton VK. Pregnancy loss (miscarriage): Comparison of treatment options and discussion of related care. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Last updated August 27, 2021. Accessed October 6, 2021.
14. **Prager S**, Micks E, Dalton VK. Pregnancy loss (miscarriage): Ultrasound diagnosis. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Last updated: July 8, 2021. Accessed October. 6, 2021.
15. **Prager S**, Micks E, Dalton VK. Pregnancy loss (miscarriage): Clinical presentations, diagnosis, and initial evaluation. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Last updated: July 9, 2021. Accessed October. 6, 2021.
16. **Prager S**, Micks E, Dalton VK. Septic abortion: Clinical presentation and management. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Last updated August 13, 2021. Accessed October 6, 2021.
17. Mark A, Foster AM, Jones RK, **Prager SW**, Reeves MF, Ragsdale KH. The pandemic year: Research at the National Abortion Federation's 2021 Virtual Annual Meeting. Contraception 103 (2021) 371-372. https://doi.org/10.1016/j.contraception.2021.03.001
18. Mark A, Foster AM, Madera M, **Prager S**, Reeves M, Rice WS, Jones RK. The National Abortion Federation's 45th Annual Meeting: Together Again. Contraception. 2022 Mar 10:S0010-7824(22)00063-4. doi: 10.1016/j.contraception.2022.03.001. PMID: 35278408
19. **Sarah Prager**. Managing Miscarriage in the Emergency Department and Beyond - In any medical setting, here are a few ways to provide support. MedPage Today. February 14, 2023. https://www.medpagetoday.com/opinion/second-opinions/103099?trw=no

Abstracts

1. Jovanovic-Peterson L, Terbell H, **Prager S**, Peterson C. Effects of the Menstrual Cycle on Insulin Resistance and Glucose Disposal Rate in Type-1 Diabetic Women. Diabetes 1997; 46 (Supp2):104A.
2. **Prager S**, Steinauer J, Greene Foster D, Darney P, Drey, E, Characteristics of Women Presenting for Repeat Elective Abortion. Oral presentation, ACOG Annual Clinical Meeting, May 2006, Washington DC. Obstet Gynecol 2006; 107:9S.
3. **Prager S**, Chan E, Krieger E, Fish B, Paramsothy, B, Knopp R. Effects of Patch Versus Oral Contraception on Coagulation Factors: A Randomized Crossover Study. Poster presented, ARHP, September 2009, Los Angeles, CA. Contraception, August 2009, Vol. 80, Issue 2, p 214.
4. **Prager S**, Krieger E, Chan E, Fish B, Paramsothy B, Knopp R. Within-cycle Variation in Coagulation Factors Seen with Patch and Oral Contraception: a Randomized Crossover Study. Poster presented, ARHP, September 2009, Los Angeles, CA. Contraception, August 2009, Vol. 80, Issue 2, p 218.
5. **Prager S**, Neukom J, Gupta P, Chilambwe J, Siamwanza N, Eber M, Vwalika B, Blumenthal P. Introduction of Post Placental/Partum IUD insertion (PPIUD) in Lusaka, Zambia: Feasibility of Training Nurse Midwives. Poster presented, ARHP, September 2009, Los Angeles, CA. Contraception, August 2009, Vol. 80, Issue 2, pp 213-214.
6. Darney B, Kimball J, VanDerhei D, Stevens N, **Prager S**. Outpatient surgical miscarriage management (MM): Current practice among family medicine residents and faculty. Poster presented, ARHP, September 2009, Los Angeles, CA. Contraception, August 2009, Vol. 80, Issue 2, pp 199-200.

Last Updated: 2/14/2023

7. Blumenthal P, Shiliya N, Neukom J, Chilambwe J, Vwalika B, **Prager S**, Gupta P, Espey E, Eber M. Expulsion rates and satisfaction levels among postpartum IUD users in peri-urban Lusaka, Zambia. Poster presentation: North American Forum on Family Planning; Oct. 24-26, 2011; Washington, DC. Contraception, September 2011, Vol. 84, Issue 3, pp 320.
8. Darney BG, Weaver M, Kimball J, Stevens NG, **Prager SW**. Bringing uterine evacuation skills back into primary care: Impact of the Residency Training Initiative in Miscarriage Management (RTI-MM). Poster presentation: North American Forum on Family Planning; Oct. 24-26, 2011; Washington, DC. Contraception, September 2011, Vol. 84, Issue 3, pp 309-310.
9. Amies Oelschlager A, Debiec K, Micks E, Nizamic T, Mantrala M, **Prager S**. Safety of long acting reversible contraception for adolescents with cardiovascular disease. Annual Clinical Meeting for North American Society of Pediatric and Adolescent Gynecology, San Diego April, 2013. J Pediatr Adolesc Gynecol. 26(2):e50.
10. Amies Oelschlager A, Debiec K, Micks E, Nizamic T, Mantrala M, **Prager S**. Young adolescence (age ten to fourteen) is not a contraindication to the use of the levonorgestrel intrauterine system. Annual Clinical Meeting for North American Society of Pediatric and Adolescent Gynecology, San Diego April, 2013. J Pediatr Adolesc Gynecol. 26(2):e58.
11. Amies Oelschlager A, Debiec K, Micks E, **Prager S**. Use of the levonorgestrel intrauterine system in adolescents with known uterine didelphys or unicornuate uterus. Annual Clinical Meeting for North American Society of Pediatric and Adolescent Gynecology, San Diego April, 2013. J Pediatr Adolesc Gynecol. 26(2):e58.
12. Nizamic T, Amies Oelschlager A, Debiec K, Smith J, Micks MED, **Prager S**. Safety and Efficacy of the Levonorgestrel Intrauterine System in Transplant Patients. Poster presentation at ACOG Annual Clinical Meeting, May 7, 2013. Am J Transplant. 2013; 13(suppl 5).
13. Callegari L, **Prager S**, Schwarz EB, Schiff M. Factors associated with contraceptive nonuse among obese and non-obese women. Poster presented at the North American Forum on Family Planning (the Forum), October 5-7, 2013, Seattle, WA. Contraception. September, 2013. Vol. 88, Number 3, page 469.
14. Micks E, O'Day D, Naluai-Cecchini T, Deng M, Souter V, Doherty D, **Prager S**, Glass I. Determining quality of fetal tissues exposed to digoxin preceding dilation and evacuation: maximizing opportunities to participate in research. Contraception, 2015 Oct. 92(4): 367.
15. Ingalls C, Benson L, Micks E, **Prager S**. Obesity in Surgical Abortion: A Risk Factor for Complications? Obstetrics & Gynecology. Vol. 127, No. 5 (supplement), May 2016.
16. Benson L, Micks E, **Prager S**. Heterosexual Anal Intercourse in the United States. Obstetrics & Gynecology, Vol. 127, No. 5 (supplement), May 2016.
17. Benson L, Gilmore K, Micks E, Prager S. Heterosexual Anal Intercourse among Teenagers in the United States. Journal of Pediatric and Adolescent Gynecology 2016;29(2):209.

MEDIA CONSULTATIONS

Mannino, Barbara. "When it comes to family size, money matters in more ways than one." Fox Business, September 30, 2011.
http://www.foxbusiness.com/features/2011/09/30/when-it-comes-to-family-size-money-matters-in-more-ways-than-one.html.

Last Updated: 2/14/2023

Collins, Sonya. “Comparing birth control pill types.” WebMD, April 11, 2012: http://www.webmd.com/sex/birth-control/features/comparing-birth-control-pill-types-combination-mini-pills-more.

Gohring, Nancy. “The Catholic Church is Managing Many Local Hospitals. How Will it Affect Your Health Care?” Seattle Magazine, June 2014: http://seattlemag.com/article/catholic-church-managing-many-local-hospitals-how-will-it-affect-your-health-care.

Andrews, Eve. “Watch me get an IUD – for the planet.” Grist, January 20, 2015: http://grist.org/living/watch-me-get-an-iud-for-the-planet/.

VanDusen Wilson, Heather. “IUDs regaining women’s trust decades after Dalkon scandal.” HS NewsBeat, February 27, 2015: http://hsnewsbeat.uw.edu/story/iuds-regaining-women%E2%80%99s-trust-decades-after-dalkon-scandal.

Reddy, Sumathi. “Solving the Mystery of Miscarriages.” The Wall Street Journal, June 15, 2015: http://www.wsj.com/articles/solving-the-mystery-of-miscarriages-1434389396.

Szabo, Liz. “ACLU sues Catholic hospital chain over emergency abortions.” USA Today, October 1, 2015: http://www.usatoday.com/story/news/2015/10/01/aclu-sues-catholic-hospital-chain-over-emergency-abortions/73147778/.

Ta, Thanh. “Washington doesn’t value women’s health care enough.” Seattle Times, November 1, 2015: http://www.seattletimes.com/opinion/washington-doesnt-value-womens-health-care-enough/.

Doheny, Kathleen. “8 Miscarriage Facts Every Woman Should Know.” Everyday Health, February 22, 2016: http://www.everydayhealth.com/pregnancy/miscarriage-facts-every-woman-should-know/.

Schneider, Mary Ellen. “Expert roundtable explores 50 years of contraception.” Ob.Gyn. News, July 6, 2016. http://www.obgynnews.com/news/conference-news/american-college-of-obstetricians-and-gynecologists/single-view/video-expert-roundtable-explores-50-years-of-contraception/a954f7920a426736b46f1f207324adb6.html.

Nogrady, Bianca. “Progress and set backs in injectable male contraceptive.” OB.GYN.News, December 2016. Vol. 51, No. 12. http://www.mdedge.com/obgynnews/article/116520/reproductive-endocrinology/injectable-male-contraceptive-par-other

Hannah Myrick. “Birth Control Resources On and Around Campus.” University of Washington Daily. January 18, 2017. http://www.dailyuw.com/wellness/article_151b7fde-ddfb-11e6-a24a-6fc508ad07a0.html

Last Updated: 2/14/2023

Hannah Myrick. “UW Family Planning Division unites the community”. University of Washington Daily. Feb. 9, 2017.
http://www.dailyuw.com/special_sections/article_30270ada-ee6a-11e6-9cf3-875f739ddc3e.html

Thomson-DeVeaux, Amelia. “Some States Are Making it Easier To Get Birth Control.” FiveThirtyEight, April 24, 2017
https://fivethirtyeight.com/features/some-states-are-making-it-easier-to-get-birth-control/?ex_cid=538email

Prager, Sarah and Espey, Eve. “Contraception coverage rollback is discriminatory.” OB.GYN. News, October 12, 2017
http://www.mdedge.com/obgynnews/article/149146/contraception/contraception-coverage-rollback-discriminatory

Prager, Sarah and Micks, Elizabeth. "Birth-control rules: Poor women are target", Seattle Times, October 14, 2017
https://www.seattletimes.com/opinion/letters-to-the-editor/birth-control-rules-poor-women-are-target/?utm_source=email&utm_medium=email&utm_campaign=article_left_1.1

Kaci Aitchison. “Ask the Expert: Conversations about women’s health care” Q13 News, October 19, 2017
http://q13fox.com/2017/10/03/have-questions-for-our-experts/

Kristen Domonell. “Birth Control Pills Raise Breast Cancer Slightly, But Don’t Panic” Right as Rain by UW Medicine, January 16, 2018
https://rightasrain.uwmedicine.org/well/research/birth-control-pills-raise-breast-cancer-risk-slightly-dont-panic

Emilia Benton. “This Is Exactly How Effective Your Morning-After Pill Is, According to Doctors” Popsugar Fitness, February 7, 2018
https://www.popsugar.com/fitness/What-Does-Plan-B-Pill-Do-44476014

Caroline Kee. “Why Misoprostol Is So Much More Than A Pill Used For Medical Abortions” Buzzfeed, June, 28, 2018
https://www.buzzfeed.com/carolinekee/heres-how-misoprostol-works-miscarraige?utm_term=.qvVy34mr4#.bxzd3QjwQ

Kimelman, Judy and Prager, Sarah. “Don’t allow cuts to women’s health services.” Seattle Times, July 27, 2018
https://www.seattletimes.com/opinion/dont-allow-cuts-to-womens-health-services/

Stinchcombe, Colleen. “Can Traveling Really Make Your Period Late?” Self, August, 10, 2018
https://www.self.com/story/traveling-late-period

Julie Rosing. “Papa Don’t Preach” Lady Parts Justice Podcast, August 18, 2018. (Prager interview starts at 37:45) https://ladypartsjustice.com/episode-18-papa-dont-preach/

Last Updated: 2/14/2023

Brut. “Abortion Provider talks Kavanaugh nom”, September 5, 2018. https://www.facebook.com/brutamerica/videos/vb.1691667177798461/705560599796671/?type=2&theater

Anna Medaris Miller. “Missed Miscarriage: A Missing Conversation” U.S.News & World Report, October 9, 2018. https://health.usnews.com/health-care/patient-advice/articles/2018-10-09/missed-miscarriage-a-missing-conversation

Anna Medaris Miller. “Miscarriage: When Language Deepens Pain” U.S. News & World Report, Dec. 13, 2018. https://health.usnews.com/health-care/patient-advice/articles/2018-12-13/miscarriage-when-language-deepens-pain

Angela Kabotje. “What You Should Know About Exercising After Having a Baby”. Right as Rain, by UW Medicine. March 25, 2019. https://rightasrain.uwmedicine.org/life/parenthood/exercise-after-baby

Jyoti Madhusodanan. “How to Recognize Miscarriage Symptoms and Cope With the Aftermath”. New York Times Parenting. May 8, 2019. https://parenting.nytimes.com/pregnancy/miscarriage

Sharon Worcester. “ Managing 2nd Trimester Loss: Shared Decision Making, Honoring Patient Preference”. OBGYN News. May 8, 2019. https://www.mdedge.com/obgyn/article/200535/obstetrics/managing-2nd-trimester-loss-shared-decision-making-honor-patient

Anna Medaris Miller. “‘A vanishingly small number’ of women have abortions in the third trimester. Here’s why most of them do it.”. Insider. May 23, 2019 https://www.insider.com/what-is-a-late-term-abortion-why-women-have-them-2019-5

David Crary and Carla K Johnson. “Overturning Roe V. Wade wouldn’t turn back the clock to 1973”. Associated Press. May 27, 2019 https://www.adirondackdailyenterprise.com/news/local-news/2019/05/overturning-roe-v-wade-wouldnt-turn-back-the-clock-to-1973/

Brangien Davis. “At SIFF, a day in the life of doctors who provide abortion”. Crosscut. May 28, 2019 https://crosscut.com/2019/05/siff-day-life-doctors-who-provide-abortions

Jenny Morber. “Why don’t more women talk about pregnancy headaches?”. InStyle. May 29, 2019 https://www.instyle.com/beauty/health-fitness/pregnancy-headaches

Annie Kuo. “Film Review: Our Bodies Our Doctors”. UW Medicine Huddle. May 29, 2019 https://huddle.uwmedicine.org/news/film-review-our-bodies-our-doctors?mkt_tok=eyJpIjoiTkRSbU9EVXpPRGRqTmpJeCIsInQiOiJjK011dWRrVVY1cXdpUGNyY1RISmF4UHFiSk93MFlaU3JKR2NYTHpyNmhTaE5CQWo4Y29ZMTlvYzRndWZKYVlwMGkzYjI1UU1IWGVCcHExdXNyUFpsc3I0Y3A0V3BGaWJENFdkcDV6QVF1TmVGYlIEMlNxQlYxWjVUeG1kamJHcSJ9

Last Updated: 2/14/2023

Jan Haaken. “Our Bodies Our Doctors.” Documentary film released 2019. https://www.youtube.com/watch?v=LvexHlJTlOE

KING5. “Take 5”. June 28, 2019 https://www.iqmediacorp.com/ClipPlayer/?ClipID=79161fbc-732a-4246-8c6f-de5454786524

Jennifer Block.”Not Your Grandmother’s Abortion: exerpt from Everything Below the Waist: Why Healthcare Needs a Feminist Revolution.” The Cut, New York Magazine. July 1, 2019 https://www.thecut.com/2019/07/excerpt-from-everything-below-the-waist.html

Katie Herzog. “The Mountain Climber Who Became an Abortion Provider”. The Stranger. July 31, 2019. https://www.thestranger.com/features/2019/07/31/40900670/the-mountain-climber-who-became-an-abortion-provider

Sharon Worcester. “Early pregnancy loss and abortion: Medical management is safe, effective”. OBGYN News. August 6, 2019. https://www.mdedge.com/obgyn/article/205944/obstetrics/early-pregnancy-loss-and-abortion-medical-management-safe-effective?utm_source=Clin_MDEOBGYN_obstetrics_090719_F&utm_medium=email&utm_content=Medical%20management%20of%20early%20pregnancy%20loss%20|%20Tranexamic%20acid%20for%20PPH

Katherine Brooks. “Improving Global Health for Women”. The Huddle. August 21, 2020. https://huddle.uwmedicine.org/people/employee-stories/sarah-prager-improving-global-health-women.

Heidi Splete. “Fertility Delay Varied by Contraceptive Method in Study”. Medscape Medical News. November 13, 2020. https://www.medscape.com/viewarticle/940972.

Will Pass. “Maternal Caffeine Consumption, Even Small Amounts, May Reduce Neonatal Size”. Medscape Medical News. March 29, 2021. https://www.medscape.com/viewarticle/948303

David Martin Davies. “Dare to Listen: Texas’ Abortion Law and the Future of Reproductive Rights”. Texas Public Radio. September 22, 2021. https://www.facebook.com/events/374825954249716

McKenna Princing. “Is it safe to Stop Your Period With Birth Control?”. Right as Rain by UW Medicine. October 4, 2021. https://rightasrain.uwmedicine.org/well/health/menstrual-suppression.

Dennis Thompson. “Abortion Remains Medically Safe for U.S. Women”. HealthDay News. November 24, 2021. https://consumer.healthday.com/11-22-experts-lay-out-the-science-behind-access-to-abortion-2655538532.html

Last Updated: 2/14/2023

Ciara McCarthy. “Texas law restricting access to abortion pills takes effect as 6-week ban remains”. Fort Worth Star-Telegram. December 2, 2021.
https://www.star-telegram.com/news/local/crossroads-lab/article256253537.html

Megan Burbank. “Abortion Pills Aren’t a Silver Bullet”. The New Republic. December 31, 2021.
https://newrepublic.com/article/164904/abortion-pills-roe-v-wade

Heidi Splete. “Increased access to LARC may improve birth outcomes”. January 12, 2022.
https://www.mdedge.com/obgyn/article/250690/contraception/increased-access-larc-may-improve-birth-outcomes

Heidi Splete. “IUDs Tie Tubal Ligation for Pregnancy Prevention”. February 23, 2022. Medscape Medical News. https://www.medscape.com/viewarticle/969027?src=

Ciara McCarthy. “More Texans are requesting abortion pills online after six-week ban, reserach finds”. Fort Worth Star-Telegram. February 25, 2022.
https://www.star-telegram.com/news/local/crossroads-lab/article258745563.html

Megan Burbank. “WA abortion clinics are preparing for Roe v. Wade to be overturned”. Crosscut. February 22, 2022.
https://crosscut.com/news/2022/02/wa-abortion-clinics-are-preparing-roe-v-wade-be-overturned

CREOGs Over Coffee. “Postpartum IUD Placement with Dr. Sarah Prager”. April 3, 2022.
https://creogsovercoffee.com/notes/2022/4/3/postpartum-iud-placement-with-dr-sarah-prager

Kaitlin Sullivan. “‘Heartbeat Bills:’ Is there a so-called fetal heartbeat at six weeks of pregnancy?”. NBC News. April 17, 2022.
https://www.nbcnews.com/health/womens-health/heartbeat-bills-called-fetal-heartbeat-six-weeks-pregnancy-rcna24435

Ciara McCarthy. “What happens if Roe v. Wade is overturned? Why Texas is a bellwether for the nation”. Fort Worth Star-Telegram. May 3, 2022.
https://www.star-telegram.com/news/local/crossroads-lab/article261019502.html

Evening Debrief. Newsy. May 3, 2022.
https://video.snapstream.net/Play/4bccqGU9oFjPS9iBXuC848?accessToken=cx1z5qmhafxoz

Angela Cabotaje. “Why Abortion Is Healthcare, Explained”. Seattle Met. May 9, 2022.
https://www.seattlemet.com/health-and-wellness/2022/05/abortion-is-healthcare-womens-health-seattle-doctor-obgyn

Charlotte Huff. “In Texas, abortion laws inhibit care for miscarriages”. NPR News. May 10, 2022.
https://www.npr.org/sections/health-shots/2022/05/10/1097734167/in-texas-abortion-laws-inhibit-care-for-miscarriages

Dana G. Smith. “What is at risk if Roe v Wade is repealed in the US?”. New Scientist. May 11, 2022.

Last Updated: 2/14/2023

https://www.newscientist.com/article/mg25433863-900-what-is-at-risk-if-roe-v-wade-is-repealed-in-the-us/

Julia Craven. “Life After Roe: Don’t Trust DIY Abortion Advice on TikTok These are the risks involved.”. The Cut New York Magazine. May 23, 2022. https://www.thecut.com/article/diy-abortion-what-it-is-and-its-risks.html

Megan Burbank. “Abortion rights in WA fall into limbo at religious hospitals”. Crosscut. June 13, 2022. https://crosscut.com/news/2022/06/abortion-rights-wa-fall-limbo-religious-hospitals

Stacy Weiner. AAMC News. “How the repeal of Roe v. Wade will affect training in abortion and reproductive health”. June 24, 2022. https://www.aamc.org/news-insights/how-repeal-roe-v-wade-will-affect-training-abortion-and-reproductive-health

Franque Thompson. “UW doctors worry Roe v. Wade ruling could impact healthcare services”. Q13 News, June 24, 2022. https://www.q13fox.com/news/uw-doctors-worry-roe-v-wade-ruling-will-impact-healthcare-services.amp

Eric Boodman. “In a doctor’s suspicion after a miscarriage, a glimpse of expanding medical mistrust”. STAT News. June 29, 2022. https://www.statnews.com/2022/06/29/doctor-suspicion-after-miscarriage-glimpse-of-expanding-medical-mistrust/

Andrea Rice. “Roe v. Wade: The Mental and Physical health Effects of Anti-Abortion Laws”. Healthline. June 29, 2022. https://www.healthline.com/health-news/roe-v-wade-the-mental-and-physical-health-effects-of-anti-abortion-laws

Patrick Adams. “The Women Who Leave Anti-Abortion Picket Lines to Get Abortions”. The Daily Beast. July 3, 2022. https://www.thedailybeast.com/the-women-who-leave-anti-abortion-picket-lines-to-get-abortions?ref=scroll

Society of Family Planning Source for Science Podcast. “Clinician perspectives on self-managed abortion”. July 13, 2022. https://www.societyfp.org/about-sfp/podcast/#listen-on

Pam Belluck. “After New Abortion Laws, Some Patients Have Trouble Obtaining Miscarriage Treatment”. New York Times. July 17, 2022. https://www.nytimes.com/2022/07/17/health/abortion-miscarriage-treatment.html

Ari Cofer. “Debunking 6 Common Abortion Myths You Might Hear”. Right as Rain by UW Medicine. July 18, 2022. https://rightasrain.uwmedicine.org/well/health/6-abortion-myths

Elizabeth Cohen, Danielle Herman, John Bonifield. “In some states, doctors weight ‘ruinous’ litigation against proper care for women who have miscarriages”. CNN. July 20, 2022. https://www.cnn.com/2022/07/20/health/doctors-weigh-litigation-miscarriage-care/index.html

Last Updated: 2/14/2023

Adam Piore. “Doctors: ‘Chilling Effect’ of Abortion Laws Imperils Women’s Lives”. Newsweek. 7/21/22.
https://www.newsweek.com/doctors-chilling-effect-abortion-laws-imperils-womens-lives-1726503

Nina Shapiro “Can you reverse abortions? Some say yes; others call the treatment unethical, possibly dangerous”. Seattle Times. 8/15/2022.
https://www.seattletimes.com/seattle-news/can-you-reverse-abortions-some-say-yes-others-call-the-treatment-unethical-possibly-dangerous/

Caroline Shannon-Karasik and Sarah Jaffe. “What is a missed miscarriage? Experts explain”. Romper. October, 10/21/2022. https://www.romper.com/pregnancy/missed-miscarriage

Patrick Adams. “Many ERs offer minimal care for miscarriage. One group wants that to change”. NPR. Jan 4, 2023.
https://www.npr.org/sections/health-shots/2023/01/04/1146801914/many-ers-offer-minimal-care-for-miscarriage-one-group-wants-that-to-change

Libby Denkman and Alec Cowan. “In a post-Roe world, miscarriage treatment becomes more difficult”. KUOW. Jan 25, 2023.
https://kuow.org/stories/in-a-post-roe-world-miscarriage-treatment-becomes-more-difficult

Elise Takahama. “New UW program aims to expand training for abortion providers”. Seattle Times. February 13, 2023.
https://www.seattletimes.com/seattle-news/health/new-uw-program-aims-to-expand-training-for-abortion-providers/

INVITED LECTURES/PRESENTATIONS

UVM/Fletcher Allen Health Care: *"The History of Abortion”*
Burlington, VT, May 25, 2004

Women’s Health Elective: “Medical and Surgical Abortion”
San Francisco, CA, November 2, 2004

ACOG Annual Clinical Meeting: *“Prophylactic Antibiotics for Abortion”*
San Francisco, CA, May 11, 2005

UCSF/SFGH Faculty Seminar: *“The History of Abortion”*
San Francisco, California, August 24, 2005

South Bay Mid-Level Practitioner Continuing Medical Education
Sponsored by FEI Women’s Health: *“Intrauterine Contraception (IUC): A Liberal’s View”*
San Mateo, CA, September 22, 2005

Physicians for Reproductive Choice and Health: *Round table presentation regarding Proposition 73,* San Francisco, CA, September 29, 2005

CNM group: *"Contraceptive use in Women with Medical Conditions"*
San Francisco, CA, November 17, 2005

University of California, Berkeley; Tang Health Center: *"Introduction to the IUD for Primary Care Providers",* Berkeley, California, April 27, 2006

ACOG Annual Clinical Meeting: "Intrauterine Contraception in Nulliparous Women"
Washington, DC, May 9, 2006

Instituto Nacional de Salud Publica, Graduate Program in Reproductive Health
"Overview of Intrauterine Contraception", Cuernavaca, Mexico, May 24, 2006

Association of Reproductive Health Professionals (Co-Presented with Dr. Eleanor Drey)
"A New Look at Post Abortion IUD Insertion", La Jolla, CA, September 8, 2006

Medical Students for Choice/Law Students for Choice: *"Medical Perspectives on the Federal (Partial Birth) Abortion Ban",* Seattle, WA, November 7, 2006

STD Update Course: *"Contraceptive Update";* Seattle, WA, February 6, 2007

Workshop on Psychosocial Issues in Abortion Care: *"Emotional issues in doing and teaching abortion",* San Francisco, CA, February 18, 2007

Women's Healthcare Update: *"Contraceptive Implant Overview and Principles of IUD Insertion",*
Seattle, WA, March 2, 2007

Medical Students for Choice Annual Meeting: *"New Frontiers in Contraception"*
St. Petersburg, FL, March 24, 2007

Medical Students for Choice Annual Meeting: *"The Pro-Choice Medical Student's Guide to Applying for Residency",* St. Petersburg, FL, March 25, 2007

University of Washington School of Medicine-Ob/Gyn Faculty Development Workshop
"Contraception Update – New Methods and New Thoughts on Old Methods"
Seattle, WA, April 20, 2007

Family Planning Fellowship Annual Meeting: Promoting IUC Use in Clinical Practice
"Intrauterine Contraception in Adolescent and Nulliparous Women"
San Diego, CA, May 4, 2007

Family Planning Fellowship Annual Meeting: Promoting IUC Use in Clinical Practice
"Intrauterine Contraception: Patient Selection, Preparation and Follow-up"
San Diego, CA, May 4, 2007

SARAH PRAGER, M.D., M.A.S.

ACOG Annual Clinical Meeting: *"Non-Contraceptive Uses of the Levonorgestrel Intrauterine System",* San Diego, CA, May 7, 2007

ACOG Annual Clinical Meeting: *"What Really Is the Deal with Infection and Medical Abortion?",* San Diego, CA, May 8, 2007

Washington State Association of Abortion Providers: *"Misoprostol: a Review of the Literature",* Seattle, WA, May 17, 2007

Public Health Seattle and King County: Sexually Transmitted Disease Conference *"Contraception Update",* Seattle, WA, May 22, 2007

University of Washington Cardiac Care Clinic: *"Contraception for the Cardiac Patient"* Seattle, WA, May 24, 2007

University of Vermont/Fletcher Allen Health Care, Department of Obstetrics and Gynecology Grand Rounds: *"This is not your mother's IUD: an update on intrauterine contraception",* Burlington, VT, September 4, 2007

University of Washington School of Medicine
35th Annual Advances in Family Practice and Primary Care
"Treatment Options for First Trimester Loss", Seattle, WA, September 11, 2007

University of Washington School of Medicine, Department of Obstetrics and Gynecology Grand Rounds: *"This is not your mother's IUD: an update on intrauterine contraception",* Seattle, WA, September 19, 2007

National Abortion Federation Risk Management Seminar, Panel discussion on second trimester provision and training; Victoria, Canada, October 16, 2007

Washington State Academy of Physician Assistants (WAPA)
19th Annual Recertification Review Course Winter conference and AAPA Western Regional Meeting: IUD Insertion Workshop; Seattle, WA, January 29, 2008

19th Annual Recertification Review Course Winter conference and AAPA Western Regional Meeting: *"Contraceptive Review and Update",* Seattle, WA, January 29, 2008

David Geffen School of Medicine at the University of California, Los Angeles
Department of Obstetrics and Gynecology Grand Rounds: *"This is not your mother's IUD: an update on intrauterine contraception",* Los Angeles, CA, February 1, 2008
Washington State Academy of Physician Assistants (WAPA)

David Geffen School of Medicine at the University of California, Los Angeles
Department of Obstetrics and Gynecology Resident Didactics:
"Contraceptive Conundrums", Los Angeles, CA, February 1, 2008

Workshop on Psychosocial Issues in Abortion Care, Panel Discussion: Your Role as a Family Planning Specialist; San Francisco, CA, February 24, 2008

Last Updated: 2/14/2023

SARAH PRAGER, M.D., M.A.S.

University of Washington Department of Family Medicine Faculty Development
Values Clarification Workshop on Abortion; Seattle, WA, February 27, 2008

Women's Healthcare Update, University of Washington CME:
"What's New in Contraception", Seattle, WA, March 7, 2008

Swedish Family Medicine, Cherry Hill Campus, Department of Family Medicine Resident Didactics: Values Clarification Workshop on Abortion, Seattle, WA, March 11, 2008

Center for Health Training, 37th Annual Regional Reproductive Health (RH) 2008 Conference:
"This Is Not Your Mother's IUD: An Update on Intrauterine Contraception"
Bellevue, WA, March 19, 2008

Center for Health Training, 37th Annual Regional Reproductive Health (RH) 2008 Conference:
"Menstrual Irregularities and Abnormal Bleeding"
Bellevue, WA, March 21, 2008

University of Washington School of Pharmacy: *"Non-Oral Methods of Hormonal Contraception",* Seattle, WA, April 22, 2008

University of Washington School of Medicine, Department of Family Medicine Faculty Didactics: *"Medical Abortion: protocols, complications and management"; "Hands-on practicum: manual vacuum aspiration"; "Surgical Abortion Techniques, complications and management",* Seattle, WA, April 24, 2008

ACOG Annual Clinical Meeting: *"Non-Contraceptive Uses and Benefits of the Levonorgestrel Intrauterine System",* New Orleans, LA, May 6, 2008

University of Washington School of Medicine, Department of Family Medicine Faculty Didactics: *"Contraception Update"; "Ultrasound Techniques in Early Abortion"; "Options Counseling"; "How To Teach Abortion",* Seattle, WA, June 12, 2008

University of Washington School of Medicine, Department of Adolescent Medicine
"Contraceptive Update", Seattle, Washington, July 2, 2008

University of Washington School of Medicine, Department of Psychiatry
"Contraception for the Psychiatrist", Seattle, Washington, September 4, 2008

University of Washington School of Medicine, 36th Annual Advances in Family Practice and Primary Care: *"What's new in Contraception?",* Seattle, WA, September 11, 2008

Family Medicine Residency Network, Resident Training Initiative in Miscarriage Management (RTI-MM) Program: *"Management of Early Pregnancy Loss (EPL)",*
"Surgical Management of EPL", "Papaya Workshop", Seattle, WA, September 29, 2008

Washington State Obstetrics Association Annual Meeting
"This Is Not Your Mother's IUD", Seattle, WA, December 6, 2008

Last Updated: 2/14/2023

Washington State Academy of Physician Assistants (WAPA)
20th Annual Recertification Review Course and Winter conference
"Contraceptive Review and Update". Seattle, WA, January 27, 2009

Group Health Cooperative CME, Obstetrics and Gynecology for Primary Care
"IUD Updates", "Miscarriage Management", Seattle, WA, February 27, 2009

University of Washington, Hall Health Student Health Center
"What's New in Contraception", Seattle, WA, March 10, 2009

Swedish Family Medicine, Cherry Hill Campus, Department of Family Medicine Resident Didactics: Values Clarification Workshop on Abortion, Seattle, WA, March 10, 2009

Group Health Cooperative Faculty Didactic: *"First Trimester Abortion Care"*
Seattle, WA, March 10, 2009

Women's Healthcare Update, University of Washington CME
"Contraception for Menstrual Suppression: New Applications of an Old Idea"
Seattle, WA, March 20, 2009

Workshop on Psychosocial Issues in Abortion Care, Panel Discussion: Promoting Psychosocial Wellbeing, San Francisco, CA, April 4, 2009

Yakima Valley Memorial Hospital, Department of Obstetrics and Gynecology
"What's New in Contraception", Yakima, WA, April 24, 2009

ACOG Annual Clinical Meeting: *"Why Go To the OR? Outpatient management of Early Pregnancy Failure",* Chicago, IL, May 4, 2009

Diabetes in Pregnancy Study Group West Annual Meeting
"The Effects of Patch versus Oral Contraception on Lipoproteins and Coagulation Factors: a Randomized Crossover Study", Seattle, WA, May 16, 2009

Washington State Association of Abortion Providers: *"Medical Abortion Update"*
Seattle, WA, May 20, 2009

University of Utah, Department of Obstetrics and Gynecology Grand Rounds
"Do Nothing, Do Something, Do Surgery: Management of Early Pregnancy Loss"
Salt Lake City, UT, August 20, 2009

Southwest Washington Hospital Center, Department of Obstetrics and Gynecology Grand Rounds: *"Do Nothing, Do Something, Do Surgery: Management of Early Pregnancy Loss",*
Vancouver, WA, September 9, 2009

Washington Hospital Center, Department of Obstetrics and Gynecology Grand Rounds
"Do Nothing, Do Something, Do Surgery: Management of Early Pregnancy Loss"
Washington, D.C., September 17, 2009

Last Updated: 2/14/2023

SARAH PRAGER, M.D., M.A.S.

University of California, Irvine Department of Obstetrics and Gynecology Grand Rounds
"Medical Abortion: Surgery Is Not the Only Option", Irvine, CA, October 2, 2009

University of Washington/Harborview Hospital, Department of Emergency Medicine Copass Rounds: *"Vaginal bleeding, pregnancy and other ob/gyn issues in the Emergency Room",* Seattle, WA, October 13, 2009

Leadership Workshop 2009, Fellowship in Family Planning: *"Advocating for Change while Balancing Professional and Personal Needs",* Chicago, IL, November 6, 2009

Washington Academy of Family Physicians, 60th Annual Scientific Assembly
"Do Nothing, Do Something, Do Surgery: Management of Early Pregnancy Loss"
"Papaya Workshop – learning uterine aspiration with a manual vacuum aspirator on a papaya model", Cle Elum, WA, November 15, 2009

University of Washington Medical Center/Harborview Medical Center
Sexually Transmitted Disease Program: *"Continuous Contraception and Contraception Update",* Seattle, WA, December 29, 2009

University of Washington Law School, Disability Law Alliance Panel Discussion
"Selective Abortion on the basis of Disability", Seattle, WA, March 2, 2010

Women's Healthcare Update, University of Washington CME
"Contraception for the Medically Complex Patient", Seattle, WA, March 26, 2010

Center for Health Training, 39th Annual Regional Reproductive Health (RH) 2010 Conference:
"Forget about it! Long-Acting Reversible Contraception (LARC)"
Bellevue, WA, April 8, 2010

Society for Teachers of Family Medicine, Annual Spring Conference, 2010: *"Outpatient Miscarriage Management Should Be a Part of Every Resident's Medical Home"*
With Dr. J. Mark Beard and Dr. Nancy Stevens, Vancouver, BC Canada, April 26, 2010

Infectious Disease Society of Obstetrics and Gynecology (IDSOG) Annual Scientific Meeting:
"Contemporary IUDs and Infection Risk"
Santa Fe, NM, August 5, 2010

University of Washington School of Medicine, 38th Annual Advances in Family Practice and Primary Care: *"Contraception for the Medically Complex Patient"*
Seattle, WA, September 14, 2010

University of Washington School of Law: *"Federal Abortion Ban: Clinical Implications"*
Seattle, WA, October 19, 2010

Cedars-Sinai Medical Center Department of Obstetrics and Gynecology, Grand Rounds:
"Contemporary IUDs and Infection Risk", Los Angeles, CA, January 26, 2011

Last Updated: 2/14/2023

Women's Healthcare Update, University of Washington CME
"Contraception for the Medically Complex Patient", Seattle, WA, March 24, 2011

ACOG Annual Clinical Meeting: *"Why Wait? Immediate Post Partum IUD Insertion",* Washington D.C., May 3, 2011

Association of Reproductive Health Professionals Annual Meeting: "*Evidence-based First Trimester Abortion Care"*, Las Vegas, NV, September 15, 2011

Association of Reproductive Health Professionals Annual Meeting: "*Report on the Resident Training Initiative in Miscarriage Management (RTI-MM): Systems Based Change on Clinic-Based Provision of Miscarriage Management"*, Las Vegas, NV, September 16, 2011

Seattle Gynecological Society Fall Assembly: *"What's New in Contraception"*, Seattle, WA, October 1, 2011

North American Forum on Family Planning: "*Around the World in 80 Days: Lessons learned in postpartum IUD trainings in the developing world"*, Washington, DC, October 24, 2011

North American Forum on Family Planning: "*Ensuring Broader Exposure to Uterine Evacuation Techniques"*, Washington, DC, October 24, 2011

Washington State Association of Abortion Providers: "*Evidence-based use of Long Acting Reversible Contraception (LARC)"*, Seattle, WA, November 9, 2011

Washington State Academy of Physician Assistants (WAPA)
23th Annual Recertification Review Course and Winter conference
"Do Nothing, Do Something, Do Surgery: An Overview of Miscarriage Management". Seattle, WA, January 30, 2012

University of Nevada, Las Vegas: Grand Rounds and simulation courses
"*Manual Vacuum Aspiration", "Interval and Immediate Post Partum IUD insertion", "Diaphragm Fitting"*. Las Vegas, Nevada, February 2, 2012

Center for Health Training, 41st Annual Regional Reproductive Health (RH) 2010 Conference: *"Case Management: Contraceptives for Women with Chronic Conditions",* presented with Dr. Deborah Oyer, Portland, OR, March 21, 2012

Women's Healthcare Update, University of Washington CME
"What's New in Contraception and Family Planning", Seattle, WA, March 22, 2012

ACOG Annual Clinical Meeting: *"Surgical Miscarriage Management in the Office Setting",* San Diego, CA, May 8, 2012

ACOG Annual Clinical Meeting: *"Medical management of spontaneous and elective abortion",* San Diego, CA, May 8, 2012

NeighborCare Grand Rounds: "*Early Pregnancy Loss and Manual Vacuum Evacuation*", Seattle, WA, August 15, 2012

STI Conference: "*What's New in Contraception*", Boise, ID, September, 12, 2012

University of Washington Grand Rounds: "*Medical Abortion: everything you ever wanted to know but were afraid to ask*", Seattle, WA, October 3, 2012.

International Federation of Obstetrics and Gynecology (FIGO), "*Expanding MVA training and competence in rural areas*" (panel discussion), Rome, Italy, October, 9, 2012.

International Federation of Obstetrics and Gynecology (FIGO), "*Around the world in 80 days: immediate postpartum IUD insertion*" (panel discussion), Rome, Italy, October, 10, 2012.

Washington State Academy of Physician Assistants (WAPA)
24th Annual Recertification Review Course and Winter conference
"Do Something, Do Nothing, Do Surgery: An Overview of Miscarriage Management". Seattle, WA, January 28, 2013

STI Conference: "*What's New in Contraception*", Seattle, WA, January, 1, 2013

Current Concepts in Drug Therapy: "*Case Management: Contraceptives for Women with Chronic Conditions*", Seattle, WA, March 7, 2013

Women's Health Care Update: "*Case Management: Contraceptives for Women with Chronic Conditions*", Seattle, WA, March 29, 2013

ACOG Annual Clinical Meeting: *"Medical management of spontaneous and elective abortion",* New Orleans, LA, May 7, 2013

University of Hawaii Grand Rounds, "*Post Partum IUD insertions: a viable option*", Honolulu, HI, June 26, 2013

Fellowship in Family Planning Global Health Placements Workshop, "*Making Global Health Relevant Domestically*", October, 2013

University of Vermont Department of OBGYN Grand Rounds, *"Contraception for the medically complex patient"*, Burlington, VT, October, 22, 2013

STI Conference: "*Contraception Update*", Seattle, WA, January, 29, 2014

Fellowship in Family Planning Annual Meeting: "*Controversies in Family Planning Panel Discussion*", Chicago, IL, April 25, 2014

ACOG Annual Clinical Meeting: *"Medical management of spontaneous and elective abortion",* Chicago, IL, April 28, 2014

Last Updated: 2/14/2023

SARAH PRAGER, M.D., M.A.S.

Women's Health Care Update: "*Medical Management Early Pregnancy Loss*", Seattle, WA, March 27, 2015

Madigan Department of OBGYN Grand Rounds, "*Medication management of spontaneous and elective abortion"*, Lakewood, WA, April 1, 2015

ACOG Annual Clinical Meeting: *"Medical management of spontaneous and elective abortion",* San Francisco, CA, May 3, 2015

Peace Health Hospital Grand Rounds: *"Do Nothing, Do Something, Do Surgery: Management of Early Pregnancy Loss"*, Bellingham, WA, May 13, 2015

Brown University Department of OBGYN Grant Rounds, "*Postpartum IUD insertions: a viable option*", Providence, RI, August 3, 2015.

Yakima Regional Hospital OBGYN Grand Rounds, "*Postpartum IUD insertions: a viable option*", September 25, 2015

FIGO, *"Outpatient management of early pregnancy loss (EPL) including incomplete abortion"*, Vancouver, BC, Canada, October 8, 2015

Washington Women's Foundation Discovery Days, *"Family Planning Impacts on Maternal and Child Health"*, Seattle, Washington, November 10, 2015

North American Forum of Family Planning, "Digital Learning for Early Pregnancy Loss Management", Chicago, IL, November 14, 2015

ACOG Annual Clinical Meeting: *"Medical management of spontaneous and elective abortion",* San Francisco, CA, May 17, 2016

ACOG Annual District Meeting, District XIII and XI: *"Rethinking the Well-Woman Exam"* Kona, Hawaii, September 24, 2016

ACOG Annual District Meeting, District XIII and XI: *"Opportunistic Salpingectomy versus Bilateral Tubal Ligation".* Kona, Hawaii, September 23, 2016

University of Texas, Southwestern, Department of OBGYN Grand Rounds: *"Contraception for the Medically Complicated Patient"*. Dallas, TX, October12, 2016

Washington State Obstetrics Association Annual Meeting: "*Everything You'd Ever Want to Know about Immediate Postpartum LARC Insertion"*. Seattle, WA, December 1, 2016

Women's Health Care Update: "*Medical Abortion: An Effective, Non-Invasive Option*", Seattle, WA, March 24, 2017

ACOG Annual Clinical Meeting: *"Medical management of spontaneous and elective abortion",* San Diego, CA, May 8, 2017

Last Updated: 2/14/2023

SARAH PRAGER, M.D., M.A.S.

ACOG Annual District Meeting, District II: *"Management of Early Pregnancy Loss"*, Bermuda, October 6, 2017

National Abortion Federation Annual Meeting: *"Establishing Trans Health Services Workshop"*, Seattle, WA, April 21, 2018

National Abortion Federation Annual Meeting: *"The Future of Compassionate Abortion Care: Teaching Word Choice"*, Seattle, WA, April 23, 2018

National Abortion Federation Annual Meeting: *"The Human Right to Abortion: What it Means, and Why It Matters"*, Seattle, WA, April 23, 2018

ACOG Annual Clinical and Scientific Meeting: *"Medical management of spontaneous and elective abortion",* Austin, TX, April 27, 2018

ACOG Annual Clinical and Scientific Meeting: *"Family Planning Update for the Comprehensive OB-GYN",* Austin, TX, April 27, 2018

University of British Columbia: *"Professionalism and Conscientious Objection in Obstetrics and Gynecology"*; Vancouver, BC, Canada, July 20, 2018

FIGO: "*Abortion Technology Workshop",* Rio de Janeiro, Brazil, October 14, 2018

FIGO: "*Second Trimester Abortion*", Rio de Janeiro, Brazil, October 18, 2018

North American Forum on Family Planning: "*Yes We Can! Interdisciplinary management of early pregnancy loss in the emergency department*", New Orleans, LA, October, 21, 2018

Ethiopian Society of Obstetricians and Gynecologists Annual Meeting: *"Updates on the Management of Contraception for Women with Medical Conditions"*, Addis Ababa, Ethiopia, February 4, 2019

Women's Healthcare Update: "*Making Sense of Complex Contraception"*, Seattle, WA, March 28, 2019

ACOG Annual Clinical and Scientific Meeting: "*Evidence-based management of second trimester fetal loss"*, Nashville, TN, May 4, 2019

ACOG Annual Clinical and Scientific Meeting: *"Medical management of spontaneous and elective abortion",* Nashville, TN, May 5, 2019

Saint Paul's Hospital Millennium Medical College Center of Excellence in Reproductive Health: 1st National Symposium on Reproductive Health. "*Evidence-Based Medical Management of Abortion in the Second Trimester: A Protocol for St. Paul and Ethiopia*". Addis Ababa, Ethiopia, November 1, 2019

Ethiopian Society of Obstetricians and Gynecologists (ESOG) Annual Meeting 2020: *"Male Contraceptives: Current and Future Approaches"*, Addis Ababa, Ethiopia, February 15, 2020.

Last Updated: 2/14/2023

SARAH PRAGER, M.D., M.A.S.

Ethiopian Society of Obstetricians and Gynecologists (ESOG) Annual Meeting 2020: *"Second Trimester Abortion Care: Current Status and Approaches"*, Addis Ababa, Ethiopia, February 16, 2020.

Ethiopian Society of Obstetricians and Gynecologists (ESOG) Annual Meeting: Plenary Session: *"Emerging Issues in Sexual and Reproductive Health and Rights (SRHR): Opportunities and Challenges"*, Addis Ababa, Ethiopia, February 17, 2020.

National Remote OBGYN Resident Didactics: *"Medication management of abortion and pregnancy loss"*. 5/19/2020.
https://obgyn.ucsf.edu/residency-program/national-curriculum.

Contraceptive Technology: *"Management of first trimester abortion and early pregnancy loss"*. 9/23/2020.

Contraceptive Technology: *"Medication management of abortion and pregnancy loss"*. 9/25/2020.

Society of Family Planning: *"Early Pregnancy Assessment Clinics: let's standardize algorithms, combine with family planning, and overcome disparities"*. 10/10/2020.

ASRM: *"A Team Approach to Providing Early Pregnancy Loss Care in the Emergency Department and Outpatient Settings"*. 10/17/2020

St. Paul's Institute for Reproductive Health Research, Second Annual Conference: *"Provision of abortion and family planning services amid COVID-19: challenges and mitigations"*. 11/14/2020.

ASRM Live Zoom Q&A: *"A Team Approach to Providing Early Pregnancy Loss Care in the Emergency Department and Outpatient Settings"*. 12/05/2020

Ethiopian Society of Obstetricians and Gynecologists (ESOG) Annual Meeting 2021: *"Update on Hormonal Contraception"*, Addis Ababa, Ethiopia, February 15, 2021.

Ethiopian Society of Obstetricians and Gynecologists (ESOG) Annual Meeting 2021: *"Updates on Second Trimester Surgical Abortion Care"*, Addis Ababa, Ethiopia, February 15, 2021.

MedStar Washington Hospital Center/MedStar Georgetown University Hospital Virtual Grand Rounds: "*Abortion and Abortion Training in Ethiopia*", Washington, D.C., March 11, 2021.

University of Washington Medical School Educational Series: *"Let's talk About: Reproductive Health and Rights"*, Seattle, WA, March 31, 2021.

John Gibbons, Jr., MD, Medical Student Lecture: *OB-GYN as a Career*. ACOG Annual Clinical Meeting. April 23, 2021. Virtual meeting.

University of Kansas Medical Center Grand Rounds: *Medication Management of Pregnancy Loss in the First and Second Trimester.* April 30, 2021. Virtual presentation.

Last Updated: 2/14/2023

Making the Connection: Engaging, Empowering, and Sustaining State Advocacy Leaders. May 17, 2021. ACOG Virtual Presentation.

Rutgers Grand Rounds: *Early Pregnancy Loss Management in the Emergency Department.* July 9, 2021. Virtual Presentation.

UT Austin Grand Rounds: *Early Pregnancy Loss Management in the Emergency Department*. October 21, 2021. Virtual presentation.

University of Washington Grand Rounds: *Medication Management of Abortion and Pregnancy Loss.* March 2, 2022. Virtual presentation

The Center for International Reproductive Health Training (CIRHT) -Kigali Conference: *Establishing a family planning fellowship in the Sub-Saharan Region (or Africa) - the experience of Ethiopia*. Kigali, Rwanda. October 7, 2022.

Annual Deisher Provider Grant Rounds for Seattle Children's Hospital: "*Family Planning for Pediatricians: Practice, Pitfalls, and Allyship*". Seattle, Washington. October 20, 2022.

Society of Family Planning Annual Conference. "Late Breaking News: Mifepristone REMS and Legal Strategy to Protect Mifepristone. Moderator and speaker for Panel Presentation. Baltimore, MD. December 4, 2022.

2023 Washington State of Reform Health Policy Conference. "Reproductive health policies & protections. Panel presentation with Dr. Meghan Eagen-Torkko, ARNP and Leah Rutman, JD. Seattle, WA. January 5, 2023.

31st Annual Conference of Ethiopian Society of Obstetricians and Gynecologists (ESOG). "What's NEXT in contraception?". Addis Ababa, Ethiopia. February 11, 2023.

Exhibit 16

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF BRIAN REED

I, Brian Reed, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am the Administrator of Women's and Children's Services at the University of Washington (UW). In this role, I oversee strategy, planning, and operations for the provision of women's and children's services across four UW hospital sites located in the greater Seattle area.

3. For the past four months, I have been participating in a work group at UW that is implementing the amended requirements for the FDA's mifepristone risk evaluation and mitigation strategy (REMS). This includes the requirement that mifepristone be dispensed by or under the supervision of a certified prescriber or by certified pharmacies for prescriptions issued by certified prescribers. It also requires the use of Prescriber (or Provider) and Patient Agreement forms. While mifepristone has been subject to a REMS for years, the latest updated requirements went into effect on January 3, 2023.

4. My work on the project for building telehealth medication abortion services at UW began last summer. Initially, we considered working with third-party providers to mail mifepristone, but decided instead to set up this process in house.

5. Once we decided to set up an in-house process to mail mifepristone, we turned to implementation. It has not been an easy process, particularly because

ensuring compliance with the REMS has involved developing new technical processes not required for other drugs.

6. Ordinarily, to make an FDA-approved drug available for prescription by UW providers, we would simply add the drug into a system called Epic, with no further steps required. For mifepristone, however, because of the REMS, we have had to create new systems and work-flows to ensure remote signature of the required forms by patients and prescribers, as well as additional pharmacy-related work-flows to ensure UW's pharmacies can meet their verification requirements.

7. This work would not exist without the REMS and has created an additional burden on both providers and staff involved in implementation. There may be long-term effects of the new REMS program for in-person visits pending further clarification of the REMS requirement for in-person dispensing. The work REMS has created has delayed telehealth access to medication abortions by over two months for patients seeking this care from UW.

The REMS Impose Onerous Requirements on Providers and Raise Safety Concerns

8. UW has hundreds of providers who are eligible to provide telehealth services, but not all of them are able to prescribe mifepristone, in part, due to the REMS restrictions. To comply with the mifepristone REMS, I am currently working to determine which UW prescribers are interested in prescribing

mifepristone via telehealth. For those providers who are interested, I must then ensure that they sign a Prescriber Agreement form and submit it to the UW mail order pharmacy as well as an internal secure database.

9. My work currently involves outreach to interested providers, but it will eventually include training on how to electronically complete the Prescriber Agreement form for telehealth visits and the additional steps required to submit the prescription to the UW mail order pharmacy.

10. UW is also in the process of creating a secure database (referenced above) with this information that would allow UW Medicine to check that the provider has submitted the form and is therefore eligible to write the prescription. Both UW Medicine and the UW mail order pharmacy will need to be able to access the database. With that said, I am aware that there is significant concern about us creating a database of our medication abortion providers due to safety concerns related to abortion.

11. UW is extremely careful in maintaining the safety of our organization and our providers, particularly in the reproductive healthcare space. For instance, we have had internal conversations on the pros and cons of allowing a patient to choose a specific provider for their medication abortion telehealth appointment, or instead only allowing a patient to request a telehealth medication abortion appointment at a particular location without selecting a provider. The latter better protects the identity of our providers who provide medication

abortion, but that is not our normal practice and it is technically more difficult to implement. We have also had to rethink how we design and build our women's health clinics and whether we should move clinics from the first to the second floor for safety.

The REMS Unnecessarily Impose Significant Burdens on Patients and Create Barriers to Access

12. In addition to the burdens on the providers, the REMS impose additional burdens on patients. UW has dedicated substantial resources to make the REMS-required Patient Agreement form available to telemedicine patients. REMS requires this form to be signed by both the patient and a certified prescriber before the provider has met their obligation under the Prescriber Agreement form and the prescription can be filled by the UW mail order pharmacy. While signing the form is a simple task to complete in person, it poses significant challenges in the telehealth setting. Previously, we did not have any system in place to obtain virtual signatures like this.

13. Our REMS implementation committee has dedicated significant efforts to this REMS component, including making the Patient Agreement form accessible to telemedicine patients in a HIPAA-compliant manner, designing a method to securely transmit the form to the patient for their signature and then securely re-route the form back to the provider for their signature, and ensuring

timely transmission of the form from the registered provider into the patient's medical record.

14. Additionally, there are significant equity and access issues with obtaining virtual signatures, as not everyone has access to a printer or scanner. To attempt to provide equal access, we will be using a form-fillable PDF to be delivered to the patient during or just after their telehealth abortion appointment. We had to develop a way to track the patient's signature so that the pharmacy knew it was completed before dispensing mifepristone. But this process only works if a person has reliable access to a computer or smartphone and a reliable Internet connection. This is an entirely new process for our providers and patients. We are still developing this process and the necessary training, and it is not fully operational yet.

15. There are also patient equity concerns regarding mail order prescriptions. For our initial rollout of telehealth abortion appointments, we are planning to require all telehealth patients to have mifepristone dispensed using UW's mail order pharmacy. This is due to administrative burdens created by the REMS. While mail order works well for many patients, we are aware that it is not a good option for individual in rural communities that only have a PO Box (which we cannot ship medications to). It likewise makes delivery of medication to people who are unhoused or unstably housed, or who do not have a permanent physical address a significant challenge.

16. All told, we have spent countless hours and many meetings so far to implement the REMS, with outstanding tasks remaining. I would estimate that there are probably 15 to 20-plus people working on the new electronic forms and processes, including UW medical providers, and administrators and staff from the medical and pharmacy sides.

17. I would estimate that I, personally, have spent approximately 45 hours working on mifepristone REMS implementation. Had I not been working on REMS implementation, I could have spent this time on other projects, such as implementing a new fetal surgery services and NICU cardiac service for newborns and babies in utero who have anatomical anomalies to provide them with the earlies possible intervention.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 17th day of February, 2023, at Seattle, WA.

Brian R Reed

Brian R Reed CTRS, MHA

Exhibit 17

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF SAMANTHA ROLLAND IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

I, Samantha Rolland, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am the Vital Records Epidemiology Supervisor with the Washington State Department of Health. I have held this position since December 2019.

3. The Department of Health tracks data related to abortions in Washington, including the number of abortions, the methods, and rates of complications. In my role as the Vital Records Epidemiology Supervisor, I supervise the collection of these data.

4. I have bachelor's and master's degrees in microbiology from Brigham Young University, a Ph.D. in microbiology and molecular genetics from the University of Vermont, and a Masters of Public Health from Johns Hopkins University.

5. Based on my review of the data DOH collects, I am aware that mifepristone is commonly used for medication abortions in Washington.

6. In 2021 there were 15,358 Washington resident abortions that occurred in Washington.[1] Of these, 9,060 (59.0%) were medication abortions

---

[1]DOH defines residency based on patient's reported state of residence, and an abortion as having occurred in Washington based on the facility's location where applicable. In cases of medication abortions where the medication is

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

involving the use of mifepristone. Of these 9,060 mifepristone abortions, 142 (1.6%) reported complications, with the two most commonly reported complications being retained products of conception (52.1%) and a failed abortion (45.1%). Fewer than 0.1% of mifepristone abortions in 2021 resulted in a complication severe enough to warrant hospitalization.

7. In 2020, there were 15,487 Washington resident abortions that occurred in Washington. Of these, 8,550 (55.2%) were medication abortions involving the use of mifepristone. Of these 8,550 mifepristone abortions, 175 (2.0%) reported complications, with the two most commonly reported complications being retained products of conception (58.3%) and a failed abortion (36.0%). Fewer than 0.1% of mifepristone abortions in 2020 resulted in a complication severe enough to warrant hospitalization.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 14th day of February 2023, at Olympia, Washington.

Sam Rolland

SAMANTHA ROLLAND
Vital Statistics Epidemiology Supervisor
Washington Department of Health

---

mail-ordered and there is no physical facility located in Washington, DOH uses the patient's state of residence as the abortion location.

Exhibit 18

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF GRACE SHIH, MD, MAS

I, Grace Shih, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am an Associate Professor in the Department of Family Medicine, with a clinical practice at the University of Washington (UW) Primary Care at Northgate where I practice family medicine and run the Reproductive Health clinic. I oversee training UW School of Medicine family medicine residents on reproductive care. I am also the Director of the Family Medicine Residency Network, a group of thirty-three family medicine residency programs at different university medical facilities and family medicine clinics throughout Washington, Wyoming, Alaska, Montana and Idaho.

3. I completed my medical degree at the University of Florida and my family medicine residency at Brown University. I completed my Family Planning Fellowship at the University of California, San Francisco. I am also board certified in family medicine. My CV is attached as Exhibit A. I have published research on comprehensive family planning including abortion care, particularly with regards to family medicine training and integration into primary care services[1]. *See* Exhibit A for the full list of my published research.

---

[1] Witt L.B., Wolff S., Shih G., French V., *Abortion and contraception in medical school curricula: a survey of North American family medicine clinical curriculum directors*, Teach Learn Med,13:1-9 (Jan. 2023); Verma N., Goyal V.,

4. I am submitting this declaration in support of the State of Washington's motion for a preliminary injunction.

My Patients & My Practice at UW

5. I treat patients in a family medicine practice at UW. As UW is a teaching institution, I also supervise and train medical residents and students.

6. My areas of clinical interest include family planning and contraception (intrauterine devices and implant contraception placement and

---

Grossman D., Peritt J., Shih G., *Society of Family Planning Interim Clinical Recommendations: Self-Managed Abortion*, Contraception (2022); Miles C., Weidner A., Summit A.K., Thomson C.J., Zhang Y., Cole A.M., Shih G., P*atient opinions on sexual and reproductive health services in primary care in rural and urban clinics*, Contraception 114:26-31 (Oct. 2022); Wallace R., Shih G., *Complex Family Planning - Demarginalizing abortion care requires uplifting primary care and non-CFP providers,* Contraception 105:86, (Jan. 2002); Thomson C.J., Zhang Y., Weidner A., Summit A.K., Miles C., Cole A.M., Shih G., *Patient Concerns about Accessing Sexual and Reproductive Health Services Outside of Primary Care: A Survey in Rural and Urban Settings in the Pacific Northwest*, Contraception 15:S0010-7824(22)00396-1 (Oct. 2022); Zhang Y., Sheth S., Weidner, A.K.H., Egwuatu, P., Webb, L., Shih G., *Immediate Postpartum IUD Training Within a Regional Network of Family Medicine Residencies*. PRiMER 1;5:24 (July 2021).

removal, medication and aspiration abortion, uterine aspiration for miscarriage management, and vasectomy), reproductive health (fertility counseling, colposcopy), gender affirming care, women's health, and adolescent medicine.

7. As part of my practice, I treat patients who are pregnant, including those facing unintended pregnancies.

8. When I treat such patients, I always begin the patient visit by establishing rapport and creating a safe environment for open and honest conversation. I ask patients open-ended questions to determine their desires for their pregnancy. I ensure that their decision is their own. I review the patient's medical history, symptoms, and estimate gestational age. When necessary, I perform a physical exam and/or obtain relevant imaging/labs. For patients desiring abortion, I counsel them on the kinds of abortion for which they are eligible. I then discuss with the patient the risks, benefits and alternatives for each kind of abortion care for which they are eligible and answer any questions they may have to ensure that they have the information they need to make an informed decision about their care. If they are eligible for, and choose, a medication abortion, we proceed with a more detailed conversation on medication abortion, including a discussion of the medications mifepristone and misoprostol, which are a part of a two-drug regimen to end early pregnancy.

9. In my counseling, I discuss the medication abortion process. I describe how mifepristone and misoprostol work, the timing on how to take the

medications, and the route to take the medications. I review the side effects and rare complications. I explain that medication abortion with mifepristone and misoprostol is highly effective. In the rare event it does not work, I let them know we can provide more medications and/or an aspiration procedure. I review reasons for which they should contact our office and/or speak with a provider. Because mifepristone is subject to certain Risk Evaluation and Mitigation Strategy (REMS) requirements, I also review the Patient Agreement Form with the patient as part of my counseling. After answering any questions, I ask whether they consent to a medication abortion, and if they do, I confirm that consent in their medical record. I then repeat the instructions for how and when to take their medication, walk them through the follow-up process, explain what they should do if they experience any of the (very rare) serious complications associated with mifepristone, and answer any questions they may have.

10. As UW is currently only dispensing mifepristone for medication abortion in person, I then provide the patient with the mifepristone. To comply with the Risk Evaluation and Mitigation Strategy (REMS) requirements associated with mifepristone, I then have the patient sign the Patient Agreement form, and I sign it as well. I give one copy of the form to the patient, along with the Medication Guide and medication, and I place the copy of the signed Patient Agreement form in the patient's record. I also record the NDC (National Drug Code) and lot number for the mifepristone in the patient's record.

11. I also give the patient my pager number and/or the clinic number and let them know that they should call us if they have any concerns. We rarely receive calls from patients regarding mifepristone, but if we do, they are generally questions related to pain management or bleeding.

12. Among the patients I have treated, I am not aware of any who have experienced a serious adverse reaction from mifepristone.

13. I also prescribe mifepristone, in combination with the drug misoprostol, to patients who are experiencing a miscarriage. Using this two-drug regimen to manage miscarriage has been the basic standard of care at UW since approximately 2019. The patients I treat for miscarriage are required to sign the same Patient Agreement Form as patients receiving mifepristone for a medication abortion.

14. Because the Patient Agreement Form covers topics that I already cover with the patient in my routine counseling, the form does not provide the patient with any information I would not otherwise provide them. Instead, it is an added burden for myself and my patients. As a provider, it adds one more checkbox on an already complex visit. At minimum, the form requires extra time for review. Because the form is generic, if there are special circumstances the patient and I have already discussed and differ from the form, this takes extra time for explanation. For example, the form states "I have decided to take mifepristone and misoprostol to end my pregnancy." This does not apply to

patients experiencing miscarriage and requires extra explanation and may be confusing and/or traumatic for them to read. There is also the administrative time to ensure up-to-date forms are being used and signed forms are properly saved. For the patient, this puts one more piece of paper in their file identifying them as having used mifepristone. I find this unnecessary paperwork concerning, given the heightened external risks for some patients seeking mifepristone for abortion care.

My Work Implementing the Mifepristone REMS

15. In addition to my regular duties, I have been participating in a workgroup at UW implementing the amended REMS on dispensing mifepristone, which took effect on January 3, 2023. Implementing the new REMS has required a great deal of time and effort from numerous stakeholders across the University.

16. I have been involved with UW's implementation of the REMS on the provider front. This has involved a lot of time and thought as to how best to implement the REMS in the telehealth space.

17. One of the major challenges the REMS has presented is the difficulty of obtaining a signed Patient Agreement Form in telehealth appointments. An enormous amount of effort has been spent determining the most secure way to provide the required Patient Agreement Form to the client in the telehealth setting in a way that will be accessible to most patients and allow

the form to be signed and securely transferred back to UW. Once signed forms are securely received by UW, the providers must then be notified so the mifepristone prescription process can be completed. The additional need to obtain a signed form transforms a telehealth visit from one in which a telehealth provider can complete a prescription during the visit to one in which a telehealth provider must be "on hold" until receipt of the signed form is confirmed and then the prescription may be completed. While some patients may be able to sign the form quickly, others may face barriers to internet access or other technology requirements, delaying their ability to complete the required documentation and subsequently delaying time-sensitive medical care. The FDA currently approves of mifepristone-misoprostol abortion up to 70 days gestation. The earliest most people are aware they are pregnant is at the time of missed period or ~30 days gestation. Once the decision has been made to pursue medication abortion, delaying the process even by a few days may make them ineligible to select medication abortion. In general, delays in abortion care incur higher risks for both medication and procedural abortion care.

18. Another obstacle associated with the REMS is the Prescriber Agreement Form. Specifically, we have to identify all UW providers who may want to prescribe mifepristone in the telehealth space and ensure that they complete a Prescriber Agreement form and transmit it to the UW Pharmacy (which is becoming a certified pharmacy pursuant to the REMS). This is a major

hurdle, as UW has hundreds of providers—including medical residents—who could potentially prescribe mifepristone in the telehealth setting. We are currently conducting outreach to let providers know that mifepristone for medication abortion and miscarriage management can now be prescribed in the telehealth setting and filled at UW pharmacies—but only if the provider has a Prescriber Agreement form on file with UW pharmacies. It is a significant logistical burden to identify *who* is interested in becoming a certified provider, connect with that provider to explain the process, and then follow up to ensure that they have found the time in their busy schedule to sign the provider form and transmit it to the UW pharmacy. I anticipate that this requirement will present an ongoing administrative burden as new residents and other providers join the UW.

19. I estimate that I have worked approximately 30 hours on this project to date, with additional work still to do, including training residents and other family medicine colleagues on how to use the newly-developed interfaces for the Patient Agreement Form, attending committee meetings, and coordinating with committee members regarding various REMS implementation tasks outside of those meetings.

The REMS Unnecessarily Impose Significant Burdens on Medical Providers' Abortion Care Practice

20. The January 2023 mifepristone REMS continue to discourage family medicine providers from prescribing mifepristone in their practice.

21. First, the simple fact that a REMS exists for mifepristone creates a major hurdle for getting family medicine doctors to prescribe the drug. Indeed, in my conversations with family medicine physicians, the mere existence of the mifepristone REMS creates a mistaken impression among family medicine doctors—who are generalists—that mifepristone is a dangerous medication. The REMS leads some providers to erroneously conclude that the drug is either more dangerous or more complicated to prescribe than it is, leading them to believe they are not qualified to prescribe it or that its use requires expertise beyond the scope of their practice. As a result, some family medicine doctors who provide pregnancy-related care and are otherwise qualified to prescribe mifepristone choose not to prescribe it.[2]

---

[2] In addition to my personal experience speaking to fellow providers, I am also aware of published studies concluding that the REMS give providers the mistaken impression that mifepristone is riskier than it is and appropriate only for specialists to provide. *See* Danielle Calloway, Debra B. Stulberg, and Elizabeth Janiak, *Mifepristone restrictions and primary care: Breaking the cycle of stigma through a learning collaborative model in the United States*, Contraception 104 (2021) 24-28; Sarah Neill, Alisa B. Goldberg, and Elizabeth Janiak, *Medication management of early pregnancy loss: the impact of the US Food and Drug Administration Risk Evaluation and Mitigation Strategy,* Obstetrics & Gynecology 139(1) (May 2022).

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

22. Second, the Prescriber Agreement Form required by the REMS poses additional barriers to getting more family medicine providers to prescribe mifepristone. Because Prescriber Agreement Forms are not typically required for the types of medications prescribed by family medicine doctors, there is often confusion as to why the form is required. For other family medicine doctors, the Prescriber Agreement Form is an administrative headache that generally requires a provider getting clinic buy in to prescribe a medication the provider is otherwise qualified to provide. If a provider has few patients for whom they anticipate prescribing mifepristone, the provider may simply determine that it is not worth the extra work to become certified.[3]

---

[3] Razon, N., Wulf, S., Perez, C., McNeil, S., Maldonado, L., Fields, A.B., Carvajal, D., Logan, R., Dehlendorf, C., *Exploring the impact of mifepristone's risk evaluation and mitigation strategy (REMS) on the integration of medication abortion into US family medicine primary care clinics*, Contraception 109:19-24 (May 2022); Lee, C.M., Johns, S.L., Stulberg, D.B., Allen, R.H., Janiak, E., *Barriers to abortion provision in primary care in New England, 2019-2020: A qualitative study*, Contraception 117:39-44 (Jan. 2023); Goodman, S., Shih, G., Hawkins, M., Feierabend, S., Lossy, P., Waxman, N.J., Gold, M., Dehlendorf, C., *A long-term evaluation of a required reproductive health training rotation with opt-out provisions for family medicine residents*, Fam. Med. 45(3):180-6 (Mar. 2013).

23. Other providers do not want to complete the Prescriber Agreement Form as they have concerns that by certifying that they are a qualified medication abortion provider, they could be exposing themselves to harassment or violence by anti-abortion activists or to potential prosecution by law enforcement in states where abortion is now illegal. This fear is particularly acute for physicians who may hold medical licenses in multiple states, including those that have abortion laws different from Washington. The fact that a provider has to send their Prescriber Agreement Form to ***every*** individual certified pharmacy to which it may send mifepristone prescriptions further compounds this fear.

24. I can personally attest that the fear of being publicly identified as an "abortionist" is real. My name, picture, medical licenses, and business address (along with a list of "abortion mill[s]") are listed on the website "AbortionDocs.org," which describes itself as "the largest collection of documents on America's Abortion Cartel." The website is a project of the anti-abortion organization Operation Rescue. A copy of the webpage containing my picture and professional information is attached as Exhibit B to my declaration. Having been publicly identified on this website in this way myself, I can certainly understand why medical providers fear having their identity made known to anti-abortion activists and being publicly identified as an "abortionist."

25. The Prescriber Agreement Form also presents a significant barrier to mifepristone use among resident physicians. At UW, we get residents from all

over the country—including states where medication abortion is illegal. For a resident to prescribe mifepristone via telehealth, they too have to complete a Prescriber Agreement Form. Signing such a form raises many of the same concerns for residents that it does for providers—e.g., confusion about its necessity and concerns regarding their safety and the potential legal implications if they plan to later practice in a state where abortion is illegal. Likewise, they may be concerned about future employment prospects given the proliferation of religiously-affiliated and specifically Catholic-run medical institutions, which as a general rule, are anti-abortion.

26. These REMS-related fears may negatively impact the education UW residents receive. In our family medicine residency training program, we train everyone in abortion care. But if the REMS leads residents to "opt out" of such training due to the fear or stigma of being a "certified" medical abortion provider, future family medicine doctors will be less equipped to serve their patients' needs.

27. Further, the "certified pharmacy" required by the REMS places an additional administrative workload on the shoulders of already overworked healthcare providers. The pharmacy certification requirement means that a doctor cannot simply call-in a mifepristone prescription to the patient's desired pharmacy. Instead, the doctor must research available certified pharmacies near the patient and then send their prescriber agreement form to the pharmacy before

sending the patient's prescription. If a prescriber fails to take this step and sends the prescription to a pharmacy that is not certified, or neglects to send their prescriber agreement form with the prescription, the patient's prescription will be delayed. Given the time-sensitive nature of medication abortion, this delay could have a significant impact on the patient's ability to have a medication abortion.

28. The fear of personal, political, and professional consequences for providing abortion care ultimately means that fewer providers are trained and qualified to provide this necessary medical care in Washington.

The Mifepristone REMS Impedes Patients' Access to Safe and Necessary Medication Abortions With their Primary Care Physicians

29. There is a growing body of research supporting patients' general desire to receive abortion care within the primary care setting.[4] When a patient

---

[4] Miles, C., Weidner, A., Summit, A.K., Thomson, C.J., Zhang, Y., Cole, A.M., Shih, G., *Patient opinions on sexual and reproductive health services in primary care in rural and urban clinics,* Contraception 114:26-31 (Oct. 2022); Thomson, C.J., Zhang, Y., Weidner, A., Summit, A.K., Miles, C., Cole, A.M., Shih, G., *Patient Concerns about Accessing Sexual and Reproductive Health Services Outside of Primary Care: A Survey in Rural and Urban Settings in the Pacific Northwest*, Contraception 15:S0010-7824(22)00396-1 (Oct. 2022); Hatcher-Lee, M., Cox, C., Shih, G., *If, when, and how to discuss available*

has a visit with their primary care physician, the patient is familiar with the clinic, knows the front office staff, is in a physical space where they have had trusted contact with physicians, and may have more privacy then they may experience walking into a specialty clinic. If abortion services are only available outside of primary care, patients worry about increased costs, insurance coverage for specialty services, and additional wait time for a referral. Thus, there is a significant benefit to increasing access to abortion care in primary care practices. But the REMS and its continued "certified prescriber" requirement have prevented medication abortion from becoming an established part of family medicine. This, in turn, means that many patients who would like to receive a medication abortion from their primary care physician are unable to.

The 2023 REMS Are Scientifically and Medically Unnecessary

30. There is no objective medical basis for or value to the mifepristone REMS program. In fact, mifepristone is on the World Health Organization's (WHO) list of essential medications. This core list includes "minimum medicine

---

abortion services in the primary care setting, Women & Health, 14:1-12 (Aug. 2017); Godfrey, E.M., Rubin, S.E., Smith, E.J., Khare, M.M., Gold, M., *Women's preference for receiving abortion in primary care settings,* J. Womens Health (Larchmt) 19(3):547-53 (Mar. 2010).

needs for a basic health-care system, listing the most efficacious, safe, and cost-effective medicines for priority conditions."[5]

31. From my experience counseling patients on medication abortion, the Patient Agreement Form is duplicative of the information contained in the mifepristone Medication Guide, as well as the informed consent counseling that providers are already required to provide.

32. Having a provider become a "certified" mifepristone prescriber is also unnecessary and burdensome. Mifepristone is among the safest drugs family care providers prescribe. It is less dangerous than insulin, warfarin, penicillin, and most antibiotics. It is even less dangerous than acetaminophen (Tylenol), which can be purchased over-the-counter without a prescription. Yet mifepristone is one of the very few drugs that many family medicine providers might prescribe that is burdened by a REMS. While I am willing to be a "certified" mifepristone provider, many other providers are not for the reasons I discuss above. This, in turn, harms patients as the number of "certified" providers continues to remain limited.

33. Removing the REMS for mifepristone would significantly increase the number of family medicine providers who would be willing to offer medication abortion care. This opinion is based on my familiarity with the

---

[5] World Health Organization, Model List of Essential Medicines, 21st Ed. (2019).

literature on this issue, as well as my experience training medical residents over the last 15 years at UW and University of California, San Francisco. Each year, when I train residents on medication abortion in clinic, I would estimate that approximately half of the resident class (usually five residents in a class of 10) indicate that they are passionate about providing abortion care and hope to integrate abortion care into their family care practice. However, on average only about one resident in each class ends up incorporating abortion care (medication or procedural) into their future primary practice. Some classes have *no* residents that incorporate abortion into their practices. The low number of residents ultimately providing medication abortion is attributable in large part to the barriers imposed by the REMS, including the administrative burden and safety concerns discussed above.

34. Finally, allowing mifepristone to be dispensed only by "certified pharmacies" serves no value given the highly regulated environment in which pharmacies already operate. Instead, it harms patients by limiting their ability to access mifepristone at the pharmacy of their choice, and creates additional administrative burdens—which I have experienced firsthand in working to implement the REMS at UW—for both providers and pharmacies, which serve as additional deterrents to participating in the mifepristone REMS program.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this __19___ day of February, 2023, at Anaheim, California.[6]

Grace Shih, MD, MAS

[6] I live and work in Washington, but I am signing this declaration while on vacation.

Exhibit A

Grace Shih, MD MAS

PERSONAL DATA

Address: 331 NE Thornton Place, Seattle, WA 98125
Email: ghshih@uw.edu
Work Phone: (206) 520-2405
Cell Phone: (617) 676-7797
Fax: (206) 520-2450

EDUCATION

1994-1998	Bachelor of Arts Emory University Majors: Music, Physics
1999-2003	Doctor of Medicine University of Florida
2008-2010	Master's Degree in Clinical Research University of California, San Francisco

POSTGRADUATE TRAINING

2004	Internship in Obsetrics and Gynecology Albert Einstein Medical Center
2005-2008	Internship and Residency in Family Medicine Brown University Area of concentration: Maternal and child health
2008-2010	Fellowship in Family Planning University of California, San Francisco
2010-2011	Leadership Training Academy Physicians for Reproductive Health
2014-2015	WWAMI Network Faculty Development Fellowship University of Washington
2017-2018	Certificate Program in Patient Safety and Quality University of Washington
2020	Wiki Scholars Program

Society of Family Planning

2021-22 STFM CERA Fellowship

FACULTY POSITIONS

2010-2012 Assistant Clinical Professor
Department of Family and Community Medicine
University of California, San Francisco

2011-2012 Assistant Clinical Professor
Department of Obstetrics, Gynecology and Reproductive Sciences
University of California, San Francisco

2013-2014 Acting Assistant Professor
Department of Family Medicine
University of Washington

2014 Assistant Professor
Department of Family Medicine
University of Washington

2016-2017 Interim Program Director
University of Washington Family Medicine Residency

2018-present Associate Professor
Department of Family Medicine
University of Washington

2019-2020 Associate Director, Reproductive Health Advocacy Project (RHAP) Fellowship
2020-present Co-Director, Reproductive Health Advocacy Project (RHAP) Fellowship
Department of Family Medicine
University of Washington

2019-2022 Associate Director of Faculty Development
WWAMI Family Medicine Residency Network (FMRN)
Department of Family Medicine
University of Washington

2022-present Director, WWAMI Family Medicine Residency Network (FMRN)
Department of Family Medicine
University of Washington

HOSPITAL POSITIONS

2010-2012	Attending physician Outpatient family medicine and obstetrics San Francisco General Hospital San Francisco, CA
2011-2012	Medical Director New Generation Health Center (Teen family planning clinic) University of California, San Francisco San Francisco, CA
2013-2014	Director, Second Trimester Abortion Services
2021-present	Director, Vasectomy Services Planned Parenthood of the Great Northwest, Hawaii, Alaska, Indiana, and Kentucky Seattle, WA

CURRENT EMPLOYMENT

See above, N/A

HONORS

1995	Alexander Means Scholar, four-year full tuition scholarship, Emory University
1995	Barry Goldwater Scholar, scholarship for excellence in science
1996	Hughes Science Scholar, scholarship for excellence in science
1996	*Phi Beta Kappa*, Emory College
2003	Gold Humanism Honor Society
2003	Caroline Annette Cody Award for dedication to underserved communities, University of Florida School of Medicine
2003	Rotary Cultural Ambassador Scholarship Scholarship to study Spanish and medicine in Quito, Ecuador
2007	Benjamin Josephson Scholar in International Medicine, Brown University
2011, 2012	Excellence in Resident Teaching, Department of Obstetrics Gynecology, UCSF
2013	Full Fellow, Society of Family Planning
2015	MEDEX Golden Apple Teaching Award, UW
2016	Faculty Morale and Support Award, Department of Family Medicine, UW
2015, 2016	Chief Resident Award, Department of Family Medicine, UW
2019	UW Patient Reported Assessment In Doctor Satisfaction and Excellence (PRAISE) Award
2018, 19, 20	Faculty Teaching Award, Department of Family Medicine, UW
2021	HEAR Committee faculty co-lead - Justice, Equity, Diversity, and Inclusion (JEDI) Excellence Award by the UW Department of Family Medicine

2021 Faculty lead, UWNC Northgate Reproductive Clinic Team - Clinical Excellence Award by the UW Department of Family Medicine.

BOARD CERTIFICATION

7/09-present Diplomate, American Board of Family Medicine

CURRENT LICENSES

7/08-present Drug Enforcement Agency
12/12-present Medical license, Medical Board of Washington State
7/18-present Buprenorphine Certificate Waiver
4/20-present NCC Certification of Added Qualification in Electronic Fetal Monitoring

DIVERSITY, EQUITY, AND INCLUSION

Committee Membership & Leadership

2014-2018 Member, UW Department of Family Medicine Diversity Committee

2017-present Faculty co-lead, UWFMR Health Equity and Anti-Racism (HEAR) Committee
- Lead race-based caucusing
- Organize and facilitate HEAR curriculum
- Oversee URM Sub-I

2020 Conference Chair, Moving Toward an Anti-Racist Culture of Medicine, WWAMI Network Collaborative Conference. Seattle, WA. September 2020. 300 participants.

2021 Justice, Equity, Diversity, and Inclusion (JEDI) Excellence Award by the UW Department of Family Medicine, HEAR Committee faculty co-lead

2021-present Faculty lead, WWAMI Racial Affinity Cacusing (RAC) Project

Scholarship

2009 Understanding Black, Latino, and White couples' attitudes toward sterilization. Fellowship in Family Planning Annual Conference, Chicago, IL. April 2009.

2011 **Shih G**, Vittinghoff E, Steinauer J, Dehlendorf C. Racial and ethnic disparities in contraceptive use in California. Perspect Sex Reprod Health. 2011 September; 43(3): 173-180.

2016 Working toward a more diverse healthcare workforce: Evidence and Strategies. Oral presentation, Society for Teachers of Family Medicine Annual Conference, Minneapolis, MN. May 2016.

2019 **Shih G**, Rind C, Heinen C. All-staff training session to improve transgender sensitivity. Poster presentation, National Transgender Health Summit, San Francisco, CA. April 2019.

2020 Ainsworth S, Foster A, Perritt J, **Shih G**, Yanow S. Self-Managed Abortion: Clinical, Activist, and Reproductive Justice Perspectives. National Abortion Federation, Webinar. October 2020.

2021 Simon C, Zhang Y, Evans D, **Shih** G, Lindley A, Credit G, Frederickson E, Nelson J. Innovations in Recruitment of URM Applicants during a Pandemic: Creating a Virtual URM Sub-Internship. Virtual Presentation, Annual STFM Conference May 2021.

2021 **Shih G**, Lindley AR, Zhang Y, Evans DV. Reaching Out While Staying In: Underrepresented in Medicine Recruitment at the University of Washington Family Medicine Residency. J Grad Med Educ. 2021 Jun;13(3):441.

2021 UW CLIME Education Grant, $5K
Grant to implement and evaluate racial affinity caucusing for WWAMI residents.

Teaching and Mentorship

2019 "Reproductive Coercion: History & Current Perspectives," Residency didactics (~30)

2020 Mentored 2 Under-represented in Medicine (URM) Sub-Is by arranging in/outpatient virual rounding experiences, reviewing/editing application materials, providing mentorship, and connecting each sub-I with other residents/faculty in our program

2020 Journal Club: "Racial Inequities in referral for cardiac catheterization" (~30)

2021 "Examining Contraceptive Coercion," Virtual talk for medical students (~50)

2020-present STFM Mentor, Mentoring Underrepresented Faculty for Academic Excellence (MUFAE)
Dr. Odinaka Anyanwu, Brown University FMR Faculty
Dr. Angela Echiverri, Contra Costa Regional Medical Center FMR Faculty

Volunteer Activities & Special Training

2019 Faculty co-lead, Doctor for a Day collaboration with Federal Way High School (racially diverse school with <17% white student population) and UWSOM

2019 National Coalition Building Institute (NCBI) International Training – Diversity Equity and Inclusion Model Training

2020-2022 Steering Committee, People's Free Telehealth

PROFESSIONAL ORGANIZATIONS

2009-present Society of Teachers of Family Medicine
2009-present American Academy of Family Physicians
2010-present Physicians for Reproductive Health
2011-present Society of Family Planning, Full Fellow
2014-present Washington Academy of Family Physicians (WAFP)

TEACHING RESPONSIBILITIES

Medical and PA Student Education

7/09-7/12 UCSF Medical Student Teaching
Taught 3rd and 4th year medical students (~50 students/session) in 1-2 lectures/year on women's health topics such as cervical cancer screening, contraception, and abortion care.

5/2014 UW MedEx Program
Taught 1st year PA students (~100 students) half-day workshop on contraception.

11/17-11/19 UW Medical Students
Taught 1st and 2nd year medical students (~10 students/year) 1-2 lectures on human sexuality, family planning, and OBGYN Skills

Resident Education

7/08-6/12 UCSF Ob-Gyn Residency Teaching
Provided monthly teaching sessions for Ob-Gyn residents on their family planning rotation (~10 residents/year).

7/08-6/12 UCSF Family Medicine Residency Teaching
I was a Team Lead for family medicine residents (4/year) which included clinical precepting, advising, and mentoring. I also co-led the procedure clinic, provided OB supervision, and didactic teaching. Curricular responsibilities include women's health, family planning, and obstetrics.

7/13-present UW Family Medicine Residency Teaching
I provide education via clinic precepting, hospital service attending, OB attending, seminars, and didactic teaching. My curricular areas of responsibility have included women's health, obstetrics, family planning, transgender care, health equity and anti-racism, advocacy, practice management, and scholarship and research.

Fellow Education

7/19-present RHAP Fellows and Complex Family Planning (CFP) Fellows
I provide education for our RHAP fellow (1 UW family medicine fellow, 6 total RHAP fellows nationally) and CFP fellows (2 UW OBGYN fellows) each year on topics including: second trimester abortion, complications in uterine aspiration, cervical preparation, transgender care, vasectomy, ectopic pregnancy, didactic teaching, precepting, and reproductive justice.

Faculty Development and Continuing Medical Education

2010-11 UCSF Family Planning Faculty Teaching
I taught 1 lecture/year to the Family Planning division (~10 faculty/year).

2014-17 UW Faculty Early Pregnancy Ultrasound Workshop
Each year, I held a hands-on ultrasound workshop for UW faculty (~5 faculty/year).

2016 Advanced Life Support in Obstetrics (ALSO) Course Instructor
- Shoulder Dystocia
- First trimester bleeding

2018-present WWAMI Hybrid Faculty Development Program (Seattle, WA)
Each year, I help teach approximately 16 faculty hybrid participants in a year-long fellowship. This program consists of two 2-day in-person sessions and two 2-day

virtual sessions. I provide approximately 4 hours of formal, didactic teaching each year. My curricular responsibility include DEI work, advising and mentoring, and time management.

2018-present WWAMI Faculty Development Fellowship (Seattle, WA)
Each year, I help teach a cohort 12 faculty fellows. I teach approximately 20 hours/year. My curricular responsibility include didactic skills, precepting, advising and mentoring, faculty relationships, career guidance/coaching, cognitive reasoning, time management, and scholarship & research.

ADVISING

2009-2011	Miriam Sheinbein (Planned Parenthood MarMonte Director of Primary Care)
2014	Elizabeth Alcut (UWNC physician)
2014-2015	Ying Zhang (NRSA Fellow, UW Residency faculty)
	Alyce Sutko (Group Health physician, Planned Parenthood physician)
2014-2016	Megan Hatcher-Lee, Medical Student Research Training Program (MSRTP) Advisor (Family Medicine Resident)
2013-2016	Angad Singh (UW Physician lead for eHealth)
	Meena Chelvakumar (Clinical Assisant Professor, Stanford University)
2014-2017	Roshan Najafi (Family physician)
	Michelle Dumond (Fogarty Global Health Fellow)
	Andrea Jochim (Clinical faculty, Harborview Medical Center)
2015-2018	Tara Simpson (UW Global Health Fellow, HealthPoint Residency Faculty)
	Sonali Sheth (UWNC Family physician)
	Lamya Khoury (Family physician)
2015-2018	Patricia Egwuatu (Kaiser Family Medicine Residency Faculty)
2017-2020	Justin Kappel (Clinical faculty, University of Washington)
2019-2020	Jackie Yeh (RHAP Fellow, family physician)
2020-2021	Christie Miles (RHAP Fellow, family physician)
	Aishat Olatunde (UW Complex Family Planning Fellow)
	Monica Agarwal (RHAP Fellow)
2021-2022	Sheila Attaie (RHAP Fellow, family physician)
	CFP Fellow Jennifer Chin (UW Complex Family Planning Fellow)
	Odinaka Anyanwu (Brown University Family Medicine Faculty)
2022-2023	Samantha Glass (RHAP Fellow, family physician)
	Mari Yakimoto (UW Family Medicine Faculty)
	Angela Echiverri (Contra Costa Regional Medical Center Family Medicine Faculty)
	UW FMR PGY3 Natalie Cheung-Jones
	UW FMR PGY2 Amanda Valdes

EDITORIAL RESPONSIBILITIES

2022 Co-Editor, TEACH Early Abortion Training Curriculum, 7th Edition. UCSF Bixy Center for Global Reproductive Health: San Francisco, CA (2022).

SPECIAL INTERNATIONAL AND NATIONAL RESPONSIBILITIES

2014-2019	Board Member, Association of Reproductive Health Professionals (ARHP)
2013-2016	Board Member, Training Early Abortion for Comprehensive Healthcare (TEACH)
2018-2019	Vice-Chair, Reproductive Health Member Interest Group, AAFP
2013-present	Co-founder and faculty, Continued Reproductive Education for Advanced Training Efficacy (CREATE)
2019-2021	Co-Chair, Reproductive Health Member Interest Group, AAFP
2020-2021	Member, National Summit on Family Medicine Residency Education I was invited to participate in a national dialogue on the future of residency training in family medicine hosted by AAFP, ABFM, ACOFP, ADFM, NAPCRG, and STFM.
2020-2021	Research Advisory Group, Gynuity International Gynuity International is an organization that focuses on research and policy change to improve reproductive and maternal health outcomes. I was invited to participate in their research advisory group to evaluate clinical protocols and policies on medication abortion.
2020-2022	Conference Planning Committee, AAFP Residency Leadership Summit (RLS)
2018-present	GME Committee Member, STFM
2020-present	Mentoring Underrepresented Faculty for Academic Excellent (MUFAE), STFM
2020-present	CERA Survey Peer Reviewer, STFM
2020-present	Advisory Committee, Midwest Access Project Midwest Access Project is a national nonprofit organization dedicated to offering comprehensive preoductive health training to providers from all disciplines.
2022-present	CERA Mentor Director, CERA Steering Committee, STFM
2023-present	Faculty, American College of Obestrics and Gynecology (ACOG) Implementating Progress in Abortion Care and Training Program I am ACOG faculty that teaching abortion care at residency programs across the nation. Sites: Long Beach Family Medicine Residency Program (2023)

SPECIAL LOCAL RESPONSIBILITIES

Residency Responsibilities

2014-2017	Lead, Scholarship and research UWFMR
2015-2017	WWAMI Region Practice & Research Network (WPRN) – UWNC-Northgate research champion
2016-2018	Residency recruitment lead, UW Family Medicine Residency
2013-present	Faculty lead, UWNC-Northgate Reproductive Health Clinic
2013-present	Faculty mentor, UWFMR Reproductive Health Interest Group
2017-present	Faculty lead, UWFMR Health Equity and Anti-Racism (HEAR) Committee

Departmental Responsibilities

2015	Member, UW CME Chair Search Committee
2016	Member, UW Associate Program Director Search Committee

2018-2019 Member, UW Deparment Scholarship Forum Planning Committee
2019 Member, UWNC Northgate Clinic Chief Search Committee
2019 Member, UWDFM 50th Anniversary Planning Committee
2017-2021 Member, UW Chairman's Advisory Committee
2020-2021 Member, UWDFM 50th Awards Selection Committee
2015-2023 Member, UW CME Advisory Committee
2015-2023 Course Chair, UW Annual Advances in Family Medicine and Primary Care Conference
2020-present Member, UWDFM A&P Committee
2022-present Member, UWSOM Telemedication Abortion Implementation Task Force

External Responsibilities
2018-2022 Reproductive Health Advocacy Project Liaison to AAFP
2013-present Selection Committee, UW Fellowship in Family Planning, Department of Ob-Gyn

RESEARCH FUNDING AND OTHER GRANTS

7/09-7/12 Principal Investigator
Foundation for Fellowship in Family Planning, $65K
Understanding Black, Latino, and White couples' attitudes toward sterilization
10/09-7/12 Principal Investigator
Foundation for Fellowship in Family Planning, $30K
Knowledge and practice patterns regarding vasectomy among Family PACT providers
7/10-7/12 Principal Investigator
UCSF Reproductive Health Education in Family Medicine (RHEDI) Grant, $70K
Reproductive health training grant
9/12-7/14 Co-Principal Investigator (UCSF)
Hewlett Foundation, $271K Total
Emphasizing characteristics of a long-acting reversible contraception to enhance use
9/12-7/14 Co-Principal Investigator (UCSF)
Hewlett Foundation, $150K total
Making the Copper IUD available for EC: A feasibility and acceptability study
7/13-7/18 Principal Investigator
UW Reproductive Health Education in Family Medicine (RHEDI) Grant, $70K/year
Reproductive health training grant
3/21-3/22 King County Academy of Family Physicians
People's Free Telehealth Grant, $10K
Grant to support the development of free telehealth service for Washington state.
5/21-5/22 UW CLIME Education Grant, $5K
Grant to implement and evaluate racial affinity caucusing for WWAMI residents.

BIBLIOGRAPHY: PEER REVIEWED JOURNALS

Shih G in bold, residents and students in Italics

1. Magee SR, **Shih G.** Malabsorption of oral antibiotics in pregnancy after gastric bypass surgery. J Am Board of Fam Med. 2007 May-June. 20(3):310-313.
2. Magee S, King W, **Shih G**, et al. Biomonitoring in Rhode Island. Med Health RI. 2008 March. 91(3):88-90.
3. **Shih G,** Njoya M, Lessard M, Labrecque M. Minimizing Pain During Vasectomy: the Mini Needle Anesthetic Technique. J Urol. 2010 May ;183(5): 1959-63.
4. **Shih G,** Turok D, Parker W. Vasectomy: the other (better) form of sterilization. Contraception. 2011 Apr;83(4):310-5
5. Turok D, **Shih G,** Parker W. Reversing the United States sterilization paradox by increasing vasectomy utilization. Contraception. 2011 Apr;83(4):289-290.
6. **Shih G**, Vittinghoff E, Steinauer J, Dehlendorf C. Racial and ethnic disparities in contraceptive use in California. Perspect Sex Reprod Health. 2011 September; 43(3): 173-180.
7. King E, **Shih G**, et al. Mercury, lead, and cadmium in umbilical cord blood. J Environ Health. 2013 Jan-Deb;75(6):38-43.
8. Goodman S, **Shih G**, et al. A long-term evaluation of an opt-out reproductive health training rotation with opt-out provisions for family medicine residents. Fam Med. 2013 Mar; 45(3): 180-6.
9. **Shih G,** Dube K, *Sheinbein M*, Borerro S, Dehlendorf C. "He's a real man": A Qualitative study of the social context of couples' vasectomy decisions among a racially diverse population. Am J Mens Health. 2013 May; 7(3): 206-13.
10. **Shih G,** Dube K, Dehlendorf C. "We never thought of a vasectomy": A Qualitative study of men and women's counseling around sterilization. Contraception. 2013 September; 88(3): 376-381
11. *Nguyen B*, **Shih G**, Turok DK. Putting the man in contraceptive mandate. Contraception. 2014 Jan; 89(1):3-5.
12. Roth M, **Shih G**, et al. Acceptability of a transdermal gel-based male hormonal contraceptive in a randomized controlled trial. Contraception. 2014 Oct; 90(4): 407-12
13. **Shih G**, *Zhang Y*, Bukowski K, Chen A. Bringing men to the table: Sterilization can be for him or for her. Clin Obstet Gynecol. 2014 Dec; 57(4): 731-40
14. **Shih G**, Whited A. When is the best time to clamp the umbilical cord after a routine term vaginal delivery? FPIN HDA: Evidence-Based Practice. 2015; 18(6): 10-11
15. Goodman S, McNeil S, **Shih G**. Simulation for Managing Hemorrhage as a Complication of Uterine Aspiration. MedEdPORTAL Publications; 2015.
16. *Nguyen B*, *Jochim A*, **Shih G**. Offering the full range of contraceptive options: a survey of interest in vasectomy training in the US family planning community. Contraception. 2017 May; 95(5):500-504.
17. Khoury L, **Shih G**. For women of average risk, what are the best tests to screen for Down's Syndrome in the first trimester? FPIN HDA: Evidence-Based Practice. 2017.
18. *Hatcher-Lee M*, Cox C, **Shih G**. If, when, and how to discuss available abortion services in the primary care setting. Women & Health. 2017 Aug 14:1-12.
19. Weidner A, Stevens N, **Shih G**. Associations Between Program-Level Abortion Training and Graduate Preparation for and Provision of Reproductive Care. Fam Med. 2019 Oct;51(9):750-755.

20. **Shih G**, Wu J, Harper D. Awareness and Attitudes Around the New Subspecialty Within Ob/Gyn Called Complex Family Planning: A CERA Survey of Family Medicine Chairs. Fam Med. 2020 Nov;52(10):702-706.
21. Zhang Y, *Sheth S*, Weidner AKH, *Egwuatu P*, *Webb L*, **Shih G**. Immediate Postpartum IUD Training Within a Regional Network of Family Medicine Residencies. PRiMER. 2021 Jul 1;5:24.
22. **Shih G**, Lindley AR, Zhang Y, Evans DV. Reaching Out While Staying In: Underrepresented in Medicine Recruitment at the University of Washington Family Medicine Residency. J Grad Med Educ. 2021 Jun;13(3):441.
23. Wallace R, **Shih G.** Complex Family Planning - Demarginalizing abortion care requires uplifting primary care and non-CFP providers. Contraception. 2022 Jan;105:86. PMID: 34600932.
24. **Shih G**, Stulberg D, Barreto TW, Andrilla CHA, *Guzman S*, Nothnagle M. Faculty and Resident Contraceptive Opt Outs and Training Site Restrictions: A CERA Study. Fam Med. 2022 Feb;54(2):123-128. PMID: 35143684.
25. *Miles C*, *Ennamuri D*, *Yeh J*, **Shih G**. Would you be interested in DMPA-SC? An implementation project in two urban primary care clinics. Contraception. 2022 Aug;112:116-119. PMID: 35123982.
26. *Patel J*, Nguyen BT, **Shih G**, Or M, Harper DM. Vasectomy Training in Family Medicine Residency Programs: A National Survey of Residency Program Directors. Fam Med. 2022 Jun;54(6):438-443. PMID: 35675457.
27. *Miles C*, Weidner A, Summit AK, Thomson CJ, Zhang Y, Cole AM, **Shih G**. Patient opinions on sexual and reproductive health services in primary care in rural and urban clinics. Contraception. 2022 Oct;114:26-31. PMID: 35489391.
28. Thomson CJ, Zhang Y, Weidner A, Summit AK, *Miles C*, Cole AM, **Shih G**. Patient Concerns about Accessing Sexual and Reproductive Health Services Outside of Primary Care: A Survey in Rural and Urban Settings in the Pacific Northwest. Contraception. 2022 Oct 15:S0010-7824(22)00396-1. PMID: 36257376.
29. Verma N, Goyal V, Grossman D, Peritt J, **Shih G**. Society of Family Planning Interim Clinical Recommendations: Self-Managed Abortion. Contraception.
30. Weidner A, Ormsby M, **Shih G**. What's Worth Doing in Virtual Recruitment? A Regional Survey of Program Directors and Incoming Interns. Fam Med. 2022 Nov;54(10):784-790. PMID: 36350743.
31. Witt LB, Wolff S, **Shih G**, French V. Abortion and contraception in medical school curricula: a survey of North American family medicine clinical curriculum directors. Teach Learn Med. 2023 Jan 13:1-9. PMID: 36636862.

BIBLIOGRAPHY: OTHER PEER-REVIEWED SCHOLARLY WORK

1. **Shih G**, Zhang Y, McNeil S. *Continuing Reproductive Education for Advanced Training Efficacy: A Novel Collaborative Program to Support Abortion Practice and Family Planning Advocacy Beyond Residency*. STFM Education Column. July 2018.
2. **Shih G**, Wallace R. *First trimester pregnancy termination: Uterine aspiration.* UpToDate. July 2018, 2020, 2022.

3. **Shih G**. *Abortion by Dilation and Evacuation*. Online Training Module. National Abortion Federation. April 2019.
4. **Shih G**, Wallace R. *First trimester pregnancy termination: Uterine aspiration.* UpToDate. July 2019, 2020.
5. **Shih G**. *No Scalpel Vasectomy.* STFM and AFMRD Family Medicine Residency Curriculum Resource. 2018, 2020, 2022.
6. *Chin J*, Ross V, Unger E, **Shih G**, Zhang Y. *Trauma Informed Care for Reproductive Health Services: Fundamentals and Case Discussions*. STFM and AFMRD Family Medicine Residency Curriculum Resource. 2022.
7. Fleming M, **Shih G**, Goodman S and the TEACH Collaborative Working Group. TEACH Abortion Training Curriculum, 7th Edition. UCSF Bixby Center for Global Reproductive Health: San Francisco, CA (2022). Bixby Doc: 2020-001(07/22)

BIBLIOGRAPHY: BOOK CHAPTERS

1. **Shih G**. Chapter: Interstitial Pulmonary Fibrosis. *Ferri's Clinical Advisor*. Mosby Elsevier (2008).
2. Boston Women's Health Book Collective. *Our bodies, ourselves*. New York: Simon & Schuster (2011).
3. Goodman S, Wolfe M, **Shih G**, et al. *Early Abortion Training Workbook, Fourth Edition*. Bixby Center for Global Reproductive Health: San Francisco, CA (2012).

BIBLIOGRAPHY: OTHER PUBLICATIONS

1. **Shih G** (2011). *Life sucks. Or is it just my birth control?,* Bedsider.org (National Campaign to Prevent Teen and Unplanned Pregnancy)
2. **Shih G** (2011). *Consider mother's safety*, USA TODAY, Letter to the Editor
3. **Shih G** (2011). *Where in the world is birth control for men?,* Bedsider.org
4. **Shih G** (2011). *Side effect spotlight: What's up with spotting?,* Bedsider.org
5. **Shih G** (2012). *Does being overweight affect your birth control?*, Bedsider.org
6. **Shih G** (2012). *5 myths about herpes, busted,* Bedsider.org
7. **Shih G** (2013). *Um…Can I get pregnant if?*, Bedsider.org
8. **Shih G** (2014). *Beyond Training: Pearls for Practice,* TEACHtraining.org (Training in Early Abortion for Comprehensive Healthcare)
9. **Shih G** (2014). *Provider Perspectives: Deciding on emergency contraception*, Bedsider.org
10. **Shih G** (2017). *Getting the snip: Should it be me or my partner?,* Bedsider.org
11. **Shih G** (2017). *Birth Control Bullies: When your partner wants your birth control to fail*, Bedsider.org
12. **Shih G** (2017). *5 Vasectomy myths, busted*, Bedsider.org
13. **Shih G** (2021). *How to navigate self-managed abortion issues such as access, wait times, and complications – a family physician explains*. Theconversation.com
14. **Shih G** (2023). *What the FDA's rule changes allowing the abortion pill mifepristone to be dispensed by pharmacies mean in practice – 5 questions answered*. Theconversation.com

MANUSCRIPTS SUBMITTED

None

ABSTRACTS

None

PRESENTATIONS: NATIONAL/INTERNATIONAL

1. **Shih G**. Understanding Black, Latino, and White couples' attitudes toward sterilization. Fellowship in Family Planning Annual Conference, Chicago, IL. April 2009.
2. **Shih G.** Abortion: The Role of Family Medicine. Grand Rounds at Brown University, Pawtucket, RI. April 2010.
3. **Shih G**, Turok D, Parker W, Curington J. No-Scalpel Vasectomy and Occlusion Techniques. Association Reproductive Health Professionals Annual Meeting, Atlanta, GA. September 2010.
4. **Shih G.** Vasectomy: The (other) form of sterilization, Reproductive Health Annual Conference, Portland, OR. March 2012.
5. **Shih G.** New Developments in Contraception. Association Reproductive Health Professionals Annual Meeting, New Orleans, LA. September 2012.
6. **Shih G**, Miller S. Where are the men? Strategies to include men in family planning. Association Reproductive Health Professionals Annual Meeting, New Orleans, LA. September 2012.
7. **Shih G.** Knowledge and practice patterns regarding vasectomy among Family PACT providers. American Public Health Association Annual Meeting, San Francisco, CA. October 2012.
8. **Shih G.** He's a real man: A Qualitative study of the social context of couples' vasectomy decisions among a racially diverse population. American Public Health Association Annual Meeting. San Francisco, CA. October 2012.
9. **Shih G.** Oral Presentation, Association of Reproductive Health Professionals. Webinar, New Developments in Contraception. October 2012.
10. Wallace R, **Shih G.** eLearning for Pregnancy Loss: New Strategies to Teach Miscarriage Management in Family Medicine Settings. Society of Teachers of Family Medicine Annual Meeting. San Antonio, TX. May 2014.
11. Roth M, **Shih G**, Amory J. High Acceptability of a Combination of Nestorone® and Testosterone Gels for Male Hormonal Contraception in a Randomized Controlled Trial (Poster). International Congress of Endocrinology (ICE/ENDO) Annual Meeting. Chicago, IL. June 2014.
12. **Shih G,** Hatcher M, Weidner A. Designing your own qualitative study: A beginner's guide. Society for Teachers of Family Medicine Annual Conference, Orlando, FL. April 2015.

13. Zhang Y, MacNeil S, Castillo P, **Shih G**, Prine L. Teaching advocacy to residents and students: Introducing trainees to health policy through resolution writing. Society for Teachers of Family Medicine Annual Conference, Orlando, FL. April 2015.
14. Castillo P, **Shih G**, Ross V, Overstreet F, Chen F. Working toward a more diverse healthcare workforce: Evidence and Strategies. Society for Teachers of Family Medicine Annual Conference, Minneapolis, MN. May 2016.
15. Wallace R, Prine L, **Shih G.** Pregnancy Loss and Papayas: Use of an innovative video-based curriculum and a hands-on simulation to learn patient-centered miscarriage care in the flipped classroom. Society for Teachers of Family Medicine Annual Conference, Minneapolis, MN. May 2016.
16. **Shih G**, Collins K, Raetz J. Creating scholarly success in residency programs: Evidence & strategies. Society for Teachers of Family Medicine Annual Conference, Minneapolis, MN. May 2016.
17. **Shih G**, Zhang Y, Weidner A. Conducting qualitative data analysis: A basic "how to" seminar. Society for Teachers of Family Medicine Annual Conference, Minneapolis, MN. May 2016.
18. Zhang Y, MacNeil S, **Shih G.** The Strength of the Written Word: Letter-writing as a Powerful Tool for Advocacy and Scholarship. Society of Teachers of Family Medicine Annual Conference, Minneapolis, MN: May 1, 2016.
19. Nguyen B, White K, **Shih G**, Turok D. If sterilization is the question, then vasectomy should be the answer: Increasing the vasectomy workforce. Seminar, North American Forum on Family Planning, Denver, CO. November 2016.
20. Nguyen B, Jochim A, **Shih G.** Vasectomy training in family planning fellowships: Offering the full range of contraceptive options. Poster presentation, North American Forum on Family Planning, Denver, CO. November 2016.
21. Trouton K, **Shih G,** Reeves M, Mark A**.** Second Trimester Abortions: A Beginner's Workshop. National Abortion Federation, Seattle, WA. April 2018.
22. **Shih G.** Women's Health Update. Annual Advances in Family Medicine and Primary Care. Seattle, WA. September 2018.
23. **Shih G**, Rind C, Heinen C. All-staff training session to improve transgender sensitivity. Poster presentation, National Transgender Health Summit, San Francisco, CA. April 2019.
24. **Shih G**, Evans D. Teaching one-minute preceptor with real audio-recordings: A simple, replicable tool for faculty development. Society of Teachers of Family Medicine Annual Conference, Toronto, Canada. May 2019
25. **Shih G**. Self-Managed Abortion: What family medicine physicians need to know. Chat and Chew. Philadelphia, PA. September 2019.
26. **Shih G**, Lindley A, Zhang Y. Intrauterine Procedures: IUDs, EMB, and aspiration. Annual Advances in Family Medicine and Primary Care. Seattle, WA. September 2019.
27. **Shih G**, Ti A. Updates in Contraception: From Emergency Contraception to Permanent Methods. AAFP FMX Annual Conference. Virtual. September 2020.
28. **Shih G.** Updates in Contraception: From Emergency Contraception to Permanent Methods. Annual Advances in Family Medicine and Primary Care. Virtual. September 2020.
29. **Shih G**, panel presentation. Introduction to the Changing Landscape of Medication Abortion. Reproductive Health Access Project, Webinar. October 2020.

30. Ainsworth S, Foster A, Perritt J, **Shih G**, Yanow S. Self-Managed Abortion: Clinical, Activist, and Reproductive Justice Perspectives. National Abortion Federation, Webinar. October 2020.
31. Simon C, Zhang Y, Evans D, **Shih** G, Lindley A, Credit G, Frederickson E, Nelson J. Innovations in Recruitment of URM Applicants during a Pandemic: Creating a Virtual URM Sub-Internship. Virtual Presentation, Annual STFM Conference May 2021.
32. **Shih G**, Lee I, Thompson C. Professional Life Hacks: Making the Most of Your Limited Time. Society of Teachers of Family Medicine Annual Conference. Virtual. May 2021.
33. Lee I, **Shih G**. Defining Your Why and Your What: Using Mission Statements as a Career Compass. Society of Teachers of Family Medicine Annual Conference. Virtual. May 2021.
34. **Shih G,** Lee I. Drawing the line: Identifying and exploring dual relationships between faculty and residents. Society of Teachers of Family Medicine Annual Conference. Live Webinar. May 2021.
35. Graham T, Larson P, Lyon C, **Shih G**, Sokol R, Vasagar B. Faculty for Tomorrow Workshop for Residents. Society of Teachers of Family Medicine Annual Conference. Live Workshop. May 2021.
36. Ormsby M, Weidner A, **Shih G**. Virtual Recruitment: What Do Students Actually Care About? AAFP Residency Leadership Summit Annual Conference. Seminar. March 2022
37. **Shih G,** Lee I. Shifting Ground: Faculty Navigating Multiple Roles with Residents. Seminar. Society of Teachers of Family Medicine Annual Conference. Indianapolis, IN. May 2022.
38. Ormsby M, Weidner A, **Shih G**. Virtual Recruitment: What Do Students Actually Care About? Lecture-Discussion. Society of Teachers of Family Medicine Annual Conference. Indianapolis, IN. May 2022.
39. *Bittner M*, Gold M, *Hutman-Zahler A*, Karlin J, **Shih G**, Bass M. Self-Managed Abortion: Data from an Anonymous Support Hotline. Poster Presentation. Society of Teachers of Family Medicine Annual Conference. Indianapolis, IN. May 2022.
40. Lyon A, **Shih G**, Lawler E, Wallace R. Preparing for the (Criminal) Onslaught: Representing Our Clients in the Wake of Dobbs. National Association for Public Defense Women's Conference. Virtual Seminar. September 2022.

PRESENTATIONS: REGIONAL

1. Godfrey E, **Shih G.** Adolescent Women's Healthcare: Addressing STI's, Contraception & Pregnancy. Washington Association of Family Physicians Annual Meeting, Cle Elum, WA. May 2013.
2. Godfrey E, **Shih G.** Reproductive Sexual Health Using Clinical Cases and Guideline Tools. 41st Annual Advances in Family Practice and Primary Care. Seattle, WA. September 2013.
3. **Shih G**, Whited A. FPIN Help Desk Answer: When is the best time to clamp the umbilical cord after a routine term vaginal delivery? WWAMI Faculty Development Fellowship Meeting. Seattle, WA. October 2014.
4. **Shih G.** WWAMI program differences in graduates' reproductive health practices. WWAMI Faculty Development Fellowship Meeting. Seattle, WA. May 2015.
5. WWAMI Chief Resident Conference, Seattle, WA. Annually since May 2015. Topics:
    - Running effective meetings

- Interactive Teaching Strategies
- Difficult Conversations
- Precepting
- Leadership Strategies

6. WWAMI Faculty Development Fellowship, Seattle, WA. Annually since July 2018. Topics:
    - Advising and Mentoring
    - Adult Learning Principles and Applications
    - Precepting
    - Interactive Teaching Tools
    - Tech Tools for Teaching
    - Assessing Clinical Knowledge
    - Individual Learning Plans – Professionalism
    - Individual Learning Plans – Medical Knowledge
    - Professional boundaries
    - Faculty Lift: Understanding the distribution of residency faculty roles
    - Creating an effective research poster
    - Family medicine scholarship overview
    - Time Management
7. **Shih G**, McGuire M, Stevens N. Managing dual relationships. WWAMI Faculty Development Webinar. Seattle, WA. February 2019.
8. Miles C, **Shih G.** Patient opinions on sexual and reproductive health services in primary care. WPRN Annual Conference. Seattle, WA. January 2022.
9. Attaie S, **Shih G.** Shifting landscape of reproductive health. WWAMI Faculty Development Webinar, Virtual. July 2022.
10. **Shih G**, Ennamuri D, Miles C. Uterine aspiration: Papaya Workshop. WAFP Student and Resident Annual Conference. Olympia, WA. February 2023.

PRESENTATIONS: LOCAL

1. Zhang Y, Castillo P, Sutko A, Chelvakumar M, **Shih G.** Key Articles in Reproductive Health. Continued Reproductive Education for Advanced Training Efficacy (CREATE) Program for Abortion Care - Participants from University of Washington, Kaiser, Swedish-Cherry Hill, and Swedish-First Hill Family Medicine Residency Programs. September 2015.
2. Zhang Y, **Shih G.** Abortion Complications: Uterine Perforation. Continued Reproductive Education for Advanced Training Efficacy (CREATE) Program for Abortion Care - Participants from University of Washington, Kaiser, Swedish-Cherry Hill, and Swedish-First Hill Family Medicine Residency Programs. March 2016.
3. Zhang Y, Sheth S, Khoury L, Sutko A, **Shih G.** Key Articles in Reproductive Health. Continued Reproductive Education for Advanced Training Efficacy (CREATE) Program for Abortion Care - Participants from University of Washington, Kaiser, Swedish-Cherry Hill, and Swedish-First Hill Family Medicine Residency Programs. September 2016.
4. Attaie S, **Shih G.** UW Primary Care Lightning Rounds: Repro Health Update, Virtual. July 2022.

5. Miles C, Thomson C, **Shih G**. Patient preferences and concerns around sexual and reproductive services in primary care. UWDFM Research Seminar. March 2022.

SCHOLARLY SERVICE

2010-present	Reviewer, Contraception Journal
2013-present	Manuscript Reviewer, Journal of Women's Health, Issues & Care
2013-present	Manuscript Reviewer, American Journal of Men's Health
2014-present	Manuscript Reviewer, Family Medicine
2021	Reviewer, Uganda's Coalition for Abortion Telemedicine Handbook to Self Managed Abortion
2022	Medical expert, KING-5 TV News, Vasectomy
2022	Medical expert, KIRO-7 TV News, Vasectomy
2023	Medical expert, KUOW National Public Radio (NPR), Vasectomy

COMMUNITY SERVICE

2010	Shoulder to Shoulder International – Volunteer physician and women's health committee member for non-profit organization committed to health of Intibuca, Honduras.
2012	No-Scalpel Vasectomy International (NSVI)- Volunteer physician for medical mission to Philippines to teach and provide vasectomies
2012-present	Vasectomy Network – Founder & manager of online community of vasectomy providers (550 members)
2020-present	Miscarriage and Abortion Hotline – Volunteer physician

Exhibit B

Grace H. Shih

Shih, Grace -- pic 1 small

ABORTION MILL

Shelton Health Center-Planned Parenthood
Seattle Northgate-Planned Parenthood
Seattle Health Center-Planned Parenthood -- (PP of the Great Northwest and Hawaiian Islands)

MEDICAL SCHOOL

University of Florida School of Medicine, 2003

ADDRESS

2001 E Madison, Seattle, WA 98122

PROCEDURES

Surgery: **YES**
Medication: **YES**

OTHER INFO

Abortionist Grace Shih is an Associate Professor in the Family Medicine Dept at the University of Washington. She completed a Family Planning abortion-training fellowship at UCSF, and helped co-author the "CREATE" abortion-training curriculum. She works at multiple Planned Parenthood abortion clinics.

Former abortionist at: West Seattle Health Center – Planned Parenthood

PHOTOS

DOCUMENTS

MISC DOCUMENTS

SHIH, GRACE -- 2020 PROVIDENCE DIRECTORY - LISTING AT MANY PP ABORTION CLINICS
2020 insurance listings at numerous Planned Parenthood abortion clinics, including Shelton, Issaquah, Puyallup, Seattle (Madison St), Federal Way, Marysville, Olympia, Kenmore, Seattle Northgate, West Seattle (now White Center PP), First Hill (Seattle), Bremerton, Centralia, and Kent Valley.

SHIH, GRACE -- EHEALTHINSURANCE.COM (SCREENSHOT) -- AT THREE PP ABORTION CLINICS
Listings at West Seattle, Seattle (Madison St), and Northgate Planned Parenthood abortion clinics.

SHIH, GRACE -- EHEALTHINSURANCE.COM (SCREENSHOT) - LISTING AT SHELTON PP
Listing at Shelton Planned Parenthood abortion clinic.

UCSF ABORTION TRAINING MANUAL -- CO-AUTHOR GRACE SHIH
Abortion curriculum for UCSF, co-authored by Grace Shih, MD. See page 3.

UW DEPT OF FAMILY MEDICINE -- GRACE SHIH, MD - ABORTION BIO
Abortionist career info from the UW Dept of Family Medicine.

UW MEDICINE -- GRACE SHIH, MD, MAS -- ABORTIONS, FAMILY PLANNING FELLOWSHIP AT UCSF
Shih performs abortions and completed her abortion-training Family Planning Fellowship at UCSF.

CONTINUING REPRODUCTIVE EDUCATION FOR ADVANCED TRAINING EFFICACY (CREATE) -- ABORTION TRAINING
"CREATE" abortion training article, co-authored by Grace Shih, MD.

HEALTH.USNEWS.COM -- DR. GRACE H. SHIH -- AT SEATTLE PP
Listing at Seattle PP abortion clinic.

SHIH, GRACE H. -- DOXIMITY.COM -- CREDENTIALS; LISTING AT SEATTLE PP
Listing at Seattle PP abortion clinic.

APPLICATION FOR WA STATE LICENSE
Shih's application for license in WA State

LICENSE

SHIH, GRACE HONG -- WASHINGTON STATE MEDICAL LICENSE - VALID THROUGH 08-01-2021

SHIH, GRACE HONG -- CALIFORNIA MEDICAL LICENSE - CANCELLED

SUBSCRIBE GET THE LATEST NEWS ON ABORTION DOCS NAME EMAIL SUBMIT

© OPERATION RESCUE, 2023.

Exhibit 19

ROBERT W. FERGUSON
Attorney General
NOAH GUZZO PURCELL, WSBA #43492
Solicitor General
KRISTIN BENESKI, WSBA #45478
First Assistant Attorney General
COLLEEN M. MELODY, WSBA #42275
Civil Rights Division Chief
ANDREW R.W. HUGHES, WSBA #49515
LAURYN K. FRAAS, WSBA #53238
Assistant Attorneys General
TERA M. HEINTZ, WSBA #54921
(application for admission forthcoming)
Deputy Solicitor General
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF ANGAD SINGH, M.D.

I, Angad Singh, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am a board-certified family physician with dual board certifications in Family Medicine and Clinical Informatics, providing urgent care services at multiple University of Washington (UW) Medicine Primary Care locations. I serve as the Associate Chief Medical Information Officer for UW Medicine with a primary focus on ambulatory care and health equity.

Work on the 2023 Mifepristone REMS

3. In addition to my regular duties, for the past 6 months, I have participated operationalizing at UW the FDA's updated risk evaluation and mitigation strategy (REMS) for mifepristone, which went into effect on January 3, 2023. My work on this project has primarily involved creating and implementing processes and technological solutions so UW can provide telemedicine access to medication abortion care in compliance with the 2023 REMS.

4. The initial work group was led by Brian Reed, the Administrator of Women's and Children's Services at UW Medicine. There are approximately 20-25 participants in the work group, in addition to myself.

5. The work group started by gaining an understanding of what currently exists for telehealth abortion care in our health system and identifying

what would be needed to build out the process for abortion services consistent with the 2023 REMS.

6. In addition to the work group itself, there are several IT teams working on building out the workflow for telehealth medication abortions. Myself and my team coordinate the various elements that must be considered when constructing a possible workflow for this type of medical visit, including (1) creation of an appointment and appointment types, (2) development of the Patient Agreement Form and Prescriber Agreement Forms, (3) creation and maintenance of a certified prescriber database, (4) integration of automated rules in the prescription workflow, (5) integration with our electronic health record (EHR)'s patient portal, (6) management of IT security, patient privacy, and provider safety concerns, and (7) integration of health equity considerations. We meet once per week to discuss the necessary technical and workflow considerations and offer guidance on how systems could be configured. Beyond the IT team, we have engaged the UW Medicine Digital Health Office and our electronic health vendor for more nuanced considerations around best practice, technological possibilities, and impacts on providers and patients.

Implementation Challenges Regarding the 2023 Mifepristone REMS

7. Because of the unique requirements for prescribing and dispensing mifepristone under the REMS, making medication abortions available via telehealth has involved creating an entirely new set of systems and workflows.

Operationalizing these new processes has presented a host of challenges for my team and for other constituent groups at UW. These challenges would not be present if mifepristone could be prescribed without REMS, like nearly all other prescribed medications.

Patient Appointments for Medication Abortion

8. For instance, the process has involved developing a new way for patients to identify and secure a remote appointment for medication abortion with a REMS certified provider, including a new appointment type. Since the REMS requires certain perquisites for a provider to be an eligible prescriber of mifepristone, limiting an appointment type to a set of medical providers that is evolving as they gain REMS certification creates both technical and operational challenges. We have considered and continue to consider whether we have patients book a generic appointment with a clinic (which could later be changed to a specific provider), or have a patient select a specific provider at the outset. While allowing patients to select a specific provider would be the norm in many other but not all care settings, this is complicated by the above-noted fact that appointments for a medication abortion can only be made with a certified prescriber under the mifepristone REMS. We also had to consider the implications of our technical design on physical safety and assess whether we could potentially be creating additional safety risks for our providers if a patient with malicious intent is able to identify a named prescriber by viewing the

scheduling portal. On the other hand, masking provider names in favor of generic appointments raises technical challenges on the back-end to limit scheduling with only REMS certified providers and makes it more difficult to ensure patient loads are appropriately divided and that each provider can easily identify their patients from a pool of generic appointments. These are design trade-offs not normally considered in establishing a routine telehealth appointment.

9. Further, in building-out the appointment process, we considered the various mechanisms a patient might use to schedule a telehealth appointment. For the time of the appointment itself, we also considered whether to share a link to join the appointment for this type of visit via an embedded link in the patient portal for those who have an account, or via text message or email for those who do not. In making these determinations, we were mindful that some of our patients may have ready access to certain telehealth technologies while others do not, including but not limited to those with financial strain, those who lack knowledge or comfort with using video conferencing tools, or those in rural areas that do not have the same broadband access as other parts of the state. These issues were significant considerations for us in our team's effort to establish equitable access to medication abortion care.

Patient and Prescriber Agreement Forms for Mifepristone REMS

10. With the recent amendments to the REMS, we also had to consider how the Patient Agreement and Prescriber Agreement Forms should be

integrated electronically into the larger telehealth workflow. This required considerable time and effort. Among other things, we had to create a new system to generate and transmit the Patient Agreement Form to the patient for their signature; determine how to securely re-route the form back to the provider for their signature; and then determine how to ensure transmission of the form from the registered provider to the certified UW pharmacy for storage and reference.

11. Given the time-sensitive nature of abortion care, we were keen on creating a prompt, reliable system for the patient and provider to complete the REMS-required Patient Agreement Form. We have considered creating built-in reminders, expiration dates, and other solutions to ensure compliance and prevent the process from stalling if, for example, a form or signature-reminder message is inadvertently deleted or fails to deliver to a patient. Such automatic mechanisms are critical in light of the REMS requirement for a signed Patient Agreement Form but each represents another technically-challenging, time-intensive and multidisciplinary process that requires careful consideration to ensure it is not creating a severe workflow burden.

Pharmacy Verification Requirements

12. Additional steps also had to be added to the workflow to comply with the new REMS verification requirements for certified pharmacies. For instance, before dispensing a prescription, a pharmacy needs to verify that the prescriber is certified in the Mifepristone REMS Program by confirming that

their Prescriber Agreement Form was received with the prescription or is on file with the pharmacy. We are navigating the technical challenges of maintaining a secure, reliable, dynamic list of certified prescribers within the hospital's system. While we recognize that creating a list of certified medication abortion providers can create additional risk for those providers, such a list is necessary in order to ensure compliance with the REMS requirements. If any automated hard stops are required to be built into the electronic health record (EHR), we would need to create an additional database of certified providers that could be used as a reference in the EHR. In this case, ensuring that these two databases, which will necessarily be hosted on separate systems, are always in-sync is a difficult, but critical issue we have had to address to follow the requirements outlined by REMS for mifepristone.

13. Beyond the technical design considerations to reference certified REMS providers at UW, we are considering the operational impacts that this could have. For example, every time a provider is newly certified to prescribe mifepristone (or if a provider's qualifications lapse or a provider leaves UW), a technical analyst would need to manually update the EHR list via a help desk ticket and/or a member of the pharmacy team would separately need to update the pharmacist-facing list to match. This is a labor-intensive process, creates a lag time for a mifepristone prescription to be filled, and introduces the risk of human error with transcription.

14. At each phase of this workflow, we also have been considering flags or other controls that might need to be created to ensure that mifepristone cannot be prescribed or dispensed until each REMS step has been completed. While such automatic rules built into the EHR would potentially reduce the risk of noncompliance, they would also increase the risk of a technical error stalling a patient's access to mifepristone and required the increased effort of ongoing maintenance.

Safety and Data Security Concerns

15. We are continually discussing potential weak points in the new workflow, in terms of sensitive patient and provider data and overall care experience.

16. The Patient Agreement Form, for example, creates one more sensitive document with identifying information in a patient's file that must be appropriately protected.

17. We have also had to determine how to securely share the digital Patient Agreement Form and the link to join the telehealth appointment. Given the sensitivities associated with medication abortion, we are taking added technological and training precautions to reduce the risk that any digital tools or reminders related to the Patient Agreement Form or telemedicine link could not be inadvertently accessed by someone whom the patient does not wish to have access, such as a minor patient's parent. But building in these privacy safeguards

also creates additional risk that a patient might not receive the reminder, which would slow down access and require additional provider work and add patient burden.

Training

18. Beyond building the systems required to operationalize REMS-compliant telemedicine abortions, looking forward, UW will need to devote substantial resources to training each touchpoint on the new processes. Trainings will need to be created for staff involved in appointing, for providers, for pharmacists, and for those in medical records. IT will also need to be prepared to assist on the various systems and practice sessions will need to be run before the go-live date to troubleshoot any unforeseen issues.

Burden of Complying with the 2023 Mifepristone REMS

19. All told, I anticipate that the process of implementing telemedicine abortion care compliant with the 2023 REMS will take at least 10 months. On the IT side, we started our work in September 2022 (in anticipation of the 2023 REMS) and expect to have the technical components ready by April 2023, with additional follow-up and training work lasting until approximately June 2023.

20. Specifically on the IT side, there are approximately 10 individuals representing both physician informaticists and technical analysts who are contributing to the work effort in addition to approximately two staff members from our EHR vendor who have provided consultative support on the technical

considerations of implementing electronic consents. To date, I estimate that UW personnel on my IT team have spent approximately 150 hours implementing the mifepristone REMS, and will be expending an estimated additional 150 hours as we continue to finalize workflow considerations, design training material, and roll out the initiative.

21. Without the REMS in place for mifepristone, prescription and distribution of mifepristone via telehealth appointments would be routine and would not require the many hours and resources that have been and will be devoted to operationalizing this process. This is valuable time that UW employees could otherwise spend treating patients, teaching clinical medicine, conducting research, or attending to other critical job functions.

22. In my professional opinion, as both a practicing board-certified family physician and a board-certified physician informaticist, I do not believe the mifepristone REMS requirements are reducing medical risk, but instead create significant administrative barriers for hospital systems, providers, and pharmacies. These barriers, in turn, will make it harder for patients to access mifepristone.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 21st day of February, 2023, at Seattle, Washington.

Angad Singh MD

Angad Singh, MD

ATTORNEY GENERAL OF WASHINGTON
Complex Litigation Division
800 Fifth Avenue, Suite 2000
Seattle, WA 98104-3188
(206) 464-7744