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
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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
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Supp. 20 summary review	Mar. 29, 2016	FDA 0412-0439
Supp. 20 cross discipline team leader review	Mar. 29, 2016	FDA 0440-0526
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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

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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

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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

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President and Chief Executive Officer, Reproductive Health Technologies Project (Feb. 25, 2016)		
Medical Officer's Review	Jan. 27, 2000	FDA 1266-1280
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Misoprostol 2012 label		FDA 1296-1309
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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

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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

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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

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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

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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

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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

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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

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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 State*s, 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
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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

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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

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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
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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
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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

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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

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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

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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

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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

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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

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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