TIMELINE OF MEDICATION ABORTION IN THE UNITED STATES

Sept. 2000 — FDA approves first abortion pill, Mifeprex, in the U.S. with a restricted distribution system.[1]

Sept. 2007 — HR 3580 signed into law, authorizing FDA to create the Risk Evaluation & Mitigation Strategies (REMS) program.[2]

June 2011 — FDA establishes a REMS program for Mifeprex.[3]

Mar. 2016 — Mifeprex label is updated to align with current medical practices, but REMS are left in place.[4]

Oct. 2017 — Research shows use of telemedicine for medication abortion increases access to earlier abortion care.[5]

Jan. 2018 — Leading medical associations – including AMA, ACOG, & AAFP – call on FDA to lift the REMS.

June 2018 — Research shows benefits of adding Mifeprex to current miscarriage management regimen.

Apr. 2019 — FDA approves generic form of mifepristone; the same REMS restrictions apply.[9]

Aug. 2019 — Studies confirm the safety of dispensing medication abortion via telemedicine.

Sept. 2020 — The 20th anniversary of FDA approval of Mifeprex.

1. Center for Drug Evaluation and Research. "Approval Letter for Mifeprex: NDA 20-687." U.S. Food and Drug Administration. 2000. Washington, DC. https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf
2. U.S. Food and Drug Administration. "Regulatory Information: Food and Drug Administration Amendments Act (FDAAA) of 2007." U.S. Department of Health and Human Services. 2007. Washington, DC. https://www.fda.gov/regulatoryinformation/.htm
3. U.S. Food and Drug Administration. "Initial REMS Approval: NDA 20-687." Danco Laboratories. 2011. New York, NY. http://www.earlyoptionpill.com/wp-content/uploads/2016/02/REMS-March2016.pdf
4. U.S. Food and Drug Administration. "Drug Safety: Mifeprex (mifepristone) Information – FDA Approved Regimen 2016." U.S. Department of Health and Human Services. 2018. Washington, DC. https://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111323.htm
5. Grossman, Daniel, et al. "Safety of Medical Abortion Provided Through Telemedicine Compared With In Person." American Journal of Obstetrics and Gynecology. 2017. Washington, DC. https://journals.lww.com/greenjournal/Fulltext/2017/10000/Safety_of_Medical_Abortion_Provided_Through.16.aspx