

AAF: How Chemical Abortion Harms American Women and Children

2000: Clinton's FDA issued initial safety guidelines for the chemical abortion pill Mifeprex (chemical name, mifepristone).

- The original warning label stated, "If Mifeprex results in incomplete abortion, surgical intervention may be necessary. Prescribers should determine in advance whether they will provide such care themselves or through other providers. Prescribers should also give patients clear instructions of whom to call and what to do in the event of an emergency following administration of Mifeprex."
- The FDA required in-person dispensing by a qualified physician to a woman who was less than 7 weeks pregnant and for prescribers to "report any 'hospitalization, transfusion, or other serious event" to the Population Council, the sponsor of Mifeprex for FDA approval.²

2016: Obama's FDA loosened restrictions on mifepristone use, increasing its danger.

- Allowed chemical abortion pills to be used at-home to terminate pregnancies up to 10 weeks, removed the requirement for in-person follow-up appointments, and allowed healthcare providers other than physicians to prescribe the drug.³⁴
- Changed reporting requirements to only require prescribers to report maternal deaths and removed the requirements to report any hospitalization, blood transfusions, and other serious events caused by the chemical abortion pill.⁵

2021: Biden's FDA eliminated in-person interaction safety protocols.

- Allowed telemedicine prescription of the chemical abortion pill, eliminating in-person requirements necessary for discovering ectopic pregnancies.⁶
- Created a loophole enabling human traffickers to gain access to mail-order chemical abortion pills.⁷

2023: Biden's FDA completely eliminated remaining in-person interaction with pharmacists.

Permanently removed the remaining in-person dispensing requirement for the chemical abortion pill and created a pharmacy certification process for mail-order distribution to patients with a prescription.⁸

For more information, see resources linked below or contact AAF General Counsel Marc Wheat at (202) 780-4848

https://advancingamericanfreedom.com/mifepristone-resource-congressional-staff-report-the-fda-and-ru-486-lowering-the-standard-for-womenshealth/

https://advancingamericanfreedom.com/mifepristone-resource-congressional-hearing-ru-486-demonstrating-a-low-standard-for-womens-health/

https://advancingamericanfreedom.com/mifepristone-resource-judicial-watch-special-report-the-clinton-ru-486-files/

Appeal from the United States District Court for the Northern District of Texas USDC No. 2:22-CV-223, https://www.ca5.uscourts.gov/opinions/pub/23/23-10362-CV1.pdf

² FDA Approval Memorandum to Population Council (Sept. 28, 2000), <u>https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.pdf</u> ³ Rachel K. Jones and Heather D. Boonstra, Guttmacher Institute, "The Public Health Implications of the FDA Update to the Medication Abortion Label,"

https://www.gutmacher.org/article/2016/06/public-health-implications-fda-update-medication-abortion-label
⁴ GAO-18-292 Revised Mifeprex Labeling: Food and Drug Administration Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts. Report to Congressional Requesters. Food and Drug Administration. 2018. p.7. Published March 2018. Accessed November 13, 2020. <u>https://www.gao.gov/assets/700/690914.pdf</u>

⁵ U.S. Food & Drug Admin., Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation (current as of Jan. 4, 2023), available at <u>https://tinyurl.com/4jx2vdrx</u> (last visited Feb. 9, 2023); U.S. Gov't Accountability Off., GAO-18-292, Food and Drug Administration: Information on Mifeprex Labeling Changes and Ongoing Monitoring Efforts (Mar. 2018), <u>https://www.gao.gov/assets/gao-18-292.pdf</u> (report to Congressional Requesters). Pam Belluck, F.D.A. Will Permanently Allow Abortion Pills by Mail, The New York Times, https://www.nytimes.com/2021/12/16/health/abortion-pills-fda.html

⁷ Brief for Charlotte Lozier Institute as Amicus Curiae at 10, FDA v. Alliance for Hippocratic Medicine, 22A902 (2024)

https://www.supremecourt.gov/DocketPDF/22/22A902/263831/20230418122313449_Amicus%20Brief%20of%20Charlotte%20Lozier%20Institute.pdf. ⁸ "Understanding the Practical Implications of the FDA's December 2021 and January 2023 Mifepristone REMS Decisions," The American College of Obstetricians and Gynecologists, https://www.acog.org/news/news-articles/2022/03/understanding-the-practical-implications-of-the-fdas-december-2021-mifepristone-rems-decision