



# UNDERSTANDING ABORTION PILLS

## Q&A on Chemical Abortion

### *What* is chemical abortion?

Chemical abortion is a two-drug process meant to kill and expel a developing child from the womb early in a pregnancy.

Proponents call it “medication abortion,” but that is misleading. “Medication” indicates something to manage a patient’s illness. The first drug—mifepristone (brand name Mifeprex, originally called RU-486)—was not developed as a treatment or cure, but to end a child’s life. Thus “chemical abortion” is the more accurate term.

Misoprostol (original brand name Cytotec) is the second drug needed to complete a chemical abortion. In 1988 Cytotec was approved by the U.S. Food and Drug Administration (“FDA”) to prevent gastric ulcers in patients at high risk of complications from long-term use of non-steroidal anti-inflammatory drugs (NSAIDs). When the *unapproved*, off-label use of Cytotec for abortion and labor induction led to serious complications—including uterine rupture, birth defects and unexpected fetal deaths—its manufacturer and the FDA warned against giving Cytotec to pregnant women.<sup>1</sup>

### *How* does a chemical abortion work?

Mifepristone blocks progesterone, a hormone essential to maintaining pregnancy. This leads to the breakdown of the uterine lining and cuts off the child’s supply of oxygen and nutrients. Mifepristone alone will usually kill the developing child, but his or her remains may not be expelled. This can lead to infection, sepsis, and even the mother’s death. Therefore a second pill—misoprostol—is taken 24 to 48 hours later, to

induce uterine contractions strong enough to expel the dead child and placenta.

Beginning in 2012, Drs. George Delgado and Mary Davenport pioneered the Abortion Reversal Protocol (ARP), giving high doses of progesterone after a woman has taken mifepristone but regrets her decision and has not taken misoprostol. The ARP has a 66% success rate in saving babies’ lives.<sup>2</sup>

### *What* are the risks of chemical abortion?

The FDA’s record of “adverse events” cites 32 women’s deaths from September 2000 through December 2022. Although the FDA stopped requiring reports of non-fatal adverse events in 2016, it reports a total of 4,218 adverse events, including 1,049 hospitalizations (excluding deaths), 604 cases of blood loss requiring transfusions, 97 ectopic pregnancies, and 418 infections (75 of them “severe”).<sup>3</sup> A study of almost 55,000 women receiving abortions in California’s Medicaid program found that the rate of complications requiring treatment after chemical abortions was 5.2%, *four times* higher than for first-trimester aspiration abortions.<sup>4</sup> Complications are likely underreported in the U.S., as many are treated in hospital emergency rooms where physicians may not know about the abortion or not code it as such in medical records.

Scandinavian countries, where national health reporting is more thorough, have found higher complication rates. A Finnish study found a nearly “fourfold higher” incidence of adverse events for chemical abortions compared to surgical abortions, reporting that incidence as 20%. Risk of hemorrhage was nearly *eight times* higher, at 15.6%.<sup>5</sup>

## How has the FDA attempted to protect the lives and health of women using chemical abortion?

According to a lawsuit filed in November 2022 by the Alliance for Hippocratic Medicine and others, the FDA has ignored risks to women, its own regulations, and federal statutes to promote chemical abortion.<sup>6</sup>

The FDA approved mifepristone for abortion in 2000 using an “accelerated” review process that applies only to “certain new drugs that . . . treat[] serious or life-threatening *illnesses* and that provide *meaningful therapeutic benefit to patients over existing treatments.*” Even the pro-abortion Population Council, which holds the U.S. patents for the drug, had objected that pregnancy is not an “illness.”<sup>7</sup> And studies show that chemical abortion does not have a “meaningful therapeutic benefit” over surgical abortion, as its risks are higher and it may even require a follow-up surgical abortion if fetal remains are not completely expelled. The FDA also set no age restrictions, despite the absence of a study establishing the drugs’ safety for minor girls – and it failed to incorporate safeguards used in the clinical trial submitted to justify FDA approval, such as the requirement for an ultrasound exam to confirm gestational age and detect a dangerous ectopic pregnancy.<sup>8</sup>

The FDA did require some safeguards at first. The drugs could be taken only if less than 49 days (7 weeks) had elapsed since the onset of the woman’s last menstrual period. And there had to be three in-person visits to a physician: The first to be counseled on benefits and risks and to take Mifeprex; the second, about two days later, to take misoprostol; and the third, about two weeks later, to confirm a completed abortion.<sup>9</sup>

In 2002, pro-life medical groups filed a Citizen Petition with the FDA, objecting to its inadequate protections for women. The petition was ignored for many years.

In 2016, the FDA finally responded by *rejecting* the petition, and simultaneously *weakening* the safeguards of 2000: Health professionals other than physicians could prescribe the drugs; they could



do so up to 70 days instead of 49; only one in-person visit was required; the dosing regimen was changed, allowing a second dose of misoprostol if the first did not succeed; and only *fatal* “adverse events” needed to be reported. Studies cited by the FDA to justify these changes had not evaluated chemical abortions provided under these conditions.<sup>10</sup>

In 2019, the FDA expanded the availability of mifepristone by authorizing an “abbreviated new drug application” for a generic version of the drug, under the same conditions as for Mifeprex.<sup>11</sup> A new Citizen Petition was filed, objecting to the latest developments.

In April 2021, early in the Biden administration, the FDA said it would not enforce the requirement for an in-person visit during the COVID pandemic. In December it made this decision permanent, allowing consultation and diagnosis by “telemedicine” and distribution of the drugs by mail. In so doing, the FDA rejected most of the latest Citizen Petition, and violated federal statutes barring the use of the U.S. mail, express companies, or other common carriers to ship abortion drugs.<sup>12</sup> These latest changes increase risks to women by removing the opportunity for professional assessment of factors such as the stage of pregnancy and whether it is ectopic, and by preventing meaningful follow-up. They also make abortion drugs more readily exploited by abusers and human traffickers.

## What is the status and importance of this controversy?

Ironically, by rejecting the Citizen Petitions of 2002 and 2019, the FDA has enabled medical groups and physicians to claim standing to sue on behalf of themselves and their female patients.<sup>13</sup> The Alliance for Hippocratic Medicine's case is ongoing, and will be heard by the U.S. Supreme Court in March 2024.<sup>14</sup>

The issues at stake are of great importance. Say Plaintiffs: "The FDA's actions have exposed women and girls to suffering physical pain, medical complications, and emotional trauma—and continue to do so. In addition, these actions harm doctors and their medical associations by causing them to respond to the FDA's failure to protect women and girls. The vital public interest in protecting women, girls, and their doctors from the harmful effects of chemical abortion.... is particularly strong where the unlawful actions likely were undertaken with the unlawful purposes

of bringing into being an illegal market—in this case, a nationwide mail-order abortion industry."<sup>15</sup> In that market, potentially harmful drugs would be mailed directly to girls and women who did not see a medical professional in person and may be injured or killed without public knowledge of the cause.

This case is also important to an Administration pledged to maximize nationwide access to abortion<sup>16</sup>, as chemical abortions now make up a majority of all abortions in the U.S.<sup>17</sup>

For both sides, the stakes are especially high since the Supreme Court's June 2022 decision overturning *Roe v. Wade*.<sup>18</sup> Many states have responded by enacting laws against abortion, which could be explicitly overturned or rendered ineffectual by a federal mandate to allow delivery of abortion drugs through the U.S. Postal Service. This case will help determine whether abortion is promoted throughout the country as a routine form of "medication."

1 G.D. Searle's FDA-approved drug labeling, "Cytotec misoprostol tablets: WARNINGS" (Feb. 2018), [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2018/019268s051lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/019268s051lbl.pdf). All online materials accessed in February 2024.

2 Charlotte Lozier Institute, "Abortion Pill Reversal: A Record of Safety and Efficacy" (Sept. 24, 2021), <https://lozierinstitute.org/abortion-pill-reversal-a-record-of-safety-and-efficacy>; G. Delgado et al., "A case series detailing the successful reversal of the effects of mifepristone using progesterone," *Issues in Law & Medicine* 33 (2018), pp. 21-31, <https://pubmed.ncbi.nlm.nih.gov/30831017/>; P. DeBeasi, "Mifepristone Antagonization with Progesterone to Avert Medication Abortion: A Scoping Review," *The Linacre Quarterly* 90 (2023), pp. 395-407, [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10638961/pdf/10.1177\\_00243639231176592.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10638961/pdf/10.1177_00243639231176592.pdf).

3 FDA, "Mifepristone U.S. Post-Marketing Adverse Events Summary through 12/31/2022," <https://www.fda.gov/media/164331/download>.

4 U. Upadhyay et al., "Incidence of emergency department visits and complications after abortion," *Obstetrics & Gynecology* 125 (2015), pp. 175-183, <https://pubmed.ncbi.nlm.nih.gov/2571183/>; [Incidence of emergency department visits and complications after abortion - PubMed \(nih.gov\)](https://pubmed.ncbi.nlm.nih.gov/2571183/).

5 M. Niinimäki et al., "Immediate Complications After Medical Compared With Surgical Termination of Pregnancy," *Obstetrics & Gynecology* 114 (2009), pp. 795-804, [https://journals.lww.com/greenjournal/Abstract/2009/10000/Immediate\\_Complications\\_After\\_Medical\\_Compared.14.aspx](https://journals.lww.com/greenjournal/Abstract/2009/10000/Immediate_Complications_After_Medical_Compared.14.aspx).

6 See Plaintiffs' Brief in Support of Their Motion for Preliminary Injunction (henceforth "Plaintiffs' Brief"), *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, U.S. District Court for the Northern District of Texas, Amarillo Division (Case No. 2:22-cv-00223-Z), Nov. 18, 2022, <https://adfllegal.org/sites/default/files/2022-11/Alliance-for-Hippocratic-Medicine-v-FDA-2022-11-18-Brief-in-Support-of-MPI.pdf>.

7 Plaintiffs' Brief, pp. 14-15, citing 21 C.F.R. § 314.500 (emphasis added).

8 *Id.*, p. 18.

9 The FDA later incorporated these standards into a Risk Evaluation and

Mitigation Strategy (REMS) to be included in the manufacturer's Medication Guide. See Danco Laboratories, "NDA 20-687 MIFEPREX (mifepristone) Tablets, 200 mg" (2011), [https://www.accessdata.fda.gov/drugsatfda\\_docs/REMS/Mifeprex\\_2011-06-08\\_Full.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/REMS/Mifeprex_2011-06-08_Full.pdf).

10 Plaintiffs' Brief, p. 19. For the 2016 changes to the REMS see [https://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2016/020687Orig1s020RemsR.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf).

11 Plaintiffs' Brief, pp. 21-23.

12 "18 U.S.C. § 1641 prohibits the mailing or delivery by any letter carrier of '[e]very article or thing designed, adapted, or intended for producing abortion' and '[e]very article, instrument, substance, drug, medicine, or thing, which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion'...18 U.S.C. § 1462 forbids the use of 'any express company or other common carrier' to transport chemical abortion drugs 'in interstate or foreign commerce.'" *Id.*, pp. 20-21. For the current (2023) REMS see [https://www.accessdata.fda.gov/drugsatfda\\_docs/rems/Mifepristone\\_2023\\_03\\_23\\_REMS\\_Full.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_REMS_Full.pdf).

13 Plaintiffs' Brief, pp. 8, 11, citing 21 C.F.R. § 10.45.

14 For an ongoing record of developments in the case see Alliance Defending Freedom, "Case Documents," at <https://adfllegal.org/case/alliance-hippocratic-medicine-v-us-food-and-drug-administration>.

15 Plaintiffs' Brief, pp. 24-25.

16 Statement by Vice President Harris on 5th Circuit Decision in *Alliance for Hippocratic Medicine v. FDA*, The White House, Aug. 16, 2023, <https://www.whitehouse.gov/briefing-room/statements-releases/2023/08/16/statement-by-vice-president-harris-on-5th-circuit-decision-in-alliance-for-hippocratic-medicine-v-fda/>.

17 Guttmacher Institute, "Medication Abortion Now Accounts for More Than Half of All U.S. Abortions," Jan. 1, 2022, <https://www.guttmacher.org/node/33429/printable/print>.

18 *Dobbs v. Jackson Women's Health Organization*, 597 U.S. 215 (2022), <https://supreme.justia.com/cases/federal/us/597/19-1392/#tab-opinion-4600822>.

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