

AHM v FDA Fact Sheet

Federal agencies that act lawlessly must be held accountable. The FDA illegally approved dangerous chemical abortion drugs and has evaded its legal responsibility to answer the American people's questions for two decades. The FDA put politics ahead of the health of women and girls when it impermissibly failed to study how dangerous this drug regimen is and when it unlawfully removed every meaningful safeguard that it previously implemented. The FDA should have to answer for the damage it has done to the rule of law and the harm it has caused to countless girls and women.

The FDA approved chemical abortion drugs without basis and has spent decades removing what few safeguards were left.

- When the FDA approved chemical abortion drugs, it did so illegally. It did not comply with the legal requirement to study the danger chemical abortion drugs posed to minors despite approving these drugs for their use by young girls. It also unlawfully relied on flawed and irrelevant studies. And it approved the drug by misusing its authority for expedited approval.
- The FDA has never required an ultrasound prior to a chemical abortion. An ultrasound is the best way to confirm the baby's age and to make sure the pregnancy is not ectopic. Without an ultrasound, the risks involved in a chemical abortion skyrocket.
 - Ectopic pregnancies occur in [1 out of every 50 pregnancies](#).

Timeline:

- 1994: At the urging of the Clinton Administration, French drug manufacturer Roussel Uclaf donates for free the U.S. patents rights for RU-486 to the Population Council.
- 1996: The Population Council submits an approval for chemical abortion drugs with the FDA.
- 2000: The FDA approves the Population Council's application. Chemical abortions are now legal in the United States.
- 2002: ADF clients submit citizen petition to challenge the FDA's approval.
- 2016: The FDA denies citizen petition. On the same day, the FDA extends chemical abortion for babies from 7 weeks' gestation up to 10 weeks' gestation. The FDA changed the drugs' dosage and route of administration, reduced the number of in-person office visits from three to one, expanded who could prescribe and administer chemical abortion drugs beyond medical doctors, and eliminated the requirement for prescribers to report non-lethal complications from chemical abortion drugs.
- 2019: ADF clients submit citizen petition to challenge the FDA's 2016 changes.
- 2021: The FDA announces a temporary removal of the in-person dispensing requirement while the COVID public health emergency remains.
- 2021: The FDA denies citizen petition. On the same day, the FDA decides to permanently remove the in-person dispensing requirement.

