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The History of Abortion Pills and How to Protect Future Access

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Understanding the history of abortion pills in the United States is foundational to effective abortion policymaking today. A new open access book, *Abortion Pills: US History and Politics*, explains the science behind abortion pills, how the U.S. Food and Drug Administration (FDA) and states have regulated abortion pills over time, the medical system's evolving best practices for medication abortion based on ongoing research, and the important role abortion pills are playing in maintaining abortion access after the Supreme Court overturned *Roe v. Wade* in 2022. Policymakers in positions of power that are amenable to safeguarding access to abortion must take action in order to protect medication abortion.

Medication abortion involves two drugs: mifepristone and misoprostol. Patented in France in 1980 and approved by the FDA in 2000, mifepristone blocks the pregnancy-sustaining hormone progesterone. Misoprostol, a common ulcer medication, is taken 24-48 hours later to cause contractions that expel the contents of the uterus. This combination of medications, now used in close to two-thirds of abortions in the United States, is over 95 percent effective and safer than Tylenol. While the two-drug regimen is the gold standard for medication abortion, misoprostol can be used alone with similar rates of efficacy and safety, although more cramping.

When the FDA approved mifepristone in 2000, the agency tightly restricted the medication out of an abundance of caution due to anti-abortion political pressure, including threats from Republican Congressmembers. FDA prohibited retail pharmacies from stocking and dispensing mifepristone, instead requiring mifepristone to be dispensed by physicians registered with the drug distributor Danco Laboratories. FDA approved use of mifepristone for only the first seven weeks after a patient's last menstrual period and required patients to make three office visits to obtain the medications. The FDA required secure manufacturing, receiving and holding areas for the drug, and secure shipping procedures. Due to these burdensome restrictions, most physicians were not able to prescribe mifepristone, and abortion access did not significantly expand after FDA approval, despite the hopes of abortion pill advocates.

As medical practice evolved over the years and research showed that a lower dosage than the FDA's original protocol was safer and just as effective, clinicians shifted to the lower dosage. But several anti-abortion states required physicians to use the higher dose, so the drug sponsor Danco Laboratories returned to the FDA in 2015 requesting they change the recommended dosage. In 2016, FDA made several adjustments to its regulation of mifepristone, including allowing any qualified clinicians to prescribe the medication, approving use of the medication through 10 weeks of pregnancy, and lowering the recommended dosage. In 2019, FDA approved a generic form of mifepristone, made by GenBioPro.

During the COVID-19 pandemic, FDA removed in-person dispensing requirements on all drugs except mifepristone. The American College of Obstetricians and Gynecologists filed a lawsuit against the Trump

administration requesting removal of the in-person dispensing requirement. A Maryland federal district court granted that request in July 2020, for the first time allowing patients to access the medication by mail after a telehealth consultation.

The Trump administration appealed that decision twice to the Supreme Court, finally prevailing in January 2021 right before Trump left office. After his inauguration, President Joseph Biden directed the FDA to consider lifting the in-person dispensing requirement for the duration of the pandemic, which they did in April 2021. He then directed them to consider permanently removing this requirement, which they did in December 2021. FDA also allowed pharmacies to dispense the medication for the first time, although requiring that they be certified to do so.

As a result of the permanent removal of the in-person dispensing requirement, telehealth abortion clinics proliferated across the country, expanding access to people living in rural areas and making abortion more affordable. Whereas clinic-based medication abortion costs on average $550, telehealth abortion is available for $150 or less. Today, telehealth abortion makes up 20 percent of all abortions.

However, many states have passed laws restricting telehealth abortion, including only allowing physicians to prescribe mifepristone, requiring in-person dispensing and banning mailing of abortion pills. Lawsuits in several states, including North Carolina, West Virginia, andVirginia, are challenging state restrictions on abortion pills that are counter to FDA regulations, arguing that these restrictions are preempted by federal law and medically unnecessary. A lawsuit in Hawaii is seeking a court order requiring the FDA to entirely remove remaining restrictions on the mifepristone, including the requirement that only certified providers may dispense the medication.

Meanwhile, eight states have passed abortion provider shield laws allowing clinicians within their borders to treat patients located outside of their states. These laws protect clinicians from investigation, criminal prosecution and civil liability for providing reproductive health services protected by their states' laws. Multiple telehealth abortion providers located in these states are now serving patients in all 50 states, including states that ban clinicians within their borders from providing abortions. In December 2024, Texas attorney general Ken Paxton filed a lawsuit against a New York doctor who provided abortion pills to a woman in Texas. Then a Louisiana grand jury indicted the same doctor. New York attorney general Leticia James and Governor Kathy Hochul have pledged to protect the doctor from these lawsuits and defend the state's telemedicine provider shield law.

Anti-abortion activists and politicians have tried to roll back FDA approval of mifepristone through the courts. In November 2022, a group of anti-abortion doctors and a dentist filed a lawsuit in Amarillo, Texas, asking the court to ban mifepristone nationwide. In June 2024, the U.S. Supreme Court ruled the plaintiffs lacked standing and dismissed the lawsuit, although the Texas lower court has now granted a motion to intervene filed by three states—Kansas, Missouri and Idaho. Meanwhile, the Heritage Foundation's Project 2025 policy agenda calls on the Trump administration to roll back FDA approval of mifepristone, either to 2016, thereby eliminating telehealth abortion, or altogether removing mifepristone from the market nationwide. This agenda also calls on the Department of Justice to enforce an unprecedented interpretation of a nineteenth century anti-obscenity law called The Comstock Act to criminally prosecute anyone who mails abortion pills.

State policymakers can take several steps to expand medication abortion access, including:

- removal of restrictions on telemedicine abortion such as medically unnecessary ultrasounds,
- allowing all qualified clinicians to prescribe abortion pills,
- passing telemedicine provider shield laws so clinicians can serve patients wherever they are located,
- adopting digital privacy measures to protect clinicians' and patients' confidential information, expanding full insurance coverage for telemedicine abortion services, and
- prohibiting "abortion pill reversal," an unproven, experimental and potentially dangerous practice promoted by unregulated anti-abortion pregnancy centers (also known as "crisis pregnancy centers").
- expanding full insurance coverage for telemedicine abortion services.

States can also require public university health centers to provide medication abortion, as California and Massachusetts have done, and stockpile abortion medications in case the Trump administration restricts access to mifepristone. Furthermore, state policymakers should take steps to ensure that no person is criminalized for self-managing an abortion, and that prosecutors do not misapply criminal laws to punish someone for the outcomes of their pregnancy. If the Trump administration reverses or rolls back FDA approval of mifepristone, states can support clinicians in offering misoprostol alone, which is also very effective in ending pregnancy. These measures will preserve and expand access to abortion at this critical moment when federal attacks on abortion are impacting pregnant people in half of the states in the country.

Read more in Carrie Baker, *Abortion Pills: US History and Politics* (Amherst College Press, 2024).