The Network for Public Health Law

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REPRODUCTIVE HEALTH AND EQUITY

FACT SHEET

Medication Abortion: A Primer

Introduction

The majority of abortions in the U.S. are medical abortions, a safe and effective method for early pregnancy, initiated by patients using a medication regimen. Medical abortions, also called chemical abortions or abortion pills, are one of the new battlegrounds on which political and legal wars are being fought.

The Regimen

In the United States, the two-drug regimen for medication abortion consists of mifepristone and misoprostol. One 200mg oral dose of mifepristone is followed by 800µg of misoprostol, either buccally (in the cheek) or vaginally. Mifepristone, originally marketed under the brand name Mifeprex, blocks progesterone, a hormone essential for maintaining the pregnancy, signaling to the body that the pregnancy is no longer viable. Misoprostol is taken 24-48 hours after mifepristone and causes the expulsion of the products of conception like an early miscarriage. Taken together, the medications are more than 95% effective at ending the pregnancy, and severe adverse events are uncommon. Mifepristone is the subject of many legal challenges. Notably, mifepristone is also used to treat Cushing's Syndrome and misoprostol is used to prevent ulcers.

2000 Approval

Mifeprex was first approved by the Food and Drug Administration in September 2000 after four years of back and forth between the FDA and the drug sponsor. The original approval was for use up to 49 days from a missed period. (In 2016, Mifeprex was approved for use up to 70 days from a missed period). The FDA required that the medication "be provided by or under the supervision of a physician" who met a list of qualifications. The FDA also imposed restrictions on the distribution of the medication.

2011 Risk Evaluation and Mitigation Strategy

In 2007, the Food, Drug and Cosmetic Act was amended to permit the FDA to require certain drugs submit a "risk evaluation and mitigation strategy" ("REMS") if "necessary to ensure that the benefits of the drug outweigh the risks of the drug." The REMS for Mifeprex was approved in 2011. The REMS required that only physicians who were specifically certified by Mifeprex's manufacturer could dispense the drug. Further, the medication

could only be dispensed "in certain health care settings," and noted that the medication would not be dispensed from retail pharmacies.

2021 Enforcement Discretion and 2023 REMS

A generic for mifepristone was approved in 2019. In 2020, the COVID pandemic changed the way many of those living in the U.S. received medical care. In 2021, the FDA noted that it would "exercise enforcement discretion during the COVID-19 PHE with respect to the dispensing of mifepristone through the mail either by or under the supervision of a certified prescriber, or through a mail-order pharmacy when such dispensing is done under the supervision of a certified prescriber." In 2023, the in-person dispensing requirement was removed from the REMS, allowing the medication to be dispensed not only in clinics but at certified retail pharmacies and by mail.

Legal Challenges

There are currently four federal court cases involving medication abortion. For an introduction to the *Alliance for Hippocratic Medicine v. FDA* and a thorough analysis of the preemption issues at play when states attempt to regulate FDA-approved medication, please read the Network's Medication Abortion: A Federal-State Legal Tug-of-War.

Oral argument has been heard in both *Alliance for Hippocratic Medicine v. FDA* and *State of Washington v. FDA*. In *Alliance for Hippocratic Medicine*, the plaintiffs aim to completely remove mifepristone from the market. In *State of Washington v. FDA*, a coalition of Attorneys General aim to remove all restrictions on mifepristone, making it more accessible.

The Network is following all reproductive health-related legal challenges and will provide updates and analyses as decisions are released.

Misoprostol-only Protocol: A Path Forward

If the court in Alliance for Hippocratic Medicine rules against the FDA, there could be a nationwide injunction that removes mifepristone from the market entirely. While a decision in favor of the plaintiffs in Alliance for Hippocratic Medicine would likely result in further limiting access to reproductive health care in the U.S., providers have had time to find alternate means to provide their patients with medication abortions should mifepristone be taken off the market. Misoprostol-only abortions are common globally and the World Health Organization provides a misoprostol-only protocol. Studies have put the efficacy of misoprostol-only abortions between 78% and 98%. Severe adverse side effects are uncommon. Recently, the Society of Family Planning has endorsed a new protocol for misoprostol-only medication abortions in the United States should mifepristone no longer be available. The protocol emphasizes patient education and access in times of continuing uncertainty.

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