



## Medication Abortion – Just the Facts

September 2021

During **Abortion Justice Week of Action (Sept. 27 – Oct.1)**, we are uplifting the issue of medication abortion and restrictive REMS, especially when access to abortion care at women’s health clinics is threatened across the country and prohibited in Texas now. September 27, 2021, is the 21st anniversary of the U.S. Food and Drug Administration (FDA)’s approval of the abortion pill mifepristone.

The use of mifepristone has increased significantly over the years. In 2017, 40 percent of all recorded abortions and 60 percent of abortions performed up to 10 weeks of gestations – though the rate is likely higher due to self-managed abortions which are not recorded. Most women seeking abortions now use this safe and effective medication.

Former NOW president, Ellie Smeal, was instrumental in bringing the drug mifepristone/misoprostol – then referred to as RU-486, to the United States. NOW testified at the FDA’s Advisory Committee meetings in support of agency approval in the late 1990s. Learn more about NOW’s involvement in the FDA’s approval of mifepristone, [here](#).

Reproductive rights advocates and the Biden Administration are pushing back against efforts to limit access to medication abortion (mifepristone). During the early months of the pandemic, abortion rights opponents tried to prevent women from accessing medication abortion via telehealth (using telecommunications for patients and providers in different locations) when a visit to a doctor’s office was difficult or impossible. Once President Biden took office and lawsuits were brought, administrative efforts were made to improve access and re-evaluate unnecessary restrictions – Risk Evaluation and Mitigation Strategies (REMS) on abortion medication.

### **Why is the FDA reviewing the restrictions on medication abortion?**

The FDA approved mifepristone in 2000 and then put the REMS into effect in 2011, requiring reviewal to determine whether it is medically necessary. In early May 2021, the American Civil Liberties and the Department of Justice filed a joint status report as part of the ongoing litigation in *Chelius v. Becerra*. This case challenges that the REMS create an undue burden on

women seeking abortions and violate the Administrative Procedure Act since there is no scientific evidence to prove why the REMS is needed for mifepristone.

The FDA had been ordered to suspend the in-person requirements in July 2020, when a federal court ruled in the *American College of Obstetricians and Gynecologists v. FDA* that the in-person requirements were dangerous during the COVID-19 pandemic. The Trump Administration successfully petitioned the Supreme Court to reinstate the rule several months later. On April 12, 2021, the FDA announced that they would not enforce the in-person dispensing requirement or the requirement for an in-person signature on the REMS Patient Agreement form for mifepristone for the duration of the COVID-19 public health emergency.

### **Why does it matter?**

Medication abortion must be made widely accessible to move forward in the fight for reproductive justice, especially as it becomes more difficult for women to access in-person care at abortion clinics in a convenient and timely manner. Suspension of these in-person requirements in the REMS allows medication abortion to be prescribed via telehealth and mailed directly to women seeking abortions, making access to abortion care available to more. Women often must travel hours to go to an abortion clinic to receive the medication that they then take at home, which puts on an undue travel burden on them and disproportionately affects women of color and women impacted by poverty.

Access to this type of reproductive care has been challenging during the COVID-19 pandemic, with travel restrictions and the risk of contracting COVID-19, exacerbated by anti-abortion rights protesters who have gathered at abortion clinics, reportedly, to attempt to spread the COVID-19. Legislation in many states has remained staunchly anti-abortion. Over 40 bills in 23 states have been introduced that put some restrictions on medication abortion. Including one in Texas that restricts medication abortion after 49 days, rather than the FDA's 70 days, essentially banning it. Several states, like Oklahoma, have introduced REMS-like requirements that healthcare providers have certification to distribute medication abortion. Only seven states have moved forward in unrestricted access to medication abortion.

Anti-abortion activists have also circulated false statistics about medication abortion, now taking a "pro-science" approach to sway both the FDA and the public in their favor. They use out-of-context factual studies to claim that medication abortion is 4x more harmful than procedures, harms women physically and can lead to infertility, and prescribing it through telehealth causes psychological harm to women from making them "perform their own abortions."

### **What is the status?**

Scientists, researchers, and medical professionals have been sending evidence to the FDA in favor of removing the REMS, and the science speaks for itself. Data shows that prescribing mifepristone through telehealth does not lead to poorer results.

- A 2020 [U.K. study](#) shows evidence that telehealth medication abortion is just as safe and effective as the traditional in-person medication abortion model.
- Data from [a study](#) conducted revealed that among 110 medication abortions, 95 percent were completed successfully at home.

This crucial evidence proves that the decision to first enact the REMS in 2011 was based on arbitrary reasons and caused more harm than good regarding access to abortion care. Even with the FDA's decision to ease its enforcement of the REMS, 19 states have banned the use of telehealth, five states have banned medication abortion, and an additional fifteen states have in-person requirements for dispensing the drug. Nevertheless, this prolonged suspension of the REMS can provide the necessary data to the FDA to prove that mifepristone is perfectly safe to distribute through telehealth, mail, and pharmacies.

### **What happens next?**

The FDA has until December 1, 2021, to decide on the REMS.

Three potential scenarios could result -

- First, the FDA could lift the ban entirely, achieving more access to abortion on the federal level.
- Second, they could permanently remove the in-person requirements while keeping the one that makes it necessary for healthcare providers to become certified to administer the drug.
  - Though medication abortion would be widely available through telehealth and at pharmacies, women would still need to find an accredited provider to prescribe it to them, maintaining a hindrance to its accessibility.
- Lastly, the FDA would not lift the ban at all, which would be a considerable loss for reproductive rights.

With the FDA remaining tightlipped about their investigation, we will remain unsure of their decision until it is released. In the meantime, some progress has been made in Congress. Representatives Carolyn Maloney, Diana DeGette, Barbara Lee, and Ayanna Pressley introduced a new House resolution (H.Res. 589) calling for policies related to medication abortion to be rooted in science and maintain equitable access to prevent bias from getting in the way. More than 70 Democrats joined as cosponsors, and over 40 reproductive rights, reproductive justice, legal advocacy, and medical organizations have endorsed it.

### **What are resources for women seeking a medication abortion?**

Planned Parenthood offers information on booking an appointment to access medication abortion both through in-person appointments and through telehealth. It also provides useful statistics on mifepristone, what it is, and how it works. Other sources explain how to take it,

advantages and disadvantages and further considerations, side-effects, costs, and how to talk to a healthcare provider about medication abortion.

[The Abortion Pill | Get the Facts About Medication Abortion \(plannedparenthood.org\)](https://www.plannedparenthood.org/learn/abortion/medication-abortion)

[21 Years After FDA Approval, Abortion Pill Is More Critical Than Ever - Ms. Magazine \(msmagazine.com\)](https://www.msmagazine.com/21-years-after-fda-approval-abortion-pill-is-more-critical-than-ever/)

Expanding Medication Abortion Access (EMAA Project), [emaaproject.org](https://emaaproject.org)

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