

Bad Medicine: The Government's Restriction on Medication Abortion

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Governmental attacks on women's reproductive health are escalating, putting ideology above science. But the Food and Drug Administration (FDA) has an opportunity to help remedy this dire situation, and to enable – rather than impede – people's access to essential health care.*

In 2011, the FDA issued a restriction on medication abortion, placing mifepristone under the Risk Evaluation and Mitigation Strategy (REMS). This restriction greatly reduced access to medication abortion by requiring people to acquire mifepristone in person at one of a limited number of health facilities – even though they could safely take the medication at home. Classifying mifepristone as a REMS medication fails the FDA's mission to protect public health by ensuring the safety, efficacy, and security of medication;¹ rather, the REMS restriction is **bad medicine**. It creates unnecessary barriers to medication abortion, creating an undue burden on people's reproductive rights by limiting their options for obtaining an abortion and protecting their reproductive health. Furthermore, the REMS is not supported by the body of evidence proving the safety and efficacy of medication abortion care.

Especially now, during the COVID-19 pandemic, people have an urgent need for high-quality, affordable health care in the safety of their own homes that doesn't force them to expose themselves to unnecessary risk. An ongoing lawsuit has temporarily blocked the FDA from enforcing the REMS requirement that people obtain the medication in person at a hospital, medical office, or clinic, based on the unique circumstances of the

* Note on language describing identities: The National Partnership for Women & Families strives to use language that is inclusive of people's self-described intersectional identities, recognizing that there is great diversity in the terms people use to describe themselves. We use "Black" to include African-American, and "Latino" to include Hispanics of all races, except where the cited research uses specific terminology (for example, "non-Hispanic white"). Similarly, we recognize and respect that pregnant people and people seeking abortion care have a range of gendered identities, and do not always identify as women. In recognition of the diversity of identities, this report uses both gendered terms such as "women" and gender-neutral terms such as "people" and "pregnant people."

pandemic.[†] While this is a welcome development, it is insufficient. It is past time for the FDA to permanently remove the REMS on medication abortion.

Background

All people deserve access to abortion – no matter their age, race, gender, sexual orientation, income or immigration status – because every person must be able to make their own decisions about their health, their families, their lives, and their futures. This right to choose to have an abortion cannot be just on paper. People must have actual access to the full range of abortion options, including medication abortion, which enables them to exercise their rights in the privacy and safety of their own homes and, during the pandemic, mitigates the added risk of exposure to COVID-19. During these challenging times of racial reckoning, economic turmoil, and public health crisis, protecting access to high-quality reproductive health care is more critical than ever. The last thing our government should be doing is making it harder for people to stay healthy by promoting **bad medicine**.

Laws and regulations that obstruct access to high-quality care promote **bad medicine**. According to the National Academy of Medicine, high-quality care “meets [the patient’s] needs and is based on the best scientific knowledge.”² It is the right care at the right time in the right setting for the individual patient.³ High-quality care aligns with the patient’s values, preferences, and needs, and should be accessible and affordable. In contrast, bad medicine restrictions undermine high-quality care. These restrictions deny people access to care that meets their needs and preferences. They disregard scientific evidence, make care harder to provide, and increase health inequities.

WHAT IS THE FDA’S REMS PROGRAM?

The mission of the Food and Drug Administration (FDA) is to “protect the public health by ensuring the safety, efficacy and security of ... drugs.”⁴ In 2007, the FDA established the Risk Evaluation and Mitigation Strategy (REMS), a drug safety program it can impose on certain medications “that are known or suspected to cause serious adverse effects that cannot be mitigated simply by the label instructions.”⁵

[†] On August 13, 2020, the U.S. Court of Appeals for the Fourth Circuit denied the FDA’s appeal to stay the injunction while litigation continues. https://www.aclu.org/sites/default/files/field_document/fourth_circuit_order_denying_stay_motion_8.13.20_0.pdf. The FDA has appealed the injunction to the Supreme Court, but as of publication of this paper, the Court has not yet granted certiorari. https://www.supremecourt.gov/DocketPDF/20/20A34/151289/20200826115042080_20A-%20FDA%20v.%20ACOG%20Stay%20Application%20FINAL%20a.pdf

REMS is typically reserved for drugs with significant safety concerns, where there may be a particular risk associated with the medication, and additional interventions are necessary to ensure safe use.⁶ It is often used in conjunction with black box warnings.⁷ Examples of medications that use REMS include antipsychotics, opioids, and some drugs used to treat cancer, type-2 diabetes, and hypertension.⁸

A REMS classification may include a number of requirements for medications that pose a serious risk of abuse or overdose, such as specific medication guides and patient package inserts, special packaging, and safe disposal regimens.⁹ As a part of the REMS, the FDA may also require certain “elements to assure safe use” (ETASU), which can include any one or a combination of the following:

- Prescribing providers have particular training or expertise, or are specially certified.
- Dispensing pharmacies, practitioners, or health care settings are specially certified.
- The medication is dispensed only in certain health care settings.
- Patients must have evidence or other documentation of safe use conditions, such as laboratory test results.
- Individual patients are monitored.
- Individual patients are enrolled in a registry.¹⁰

Even so, by law, REMS must “not be unduly burdensome on patient access to the drug, considering in particular ... patients who have difficulty accessing health care (such as patients in rural or medically underserved areas).”¹¹

In 2011 the FDA classified mifepristone, one of the pills used for medication abortion, under their REMS program and imposed additional “elements to assure safe use” (ETASU; see sidebar). Mifepristone’s REMS requires, among other things, that individual prescribing providers be certified in the mifepristone REMS program (administered by the FDA) and that the pill be distributed only in a health care facility by or under the supervision of a certified prescriber.¹²

What Is Medication Abortion?

Medication abortion is an FDA-approved option for ending a pregnancy up to 10 weeks of gestation.¹³ It generally involves the use of two separate medications, taken in pill form: mifepristone, available under the brand name Mifeprex, and misoprostol. The

mifepristone is taken first to block progesterone, a hormone essential to the development of a pregnancy. Between 24 and 48 hours later, the misoprostol is taken to empty the uterus in a process similar to an early miscarriage. Follow-up with the provider is done seven to 14 days later,¹⁴ and may be over the phone.¹⁵

Evidence shows that medication abortion is extremely safe and effective. A 2018 National Academies of Science, Engineering, and Medicine review of medication abortion care found an overall effectiveness rate of 96.7 percent for gestations up to nine weeks.¹⁶ Other research shows that serious complications requiring hospitalization or transfusion occur in less than 0.4 percent of patients.¹⁷ In addition to its proven safety, medication abortion care also offers people more control and privacy in the process.¹⁸

Given these benefits, it makes sense that an increasing proportion of people choosing abortion care select medication abortion. Between 2014 and 2017, medication abortions as a share of all abortions rose by more than a third, from 29 percent to nearly 40 percent.¹⁹

Because of its record of safety, efficacy, and cost-effectiveness, and its importance in overall reproductive health, the World Health Organization has included medication abortion on its list of essential medicines.²⁰ Yet the REMS classification of mifepristone places a host of unnecessary and arbitrary obstacles to providing and obtaining this form of safe abortion care, impeding access without any medical benefit.²¹

Why Is the Medication Abortion REMS Bad Medicine?

Given medication abortion's indisputable safety record, there is no evidence-based reason for the FDA to impose the REMS on it. Continued use of the REMS for medication abortion not only ignores science, but also sacrifices the health, well-being, and autonomy of women.

REMS on Medication Abortion Denies People Access to Care that Meets Their Needs and Preferences.

For the vast majority of people seeking abortion care early in pregnancy, medication abortion is a safe and effective option and should be available without arbitrary barriers.[‡] Many people choose medication abortion over an in-clinic abortion procedure because it provides more control and privacy.²² Those who access this form of care

[‡] For a small fraction of people, medication abortion is contraindicated, and a clinical abortion procedure is a safer option. This may include people who have ectopic pregnancies, adrenal problems, are taking long-term corticosteroid, are allergic to the medication, have bleeding problems or are taking blood-thinning medication, have inherited porphyria, or have an intrauterine device (IUD). <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex>

report that they value being able to control the timing and place where they take the medication abortion pills, including taking them at home, where they can be supported by loved ones.²³ This can be particularly important for certain groups of people who want to minimize the level of clinical intervention or number of interactions with the health care system. For example, people of color – who have faced racism and trauma by the medical establishment through reproductive coercion, forced sterilization, experimentation, and other forms of discrimination throughout history²⁴ – may want to limit their interaction with medical institutions and retain control over their bodies. Sexual assault survivors and other people with histories of physical trauma may also prefer medication abortion for similar reasons related to bodily autonomy.²⁵

The REMS label on mifepristone also limits people’s ability to go to the provider of their choice and can force people to travel to a provider much farther away. As discussed below, the REMS has reduced the number of practitioners able or willing to provide medication abortion, leaving many people – especially those living in rural areas or places with few or no abortion providers – without ready access to this form of care.²⁶ Increasing the distance necessary to travel to get an abortion is correlated with a decrease in people actually being able to get care.²⁷ Even if someone is ultimately able to get an abortion, longer travel and the resulting delays can push people to get abortion care later than they wanted,²⁸ including in some cases, past the gestational age for which medication abortion is available.²⁹ Those people would then be required to undergo a clinical abortion procedure they may not have wanted.

Delays in care, being forced into certain procedures, and losing access to trusted providers is the exact opposite of high-quality care. These circumstances could also bring up past traumas for people previously harmed by the health care system. No matter someone’s reason for choosing medication abortion, they should not be denied access to their preferred method. The medication abortion REMS only adds to the obstacles people must overcome to get the care they need. For some, it blocks their ability to access abortion altogether.

Evidence Does Not Support REMS on Medication Abortion.

REMS is generally required for medications where the potential risks require added intervention to ensure that the medication’s benefits outweigh any “serious adverse experience,” including death, risk of death, or hospitalization.³⁰ However, mifepristone does not fit that criteria. The overwhelming weight of evidence clearly shows that mifepristone is a safe medication. There are many other commonly used medications with higher rates of adverse reaction that are not subject to REMS. For example, acetaminophen (brand name Tylenol) has a much higher rate of adverse reactions – yet

it is sold without a prescription, let alone a REMS designation.³¹ In fact, the FDA approved mifepristone (when sold under the brand name Korlym) for the treatment of Cushing's syndrome without a REMS.³² Therefore, not only does the FDA's REMS classification ignore established science, it also contradicts the FDA's own prior decision.

The evidence of mifepristone's safety – and the irrationality of subjecting it to REMS – is clear. Leading health care professional organizations agree that applying REMS to medication abortion is unnecessary and burdensome. In 2017, the Mifeprex REMS Study Group, composed of prominent researchers in the field, recommended that the REMS be “expeditiously withdrawn” due to the lack of “any demonstrated or even reasonably likely advantage” in safety.³³ In 2018, the American College of Obstetricians and Gynecologists (ACOG) called the REMS outdated and asserted that it “substantially limit[s] access” to medication abortion.³⁴ ACOG, along with professional organizations such as the American Public Health Association, the Society of Family Planning, and other medical and scientific experts have asked the FDA to remove the medication abortion REMS.³⁵ Other leading medical organizations such as the American Academy of Family Physicians and the American Medical Association have also adopted positions supporting removal of the REMS.³⁶ Even Dr. Jane Henney, the FDA commissioner who led the agency when mifepristone was first approved in 2000, has publicly called on the FDA to re-evaluate the mifepristone REMS. She recently stated that the “current restricted distribution system is not aligned with the limited risks that are now known to be posed by the drug,”³⁷ and that the REMS classification is therefore burdensome.³⁸

The science is clear and conclusive: Mifepristone is a safe medication that does not merit a REMS label.

REMS on Medication Abortion Unnecessarily Makes Care Harder to Provide.

Medication abortion can be safely offered in a variety of settings and by a range of health care providers,³⁹ yet the REMS classification imposes unnecessary obstacles that make it much more challenging for providers to offer this high-quality form of reproductive health care. Unlike with most other medications, people seeking medication abortion cannot pick up mifepristone from a retail pharmacy; instead, they can only obtain it from a “certified medical provider.”⁴⁰ Out of the 16 medications that have an in-person distribution requirement,⁴¹ mifepristone is the only one the FDA requires to be picked up in a health care setting but also allows self-administration at home.⁴²

In order to become a certified provider under the REMS and be able to stock and distribute mifepristone, an individual provider must register with the drug manufacturer,⁴³ a process that can be difficult and even unachievable for some. First,

some providers must navigate administrative opposition to abortion at their hospital or medical clinic, and the institution may withhold approval to register or to stock the medication.⁴⁴ Second, the process of certification, contracting, and ordering that is required to provide mifepristone is far more complicated than for the vast majority of medications.⁴⁵ Third, due to violence against and harassment of abortion providers,⁴⁶ some would-be providers are uncomfortable with having their names on the drug manufacturer's list of medication abortion providers that may be made public.⁴⁷ Additionally, 33 states have exploited the REMS classification to limit the pool of would-be prescribers even further by enacting laws that allow only licensed physicians – and not advanced practice clinicians like nurse practitioners – to dispense mifepristone.⁴⁸

The REMS classification has a direct negative impact on providers' ability to effectively care for their patients who seek abortion. According to a recent survey of obstetricians-gynecologists, nearly three out of four had patients in the previous year who sought abortion services, but fewer than one out of four were able to provide the care.⁴⁹ Of those not providing abortion care, nearly 30 percent stated they would prescribe medication abortion if the REMS restrictions were changed.⁵⁰

By severely reducing the number and types of providers able to dispense medication abortion, the REMS classification substantially reduces access to a safe, essential medication.

REMS on Medication Abortion Increases Health Inequities Because It Disproportionately Harms People with Low-Incomes and Communities of Color.

By law, REMS must “not be unduly burdensome on patient access to the drug, considering in particular ... patients who have difficulty accessing health care (such as patients in rural or medically underserved areas).”⁵¹ Unfortunately, as is the case with other facets of health care, people with low incomes and Black, Indigenous, and other People of Color (BIPOC) communities bear the brunt of bad medicine policies – including the REMS on medication abortion.

Having a low income and the experience of being a BIPOC person in this country are two factors that independently undermine one's health, both in terms of one's exposure to health risks and access to health and health care resources. Experiencing them together multiplies their negative impact. For women and LGBTQI people, their intersectional identities in the current socioeconomic cultural context makes this even worse. The challenges they face to accessing high-quality health care are even greater when they seek abortion care. What's worse, these barriers perpetuate a cycle of oppression and marginalization. People with low incomes who have insurance coverage get it through Medicaid, which is banned from covering abortions by the Hyde

amendment, thus forcing people to pay for this service from their own pocket.⁵² The care itself can be incredibly cost-prohibitive,⁵³ and when considering additional costs such as transportation, child care, and hotel and other travel costs, people can then be forced to choose between paying for rent or food and accessing abortion care.⁵⁴

While the largest group of people enrolled in Medicaid are non-Hispanic white,⁵⁵ because of rampant racial and ethnic income inequality resulting from structural racism and discrimination,⁵⁶ BIPOC people are much more likely to access health insurance through Medicaid: Roughly one out of three Black, Hispanic, and American Indian/Alaska Native people, compared to just under one in seven white people, receive their health insurance through Medicaid.⁵⁷ This structural discrimination makes abortion access especially difficult for BIPOC people. Being denied an abortion also has long term socioeconomic impacts, as studies have shown that women who are denied an abortion are more likely to fall into poverty than are women who were able to obtain the care they needed,⁵⁸ perpetuating the cycle of poverty. This discriminatory impact of abortion restrictions is clearly a substantial burden on people's access that further negates the validity of the REMS classification on medication abortion.

The Heightened Urgency of Medication Abortion Access During the COVID-19 Pandemic

Access to medication abortion is even more necessary during the unprecedented COVID-19 public health crisis. In a time when social distancing is the best way to stop the spread of this deadly disease, people should not be forced to leave their homes and unnecessarily expose themselves or others to the virus when safer health care options can be made available. Research shows that medication abortion via telemedicine is as safe and effective as an in-person visit and could even allow patients to access care earlier in their pregnancies.⁵⁹

In the initial months of the pandemic, many states used the COVID-19 crisis to further restrict abortion access. Given the public health emergency and the resulting shortages of personal protective equipment for providers, 39 states banned medical procedures that were not considered "necessary."⁶⁰ Some states, such as Texas and Ohio, excluded abortion from their lists of "necessary procedures,"⁶¹ despite the fact that abortion care is both essential and time-sensitive.

Simultaneously, more people began trying to access abortion care via telemedicine, as compared to prior to the pandemic, both because of confusion about and barriers to accessing in-clinic care, and in order to minimize the need to leave their homes and potentially exposing themselves to the virus.⁶² In a span of three weeks from late March into April 2020, more than 3,300 people in the United States requested help from Aid

Access, a European organization that helps pregnant people access medication abortion by mail, increasing by more than a quarter from pre-COVID levels.⁶³ The increase was greater in states that had either high COVID-19 rates or more strict COVID-related restrictions on in-clinic abortion access.⁶⁴ And TelAbortion, a pilot study in the U.S. that allows people seeking an abortion to have video consultations with certified providers and then receive the medication abortion pills by mail, found about twice as many people had abortions through the program in March and April compared to January and February 2020.⁶⁵

In its early response to the COVID-19 crisis, the FDA took the proactive step of eliminating certain REMS requirements for other medications, namely those that require laboratory testing or imaging studies,⁶⁶ but it left in place in-person distribution requirements, meaning people still had to go into health care facilities for abortion care.

This spurred renewed calls to remove the REMS from mifepristone. In an April 2020 letter to the FDA, more than 550 organizations, health care providers, and researchers called on the FDA to lift the REMS on mifepristone, specifically the in-person distribution requirement, stating that “it is imperative that patients, especially those who are vulnerable or who live in rural areas, can use telehealth and mail-order pharmacy services to access needed health care without unnecessary restrictions, particularly for medications that do not pose a risk of abuse or overdose.”⁶⁷

Fortunately, in July, a federal court temporarily blocked the FDA from enforcing the REMS requirement that patients acquire mifepristone in person at a health facility, but only for the duration of the pandemic.⁶⁸ The lawsuit, brought by the American Civil Liberties Union on behalf of a coalition of medical experts and reproductive justice advocates led by ACOG, successfully argued that the REMS requirement unnecessarily puts patients at risk during the pandemic, and that the FDA was inappropriately singling out abortion care.⁶⁹

While the temporary ban on REMS enforcement is a welcome development, it is just a stopgap measure. The FDA must permanently eliminate the REMS classification of mifepristone as a foundational step toward ensuring that everyone has access to all forms of abortion care.

Conclusion

The REMS restriction on medication abortion is bad medicine and must be permanently eliminated. It has no basis in science. It makes abortion care harder to access because it unnecessarily requires mifepristone to be dispensed in person by a medical provider – rather than at a retail pharmacy or by mail. Moreover, it severely limits the number of

practitioners able to prescribe medication abortion, which renders many health care providers unable to meet their patient’s needs and preferences. It disproportionately burdens people who already have to struggle with deep health and health care inequities – in abortion and reproductive health, and beyond – particularly BIPOC people and those with low incomes. While the temporary lifting of this restriction during the COVID-19 pandemic is bringing much-needed relief to those seeking medication abortion now, it is not enough. The FDA must take swift action to permanently remove the REMS from mifepristone.

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² Institute of Medicine. *Crossing the Quality Chasm: A New Health System for the 21st Century* (Washington, D.C.: National Academies Press, 2001), <http://doi.org/10.17226/10027>

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