

Improve Abortion Access by Abolishing an Unnecessary FDA Restriction

Carole Joffe, University of California, San Francisco

Abortion access, extremely difficult for many before the coming of COVID-19, has become exponentially more challenging because of the pandemic. This is both because of legitimate public health concerns — cautions about the travel that many abortion patients (and providers) must undertake and concerns about staff 's health — as well as the ever-present abortion politics which have led a number of red state governors to mandate the closing of abortion services. But one way of improving access for abortion patients, who are disproportionately low-income women of color, is to loosen restrictions on the provision of medication abortion.

Medication abortion, which involves two different drugs, mifepristone and misoprostol, constitutes about 40% of all U.S. abortions and is particularly suited to the current crisis because it can be provided with little clinician-patient contact. Already, abortion providers have been coming up with ways to make medication abortion easier to get; for example, video conferencing with patients to determine eligibility, and reducing or eliminating the tests a patient must take beforehand (which experts state would be safe).

But a regulation put in place by the FDA in 2000, when mifepristone was first approved for use in this country, is hampering the most efficient way to deliver these drugs. Misoprostol was already approved for other purposes, but mifepristone was placed in the REMS ("Risk Evaluation and Mitigation Strategy,") program, a drug safety program for drugs deemed especially dangerous. This categorization has meant that pharmacies cannot stock the drug, and it can only be dispensed at a clinic, doctors' offices, or a hospital.

Given the impressive safety record of medication abortion over the last 20 years, reproductive health experts have argued that the REMS requirement is not necessary and a serious impediment to abortion access, especially at the current moment. Elizabeth Warren and two other Democratic Senators have called on the FDA to temporarily lift the requirement on mifepristone in light of the pandemic, something the Agency has done for other drugs in this program. If the REMS requirement were abolished — something the FDA has thus far refused to do — providers could ascertain via videoconference if a person was a suitable candidate for medication abortion, and then the relevant drugs could be mailed to her by the clinician or by a mail order pharmacy.

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