Medical Xpress

Many women can't access miscarriage drug because it's also used for abortions

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Credit: George Hodan/public domain

Since losing her first pregnancy four months ago, 32-year-old Lulu has struggled to return to her body's old rhythms. Lulu, who asked to be identified by her first name to protect her privacy, bled for six full weeks after her miscarriage and hasn't had a normal menstrual cycle since.

Such disruptions aren't uncommon after miscarriage, which affects roughly one in 10 known pregnancies. But for Lulu, they've also served as a persistent reminder that she couldn't access the drug mifepristone—her preferred method of care—to help her body pass the miscarriage. Instead, her doctor prescribed a drug called misoprostol, which on its own is less effective.

"I recall clarifying with her about the kind of medication I would get," Lulu said. "When she said misoprostol … I was really shocked. I made her repeat herself."

Patients like Lulu are, experts say, a little-recognized casualty of America's fractious abortion wars. In other contexts, both mifepristone and misoprostol are used to voluntarily terminate pregnancies, and both medications are often called "abortion pills."

But while misoprostol is indicated for a wide range of medical uses, including labor induction and ulcer treatment, mifepristone is taken almost exclusively to induce abortions and manage miscarriages, the latter of which is an off-label use. The federal government regulates it tightly, as do most state governments. The drug remains widely unavailable to patients experiencing pregnancy loss—even in states that do not otherwise restrict abortion, for a variety of regulatory, cultural and political reasons.

"There's been this conflation of abortion and miscarriage management," said Dr. Elise Boos, an assistant professor of obstetrics and gynecology at Vanderbilt University and a practicing OB-GYN. "There's so much stigma and worry about the optics—and as a result, patients get suboptimal care for miscarriage."

Miscarriage patients have three options for passing pregnancy tissue, which can cause hemorrhage or infection if not removed: medication,

minor surgery or "expectant management"—waiting for the body to complete the process on its own. Since 2018, the American College of Obstetricians and Gynecologists has recommended a two-drug protocol of mifepristone and misoprostol for patients who elect the medication route. Mifepristone is taken first, to "loosen" pregnancy tissue from the uterine wall. This is followed by misoprostol to expel the tissue.

A study published in July in the *Journal of the American Medical Association* found that between 2016 and 2020, just 1% of more than 22,000 patients nationwide who took medicine to help pass their miscarriages received the recommended two-drug protocol.

That leaves tens of thousands of patients like Lulu to face longer miscarriage processes and potential medical complications, doctors say. While misoprostol also is a safe and effective treatment on its own, physicians stress, it is markedly less effective than the two-drug combination—requiring follow-up surgery to complete the miscarriage in roughly one in four cases.

"It felt like that was the reason my miscarriage was dragging on and the reason I bled for so long," Lulu said in private messages with Stateline on the discussion site Reddit, where she has chronicled her experience with miscarriage. "Of course, [it's] hard to know … but I'm convinced I would have healed much faster" with mifepristone.

Policy, stigma limit care

Doctors and reproductive health advocates blame a thicket of overlapping cultural, political and regulatory factors for limiting patient access to mifepristone.

Decades of federal data show that the drug only rarely causes serious side effects and is responsible for fewer deaths than Tylenol. The two-

drug combination is just as safe as misoprostol alone.

More than 90 countries have approved mifepristone since the late 1980s—including Canada, which since 2017 has permitted any physician or nurse practitioner to prescribe mifepristone and any pharmacist to dispense it.

In the United States, however, mifepristone is typically only available at hospitals, health clinics and doctors' offices that routinely provide abortions or that employ specialists in "complex family planning," a branch of gynecology focused on abortion, contraception and miscarriage management.

Some retail pharmacies also have begun to stock the drug since January of this year, when the Food and Drug Administration loosened some long-standing restrictions, said Abby Long, a spokesperson for Danco Laboratories, which manufactures mifepristone under the name brand Mifeprex.

But the names of those pharmacies are confidential, and few have chosen to publicize the fact that they carry the drug, Long said. Both CVS and Walgreens, the country's largest pharmacy chains, have applied for permission to dispense mifepristone, but neither has been certified yet.

Clinics that stock mifepristone also represent a small and seldom advertised subset of health care providers, said Dr. Michael Belmonte, a practicing OB-GYN in Washington, D.C., and a fellow at the American College of Obstetricians and Gynecologists. Such facilities may be inaccessible to patients living in rural or low-income communities. There also is no publicly available list of clinics, offices or pharmacies that provide mifepristone, said Belmonte.

"Typically, it's on the individual physician to understand their community," Belmonte said. "Even for me as a complex family planning specialist, I understand how complicated that is—and it's only more complicated, unnecessarily so, for a general OB-GYN or someone in family practice."

Some miscarriage patients also may balk at turning to a clinic or health center better known for performing abortions. Federal law further requires that all patients who receive mifepristone sign a form acknowledging their desire to end their pregnancy, even if they've experienced a miscarriage.

"It did feel kind of cruel to send me to what was effectively an abortion clinic for care of the loss of my wanted pregnancy," said Erika, a Pennsylvania woman whose OB-GYN referred her to a complex family planning clinic for a mifepristone prescription.

For more than a decade, the FDA has regulated mifepristone under a special framework—called a "Risk Evaluation and Mitigation Strategy," or REMS—used for drugs that the FDA maintains could pose extra risks to patients. The framework requires providers to register with a drug's manufacturer before prescribing or dispensing it.

While not complicated, especially for independent clinics and pharmacies, the certification process can dissuade providers who don't frequently dispense mifepristone, particularly those who don't provide abortions, Belmonte said. Obtaining certification has also proved time-consuming for the major pharmacy chains, which face additional hurdles related to their large geographic footprints and companywide databases.

At least 15 states place additional restrictions on prescribing and dispensing mifepristone, according to the nonprofit health care policy research organization KFF.

Typically, these restrictions bar nurse practitioners or physician assistants from prescribing abortion medications or require that patients receive mifepristone directly from a physician. Such rules will prevent pharmacies from supplying the medication in much of the country, Long said, even after the change to federal regulations.

State abortion bans also impede miscarriage care, medical groups have said. Since the Supreme Court overturned Roe v. Wade last year, 14 states have banned abortion, some with explicit allowances for treatment that saves the life of the person giving birth or that eases miscarriage. But not all state laws make that distinction, said Alina Salganicoff, the director for women's health policy at KFF, and many are written in confusing, nonmedical language that doctors struggle to interpret in real-life situations.

In Louisiana, for instance, doctors asked the state Department of Health to clarify whether the state's near-total abortion ban extends to the treatment of miscarriages, ectopic pregnancies and other pregnancy complications. As currently written, state law requires physicians to confirm a miscarriage by ultrasound before beginning treatment. Republican legislators voted down a proposed bill in May that would have granted physicians more discretion when making care decisions.

"There's a difference between the legal status of mifepristone for miscarriage care in states that are extremely hostile to abortion and the understandable concerns that providers might have given the hostility of that climate," said Julia Kaye, a senior staff attorney with the American Civil Liberty Union's Reproductive Freedom Project.

Kaye points, in particular, to letters that more than 20 Republican state attorneys general sent to major pharmacy chains earlier this year, threatening legal action against providers that dispensed or administered mifepristone, with no allowances for miscarriage care.

Legislation proposed in Alabama, Arizona and Iowa would have made it a felony to "manufacture, distribute, prescribe, dispense, sell or transfer" mifepristone for any reason.

In this political climate, stigma prevents many clinicians from prescribing mifepristone—even absent other legal or regulatory hurdles, said Dr. Debra Stulberg, the chair of the Department of Family Medicine at the University of Chicago. Stulberg leads a demonstration project aimed at helping community hospitals, federally qualified health centers and other primary care providers adopt mifepristone, which she called "the gold standard" for medically managing miscarriage.

"We see these vicious, reinforcing cycles where the culture at the local level is really responsive to policy and politics," Stulberg said. "We're both combating the stigma associated with abortion and overcoming unfounded but understandable fears about what it means to provide this medication."

A lack of 'empathy'

Abortion opponents dispute the notion that mifepristone restrictions disrupt or worsen care for early pregnancy loss. The American Association of Pro-Life Obstetricians and Gynecologists, a professional group, has argued that the adoption of mifepristone for miscarriage care is part of a larger campaign to make the drug more available for elective abortion.

Rules that require in-person appointments or bar pharmacies from shipping mifepristone in the mail help guarantee that patients receive adequate screening and follow-up care, said Dr. Kathleen Raviele, a retired OB-GYN and the former president of the Catholic Medical Association.

Misoprostol is also effective on its own, said Raviele, who argues that the two-drug regimen only serves to add cost and complication to the miscarriage management process and "confuse women" who associate mifepristone with elective abortion.

In her former practice, Raviele counseled patients to wait for their bodies to pass pregnancy tissue naturally, a process that can take up to eight weeks. She would later prescribe misoprostol or schedule a surgical procedure if the patient didn't pass the miscarriage or related pregnancy tissue—an approach that she said requires a longer, more intensive engagement between provider and patient.

"I think that, because abortion is legal in this country, doctors and other health care workers don't treat women having miscarriages with the empathy and sympathy they should," Raviele said. "There's this attitude of, "Well it's early—you can always get pregnant again.'"

But physicians and reproductive health advocates say that approach ignores both the preferences and economic realities of many patients, who may lack the time, transportation or financial resources to undergo weeks of follow-up appointments. Patients who manage their pregnancy loss with medication may also have emotional reasons for making that choice: a desire to gain control, for instance, or to shorten the duration of a painful experience.

One 33-year-old woman in West Virginia, who asked to remain anonymous, told Stateline that she chose expectant management for a recent miscarriage because a clotting disorder makes surgery riskier for her—and her doctor never told her medication was an option.

For more than seven weeks, she wrote in a message on Reddit, she passed "golf ball-size clots" and reported for "agonizing" weekly follow-up appointments at her doctor's office.

"I see all the happy pregnant women and hear babies' heartbeats from the ultrasound room," she said. "I would have given anything to not go through such a long process."

Some lawmakers and advocates are seeking to make mifepristone more available to miscarriage patients—though their efforts run up against parallel, opposing campaigns from anti-abortion groups.

One such anti-abortion group, the Alliance for Hippocratic Medicine, sued the FDA last November to challenge the agency's initial approval of mifepristone. In August, the 5th U.S. Circuit Court of Appeals ruled the FDA should place further restrictions on the drug—a decision that the Supreme Court has stayed and is expected to take up on appeal next term.

Elsewhere in the country, the ACLU and attorneys general in 12 states sued the FDA to overturn its existing restrictions on mifepristone, arguing that they conflict with the drug's well-documented safety record. Those cases are ongoing in federal court.

Since October 2022, a coalition of almost 50 leading medical associations and health advocacy groups and eight Democratic senators have also petitioned the FDA and Danco Laboratories to make miscarriage management an official indication for mifepristone.

While drugs are routinely used for off-label purposes in the United States, adding the new indication could further legitimize the use of mifepristone in miscarriage care, advocates argue, and potentially keep the drug available in the face of abortion bans or restrictions.

Long, the Danco spokesperson, said the company is considering a future update to the mifepristone label, but has not started the process of revising it.

In the meantime, many doctors and researchers say they are working to further document and publicize the role of mifepristone in miscarriage care. Vanderbilt's Dr. Boos, who has researched trends in the treatment of early pregnancy loss, said providers have a responsibility to educate patients and policymakers alike about the science behind different care options.

"These fights are being litigated by lawyers, not clinicians," Boos said of mifepristone prescriptions and abortion bans. "They don't seem to understand that if we lose mifepristone, we lose it for medication abortions, yes—but we also lose it for all these other patients."

Stateline is part of States Newsroom, a national nonprofit news organization focused on state policy.

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