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Medication Abortion Restrictions Burden Women and Providers—and Threaten U.S. Trend Toward Very Early Abortion

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Over the last several years, a wave of provisions hostile to medication abortion have been introduced by antiabortion state and federal legislators. Such provisions fall in two categories. The first requires that medication abortion protocols hew strictly to an outdated regimen specified by the Food and Drug Administration (FDA) when medication abortion was first approved, which prohibits alternative, evidence-based protocols in wide use for at least the past decade. The second requires that medication abortion be provided only by a physician who is in the same room as the patient, essentially ruling out provision by physician assistants and advanced practice nurses or by telemedicine.

Antiabortion leaders disingenuously insist that these restrictions are necessary to protect women's health and safety. The safety of medication abortion, however, has been well-established. Rather, these restrictions are an attack on abortion itself. They burden women and potentially threaten their health. They prevent providers from engaging in practices that are accepted as mainstream in other medical specialties. And, of utmost importance, they threaten provision of abortion in the earliest stages of pregnancy.

Medication Abortion: The Basics

The "abortion pill," as medication abortion is sometimes called (it is sold in the United States under the trade name "Mifeprex"), actually consists of two medications.[1,2] The first, mifepristone, works by blocking a hormone (progesterone) that is needed for pregnancy to continue. Without this hormone, the lining of the uterus begins to break down and bleeding begins. The second drug, misoprostol, induces uterine contractions and ends the pregnancy at the very early stages. For most women, the result feels similar to having a heavy period.

Medication abortion is highly effective: Its 92–95% success rate is comparable to that of surgical abortion. It is also safe, as severe complications are extremely rare. Of the 1.52 million women in the United States who used Mifeprex between 2000 and 2011, 612 were hospitalized, most frequently because they required a transfusion due to excessive bleeding.[3] During the same period, there were eight documented cases of U.S. women dying from a severe infection after taking Mifeprex;[3] FDA investigations into these deaths, however, found no evidence of a causal relationship between Mifeprex and the infections.[4]

The FDA's approval of Mifeprex in 2000 specified a regimen that involved three visits to the physician's office: first for counseling and to receive a 600 milligram (mg) oral dose of mifepristone, then two days later for a 400 microgram (µg) oral dose of misoprostol and once again, on day 14, for follow-up. (Notably, Mifeprex is not dispensed to women in pharmacies. Rather, it is available to physicians who certify in advance that they have the necessary knowledge and skills to prescribe the drugs appropriately and who agree to provide patients with detailed information about them.) Approval was for use up to 49 days after a woman's last menstrual period (seven weeks' gestation).

At the time of its approval by the FDA, medication abortion had already been on the market in various other countries. The drug was first approved for early abortion in France and China in 1988, and then was approved in Great Britain in 1991, in Sweden in 1992 and in other European countries throughout the 1990s.[5] The treatment regimen approved by the FDA was based on the original 1988 French regimen, which itself was out of date almost immediately. As early as the mid-1980s, investigators began to examine modifications to this regimen.[5–8] Studies conducted under the auspices of the World Health Organization (WHO) first indicated that mifepristone is equally effective at one-third the standard dose. Researchers also examined the prospect of eliminating the second visit, by permitting women to self-administer misoprostol; studies found in-home administration to be as safe, effective and acceptable to women as clinic administration. In addition, medication abortion was found to be effective up to 63 days' gestation (about nine weeks), although efficacy may decrease as gestation advances.

Modifications to the Regimen

On the basis of these studies, the National Abortion Federation and Planned Parenthood Federation of America published medical standards that allow for alternative Mifeprex regimens that provide numerous advantages to women, including making medication abortion available for an additional two weeks of gestational age and enhancing patient privacy (see table).[2] These modifications quickly became the accepted standard of care for medication abortion. As far back as 2001, an estimated 83% of U.S. providers were no longer using the FDA-approved regimen.[9] Today, virtually all Planned Parenthood facilities that provide medication abortion services use these evidence-based alternatives.

Indeed, prescribing drugs in ways that vary from those specified when they were originally approved is a widespread practice by physicians in every specialty of medicine, far beyond abortion care. In an examination of 160 commonly used medications, 21% of prescriptions were for "off-label" use—and the practice may be even more common for certain populations or for specific conditions.[10] For instance, because children are often excluded from clinical drug studies, examples of off-label drug use in pediatric populations are especially plentiful. Moreover, it is not unusual for off-label drug use to become widely entrenched in clinical practice, with the medications in question never taken back to the FDA for revised labeling. Antidepressants, for example, have never had FDA approval as a treatment for neuropathic pain, yet this class of drugs is considered a first-line treatment option.[11]

MEDICATION ABORTION REGIMENS

	FDA-Approved	Evidence-Based Alternatives
Mifepristone dosage	600 mg	200 mg
Home administration of misoprostol	No	Yes
Number of clinic visits required	Three or more	Two or more
Gestational limit	Up to 49 days (seven weeks of pregnancy)	Up to 63 days (nine weeks of pregnancy)

Source: reference 2.

Requirements that Mifeprex be provided in strict adherence with the antiquated FDA-approved regimen both burdens women and threatens their health. When the FDA-approved regimen is required, women are subject to a higher dose of mifepristone—600 mg, instead of the 200 mg often used. They also must make multiple visits to the doctor and are prohibited from self-administering misoprostol in the privacy of their own home. Moreover, under the FDA regimen, medication abortion is available only up to 49 days' gestation, and thus under these restrictive laws it is not a legal option for women presenting at 8–9 weeks' gestation, even though it is still safe and effective.

The Role of Midlevel Professionals

As far back as 2003, after a review of the scientific literature and consultation with experts, the WHO began recommending that midlevel providers be trained to administer medication abortion.[12] Since then, a number of professional organizations in the United States have adopted policies supporting an increased role of nurse-midwives, nurse

Telemedicine for Medication Abortion

According to a summary of a 2012 workshop convened by the Institute of Medicine, use of telemedicine and telehealth has exploded in recent years and now plays a central role in the delivery of quality health care.[16] Applications of telemedicine range from electronic communications (such as e-mails or text messages between providers and patients) to cutting-edge medical procedures (such as surgeries using robotic instruments guided by a physician at a remote console).

Alaska, for example, has been a model for the development and use of telemedicine for decades. Since the 1920s, the radio has been used to give medical advice to clinics on ships. Today, health providers in rural communities routinely perform tests and send the results to specialists in Anchorage or Fairbanks for a diagnosis and treatment plan. Other states have enthusiastically embraced telemedicine as well. Virginia's Medicaid program, for example, has supported telemedicine services since 1995 and is looking to expand their use for home health services, postoperative care, high-risk pregnancies and treatment of infections. The U.S. Department for Veteran's Affairs is another leader in telemedicine and estimates that 820,000 veterans (or about 15% of the veteran population) will be served using telemedicine in FY 2013 (i.e., via video and mobile devices).[16] According to the department, the reasons for expanding telemedicine include reducing costs, increasing quality and improving access.

The potential for telemedicine to improve women's access to early abortion care caught the attention of Jill June, president and CEO of Planned Parenthood of the Heartland. Under June's leadership, the organization's clinic network in Iowa launched a program in 2008 to provide medication abortion using telemedicine at clinic sites not regularly staffed by a physician. The network offers telemedicine for medication abortion at 16 of its 25 clinics throughout the state.

The telemedicine visit at Planned Parenthood of the Heartland is similar to face-to-face visits with the doctor. A woman in a distant clinic meets with a nurse on-site, just as she would at a physician-staffed clinic. There, the nurse reviews the woman's medical history, performs an ultrasound and counsels her on matters like what to expect from the procedure and plans for a follow-up exam.

Once that is complete, a physician steps in, virtually, using a two-way camera that allows him or her to talk directly to the patient. The doctor reviews the woman's medical records and ultrasound images, and answers any questions she may have. Then, with a click of the mouse or by entering a computer password, the doctor remotely opens a drawer in front of the woman. Inside are the mifepristone and misoprostol tablets; one she swallows immediately, under the doctor's supervision, and the other she will take later at home. Women return for a follow-up visit two weeks later. In the unlikely event the abortion is incomplete, she is scheduled for a surgical abortion at a physician-staffed clinic.

No serious complications have occurred in Iowa involving telemedicine patients, and patients report high levels of satisfaction with the process. According to a 2011 study of nearly 600 women seeking abortion at Planned Parenthood of the Heartland, telemedicine patients had comparable clinical outcomes as women who received face-to-face provision, with equivalent success rates and a low prevalence of adverse events.[17] Ninety-four percent of these patients reported being "very satisfied" with the procedure, 99% said it was easy to see and hear the doctor, and 89% said they felt comfortable asking the doctor questions during the videoconference.

practitioners and physician assistants in abortion care.[13] The American College of Obstetricians and Gynecologists, American Public Health Association and American Medical Women's Association, for example, support increased training for nurse practitioners, certified nurse midwives and physician assistants to provide medication abortion services.

Training midlevel professionals to provide services that were once the sole domain of physicians reflects a growing trend in medical practice. Data from the Centers for Disease Control and Prevention (CDC) show a 50% increase between 2000 and 2009 in hospital outpatient department visits attended only by physician assistants or advanced practice nurses.[14] In 2008–2009, 21% of visits in general medicine clinics and 19% in obstetrics and gynecology clinics were with an advanced practice nurse or physician assistant, not a physician. According to the Institute of Medicine, trained midlevel providers can deliver

primary care services—from wellness and prevention services to the management of chronic disease—at least as safely and effectively as physicians.[15] And midlevel providers are expected to play an even larger role in patient care under health care reform, which promises to expand insurance coverage to more people at a time when there is a shortage of primary care physicians.

In many ways, training midlevel providers to administer medication abortion makes sense for a procedure that requires extensive patient education and counseling—skills that are emphasized in the education of these providers. Yet, in most states, physicians are the only health professionals permitted to provide medication abortion. In these states, a woman seeking a medication abortion may have to wait a long time for an appointment and travel long distances to visit a clinic attended by a physician. The situation is made worse by provisions that require that the physician be physically present during the procedure or in-person counseling or ultrasound requirements that necessitate multiple trips to the clinic. When all of these requirements are in effect, a woman will have to make four trips to the health care provider (for counseling, to receive mifepristone, to receive misoprostol and for follow-up) and is required to complete every step of the procedure under the eye of the physician, rather than in the privacy of her home. Laws requiring the physical presence of the physician also preemptively ban the use of telemedicine—virtual consultation with a physician by video—for medication abortion (see box).

Attacks on Early Abortion

To date, two states (Arizona and Ohio) require that Mifeprex be provided in accordance with the FDA-approved regimen. Two other states (North Dakota and Oklahoma) have adopted laws with these requirements, but their laws have been enjoined by the courts and are not in effect—either temporarily pending the outcome of litigation or permanently having been ruled unconstitutional. In addition, 39 states require clinicians who perform medication abortion to be licensed physicians; 10 require in-person counseling or ultrasound, necessitating multiple clinic visits by women; and eight require that the clinician be physically present during the procedure, effectively banning the use of telemedicine and at-home administration of misoprostol.

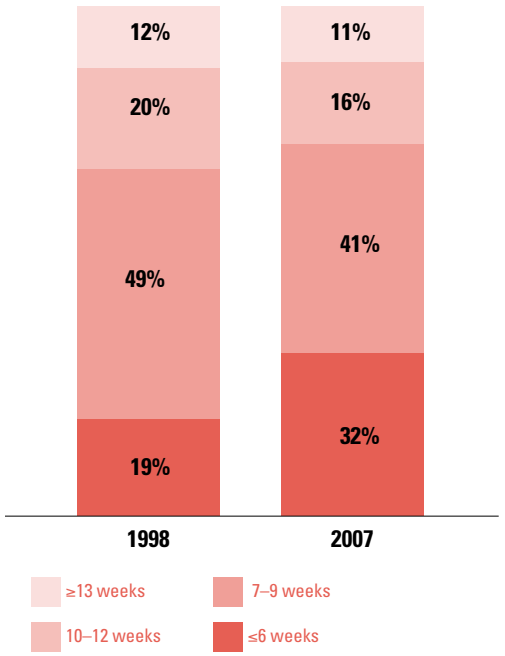
During consideration of the FY 2012 Agriculture, Rural Development and Food and Drug Administration appropriations bill in June 2011, the U.S. House of Representatives adopted an amendment that would have prohibited the use of FDA funds for mifepristone for any purpose. Introduced by Rep. Steve King (R-IA), the provision could have banned the FDA from considering changes to its protocol for medication abortion and prohibited the use of federal funds for establishing telemedicine programs that include medication abortion. Although the Senate removed the provision before final passage of the bill, King has made clear his goal to ban any federal funds earmarked for the development of telemedicine services from going to entities that might use it for the delivery of medication abortion.

These restrictions are proffered, although exclusively by abortion opponents, in the purported interest of protecting women's health and safety. According to antiabortion activists, undergoing an abortion using a protocol other than that approved by the FDA, overseen by a midlevel professional rather than a physician or in consultation with a physician by telemedicine is a "prescription for disaster." The safety justification, however, falls flat against the wealth of evidence in the other direction. Innovations in providing medication abortion—whether according to evidence-based alternatives to the original FDA-approved regimen, by a midlevel provider or through telemedicine—have a strong safety record, even as they may use less medication, have fewer side effects and require fewer visits to the provider.

Indeed, the restrictions on medication abortion are not an attempt to make the procedure safer, and certainly not to make it more effective. Rather, they are an attack on abortion itself. As Oklahoma County District Judge Donald Worthington wrote in striking down Oklahoma's law that required Mifeprex be provided in accordance with the FDA-approved regimen, the bill's restrictions are "so completely at odds with the

TREND TOWARD EARLY ABORTION

U.S women have abortions substantially earlier in pregnancy today than they did in the recent past.



Source: reference 23.

standard that governs the practice of medicine that [the bill] can serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those women who do."[18]

In reference to the opposition to the use of telemedicine for medication abortion, noted medical ethicist Arthur Caplan of the Center for Bioethics at the University of Pennsylvania said, "No one has ever said a negative word about the merits of telemedicine until Planned Parenthood used the technology to remotely open a drawer that contained abortion drugs."[19] He suggests that the legislative pushback has more to do with opposition to abortion in general than with a concern for the safety of women. "Unless [opponents] have some broader heartburn over the notion of rural areas getting access to doctors by video, I don't think this is in any way a serious complaint."[20]

Attacks on abortion are not new, but what makes this recent onslaught of restrictions both significant and especially ironic is its focus on abortion at the very earliest stages. Research demonstrates that most women obtaining an abortion want to have their abortion as early as they can. A Guttmacher survey of women having abortions found that, regardless when they had their procedure, some 60% would have preferred to have had it earlier.[21] In a study of Planned Parenthood of the Heartland's program, when women were asked why they decided to have an abortion through telemedicine, they most often said they wanted to have the abortion closer to home and as early as possible.[17]

Moreover, public support for abortion is highest for abortions performed early in pregnancy. Gallup analysis of U.S. public opinion on abortion shows that a solid majority of Americans (61%) believe abortion should generally be legal in the first three months of pregnancy; support drops to 27% for abortions in the second trimester and 14% for those in the third.[22] This pattern remained generally unchanged between 1996 and 2012.

These days, abortions overwhelmingly occur early in pregnancy. About nine in 10 abortions occur in the first 12 weeks of pregnancy, and a large majority (73%) now occur in the first nine weeks.[23] Moreover, the longer term trend is toward abortion even earlier in pregnancy. Between 1998 and 2007 (the most recent year for which data are available), the proportion of women seeking abortion in the first 12 weeks of pregnancy remained essentially stable; however, there was a decided shift toward earlier gestational ages—a 65% increase in procedures performed in the first six weeks of pregnancy (see chart). Today, an impressive 32% of all abortions are performed in the first six weeks, when the embryo is about the size of a pencil eraser.

Importantly, the availability of Mifeprex is credited with accelerating the trend toward very early abortions. Although the proportion of abortions in the first six weeks of pregnancy has grown steadily since the late 1990s, the increase was steepest between 2000 and 2002, right after the introduction of Mifeprex.[24] In addition to burdening women and providers, the new onslaught of provisions hostile to medication abortion—promoted by those whose primary concern is not

women's well-being, but the opposition to abortion at any stage—threaten this trend toward very early abortion. www.guttmacher.org

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