NARAL Pro-Choice America

Mifepristone:
The Impact of Abortion Politics on Women's Health and Scientific Research

Mifepristone is the first and only Food and Drug Administration (FDA)-approved medication providing women with a safe and effective nonsurgical option for early pregnancy termination. Mifepristone has been tested extensively and used safely and effectively worldwide since 1981 and in the United States since 2000. According to the most recent research, more than one-third of American women who got abortion care by nine weeks chose this option.[1] Yet, despite its proven safety and potential for improving aces, continued political attacks on mifepristone provide a prime example of how anti-abortion forces are putting public health at risk.

Mifepristone is Safe and Effective

Mifepristone, also known by its original name RU 486 and its trade name Mifeprex®, has undergone rigorous testing and has been used safely and effectively for more than 30 years.

- Millions of women worldwide have safely used mifepristone as an early option for nonsurgical abortion.[2]
- Since the FDA approved mifepristone in 2000, more than one and a half million U.S. women have used the drug for safe and effective nonsurgical abortion care.[3] The rate of reported adverse events for mifepristone is very low: approximately 0.2 percent.[4]
- Mifepristone is as safe as or safer than other commonly used medications. The number of adverse events associated with mifepristone is less, for example, than for such medications as Viagra and Tylenol.[5]
- Mifepristone underwent the standard, rigorous review process and clinical trials required for all new medications.[6] It was *not* "fast-tracked" through the FDA approval process as anti-choice activists claim.
- A 1998 study based on clinical trials reports very high patient satisfaction with the regimen: 96 percent of women who have used mifepristone would recommend the method to others.[7] Moreover, a 2000 report confirmed that the medication had widespread appeal to a broad range of American women, regardless of race or ethnic background.[8]
- Studies of women using mifepristone suggest that when given a choice between nonsurgical and surgical abortion care, 84 percent choose the nonsurgical option.[9]

Access to Mifepristone Improves Reproductive-Health Options

Women might prefer to use mifepristone over traditional, surgical abortion care for a variety of reasons. Mifepristone does not require surgery and requires no anesthesia. In addition, many women feel it gives them greater control over their bodies and increases their privacy.[10]

- Physicians in all 50 states, the District of Columbia, Puerto Rico, and Guam offer mifepristone.[11]
- In 2011, 59 percent of abortion providers in 1,023 facilities provided nonsurgical-abortion care. At least 17 percent of providers offer only nonsurgical-abortion care.[12]
- Between 2001 and 2011, early nonsurgical abortion has increased from six to 23 percent of all non-hospital procedures, despite the fact that the overall abortion rate had declined.[13]
- By 2005, the number of U.S. women choosing mifepristone more than doubled from the first full year of availability in 2001.[14]
- In some states, other licensed health-care professionals, such as nurse practitioners, certified nurse-midwives, and physician assistants are granted authority to prescribe mifepristone to patients, allowing women greater access to safe, reproductive-health options.[15]

Mifepristone Has Other Potential Uses

Access to mifepristone enhances the ability of researchers to study other beneficial uses of the medication. However, persistent efforts by anti-choice lawmakers to hinder access to the medication will not only block reproductive choices for some women but will also impinge upon the potential advancement of research into its various uses.

- Mifepristone can help to induce labor and treat medical problems such as infertility, endometriosis, and certain types of tumors.[16]
- Mifepristone may be useful for treating certain breast-cancer tumors, with experts estimating that the drug may be an effective treatment for 40 percent of these cases.[17]
- Additionally, researchers have suggested that mifepristone may be useful in treating HIV, Cushing's disease, and glaucoma.[18]

Evidence-Based Use of Mifepristone Is Safe, Effective, and Necessary

From 2000, when the FDA first approved Mifepristone, until 2016, most doctors used the medication in a manner that was evidence-based, or "off-label." This was common and safe, and consistent with many other medications' use.

In 2016, the FDA approved the manufacturer's application for a label change – which brought the Mifeprex label into line with standard practice.[19] Research with mifepristone has shown that alternatives to the previous FDA-approved regimen was safe, effective, and in most cases,

preferable to the FDA regimen.[20] Fortunately, the medication's new label helps to quiet the anti-choice critics.

Anti-Choice Attacks on Mifepristone

Despite FDA approval and worldwide acceptance of mifepristone, opponents of women's reproductive freedom continue their longstanding efforts to block access to the medication.

Since 2003, 21 states have signed restrictive measures into law[21]. Anti-choice politicians have employed a number of different methods to hinder access, including restricting where and how the medication is delivered:

- In 2004, Ohio Gov. Bob Taft (R) signed into law a bill that prohibits off-label use of mifepristone.[22] A federal judge issued an injunction preventing the law from going into effect,[23] but in 2009 the court ruled that physicians are prohibited from prescribing mifepristone for off-label use. In 2012, the Sixth Circuit Court of Appeals affirmed the 2009 ruling, and the law remained in effect.[24] However, the 2016 label change will nullify this and similar laws, pending subsequent litigation.
- In 2011, anti-choice Oklahoma Gov. Mary Fallin (R) signed into law a bill that prohibits the use of mifepristone outright.[25] Oklahoma courts granted first a temporary, then permanent injunction against the law finding that it violated the undue-burden standard by placing a substantial obstacle in the path of women seeking abortion services. The case was appealed to the U.S. Supreme Court, which asked the lower court to clarify the intent of the law before deciding whether to take up the case. The lower court declared that the intent of the law was to ban medication abortion outright. The U.S. Supreme Court declined to intervene in the decision, so the lower court's ruling stands.[26] However, in what has proven to be an ongoing saga, the state enacted a new restriction that prohibits off-label use of mifepristone, which also is working its way through the court system. The law has been temporarily enjoined by the state supreme court.[27]
- In 2012, anti-choice Wisconsin Gov. Scott Walker (R) signed into law a bill that prohibits the dispensing of mifepristone through telemedicine networks.[28] In response to the vague and unnecessary restrictions imposed by the new law, Planned Parenthood of Wisconsin and Affiliated Medical Services stopped providing medical-abortion care. Pro-choice allies pursued a legal challenge—which is still ongoing—but the law has been temporarily enjoined and providers resumed providing non-surgical abortion care.[29]
- Continuing the trend, also in 2012, anti-choice Arizona Gov. Jan Brewer (R) signed into law a bill that prohibits off-label use of mifepristone.[30] A judge ruled that the law could go into effect, but after an emergency appeal filed with the Ninth Circuit, a temporary injunction was issued—blocking the law from going into effect. This law is pending appeal.[31] In an odd turn of events, in 2016, anti-choice Gov. Doug Ducey (R) signed into law a similar measure, only days after the FDA approved the medication's label

change—making the law unnecessary.[32] More surprising still, a few months later, the governor signed into law a bill repealing this requirement.[33]

- In 2015, Arkansas enacted four separate bills to restrict the use of medication abortion, including the use of telemedicine to deliver that service. To add further insult, the state enacted a law lauding the importance of telemedicine for broad medical care for underserved populations, while explicitly excluding abortion from that care.[34]
- In 2016, Indiana enacted a similar law restricting the use of medication abortion in a telehealth program.[35]

In addition to the state attacks described above, anti-choice politicians in Congress and federal agencies have also tried repeatedly to block women from the option of nonsurgical abortion:

- During the George H.W. Bush administration, the FDA issued an import alert that banned mifepristone in the United States for personal use. A federal district court that examined the import alert concluded, "[T]he decision to ban the drug was based not from any bonafide concern for the safety of users of the drug, but on political considerations having no place in FDA decisions on health and safety."[36] Incoming President Bill Clinton lifted the import ban as one of his first actions as president.[37]
- In 2001, prior to his confirmation as secretary of the Department of Health and Human Services, Tommy Thompson stated an intention, if confirmed, to revisit the FDA's approval of the medication. Though Thompson ultimately backed off of his threat, mifepristone was the only medication already approved by the FDA that he singled out for further investigation.[38]
- In 2005 and 2007, anti-choice Rep. Roscoe Bartlett (R-MD) and Sen. Jim DeMint (R-SC) introduced the RU-486 Suspension and Review Act.[39] The bill would legislatively override the FDA's approval of mifepristone, and would pull the drug off the market while an entirely new, additional "review" is conducted on the drug. In 2002, then-President Bush appointed W. David Hager, an avowed anti-choice proponent, to the FDA Advisory Committee for Reproductive Health Drugs. Before his appointment, Hager had authored the Christian Medical Association's "citizen's petition" calling upon the FDA to reverse its approval of mifepristone, claiming it has endangered the lives and health of women.[40] Although Hager is no longer in this position, his biased appointment demonstrated the Bush administration's eagerness to inject politics into science.
- In 2006, Sen. David Vitter (R-LA) introduced the so-called RU-486 Patient Health and Safety Act, which would impose a number of onerous and medically unnecessary restrictions on mifepristone's availability — making it virtually impossible for any doctor to prescribe the medication.[41]
- Also in 2006, anti-choice lawmakers in the U.S. House of Representatives held a hearing to attack mifepristone and unjustly undermine public confidence in the medication. The hearing was chaired by then-Rep. Mark Souder (R-IN), who opposed all legal abortion, not just mifepristone, and stated publicly on his official website that "hopefully we will be able to accumulate enough evidence to make the FDA overturn their approval of the drug."[42]

- In 2010, Sen. Tom Coburn (R-OK) tried to ban mifepristone from the new health system established by the Affordable Care Act, even those using their own, private funds to purchase health insurance. The effort failed.[43]

Telemedicine and Medical Abortion

In 2008, Planned Parenthood of the Heartland in Iowa began using the system of telemedicine to provide medical-abortion care. Telemedicine is the delivery of a health-care service using telecommunications technology. Videoconferencing, transmission of still images, remote monitoring of vital signs, continuing medical education and nursing call centers are all considered part of telemedicine.[44] Telemedicine is becoming more commonplace – many fields of medicine including cardiology, pediatrics, dentistry, and psychiatry are using it to deliver health services. In fact, telemedicine holds such promise for delivering care in an efficient, cost-effect manner that the U.S. Senate Special Committee on Aging held a hearing to examine its full potential.[45] This type of care also holds promise for reproductive-health services, particularly in reaching patients in rural and underserved areas. Using telemedicine for early, non-surgical abortion can help provide health care to women who would otherwise not be able to receive it.

- The system of telemedicine is especially important for Americans who live in remote or rural areas and do not have access to a nearby doctor, or who need a specialist located across the country. Approximately one-fourth of Americans live in rural areas while only 10 percent of physicians practice in these areas.[46]
- Eighty-nine percent of U.S. counties have no abortion clinic, and 38 percent of women of reproductive age live in those counties.[47] It is extremely difficult for some women to travel to a reproductive-health clinic where they can access abortion services directly from a provider.
- According to a 2011 study on the use of telemedicine for medical abortion, there is no major difference in complications between in-person and telemedicine care and telemedicine patients were more likely to report satisfaction with their care.[48]

Unfortunately, yet predictably, anti-choice activists have claimed that using telemedicine to dispense mifepristone is dangerous to women because it lacks appropriate care and oversight from medical professionals. Such claims are false. In fact, medication dispensing through a telemedicine network is operationalized in this way:

- Clients at the Planned Parenthood of the Heartland clinics undergo a thorough process before receiving abortion services. "Before the video conference begins, a patient in a distant clinic meets (in person) with a nurse. There, blood tests, a medical history, an exam, an ultrasound and counseling on matters like what to expect from the procedure and plans for a follow-up exam are completed. The results are shared (by computer) with a doctor miles away, and the doctor and the patient (at all times accompanied by the nurse, who sits beside her) meet by videoconference over a private network." [49]

Efforts to Ban Telemedicine Prescription of Mifepristone

The development of telemedicine has spurred a renewed wave of attacks on non-surgical-abortion care:

- In 2016, five states introduced legislation that prohibits the use or dispensing of mifepristone through telemedicine networks: IA, IN, MN, MO, UT.
- Eighteen states have laws requiring a physician to be in the same room as the woman seeking abortion care, thus effectively banning the use of telemedicine.[50]

After learning that Planned Parenthood of the Heartland was using telemedicine technology to provide medical-abortion care in his home state, anti-choice Rep. Steve King (R-IA) became the federal leader on efforts to ban the practice.

In June 2011, King offered a surprise-attack amendment to the FY'12 Agriculture appropriations bill that was intended to block use of the nation's telemedicine system for delivery or discussion of mifepristone. The amendment passed 240-176.

In October 2011, Sen. Jim DeMint (R-SC) filed an amendment similar to Rep. King's to the FY'12 Agriculture, Commerce-Justice-Science and Transportation-HUD "minibus" appropriations bill. Because time for debate was limited, he did not bring the amendment up for consideration.

In 2012, King introduced his 2011 amendment as a free-standing bill, H.R. 5731, the Telemedicine Safety Act.[51] The bill also would bar the use of telemedicine for abortion services across state lines. Thankfully, Congress took no further action on the proposal.

However, attacks are also occurring in the states through non-legislative channels, including Rep. King's home state of Iowa. In 2013, the Iowa Board of Medicine, stacked with appointees from anti-choice Gov. Terry Branstad (R), passed a statewide proposal to ban the use of telemedicine for delivery of medication-abortion services. Planned Parenthood of the Heartland fought the rule in court, and a judge granted a stay, temporarily blocking the rule from going into effect. The judge stated that the rule "puts the health and well-being of Iowa women in jeopardy."[52]

Bans on telemedicine, as proposed by King and anti-choice legislators across the country, would set a new and radical precedent that the entire national communications system should be segregated. These bans advocate one telemedicine system for possible discussion of abortion or for providers who may also offer reproductive-health services through telemedicine – and an entirely separate system for all other health-care needs. This is outrageous on several levels, and the implications could be extremely far-reaching:

- Women's health cannot be so easily separated. What if a woman experiencing a high-risk pregnancy takes a sudden turn for the worse, and she and her doctor begin

discussing necessary emergency care? It is unrealistic in an emergency setting to ask, the woman and her doctor to log off one Internet network, video system, or phone line and reconnect to another.

- As a practical matter, how does one segregate the Internet? Telemedicine utilizes phone lines, teleconferencing systems, email, and other similar technologies. It is entirely impractical to suggest that the mere mention of abortion or the complete array of services a provider may offer, taints an entire system. These bans are so attenuated, they essentially are an electronic equivalent of saying that the federal government no longer should pay for a highway's construction if one of its hundreds of exits eventually leads to a hospital that provides abortion services.

Conclusion

For three decades, mifepristone has been an effective and safe reproductive-health-care option for women around the world. And despite the relentless torrent of anti-choice attacks, mifepristone remains an important reproductive-health option for women that should be protected.

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