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Commentary

For Medication Abortion, Science Should Guide Policy

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The U.S. Food and Drug Administration (FDA) approval of an updated label for the abortion drug Mifeprex in March 2016 (FDA, 2016a) marked an important step for access for abortion care and for evidence-based policy. Since the drug's initial approval in 2000, a strong and growing body of research has demonstrated the safety of medication abortion and supported several advances in medication abortion procedures, including changes to medication dosages and requirements for in-person office visits (Borkowski, Strasser, Allina, & Wood, 2015). The FDA's recent approval of the revised label submitted by manufacturer Danco Laboratories, LLC, represents the regulatory agency's recognition of the scientific evidence. A science-based FDA decision about a drug should be an unremarkable development, but in this case it serves to highlight problematic state laws that limit women's access to medication abortion based on a claim of health protection, despite strong evidence that the laws' requirements are unnecessary and, in some cases, unethical.

Among these laws are requirements that the procedure be performed precisely according to the FDA label, unless a statute allows for specific variations. Such laws are in force in North Dakota, Ohio, and Texas, and courts have prevented them from taking effect in Arizona, Arkansas, and Oklahoma (Guttmacher Institute, 2016). Until the FDA's approval in March 2016 of a revised Mifeprex label, providers in North Dakota, Ohio, and Texas had to adhere to an outdated protocol that presented barriers to high quality, accessible care. Although the FDA's decision reduces those barriers, it does not change the fact that several states have adopted these and other laws that limit providers' ability to shape their practice based on evidence and best practice—and, in some cases, require providers to make statements whose content is based solely on conjecture rather than science or clinical knowledge. If lawmakers truly want to advance women's health through legislation regarding medication abortion, they should understand the relevant scientific findings and base their policy proposals on evidence.

On March 31, 2016, 1 day after the FDA announced its approval of the new Mifeprex label, Arizona Governor Doug Ducey signed into law a bill that requires medication abortion to be provided according to the label that existed on December 31, 2015 (Eckholm, 2016), which was the original label approved in 2000, described below. Although the law may not withstand a likely court challenge, the fact that a state would mandate such obviously outdated practices is alarming and highlights the growing chasm between science and policy in parts of the country.

Important Changes to the Mifeprex Label

The FDA approved the antiprogestin mifepristone (brand name Mifeprex) for use as an abortifacient in combination with the prostaglandin misoprostol in 2000. Since its approval, mifepristone's safety record has remained strong; the mortality rate for medication abortion is approximately 1 per 100,000, which is slightly higher than the mortality rate for surgical abortion, but significantly lower than the maternal mortality rate for women bringing their pregnancies to term (9.8 per 100,000; Beal, 2007). Risks of fatal complications in abortions (both surgical and medical) remain very low, but they increase as gestation advances (Zane et al., 2015). In 2011, nearly 240,000 medication abortions using mifepristone were performed in the United States, and they accounted for 23% of non-hospital abortion procedures in 2011 (Jones & Jerman, 2014).

Mifeprex approval and its original label were based on the protocol used during pre-approval clinical trials in the 1980s and 1990s, but knowledge and practice for safe and effective

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medication abortion quickly advanced beyond what the original label specified (Borkowski et al., 2015; Britton & Bryant, 2015; Cleland & Smith, 2015). The March 2016 label adopts several of the evidence-based variations that are already in widespread use and recognized as standard clinical practice, including changing the drug dosage to 200 mg of oral mifepristone and 800 μg of buccal misoprostol (FDA, 2016b). The use of 200 mg of mifepristone rather than the 600 mg specified in the original label had long been recommended by the World Health Organization, the American College of Obstetricians and Gynecologists (ACOG), the Society of Family Planning, and the Planned Parenthood Federation of America (Cleland & Smith, 2015). A 2014 ACOG practice bulletin notes that regimens using 200 mg of mifepristone "have similar efficacy and lower costs" than those involving 600 mg and states, "Based on efficacy and the adverse effect profile, evidence-based protocols for medical abortion are superior" to the regimen on the original label (ACOG, 2014).

Another important change to the label is updating the gestational limit for medication abortion from 49 days to 70 (FDA, 2016b). A survey of abortion providers regarding their 2011 practices asked whether providers of medication abortion offered it up to 63 days' gestation, and most indicated that they did (Jones & Jerman, 2014). Since 2011, several large studies have demonstrated the safety and efficacy of the evidence-based protocol for gestations of up to 70 days (Abbas, Chong, & Raymond, 2015; Bracken et al., 2014; Sanhueza Smith et al., 2015; Winikoff et al., 2012). The new label reflects this recent evidence.

The new label also removes two specifications: 1) that women must return to providers' offices 2 days after receiving mifepristone to take misoprostol, the second drug in the regimen and 2) that women complete their clinical follow-up in person (FDA, 2005, 2016b). Allowing women to take misoprostol on their own schedules and without returning to a provider's office can reduce women's logistical barriers as well as costs for transportation, time off work, or childcare; for years, many providers have been following protocols permitting home use of misoprostol, and extensive evidence demonstrates the safety of doing so (Clark, Gold, Grossman, & Winikoff, 2007; Cleland, Creinin, Nucatola, Nshom, & Trussell, 2013; Wiegerinck et al., 2008). Alternatives to following up in person with medication abortion providers to confirm abortion completion include comparing baseline and post-abortion measurements of human chorionic gonadotropin, a hormone women's bodies produce during pregnancy. For instance, a woman can have blood drawn when she is prescribed mifepristone and visit a local laboratory for a second blood draw 1 to 2 weeks later; the provider can contact the woman by phone after receiving her laboratory report (ACOG, 2014). Although this still requires an in-person visit, laboratories may be more conveniently located than abortion providers and may offer extended hours or drop-in options. Some providers are already using this and other variations on in-person follow-up (Borkowski et al., 2015; Horning, Chen, Meyn, & Creinin, 2012), and research into a range of variations is ongoing. By removing the specification for patients to return to their providers to confirm abortion completion, the updated label allows for evolving evidence-based practice on follow-up visits.

Removing the requirement for in-person visits to abortion providers for misoprostol administration and follow-up can also allow providers to re-allocate limited resources previously devoted to these visits. Another change to the label, the removal of the specification that mifepristone be administered "by or under the supervision of a physician" (FDA, 2005, 2016b), also increases provider flexibility. Research demonstrates that medication abortions performed by mid-level providers (MLPs), such as nurse practitioners, nurse-midwives, and physician assistants, achieve similar safety and efficacy results to those by physicians (Barnard, Kim, Park, & Ngo, 2015). Ensuring that MLPs have the legal authority and training to provide medication abortions can increase access to safe abortion services in areas with few physicians, such as rural areas where advanced practice clinicians but not obstetricians or gynecologists are located (Foster, Jackson, LaRoche, Simmonds, & Taylor, 2015; Taylor, Safriet, & Weitz, 2009). It can also enhance the cost effectiveness of abortion care and allow providers to offer services to more women (Yarnall, Swica, & Winikoff, 2009).

The revised label still includes requirements that are far more restrictive than typical requirements for prescription drugs of a similar safety profile, including mandating signed provider and patient agreements. Distribution is still tightly controlled, and access could improve if women could obtain Mifeprex by prescription from pharmacies rather than from a provider, who must keep the drug in stock and be a registered prescriber. Overall, however, the updated label does a far better job reflecting current research on safety and efficacy, and it allows for greater flexibility that can improve women's access to abortion care.

States Limiting Providers' Ability to Offer Evidence-Based Care

Although the updated Mifeprex label allows MLPs to provide medication abortions with or without physician supervision as permitted by state law, as of March 2016 thirty-seven states allow only licensed physicians to provide medication abortion, despite research showing that MLPs can provide this service safely and effectively.[1]

Eighteen states require the clinician to be physically present for the medication abortion process (Guttmacher Institute, 2016). Requirements that the physician be physically present effectively prohibit the use of telemedicine for the medication abortion process. The telemedicine option, which allows geographically distant patients and providers to communicate electronically, may become increasingly important if more clinics providing abortion are required to close owing to state laws that reduce abortion availability. Where it is not prohibited, telemedicine can present a promising option for women in rural or other health professional shortage areas, where travelling to a clinic for multiple visits may require days off from work or even overnight stays hundreds of miles from home. After clinics in Iowa began offering medication abortions via telemedicine, researchers found that safety and efficacy outcomes for telemedicine and face-to-face procedures were similar (Grossman, Grindlay, Buchacker, Lane, & Blanchard, 2011), and that women receiving abortions were more likely to obtain them before 13 weeks' gestation (Grossman, Grindlay, Buchacker, Potter, & Schmertmann, 2013).

Limitations on who can provide medication abortion care and how will likely have an immediate and significant impact on women's access to these services. A recent analysis of trends in mifepristone use in four states—two with very restrictive

[1] Thirty-eight (38) states allow only licensed physicians to provide surgical abortion; New Jersey is the only state that limits surgical but not medication abortion to licensed physicians (Guttmacher Institute, 2016).