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Analysis: FDA Decision Ignores Data on Complications, Puts Women at Risk

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As a dangerous drug, mifepristone has been subject to regulations put in place by the Food and Drug Administration (FDA) in 2000.[1] Under these regulations, called a Risk Evaluation and Mitigation Strategy (REMS), mifepristone may only be dispensed in person by certain qualified medical providers. Despite the risks associated with mifepristone, the abortion industry has repeatedly challenged the REMS, using the coronavirus pandemic to push for easier access. In 2020, the abortion industry obtained a court order blocking part of the REMS, allowing mifepristone to be dispensed through the mail. In April 2021, FDA announced it was not enforcing the portion of the REMS that required in-person medical oversight for the duration of the public health emergency. A separate court case seeking full removal of the REMS was stayed, and the FDA informed the court that it was reviewing the REMS. On December 16, 2021, the FDA announced that the removal of the in-person dispensing requirement would be permanent. Mifepristone will now be available through the mail or in pharmacies, and the FDA has created a certification to allow pharmacies to dispense the drug.

The data relied upon by the Food and Drug Administration (FDA) to make its decision is incomplete and inadequate. Studies using better data show that mifepristone is dangerous, and that these risks are likely to increase with the rollback of the in person-requirement.

The Poor Quality of U.S. Abortion Data

When the FDA first approved mifepristone in 2000, it established a requirement that all serious adverse events be reported. Between 2000 and 2019, over 3,800 adverse events were reported to the FDA, including at least 20 deaths, more than 500 life-threatening complications, and over 2,000 severe complications.[2,3] However, an analysis of the data collected under this reporting requirement suggests that a significant number of complications were unreported and that the FDA may have missed as many as 95% of serious chemical abortion adverse events.[4] Despite this underestimation of the true

[1] Food and Drug Administration. Approved Risk Evaluation and Mitigation Strategies (REMS). Mifepristone: Shared System REMS. Accessed from: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390. See also Howard H. Medical and Social Risks Associated with Unmitigated Distribution of Mifepristone: A Primer. Charlotte Lozier Institute; On Point Series 51. 2020. Accessed from: https://lozierinstitute.org/medical-and-social-risks-associated-with-unmitigated-distribution-of-mifepristone-a-primer/

[2] Aultman K, et al. Deaths and severe adverse events after the use of mifepristone as an abortifacient from September 2000 to February 2019. *Issues Law Med*. 2021;36(1):3-26. https://pubmed.ncbi.nlm.nih.gov/33939340/

[3] Gary MM, Harrison DJ. Analysis of severe adverse events related to the use of mifepristone as an abortifacient. Ann Pharmacother. 2006;40(2):191-197. doi: 10.1345/aph.1G481

[4] American Association of Pro-Life Obstetricians and Gynecologists. Dangers of relaxed restrictions on mifepristone. Committee Opinion No. 9. 2021. Accessed from: https://aaplog.org/wp-content/uploads/2021/11/CO-9-Mifepristone-Restrictions-1.pdf

number of complications, in 2016 the FDA amended the reporting requirement to apply only to deaths, concluding that complications were rare and the rate of complications was stable.[5] The vast majority of chemical abortion-related adverse events are now no longer reflected in FDA's system.

There is no comprehensive reporting of abortions or abortion complications in the U.S. States collect abortion data and share it with the federal government on a voluntary basis. Three states, accounting for a fifth of all U.S. abortions, do not even track abortion data.[6] Even among states that require abortion providers to report abortions, data quality varies. Approximately half the states collect at least some abortion complication data, but only a quarter require health care providers in addition to the abortion center to report complications they treat.

As a result of the FDA's recent decision, underreporting of chemical abortions will no doubt increase. No guidance has been issued for states on best practices for collecting data on abortion by mail. Many states were unprepared for the suspension of the in-person requirement in 2020,[7] and with the formal removal of this requirement, state abortion reporting systems may be unable to track the increase of chemical abortions due to provision through the mail, especially if the mailed abortion drugs cross state lines from out-of-state or offshore providers.

Medicaid Data

Consequently, perhaps the most reliable source of accurate abortion data in the U.S. is the Medicaid system. Under the Hyde Amendment, federal Medicaid does not cover abortion except in cases of rape, incest, or risk to the life of the mother, but states may use their own funds to pay for abortions for Medicaid-eligible women.[8] Between 2000 and 2015, 17 states provided funding for most abortions for women enrolled in Medicaid. Data on all state-funded abortions obtained by Medicaid enrollees, as well as all other medical treatment paid for by Medicaid, is available from the Centers for Medicare and Medicaid Services (CMS).

[5] Food and Drug Administration, Center for Drug Evaluation and Research. Mifeprex clinical review. 2016. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf
[6] Kortsmit K, et al. Abortion surveillance – United States, 2019. *MMWR Surveill Summ*. 2021;70(9):1-29. doi: 10.15585/mmwr.ss7009a1.
[7] Longbons T. The impact of chemical abortion by mail. Society of St. Sebastian. Published May 20, 2021. Accessed November 17, 2021. https://www.societyofstsebastian.org/abort-by-mail-longbons
[8] New MJ. Hyde @ 40: Analyzing the Impact of the Hyde amendment with July 2020 Addendum. Charlotte Lozier Institute; On Point Series 61. 2021. https://lozierinstitute.org/hyde-40-analyzing-the-impact-of-the-hyde-amendment-with-july-2020-addendum/.

A new study using this dataset contradicts the conclusions drawn by the FDA and suggests that emergency room visits following chemical abortion are increasing.[9] The study analyzed 423,000 state-funded abortions performed on Medicaid-eligible women and found that between 2002 and 2015, the rate of abortion-related emergency room visits following chemical abortions increased by over 500 percent. Chemical abortions had a 53% higher risk of a subsequent abortion-related emergency room visit than surgical abortions, and the gap between the two abortion methods widened over the course of the study period. In 2015, the abortion-related ER visit rate for chemical abortion was 51.7 visits per 1,000 abortions, over twice the surgical rate.

Not only were chemical abortions increasingly more likely to result in a visit to the emergency room, they also had a greater likelihood of being miscoded once the woman arrived in the ER, and the problem is worsening. Between 2005 and 2015, chemical abortion went from twice as likely to four times as likely as surgical abortion to be miscoded as a miscarriage. By 2015, over 60 percent of all abortion-related emergency room visits following chemical abortions were miscoded as miscarriages.

If medical providers routinely misdiagnose or misreport abortion-related complications they encounter, complication data available in the U.S. could be even less reliable than originally thought. In fact, the rates of emergency room visits reported by this study were higher than rates published by previous studies that counted only complications coded as resulting from induced abortions.

International Context

The findings of the emergency room study correspond to the results of studies from nations with better abortion data, particularly countries with universal healthcare that have complete registries of the health outcomes of both births and induced abortions. An analysis of more than 42,000 abortions performed in Finland between 2000 and 2006 found that a fifth of the chemical abortions resulted in complications, with a complication rate four times that of surgical abortions.[10] More than 15 percent of the chemical abortions resulted in hemorrhage, compared to 2.1% of the surgical abortions. Nearly seven percent of chemical abortions were incomplete, while 1.6% of surgical abortions were incomplete.

[9] Studnicki J, et al. A longitudinal cohort study of emergency room utilization following mifepristone chemical and surgical abortions, 1999-2015. *Health Serv Res Manag Epidemiol*. 2021;8. https://doi.org/10.1177%2F23333928211053965

[10] Niinimäki M. Immediate complications after medical compared with surgical termination of pregnancy. Obstet Gynecol. 2009;114(4):795-804. doi: 10.1097/AOG.0b013e3181b5ccf9.

Similar to the U.S. Medicaid study, another registry-based study also found an increasing rate of chemical abortion complications.[11] In an analysis of nearly 5,000 abortions performed at a Swedish hospital between 2008 and 2015, the chemical abortion complication rate nearly doubled, from 4.2% in 2007 to 8.2% in 2015. In 2008, the chemical abortion complication rate was lower than the surgical rate, but by 2015, chemical abortions had a complication rate twice that of surgical abortions. In addition, the study found that chemical abortions that took place at home rather than in a medical facility resulted in a much higher complication rate, despite the fact that a physical examination was provided in advance of each abortion. For women undergoing chemical abortion via telemedicine, who have had no in-person interaction with their healthcare provider, any complications will likely be handled in an emergency or urgent care setting. Since some abortion advocacy groups encourage women to withhold the information that they had a chemical abortion when presenting at such a setting, this makes it even more difficult for emergency room providers to accurately diagnose, treat, and report these chemical abortion-related complications.[12]

Additionally, a study of more than 18,000 abortions in Finland demonstrates the increased risks associated with chemical abortion as pregnancy advances.[13] Compared to first-trimester chemical abortions, chemical abortions in the second trimester are over twice as likely to lead to infection and nearly eight times as likely to require surgical intervention.

Conclusion

In light of these findings, the FDA should restore the in-person dispensing requirement and strengthen the REMS. In addition, the federal government should issue guidance to the states, potentially by updating its Induced Termination of Pregnancy reporting handbook, which was last updated in 1997 to include chemical abortion as an abortion method.[14] Although reporting is voluntary on the part of the states and states are not required to use the federal handbook, many states look to it as a model for their own reporting forms. State health departments should also ensure that all abortion providers,

[11] Carlsson I, Breding K, Larsson P-G. Complications related to induced abortion: a combined retrospective and longitudinal follow-up study. BMC Women's Health. 2018;18(1):158. doi: 10.1186/s12905-018-0645-6.
[12] Safe2Choose. Will medical staff be able to notice that I am having an abortion? Accessed September 9, 2021. https://safe2choose.org/faq/medical-abortion-faq/during-abortion-with-pills/will-medical-staff-be-able-to-notice-that-i-am-having-an-abortion; Plan, C . Abortion pills FAQ: Can I get in trouble for using abortion pills? Accessed September 9, 2021. https://www.plancpills.org/guide-how-to-get-abortion-pills#faq
[13] Mentula MJ. Immediate adverse events after second trimester medical termination of pregnancy: results of a nationwide registry study. *Hum Reprod*. 2011;26(4):927-932. doi: 10.1093/humrep/der016.
[14] See National Center for Health Statistics. *Handbook on the Reporting of Induced Termination of Pregnancy*. 1998. DHHS Publication No. (PHS) 98-1117. https://www.cdc.gov/nchs/data/misc/hb_itop.pdf

particularly those that were not performing abortions prior to the rollback of the in-person dispensing requirement, are aware of state law regarding abortion reporting.

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