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Risking Two Lives—The Dangerous Rise of Chemical Abortion

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TOPLINE POINTS

- ★ Although chemical abortions pose serious risks to women, with 1 in 5 experiencing adverse effects, the Food and Drug Administration (FDA) has expanded access to chemical abortions over the past two years.
- ★ These regulatory changes and the overturning of *Roe v. Wade* in June 2022 have fueled an increase in "abortion-on-demand," largely through telehealth (also called teleabortions or "Skype Abortions") and direct-mail prescriptions.
- ★ Policy solutions should seek to protect the two lives at stake—the woman and the baby—and include additional safety protections for women who require in-person evaluations to determine clinical appropriateness.

Understanding Chemical Abortion

Abortion is corrosive to children, women, and society broadly because it devalues and extinguishes innocent human life. Unfortunately, federal policymakers have recently expanded access to abortion pills, also called chemical abortions, which are far more dangerous to women, enabling rapid access to abortion.

Chemical abortion is a two-drug regimen that is taken up to 10 weeks into a pregnancy to result in termination.[1] It is distinguished from surgical abortions by a lack of a medical procedure to terminate the pregnancy. Most commonly, the drug **mifepristone** is taken

[1] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation

first. Mifepristone blocks the naturally occurring hormone progesterone, thus disrupting the endometrial lining and essentially depriving the baby of the oxygen and nutrients needed for continued growth—effectively starving the child.[2] Between 24–48 hours later, the second prescription drug, **misoprostol,** is taken to induce labor, causing the uterus to contract and forcing out the deceased child.[3] When mifepristone was originally approved by the U.S. Food and Drug Administration (FDA) in 2000, it was required to be administered in a clinical setting with adequate supervision of a medical expert who was "able to assess the gestational age of an embryo and diagnose ectopic pregnancies."[4]

Since the FDA's approval of major abortifacients in 2000, the rate of chemical abortions has steadily increased, now making up 64% of abortions prior to 10 weeks gestation and 52% of all abortions, according to the Centers for Disease Control and Prevention data from 2020.[5] From 2009–2018, the use of chemical abortions increased by 120%—from 17% of abortions in 2009 to 38% in 2019.[6] Dangerous chemical abortions are now the most common method of terminating a pregnancy. They are a serious threat to women's health and deserve greater medical scrutiny.

Before the COVID-19 pandemic, elements of the chemical abortion process became remote through a site-to-site protocol from Planned Parenthood and a direct-to-patient protocol in a clinical trial. However, some components of each process still required an in-person visit.[7] Early in the pandemic, abortion providers published a protocol for a "no-test medication abortion," allowing for **fully virtual medical appointments** (also called "teleabortion") for chemical abortions without the need for labs, ultrasound, or a pelvic exam in select states—under the guise of preventing unnecessary COVID-19 exposures for women and doctors.[8,9] Though expanded access to telehealth is generally favorable, it should occur only in cases in which it is completely safe for patients, and teleabortion does not meet that standard.

Using COVID-19 to Expand Abortion-on-Demand

Efforts to use COVID-19 to expand abortion-on-demand faced early legal challenges, but abortion proponents have seen expanded success during the Biden Administration. In May 2020, the American Civil Liberties Union, the American College of Obstetricians and Gynecologists, and other plaintiffs filed a lawsuit seeking to block the in-person

[2]https://www.ncbi.nlm.nih.gov/books/NBK557612/
[3] https://www.ncbi.nlm.nih.gov/books/NBK539873/
[4] https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm
[5] https://www.cdc.gov/mmwr/volumes/71/ss/ss7110a1.htm
[6] https://www.cdc.gov/mmwr/volumes/69/ss/ss6907a1.htm
[7] https://www.guttmacher.org/gpr/2019/05/improving-access-abortion-telehealth
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7161512/
[9] https://www.kff.org/policy-watch/medication-abortion-telemedicine-innovations-and-barriers-during-the-covid-19-emergency/ [figure 1]

dispensation requirement for a chemical abortion.[10] Two months later, in July 2020, a federal district court suspended the Risk Evaluation and Mitigation Strategy (REMS) requirement that mifepristone must be distributed in person, allowing these pills to be distributed by mail for the duration of the pandemic.[11] The Trump Administration appealed this ruling, and the Supreme Court granted a stay on January 12, 2021.[12]

However, the Biden Administration began to push for more favorable abortion measures shortly after taking office. In April 2021, the FDA announced it would use enforcement discretion regarding REMS before it permanently revised the policy in December 2021 to allow chemical abortion without the safeguards of in-person evaluation.[13] In January 2023, the FDA approved the dispensation of the medication at retail pharmacies after the prescription from an authorized medical provider.[14] This policy serves to facilitate abortion-on-demand from any setting and removes safeguards.

Increases in Chemical Abortions and Concerning Evidence Regarding Safety

The interaction of these regulatory changes and the *Dobbs v. Jackson Women's Health Organization* decision on the number of abortions performed is important to consider. One national analysis aimed to determine the early impact of the *Dobbs* decision on the number of abortions nationally.[15] The researchers found an overall 6% decrease in the number of abortions from April 2022 to August 2022, but a 33% increase in virtual-only abortions provided.[16] Data monitoring and impact analysis in the years ahead are critical.

Although the FDA states that abortion-on-demand in fully virtual settings is completely safe, contradictory evidence does exist. The American Association of Pro-life Obstetricians and Gynecologists represents approximately 7,000 board-certified women's healthcare practitioners and maintains that an in-person visit is protective and medically necessary to evaluate for any medical contraindications to a chemical abortion, including accurate dating of the pregnancy.[17] A February 2020 practice guideline highlighted safety

[10] https://www.aclu.org/press-releases/new-lawsuit-challenges-fda-restriction-imposes-life-threatening-risks-patients
[11] https://www.aclu.org/press-releases/federal-court-blocks-fda-restriction-unnecessarily-imposes-covid-19-risks-patients
[12] https://www.supremecourt.gov/opinions/20pdf/20a34_3f14.pdf
[13] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation
[14] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation
[15] https://www.societyfp.org/wp-content/uploads/2022/10/SFPWeCountReport_AprtoAug2022_ReleaseOct2022-1.pdf
[16] https://www.societyfp.org/wp-content/uploads/2022/10/SFPWeCountReport_AprtoAug2022_ReleaseOct2022-1.pdf
[17] https://aaplog.org/wp-content/uploads/2021/04/AAPLOG-Statement-on-FDA-removing-mifepristone-REMS-April-2021-1.pdf

evidence and recommended the FDA REMS be strengthened rather than removed in order to minimize the risks of chemical abortions.[18]

One notable research study published in the academic journal Obstetrics and Gynecology reported on a longitudinal analysis of more than 40,000 abortions in Finland from 2000-2006. This study found that one in five women undergoing chemical abortions experienced complications—four times more than the number of women who experienced complications from surgical abortions.[19] Another academic longitudinal analysis of more than 400,000 abortions in select states in the U.S. from 1999–2015 found a greater risk of needing an emergency visit following a chemical abortion rather than surgical abortion.[20] The precise reason for the greater risk to the mother is likely multifaceted, but the fact that chemical abortions involve less physician supervision than surgical procedures is likely a factor. It will be critical to include safety measures in data and clinical monitoring in the years ahead.

Citing this evidence and more, Alliance Defending Freedom filed a lawsuit on behalf of four physician groups and four individual physicians against the FDA in November 2022.[21] While the case proceeds in court, the evidence indicates that the practice of chemical abortion-on-demand endangers the mother and kills an unborn child and could therefore benefit from additional protections for both lives involved.

Role of States in Providing Safeguards

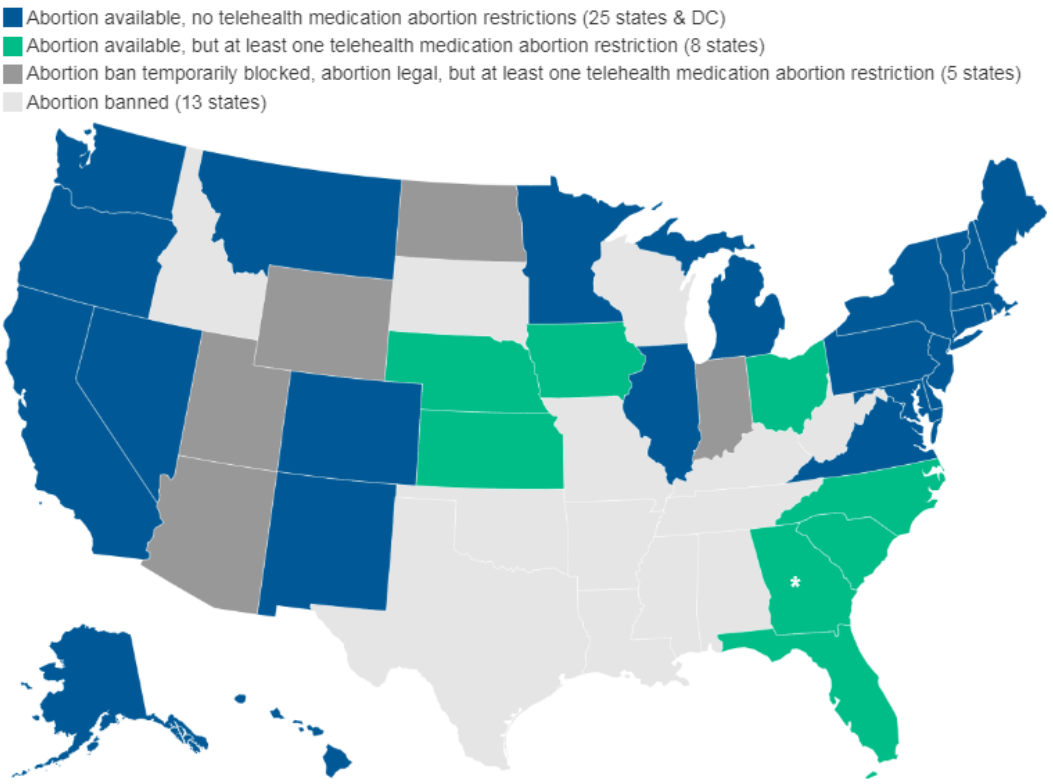
State laws play a critical role in safeguarding women by restricting the availability of teleabortions or creating in-person clinical evaluation requirements that must be met before prescribing a chemical abortifacient.[22] Teleabortion is currently allowed in 25 states and Washington, D.C., without restriction.[23] In the remaining states, abortion is either effectively banned, subject to varying exceptions, or teleabortion is limited by at least one restriction. These restrictions include physician physical presence laws/bans on telehealth provision of medication abortion, in-person counseling requirements, and ultrasound requirements (see KFF figure below).[24]

[18] https://aaplog.org/wp-content/uploads/2023/01/PG-8-Medication-Abortion.pdf
[19] https://pubmed.ncbi.nlm.nih.gov/19888037/
[20] https://journals.sagepub.com/doi/full/10.1177/23333928211053965 [Key results for a chemical rather than a surgical abortion: all ER visits (OR 1.22, CL 1.19-1.24); miscoded spontaneous (OR 1.88, CL 1.81-1.96); and abortion-related (OR 1.53, CL 1.49-1.58).]
[21] https://adflegal.org/sites/default/files/2022-11/Alliance-for-Hippocratic-Medicine-v-FDA-2022-11-18-Complaint.pdf
[22] https://www.kff.org/policy-watch/medication-abortion-telemedicine-innovations-and-barriers-during-the-covid-19-emergency/
[23] https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/
[24] https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion/

Figure 1

Availability of Telehealth for Medication Abortion in a Post-*Roe* United States

Hover over state for more details



NOTE: Status of abortion as November 23, 2022. Medication abortion telehealth restrictions include: physician physical presence laws/ bans on telehealth provision of medication abortion, in-person counseling requirements, and ultrasound requirements.
*In a Georgia, a 6-week LMP gestational limit is in effect.
SOURCE: KFF analysis of state policies and court decisions, as of November 15, 2022.
KFF analysis of Guttmacher Institute, State Laws and Policies, Medication Abortion, Counseling and Waiting Periods for Abortion, and Requirements for Ultrasound, as of November 1, 2022.
• PNG

KFF

As a result of the *Dobbs* decision, each state is empowered to determine the best way to protect women and babies in their state. Given the complex interplay between existing state abortion laws and legal/court proceedings, policy solutions that include additional safety measures regarding teleabortion should be considered. Effective policies should prioritize quality care for women by providing safeguards from the known dangers of chemical abortion. One way to accomplish this is for states to require in-person ultrasounds before any abortion to ensure accurate pregnancy dating, including chemical abortion accessed through telehealth.[25] According to a national poll by Scott Rasmussen, this approach is supported by the majority of

[25] https://agenda.americafirstpolicy.com/freedom-and-self-governance/honor-the-sanctity-of-every-innocent-human-life

Americans. 60% of those surveyed, including 58% of women, said they favored requiring a woman to have an ultrasound before deciding to have an abortion. Another example from current state legislative sessions is a policy proposed in Kansas SB 5. This policy would prohibit the use of telemedicine to prescribe drugs intended to cause an abortion and restrict the governor's power during a state of emergency to alter such prohibitions.[26]

Access to Mifepristone has garnered high-level federal and state action early in 2023. On January 13, 2023, 22 state attorneys general sent the FDA commissioner a letter asserting that the recent FDA policies "have not negated any of our laws that forbid the remote prescription, administration, and use of abortion-inducing drugs."[27] On January 20, 2023, Rep. Bob Good (VA-05) introduced the "Teleabortion Prevention Act," which, similar to legislation introduced in the previous Congress, would require a healthcare provider to do a physical examination, be present during the chemical abortion, and schedule an in-person follow-up visit.[28,29] President Biden then issued a memorandum on January 22, 2023, to the Attorney General, the Secretary of Homeland Security, and the Security of Health and Human Services directing specific actions regarding access to mifepristone.[30] In contrast, on January 26, 2023, a bicameral letter led by Senator Cindy Hyde-Smith (R-MS) and signed by 77 Senators and Members of Congress urged the FDA to pull mifepristone from the market or restore and strengthen basic health and safety requirements.[31]

All administrative and legal proceedings on teleabortion should be monitored, and America First policies should focus on immediately halting the effort to normalize abortion-on-demand and on broadly recognizing the evidence of the risk posed to women. In the upcoming state legislative sessions and the 118th Congress, policymakers should prioritize providing greater protection for the two lives involved—the mother and the baby—especially with safeguards to protect women and children from the dangers of teleabortion.

[26] http://www.kslegislature.org/li/b2023_24/measures/sb5/
[27] https://my.alabamaag.gov/Documents/news/Letter_from_Ala_Atty_Gen_Steve_Marshall_et_al_to_FDA.pdf
[28] https://good.house.gov/media/press-releases/rep-good-protects-mothers-and-babies-introducing-teleabortion-prevention-act
[29] https://www.congress.gov/bill/117th-congress/house-bill/5136/text
[30] https://www.whitehouse.gov/briefing-room/presidential-actions/2023/01/22/memorandum-on-further-efforts-to-protect-access-to-reproductive-healthcare-services/
[31] https://www.hydesmith.senate.gov/sites/default/files/2023-01/012623 Bicameral Letter to FDA re Abortion Drugs.pdf