

EMAA project and Ipas written evidence to the UN Special Rapporteur in the field of cultural rights on the right to access and take part in scientific progress

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The Expanding Medication Abortion Access (EMAA) project and Ipas respectfully submit their inputs to the Special Rapporteur on the issue of human rights obligations relating to the right to access and participate in scientific progress for her upcoming report to be presented at the Human Rights Council.

The EMMA Project seeks to improve the way the medications prescribed for medication abortion care are dispensed in the United States, to make the process consistent with the medical and scientific evidence, and to meet women's needs.

Ipas is an international organization that works with partners around the world to advance reproductive justice by expanding access to abortion and contraception so everyone can determine their future. Ipas is working to increase access to medication abortion by supporting pathways to clinic-based care and abortion self-care networks and by sharing information about abortion with pills to a broad audience in the United States.

We would like to take this opportunity to provide written evidence on the issues raised in **questions 4-8** in the call for input by providing evidence about the right to access and take part in scientific progress concerning access to safe abortion in the United States after the Supreme Court decision to eliminate the constitutional right to abortion and the approval of the state-level laws that lack the use of the best available scientific evidence and systematically collected data in its formulation, drafting, and approval processes.

Abortion rights and access to scientific progress are under threat in the United States

Abortion is health care—and a fundamental human right. Further, the right to abortion depends upon people also having other human rights: health, equality, privacy, living free from violence and discrimination, and the right to access and take part in scientific progress. Restrictive abortion laws violate these rights.

In June 2022, the United States Supreme Court overturned *Roe v. Wade*, which had guaranteed the constitutional right to abortion for almost 50 years. Since then, many states have enacted significant legal restrictions, in some cases extreme enough to effectively ban abortion entirely. While rights vary state by state, overall, people in the U.S. now have less reproductive freedom—with Black, indigenous, and people of color facing the most significant barriers to bodily autonomy.

The 2022 World Health Organization Abortion Care Guideline explains that “abortion is a safe and non-complex health-care intervention that can be effectively managed using medication or a surgical procedure in a variety of settings.” In the past two decades, medical abortion has been on the rise globally due to the increasing availability of abortion pills (misoprostol and mifepristone), the lower cost of the medication, the promotion of self-care on sexual and reproductive health, the use of telehealth, and abortion seekers' preference, as this method gives them control over their own bodies and reproductive choices.

In the United States, the Food and Drug Administration (FDA) first approved Mifeprex (mifepristone) in September 2000 for medical termination of pregnancy through seven weeks gestation, and this was extended to ten weeks gestation in 2016¹. In December 2021, the FDA permanently lifted the administrative requirement

¹ U.S. Food and Drug Administration. Clinical Review of NDA 020687/S-020 Mifeprex. March 2016.

for patients to get medical abortion pills in person at a clinic, allowing prescriptions to be delivered directly to patients. In January 2023, after a thorough review of the science and evidence, the FDA approved a program in which pharmacies can fill prescriptions both via mail and in person. The FDA has periodically reviewed the scientific literature and evidence of mifepristone's use and has taken steps to expand who can prescribe the medication and where and how the medication can be dispensed, including letting patients take mifepristone at home rather than in a clinic. These are evidence-based actions supported by hundreds of studies over two decades.

Today, mifepristone has been used by more than 5 million people in the US and has a safety and efficacy record of 99%. In 2018, medication abortion accounted for 54% of abortions before 9 weeks in the US. By 2020, medication abortion accounted for more than half of all abortions obtained in the United States, up from 39% in 2017. According to the American College of Obstetricians and Gynecologists mifepristone has helped ensure that patients can make their own private medical decisions, and it has expanded access to essential, time-sensitive reproductive health care, including miscarriage management².

The use of the courts to restrict access to medical abortion in the United States

In the wake of *Dobbs v. Jackson Women's Health Organization*, the US Supreme Court decision in June 2022 that overturned the federal constitutional right to abortion, 14 states³ have banned abortion outright, with two more states limiting legal abortion to 6 weeks. This means patients in 16 states no longer have access to an FDA-approved drug labeled safe for use up to 10 weeks.

Another 15 states have laws on the books that say only a physician can prescribe mifepristone or require a patient to come into a clinic and take the pill at the clinic; policies which the FDA has deemed are not necessary for the safe provision of mifepristone. This policy also contradicts findings from the World Health Organization and other health and medical organizations that advanced practice clinicians, such as physician assistants and nurse practitioners, can safely provide medical abortion. This means people living in these states do not have the option of consulting with a healthcare provider virtually and having the medication delivered to them in line with FDA recommendations and evidence.

In addition to state-level restrictions on medical abortion, there is ongoing litigation in four federal cases about the FDA's approval and regulation of mifepristone, one of the two drugs used in medical abortion. In the most high-stakes case, *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, the court could rule to invalidate the FDA's 23-year-old approval of mifepristone or potentially limit the distribution of this drug for abortion, even in states where abortion remains legal. While these cases focus on abortion, the outcome of the litigation will have a broader impact on FDA's scientific and regulatory authority and likely impact the development of other drugs in the future.

This case was brought by The Alliance Defending Freedom (ADF), an anti-abortion and anti-gender legal organization with a lengthy track record of denying the evidence and science on medical abortion. They filed their case in federal court in Amarillo, Texas, knowing their case would be heard by a judge with an anti-rights track record. In April, Judge Kaczmeryk ruled that the FDA had acted improperly when it first approved mifepristone and that this drug should be deemed unapproved. A circuit court (appellate court or court of

² American College of Obstetricians and Gynecologist. Improving Access to Mifepristone for Reproductive Health Indications Position Statement. Accessed Nov. 13, 2023.

<https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications>

³ The New York Times. Tracking Abortion Bans Across the Country. Updated Nov. 7, 2023. Accessed Nov. 10, 2023 <https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html>

appeals) disagreed with that radical conclusion but did agree that changes the FDA enacted over the subsequent two decades to improve access to the medication should be rolled back. The Supreme Court issued a stay in both rulings maintaining existing approval for mifepristone. Since then a new attempts to restrict how mifepristone can be used and distributed have been made. Currently, people in at least half the states can continue to have access to mifepristone.

However, the case continues. The Supreme Court may hear arguments early in 2024 and issue a ruling before July. It may postpone hearing the case. Or it may decide not to hear the case, in which case, the circuit ruling goes into effect. A ruling that would undermine FDA's authority over the drug approval process and impose radical and previously unknown requirements for FDA's drug application review process. The lawsuit has the potential to severely limit development of new drugs overall and has far-reaching implications for patients' access to FDA approved medications. The American Medical Society, American College of Obstetrician Gynecologists, Society for Maternal-Fetal Medicine, and other prominent medical associations have asked the court to recognize that "the plaintiff's arguments are fundamentally ideological, not scientific, and provide no legal justification to reverse 23 years of precedent and a wealth of scientific evidence."⁴

Abortion restrictions have exacerbated inequality in the United States

Abortion is a gender, racial equity, social and reproductive justice issue. Access to abortion care allows people to determine their own future. It can make a difference in whether a girl completes her schooling, a woman becomes gainfully employed, or a pregnant person is exposed to gender-based violence.

Restrictions on medical abortion fall hardest on people living in medically underserved communities, especially for Black, Indigenous, people of color and people with low incomes, who already face barriers to care due to systemic inequities in the United States health care system. In a recent analysis focused on inequity and abortion rights in the United States, the Guttmacher Institute points out that the "new and impending abortion restrictions and bans will undoubtedly deepen the profound inequities in abortion access that have long marked the reproductive health and well-being of pregnant people and their families".⁵

These restrictions not only lack scientific evidence, but they are not supported by vast majority of people in the United States. Data from Gallup show that 85% of Americans want abortion to be legal⁶. New, repeated polling has demonstrated that people want mifepristone to remain on the market and accessible^{7, 8}. In addition, the majority of people trust the FDA and want the agency to remain an independent body that is permitted to follow the medicine and science. People deserve to access the medication they want and need and providers should be able to prescribe this medication without unnecessary interference from politicians. In enacting state restrictions on medication abortion, state legislators have disregarded public opinion and scientific evidence.

⁴ American College of Obstetricians and Gynecologists. ACOG Leads Amicus Brief Calling Mifepristone Conclusively Safe and Effective. Feb 10, 2023. Accessed Nov. 13, 2023.

<https://www.acog.org/news/news-releases/2023/02/acog-leads-amicus-brief-calling-mifepristone-conclusively-safe-and-effective>

⁵ Fuentes, Liza (2023). Inequity in US Abortion Rights and Access: The End of Roe Is Deepening Existing Divides. Guttmacher Institute. First published online: January 17, 2023. Accessed Nov. 13, 2023.

<https://www.guttmacher.org/2023/01/inequity-us-abortion-rights-and-access-end-roe-deepening-existing-divides>

⁶ Gallup (2023). Abortion| Gallup Historical Trends. Accessed Nov. 10, 2023 <https://news.gallup.com/poll/1576/abortion.aspx>

⁷ Guskin, Emily. Most U.S. adults say the abortion pill mifepristone should stay on the market, Post-ABC poll finds. Washington Post. May 9, 2024 <https://www.washingtonpost.com/politics/2023/05/09/mifepristone-abortion-poll/>

<https://www.washingtonpost.com/politics/2023/05/09/mifepristone-abortion-poll/>

⁸ Montanaro, Domenico. Poll: Two-thirds oppose banning medication abortion. NPR. April 24, 2023.

<https://www.npr.org/2023/04/24/1171352545/poll-two-thirds-oppose-banning-medication-abortion>

Legal restrictions to medical abortion and other barriers to access to reproductive healthcare mean many women and people find it difficult or impossible to access quality abortion care and they may induce abortion themselves using unsafe methods or seek abortion from unskilled providers.

The United States governments must increase their efforts to ensure access to medical abortion information and services

In line with General Comment No. 25 of the Committee on Economic, Social and Cultural Rights that expressed that “*States should ensure access to modern and safe forms of contraception, including emergency contraception, medication for abortion, assisted reproductive technologies, and other sexual and reproductive goods and services, on the basis of non-discrimination and equality*”⁹ the US Government needs to do all that it can to expand access to accurate evidence-based information on medical abortion and to combat the vast misinformation that currently exists. The government should build on public education and outreach efforts and must create or support the public availability of materials that includes medically accurate information about medical abortion, including self-managed abortion with pills.

The US Government should also expand the content of the governmental website ReproductiveRights.gov to include: additional facts surrounding the safety and efficacy of medication abortion, including medication abortion via telehealth; links to resources that explain or demonstrate how medication abortion works; up-to-date information or links on the legality of using medication abortion; resources on how and where to access medication abortion. The constant changes in state and federal abortion laws and restrictions makes difficult for patients to access the most up to date information, especially for those that experience additional barriers including language and accessibility issues.

The US Government should use all available legal tools to keep a safe, FDA-approved medication on the US market, in line with international good practices and WHO recommendations.

The US Government must encourage and pursue policies that support evidence-based protocols and implement programs that will improve access to medical abortion, including ensuring continuity of care, removal of medically unnecessary in-person requirements, education on digital literacy, and taking steps to ensure continued access to medical abortion.

The elimination of the constitutional right to abortion in the U.S. has not only caused grave harm in the country, but also in many other countries where emboldened opposition movements are using the decision to fuel anti-abortion efforts. The United States should promote a culture that values, respect and promotes human rights and to contribute to depolitize abortion and sexual and reproductive health.

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⁹ CESCR, General Comment No. 25: Science and economic, social, and cultural rights (Article 15(1)(b), (2), (3) and (4) of the International Covenant on Economic, Social and Cultural Rights) (2020) (UN Doc. E/C.12/GC/25)