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June 20, 2024

The Supreme Court Decision on Mifepristone: A Win for Reproductive Justice, But Maybe Not for Long

The Supreme Court of the United States' term is wrapping up this month, and, as is custom, they are announcing the decisions in their most controversial cases at the end. The much-anticipated decision on access to mifepristone – a drug that in combination with another medication, misoprostol, has long been prescribed to end a pregnancy – was no exception, with the Supreme Court issuing its decision in *Food and Drug Administration (FDA) vs. Alliance for Hippocratic Medicine* on June 13, 2024. In a unanimous ruling, the Court rejected a challenge from plaintiffs who had argued the FDA had improperly approved and then expanded access to mifepristone. This decision bears directly on the continued safe and legal access to medication abortion, which can be used in the comfort and safety of a pregnant person's home. Although this ruling was a win for reproductive justice and health care access advocates, the case raises legal issues that are far from resolved—read on to learn why.

What Was at Issue in the Case, and How Did the Court Rule?

What is Mifepristone?

Mifepristone is one of two medications (the other is misoprostol) used in more than 60% of all abortions in the U.S. Mifepristone is also used for miscarriage management, the treatment of uterine fibroids, and other conditions.

Mifepristone has been approved by the FDA since 2000, following an extensive agency review of reams of data and clinical trial evidence. Since then, the FDA has updated its approval of mifepristone. In 2016, the FDA expanded the types of providers who could prescribe mifepristone, from only physicians to other licensed providers, such as nurse practitioners. In 2019, the FDA approved a generic version of mifepristone. And, in 2021, during the height of the COVID-19 pandemic, the FDA removed the requirement that mifepristone be prescribed in person, allowing people to receive it by mail. This last decision helps patients access abortion care via telehealth. These FDA decisions were based on review of real-world evidence demonstrating that mifepristone is safe and effective and that the extra restrictions put in place when the drug was first approved are no longer needed.

More than 20 years after mifepristone's initial approval, the plaintiffs—several anti-abortion organizations and individual doctors—sued the FDA in federal district court in Texas, arguing that the FDA had erred in its original approval of mifepristone, failed to demonstrate its safety, and further erred each time it acted to remove restrictions on access to the drug. The case was assigned to an infamously conservative judge, Matthew Kacsmaryk, who sided with the plaintiffs and issued a nationwide injunction on access to mifepristone. Immediately following Judge Kacsmaryk's decision, a federal district court judge in Washington state issued an

opposite ruling, leaving access to mifepristone in place and barring the FDA from placing undue restrictions on it. These dueling decisions created confusion as to where mifepristone was legal and where it wasn't. The Texas decision, which would have taken mifepristone off the market, was ultimately stayed, meaning that it would not go into effect while the case was appealed to higher courts.

In August 2023, the Fifth Circuit ruled that Judge Kacsmaryk had gone too far in overruling the FDA's initial approval of mifepristone. The court also rejected plaintiffs' claim that they had been harmed by the FDA's decision to approve a generic version of mifepristone, but agreed with plaintiffs that the FDA's decisions to loosen restrictions on access to mifepristone were beyond its authority. The Biden Administration immediately appealed to the Supreme Court.

Last week, the Supreme Court rejected the plaintiffs' claims—but without reaching the merits of the arguments from either side. Rather, as a threshold matter, the Court ruled that the plaintiffs did not have standing to bring their case. This means that there was no legal basis for plaintiffs to bring this case because they could not show sufficient harm to themselves that was caused by the government action they were challenging. This ruling effectively tosses out the whole case, but it does not prevent other plaintiffs from challenging mifepristone access if they can show standing.

What's Next?

The national legal battle around reproductive health care access is far from over. Even the battle around mifepristone has only received a slight reprieve. Because the Supreme Court did not rule on the merits, it is possible that a different group of plaintiffs could be assembled who could persuade the Court that they have standing.

The fact that the challenge made it to the Supreme Court at all has concerned many players in the health care access field. If the plaintiffs had prevailed, a widely used drug that has been on the market for decades—and that is used for a variety of purposes in addition to medication abortion—could have lost its FDA approval. This threat alarmed health care access advocates as well as drug manufacturers. Moreover, the case raised larger questions about how much deference judges should give to the FDA's authority over deeply technical matters. This could not only undermine access to mifepristone, but also access to virtually any other pharmaceutical approved by the FDA. If a future group of plaintiffs can find standing and win on a subsequent case regarding mifepristone, then the FDA's scientific expertise and independence would be compromised, imperiling access to potentially many medications approved by the FDA.

Meanwhile, reproductive justice advocates are still awaiting a ruling from the Supreme Court on two additional cases with major implications for reproductive rights, *Moyle v. United States* and *Idaho v. United States*. The cases address the tension between restrictive state abortion prohibitions and the federal Emergency Medical Treatment and Labor Act (EMTALA), which guarantees access to certain emergency medical services for people who present to a hospital emergency department with an urgent medical condition. These cases raise the legal question to what degree Idaho can restrict an emergency department's ability to perform an emergency abortion consistent with EMTALA. In the mifepristone case, Justice Brett Kavanaugh seemed to foreshadow that he believes the federal government cannot compel physicians to provide life-saving services if the physician finds them morally objectionable—a concerning suggestion for

patients whose care is often politicized. When the decision in those cases are announced, we'll explain their implications for access to reproductive care and other health care.

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