

What happened this week? On Wednesday, December 13, the Supreme Court agreed to take two consolidated cases that could have massive implications for how and when people can access the abortion pill mifepristone in the United States. While the Court considers the case, mifepristone remains legal, available, and accessible under the FDA's most recent rules which made mifepristone easier to access via telehealth and mail. The two cases are called *FDA v. Alliance for Hippocratic Medicine* and *Danco Laboratories L.L.C v. Alliance for Hippocratic Medicine*.

What is mifepristone? The FDA approved mifepristone nearly a quarter century ago. Mifepristone is one of two medications used in medication abortion. Mifepristone is also used in miscarriage care. Even before the Supreme Court overturned *Roe* in *Dobbs v. Jackson Women's Health Organization*, medication abortions made up more than half of abortions in the United States. Since *Dobbs*, abortion pills and the ability to provide them via telemedicine have only become more important for abortion access, particularly for people living in states with extreme abortion bans. All told, more than 5 million people have safely used mifepristone to end a pregnancy since the drug's approval in 2000.

What are the mifepristone use conditions at issue in the case? For political, not medical, reasons, mifepristone has always been subjected to special, extra restrictions on its use. However, mifepristone is incredibly safe. Indeed, it's proven safer than drugs like penicillin, Viagra, or Tylenol, which are not subject to similar restrictions or are even available over the counter. In 2016 and 2021, the FDA removed some of mifepristone's original access restrictions because years of use by millions of people and rigorous scientific studies showed that the restrictions were medically unnecessary and not needed for safety. Specifically, in 2016 the FDA, among other things, widened the type of health care providers authorized to dispense the drug beyond just physicians and reduced the number of required in-person clinical visits from three to one. FDA also updated the drug label to follow evidence-based best practice guidelines that had emerged since 2000, extending how many weeks into pregnancy mifepristone could be taken and changing the recommended dosage. In 2021, importantly, the FDA removed the remaining in-person dispensing requirement, paving the way for people to access medication abortion via telemedicine and to obtain the drug by mail or in person at pharmacies rather than just at a health care provider's office.

What legal issues are the Supreme Court considering?

Standing: The Court will decide whether the association of physicians who simply have a moral objection to abortion and do not actually prescribe mifepristone themselves have legal standing to bring the case challenging the FDA's 2016 and 2021 decisions. Typically, to have a right to bring a case, plaintiffs must show an actual or imminent, real and not-hypothetical injury from the law, rule, or action they're challenging. Here, the plaintiffs claim a speculative possible future injury to an unspecified member of their group.

Legal validity of 2016 and 2021 FDA rule changes: The Court will decide whether the FDA's decisions to ease restrictions in 2016 and 2021 were arbitrary and capricious – essentially

whether the agency reasonably considered and explained its actions. The Fifth Circuit's (wrong-headed and harmful) decision found that the FDA did *not* have a valid basis for these rule changes. In reviewing the Fifth Circuit's decision, the Supreme Court will look at the record the FDA considered at the time of its decisions, including the studies it relied upon and reasons it provided for the rule changes. The Supreme Court may also consider facts and context outside the administrative record, including the public's interest in the 2016 and 2021 decisions and the potential harm caused by upending them. Some of this additional context will be presented through friend of the court (*amicus*) briefs. .

What legal issues should the Supreme Court not be considering?

FDA's Original Approval of Mifepristone: Importantly, the Court decided *not* to grant the plaintiffs' request to review the validity of the FDA's original approval of mifepristone in 2000. This means that the Court will examine the later changes to use conditions but not question whether mifepristone should have been approved at all (a sliver of good news).

Comstock Act Theory: Throughout this case, the anti-abortion plaintiffs have pushed a radical theory that the 1893 Comstock Act, an anti-vice law that made sending "obscene" materials and devices through the mail a federal crime, should be revived and reinterpreted to ban sending abortion medication via the mail. The anti-abortion movement is trying to revive the Comstock Act in various contexts to try to block the modern ways we obtain health care and information. Based on the petitions and questions presented which the Supreme Court granted, it should *not* be considering this radical theory, but we should remain on the lookout if it dangerously pops up in the case regardless.

What's at stake: Substantively, the most important thing at stake in this litigation is whether people will still be able to access medication abortion virtually via telehealth appointments with a wide array of health professionals and get the medication itself through mail or physical pharmacies. If the Supreme Court finds that the FDA's 2016 and 2021 conditions use changes were arbitrary and capricious, we would be forced to return to a medically unnecessary world where people can legally access mifepristone only by traveling in person for multiple doctor's appointments. This would have obviously disastrous outcomes in a country where entire geographic regions have criminalized or banned abortion and people would need to travel tremendous distances, often across multiple states, to see an actual physician who could prescribe medication abortion. But it would also negatively affect people in states where abortion remains legal and accessible. The FDA's 2016 and 2021 changes have improved access to medication abortion for everyone in our country, including people in seemingly abortion-friendly states who also faced travel distance barriers to clinics, long waits for in-person appointments, or less access to physicians than other types of health care providers who can now prescribe and dispense medication abortion. A loss in this case will be felt across the nation, not only in ban states.

Beyond abortion, this case could also have downstream effects for the many other ways people in America now routinely use telehealth and telemedicine to receive care. While this case is specifically about abortion, any ruling that the FDA lacked a basis for reasonably believing telemedicine for abortion is safe (which it demonstrably is) would naturally call into question other types of telehealth and medication distribution that now routinely occur without in person doctor-patient contact. Ruling on the merits aside, even allowing anti-abortion activist physicians who do not provide abortion care and have no concrete stake in the issue to challenge years of settled FDA rules and practice will also cause ripples in the pharmaceutical industry that could undermine drug innovation and jeopardize access to other types of medication. Affirmation of standing in this case would open courts up to second-guessing of the FDA's medical and regulatory expertise by anyone with moral opposition to an approved drug.

What happens next? The parties will submit briefs in the case and individuals and organizations can also file friend-of-the-court or *amicus* briefs. CRHLP plans to file such a brief, so stay tuned for more. The court will likely schedule oral argument this term and could issue a ruling by the end of June.

No matter how the Supreme Court rules, abortions and medication abortions will always happen. The only question will be how difficult and legally risky those abortions will be to obtain and how much we, as a nation, will make people suffer and take unnecessary risks throughout the process. Here at CRHLP, we will continue to support the fight for as much legal and practical access as humanly possible.