UCLA School of Law Center on Reproductive Health, Law, and Policy

CRHLP Staff's Top 5 Takeaways from the Supreme Court's oral argument in *Alliance for Hippocratic Medicine v. FDA*

Today the Supreme Court heard arguments in *Alliance for Hippocratic Medicine v. FDA*, a case that could significantly impact access to mifepristone across the country. Here are the CRHLP team's top 5 takeaways from the oral argument:

1) Plaintiff's standing to bring this case was the main topic of oral argument, and for good reason: the plaintiffs likely can't establish it. The justices seemed skeptical that the plaintiffs demonstrated sufficient injury, that their alleged harm may be traced to FDA's 2016 and 2021 decisions, or that they sought the appropriate remedy.

Standing requires a concrete, non-speculative harm: Plaintiffs allege their member doctors suffer harm to their consciences, claiming that they may potentially treat people experiencing complications from medication abortion—although this is extremely unlikely based on mifepristone's safety record. Plaintiffs have not alleged that even a single member doctor has been required to treat a patient experiencing a rare serious adverse event over their objection.

Standing requires the harm be fairly traceable to the government action: Questions from Justice Kagan and Justice Barrett expressed skepticism that plaintiffs' alleged conscience harms could be traced to FDA's 2016 and 2021 decisions, which lifted certain medically unnecessary restrictions on mifepristone. As Solicitor General Elizabeth Prelogar noted, neither the 2016 nor 2021 changes led to a significant increase in the number of serious adverse events reported, so plaintiffs cannot credibly argue that they are more likely to experience this hypothetical harm as a result of FDA's actions.

Standing requires the harm be redressable by the requested relief: Plaintiffs' conscience objections to providing abortion care don't establish standing to challenge mifepristone access for all. Federal law already allows doctors to decline to participate in abortion care. What plaintiffs are really arguing here – as Justice Jackson pointed out best – is that their ability to conscientiously decline to provide care is not enough, and instead no one should have access to mifepristone because this small handful of doctors object to abortion care. Justice Gorsuch emphasized: "This case seems like a prime example of turning what could be a small lawsuit into a nationwide legislative assembly on an FDA rule."

2) The Government and Danco highlighted the strength of the scientific record considered by FDA. Plaintiffs argued that FDA did not consider the cumulative effects of the individual changes to the REMS and label made in 2016 and 2021 – an argument that was repeated by Justice Alito. But as our amicus brief details—and as Solicitor General Prelogar noted—the scientific record before FDA *did* include studies considering multiple changes in combination. Many of the studies in the scientific record were analyses of real-

world abortion care, which has incorporated many or all elements of the FDA's regulatory changes together. FDA considered these studies and determined the changes were safe in conjunction.

(Read our amicus brief—filed on behalf of over 300 leading reproductive health researchers and describing the robust scientific record supporting FDA's regulatory changes—here: bit.ly/3SB8xuU.)

3) Telehealth medication abortion is safe, despite plaintiffs' attempts to claim otherwise. Plaintiffs argued that in-person visits with ultrasound examinations are necessary prior to taking medication abortion – but studies considered by FDA and guidance from leading reproductive health and medical organizations indicate that mifepristone can be safely taken without the need for an ultrasound or other in-person visit. Indeed, the in-person visit at issue in this case never included an ultrasound requirement in the first place (which, as Justice Barrett noted, makes it even harder for plaintiffs to argue that rolling back telehealth would impact patient safety).

4) Justices expressed concern that the courts were second-guessing FDA's scientific experience. FDA, not courts, are the experts when it comes to drug approvals and regulations. Jessica Ellsworth, the attorney representing Danco (a manufacturer of mifepristone), noted that plaintiffs' arguments "would upend not just Mifeprex but virtually every drug approval and REMS modification FDA has made for decades." Justice Jackson also raised concerns about courts parsing medical and scientific studies, particularly as compared to the scientific expertise of FDA.

5) Justices Alito and Thomas brought up the Comstock Act. Comstock is a law enacted in 1873 that prohibits mailing of "obscene" materials, including abortion instruments, pornography, sex toys, and more. The Act has not been enforced for decades and is not supposed to be at issue in this case – but that didn't stop Justices Alito and Thomas from asking about it. These mentions are concerning because reviving the Comstock Act is a key facet of the anti-abortion movement's strategy for banning abortion nationwide. Although the Biden administration has refused to revive Comstock, a future presidential administration could interpret and enforce Comstock to ban not only abortion pills, but also the mailing of any instruments related to abortion care.