

## **CRHLP Staff Reflect on the Amicus Brief they helped file in *FDA v. Alliance for Hippocratic Medicine***

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### **What Happened?**

Last week, CRHLP staff members partnered with law firm Paul, Weiss, Rifkind, Wharton & Garrison, and researchers from Advancing New Standards in Reproductive Health (ANSIRH) to submit an amicus brief in *FDA v. Alliance for Hippocratic Medicine*, the most important case about abortion since the Supreme Court overturned *Roe v. Wade*. The amicus brief urges the Supreme Court to follow the science and not restrict access to mifepristone, one of the two drugs used in medication abortion. Medication abortion accounts for over half of all abortions across the United States and its safety has been rigorously tested. Despite mifepristone's 20-year record of safety and effectiveness, anti-choice doctors and activists filed suit in November 2022 seeking to force FDA to pull mifepristone from the market or otherwise limit the conditions under which it can be accessed.

### **What's at stake in the case?**

The Supreme Court is considering FDA's modifications to mifepristone's Risk Evaluation and Mitigation Strategy ("REMS") and labeling. The modifications include FDA's 2021 decision to remove the requirement for in-person dispensing and 2016 decision to extend the gestational limit to 70 days, modify the dosing regimen, and allow healthcare providers with prescriptive authority under state law (such as nurse practitioners and physician assistants) to become certified prescribers of mifepristone. Reversing FDA's modifications would require mifepristone to be dispensed only in person by certified physicians, and the drug label would recommend an unnecessarily early gestational limit and an outdated dosing regimen since proven to be less safe and effective.

The Supreme Court case is an appeal from the Fifth Circuit Court of Appeals, which held that FDA likely lacked sufficient evidence that the 2016 and 2021 changes to mifepristone's REMS and label were safe and effective. The Fifth Circuit Court of Appeals

suspended FDA's 2016 and 2021 actions, which would reinstate burdensome pre-2016 restrictions on mifepristone if the Supreme Court affirms the Fifth Circuit's decision.

### **What do we argue in the brief?**

Anti-choice doctors and activists argue that mifepristone is unsafe and that FDA's regulatory decisions were not adequately supported by scientific evidence—a claim that is patently untrue (in fact, two studies the anti-choice activists and district court relied on in claiming medication abortion is unsafe were just retracted this week). We filed this amicus brief on behalf of over 300 leading reproductive health researchers from the United States and worldwide, asking the Supreme Court to respect the clear scientific record showing that mifepristone is extremely safe and effective and to reverse the Fifth Circuit's ruling.

Our team worked closely with researchers from ANSIRH, a research program at UCSF that has conducted numerous studies on the safety and efficacy of medication abortion, to identify and summarize the key studies relevant to the safety and effectiveness of mifepristone and the changes before the Court. The brief details how FDA relied on a robust scientific record analyzing tens of thousands of patient experiences that conclusively demonstrated the safety and effectiveness of these changes. Dr. Ushma Upadhyay, an ANSIRH investigator and UCSF professor, said, "The science is abundantly clear: mifepristone is overwhelmingly safe and effective, whether provided in-clinic, via telehealth, or in a local pharmacy. Any attempts to roll back access have nothing to do with safety and everything to do with further restricting abortion across the country." Dr. Daniel Grossman, ANSIRH's director and professor of obstetrics and gynecology at UCSF, said, "The FDA has carefully reviewed study after study on mifepristone for decades and its decisions to expand how the medicine can be provided have been based on solid science. To assert otherwise is to not only throw out years of research but to make it even harder for people in the U.S. to receive abortion care—even in states where that care is legal."

### **What happens next?**

Oral argument in the case has been scheduled for Tuesday, March 26. We anticipate the Court will issue a ruling towards the end of its session in June. It is crucially important to both abortion access and FDA's regulatory authority to set the record straight and overturn the Fifth Circuit's decision. As we urged in our brief, the Supreme Court should rely on the clear and robust scientific record and preserve access to mifepristone without reimposing restrictions.

[Read the Amicus Brief here.](#)

[View the list of over 300 signatories here.](#)