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Fifth Circuit medication abortion ruling could affect more than abortion access

Cathren Cohen

The case threatens the FDA's regulatory authority and could lead to established, safe medications being challenged simply because they are politically contentious.

Abortion medication has become crucial to access in a post-*Dobbs* landscape, where more than half of U.S. states have or are expected to ban or severely restrict abortion rights. Even before *Roe* was overturned, medication abortions made up more than half of abortions in the U.S. Since *Dobbs*, abortion pills have only increased in importance, reducing demands on strained clinics, preventing the need to travel, and allowing for shipment between states or from international providers, including to banned states.

Recognizing its significance, the same movement that sought to overturn *Roe* has set their sights on mifepristone, one of two medications used in medication abortion. *Alliance for Hippocratic Medicine v. FDA* challenges the FDA's initial approval of mifepristone and three subsequent regulatory changes. First approved by the FDA in 2000, mifepristone has historically been subject to strict prescription and dispensing requirements. However, as more evidence about the medication and its safety has been collected, the FDA has implemented research-backed updates to ensure access. In recent years the agency has allowed for use of mifepristone further into pregnancy, up to 10 weeks, permitted provision via telehealth, and allowed patients to receive a prescription at a pharmacy, rather than only in registered physician offices.

Earlier this year, the case flew through the appeals process with unusual speed. Mere weeks after a district court in Texas issued a preliminary injunction that sought to revoke mifepristone's FDA approval, the case was at the Supreme Court. Last week, the 5th Circuit Court of Appeals issued the latest ruling in this case, which would preserve mifepristone's original approval but find the FDA's regulatory amendments from 2016 and 2021 arbitrary and capricious. 2023 WL 5266026 (5th Cir. Aug. 16, 2023). The 5th Circuit opinion is currently barred from going into effect under the Supreme Court's earlier emergency stay which preserves the status quo for the duration of the litigation. *Danco Labs, LLC v. Alliance for Hippocratic Med.*, 143 S.Ct. 1075 (2023) (mem). However, the ruling has potential ramifications for both abortion medication and future litigation challenging the FDA's regulatory authority.

Because it is not just the speed at which this case has progressed that is unprecedented. This case represents the first time ever that a federal judge has ruled that a drug is unsafe despite the FDA's approval. What's more, the 5th Circuit's opinion represents a significant departure from the concept of standing upon which courts are supposed to rely.

The 5th Circuit's opinion undermines the basic concept of legal standing by granting it to plaintiffs based on purely hypothetical injuries. The majority opinion finds that plaintiffs have standing because it is "fairly likely" that they may someday have to treat women "who experience severe complications after taking mifepristone." The court repeatedly adopts plaintiffs' claims that "many women face severe complications" and "large numbers of" women taking mifepristone will end up in emergency rooms where plaintiffs will be forced to treat them, divert resources from their "ordinary" patients, and potentially participate in the provision of an incomplete abortion. (Meanwhile a concurring opinion goes so far as to argue that "[d]octors who delight in working with their unborn patients" experience an aesthetic injury when an abortion occurs and the doctors are unable to care for "the unborn children in whom [they] have an interest." 2023 WL 5266026 at *35 (J. Ho, concurring)).

But mifepristone is an incredibly safe medication, less likely to cause death than other prescription drugs, such as penicillin or Viagra, and safer than some over-the-counter medications, such as Tylenol. Before the FDA updated its regulations, they reviewed decades of evidence demonstrating that restrictions such as limiting use to earlier pregnancies and in-person dispensing requirements are not medically necessary. This accurate medical evidence was available in this case: the American Medical Association (AMA), American College of Obstetricians and Gynecologists (ACOG), and nine other leading medical and public health organizations submitted an amicus brief providing the overwhelming evidence of mifepristone's safety. Their brief stated that serious side effects occur in less than 1% of patients and major adverse events (significant infection, blood loss, or hospitalization) occur in less than 0.3% of patients. However, the court ruled to grant standing based wholly on anecdotal evidence presented by plaintiffs in affidavits which run counter to the established medical evidence presented by medical experts.

It is this second-guessing of medical and regulatory expertise that reveals the potential for broader harm from the precedent of this case. The 5th Circuit has accepted the medical claims of plaintiffs (well-known anti-choice activists, who do not provide abortions, and who established their organization mere months before filing suit) over the reasoned decision making of the FDA and esteemed health care professionals. As such, the case threatens to destabilize the FDA's regulatory process and could lead to established, safe medications being challenged simply because they are politically contentious.

Pharmaceutical manufacturers seem to recognize this risk. Danco Laboratories, the manufacturer of the brand-name Mifeprex, intervened in this case on the side of the FDA to defend mifepristone's approval, while GenBioPro, a generic manufacturer, initiated its own suit against the FDA to protect against the outcome of *Alliance for Hippocratic Medicine*.

The issue is far from settled. In addition to this case, a district court in Washington issued a conflicting ruling ordering the FDA to preserve the status quo of mifepristone access (for a limited number of states), and several other lawsuits challenging state restrictions have been filed. Ultimately, courts cannot force the FDA to pull a drug from the market; Congress has established via federal law specific procedures that the agency must comply with to revise or revoke drug approvals. But the rulings from the district court in Texas and the 5th Circuit, which show a concerning willingness to disregard evidence-based arguments and well-established regulatory processes, could undermine more than just access to abortion by further jeopardizing the integrity of the courts and threatening public trust in government agencies.

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