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Medical Abortion Case in Texas Endangers Health of Millions of Women and Threatens Entire US Drug Approval Process

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Anti-abortion advocates, represented by a far-right legal organization, have filed a lawsuit before a federal judge in Texas with the sweeping aim of a nationwide ban of mifepristone, which is used in medication abortions. *Alliance for Hippocratic Medicine* v. *U.S. Food and Drug Administration* puts at risk not only the use of mifepristone for safe and legal abortions for millions of American women but opens the door for the politically motivated destruction of the entire U.S. drug approval process.

What Comes Next?

Judge Matthew Kacsmaryk will hold a hearing on March 15 on the plaintiffs' motion for a preliminary injunction banning mifepristone. After that, he could rule at any time – and many experts predict he will issue a nationwide injunction pulling mifepristone from the market, at least temporarily.

The Justice Department has asked Judge Kacsmaryk to "stay pending appeal" any injunction that he issues – making the injunction ineffective until after the Fifth Circuit Court of Appeals and Supreme Court rule on the government's appeal, a process that could last a year or more. If the Judge refuses to do that, the Justice Department has asked for a 21-day stay so it can seek a stay pending appeal from the Fifth Circuit and, if the Fifth Circuit refuses, from the Supreme Court.

What's At Stake?

Access To Safe And Effective Reproductive Care For Millions Of Women Nationwide. The combination of mifepristone and misoprostol, an ulcer medicine, has been found to have a 98 percent efficacy rate and mifepristone has been found to be safer than Tylenol or Viagra. The plaintiffs argue that the FDA's authorization of the drug over two decades ago was flawed and that the drug which has been used by over 2.5 million women is, in fact, dangerous. Twelve of the nation's leading medical and scientific organizations have filed an amicus brief demonstrating that the drug is safe and studies and meta-analyses involving tens of thousands of women have shown the same thing.

The Science-Based FDA Drug Approval Process That Has Served America Well Since 1938. The Justice Department brief explains that this lawsuit has the potential to undermine the country's process for regulating pharmaceuticals. If the courts side with the plaintiffs, it would be an unprecedented situation. Professor Greer Donley of the University of Pittsburgh Law School says, "We're talking about a judge who is a non-scientist overriding an agency full of experts about the safety and efficacy of a drug. That, to my knowledge, has never happened before."

Safe And Legal Medications Targeted For Political Purposes. If the plaintiffs in this case are successful, it would open the door to any third party with a political agenda to challenge a medication that they object to. If these plaintiffs can challenge the more than two-decades-old approval of this drug, then every group that opposes a drug or vaccine will be able to use the same playbook to bring lawsuits seeking to ban those medications. Experts fear that a wide range of approved medicines could be targeted including mRNA vaccines, COVID-19 vaccines, HIV medications, hormone therapies, drugs that are derived from stem cells, or any class of medicines that may be politically unpopular.

Access To Life-Saving Drugs That Patients Count On Every Day. An amicus brief filed by 19 leading scholars of food and drug law states, "We are not aware of any case in which a court has removed a drug from the market over FDA's objection. The effects could extend far beyond mifepristone. No drug is without risk, and a ruling for Plaintiffs could lead to challenges to FDA's benefit-risk determinations for drugs it has approved to treat other diseases and conditions. Patients who rely on life-saving medications could see their drugs removed from the market with little notice."

Innovation And Investment In New Drug Development. Pharmaceutical companies must plan years in advance which diseases and therapies to invest in. Injecting a huge dose of political uncertainty into the process could make investors and companies more hesitant to pursue innovative new treatments. Law Professor Rachel Sachs and Professor Donley recently explained that "[o]btaining approval for a new drug is expensive, time-consuming and risky. It typically involves years or decades of research and can cost hundreds of millions, or even billions, of dollars. Most drugs that enter the research and development process fail, never making it to market. The prize at the end of this ordeal is the FDA's approval to sell the product." Therefore, "[i]t could chill innovation nationwide if political actors could circumvent the agency's data-driven process by engaging the courts. Manufacturers might become wary of investing time and money into products for a wide range of conditions which may — decades down the line — be the subject of nuisance litigation."

What Are The Legal Arguments?

The plaintiffs assert several different claims:

- They contend that the FDA's approval of mifepristone in 2000 should be invalidated because (a) the agency cited regulations governing drugs that "treat serious or life-threatening illnesses" and, plaintiffs contend, mifepristone does not fall within that category, and (b) the conditions for use specified by the agency were inadequate.

- When the agency approved the drug in 2000, it used its "risk evaluation and mitigation strategy" (REMS) authority to impose restrictions designed to ensure the drug is distributed and prescribed safely. In 2016, FDA loosened those restrictions, allowing the drug to be used later in a woman's pregnancy (up to 70 gestational days), prescribed after only one in-person clinic visit and by a broader set of healthcare providers, and taken by the woman at home rather than in a doctor's office. The plaintiffs assert that these changes were not supported by the data relied upon by FDA and ask the court to restore the original, more stringent restrictions.

- The plaintiffs also invoke the Comstock Act, a criminal law prohibiting the "knowing[] mailing of "obscene or crime-inciting matter" that includes in its long

list of items "article[s] or thing[s] designed, adapted, or intended for producing abortion." They claim that this law required the FDA to prohibit the distribution of mifepristone by mail or common carrier.

This is a meritless lawsuit that should be thrown out of court – for multiple reasons.

- The plaintiffs lack "standing" to sue. To file a lawsuit in federal court, a plaintiff must assert an "actual" or "certainly impending" real-world injury. These plaintiffs are not regulated by the FDA and do not prescribe mifepristone. Their claim – that patients will come to them for help after taking the drug, which will require them to divert attention from other patients, inflicting costs and risking potential liability and emotional distress – is indistinguishable from standing arguments that have been repeatedly rejected by the Supreme Court because they "depend[] on the unfettered choices made by independent actors not before the courts and whose exercise of broad and legitimate discretion the courts cannot presume either to control or to predict."

- Most of the claims are, in addition, barred by the statute of limitations and/or failure to raise the arguments before the FDA. Federal law provides that a party seeking to challenge a decision by an administrative agency must file suit no later than six years after the decision. The challenge to the FDA's approval of the drug in 2000 is therefore untimely. (The plaintiffs try to rely on their 2002 petition to the FDA challenging that approval, but that petition was denied in 2016, more than six years before the filing of this lawsuit.) The plaintiffs filed a separate petition urging the FDA to withdraw its 2016 decision loosening the REMS standards applying to mifepristone, which the agency denied in 2021 – making the challenge to the REMS standards timely; but the plaintiffs did not challenge the 2000 approval in that petition and their claim that the petition implicitly "reopened" the approval decision is contrary to basic principles of administrative law. Also, the plaintiffs have never raised their Comstock Act argument before the FDA. Finally, even the challenge to the 2016 REMS standards is not properly before the court because it has been superseded by FDA's 2023 action further revising those standards: the 2016 decision, therefore, is no longer operative.

- The plaintiffs are wrong on the merits. As the Justice Department and a company that manufactures the drug explain in detail: there is no basis for overturning

FDA's expert determination in 2016 regarding the proper REMS standard for this drug, which was fully supported by the data cited by the agency; FDA properly rested its approval of mifepristone on its authority with respect to drugs treating serious illnesses, because pregnancy can be, many times is, accompanied by complications posing serious risks to a woman's health; and FDA's 2000 approval and accompanying standards were a proper exercise of the agency's expertise. The REMS and approval decisions are subject to deferential review and may be set aside only if found to be "arbitrary and capricious" – a high standard that the plaintiffs do not come close to satisfying. With respect to the Comstock Act, the government explained that, by 1960, "federal courts of appeals settled upon a consensus view that the Comstock Act did not prohibit the mailing or other conveyance of contraceptives or items designed to produce abortions where the sender does not intend them to be used unlawfully." (A Justice Department opinion explains in detail the basis for this conclusion.) Therefore, "even if FDA were required to consider the Comstock Act, because the Comstock Act does not prohibit the mailing or other conveyance of abortion-inducing drugs where the sender does not intend them to be used unlawfully, and given that these drugs may be used lawfully, neither FDA's decisions related to in-person dispensing nor the absence of a prior FDA affirmative prohibition on distribution by mail was inconsistent with the Comstock Act."

- The plaintiffs are not suffering, or threatened with, irreparable injury. A party is entitled to an injunction only if it can show that, without the injunction, it will suffer irreparable injury. Here, for the same reasons they lack standing, their speculative arguments about harm cannot satisfy the irreparable injury requirement. And plaintiffs' delay in filing suit – more than two decades after the drug was first approved and nearly a year after the FDA's denial of their petition regarding the REMS standards – further supports that conclusion.

- The balance of harms weighs sharply against the plaintiffs. Even when a plaintiff can demonstrate irreparable injury, a court may not grant injunctive relief if the harm to the plaintiff is outweighed by the harm that would be suffered by other parties and the harm to the public interest. Eliminating the availability of a drug that millions of women have used over two decades will inflict serious harm on Americans across the country who rely on the drug for safe and effective reproductive care. (Plaintiffs' claims that mifepristone is unsafe are wrong: a

> mountain of evidence demonstrates the drug's safety.) As the government explains, "[r]emoving access to mifepristone would cause worse health outcomes for patients who rely on the availability of mifepristone to safely and effectively terminate their pregnancies." It would interfere with Congress's decision to entrust to the FDA technical decisions regarding the safety and efficacy of drugs. And it would create a legal precedent that could disrupt the new drug approval system that has produced myriad life-saving treatments that benefit tens of millions of Americans.

Law professor Jonathan Adler, a noted conservative who was a leading voice in support of the legal challenges to the Affordable Care Act, agrees that this lawsuit should be rejected. He states: "I think it fairly clear that the plaintiffs have severe jurisdictional hurdles to overcome under existing law, and that they have failed to make their case on these questions. . . . . Whether one agrees with the FDA or [the plaintiffs] on whether it is a good idea for mifepristone to be widely available, there is little doubt about how the underlying legal issues in [the case] should be resolved. The barriers to this suit are substantial, and [the plaintiffs'] attempts to surmount them are wholly unpersuasive."

Who Is Behind The Lawsuit?

A Newly Formed "Alliance" Of Right Wing Medical Groups Is The Lead Plaintiff In The Case. The plaintiffs in this case are led by the newly formed Alliance for Hippocratic Medicine. This group was seemingly created for the sole purpose of filing this lawsuit. The Alliance for Hippocratic Medicine was only incorporated in August of 2022 and the group's website is even sparser and newer than that.

The Other Plaintiffs Include Peddlers Of Anti-Choice Misinformation And Anti-LGBT Extremist Groups. The other plaintiffs include the American Association of Pro-Life Obstetricians and Gynecologists, the American College of Pediatricians, and the Christian Medical & Dental Associations. The American College of Pediatricians is a fringe extremist group that trades on its name similar to the premiere U.S. association of pediatricians to push anti-LGBTQ junk science via the far-right media and filing amicus briefs in cases related to abortion or LGBT rights. The American Association of Pro-Life Obstetricians and Gynecologists and the Christian Medical and Dental Associations are other far-right groups that use their members' medical certifications to push false

information regarding abortion and birth control. Including the dangerous pseudoscience of "abortion reversal."

The Plaintiffs Are Represented By The Alliance Defending Freedom, An SPLC Designated Hate Group. The legal team for the plaintiffs is the Alliance Defending Freedom (ADF), one of the most prolific extremist advocacy groups in the country. Designated a hate group by the Southern Poverty Law Center, the ADF has advocated both in the U.S. and abroad for forced sterilization of trans people, criminalization of same-sex relationships, and strict restrictions on abortions. ADF receives tens of millions of dollars in dark money annually, coming often from the same sources that led the right-wing attacks on the Affordable Care Act, Social Security, and Medicare.

More Than 20 Republican Attorneys General Have Filed An Amicus Brief Supporting The Suit. Twenty-two GOP attorneys general have filed an amicus brief in support of the plaintiffs. In the brief, they argue that the 23-year-old FDA approval of mifepristone undercuts state abortion bans because the pill can be mailed or accessed online through international human rights groups. In a clear attempt to change 200 years of legal precedent, this brief holds that the federal government's obligation under the Commerce Clause to regulate interstate commerce is not only wrong but has never existed. The brief states that "no federal law manifests" Congress's ability to regulate the interstate business of abortion medication if it subverts state abortion bans.

Who Is Judge Kacsmaryk?

Alliance for Hippocratic Medicine v. FDA Is Being Heard By A Trump-Appointed Judge With A Long History of Anti-Abortion Advocacy. U.S. District Judge Matthew Kacsmaryk is hearing the mifepristone case. Kacysmaryk ascended to the federal bench from the conservative legal group First Liberty Institute and according to a Washington Post profile, the judge "has been shaped by his deep anti-abortion beliefs." As a college student, Kacsmaryk endorsed a Republican Party platform granting fetuses the full legal protections of personhood, writing that, "The Democratic Party's ability to condone the federally sanctioned eradication of innocent human life is indicative of the moral ambivalence undergirding this party." Kacysmaryk continued to develop his stridently anti-choice views in law school and in his work with First Liberty Institute.

Plaintiffs Filed Their Lawsuit In Amarillo Specifically Seeking To Have It Heard By Judge Kacsmaryk. Since his appointment to the bench by Donald Trump, Judge Kacsmaryk Kacsmaryk has been one of a group of Texas-based judges who have "largely behaved as rubber stamps for whatever far-right cause shows up in their courtrooms." Because of the way case assignments work, more than 95 percent of the civil cases filed in Amarillo go to Judge Kacsmaryk and right wing-litigants from all over the country travel to Amarillo to judge shop.

Vox.com Called Kacsmaryk "The Worst Judge In The United States." An analysis in Vox called Kacsmaryk "arguably the worst judge in the United States." He has claimed that being transgender is a "mental disorder," and that all gay people are "disordered." Kacsmaryk was the first federal judge to endorse an attack on the right to contraception after the Supreme Court struck down *Roe v. Wade* and he handed down a decision holding that LGBTQ people are not protected under a federal law prohibiting certain forms of discrimination by health providers.