The abortion pill (a.k.a. RU 486, mifepristone, Mifeprex) was approved by the FDA in 2000. But the means by which it was approved, its purpose, and its safety have caused serious concerns ever since. As a result, it has been – and continues to be – the subject of numerous court cases. Conflicting state laws have created legal dilemmas that may only be resolved by federal intervention.

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Understanding the Mifepristone Timeline

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Mifepristone (a.k.a. RU 486, brand name Mifeprex) is the first of two drugs that make up the chemical abortion technique that accounts for more than half of the abortions performed in the United States. (The second drug is misoprostol, which induces the severe cramps necessary to complete the abortion.)

"The Population Council was founded by John D. Rockefeller in 1952, after he convened a conference with 'population activists' such as Planned Parenthood's director and several well-known eugenicists."[1] In 1996, the Population Council, who held the patent, sought approval of mifepristone from the FDA.[2] The FDA delayed approval, awaiting further information on manufacturing and distribution from the manufacturer.

In 2000, the FDA approved mifepristone. But in order to do so, it treated pregnancy as an illness, and considered it under a provision that allowed accelerated approval for special drugs needed to treat life-threatening conditions. This allowed the FDA to skip some normal steps in the approval process, and gave it authority to enforce special controls on the use and distribution of the drug.

The 2000 approval of mifepristone was accompanied by several restrictions: 1) The drug could be used only up to 7 weeks of pregnancy; 2) The drug had to be administered and dispensed under the supervision of a physician[3]; 3) Three in-person visits were required, again with either a physician or his designated representative (one when the mifepristone was given, one when a second drug, misoprostol, was given, and one follow-up); 4) There was a reporting requirement for both non-fatal and fatal adverse events to the mother.

In 2016, the FDA expanded the window when mifepristone could be used to the 10th week of pregnancy. At that time, it also did away with the requirement for the second and third office visits, as well as the reporting requirement for all adverse events other than death of the mother. In addition, mifepristone's dispensing protocol was changed to allow ANY certified healthcare provider to write the prescription for, and dispense, the pills. An MD license was no longer necessary; nurses, physicians' assistants, and some medical technicians now qualified under this expanded umbrella.

In 2020, within the obscuring shadow of COVID, the first in-person office visit was suspended. That same year, abortion advocates successfully sued to suspend the requirement that pills be dispensed in person.[4] The Trump administration appealed that decision at the Supreme Court and won; the safety requirement of in-person dispensation was retained. But in April of 2021, the Biden

Administration stepped in, and the FDA removed the in-person dispensing requirement.[5] In December of 2021, it was announced that the FDA would permanently adopt the relaxed REMS ("Risk Evaluation and Mitigation Strategy," i.e., safety guardrails) that had been implemented under COVID.[6] Simultaneously, it was announced that certified pharmacists would be allowed to dispense the pills. (But it took a whole year before the conditions of certification were written on the books; thus, the most-noted announcement regarding dispensation by pharmacists came in January of 2023, when these terms were permanently formalized.)

On June 24, 2022, the US Supreme Court overturned the federal constitutional right to abortion in *Dobbs v. Jackson Women's Health Organization*. As a result, states across the country began to implement restrictions on both surgical and pill-based abortions. Thus, legal access to abortion pills began to vary from state to state.

As parenthetically mentioned above, it was in early 2023 that mifepristone's dispensing protocol was formally changed to allow a certified pharmacist to dispense the drug, under specific conditions. A prescription from a physician or other provider was still necessary. About the same time, the Biden Justice Department issued a memorandum stating they believed mifepristone could be mailed. However, numerous legal observers caution that both Federal and many state laws prevent the mailing of abortifacients.

Also in January, 2023, *GenBioPro, Inc. v. Sorsaia* was filed in West Virginia. This suit was a response to the fact that West Virginia had, to a large extent, made the abortion pill illegal in that state. GenBioPro, as the only manufacturer of a generic version of the abortifacient, tried to argue that the WV law should be found unconstitutional on the basis that the state could not outlaw a drug if the FDA had the authority to regulate access to that drug. Before the year's end, all aspects of GenBioPro's case were defeated.

On April 7, 2023, U.S. District Judge Matthew J. Kacsmaryk ruled on *Alliance for Hippocratic Medicine v. FDA* that the FDA's approval of mifepristone should be enjoined. This meant that its approval as an abortifacient by the FDA would have been suspended. However, Kacsmaryk gave a one-week window to appeal.

Abortion advocates immediately defaulted to the claim that Kacsmaryk was overriding long-standing FDA safety expertise. In so doing, they willfully ignored the evidence that Kacsmaryk laid out in the very first paragraph of his opinion:

"Over twenty years ago, the United States Food and Drug Administration ("FDA") approved chemical abortion. The legality of the 2000 Approval is now before this Court. Why did it take two decades for judicial review in federal court? After all, Plaintiffs' petitions challenging the 2000 Approval date back to the year 2002, right? Simply put, FDA stonewalled judicial review — until now. Before Plaintiffs filed this case, FDA ignored their petitions for over sixteen years, even though the law requires an agency response within '180 days of receipt of the petition.' But FDA waited 4,971 days to adjudicate Plaintiffs' first petition and 994 days to adjudicate the second. Had FDA responded to Plaintiffs' petitions within the 360 total days allotted, this case would have been in federal court decades earlier. Instead, FDA postponed and procrastinated for nearly 6,000 days."[7]

In reality, not only the safety, but the fact that the FDA even considered approval of mifepristone, was and is suspect. "The FDA has, as a matter of principle, refused to regulate drugs used by states

in lethal injections, determining that the safety or efficacy of those kinds of drugs is beyond its purview. ...The FDA's commitment to public health, to ensuring the safety, efficacy, and security of drugs used by the American public clearly means a commitment to the authorization of drugs that cure, that heal, that treat various ailments, illnesses, or conditions – not to those which take human life or put it at unnecessary risk."[8]

On April 10, 2023, The Biden administration's Department of Justice appealed Kacsmaryk's decision to the 5th Circuit.

On April 12, 2023, a three-judge panel of the 5th Circuit Court of Appeals granted a partial stay, pending appeal. On a practical level, this ruling: 1) Overturned Kacsmaryk's decision to suspend FDA approval of the drug as an abortifacient, but 2) Ordered that mifepristone's safeguards return to their pre-2016 status. The Biden administration appealed once again – this time to the U.S. Supreme Court.

On April 21, 2023, the Supreme Court released an unsigned order. (This means a vote tally is not known. We do know that Justices Alito and Thomas dissented.) This order stayed all lower court rulings and returned the issue to the 5th Circuit for a full evidentiary hearing. This returned mifepristone to the market, under the 2023 least-restrictive, most dangerous rules – at least until the 5th Circuit ruled.

The 5th Circuit hearing began on May 17. The random three-judge panel that was drawn was all Republican appointees, including two from the Trump era. On August 16th, this panel unanimously ruled to reinstate the REMS to their original, 2000 status: The gestational limit was returned to seven weeks, non-fatal adverse reporting was again required, and the original, three-visit, in-person dispensation protocols were reinstated. On a practical level, with the in-person dispensing requirements implemented, mailing of the drugs became *de facto* prohibited, pending the result of appeals to higher courts.

The 5th Circuit noted that "In loosening mifepristone's safety restrictions, the FDA failed to address several important concerns about whether the drug would be safe for the women who use it. It failed to consider the cumulative effect of removing several important safeguards at the same time. It failed to consider whether those 'major' and 'interrelated' changes might alter the risk profile, such that the agency should continue to mandate reporting of non-fatal adverse events. And it failed to gather evidence that affirmatively showed that mifepristone could be used safely without being prescribed and dispensed in person."[9] The Court also criticized the FDA, on the grounds that "It's unreasonable for an agency to eliminate a reporting requirement for a thing and then use the resulting absence of data to support its decision" to loosen safety protocols.[10]

Following the 5th Circuit's decision, the Biden administration petitioned for an appeal to the Supreme Court for a hearing on the merits. The Supreme Court needs 4 justices to agree to take a case. At least until the Supreme Court decided whether or not to take the case, the 5th Circuit's panel ruling would not go into effect (i.e., abortion pills would continue to be dispensed under then-current REMS: the 2023 least-restrictive, most dangerous rules).

On December 13, 2023, the U.S. Supreme Court announced that it would take the case, consolidating it with *Danco Laboratories v. Alliance for Hippocratic Medicine.* At that point, still

nothing changed with regard to the dispensing of abortion pills. The 2023 REMS would hold until the legal process fully played out.

On June 13, 2024, the U.S. Supreme Court unanimously ruled that the plaintiffs, including the Alliance for Hippocratic Medicine, did not have standing to challenge the FDA's regulation of mifepristone. The Court did not rule on whether or not the FDA had acted properly in removing previous safeguards. The drug would continue to be dispensed under the 2023 REMS. However, the court left the door open for others who might have standing to pick up the case (which Idaho, Kansas, and Missouri are attempting to do).

On July 15th, the U.S. Court of Appeals for the Fourth Circuit issued a critical 2-1 ruling in favor of a West Virginia pro-life law. At stake was whether or not the state had the right to prohibit the dispensing of a drug – specifically mifepristone – that the FDA had approved. This was a watershed decision, because what the suit really sought was to federalize the issue of abortion by claiming that Congress intended to grant nationwide access to mifepristone in 2007. GenBioPro (the manufacturer of mifepristone) had sued West Virginia, claiming that federal law (citing the 2007 amendments to the Federal Food Drug and Cosmetic Act) pre-empted the state's law regulating mifepristone. "Preemption in this instance would upend the federal-state balance by supplanting every state law tangentially touching a federal domain," the court wrote in its opinion in *GenBioPro v. Raynes*. The Fourth Circuit concluded that the Food Drug and Cosmetic Act "create[s] a regulatory floor, not a ceiling," and that there was no indication "Congress intended to guarantee nationwide access to mifepristone when it enacted the FDAAA."[11] It was also relevant that, in the decision, the Court recognized "states' historic and sovereign right to protect the health and safety of their citizens."[12]

* * *

Where we stand on July 16, 2025: Each state has the legal authority to govern abortion laws within its boundaries, and this includes the use of mifepristone. Thus, to the extent that mifepristone is legal under a given state's laws, it is distributed in that state according to FDA regulations.

But what about states where mifepristone is illegal? Because the current FDA regulations do not include an in-person distribution requirement, this suggests a loophole whereby some claim that the drug can be mailed. On the federal level, the Comstock Act of 1873 prohibits the mailing of abortifacients – which, ostensibly, makes prosecuting Comstock violations a federal responsibility. Biden's DOJ claimed incorrectly that Comstock was not applicable to mifepristone. To date, the Trump DOJ hasn't indicated their intention to use it.

Many state laws prohibit mifepristone from being accessed by mail. But enforcing these laws is, at best, very difficult. Out-of-state abortionists who violate other state's laws by shipping pills to those states make it a point not to identify the contents or their origin on the package. And even when the evidence is found, prosecuting the case has its own set of challenges.

When a resident of one state violates the laws of another state, arresting and extraditing the criminal can be very difficult. In 2024, Texas initiated a legal case against Dr. Margaret Carpenter, a New York doctor, for prescribing abortion pills to a woman in Texas via telemedicine. Not only did Dr. Carpenter's actions violate Texas abortion law, but they also violated its occupational licensing law, as she was practicing medicine in Texas without being licensed there. In February, 2025, a Texas

Court fined Dr. Carpenter (who failed to appear) $100,000. She refused to pay, and the state of New York refused to make her, citing its own passage of a "shield law" supposedly protecting abortionists in New York who ship pills to other states, even if it is illegal there.

Texas Attorney General Ken Paxton is seeking to bring the case before SCOTUS. If they agree to hear the case, they could decide whether or not "shield laws" violate the "full faith and credit" clause of the Constitution, which requires states to honor the judgments of other states against their citizens.

Texas is not the only state where Dr. Carpenter is facing charges. Louisiana Attorney General Liz Murrill signed an extradition form for the physician in February, 2025, after a Louisiana grand jury indicted the doctor for prescribing and shipping abortion pills to the state. (Murrill is also prosecuting the West Baton Rouge woman who allegedly ordered the pills for her pregnant minor daughter, and then may have forced her to take them. The state became involved in the case after the minor called 911.)

An extradition order is a tool that can be used to prosecute abortion providers who ship pills into states where they are illegal. Although New York is ignoring the one for Dr. Carpenter, there are other states that would honor this active warrant for her arrest. According to Murrill, "Dr. Carpenter needs to be careful with her travel plans…If New York won't cooperate, there are other states that will."

Another solution to the mifepristone-mail problem is to use RICO. This federal statute was created to combat organized crime that crosses state boundaries. It remains to be seen whether the DOJ will implement such a strategy. They may be waiting to see what happens with the Carpenter case.

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End Notes

[1] *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration,* No. 2:22-CV-223-Z, Opinion and Order at 2 (N.D. Tex., Apr. 7, 2023), p.2.
[2] Ibid.
[3] To be precise, the FDA guidelines said "under a physician's supervision." The abortion clinics chose to broadly interpret this as including a physician's designated representative.
[4] https://www.npr.org/2021/12/15/1064598531/the-fda-could-permanently-lift-some-restrictions-on-abortion-pills
[5] Ibid.
[6] Ibid.
[7] *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration,* No. 2:22-CV-223-Z, Opinion and Order at 2 (N.D. Tex., Apr. 7, 2023), p.1.
[8] O'Bannon, Randall K., "Addressing Many of the Myths the Media is Repeating about the FDA's Approval and Management of Mifeprex (Mifepristone)," May, 2023, p.3.
[9] *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration,* No. 23-10362, United States Court of Appeals for the Fifth Circuit, Document: 543-1, p.62.
[10] *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration,* No. 23-10362, United States Court of Appeals for the Fifth Circuit, Document: 543-1, p.50.
[11] https://adfmedia.org/case/genbiopro-v-raynes/
[12] *GenBioPro v. Raynes,* No. 23-2194, United States Court of Appeals for the Fourth Circuit, Document: 171, p.6