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What Is the FDA Hiding on Mifepristone?

It has 125,000 pages of documents, some of which it has held back for three decades.

By J. Marc Wheat

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The Supreme Court on Friday stayed a lower-court order that would have reinstated safety restrictions on mifepristone. That isn't the only legal battle over the abortion drug. After two years of litigation, the Food and Drug Administration admitted in March that it has more than 125,000 pages of documents, which it has withheld from public scrutiny for 30 years.

These records likely include communications between FDA officials and the White House counsel's office during the Clinton administration, internal discussions about mifepristone's original application for approval, and materials related to the controversial Population Council, a nonprofit group co-founded by the eugenicist Frederick Osborn.

Congress sought many of these documents in 1996, years before the FDA approved mifepristone. The American people deserve to know why their elected representatives never received them.

When the FDA approved mifepristone in 2000, shortly before President Clinton left office, it did so with restrictions that provided a modicum of safety protection. The drug could be dispensed only in person by a qualified physician, which protected women with life-threatening ectopic pregnancies.

The Obama and Biden administrations later expanded chemical abortion from seven to 10 weeks gestation, eliminated the in-person dispensing requirements, allowed nonphysicians to prescribe the drug, and even stopped requiring prescribers to report nonfatal adverse events to the FDA. The FDA then used the lack of adverse-event data to claim that abortion pills are safe enough to distribute through the mail.

Now we are beginning to see the consequences. Recent studies based on insurance claims have concluded that approximately 11% of women who had a chemical abortion experienced sepsis, hemorrhaging or another serious adverse event—a rate of complication more than 20 times as high as the FDA has acknowledged.

Yet federal bureaucrats still insist there's nothing to see here. That is why those FDA documents matter. Was political pressure brought to bear during the original approval process? Did officials in the Clinton White House intervene in what should have been a strictly scientific endeavor? Did FDA leadership overlook safety concerns in pursuit of ideological goals? Did the Obama and Biden administrations knowingly weaken safeguards despite evidence of mounting complications?

As required by law, the Biden FDA was supposed to release the mifepristone records in June 2024 to comply with a Freedom of Information Act request filed by Advancing American Freedom. It refused to do so.

Only after a change in administration and a successful lawsuit did the FDA finally acknowledge the existence of these documents. But even now, agency bureaucrats could slow-walk their release to a few hundred pages per month, meaning it would take decades to reach full disclosure.

Enough is enough. For the sake of women's health, it's time for transparency.

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