

# Protect Our Care WI: “A dark cloud over U.S. drug approval” - how FDA approvals could be thrown into chaos post-mifepristone case

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# A Dark Cloud Over U.S. Drug Approval

Mifepristone Case Will Create Chaos in the U.S. Drug Approval Process, Threaten Investment in Innovation, and Take Safe and Effective Life-Saving Drugs Off the Market



PROTECT  
OUR CARE

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**Washington, D.C.** — Following the announcement that the Supreme Court will hear *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration* next term, Protect Our Care is releasing a new report that describes what is at risk if the Supreme Court sets the precedent of allowing courts to overrule the FDA's drug approval decisions. The report provides a detailed look at the categories of drugs that could be most at risk from ideological opponents and friendly judges.

Earlier this year, Judge Matthew Kacsmarky invalidated the FDA's approval of mifepristone and the 5th Circuit Court of Appeals severely restricted access to mifepristone, but the Supreme Court stayed this decision. A decision to ban mifepristone would threaten millions of women's access to safe and legal abortions and open the door for the politically motivated destruction of the entire drug approval process.

The report explains if the Supreme Court opens the door, the public could lose access to other critical and lifesaving health care such as:

- other abortion and contraception products
- common vaccines opposed by anti-vaxxers
- drugs and vaccines that were developed with fetal cell lines, including ones that protect against Hepatitis A
- vital treatments for gender-affirming care and HIV prevention
- innovative cell and gene therapies
- embryonic stem cell research
- investments into future treatments with the potential to treat or cure diseases like Parkinson's, cancer, and diabetes

"A dark cloud looms over the drug approval and development processes as the Supreme Court weighs allowing politics to trump science," **said Leslie Dach, chair of Protect Our Care.** "If the lower courts' decisions stand, any third party with a political agenda can challenge a medication they object to, and judges could ignore expert opinions and arbitrarily rip away lifesaving drugs and vaccines from patients who rely on them. The entire FDA approval process would be thrown into chaos and millions of people across the nation would suffer."