Ever since overturning Roe *v. Wade* in June 2022, the battle over reproductive rights has surged. Pro-choice advocates expressed anger at the fact that women have been stripped of supposed rights. And pro-life supporters celebrated that the number of abortions, of children killed, nationwide would (hopefully) see substantial declension. Conservative and originalists rejoiced that the Supreme Court followed the Constitution by returning to the decision about abortion access to the states.

In December 2023, a new facet of the abortion debate arose as the Supreme Court announced its intention to rule on the restriction of the drug mifepristone, which is commonly used to terminate pregnancies. This ruling stems from the cases *Food and Drug Administration v. Alliance for Hippocratic Medicine* and *Danco Laboratories v. Alliance for Hippocratic Medicine*. Multiple issues are in play that involve both standing and whether FD has authority to increase access to the drug.

First, whether respondents have Article III standing to oppose the FDA's decision about the distribution of mifepristone. "The standing doctrine requires a litigant seeking federal judicial relief to demonstrate (1) a concrete and particularized and actual or imminent injury-in-fact (2) that is traceable to the allegedly unlawful actions of the opposing party and (3) that is redressable by a favorable judicial decision"[1]. Parties opposing the regulations argue that there is imminent and probable injury for women who are prescribed mifepristone if it is not banned or at least restricted. Of course, as with any drug, there are side effects, but this drug can lead to more severe effects.

Elaborating on whether standing has been sufficiently alleged, those challenging the FDA's action argue that not only is mifepristone harmful to the women taking it, but to the physicians treating them. They note that when a physician treats a woman suffering from a mifepristone complication, he or she will often have to perform or complete an abortion. And even if not, the physician must participate in the medical treatment that facilitates an abortion. The Doctors allege that being forced to provide this type of treatment conflicts with their sincerely held moral beliefs and violates their rights of conscience. Treating mifepristone patients also imposes mental and emotional strain above what is ordinarily experienced in an emergency-room setting. Next, providing emergency treatment forces the Doctors to divert time and resources away from their ordinary patients, hampering their normal practice. And finally, the Doctors allege that mifepristone patients involve more risk of complication than the average patient, and so exposes them to heightened risk of liability and increased insurance costs.[2]

The second major issue focuses on changes to condition of use and whether FDA has the statutory authority to issue the regulation. FDA altered the conditions of use so that mifepristone could be used for up to ten weeks of pregnancy. The FDA also decreased the dosage for mifepristone from 600 mg to 200 mg and increased the dosage of its sister drug, misoprostol. Ultimately, "the FDA determined based on '15 years of reporting' that the requirement was no longer warranted and that, as with the vast majority of other drugs, information on non-fatal adverse events could be 'collected in the periodic safety update reports and annual reports' submitted by the drug's sponsor to FDA."[3] As a response to these

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[1] Freeman, Wilson C. and Kevin M. Lewis. "Congressional Participation in Litigation: Article III and Legislative Standing." Congressional Research Service, *https://crsreports.congress.gov.* Nov. 8, 2019. https://crsreports.congress.gov/product/pdf/R/R45636

[2] *US Food and Drug Administration, et al. vs. Alliance for Hippocratic Medicine,* Court of Appeals Opinion, Case No. 2:22-CV-223 (5th Cir.), 16a-17a. https://www.supremecourt.gov/DocketPDF/23/23-235/279230/20230908165019043_Alliance%20for%20Hippocratic%20Medicine%20App%20FINAL.pdf

[3] *FDA vs. Alliance for Hippocratic Medicine,* Petition for Writ of Certiorari at 6. Available at https://www.supremecourt.gov/DocketPDF/23/23-

changes of use, which loosened regulation of the drug and removed tracking dangers for the safety of customers, "in 2019, two respondents filed a petition challenging FDA's 2016 changes to mifepristone's indication, labeling, and REMS (Risk Evaluation and Mitigation Strategies) and urging the agency to retain the in-person dispensing requirement. In December 2021, FDA denied that petition in relevant part. FDA determined that respondents' various criticisms of the 2016 changes were unfounded."[4] In ruling against the FDA, the Fifth Circuit determined that the 2016 criticisms did hold water and that the changes were arbitrary because "none of the studies it relied on examined the effect of implementing all of those changes together."[5]

The Fifth Circuit did not stop at the 2016 alterations in its criticism of the FDA's regulation of mifepristone. It "concluded that FDA's 2021 decision to eliminate the in-person dispensing requirement was arbitrary and capricious because the agency had relied in part on adverse-event data that the court viewed as unreliable due to the 2016 change to the reporting requirement."[6] The FDA had placed women taking the drug in increased danger. It no longer tracked the effects of mifepristone or required reporting for any adverse reactions and there had been no data recorded on the concurrent effects when all three of the 2016 alterations were implemented. The agency claimed that the drug had been in use for long enough that requiring women to report side effects was unnecessary, but they had not seen yet what happened when the dosage changed, and women used the drug later in pregnancy. The FDA's actions can be characterized as willfully negligent by allowing these changes to take effect and not keeping a record of any resulting problems. The Fifth Circuit concluded that the FDA had failed to adequately protect women who received mifepristone.

The Supreme Court should uphold the Fifth Circuit's decision and conclude that the FDA acted arbitrarily and capriciously in regulating mifepristone, which at the very least should be grounds for temporary restrictions on the drug. A potential roadblock exists for Doctors opposing the regulation in that the Supreme Court may find their claim for Article III standing weak since they have no specific allegation of a direct injury due to the drug. If their standing claim is rejected, those opposing FDA's action could identify a woman who has used mifepristone and who has suffered an injury directly from the use of mifepristone because "in assessing whether the threatened injury is fairly likely to occur, evidence of prior injury is especially probative."[7]

The abortion debate has been a large topic of conversation in recent years and this case will return it to the national stage. Conservatives should prepare to take fire for an action that, in the minds of mifepristone's supporters, works to strip women of rights even more. Access to abortion has been limited in some states and a Supreme Court ruling against a government agency seeking to ease restrictions on mifepristone would restrict it even further.

This is "the first time any court has restricted access to an FDA-approved drug based on disagreement with FDA's expert judgment about the conditions required 12 to assure that drug's safe use—much less done so after those conditions had been in effect for years."[8] Legally, this case will set a

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[4] *Id.*
[5] *Id.*
[6] *Id*
[7] *Id.*
[8] *Id.*

precedent for how the Supreme Court (and lower courts) review administrative agency's regulations of abortifacients.