ADVANCING
AMERICAN FREEDOM

**Restore Safeguards on Mifepristone in Agriculture Appropriations Bill**

I am writing to you on behalf of Advancing American Freedom's 140,000 members to safeguard the language in the Agriculture, Rural Development, Food and Drug Administration appropriations bill that restores protective safeguards that the FDA had formerly mandated on the use of mifepristone, the dangerous chemical abortion drug. The safeguards need to be revived because the rates of adverse events and traumatic complications related to mifepristone are far higher without in-person screening.

The 5th Circuit agrees that the FDA was arbitrary and capricious in doing away with protections, a violation of the Administrative Procedure Act (APA). On August 16, 2023, the 5th Circuit Court of Appeals ruled in *Alliance for Hippocratic Medicine v. FDA* (No. 23-10362), subject to the Supreme Court's prior order staying the district court's order until the disposition of any petition for certiorari, that "in loosening mifepristone's safety restrictions, 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." Judge James C. Ho, concurring in part and dissenting in part, wrote "I would add that the FDA's initial approval of mifepristone in 2000 also violates the agency's own rules and thus must be set aside under the APA as well."

In 2006, the House Republican majority concluded an investigation into the legality of the FDA's approval of mifepristone, which hinged on the question of whether mifepristone chemical abortions are safer than surgical abortions. They are not.

That conclusion has been buttressed by data that have become available since the staff report concluding investigation by the Republican-led House Government Reform Subcommittee on Criminal Justice, Drug Policy, and Human Resources in 2006. Several studies have shown that the medical risk associated with the use of chemical abortion is high. Ten percent (10%) of women, after use of chemical abortion pills, require follow-up medical treatment for failed or incomplete abortion. Maarit Niinimaki et al., Comparison of rates of adverse events in adolescent and adult women undergoing medical abortion: population register based study, BJM, April 20, 2011, at 4. Further, twenty percent (20%) of women who use mifepristone to induce abortions will have an adverse event, including hemorrhaging and infections. Maarit Niinimaki et al., Immediate complications after medical compared with surgical termination of pregnancy, 114

Obstetrics & Gynecology 795 (2009). This rate of adverse events is four times greater than the adverse event rate of surgical abortion. Id.

One in twenty women who undergo a chemical abortion will need to be rushed to an emergency room within thirty days; a rate fifty percent (50%) higher than those who undergo surgical abortions. James Studnicki et al., A Longitudinal Cohort Study of Emergency Room Utilization Following Mifepristone Chemical and Surgical Abortions, 1999-2015, Health Serv. Rsch. & Managerial Epidemiology, Nov. 9, 2021.

FDA's inexplicable cutback on adverse event reporting requires researchers to look overseas for data on mifepristone's harm to women. Even recent experience with mifepristone bears out the fact that it continues to be more dangerous than surgical abortion, meaning that even today the FDA could not legally approve mifepristone under the Subpart H accelerated approval process.

"During the COVID-19 pandemic, a small minority of countries permitted abortion providers to send abortion pills—usually mifepristone and misoprostol—by post to women after a remote consultation by video or telephone (hereafter, "telemedicine" refers to either)—that is, without any in-person contact throughout the process. This was an unprecedented move since full telemedicine had not been studied in legal, experimental conditions prior to this… In the United Kingdom… ambulance calls and responses relating to medical abortion also increased dramatically between 2018 and 2021, following the introduction [of chemical abortion] at home and then full telemedicine." Calum Miller, "Telemedicine Abortion: Why It Is Not Safe for Women," in Nicholas Colgrove, ed., *Agency, Pregnancy and Persons : Essays in Defense of Human Life* (forthcoming, 2023) at 288, 296. British researchers, "using our rights under the Freedom of Information Act… asked each of the ten NHS Ambulance Trusts in England to provide data related to the number of emergency ambulance responses made when the caller indicated complications arising from the use of abortion pills, a combination treatment of mifepristone and misoprostol. Data was requested for three time periods: A – during 2018, when all medical abortions were provided in a clinic; B – during 2019, when women were able to self-administer misoprostol (the second part of the combined treatment) at home, after having received the mifepristone (the first part of the combined treatment) at an abortion clinic; C – from April 2020, when women were able to self-administer both mifepristone and misoprostol at home… Data obtained from five NHS Ambulance Trusts in England, show that emergency ambulance responses for complications arising after a medical abortion are three times higher for women using pills-by-post at home, compared to those who have their medical abortion in a clinic." Kevin Duffy, "Emergency Ambulance Responses Three Times Higher for Pills-by Post," *Percuity* (2023) at 1. "In a related freedom of information investigation, we found that complications arising from the failure of medical abortion treatment result in 590 women presenting at the emergency department of their local NHS hospital in England every month. The treatment failure rate is 5.9%, 1-in-17." Id.

The FDA's arbitrary and capricious slackening of reporting standards put women at further risk. In 2000, the FDA approved mifepristone with certain safeguards and requirements to decrease

the dangers mifepristone could pose to women, consistent with Subpart H. See 21 C.F.R. § 314.520. Although compliance with those requirements was insufficient to prevent adverse events, they were much more stringent than the requirements imposed today. Among those requirements in 2000, prescribers were obligated to report non-fatal but serious adverse events to the drug manufacturer. Food and Drug Administration, Approved Labeling Text for Mifeprex (Sept. 28, 2000), 27 https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.htm.

Shockingly, beginning in 2016, the FDA advised prescribers need only report deaths associated with the drug, not other serious adverse events. Food and Drug Administration, Risk Evaluation and Mitigation Strategy (March 2016), https://www.fda.gov/media/164649/download. Food and Drug Administration, Risk Evaluation and Management Strategy (May 2021), https://www.fda.gov/media/164651/download. Imposing ignorance by downgrading adverse event reporting requirements and then claiming the drug is safe because there are so few reports of adverse events is a Through-The-Looking-Glass approach to public health that intentionally obscures the true dangers of mifepristone. The 5th Circuit agrees: "Recall that, because of the 2016 amendments, FDA no longer had access to perhaps the best source of data: the prescribers. The agency is responsible for its own inability to obtain probative data; it cannot then cite its lack of information as an argument in favor of removing further safeguards. As the motions panel aptly put it: "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." *Alliance for Hippocratic Medicine v. FDA* (No. 23-10362) at 50.

The data relied upon by the FDA when it approved mifepristone as an abortifacient in 2000 was insufficient to support its finding that chemical abortion was a safe alternative to surgical abortion. In the ensuing two decades, even the paucity of information collected by the FDA on the safety of chemical abortion continues to show significant dangers for women using mifepristone. Despite evidence of significant danger, the FDA continues to slacken safeguards for use of mifepristone and for reporting the dangerous consequences of its use. Such reckless disregard of data collection on women's well-being smacks more of political maneuver than medical science.

Advancing American Freedom strongly supports the language to restore the FDA-discarded protections for women who take mifepristone. If you have any questions about mifepristone, the FDA's actions, or anything else regarding this important matter, feel free to give our staff a call at (202) 780-4848. We are here to be a resource for you.

Sincerely,

Paul Teller
Executive Director
Advancing American Freedom