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AAPLOG Sues FDA Over Mifepristone Approval

Today, November 18, AAPLOG, alongside other plaintiffs, filed a lawsuit against the U.S. Food & Drug Administration (FDA) for illegally approving mifepristone (also known as "Mifeprex" and "RU-486") and misoprostol for chemical abortion, as these dangerous drugs harm women and girls. The plaintiffs, which include AAPLOG, the Alliance for Hippocratic Medicine (a coalition of pro-life medical organizations), the American College of Pediatricians, the Christian Medical and Dental Associations, and doctors Shaun Jester, Regina Frost-Clark, Steven Foley, Tyler Johnson, and George Delgado, are represented by Alliance Defending Freedom, the law firm that worked with Mississippi in the US Supreme Court Case Dobbs v Jackson Women's Health Center, the ruling for which overturned Roe v Wade. As the lawsuit explains, the FDA illegally approved mifepristone and has repeatedly removed the few safeguards governing it's use over the past two decades. The agency did not study the danger mifepristone posed to minors despite approving mifepristone for use by young girls. The FDA also has never required an ultrasound prior to a chemical abortion. An ultrasound is the best way to confirm the baby's age and to rule out an ectopic pregnancy, which occurs in 1 in every 50 pregnancies. Without an ultrasound, the risks involved in a chemical abortion skyrocket.

The FDA has not worked to correct the dangers and harms intrinsic to chemical abortions. Instead, in 2016, the FDA <u>dangerously expanded the availability</u> of chemical abortion drugs from 7 weeks of pregnancy up to 10 weeks of pregnancy, changed the dosing regimen, reduced the number of in-person

doctor visits from three to one, expanded who could prescribe and administer chemical abortion drugs beyond medical doctors, and eliminated the requirement for prescribers to report non-lethal complications from chemical abortion drugs. And in 2021, based on incomplete and unreliable data, the FDA removed the requirement that an abortionist physically meet with the woman and give her the chemical abortion drugs, thus allowing for chemical abortions by mail and telemedicine. This will only increase the danger to women, not to mention the children whose lives will be ended. As many as one out of five women who undergo a chemical abortion will suffer a complication. Women can face severe bleeding, life-threatening infections, and the inability to have future successful pregnancies—requiring emergency medical treatment, surgeries, blood transfusions, and hysterectomies. In addition, chemical abortion has a complication rate four times higher than surgical abortions.

AAPLOG has long fought against efforts by the FDA and proabortion advocates to prioritize abortion access over the health and safety of women and their preborn children. We are proud to be a part of this effort to hold the FDA accountable to its obligation to protect the health, safety, and welfare of women and girls. You can see the <u>full press release about this lawsuit here</u>.

You can also read the <u>complaint here</u> and a <u>Wall Street</u>

Journal article about this lawsuit here.