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ATTORNEY GENERAL LOPEZ URGES FEDERAL JUDGE TO ORDER THE FDA TO REVIEW ITS RESTRICTIONS ON ABORTION MEDICATION MIFEPRISTONE

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HONOLULU –Attorney General Anne Lopez is urging a federal judge in Spokane, Washington, to rule that the U.S. Food and Drug Administration's restrictions on the abortion medication mifepristone are inconsistent with the Administrative Procedure Act.

"Since 2000, more than 5.6 million patients have safely used mifepristone. We should not be afraid to increase access to a medication whose safety and efficacy is based in science and proven over time. Artificial limitations on safe and effective medication are actual limitations on access to healthcare," said Hawaiʻi Deputy Attorney General Erin Lau.

The multistate lawsuit was filed last year in the U.S. District Court for the Eastern District of Washington by 17 plaintiff states, including Hawaiʻi, and the District of Columbia.

Of the more than 20,000 drugs approved by the FDA, only 73 drugs have extra restrictions known as a Risk Evaluation and Mitigation Strategy (REMS), including highly addictive drugs such as Oxycontin. An even smaller subset of drugs carries additional restrictions known as Elements to Assure Safe Use (ETASU), including certain risky cancer drugs and high-dose sedatives. Despite its proven safety and efficacy, mifepristone has both a REMS and an ETASU restriction.

Although the REMS and ETASU restrictions have been relaxed over time, certain restrictions remain. To prescribe mifepristone, health care providers must be specially certified by the drug distributor and submit their certification form to every pharmacy to which they send a mifepristone prescription—an administratively burdensome requirement that is unique to mifepristone. The pharmacy must also be specially certified with the drug distributor before it can dispense a prescription.

In order for a patient to receive the prescription, the patient and their providers must sign an agreement that certifies the patient has decided to take the medication to end the pregnancy—regardless of whether they are seeking an abortion or are being treated for a miscarriage, which is a common use for mifepristone. These remaining requirements are excessive when considering mifepristone's safety profile.

The multistate lawsuit asserts the restrictions on prescribing and dispensing mifepristone are unduly burdensome, harmful and unnecessary, reduce access to a critically important drug, and expose providers and patients to unnecessary privacy and safety risks. The risks are exacerbated by the growing criminalization and penalization of abortion around the country in the wake of the U.S. Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*. The *Dobbs* case overturned nearly a half-century of precedent, stripping away the constitutional right to abortion recognized by the Court's *Roe v. Wade* decision.

The plaintiff states recently filed a motion for summary judgment, seeking to require the FDA to review whether mifepristone still meets the statutory requirements to impose a REMS with ETASU restriction based on its safety profile. The motion argues that decades of data conclusively show that mifepristone is safe and effective, and that medical experts have long opposed the FDA's restrictions on the medication. By keeping the restrictions on mifepristone, the states argue that the FDA is unnecessarily and unlawfully limiting access to a medication that is safer than Tylenol, Viagra, and insulin.

Along with Attorney General Lopez, attorneys general for Arizona, Colorado, Connecticut, Delaware, Illinois, Maine, Maryland, Michigan, Minnesota, Nevada, New Mexico, Oregon, Pennsylvania, Rhode Island, Vermont, Washington and Washington, D.C. joined the case.

A copy of the motion can be found here.

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