ACLU sues to challenge FDA limits on access to abortion pill

October 3 2017, by David Crary

In this Sept. 29, 2017 photo, Dr. Graham Chelius stands outside his home on the Hawaiian island of Kauai. Chelius, a family medicine doctor, is a plaintiff in a lawsuit being filed by the American Civil Liberties Union challenging U.S. Food

and Drug Administration restrictions that limit many women's access to the so-called abortion pill. Chelius would like to be able to write prescriptions so women could obtain the pill at pharmacies, which is currently banned by the FDA. (Courtesy of Chelius family via AP)

The American Civil Liberties Union sued Tuesday in a challenge to federal restrictions that limit many women's access to the so-called abortion pill.

The lawsuit, filed in U.S. District Court in Hawaii, targets long-standing restrictions imposed by the Food and Drug Administration that say the pill, marketed in the U.S. as Mifeprex, can be dispensed only in clinics, hospitals and doctors' offices. The lawsuit contends the drug—used for abortions up to 10 weeks of pregnancy—should be made available by prescription in pharmacies across the U.S.

"The abortion pill is safe, effective and legal. So why is the FDA keeping it locked away from women who need it?" said Julia Kaye, an attorney with the ACLU Reproductive Freedom Project. "The FDA's unique restrictions on medication abortion are not grounded in science—this is just abortion stigma made law."

The restrictions have been in place since the drug was approved for use in the U.S. in 2000. They stipulate that Mifeprex may not be sold in pharmacies and that all providers of the drug undergo a special certification process.

The FDA issued new guidelines for the use of Mifeprex last year, and said at the time that the restrictions continue to be necessary to ensure safe use of the drug.

The FDA confirmed this week that the agency's position has not changed since then. Regarding the lawsuit, it said the agency does not comment on pending or ongoing litigation.

The suit was filed on behalf of three health care associations and a physician, Graham Chelius. He works on the Hawaiian island of Kauai, which currently has no abortion providers.

Chelius, a family medicine doctor, says he is qualified and willing to provide medication abortion, but is unable to stock the abortion pill at the hospital where he works because of objections from some colleagues. As a result, he says, his patients must carry an unwanted pregnancy to term or make a 300-mile round trip flight to another island to get an abortion—boosting costs and sometimes delaying the procedure by several weeks. This could be avoided if the pill were available at pharmacies on Kauai.

The lawsuit is supported by the American Congress of Obstetricians and Gynecologists. Its CEO, Dr. Hal Lawrence, said there is no medical justification for the FDA restrictions.

According to a commentary earlier this year in the New England Journal of Medicine, 19 deaths have been reported to the FDA among the more than 3 million women who have used Mifeprex in the U.S. since 2000, a mortality rate lower than for pregnancy-related deaths among women.

The commentary suggested that lifting the FDA restrictions would likely increase the number of doctors willing to prescribe Mifeprex, since they would no longer have to stock the drug in their office and no longer have to be on a list of certified abortion providers. Easing the rules also might help make medical abortion more available via telemedicine to women in rural areas who live far from the nearest abortion facility, said the 10 co-authors, who included doctors and academics from Stanford,

Princeton and Columbia universities.

According to the latest federal figures, medical abortions—generally a two-pill regimen using Mifeprex and the drug misoprostol—accounted for about 22 percent of abortions in the U.S. in 2013. Surgical procedures accounted for nearly all the other abortions.

Women using the pill generally take it in the privacy of their home. Noting that, Kaye said the legal case "is primarily about where a woman must be standing when she's handed the abortion pill that's been prescribed to her."

"The FDA restriction defies common sense," she said. "There's no medical issue in whether she's handed the pill at a pharmacy or at a clinic."

There is precedent for a federal court to overturn FDA restrictions. In 2013, a federal judge in New York ordered that the most common version of the morning-after pill must be accessible over-the-counter for all customers of all ages, instead of requiring a prescription for girls 16 and younger.