Mifepristone Related Litigation

As of December 10, 2024

Bryant v. Moore (Previously Bryant v. Stein)

(Status: Ongoing | Location: North Carolina; United States Court of Appeals for the Fourth Circuit | Last Update: 12/03/2024)

In January 2023, Dr. Amy Bryant, a North Carolina physician, filed a lawsuit challenging state-imposed restrictions on the provision of and patient access to mifepristone. Dr. Bryant contended that North Carolina's regulations, which included requirements such as in-person dispensing and physician-only administration, were preempted by federal law, specifically, the FDA's updated Risk Evaluation and Mitigation Strategy (REMS) for mifepristone. On April 30, 2024, the court determined that certain state-imposed restrictions—namely, those requiring in-person prescribing, dispensing, and administration of mifepristone, as well as physician-only prescribing—were preempted by federal law and therefore invalid. However, the court upheld other state requirements, including mandatory in-person consultations, ultrasounds, and a 72-hour waiting period, finding that these did not conflict with FDA's regulations. Following this decision, both parties filed appeals. Currently, the case remains under review by the U.S. Court of Appeals for the Fourth Circuit. On August 12, the opening brief of Appellants was filed, and on October 10, the response brief from Dr. Amy Bryant was filed. On December 3, 2024, the 4th US Circuit Court of Appeals placed this case on hold pending a decision in GenBioPro v. Sorsaia/Raynes (summarized below).

Alliance for Hippocratic Medicine, et al., v. FDA

(Status: Ongoing | Location: Texas Northern District Court in Amarillo | Last Update: 11/1/2024)

In June 2024, the Supreme Court issued a unanimous decision in *Alliance for Hippocratic Medicine v. Food and Drug Administration (FDA)*. The Court ruled the plaintiffs lacked the necessary legal standing to challenge the FDA's regulation of mifepristone, including the 2016 and 2023 REMS modifications (notably, the Supreme Court did not consider the original challenge to the mifepristone approval, which the Fifth Circuit found was time barred). In November 2023, Missouri, Kansas, and Idaho filed a motion seeking to intervene in the case. In November 2024, the states sought leave to file an amended complaint that would remove the original plaintiffs and leave the state attorneys general to pursue the case. These states argued the FDA's guidelines for mifepristone infringed on state sovereignty and public health policies,

as each state had established restrictions or regulations around abortion. In November 2024, the Biden administration and Danco Laboratories (the branded drug manufacturer of mifepristone) filed a motion to dismiss the complaint for lack of jurisdiction.

Birthmark Doula Collection v. State of Louisiana
(Status: Filed Lawsuit | Location: Louisiana; District Court | Last Update: 10/31/24)

In *Birthmark v. Louisiana*, filed in October 2024, the plaintiffs challenged Louisiana's Act 246, which reclassifies mifepristone and misoprostol as controlled dangerous substances under the state's controlled substances law. The plaintiffs argue the reclassification imposes stringent regulations, potentially delaying access to these essential medications during critical emergencies, thereby endangering patients' lives. They contend that Act 246 violates the Louisiana Constitution's equal protection guarantee by discriminating against individuals based on their physical conditions. The Birthmark Doula Collective initiated the lawsuit, along with healthcare professionals and individuals directly affected by the law. They assert that the legislation contributes to the stigmatization of reproductive healthcare and could lead to increased surveillance and criminalization of healthcare providers and patients. The plaintiffs seek a declaratory judgment and a permanent injunction to prevent the enforcement of Act 246, aiming to ensure uninterrupted access to these critical medications for both patients and healthcare providers.

GenBioPro v. Sorsaia/Raynes
(Status: Ongoing | Location: West Virginia; United States Court of Appeals for the Fourth Circuit | Last Update: 10/31/24)

GenBioPro, Inc. v. Raynes is an ongoing legal case in which GenBioPro (the manufacturer of generic mifepristone) challenged West Virginia's abortion ban, arguing it is preempted by the Federal Food, Drug, and Cosmetic Act and FDA's regulations governing mifepristone. A judge from the U.S. District Court for the Southern District of West Virginia ruled that the state of West Virginia can restrict the sale of the abortion pill, (i.e., that such restrictions were not preempted). GenBioPro appealed the district court's decision to the U.S. Court of Appeals for the Fourth Circuit where the case is currently pending.

Whole Woman's Health Alliance et al. v. U.S. Food and Drug Administration et al.
(Status: Ongoing | Location: Virginia; District Court | Last Update: 10/23/2024)

On May 8, 2024, the Center for Reproductive Rights filed a lawsuit in federal district court in Virginia, on behalf of independent abortion providers in Virginia, Montana, and Kansas. This case argues for parallel relief in the *State of Washington v. FDA* because these independent abortion providers do not fall under the Washington court's jurisdiction and are not protected under the court's order. The Plaintiffs argue that the FDA violated the Equal Protection Clause of the US Constitution and the Administration Procedure Act by subjugating mifepristone to requirements that make the drug difficult to access and prescribe. On August 21, 2023 the

federal court denied CRR's request for a preliminary injunction that would have protected access to mifepristone. On October 23, 2024, the Plaintiffs issued a motion for summary judgment declaring the 2023 Mifepristone REMS unlawful and either vacating the 2023 Mifepristone REMS in its entirety or remanding it to the FDA with instructions to reconsider the REMS.

State of Washington, Oregon, et al., v. FDA
(Status: Ongoing | Location: Washington; District Court | Last Update: 10/10/2024)

In February 2023, a coalition of 17 states and the District of Columbia, led by Washington and Oregon, filed a lawsuit against the FDA in the U.S. District Court for the Eastern District of Washington. The plaintiffs argued that the FDA's mifepristone REMS imposed unnecessary restrictions on the drug despite its established safety profile. On April 7, 2023, U.S. District Judge Thomas O. Rice issued an injunction preventing the FDA from "altering the status quo and rights as it relates to the availability of Mifepristone" under 2023 REMS in the plaintiff states and DC, thereby maintaining existing access to the medication in those jurisdictions ". Subsequently, a group of Republican-led states sought to intervene in the case, aiming to impose additional restrictions on mifepristone. However, in July 2024, the Ninth Circuit Court of Appeals ruled that these states lacked the legal standing to participate in the lawsuit, effectively denying their intervention. In September 2024, the Ninth Circuit declined to grant a rehearing *en banc*. Currently, the injunction issued by Judge Rice remains in effect, ensuring that mifepristone continues to be accessible in the plaintiff states under the existing FDA guidelines.

Purcell v. Becerra (Previously Chelius v. Becerra)
(Status: Ongoing | Location: Hawaii; District Court | Last Update: 10/2/2024)

Purcell v. Becerra is an ongoing federal lawsuit initiated in October 2017, in the U.S. District Court for the District of Hawaii. The plaintiffs, including Dr. Heidi Purcell, the Society of Family Planning, and the California Academy of Family Physicians, challenge the U.S. Food and Drug Administration's (FDA) Risk Evaluation and Mitigation Strategy (REMS) for mifepristone, a medication used for early abortion and miscarriage management. The plaintiffs argue that the REMS imposes unnecessary and burdensome restrictions on mifepristone, making it difficult to access and prescribe, despite its established safety and efficacy. They contend that these restrictions violate the Equal Protection Clause of the U.S. Constitution and the Administrative Procedure Act by singling out mifepristone for undue limitations not applied to other medications with comparable safety profiles. In response to the lawsuit, the FDA announced in April 2021 that it would undertake a comprehensive review of the REMS for mifepristone. Subsequently, in January 2023, the FDA updated the REMS, removing the in-person dispensing requirement but maintaining and adding other restrictions, such as special certification for prescribers and pharmacies. The plaintiffs assert that these remaining restrictions continue to impede access to mifepristone and have persisted with their legal challenge. As of October 2024, the plaintiffs

filed a motion for summary judgment declaring the REMS unlawful under the APA, and requested the court return the issue to the FDA to reconsider the 2023 mifepristone REMS.

For more information, please contact info@emaaproject.org.