

Access to Mifepristone Hangs in the Balance

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As those in the reproductive health space scramble to keep up with the ever-changing landscape of mifepristone (Mifeprex) access, it seems that every party must have their say.

The last three months have seen updates from two federal agencies, five separate letters collectively signed by over 40 state attorneys general, announcements from two major pharmacy chains, at least one proclamation via tweet by a state governor, and further movement in the Texas case challenging FDA's approval of mifepristone. In the end, the state of mifepristone access remains unclear.

As we previously reported [here](#), the US Department of Justice (DOJ) Office of Legal Counsel (OLC) published a [memorandum opinion](#) on December 23, 2022, for the General Counsel of the US Postal Service regarding the mailing of mifepristone and misoprostol — used together to end an early pregnancy. OLC concluded that 18 U.S.C. § 1461 — originally enacted as part of the Comstock Act — does not prohibit the mailing of either mifepristone or misoprostol “where the sender lacks the intent that the recipient of the drugs will use them unlawfully.” Per OLC, “the mere mailing of such drugs to a particular jurisdiction is an insufficient basis for concluding that the sender intends them to be used unlawfully.”

Less than two weeks later, on January 3, 2023, the US Food and Drug Administration (FDA) approved modifications to the mifepristone Risk Evaluation and Mitigation Strategy (REMS). Among other things, the modified REMS allows for any pharmacy — including retail pharmacies — to become certified to dispense mifepristone so long as the pharmacy meets certain requirements. In the wake of the REMS modifications, Walgreens and CVS Health announced that they would seek certification to dispense mifepristone.

Twenty attorneys general subsequently issued letters (the February 1, 2023 Letters) to [CVS](#) and [Walgreens](#) warning against mailing “abortion pills” to their respective states. Despite OLC's memorandum opinion, the February 1, 2023 Letters state that 18 U.S.C. § 1461 “expressly prohibits” using the mail to send or receive drugs that will be “used or applied for producing

abortion.” Indeed, the letters state that the attorneys general “reject [OLC’s] bizarre interpretation” and that they “expect courts will as well.” On February 6 and February 21, 2023, the attorney general of one additional state issued letters (the February 6 and 21, 2023 Letters) to [Walgreens](#) and [CVS](#), echoing many of the same sentiments.

In response, on February 16, 2023, 23 attorneys general issued their own [letter](#) (the February 16, 2023 Letter) in support of CVS and Walgreens dispensing mifepristone and misoprostol. The February 16, 2023 Letter notes that the claim that the Comstock Act prohibits the distribution of mifepristone and misoprostol “is misguided and disregards over a century’s worth of legal precedent.” The letter further explains that “federal courts have repeatedly and consistently held that the Comstock Act does *not* categorically prohibit mailing items that can be used to terminate a pregnancy, and does not apply unless the sender intends the recipient to use them *unlawfully*.” After refuting other claims levied in the February 1, 2023 Letters, the February 16, 2023 Letter concludes by reiterating that the 23 attorneys general “stand in full support of pharmacies like Walgreens and CVS becoming FDA-certified to dispense and mail these essential medications and to make them available as broadly as possible.”

Walgreens recently confirmed that it will not dispense mifepristone in the 21 states whose attorneys general signed onto the February 1, 2023 Letters and February 6 and 21, 2023 Letters. It appears that Walgreens issued individual responses to the 21 state attorneys general who signed these letters, stating that “Walgreens does not intend to dispense Mifepristone within your state and does not intend to ship Mifepristone into your state from any of our pharmacies.” (See, e.g., [Walgreens February 17, 2023 Letter to Kansas AG Kobach](#); [Walgreens February 21, 2023 Letter to Arkansas AG Griffin](#); [Walgreens February 1, 2023 Letter to Indiana AG Rokita](#); [Walgreens February 21, 2023 Letter to Ohio AG Yost](#)).

We note that certain states have laws preventing mifepristone from being dispensed by any individual except a physician. In such states, even where abortion is legal, it is therefore prohibited for a pharmacy to dispense mifepristone.

Following Walgreens’ confirmation that it will not dispense mifepristone in 21 states, California Governor Gavin Newsom announced on March 6, 2023, via [Twitter](#), that the state of California will cease all business with the pharmacy chain. Governor Newsom’s tweet asserted that California would not do business with “any company that cowers to the extremists and puts women’s lives at risk.”

In response, Walgreens released the following statement via [Twitter](#) that same day:

We want to be very clear about what our position has always been: Walgreens plans to dispense Mifepristone in any jurisdiction where it is legally permissible to do so. Once we are certified by the FDA, we will dispense this medication consistent with federal and state laws. Providing legally approved medications to patients is what pharmacies do, and is rooted in our commitment to the communities in which we operate.

Nonetheless, the office of Governor Newsom [announced](#) two days later that the California Department of General Services had given formal notice that “it is withdrawing a planned renewal of [a contract with Walgreens], and instead will explore other options for furnishing the same services.

Under this contract, Walgreens has received about \$54 million from the State.”

At the time of publication of this Alert, it appears that CVS has not yet publicly addressed any of the letters issued by the state attorneys general.

Finally, the court in *Alliance for Hippocratic Medicine, et al. v. US Food and Drug Administration, et al.*, 2:22-cv-00223 (N.D. Tex. Nov. 18, 2022) held a hearing on March 15, 2023, on the plaintiffs’ motion for a preliminary injunction. Among other things, the motion seeks an order requiring FDA and HHS to withdraw or suspend FDA’s approvals of Mifeprex and generic mifepristone. After the hearing, the court indicated that a written order on the motion would be forthcoming.

As before, the landscape of mifepristone access remains ever-shifting and troublingly unclear. ArentFox Schiff will be closely monitoring the situation and providing updates as they come, including an update covering the order on the motion for a preliminary injunction in *Alliance for Hippocratic Medicine*, when issued.

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