



OFFICE OF THE ATTORNEY GENERAL
CONNECTICUT

WILLIAM TONG
ATTORNEY GENERAL

April 14, 2023

The Honorable Governor Ned Lamont
Office of the Governor
State Capitol
210 Capitol Avenue
Hartford, CT 06106

Re: Formal Opinion on Mifepristone Access in Connecticut

Dear Governor Lamont:

In response to your request, my opinion is that the Food and Drug Administration (FDA) approval of both branded and generic mifepristone remains in full force and effect in Connecticut under the status quo prior to this month's federal court orders.

The FDA first approved mifepristone in 2000. Followed by misoprostol in a two-medication regimen, mifepristone is the gold standard for medication abortion and miscarriage care, used safely and effectively by 5.6 million patients to date. Over the years, the FDA modified its requirements for using, prescribing, and dispensing mifepristone as it received and reviewed new data. The most recent set of requirements, issued in January 2023, are known as the "2023 REMS," short for "Risk Evaluation and Mitigation Strategy."

On April 7, 2023, a federal judge in Texas issued a preliminary order commanding the FDA to "stay" its 23-year-old approval of mifepristone. Our office strongly disagrees with that order – issued in *Alliance for Hippocratic Medicine v. FDA*, No. 22-223 (N.D. Tex.) ("*AHM*") – on procedure, substantive law, and underlying science. The U.S. Court of Appeals for the Fifth Circuit has put a critical element of the preliminary order on hold, and the FDA has asked the Supreme Court to prevent any aspect of the order from taking effect pending appeal. We supported that request with a friend-of-the-court brief, and we look forward to the preliminary order's complete reversal.

But regardless of the appeals process: Neither the *AHM* preliminary order nor the Fifth Circuit ruling is binding in, or on, the state of Connecticut.

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Instead, a separate federal court order – also issued on April 7, and reiterated on April 13 – forbids the FDA from “altering the status quo and rights as it relates to the availability of mifepristone” in Connecticut. Order Granting Motion for Clarification and Motion to Expedite, *Washington v. FDA*, No. 23-3026 (E.D. Wash. Apr. 13, 2023).

In that case, *Washington v. FDA*, Connecticut partnered with 16 other states and the District of Columbia in suing the FDA to promote and ensure access to mifepristone. We won a federal court order from Judge Thomas Rice compelling the FDA to maintain the mifepristone status quo under the 2023 REMS. Judge Rice’s order took effect before the *AHM* preliminary order and specifically applies to Connecticut “irrespective” of the Texas proceeding or the Fifth Circuit’s order.

Because Judge Rice’s injunction controls here, the FDA must maintain mifepristone’s approval in Connecticut under the pre-litigation status quo. That means, among other things, that the FDA must:

- Maintain approval of branded and generic mifepristone;
- Maintain authorization of mifepristone for use through ten weeks’ gestation;
- Maintain authorization to dispense mifepristone without any mandatory in-person visit;
- Maintain authorization for health care providers, including some non-physicians, to prescribe and administer mifepristone subject to the January 2023 REMS;
- Omit any requirement that non-fatal adverse events be reported;
- Maintain authorization for certified pharmacies to dispense mifepristone subject to the January 2023 REMS;
- Maintain the dosage of mifepristone at 200 mg.

I specifically highlight two important implications of my opinion that mifepristone remains FDA-approved in Connecticut under the 2023 REMS.

First: Connecticut must continue to cover mifepristone prescriptions for beneficiaries of HUSKY, our Medicaid program. That obligation comes from both caselaw and state regulations. *See Doe v. Maher*, 40 Conn. Supp. 394 (1986) (holding that the state constitution requires HUSKY to cover medically necessary abortions); Regs. Conn. State Agencies § 17b-262-348(r)(3) (requiring the Department of Social Services to cover all abortions deemed medically necessary by a provider).

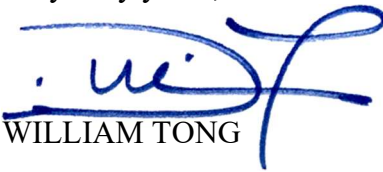
Second: The State has no basis to take disciplinary action against a health care provider simply for prescribing mifepristone, if the provider may prescribe mifepristone under the 2023

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REMS and complies with the Department of Public Health's March 2023 abortion policies and procedures. Prescription of mifepristone, by itself, is not "illegal conduct" exposing a provider to discipline. Of course, nothing in this letter prevents or protects against discipline for any otherwise sanctionable conduct, including negligence and incompetence.

The Attorney General's Office is deeply engaged in ongoing litigation over abortion rights and reproductive justice. We will promptly issue further opinions, guidance, and communication to reflect any further developments.

Very truly yours,



WILLIAM TONG