

State Legal Initiatives to Restrict and Protect Mifepristone Access

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Mifepristone, an established progesterone receptor antagonist, comprises the centerpiece of widely deployed regimens for the medical termination of intrauterine gestation.¹⁻⁵ Approved as the brand Mifeprex by the U.S. Food and Drug Administration (FDA) on September 28, 2000 for the “medical termination of intrauterine pregnancy,” mifepristone has since come to account for over half of all the abortions carried out in the U.S.⁶ More recently, however, in the course of litigating the *Alliance for Hippocratic Medicine v. FDA*, the very validity of the approval of mifepristone by the FDA has been called into question.⁷ On April 7, 2023, in the Northern District of Texas, Judge Matthew Kacsmaryk issued an injunction staying FDA’s approval of mifepristone (i.e., essentially ordering FDA to treat it as unapproved). On the same day, Judge Thomas O. Rice of the U.S. District Court for the Eastern District of Washington acted to preserve access to mifepristone by ordering the FDA to maintain the status quo and permit the continued use of mifepristone; this decision covered 17 states (including Rhode Island) and the District of Columbia.⁸ The Texas order, and its modification by the U.S. Court of Appeals for the Fifth Circuit, was stayed by the U.S. Supreme Court in April 2023 and further modified by a different Fifth Circuit panel of three judges in August. On December 13, 2023, the U.S. Supreme Court agreed to hear the case in order to resolve the conflicting rulings; the Court will ultimately decide the fate of

mifepristone sometime in the spring of 2024. Until that time, the Texas injunction is not in force and mifepristone is available nationwide. Faced with legal uncertainty as to the ultimate status of mifepristone and an unresolved national pro-life and pro-choice debate, several states have recently taken it upon themselves to step into the breach in abortion-restrictive and protective directions, as we discuss in this Commentary.

First, we deal with the threats. On March 17, 2023, Wyoming Governor Samuel M. Gordon signed into law an act passed by state’s legislature “*Prohibiting Chemical Abortions*” [SF0109].⁹ This new state statute makes it “unlawful to prescribe, dispense, distribute, sell or use any drug for the purpose of procuring or performing an abortion on any person.”¹⁰ The newly crafted ban on abortifacient drugs goes on to state that any physician or other person who violates the statute “is guilty of a misdemeanor punishable by imprisonment for not more than six (6) months, a fine not to exceed nine thousand dollars (\$9,000.00), or both.”¹¹ Seeking to prevent the aforementioned state statute from going into effect on July 1, 2023, a number of nonprofit organizations filed a suit against the state. A ruling was issued from the bench on June 22, 2023 by Judge Melissa M. Owens of the Teton County Ninth District Court granting the plaintiffs a temporary restraining order. The same judge on March 22 had blocked a broader ban on abortions passed by the legislature, the “*Life is a Human*

Right Act” [HB0152]. The Wyoming Supreme Court has declined to weigh in on whether the new abortion laws violate the right to health care guaranteed in the Wyoming state constitution, instead sending the case back to Judge Owens for further action. In the meantime, abortion remains legal in Wyoming.¹⁰

A different threat relates to attempts to restrict intra- and interstate travel for abortion. In a law with an effective date of May 5, 2023, Idaho (which has some of the U.S. strictest abortion restrictions) created a new criminal offense of “abortion trafficking,” with a penalty of two to five years in prison, that applies to any adult “who, with the intent to conceal an abortion from the parents or guardian of a pregnant, unemancipated minor, either procures an abortion” or “obtains an abortion-inducing drug for the pregnant minor to use for an abortion by recruiting, harboring, or transporting the pregnant minor within this state.”¹¹ On July 11, a lawsuit was filed in Federal Court challenging the law as violating the Federal Constitution’s First Amendment freedom of speech, the right to interstate travel, and alleging the law lacks sufficient clarity to be lawful.¹² On November 9, U.S. Magistrate Judge Debora Grasham issued a preliminary injunction, blocking the state from enforcing the law for the time being. Depending on how the case is resolved, other states may copy this approach or even become more aggressive and seek to design similar laws that apply beyond minors.

As states like Wyoming and Idaho seek to restrict abortion access, including by limiting access to mifepristone, we see other states trying to protect abortion access including for out-of-state parties. On May 10, 2023, Philip B. Scott, the Republican Governor of Vermont, signed a so-called “shield law” [H.89/S.37] titled: “An act relating to access to legally protected health care activity and regulation of health care providers.”⁹ The Act defines its key term “Reproductive health care services” to “include medication that was approved by the U.S. Food and Drug Administration (FDA) for termination of a pregnancy as of January 1, 2023, regardless of the medication’s current FDA approval status,” which clearly covers mifepristone.¹³ Among the protections it gives those prescribing mifepristone is to prohibit medical malpractice insurers from adjusting a health care provider’s risk classification or to apply additional premium charges if:

- the health care provider provides or assists in the provision of legally protected health care activity in this State that is unlawful in another state;

- another state’s laws create potential or actual liability for that activity; or
- abusive litigation against a provider concerning legally protected health care activity resulted in a judgment against the provider.¹³

It also prohibits a health care provider from being subject to professional disciplinary action “solely for providing or assisting in the provision of legally protected health care activity” and prohibits taking “adverse action on an application for certification, registration, or licensure of a qualified health care provider based on a criminal or civil action or disciplinary action by a licensing board of another state that arises from the provision of or assistance in legally or assisting in the provision of legally protected health care services.”¹³

More recently, the New York State Legislature passed its version of a “shield law” [A01709B/S1066-B] with an eye towards protecting New York-based health care providers who “prescribe abortion medication to out-of-state patients by means of telehealth.”¹⁴ New York Governor Kathy Hochul signed the bill into

law on June 23, 2023. The new law seeks, among other things, to protect reproductive health service providers that provide legally protected health activities, and includes protections from extradition, arrest and legal proceedings in other states relating to such services.¹⁴ Currently, 22 states and the District of Columbia have shield laws in place, and five – Massachusetts, Washington, Vermont, Colorado and New York – have specific telemedicine protections.¹⁵

The ever-growing preoccupation of the states with abortion in general and with mifepristone in particular, has everything to do with the fallout from *Dobbs v. Jackson Women’s Health Organization*. Justice Alito’s opinion for the Court in *Dobbs* purported to return the authority to regulate abortion to the states and away from the courts. The reality is that proliferation of laws on both sides of the abortion debate is instead likely to embroil the courts for years to come. ❖

References

1. Adashi EY, Rajan RS, O’Mahony DP, Cohen IG. The next two decades of mifepristone at FDA: History as destiny. *Contraception* 2022;(109):1-7.
2. Neilson JP, Hickey M, Vazquez J. Medical treatment for early fetal death (less than 24 weeks). *Cochrane Database Syst Rev* 2006;3:CD002253-CD002253.
3. Schreiber CA, Creinin MD, Reeves MF, Harwood BJ. Mifepristone and misoprostol for the treatment of early pregnancy failure: a pilot clinical trial. *Contraception* 2006;74:458-462.
4. Kollitz KM, Meyn LA, Lohr PA, Creinin MD. Mifepristone and misoprostol for early pregnancy failure: a cohort analysis. *Am J Obstet Gynecol* 2011;204(5):386.e1-386.e6.
5. Creinin MD, Schwartz JL, Pymar HC, Fink W. Efficacy of mifepristone followed on the same day by misoprostol for early termination of pregnancy: report of a randomised trial. *BJOG* 2001;108:469-473.
6. Jones RK, Kirstein M, Philbin J. Abortion incidence and service availability in the United States, 2020. *Perspectives on Sexual and Reproductive Health*. 2022 Dec;54(4):128-41.
7. Zettler OJ, Adashi EY, Cohen IG. *Alliance for Hippocratic Medicine v. FDA – Dobbs’s Collateral Consequences for Pharmaceutical Regulation*. *N Engl J Med* 2023 Mar 9;388(10):e29. Doi: 10.1056/NEJMp2301813. Epub 2023 Feb 22.
8. United States District Court Eastern District of Washington. Order Granting in Part Plaintiffs’ Motion for Preliminary Injunction. April 7, 2023 (<https://int.nyt.com/data/document-tools/court-decision-keeping-mifepristone-available/1d2b761e-9ab275f7/full.pdf>).
9. State of Wyoming 67th Legislature. SF0109 – Prohibiting chemical abortions. March 17, 2023 (<https://wyoleg.gov/Legislation/2023/SF0109>).
10. Merzbach H. Wyoming Supreme Court declines to take up state abortion case. Wyoming Public Radio. April 9, 2024. (<https://www.wyomingpublicmedia.org/politics-government/2024-04-09/wyoming-supreme-court-declines-to-take-up-state-abortion-case>)
11. Idaho Code § 18-623 (2023) (<https://legislature.idaho.gov/wp-content/uploads/sessioninfo/2023/legislation/H0242.pdf>)

12. Varney S. Groups sue to overturn Idaho 'Abortion Trafficking' law targeting teens. KFF Health News. July 11, 2023. (<https://kffhealthnews.org/news/article/idaho-abortion-travel-ban-law-suit-challenge/>)
13. Vermont General Assembly. H.89/S.37. An act relating to civil and criminal procedures concerning legally protected health care activity. May 10, 2023 (<https://legislature.vermont.gov/bill/status/2024/H.89>).
14. New York State Senate. S01066B. An Act to amend the criminal procedure law, the executive law, the civil practice law and rules, the insurance law and the education law, in relation to legally protected health activity providers. June 23, 2023. (<https://www.nysenate.gov/legislation/bills/2023/S1066/amendment/B>).
15. Seigel R, Leiter AB. State Abortion Shield Laws: Key Findings and Infographic. Manatt Health. September 26, 2023. (<https://www.manatt.com/insights/white-papers/2023/state-abortion-shield-laws-key-findings-and-infogr>)

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Disclosures

Financial Disclosures/Conflicts: Professor Adashi and Mr. O'Mahony declare no conflict of interest. Prof. Cohen is a member of the ethics advisory board for Illumina and the Bayer Bioethics Council.

Funding/Support: None. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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