Battles Over Medication Abortion Threaten the Integrity of Drug Approvals in the U.S.

Health Policy Portal

Liam Bendicksen[1] *and Aaron S. Kesselheim*[1,2]

1: PORTAL, BRIGHAM AND WOMEN'S HOSPITAL, BOSTON, MA, USA;
2: HARVARD MEDICAL SCHOOL, BOSTON, MA, USA.

Keywords: Medication Abortion; Federal Courts; U.S. Food and Drug Administration; Drug Approvals; Mifepristone.

Abstract: Legal challenges to the FDA's approval of mifepristone have destabilized patients' ability to access controversial medicines like medication abortion. We argue that federal courts' receptiveness to this litigation undermines the coherence and integrity of prescription drug regulation in the U.S.

On April 7, 2023, a federal judge in Texas suspended the U.S. Food and Drug Administration's approval of mifepristone, an abortion drug.[1] The judge's order was unprecedented and threatened to jeopardize the integrity of the FDA's prescription drug regulation.[2] The Supreme Court later intervened to keep mifepristone on the market pending further review.[3] Unless it is subsequently dismissed in strong terms, however, this litigation spells trouble for the FDA's regulatory authority and the stability of the US drug approval process.

To our knowledge, the nationwide order issued by Judge Matthew Kacsmaryk, a Trump appointee, marks the first time in history that a judge has reversed a drug approval over the FDA's objections.[4] After Judge Kacsmaryk issued an injunction suspending the FDA's approval of mifepristone, the Fifth Circuit Court of Appeals issued another order upholding much of Kacsmaryk's order.[5] This included suspending the ability of a manufacturer of generic mifepristone to sell its FDA approved product, even though that company was not a party before the court.

These orders sowed doubt on the ability of physicians to prescribe mifepristone to their patients.[6] If the Supreme Court ultimately decides to support revocation of the FDA's approval of mifepristone, millions of people would lose access to safe and effective abortion and miscarriage care;[7] more people would carry unwanted pregnancies to term, worsening already staggering and inequitable rates of maternal mortality in the US.[8]

Judge Kacsmaryk's decision to second-guess the FDA's evaluation of the costs and benefits of a prescription drug will have consequences for pharmaceutical innovation and patients' access to lifesaving medications. In this new legal landscape, providers and patients cannot be certain that judges will not remove other drugs from the market. Could hormonal treatments for gender-affirming care be next? What about oral contraceptives? The prospect of this uncertainty is not mere speculation; in September 2022, another federal judge ruled that a law requiring private insurers to cover preventive medications proven to reduce the spread of HIV violated the rights of religious plaintiffs.[9]

Pharmaceutical firms, in turn, may not invest in medically beneficial drugs related to conditions that evoke

Liam Bendicksen *is a research assistant with PORTAL.* **Aaron S. Kesselheim, M.D., J.D., M.P.H.,** *is a Professor of Medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics in the Department of Medicine at Brigham and Women's Hospital. Within the Division, Aaron created and leads the Program On Regulation, Therapeutics, And Law (PORTAL), an interdisciplinary research core focusing on intersections among prescription drugs and medical devices, patient health outcomes, and regulatory practices and the law.*

About This Column

Aaron Kesselheim serves as the editor for Health Policy Portal. Dr. Kesselheim is the *JLME* editor-in-chief and director of the Program On Regulation, Therapeutics, And Law at Brigham and Women's Hospital/Harvard Medical School. This column features timely analyses and perspectives on issues at the intersection of medicine, law, and health policy that are directly relevant to patient care. If you would like to submit to this section of *JLME*, please contact Dr. Kesselheim at akesselheim@bwh.harvard.edu.

The Journal of Law, Medicine & Ethics, 51 (2023): 448-449. © 2023 The Author(s)
DOI: 10.1017/jme.2023.76

social controversy if they believe those drugs may be barred from sale nationwide due to hostile legal challenges. Introducing additional uncertainty about patients' access to prescription drugs and firms' ability to sell their products after regulatory approval would undermine a coherent and consistent prescription drug ecosystem.

Courts have a role in ensuring that the FDA follows its own rules and makes drug approval decisions on the basis of sound science. Eroding the FDA's authority over drug approvals, however, undermines the very foundations of this country's drug market. Judge Kacsmaryk's order is only the latest in a series of concerning legal challenges to the FDA's expertise. In other lawsuits concerning the West Virginia legislature's attempt to ban medication abortion, federal courts may soon grapple with the issue of whether states can place onerous restrictions on the use of FDA-approved drugs.[10] Allowing states to ban medication abortion and other drugs would unduly limit patients' health care options, creating a patchwork of prescription drug access across US states and territories.[11]

Other courts have recognized the dangers of going down this road. When Massachusetts attempted to ban the sale of a very potent opioid within its borders in 2014, a federal judge intervened. Judge Rya Zobel wrote that "[i]f the Commonwealth were able to countermand the FDA's determinations and substitute its own requirements, it would undermine the FDA's ability to make drugs available to promote and protect the public health."[12]

Though a conflicting order from a federal judge in Washington State helped bring the mifepristone litigation before the Supreme Court in a timely manner, this may not be the case in the future.[13] One option that has been proposed to protect the long-term stability of the U.S. prescription drug ecosystem is for Congress to prohibit judges from issuing nationwide injunctions that ban prescription drugs.[14] More fundamentally, patients should not have to rely on drug manufacturers' economic self-interest to protect their access to essential medicines. In this context and beyond, the federal government should step in to ensure the availability of medicines like mifepristone if or when drugmakers decide that fighting legal battles is not worth the cost to their bottom line.

For now, the future of medication abortion depends on the Supreme Court allowing the FDA's approvals of generic and brand mifepristone to remain intact. The FDA must be able to fairly regulate prescription drugs without interference from judges offering politically motivated interpretations of the law.

Pharmaceutical firms, in turn, may not invest in medically beneficial drugs related to conditions that evoke social controversy if they believe those drugs may be barred from sale nationwide due to hostile legal challenges. Introducing additional uncertainty about patients' access to prescription drugs and firms' ability to sell their products after regulatory approval would undermine a coherent and consistent prescription drug ecosystem.

Note
The authors have no conflicts of interest to disclose.

References

1. *Alliance for Hippocratic Medicine v. US Food and Drug Administration*, 2:22-CV-223-Z [ND Tex 2023].
2. P. J. Zettler et al., "Alliance for Hippocratic Medicine v. FDA — Dobbs's Collateral Consequences for Pharmaceutical Regulation," *New England Journal of Medicine* 388, no. 10 (2023): e29.
3. *US Food and Drug Administration v. Alliance for Hippocratic Medicine*, No. 22A901 [S Ct 2023].
4. See Zettler et al., *supra* note 2.
5. *Alliance for Hippocratic Medicine v US Food and Drug Administration*, No. 23-10362 [5th Cir 2023].
6. S. Novack, "'You Know What? I'm Not Doing This Anymore,'" *Slate*, March 21, 2023, *available at* <https://slate.com/news-and-politics/2023/03/texas-abortion-law-doctors-nurses-care-supreme-court.html> (last visited June 20, 2023).
7. "Medication Abortion and the Stakes of the Lawsuit That Could Block Access to Mifepristone Nationwide," NARAL Pro Choice America, February 10, 2023, *available at* <https://www.prochoiceamerica.org/wp-content/uploads/2023/02/New-NARAL-Research_-Medication-Abortion-and-the-Lawsuit-That-Could-Block-Access-to-Mifepristone-Nationwide-Final-Copy-.pdf> (last visited June 20, 2023).
8. J. K. Taylor, "Structural Racism and Maternal Health Among Black Women," *Journal of Law, Medicine & Ethics* 48, no. 3 (2020): 506-517.
9. *Braidwood Management Inc. v. Becerra*, 4:20-CV-00283-O [ND Tex 2022].
10. *GenBioPro, Inc. v. Sorsaia,* 2:23-CV-0058 [SD W Va 2023].
11. P. J. Zettler et al., "Mifepristone, Preemption, and Public Health Federalism," *Journal of Law and the Biosciences* 9, no. 2 (2022): 1-32.
12. *Zogenix, Inc. v. Patrick*, 1:14-CV-11689-RWZ [D Mass 2014].
13. *State of Washington v. US Food and Drug Administration*, 1:23-CV-03026-TOR [ED Wash 2023].
14. N. Bagley and S. Bray, "Judges Shouldn't Have the Power to Halt Laws Nationwide," *Atlantic*, October 31, 2018, *available at* <https://www.theatlantic.com/ideas/archive/2018/10/end-nationwide-injunctions/574471/> (last visited June 20, 2023).

The Journal of Law, Medicine & Ethics, 51 (2023): 446-447. © 2023 The Author(s)