Mifepristone Paternalism at the FDA

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Abstract: This article explores the role of the Food and Drug Administration (FDA) in drug approval and restrictions to mifepristone access in the context of historical regulation and current litigation.

Introduction

The U.S. Food and Drug Administration's (FDA) December 2021 action to permanently remove the in-person prescribing requirement for mifepristone was hailed as a beacon of hope in a time of legal uncertainty. Given that medication abortion accounts for over 50% of abortions in the US,[1] the widespread availability of telehealth services to access the medication would expand the number of patients able to receive mifepristone in the mail through certified prescribers and pharmacies. The FDA's subsequent decision to allow distribution of mifepristone through commercial pharmacies further relaxed stringent controls over access to the drug. However, given the Supreme Court's decision in *Dobbs v. Jackson Women's Health Organization*, state legislative activity, ongoing litigation, and the practical implications of the FDA's restrictions, access to medication abortion has been stymied despite an increase in demand across all 50 states.[2]

This article explores the landscape of federal restrictions to mifepristone access and corresponding FDA regulatory activity in the wake of *Dobbs*. The article builds off scholarship describing the phenomenon of pharmaceutical paternalism in regulatory decision-making and implementation. The article will briefly explore the literature addressing paternalism in this realm, especially as historically related to women's health and reproductive care. The article also examines access restrictions for mifepristone presented in the FDA-required Risk Evaluation and Mitigation Strategy (REMS) framework designed to assure safe use of the product. While the FDA has removed burdensome in-person prescribing requirements and increased access by allowing commercial pharmacies to distribute the drug, other overly burdensome and unnecessary restrictions remain, including prescriber and patient agreement and consent forms. Finally, the article briefly describes current litigation involving

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challenges to the FDA's authority over mifepristone for both its approval in 2000 and the scope of the REMS.

Pharmaceutical Paternalism

The scholarly debate regarding the role of regulators or other actors to limit or otherwise impact access to consumer goods or services is rich and well established. Commentators describe actions to restrict access to potentially harmful consumer products as paternalistic in nature. Ronald Dworkin defines paternalism as "interference with a person's liberty of action justified by reasons referring exclusively to the welfare, good, happiness, needs, interests, or values of the person being coerced."[3] In the public health realm, these debates have taken aim at diverse topics such as legally imposed limitations on sugary soda consumption, smoking and vaping, and access to unapproved drugs.[4] At the heart of the discussions are principles of personal autonomy and liberty as they relate to the protection of both the public's health as well as individual health and safety.

The term "pharmaceutical paternalism" contemplates the role of the FDA as a gatekeeper responsible for manufacturing, marketing, and access to chemically synthesized drugs and biological drugs.[5] Congress charged FDA to review and approve new drug and biologic products that enter the national market based on substantial evidence of safety and efficacy for an intended use in a particular patient population. The traditional means of demonstrating safety and efficacy are through three phases of clinical trials, though recent legislative changes have introduced numerous accelerated mechanisms into the regulatory framework such as Fast Track, breakthrough status, and Priority Review.[6] The FDA also has an expanded access, or compassionate use, policy for allowing individual access for seriously ill patients to unapproved drugs that have undergone at least one phase of clinical trials.[7] In addition, the recent federal Right to Try Act codifies an alternate route to access unapproved drugs.[8]

Prime scholarly examples of pharmaceutical paternalism focus on access to drugs not yet approved by the FDA as safe and effective, as required by federal law to protect the public health. Other instances described as pharmaceutical paternalism address restrictions on access to approved drugs because of novelty of the chemical or biological compound, or safety or efficacy concerns requiring further assessment in post-market studies and adverse event reporting. In the context of mifepristone, restrictions to access are not as closely tied to safety concerns, as studies demonstrate safety and effectiveness of the drug for its intended purpose and over two decades of approval clearly identify the range of potential adverse events.

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The literature regarding pharmaceutical paternalism takes aim chiefly at access to *unapproved* drugs — those not having FDA approval to enter the market. Cases such as *United States v. Rutherford*[9] and *Abigail Alliance von Eschenbach*[10] establish that no constitutional protection exists for access to unapproved drugs. The FDA's expanded access program and the Right to Try Act provisions enable individual access to this category of drugs. The expanded access assessments focus on whether and to what extent individuals facing serious or life-threatening diseases or disorders should be able to access experimental drug treatments that have not yet received FDA approval.[11] However, neither the statute nor the regulations mandate that the drug sponsor provide access to the drug undergoing investigational clinical trials.

A second category of drugs critiqued in the pharmaceutical paternalism literature are FDA-approved drugs subject to access or distribution restrictions

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rather than being directly available over the counter. These are *approved* drugs. Basically, prescription status is an FDA-imposed restriction on access. The FDA may impose prescription status based on the novelty of the chemical or biological compound, the toxicity or potential for harmful effects, the method of use, or any collateral measures necessary for use.[12] In addition, the FDA may utilize REMS to require additional requirements or restrictions.[13] The FDA often utilizes REMS for products approved through the accelerated pathways and those that have significant toxicity profiles, are difficult to administer, are not able to be administered by a patient on their own, or raise safety or efficacy concerns requiring further assessment in post-market studies and adverse event reporting.

Through REMS, the FDA may require additional mechanisms to ensure patient safety including a medication guide for patients; additional physician prescribing information; targeted communications to health care providers and pharmacies; and labeling and promotion requirements or limitations.[14] These types of REMS mechanisms provide enhanced information to patients, providers, and pharmacies. The FDA can also use REMS to impose limitations on access, prescribing, and dispensing to assure safe use by patients, which are called elements to assure safe use, or ETASU.[15] FDA currently requires roughly half of 62 products subject to REMS to include documented patient agreement or consent as a mechanism to assure safe use, and there is variability in how those agreement and consent forms are framed and in the safety profiles of the other products with similar restrictions in comparison to mifepristone.

Mifepristone resides in a third category of drugs subject to pharmaceutical paternalism: FDA-approved drugs subject to access restrictions based on reasons other than safety or efficacy concerns, or any of the reasons identified above. In the context of mifepristone, restrictions to access are not as closely tied to safety concerns. Approved by the FDA in 2000, the innovator drug Mifeprex (mifepristone) is an abortifacient, progesterone receptor antagonist regime approved for the termination of pregnancy. Mifepristone is used to induce abortion within ten weeks of pregnancy, followed by ingestion of misoprostol within 24-48 hours. Mifeprex and its generic version have over two decades of extensive use in the U.S., clearly establishing the range of known adverse events; it has been approved even longer in other countries with similar safety and efficacy data.[16] Historically, drug products tailored to reproductive health and abortion are restricted largely for other reasons. The history of FDA scrutiny and regulation of RU-486 (*i.e.,* Mifeprex), Plan B emergency contraception (commonly known as the morning after pill), and oral contraceptives (birth control pills) amply illustrate this fact. Contraception in the form of birth control pills and emergency contraception remains legal in all states, although given political positioning in the wake of *Dobbs*, reproductive justice advocates are concerned that conservative states may now take aim at these as well. In *Dobbs*, Justice Alito stated "[t]o ensure that our decision is not misunderstood or mischaracterized, we emphasize that our decision concerns the constitutional right to abortion and no other right,"[17] which includes the fundamental right to contraception recognized in *Griswold v. Connecticut*.[18] Notably, the FDA's nonprescription advisory committee voted unanimously in May 2023 to recommend that the FDA approve Perrigo's Opill, a progestin-only daily contraceptive, for over-the counter use.[19] The FDA has yet to make a decision.

After *Dobbs*, all state laws that ban or restrict access to abortions include medication abortion. In addition, various states have passed legislation prohibiting or limiting access to mifepristone through the mail and telehealth services.[20] Others are advocating for expansion of the approved use of mifepristone. A group of doctors and abortion rights advocates, including the American College of Obstetricians and Gynecologists and the American Medical Association, petitioned the FDA to urge Danco to submit a supplemental new drug approval application to broaden the indications of use to allow the use of mifepristone for miscarriage management.[21] Several Senators have followed suit, urging Danco to request an expansion of its approved intended uses.[22]

Mifepristone and the FDA's Regulatory Paternalism Through REMS

The FDA's approach to medication abortion has garnered that characterization of paternalistic regulation.[23] Post-approval, the FDA has imposed various REMS requirements.[24] The requirements apply to both the innovator brand drug Mifeprex manufactured by Danco and the generic mifepristone manufactured by GenBioPro. In 2019, when the FDA approved the generic version, the agency also established a shared system REMS, which included the following elements to assure safe use (ETASU) that apply to both products:

- Mifeprex must be ordered, prescribed and dispensed by or under the supervision of a healthcare provider who prescribes and who meets certain qualifications;

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- Healthcare providers who wish to prescribe Mifeprex must complete a Prescriber Agreement Form prior to ordering and dispensing Mifeprex;
- Mifeprex may only be dispensed in clinics, medical offices, and hospitals by or under the supervision of a certified healthcare provider;
- The healthcare provider must obtain a signed Patient Agreement Form before dispensing Mifeprex.[25]

Over a year into the COVID pandemic, in April 2021, the FDA suspended the in-person prescription and dispensing requirement within the REMS through the exercise of enforcement discretion. Prior litigation had enjoined the FDA from requiring in-person dispensing for a period of six months.[26] In December 2021, the FDA revised the ETASU to require the following elements, officially removing the in-person prescribing and dispensing requirements and providing that dispensing pharmacies must be certified by the FDA:

- Mifepristone must be prescribed by or under the supervision of a certified healthcare provider who meets certain qualifications, including signing a Prescriber Agreement Form;
- The healthcare provider must obtain a signed Patient Agreement Form from the patient after counseling and prior to prescribing Mifeprex;
- Pharmacies that dispense mifepristone must be certified.[27]

The first and third of the three current ETASU requirements, as they relate to qualifications, are seemingly reasonable and justifiable given the intended use of the drug and the relationship between the prescriber and dispensing pharmacy. The first requires that the prescriber must be a certified healthcare provider meeting certain qualifications and sign a prescriber agreement form. Both the Mifeprex and mifepristone prescriber form requires the prescriber to agree that they meet the enumerated qualifications: the ability to diagnose duration of pregnancy accurately, the ability to diagnose ectopic pregnancies, the ability to provide surgical intervention if incomplete abortion or severe bleeding results from use or to provide such care through others, and the review and understanding of prescribing information.[28] The forms also lists six guidelines for use: review of the patient agreement form, obtain patient's signature on the patient agreement form, provide the patient a copy of the patient agreement form and the medication guide, place the signed patient agreement form in the patient's medical record, record the serial number from each package in each patient's medical record, and report any patient deaths to the respective manufacturer.[29] The third requirement, that dispensing pharmacies must be certified, is straightforward and a typical aspect of ETASU. The FDA eased this requirement in January 2023, announcing that commercial pharmacies could apply and be certified to distribute mifepristone.[30]

The second requirement, that the prescriber must obtain a signed patient agreement form, is unnecessary given the requirement to provide the patient with the medication guide and the requirements contained in the qualifications of the prescriber. The form directs the healthcare provider to counsel the patient on the risks of mifepristone and acquire the patient's signature on a document that largely recites a conversation that would logically transpire while counseling the patient. Relevant aspects of the patient agreement form include that the patient has decided to take mifepristone to end a pregnancy and will follow provider advice, the patient understands how to administer the drugs (and lists directions), the provider has discussed risks (and lists them), the patient will contact the provider should certain symptoms arise (and lists them), the patient has emergency care contact information, the patient is to follow up 7-14 days following administration to assure termination of pregnancy, the patient is aware of the possibility that treatment will not work, the patient was informed of whether the healthcare provider would provide any surgical procedures or received a referral, the patient has been provided the medication guide, and the provide has answered all of patients questions.[31] The Prescriber Agreement Form requires the signed Patient Agreement Form placed in the patient's medical record.[32] Yet there is no requirement for the prescriber to inform the patient that the form will be a permanent part of their medical record.

The patient agreement form raises several important issues with respect to mifepristone drug access and implications. First, the safety profile of mifepristone is well established and thus the patient agreement form is excessive given the actual risks to pregnant people taking it for terminating a pregnancy. "Overall, 2.2 per 1000 women (95% CI 1.9-2.5) experienced a complication, most commonly, heavy bleeding. Mifepristone abortion mortality is estimated to be 1.1 per 100,000 based on one death (95% CI 0.3-5.9)."[33] Studies have demonstrated that the safety of mifepristone is high, and few medical complications arise with routine clinical use.[34] The new drug approval review materials available on the FDA's website also demonstrate the safety and efficacy of mifepristone.[35]

Second, mifepristone does not have a similar risk profile compared to other FDA-approved drugs with

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similar requirements. The FDA currently requires 31 of 62 products subject to REMS to include documented patient agreement or consent form as a mechanism to assure safe use, and there is variability in those requirements. The vast majority of those 31 products subject to an ETASU REMS are due to serious risks to an unborn fetus, significant toxicity levels, potential for addition or abuse, or dangerous drug interactions. Given its approved intended use to terminate pregnancy, mifepristone does not raise any of those risks. Third, a patient agreement form seems unnecessary for mifepristone because the patient receives counseling by the physician prior to prescription and receives a detailed medication guide. Does the FDA not trust that women and pregnant people can comprehend the medication guide and physician's instructions? The FDA routinely requires patient comprehension studies for communications to patients — it could do so here for the medication guide as support to eliminate the consent form. In fact, mifepristone is also approved "for the control of hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery."[36] The approved drug, Korlym, is subject only to the distribution of a medication guide to patients. There is no patient agreement form or any type of elements to assure safe use associated with the prescription of the exact same drug at an increased 300mg dose for that indication.

Recent Legal Challenges to Mifepristone Access

State legislative efforts and REMS are not the only means restricting or attempting to further restrict access to mifepristone. Litigation in several states challenges the FDA's regulatory activity in opposing ways. Litigation originating in the Northern District of Texas directly challenges the federal statutory authority of the FDA and the procedures underlying the approval of Mifeprex. In *Alliance for Hippocratic Medicine v. FDA*, plaintiffs urged the court to remove mifepristone from the market based on the allegation that the agency used inappropriate approval mechanisms to approve the drug in 2000 and implement revisions to restrictions without adequate scientific support.[37] On April 7, 2023, the district court judge stayed the FDA's approval of mifepristone and stayed the application of the order for seven days allowing the government to seek relief from the court of appeals.[38] The Fifth Circuit issued a partial stay five days later, limiting the scope and timeframe of the injunction to changes made post-2016 to the REMS.[39] The Supreme Court weighed in on April 21, 2023, staying the order of the Northern District of Texas "pending disposition of the appeal in the Fifth Circuit and disposition of a petition of writ of certiorari, if such writ is timely sought."[40] The Fifth Circuit heard oral arguments on May 17, 2023 and issued their decision in August 2023, maintaining their prior position. This direct challenge to the drug approval process threatens the entire structure of the pharmaceutical regulatory system[41] and will undoubtedly ultimately play out at the Supreme Court.

Several other lawsuits have made their way into the courts and promise to contribute to the outcome of the legal challenges to the authority of the FDA. On the same day as the Northern District of Texas decision, the Eastern District of Washington issued an opinion in a case against the FDA, enjoining the FDA from removing mifepristone from the market and enjoining enforcement of REMS restrictions.[42] The case was brought by eighteen states asking the court to affirm that FDA's conclusion that mifepristone is safe and effective. In Maryland, GenBioPro, the generic manufacturer of mifepristone, filed suit against the FDA on April 19, 2023, urging the court to enjoin the FDA from any action that would remove mifepristone from the market.[43] The courts are hearing legal arguments from various perspectives and from a spectrum of plaintiffs.

Conclusion

As the landscape of abortion access continues to evolve through legislation and litigation, the FDA continues to play an important role in assuring the safety and efficacy, and accessibility, to medication abortion. The historical pharmaceutical paternalism connected to mifepristone is unwarranted and unduly restrictive in the face of scientific certainty regarding the safety of the drug and the ability of patients to comprehend medical information about use of the drug. Eliminating unnecessary restrictions to mifepristone contained within the REMS at the federal level will ensure greater access as states volley to control access through legislation and litigation.

Note

The author has no conflicts to disclose.

References

1. R. K. Jones, E. Nash, L. Cross, J. Philbin, and M. Kerstein, "Medication Abortion Now Accounts for More Than Half of All US Abortions," Guttmacher Institute, January 1, 2022, *available at* <https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions> (last visited June 28, 2023).

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https://doi.org/10.1017/jme.2023.98 Published online by Cambridge University Press

2. A. R.A. Aiken, J. E. Starling, J. G. Scott, and R. Gomperts, "Requests for Self-Managed Medication Abortion Provided Using Online Telemedicine in 30 States Before and After the Dobbs v. Jackson Women's Health Organization Decision," *Journal of the American Medical Association* 328, no. 17 (2022): 1768-1770.
3. R. Dworkin, "Paternalism," *The Monist* 56, no. 1 (1972): 64-84.
4. See M.A. Rothstein, "Autonomy and Paternalism in Health Policy," *Journal of Law, Medicine & Ethics* 42, no. 4 (2014): 590-594; D.A. Friedman, "Public Health Regulation and the Limits of Paternalism," *Connecticut Law Review* 46, no. 5 (2014): 1687-1770; W.E. Parmet, "Beyond Paternalism: Rethinking the Limits of Public Health Law," *Connecticut Law Review* 46, no. 5 (2014): 1771-1794.
5. See R.A. Epstein, "Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex," *Yale Journal of Health Policy, Law and Ethics* 5, no. 2 (2005): 741-770; J. Flanigan, *Pharmaceutical Freedom: Why Patients Have a Right to Self-Medicate*, 1st ed. (Oxford University Press 2017); D. Tiera, "A Defense of Pharmaceutical Paternalism," *Journal of Applied Philosophy* 37, no. 4 (2020): 528-542.
6. J. Paradise, "Three Framings of 'Faster' at the FDA and the Federal Right to Try," *Wake Forest Journal of Law and Policy* 11, no. 1 (2020): 53-84.
7. *Id.*
8. *Id.*
9. *U.S v. Rutherford*, 99 S. Ct. 2470, 442 U.S. 544 (1979).
10. *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007), cert denied, 552 U.S. 1159 (2008).
11. U.S. Food and Drug Administration, Guidance for Industry: Individual Patient Expanded Access Applications: Form IDA 3926 (June 2016), *available at* <https://www.fda.gov/media/91160/download> (last visited June 28, 2023).
12. Federal Food, Drug, and Cosmetic Act (FDCA) § 503(b)(1) (2022).
13. J. Paradise, "REMS as a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?" *Houston Journal of Health Law and Policy* 15 (2015): 43-82.
14. FDCA § 505-1(c)-(f)/21 U.S.C. § 355-1(c)-(f) (2022).
15. *Id.*
16. J.T. Henderson, A.C. Hwang, C.C. Harper, and F.H. Stewart, "Safety of Mifepristone Abortions in Clinical Use," *Contraception* 72, no. 3 (2005): 175-178.
17. *Dobbs v. Jackson Women's Health*, 597 U.S. ___ (2022).
18. *Griswold v. Connecticut*, 381 U.S. 479 (1965).
19. "FDA Joint Advisory Committee Votes in Favor of Perrigo's Opill® Daily Oral Contraceptive for OTC Use," PR Newswire, May 10, 2023, *available at* <https://www.prnewswire.com/news-releases/fda-joint-advisory-committee-votes-in-favor-of-perrigos-opill-daily-oral-contraceptive-for-otc-use-301821255.html> (last visited June 28, 2023).
20. See P.J. Zettler and A. Sarpatwari, "State Restrictions on Mifepristone Access — The Case for Federal Preemption," *New England Journal of Medicine* 386, no. 8 (2022): 705-707.
21. A. Aboulenein, "Doctors Urge U.S. FDA to Add Miscarriage Management to Abortion Pill Label," Reuters, October 4, 2022.
22. Letter from Senators Hirono, Hasssan, Warren, and Blumenthal to Danco Laboratories (February 1, 2023), *available at* <https://www.hirono.senate.gov/imo/media/doc/2023.02.01_FINAL_Miscarriage%20Management%20Mifepristone%20Label.pdf> (last visited June 28, 2023).
23. See G. Donley, "Medication Abortion Exceptionalism," *Cornell Law Review* 107, no. 3 (2022): 627-704.
24. U.S. Food and Drug Administration, Mifepristone Shared System REMS, *available at* <https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=390> (last visited June 28, 2023).
25. U.S. Food and Drug Administration, Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks of Gestation, *available at* <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation> (last updated January 4, 2023).
26. *American College of Obstetricians et al v. FDA,* Case 8:20-cv-01320-TDC (D.C. Md. 2020).
27. Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks of Gestation, *supra* note 25.
28. U.S. Food and Drug Administration, Mifeprex Prescriber Agreement Form, available at <https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_Danco_Laboratories_LLC.pdf> (last visited June 28, 2023); U.S. Food and Drug Administration, Mifepristone Prescriber Agreement Form, available at <https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Prescriber_Agreement_Form_for_GenBioPro_Inc..pdf> (last visited June 28, 2023).
29. Mifeprex Prescriber Agreement Form, *supra* note 28; Mifepristone Prescriber Agreement Form, *supra* note 28.
30. A. Aboulenien, "U.S. FDA Allows Abortion Pills to be Sold at Retail Pharmacies," Reuters, January 4, 2023.
31. U.S. Food and Drug Administration, Mifepristone Patient Agreement Form, *available at* <https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_03_23_Patient_Agreement_Form.pdf> (last visited June 28, 2023).
32. Mifeprex Prescriber Agreement Form, *supra* note 28; Mifepristone Prescriber Agreement Form, *supra* note 28.
33. Henderson, Hwang, Harper, and Stewart, *supra* note 16.
34. *Id.*
35. U.S. Food and Drug Administration, Mifeprex NDA Review Materials, *available at* <https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_mifepristone.cfm> (last visited June 28, 2023).
36. U.S. Food and Drug Administration, Korlym NDA Approval Letter No. 202107, February 17, 2012, *available at* <https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2012/202107s000ltr.pdf> (last visited June 28, 2023).
37. *Alliance for Hippocratic Medicine, et al. v. FDA,* Case 2:22-cv-00223-Z (N.D. Texas 2023).
38. *Id.*
39. *Alliance for Hippocratic Medicine, et al., v. FDA*, et al., Case No. 23-10362 (5th Cir. 2023).
40. *Danco Laboratories, LLC v. Alliance for Hippocratic Medicine, et al.*; *FDA, et al. v. Alliance for Hippocratic Medicine, et al.*, 598 U.S. ___ (2023).
41. See P.J. Zettler, E.Y. Adashi, and I.G. Cohen, "Alliance for Hippocratic Medicine v. FDA – Dobbs's Collateral Consequences for Pharmaceutical Regulation," *New England Journal of Medicine* 388, no. e29 (2023), doi: 10.1056/NEJMp2301813.
42. *State of Washington, et al. v. FDA, et al.*, Case No. 1:23-CV-3026-TOR (E.D. Wa. 2023).
43. *GenBiPro, Inc. v. FDA, et al.*, Case No 1:23-cv-01057-SAG (D. Md), filed April 19, 2023.

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