
RECENT GUIDANCE

REPRODUCTIVE RIGHTS — MEDICATION ABORTION — FDA LIFTS IN-PERSON DISPENSING REQUIREMENT FOR MIFEPRISTONE ABORTION PILL. — Update to FDA’s Risk Evaluation and Mitigation Strategy for Mifepristone on Dec. 16, 2021, Eliminating In-Person Dispensing Requirement.

Mifepristone-initiated medication abortion¹ is a safe and effective method of terminating a pregnancy. However, access to mifepristone has been stringently regulated by the Food and Drug Administration (FDA) since the drug was first authorized for distribution in 2000.² The agency has always imposed intensive dispensing restrictions, including in-person prescription and counseling processes.³ But on December 16, 2021, during a year when reproductive rights appeared increasingly vulnerable,⁴ the Biden FDA offered a glimmer of hope to reproductive rights advocates. In response to medical professionals’ advocacy, the agency removed the federal in-person dispensing requirement for medication abortion⁵ from mifepristone’s drug protocols — the Risk Evaluation and Mitigation Strategy (REMS) for Mifepristone⁶ — allowing pregnant people in thirty-one states to access medication abortion by mail.⁷ While

¹ Medication abortion occurs through a two-step regimen of mifepristone followed by misoprostol. Becky Little, *The Science Behind the “Abortion Pill,”* SMITHSONIAN MAG. (June 23, 2017), <https://www.smithsonianmag.com/health-medicine/science-behind-abortion-pill-180963762> [<https://perma.cc/C6AH-MNYL>]. Mifepristone is restricted by the Food and Drug Administration (FDA) Risk Evaluation and Mitigation Strategies. See U.S. FOOD & DRUG ADMIN., RISK EVALUATION AND MITIGATION STRATEGY (REMS) SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200MG (2021) [hereinafter REMS FOR MIFEPRISTONE]. The FDA did not make a formal announcement of this change but updated Question 5 on the webpage *Questions and Answers on Mifeprex*, U.S. FOOD & DRUG ADMIN. (Dec. 16, 2021), <https://www.fda.gov/drugs/post-market-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex> [<https://perma.cc/V7RX-ZUAX>]. Notification letters have been sent to all mifepristone applicants, whose input will be incorporated in altering the new REMS, which will reflect this change. The updated policy removing in-person dispensing requirements is active as of December 16, 2021.

² See Deb Gordon, *As FDA Considers Easing Medication Abortion Restrictions, New Study Finds Patients Prefer Flexibility*, FORBES (Nov. 1, 2021, 1:00 PM), <https://www.forbes.com/sites/debgordon/2021/11/01/as-fda-considers-easing-medication-abortion-restrictions-new-study-finds-patients-prefer-flexibility> [<https://perma.cc/B34H-HA7E>].

³ See REMS FOR MIFEPRISTONE, *supra* note 1.

⁴ See Elyssa Spitzer & Nora Ellmann, *State Abortion Legislation in 2021*, CTR. FOR AM. PROGRESS (Sept. 21, 2021), <https://www.americanprogress.org/article/state-abortion-legislation-2021> [<https://perma.cc/ZQ7C-TGE8>] (finding that 2021 saw the highest number of abortion restrictions legislated in a single year in American history).

⁵ See REMS FOR MIFEPRISTONE, *supra* note 1.

⁶ *Id.*

⁷ “Medication by mail” entails a telemeeting with a clinician followed by a pharmacy mailing the abortifacient pills to the patient. Nineteen states have banned telemedicine visits for abortion, so the in-person requirement exists at the state level. Federal policy sets the baseline for access to mifepristone as an abortifacient. State laws can impose greater (but not lesser) restrictions. See

the REMS update is an important victory that demonstrates how medical professionals can successfully advocate for broader abortion access through administrative agencies, its precarity ultimately reveals the practical and doctrinal limits of agency action as an avenue for reproductive rights advocacy.

Since the approval of mifepristone (Mifeprex) in 2000, the FDA has required patients seeking medication-abortion pills to visit certified clinics, often traveling prohibitively long distances or crossing state lines.⁸ This in-person requirement was part of the FDA's REMS protocols for mifepristone⁹ and mirrored requirements for high-risk medications such as injectable schizophrenia drugs.¹⁰ During the COVID-19 pandemic, the FDA exercised enforcement discretion to relax the in-person dispensing requirement for many riskier drugs subject to REMS, reasoning that making these medicines mailable reduced coronavirus transmission risks.¹¹ Still, the agency continued enforcing stringent in-person dispensing protocols for mifepristone for another year, incurring accusations of political bias based on mifepristone's use as an abortifacient.¹²

On April 20, 2020, two medical professional organizations — the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) — sent a letter to the FDA, urging the agency to lift the in-person dispensing requirement for mifepristone.¹³ Submitted on behalf of 60,000-plus obstetric-gynecologists, the letter argued that the requirement put patients and providers at unnecessary risk of COVID-19 transmission in seeking a

State Laws and Policies: Medication Abortion, GUTTMACHER INST. (Apr. 1, 2022), <https://www.guttmacher.org/state-policy/explore/medication-abortion> [https://perma.cc/WZ36-NKKJ]; Pam Belluck, *F.D.A. Will Permanently Allow Abortion Pills by Mail*, N.Y. TIMES (Dec. 16, 2021), <https://www.nytimes.com/2021/12/16/health/abortion-pills-fda.html> [https://perma.cc/N8WL-Z37F].

⁸ See Sarah Christopherson & Olivia Snavelly, *The FDA's Convoluted Stance on Abortion Pills Doesn't Protect Patients — It Endangers Them*, NAT'L WOMEN'S HEALTH NETWORK (May 8, 2020), <https://nwhn.org/the-fdas-convoluted-stance-on-abortion-pills-doesnt-protect-patients-it-endangers-them> [https://perma.cc/3FDP-MLUY].

⁹ See REMS FOR MIFEPRISTONE, *supra* note 1.

¹⁰ See *Risk Evaluation and Mitigation Strategies: REMS*, U.S. FOOD & DRUG ADMIN. (Dec. 17, 2021), <https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems> [https://perma.cc/U46Y-8VCR]. Mifeprex REMS are likely politically motivated by anti-abortion bias. See Christopherson & Snavelly, *supra* note 8. Mifeprex, marketed for pregnancy termination, is subject to a REMS, while Korlym, which uses the exact same chemical composition of mifepristone (in a higher dose) to treat high blood sugar, is FDA-approved without a REMS. *Id.*

¹¹ See U.S. FOOD & DRUG ADMIN., POLICY FOR CERTAIN REMS REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY 7 (2020).

¹² Carolyn B. Maloney & Ayanna Pressley, *Why the FDA Must Lift Unnecessary Restrictions on Medication Abortion Care Now*, ELLE (Feb. 17, 2021), <https://www.elle.com/culture/career-politics/a35534458/fda-restrictions-medication-abortion> [https://perma.cc/2ZWC-MWSB].

¹³ Letter from Maureen G. Phipps, Chief Exec. Officer, Am. Coll. of Obstetricians & Gynecologists, and Judette Louis, President, Soc'y for Maternal-Fetal Med., to Stephen Hahn, Comm'r, FDA (Apr. 20, 2020) (on file with the Harvard Law School Library).

time-sensitive healthcare service.¹⁴ Trump–FDA Commissioner Stephen Hahn did not acknowledge this letter. On May 27, 2020, ACOG filed suit in the U.S. District Court for the District of Maryland, seeking to enjoin enforcement of the FDA’s in-person dispensing requirement during the pandemic.¹⁵ ACOG complained that the FDA retained the mifepristone in-person dispensing requirement against medical authorities’ advice,¹⁶ evincing discriminatory treatment of mifepristone prescribers and patients due to bias arising from mifepristone’s status as an abortion drug.¹⁷ The court granted ACOG’s preliminary nationwide injunction, allowing mifepristone to be dispensed by mail during the COVID-19 pandemic.¹⁸ Applying the undue burden test from *Whole Woman’s Health v. Hellerstedt*¹⁹ and *June Medical Services v. Russo*,²⁰ the court found that the in-person dispensing requirement imposed “a ‘substantial obstacle’” to patients’ free exercise of the fundamental right of choice.²¹

The Trump FDA filed for an emergency stay of the injunction, hoping to continue to enforce the in-person requirement.²² The case was remanded to and reaffirmed by the district court.²³ The FDA then renewed its stay application,²⁴ and upon review, the Court granted the stay, reinstating in-person dispensing requirements on January 12, 2021.²⁵ Chief Justice Roberts cited a need for agency deference during

¹⁴ *Id.*

¹⁵ Complaint at 39, *Am. Coll. of Obstetricians and Gynecologists (ACOG) v. FDA*, 472 F. Supp. 3d 183 (D. Md. 2020) (No. 20-cv-01320).

¹⁶ *Id.* at 29.

¹⁷ *Id.* at 30. The complaint addressed the unequal burden that fell on low-income pregnant persons and people of color. *Id.* at 5. This logic appeared in expert declarations to the court as well as in the opinion by Judge Chuang. See *ACOG*, 472 F. Supp. 3d at 214–15.

¹⁸ *ACOG*, 472 F. Supp. 3d at 233.

¹⁹ 579 U.S. 582 (2016).

²⁰ 140 S. Ct. 2103 (2020); see also *CTR. FOR REPROD. RTS., THE UNDUE BURDEN STANDARD AFTER JUNE MEDICAL SERVICES V. RUSSO* 4 (2020).

²¹ See *ACOG*, 472 F. Supp. 3d at 217 (quoting *Whole Woman’s Health*, 136 S. Ct. at 2317–18).

²² Application for a Stay of the Injunction Issued by the United States District Court for the District of Maryland at 1, *FDA v. Am. Coll. of Obstetricians and Gynecologists*, 141 S. Ct. 578 (2020) (mem.) (No. 20A34). Emergency stays are part of the Supreme Court’s shadow docket, “a range of orders and summary decisions that defy [the Court’s] normal procedural regularity.” William Baude, *Foreword: The Supreme Court’s Shadow Docket*, 9 N.Y.U. J.L. & LIBERTY 1, 1 (2015). Shadow docket decisions, including the choice not to enjoin Texas’s S.B. 8 abortion ban, have severely constrained reproductive freedoms. See *Professor Vladeck Offers Senate Testimony on Texas’s Abortion Ban and the Shadow Docket*, TEX. L. NEWS (Oct. 4, 2021), <https://law.utexas.edu/news/2021/10/04/professor-vladeck-offers-senate-testimony-on-texas-abortion-ban-and-the-shadow-docket> [https://perma.cc/2LNM-TF9Q].

²³ *FDA v. Am. Coll. of Obstetricians and Gynecologists*, 141 S. Ct. 10 (2020); *Am. Coll. of Obstetricians and Gynecologists v. FDA*, 506 F. Supp. 3d 328, 347 (D. Md. 2020).

²⁴ *FDA v. Am. Coll. of Obstetricians and Gynecologists*, 141 S. Ct. 578, 581 (2020) (Sotomayor, J., dissenting from grant of application for stay).

²⁵ *Id.* at 578–79 (mem.).

the pandemic.²⁶ Justice Sotomayor dissented,²⁷ writing that this decision flouted the Court's undue burden test.²⁸

On April 12, 2021, a few months after President Biden's inauguration, the Biden FDA issued a letter ("the Letter") announcing that it would not enforce the in-person dispensing requirement for mifepristone.²⁹ The Letter, from Acting Commissioner Janet Woodcock, was addressed to ACOG and SMFM, in response to their April 20, 2020 letter.³⁰ The Letter authorized mail distribution of mifepristone via "enforcement discretion" regarding pandemic-context in-person protocols.³¹ It marked the first time that the in-person dispensing requirement for mifepristone had been lifted, making it the most significant federal liberalization of medication-abortion access at the time. On May 7, 2021, the FDA initiated a voluntary full review of the overall REMS protocols, in response to the ACOG litigation and to a pending 2017 lawsuit challenging the constitutionality of a REMS protocols for mifepristone.³²

On December 16, 2021, FDA released a REMS update following the review. In another letter to a group of medical professionals who had challenged the constitutionality of the REMS,³³ the FDA announced that it would remove the in-person dispensing requirement, allowing certified pharmacies to mail mifepristone pills.³⁴ The FDA accordingly revised the Medication Guide and informational materials.³⁵

Although the REMS update was an important victory that illustrates how medical professionals can successfully lobby for broader abortion access through administrative agencies, the precarity of this agency action evinces the practical and doctrinal limits of agency advocacy as an avenue toward reproductive freedom. In the short term, this agency advocacy is undeniably effective. The update significantly expanded abortion access for pregnant people in most states. It is unlikely to face judicial scrutiny due to jurisprudence surrounding both agency deference

²⁶ *Id.* at 579 (Roberts, C.J., concurring in the grant of application for stay).

²⁷ Justice Kagan joined in the dissent.

²⁸ *FDA*, 141 S. Ct. at 584 (Sotomayor, J., dissenting from grant of application for stay).

²⁹ See Letter from Janet Woodcock, Acting Comm'r, FDA, to Maureen G. Phipps, Chief Exec. Officer, Am. Coll. of Obstetricians and Gynecologists, and William Grobman, President, Soc'y for Maternal-Fetal Med. (Apr. 12, 2021) (on file with the Harvard Law School Library).

³⁰ See *id.*

³¹ *Id.* (noting the COVID-19 health risks imposed by in-person dispensing).

³² See Joint Motion to Stay Case Pending Agency Review at 2, *Chelius v. Becerra*, No. 17-cv-00493 (D. Haw. May 7, 2021); *FDA Announces Long Sought-After Review of Harmful Restrictions on Medication Abortion*, ACLU (May 7, 2021), <https://www.aclu.org/press-releases/fda-announces-long-sought-after-review-harmful-restrictions-medication-abortion> [<https://perma.cc/KZ3D-FU9B>].

³³ Letter from Patrizia Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch., to Graham Chelius, Soc'y of Fam. Plan., Cal. Acad. of Fam. Physicians (Dec. 16, 2021) (on file with the Harvard Law School Library).

³⁴ *Id.*

³⁵ See REMS FOR MIFEPRISTONE, *supra* note 1.

and Article III standing. Still, while the update expands abortion access, its limits demonstrate agency action's constraints. Overall, the FDA's limited jurisdiction covers medication but not surgical abortion. Even for medication abortion, barriers remain. Legally, the update is limited by state laws' potential to be more restrictive than FDA regulations, as well as by the possibility of a future administration reinstating the in-person requirements, which would likely withstand legal challenge.

Pragmatically, lifting the in-person requirement expands abortion access. Pregnant people in thirty-one states can now access mifepristone-misoprostol medication abortion by mail, either from a certified prescriber or a mail-order pharmacy.³⁶ This is especially significant in the context of the broader rise of medication abortions (in 2019, nearly forty-four percent of U.S. abortions).³⁷ Medication abortion retains several advantages over surgical abortion. It is safe to manage on one's own³⁸ and enlarges the range of abortion providers; in eighteen states pills for termination can be provided by qualified nonphysician professionals.³⁹ Moreover, self-managed abortions are harder to capture or eliminate with Targeted Regulation of Abortion Providers (TRAP) laws,⁴⁰ and providers offering telemedicine counseling are exposed to less risk of bias-driven violence than those performing surgical abortions in clinics.⁴¹ The update instantiated medical abortion as a more prominent feature of the shifting national abortion-access landscape.

Agency action can improve abortion access in a manner less susceptible to legal challenge, as Article III standing doctrine insulates REMS updates from judicial review. Despite anti-abortion advocates' widespread criticism of the update, none have brought legal challenges.⁴² It is unclear whether any individual or group could serve as a plaintiff

³⁶ Nineteen states legislatively mandate that prescribing clinicians must be in the physical presence of patients. See *State Laws and Policies: Medication Abortion*, *supra* note 7.

³⁷ See Katherine Kortsmit et al., *Abortion Surveillance — United States, 2019*, MORBIDITY & MORTALITY WKLY. REP., Nov. 26, 2021, at 6, <https://www.cdc.gov/mmwr/volumes/70/ss/pdfs/ss7009a1-H.pdf> [<https://perma.cc/W8RM-DYUN>].

³⁸ Olga Khazan, *The Abortion Backup Plan No One Is Talking About*, THE ATLANTIC (Oct. 15, 2021, 6:00 PM), <https://www.theatlantic.com/politics/archive/2021/10/plan-c-secret-option-mail-order-abortion/620324> [<https://perma.cc/9L2F-SPF3>].

³⁹ See *State Laws and Policies: Medication Abortion*, *supra* note 7.

⁴⁰ These laws specifically target the clinics and in-person locations where surgical abortions and abortion consultations take place. See *Targeted Regulation of Abortion Providers (TRAP)*, CTR. FOR REPROD. RTS. (Aug. 28, 2015), <https://reproductiverights.org/targeted-regulation-of-abortion-providers-trap> [<https://perma.cc/NWP7-FGC6>]. Self-managed abortions evade these restrictions.

⁴¹ From 1977 to 2019, there have been 11 murders, 26 attempted murders, 42 bombings, 189 arsons, and thousands of incidents of other criminal activities directed at abortion providers. See NAT'L ABORTION FED'N, 2019 VIOLENCE AND DISRUPTION STATISTICS 11 (2020).

⁴² Informal actions have been suggested, such as a recent request to review the Center for Drug Evaluation and Research reports. See Letter from Jordan Sekulow, Exec. Dir., Am. Ctr. for L. & Just., et al. to FDA (June 7, 2021) (on file with the Harvard Law School Library).

because of the lack of a cognizable injury,⁴³ a classic requirement for Article III standing.⁴⁴ As the Roberts Court narrows standing doctrine,⁴⁵ a judicial challenge to the REMS update remains difficult.

The removal of the in-person dispensing requirement would likely survive the *FCC v. Fox Television Stations*⁴⁶ standard of review that governs agency changes in policy. *Fox* outlines a standard of arbitrary and capricious review that requires that an agency “examine the relevant data and articulate a satisfactory explanation for its action,”⁴⁷ and that the agency “display awareness that it *is* changing position” and “show that there are good reasons for the new policy.”⁴⁸ The Biden FDA’s rationale included evidence that the safety of medication abortion is unaffected by a lack of in-person dispensing. In 2016, the Obama FDA lengthened eligibility from forty-nine to seventy days’ gestation based on scientific research.⁴⁹ This change went unchallenged, enabling more than four million safe and effective U.S. medication abortions.⁵⁰ Barriers to judicial review and likely application of the *Fox* standard render the update a temporarily incontrovertible victory.

This administrative win has practical limits. The FDA’s purview is restricted to medication abortion, a circumscribed avenue to reproductive freedom. Medication-abortion regimens are authorized until ten weeks into pregnancy, while traditional surgical abortions can occur until twenty-three weeks.⁵¹ REMS barriers disproportionately affect the

⁴³ However, at the individual level, this argument may not protect abortion providers or assistants from private civil actions in states that have legislated a new private cause of action against abortion providers under the logic of a “tort of outrage,” such as in Texas under S.B. 8. See Transcript of Oral Argument at 47–49, *Whole Woman’s Health v. Jackson*, 142 S. Ct. 522 (2021) (No. 21-463), https://www.supremecourt.gov/oral_arguments/argument_transcripts/2021/21-463_6kgm.pdf [<https://perma.cc/VR5F-55QX>]. These private causes of action are still highly contested by Justices Sotomayor, Kagan, and Breyer who argued that this decision “betray[ed]” America’s “constitutional system of government.” *Jackson*, 142 S. Ct. at 546 (Sotomayor, J., dissenting).

⁴⁴ See *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560, 563 (1992).

⁴⁵ See *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2204–05 (2021); Erwin Chemerinsky, *What’s Standing After TransUnion LLC v. Ramirez*, 96 N.Y.U. L. REV. ONLINE 269, 282–86 (2021).

⁴⁶ 556 U.S. 502 (2009).

⁴⁷ *Id.* at 513 (citing *Motor Vehicle Mfrs. Ass’n v. State Farm Ins. Co.*, 463 U.S. 29, 43 (1983)).

⁴⁸ *Id.* at 515.

⁴⁹ See CTR. FOR DRUG EVALUATION & RSCH., FDA, APPLICATION NUMBER: 020687ORIG1S020 MEDICAL REVIEWS 6 (2016); ADVANCING NEW STANDARDS IN REPROD. HEALTH, ANALYSIS OF MEDICATION ABORTION RISK AND THE FDA REPORT “MIFEPRISTONE U.S. POST-MARKETING ADVERSE EVENTS SUMMARY THROUGH 12/31/2018,” at 2 (2019).

⁵⁰ See Press Release, Planned Parenthood, *Leading with Science: FDA Is Reviewing Unnecessary Medication Abortion Restrictions* (May 7, 2021), <https://www.plannedparenthood.org/about-us/newsroom/press-releases/leading-with-science-fda-is-reviewing-unnecessary-medication-abortion-restrictions> [<https://perma.cc/C967-94M8>].

⁵¹ See *Medical Versus Surgical Abortion*, UCSF HEALTH, <https://www.ucsfhealth.org/treatments/surgical-abortion-second-trimester> [<https://perma.cc/4YLN-JPQX>].

most marginalized pregnant people seeking abortions.⁵² Racially marginalized, trans*, and nonbinary pregnant individuals face prohibitive challenges beyond travel.⁵³ Access is further constrained by ignorance of the REMS update, exacerbated by a lack of both internet and comprehensive sex education.⁵⁴ REMS-altering agency advocacy must be driven by medical professionals, which risks perpetuating the prioritization of physicians' expertise over patients' self-knowledge and self-advocacy.⁵⁵ Many advocates thus call for a complete REMS repeal.⁵⁶

State regulations further restrict the potential effects of this victory. The REMS sets a federal regulatory floor, but states can be more restrictive. Nineteen states — five in 2021 alone — have legislatively mandated in-person dispensing.⁵⁷ These laws functionally overwrite the FDA guidance, making it impossible for people in those states to access mifepristone by mail. At the extreme, medication abortion is vulnerable to criminal prosecution of self-managed abortions in six states.⁵⁸ Anti-abortion legislators' "abortion reversal" campaigns⁵⁹ presage outright bans on medication abortion and restrictions on provider eligibility.⁶⁰

⁵² See Alexandra Thompson et al., *The Disproportionate Burdens of the Mifepristone REMS*, 104 CONTRACEPTION 16, 16 (2021).

⁵³ See *id.* at 17–18; Heidi Moseson et al., *Abortion Experiences and Preferences of Transgender, Nonbinary, and Gender-Expansive People in the United States*, 224 AM. J. OBSTETRICS & GYNECOLOGY 376e.1, 376e.1 (2021).

⁵⁴ See Khazan, *supra* note 38; *Sex Education Laws and State Attacks*, PLANNED PARENTHOOD, <https://www.plannedparenthoodaction.org/issues/sex-education/sex-education-laws-and-state-attacks> [<https://perma.cc/9K9L-47T7>].

⁵⁵ Physicians' opinions on abortion have been prioritized over the opinions of patients throughout the past century. Abortion and other birth work was medicalized and removed from community health settings in the nineteenth century. *Roe v. Wade* structured the right to abortion such that physicians' expertise would be central to constitutional claims on that right. See generally MARY ZIEGLER, *ABORTION AND THE LAW IN AMERICA* (2020).

⁵⁶ See Letter from ACLU et al. to Joseph R. Biden, Jr., President (Mar. 18, 2021) (on file with the Harvard Law School Library).

⁵⁷ See Kate Zernike, *Abortion Pills, Once a Workaround, Are Now a Target*, N.Y. TIMES (Apr. 6, 2022), <https://www.nytimes.com/2022/04/06/us/abortion-pills.html> [<https://perma.cc/ANSA-5UQ5>]. But see Patricia J. Zettler & Ameet Sarpatwari, *State Restrictions on Mifepristone Access — The Case for Federal Preemption*, 386 NEW ENG. J. MED. 705, 706 (2022).

⁵⁸ See IF/WHEN/HOW, *FULLFILLING ROE'S PROMISE* (2019). But see Carrie N. Baker, *Self-Managed Abortion Is Medically Very Safe. But Is It Legally Safe?*, MS. MAG. (Apr. 1, 2020), <https://msmagazine.com/2020/04/01/self-managed-abortion-is-medically-very-safe-but-is-it-legally-safe> [<https://perma.cc/E9ZT-Z4P9>] (“[T]here have been no successful prosecutions of women who self-managed an abortion using pills in early pregnancy.”).

⁵⁹ See Kayla Epstein, *Some Lawmakers Push “Abortion Reversal” Treatments. A Study Shows How Dangerous They Are.*, WASH. POST (Dec. 24, 2019), <https://www.washingtonpost.com/health/2019/12/24/some-lawmakers-push-abortion-reversal-treatments-new-study-shows-how-dangerous-they-are> [<https://perma.cc/Y44P-D2S7>].

⁶⁰ See *Potential Legal Flaws in State Restrictions Targeting Mifepristone*, ACLU, <https://www.aclu.org/other/potential-legal-flaws-state-restrictions-targeting-mifepristone> [<https://perma.cc/GWE8-7GHP>]. Citizens in different states are often vulnerable to time-based bans that can include bans on medication abortion, such as S.B. 8 in Texas.

Agency actions can also be reversed by an unfriendly administration, and such a reversal would likely withstand legal challenge. A conservative administration could resume enforcing the 2020 REMS in-person dispensing requirement, and administrative law could insulate the decision from judicial review.⁶¹ Under *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Insurance Co.*,⁶² a “rational connection between the facts found and the choice made” in a rescission decision could pass arbitrary and capricious review and could justify a policy reversion.⁶³ Although the recent administrative-advocacy archetype has been medical experts seeking to expand abortion access, medical professionals’ willingness to produce anti-abortion rationales for agencies should not be underestimated.⁶⁴ Even a full REMS repeal would likely last only until the next abortion-unfriendly administration.

Recourse to agencies has provided a momentary victory for access to medication abortion. However, for lasting, expansive access to mifepristone, agency action would have to be bolstered by advocacy to state and federal legislatures. A total repeal of REMS protocols for mifepristone would be the first step toward expanded medication-abortion access. But even if the FDA reverts to a more stringent REMS, states can help protect medical abortion. States can pass legislation to maintain the longest possible time allowance (ten weeks), expand provider eligibility, and even enshrine a right to medical abortion in state constitutions and state law.⁶⁵ In the wake of the REMS update, advocates for reproductive freedom must strategically weave administrative, judicial, and legislative activism to protect access to medication abortion, an innovative avenue to one of the most polarizing American constitutional rights.

⁶¹ A parallel dynamic existed in *Karnoski v. Trump*, 926 F.3d 1180 (9th Cir. 2019), in which the Ninth Circuit held that the Trump Administration’s reversion to trans* exclusion from the military (repealing the Obama-era trans*-inclusive Carter policy) was a well-reasoned policy meriting deference because it was justified by a procedurally sound research panel. *See id.* at 1187, 1202.

⁶² 463 U.S. 29 (1983).

⁶³ *Id.* at 43 (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)). In practice, *State Farm* still sets a high bar to justify a rescission, necessitating a searching inquiry of agencies’ proffered justifications. *See id.* at 46–57.

⁶⁴ *See* Marisa Endicott, *They’re Doctors. They’re Also Incredibly Effective — and Dangerous — Anti-Abortion Activists.*, MOTHER JONES (June 4, 2020), <https://www.motherjones.com/politics/2020/06/american-association-pro-life-obstetricians-gynecologists-aaplog-anti-abortion-doctors-june-medical-supreme-court-decision> [<https://perma.cc/EMD9-YDFR>] (describing the work of the American Association of Pro-Life Obstetricians and Gynecologists (AAPLOG), an anti-abortion, anti-LGBTQ group that broke off from ACOG after disagreeing with the organization’s pro-choice policy choices); Citizen Petition from Donna J. Harrison, Exec. Dir., Am. Ass’n of Pro-Life OB/GYNs, to FDA (Mar. 29, 2019), <https://aaplog.org/wp-content/uploads/2021/01/Citizen-Petition-Final-FDA-Mif-REMS.pdf> [<https://perma.cc/34Y5-6VCB>] (requesting that the FDA strengthen in-person dispensing limitations and offering a purportedly medical rationale for suggested stringency).

⁶⁵ *See What if Roe Fell?*, CTR. FOR REPROD. RTS., <https://maps.reproductiverights.org/what-if-roe-fell> [<https://perma.cc/9BTG-5VAE>]. *See generally* Scott A. Moss & Douglas M. Raines, *The Intriguing Federalist Future of Reproductive Rights*, 88 B.U. L. REV. 175 (2008); Linda J. Wharton, *Roe at Thirty-Six and Beyond: Enhancing Protection for Abortion Rights Through State Constitutions*, 15 WM. & MARY J. WOMEN & L. 469 (2009).