Stanford Law Review

Volume 76 February 2024

ARTICLE

Abortion Pills

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Abstract. Abortion is now illegal in roughly a third of the country, but abortion pills are more widely available than ever before. Clinics, websites, and informal networks facilitate the distribution of abortion pills, legally and illegally, across the United States, while anti-abortion advocates and legislators are adopting all manner of strategies to attack pills. This Article is the first in the legal literature to explore this defining aspect of this new environment and the novel issues it raises at the level of state law, federal policy, and on-the-ground advocacy.

The Article begins by detailing anti-abortion strategies to stop pills by any means necessary. These tactics include a federal lawsuit attacking the approval and regulation of mifepristone, one of two abortion pills; a revival of the long-unenforced Comstock Act's ban on mailing anything that induces an abortion; a redefinition of abortion's location to chill the provision of medication abortion; attacks on online information and pill supply chains; and attempts to target both those who take abortion pills and those who help others access them. We then consider the opposing movement to increase access to abortion pills: abortion shield laws that protect cross-border telehealth, efforts to evade abortion bans through missed period pills and advance provision, and pharmacist prescribing of abortion pills. Finally, we examine how the U.S. Food and Drug Administration (FDA) can use its powers to increase or decrease access to pills, including lifting the unnecessary restrictions on medication abortion, changing the pills' labels, or asserting that FDA rules governing medication abortion partially preempt state abortion bans.

The Article concludes by offering the first analysis of how, after *Roe*'s reversal, abortion pills and their attendant controversies are transforming the abortion debate in this country. With pills, state governments and the medical establishment will lose even more control over abortion; rather, informal and underground networks will meet much of the demand for abortion pills, cutting out gatekeepers. The wide availability of pills will also reshape the definition of abortion—which is ill-suited for the ambiguities of drug

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provision—and could destigmatize abortion care. At the same time, however, attempts to punish people who provide or use pills will exacerbate the public health and criminal justice consequences that new abortion bans have wrought, entrenching existing class and race disparities. Thus, as abortion pills proliferate—both within and outside of law—abortion inequities could as well. Ultimately, these emerging legal issues will profoundly alter how people think about abortion.

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Introduction

We are at the beginning of a new war on drugs in this country—this time, a war on abortion pills. The existing War on Drugs has spanned decades,[1] yet despite federal and state bans, drug use in this country has never come close to being eradicated.[2] Instead, the expensive and ineffectual campaign has institutionalized longstanding racism and entrenched a punitive approach to drug policy.[3] One clear lesson from this war is that drug use is difficult to stop, no matter how stiff the penalties.[4] The war on abortion pills has already begun,[5] and it is bound to repeat some of the same mistakes, igniting public backlash that will shape the abortion debate for years to come.[6]

While abortion is now illegal in roughly a third of the states,[7] medication abortion is more widely available than ever before and now accounts for more than half of all abortions in the United States.[8] Abortion can be accomplished with pills mailed from online pharmacies or distributed by providers.[9] So while

1. For a discussion of the history of the regulation and prohibition of drugs, see *Gonzales v. Raich*, 545 U.S. 1, 10-15 (2005).
2. *See generally National Survey on Drug Use and Health (NSDUH)*, SUBSTANCE ABUSE & MENTAL HEALTH SERVS. ADMIN., https://perma.cc/56WA-SRS7 (archived Dec. 21, 2023) (reporting annual data on the national use of tobacco, alcohol, and illicit drugs).
3. *See* Charles Silver, *The War on Abortion Could Turn the US into a Police State*, HEALTH AFFS.: FOREFRONT (June 27, 2022), https://perma.cc/CV3Z-Q5ZW (to locate, select "View the live page"); *see also* Mary Ziegler & Aziza Ahmed, Opinion, *Why a 'War on Abortion' Is Doomed to Fail*, CNN (updated Mar. 23, 2022, 10:00 AM EDT), https://perma.cc/88DV-PYHM.
4. *See generally* Meagan K. Nettles, Comment, *The Sobering Failure of America's "War on Drugs": Free the P.O.W.s*, 55 CAL. W. L. REV. 275, 276, 286-87 (2018); CHRISTOPHER J. COYNE & ABIGAIL R. HALL, CATO INST., POL'Y ANALYSIS NO. 811, FOUR DECADES AND COUNTING: THE CONTINUED FAILURE OF THE WAR ON DRUGS (2017), https://perma.cc/MY5B-DFHA (describing the consensus among scholars that the War on Drugs has failed).
5. Of course, abortion pills are different from recreational drugs. *See infra* notes 432-45 and accompanying text.
6. *See* Vanessa Williamson & John Hudak, *The War on Abortion Drugs Will Be Just as Racist and Classist*, BROOKINGS (May 9, 2022), https://perma.cc/CCS5-KPWU. *See generally* Lynn M. Paltrow, *The War on Drugs and the War on Abortion: Some Initial Thoughts on the Connections, Intersections and the Effects*, 28 S.U. L. REV. 201 (2001).
7. *See* Caroline Kitchener, Kevin Schaul, N. Kirkpatrick, Daniela Santamariña & Lauren Tierney, *States Where Abortion Is Legal, Banned or Under Threat*, WASH. POST, https://perma.cc/9ZTW-KKFZ (last updated Dec. 7, 2023, 1:27 PM EST).
8. *See* Rachel K. Jones, Elizabeth Nash, Lauren Cross, Jesse Philbin & Marielle Kirstein, *Medication Abortion Now Accounts for More Than Half of All US Abortions*, GUTTMACHER INST. (updated Dec. 1, 2022), https://perma.cc/DJ2U-RCQ9.
9. *See id.*

some state actors are working to stop the use of pills,[10] websites and informal networks openly facilitate their distribution in every state.[11] Thus, at the moment that abortion bans are proliferating, the anti-abortion movement's goal of ending all abortion nationwide seems increasingly out of reach.

Because of abortion pills, abortion provision has radically changed in the last several years and faces never-before-answered legal questions that this Article is the first to tackle. We highlight the impending battles over pills and how those battles will change the national discourse around abortion.

In *Dobbs v. Jackson Women's Health Organization*, the Supreme Court overturned *Roe v. Wade* and granted states broad leeway to ban abortion at any stage of pregnancy.[12] During the *Roe* era, physical location was central to how people gained access to abortion. "Abortion deserts" made up large swaths of the South and Midwest.[13] These regions contained few providers, forcing many people to travel long distances to access care.[14] And until recently, the federal government required people to pick up abortion pills at clinics, so medication abortion carried logistical and financial burdens of travel similar to obtaining procedural care.[15] Before *Roe*, when abortion accomplished by a medical procedure was the only option, place mattered even more. If a person did not live in a state that allowed abortion, their options were limited to out-of-state travel or finding an underground in-state provider, sometimes risking their lives, health, and future fertility in the process.[16] In both of these eras—before and after *Roe*—women of color,[17] poor

10. *See infra* Part II; Kimberly Kindy, *Most Abortions Are Done at Home. Antiabortion Groups Are Taking Aim.*, WASH. POST (Aug. 14, 2022, 6:00 AM EDT), https://perma.cc/XV6X-L54L.

11. *See infra* Part V.A.

12. Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2242-43 (2022) (overruling Roe v. Wade, 413 U.S. 113 (1973)).

13. *See* Alice F. Cartwright, Mihiri Karunaratne, Jill Barr-Walker, Nicole E. Johns & Ushma D. Upadhyay, *Identifying National Availability of Abortion Care and Distance from Major US Cities: Systematic Online Search*, 20 J. MED. INTERNET RSCH. e186, at 7 (2018), https://perma.cc/8X92-83NN.

14. *See* Lisa M. Kelly, *Abortion Travel and the Limits of Choice*, 12 FIU L. REV. 27, 27 (2016).

15. *See* Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV 627, 638-42 (2022).

16. *See* LESLIE J. REAGAN, WHEN ABORTION WAS A CRIME: WOMEN, MEDICINE, AND LAW IN THE UNITED STATES, 1867-1973, at 198-200 (1997); CAROLE JOFFE, DOCTORS OF CONSCIENCE: THE STRUGGLE TO PROVIDE ABORTION BEFORE AND AFTER ROE V. WADE 86-91 (1995).

17. Not every person capable of becoming pregnant is a woman; trans men, girls, and gender nonbinary patients also need access to abortion and reproductive healthcare. There are also times, however, when gender's intersection with abortion is important and relevant. This Article does its best to thread that needle by using a variety of terms in its discussion. For more context, see Jessica A. Clarke, *They, Them, and Theirs*, 132

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people, and people from rural areas disproportionately shouldered the burdens of travel.[18]

Abortion's past, however, is not abortion's future. In this new era, abortion provision does not always depend on location.[19] Contemporary abortion can be effectively and safely accomplished using pills through at least ten to twelve weeks of pregnancy at a location the patient chooses.[20] In most states where abortion is legal, virtual clinics counsel patients online before mailing abortion pills to the patient.[21] And even in states that ban abortion (including medication abortion), online sources and distribution networks make abortion pills relatively accessible and difficult for the state to control.[22] When attempts to police out-of-state providers fail, anti-abortion legislators and activists will work to regulate, criminalize, and punish others in the information and distribution chains. And abortion providers and activists will respond with new ways to get pills into the hands of those seeking them.

This Article tackles the novel issues raised by the proliferation of abortion pills both descriptively and normatively. First, we map how impending legal battles will advance or constrain the availability of abortion pills. Then, we highlight the normative consequences of those battles beyond their immediate impact—how abortion pills and their attendant controversies will shape and change our nation's abortion debate. Though pills cannot be stopped, they can be pushed underground, potentially deepening the public-health and criminal-justice consequences that abortion bans have already catalyzed.

HARV. L. REV. 894, 954-57 (2019). *See also* LORETTA J. ROSS & RICKIE SOLINGER, REPRODUCTIVE JUSTICE: AN INTRODUCTION 6-8 (2017).

18. *See* DAVID S. COHEN & CAROLE JOFFE, OBSTACLE COURSE: THE EVERYDAY STRUGGLE TO GET AN ABORTION IN AMERICA 13-14, 57, 72-80, 216 (2020). *See generally* MICHELE GOODWIN, POLICING THE WOMB: INVISIBLE WOMEN AND THE CRIMINALIZATION OF MOTHERHOOD (2020).

19. As discussed in Part II.C below, this broad statement does not mean that all patients are free from the challenges of place and location. *See* David S. Cohen, Greer Donley & Rachel Rebouché, *The New Abortion Battleground*, 123 COLUM. L. REV. 1, 2-3 (2023); B. Jessie Hill, *The Geography of Abortion Rights*, 109 GEO. L.J. 1081, 1088 (2021); I. Glenn Cohen, *Travel to Other States for Abortion After* Dobbs, 22 AM. J. BIOETHICS, no. 8, 2022, at 42, 42.

20. *Medication Abortion*, GUTTMACHER INST., https://perma.cc/RS4P-TAR4 (last updated Oct. 31, 2023) ("[M]edication abortion is approved by the FDA for use up to 10 weeks of gestational age and it is used safely off-label at later gestations."). In 2000, the FDA approved medication abortion through seven weeks of gestation, but in 2016, it extended approval to ten weeks. *See* Donley, *supra* note 15, at 638, 641. As discussed below, some providers are offering medication abortion off-label through twelve weeks of pregnancy. *See infra* note 384 and accompanying text.

21. *See* Cohen et al., *supra* note 19, at 5-6.

22. *See infra* Part V.A.

After describing the regulation of medication abortion and the uptake of online abortion services in Part I, we begin Part II with an exploration of prominent anti-abortion strategies to limit access to abortion pills. A high-profile example is a case the Supreme Court will decide in 2024 attacking mifepristone—the only federally approved abortifacient—by claiming that it was inappropriately approved and improperly regulated. We next track efforts that rely on the Comstock Act, a dormant 150-year-old federal law that threatens the legality of mailing abortion pills anywhere, even in states where abortion remains legal. We then address attempts to punish out-of-state providers if any part of the medication abortion process happens within an anti-abortion state's borders—a threat that has already caused some providers to refuse services for out-of-state residents. Anti-abortion efforts will also target reliable sources of information about medication abortion, as well as the manufacturing and distribution chains. This Part concludes by describing efforts to target the people who take abortion pills or help others access them.

In Part III, we explore the movement to increase access to abortion pills as a way of mitigating the damage of *Dobbs*. The first effort is the passage of shield laws that protect those who provide telehealth for abortion across state lines. Activists also hope to protect abortion access through practices such as advance provision (the dispensation of abortion pills before a potential unwanted pregnancy) and menstrual regulation or "missed period pills" (dispensation to induce a period without taking a pregnancy test). Another effort is nascent: states allowing pharmacists to prescribe medication abortion, thereby creating a workaround that mimics over-the-counter provision without violating federal food and drug laws.

Next, in Part IV, we explore the role and power of the Food and Drug Administration (FDA) as it faces pressure in both directions over its rules governing medication abortion. We discuss how the FDA could adjust its distribution limitations to make the drug easier or harder to access. Ironically, the agency's unnecessarily strict regulation of medication abortion also provides the building blocks to argue that the FDA has the sole and preemptive authority to regulate abortion pills, potentially invalidating all or part of state abortion bans. We then discuss additional tools the agency could use to increase or decrease access to abortion pills, including modifying the mifepristone label to permit its use throughout the first trimester or limit its use to earlier gestational ages.

After surveying these strategies and the legal questions they raise, Part V concludes with an exploration of how these battles will set the terms for the abortion debate after *Dobbs*. We start with a discussion of how informal distribution networks will eliminate gatekeepers and challenge traditional conceptions of abortion as controlled by doctors. We then emphasize how pills challenge traditional definitions of abortion given that medication abortion drugs are used for various purposes, blurring the line between

abortion and pregnancy loss. Abortion pills are predominantly taken privately and early in pregnancy, mimicking miscarriage—a common experience that may prove difficult to vilify. We conclude with a discussion of criminalization and surveillance. As people seek pills outside the traditional healthcare system, online activity and personal data will inevitably become part of state prosecutions. The brunt of investigations and criminalization will fall, as they always do, most heavily on poor people and people of color. Thus, as abortion pills proliferate—both inside and outside of the law—certain inequities will as well.

These emerging legal questions will profoundly alter perceptions and acceptance of abortion. The battle over abortion pills will have unacceptable consequences for health, liberty, and equality that could galvanize even those who might otherwise disfavor abortion rights.[23] The lesson for the War on Abortion Pills from the War on Drugs is clear: Invasive, punitive state action will not stop abortion. Rather, it will harm public health, hurt those most vulnerable to state power, and force abortion services into informal networks.[24] But unlike the War on Drugs, the War on Abortion Pills will be fought over medications approved by the federal government and a personal liberty that people exercised as a matter of constitutional right for half a century.

I. The Abortion Pill Revolution

Medication abortion terminates a pregnancy with pills rather than a procedure. There are a variety of medication regimens available, but the two most common worldwide are: (1) 200 mg of mifepristone followed by 800 μg of misoprostol 24-48 hours later, or (2) 800 μg of misoprostol on its own with additional doses as necessary to complete the abortion.[25] Most medical organizations prefer the two-drug regimen because it has historically been the most effective, and doctors in the United States use that regimen almost exclusively.[26]

23. *See* Rachel Rebouché & Mary Ziegler, *Why Direct Democracy Is Proving So Powerful for Protecting Abortion Rights*, ATLANTIC (Nov. 11, 2022), https://perma.cc/2CWT-WZMA (noting that Kansas, a state with strong anti-abortion politics, nevertheless voted down abortion restrictions in ballot initiatives).

24. *Cf.* BETSY PEARL, CTR. FOR AM. PROGRESS, ENDING THE WAR ON DRUGS: BY THE NUMBERS 1 (2018), https://perma.cc/5LLK-DA2U ("Incarcerating people for drug-related offenses has been shown to have little impact on substance misuse rates. Instead, incarceration is linked with increased mortality from overdose." (footnote omitted)), *noted in* GOODWIN, *supra* note 18, at 119.

25. WORLD HEALTH ORG., MEDICAL MANAGEMENT OF ABORTION, at vii-xi, xi tbl.1 (2018), https://perma.cc/6GHJ-B4PS.

26. *Medication Abortion Up to 70 Days of Gestation*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (Oct. 2020), https://perma.cc/7QQ6-X5UD (setting out the preferred

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The two drugs work differently and have distinct regulatory profiles. Mifepristone blocks the hormone progesterone, which is necessary for a pregnancy to continue, and misoprostol causes uterine contractions that expel fetal tissue.[27] Mifepristone, the only drug approved by the FDA to end a pregnancy, is more expensive and difficult to obtain than misoprostol.[28] This is largely due to the agency's imposition of strict controls on the drug.[29] Misoprostol, on the other hand, was approved as a stomach ulcer medication in 1988 and has not been approved by the FDA for abortion.[30] It is less expensive than mifepristone and regulated comparably to most other prescription drugs.[31] Misoprostol is prescribed off-label[32] for a variety of

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two-drug regimen in the United States); Rachel K. Jones, Marielle Kirstein & Jesse Philbin, Guttmacher Inst., *Abortion Incidence and Service Availability in the United States, 2020*, 54 PERSPS. ON SEXUAL & REPROD. HEALTH 128, 130 (2022).

27. Sarah McCammon, *Why an Ulcer Drug Could Be the Last Option for Many Abortion Patients*, NPR (updated Feb. 24, 2023, 8:51 AM ET), https://perma.cc/V2MC-UPAR ("Under the current two-drug protocol, the patient first takes mifepristone, which works by blocking progesterone, a hormone that helps a pregnancy progress. The second drug, misoprostol, then causes contractions to bring on what's essentially a medically induced miscarriage.").

28. *See* Mara Gordon, *Medication Abortion Is Still Possible with Just One Drug. Here's how It Works*, NPR (Apr. 10, 2023, 11:12 AM ET), https://perma.cc/SNJ6-GWLG ("[M]isoprostol is easier to access than mifepristone. Even before the Texas judge's ruling, mifepristone was subject to special FDA regulations that meant that most commercial pharmacies did not carry it, and patients could only get it at clinics that provide abortions or via pharmacies that had specially registered with the FDA. Misoprostol, however, isn't subject to these regulations, so it's stocked in almost all pharmacies and hospitals."); McCammon, *supra* note 27.

29. *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA, https://perma.cc/927R-CFLH (last updated Mar. 23, 2023) (setting out the rules for dispensing and prescribing mifepristone under the FDA's risk management protocol).

30. *See* Donley, *supra* note 15, at 633-34; Sarah Varney, *One Texas Judge Will Decide Fate of Abortion Pill Used by Millions of American Women*, KFF HEALTH NEWS (Feb. 24, 2023), https://perma.cc/J372-LC3F.

31. Gordon, *supra* note 28; McCammon, *supra* note 27.

32. An off-label use means one that the FDA has not evaluated. It is common for doctors to prescribe drugs approved for other uses when evidence surfaces that they are safe and effective for the off-label use. But until the FDA approves the drug for that use, such prescriptions are off-label. Unlike providers, the manufacturer can only promote the drug for the use approved in the label; otherwise, the FDA considers the drug misbranded. Shariful A. Syed, Brigham A. Dixson, Eduardo Constantino & Judith Regan, *The Law and Practice of Off-Label Prescribing and Physician Promotion*, 49 J. AM. ACAD. PSYCHIATRY L. 53, 53-57 (2021); Nathan Cortez, *The Statutory Case Against Off-Label Promotion*, 83 U. CHI. L. REV. ONLINE 124, 126 (2016) ("'[P]romoting an approved drug for off-label uses is not itself a prohibited act under the [Food, Drug, and Cosmetic Act], nor is it an element of any prohibited act.' Instead, the FDA argues, off-label promotion 'plays an *evidentiary* role in determining whether a drug is misbranded.'"

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obstetric uses, including miscarriage management, labor induction, and abortion.[33]

When the FDA approved mifepristone as an abortifacient in 2000, it required the manufacturer to adhere to distribution limitations that had been rarely applied to other drugs and that were, as many have argued, excessive in light of the drug's safety.[34] Indeed, after more than twenty years on the U.S. market, mifepristone has become one of the most studied drugs available and has proven to be exceptionally safe[35]—many times safer than common drugs like penicillin or Viagra[36] and fourteen times safer than childbirth.[37] It is currently FDA-approved only through the first ten weeks of pregnancy, but some providers use it off-label throughout the first trimester.[38]

Despite the drug's exemplary safety record, the FDA imposed a Risk Evaluation and Mitigation Strategy (REMS) with "Elements to Assure Safe Use," which is a tool Congress created to help the FDA regulate particularly risky products.[39] Mifepristone's current REMS has several parts. First, providers must be specially certified to prescribe mifepristone. That is, providers submit a form to the drug sponsor certifying that they can "assess the duration of pregnancy accurately," "diagnose ectopic pregnancies," and "provide surgical intervention" or "have made plans to provide such care through others."[40] Next, providers must review and have patients sign a Patient Agreement Form.[41] The Patient Agreement Form sets out mifepristone's benefits and risks, duplicating the informed consent process

(quoting Brief and Special Appendix for the United States at 51, United States v. Caronia, 703 F.3d 149 (2d Cir. 2012) (No. 09-5006-cr), 2010 WL 6351497)).

33. *See* Donley, *supra* note 15, at 633-34.

34. For a comprehensive description of the FDA's regulation of mifepristone, see *id.* at 637-42.

35. *Id.* at 634-35 (describing the data).

36. 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), https://perma.cc/W9T2-BVE4.

37. *Id.*

38. *See infra* Part IV.B.

39. FDA, Ref. ID 5103833, Risk Evaluation and Mitigation Strategy (REMS): Single Shared System for Mifepristone 200 MG (2023), https://perma.cc/Q46H-KR3L; *see* CONG. RSCH. SERV., R44810, FDA RISK EVALUATION AND MITIGATION STRATEGIES (REMS): DESCRIPTION AND EFFECT ON GENERIC DRUG DEVELOPMENT 5-6 (2018), https://perma.cc/Z36R-TZAX; Cohen et al., *supra* note 19, at 53-54.

40. FDA, *supra* note 39, at 1.

41. *Id.* at 1-2.

already required for every healthcare provider.[42] Finally, the REMS allows only certified pharmacies to dispense the drug (either by mail or in person); these pharmacies must attest that they will engage in a number of recordkeeping, medication-tracking, and confidentiality measures.[43] The pharmacy certification requirement—described below and finalized in January 2023—was part of FDA's removal of the longstanding rule that patients had to collect the drug at a healthcare facility, almost always a clinic.[44] The old rule forced patients to travel to pick up a prescription they could safely take at home without any provider supervision.[45] This rule had negated much of the promise of abortion pills, subjecting them to some of the same burdens as procedural abortion. On the heels of litigation during the COVID-19 pandemic,[46] the FDA lifted the in-person requirement, thus ushering in the broader uptake of telehealth and mailed abortion pills.

In the wake of the FDA's decision, virtual clinics have proliferated and some abortion providers have refashioned their practices to serve patients online, revealing what is possible for medication abortion care when the means of pill dispensation change. According to estimates of shifting abortion numbers available in 2023, the number of monthly virtual abortions has increased by 72% to nearly 7,000 per month.[47] Telehealth for abortion is now legally available in twenty-four states and Washington, D.C.[48] Typically, providers prescribe pills to patients physically present in the states in which they hold medical licenses. Patients receive instructions on the clinic's website and then typically complete a questionnaire or meet the provider virtually to assess the suitability of medication abortion.[49] To assess gestational age, patients report the first day of their last menstrual cycle.[50] Virtual clinics offer

42. *Id.* attach. (Patient Agreement Form: Mifepristone Tablets, 200 mg); *see* Donley, *supra* note 15, at 655; Alexandra Thompson et al., Commentary, *The Disproportionate Burdens of the Mifepristone REMS*, 104 CONTRACEPTION 16, 17 (2021).

43. FDA, *supra* note 39, at 3.

44. Donley, *supra* note 15, at 630-31.

45. *Id.* at 630-31, 654.

46. *See* Rachel Rebouché, *The Public Health Turn in Reproductive Rights*, 78 WASH. & LEE L. REV. 1355, 1361-65 (2021).

47. SOC'Y OF FAM. PLAN., #WECOUNT REPORT: APRIL 2022 TO JUNE 2023, at 3 (2023), https://perma.cc/DJ8D-TDPN.

48. *The Availability and Use of Medication Abortion*, KFF, https://perma.cc/4HG6-Y3CU (last updated Sept. 29, 2023).

49. Carrie N. Baker, *Online Abortion Providers Cindy Adam and Lauren Dubey of Choix: "We're Really Excited About the Future of Abortion Care,"* MS. MAG. (Jan. 14, 2022), https://perma.cc/2AHV-AZNL.

50. *See* Carrie N. Baker, *Abortion Pill FAQs: Get the Facts About Medication Abortion*, MS. MAG. (May 4, 2022), https://perma.cc/52KP-DMS2.

intake and counseling that is asynchronous, synchronous, or both.[51] Consent forms are completed online, and information about what to expect is sent to the patient.[52]

Once the consent process is completed, the provider or online pharmacy mails the patient the medication. Though delivery times vary, most patients receive the pills within five days and some by overnight delivery.[53] Online pharmacies, such as Honeybee Health, ship abortion pills to states where it is legal, and they have seen an increase in demand since *Dobbs*.[54] Brick-and-mortar pharmacies, once certified, enable patients to pick up their abortion pills like any other prescription.[55] The cost through virtual clinics ranges from $40 to $300[56]—popular providers include 145 Abortion Telemedicine ($145),[57] Aid Access ($150),[58] and carafem ($249)[59]—which is still less than medication abortions offered at brick-and-mortar clinics.[60] The rise of entirely virtual clinics has created additional capacity to care for patients who need procedural abortions.[61] Many of those patients are people traveling from states with bans.[62]

As we have noted elsewhere, virtual abortion care is not a cure-all for the reversal of *Roe*.[63] The digital divide and broader disparities in the availability of healthcare constrict access to mailed pills.[64] And virtual clinics cannot assist

51. Claire Cain Miller & Margot Sanger-Katz, *Virtual Clinics Have Been a Fast-Growing Method of Abortion. That Could Change.*, N.Y. TIMES (Apr. 14, 2023), https://perma.cc/C5AK-Q9Q8.

52. Baker, *supra* note 49.

53. *Id.*; *Abortion by Mail*, AID ACCESS, https://perma.cc/J7JR-WH7F (archived Dec. 28, 2023).

54. *See* Abigail Abrams, *Meet the Pharmacist Expanding Access to Abortion Pills Across the U.S.*, TIME (June 13, 2022, 7:00 AM EDT), https://perma.cc/X629-4ZJJ; Carrie N. Baker, *After Backlash, Walgreens Re-Pledges to Sell Abortion Pill Mifepristone*, MS. MAG. (updated Mar. 8, 2023, 2:50 PM PT), https://perma.cc/3QCJ-X4U7.

55. Alice Miranda Ollstein & Lauren Gardner, *Pharmacies Begin Dispensing Abortion Pills*, POLITICO (Oct. 6, 2023, 2:10 PM EDT), https://perma.cc/72RP-8ZNT.

56. Baker, *supra* note 50.

57. 145 ABORTION TELEMEDICINE, https://perma.cc/3Q9F-ZLM8 (archived Feb. 8, 2024).

58. *Abortion by Mail*, *supra* note 53.

59. *Appointments and Cost*, CARAFEM, https://perma.cc/J4KC-DF4W (archived Feb. 8, 2024).

60. In 2020, the median cost of a medication abortion provided by a brick-and-mortar clinic was $560. Ushma D. Upadhyay, Chris Ahlbach, Shelly Kaller, Clara Cook & Isabel Muñoz, *Trends in Self-Pay Charges and Insurance Acceptance for Abortion in the United States, 2017-20*, 41 HEALTH AFFS. 507, 512 exh. 2 (2022).

61. *See* Abrams, *supra* note 54; *see also* Cohen et al., *supra* note 19, at 99.

62. The rate of abortions in states with restricted access decreased 32% in the immediate aftermath of *Dobbs*, while reported abortions in states where abortion remained legal increased by 11%. SOC'Y OF FAM. PLAN., #WECOUNT REPORT 3 (2022) https://perma.cc/74WJ-SJC2.

63. *See* Cohen et al., *supra* note 19, at 7.

64. *Id.* at 91-92.

those who need or want in-person care.[65] But state laws are the most formidable barriers to telehealth for abortion. Virtual services are offered where abortion by telehealth is legal, and increasingly where it is banned if the provider is in one of six shield states.[66] State laws prohibit telehealth for abortion in nineteen states.[67]

Nevertheless, mailed abortion pills can cross borders in ways that undermine abortion bans.[68] Virtual clinics require a patient's mailing address to be in a state where the provider is licensed and where telehealth for abortion is permitted. But most virtual clinics do not require that patients stay in the state to take the medications. So long as the clinic sends the pills to an address in the state where abortion is legal, the patient—or someone assisting the patient—can pick up the pills when convenient and take them somewhere else, including to a state where abortion is banned.[69] Moreover, information abounds online about how to use mail forwarding to circumvent abortion bans. A new organization, Mayday Health,[70] for example, offers step-by-step instructions on how to set up temporary addresses in abortion-permissive states and forward mail into other states.[71]

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65. Rachel Rebouché, Greer Donley & David S. Cohen, Opinion, *The FDA's Telehealth Safety Net for Abortion Only Stretches So Far*, HILL (Dec. 18, 2021, 11:01 AM ET), https://perma.cc/9CSB-X66P (discussing the ease of virtual telemedicine for some patients but noting that some patients may be too advanced in pregnancy to use medication abortion or may prefer in-person care). Patients may choose procedural abortions for any number of reasons, such as terminating a pregnancy in a single procedure rather than over one or two days.

66. *See infra* notes 263-67. Fourteen states ban almost all abortion within their borders. *Tracking Abortion Bans Across the Country*, N.Y. TIMES, https://perma.cc/SD2A-H65Z (last updated Jan. 8, 2024, 9:30 AM ET). An additional five states require a physician to be present upon delivery of medication abortion. *Medication Abortion*, *supra* note 20.

67. *See After Roe Fell: Abortion Laws by State*, CTR. FOR REPROD. RTS., https://perma.cc/M62A-WTTN (archived Feb. 8, 2024) (to locate, select "View the live page," then select "Abortion Bans," then select "Abortion Bans in Effect," and then select either "Telemedicine ban" or "Trigger ban") (showing eighteen states with telemedicine bans and one additional state—Idaho—with a trigger ban but not a specific telemedicine ban).

68. Plan C has been a hub for information about virtual clinics as well as self-managed care. *See* Patrick Adams, Opinion, *Amid Covid-19, a Call for M.D.s to Mail the Abortion Pill*, N.Y. TIMES (May 12, 2020), https://perma.cc/ZH89-F2LR.

69. *See* Jareb A. Gleckel & Sheryl L. Wulkan, *Abortion and Telemedicine: Looking Beyond COVID-19 and the Shadow Docket*, 54 U.C. DAVIS L. REV. ONLINE 105, 120 (2021).

70. MAYDAY HEALTH, https://perma.cc/74G6-C2MQ (archived Dec. 28, 2023).

71. *Mail Forwarding*, MAYDAY HEALTH, https://perma.cc/UM49-4EV6 (archived Dec. 28, 2023). Mayday is explicit that its goal is to "share information on how to access safe abortion pills in any state." MAYDAY HEALTH, *supra* note 70 (to locate, select "Our Mission"). Although Mayday provides mail-forwarding instructions, its website notes that providers in certain shield states now ship directly no matter where the patient

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Most virtual providers, like those practicing in other areas of medicine, ask patients to self-report their locations at the time of prescription.[72] One virtual clinic, Abortion on Demand, uses software to confirm patient location at intake and requires patients to provide photo identification.[73] Abortion on Demand also uses software to "confirm you are physically in the state you selected at the time of your scheduled video appointment," which "needs to match the state selected for your medication abortion packet sent in the mail."[74] But other virtual clinics do not restrict their services in this way, allowing patients to obtain pills without the provider knowing their location.[75] That is not to say masking one's location is without risk. Strategies designed to circumvent a state's abortion ban could have profound costs, particularly for those already vulnerable to state surveillance and punishment, as discussed in Part V below.

International providers and pharmacies expand options even further, shipping abortion pills directly to states with abortion bans.[76] A pregnant person can buy medication abortion online from an international distributor or pharmacy.[77] People enlisted the help of an organization, Aid Access, that, until June 2023, worked exclusively with European doctors to review an online patient consultation form and dispense the pills via mail through a pharmacy in India.[78] Aid Access charges $150, which is hundreds of dollars less than medication abortion provided by a brick-and-mortar clinic.[79]

But while pills prescribed through a U.S.-telehealth consultation typically arrive within five days,[80] pills from abroad can take up to a full month to clear

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lives. *Mail Forwarding*, *supra*; *see also infra* notes 263-67 and accompanying text (discussing shield laws).

72. *See* Cohen et al., *supra* note 19, at 17.

73. *Frequently Asked Questions*, ABORTION ON DEMAND, https://perma.cc/ZV83-4L87 (archived Dec. 28, 2023).

74. *See id.*

75. *See, e.g.*, *Options*, MAYDAY HEALTH, https://perma.cc/7ZXS-DDF7 (archived Dec. 28, 2023).

76. *See* Chloe Murtagh, Elisa Wells, Elizabeth G. Raymond, Francine Coeytaux & Beverly Winikoff, *Exploring the Feasibility of Obtaining Mifepristone and Misoprostol from the Internet*, 97 CONTRACEPTION 287, 287 (2018).

77. *See infra* Part V.A (detailing the provision of abortion pills through online sources other than U.S.-based telehealth providers).

78. Marie Solis, *The Unbearable Stress of Waiting for Abortion Pills to Come in the Mail*, VICE (Feb. 26, 2020, 9:30 AM), https://perma.cc/PNM7-692P; Caroline Kitchener, *Blue-State Doctors Launch Abortion Pill Pipeline into States with Bans*, WASH. POST (July 19, 2023, 8:19 PM EDT), https://perma.cc/6VM8-3YX8.

79. *Abortion by Mail*, *supra* note 53; Upadhyay et al., *supra* note 60, at 512 exh. 2.

80. *Abortion by Mail*, *supra* note 53.

customs.[81] Given that abortion is a time-sensitive intervention with risks and side effects that increase as the pregnancy progresses, this delay can be significant; administering medication abortion too late in pregnancy can result in health complications.[82] Nevertheless, demand for Aid Access increased quickly after the Supreme Court overturned *Roe*.[83]

Over the summer of 2023, the Aid Access model changed.[84] States began passing shield laws specifically aimed at protecting providers in abortion-supportive states who were using telehealth to see patients located in anti-abortion states. Aid Access now uses U.S. medical providers to ship abortion pills without delays.[85] This new model could make reliance on international sources obsolete and has increased the ability of people in the United States, particularly those in states with bans, to access pills.[86]

In addition to virtual providers, online resources publicize the ways people can obtain pills, even in states that ban abortion. A leader in this regard is Plan C, an organization that offers information about gaining access to abortion pills in all fifty states and was instrumental to the campaign to untether abortion pills from clinical delivery.[87] Detailed instructions on medication abortion are also available in twenty-six languages at HowToUseAbortionPill.org.[88] The Miscarriage and Abortion Hotline has clinicians available to answer questions about medication abortion use, and the website *Self-Managed Abortion; Safe & Supported* has an online portal to contact trained counselors.[89] As detailed in Part V, networks of activists have also

81. *See* Solis, *supra* note 78. It is unclear whether U.S. Customs pays special attention to Aid Access packages. *See id.*; Stephania Taladrid, *The Post-Roe Abortion Underground*, NEW YORKER (Oct. 10, 2022), https://perma.cc/HCG4-X4ZQ.

82. *See* Solis, *supra* note 78.

83. Abigail R.A. Aiken, Jennifer E. Starling, James G. Scott & Rebecca Gomperts, *Requests for Self-Managed Medication Abortion Provided Using Online Telemedicine in 30 US States Before and After the* Dobbs v Jackson Women's Health Organization *Decision*, 328 JAMA 1768, 1768-1770 (2022). Once Texas's abortion ban became effective, Aid Access saw demand for their services increase 1,180% within the first week, leveling out to a 245% increase over the pre-ban demand in the subsequent three weeks. Abigail R.A. Aiken, Jennifer E. Starling, James G. Scott & Rebecca Gomperts, *Association of Texas Senate Bill 8 with Requests for Self-Managed Medication Abortion*, 5 JAMA NETWORK OPEN e221122, at 1 (2022).

84. Kitchener, *supra* note 78.

85. *Id.*

86. *Id.*

87. *See* PLAN C, https://perma.cc/VD39-QSQ5 (archived Dec. 28, 2023).

88. *How to Use the Abortion Pill*, HOW TO USE ABORTION PILL, https://perma.cc/LD6S-HJ83 (archived Dec. 28, 2023).

89. M + A HOTLINE, https://perma.cc/8HB2-AFTQ (archived Dec. 28, 2023); SASS, https://perma.cc/H2L5-8HAK (archived Dec. 28, 2023).

distributed thousands of pills to people without the involvement of any healthcare professionals. As a result, even if legal markets for abortion pills shrink, they may still be relatively accessible through underground markets no matter what the FDA or courts do.

With mifepristone under threat, there has been renewed attention on a misoprostol-only regimen.[90] Misoprostol-only abortions have historically been criticized as "a 'second tier' product . . . for already disenfranchised groups of women" because expulsion of fetal tissue may take longer and be somewhat less effective without mifepristone.[91] Yet taking misoprostol alone is recommended by the World Health Organization and is one of the most common methods of medication abortion worldwide because it is available in many countries without a prescription and at a low cost.[92] Misoprostol requires a prescription in the United States but is cheaper and more widely available than the mifepristone-misoprostol protocol.[93] Research on efficacy is ongoing: An early set of studies suggested that misoprostol alone is at least 80% effective,[94] while more recent research indicates effectiveness rates around 95%.[95] Studies also show high levels of efficacy and patient satisfaction with misoprostol-only abortions when there is proper counseling and support.[96] Depending on how the abortion pill battles described in the next Part resolve, misoprostol-only abortions may become more commonplace.

The revolutionary potential of mailed abortion pills cannot be understated. Separating abortion from in-person procedural care has created new avenues to safe abortion,[97] even in states that ban it. And this form of

90. *See* Gordon, *supra* note 28.

91. *See* FRANCINE COEYTAUX & ELISA WELLS, A TALE OF TWO NEW METHODS: APPLYING THE LESSONS LEARNED FROM EMERGENCY CONTRACEPTION TO MISOPROSTOL FOR EARLY ABORTION 11-12, 18, 24 (2016), https://perma.cc/B4UB-K5HU (noting concerns about misoprostol but expressing support for expansion of the misoprostol-only regimen).

92. Jessica Cohen et al., *Reaching Women with Instructions on Misoprostol Use in a Latin American Country*, REPROD. HEALTH MATTERS, Nov. 2005, at 84, 85; *see also* Heidi Moseson et al., *Effectiveness of Self-Managed Medication Abortion with Accompaniment Support in Argentina and Nigeria (SAFE): A Prospective, Observational Cohort Study and Non-Inferiority Analysis with Historical Controls*, 10 LANCET GLOB. HEALTH e105, e105-06 (2022).

93. *See* Gordon, *supra* note 28.

94. *See* Elizabeth G. Raymond, Margo S. Harrison & Mark A. Weaver, *Efficacy of Misoprostol Alone for First-Trimester Medical Abortion: A Systematic Review*, 133 OBSTETRICS & GYNECOLOGY 137, 142 (2019).

95. *See* Moseson et al., *supra* note 92, at e111-12.

96. *See, e.g.*, *id.*; Daniel Grossman et al., *A Harm-Reduction Model of Abortion Counseling About Misoprostol Use in Peru with Telephone and In-Person Follow-Up: A Cohort Study*, 13 PLOS ONE e0189195, at 11 (2018).

97. As this Article was being finalized, new research was published indicating that mailed abortion pills are 97.7% effective and are safe for more than 99% of people using them.
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abortion will likely be highly resilient; as one method to obtain pills becomes limited or is shut down, another will open. The next Part considers the coming conflicts over mailed medication abortion and analyzes future abortion-restrictive efforts.

II. Policing Pills

States with general abortion bans prohibit all abortion, including medication abortion.[98] Abortion pills, though, pose a unique challenge to enforcing those laws. National anti-abortion groups have recognized as much, calling medication abortion "the new frontier of abortion," requiring "new approaches."[99] As a result, anti-abortion efforts have focused much of their post-*Dobbs* energy on pills. This Part reviews several of those tactics.[100]

A. Challenging Mifepristone's FDA Approval and Regulation

The most high-profile attempt to target medication abortion is the federal case in Texas seeking to invalidate the FDA's approval and regulation of mifepristone—*FDA v. Alliance for Hippocratic Medicine*—which the Supreme Court is hearing in 2024.[101] If the lawsuit is successful, mifepristone could become more tightly regulated, with the Court reimposing old requirements that made mifepristone difficult to access. This lawsuit originally alleged that the FDA inappropriately used its authority to approve medication abortion; that medication abortion is unsafe; and that the Comstock Act, discussed in

Ushma D. Upadhyay et al., *Effectiveness and Safety of Telehealth Medication Abortion in the USA*, NATURE MED. (Feb. 15, 2024), https://perma.cc/TV7D-XPFW.

98. *See, e.g.*, ALA. CODE § 26-23H-4 (2023). As explored in Part IV.C below, there is an argument that states cannot ban an FDA-approved drug that is regulated as closely as medication abortion.

99. Kindy, *supra* note 10; *see also* Rachel Roubein with McKenzie Beard, *The Fight Over Medication Abortion Is Just Getting Started*, WASH. POST (Nov. 29, 2022, 8:01 AM EST), https://perma.cc/8KSU-RHRD (quoting the chief legal officer and general counsel of Americans United for Life as saying that stopping abortion pills is "the No. 1 issue for those who desire to protect life and women").

100. The strategies detailed in this Part are not exhaustive, and we are certain that other creative attempts to ban abortion pills are on their way. For instance, in November 2022, anti-abortion activists signaled a new strategy by petitioning the FDA to require all users of medication abortion to collect the products of conception in a medical waste bag and return it to providers for proper disposal, claiming that abortion pills were an environmental problem. Students for Life Am., Citizen Petition 1-2 (2022), https://perma.cc/92SB-CMD8.

101. All. for Hippocratic Med. v. FDA, 78 F.4th 210 (5th Cir. 2023), *cert. granted sub nom.* FDA v. All. for Hippocratic Med., 144 S. Ct. 537 (2023).

greater depth in Part II.B below, makes it illegal to mail abortifacients.[102] Now the plaintiffs are arguing that, even if their challenges to the drug's approvals are time barred, the agency's loosening of its distribution limitations was improper.[103] Reverting to the FDA's previous regulation of mifepristone would also significantly disrupt access to the drug.[104]

The plaintiffs' original allegation that mifepristone was improperly approved relates to the FDA's use of Subpart H to approve mifepristone. Subpart H is a regulatory pathway the FDA created in response to the agency's sluggish approval of new drugs to treat HIV at the height of the HIV/AIDS epidemic.[105] Its purpose was to accelerate approval for new drugs to treat serious or life-threatening illnesses by allowing companies to prove efficacy with a surrogate endpoint—e.g., tumor shrinkage instead of survival rates for a cancer drug.[106] Separately, it also allowed the agency to impose post-approval distribution limitations before Congress created the REMS program.[107]

The only part of Subpart H the agency relied upon in approving mifepristone was the provision that permitted post-approval distribution restrictions.[108] The manufacturer did not rely on a surrogate endpoint to prove efficacy, and the FDA never accelerated approval of mifepristone.[109] In fact, the agency rejected the drug's approval twice before finally approving it four years after the manufacturer submitted its application.[110] At the time of mifepristone's approval in 2000, Subpart H was the agency's only avenue for

102. Complaint paras. 22, 115-117, 205, 260, 390-396, All. for Hippocratic Med. v. FDA, No. 22-cv-00223 (N.D. Tex. Nov. 18, 2022), 2022 WL 17091784.

103. *Id.* paras. 369-81.

104. Application to Stay the Order Entered by the United States District Court for the Northern District of Texas and for an Administrative Stay at 38-39, FDA v. All. for Hippocratic Med., No. 22A902, 2023 WL 2942266 (U.S. Apr. 14, 2023), 2023 WL 3127519.

105. Lewis A. Grossman, *FDA and the Rise of the Empowered Patient*, *in* FDA IN THE TWENTY-FIRST CENTURY: THE CHALLENGES OF REGULATING DRUGS AND NEW TECHNOLOGIES 59, 65-67 (Holly Fernandez Lynch & I. Glenn Cohen eds., 2015). Subpart H is codified at 21 C.F.R. §§ 314.500-.560 (2023).

106. Grossman, *supra* note 105, at 65-67.

107. 21 C.F.R. § 314.520 (2023).

108. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-751, FOOD AND DRUG ADMINISTRATION: APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX app. I (2008), https://perma.cc/4NLP-R3PD.

109. *See id.* at 27 & n.49, app. I; *see also* Brief of Food and Drug Law Scholars as Amicus Curiae in Support of Defendants' Opposition to Plaintiffs' Motion for Preliminary Injunction at 5 n.6, All. for Hippocratic Med. v. FDA, No. 22-cv-00223 (N.D. Tex. Feb. 13, 2023), 2023 WL 2974513 [hereinafter Brief of Food and Drug Law Scholars]. Greer Donley was one of the primary amici who helped organize and draft this brief.

110. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 108, at 14-15.

limiting the distribution of new drugs after it approved them.[111] In other words, the agency used its Subpart H authority to regulate mifepristone more harshly than the vast majority of drugs, not more leniently or more expediently as the lawsuit implies.[112] Indeed, mifepristone's sponsor objected to relying on Subpart H because it worried the classification would inappropriately suggest the drug was risky.[113] In 2008, the Government Accountability Office (GAO) audited the FDA's approval of mifepristone and concluded that "the approval process for [mifepristone] was generally consistent with the approval processes for the other eight Subpart H restricted drugs."[114]

The plaintiffs allege that the FDA inappropriately used Subpart H to approve mifepristone because pregnancy is not an illness, which Subpart H requires.[115] However, the FDA uses the words "illness" and "condition" interchangeably; indeed, it did so in the preamble to the Subpart H regulations.[116] Further, when Congress passed the statute that created the REMS program in 2007, it used the terms "disease" and "condition" knowing that mifepristone would, as a result, be included in the REMS program.[117] As scholars have argued, when the FDA then used its deeming authority to reposition mifepristone under a REMS, the FDA cured any potential defect in mifepristone's original approval.[118]

Moreover, pregnancy itself can cause serious illness at any point in gestation and without any warning.[119] In finding that the FDA acted appropriately, the GAO noted the FDA's position that "[it] has broad discretion [under Subpart H] to determine which conditions or illnesses may be considered serious or life threatening, and that in the case of [mifepristone] it

111. *See id.* at 2, 10; Brief of Food and Drug Law and Health Law Scholars as Amici Curiae in Support of Plaintiff-Appellant at 10-11, GenBioPro, Inc. v. Raynes, No. 23-2194 (4th Cir. Feb. 14, 2024).

112. *See* Greer Donley & Patricia Zettler, Opinion, *The Case Against Medical Abortion Rejects Science and Embraces Falsehoods*, HILL (Nov. 27, 2022, 1:00 PM ET), https://perma.cc/85ZL-UMJS.

113. *See* U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 108, at 6, 22.

114. *Id.* at 25.

115. Complaint, *supra* note 102, paras. 49-51.

116. *New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval*, 57 Fed. Reg. 58942, 58946 (Dec. 11, 1992), https://perma.cc/5TGW-AZNZ; *see also* Brief of Food and Drug Law Scholars, *supra* note 109, at 5-9.

117. *See* Brief of Food and Drug Law Scholars, *supra* note 109, at 6, 10 (quoting Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 901(b), 121 Stat. 823, 926 (codified at 21 U.S.C. § 355-1(a)(1))).

118. *See id.* at 9-11.

119. *See Pregnancy Complications*, OFF. ON WOMEN'S HEALTH, https://perma.cc/5CDY-APTZ (last updated Dec. 29, 2022). *See generally* WILLIAMS OBSTETRICS chs. 40-68 (F. Gary Cunningham et al. eds., 26th ed. 2022).

considered the potential in any pregnancy for serious or life-threatening complications—such as hemorrhage—in its determination."[120] The GAO's thorough, independent report significantly undermines the plaintiffs' position that the FDA acted inappropriately.

The plaintiffs make other unconvincing claims[121]—for instance, that medication abortion is unsafe as a general matter and is, in particular, less safe than procedural abortion.[122] However, the Food, Drug & Cosmetic Act (FDCA) and its implementing regulations do not require drugs to be as safe or effective as procedural (or even pharmacological) alternatives; they need only be safe and effective on their own[123]—a threshold that medication abortion clearly exceeds. As noted, mifepristone is many times safer than widely used medications and fourteen times safer than childbirth.[124] And compared to procedural abortion, medication abortion has almost the same effectiveness, with only slightly higher (though still minimal) rates of complications.[125]

Nonetheless, the plaintiffs have already had some success in the lower courts, not because of the merits but rather because of the judges hearing the case. The plaintiffs filed before a federal judge widely thought to be sympathetic to anti-abortion arguments sitting in a federal circuit that is also known for its antipathy to abortion rights.[126] Their success is exceptional, given that no court has revoked a New Drug Approval (NDA) for a drug already on the market over the FDA's objection based on a differing opinion about the drug's safety and effectiveness.[127] Such revocation would bypass the

120. U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 108, at 22.

121. The FDA's response brief convincingly argues that the plaintiffs lack standing, that their claims are untimely and unexhausted, and that they are unlikely to suffer irreparable harm. *See* Defendants' Opposition to Plaintiffs' Motion for a Preliminary Injunction at 8-9, 16, 31, All. for Hippocratic Med. v. FDA, No. 22-cv-00223 (N.D. Tex. Jan. 13, 2023), 2023 WL 3011645; *see also* Jonathan H. Adler, *Assessing the Legal Claims in Alliance for Hippocratic Medicine v. FDA*, REASON: VOLOKH CONSPIRACY (Mar. 8, 2023, 2:50 PM), https://perma.cc/2F36-VNF3 (arguing, on a leading conservative legal blog, that the procedural hurdles in this lawsuit are likely insurmountable as a matter of law).

122. *See* Complaint, *supra* note 102, paras. 260-62.

123. *See* 21 U.S.C. § 355(b)(1)(A), (c)(1), (d); 21 C.F.R. pt. 310 (2023).

124. *See supra* notes 35-37 and accompanying text; Donley, *supra* note 15, at 652-53.

125. Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTETRICS & GYNECOLOGY 175, 181 (2015).

126. *See* Caroline Kitchener & Ann E. Marimow, *The Texas Judge Who Could Take Down the Abortion Pill*, WASH. POST (Feb. 25, 2023, 6:00 AM EST), https://perma.cc/D5WB-A9E3; David S. Cohen, Greer Donley & Rachel Rebouché, *The FDA's Step Forward on Medication Abortion Isn't Even Close to Enough*, SLATE (Jan. 5, 2023, 12:31 PM), https://perma.cc/2JGN-DTH7.

127. Brief of Food and Drug Law Scholars, *supra* note 109, at 16-19; Greer Donley & Patricia J. Zettler, *Response to* Listening to Mifepristone, 80 N.Y.U. ANN. SURV. AM. L. 63, 65-68 (2023).

procedural protections for holders of NDAs explicitly required by Congress before the agency can withdraw its approval of a product. Pharmaceutical companies often voluntarily recall products when the FDA finds serious safety or efficacy concerns, but if the FDA moves to revoke an approval over a company's objection, section 355(e) of the FDCA requires it to hold a public hearing and issue a formal decision before it can do so.[128] A nonexpert court overriding the FDA's scientific judgment and Congress's procedural protections would have significant reverberations throughout food and drug law, disincentivizing pharmaceutical innovation.[129] These consequences explain why major pharmaceutical companies filed an amicus brief supporting the FDA.[130]

Nevertheless, in a widely criticized opinion that adopted the anti-abortion plaintiffs' arguments and rhetoric almost in their entirety, the U.S. District Court for the Northern District of Texas issued a preliminary injunction in April 2023 suspending mifepristone's approval.[131] On emergency appeal, the Fifth Circuit stayed the district court's suspension of mifepristone's approval but affirmed the injunction's suspension of all FDA action starting in 2016, reinstating a harsher mifepristone REMS and an outdated mifepristone label.[132] Before the injunction could take effect, however, the Supreme Court stayed the order until final disposition at the Supreme Court, which should occur in the summer of 2024.[133]

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128. 21 U.S.C. § 355(e).

129. *See* Greer Donley & Rachel Sachs, Opinion, *The Stakes in the Texas Abortion Medication Suit Are Broader than Just One Pill*, WASH. POST (Mar. 3, 2023, 7:45 AM EST), https://perma.cc/R6D3-XUY9. Future litigation targeting controversial healthcare products—such as medications for COVID-19, HIV, and gender-affirming care, as well as vaccines in general—could have drastic effects on the availability of products. *See id.*

130. Brief of Pharmaceutical Companies, Executives, and Investors as Amici Curiae in Support of Appellants' Motion for Stay Pending Appeal at 3, All. for Hippocratic Med. v. FDA, No. 23-10362 (5th Cir. Apr. 11, 2023), ECF No. 118 ("[T]he district court's lawless opinion will empower any plaintiff to grind drug approvals to a halt, disrupting patients' access to critical medicines. That outcome would chill crucial research and development, undermine the viability of investments in this important sector, and wreak havoc on drug development and approval generally, causing widespread harm to patients, providers, and the entire pharmaceutical industry."); *see also* Letter in Support of FDA's Authority to Regulate Medicines (2023), https://perma.cc/XS78-A2WR; Carma Hassan, *Drugmakers Sign Letter Supporting FDA and Calling for Reversal of Texas Judge's Mifepristone Ruling*, CNN (Apr. 10, 2023, 3:12 PM EDT), https://perma.cc/9XZP-TX2A.

131. All. for Hippocratic Med. v. FDA, No. 22-CV-223, 2023 WL 2825871, at *32 (N.D. Tex. Apr. 7, 2023), *aff'd in part, vacated in part*, 78 F.4th 210 (5th Cir. 2023), *cert. granted sub nom.* FDA v. All. for Hippocratic Med., 144 S. Ct. 537 (2023).

132. All. for Hippocratic Med. v. FDA, No. 23-10362, 2023 WL 2913725, at *1 (5th Cir. Apr. 12, 2023).

133. Danco Lab'ys v. All. for Hippocratic Med., 143 S. Ct. 1075 (2023) (Alito, J., in chambers).

In the meantime, the Fifth Circuit ruled in August 2023 that the plaintiffs likely failed to (1) timely challenge the brand approval and (2) plead an injury with regard to mifepristone's generic approval. However, the Circuit found that the agency's subsequent changes expanding the mifepristone label and loosening the mifepristone REMS were likely to be arbitrary and capricious and thus unlawful.[134] The decision contradicts longstanding precedent regarding justiciability and administrative law.[135] The Fifth Circuit's decision will have no immediate effect because of the Supreme Court's stay, but if the Supreme Court issues a similar decision, the effects would be significant.[136]

Mifepristone's pre-2016 label approved its use only through seven weeks of pregnancy at a much higher dose that involves greater side effects.[137] Though doctors are not bound by the label and could prescribe the drug using the current dose during the first trimester, manufacturers and distributors would have to relabel the product before shipping it in interstate commerce,[138] almost certainly leading to disruptions in the supply chain, at least in the short term.[139] But even more importantly, returning to the pre-2016 REMS would reimpose requirements that forced patients to pick up the medications in person at a healthcare facility, ending virtual provision and requiring travel to a clinic, perhaps multiple times.[140] This would likely overwhelm the already overburdened brick-and-mortar clinics. And the old REMS would also reduce the number of abortion providers by reimposing a requirement that only physicians prescribe the drug.[141] The cumulative result would be a drastic

134. All. for Hippocratic Med. v. FDA, 78 F.4th 210, 246 (5th Cir. 2023).

135. *See* Adam Unikowsky, *The Fifth Circuit's Mifepristone Opinion Is Wrong: Part 1 of 2: Standing*, ADAM'S LEGAL NEWSL. (Aug. 17, 2023), https://perma.cc/Z5YN-TFUT; Adam Unikowsky, *The Fifth Circuit's Mifepristone Opinion Is Wrong: Part 2 of 2: The Merits*, ADAM'S LEGAL NEWSL. (Aug. 20, 2023), https://perma.cc/B6P2-WJRE.

136. David S. Cohen, Greer Donley & Rachel Rebouché, *The 5th Circuit's New Abortion Pill Ruling Targets Patients Directly*, SLATE (Aug. 17, 2023, 1:21 PM), https://perma.cc/4JXD-2MLY.

137. *Id.*; *cf.* Cui-Lan Li et al., *Effectiveness and Safety of Lower Doses of Mifepristone Combined with Misoprostol for the Termination of Ultra-Early Pregnancy: A Dose-Ranging Randomized Controlled Trial*, 22 REPROD. SCIS. 706, 710 (2015), https://perma.cc/QHJ7-UFPK (finding that lower doses of mifepristone result in reduced bleeding and fewer side effects).

138. Emergency Application for Stay of Preliminary Injunction Pending Appeal at 32, *Danco Lab'ys*, 143 S. Ct. 1075, 2023 WL 3122097.

139. *Id.*

140. *Id.* at 38-39 (explaining how returning to the pre-2016 REMS would increase in-person appointments, which in turn require more travel especially with many clinics having closed because of *Dobbs*).

141. *See* Application to Stay the Order Entered by the United States District Court for the Northern District of Texas and for an Administrative Stay at 9-10, FDA v. All. for Hippocratic Med., No. 22A902 (U.S. Apr. 14, 2023), 2023 WL 3127519, *stay granted sub nom. Danco Lab'ys*, 143 S. Ct. 1075 (Alito, J., in chambers).

change to the status quo of abortion provision with significant reductions in access in abortion-supportive states.

Even so, the FDA will have some discretion once the Supreme Court's final order is issued. First, if the Court orders the FDA to revoke the mifepristone approval (counter to what the Fifth Circuit held), the agency could interpret this demand to require it to start the procedures under Section 355(e). This would mean that mifepristone remains on the market for the months—or even years—necessary to conduct the requisite hearings and deliberations. In the meantime, the sponsor could submit a new NDA for approval that is not based on Subpart H. The FDA could then start the months-long process of approving mifepristone anew—the evidence would be readily available—while the drug remains legally available.

Second, if the Court bypasses the agency and suspends mifepristone's approval outright—as the district court initially did and one judge in the Fifth Circuit sought—the FDA could exercise its enforcement discretion, providing manufacturers and distributors safe harbor to continue selling the drug. The agency could refuse to enforce (1) the requirements found in the pre-2016 REMS that are no longer part of the current REMS or (2) the misbranding regulations when mifepristone is marketed with the 2023 label. The agency has used its enforcement discretion previously for other controversial drugs, like execution drugs, and the Supreme Court has affirmed the agency's authority to do so.[142] It has even used this discretion for mifepristone in the past, allowing providers to mail the drug directly to patients during the COVID-19 pandemic when the REMS still required that patients pick up the drug in person.[143] Even Justice Alito recognized the power of the FDA's enforcement discretion when he dissented from the issuance of the Court's stay.[144]

Enforcement discretion relies on our government's constitutional structure: It is the executive branch, not the judicial branch, that decides if and when to enforce statutes.[145] Given that the FDA lacks the capacity to enforce

142. *See* Heckler v. Chaney, 470 U.S. 821, 827-38 (1985) (affirming the FDA's broad enforcement discretion in the context of lethal injection drugs); David S. Cohen, Greer Donley & Rachel Rebouché, *Actually, One Texas Judge Is Not the Final Decision-Maker on Medication Abortion*, SLATE (Feb. 28, 2023, 2:11 PM), https://perma.cc/C29G-7AME.

143. Letter from Janet Woodcock, Acting Comm'r, FDA, to Maureen G. Phipps, CEO, Am. Coll. of Obstetricians & Gynecologists, and William Grobman, President, Soc'y for Maternal-Fetal Med. (Apr. 12, 2021), https://perma.cc/5KFR-EW2D.

144. *Danco Lab'ys*, 143 S. Ct. at 1076 (Alito, J., in chambers, dissenting) ("The FDA has previously invoked enforcement discretion to permit the distribution of mifepristone in a way that the regulations then in force prohibited, and here, the Government has not dispelled legitimate doubts that it would even obey an unfavorable order in these cases, much less that it would choose to take enforcement actions to which it has strong objections.").

145. U.S. CONST. art. II, § 3; United States v. Texas, 143 S. Ct. 1964, 1971 (2023).

every violation of the FDCA,[146] the FDA currently has a risk-based enforcement strategy for unapproved drugs that deprioritizes those posing low safety risks, which would be true for mifepristone.[147] Nonexpert courts should not be able to second-guess how the agency prioritizes its limited resources. Importantly, enforcement discretion does not require the agency to "ignore" a court order; rather, enforcement discretion is needed only if the agency abides by a court order suspending its approval or regulation of mifepristone.[148] If the agency ignored the suspension, there would be no need for enforcement discretion at all. Though a notice of enforcement discretion would certainly become the subject of litigation itself—as is true in the underlying Texas litigation, which includes a challenge to the FDA's use of enforcement discretion during the pandemic[149]—it could at least buy time in the short term while, for instance, a new drug application is filed.

Even if the FDA has enforcement discretion, must other entities and individuals that provide abortion abide by a court order? A court order could theoretically prohibit Danco Laboratories, the brand-named manufacturer who has intervened in the case, from distributing the drug. But because judges only have the power to bind parties to a case,[150] nonparties—including the generic manufacturer of mifepristone, clinics, providers, and patients—could rely on the FDA's enforcement discretion and continue as before without violating a binding court order.

Practically speaking, the FDA under a Biden presidency is unlikely to pursue an enforcement action related to mifepristone. But whether the agency will formally announce its enforcement discretion is another question. A formal notice provides reliance that would make it difficult for a future Republican administration to override retrospectively.[151] Without a formal notice against enforcement, the manufacturers and distributors of mifepristone might conclude that it is too risky to distribute the drug (if it is unapproved) or rely on the 2023 REMS (if the pre-2016 REMS governs). If so, this could lead to ripple effects that challenge and strain abortion provision in

146. *See Heckler*, 470 U.S. at 831-32.

147. *Unapproved Drugs*, FDA, https://perma.cc/5AYN-R7JW (last updated June 2, 2021); *see supra* notes 34-38 and accompanying text.

148. *See* David S. Cohen, Greer Donley & Rachel Rebouché, Opinion, *To Protect Abortion Access, the FDA Should Decline to Enforce a Mifepristone Ban*, GUARDIAN (Apr. 12, 2023, 6:15 AM EDT), https://perma.cc/LJS4-Z96H.

149. Oddly, the Fifth Circuit never addressed the argument that it lacked the authority to review the 2021 enforcement discretion notice for mifepristone. *See generally* All. for Hippocratic Med. v. FDA, 78 F.4th 210 (5th Cir. 2023).

150. FED. R. CIV. P. 65(d)(2).

151. *See* Cox v. Louisiana, 379 U.S. 559, 571 (1965); United States v. Cox, 906 F.3d 1170, 1191 (10th Cir. 2018).

states where abortion remains legally protected. As noted, most abortions in the United States are completed with pills, and almost all of them occur with the mifepristone-misoprostol combination.[152]

Even if this lawsuit is successful, because the plaintiffs did not challenge the approval of misoprostol, the Court's decision would not impact the off-label use of that drug by itself for abortion.[153] Abortion providers have already prepared for the possibility of transitioning to misoprostol-only abortions.[154] As noted, misoprostol-only abortions are often seen as less effective (though recent research has challenged that conclusion).[155] If access to mifepristone becomes strained, misoprostol-only abortions could become commonplace. Misoprostol-only abortions might preserve access but at a potential public health cost if patients are forced into a possibly less effective regimen that has more side effects.

Patients might have other ways to obtain mifepristone legally and extralegally, regardless of the outcome of the case. The FDA's personal-use exemption allows individual patients to buy unapproved drugs from international markets for their own personal use, at least in certain contexts.[156] Indeed, the personal-use exemption's application to mifepristone—then known as RU-486—was tested leading up to mifepristone's approval in 2000.[157] As such, federal law should not impose a barrier for people buying mifepristone or misoprostol online from international sources for their own use (though state laws might). Even if it becomes harder to access mifepristone because of this case, people will continue to be able to obtain it outside of the formal healthcare system, potentially creating other public health consequences.[158]

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152. *See supra* notes 8, 26 and accompanying text.

153. A ruling that revives the Comstock Act as a ban on mailing any abortifacient, *see infra* Part II.B, could also threaten misoprostol-only abortions, though such a ruling from a district court judge would have limited impact beyond the parties to the case.

154. *See, e.g.*, Elizabeth G. Raymond et al., Commentary, *Medication Abortion with Misoprostol-Only: A Sample Protocol*, 121 CONTRACEPTION art. 109998, at 1-2 (2023). Quickly doing so could trigger drug shortages. *See* Oceane Duboust & Natalie Huet, *France Fears Abortion Pill Shortage as US States Stockpile Misoprostol amid Supreme Court Battle*, EURONEWS: HEALTH (updated Apr. 20, 2023, 10:31 PM), https://perma.cc/VA9T-NQHE; Rachel Gilmore, *Canada Has Been Facing an Abortion Pill Shortage. Here's What to Know*, GLOB. NEWS (Dec. 16, 2022, 5:23 PM), https://perma.cc/CPH3-4YWZ.

155. *See supra* notes 90-97 and accompanying text.

156. *See Personal Importation*, FDA, https://perma.cc/PX6N-DD7T (last updated Dec. 7, 2023).

157. Donley, *supra* note 15, at 670-673. Under President George H.W. Bush, the FDA used an import alert to ban the importation of mifepristone for personal use, underscoring the various tools the FDA has to try to limit or expand medication abortion access. *See id.* This was challenged in court, eventually removed under President Clinton, and never reimposed. *Id.*

158. For a detailed discussion on obtaining abortion pills through these informal networks, see Part V.A below.

B. The Comstock Act

A little-known part of an old federal law, the Comstock Act, has become a major component of the legal attacks on abortion pills. The Act was named after Anthony Comstock, a nineteenth-century anti-abortion and anti-birth control crusader.[159] The law dates back to 1873,[160] when women could not vote and had no separate legal status apart from their husbands.[161] As originally written, the law prohibited importation and mailing of articles "designed or intended for the prevention of conception or procuring of abortion."[162] In 1876, the law was updated to clarify that the obscene material covered by the Act was "non-mailable matter, and shall not be conveyed in the mails, nor delivered from any post-office nor by any letter-carrier."[163] In 1909, the law was expanded to include mailing through express mail services or other common carriers.[164]

For the first forty years of its existence, the Comstock Act was successfully enforced. Two years before his death, Anthony Comstock estimated that, under the law, more than 3,500 people were convicted and almost 160 tons of literature were destroyed.[165] However, enforcement of the law and its encroachment into people's private lives incited public backlash that ultimately culminated in the law's disuse.[166]

A series of state and federal court challenges also drastically limited the application of the Comstock Act and its state analogues.[167] In 1930, dicta from

159. *See generally* AMY SOHN, THE MAN WHO HATED WOMEN: SEX, CENSORSHIP, AND CIVIL LIBERTIES IN THE GILDED AGE (2021). The Comstock Act is a series of laws, including state versions, and some people thus use the plural "Comstock Acts" when referring to them. Here, we use the singular but, in doing so, refer to all of the statutes covered by this moniker. *See* Note, *Judicial Regulation of Birth Control Under Obscenity Laws*, 50 YALE L.J. 682, 682-83 (1941) (discussing the Comstock Acts).

160. Margaret A. Blanchard & John E. Semonche, *Anthony Comstock and His Adversaries: The Mixed Legacy of This Battle for Free Speech*, 11 COMMC'N. L. & POL'Y 317, 326-27 (2006).

161. *See* Reva B. Siegel, *She the People: The Nineteenth Amendment, Sex Equality, Federalism, and the Family*, 115 HARV. L. REV. 947, 981-87 (2002) (explaining the connection between coverture and lack of voting rights for women).

162. Comstock Act, ch. 258, § 2, 17 Stat. 598, 599 (1873).

163. Act of July 12, 1876, ch. 186, 19 Stat. 90.

164. Act of Mar. 4, 1909, ch. 321, § 245, 35 Stat. 1088, 1138 (codified as amended at 18 U.S.C. § 1461).

165. *See* Margaret A. Blanchard, *The American Urge to Censor: Freedom of Expression Versus the Desire to Sanitize Society—From Anthony Comstock to 2 Live Crew*, 33 WM. & MARY L. REV. 741, 758 (1992).

166. *See id.*

167. *See, e.g.*, People v. Sanger, 118 N.E. 637, 637-38 (N.Y. 1918) (explaining that the law "protect[s] the physician who in good faith gives [contraceptive] help or advice to a married person to cure or prevent disease" and extending that protection to "druggist[s]" as well).

the Second Circuit indicated that the Act only applies when the sender had an intent to mail or ship items for "*illegal* contraception or abortion or for indecent or immoral purposes."[168] The Sixth Circuit adopted this reasoning three years later, holding that there must be intent to ship for "condemned purposes."[169] As the Second Circuit further explained in 1936, any other interpretation of the broad language of the Comstock Act would have the anomalous result of making illegal *any* item that *could* be used for contraception or abortion.[170] Cases that narrowly interpreted the Comstock Act are widely considered to have paved the way for broad legalization of birth control,[171] and *Griswold v. Connecticut* put the constitutional nail in the Comstock coffin.[172] Congress deleted references to birth control from the statute in 1971.[173]

Although these cases all dealt with contraception, the Comstock Act's abortion provisions became dead letters as well. Language from each of the cases discussed above limited those abortion provisions to *unlawful* abortions, either because of explicit statutory text or because of the same reasoning used for contraception.[174] Without this interpretation, the Act's ban would cover every abortion—including those to save the life of the pregnant person—that was legal at the time of the Act's passage.[175] Even so, prior Comstock decisions leave some ambiguity as to whether "unlawful" refers to state or federal law. As of the time of writing, there is no ban on medication abortion under federal law, so if federal law is the relevant inquiry, the Comstock Act would not apply to abortion pills *anywhere*. If the term "unlawful" refers to legality under state law, however, then the Comstock Act would restrict the mailing of abortion pills for the purpose of violating a state's abortion law. That said, the

168. Youngs Rubber Corp. v. C.I. Lee & Co., 45 F.2d 103, 108 (2d Cir. 1930) (emphasis added).

169. Davis v. United States, 62 F.2d 473, 475 (6th Cir. 1933).

170. *See* United States v. One Package, 86 F.2d 737, 739 (2d Cir. 1936); *see also Davis*, 62 F.2d at 475 (explaining that the Comstock Act "must be given a reasonable construction").

171. *See* Note, *supra* note 159, at 684-85; *see also* United States v. Nicholas, 97 F.2d 510, 511 (2d Cir. 1938); Consumers Union of U.S., Inc. v. Walker, 145 F.2d 33, 34-35 (D.C. Cir. 1944); Poe v. Ullman, 367 U.S. 497, 546 n.12 (1961) (Harlan, J., dissenting).

172. 381 U.S. 479, 480-81 (1965).

173. Act of Jan. 8, 1971, Pub. L. No. 91-662, 84 Stat. 1973 (codified as amended in scattered sections of the U.S. Code); Sheryl L. Herndon, *The Communications Decency Act: Aborting the First Amendment?*, 3 RICH. J.L. & TECH. 2, 2 (1997).

174. *See* Youngs Rubber Corp. v. C.I. Lee & Co., 45 F.2d 103, 108 (2d Cir. 1930); *One Package*, 86 F.2d at 739; *see also* Bours v. United States, 229 F. 960, 964 (7th Cir. 1915) (reading a life exception into the Comstock Act's abortion provision).

175. *See* Roe v. Wade, 410 U.S. 113, 138-39 (1973).

Comstock Act has never been interpreted to ban mailing material that was related to lawful abortions.[176]

In 1994, Congress increased the fine under the law, but only for a related provision about distributing information about abortion, not mailing pills or articles for abortion.[177] In the Telecommunications Act of 1996, the language was broadened to include information communicated through computers, but this provision was widely considered an unconstitutional restriction on free speech and was never enforced.[178]

Currently, the abortion provisions of the Act are in 18 U.S.C. §§ 1461 and 1462. Relevant to abortion pills, Section 1461 declares as nonmailable matter:

> Every article or thing designed, adapted, or intended for producing abortion, or for any indecent or immoral use; and
>
> Every article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use or apply it for producing abortion, or for any indecent or immoral purpose . . . .[179]

Section 1462, which applies to express companies or other common carriers, contains a shorter definition of prohibited items: "any drug, medicine, article, or thing designed, adapted, or intended for producing abortion."[180]

Before *Dobbs*, these provisions were considered unenforceable with respect to abortion. The federal government had stopped enforcing the Comstock Act in 1936, after *United States v. One Package* and long before *Roe*;[181] after *Roe*, the law was presumed unconstitutional despite remaining on the books. And the prohibitions on distributing any item that could be used to procure an abortion

176. *See One Package*, 86 F.2d at 739 ("Nor can we see why the statute should, at least in section 1, except articles for producing abortions if used to safeguard life, and bar articles for preventing conception though employed by a physician in the practice of his profession in order to protect the health of his patients or to save them from infection.").

177. Violent Crime Control and Law Enforcement Act of 1994, § 330016(1)(K)-(L), Pub. L. No. 103-322, 108 Stat. 1796, 2147 (codified as amended at 18 U.S.C. §§ 1461-1462); Herndon, *supra* note 173, at 2-3.

178. Telecommunications Act of 1996, § 507(a), Pub. L. No. 104-104, 110 Stat. 56, 137 (codified at 18 U.S.C. § 1462); Herndon, *supra* note 173, at 3 (noting that the law was immediately understood to be at odds with the First Amendment and thus was not enforced). The Clinton administration noted in a filing in a case challenging part of the 1996 act that "the Department [of Justice] has a longstanding policy that previous such provisions are unconstitutional and will not be enforced" and that no one will be prosecuted under the new law. ACLU v. Reno, 929 F. Supp. 824, 829 n.7 (E.D. Pa. 1996) (quoting Defendant's Opposition to Plaintiffs' Motion for a Temporary Restraining Order at 19 n.11, *ACLU*, 929 F. Supp. 824 (No. 96-963), 1996 WL 33489555).

179. 18 U.S.C. § 1461.

180. 18 U.S.C. § 1462(c).

181. 86 F.2d 737 (2d Cir. 1936); *see* Greer Donley, *Contraceptive Equity: Curing the Sex Discrimination in the ACA's Mandate*, 71 ALA. L. REV. 499, 509-10 (2019).

had never been raised in any modern abortion litigation, including a recent, pre-*Dobbs* case that challenged the FDA's decision to permit the mailing of abortion pills.[182]

After *Dobbs*, however, opponents of abortion have made raising Comstock from the dead a key part of their current strategy. It has appeared in anti-abortion legal briefs,[183] threatening letters from state legislators and attorneys general,[184] and local ordinances attempting to ban abortion within city limits.[185] More prominently, the lawsuit challenging the FDA's approval of mifepristone, discussed in Part II.A, also invokes the Comstock Act as a basis for declaring the FDA's approval *ultra vires*, or beyond the agency's legal power.[186] As a result, the Supreme Court may weigh in on Comstock this term. Technically, Comstock only declares items nonmailable; it does not make abortion pills illegal and thus does not stop the FDA from approving an abortifacient. However, the Act would erect obstacles to the drug's distribution if it could not be shipped through the mail or an express carrier.[187] In a partial dissent in the Fifth Circuit decision regarding mifepristone, one of the judges argued not only that the FDA's decision to remove the in-person dispensing requirement was illegal under Comstock but also that Comstock bars shipment with private carriers because they use online systems for shipping.[188]

So far, abortion providers, abortion-rights organizations, pharmacies, and drug manufacturers have ignored the Comstock Act.[189] As the first courts to address the Act noted, the plain language of the Comstock Act is so broad that it would cover almost every medical instrument, supply, or drug that could

182. *See generally* FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578 (2021) (Roberts, C.J., in chambers).

183. *See, e.g.*, Defendant's Memorandum in Opposition to Plaintiff's Motion for Leave to File Amended Complaint at 2, 11-12, 19-20, GenBioPro, Inc. v Dobbs, No. 20-cv-00652 (S.D. Miss. Aug. 4, 2022), ECF No. 44.

184. *See, e.g.*, Letter from Utah House of Representatives to Utah Abortion Fund 2 (Sept. 15, 2022), https://perma.cc/UT9W-M2TD; Letter from Andrew Bailey, Att'y Gen., Mo., to Danielle Grey, Exec. Vice President, Walgreens Boots All., Inc. (Feb. 1, 2023), https://perma.cc/854U-SVNN.

185. *See, e.g.*, Hobbs, N.M., Ordinance No. 1147 (Nov. 7, 2022) (codified at HOBBS, N.M., MUN. CODE ch. 5.52), https://perma.cc/B6N3-PBY4; Grant McGee, *Clovis Passes Anti-Abortion Ordinance*, QUAY CNTY. SUN (Jan. 11, 2023), https://perma.cc/4EAB-3FJR. A similar ordinance was defeated in Pueblo, Colorado. Elliott Wenzler, *Pueblo Rejects Abortion Ban, Tossing First Attempt to Challenge State Law Protecting the Procedure*, COLO. SUN (Dec. 12, 2022, 9:53 PM MST), https://perma.cc/M2TK-6XB2.

186. Complaint, *supra* note 102, paras. 22, 115-17, 391-96, L.

187. *See* All. for Hippocratic Med. v. FDA, No. 22-CV-223, 2023 WL 2825871, at *18 (N.D. Tex. Apr. 7, 2023); All. for Hippocratic Med. v. FDA, 78 F.4th 210, 267-69 (5th Cir. 2023) (Ho, J., concurring in part and dissenting in part).

188. *All. for Hippocratic Med.*, 78 F.4th at 268 (Ho, J., concurring and dissenting).

189. *See, e.g.*, PLAN C, *supra* note 87.

possibly be used for any abortion.[190] In other words, absent the narrowing construction applied by the federal circuit courts of the early 1900s, the law's plain terms could effectively ban *all* abortion nationwide because almost every pill, instrument, or other item used in an abortion clinic or by a virtual abortion provider moves through the mail or an express carrier at some point. Moreover, this ban would have no exceptions, including for the life or health of the pregnant person.[191]

The Department of Justice has rejected the anti-abortion view of Comstock and in doing so illustrated the problems of applying the Act. In December 2022, the Office of Legal Counsel released a memo on the Comstock Act's applicability.[192] After recounting the history of the Comstock Act and the federal appeals court rulings that narrowed it, the memo focuses on the intent required to prove criminality under the Act.[193] The memo concludes that, because mailing only for illegal abortions is covered, the Act does not "prohibit the conveyance of articles intended for preventing conception or producing an abortion where the sender lacks the intent that those items should be used unlawfully."[194] Mailing pills to states where abortion is legal would certainly not meet this standard, but the memo goes further and states that, absent possessing specific intent to accomplish an illegal abortion, someone mailing pills into a state where abortion is generally banned would also not violate the Act.[195] The memo lists eight possible legal uses for abortion pills within states where abortion is banned, including for health- or life-saving abortions, for miscarriage management, or for abortions before the gestational limit.[196] Thus, the government "could not reasonably assume that the drugs are nonmailable simply because they are being sent into a jurisdiction that significantly restricts abortion."[197] As a result, abortion pills, under this interpretation, remain legally mailable under federal law throughout the country.[198] The memo further argues that Congress and the Postal Service ratified this interpretation through subsequent acts.[199]

190. *See supra* notes 167-70 and accompanying text.

191. *See supra* notes 174-75 and accompanying text.

192. Application of the Comstock Act to the Mailing of Prescription Drugs That Can Be Used for Abortions, 46 Op. O.L.C., slip op. (Dec. 23, 2022) [hereinafter OLC Memo], https://perma.cc/9KG4-7UT2.

193. *Id.* at 3-11.

194. *Id.* at 16.

195. *Id.* at 17.

196. *Id.* at 18-20.

197. *Id.* at 20.

198. Of course, the OLC memo only covers whether mailing pills violates the federal Comstock Act and does not express any view on state law implications.

199. OLC Memo, *supra* note 192, at 11-16.

Beyond these judicial and executive interpretations of the Comstock Act, prosecuting someone for violating a statute that has been unenforced for almost a century raises questions of fundamental fairness.[200] Paraphrasing Judge Bork, Judge Posner explained, "[T]he sudden revival of a long forgotten law carrying harsh penalties . . . might encounter a defense of desuetude."[201] Despite the doctrine's grounding in democratic self-governance and the fair warning requirements of the Due Process Clause, U.S. courts have generally been loath to adopt the defense of desuetude.[202] But prosecutions under the Comstock Act's prohibitions on mailing abortion pills may renew interest in this defense.[203] Further, now that the Department of Justice has publicly stated that the law does not apply to those mailing pills without a specific intent to procure illegal abortions, prosecuting someone under a different interpretation raises even more serious questions of government entrapment.[204] Moreover, applying a law that has not been enforced for almost a century to prohibit mailing *all* things that can cause an abortion, not just pills, would have the absurd effect of banning abortion nationwide without any new legislative action.[205] And finally, courts might consider whether imposing a law about abortion from a period when women were not a part of the legislature, could not vote, and lacked basic civil rights would be inconsistent with basic premises of equality and due process.

C. The Location of Abortion

In the wake of *Dobbs*, questions about the extraterritorial effect of anti-abortion laws have loomed large. In a previous article, we charted how such extraterritorial application of abortion laws could work.[206] We noted that states could pass laws that specifically target extraterritorial conduct or try to prosecute extraterritorial abortions under already existing criminal laws.

200. *See* Cory R. Chivers, *Desuetude, Due Process, and the Scarlet Letter Revisited*, 1992 UTAH L. REV. 449, 464-65 (1992).

201. *See* Cent. Nat'l Bank of Mattoon v. U.S. Dep't of Treasury, 912 F.2d 897, 906 (7th Cir. 1990) (suggesting this should be reserved for "extreme cases").

202. *See* Joel S. Johnson, *Dealing with Dead Crimes*, 111 GEO. L.J. 95, 108-13 (2022).

203. *Cf.* GenBioPro, Inc. v. Sorsaia, No. 23-0058, 2023 WL 3211847, at *7 (S.D. W. Va. May 2, 2023) (declining to apply the "widely abrogated 19th century statute" that has been applied only to illegal abortion "consistently since 1915"), *appeal docketed*, No. 23-2194 (4th Cir. Nov. 15, 2023).

204. *See* Cox v. Louisiana, 379 U.S. 559, 571 (1965); United States v. Cox, 906 F.3d 1170, 1191 (10th Cir. 2018).

205. For a general explanation and discussion of the doctrine of absurdity, see Glen Staszewski, *Avoiding Absurdity*, 81 IND. L.J. 1001 (2006).

206. *See* Cohen et al., *supra* note 19, at 22-53; Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2337 (2022) (Breyer, Sotomayor & Kagan, JJ., dissenting) ("Finally, the majority's ruling today invites a host of questions about interstate conflicts.").

In the context of abortion pills, the question of extraterritorial application is even more complicated because anti-abortion states could try to claim an abortion occurred in their territory.[207] First, telehealth means that a provider could be in an abortion-supportive state like Massachusetts but meeting (either knowingly or unknowingly) with an abortion patient online who is physically located in an anti-abortion state like Texas. As described in Part III below, the standard for telehealth is that the care occurs where the patient is located.[208] So Texas could argue that the abortion occurred in Texas if the patient was located there for the telehealth consultation, received the pills by mail there, or consumed them there—even though the provider was in a state that permits telehealth for abortion. Prosecuting an out-of-state provider in this context would still raise issues of extraterritorial application of Texas law, but it would be easier for Texas to argue that its laws should govern when the patient remained in Texas rather than when the patient traveled to another state for care.

Second, where does a medication abortion take place for people who travel to states where abortion remains legal? Consider four different possible locations related to an in-person visit to obtain abortion pills:

> 1) Where the patient interacts with the medical professional and receives the pills.
>
> 2) Where the patient ingests the mifepristone. This could be in the medical office, or it could be later when the patient returns home.
>
> 3) Where the patient ingests the misoprostol. This usually occurs twenty-four hours after the mifepristone is taken.
>
> 4) Where the patient expels the products of conception.[209] This could occur within hours of taking the misoprostol or up to a few days later.[210]

Given the time lapse that can occur between these four different steps, it is possible that the abortion patient could be in four different locations over the course of completing the abortion. Telehealth complicates these scenarios, as the provider and patient could be in separate locations for the initial consultation.[211] The more likely situation for a traveling patient, though, is that

207. The discussion in this Subpart is about state-to-state variation, but problems similar to those identified here could arise within a state where abortion is permitted if the patient accesses abortion via telehealth while residing in a town that has passed an anti-abortion local ordinance.

208. *See infra* note 259 and accompanying text.

209. Cohen et al., *supra* note 19, at 42.

210. *See* Andrea Henkel, Klaira Lerma, Paul D. Blumenthal & Kate A. Shaw, *Evaluation of Shorter Mifepristone to Misoprostol Intervals for Second Trimester Medical Abortion: A Retrospective Cohort Study*, 102 CONTRACEPTION 327, 330 tbl.2 (2020).

211. Imagine a provider in New York communicates via telehealth with a patient physically located in Pennsylvania. Because of Pennsylvania rules, the provider cannot mail the pills into that state, so the provider mails them to a P.O. box in New Jersey,

footnote continued on next page

the patient would be in an abortion-supportive state for steps one and two but then return to their home state (where abortion might be banned) for steps three and four. The anti-abortion state would argue that the abortion occurred within its jurisdiction and that it is not trying to punish extraterritorial conduct

Because abortion is statutorily defined by state law, there will be no consistent answer to the questions raised here. One state could consider an abortion to have taken place where the medication is prescribed or given to the patient. This is the approach taken by North Dakota in its provisions regarding medication abortion.[212] Other states, though, could choose to follow a different rule, considering an abortion to take place wherever either the mifepristone or misoprostol is ingested or where the products of conception are expelled. Thus far, no state statute has explicitly followed this path, but anti-abortion states could change their statutes to define abortion to occur where any part of the abortion process occurs.

Even without a statutory change to abortion laws, states also could attempt to interpret existing law to apply when any part of the abortion occurs in their borders. For instance, a group of Texas legislators sent letters to organizations that are helping Texans access legal abortion elsewhere, claiming that Texas's "criminal prohibitions extend to drug-induced abortions if any part of the drug regimen is ingested in Texas, even if the drugs were dispensed by an out-of-state abortionist."[213] Prosecutors might try to charge based on this theory, though there are practical challenges to doing so. As discussed in Part V, most abortion definitions specifically exclude the removal of dead pregnancy tissue.[214] Typically, medication abortion is described in this way: Mifepristone stops the pregnancy from developing and misoprostol induces contractions to expel the tissue.[215] Thus, if the misoprostol only expels

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where the patient picks them up. The patient, who is traveling to see family, then travels to Delaware, where she takes the mifepristone. Then she goes to Maryland a day later where she takes the misoprostol. Then, when she finally arrives in Virginia, she expels the products of conception. There are six different states in this admittedly far-fetched hypothetical—when and in which one did the abortion take place?

212. N.D. CENT. CODE § 14-02.1-03.5(1) (2023); *see also* MKB Mgmt. Corp. v. Burdick, 855 N.W.2d 31, 49 (N.D. 2014) (per curiam) (Vande Walle, C.J., concurring) (discussing the contours of the state's restrictions on medication abortion and declaring that abortion takes place when mifepristone is administered, which must, by statute, be in a doctor's office).

213. Letter from Mayes Middleton, Chairman, Tex. Freedom Caucus, to Yvette Ostolaza, Chair of the Mgmt. Comm., Sidley Austin LLP (July 7, 2022), https://perma.cc/GGK7-QP59.

214. *See infra* Part V.B.

215. *See, e.g.*, *How Does the Abortion Pill Work?*, PLANNED PARENTHOOD, https://perma.cc/3A3L-FQHY (archived Dec. 31, 2023).

nonviable pregnancy tissue after the mifepristone has ended the pregnancy, then the misoprostol may not be an abortion at all. Though research is inconclusive on how often a pregnancy ends after mifepristone alone,[216] this uncertainty could create enforcement challenges.

Nevertheless, ambiguity breeds confusion and chills care. The fear that anti-abortion states could prosecute providers or helpers for conduct legal in their home state—but potentially illegal elsewhere—has led to changes in care for out-of-state patients. Some abortion clinics have publicly announced that they now require patients to consume all pills in the state where abortion is legal or that they will not provide pills to patients who are from states where abortion is banned.[217] This uncertainty is erecting barriers to accessing pills.[218]

D. Information Bans, Misinformation, and Supply Chains

One of the widely recognized threats to anti-abortion efforts is the online proliferation of information about abortion pills. As noted in Part I, websites help people all over the country—including in states that ban abortion—access abortion pills.[219] The Comstock Act's ban on information dispensation, to the extent the Act is enforceable, already provides the anti-abortion movement an opportunity to challenge the distribution of information about abortion pills.[220] But also on the horizon is state legislation attacking those who provide information about pills. The National Right to Life Committee's (NRLC) model anti-abortion bill includes specific provisions to this effect,[221] language copied almost verbatim in a South Carolina bill introduced soon after *Dobbs*.[222] This bill did not move out of

216. In a meta-analysis of thirteen published studies, mifepristone alone ended a pregnancy 53% to 88% of the time with a pregnancy continuing 8% to 46% of the time. Daniel Grossman et al., *Continuing Pregnancy After Mifepristone and "Reversal" of First-Trimester Medical Abortion: A Systematic Review*, 92 CONTRACEPTION 206, 209 tbl.1 (2015).

217. Katheryn Houghton & Arielle Zionts, *Montana Clinics Preemptively Restrict Out-of-State Patients' Access to Abortion Pills*, NPR (July 7, 2022, 5:00 AM EST), https://perma.cc/LG7G-5PDM.

218. If an abortion provider does not change their practices and a state attempts to prosecute, the provider could argue that the relevant statute, with its unclear definitions and application, is void for vagueness under the Due Process Clause. *See* Clarissa Byrne Hessick, Johnson v. United States *and the Future of the Void-for-Vagueness Doctrine*, 10 N.Y.U. J.L. & LIBERTY 152, 165 (2016).

219. *See supra* notes 87-89 and accompanying text.

220. 18 U.S.C. §§ 1461-1462.

221. Memorandum from James Bopp, Jr., Gen. Couns., Nat'l Right to Life Comm., et al., to Nat'l Right to Life Comm. 13 (June 15, 2022) [hereinafter NRLC Memo], https://perma.cc/M55Q-HJZS.

222. S. 1373, 124th Gen. Assemb. (S.C. 2022).

committee,[223] but bills banning abortion-related information are expected to reappear in state legislatures.[224] Legislators in Texas, for example, have floated the idea of requiring internet providers to block abortion pill websites, though it is unclear how this would work in practice.[225]

The First Amendment[226] should protect information about abortion pills online, even in states where abortion is illegal,[227] but the threat of a bill like the NRLC's model is that online platforms will nevertheless censor abortion pill information out of fear that they could face liability or criminal sanctions.[228] As we have seen with providers preemptively altering clinical practice in response to fears of extraterritorial prosecution,[229] the threat of such bills, even if ultimately unenforceable, could accomplish the same goal by chilling the availability of online abortion pill information.

A related tactic is to flood the internet with misinformation to thwart people's attempts to find pills. Fake abortion clinics, often called crisis pregnancy centers, have long used misinformation to prevent people from obtaining abortions.[230] That has included: (1) inaccurate information about abortion, such as misestimating gestational dates to time people out of abortion care; (2) exaggerating the risks of abortion; (3) promoting unfounded theories linking abortion to infertility, breast cancer, or depression; and (4) stating that

223. *See* Paige Collings, *Victory! South Carolina Will Not Advance Bill that Banned Speaking About Abortions Online*, ELEC. FRONTIER FOUND. (Aug. 26, 2022), https://perma.cc/7AES-FZRW.

224. Cat Zakrzewski, *South Carolina Bill Outlaws Websites that Tell How to Get an Abortion*, WASH. POST (updated July 22, 2022, 5:27 PM EDT), https://perma.cc/G7TU-QE8K.

225. Caroline Kitchener, *Conservatives Complain Abortion Bans Not Enforced, Want Jail Time for Pill "Trafficking,"* WASH. POST (updated Dec. 14, 2022, 7:30 AM EST), https://perma.cc/9883-HRVU.

226. It is beyond the scope of this Article to outline the contours of the First Amendment as they relate to abortion pill information. But at a high level, the Amendment should protect truthful information about abortion pills and how to obtain them, so long as it does not cross the line into advocacy to break the law. *See* John Villasenor, *The First Amendment and Online Access to Information About Abortion: The Constitutional and Technological Problems with Censorship*, 20 NW. J. TECH. & INTELL. PROP. 87, 103-05 (2022) (discussing an exception to First Amendment protection for "speech incident to criminal conduct").

227. *See id.* at 104-05.

228. *See* Collings, *supra* note 223; Carrie N. Baker & Carly Thomsen, *Facebook Profits from Anti-Abortion Misinformation While Suppressing Medically Accurate Abortion Facts*, MS. MAG. (Nov. 30, 2021), https://perma.cc/T9UB-NC76.

229. *See supra* note 217 and accompanying text.

230. *See* COHEN & JOFFE, *supra* note 18, at 39-43, 70-72.

medication abortion can be "reversed."[231] An online version of this model could do even more, such as: (1) purporting to sell abortion pills but telling consumers that they are backordered and never sending them; (2) selling fake pills, hoping to delay or thwart people from getting real pills; or (3) using websites to entrap and report potential abortion patients.[232] And there is already concern about misinformation and sham pill websites proliferating on the internet.[233] These efforts could run afoul of consumer fraud and protection laws.

In addition to misinformation, anti-abortion laws also will attempt to stop the supply chain of pills. The NRLC recommends criminalizing the manufacture, sale, or distribution of abortion pills.[234] The specific model language, under the section heading "Trafficking in Abortifacients Prohibited," bans these activities "when the person knows, or has reason to know, that a person to whom the person sells or distributes an abortifacient intends to use it to cause an abortion."[235]

This type of provision, if enacted, could sweep in a wide variety of conduct. It would certainly constrain the activity of abortion pill manufacturers and pharmacists. Nothing on the face of the model law limits the text to illegal abortions, and even though abortion pill manufacturers are not intentionally sending pills into anti-abortion states, those states will argue that manufacturers know that pills nevertheless cross state borders. The threat of potential liability could encourage the manufacturers and distributors of mifepristone and misoprostol to create controls to try to prevent pills from ending up in anti-abortion states.[236] Combining these theories with a state's general aiding and abetting statute, this provision could also capture someone who tells a friend or family member about Aid Access or any pill distribution resource under the theory that the person is assisting with the distribution of

231. *Id.* at 40-41; Andrea Swartzendruber et al., *Sexual and Reproductive Health Services and Related Health Information on Pregnancy Resource Center Websites: A Statewide Content Analysis*, 28 WOMEN'S HEALTH ISSUES 14, 16-17 (2018).

232. *See* Greer Donley, Rachel Rebouché & David S. Cohen, Opinion, *Abortion Pills Will Change a Post-Roe World*, N.Y. TIMES (June 23, 2022), https://perma.cc/L9K5-CC22.

233. *See, e.g.*, Marcia Frellick, *More Illegal Sites Running Online Abortion Pill Scams*, WEBMD (Aug. 4, 2022), https://perma.cc/E8ZT-556A; *Warning, Fake Abortion Pills for Sale Online!!*, WOMEN ON WAVES, https://perma.cc/P7BT-6DG6 (archived Dec. 31, 2023); The Journal, *The Booming, Unregulated Marketplace for Abortion Pills*, WALL. ST. J. (Aug. 30, 2022, 4:15 PM), https://perma.cc/RXY7-TPFQ.

234. NRLC Memo, *supra* note 221, at 6-7.

235. *Id.* at 14. At least one bill containing similar language has been introduced in a state legislature. *See* H.B. 163, 102d Gen. Assemb., 1st Reg. Sess. (Mo. 2022).

236. *Cf. In re* Nat'l Prescription Opiate Litig., 82 F.4th 455, 457 (6th Cir. 2023) (litigation attempting to hold opioid manufacturers liable for intentionally dispensing drugs in a way that led to an oversupply into the illegal market).

pills. This was reportedly the theory the Attorney General of Mississippi used when she subpoenaed documents from Mayday Health for allegedly aiding and abetting the distribution of abortion pills in the state.[237]

E. Targeting Individuals Who Use Pills

So far in the post-*Dobbs* landscape, the abortion bans that exist criminalize the behavior of abortion providers and, through general criminal aiding and abetting laws, those who assist them.[238] They do not apply to pregnant people who have abortions, though there have been proposals in state legislatures,[239] supported by some in the anti-abortion movement, that would punish pregnant people and those who help them under state abortion law.[240] As of the start of 2024, only Nevada criminalizes the actions of a person who self-manages their abortion.[241] Other criminal provisions, however, have been used to criminally investigate or arrest at least forty-seven people involved with self-managed abortion between 2000 and 2020.[242] Roughly three-quarters of these cases have been against the person procuring an abortion, and the other quarter against people helping them.[243] These cases disproportionately target people of color, and a significant majority were against people who used pills as their method of abortion.[244]

Discussed in greater depth in Part V, these other, non-abortion criminal laws that have been used to investigate or prosecute self-managed abortion include statutes that prohibit feticide, child abuse, practicing medicine without a license, or concealing human remains after the death of another person.[245] The Attorney General of Alabama, for instance, declared in January

237. *See* Yascha Mounk, *Why Freedom of Speech Is the Next Abortion Fight*, ATLANTIC (Aug. 22, 2022), https://perma.cc/JUA5-J45H.

238. *See, e.g.*, ALA. CODE § 26-23H-4(a) (2023) (making it unlawful "to intentionally perform or attempt to perform an abortion").

239. And in Texas, anti-abortion activists have found a prosecutor who is looking for the perfect test case. *See* Kitchener, *supra* note 225.

240. *See, e.g.*, Rick Rojas & Tariro Mzezewa, *After Tense Debate, Louisiana Scraps Plan to Classify Abortion as Homicide*, N.Y. TIMES (May 12, 2022), https://perma.cc/9XTW-CG72; The Daily, *The Effort to Punish Women for Having Abortions*, N.Y. TIMES (Aug. 23, 2022), https://perma.cc/FWD8-BA44.

241. NEV. REV. STAT. § 200.220 (2023); *After Roe Fell: Abortion Laws by State*, *supra* note 67 (to locate, select "View the live page," then select "Abortion Bans," then select "Abortion Bans in Effect," and then select "Criminalization of self-managed abortion").

242. LAURA HUSS, FARAH DIAZ-TELLO & GOLEEN SAMARI, IF/WHEN/HOW, SELF-CARE, CRIMINALIZED: THE CRIMINALIZATION OF SELF-MANAGED ABORTION FROM 2000 TO 2020, at 36 (2023), https://perma.cc/ZX7L-7E95.

243. *Id.* at 22.

244. *Id.*

245. *See infra* Part V.D.

2023 that, even though the state's abortion law does not apply to the pregnant person, the state's chemical endangerment law could be used to prosecute people using abortion pills.[246] People who use pills later in pregnancy, often near or after viability, are particularly at risk of criminalization as some states have interpreted their child abuse laws to apply to any fetus after viability.[247] And though the pregnant person is typically excluded from abortion bans, prosecutors may still try to prosecute patients under abortion statutes.[248] Even if these prosecutions are not authorized by the state's abortion statute, the risk is that the defendant will plead guilty before that determination, as there is a long history of pregnant people accepting plea deals in cases that should never have been prosecuted.[249] Not only will state actors disproportionately investigate and charge women of color, as we discuss in Part V.D, but studies suggest that the same population will be offered and then take harsher plea deals because of demonstrated racial disparities in charge reduction.[250]

Prosecutions for the use of abortion pills, both in states where abortion remains legal and those where it is not, are likely to continue and possibly increase.[251] With the risks of digital surveillance, as well as reporting from healthcare providers or other intermediaries,[252] some portion of people who obtain or use abortion pills in the post-*Dobbs* landscape will confront aggressive prosecutors who will try to use a variety of criminal laws to punish them. There are organized efforts to combat these prosecutions,[253] but not everyone charged will have access to these resources, and legal help may be unsuccessful. As a result, it is not hard to imagine a future in which more people are jailed for crimes related to abortion pills.

People using or assisting in the use of abortion pills have also been targeted civilly. In March 2023, a man sued three of his ex-wife's friends who used informal networks to procure abortion pills to end her pregnancy in the weeks

246. Craig Monger, *'Self-Managed' Abortions Could Still Bring Criminal Prosecution Under Child Chemical Endangerment Laws*, 1819 NEWS (Jan. 7, 2023), https://perma.cc/U8T9-7LMD.

247. *See, e.g.*, Whitner v. State, 492 S.E.2d 777, 778-79 (S.C. 1997).

248. *See* Jolie McCullough, *After Pursuing an Indictment, Starr County District Attorney Drops Murder Charge over Self-Induced Abortion*, TEX. TRIB. (Apr. 10, 2022, 3:00 PM CT), https://perma.cc/6WFK-8MSH.

249. *See, e.g.*, *Whitner*, 492 S.E.2d at 778-79; Crawley v. Catoe, 257 F.3d 395, 396-97 (4th Cir. 2001).

250. *E.g.*, Carlos Berdejó, *Criminalizing Race: Racial Disparities in Plea-Bargaining*, 59 B.C. L. REV. 1187, 1213-15 (2018).

251. *See infra* Part V.D.

252. *See* Elizabeth E. Joh, *Dobbs Online: Digital Rights as Abortion Rights*, *in* FEMINIST CYBERLAW (Amanda Levendowski & Meg Leta Jones, eds., forthcoming 2024) (manuscript at 1, 7-8), https://perma.cc/64E6-GWNE.

253. *See, e.g.*, REPRO LEGAL DEF. FUND, https://perma.cc/A843-MBWK (archived Dec. 31, 2023).

after *Dobbs*.[254] The Texas state court lawsuit claims that they are liable to the ex-husband for over one million dollars in damages.[255] The lawsuit's prospects are not strong given allegations in a countersuit that the ex-husband violated state privacy laws to obtain the woman's text messages, that he knew his ex-wife had obtained the pills but did not stop her from using them, and that he attempted to use the threat of legal liability as leverage in the divorce.[256] Nonetheless, even though this lawsuit will likely stall, civil lawsuits targeting those who use or assist in the use of abortion pills are sure to proliferate.[257]

III. Promoting Pills

As Rebecca Gomperts, a Dutch physician and the founder of Aid Access, said in the wake of *Roe* being overturned: "We will continue to serve women who need it. We're not going to stop."[258] Adopting a similar ethic, abortion-supportive states are exploring ways to protect providers who ship pills to people in states that ban abortion. Advocates are shaping the definition of abortion to distribute pills for other uses, like menstrual regulation, or in advance of a pregnancy. And some states will experiment with pharmacist prescribing to mimic the benefits of over-the-counter abortion pills without running afoul of the FDA. We detail these strategies below.

A. Telehealth Rules

Standard telehealth practice considers medical care to have occurred where the patient is located.[259] Accordingly, the provider must be licensed to practice in the state where the patient is located and follow that state's laws.[260]

254. Plaintiff's Original Petition at 1-3, Silva v. Noyola, No. 23-CV-0375 (Tex. Dist. Ct. Mar. 9, 2023).

255. *Id.* at 11.

256. *See* Defendants/Counter-Plaintiffs Jackie Noyola's and Amy Carpenter's Original Answer and Counterclaims at 1-3, 14-15, Silva v. Noyola, No. 23-CV-0375 (Tex. Dist. Ct. May 1, 2023).

257. *See* Eleanor Klibanoff, *Three Texas Women Are Sued for Wrongful Death After Allegedly Helping Friend Obtain Abortion Medication*, TEX. TRIB. (updated Mar. 10, 2023, 4:00 PM CT), https://perma.cc/4Q6V-M9MY (quoting one of the ex-husband's attorneys as saying "[a]nyone involved in distributing or manufacturing abortion pills will be sued into oblivion").

258. David Ingram, *A Dutch Doctor and the Internet Are Making Sure Americans Have Access to Abortion Pills*, NBC NEWS (July 7, 2022, 6:00 AM PDT), https://perma.cc/8X2L-ZU4W.

259. *See* FED'N OF STATE MED. BDS., THE APPROPRIATE USE OF TELEMEDICINE TECHNOLOGIES IN THE PRACTICE OF MEDICINE 4 (2022), https://perma.cc/FKU7-554G.

260. *Id.* ("A physician must be licensed, or appropriately authorized, by the medical board of the state where the patient is located.").

Against this legal backdrop, a state with an abortion ban would consider a provider to have broken its laws (both an abortion ban and its medical licensing laws) if that provider used telehealth to provide abortion for a patient located in its state regardless of whether the provider was located in a state where abortion by telehealth is legal.[261] The provider's abortion-supportive home state might also view this conduct as practicing medicine without a license because the provider did not have a license in the patient's state.[262] This creates a significant barrier to a provider's willingness to provide abortion via telehealth and then mail pills into states that ban abortion—the legal and professional risks are too high. As a result, abortion-supportive states have passed laws seeking to protect providers offering telehealth for abortion to out-of-state patients.

Around the time *Dobbs* was decided, a number of states crafted laws or executive orders designed to shield their citizens from extraterritorial lawsuits and prosecutions related to abortion.[263] Six of the states with shield laws (California, Colorado, Massachusetts, New York, Vermont, and Washington) address the issue of cross-state telehealth for abortion by defining protected reproductive healthcare, within the shield law, as care provided regardless of the patient's location.[264] This means that a Massachusetts provider, for example, licensed and located in Massachusetts, should be covered by the state's shield protections when providing abortion care for a patient via telehealth no matter where the patient is located.[265] Though shield laws may shift the focus

261. *See* Cohen et al., *supra* note 19, at 50.

262. *See id.* at 27-30.

263. *Id.* at 42-52. The authors were involved in drafting and advocating for these laws and have also written extensively about them elsewhere. *See* Cohen et al., *supra* note 19, at 42-52; David S. Cohen, Greer Donley & Rachel Rebouché, *Abortion Shield Laws*, NEJM EVIDENCE ra2200280, at 2 (2023); David S. Cohen, Greer Donley, Rachel Rebouché & Isabelle Aubrun, *Understanding Shield Laws*, 51 J.L. MED. & ETHICS 584 (2023), https://perma.cc/46HU-96VM.

264. Act of Sept. 27, 2023, §§ 6, 15, 16, 2023 Cal. Legis. Serv. ch. 260 (West) (codified at CAL. CIV. CODE § 1798.300(d)(1)(C) (West 2024); CAL. PEN. CODE §§ 847.5(b)-(c), 1299.02(d) (West 2024)); Act of April 14, 2023, § 5, 2023 Colo. Sess. Laws 239, 243 (codified at COLO. REV. STAT. § 12-30-121(d) (2024)); Act of July 29, 2022, § 3, 2022 Mass. Acts ch. 127 (codified at MASS. GEN. LAWS ch. 12, § 11I1/2(a) (2023)); Act of June 23, 2023, § 1, 2023 N.Y. Laws ch. 138 (codified at N.Y. CRIM. PROC. LAW § 570.17(1)(b)(ii) (McKinney 2023)); Act of May 10, 2023, § 1, 2023 Vt. Acts & Resolves no. 14 (codified at VT. STAT. ANN. tit. 1, § 150(b)(1)(B), (b)(3) (2023)); Act of April 27, 2023, ch. 193, § 13, 2023 Wash. Sess. Laws 885, 897 (codified at WASH. REV. CODE § 7.115.020(1) (2023)); *see also* Rebecca Grant, *Group Using 'Shield Laws' to Provide Abortion Care in States that Ban It*, GUARDIAN (July 23, 2023, 7:00 AM EDT), https://perma.cc/9XXW-EAHX.

265. Massachusetts providers, under the shield law, still must comply with Massachusetts law and the relevant standard of care; the shield law does not cover an action against a provider if "a cause of action exists under the laws of the commonwealth if the course of conduct that forms the basis for liability had occurred entirely in the

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from the patient's location to the provider's location, other state laws and regulations, such as those governing telehealth generally, continue to define the site of care as where the patient is.[266] This model does not change any aspect of state law with respect to the location of care. Nevertheless, as mentioned in Part I, the uptake of this type of shield law encouraged Aid Access to rely on U.S. providers to send pills to every state in the country, including thousands of packages into anti-abortion states.[267]

Rather than qualify the definition of protected reproductive healthcare, states could explicitly define—both in a shield law and in the state statutes governing abortion generally—the location of abortion care as the provider's physical location rather than the patient's. Thus, the state from which the provider offers telehealth would not consider the provider to be practicing without a license or in violation of its own abortion laws when the provider treats patients who are in other states. This would not change how the *patient's* home state defines where care occurs. But if the provider was sued in a court in the *provider's* home state, that court could consider all the conduct—the provider's and the patient's—to have occurred in the provider's state.[268] No state has yet passed a provision with this language, and the state shield-law language ("regardless of patient location") has yet to be interpreted by an agency, board, or court.

To be clear, shifting the location of care is a significant departure from the standard of care, the provisions of state medical practice acts, and the guidance of professional organizations.[269] A model medical practice act authored by the

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commonwealth, including any contract, tort, common law or statutory claims." MASS. GEN. LAWS ch. 12, § 11I1/2(f) (2023). One potential interpretation is that if the provider does not have a license in the state where the patient is located, then that provider is acting contrary to Massachusetts licensure laws. Another interpretation is that, for the provision of protected reproductive health services, the relevant question is only whether the care complied with the state's abortion law (and the relevant standard of care assumed under that law).

266. *See, e.g.*, WASH. MED. COMM'N, GUI2014-03, APPROPRIATE USE OF TELEMEDICINE 1 (2014), https://perma.cc/2HRA-RSPN ("The practice of medicine occurs at the location of the patient.").

267. *See supra* notes 84-86 and accompanying text.

268. A conflict of laws can occur when the place of conduct—where provider operates from—differs from the place of purported injury—where the abortion occurs. *See* Joseph William Singer, *Conflict of Abortion Laws*, 16 NE. U. L. REV. (forthcoming 2024) (manuscript at 7-8), https://perma.cc/NZJ8-ASGF.

269. *See, e.g.*, VT. STAT. ANN. tit. 26, § 1420a (2023) ("The Compact also adopts the prevailing standard for licensure and affirms that the practice of medicine occurs where the patient is located at the time of the physician-patient encounter, and therefore, requires the physician to be under the jurisdiction of the state medical board where the patient is located."); MO. REV. STAT. § 334.1605 (2023) (same). Section 10(a) of the Uniform Telehealth Act defines care as occurring at the location of the patient, in accordance with the current practice. UNIF. TELEHEALTH ACT § 10(a) (UNIF. L. COMM'N 2022),

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Federation of State Medical Boards states: "[T]he practice of medicine is determined to occur where the patient is located in order that the full resources of the state are available for the protection of that patient."[270] It goes on to provide that "[a] physician located in another state practicing within the state by electronic or other means without a license (full, special purpose or otherwise) issued by the [state medical board] should be deemed guilty of a felonious offense."[271] It concludes that state medical boards should be authorized to take disciplinary action against "practicing medicine in another state or jurisdiction without appropriate licensure."[272]

There are important reasons for defining care as occurring where the patient is located. For example, the state where the patient resides typically has a strong interest in protecting the patient's safety.[273] Telehealth regulation has followed this standard so that telehealth and in-person care are treated the same, from how providers are reimbursed to how patient-physician relationships are formed.[274] One way to mainstream and expand telehealth is to facilitate cross-border care while respecting the states' role in protecting patient safety.[275]

Consider the operation of interstate licensure compacts.[276] The Interstate Medical Licensure Compact (IMLC) was created with assistance from the Federation of State Medical Boards to offer physicians a streamlined, less cumbersome process to seek permission to practice outside their home states.[277] The impetus for the IMLC was the increasing use of

https://perma.cc/GG2L-XZPV; Press Release, Interstate Med. Licensure Compact (June 29, 2022), https://perma.cc/5KAF-UB32.

270. A GUIDE TO THE ESSENTIALS OF A MOD. MED. PRAC. ACT § II(C) (FED'N OF STATE MED. BDS. OF THE U.S., INC., 2003), https://perma.cc/A9N6-LTTQ.

271. *Id.* § XV(D).

272. *Id.* § IX(D)(39).

273. *See* Barsky v. Board of Regents, 347 U.S. 442, 449 (1953) ("[A] state has broad power to establish and enforce standards of conduct within its borders relative to the health of everyone there."); *see also* Elizabeth Weeks Leonard, *State Constitutionalism and the Right to Health Care*, 12 J. CONST. L. 1325, 1347-1348 (2010) (discussing state constitutional provisions that protect the health of residents); Letter from James L. Madara, CEO, Am. Med. Ass'n, to Sheldon A. Wasserman, Ref. Comm. Chair, Fed'n of State Med. Bds. (Apr. 21, 2022) [hereinafter AMA Letter], https://perma.cc/4MWK-SLCU (suggesting that states have a strong interest in protecting patients).

274. Gabriela Weigel et al., *Opportunities and Barriers for Telemedicine in the U.S. During the COVID-19 Emergency and Beyond*, KFF (May 11, 2020), https://perma.cc/5MD5-JN4P.

275. *See* UNIF. TELEHEALTH ACT, *supra* note 269, at 1 (explaining the objectives of the Uniform Telehealth Act); A GUIDE TO THE ESSENTIALS OF A MOD. MED. PRAC. ACT, *supra* note 270, § II(C); *see also* Singer, *supra* note 268 (manuscript at 114-15).

276. *See A Faster Pathway to Physician Licensure*, INTERSTATE MED. LICENSURE COMPACT, https://perma.cc/NG58-UWHG (archived Dec. 31, 2023).

277. *Id.*

telehealth.[278] Thirty-seven states participate in the IMLC,[279] and, to facilitate states' enactment of laws that encourage cross-border licensure, the IMLC assures member states that physicians subject to discipline in one state will be subject to discipline in another.[280] In this vein, the IMLC obligates member states to share information about complaints and actions against physicians.[281] The reasons for those assurances are, broadly, a state's interests in protecting its residents from negligence, fraud, or harm.[282] But here lies a tension with the six shield laws mentioned above.[283] In protecting providers from discipline, regardless of the patient location, state statutes turn the idea of disciplinary reciprocity on its head. Rather than disciplining an in-state provider for mailing medications into another state where they do not have a license, the shielding state will forgo action against the provider's license if the medications are legally protected reproductive healthcare as defined by the provider's state shield law.

Shifting the location of patient care from patient to provider under shield laws would be dramatic and is perhaps unlikely to be adopted for types of healthcare other than abortion.[284] Professional organizations and state medical boards could carve out more explicit exceptions for abortion care given the increasing number of abortion travelers and need for telehealth for abortion.[285] One place to do that is in licensure laws, making clear that providers in states that provide telehealth for abortion to out-of-state patients are practicing within the scope of their medical licenses so long as they comply

278. *Id.* ("Recognizing that physicians will increasingly practice in multiple states as a result of telemedicine, U.S. state medical boards in 2013 began actively discussing the idea of creating the Compact in order to help streamline traditional medical-license application processes.").

279. *Id.*

280. RULE ON COORDINATED INFO. SYS., JOINT INVESTIGATIONS AND DISCIPLINARY ACTIONS § 6.5 (INTERSTATE MED. LICENSURE COMPACT COMM'N 2023), https://perma.cc/G9JL-TFE6.

281. *Id.* § 6.3.

282. *See* Cohen et al., *supra* note 19, at 97; Interstate Med. Licensure Compact Comm'n, Opinion Letter (Dec. 1, 2023), https://perma.cc/YDD2-UHQR.

283. *See supra* notes 263-67 and accompanying text.

284. One exception is gender-affirming care, which some states include in their shield protection. *See, e.g.*, MASS. GEN. LAWS ch. 12, § 11I1/2 (2023).

285. The Uniform Telehealth Act seeks, as far as possible, to put telehealth on par with in-person care. In so doing, it applies the rules of the patient's, not the provider's, home state. UNIF. TELEHEALTH ACT, *supra* note 269, § 5 cmts. 1-2, § 6 cmt. 5 ("Out-of-state practitioners must be mindful . . . [that] any requirements with respect to the delivery of health care within this state will apply, including . . . limitations on the prescription of controlled substances."). States, if they enact the Uniform Telehealth Act, could write in exceptions for abortion care that tether the site of care to the practitioner's location rather than to the patient's location.

with the standard of care and the laws of their home state.[286] The sheer complexity of interstate abortion conflicts on the horizon, as well as the health consequences of unwanted pregnancies being carried to term, may militate for treating abortion somewhat differently.[287]

B. Missed Period Pills and Advance Provision

Another strategy to increase access to abortion pills involves prescribing them without a known pregnancy. As discussed in greater depth in Part V, almost all states define abortion through the intent to terminate a pregnancy, and many require knowledge of the pregnancy.[288] These intent and knowledge elements are crucial because abortion pills are prescribed for a variety of uses, such as miscarriage care or labor induction.[289] But can providers prescribe the pills with intent to end a known pregnancy when a pregnancy has not been diagnosed?

The use of missed period pills involves prescribing the same drugs used for medication abortion but without a pregnancy test and with the intent to induce a period, not to provide an abortion.[290] This practice is also called menstrual regulation and has been practiced for centuries.[291] Before home

286. The American Medical Association affirmed its support for the Federation of State Medical Boards' Telemedicine Policy, which dictates that physicians must be licensed in the state where the patient is located, but provides for exceptions to that rule. AMA Letter, *supra* note 273, at 1 ("Physicians must be licensed in the state where the patient is located, but flexibilities are warranted to promote continuity of care, allow patients to obtain an initial consultation through physician-to-physician consultations, or allow prospective patient screening by a specialist." (summarizing FED'N OF STATE MED. BDS., THE APPROPRIATE USE OF TELEMEDICINE TECHNOLOGIES IN THE PRACTICE OF MEDICINE 4-6 (2022), https://perma.cc/7DJE-HZZP)).

287. We recognize, of course, that abortion exceptionalism has historically created burdens for abortion access. *See generally* Caitlin E. Borgmann, *Abortion Exceptionalism and Undue Burden Preemption*, 71 WASH. & LEE L. REV. 1047 (2014). Nonetheless, given the post-*Dobbs* crisis for access, we believe treating abortion differently in the way described in this Subpart would be beneficial to facilitating access in the current environment.

288. *See, e.g.*, ARK. CODE ANN. § 5-61-303(1)(A) (2023); CAL. HEALTH & SAFETY CODE § 123464(a) (West 2023); FLA. STAT. § 390.011(1) (2023); IDAHO CODE § 18-604(1) (2023); 775 ILL. COMP. STAT. 55/1-10 (2023); N.C. GEN. STAT. § 90-21.81(4e) (2023); N.M. STAT. ANN. § 30-5A-2(A) (2023); OKLA. STAT. tit. 63, § 1-757.2(1) (2023); S.C. CODE ANN. §44-41-610(1) (2023).

289. *See* Brittni Frederiksen, Matthew Rae, Tatyana Roberts & Alina Salganicoff, *Abortion Bans May Limit Essential Medications for Women with Chronic Conditions*, KFF (Nov. 17, 2022), https://perma.cc/UP74-KDHU.

290. *See* Wendy R. Sheldon, Meighan Mary, Lisa Harris, Katherine Starr & Beverly Winikoff, *Exploring Potential Interest in Missed Period Pills in Two US States*, 102 CONTRACEPTION 414, 414 (2020).

291. *See* Etienne van de Walle, *Flowers and Fruits: Two Thousand Years of Menstrual Regulation*, 28 J. INTERDISC. HIST. 183, 183-84 (1997); Rachel Rebouché, *Reproducing*

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pregnancy tests were available in the late 1970s, it could take time for people to learn they were pregnant.[292] After all, missed periods happen for a variety of reasons.[293] And because miscarriages occur in up to 25% of pregnancies, people frequently do not know if a late period was actually early pregnancy loss.[294] As a result, products for "menstrual regulation" were historically sold openly—even when abortion was illegal in the century before *Roe*.[295]

Menstrual regulation, however, is not a bygone practice. Other countries have allowed menstrual regulation alongside abortion bans.[296] For instance, in Bangladesh, abortion is illegal except to save a pregnant person's life, but menstrual regulation with medication is permitted through nine weeks from a person's last period.[297] In the United States, state laws that ban abortion may not apply in some states if the provider intended to induce a period, not terminate a pregnancy, and never tested or confirmed whether the patient was pregnant.[298] Though period pills, which are the same regimen as medication abortion, have been offered in states that permit abortion, they could also become a mechanism for in-state providers to evade bans in anti-abortion states, absent changes to those states' abortion definitions (discussed in Part V below).[299]

A similar strategy is advance provision of abortion pills to end a potential future pregnancy.[300] If an unintentional pregnancy arises in the future,

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Rights: The Intersection of Reproductive Justice and Human Rights, 7 U.C. IRVINE L. REV. 579, 601 (2017).

292. *See* Andrea Tone, *Medicalizing Reproduction: The Pill and Home Pregnancy Tests*, 49 J. SEX RSCH. 319, 324-25 (2012) (discussing methods of pregnancy detection before the home pregnancy test).

293. *See* Rhea Monga & Devaki Gokhale, *Menstrual Irregularities: Understanding the Role of Influential Factors*, CARDIOMETRY, Dec. 2022, at 378, 383 ("Menstrual irregularities occur from a complex interplay of multiple factors, the majority of which are governed by the lifestyle of an individual. A balance between exercise, diet, sleep and mental health can help menstrual irregularities.").

294. *See* Greer Donley & Jill Wieber Lens, *Abortion, Pregnancy Loss, & Subjective Fetal Personhood*, 75 VAND. L. REV. 1649, 1654, 1692 (2022).

295. *Id.* at 1697.

296. Susheela Singh et al., *The Incidence of Menstrual Regulation Procedures and Abortion in Bangladesh, 2014*, 43 INT'L PERSPS. ON SEXUAL & REPROD. HEALTH 1, 1 (2017).

297. *Id.*

298. Studies suggest that some patients prefer taking pills with the intent to induce a period without having to learn if they are pregnant. Sheldon et al., *supra* note 290, at 418; *see also* Invisibilia, *A Little Bit Pregnant*, NPR, at 18:30 (Sept. 16, 2022), https://perma.cc/28ND-5XG7.

299. *See Providers*, PERIOD PILLS PROJECT, https://perma.cc/4PQV-U32D (archived Dec. 31, 2023).

300. *See* Katherine Ehrenreich, M. Antonia Biggs & Daniel Grossman, Editorial, *Making the Case for Advance Provision of Mifepristone and Misoprostol for Abortion in the United States*, 48 BMJ SEXUAL & REPROD. HEALTH 238, 238 (2022).

advance provision ensures that the person would have the pills in hand. Many abortion providers have started offering advance provision.[301] Advance provision could be offered in states with abortion bans if the law defines abortion as ending a known (or knowable) pregnancy at the time of the provider's interaction with the patient. Many state abortion laws require a provider to know a person is pregnant.[302] However, advance provision may satisfy a law's knowledge element, subjecting people to prosecution, because the pills are prescribed to terminate a future pregnancy.

There are also downsides to advance provision. Pills may have diminished efficacy if taken past their expiration dates,[303] and unused medications are wasted. Moreover, any counseling the patient received, like describing at what point in pregnancy to take the pills, could be forgotten (although online resources abound). For these reasons, many providers are uncomfortable prescribing in advance, especially for an unwanted pregnancy that may never materialize.

C. Pharmacist Prescribing

States that support abortion rights could take additional steps to make medication abortion easier to access. Additional avenues to abortion pills would not only help in-state patients but would also ease access for patients traveling into abortion-supportive states. The federal drug regulatory scheme creates a national floor that preempts state law, leaving little leeway for states to veer from that floor in regulating drugs. But there is at least one way that abortion-supportive states could pursue a new avenue: pharmacist prescribing.[304]

Pharmacist prescribing is a tool states could use to obtain many of the benefits of moving a drug over-the-counter (OTC) without waiting for the FDA to approve the OTC switch. Without the FDA's approval, a drug cannot be sold without a prescription.[305] Advocates want to make abortion pills available OTC,[306] but this is a long-term goal that will first involve removing

301. *See Providers*, *supra* note 299.

302. *See* sources cited *supra* note 288.

303. *Don't Be Tempted to Use Expired Medicines*, FDA, https://perma.cc/7S75-7BPE (last updated Feb. 8, 2021).

304. Just before this Article was finalized, pharmacists in Washington were on the verge of becoming the first in the country to prescribe abortion pills. *See* Patrick Adams, *In Washington State, Pharmacists Are Poised to Start Prescribing Abortion Drugs*, NPR (Jan. 22, 2024, 11:31 AM ET), https://perma.cc/KRT2-FAHG.

305. Pat Clarke, *How FDA Strives to Ensure the Safety of OTC Products*, FDA (Mar. 10, 2016), https://perma.cc/JS7V-6ADZ.

306. *E.g.*, Lewis A. Grossman, Freedom Not to See a Doctor: The Path to Over-the-Counter Abortion Pills 6 (Mar. 25, 2023) (unpublished manuscript), https://perma.cc/P4Y9-CXDJ.

intermediate barriers, like the mifepristone REMS,[307] and then producing data showing that consumers can safely and effectively use a drug without the help of a provider.[308]

Although states cannot circumvent the FDA and allow a drug to be sold OTC, they can allow pharmacists to prescribe the drug.[309] States have general police powers to control the practice of medicine in their states, including what types of providers can prescribe what types of drugs.[310] Of course, pharmacy prescription would not be a possibility in the fifteen states that permit only physicians to offer medication abortion or the fourteen states with a ban on abortions.[311]

Pharmacists generally do not have the power to prescribe, but states have increasingly granted them this power for some products, including vaccines and opioid antagonists.[312] But the most relevant example is hormonal birth control. Advocates have long argued that the FDA should approve hormonal birth control for OTC use,[313] which was finally realized with the approval of one form of OTC hormonal birth control in 2023.[314] But even before the FDA approved the OTC switch, many states passed laws that allow pharmacists to prescribe some or all forms of FDA-approved birth control.[315] As of August 2023, twenty-eight states and the District of Columbia allow this in some

307. Mifepristone certainly will not be approved for OTC use when it is still deemed by the agency to be risky enough to need extra controls through its REMS program. *See supra* Part I. The first step in a long-term push for OTC abortion pills would thus be to remove the REMS. The FDA has, in the past, demonstrated a reluctance to allow contraceptives to be sold over the counter. *See* Jessica Dye, *Groups Say FDA's Plan B Decision Falls Short of Court Order*, REUTERS (updated May 1, 2013, 11:52 AM PDT), https://perma.cc/9F56-4S72. But in July 2023, the agency approved one daily oral contraceptive for OTC use, Opill (norgestrel). *See* Press Release, FDA, FDA Approves First Nonprescription Daily Oral Contraceptive (July 13, 2023), https://perma.cc/ALC3-9PFK. About a decade earlier, the courts had to demand that the agency approve emergency contraception for OTC use because the agency refused to do so itself. Dye, *supra*. In other words, this uphill battle will take time.

308. *See* sources cited *supra* note 307.

309. *See, e.g.*, Ned Milenkovich, *Pharmacist Prescribing: Road Less Traveled Is Getting Busier*, PHARMACY TIMES, May 2022, at 52, 52.

310. *See* Edward P. Richards, *The Police Power and the Regulation of Medical Practice: A Historical Review and Guide for Medical Licensing Board Regulation of Physicians in ERISA-Qualified Managed Care Organizations*, 8 ANNALS HEALTH L. 201, 201 (1999).

311. *Medication Abortion*, *supra* note 20.

312. *See* Milenkovich, *supra* note 309, at 52.

313. *See, e.g.*, Press Release, Am. Coll. of Obstetricians & Gynecologists, ACOG Statement on FDA Submission for Over-the-Counter Access to Contraception (July 11, 2022), https://perma.cc/UQZ5-SJUA.

314. Press Release, FDA, *supra* note 307.

315. *Pharmacist-Prescribed Contraceptives*, GUTTMACHER INST., https://perma.cc/L2PA-UPJ3 (last updated Aug. 31, 2023).

capacity.[316] Given that the FDA has only approved one OTC hormonal contraceptive, pharmacist prescribing remains an important part of expanding access to other types of hormonal birth control.

Pharmacist prescribing of birth control does not violate federal law because patients still need a prescription from a provider. But when a pharmacist *is* the provider, patients need not schedule an independent appointment with a doctor; instead, they can go to a neighborhood pharmacy, talk to the pharmacist about birth control, and pick up the prescription and medication in the same visit.[317] Ample data from both the United States and abroad demonstrate that medication abortion can be safely and effectively used without any provider.[318] To enable pharmacist prescribing, states could (1) enact legislation or create a policy that grants all pharmacists certain powers; or (2) modify regulations or protocols that allow pharmacists to enter collaborative practice agreements with already authorized prescribers. The former is more permissive, as it outlines the conditions under which all pharmacists can prescribe a medication.[319] The latter is less permissive because it empowers only those pharmacists who have entered into an agreement with a prescriber who serves as a supervisor.[320]

Pharmacists prescribing medication abortion could increase access to pills in abortion-supportive states.[321] Clinics in some abortion-supportive states that border anti-abortion states now face weeks-long wait times due to the influx of out-of-state abortion patients,[322] so increasing the options for patients in those states is essential to providing timely care. Abortion travelers could access abortion medication at the closest participating pharmacy rather than finding an appointment at an overburdened clinic.

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316. *Id.*

317. *See* M. Antonia Biggs et al., *A Cross-Sectional Survey of U.S. Abortion Patients' Interest in Obtaining Medication Abortion Over the Counter*, 109 CONTRACEPTION 25, 26 (2022); Kierra B. Jones, *Advancing Contraception Access in States Through Expanded Pharmacist Prescribing*, CTR. FOR AM. PROGRESS (Jan. 31, 2023), https://perma.cc/3JCV-7R5N.

318. *E.g.*, Abigail R.A. Aiken, Evdokia P. Romanova, Julia R. Morber & Rebecca Gomberts, *Safety and Effectiveness of Self-Managed Medication Abortion Provided Using Online Telemedicine in the United States: A Population Based Study*, 10 LANCET REG'L HEALTH art. 100200, at 2, 6; Moseson et al., *supra* note 92, at e106, e111-12.

319. *See* Alex J. Adams & Krystalyn K. Weaver, *The Continuum of Pharmacist Prescriptive Authority*, 50 ANNALS PHARMACOTHERAPY 778, 780 tbl.1 (2016).

320. *Id.*

321. We first suggested this as a strategy here: Rachel Rebouché, David S. Cohen & Greer Donley, *The Coming Legal Battles over Abortion Pills*, POLITICO (May 24, 2022, 2:45 PM EDT), https://perma.cc/GM8D-5HTP.

322. *See, e.g.*, Margot Sanger-Katz, Claire Cain Miller & Josh Katz, *Interstate Abortion Travel Is Already Straining Parts of the System*, N.Y. TIMES (July 23, 2022), https://perma.cc/A4Y8-73XK.

This strategy, however, faces challenges. First, unlike birth control, which is on the market without restrictions, mifepristone is subject to the REMS restrictions. Theoretically, a pharmacist—like any other healthcare provider—could comply with a REMS. Indeed, in 2016 the FDA removed a requirement that permitted only physicians to become certified to prescribe mifepristone.[323] To become certified now, a provider must attest that they can: (1) assess the duration of a pregnancy; (2) diagnose ectopic pregnancies; and (3) provide (or have a plan in place for others to provide) emergency medical care, to the extent it is needed.[324]

Although these qualifications might initially appear outside of a pharmacist's purview, varied healthcare providers specializing in practices typically unrelated to reproductive health, such as ophthalmologists and radiologists, have become certified to prescribe mifepristone.[325] The first condition can be met by asking patients about their last period and calculating the gestational age.[326] The second condition may be sufficiently satisfied by asking patients standard questions about whether they have experienced the symptoms of ectopic pregnancy.[327] Before the COVID-19 pandemic, it was common for providers to conduct ultrasounds to date the pregnancy and rule out ectopic pregnancy, but that is no longer necessary for medication abortion unless the patient is unsure of when their last period occurred or is experiencing symptoms of ectopic pregnancy.[328] As to the third certification requirement, abortion providers have long relied on emergency rooms to

323. Donley, *supra* note 15, at 641.

324. FDA, *supra* note 39, at 1.

325. *See* Donley, *supra* note 15, at 654.

326. *See* A.R.A. Aiken, P.A. Lohr, J. Lord, N. Ghosh & J. Starling, *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided via Telemedicine: A National Cohort Study*, 128 BJOG 1464, 1468 fig.2 (2021), https://perma.cc/WEM9-EK25.

327. *See id.* Screening cannot diagnose ectopic pregnancies—only ultrasounds can. However, just as ophthalmologists can rely on other providers to conduct an ultrasound if the patient is at risk of ectopic pregnancy, pharmacists may be able to similarly rely on other medical professionals.

328. *See id.* at 1471 ("The telemedicine-hybrid model resulted in very low rates of undiagnosed ectopic pregnancy and later than expected gestations. . . . Ultrasound is not used to screen for ectopic pregnancy in the general population—it is only used where signs and symptoms suggest a need."); Ushma D. Upadhyay et al., *Outcomes and Safety of History-Based Screening for Medication Abortion: A Retrospective Multicenter Cohort Study*, 182 JAMA INTERNAL MED. 482, 483 (2022) ("Typically, clinicians perform ultrasonography or a pelvic examination before treatment to determine the duration and location of the pregnancy. However, during the COVID-19 pandemic, some clinics relied on patient history alone, without ultrasonography or pelvic examination, to reduce physical contact. . . . [T]hese changes enabled the emergence of several new online services that offered medication abortion entirely remotely using telemedicine and mail.").

provide rarely needed emergency care, and pharmacists could do the same.[329] There is, of course, a significant difference for pharmacists: Unlike licensed abortion providers, they are not accustomed to diagnosing or treating patients.

Second, even though a pharmacist could become certified to prescribe mifepristone if the states granted them prescribing powers, the REMS imposes another requirement: pharmacy certification. For pharmacies to become certified to dispense mifepristone, they must institute protocols for tracking shipments, keeping records, reporting certain adverse events, and maintaining provider confidentiality.[330] Certification also requires the pharmacy to designate a representative in charge of certification and compliance.[331] This strategy depends on the willingness of brick-and-mortar pharmacies to jump through the hoops of certification—if a pharmacy is not certified to dispense, then it is irrelevant if the pharmacist is certified to prescribe. Pharmacy chains such as CVS and Walgreens have announced plans to seek certification and to carry medication abortion at certain locations,[332] while a handful of independent pharmacies have received certification and begun dispensing pills.[333]

Abortion-supportive states could also allow pharmacists to prescribe misoprostol-only medication abortions. Because misoprostol was initially approved to treat ulcers and is on the market without a REMS, pharmacists could prescribe it without restrictions, just like they do for birth control and vaccines. And like with birth control,[334] there are methods available to screen out patients with higher risk factors.[335] While there may be concerns with pharmacists prescribing misoprostol for an off-label use, there is precedent for

329. *See* Letter from Patrizia Cavazzoni, Director, FDA, Ctr. for Drug Evaluation & Rsch., to Donna J. Harrison, Exec. Dir., Am. Ass'n of Pro-Life Obstetricians & Gynecologists, and Quentin L. Van Meter, President, Am. Coll. of Pediatricians 12, 19 (Dec. 16, 2021) [hereinafter 2021 Response Letter], https://perma.cc/2L5D-24DD.

330. FDA, *supra* note 39, at 3.

331. *Id.*

332. Pam Belluck, *CVS and Walgreens Plan to Offer Abortion Pills Where Abortion Is Legal*, N.Y. TIMES (Jan. 5, 2023), https://perma.cc/7VQX-BFW4.

333. Ollstein & Gardner, *supra* note 55.

334. *See* AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, COMM. ON GYNECOLOGICAL PRAC., COMM. OP. NO. 788, OVER-THE-COUNTER ACCESS TO HORMONAL CONTRACEPTION, *in* 134 OBSTETRICS & GYNECOLOGY e96, e101 (2019), https://perma.cc/5ZL8-E5ZP.

335. *E.g.*, Aiken et al., *supra* note 326, at 1468 fig.2 (listing questions to screen for high risk factors); Ipas, Print and Assembly Instructions for Gestational Dating Wheel for MA (n.d.), https://perma.cc/79GU-YEDZ (providing a wheel tool, which can be printed and assembled at home, that allows a patient to assess potential length of gestation); *see also* Thoai Ngo, *To Protect Access to Medication Abortion in the US, Make the Misoprostol-Only Regimen a Reality*, HEALTH AFFS.: FOREFRONT (Sept. 23, 2022), https://perma.cc/Z2AE-FJY5.

off-label pharmacy prescriptions: emergency contraception.[336] Before there was an emergency contraceptive product on the market, research had shown that regular birth control pills could be used off-label to delay ovulation and prevent pregnancy.[337] If states gave pharmacists prescribing power for mifepristone and misoprostol, in combination or alone, under specified conditions, they could open the door for misoprostol-only abortions directly through a pharmacy.[338] This would mirror the practice of other countries, where misoprostol is sold over-the-counter purportedly for ulcers but is used to induce an abortion.[339]

Third, other barriers to reproductive healthcare would remain. For instance, where individual pharmacists are allowed to refuse to prescribe abortion medication, it may be harder for patients to find a pharmacist willing to dispense.[340] And willing pharmacists might face difficulties securing reimbursement for their time evaluating, counseling, and prescribing contraceptives to patients.[341] Most importantly, pharmacists would be subject to all of a state's abortion laws—including any reporting requirements, waiting periods, or informed consent rules—which could be a significant deterrent in many places. And some pharmacists, who are largely generalists unlike most of today's abortion providers, might not understand the needs of abortion seekers.

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336. There is also (unsettling) recent precedent: After the FDA refused to approve ivermectin to treat COVID-19—the drug was already on the market to treat parasites—Tennessee passed a law allowing pharmacists to prescribe it, presumably for treatment of COVID-19. Blake Farmer, *Tennessee Will Make Ivermectin Available Without a Prescription, Despite Research Showing No Benefit for COVID Treatment*, WPLN NEWS (Apr. 7, 2022), https://perma.cc/CL2Q-QFTY.

337. Heather Boonstra, *Emergency Contraception: The Need to Increase Public Awareness*, GUTTMACHER REP. ON PUB. POL'Y, Oct. 2002, at 3, 4, https://perma.cc/VHE6-CST8; COEYTAUX & WELLS, *supra* note 91, at 8-9.

338. Some states require providers to follow the FDA label for abortion drugs. Rachel K. Jones & Heather D. Boonstra, *The Public Health Implications of the FDA Update to the Medication Abortion Label*, GUTTMACHER INST. (June 30, 2016), https://perma.cc/NWP9-LL7Z.

339. *See, e.g.*, Deborah L. Billings, Dilys Walker, Guadalupe Mainero del Paso, Kathryn Andersen Clark & Ila Dayananda, *Pharmacy Worker Practices Related to Use of Misoprostol for Abortion in One Mexican State*, 79 CONTRACEPTION 445, 446 (2009); S.H. Costa, *Commercial Availability of Misoprostol and Induced Abortion in Brazil*, 63 INT'L J. GYNECOLOGY & OBSTETRICS S131, S132-33 (1998).

340. *See* Holly Teliska, Note, *Obstacles to Access: How Pharmacist Refusal Clauses Undermine the Basic Health Care Needs of Rural and Low-Income Women*, 20 BERKELEY J. GENDER L. & JUST. 229, 229-231 (2005).

341. *See* Erin N. Deja & Joseph L. Fink III, *Pharmacists Prescribing Birth Control: Improving Access and Advancing the Profession*, PHARMACY TIMES (Nov. 16, 2016), https://perma.cc/42TL-GQ3U.

Even with these caveats and limitations, pharmacist prescribing of abortion pills would be a novel way for abortion-supportive states to create additional avenues to medication abortion. Like telehealth rules and missed period pills, pharmacist prescribing pushes the boundaries of how medication abortion is delivered. The next Part assesses potential interventions of the federal government, through the FDA, for expanding or restricting the availability of medication abortion.

IV. The Food and Drug Administration: The Politics of Pills

The federal government has its own role to play—and that role may change depending on who is the President. The Biden administration has used executive power to try to mitigate some of the fallout from *Dobbs*.[342] But the agency with the most power over abortion medication—the FDA—aims to be politically independent[343] and has so far acted cautiously, opting for characteristically slow and incremental change.[344] Nonetheless, we discuss how the FDA could impact access to abortion pills by altering mifepristone's REMS and label. We also explore the FDA's role in asserting a preemption argument to blunt state abortion bans.

At the outset, we note that though the FDA will face pressure to institute more dramatic changes from both sides—like revoking its approval of abortion pills or making them available OTC[345]—the agency is unlikely to do so any time soon. Before the FDA can withdraw approval of a product on the basis of safety or efficacy, it must prove the drug's risks outweigh its benefits.[346] This burden would be difficult to meet given the extensive research supporting the

342. *See* Cohen et al., *supra* note 19, at 76 (describing efforts to protect medically necessary abortions through the Emergency Medical Treatment & Labor Act); *id.* at 79 (describing efforts to protect abortion information through the Health Insurance Portability and Accountability Act (HIPAA)); *id.* at 72 n.394 (describing efforts to protect some abortions for veterans); *id.* at 66-67, 67 n.370 (describing efforts to protect pharmacy access to abortifacients used for other purposes).

343. *See* Christina Fuleihan, *Shattering the Mirage: The FDA's Early COVID-19 Pandemic Response Demonstrates a Need for Reform to Restore Agency Credibility*, 48 AM. J.L. & MED. 307, 310-11 (2023), https://perma.cc/V8J6-GK4H (noting that "scientific integrity is often prioritized within scientific agencies" but acknowledging that the FDA faces political pressures).

344. *See, e.g.*, David Cohen, Greer Donley & Rachel Rebouché, Opinion, *The FDA's Abortion Pill Update Includes Pointless and Harmful Restrictions*, HILL (Jan. 9, 2023, 2:00 PM ET), https://perma.cc/YA38-98PA (arguing that the FDA did not go far enough when it removed the in-person dispensing requirement).

345. *See* Eli Y. Adashi, Rohit S. Rajan, Daniel P. O'Mahony & I. Glenn Cohen, *The Next Two Decades of Mifepristone at FDA: History as Destiny*, 109 CONTRACEPTION 1, 5 (2022) (describing how Congress could pressure the FDA to withdraw mifepristone's approval).

346. *See* 21 U.S.C. § 355(e).

safety and efficacy of abortion pills.[347] Moreover, before withdrawing a drug's approval, the FDA must first hold a hearing, allow the drug's sponsor and the public to object, and then render a final scientific determination, which opponents could challenge as arbitrary and capricious.[348] The reality is that the FDA only forcibly withdraws approval in rare circumstances, typically involving an accelerated initial approval and a drawn-out, contentious process.[349] Withdrawals are typically achieved by the agency pressuring the drug sponsor, which is often a repeat player before the FDA with incentives to acquiesce, to remove the product from the market voluntarily.[350]

On the other end of the spectrum, making mifepristone available OTC may be scientifically supportable, but there are many steps that must occur first. The FDA would need to remove the REMS—a big battle in its own right, discussed below[351]—and evaluate the safety of mifepristone under normal rules before finally approving it for OTC distribution. Indeed, the battle to make a progesterone-only hormonal birth control available OTC succeeded, but fifty years after it was approved for prescription use.[352] Thus, this Part focuses on tools the agency could use to alter the accessibility of abortion pills in the near term.

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347. *See* Donley, *supra* note 15, at 634-35 (describing the data on mifepristone). The case brought by the Alliance for Hippocratic Medicine, described above in Part II, is designed to undermine mifepristone's safety record and to cast doubt on prior FDA decisionmaking. *See* Christina Jewett & Pam Belluck, *Abortion Ruling Could Undermine the F.D.A.'s Drug-Approval Authority*, N.Y. TIMES (updated Apr. 11, 2023), https://perma.cc/C2K9-CQR7. But it still does not present evidence that could come close to meeting the standard for revoking an NDA. *See* Brief of Food and Drug Law Scholars, *supra* note 109, at 11-13.

348. *See* 21 U.S.C. § 355(e); 21 C.F.R. § 314.530 (2023); 5 U.S.C § 706; Agnes Vitry, Tuan Nguyen, Vikky Entwistle & Elizabeth Roughead, *Regulatory Withdrawal of Medicines Marketed with Uncertain Benefits: The Bevacizumab Case Study*, 8 J. PHARM. POL'Y & PRAC. art. 25, at 2 (2015), https://perma.cc/7L95-WHMU.

349. *See, e.g.*, Christina Jewett, *F.D.A. Rushed a Drug for Preterm Births. Did It Put Speed over Science?*, N.Y. TIMES (Mar. 25, 2022), https://perma.cc/5MCG-4VVR; Vitry et al., *supra* note 348, at 2 (describing the FDA's "highly contested" decision to remove an indication from the label of a popular cancer drug—one of the rare examples in recent memory).

350. *See* Matthew Perrone, *FDA Forces Unproven Premature Birth Drug Makena Off Market*, AP NEWS (Apr. 6, 2023, 8:58 AM PST), https://perma.cc/Z9MD-ZHA6 ("The final decision [to withdraw approval of a premature birth drug] marks the first time the agency formally forced the removal of a drug that it initially approved based on promising early data. In all prior cases, drugmakers voluntarily pulled medications after the FDA made clear it intended to order removal.").

351. *See infra* Part IV.A.

352. *See* Pam Belluck, *F.D.A. Approves First U.S. Over-the-Counter Birth Control Pill*, N.Y. TIMES (July 13, 2023), https://perma.cc/E9MG-GCEZ.

A. The Mifepristone REMS

Since the FDA approved mifepristone in 2000,[353] it has imposed distribution limitations, originally under Subpart H but later under a REMS.[354] As explained above, mifepristone's current REMS includes a Patient Agreement Form and certification of both the provider and the pharmacy.[355] The most recent REMS was finalized in early 2023 after the agency considered changes to the REMS in 2021.[356] In this round of REMS modifications, the agency determined that the REMS must be maintained but modified to lift the in-person dispensing requirement and add the pharmacy certification requirement.[357]

This was not the first time—and it will not be the last—that the agency reconsidered the mifepristone REMS.[358] The agency can consider REMS changes of its own volition and *must* consider sponsor requests to modify the REMS submitted through a process known as an sNDA (Supplemental New Drug Application), where the sponsor asks the agency to modify some aspect of the original approval.[359] Advocates on both sides of the aisle can also request REMS changes through citizen petitions, which similarly require an agency response, but that response is frequently delayed.[360]

Removing the REMS would be the most straightforward way for the federal government to expand abortion access, as it is squarely within the agency's expertise and fully consistent with its statutory mandate and the scientific evidence.[361] Leading medical associations like the American College of Obstetricians and Gynecologists and the American Medical Association agree that the REMS is medically unnecessary.[362] If the FDA removes the

353. Donley, *supra* note 15, at 638.

354. *Id.* at 638-40.

355. *See supra* notes 39-43 and accompanying text.

356. *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra* note 29.

357. *Updated Mifepristone REMS Requirements*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (Jan. 2023), https://perma.cc/DZ4N-W7V2.

358. *See id.* (linking to the previous mifepristone REMS).

359. 21 U.S.C. § 355-1(d), (g)(2)(B), (g)(2)(C); 21 C.F.R. § 314.70.

360. *See* Bradley Merrill Thompson, *Unpacking Averages: FDA's Extraordinary Delay in Resolving Citizen Petitions*, EPSTEIN BECKER & GREEN, P.C.: HEALTH LAW ADVISOR (Oct. 3, 2023), https://perma.cc/L2K5-QEUS.

361. *See* Donley, *supra* note 15, at 663-66, 684 (explaining that removing a policy that might be arbitrary and capricious is an easy way for the government to promote abortion access).

362. *Improving Access to Mifepristone for Reproductive Health Indications*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (Mar. 2021), https://perma.cc/AEL6-XS4M; *Supporting Access to Mifepristone (Mifeprex) H-100.948*, AM. MED. ASS'N, https://perma.cc/QKQ2-ZXHN (last updated 2023); *see also* Letter from John S. Cullen, Bd. Chair, Am. Acad. of Fam. Physicians, to Stephen M. Hahn, Comm'r, FDA (Mar. 25, 2020), https://perma.cc/7242-Q62N.

REMS, people in states that permit abortion could get a prescription for abortion pills from any provider, not just a "certified" one, so long as that provider complied with their state's abortion laws.[363] Patients in these states could also pick up their prescription at any pharmacy, not just a "certified pharmacy."[364] These changes would help mainstream and destigmatize abortion, increase the number of abortion providers, and allow patients to receive the medication more quickly.[365] Abortion travelers would also benefit from these changes, as they could more easily access abortions in the states to which they travel.[366]

On the other hand, an administration opposed to abortion rights could strengthen or add to the REMS, making mifepristone harder to access. The FDA could reinstate the in-person dispensing requirement, in effect banning telehealth for abortion nationwide. It could even require patients to ingest each medication in person, meaning patients would have to visit a clinic multiple times.[367] The FDA could also acquiesce to demands for new requirements, such as a mandate that patients collect the medical waste from an abortion that passes at home for special disposal—the subject of a recent anti-abortion citizen petition.[368]

Any action on the mifepristone REMS would expose the FDA to accusations of playing politics and be subject to legal challenge, but eliminating the REMS is in line with decades of research showing that mifepristone does not need a REMS to be prescribed and dispensed safely.[369] In contrast, imposing additional restrictions under the REMS would be contrary to that evidence and thus more susceptible to an arbitrary and capricious challenge under the Administrative Procedure Act.[370] Moreover, though REMS changes are federal, they will only affect states where abortion is still occurring. Thus, lifting the REMS would have no effect in states where abortion is outlawed, but strengthening the REMS would restrict care in abortion-supportive states,

363. Donley, *supra* note 15, at 701-02.

364. *Id.*

365. *See id.* at 701-03. Ninety-six percent of abortions occur in abortion clinics or nonspecialized clinics. Jones et al., *supra* note 26, at 134.

366. Donley, *supra* note 15, at 696-97; *cf.* Cohen et al., *supra* note 19, at 10-11.

367. This practice was eliminated in the 2016 REMS. *See* Donley, *supra* note 15, at 641.

368. Alice Miranda Ollstein, *The Next Abortion Fight Could Be over Wastewater Regulation*, POLITICO (updated Nov. 23, 2022, 7:06 AM EST), https://perma.cc/8UXB-LKKA.

369. *See supra* notes 34-38 and accompanying text; Donley, *supra* note 15, at 651-55.

370. *See* Donley, *supra* note 15, at 684-89; Administrative Procedure Act, Pub. L. No. 79-404, ch. 324, § 10(e), 60 Stat. 237, 243-44 (1946) (codified at 5 U.S.C. § 706).

making the agency vulnerable to accusations of interfering with a state's freedom to set its own abortion policy.[371]

There is no indication that the FDA is eager to change the REMS any time soon, especially having just concluded a mifepristone REMS review in 2023.[372] Nevertheless, multiple lawsuits have been filed to remove the mifepristone REMS as unsupported by science—mirror-image litigation to the *Alliance for Hippocratic Medicine v. FDA* case described in Part II.A. A group of attorneys general from abortion-supportive states has sued the FDA in the Eastern District of Washington, arguing that the REMS should be removed;[373] several clinics in other states have done the same in Virginia;[374] and a district court judge in Hawaii has resumed a 2017 lawsuit challenging the mifepristone REMS.[375]

These lawsuits have already played a key role in keeping medication abortion accessible. For instance, on the same day that the district court in *Alliance for Hippocratic Medicine* issued a preliminary injunction that would have suspended mifepristone's approval, the Eastern District of Washington issued a preliminary injunction ordering the agency to maintain the status quo with regard to mifepristone's accessibility.[376] These conflicting judgments get to the heart of the battle over facts and evidence; mifepristone's safety record is clear and should not bear the brunt of anti-abortion politics.

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371. *Cf.* Dobbs v. Jackson Women's Health Org., 142 S. Ct. 2228, 2284 (2022) ("The Constitution does not prohibit the citizens of each State from regulating or prohibiting abortion. . . . We now . . . return that authority to the people and their elected representatives.").

372. *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra* note 29.

373. Amended Complaint paras. 1-8, Washington v. FDA, No. 23-cv-03026, 2023 WL 2825861 (E.D. Wash. Mar. 9, 2023), 2023 WL 7461669. On the same day the Texas district judge initially ruled to suspend the approval of mifepristone, *see supra* note 131 and accompanying text, the judge in this case issued a preliminary injunction blocking the FDA from changing the status quo while the litigation proceeds. Washington v. FDA, No. 23-CV-3026, 2023 WL 2825861, at *10-11 (E.D. Wash. Apr. 7, 2023), *appeal docketed*, No. 23-35294 (9th Cir. May 1, 2023). These conflicting orders may have factored into the Supreme Court's decision to stay the Texas litigation. *See supra* notes 131-33 and accompanying text.

374. Whole Woman's Health All. v. FDA, No. 23-cv-00019, 2023 WL 5401885, at *1, *9-10 (W.D. Va. Aug. 21, 2023) (denying plaintiffs' motion for preliminary injunction in light of the injunction issued in the Washington case).

375. Chelius v. Becerra, No. 17-00493, 2023 WL 5041616, at *1, *8 (D. Haw. Aug. 8, 2023); Mary Anne Pazanowski, *Abortion Drug Rule Case Moves Forward in Hawaii Federal Court*, BLOOMBERG L. (Aug. 9, 2023, 10:15 AM PDT), https://perma.cc/FUR4-B8XQ.

376. *See supra* note 373.

B. Changing the Mifepristone Label

In addition to removing the mifepristone REMS, the FDA could change the drug's label as it has done before. In 2016, the agency recognized the extensive data showing that medication abortion was safe and effective with a lower dose through ten weeks of pregnancy, beyond the previously approved seven weeks.[377] As a result, it modified the drug's label to approve the lower dose through ten weeks.[378] Advocates on both sides have promoted arguments that medication abortion's label should be changed—either to extend or limit the gestational age.[379] Though changes to a drug's label are important, doctors frequently and lawfully prescribe drugs off-label.[380]

Extensive evidence shows that medication abortion is safe and effective through at least twelve weeks of gestation.[381] For instance, the World Health Organization (WHO) maintains that "in gestational ages less than 12 weeks, pregnant persons can safely and effectively manage their own medical abortions using mifepristone and misoprostol in combination or misoprostol alone."[382] The WHO recommends the same abortion protocol through the twelfth week of pregnancy and beyond (with the assistance of a healthcare provider).[383] Relying on this recommendation, some providers in the United States have started prescribing medication abortion off-label through up to thirteen weeks of pregnancy.[384] Between ten and thirteen weeks, additional doses of misoprostol may be recommended.[385] Though people can and do self-

377. *See supra* note 137 and accompanying text; Donley, *supra* note 15, at 641.

378. Donley, *supra* note 15, at 641.

379. *Compare* Sarah Zhang, *The Abortion Pill Can Be Used Later than the FDA Says*, ATLANTIC (June 29, 2022), https://perma.cc/G7WV-Z4TN (arguing that abortion pills can be used into the second trimester of pregnancy), *with* Am. Ass'n of Pro-Life Obstetricians and Gynecologists & Am. Coll. of Pediatricians, Citizen Petition 1 (2019) [hereinafter 2019 Citizen Petition], https://perma.cc/3EBK-PRGX (arguing that abortion pills should only be approved through seven weeks).

380. Katrina Furey & Kirsten Wilkins, Commentary, *Prescribing "Off-Label": What Should a Physician Disclose?*, 18 AMA J. ETHICS 587, 588-90 (2016).

381. WORLD HEALTH ORG., *supra* note 25, at 25-30 (describing the studies relied on by the World Health Organization to recommend medication abortion through twelve weeks of gestation).

382. WORLD HEALTH ORG., WHO RECOMMENDATIONS ON SELF-CARE INTERVENTIONS: SELF-MANAGEMENT OF MEDICAL ABORTION, 2022 UPDATE 3 (2022), https://perma.cc/5K5X-V6RP.

383. *See* WORLD HEALTH ORG., *supra* note 25, at 29.

384. *See, e.g.*, *Verified Abortion Providers Serving California*, ABORTIONFINDER, https://perma.cc/3XPB-A52W (archived Jan. 1, 2024).

385. *See, e.g.*, NISHA VERMA, VINITA GOYAL, DANIEL GROSSMAN, JAMILA PERRITT & GRACE SHIH, SOC'Y OF FAM. PLAN., SOCIETY OF FAMILY PLANNING INTERIM CLINICAL RECOMMENDATIONS: SELF-MANAGED ABORTION 6 (2022), https://perma.cc/6SZU-4K96 ("Another recommended regimen >10-12 weeks' gestation involves mifepristone

footnote continued on next page

manage abortions in the second trimester with medication, it is less effective and carries higher risks as the pregnancy progresses.[386]

The sponsor of mifepristone could submit an sNDA to extend the drug's approval through twelve or thirteen weeks.[387] If the FDA approved the medication abortion regimen for additional weeks, it would make abortion less expensive and more accessible for people needing abortions in that timeframe because the alternative, procedural abortion, requires in-person care, which can be more expensive, less private, and logistically difficult.[388] Due to the weeks-long wait times that have become common after *Dobbs*, many people are not able to access abortion in the first ten weeks, making it all the more critical to expand access to pills.[389]

Alternatively, an anti-abortion administration could attempt to reduce the gestational weeks for approved use of medication abortion. For instance, in a 2019 citizen petition that was ultimately rejected in 2021, the American Association of Pro-Life Obstetricians and Gynecologists and the American College of Pediatricians requested that the FDA revert to the seven-week approval period.[390] Students United for Life made a similar request in 2022 that the agency rejected in 2023.[391] Though off-label prescribing mitigates some of the concerns of label changes, a label change can nevertheless chill prescribing

200 mg orally, followed 24-48 hours later with misoprostol 800 μg used vaginally, sublingually, or buccally and then misoprostol 400-800 μg every 3 hours until expulsion of pregnancy tissue."); *A Repeat Dose of Misoprostol 800mcg Following Mifepristone for Outpatient Medical Abortion at 64-70 and 71-77 Days of Gestation: A Retrospective Chart Review*, GYNUITY HEALTH PROJECTS (July 22, 2020), https://perma.cc/X96D-G4BB.

386. *See* Heidi Moseson et al., *Effectiveness of Self-Managed Medication Abortion Between 13 and 24 Weeks Gestation: A Retrospective Review of Case Records from Accompaniment Groups in Argentina, Chile, and Ecuador*, 102 CONTRACEPTION 91, 95 tbl.2 (2020) (concluding that, in the second trimester, the efficacy of self-managed medication abortion alone was around 76% with at least 11% needing surgical intervention to complete the abortion). Without treatment, an incomplete abortion can cause infection, sepsis, and hemorrhage. Ashley Redinger & Hao Nguyen, *Incomplete Abortions*, NAT'L LIBR. OF MED., https://perma.cc/89D3-MKYU (last updated June 27, 2022).

387. 21 C.F.R. § 314.70 (2022).

388. *See* Cohen et al., *supra* note 19, at 15, 95; Donley, *supra* note 16, at 657.

389. *See* Cohen et al., *supra* note 19, at 11, 12 n.45; Oriana González, *Clinics Forced to Push Abortions Later in Pregnancy amid State Bans*, AXIOS (Sept. 9, 2022), https://perma.cc/28F3-5XGJ.

390. 2019 Citizen Petition, *supra* note 379, at 1; 2021 Response Letter, *supra* note 329, at 7.

391. *See* Letter from Patrizia A. Cavazzoni, Dir., FDA, Ctr. for Drug Evaluation & Rsch., to Kristan Hawkins, President, Students for Life of Am., and Kristi Hamrick, Chief Media & Pol'y Strategist, Students for Life of Am. 1-2 (Jan. 3, 2023), https://perma.cc/7ZLM-Z64W.

practices due to fears about liability.[392] Shortening the approved use for mifepristone to seven weeks might force some people back into clinics for procedural care, increasing the costs and burdens of their abortion. Any decision to further restrict mifepristone, however, would be vulnerable to an arbitrary and capricious challenge under the Administrative Procedure Act (the same basis for attack in the *Alliance* litigation) as contrary to the evidence.[393]

Finally, the mifepristone label could also be modified to add new indications (i.e., a new approved use for the drug). For instance, in 2022, nearly fifty medical organizations submitted a citizen petition requesting that the FDA work with mifepristone's sponsor to add miscarriage management to the drug's label.[394] Though adding miscarriage management to the mifepristone label would not have a direct impact on abortion access, it could play an important role in destigmatizing the medication and thwarting state abortion bans that might otherwise target mifepristone. For instance, in the 2022 legislative term, state legislators in Alabama and Arizona introduced bills that would ban mifepristone entirely, relying on the fact that the drug only has one approved use: abortion.[395] These bans would be much harder to implement if mifepristone were approved for multiple uses because its impact beyond abortion care would be more obvious.[396] Importantly, adding an indication to mifepristone's label could also mitigate the damage associated if litigation successfully invalidates mifepristone's approval for abortion. If mifepristone had an alternative approved use, it would remain on the market and providers could continue to prescribe it off-label for abortion.[397]

392. *See generally* James B. Riley, Jr. & P. Aaron Basilius, *Physicians' Liability for Off-Label Prescriptions*, HEMATOLOGY & ONCOLOGY NEWS & ISSUES, May/June 2007, at 24 (2007), https://perma.cc/2HMD-LWY7.

393. *See supra* notes 134, 348, 370 and accompanying text.

394. Am. Coll. of Obstetricians & Gynecologists, Citizen Petition 1 (2022), https://perma.cc/4P64-B5JS. Greer Donley was one of the primary drafters of this petition. The FDA rejected the Petition in January 2023 on the ground that the drug sponsor must first file an sNDA to request the new indication. Letter from Patrizia A. Cavazzoni, Dir., FDA, Ctr. for Drug Evaluation & Rsch., to Maureen G. Phipps, Am. Coll. of Obstetricians & Gynecologists (Jan. 3, 2023), https://perma.cc/VPK2-43R3.

395. *Id.* at 10 (citing H.B. 261, 2022 Leg., Reg. Sess. (Ala. 2022); and H.B. 2811, 55th Leg., 2d Reg. Sess. (Ariz. 2022)).

396. *See infra* Part V.B; OLC Memo, *supra* note 192, at 20-21.

397. Mifepristone is also sold under the brand name Korlym to treat Cushing's syndrome. Sarah Jane Tribble, *How a Drugmaker Turned the Abortion Pill into a Rare-Disease Profit Machine*, WASH. POST (Apr. 10, 2018, 5:15 AM EDT), https://perma.cc/5MS2-A69K. However, because Korlym is dosed differently and sold only through a specialty pharmacy at a significantly higher price point in monthly regimens, this version of mifepristone is not a viable option for off-label use as an abortion pill. *See id.*

C. Preemption

As we argued in a previous article, *The New Abortion Battleground*, the FDA's regulation of medication abortion should partially preempt state abortion bans.[398] Those bans should not be able to prohibit the sale and distribution of abortion pills.[399] The Constitution's Supremacy Clause demands that federal law trump state law when the two conflict.[400] But where, as here, Congress has not issued an explicit preemption statement, identifying a true conflict of laws can be complicated. The central question is whether a state can overregulate or ban a drug approved by the FDA, especially one that has been regulated under a REMS, like mifepristone.[401] If not, the implications would be enormous: Every state's abortion ban would have to include an exception for mifepristone that is prescribed and dispensed according to the FDA's REMS. Because Congress seemed to demand that the FDA provide both the ceiling and the floor of regulation when issuing a REMS,[402] there is a strong argument that states cannot regulate a REMS product differently than the FDA.[403]

Since we first made this argument in February 2022,[404] the Biden administration has signaled interest in the theory. On the day *Roe v. Wade* was overturned, Attorney General Merrick Garland announced, "[T]he FDA has approved the use of the medication Mifepristone. States may not ban Mifepristone based on disagreement with the FDA's expert judgment about its safety and efficacy."[405] The Department of Health and Human Services reiterated this statement and said that it was working with the Department of Justice "to help ensure access to care and preserve FDA's role in determining what is safe and effective for patients."[406] This statement was issued in a report

398. Cohen et al., *supra* note 19, at 52-71.

399. *See id.* at 53; I. Glenn Cohen, Melissa Murray & Lawrence O. Gostin, Opinion, *The End of* Roe v Wade *and New Legal Frontiers on the Constitutional Right to Abortion*, 328 JAMA 325, 325 (2022).

400. U.S. CONST. art. VI, cl. 2.

401. *See* Cohen et al., *supra* note 19, at 53-54.

402. *See id.* at 57-58.

403. *See id.* at 64-65.

404. *See id.* at 43, 52-67.

405. Press Release, U.S. Dep't of Just., Attorney General Merrick B. Garland Statement on Supreme Court Ruling in Dobbs v. Jackson Women's Health Organization (June 24, 2022), https://perma.cc/T9NR-TLKZ.

406. U.S. DEP'T OF HEALTH & HUM. SERVS., HEALTH CARE UNDER ATTACK: AN ACTION PLAN TO PROTECT AND STRENGTHEN REPRODUCTIVE CARE 8 (2022), https://perma.cc/G7E8-CRA8.

outlining the agency's response to the *Dobbs* decision under a header titled, "Federal Preemption—Protecting Access to Medication Abortion."[407]

In January 2023, the first post-*Dobbs* preemption lawsuits were filed.[408] The generic mifepristone drug manufacturer, GenBioPro, challenged West Virginia's general abortion ban.[409] On the same day, an abortion provider challenged North Carolina's laws, which permit abortion but restrict the provision of medication abortion.[410] Under the state's laws, only physicians can prescribe mifepristone, pills can only be dispensed in person at a surgical facility, and additional informed consent must be provided.[411] These cases represent two different threads of preemption theory—challenges to general abortion bans and challenges to health laws that regulate medication abortion more harshly than does the FDA.[412] The West Virginia lawsuit has the potential to be much more significant, as a win could create an exception for medication abortion in states with abortion bans. In many ways, this challenge is the inverse of the litigation in Texas attacking mifepristone's FDA approval as it would restore some abortion access nationwide.[413] By contrast, the North Carolina litigation could have important effects in the few states that permit but overregulate abortion without affecting abortion availability elsewhere. In August 2023, the district court ruled that West Virginia's telemedicine abortion ban was preempted, leaving the state's general abortion ban untouched.[414] This will certainly not be the end of the inquiry, as GenBioPro is appealing the ruling.[415]

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407. *Id.*

408. In 2020, GenBioPro sued Mississippi for regulating medication abortion beyond the REMS, but after *Dobbs*, GenBioPro voluntarily dismissed its case. Notice of Voluntary Dismissal Without Prejudice, GenBioPro, Inc. v. Dobbs, No. 20-cv-00652 (S.D. Miss. Aug. 18, 2022), ECF No. 46; *see* Cohen et al., *supra* note 19, at 70-71.

409. *See* Complaint para. 15, GenBioPro, Inc. v. Sorsaia, No. 23-cv-00058, 2023 WL 5490179 (S.D. W. Va. Jan. 25, 2023), ECF No. 1.

410. *See* Complaint paras. 8, 12, Bryant v. Stein, No. 23-cv-77 (M.D.N.C. Jan. 25, 2023), ECF No. 1.

411. *See id.* para. 8.

412. For an in-depth discussion of these two strands, see Cohen et al., note 19 above, at 53-71.

413. *See supra* notes 101-04 and accompanying text.

414. GenBioPro, Inc. v. Sorsaia, No. 23-cv-00058, 2023 WL 5490179, at *8, *11 (S.D. W. Va. Aug. 24, 2023) (finding that "West Virginia's [abortion ban] has limited *when* an abortion may be performed, without touching *how* medication abortion is to be performed," but that "the telemedicine restriction dictates the manner in which mifepristone may be prescribed," which "is a determination which Congress has allocated to the FDA."), *appeal filed sub nom.* GenBioPro, Inc. v. Raynes, No. 23-2194 (4th Cir. Feb. 7, 2024).

415. *See* Opening Brief of Plaintiff-Appellant GenBioPro, Inc., *Raynes*, No. 23-2194 (4th Cir. Feb. 7, 2024), ECF No. 31.

Though the preemption theories have legs[416] and the challenges were filed in a circuit that should take them seriously—the Fourth Circuit—there are doubts as to whether the current Supreme Court would permit any victory to stand. To be sure, the conservative justices have traditionally supported preemption based on federal food and drug law.[417] And Chief Justice Roberts in particular might appreciate a perceived compromise where states must permit abortion through ten weeks completed with medication.[418] But the Court that just overturned *Roe* may be unlikely to permit such a large exception to state abortion bans, especially if the scope of that exception is controlled by a government agency. Nevertheless, early victories could still improve access on the ground temporarily.[419]

One of the principal questions surrounding these cases is whether the FDA will or should get involved. The agency could intervene in a few different ways: (1) the Department of Justice could work with the FDA to bring its own preemption lawsuit; (2) the FDA could promulgate a rule or publish a policy related to preemption, which would become the subject of litigation; or (3) the FDA could support the preemption litigation filed by other parties in an amicus brief. The Biden administration faces pressure to defend abortion access, which might make it difficult for the agency to resist supporting preemption litigation.[420] On the other hand, the FDA under a Republican administration could do the opposite: place its thumb on the scale against preemption, either in litigation or regulation.

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416. *See, e.g.*, Cohen et al., *supra* note 19, at 53-71 (arguing that the FDA's regulation of medication abortion at least partially preempts state abortion bans); Peter Grossi & Daphne O'Connor, *FDA Preemption of Conflicting State Drug Regulation and the Looming Battle Over Abortion Medications*, 10 J.L. & BIOSCIENCES lsad005, at 28, 31 (2023) (same); Patricia J. Zettler, Annamarie Beckmeyer, Beatrice L. Brown & Ameet Sarpatwari, *Mifepristone, Preemption, and Public Health Federalism*, 9 J.L. & BIOSCIENCES lsac037, at 11-25 (2022) (same); Patricia J. Zettler & Ameet Sarpatwari, *State Restrictions on Mifepristone Access—The Case for Federal Preemption*, 386 NEW ENG. J. MED. 705, 706 (2022) (same). *But see* Jared Huber, Note, *Preemption Exemption: FDA-Approved Abortion Drugs After* Dobbs, 98 NOTRE DAME L. REV. 2217, 2219-20 (2023) (arguing that the FDA's regulation of medication abortion does not preempt state abortion bans).

417. *See* Grossi & O'Connor, *supra* note 416, at 3-4.

418. *See* Stuart Gerson, Commentary, *Understanding John Roberts: A Conservative Institutionalist Concerned with Durability of the Law and Respect for the Court*, JURIST (July 31, 2020, 2:17:13 PM), https://perma.cc/RK87-9CZQ (explaining that the Chief Justice is perceived to be an institutionalist who cares deeply about the Court's reputation).

419. *See* David S. Cohen, Greer Donley & Rachel Rebouché, Essay, *Rethinking Strategy After* Dobbs, 75 STAN. L. REV. ONLINE 1, 7 (2022) (encouraging creative litigation); *supra* note 414 and accompanying text.

420. *See* Michael D. Shear & Sheryl Gay Stolberg, *Under Pressure, Biden Issues Executive Order on Abortion*, N.Y. TIMES (July 8, 2022), https://perma.cc/G7N2-FDH2.

Beyond the political calculations of the current President, the FDA likely has its own concerns. The agency's credibility suffered significantly during and in the aftermath of the opioid crisis,[421] as well as the COVID-19 pandemic.[422] As a result, it might want to avoid the appearance of partisanship. There are times when the FDA is duty-bound to act, like when it must respond to an sNDA or a citizens petition, even if its decision will have political implications.[423] But the FDA has no statutory obligation to initiate litigation, file an amicus brief, or regulate regarding preemption.[424] Furthermore, preemption would make the FDA's policy the law of the country, even in states with abortion bans, setting up battles between state and federal powers that the FDA might want to avoid. By contrast, changing the label or removing the REMS would not have any impact on state abortion bans without preemption.

Finally, there is the concern that the FDA's involvement—particularly if intended to support preemption arguments—could harm the effort. The Supreme Court's recent precedent increasingly demonstrates intense skepticism toward federal agencies.[425] If the FDA becomes actively involved in the preemption litigation, it could transform a case about a company's right to sell its FDA-approved product into a case about government overreach, an easy target for conservative judges.[426]

Despite these political quandaries, there are health and safety issues militating for the FDA's involvement. Under abortion bans, infant mortality

421. *See* Andrew Kolodny, *How FDA Failures Contributed to the Opioid Crisis*, 22 AMA J. ETHICS 743, 744 (2020).

422. *See* Celine Castronuovo & Jeannie Baumann, *Trump Covid Report Stirs Calls for FDA to Rebuild Public Trust*, BLOOMBERG L. (Aug. 26, 2022, 2:25 AM PDT), https://perma.cc/EE5B-5VLE.

423. 21 C.F.R. § 314.70 (2023); 21 C.F.R. § 10.30 (2023); *see also* Erica M. Cox, Anita V. Edmund, Erica Kratz, Sarah H. Lockwood & Aishwarya Shankar, *Regulatory Affairs 101: Introduction to Expedited Regulatory Pathways*, 13 CLINICAL & TRANSLATIONAL SCI. 451, 451 (2020).

424. Courts have found that agencies like the FDA can decide how to prioritize their time and staff. *See* Heckler v. Chaney, 470 U.S. 821, 831-32 (1985).

425. *See* Gillian E. Metzger, *The Roberts Court and Administrative Law*, 2019 SUP. CT. REV. 1, 2-3 (2020); Gillian E. Metzger, *Foreword: 1930s Redux: The Administrative State Under Siege*, 131 HARV. L. REV. 1, 17-28 (2017).

426. For instance, a court might use the major questions doctrine to invalidate agency action to secure abortion rights. *See* Daniel T. Deacon & Leah M. Litman, *The New Major Questions Doctrine,* 109 VA. L. REV. 1009, 1015-16 (2023). Though courts, including the Supreme Court, might disparage the FDA's involvement, lower courts might find differently. *See* Cohen et al., *supra* note 419, at 12. Other administrative law doctrines, like deference to agency action, could bolster a case for preemption. *See* Cohen et al., *supra* note 19, at 68-69.

and maternal mortality rates will increase.[427] Abortion bans also cause delays in life-saving care that impair maternal health.[428] And because most abortion bans also prohibit abortions for severe fetal anomaly, there will be more stillborn babies and infants who die quickly after birth.[429] Finally, the underground markets for abortion pills might increase the risks of abortion—people may start taking drugs too late in pregnancy or drugs with unknown potency or authenticity.[430] These public health problems could be blunted with a floor of national access to FDA-regulated medication abortion.[431]

V. How Pill Battles Will Set the Terms of the Abortion Debate

Though the victories and losses over pills' accessibility will influence how and where abortion pills are accessed, one thing is clear: Pills are here to stay. As in the War on Drugs, federal and state policy will determine not only whether people can obtain pills, but also how they do so, whether the justice system will be involved, and if public health will be compromised. As abortion pills cause states to lose control of abortion, state actors will respond by attempting to tighten their grip. Attempts to close all of the avenues to obtain abortion pills—both formal and informal, legal and extralegal—will require actions and policies most people will find unpalatable, catalyzing paradigm shifts in how people think and talk about abortion.

We outline a few of these significant changes below. Each of these developments will challenge mainstream assumptions about abortion. In short, pills will disrupt the status quo in ways that touch more people than ever before. We should expect adverse public health consequences, infringements on basic civil liberties, and racial as well as class inequities. But along with those costs we also may witness a sea change in the broader acceptability of abortion.

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427. *See* Elyssa Spitzer, Tracy Weitz & Maggie Jo Buchanan, *Abortion Bans Will Result in More Women Dying*, CTR. FOR AM. PROGRESS (Nov. 2, 2022), https://perma.cc/5R9R-C3MQ; Donley & Lens, *supra* note 294, at 1716.

428. *See* Anjali Nambiar et al., *Maternal Morbidity and Fetal Outcomes Among Pregnant Women at 22 Weeks' Gestation or Less with Complications in 2 Texas Hospitals After Legislation on Abortion*, 227 AM. J. OBSTETRICS & GYNECOLOGY 648, 649 (2022), https://perma.cc/2MH8-BQCF.

429. Donley & Lens, *supra* note 294, at 1716.

430. The FDA has made clear in statements online that it disapproves of people buying medication abortion from international sources, which have different packaging and labeling and are thus not FDA-approved. *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra* note 29. Preemption is the best way to make the FDA-approved medication abortion product more available, thus reducing the need for underground markets.

431. Cohen et al., *supra* note 148.

A. Informal Networks and Removing Gatekeepers

In the past several years, domestic and international networks that assist people in obtaining pills have increased in importance.[432] Their work is supported by abortion activists who publicize all the ways people can obtain pills, even if not legal.[433] Though we have no reliable data on how many people are being served by these resources, we know they are already distributing pills to people in states that ban abortion.[434]

The biggest distributor of pills into states with abortion bans is Aid Access, which, as we noted above, now relies on U.S.-based medical providers to mail thousands of packages of pills a month into states with bans.[435] Aid Access has helped to disrupt traditional understandings of abortion provision through its telehealth and abortion-by-mail model. But in some sense, its model is based on the traditional patient-provider setup.

Aside from Aid Access, people obtain pills through various means without *any* provider involved at all. They buy pills online directly from an international pharmacy or turn to networks run by activists, not doctors, often providing pills for free. Domestically, for instance, Red State Access provides residents of states with "active bans" information about where they can find pills free of charge.[436] The site contains very little information other than a list of emails for people to contact.[437] It strongly encourages the use of privacy apps or browsers while exploring the site and contacting the network.[438] It lists organizations such as AccessMA and WeSaveUs that provide the pills.[439] Given the underground nature of this work, the networks are constantly shifting.[440]

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432. *See* Caroline Kitchener, *Covert Network Provides Pills for Thousands of Abortions in U.S. post Roe*, WASH. POST (Oct. 18, 2022, 6:00 AM EDT), https://perma.cc/8J6U-M8HW.

433. *See infra* notes 442-49 and accompanying text.

434. *See* Claire Cain Miller & Margot Sanger-Katz, *The (Incomplete) Revolution in Counting Abortions*, N.Y. TIMES (Dec. 8, 2022), https://perma.cc/LJ3F-MNSL.

435. *See supra* notes 83-86 and accompanying text.

436. RED STATE ACCESS, https://perma.cc/T6TB-529A (archived Jan. 1, 2024); Steph Black, *The Activist Offering: The Other Front Line*, PROGRESSIVE MAG. (Jan. 10, 2023, 12:47 PM), https://perma.cc/A45B-N33K.

437. RED STATE ACCESS, *supra* note 436.

438. *Id.*

439. *Id.*

440. When we first completed a draft of this Article in January 2023, Red State Access was listed as a resource for pills on Plan C's website for many states. At the time of publication, however, Red State Access is no longer listed on Plan C. AccessMA and WeSaveUs are included on Plan C's webpages for specific states. *E.g.*, *How to Get the Abortion Pill Online in Alabama*, PLAN C, https://perma.cc/PN3G-7A79 (archived Jan. 1, 2024); *How to Get the Abortion Pill Online in Indiana*, PLAN C, https://perma.cc/C92P-

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Internationally, a variety of groups in Mexico have facilitated the transit of pills into the United States.[441] These networks rely on in-kind donations from international pharmacies or individuals in Mexico—where misoprostol can be purchased without a prescription—as well as bulk purchases from India, where the drugs cost less.[442] Activists acquire pills in bulk, sometimes with mifepristone and sometimes without.[443] They then either provide the pills directly to pregnant people who can travel into Mexico or transport the pills across the border and distribute them via clandestine networks.[444] The *Washington Post* profiled one of the groups, Las Libres, which indicated that it was on track in 2022 to help 20,000 people in the United States terminate pregnancies.[445]

These networks use third-party organizations to publicize how abortion pills can be obtained. Plan C has information about the organizations and has vetted them for consumers.[446] Another organization, Shout Your Abortion, has put up billboards, used guerilla light projections,[447] flown advertising airplanes with banners behind them, distributed abortion pill boxes that contain information about where to find pills (rather than the pills themselves), and promoted abortion pills onstage at the People's Choice

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K5ZR (archived Jan. 1, 2024). Given the nature of informal networks, it is not surprising that there will be ongoing changes.

441. *See, e.g.*, Decca Muldowney, *Inside the Secretive Network of Abortion Pill Vigilantes*, DAILY BEAST (May 23, 2023, 3:59 AM EDT), https://perma.cc/R3K2-XB5S; Kitchener, *supra* note 432.

442. Kitchener, *supra* note 432. Many of these networks were formed before the Supreme Court of Mexico decriminalized abortion in 2021. Acción de Inconstitucionalidad 148/2017, Pleno de la Suprema Corte de Justicia de la Nación [SCJN], Gaceta del Semanario Judicial de la Federación, Undécima Época, Libro 14, Junio de 2022, Tomo II, página 873 (Mex.), *as translated in* SCJN, DECRIMINALIZATION OF ABORTION (2021), https://perma.cc/QK2P-KZBF; *see also* Simon Romero & Emiliano Rodríguez Mega, *Mexico's Supreme Court Decriminalizes Abortion Nationwide*, N.Y. TIMES (Sept. 6, 2023), https://perma.cc/HJ76-8HQC.

443. *See, e.g.*, Taladrid, *supra* note 81; Alexa Ura & Greta Díaz González Vázquez, *Volunteer Networks in Mexico Aid At-Home Abortions Without Involving Doctors or Clinics. They're Coming to Texas.*, TEX. TRIB. (Aug. 4, 2022, 5:00 AM CT), https://perma.cc/ET2B-5WFU; *see also* Yvonne Marquez, *How Mexican Activists Are Providing Texans with Medication Abortions*, TEX. STANDARD (July 13, 2022, 2:51 PM), https://perma.cc/HWK2-LHKT.

444. Elizabeth Navarro, *An Abortion Network that Works*, LUX MAG., https://perma.cc/4WEA-2PLZ (archived Jan. 1, 2024).

445. Kitchener, *supra* note 432.

446. *See, e.g.*, *How to Get the Abortion Pill Online in Texas*, PLAN C, https://perma.cc/W894-KBQD (archived Jan. 1, 2024).

447. Nicole Brodeur, *'We Are Everywhere': Abortion-Rights Activists Loom Large on Capitol Hill Monday Night*, SEATTLE TIMES (updated June 27, 2016, 10:37 PM), https://perma.cc/XQC4-CPPW.

Awards.[448] Many other organizations and networks, along with people in states with fewer restrictions on helping friends in states with abortion bans, share the goal of making it easier for people to discover and obtain abortion pills outside the formal healthcare system. *Dobbs* ushered in a new movement for abortion pill information.[449]

Perhaps the most significant paradigm shift resulting from these informal and extralegal networks is the move away from a medical gatekeeper model.[450] When the Supreme Court held that the Constitution protected a right to abortion in *Roe*, the Court framed abortion as "'inherently, and primarily, a medical decision' to be made in consultation with a 'responsible physician.'"[451] Scholars have argued that *Roe* and its progeny solidified this "medical gatekeeper model,"[452] with Reva Siegel arguing that this framework elevated the rights of physicians above those of women.[453] This model of abortion traces back to the first wave of abortion laws in this country in the mid- to late-1800s, when states, at the behest of the medical profession, criminalized the provision of abortion by informal providers.[454] But with abortion no longer a constitutional right, informal and extralegal networks have stepped in, as they have done in past eras, untethering abortion

448. *'It's Time to Raise Hell': Activists Today Are Shouting About Abortion Pills*, REWIRE NEWS GRP. (Dec. 1, 2021, 8:30 AM), https://perma.cc/E98K-EEAC; Nardine Saad, *Lizzo Used People's Choice Awards Speech to 'Amplify Marginalized Voices' of These 17 Activists*, L.A. TIMES (updated Dec. 9, 2022, 8:43 AM PT), https://perma.cc/9CAH-YBJV; E! News, *Lizzo Brings Out Activists & Game Changers to Accept PCAs Award | E! News*, YOUTUBE, at 03:48-04:05 (Dec. 7 2022), https://perma.cc/BVU8-S27U (to locate, select "View the live page").

449. Some organizations, such as Reproaction, have also focused on informing the public about pills now that *Roe* has been overturned. *Understanding and Advocating for Self-Managed Abortion*, REPROACTION, https://perma.cc/AN8F-MGRL (archived Jan. 1, 2024).

450. *See generally* Maya Manian, A Health Justice Approach to Abortion (updated Jan. 16, 2024) (unpublished manuscript), https://perma.cc/J5Y8-HALT.

451. *See* Yvonne Lindgren, *When Patients Are Their Own Doctors:* Roe v. Wade *in an Era of Self-Managed Care*, 107 CORNELL L. REV. 151, 161 (2021) (quoting Roe v. Wade, 410 U.S. 113, 153, 166 (1973)).

452. *E.g.*, *id.* at 174-88.

453. *See* Reva B. Siegel, Roe*'s Roots: The Women's Rights Claims that Engendered Roe*, 90 B.U. L. REV. 1875, 1897 (2010); Reva Siegel, *Reasoning from the Body: A Historical Perspective on Abortion Regulation and Questions of Equal Protection*, 44 STAN. L. REV. 261, 273 n.43 (1992).

454. Brief of 281 American Historians as Amici Curiae Supporting Appellees at 13-16, Webster v. Reprod. Health Servs., 492 U.S. 490 (1989), 1989 WL 1127703, *reprinted in* PUB. HISTORIAN, Summer 1990, at 57, 65-67.

provision from medical gatekeepers and re-vesting control in individuals.[455] Pills make this possible.[456]

The impulse to reaffirm the medical gatekeeper model will not fade away with *Roe* overturned. Many of the battles mentioned above will involve debates about the role of providers.[457] Even though the medical profession has at times been a barrier to progress, there are reasons for its involvement. Informal networks operating outside of government regulation and control will inevitably make mistakes. They might wind up distributing pills with impurities, allergens, improper labels, or incorrect doses.[458] And some people seeking pills from informal networks will almost certainly take the pills later into pregnancy, raising questions about their efficacy.[459] International pharmacies shipping non-FDA approved versions of drugs might have quality control issues.[460] But the proliferation of abortion pills means that the model for care will inevitably evolve to include options beyond the services of medical professionals.

B. The Definition of Abortion

In Part II.C, we explored how the process of a medication abortion (i.e., separate times and locations for each step complicates *when* and *where* the abortion occurred.[461] Telehealth provision of abortion pills adds another

455. *See* Lindgren, *supra* note 451, at 207 ("The technology of self-managed abortion care, along with evidence that it is being accessed by tens of thousands of people each year, reveals that the constitutional architecture that undergirds the abortion right needs to accommodate this new technology and changing practice.").

456. Key players in both the anti-abortion and abortion-rights movements have historically understood abortion pills as potentially disrupting the gatekeeper model. *See* MARY ZIEGLER, ABORTION AND THE LAW IN AMERICA: ROE V. WADE TO THE PRESENT 137, 160 (2020).

457. *See, e.g.*, COEYTAUX & WELLS, *supra* note 91, at 9 ("Efforts to make misoprostol available for abortion will be similarly affected by politics and the perception that clinical oversight is needed to ensure safe usage.").

458. *See, e.g.*, *Warning, Fake Abortion Pills for Sale Online!!*, *supra* note 233; Ann M. Moore et al., *Online Abortion Drug Sales in Indonesia: A Quality of Care Assessment*, 51 STUD. FAM. PLAN. 295, 302 (2020).

459. *See* COEYTAUX & WELLS, *supra* note 91, at 9; Heidi Moseson et al., *Effectiveness of Self-Managed Medication Abortion Between 9 and 16 Weeks of Gestation*, 142 OBSTETRICS & GYNECOLOGY 330, 334 (2023).

460. *See* Kendall Taggart, *Access Isn't the Only Problem for Abortion Pills. Sometimes They're Suspect.*, BLOOMBERG (Aug. 1, 2023, 2:30 PM PDT), https://perma.cc/675H-GAFB.

461. As we have discussed elsewhere, people expect to be able to take advantage of another state's laws when they spend the time and money to travel there. *See* Cohen et al., *supra* note 19, at 25. For people to expend great resources to obtain pills legally only to have their abortions punished because a prosecutor exploits statutory ambiguity about

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complexity because the patient and provider may be in separate states.[462] But beyond the abortion's time and location, abortion pills also render it more challenging to define *if* an abortion has occurred.

The demise of *Roe* and the rise of abortion pills will put the definition of abortion in the spotlight. One main source of ambiguity is the fact that all of the medications that can end a pregnancy have other uses. As a result, banning any particular abortion-inducing drug means depriving patients of treatments they rely on for other medical conditions. Mifepristone, for instance, is also used for Cushing's syndrome, brain tumors, endometriosis, and miscarriage.[463] Misoprostol is also used for ulcers, miscarriage, IUD insertion, and labor induction.[464] Another drug, methotrexate, which is used to treat ectopic pregnancy (technically an abortion under some states' definitions[465]), is more commonly prescribed for arthritis, cancer, and psoriasis.[466] Patients in states that have made abortion illegal following *Dobbs* have had trouble gaining access to these drugs. For instance, pharmacists have refused to dispense them, and providers have conditioned their prescription on birth control.[467]

Yet abortion bans theoretically allow for other uses because almost all states define abortion by reference to intent.[468] For instance, Alabama defines abortion as "[t]he use or prescription of any instrument, medicine, drug, or any other substance or device with the intent to terminate the pregnancy."[469] So if a drug is used for a different intent—to treat arthritis or induce labor, for example—then the abortion ban should not apply. While seemingly

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when and where the abortion occurs risks undermining people's understanding of their basic right to travel.

462. *See supra* Part III.A.

463. *See Mifepristone (Mifeprex)*, MEDLINEPLUS, https://perma.cc/Z78H-GZXF (last updated Dec. 15, 2023).

464. *See Misoprostol*, MEDLINEPLUS, https://perma.cc/E7LV-K59M (last updated Apr. 15, 2023); Ashley Waddington & Robert Reid, *More Harm than Good: The Lack of Evidence for Administering Misoprostol Prior to IUD Insertion*, 34 J. OBSTETRICS & GYNAECOLOGY CAN. 1177, 1177 (2012).

465. *See* Greer Donley & Caroline M. Kelly, *Abortion Disorientation*, 74 DUKE L.J. (forthcoming) (manuscript at 31-34), https://perma.cc/8THF-GX29 (explaining that "[e]ctopic and molar pregnancies are also abortions under many state abortion definitions by virtue of not being explicitly exempted from the general definition").

466. *See Methotrexate*, MEDLINEPLUS, https://perma.cc/Q7BY-RC4P (last updated Apr. 15, 2017); Frances Stead Sellers & Fenit Nirappil, *Confusion Post-Roe Spurs Delays, Denials for Some Lifesaving Pregnancy Care*, WASH. POST (July 16, 2022, 9:09 AM EDT), https://perma.cc/E6JU-TY2M.

467. *See, e.g.*, Katie Shepherd & Frances Stead Sellers, *Abortion Bans Complicate Access to Drugs for Cancer, Arthritis, Even Ulcers*, WASH. POST (updated Aug. 8, 2022, 11:10 AM EDT), https://perma.cc/3B7W-FYC3.

468. *See supra* note 288 and accompanying text.

469. ALA. CODE § 26-23H-3(1) (2023).

straightforward, determining whether prescribing these medications falls under the scope of an abortion ban is complicated for many reasons.

First, even when the primary healthcare provider knows that an abortifacient is being prescribed for another use, other providers in the chain—especially pharmacists—may not be privy to the intended use of a drug.[470] Prescriptions are typically sent to the pharmacy without any indication for use, so the pharmacist has no way to know if the drug is being used for abortion or something else.[471] This explains why, after *Dobbs*, some pharmacists refused to dispense drugs that could be used for abortion, like misoprostol for miscarriage or methotrexate for arthritis, harming people's access to needed medications.[472] Bigger chains, like CVS, eventually instituted procedures in states that ban abortion to verify the use of these drugs for non-abortion purposes before dispensing them.[473] But delays and access issues may still persist if pharmacists continue to have concerns about abortion liability.

Second, fear of overzealous prosecutors may cause providers to change their prescribing habits for abortifacients for alternative uses.[474] For instance, rheumatologists frequently prescribe methotrexate for arthritis.[475] Though this should not come under the ambit of an abortion ban because there is no intent to end a pregnancy, what happens if methotrexate is prescribed to a person who is pregnant? Could the provider's intent to end a pregnancy be inferred? Rheumatologists typically do not prescribe methotrexate to pregnant patients,[476] but providers may not know a patient is pregnant, either because the patient does not know themselves or did not disclose it. And because

470. *See* Celine Castronuovo, *Abortion Drug Bans Make Pharmacies Wary of Common Arthritis Pill*, BLOOMBERG L. (July 14, 2022, 2:50 AM PDT), https://perma.cc/PS2L-HFY9 (explaining that, after *Dobbs*, some pharmacists were hesitant to fill prescriptions for drugs that could be used for abortion); Lauren Coleman-Lochner, Carly Wanna & Elaine Chen, *Doctors Fearing Legal Blowback Are Denying Life-Saving Abortions*, BLOOMBERG (July 12, 2022, 7:30 AM PDT), https://perma.cc/6E3A-D7CR.

471. *See* Kathryn Mercer et al., *Including the Reason for Use on Prescriptions Sent to Pharmacists: Scoping Review*, 8 JMIR HUM. FACTORS e22325, at 2 (2021); *Guidance to Nation's Retail Pharmacies: Obligations Under Federal Civil Rights Laws to Ensure Nondiscriminatory Access to Health Care at Pharmacies*, U.S. DEP'T OF HEALTH & HUM. SERVS., https://perma.cc/4ZKP-YJVU (last updated Sept. 29, 2023).

472. *See, e.g.*, Coleman-Lochner et al., *supra* note 470.

473. Katie Barlow, *CVS Requiring Verification on Drugs with Possible Abortion Use in 5 States*, FOX 5 DC (updated July 22, 2022, 5:00 PM), https://perma.cc/DY6L-8GZA; *see also* Nadia Kounang, *First on CNN: HHS Announces Actions from Walgreens and CVS to Ensure Women's Access to Medications*, CNN (updated June 17, 2023, 8:57 AM EDT), https://perma.cc/QH6Q-6RKP.

474. *See, e.g.*, Ian Millhiser, *Can Pharmacists Refuse to Fill Prescriptions for Drugs that Can Be Used in Abortions?*, VOX (July 15, 2022, 6:00 AM EDT), https://perma.cc/HV65-Z7M7.

475. *See id.*

476. *See* MotherToBaby, Methotrexate 1 (2023), https://perma.cc/SP4Q-G5HZ.

providers frequently prescribe methotrexate to patients capable of becoming pregnant, they risk exposing themselves to legal liability if they do not take steps to protect themselves.[477] Is it enough to ask the patient if they are pregnant? Should they require their patient use birth control or provide proof of sterility? Or must they require their patient to take a regular pregnancy test before getting a prescription refill? Unfortunately, news stories reflect these scenarios.[478] These practices condition healthcare on avoiding pregnancy or using birth control, raising questions about reproductive coercion and sex discrimination given that patients identifying as men do not face similar prerequisites for medically necessary healthcare.[479]

As Part III.B explained, missed period pills exploit this ambiguity in a drug's use.[480] Just as methotrexate is used to treat arthritis, missed period pills are used to induce a period, not terminate a "known pregnancy."[481] In this situation, an intentional decision to avoid discovering pregnancy could create an after-the-fact impossibility of knowing whether a live pregnancy was ended. State legislatures could respond to this by requiring a pregnancy test before any abortifacient is prescribed (or amending the definitional scope of abortion), but this would be similarly coercive and discriminatory.

Third, one common alternative use of these drugs is for pregnancy loss.[482] Both mifepristone and misoprostol are used as a treatment for missed miscarriage—a miscarriage that is discovered, usually after an ultrasound, before the pregnant person's body has recognized it.[483] It often takes weeks for bodily recognition to occur,[484] and even when it does, the body can sometimes struggle to expel the tissue on its own (known as an incomplete miscarriage).[485] In these situations, patients are given a few options: Wait to see if the

477. *See* Rob Volansky, *'Strange Times': Prescribing Methotrexate Legally 'Low Risk' Post-*Roe, HEALIO RHEUMATOLOGY (Nov. 14, 2022), https://perma.cc/9EQD-BTS9 (quoting Greer Donley).

478. *See, e.g.*, Shepherd & Sellers, *supra* note 467.

479. *See Guidance to Nation's Retail Pharmacies*, *supra* note 471.

480. *See supra* notes 290-99 and accompanying text; *see also* Carrie N. Baker, *Period Pills: Another Option for Fertility Control*, MS. MAG. (Oct. 20, 2022), https://perma.cc/L9DY-22EH.

481. *See supra* note 288 and accompanying text.

482. *See* Donley & Lens, *supra* note 294, at 1666.

483. *Id.*

484. *See* Krissi Danielsson, *Diagnosis of a Miscarriage Without Bleeding*, VERYWELL FAM. (updated Oct. 17, 2021), https://perma.cc/3ZNV-TVDP.

485. Am. Coll. of Obstetricians & Gynecologists, *supra* note 394, at 4-5.

miscarriage will resolve on its own, known as expectant management, or use medical interventions—drugs or procedures—to complete the miscarriage.[486]

Miscarriage management should not theoretically fall under the ambit of abortion bans because there is no intent to terminate. In fact, many states specifically exclude removing an already dead fetus from the definition of abortion.[487] But though people assume that the line between abortion and miscarriage is clear, numerous situations belie that assumption.[488] For instance, miscarriages that occur before the documentation of a fetal heartbeat—which are most miscarriages[489]—are difficult to diagnose. Many providers distinguish between a live and dead pregnancy via fetal cardiac activity.[490] But if cardiac activity was never identified, then miscarriage is diagnosed with blood tests or ultrasound imaging over a few days or weeks to see if pregnancy hormones are decreasing and the embryo's growth has stopped.[491] Sometimes these kinds of tests, however, are unnecessary—for instance, when the person is sure of the last missed period or ovulation date and therefore knows the pregnancy is measuring weeks behind when it should be.[492] Now that abortion is a crime in roughly a third of the country, physicians are afraid to use active measures, like medication, to treat these patients without independent confirmation that the pregnancy has ended. For instance, Christina Zielke experienced a life-threatening emergency while having a miscarriage in Ohio because providers initially refused to treat her until additional tests could confirm the miscarriage days later.[493] Even after the detection of a heartbeat, lines can blur, as a miscarriage or stillbirth can be inevitable and in process while the fetus still has a heartbeat.[494] In these cases,

486. *Id.* at 4. Though some people prefer to avoid medical intervention, expectant management can take up to eight weeks and comes with higher risks. *Id.* at 4-5. Some people prefer active measures to speed up the miscarriage process and reduce their risks. *Id.*

487. *See, e.g.*, ALA. CODE § 26-23H-3(1) (2023); FLA. STAT. § 390.011(1) (2023); IDAHO CODE § 18-604(1)(b) (2023); 775 ILL. COMP. STAT. § 55/1-10 (2023).

488. *See* Donley & Lens, *supra* note 294, at 1707-12 (arguing that the line between miscarriage and abortion is blurred).

489. Krissi Danielsson, *Making Sense of Miscarriage Statistics*, VERYWELL FAM. (updated Oct. 25, 2022), https://perma.cc/943K-QLXQ.

490. *See id.* at 1680, 1711-12 (describing the process of determining an early miscarriage, often before cardiac activity has developed).

491. *See id.*; *Miscarriage*, MAYO CLINIC (Sept. 8, 2023), https://perma.cc/EL3Q-624H.

492. Donley & Lens, *supra* note 294, at 1680, 1711-12.

493. *See* Selena Simmons-Duffin, *Her Miscarriage Left Her Bleeding Profusely. An Ohio ER Sent Her Home to Wait*, NPR (Nov. 15, 2022, 12:01 PM ET), https://perma.cc/3Q3J-S7AR.

494. *See* Donley & Kelly, *supra* note 465 (manuscript at 28-31).

hastening a miscarriage is classified as an abortion, and providers are delaying that care until the fetus's heart stops or the pregnant person is close to death.[495]

Definitional blurriness also has impacted the treatment of ectopic pregnancies. Ectopic pregnancy occurs when a pregnancy implants outside of the uterus, most often in a fallopian tube, where it cannot survive.[496] Eventually, the pregnancy may outgrow the tube, causing it to rupture, killing the embryo and threatening the pregnant person's life.[497] When ectopic pregnancy is caught before rupture, it can be treated with methotrexate, which ends the pregnancy.[498] However, that treatment occurs *before* the pregnancy has ended on its own.[499] As a result, unless an abortion ban specifically excludes ectopic pregnancy from its definition of an abortion (as many states do[500]), the use of methotrexate to end an ectopic pregnancy would be both legally and medically an abortion.[501] Though the ectopic pregnancy will eventually become life-threatening and should be covered under the life exceptions in abortion bans, doctors have refused to treat pregnant patients until their lives are threatened when the pregnancy ruptures, compromising the person's health and future fertility for no medical reason.[502] For instance, Mayron Hollis almost died in Tennessee after being denied an abortion to treat an ectopic pregnancy that had implanted on her c-section scar.[503]

As Greer Donley and Jill Weiber Lens have explained, abortion bans do not properly account for the reality of pregnancy—where the line between abortion and pregnancy loss can be blurred—causing patients to suffer and threatening the standard of reproductive healthcare.[504]

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495. *See id.*; *see also* Sarah Varney, *How the Texas Trial Changed the Story of Abortion Rights in America*, KFF HEALTH NEWS (Aug. 7, 2023), https://perma.cc/V7FG-HAGE.

496. *Ectopic Pregnancy*, MAYO CLINIC (May 12, 2022), https://perma.cc/W2UP-CJTE.

497. Beata E. Seeber & Kurt T. Barnhart, *Suspected Ectopic Pregnancy*, 107 OBSTETRICS & GYNECOLOGY 399, 399 (2006).

498. *Id.* at 405.

499. *See id.* at 404-05.

500. *See, e.g.*, ALA. CODE § 26-23H-3(1) (2023); IDAHO CODE § 18-604(1)(c) (2023); OKLA. STAT. tit. 63, § 1-757.2(1)(c) (2023).

501. *See* Sellers & Nirappil, *supra* note 466 (highlighting the uncertainty).

502. *See, e.g.*, Caroline Kitchener, *The Texas Abortion Ban Has a Medical Exception. But Some Doctors Worry It's Too Narrow to Use.*, WASH. POST (Oct. 22, 2021, 2:30 PM EDT), https://perma.cc/GK82-4WU5 (noting that, after *Dobbs*, a patient with an ectopic pregnancy in Texas was denied care); Nadine El-Bawab, *Tennessee Woman Gets Emergency Hysterectomy After Doctors Deny Early Abortion Care*, ABC NEWS (May 31, 2023, 3:10 AM), https://perma.cc/4WQZ-4L2P.

503. El-Bawab, *supra* note 502.

504. *See* Donley & Lens, *supra* note 294, at 1711-16.

Fourth and finally, even when the distinctions between abortion and loss are logically coherent, there are practical challenges to deciphering the difference between self-managed abortion and miscarriage: The two events are physically identical and the same medications can be used for both.[505] What that means is that when someone presents at an emergency room pregnant and bleeding, the person could be experiencing complications from either a miscarriage or an abortion.[506] There presently is no blood test or physical exam in practice that discerns the difference, so unless the person confesses that they took medications to end the pregnancy, only a non-clinical investigation would reveal a self-managed abortion.[507] For all the reasons discussed in Part V.D below, these types of investigations will involve problematic invasions of privacy—ones that will inevitably harm low-income people and women of color disproportionately and include patients who have experienced miscarriage.[508]

There are no easy answers for an anti-abortion movement that wants to stop the proliferation of abortion pills. Anti-abortion advocates will have a hard time convincing the public that the anti-abortion movement is "pro-woman, pro-life"[509] when the collateral damage of its abortion bans piles up.[510] Indeed, the movement's decision to sacrifice people's health in the name of eradicating all abortion is playing out in the national spotlight and could strengthen public support for abortion rights.[511] The public is learning firsthand of the harsh consequences created by abortion bans, including for ten-year-old rape victims,[512] people facing life-threatening pregnancy loss,[513]

505. *See id.* at 1707.

506. *Id.*

507. *See* VERMA ET AL., *supra* note 385, at 12. On rare occasions, when misoprostol is inserted vaginally in a medication abortion, fragments of the pills can be identified. *See id.* at 6; Angeline Ti, *Insights: Misoprostol-Only Medication Abortion*, REPROD. HEALTH ACCESS PROJECT (Feb. 28, 2023), https://perma.cc/79CS-HZJX. As we were finishing this Article, news broke that researchers in Poland had developed a test that can detect the presence of mifepristone in the blood. *See* Patrick Adams, Opinion, *In Poland, Testing Women for Abortion Drugs Is a Reality. It Could Happen Here.*, N.Y. TIMES (Sept. 14, 2023), https://perma.cc/PUN8-F7H6. It is too soon to know anything more about this test's efficacy and legitimacy or whether and how it will be used in the United States.

508. *See infra* Part V.D.

509. *See* Reva Siegel, *Why Restrict Abortion? Expanding the Frame on June Medical*, 2020 SUP. CT. REV. 277, 281 (2021).

510. *See* Varney, *supra* note 495.

511. *See* Laura Santhanam, *Support for Abortion Rights Has Grown in Spite of Bans and Restrictions, Poll Shows*, PBS NEWSHOUR (Apr. 26, 2023, 5:00 AM EST), https://perma.cc/MJW3-RKVA.

512. *See, e.g.*, Anne Flaherty, *Case of 10-Year-Old Rape Victim Challenges Anti-Abortion Rights Movement*, ABC NEWS (July 16, 2022, 5:06 AM), https://perma.cc/QZR6-JHRN.

513. *See, e.g.*, Simmons-Duffin, *supra* note 493.

and those with a serious prenatal diagnosis.[514] And perhaps counterintuitively, abortion bans, by encompassing and having an effect on those traditionally considered blameless for their pregnancy loss, could help break down the boundary between "good" and "bad" abortions.

C. Undermining Abortion Stigma

Medication abortion could change the nature and depth of abortion stigma—"a negative attribute ascribed to women who seek to terminate a pregnancy that marks them, internally or externally, as inferior to ideals of womanhood."[515] Historically, the anti-abortion movement stigmatized abortion by stigmatizing abortion *procedures*.[516] Abortion *pills*, however, will be harder to villainize.

Anti-abortion advocates have long attacked second-trimester abortion procedures by characterizing them as "gruesome."[517] In the 2000s, the anti-abortion movement set its sights on a rare second-trimester procedure known as a dilation and extraction (D&X), which it denigrated as a "partial-birth abortion."[518] Litigation challenging state D&X bans—and eventually, a federal ban—played out in the courts and national debate, focusing the public's gaze on the mechanics of second-trimester abortion.[519] In the last few years, the anti-abortion movement used this tactic to try to ban the most common form of second-trimester abortion, dilation and evacuation (D&E).[520] It dubbed these abortions "dismemberment abortions" because the fetus was removed in parts.[521] Many states passed D&E bans, and after a circuit split emerged, the bans were destined for the Supreme Court until *Dobbs* mooted the issue.[522]

The increasing uptake and availability of medication abortion can change that conversation. Almost all medication abortions are early abortions, and pregnancy tissue in early pregnancy, especially in the first ten weeks, is

514. *See, e.g.*, Frances Stead Sellers, Thomas Simonetti & Maggie Penman, *The Short Life of Baby Milo*, WASH. POST (May 19, 2023, 6:00 AM), https://perma.cc/A8FA-6KBQ.

515. Alison Norris et al., *Abortion Stigma: A Reconceptualization of Constituents, Causes, and Consequences*, 21 WOMEN'S HEALTH ISSUES S49, S50 (2011) (emphasis omitted) (quoting Anuradha Kumar, Leila Hessini & Ellen M.H. Mitchell, *Conceptualising Abortion Stigma*, 11 CULTURE HEALTH & SEXUALITY 625, 628 (2009)).

516. *See* Greer Donley & Jill Wieber Lens, *Second-Trimester Abortion Dangertalk*, 62 B.C. L. REV. 2145, 2157-63 (2021).

517. *See, e.g.*, *id.* at 2148.

518. *Id.* at 2157-60.

519. *See id.* at 2159.

520. *Id.* at 2160-63.

521. *Id.* at 2160.

522. *Id.* at 2160-63.

difficult to personify as a baby or even only as a developed fetus.[523] The six-to-eight-week image pregnant patients see during their first ultrasound looks like a circle with a miniscule flutter if cardiac activity is detected.[524] To the naked eye, early pregnancy tissue looks like blood clots and tissue, which is what people see after an early abortion or miscarriage.[525] Not until closer to the second trimester are fetal parts easily discernable without magnification.[526]

Anti-abortion activists might be able to decry that an "unborn life" was prematurely ended with medication, but targeting the *way* it was ended will require different rhetoric. Like an early miscarriage, a pregnancy ended by medication ends the way many pregnancies end: expulsion from the pregnant person's body without a provider's procedural intervention. There is, however, a significant caveat: If medication abortion is used later in pregnancy, the fetal tissue will be more developed.[527] Because abortion bans delay care and increase desperation,[528] there may be an increasing number of people self-managing abortions later in pregnancy.[529] And people who use pills on their own in the second trimester are much more likely to be caught, punished, and villainized.[530]

523. *See* Poppy Noor, *What a Pregnancy Actually Looks Like Before 10 Weeks—In Pictures*, GUARDIAN (Oct. 19, 2022, 1:00 AM EDT), https://perma.cc/3GU5-655G; Carol Sanger, *Seeing and Believing: Mandatory Ultrasound and the Path to a Protected Choice*, 56 UCLA L. REV. 351, 368 (2008).

524. *See, e.g.*, Gil Wilshire, Mo. Fertility, *Sonogram: 6 Weeks Pregnant!*, YOUTUBE (Aug. 19, 2020), https://perma.cc/9UK5-TBPL (to locate, select "View the live page"); Robyn Horsager-Boehrer, *Patience Is Key: Understanding the Timing of Early Ultrasounds*, UT SW. MED. CTR.: MEDBLOG (Nov. 20, 2018), https://perma.cc/6QDJ-LWP2; Kate Daley, *What to Expect at Your 6-Week Ultrasound Appointment*, TODAY'S PARENT (updated May 11, 2022), https://perma.cc/52G5-QUDQ.

525. *See* Noor, *supra* note 523; Rebecca Cohen, *What Happens After a Miscarriage? An Ob-Gyn Discusses the Options.*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (updated June 2022), https://perma.cc/R9TQ-CGQ6 ("The pregnancy tissue may look like large blood clots, or it may look white or gray. It does not look like a baby.").

526. *See* Alaska Native Med. Ctr., Management of Miscarriage and Early 2nd Trimester Intrauterine Fetal Demise Summary & Recommended Management 4 (2023), https://perma.cc/7MTM-4U6T ("Proceed with caution with >11wks GA and appropriately counsel about bleeding precautions and that they may be seeing fetal parts."); Noor, *supra* note 523.

527. *See* Lux Alptraum, *Why Are We Restricting the Abortion Pill to First-Trimester Pregnancies?*, CUT (July 8, 2022), https://perma.cc/6LPK-Y6BK.

528. *See* González, *supra* note 389.

529. Anna North, *People Are Using Abortion Medication Later in Their Pregnancies. Here's What that Means*, VOX (June 18, 2023, 7:00 AM EDT), https://perma.cc/V8UM-JU9F.

530. *See* HUSS ET AL., *supra* note 242, at 23.

Moreover, not just abortion procedures, but also abortion clinics, have long been targets of the anti-abortion movement.[531] But with abortion pills, both are more removed from the abortion experience as the pregnant person ends the pregnancy herself. Clinics are described as "abortion mills" by opponents of abortion and are accused of not taking proper care of patients.[532] They are often marginalized and physically separated from traditional healthcare facilities, making it easier to target them with harassment and violence.[533] This environment has contributed to the stigmatization of abortion care.[534] But medication abortions typically happen in a private space, often at home.[535] And for people obtaining pills through informal networks, the entire process takes place outside the formal medical system.[536] This detachment from abortion clinics and providers can undermine many of the stereotypes and myths that have surrounded abortion. But despite their benefits, operating through informal networks, ordering medication online, and taking pills "in secret" could pull abortion care further into the shadows, worsening shame and stigma.

When abortion was legal nationwide, the anti-abortion movement painted a picture of abortion that never corresponded to reality—abortions on nearly full-term fetuses in unsafe clinics.[537] Mailed medication abortion in the first trimester contradicts every aspect of that depiction.[538] And now public support for abortion after the first trimester is at its highest since 1996.[539] Perhaps we

531. *See* DAVID S. COHEN & KRYSTEN CONNON, LIVING IN THE CROSSHAIRS: THE UNTOLD STORIES OF ANTI-ABORTION TERRORISM, at ix-x (2015).

532. *See id.* at 39; Donley, *supra* note 15, at 693; Taida Wolfe & Yana van der Meulen Rodgers, *Abortion During the COVID-19 Pandemic: Racial Disparities and Barriers to Care in the USA*, 19 SEXUALITY RSCH & SOC. POL'Y 541, 541 (2022).

533. *See* Donley, *supra* note 15, at 692.

534. *Id.*

535. Lindgren, *supra* note 451, at 188-89.

536. This also raises the prospect that the overturning of *Roe*, along with the increased access to informal networks for pills, threatens the accurate counting of abortion in this country. *See, e.g.*, SOC'Y FAM. PLAN., *supra* note 47, at 8 ("We are unable to estimate the number of abortions that occurred outside the formal healthcare system, such as via Aid Access or volunteer accompaniment networks in Mexico.").

537. *See* Lori Robertson, *The Facts on the Born-Alive Debate*, FACTCHECK.ORG (Mar. 4, 2019), https://perma.cc/7EZ5-BVH5; Robert Farley, *Noem's Misleading Claim About Safety of Medication Abortion*, FACTCHECK.ORG (updated Feb. 8, 2024), https://perma.cc/Z487-A372.

538. *See* Donley, *supra* note 15, at 61-93 (discussing how telehealth and medication abortion will reduce stigma by de-linking abortion from stigmatized spaces).

539. Lydia Saad, *Broader Support for Abortion Rights Continues Post-Dobbs*, GALLUP (June 14, 2023), https://perma.cc/86JG-AVAB; *see also* Ushma D. Upadhyay, Editorial, *Barriers Push People into Seeking Abortion Care Later in Pregnancy*, 112 AM. J. PUB. HEALTH 1280, 1281 (2022) (arguing that abortion bans delay care and can lead to later abortions).

are witnessing a retreat from abortion stigma throughout pregnancy because of the real-time failure of anti-abortion tropes, and the abortion bans expressing them, to account for when and how so many pregnancies end.

D. Surveillance, Investigation, and Backlash

As has been true with the War on Drugs,[540] state actors will insert themselves into people's private affairs in alarming ways as abortion bans proliferate and individuals seek to self-manage their abortions with pills. Investigation into people's abortion decisions will likely occur in emergency rooms, through their mail, and in their homes—spaces that have already been targeted for state surveillance of reproductive decisions.[541] In the coming era, investigations will also extend into digital technology as more personal data are collected and stored in apps, phones, and smart devices.[542] What people search for on the internet, order online, and express in their electronic communications could be used to target those who self-managed abortions. These new invasions of privacy may be particularly unpalatable to the public and will continue to raise questions about race and class disparities.

As noted above, a recent study reports that, over the last couple of decades, there were at least sixty-one criminal investigations or cases against people for self-managed abortion.[543] Many cases were first reported to law enforcement by healthcare providers or social workers, but there were also reports from close acquaintances, 911 calls, and anonymous tips.[544] Among the adult

540. *See* GOODWIN, *supra* note 18, at 119 ("The drug war drafts police, prosecutors, and judges to carry out its mission and metaphorically casts some of America's most vulnerable as enemy combatants to be tracked, policed, and—if caught—jailed.").

541. To contrast previous interventions with contemporary digital tracking, see Aziz Z. Huq & Rebecca Wexler, *Digital Privacy for Reproductive Choice in the Post-*Roe *Era*, 98 N.Y.U. L. REV. 555, 618-43 (2023) (describing "digital battlefields" that will arise because *Roe* has been overturned). *See also* Eric Boodman, Tara Bannow, Bob Herman & Casey Ross, *HIPAA Won't Protect You if Prosecutors Want Your Reproductive Health Records,* STAT (June 24, 2022), https://perma.cc/S5EY-H4UA (discussing HIPAA's application to various modern tracking data).

542. *See* Joh, *supra* note 252 (manuscript at 4).

543. HUSS ET AL., *supra* note 242, at 21, 36-38; *see also* Nat'l Advocs. for Pregnant Women, Arrests and Other Deprivations of Liberty of Pregnant Women, 1973-2020, at 1 (2021), https://perma.cc/3GMM-KSTJ (noting that between 1973-2020 there were over 1,600 cases "in which being pregnant was a necessary element of the crime or a 'but for' reason for the coercive or punitive action taken").

544. HUSS ET AL., *supra* note 242, at 30-31 ("39% of the cases were reported to law enforcement by health care providers and 6% by social workers. About a quarter of adult cases (26%) were reported to law enforcement by acquaintances entrusted with information, such as friends, parents, or intimate partners. Another 18% came to the attention of police by other means, including police recovery of fetal remains,
footnote continued on next page

defendants, people of color were disproportionately represented, and a majority of cases involved low-income people.[545] The participation of healthcare providers in reporting these individuals fosters distrust, leaving abortion-seekers with even fewer options to seek medical advice and care.[546]

Pre-*Dobbs* cases highlight how data surveillance and reporting by healthcare providers can lead to criminal actions against those who use pills, even when it is not clear that a crime has been committed.[547] For instance, in 2012, Jennifer Whalen brought her daughter to the local emergency room for bleeding after her daughter took abortion pills obtained online.[548] Soon after, hospital personnel reported Whalen to local authorities, and the police searched her home and found the empty pill box.[549] The local district attorney charged Whalen with four different crimes, including a felony for offering medical consultation about an abortion without a license; she ultimately pled guilty to the felony and was sentenced to serve nine-to-eighteen months in prison.[550]

Other pre-*Dobbs* cases reveal how technology could be marshaled against people ending pregnancies once law enforcement is involved in an investigation.[551] In 2018, a Mississippi woman, Latice Fisher, was charged with second-degree murder for the death of her newborn child on the theory that the child was born alive and then died by asphyxiation.[552] The prosecution relied on Fisher's cell phone data that revealed searches for buying abortion pills to argue that her premature labor was induced.[553] The grand jury rejected

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anonymous tips to police, or a 911 call on behalf of the pregnant person. The law enforcement trigger was unknown in the remaining 11% of adult cases.").

545. *Id.* at 22, 25.

546. *See* GOODWIN, *supra* note 18, at 85-86.

547. *See id.* at 85 (describing the "troubling pattern of states unconstitutionally depriving pregnant women of their bodily integrity, privacy, and civil liberties, with doctors as overseers to that politicized agenda").

548. Emily Bazelon, *A Mother in Jail for Helping Her Daughter Have an Abortion*, N.Y. TIMES MAG. (Sept. 22, 2014), https://perma.cc/9KK5-A8LE.

549. *Id.*

550. *Id.*

551. Americans' views differ on whether law enforcement should be able to use different types of data in criminal investigations. *See* BROOKE AUXIER ET AL., PEW RSCH. CTR., AMERICANS AND PRIVACY: CONCERNED, CONFUSED AND FEELING LACK OF CONTROL OVER THEIR PERSONAL INFORMATION 7-8, 34-36 (2019), https://perma.cc/C2PL-BRAK.

552. *See* Teddy Wilson, *'Prosecution in Search of a Theory': Court Documents Raise Questions About Case Against Latice Fisher*, REWIRE NEWS GRP. (Feb. 21, 2018, 12:16 PM), https://perma.cc/T3WW-FC96; Alex Holloway, *New Info Suggests Baby Left in Toilet May Have Been Born Dead*, DISPATCH (May 9, 2019), https://perma.cc/3K57-9ZEW.

553. Wilson, *supra* note 552.

the charges but only after the prosecutor admitted that a forensic test used in the case was potentially unreliable.[554]

Investigations like these continue. In 2022, Lizelle Hererra was charged with murder in Texas for allegedly terminating a pregnancy—by all accounts with pills—after a hospital reported her to local authorities.[555] Importantly, there was no law in Texas that permitted Herrera's prosecution, and the charges were later dropped;[556] but the very act of charging her likely had a chilling effect throughout the state.[557]

In another 2022 case, a Nebraska mother obtained abortion pills for her pregnant daughter, who successfully used the pills to terminate her pregnancy at about twenty-nine weeks.[558] Law enforcement obtained a warrant to search the daughter's private Facebook messages, in which she told her mother of her urgent desire to end her pregnancy.[559] Both the daughter and mother pled guilty to various non-abortion crimes, including concealing human skeletal remains and giving false information to a police officer, with the mother also pleading guilty to violating the state's abortion laws; the daughter—a minor at

554. Ryan Phillips, *Infant Death Case Heading Back to Grand Jury*, STARKVILLE DAILY NEWS (updated May 9, 2019), https://perma.cc/2LYR-MQ2U; Patricia Hurtado & Francesca Maglione, *In a Post-Roe World, More Miscarriage and Stillbirth Prosecutions Await Women*, FORTUNE (July 5, 2022, 12:45 PM PDT), https://perma.cc/S3YP-2QKF. Similarly, in 2013, Purvi Patel ordered abortion pills online from an overseas supplier. Patel v. State, 60 N.E.3d 1041, 1043 (Ind. Ct. App. 2016). The prosecution offered evidence from Patel's iPad—a customer service email from a company that sold abortion pills—as well as text messages to a friend in which Patel had expressed a desire to get an abortion. *Id.* at 1045, 1047. A jury convicted her of child neglect and feticide, and she was sentenced to twenty years in prison. *Id.* at 1044. On appeal, the feticide conviction was overturned, but the child-neglect conviction was upheld. *Id.*

555. McCullough, *supra* note 248; Carrie N. Baker, *Texas Woman Lizelle Herrera's Arrest Foreshadows Post-Roe Future*, MS. MAG. (Apr. 16, 2022), https://perma.cc/8FJ7-96QY; Carrie N. Baker, *How Grassroots Activists Forced a Texas District Attorney to Drop Murder Charges for Self-Induced Abortion*, MS. MAG (Apr. 18, 2022), https://perma.cc/ALX5-RT25; James Dobbins, *Why Was a Texas Woman Charged with Murder for a 'Self-Induced' Abortion? Officials Won't Say.*, TEX. OBSERVER (Apr. 15, 2022, 9:52 AM CDT), https://perma.cc/DQG9-68XT. Herrera's arrest took place before *Dobbs* but while Texas's extremely restrictive SB8 was in effect.

556. *See* Baker, *supra* note 555.

557. *See* Mary Ziegler, Opinion, *Lizelle Herrera's Texas Arrest Is a Warning*, NBC NEWS: THINK (Apr. 16, 2022, 1:30 AM PDT), https://perma.cc/9KSX-FYFY.

558. Shaila Dewan & Sheera Frenkel, *A Mother, a Daughter and an Unusual Abortion Prosecution in Nebraska*, N.Y. TIMES (Aug. 18, 2022), https://perma.cc/NNW8-BPMZ; Josh Funk, *Nebraska Woman Pleads Guilty to Burning Fetus After Abortion*, AP NEWS (May 23, 2023, 7:13 AM PST), https://perma.cc/7QYT-K3J7.

559. *See* Dewan & Frenkel, *supra* note 558.

the time, but charged as an adult—was sentenced to ninety days in jail, while the mother was sentenced to two years in prison.[560]

As these cases reveal, even if no state expands its abortion bans to apply to the pregnant person, prosecutors can, with the help of digital surveillance and the reports of third parties, nevertheless use a variety of criminal laws to punish people who use pills.[561] As Cynthia Conti-Cook notes, "[d]igital evidence fills a gap for prosecutors keen on prosecuting women for their pregnancy outcomes."[562] This type of evidence seems especially relevant when there are questions about whether an abortion or pregnancy loss occurred, though "sift[ing] through an accused person's most personal thoughts, feelings, movements, and medically-related purchases during their pregnancy" is often not dispositive of how the pregnancy ended.[563] As Anya Prince has explained, companies can know about a pregnancy even if the pregnant person has not disclosed the pregnancy to anyone else and taken great lengths to hide it.[564] And many people are using apps to track their health, including menstrual tracking apps.[565] Though these resources may appear private and contained on an app on a password-protected phone,[566] the deeply personal information housed therein, from menstrual cycle dates to sexual activity or alcohol use, is often not secure.[567]

Despite a willingness to provide personal data online in apps and on websites, most people maintain strong beliefs regarding the value of their privacy.[568] A study conducted by the American Medical Association found that more than 92% of patients surveyed felt that privacy is a right and that their health data should not be available for purchase.[569] But patients may not

560. *Id.*; Margery A. Beck, *18-Year-Old Nebraska Woman Sentenced to 90 Days in Jail for Burning Fetus After Abortion*, AP NEWS (July 20, 2023, 10:55 AM PDT), https://perma.cc/9DQR-3GQQ; Jesus Jiménez, *Mother Who Gave Abortion Pills to Teen Daughter Gets 2 Years in Prison*, N.Y. TIMES (Sept. 22, 2023), https://perma.cc/56VM-LSRE.

561. *See* Joh, *supra* note 252 (manuscript at 4); Anya E.R. Prince, *Reproductive Health Surveillance*, 64 B.C. L. REV. 1077, 1110-21 (2023).

562. Cynthia Conti-Cook, *Surveilling the Digital Abortion Diary*, 50 U. BALT. L. REV. 1, 50 (2020).

563. *Id.* at 51; *see also* Prince, *supra* note 561, at 1110-21.

564. Prince, *supra* note 561, at 1085-91.

565. *See* Kaiser Fam. Found., Health Apps and Information Survey 4-7 (2019), https://perma.cc/R5GD-QCXU.

566. Leah R. Fowler & Stephanie R. Morain, *Schrödinger's App*, 46 AM. J.L. & MED. 203, 207 (2020); Conti-Cook, *supra* note 562, at 24.

567. *See* Conti-Cook, *supra* note 567, at 5-6, 13.

568. *See* Daniel J. Solove, *The Myth of the Privacy Paradox*, 89 GEO. WASH. L. REV. 1, 1-6 (2021).

569. Am. Med. Ass'n, Patient Perspectives Around Data Privacy (2022), https://perma.cc/7KM5-BMYD.

realize the limitations of health privacy laws, especially in the course of a criminal investigation.[570] Indeed, a majority of Americans report being concerned about how the government and private companies use their data, while also feeling that data collection is inevitable.[571] And support for privacy rights holds across the political spectrum, with particular support for privacy rights from conservatives.[572]

Yet the policing of pregnant people is in no way new, even if the means have evolved.[573] With the increasing size of people's digital footprints and the proliferation of abortion pills, anti-abortion states and advocates will have the tools to punish those who terminate pregnancies (and those who help them).[574] Some state actions to target people who obtain pills are sure to be unpopular, and, indeed, the cases cited above have provoked public outcry.[575] With pills, abortions are moving from clinics to the home. By necessity, investigations into abortion crimes will thus involve home searches—such as what occurred with Jennifer Whalen described above[576]—potentially testing people's

570. At issue in the Supreme Court case *Ferguson v. City of Charleston* was a substance abuse program in which hospital staff preserved urine drug tests of pregnant patients for use in future criminal proceedings. 532 U.S. 67, 71-72 (2001). The Court ruled that although the program may have been designed to promote health through increasing uptake of treatment, "the immediate objective of the searches was to generate evidence *for law enforcement purposes*," in violation of the Fourth Amendment. *Id.* at 82-84. However, the Court also made clear that hospital staff might provide evidence for criminal investigations so long as they ensure their patients "are fully informed about their constitutional rights." *Id.* at 84-85. On remand, the Fourth Circuit concluded that the patients did not give informed consent to the searches. Ferguson v. City of Charleston, 308 F.3d 380, 404 (4th Cir. 2002). For a full discussion of health privacy laws in the abortion context, see generally Stacey A. Tovino, *Confidentiality over Privacy*, 44 CARDOZO L. REV. 1243 (2023).

571. *See* AUXIER ET AL., *supra* note 551, at 2. In surveys, people expressed more concern over personal information collection by social media sites than by law enforcement. *Id.* at 20.

572. *Id.* at 41 (comparing the 42% of Democrats or Democrat-leaning independents who support private data use for social good to only 28% of Republican or Republican-leaning independents support for the same).

573. *See* Grace Howard, *The Pregnancy Police: Surveillance, Regulation, and Control*, 14 HARV. L. & POL'Y REV. 347, 350-51 (2020). *See generally* GOODWIN, *supra* note 18 (explaining and analyzing the various ways states have criminalized people for pregnancy outcomes). Wendy Bach describes the effect of Tennessee's contemporary fetal assault law—which made it a crime for a pregnant woman to transmit narcotics to a fetus in the name of substance abuse assistance—through the cases of 120 prosecuted pregnant people. WENDY BACH, PROSECUTING POVERTY, CRIMINALIZING CARE 1-10 (2022).

574. Leah R. Fowler & Michael R. Ulrich, *Femtechnodystopia*, 75 STAN. L. REV. 1233, 1235-38 (2023).

575. *See, e.g.*, *Tell DA Scott Colom: Drop the Charges Against Latice Fisher*, COLOR OF CHANGE, https://perma.cc/H9PN-DPN5 (archived Jan. 2, 2024) (internet petition in support of Latice Fisher).

576. *See supra* notes 548-50 and accompanying text.

tolerance for abortion investigations. Yvette Lindgren has argued that "[m]edication abortion in the home, both self-induced and under a doctor's supervision, falls squarely within privacy law's traditional framework of zonal privacy."[577] Intrusive policing of pills in many ways represents a regression to the use of criminal law for policing the morals of intimate life, including "the unwelcomed presence of the police officer under the bed."[578] Those who assume they have a right to privacy in the home could risk becoming ensnared in a new wave of Comstock-like investigations.[579]

Backlash against government surveillance of personal information will only occur if the costs and the targets of state investigations are visible. Privacy doctrines have been of little help to those vulnerable to state power, such as those receiving financial assistance from the state.[580] The majority of those seeking abortions are low-income people, and people of color are disproportionately represented.[581] In many ways, abortion pills offer important benefits to these communities: They maintain safety and efficacy at a much lower price and allow access in states with bans for people who cannot afford to travel for care.[582] Further, the privacy of mailed pills can protect people who otherwise might be in danger if their pregnancy was discovered and blunt the race and class inequality that has historically marked doctor-patient relationships.[583]

Yet post-*Dobbs*, the benefits of pills for marginalized populations are met with a devastating catch. These communities will be disproportionately targeted for investigation and criminalization, as they have been in the past.[584] As Michele Goodwin has detailed, during the War on Drugs, "[s]tates responded [to racist fears] by prosecuting Black women under existing child abuse statutes for drug dependence occurring during pregnancy" while largely ignoring drug dependency in pregnant white women.[585] Similarly, Dorothy Roberts has demonstrated that drug prosecutions in pregnancy have been used as vehicles to extract other reproductive injustices, such as coerced birth

577. Yvonne Lindgren, *The Doctor Requirement:* Griswold*, Privacy, and At-Home Reproductive Care*, 32 CONST. COMMENT. 341, 358 (2017).

578. Melissa Murray, Essay, Griswold*'s Criminal Law*, 47 CONN. L. REV. 1045, 1071 (2015) (describing the evolution away from criminalizing sexual morality).

579. *See* Lindgren, *supra* note 577, at 357; *supra* Part II.B.

580. *See, e.g.*, Harris v. McRae, 448 U.S. 297, 316-18 (1980).

581. COHEN & JOFFE, *supra* note 18, at 13.

582. *See supra* notes 84-86 and accompanying text.

583. *See* Lindgren, *supra* note 577, at 362; Lindgren, *supra* note 451, at 168.

584. *See* GOODWIN, *supra* note 18, at 88-89.

585. *Id.*

control and child removal proceedings.[586] If we continue to live in a country in which those with sufficient resources can obtain abortions without fear of punishment, but everyone else is at the mercy of the carceral state, the liberatory potential of abortion pills will never be fully realized. This, too, is a lesson from the War on Drugs, which continues to add to the endemic of mass incarceration and to have devastating effects for the country's most marginalized people.[587] Burdens that vary based on privilege have also characterized abortion provision for far too long.[588] With the policing of pills, the disproportionate racial and class impact of abortion policies will take on even greater prominence.

Historically, the reproductive rights movement—like the public at large—paid too little attention to the plight of Black and other marginalized women.[589] By focusing on rights and not access to abortion, and by defending the right to avoid procreation above the equally important rights to bear and parent the children one wants, the movement prioritized the needs of wealthy, white women over the needs of low-income people and women of color.[590] In recent years, many in the movement have sought to recognize these past wrongs, focus on the concerns of communities of color, and work toward reproductive justice.[591] But the problems pills pose will be a litmus test for this resolution. Not only will mainstream reproductive rights organizations need to respond to the unequal criminalization of pills, but they will need to prioritize and secure meaningful support, both from public and private sources, for those who cannot afford to travel.

In ushering in the sea change pills promise, we must learn from the mistakes of an earlier era, which sidelined the material constraints and

586. *See generally* DOROTHY ROBERTS, KILLING THE BLACK BODY: RACE, REPRODUCTION, AND THE MEANING OF LIBERTY 150-201 (1997).

587. *See generally* MICHELLE ALEXANDER, THE NEW JIM CROW: MASS INCARCERATION IN THE AGE OF COLORBLINDNESS (2010) (explaining the roots of mass incarceration and its connection with racial injustice).

588. *See generally* ROSS & SOLINGER, *supra* note 17 (explaining the history of reproductive justice and its focus on the impact of policies on the most marginalized populations).

589. *See* ROBERTS, *supra* note 586, at 56-103 (canvasing the racism that has underscored the reproductive rights movement); Loretta J. Ross et al., *Just Choices: Women of Color, Reproductive Health and Human Rights*, *in* POLICING THE NATIONAL BODY: SEX, RACE, AND CRIMINALIZATION 147, 148 (Jael Silliman & Anannya Bhattacharjee eds., 2002); JENNIFER NELSON, MORE THAN MEDICINE: A HISTORY OF THE FEMINIST WOMEN'S HEALTH MOVEMENT 167-92 (2015) (describing the ways in which mainstream reproductive rights organizations ignored issues of race).

590. *See* sources cited *supra* note 589; Zakiya Luna & Kristin Luker, *Reproductive Justice*, 9 ANN. REV. L. & SOC. SCI. 327, 343 (2013).

591. Sarita Gupta & Silvia Henriquez, *In the Wake of Roe, a Resurgent Fight for Reproductive Justice*, FORD FOUND. (Jan. 19, 2023), https://perma.cc/6TME-S22C (describing many organizations adopting reproductive justice approaches).

discrimination that set the terms of who can access abortion care and why they seek it in the first place. Especially with regard to pills, abortion activists must dedicate themselves not only to winning hearts and minds but also to pursuing deeper, systemic change.

Conclusion

In the 1980s, Brazilian women began using misoprostol to end pregnancies outside of the medical system despite a strict legal environment prohibiting all abortions.[592] In 1991, the Brazilian government responded to this novel use of the drug with strict controls, but sales and use only increased.[593] The government tried again with even harsher protocols in 1998.[594] Many people faced criminal penalties as a result of the new laws, but the informal, clandestine market for misoprostol continued, with the pills being sold openly in the country.[595] Surveys in 2010 and 2016 estimated that almost half of those in Brazil who ended their pregnancies did so with pills.[596] As one court in Brazil recognized, the supply and demand associated with the drug made it futile to try to control the pills by law and only exacerbated dysfunctions in the legal and health systems.[597]

Here, as in Brazil, anti-abortion law and policy will not be able to stop abortion pills. Instead, rather than affecting *whether* they are accessed, the battles over pills will only affect *how*. If pills are harder to access legally or information about them is censored, people will be forced to access them in extralegal and possibly unsafe ways. In addition, removing mifepristone from the legally approved market will only increase reliance on misoprostol and international, non-FDA-approved versions of mifepristone. Criminalizing the purchase or use of these medications will only lead to delays in care, public health catastrophes, and the surveillance and incarceration of more poor and marginalized people. Simultaneously, the expanded use of pills will change the terms of the abortion debate in a way that destigmatizes abortion and refocuses the public's attention away from the state and the medical profession and onto the individual pregnant person, the public health consequences of bans, and the systemic disparities related to surveillance and criminalization.

592. *See* Mariana Prandini Assis & Joanna N. Erdman, *In the Name of Public Health: Misoprostol and the New Criminalization of Abortion in Brazil*, 8 J.L. & BIOSCIENCES lsab009, at 2-3 (2021).

593. *See id.* at 3-4.

594. *See id.* at 4.

595. *See id.* at 4, 16-17.

596. *Id.* at 17.

597. *Id.*

When people can access medication abortion legally—or find safe and legitimate sources extralegally—abortion pills will blunt some of the worst effects of *Dobbs*. Abortion pills enable safe, effective, and cheap abortion access throughout the country—despite abortion bans. Try as the anti-abortion movement might, abortion pills will continue to be available to those who seek them. The abortion pill battles we describe in this Article, however they are resolved, will not change that reality; they will only change how the pills are accessed, who is punished, and the public health effects of use.