Who Regulates Abortion Now?

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ABSTRACT: Contrary to both conventional wisdom and recent Supreme Court pronouncements, abortion is not simply a matter of state oversight. For a quarter century now, the federal government has been intimately involved in "regulating" abortion through the U.S. Food and Drug Administration's approval and continued oversight over mifepristone and other abortion medications. This Article considers the extent to which federal abortion law both coexists and conflicts with state law, as it does with most areas of medicine. We evaluate which body of law is better able at achieving the goals of modern medicine that is evidence-based, ethical, consistent, and individualized.

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INTRODUCTION

When the Supreme Court overturned *Roe v. Wade* in *Dobbs v. Jackson Women's Health Org.*,[1] the majority reasoned that federal courts should "return the issue of abortion" to states. But even before *Dobbs*, the question of abortion had long since outgrown such a simplistic framing. In 2000, the U.S. Food and Drug Administration ("FDA") approved the drug Mifeprex (mifepristone) as safe and effective "for the medical termination of intrauterine pregnancy."[2] The approval shifted the center of gravity for abortion away from exclusive control by states (subject to federal constitutional boundaries) toward concurrent oversight by states and federal drug regulators. Medication abortion gradually became a viable alternative to surgical abortion, accessible in very different ways. And within two decades, it became the more common method of abortion in part because of these differences. By 2020, fifty-three percent of nonhospital abortions were medication abortions, rising to sixty-three percent in 2023 after *Dobbs*.[3] The terms by which patients can access medication abortion have been carefully and exhaustively overseen by the FDA since its

1. Dobbs v. Jackson Women's Health Org., 597 U.S. 215, 232, 256, 259, 292, 302 (2022) (repeating the justification that the issue of abortion should be returned "to the people and their elected representatives").

2. Letter from Ctr. for Drug Evaluation & Rsch., FDA, to Sandra P. Arnold, Vice President, Corp. Affs., Population Council, on Approval for NDA 20-687, Mifeprex (Mifepristone) (2000), https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2000/20687appltr.htm [https://perma.cc/R8G4-47BP]; *Drug Approval Package*, FDA. (June 18, 2001), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_mifepristone.cfm [https://perma.cc/28VB-TQ29]. Note that mifepristone was previously known as RU-486.

3. Rachel K. Jones & Amy Friedrich-Karnik, *Medication Abortion Accounted for 63% of All US Abortions in 2023—an Increase from 53% in 2020*, GUTTMACHER INST. (Mar. 19, 2024), https://www.guttmacher.org/2024/03/medication-abortion-accounted-63-all-us-abortions-2023-increase-53-2020 [https://perma.cc/TB6M-4MAJ].

approval.[4] The repeated refrain in *Dobbs* that federal courts should "return" abortion to the states thus ignores over two decades of federal oversight.

Before *Dobbs*, medication abortion had already changed the way abortion is practiced in the United States; after *Dobbs*, it has changed the national discourse around abortion.[5] Today, it is no longer meaningful to talk of state control over abortion without also acknowledging the complicated ways in which state policies can conflict with federal policies as well as the ways in which interstate conflicts shape access to abortion.[6] For example, can states legally ban the use of a federally-approved drug or impose conditions that are inconsistent with federal conditions of approval? Shortly after *Dobbs*, the Biden Administration emphasized that "[s]tates may not ban mifepristone based on disagreement with FDA's expert judgment about its safety and efficacy."[7] States, meanwhile, maintain that any local effects on medication abortion are merely incidental to state authority to regulate the practice of medicine. And antiabortion advocates increased their efforts to invalidate the FDA's approval of mifepristone after *Dobbs*, as the availability of medication abortion presented a practical limit on the effectiveness of state abortion bans.

Not surprisingly, these post-*Dobbs* questions quickly reached the Supreme Court. During the October 2024 term, the Court considered *FDA v. Alliance for Hippocratic Medicine*,[8] a challenge to the agency's regulation of mifepristone.[9] On appeal was the Fifth Circuit's decision that the FDA's tailored framework for managing the benefits and risks of mifepristone were likely arbitrary and capricious.[10] The Supreme Court rejected the challenge on standing grounds—leaving the current FDA regulations in place—but left open the possibility of future challenges on the merits. Thus, the availability of mifepristone remains precarious. In addition, the case has implications beyond mifepristone or

4. *See generally* U.S. GOV'T ACCOUNTABILITY OFF., GAO-08-751, FOOD AND DRUG ADMINISTRATION: APPROVAL AND OVERSIGHT OF THE DRUG MIFEPREX (2008) (detailing the FDA's regulation of Mifeprex).

5. David S. Cohen, Greer Donley & Rachel Rebouché, *Abortion Pills*, 76 STAN. L. REV. 317, 320–21 (2024).

6. David S. Cohen, Greer Donley & Rachel Rebouché, *The New Abortion Battleground*, 123 COLUM. L. REV. 1, 2–3 (2023).

7. U.S. DEP'T OF HEALTH & HUM. SERVS., HEALTH CARE UNDER ATTACK: AN ACTION PLAN TO PROTECT AND STRENGTHEN REPRODUCTIVE CARE 8 (2022), https://www.hhs.gov/sites/default/files/hhs-report-reproductive-health.pdf [https://perma.cc/2TXS-Y32S]; Exec. Order No. 14,076, 87 Fed. Reg. 42,053 (July 8, 2022); Press Release, Merrick B. Garland, Att'y Gen., U.S. Dep't of Just., Statement on Supreme Court Ruling in *Dobbs v. Jackson Women's Health Organization* (June 24, 2022), https://www.justice.gov/opa/pr/attorney-general-merrick-b-garland-statement-supreme-court-ruling-dobbs-v-jackson-women-s [https://perma.cc/E5EF-7X4U].

8. *See generally* FDA v. All. for Hippocratic Med., 602 U.S. 367 (2024).

9. The Fifth Circuit Court of Appeals held that the challenge to the FDA's original approval in 2000 was likely barred by the statute of limitations, All. for Hippocratic Med. v. FDA, 78 F.4th 210, 222, 245 (5th Cir. 2023), but the District Court had held otherwise. All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507, 533 (N.D. Tex. 2023). However, the Supreme Court declined to grant certiorari on that question.

10. All. for Hippocratic Med. v. FDA, 78 F.4th 210, 249 (5th Cir. 2023), *rev'd and remanded*, 602 U.S. 367 (2024).

even abortion, raising deeper questions regarding who can regulate "medicine" and to what ends. If abortion is "medicine"—a medical procedure, a medical product, or both—then who should regulate it?

Just as before *Dobbs*, federal authorities continue to determine which drugs can be prescribed[11] while state authorities help define the permissible scope of medical practice.[12] However, since *Dobbs*, several states have tried to ban the use of a medication approved as safe and effective by federal regulators.[13] What should we do when concurrent oversight over "medicine" by state and federal authorities clashes in this way?

In the long term, these disputes are about more than just preemption; they are about how we regulate medicine in a world of telehealth, remote prescribing, and health care delivery models that increasingly blur the line between medical practice (regulated by states) and medical products (regulated at the federal level). These disputes also speak to ongoing battles over the permissibility of gender-affirming care, the regulation of laboratory-developed tests ("LDTs"),[14] and other evolutions in medicine. Thus, the question "*Who regulates abortion now?*" is also a question of "*Who regulates medicine now?*"

The answers to these questions, we posit, depend on what we want out of medicine. We argue that most patients want medicine to be evidence-based (applying the best scientific and medical knowledge available at the time), ethical (adhering to the ethical standards adopted by professional societies), consistent (encouraging similar care for similarly-situated patients), and individualized (accounting for each patient's specific needs, preferences, and circumstances). Our laws and regulations should prioritize, not frustrate, these values. We then show that federal regulation has been superior at encouraging these values, while state regulation in abortion-restrictive states undermines these values, resulting in medical care that is less evidence-based, less ethical, less consistent, and less individualized in service of "winning" deeply-contested moral and ideological debates.

When the Supreme Court decided *Alliance for Hippocratic Medicine* in 2024, it could have considered the broader implications on who regulates medicine, how, and why. But it didn't. Nor did it take that opportunity in another recent abortion case involving a clash between Idaho's strict abortion ban and the obligation imposed on hospitals by federal law to stabilize patients who present with an emergency medical condition. The Court in that case, *Moyle v. United States*, dismissed certiorari as improvidently granted and left in place a lower-court injunction that prevents enforcement of the Idaho ban to

11. *See infra* Section II.A.2.

12. *See infra* Section II.A.1.

13. *See infra* Section III.C (showing that twenty-nine states deviate from the conditions of FDA approval for mifepristone, while fourteen states have near-total abortion bans).

14. *See* Press Release, FDA, FDA Takes Action Aimed at Helping to Ensure the Safety and Effectiveness of Laboratory Developed Tests (Apr. 29, 2024), https://www.fda.gov/news-events/press-announcements/fda-takes-action-aimed-helping-ensure-safety-and-effectiveness-laboratory-developed-tests [https://perma.cc/8B84-T97U].

the extent it conflicts with federal law.[15] We are thus left with the same questions about the balance of state and federal power. State legislatures that are preoccupied with settling highly contentious moral debates, or more cynically taking political advantage of "wedge" issues, should give way to federal approaches that prioritize evidence-based medicine and other widely-held patient values. We show that many state legislatures have abandoned their traditional deference to practitioners and protections of their professional medical judgment from outside interference, particularly in matters of reproductive care like abortion and contraception.

Of course, many restrictive state laws are not really about *medicine*. For example, conservative states used so-called "TRAP" laws (targeted regulation of abortion providers) to require abortion clinics to follow architectural specifications designed for ambulatory surgery centers and to require their providers to have admitting privileges at a nearby hospital; these laws were designed to drive abortion clinics out of business rather than to protect patient safety or improve the quality of care patients received.[16] After *Dobbs*, state laws can be agnostic, at best, about evidence-based medicine.[17] Indeed, some state legislatures are even on record warning of the risks of "evidence-based" medicine.[18]

In addressing larger questions about the proper scope of and motivations for regulating medicine, we focus on medication abortion. Ultimately, we find that abortion is as much a federal matter now as it is a state matter, and that this is preferable to the extent federal regulation prioritizes evidence-based medicine. Broadening this claim, we argue that the wisest approach policymakers can take with new or controversial medical practices and technologies is to leave breathing room for continued debate and understanding, rather than replace professional judgment with the state's own highly-contested judgment. Otherwise, practitioners may face the agonizing decision of having to choose between their legal obligations and their ethical obligations to patients.[19]

We lay out our argument in four parts. Part I describes how the FDA's approval of mifepristone in 2000 established a new center of gravity for regulating abortion by introducing federal drug regulation and its rigorous

15. Moyle v. United States, 603 U.S. 324, 325 (2024) (per curiam).

16. *See* Reva B. Siegel, *Why Restrict Abortion? Expanding the Frame on* June Medical, 2020 S. CT. REV. 277, 306–09.

17. The Supreme Court twice considered challenges to such laws and invalidated them under the constitutional undue burden standard set forth in *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 873–74 (1992). *See* Whole Woman's Health v. Hellerstedt, 579 U.S. 582, 611–12 (2016) (invalidating Texas TRAP law in large part because there was no evidence that it would make even a single patient safer); June Med. Servs. L.L.C. v. Russo, 591 U.S. 299, 308 (2020) (invalidating Louisiana TRAP law). These cases were premised on *Roe*/*Casey*, however, and are no longer good law. *See* Dobbs v. Jackson Women's Health Org., 597 U.S. 215, 231 (2022).

18. *See, e.g.*, H.B. 2684, 54th Gen. Assemb., Reg. Sess., § A(13) (Okla. 2014) (making a legislative finding that "'[o]ff-label' or so-called 'evidence-based' use of abortion-inducing drugs may be deadly").

19. Matthew K. Wynia, *Professional Civil Disobedience — Medical-Society Responsibilities After* Dobbs, 387 NEW ENG. J. MED. 959, 959 (2022).

scientific standards. Part II explains how traditional federal regulation of medical products can intersect with traditional state regulation of medical practice, and how various "inversions" in this basic state of affairs presaged the current conflicts around medication abortion. Part III then details the current conflicts regarding medication abortion, including state deviations from federal approval of mifepristone and misoprostol, and ongoing preemption litigation. Part IV then plants our stake: If debates about medication abortion are really debates about what we want out of medicine, what *do* we want and how do we best achieve it? We argue that most patients want medicine that is evidence-based, ethical, consistent, and individualized, and then show that federal regulation of abortion medication is far superior to state restrictions on abortion practice on these grounds. To be sure, abortion is politically controversial. But it is not at all medically or scientifically controversial. Our laws should reflect that.

I. A NEW CENTER OF GRAVITY

The FDA approved mifepristone in 2000 for use in inducing abortion, and it was the first drug approved for this purpose.[20] This approval marked the beginning of a shift in the center of gravity for regulating abortion, away from exclusive control by states (subject to federal constitutional boundaries) toward joint oversight by states and federal drug regulators. As medication abortion became a viable alternative to surgical abortion, accessible in very different (and more flexible) ways, the national discourse gradually shifted as well.[21] Although the majority in *Dobbs* made grand and repetitive pronouncements about returning the abortion issue "to the states," the reality is much more complicated. Today, questions over who regulates abortion are front and center.[22] But to understand the tensions, it is important to understand the origins, usage, efficacy, and accessibility of the prescription pills that can be used to induce abortion.[23]

A. DEVELOPMENT AND APPROVAL OF MEDICATION ABORTION

The term "medication abortion" refers usually to a two-drug regimen used to induce an abortion.[24] The first drug, mifepristone, blocks progesterone, a

20. Letter from Ctr. for Drug Evaluation & Rsch., FDA, to Sandra P. Arnold, Vice President, Corp. Affs., Population Council, *supra* note 2; *Drug Approval Package*, *supra* note 2. Note that mifepristone was previously known as RU-486.

21. Cohen et al., *supra* note 5, at 321.

22. Cohen et al., *supra* note 6, at 52–53.

23. The medical community uses the term "induced abortion" to describe the intentional termination of a pregnancy and "spontaneous abortion" to describe a miscarriage. Although misoprostol may be used treat an incomplete miscarriage, this would not be characterized as an induced abortion.

24. *See generally The Availability and Use of Medication Abortion*, KAISER FAM. FOUND. (Oct. 7, 2024), https://www.kff.org/womens-health-policy/fact-sheet/the-availability-and-use-of-medication-abortion [https://perma.cc/SUD3-XZ88] (explaining the process of and costs and risks

hormone essential to the development of an embryo or fetus. The second drug, misoprostol, is taken twenty-four to forty-eight hours after the first; it induces cramping and bleeding that leads to the emptying of the contents of the uterus.[25] The expulsion of the uterine contents usually takes four to five hours, although it can take longer.[26] Success can be confirmed in a variety of ways a few weeks later, including by ultrasound or by a reduced-sensitivity pregnancy test.[27] It is possible to induce an abortion using only misoprostol (in higher doses), although the efficacy rate is slightly lower than with the two-drug regimen, and the process is likely to involve more pain and discomfort.[28] The "miso-only" method is not specifically approved by the FDA, but because misoprostol is available for other conditions (including incomplete miscarriage), it can be prescribed off-label for this purpose.[29] Because mifepristone had no other FDA-approved use, however, it could not be sold in the United States without an approval specifically to induce abortion.[30] With either regimen,

associated with medication abortions). On medication abortion after *Dobbs*, see generally Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627 (2022) (arguing that "mifepristone fails to meet the statutory criteria for a REMS, and that the FDA's improper regulation of mifepristone is a part of a larger history of biased decision-making over sexual and reproductive health"); Recent Guidance, *Reproductive Rights — Medication Abortion — FDA Lifts In-Person Dispensing Requirement for Mifepristone Abortion Pill. — Update to FDA's Risk Evaluation and Mitigation Strategy for Mifepristone on Dec. 16, 2021, Eliminating In-Person Dispensing Requirement*, 135 HARV. L. REV. 2235 (2022) (contextualizing the 2021 REMS update); Rachel Rebouché, *Remote Reproductive Rights*, 48 AM. J.L. & MED. 244 (2022) ("map[ping] the emergence of virtual abortion care and analyz[ing] the potential trajectory of medication abortion access.").

25. *The Availability and Use of Medication Abortion*, *supra* note 24. For patient-friendly information, see also *How Does the Abortion Pill Work?*, PLANNED PARENTHOOD, https://www.plannedparenthood.org/learn/abortion/the-abortion-pill/how-does-the-abortion-pill-work [https://perma.cc/9HNC-2DUL].

26. *How Does the Abortion Pill Work?*, *supra* note 25.

27. *See* Fariba Behnamfar, Mehrdad Mahdian, Fereshteh Rahimi & Mansoureh Samimi, *Misoprostol Abortion: Ultrasonography Versus Beta-hCG Testing for Verification of Effectiveness*, 29 PAK. J. MED. SCIS. 1367, 1368 (2013); Elizabeth G. Raymond et al., *"False Positive" Urine Pregnancy Test Results After Successful Medication Abortion*, 103 CONTRACEPTION 400, 401 (2021); WORLD HEALTH ORG., MEDICAL MANAGEMENT OF ABORTION 33 (2018), https://iris.who.int/bitstream/handle/10665/278968/9789241550406-eng.pdf [https://perma.cc/7A9A-UY69]; see *also* DANCO LAB'YS, LLC, HIGHLIGHTS OF PRESCRIBING INFORMATION: MIFEPREX 4 (Mar. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s026lbl.pdf#page=16 [https://perma.cc/FZ93-ZCNK].

28. *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, 145 (2019); *see also How Do I Have an Abortion Using Only Misoprostol?*, PLANNED PARENTHOOD, https://www.plannedparenthood.org/learn/abortion/the-abortion-pill/how-do-i-have-an-abortion-using-only-misoprostol [https://perma.cc/LB3D-488L].

29. Misoprostol is currently FDA-approved only to prevent and treat gastric ulcers induced by the use of NSAIDs. *See* Marissa Krugh, Preeti Patel & Christopher V. Maani, *Misoprostol*, NAT'L LIBR. OF MED. (Feb. 19, 2024), https://www.ncbi.nlm.nih.gov/books/NBK539873 [https://perma.cc/M8AF-PS6M].

30. *See generally* Donley, *supra* note 24, at 637–39. Before the FDA's approval of Mifeprex for abortion, it was not approved for any such reason. *Id.* In 2012, the FDA approved Mifepristone to treat hyperglycemia caused by Cushing's Syndrome. *See* Sarah Jane Tribble, *How a Drugmaker*

the physical process is very similar to experiencing a miscarriage, which is referred to, in medical terms, as a spontaneous abortion.[31]

Mifepristone is approved both in a brand-name form (Mifeprex) and as a generic. Mifeprex was first approved by the FDA in 2000.[32] The New Drug Approval ("NDA") application requested approval of the drug "for the medical termination of intrauterine pregnancy through [forty-nine] days' pregnancy."[33] In the medical field, pregnancy is typically dated from the first day of the last menstrual period prior to conception ("LMP").[34] Traditional guidelines hold that, for a normal twenty-eight-day menstrual cycle, conception typically occurs around day fourteen, or about two weeks after the LMP.[35] Thus, under this original approval, Mifeprex was approved for use to terminate pregnancies prior to the end of the seventh week of pregnancy—or the end of the fifth week post-conception.[36]

The original approval came with a series of risk mitigation conditions.[37] Mifeprex had to "be provided by or under the supervision of a physician who"

Turned the Abortion Pill into a Rare-Disease Profit Machine, KAISER FAM. FOUND. HEALTH NEWS (Apr. 10, 2018), https://kffhealthnews.org/news/how-a-drugmaker-turned-the-abortion-pill-into-a-rare-disease-profit-machine [https://perma.cc/9ZFX-WMUF].

31. *See generally The Availability and Use of Medication Abortion*, *supra* note 24.

32. *See* Letter from Ctr. for Drug Evaluation & Rsch., FDA, to Sandra P. Arnold, Vice President, Corp. Affs., Population Council, *supra* note 2.

33. *Id.*

34. *See, e.g.*, AM. COLL. OBSTETRICS & GYNECOLOGY, COMMITTEE OPINION 700: METHODS FOR ESTIMATING THE DUE DATE 1 (2017), https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2017/05/methods-for-estimating-the-due-date.pdf?rev=e94ee470b78b466ca0d9e6c4ab127979&hash=5A6DE3B09B00A8E9A90DD402DC58BDA [https://perma.cc/68H9-6XYH]; *Conception*, CLEVELAND CLINIC (Sept. 6, 2022), https://my.clevelandclinic.org/health/articles/11585-conception [https://perma.cc/B4FV-SVF5].

35. *See, e.g.*, CLEVELAND CLINIC, *supra* note 34; Allen J. Wilcox, David Dunson & Donna Day Baird, *The Timing of the "Fertile Window" in the Menstrual Cycle: Day Specific Estimates from a Prospective Study*, 321 BMJ 1259, 1261 (2000).

36. *See generally* Max Mongelli, *Evaluation of Gestation*, MEDSCAPE (Oct. 19, 2021), https://emedicine.medscape.com/article/259269-overview [https://perma.cc/G5DN-8EX5] (explaining three basic methods for estimating gestational age, including menstrual history).

37. The evolution of FDA regulation of mifepristone can be tracked through this archive site: *Historical Information on Mifepristone (Marketed as Mifeprex)*, FDA (Oct. 22, 2016), http:/www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111334.htm [http://wayback.archive-it.org/7993/20161022205309/http:/www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111334.htm]. The original use and distribution restrictions imposed in 2000 were not called REMS. After Congress authorized the agency to use REMS programs in 2007, the agency couched these conditions as REMS programs. As of the mid 1990s, they were known as "risk minimization action plans" or "RiskMAPs." *See* PETER BARTON HUTT ET AL., FOOD AND DRUG LAW 1070 (5th ed. 2022); Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 505-1, 121 Stat. 823, 926–39 (codified at 21 U.S.C. § 355-1 (2018)); FDA, MIFEPREX RISK EVALUATION AND MITIGATION STRATEGY (REMS) 1–3 (2011), https://www.fda.gov/media/164648/download [https://perma.cc/86RV-5R8A]; FDA, MIFEPREX RISK EVALUATION AND MITIGATION STRATEGY (REMS) 1–4 (2016), https://www.fda.gov/media/164649/download [https://perma.cc/WB3H-G6L3]; FDA, MIFEPRISTONE RISK EVALUATION AND MITIGATION STRATEGY (REMS) 1–3 (2019), https://www.fd

had the ability to assess gestational age, diagnose ectopic pregnancies, provide surgical intervention in the event of complications, and comply with various recordkeeping requirements.[38] Unlike most prescription drugs, mifepristone could not be dispensed at a pharmacy but had to be given to a patient directly by a physician.

In the years after approval, studies showed that Mifeprex could be safe and effective at lower doses and without some of the original restrictions, and virtually all providers had converted to a protocol consistent with these studies rather than the one described in the original FDA-approved labeling.[39] In 2016, the FDA approved Mifeprex for use through the end of the tenth week of pregnancy (seventy days gestation).[40] It also approved new labeling that reduced the recommended dose of Mifeprex from 600 mg (3 x 200 mg tablets) to 200 mg (1 x 200 mg tablet) and changed the recommendation for misoprostol to 800 mcg dissolved in the cheek or mouth from 400 mcg in tablets taken orally.[41] This set of changes also dispensed with the recommendation of an in-person visit fourteen days after Mifeprex was administered and replaced it with an "assessment" of the patient between seven and fourteen days later with the option of prescribing a repeat dose of misoprostol.[42] In 2019, FDA approved a generic form of the drug, mifepristone, for use in the same manner as Mifeprex.[43] Both forms were subject to the restrictions set out in the Mifepristone Risk Evaluation and Mitigation Strategies ("REMS") program.[44]

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a.gov/media/164650/download [https://perma.cc/LC8N-M3LR]; FDA, MIFEPRISTONE RISK EVALUATION AND MITIGATION STRATEGY (REMS) 1–3 (2021), https://www.fda.gov/media/164651/download [https://perma.cc/X64H-SKSY]; *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Jan. 17, 2025), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation [https://perma.cc/LEY7-E9TM].

38. *See generally* FDA, MIFEPREX RISK EVALUATION AND MITIGATION STRATEGIES (REMS) (2011), https://www.fda.gov/media/164648/download [https://perma.cc/9KM6-Z9CS]; FDA, MIFEPREX RISK EVALUATION AND MITIGATION STRATEGIES (REMS) (2016), https://www.fda.gov/media/164649/download [https://perma.cc/AT2Y-59FK].

39. *See, e.g.*, Elizabeth G. Raymond, Caitlin Shannon, Mark A. Weaver & Beverly Winikoff, *First-Trimester Medical Abortion with Mifepristone 200 mg and Misoprostol: A Systematic Review*, 87 CONTRACEPTION 26, 30 (2013); 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).

40. DANCO, MIFEPREX (MIFEPRISTONE): FDA APPROVES UPDATED LABELING 1, http://www.earlyoptionpill.com/wp-content/uploads/2016/03/Mifeprex-Label-Update_Press-Release_March302016.pdf [https://perma.cc/TF8D-6EHX].

41. *See id.*; *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra* note 37.

42. *See* FDA, HIGHLIGHTS OF PRESCRIBING INFORMATION: MIFEPREX 4 (2023), https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/020687Orig1s025Lbl.pdf [https://perma.cc/K8TM-3X43].

43. *See generally* FDA, HIGHLIGHTS OF PRESCRIBING INFORMATION: MIFEPRISTONE (2023), https://www.fda.gov/media/164653/download?attachment [https://perma.cc/V9NY-L33Q].

44. *Id.*

In 2021, the FDA reviewed the Mifepristone REMS program and decided to modify some of its features. The FDA temporarily lifted the requirement that the medication be dispensed in person due to the Covid-19 pandemic, although it still could only be dispensed by certified prescribers.[45] But in 2023, the FDA permanently removed the requirement of in-person dispensing.[46] The modified REMS also established a protocol for allowing pharmacies to be certified to dispense the medication directly to patients (when prescribed by a physician).[47] If permitted by state law, a patient can now see a doctor via telehealth and receive both mifepristone and misoprostol through the mail.

To summarize the approach permitted under the new REMS: The standard protocol for medication abortion using a two-drug regimen involves the administration of 200 mg of mifepristone taken orally followed six to seventy-two hours later by 800 ug of misoprostol. No follow-up visit is required, and this regimen is approved until seventy days after the last menstrual period.[48] There is also a standard protocol for medication abortion using only misoprostol, but there is no specific FDA approval or restriction on this method.[49] The usual protocol is the administration of 800 ug of mifepristone either sublingually or vaginally every three hours (four pills at a time, and twelve pills in total), with a recommended visit to a provider seven to fourteen days later to ensure the abortion was successful.

The current approval for the two-drug regimen may still be too restrictive from a safety and efficacy standpoint.[50] Professor Greer Donley argues persuasively "that mifepristone fails to meet the statutory criteria for a REMS because the benefits of the drug outweigh the risks even without any distribution limitations."[51] Although there is not extensive research, there are reliable studies suggesting that medication abortion can be done safely beyond ten weeks and

45. *See generally* FDA, RISK EVALUATION AND MITIGATION STRATEGY (REMS): SINGLE SHARED SYSTEM FOR MIFEPRISTONE 200MG (2021), https://www.fda.gov/media/164651/download [https://perma.cc/XU5Q-LLLL].

46. *See Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra* note 37.

47. *Id.*

48. *The Availability and Use of Medication Abortion*, *supra* note 24.

49. *Id.*

50. *See infra* Section I.B. As discussed below, leading medical societies take the position that mifepristone can be dispensed safely and effectively without REMS. *See infra* notes 405–17 and accompanying text.

51. Donley, *supra* note 24, at 650–51; *see also* Lewis A. Grossman, *Freedom Not to See a Doctor: The Path Toward Over-the-Counter Abortion Pills*, 2023 WIS. L. REV. 1041, 1099–1120 (arguing that the FDA should authorize the sale of abortion pills without a prescription given the evidence that the need for a prescription substantially impedes access). Donley argues that the imposition of REMS reflects "a larger pattern of gender bias in the FDA's decision making" and "a history of placing political concerns over its scientific mission when it comes to issues concerning female sexuality and reproduction." Donley, *supra* note 24, at 631. On the politics involved in mifepristone approval, see generally Aziza Ahmed, *Abortion Experts*, 2022 U. CHI. LEGAL F. 1 (2023).

even beyond the first trimester.[52] For example, the World Health Organization ("WHO") has supported use of medication abortion through the end of the twelfth week of pregnancy.[53]

B. SAFETY, EFFICACY, AND USAGE

Before the FDA relaxed the REMS for mifepristone in 2023, it could only be given to a patient in person by a physician. Patients would thus have to schedule an in-person appointment and would take mifepristone in the provider's office. A patient would then be sent home with misoprostol, along with instructions for how and when to take those pills. When taken correctly, the two-drug regimen successfully terminates a pregnancy 99.6% of the time.[54] The efficacy rate is only slightly below that of surgical abortions, which successfully terminate a pregnancy 99.8% of the time.[55] With either medication regimen, an unsuccessful abortion must be followed up with a surgical abortion, although a repeat dose of misoprostol can be given after a medication abortion (before a certain point in gestation) in order to increase the likelihood of success.[56]

Regardless of how it is performed, abortion is a very safe medical procedure. For medication abortion done with the two-drug regimen, the risk of major complications is 0.4%,[57] and the risk of death is less than 0.001%.[58] The most common adverse effects are nausea, vomiting, diarrhea, headache, and dizziness.[59] Less than one percent of patients will seek emergency care for heavy bleeding, and less than 0.1% will require a blood transfusion.[60] Much of the counseling about risks relates to detecting and reacting to an unsuccessful

52. *See, e.g.*, Heidi Moseson et al., *Effectiveness of Self-Managed Medication Abortion Between 9 and 16 Weeks of Gestation*, 142 OBSTETRICS & GYNECOLOGY 330, 332–35 (2023); *see also* Roni Caryn Rabin, *Misoprostol Alone Safely Ends Pregnancies After 10 Weeks, Study Suggests*, N.Y. TIMES (July 6, 2023), https://www.nytimes.com/2023/07/06/health/abortion-misoprostol.html (on file with the *Iowa Law Review*) (describing successful abortions when women took only misoprostol); Am. Coll. of Obstetricians & Gynecologists, *Second-Trimester Abortion*, 121 OBSTETRICS & GYNECOLOGY 1394, 1395–96 (2013).

53. *Abortion*, WORLD HEALTH ORG. (May 17, 2024), https://www.who.int/news-room/fact-sheets/detail/abortion [https://perma.cc/KK2V-LMLZ].

54. Luu Doan Ireland, Mary Gatter & Angela Y. Chen, *Medical Compared with Surgical Abortion for Effective Pregnancy Termination in the First Trimester*, 126 OBSTETRICS & GYNECOLOGY 22, 24 (2015).

55. *Id.*; *see also Abortion Pill Side Effects: Your Guide to What to Expect*, CARAFEM, https://carafem.org/abortion-pill-effects [https://perma.cc/7W86-2P6K] (describing common concerns and the efficacy of mifepristone).

56. *See* Guttmacher Inst., *Use of Misoprostol to Treat Incomplete Abortion Should Be Limited to the First 12 Weeks of Pregnancy*, 40 INT'L PERSPS. ON SEXUAL & REPROD. HEALTH 215, 215 (2014).

57. Raymond et al., *supra* note 39, at 30.

58. *See* Mitchell Creinin, Paul Blumenthal & Lee Shulman, *Mifepristone-Misoprostol Medical Abortion Mortality*, MEDSCAPE (Apr. 14, 2006), https://www.medscape.com/viewarticle/529318?&icd=login_success_email_match_fpf (on file with the *Iowa Law Review*).

59. *Medication Abortion Up to 70 Days of Gestation*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (Oct. 2020), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation [https://perma.cc/D2GB-TKVZ].

60. *Id.* at 33.

abortion rather than to side effects or complications.[61] This type of counseling is relevant to both the single- and two-drug regimen, but the efficacy rate is likely lower for misoprostol-only abortions. This is hard to measure precisely because many of the abortions done using only misoprostol are "self-managed" and involve no contact with a health care provider. Studies of self-managed abortion ("SMA") using only misoprostol have found efficacy rates between ninety-three and ninety-nine percent, meaning that one to seven percent of these medication abortions will require surgical intervention to complete the process.[62] But a recent meta-analysis of outcomes in clinically managed abortions using only misoprostol found that only seventy-eight percent of study participants had a complete abortion without the need for surgical intervention.[63] The studies, however, did not all involve the same dosages and timing, so it is possible that the efficacy rate is higher with some protocols.[64]

The usage of medication abortion has steadily increased since Mifeprex first became available in 2000. Between 2000 and 2016, over 2.75 million women in the United States had used the drug to terminate a pregnancy.[65] By 2020, medication abortions already accounted for fifty-three percent of nonhospital abortions.[66] This number had increased to sixty-three percent within a year of the *Dobbs* decision (2022) and will likely continue to increase.[67] Perhaps counterintuitively, the number of total abortions in the United States appears to have *risen* slightly after the *Dobbs* decision.[68] And an increasing number of medication abortions are self-managed. By one estimate, between

61. *Id.* at 33–34.

62. Raymond et al., *supra* note 39, at 28; *see also* Dana M. Johnson, *The Promise of Abortion Pills: Evidence on the Safety and Effectiveness of Self-Managed Medication Abortion and Opportunities to Expand Access*, 76 SMU L. REV. 135, 152–55 (2023) (reviewing available research on safety and effectiveness of medication abortion).

63. *See* Raymond et al., *supra* note 27, at 137.

64. *Id.*

65. *The Availability and Use of Medication Abortion*, *supra* note 24.

66. 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. (Dec. 1, 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions [https://perma.cc/V7AW-EZSP].

67. Jones & Friedrich-Karnik, *supra* note 3; *accord* Dobbs *Decision Drove Two Big Spikes in Medication Abortion Requests*, KFF HEALTH NEWS (Nov. 2, 2022), https://kffhealthnews.org/morning-breakout/dobbs-decision-drove-two-big-spikes-in-medication-abortion-requests [https://perma.cc/S3DY-4SNU]; Annette Choi, *Telehealth Medication Abortions Surged Since* Dobbs *Decision. They Could Become Harder to Access if the Latest Court Decision Stands*, CNN HEALTH (Apr. 19, 2023, 4:51 PM), https://www.cnn.com/2023/04/14/health/telehealth-medication-abortion-access-dg/index.html [https://perma.cc/R8NU-3JK7].

68. *See, e.g.*, Claire Cain Miller & Margot Sanger-Katz, *Despite State Bans, Legal Abortions Didn't Fall Nationwide in Year After* Dobbs, N.Y. TIMES (Oct. 24, 2023), https://www.nytimes.com/2023/10/24/upshot/abortion-numbers-dobbs.html (on file with the *Iowa Law Review*); Press Release, Guttmacher Inst., Number of Abortions in the United States Likely to Be Higher in 2023 than in 2020 (Jan. 17, 2024), https://www.guttmacher.org/news-release/2024/number-abortions-united-states-likely-be-higher-2023-2020 [https://perma.cc/8NHD-668J] (reporting results from Monthly Abortion Provision Study).

two and seven percent of people in the United States have terminated a pregnancy using medication without ever consulting a medical provider.[69]

C. ATTITUDES AND ACCEPTANCE

Unlike most other types of medical care, the availability of abortion care is affected not only by formal requirements like FDA approval and state laws, but also by the number of providers and their willingness to participate in such care. Despite some controversy surrounding the original approval of Mifeprex,[70] the medical community strongly supports its use for abortion. The official position of the American College of Obstetricians and Gynecologists ("ACOG"), the leading professional organization for women's health providers, is that "[m]edication abortion . . . is a safe and effective method of providing abortion."[71] Moreover, ACOG's view is that the REMS restrictions imposed by FDA, even in their current relaxed form, "do not make the care safer, are not based on medical evidence or need, and create barriers to clinician and patient access to medication abortion."[72] The organization's official recommendation is that the REMS restrictions be removed completely.[73] Surveys of individual providers also find a high-level of support for access to abortion care, whether they themselves are involved in such care or not. They also show that background conditions like the Covid-19 pandemic and restricted access after *Dobbs* have fueled an increase in support for medication abortion, and even for self-managed abortion.[74] About half of surveyed providers in one study expressed an interest in a "more de-medicalized model of abortion care."[75] As one provider responded, speaking about self-managed abortion:

> COVID has changed a lot. I think it's helped us push into the modern age of telehealth quicker than we would have otherwise. It's finally gotten a lot of people to start really critically thinking about the data on how much of what we do is actually necessary, clinically

69. *See* Jennifer Karlin et al., *Greasing the Wheels: The Impact of COVID-19 on US Physician Attitudes and Practices Regarding Medication Abortion*, 104 CONTRACEPTION 289, 289 (2021); Daniel Grossman et al., *Self-Induction of Abortion Among Women in the United States*, 18 REPROD. HEALTH MATTERS 136, 137 (2010); Jenna Jerman, Tsuyoshi Onda & Rachel K. Jones, *What Are People Looking for When They Google "Self-Abortion"?*, 97 CONTRACEPTION 510, 510 (2018); Daniel Grossman et al., *Knowledge, Opinion and Experience Related to Abortion Self-Induction in Texas*, 92 CONTRACEPTION 360, 360–61 (2015).

70. *See* R. Alta Charo, *A Political History of RU-486*, *in* BIOMEDICAL POLITICS 43, 45 (Kathi E. Hanna ed., 1991).

71. *Medication Abortion Up to 70 Days of Gestation*, *supra* note 59.

72. *Id.*

73. *Id.*

74. Karlin et al., *supra* note 69, at 289–90.

75. *Id.* at 290.

> for patient safety and outcomes, versus what have we just always done and is traditional.[76]

Provider attitudes are not static. As medical students and residents will have less exposure to abortion in training and practice, it will be important to track attitudes among newer providers in the post-*Dobbs* world. It is likely, however, that provider support for medication abortion will only increase. One study from 2017 found that virtually all medical students in a qualitative study viewed abortion care as an important component of patient autonomy and welfare, as well as a factor in promoting social justice.[77]

With the FDA's elimination of the in-person provision requirement, it is also important to consider the attitudes of pharmacists, who will play a larger role in medication abortion than under the more restrictive REMS. There is already an elaborate set of rules in place to accommodate religious and moral objections of pharmacists to being involved in dispensing birth control; that same system can be utilized to accommodate, where appropriate, their potential objections to dispensing abortion medications. But little is known about how widespread pharmacist refusals might be since their involvement in the process is such a recent development.[78] One recent study showed that pharmacists view dispensing of abortion medication to be necessary and acceptable as long as adequate safeguards exist to protect patient safety, to prevent liability for pharmacists, and to preserve some space for religious and other objections.[79] And it may be that *Dobbs* will provoke greater support from pharmacists as the plight of patients who suffer an unwanted pregnancy in an abortion-hostile state becomes more obvious.

The importance of medication abortion also turns on patient attitudes and preferences. The vast majority of abortions in the United States occur before the tenth week of gestation, which means that most patients are able

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76. *Id.* at 292. On physician attitudes about medication abortion, see also Laura E.T. Swan, Abigail S. Cutler, Madison Lands, Nicholas B. Schmuhl & Jenny A. Higgins, *Physician Beliefs About Abortion Safety and Their Participation in Abortion Care*, SEXUAL & REPROD. HEALTHCARE 1, 2–3 (Sept. 2023), https://www.sciencedirect.com/science/article/pii/S1877575623001064/pdfft?md5=61f68df4785bd28aa56586985bc1acae&pid=1-s2.0-S1877575623001064-main.pdf [https://perma.cc/BY8S-HJR9]; COLLABORATIVE FOR REPROD. EQUITY, UNIV. OF WIS., PHYSICIAN SUPPORT OF UNRESTRICTED ABORTION SERVICES IN WISCONSIN (2021), https://core.wisc.edu/wp-content/uploads/sites/1349/2021/11/SMPH-Survey-Brief_November-2021.pdf [https://perma.cc/F86E-JA6X].

77. *See* Deborah Bartz, Elizabeth Janiak, Courtney Jackson, Lori Berkowitz & Jody Steinauer, *Medical Student Attitudes on Abortion Reflect Professionalism: A Qualitative Exploration*, 130 OBSTETRICS & GYNECOLOGY 54S, 54S (2017).

78. *Refusing to Provide Health Services*, GUTTMACHER INST. (Aug. 31, 2023), https://www.guttmacher.org/state-policy/explore/refusing-provide-health-services [https://perma.cc/B92Q-RFSJ].

79. *See* Selina Sandoval et al., *A Qualitative Analysis of Pharmacists' Attitudes Towards Provision of Medication Abortion*, BMC HEALTH SERVS. RSCH. 1, 7 (May 30, 2023), https://bmchealthservres.biomedcentral.com/counter/pdf/10.1186/s12913-023-09543-z.pdf [https://perma.cc/M726-433K].

to safely choose between medical and surgical abortion.[80] For patients in abortion-hostile states after *Dobbs*, medication abortion obviously is more accessible because pills can be obtained through the mail or other means that do not require travel out of state. For patients in states where abortions are legal, the decision between methods can be multi-factored. Patient attitudes about medication abortion are driven largely by accessibility of in-person providers and the perceived risks of surgical versus medication abortion.[81] Many patients choose a surgical abortion because it is quicker, more certain, and marginally more effective. Some choose medication abortion to avoid surgical risks like infection or perforation of pelvic organs. Regardless of individual reasons, we know that the proportion of abortions done with medication has increased substantially in recent years and likely will continue to do so.[82]

Public attitudes about medication abortion also play a role in usage, access, and legality. In general, legal abortion enjoys very broad support in the United States. Public opinion polls show that more than seventy percent of adults believe abortion should be legal in most circumstances.[83] And as we have seen in the short time since the *Dobbs* opinion was released, abortion rights do well with voters—most abortion measures that have reached voters through referenda or other forms of direct democracy have been resolved in favor of abortion rights, even in "red" (Republican-leaning) states like Kansas and Ohio.[84] We know less about public opinion with respect to medication abortion specifically, although there are a few data points. There is very strong support for abortion in general, slightly less for medication abortion, and less

80. *See* STEPHANIE RAMER ET AL., CDC, ABORTION SURVEILLANCE – UNITED STATES, 2022, at 6 (2024), https://www.cdc.gov/mmwr/volumes/73/ss/pdfs/ss7307a1-H.pdf [https://perma.cc/7CA5-UBZE] (reporting that 78.6% of abortions in the United States in 2022 occurred by the 9th week of gestation, and 92.8% occurred by the 13th week).

81. *See* Abigail R.A. Aiken, Kathleen Broussard, Dana M. Johnson & Elisa Padron, *Motivations and Experiences of People Seeking Medication Abortion Online in the United States*, 50 PERSPS. ON SEXUAL & REPROD. HEALTH 157, 158–62 (2018).

82. Yvonne Lindgren, *When Patients Are Their Own Doctors:* Roe v. Wade *in an Era of Self-Managed Care*, 107 CORNELL L. REV. 151, 157–58 (2021).

83. *See, e.g.*, *Public Opinion on Abortion*, PEW RSCH. CTR. (May 13, 2024), https://www.pewresearch.org/religion/fact-sheet/public-opinion-on-abortion [https://perma.cc/Y3M7-6PKW]; *see also* Sarah Raifman, M. Antonia Biggs, Lauren Ralph, Katherine Ehrenreich & Daniel Grossman, *Exploring Attitudes About the Legality of Self-Managed Abortion in the US: Results from a Nationally Representative Survey*, 19 SEXUALITY RSCH. & SOC. POL'Y 574, 574 (2021) (finding seventy-six percent of survey respondents supported legal abortion). Yvonne ("Yvette") Lindgren argued before *Dobbs* that the right to abortion should be reframed to protect "direct access to abortion that is not dependent upon the provider-patient relationship" given advances in medical technology and lessons from the pandemic about the safety of self-managed abortion. Lindgren, *supra* note 82, at 156.

84. *See* Allison McCann & Amy Schoenfeld Walker, *How Ballot Measures Will Change Abortion Access*, N.Y. TIMES (Nov. 6, 2024), https://www.nytimes.com/interactive/2024/11/06/us/elections/abortion-ballot-results-laws-election.html (on file with the *Iowa Law Review*); Veronica Stracqualursi, Devan Cole & Paul LeBlanc, *Voters Deliver Ringing Endorsement of Abortion Rights on Midterm Ballot Initiatives Across the U.S.*, CNN (Nov. 9, 2022), https://www.cnn.com/2022/11/09/politics/abortion-rights-2022-midterms/index.html [https://perma.cc/648L-AYZ9].

still for self-managed medication abortion.[85] For example, a study of attitudes toward medication abortion prescribed by telemedicine during the Covid-19 pandemic showed that more respondents favored it than opposed it.[86]

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The introduction of abortion pills did more than offer a safe and effective alternative to surgical abortion; it also shifted the focus of legal contests and added a new regulatory dimension not implicated by surgical abortion. These new contests do not occur on untrodden ground; rather, they take place on a field long divided between state authority over medical practice and federal authority over medical products. Thus, to answer the question posed in our title, "*Who regulates abortion now?*", we must first understand who regulates *medicine*.

II. ABORTION AS MEDICINE

A. TRADITIONAL JURISDICTION OVER MEDICINE

To understand the current struggle over medication abortion, one must first understand how federal and state governments traditionally allocate jurisdiction over "medicine." For over a century, authority over "medicine" has been bifurcated: "[S]tates regulate medical *practice*, while the federal government regulates medical *products*," including pharmaceuticals.[87] Although the practice/products distinction has never been perfectly drawn, it has endured over a century of scientific, technological, and social progress that has revolutionized medicine in all its forms.[88] Here, in Part II, we describe these traditional lines of demarcation before describing in Part III various incursions in both directions—federal efforts to influence medical practice and state efforts to regulate medical products.

1. State Regulation of Medical Practice

Since 1889, federal courts have recognized state authority to regulate the practice of medicine.[89] The Tenth Amendment to the U.S. Constitution reserves for states all powers not expressly delegated to the federal government,[90] including general "police power[s]" that authorize states to protect "the lives,

85. *See* Mallory Newall, Charlie Rollason & Bernard Mendez, *Most Americans Support Access to Medication Abortion*, IPSOS (Mar. 29, 2024), https://www.ipsos.com/en-us/most-americans-support-access-medication-abortion [https://perma.cc/RMX2-XK5B].

86. *See* Kathryn J. LaRoche, Kristen N. Jozkowski, Brandon L. Crawford & Katherine R. Haus, *Attitudes of US Adults Toward Using Telemedicine to Prescribe Medication Abortion During Covid-19: A Mixed Methods Study*, 104 CONTRACEPTION 104, 109 (2021).

87. Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 430 (2015).

88. *See, e.g.*, Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 888 (2017); Nathan Cortez, *Substantiating Big Data in Health Care*, 14 I/S 61, 72–81 (2017).

89. Dent v. West Virginia, 129 U.S. 114, 122–23 (1889).

90. U.S. CONST. amend. X.

limbs, health, comfort, and quiet of all persons."[91] Thus, for decades the Supreme Court has recognized that states' police power "extends naturally to the regulation of all professions concerned with health."[92] Over the years, various challengers have tried to invalidate state regulation of medical practice under the First and Fourteenth Amendments, but these cases are mostly unsuccessful.[93]

Of course, there is not a single uniform definition of what "the practice of medicine" entails, largely because each state defines it by statute. Definitions offered in the late 1800s and early 1900s described the practice of medicine simply as the "art of healing,"[94] maintaining a physician–patient relationship,[95] or "administer[ing] drugs or perform[ing] surgery."[96] Modern statutes tend to focus on the act of diagnosing and treating any mental or physical disease or condition.[97] Some states add that advertising or holding oneself out as a doctor also constitutes the practice of medicine.[98] Importantly, the "practice of medicine" can be very broad, including the practice of pharmacy, dentistry, and other specialties authorized to practice independently under state law.[99] At the outer boundaries, states may disagree on whether activities such as reviewing claims for insurance companies, testifying as an expert witness, or administering lethal injections constitute the practice of medicine.[100] But most states agree that the basic acts of diagnosing and treating patients qualify.[101]

State regulation of medical practice can vary, but all fifty states use a state board of medicine to oversee both licensing and practice standards.[102] Certain licensing requirements are relatively uniform across states, such as "graduating from an accredited medical school, completing at least one year of a residency or fellowship, and passing a licensing examination."[103] State statutes, typically called a "Medical Practice Act," also authorize boards to discipline physicians for incompetence, impairment, substance abuse, or aiding the unauthorized

91. Slaughter-House Cases, 83 U.S. (16 Wall.) 36, 62–63 (1872).

92. Barsky v. Bd. of Regents of the Univ. of N.Y., 347 U.S. 442, 449, 451–52 (1954).

93. Zettler, *supra* note 87, at 448–49 (citing unsuccessful challenges but discussing two successful challenges to state laws in Oklahoma and Arizona prohibiting off-label use of abortifacients, which courts found violated patients' constitutional rights, though these cases predated *Dobbs*).

94. Editorial, *What Constitutes the Practice of Medicine?*, 299 JAMA 463, 463 (2008).

95. William C. Tait, *The Legal Definition of the Practice of Medicine*, 2 CAL. ST. J. MED. 119, 119 (1904).

96. Zettler, *supra* note 87, at 435 (citing Smith v. Lane, 31 N.Y. Sup. Ct. (24 Hun) 632, 634–35 (1881); Nelson v. State Bd. of Health, 57 S.W. 501, 505 (Ky. 1900); State v. Liffring, 55 N.E. 168, 168–69 (Ohio 1899); State v. Mylod, 40 A. 753, 755–56 (R.I. 1898)).

97. *Id.* (citing, *e.g.*, ARIZ. REV. STAT. ANN. § 32-1401 (2023); OR. REV. STAT. ANN. § 677.085 (West 2008)).

98. *Id.* (citing OR. REV. STAT. ANN. § 677.085).

99. *Id.* at 430 n.7.

100. *Id.* at 436.

101. *Id.*

102. Nathan Cortez, *The Law of Licensure and Quality Regulation*, 387 NEW ENG. J. MED. 1053, 1054 (2022); Zettler, *supra* note 87, at 450.

103. Zettler, *supra* note 87, at 450.

practice of medicine, among other actions.[104] And, per most state licensing schemes, boards can initiate a variety of disciplinary actions that range from minor (reprimands) to major (suspending or revoking a license).[105]

Physicians are also governed by professional codes of ethics, such as the American Medical Association's Code of Medical Ethics.[106] Although not legally binding, sometimes state laws sanction physicians for violating these otherwise voluntary codes.[107] But again, the sources of law here are state rather than federal.

Key to our arguments below is that state oversight is largely focused on patient safety, seeking to ensure at least a minimum level of practitioner competence and training. Other laws are designed to ensure that physicians can use their best professional judgment to diagnose and treat patients, without interference from non-practitioners. Sometimes states do intrude on physician decision-making or the physician–patient relationship itself, but these tend to be narrowly-focused laws motivated by concerns regarding patient welfare. For example, Professor Patricia J. Zettler has identified state laws that require physicians to distribute standardized pamphlets to their patients about blood transfusions and certain cancers (breast, prostate, gynecological),[108] laws that require newborns to be given eyedrops within a certain timeframe after birth to prevent eye infections,[109] and laws that require newborns to be screened for certain genetic or metabolic disorders.[110] Otherwise, in the long tradition of regulating medical practice, states tend to leave clinical decision-making to clinicians. Finally, states also regulate medical practice via state courts, which can hold practitioners liable for medical malpractice and, in theory, deter substandard care.[111] Thus, virtually all state schemes are designed to ensure patient safety and quality care.

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104. *Id.* at 450–51; Nadia N. Sawicki, *Character, Competence, and the Principles of Medical Discipline*, 13 J. HEALTH CARE L. & POL'Y 285, 290–92 (2010).

105. Zettler, *supra* note 87, at 450–51; Nadia Sawicki, *Complaints to Professional and Regulatory Bodies*, *in* THE OXFORD HANDBOOK OF U.S. HEALTH LAW 467–69 (I. Glenn Cohen et al. eds., 2017).

106. AMA CODE OF MED. ETHICS, https://code-medical-ethics.ama-assn.org [https://perma.cc/G5KG-SLN4].

107. *See, e.g.*, OHIO REV. CODE § 4731.22(B) (2024).

108. Zettler, *supra* note 87, at 452; MED. BD. OF CAL., GUIDE TO THE LAWS GOVERNING THE PRACTICE OF MEDICINE BY PHYSICIANS AND SURGEONS 70–71 (7th ed. 2013).

109. Zettler, *supra* note 87, at 452 (citing MASS. GEN. LAWS ANN. ch. 111, § 109A (West 2015); MICH. COMP. LAWS ANN. § 333.5125 (West 2016); N.H. REV. STAT. ANN. § 132:6 (LexisNexis 2012)).

110. Zettler, *supra* note 87, at 452.

111. *Id.*; *see also* Theodore Silver, *One Hundred Years of Harmful Error: The Historical Jurisprudence of Medical Malpractice*, 1992 WIS. L. REV. 1193, 1212–13 (noting that the physician's duty is measured by professional norms); Michelle M. Mello, Amitabh Chandra, Atul A. Gawande & David M. Studdert, *National Costs of the Medical Liability System*, 29 HEALTH AFFS. 1569, 1570 (2010) (discussing the benefits and components of the medical liability system). Whether malpractice liability does indeed deter substandard care is still debated. *See, e.g.*, Michelle M. Mello & Troyen A. Brennan, *Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform*, 80 TEX. L. REV. 1595, 1606–15 (2002).

But states go beyond quality and safety when they restrict medical practice for other reasons. For example, most states have adopted mandatory generic substitution laws that require pharmacists to dispense generic drugs, "essentially overriding a physician's recommendation for a brand-name drug."[112] These laws are animated by economic motives, not patient safety motives. And, of course, states intrude on medical practice in areas deemed to be controversial, including abortion and physician-assisted suicide.[113] There, state policymakers override the judgments of clinical decision-makers.

Importantly, not all state intrusions into medical practice are instances of non-professionals overriding the judgments of professionals. State medical boards are largely comprised of physicians themselves, which some argue can make the boards overly sympathetic to other physicians.[114] Oversight by state medical boards is frequently critiqued as "feeble," "weak," and "dangerously lax."[115] Boards are criticized for rarely bringing disciplinary actions, and the actions they do bring are less concerned with substandard care than they are inappropriate sexual relations with patients or impairment by drugs or alcohol, or other "unprofessional conduct."[116] Indeed, studies show that less than one half of one percent of the roughly one million physicians nationwide are disciplined by state medical boards each year.[117] Another study found that for every one thousand physicians, only five face sanctions,[118] and when they do, sanctions are relatively mild, such as mandatory fines or training rather than license suspensions or revocations.[119] In any case, state oversight has been characterized as largely "self-regulation" by the profession.[120]

Thus, despite its many imperfections, state jurisdiction over medical practice has endured for well over a century in the United States. During roughly the

112. Zettler, *supra* note 87, at 451.

113. *Id.*

114. Richard S. Saver, *Physicians Spreading Medical Misinformation: The Uneasy Case for Regulation*, 108 MINN. L. REV. 911, 966–67 (2023).

115. *See, e.g.*, *id.* at 937, 966; SIDNEY WOLFE & ROBERT E. OSHEL, PUB. CITIZEN'S HEALTH RSCH. GRP., RANKING OF THE RATE OF STATE MEDICAL BOARDS' SERIOUS DISCIPLINARY ACTIONS, 2017-2019, at 11 (2021), https://www.citizen.org/wp-content/uploads/2574.pdf [https://perma.cc/Z2QB-78ZK].

116. Saver, *supra* note 114, at 937; James M. Dubois, Emily E. Anderson, John T. Chibnall, Jessica Mozersky & Heidi A. Walsh, *Serious Ethical Violations in Medicine: A Statistical and Ethical Analysis of 280 Cases in the United States from 2008–2016*, 19 AM. J. BIOETHICS 16, 28 (2019).

117. Christopher G. Roy, *Patient Safety Functions of State Medical Boards in the United States*, 94 YALE J. BIOLOGY & MED. 165, 170 (2021) (finding 0.4% of roughly 970,000 physicians were disciplined in 2017); Aaron Young et al., *FSMB Census of Licensed Physicians in the United States, 2020*, 107 J. MED. REG. 57, 59 (2021); *see* Saver, *supra* note 114, at 966 (finding that 0.3% of the roughly one million physicians were disciplined in 2022).

118. James M. DuBois et al., *Preventing Egregious Ethical Violations in Medical Practice: Evidence-Informed Recommendations from a Multidisciplinary Working Group*, 104 J. MED. REG. 23, 23 (2018).

119. Elizabeth Pendo, Tristan McIntosh, Heidi A. Walsh, Kari Baldwin & James M. DuBois, *Protecting Patients from Physicians Who Inflict Harm: New Legal Resources for State Medical Boards*, 15 ST. LOUIS U. J. HEALTH L. & POL'Y 7, 13, 20–22 (2021).

120. Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 168 (2004).

same period of time, the federal government began to assert authority over a different sphere of "medicine."

2. Federal Regulation of Medical Products

Since the early 1900s, the federal government has asserted jurisdiction to regulate medical *products*. The earliest such law may have been the Vaccine Act of 1813, which required physicians to use "genuine vaccine matter" when inoculating patients against smallpox, though the law was repealed in 1822.[121] For the next nine decades, Congress would pass laws regulating foreign commerce in food and drugs while resisting growing calls (to some, "a full-fledge public outcry") for comprehensive domestic regulation to harmonize the smattering of state and local laws.[122] Although the first such bill was proposed in 1879, it "would take [twenty-seven] years before such a law ultimately would be enacted by Congress as the Pure Food and Drugs Act of 1906."[123] Four years earlier, Congress had passed the Biologics Control Act of 1902, which authorized the Surgeons General of the Army, Navy, and Marines to issue and revoke licenses to sell vaccines, anti-toxins, and other biological products.[124] But the seminal moment arrived in 1906 with the Pure Food and Drugs Act, which banned from interstate commerce any "adulterated or misbranded" drugs.[125]

Thus began the federal government's century-long project of regulating drugs.[126] Today, federal law still centers on the landmark Food, Drug, and Cosmetic Act ("FDCA") of 1938,[127] which superseded the 1906 Act. The 1938 Act built on the earlier act's adulteration and misbranding provisions, allowing the government to use criminal prosecutions, injunctions, and product seizures against individuals and firms that violated federal requirements.[128] The 1938 Act also required drug manufacturers to demonstrate the safety of their products before marketing and for the first time provided federal oversight of medical devices.[129] The law has been amended roughly three

121. Act of Feb. 27, 1813, ch. 37, §§ 1–2, 2 Stat. 806, 806–07 (repealed 1822).

122. HUTT ET AL., *supra* note 37, at 6–7.

123. *Id.* at 7.

124. Act of July 1, 1902, Pub. L. No. 57-244, 32 Stat. 728, *superseded by* Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040.

125. Act of June 30, 1906, Pub. L. No. 59-384, 34 Stat. 768.

126. Most scholars (and the FDA itself) point to the 1906 Act rather than the 1813 Act or even the 1902 Act as the germinal moment in food and drug regulation, as authority to implement the 1906 Act was placed in the Bureau of Chemistry in the U.S. Department of Agriculture, before being shifted to the new Food, Drug, and Insecticide Administration in 1927, which was shortened to the Food and Drug Administration in 1930. *See Milestones in U.S. Food and Drug Law*, FDA (Jan. 30, 2023), https://www.fda.gov/about-fda/fda-history/milestones-us-food-and-drug-law [https://perma.cc/998S-W3S9].

127. Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040.

128. HUTT ET AL., *supra* note 37, at 11–12.

129. *Id.*

hundred times since 1938,[130] with the most significant reforms introduced via the Drug Amendments of 1962.[131] The so-called Kefauver-Harris Amendments offered even more comprehensive federal oversight of medical products, including full premarket review by the FDA to ensure that drugs are safe and effective for their intended uses before being marketed.[132] To this day, the FDA's gatekeeping authority to approve new drugs under the Act serves as the lodestar for drug regulation,[133] with dozens of later amendments augmenting the agency's powers over drugs after approval.[134] Thus, the FDCA provides a comprehensive federal scheme to regulate drugs, while expressly disclaiming any federal authority over medical practice.[135]

For decades, courts have tried to preserve this basic division of responsibility between federal jurisdiction over medical products and state jurisdiction over medical practice, even in difficult cases. In *United States v. Evers*, when the Fifth Circuit was asked to determine whether a physician prescribing drugs for unapproved uses was practicing medicine or misbranding products, the court noted that the FDA "was obviously intended to control the availability of drugs for prescribing by physicians," but "was not intended to regulate the practice of medicine."[136] More recently, in *United States v. Regenerative Sciences*, when the D.C. District Court was asked whether a stem cell therapy qualified as a medical product or as medical practice, it observed that "Congress has left the practice of medicine to the States to regulate[, and] FDA does not disagree with these principles."[137] On appeal, the court's decision that the stem cell therapy was properly regulated by the FDA was affirmed by the D.C. Circuit, which found not only that FDA's jurisdiction cannot turn "on state-by-state definitions of the 'practice of medicine,'" but that the federal law's "breadth—and, more specifically, its applicability to doctors—is evident."[138] The D.C. Circuit likewise rejected the lower court's reliance on the *Evers* decision from 1981, noting that the statute "does not exempt doctors in such a

130. *Id.*

131. Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780.

132. HUTT ET AL., *supra* note 37, at 12–13; Drug Amendments of 1962, Pub. L. No. 87-781, § 102, 76 Stat. 780, 781.

133. For a magisterial history of the government's early and ongoing efforts to regulate drugs, see generally DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA (Ira Katznelson, Martin Shefter & Theda Skocpol eds., 2010).

134. HUTT ET AL., *supra* note 37, at 13–15.

135. *Id.* at 12; 21 U.S.C. § 823(g)(2)(H)(i) ("Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided."), *amended by* 21 U.S.C. § 823(g) (effective Dec. 29, 2022) (deleting quoted language).

136. United States v. Evers, 643 F.2d 1043, 1048 (5th Cir. 1981) (emphasis omitted).

137. United States v. Regenerative Scis., LLC, 878 F. Supp. 2d 248, 254–55 (D.D.C. 2012), *aff'd*, 741 F.3d 1314 (D.C. Cir. 2014).

138. *Regenerative Scis., LLC*, 741 F.3d at 1319.

categorical manner."[139] Thus, though the line between products and practice has never been perfectly drawn, it endures.

B. INVERSIONS

Of course, the bifurcation between state and federal oversight over "medicine" has never been absolute. Here in Section II.B, we describe various "inversions"—instances in which the federal government has tried to regulate medical practice or states have tried to regulate medical products. Considering how medicine has evolved over the last 150 years, it is not surprising to see at least some incursions. When states first began regulating medical practice in the 1870s, "medicine was dominated by unlicensed solo practitioners who treated patients with self-made remedies, local differences in practice standards were to be expected, and courts viewed the federal government's commerce powers as quite limited."[140] By today's standards, the medicine of that era was quite primitive. Medical practice was provincial and based largely on custom, in contrast to the rapid diffusion of evidence-based medical knowledge today; medical products tended to be homemade remedies or even snake oils and elixirs rather than the sophisticated pharmaceutical and biologics we use now;[141] even our basic scientific understanding of human physiology and disease is far beyond what prevailed 150 years ago.

So when do states and the federal government breach each other's territories? And why? Do these breaches reflect efforts to further ensure quality, safety, and evidence-based medicine amid tremendous industrial and technological change? Or do they represent moral judgments less concerned with those things?

1. Federal Regulation of Medical Practice

Despite repeated disavowals of intent to interfere with the practice of medicine, the federal government does, on occasion, interfere with the practice of medicine. From the Social Security Amendments of 1954[142] to the Food and Drug Administration Amendments Act of 2007,[143] Congress has repeated some version of the refrain, "Nothing in this Act shall be construed to control

139. *Id.* at 1324.

140. Zettler, *supra* note 87, at 432, 434 n.30 ("Although physician licensure first appeared in the seventeenth century, those earlier licensure policies were 'guild-like' and largely abandoned by 1850."); Timothy Stoltzfus Jost, *Oversight of the Quality of Medical Care: Regulation, Management, or the Market?*, 37 ARIZ. L. REV. 825, 828 (1995).

141. *See, e.g.*, CARPENTER, *supra* note 133, at 75–80; PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 60–79 (1982); PHILIP J. HILTS, PROTECTING AMERICA'S HEALTH 19–24 (2003).

142. Social Security Amendments of 1954, Pub. L. No. 83-761, § 106, 68 Stat. 1052, 1080 (codified at 42 U.S.C. § 416) ("Nothing in this [subchapter] shall be construed as authorizing the [Commissioner of Social Security] or any other officer or employee of the United States to interfere in any way with the practice of medicine . . . .").

143. Drug Addiction Treatment Act of 2000, Pub. L. No. 106-310, § 3502, 114 Stat. 1222, 1226 (codified at 21 U.S.C. § 823(g)(2)(H)(i)) ("Nothing in such regulations or practice guidelines may authorize any Federal official or employee to exercise supervision or control over the practice of medicine or the manner in which medical services are provided.").

or interfere with the practice of medicine." Indeed, the very first words of the massive 1,078-page Medicare statute declare: "Nothing in this [statute] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided . . . ."[144]

Nevertheless, despite such declarations, the federal government oversees the practice of medicine in numerous ways. As Zettler finds, "the federal government exercises an enormous amount of control over certain areas of medicine," including "wide-ranging oversight, such as regulating the use of controlled substances, influencing medical decision-making through Medicare payment policies, and [providing] incentives for improving the quality of medical care, to narrower instances of oversight such as the federal ban on off-label use of Human Growth Hormone."[145]

Some federal laws directly regulate medical practice—such that practitioners are subject to penalties—and others regulate medical practice only indirectly.[146] Even a non-exhaustive list of federal statutes that touch medical practice shows the breadth of federal involvement:

Table 1

Statute	Influence on medical practice
Affordable Care Act ("ACA")[147]	Offers numerous incentives for improving the quality of care provided to Medicare patients.
Americans with Disabilities Act ("ADA")[148]	Affects practitioners' decisions about which patients to treat, including decisions to decline treatment.
Anabolic Steroids Control Act[149]	Prohibits prescribing, dispensing, or administering Human Growth Hormone ("HGH") for non-FDA-approved uses.

144. Health Insurance for the Aged Act, Pub. L. No. 89-97, § 102(a), 79 Stat. 290, 291 (1965) (codified at 42 U.S.C. § 1395). Note that as of 2021, the official Government Printing Office ("GPO") PDF of 42 U.S.C. § 1395 ran from page 2747 of the U.S. Code to page 3825. *Title 42-The Public Health and Welfare*, GOV'T PRINTING OFF. 2747–3825, https://www.govinfo.gov/content/pkg/USCODE-2021-title42/pdf/USCODE-2021-title42-chap7-subchapXVIII.pdf [https://perma.cc/VN6A-Z7NK]. Interestingly, the Senate report for the bill did not explain *why* Congress included this language. *See* S. REP. NO. 89-404 (1965). As Noah emphasizes, however, these provisions seem to express more "deference to professional autonomy rather than the primacy of state regulation." Noah, *supra* note 120, at 167; *see also id.* at 165–66, 166 n.70 (discussing Congress's inclusion of language "designed to reassure physicians that the federal government would not encroach on the practice of medicine"); STARR, *supra* note 141, at 349, 351, 376–77.

145. Zettler, *supra* note 87, at 454 (footnotes omitted).

146. *Id.* at 455–62.

147. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 1501(a), 124 Stat. 119, 242–44 (2010) (codified at 42 U.S.C. § 18091).

148. 42 U.S.C. §§ 12101–12213; Bragdon v. Abbott, 524 U.S. 624, 641 (1998).

149. Anabolic Steroids Control Act of 1990, Pub. L. No. 101-647, § 1904, 104 Stat. 4851, 4853 (codified at 21 U.S.C. § 333(e)).

Controlled Substances Act ("CSA")[150]	Limits what controlled substances may be prescribed, by whom, under what circumstances, and in some cases how.
Emergency Medical Treatment and Active Labor Act ("EMTALA")[151]	Requires hospitals with emergency departments to screen and at least stabilize patients seeking treatment.
Federal Food, Drug, and Cosmetics Act[152]	Determines what drugs, devices, and biologics may be prescribed and the information produced about them.
Food and Drug Administration Amendments Act of 2007[153]	Authorizes FDA to require Risk Evaluation and Mitigation Strategies for drugs, which can include special prescriber training, dispensing locations, and testing requirements, among other things.
Medicare Statute[154]	Determines which items and services will be covered for Medicare patients and how much Medicare will pay, which often affects diagnostic and treatment decisions.
Partial-Birth Abortion Ban Act[155]	Prohibits physicians from knowingly performing an "intact dilation and evacuation" abortion procedure.

Consider just one example above. The Medicare statute authorizes the Centers for Medicare and Medicaid Services ("CMS") within the U.S. Department of Health and Human Services ("HHS") to determine which "items and services" are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[156] These coverage decisions often loom large over physicians treating Medicare patients. Indeed, studies confirm that changes in Medicare policies affect treatment decisions, even for cancer patients.[157] For example, a study found that even though Medicare reimbursement rates do not affect providers'

150. Controlled Substances Act, Pub. L. No. 91-513, §§ 100–411, 84 Stat. 1242, 1242–84 (1970) (codified as amended at 21 U.S.C. § 801–865).

151. 42 U.S.C. § 1395dd.

152. 21 U.S.C. §§ 301–399i.

153. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, §§ 901–921, 121 Stat. 823, 922–62 (codified at 21 U.S.C. § 355-1(a)).

154. 42 U.S.C. §§ 1395, 1395g, 1395y(a).

155. Partial-Birth Abortion Ban Act of 2003, Pub. L. No. 108-105, 117 Stat. 1201 (codified at 18 U.S.C. § 1531(a)); Gonzalez v. Carhart, 550 U.S. 124, 154–56 (2007) (upholding the Act under *Roe* and *Casey*).

156. 42 U.S.C. § 1395y(a)(1)(A).

157. *See, e.g.*, Mireille Jacobson et al., *Does Reimbursement Influence Chemotherapy Treatment for Cancer Patients?*, 25 HEALTH AFFS. 437, 440–43 (2006); Neil R. Powe et al., *Medicare Payment Policy and Recombinant Erythropoietin Prescribing for Dialysis Patients*, 22 AM. J. KIDNEY DISEASES 557, 559–66 (1993).

threshold decision whether to administer chemotherapy to metastatic cancer patients, reimbursement rates did induce prescribers to use more costly chemotherapy regimens.[158] Thus, even though the very first words of the Medicare statute declare that nothing in the act will allow the federal government to "exercise any supervision or control over the practice of medicine,"[159] the statute does precisely that—albeit indirectly. Moreover, federal courts have rejected challenges that various Medicare policies violate this non-interference language.[160]

Another wrinkle is that federal law does not hold back in regulating physician scientists in the course of conducting biomedical research.[161] There are extensive federal protections for human research subjects,[162] and these protections generally disappear outside clinical trials.[163] Thus, it is medical *practice* rather than medical *practitioners* that federal law ostensibly tries to avoid.

Yet, if there are constraints on the federal government's ability to regulate practice, they derive more from congressional reluctance than a lack of constitutional authority.[164] Many scholars today recognize that Congress could justify greater federal regulation of medical practice pursuant to its commerce, spending, and taxing powers under Article I.[165] Early decisions by the Supreme Court were skeptical that the federal government had authority over medical practice, declaring in the 1925 case *Linder v. United States* that "[o]bviously, direct control of medical practice in the states is beyond the power of the federal government."[166] Though later courts quoted this language approvingly, most courts nevertheless upheld federal actions that seemed to touch medical practice in some way;[167] the few that invalidated federal action ruled on

158. Jacobson et al., *supra* note 157, at 441–42.

159. 42 U.S.C. § 1395.

160. Zettler, *supra* note 87, at 466 n.230 (citing cases).

161. Lars Noah, *Informed Consent and the Elusive Dichotomy Between Standard and Experimental Therapy*, 28 AM. J.L. & MED. 361, 362, 379–400 (2002).

162. *See, e.g.*, *Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEP'T HEALTH & HUM. SERVS. (Mar. 27, 2024), https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html [https://perma.cc/WVM5-B395].

163. Noah, *supra* note 161, at 379, 392–93.

164. As Patti Zettler posits, physicians and physician groups lobby Congress extensively and have been successful over the last century convincing Congress to avoid granting the federal government explicit authority over medical practice. Zettler, *supra* note 87, at 441–46.

165. *See, e.g.*, *id.* at 467–74; Noah, *supra* note 120, at 169.

166. Linder v. United States, 268 U.S. 5, 18, 22–23 (1925) (overturning a physician's conviction under the federal Harrison Anti-Narcotic Act for prescribing narcotics because the statute was designed as a tax law and was not intended to regulate medical practice).

167. *See, e.g.*, United States v. Singh, 390 F.3d 168, 189–90 (2d Cir. 2004) (rejecting an argument that a provision in the CSA allowing the forfeiture of medical licenses for certain violations exceeded federal authority under the Tenth Amendment, finding that forfeiture has only a de minimis effect on states' ability to regulate the practice of medicine); Metrolina Fam. Prac. Grp., P.A. v. Sullivan, 767 F. Supp. 1314, 1320–22 (W.D.N.C. 1989) (rejecting an argument by physicians that a Medicare statute that limited the amount physicians can charge Medicare patients violated exceeded federal authority under the Tenth Amendment because any effects

statutory rather than constitutional grounds.[168] One reason may be that *Linder* was decided "during the *Lochner* era," when "the Supreme Court viewed the federal government's commerce powers as quite limited."[169] Another reason may be that the Court itself seemed to retreat from *Linder* just a year later in *Lambert v. Yellowley* (1926), when it rejected a physician's challenge to the National Prohibition Act of 1919, which limited the amount of liquor physicians could lawfully prescribe.[170] The Court in *Lambert* found that "there is no right to practice medicine which is not subordinate to . . . the power of Congress to make laws necessary and proper for carrying into execution the Eighteenth Amendment."[171] Later cases would recognize congressional authority to regulate medical practitioners under Article I's taxing, spending, and commerce powers.[172] Thus, today, scholars generally agree that nothing in the Constitution would prohibit greater federal regulation of medical practice.[173]

Still, physicians and physician groups have long opposed federal bills that would directly regulate medical practice.[174] Almost a century ago, the American Medical Association's ("AMA") opposition to federally-funded health insurance led the Franklin D. Roosevelt Administration to omit health insurance from the Social Security Act of 1935.[175] Although Congress would create Medicare and Medicaid in 1965, pressure from organized medicine led Congress to declare that nothing in the act would touch medical practice.[176] More recently,

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on medical practice are merely incidental to the much larger effort to develop a national insurance program); Doe v. United States (*In re* Grand Jury Proceedings), 801 F.2d 1164, 1169–70 (9th Cir. 1986) (rejecting an argument that a federal investigation into physicians' alleged illegal dispensing of anabolic steroids and androgenic hormones exceeded the federal government's authority under the Tenth Amendment because the Commerce Clause empowers the federal government to regulate prescription drugs).

168. Zettler, *supra* note 87, at 438–39, 438 n.55 (citing cases that invalidated federal actions on statutory rather than constitutional grounds and discussing the two outliers, *United States v. Evers*, 453 F. Supp. 1141, 1150 (M.D. Ala. 1978), and *Oregon v. Ashcroft*, 368 F.3d 1118, 1124 (9th Cir. 2004)).

169. *Id.* at 438.

170. Lambert v. Yellowley, 272 U.S. 581, 596–97 (1926).

171. *Id.* at 596.

172. Zettler, *supra* note 87, at 467–74 (citing cases recognizing congressional authority to regulate medical practitioners under Article I's taxing, spending, and commerce powers).

173. *See, e.g.*, *id.* at 440; Noah, *supra* note 120, at 192. *But see* PAUL D. CLEMENT & LAURENCE H. TRIBE, LABORATORY TESTING SERVICES, AS THE PRACTICE OF MEDICINE, CANNOT BE REGULATED AS MEDICAL DEVICES 11 (2015), http://www.acla.com/wp-content/uploads/2015/01/Tribe-Clement-White-Paper-1-6-15.pdf [https://perma.cc/A65C-QVGA]; RICHARD A. EPSTEIN, CTR. FOR LEGAL POL'Y, MANHATTAN INST., THE FDA'S MISGUIDED REGULATION OF STEM-CELL PROCEDURES: HOW ADMINISTRATIVE OVERREACH BLOCKS MEDICAL INNOVATION 2 (2013), https://media4.manhattan-institute.org/pdf/lpr_17.pdf [https://perma.cc/VFQ2-9GC5].

174. Zettler, *supra* note 87, at 442.

175. *Id.*

176. Health Insurance for the Aged Act, Pub. L. No. 89-97, § 102(a), 79 Stat. 290, 291 (1965) (codified at 42 U.S.C. § 1395).

AMA opposition to the Clinton health reform plan helped ensure its demise.[177] Those with battle scars from the Clinton reform efforts worried that organized medicine would likewise kill Obama's health reform bills.[178] It was not until the bills made major concessions, such as removing a "public option" for government sponsored health plans, that the AMA pledged official support.[179] The medical profession thus has a long, well-documented history of asserting its sovereignty in matters of federal law and policy.[180]

Thus, despite abundant counterexamples, the conventional wisdom that the federal government does not regulate medical practice endures. Federal interventions tend to be on the sly—disclaiming direct oversight while shaping practice indirectly. Of course, states themselves do not maintain perfect lane discipline either.

2. State Regulation of Medical Products

If the federal government is guilty of incursions, then so are states. And unlike federal efforts to regulate medical practice, state efforts to regulate medical products tend to be more forthright, openly challenging federal primacy.

As a historical matter, state regulation of drugs and devices is not entirely novel. State food and drug statutes predated the first federal statute, the Pure Food and Drugs Act of 1906.[181] In fact, almost a decade before Congress passed the 1906 Act, the Association of Food and Drug Officials ("AFDO") was formed by state policymakers to harmonize the numerous state laws already in effect.[182] And these laws have not disappeared. As of 2021, the AFDO's Uniform State Food, Drug, and Cosmetic Act is on the books in forty-five of the fifty states,[183]

177. Robert J. Blendon, Mollyann Brodie & John Benson, *What Happened to Americans' Support for the Clinton Health Plan?*, 14 HEALTH AFFS. 7, 8 (1995); Robert Pear, *Clinton's Health Plan; A.M.A. Rebels Over Health Plan in Major Challenge to President*, N.Y. TIMES (Sept. 30, 1993), https://www.nytimes.com/1993/09/30/us/clinton-s-health-plan-ama-rebels-over-health-plan-major-challenge-president.html (on file with the *Iowa Law Review*).

178. Jacob S. Hacker & Theda Skocpol, *The New Politics of U.S. Health Policy*, *in* THE NATION'S HEALTH 186, 189–90 (Philip R. Lee, Carroll L. Estes & Fatima M. Rodriguez eds., 6th ed. 2001).

179. Robert Pear, *Doctors' Group Opposes Public Insurance Plan*, N.Y. TIMES (June 10, 2009), https://www.nytimes.com/2009/06/11/us/politics/11health.html (on file with the *Iowa Law Review*). Note, of course, that physicians are far from monolithic on their views of health reform. *See, e.g.*, Salomeh Keyhani & Alex Federman, *Doctors on Coverage – Physicians' Views on a New Public Insurance Option and Medicare Expansion*, 361 NEW ENG. J. MED. e24(1), e24(4) (2009); Salomeh Keyhani & Alex Federman, *Health Care Reform and the AMA*, 362 NEW ENG. J. MED. 2230, 2230–32 (2010).

180. *See, e.g.*, STARR, *supra* note 141, at 3–29.

181. HUTT ET AL., *supra* note 37, at 425.

182. *Id.* Of course, Congress had been considering national food and drug legislation for over a quarter century before 1906. *Id.* at 7 (describing the introduction of national legislation in 1879).

183. *Id.* at 425 (noting, however, that state laws can still vary, even under when the Uniform Act has been adopted).

with provisions that parallel key provisions in federal law, including prohibiting adulteration, misbranding, and the like.[184]

Nevertheless, over the last century, federal law came to dominate the field. State statutes are written to be virtually identical to the Federal FDCA,[185] and states largely defer to FDA enforcement, rarely enforcing their own laws.[186] As federal law waxed, state laws naturally waned.

But they did not disappear. When states do attempt to deviate from federal law, questions of preemption obviously arise. Article VI of the U.S. Constitution declares that "the Laws of the United States . . . shall be the supreme Law of the Land . . . ."[187] Modern preemption doctrine is both capacious and convoluted, and it is beyond our remit here to consider all the ways in which state requirements may or may not be preempted by federal law.[188] In Section III.E, we will evaluate ongoing preemption litigation regarding mifepristone. For present purposes, it is worth noting that the Supreme Court has had several occasions to discern whether the FDCA intends to preempt specific state requirements, particularly state tort liability.[189] These decisions, and the lower

184. *See, e.g.*, TEX. HEALTH & SAFETY CODE ANN. §§ 431.001–431.415 (West 2024) (comprising the Texas Food, Drug, and Cosmetic Act).

185. Zettler, *supra* note 88, at 860–61.

186. *Id.* at 861.

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

188. For examples of more fulsome discussions, see Zettler, *supra* note 88, at 861–88; Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 27–42, 52–53.

189. In 1996, the Court held that even though the FDCA includes an express preemption clause for medical devices, Medical Device Amendments of 1976, Pub. L. No. 94-295, § 521, 90 Stat. 539, 574 (codified at 21 U.S.C. § 360k(a)), Congress did not intend to preempt state tort actions against medical device manufacturers when their devices were cleared through the FDA's 510(k) notification process (rather than those fully approved via the more rigorous premarket approval ("PMA") process). Medtronic, Inc. v. Lohr, 518 U.S. 470, 493–95 (1996). Then, in 2008, the Supreme Court confirmed that medical devices fully approved through the PMA process would be immune from state law requirements that differed from or added to federal requirements. Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008). During this period, the Court also confronted whether the drug provisions in the FDCA—which again, lack an express preemption clause—should preempt state requirements for drugs, either because federal law occupies the entire field of drug regulation (so-called "field preemption"), or because state law conflicts with federal law (so-called "conflict preemption"). *See, e.g.*, Lefaivre v. KV Pharm. Co., 636 F.3d 935, 941 (8th Cir. 2011) (finding that the federal scheme to regulate drugs "is *not* 'so pervasive in scope that it occupies the field'" (quoting *In re* Aurora Dairy Corp. Organic Milk Mktg. & Sales Pracs. Litig., 621 F.3d 781, 792 (8th Cir. 2010))). *But see* Ouellette v. Mills, 91 F. Supp. 3d 1, 12 (D. Me. 2015) (observing "clear Congressional intent to occupy the field of pharmaceutical importation"); R.F. v. Abbott Lab'ys, 162 N.J. 596, 625 (2000) (finding FDA control and scrutiny of a blood test "was so pervasive" that FDA "left no room" for state regulation); HUTT ET AL., *supra* note 37, at 436–48. The Supreme Court held in 2008 that the FDCA did not preempt certain tort claims against a drug manufacturer because simultaneous compliance with both federal and state requirements was not impossible. Wyeth v. Levine, 555 U.S. 555, 574–76 (2008). However, in 2011, the Court found that it was impossible for a generic drug manufacturer to comply with both federal and state requirements simultaneously. PLIVA, Inc. v. Mensing, 564 U.S. 604, 618 (2011). And in 2013, the Court held that the FDCA preempted a design defect claim against a

court decisions following them, demonstrate that state law has not fully waned, even in the presence of comprehensive federal regulation.

The most common preemption conflict arises when a plaintiff sues a manufacturer in state court claiming injury from an FDA-regulated product. For most of the agency's history, the FDA did not object to state tort liability conflicting with or serving as a barrier to accomplishing federal objectives; the agency's longstanding view was that tort liability could complement federal oversight by uncovering problems with FDA-regulated products.[190] Of course, state judgments and verdicts can create new or additional requirements that can conflict with federal law. Thus, when a plaintiff claims injury because a product's labeling failed to warn of a risk that materialized, a state judgment or verdict might find that the FDA-approved labeling was deficient.[191] Or, in rarer cases, a state verdict might find that a product was defectively designed, notwithstanding FDA's review.[192] For decades the agency did not object to this basic state of affairs.[193] It was thus an abrupt departure when the FDA under the George W. Bush Administration asserted that federal labeling rules preempted state requirements.[194] Nevertheless, although it is contested whether federal regulation and state tort liability *should* coexist, they no doubt have coexisted for over a century.[195]

But state court decisions are only one species of state intervention. A separate species involves attempts by state policymakers to assert authority over medical products they know to be regulated by the FDA. Sometimes states try to sidestep FDA jurisdiction by claiming to regulate not the product but the practice of medicine surrounding it. Other times state policymakers try to

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generic drug manufacturer under New Hampshire law. Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 480 (2013).

190. David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 GEO. L.J. 461, 475–76 (2008).

191. Zettler, *supra* note 88, at 860; Kessler & Vladeck, *supra* note 190, at 462–63.

192. Tobin v. Astra Pharm. Prods., Inc., 993 F.2d 528, 537–38 (6th Cir. 1993) (discussing a successful design defect claim under Kentucky law after both plaintiff's experts and FDA advisory committee members identified several methodological flaws in clinical trials).

193. *See, e.g.*, *Wyeth*, 555 U.S. at 574 ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express preemption provision at some point during the FDCA's 70-year history.").

194. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934–35 (Jan. 24, 2006) ("State law actions also threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs.").

195. Contrast, for example, the majority and dissenting opinions in *Wyeth*. Justice Stevens, writing for the majority, emphasized "the longstanding coexistence of state and federal law and the FDA's traditional recognition of state-law remedies," *Wyeth*, 555 U.S. at 581, while Alito, writing for the dissent, notes that "state tort suits can peacefully coexist with the FDA's labeling regime, and they have done so for decades. But this case is far from peaceful coexistence." *Id.* at 628 (Alito, J., dissenting) (citation omitted).

poke the federal bear—enacting laws they know will conflict with federal policy either for symbolic reasons,[196] or to provoke federal action.

Efforts to sidestep FDA jurisdiction are often preempted. For example, in 2014—in what was considered "a highly unusual move" at the time[197]—Massachusetts prohibited use of the newly FDA-approved drug Zohydro ER, a high-dose opioid made without common abuse deterrents such as crush-resistant coating.[198] Styled as an effort to regulate medical *practice* rather than products, the Massachusetts State Department of Public Health banned prescribing, dispensing, and administering the Zohydro ER until the manufacturer adopted an "abuse-resistant formulation."[199] A federal court quickly invalidated the prohibition as preempted by federal law, characterizing it as an obstacle to achieving federal objectives because it would "countermand the FDA's determinations and . . . undermine the FDA's ability to make drugs available to promote and protect the public health."[200]

This was not the first state effort to ban use of an FDA-approved product. In the 1990s, the Tennessee Board of Medical Examiners banned prescriptions of the diet drug fenfluramine and its derivatives, years before the FDA withdrew approval for them.[201] And, of course, after the FDA approved mifepristone in 2000, Oklahoma proposed a bill that would have banned its use within the state, though the bill did not pass.[202]

Aside from outright bans on FDA-approved products, several states have tried to adopt conditions on use that are either more restrictive or less restrictive than the federal approach. On the more restrictive side, both Massachusetts and Vermont imposed restrictions on the use of Zohydro that exceeded federal requirements, directing physicians, for example, to consider the patient's risk of drug abuse, document that other pain treatments were inadequate, and enter

196. For a discussion of the use of symbolic laws, see Nathan Cortez & Lindsay F. Wiley, *Hortatory Mandates*, 91 GEO. WASH. L. REV. 617, 628–37 (2023).

197. Zettler, *supra* note 88, at 847.

198. Noah, *supra* note 188, at 6 (describing Governor Deval Patrick's emergency declaration authorizing the Massachusetts Department of Public Health to prevent sales in Massachusetts until abuse concerns were addressed); Zettler, *supra* note 88, at 847; Milton J. Valencia, *Mass. Limits Use of the Potent Painkiller Zohydro*, BOS. GLOBE (Apr. 23, 2014, 12:00 AM), https://www.bostonglobe.com/metro/2014/04/22/governor-deval-patrick-administration-enacts-new-restrictions-zohydro/GpIZM4OUOgZg7cWEI8XV5N/story.html (on file with the *Iowa Law Review*).

199. Zogenix, Inc. v. Patrick, No. 14-11689, 2014 WL 1454696, at *1–2 (D. Mass. Apr. 15, 2014).

200. *Id.* at *2 (citation omitted).

201. Noah, *supra* note 188, at 21–22; TENN. COMP. R. & REGS. 0880-2-.14(3)(C) (2003), *superseded in part by statute*, 1997 Tenn. Pub. Acts 236, § 3 (codified at TENN. CODE ANN. § 63-6-214(m)–(n) (2023)). In 1960, some states attempted to bar the use of oral contraceptives after FDA approval, but these efforts predated the modern FDA approval process enacted via the 1962 Drug Amendments. *See* Noah, *supra* note 188, at 16–17. These efforts were struck down by the Supreme Court. *See* Griswold v. Connecticut, 381 U.S. 479, 485–86 (1965); Carey v. Population Servs. Int'l, 431 U.S. 678, 686–91 (1977).

202. H.B. 1038, 48th Gen. Assemb., Reg. Sess. (Okla. 2001).

into a "Pain Management Treatment Agreement" with each patient.[203] Although the same federal judge that enjoined the previous ban in Massachusetts found aspects of these new restrictions problematic, she vacated her previous injunction, finding that state regulation targeted at prescriber and pharmacist behavior would not frustrate federal objectives in regulating the product's manufacturer.[204] Other states have, on occasion, sought to impose additional requirements on FDA-approved drugs, focusing largely on contraceptives and controlled substances, but also targeting antibiotics and diet drugs.[205]

Conversely, states concerned with overly-strict federal regulation have tried to adopt more permissive policies, such as in the case of the 2013 Maine law that allowed residents to import unapproved drugs from pharmacies in select countries (Australia, Canada, Ireland, New Zealand, and the United Kingdom).[206] As in the Zohydro case, a federal court found the state law to be preempted, notwithstanding the state's arguments that the statute was a form of medical practice regulation.[207]

States may also deviate from federal policy to prompt the federal government to reconsider its approach. For example, beginning in 2014, dozens of states passed so-called "right-to-try" bills that purported to authorize patients who are terminally ill or seriously ill to access drugs not yet approved by the agency.[208] Although FDA has long maintained procedures for granting "expanded access" to such drugs prior to approval,[209] critics argued that the

203. 243 MASS. CODE REGS. 2.07(25) (2015); Letter from Ronald J. Klein, Exec. Officer, Vt. Bd. of Pharmacy & Linda Davidson, Exec. Dir., Vt. Bd. of Nursing, to Health Care Prescribers or Dispensers (Apr. 15, 2014), [https://perma.cc/VK7K-JNCK]; Zettler, *supra* note 88, at 848.

204. Zogenix, Inc. v. Patrick, No. 14-11689, 2014 WL 4273251, at *2–3 (D. Mass. Aug. 28, 2014).

205. Noah, *supra* note 188, at 16–22. For example, in *Whalen v. Roe*, the Supreme Court declined to invalidate a New York law that required triplicates of prescriptions for Schedule II controlled substances, with a copy sent to state officials, but the plaintiffs challenged the law under substantive due process grounds that the law would violate patient privacy rather than federal preemption grounds, even though the law exceeded federal recordkeeping requirements. Whalen v. Roe, 429 U.S. 589, 603–04 (1977); Noah, *supra* note 188, at 48–50 (noting confusing dictum by Justice Stevens that "the State no doubt could prohibit entirely the use of particular Schedule II drugs."); B. Jessie Hill, *The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 304 (2007) (calling the statement by Justice Stevens about states outlawing specific drugs "pure dicta").

206. ME. REV. STAT. ANN. tit. 32, § 13731(1)(B)–(C) (West 2024).

207. Ouellette v. Mills, 91 F. Supp. 3d 1, 9, 12 (D. Me. 2015) (finding that Congress intended "to occupy the field of pharmaceutical importation").

208. Zettler, *supra* note 88, at 848, 881; Brady Dennis & Ariana Eunjung Cha, *'Right to Try' Laws Spur Debate over Dying Patients' Access to Experimental Drugs*, WASH. POST (May 16, 2014), https://www.washingtonpost.com/national/health-science/right-to-try-laws-spur-debate-over-dying-patients-access-to-experimental-drugs/2014/05/16/820e08c8-dcfa-11e3-b745-87d39690c5c0_story.html (on file with the *Iowa Law Review*).

209. 21 C.F.R. §§ 312.300–320 (2024). Scholars argue that the state right-to-try bills are largely "symbolic gestures." Noah, *supra* note 188, at 24; Patricia J. Zettler & Henry T. Greely, *The Strange Allure of State "Right-to-Try" Laws*, 174 JAMA INTERNAL MED. 1885, 1885–86 (2014).

process was too cumbersome.[210] The libertarian Goldwater Institute thus drafted model "right-to-try" legislation that numerous states adopted. As written, the state laws provided access to drugs after the sponsor successfully completed preliminary Phase I trials demonstrating that the drug is safe enough to continue studying in larger human trials.[211] Eventually, forty-one states passed some version of a "right-to-try" law before Congress in 2018 passed a federal version.[212] These state laws resembled in some ways the laws passed by dozens of states authorizing use of medical marijuana, which are contrary to federal law[213] but not inconsistent with the U.S. Department of Justice's non-enforcement policy.[214] Decades earlier, roughly half of states legalized the use of amygdalin (Laetrile) within their borders for cancer, despite the FDA ruling that it could not be lawfully marketed.[215]

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210. CHRISTINA CORIERI, GOLDWATER INST., EVERYONE DESERVES THE RIGHT TO TRY: EMPOWERING THE TERMINALLY ILL TO TAKE CONTROL OF THEIR TREATMENT 1 (2014), https://www.goldwaterinstitute.org/wp-content/uploads/cms_page_media/2015/1/28/Right%20To%20Try.pdf [https://perma.cc/4LA4-M895].

211. 21 C.F.R. § 312.21(a) (2024) (defining clinical trial phases).

212. Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017, Pub. L. No. 115–176, 132 Stat. 1372 (2018). Both the state and federal versions of these laws have been criticized for mischaracterizing a complex FDA approval process, providing false hope for patients, and actually failing to expand patient access to therapies as intended. *See, e.g.*, James Hamblin, *The Disingenuousness of 'Right to Try'*, ATLANTIC (June 2, 2018), https://www.theatlantic.com/health/archive/2018/06/right-to-try/561770 (on file with the *Iowa Law Review*); Nicholas Florko, *A Year After Trump Touted 'Right to Try,' Patients Still Aren't Getting Treatment*, STAT (Jan. 29, 2019), https://www.statnews.com/2019/01/29/right-to-try-patients-still-arent-getting-treatment [https://perma.cc/ZD5G-L8JL]. The FDA reports on annual summaries it receives from manufacturers under the Right to Try Act. *See Right to Try Annual Reporting Summary*, FDA (June 6, 2024), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try-annual-reporting-summary [https://perma.cc/CM5H-UCWQ].

213. Per the CSA, marijuana is a Schedule I drug, meaning that there is a high likelihood of addiction, no safe dose, and no "currently accepted medical use[s]." 21 U.S.C. §§ 812(b)(1), (c)(c)(10).

214. Zettler, *supra* note 88, at 849, 877–81; Consolidated Appropriations Act, 2016, Pub. L. No. 114-113, § 542, 129 Stat. 2242, 2332–33 (2015); Memorandum from James M. Cole, Deputy Att'y Gen., U.S. Dep't of Just., to all U.S. Attorneys 1–3 (Aug. 29, 2013), https://www.dfi.wa.gov/documents/banks/cole-memo-08-29-13.pdf [https://perma.cc/UXT9-LEXH]. Notably, the Biden Administration directed the DEA and FDA to consider down-scheduling marijuana from Schedule I to Schedule II. *See Statement from President Biden on Marijuana Reform*, WHITE HOUSE (Oct. 6, 2022), https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/06/statement-from-president-biden-on-marijuana-reform [https://perma.cc/EW5L-6TWA]. On May 21, 2024, the government proposed such a rule. *See* Schedules of Controlled Substances: Rescheduling of Marijuana, 89 Fed. Reg. 44597 (May 21, 2024) (to be codified at 21 C.F.R. pt. 1308).

215. HUTT ET AL., *supra* note 37, at 845; Laetrile: Commissioner's Decision, 42 Fed. Reg. 39768, 39768–69 (Aug. 24, 1977). *See generally* United States v. Rutherford, 442 U.S. 544 (1979) (upholding the FDA's approach); LEWIS A. GROSSMAN, CHOOSE YOUR MEDICINE: FREEDOM OF THERAPEUTIC CHOICE IN AMERICA 149–61 (2021) (describing in depth the Laetrile controversy and litigation); *see also In re* Hofbauer, 393 N.E.2d 1009, 1014–15 (N.Y. 1979) (concluding that parents who (unsuccessfully) treated son's cancer with Laetrile instead of conventional treatments were not guilty of neglect because a physician recommended the treatment and it "ha[d] not been totally rejected by all responsible medical authority").

These efforts reflect a strategic choice by states to confront federal policy. States can also enact laws that confront a *lack* of federal policy. In 2004, California passed a "track and trace" law to address the distribution of counterfeit and substandard drugs.[216] At the time, federal law had not yet established such requirements, so the California law specified that it would "[u]pon the effective date of federal legislation or adoption of a federal regulation . . . become inoperative."[217] The California law is perhaps unusual in inviting preemption, but ultimately it succeeded in spurring Congress to act.[218]

Finally, federal law includes notes of grace toward states attempting to regulate medical products under federal jurisdiction. Both the Federal FDCA and the CSA state that they do not invalidate state laws "unless there is a direct and positive conflict between" federal and state law or when "there is a . . . positive conflict" that makes it "so that the two cannot consistently stand together."[219] Such language suggests that Congress did not intend to completely preclude state law from coexisting side-by-side with federal law.[220]

Of course, it is one thing for state law to stand together with federal law, but quite another for state law to supplant or undermine federal law. And it is this latter situation that confronts us in the current medication abortion litigation.

III. GRAVITATIONAL PULLS AFTER *DOBBS*

The federal-state tensions over medicine are evident in modern battles over medication abortion. But even before *Dobbs*, the gravitational pulls from both sides strengthened as abortion opponents and advocates dug in. After *Dobbs*, the tug-of-war has grown even more complex. In Part III, we evaluate these battles before and after *Dobbs*, drawing lessons that inform our recommendations in Part IV.

A. LEGALITY OF SELF-MANAGED ABORTION

Perhaps the most important gravitational pull away from states has been the steady rise of self-managed abortion, particularly in abortion-hostile states. Thus, it is worth considering the legality of self-managed abortion ("SMA"). The restrictions on medication abortion, like the restrictions on abortion more generally, do not apply in most states to the person who is pregnant. Texas, for example, enacted a near-total abortion ban that took effect after *Dobbs* but retained the provisions of the code that expressly exempted criminal liability for the "death of an unborn child" if the conduct charged was "committed by the mother of the unborn child."[221] This was also true before

216. S.B. 1307, 2003–2004 Leg., Reg. Sess. (Cal. 2004), *repealed by*, S.B. 600, 2013–2014 Leg., Reg. Sess. (Cal. 2014).

217. CAL. BUS. & PROF. CODE § 4034.1(a)(1) (repealed 2015).

218. Drug Quality and Security Act, Pub. L. No. 113-54, 127 Stat. 587, 599–640 (2013).

219. Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793; 21 U.S.C. § 903.

220. Noah, *supra* note 188, at 8–9.

221. TEX. PENAL CODE ANN. § 19.06(1) (West 2023) (providing exemptions from homicide charges); *id.* § 22.12 (providing an exemption from assault charges).

the post-*Dobbs* ban took effect; even though abortion was regulated in many other ways and banned in most circumstances after twenty weeks of gestation, none of the rules applied to an SMA.[222] This is true in most states, which do not have laws that prevent individuals from using medication for an SMA (though the laws may limit the legal ways to acquire the medication). Even Wyoming's strict ban on "chemical abortion" expressly exempts the pregnant woman from the prohibition.[223] Oklahoma has a law providing "No woman shall perform or induce an abortion upon herself, except under the supervision of a duly licensed physician," but the state's attorney general has opined that a woman who violates it cannot be criminally charged.[224] But Oklahoma is an outlier.

SMA is not new. The term is used to describe "any actions or activities undertaken to end a pregnancy outside of the formal healthcare system, with or without the involvement of a health care provider."[225] Prior to the development of medications like mifepristone designed for abortion, SMA involved "the use of herbs, botanicals, supplements, teas, self-harm, or obtaining a clandestine procedural abortion."[226] Providers of abortion advertised remedies for "female troubles."[227] The proverbial coat-hanger abortion was a form of SMA.[228] But today, the vast majority of abortions done outside of a doctor's office or clinic involve the use of abortion medications—either mifepristone and misoprostol, or misoprostol alone. Those procedures, referred to as self-managed medication abortions ("SMMA"), had become more common due

222. *See generally* TEX. HEALTH & SAFETY CODE ANN. (West 2024), which was superseded by the state's abortion ban in August 2022.

223. WYO. STAT. ANN. § 35-6-139(d) (2023) ("A woman upon whom a chemical abortion is performed or attempted shall not be criminally prosecuted . . . [under] this section.").

224. *See* OKLA. STAT. ANN. tit. 63, § 1-733 (West 2023); Op. Att'y Gen. Okla., No. 2023-12 (Nov. 21, 2023), https://oklahoma.gov/content/dam/ok/en/oag/opinions/ag-opinions/2023/ag_opinion_2023-12-2.pdf [https://perma.cc/QY65-QAR6]. Several states are currently considering bills that would open the door to prosecution of people who induce their own abortion. *See* Anna Claire Vollers, *GOP Lawmakers Push to Charge Women with Homicide for Seeking Abortions*, STATELINE (Mar. 6, 2025, 5:00 AM), https://stateline.org/2025/03/06/gop-lawmakers-push-to-charge-women-with-homicide-for-seeking-abortions [https://perma.cc/6NQX-AC4P].

225. Melissa Madera et al., *Experiences Seeking, Sourcing, and Using Abortion Pills at Home in the United States Through an Online Telemedicine Service*, QUALITATIVE RSCH. HEALTH 1 (Apr. 14, 2022), https://www.sciencedirect.com/science/article/pii/S2667321522000373?via%3Dihub [https://perma.cc/SY76-KLLU].

226. *Id.*

227. *See* Reva B. Siegel & Mary Ziegler, *Comstockery: How Government Censorship Gave Birth to the Law of Sexual and Reproductive Freedman, and May Again Threaten It*, 134 YALE L.J. 1068, 1092 (2025).

228. *See* Rebecca J. Rosen, *Consider the Coat Hanger*, ATLANTIC (Aug. 23, 2012), https://www.theatlantic.com/technology/archive/2012/08/consider-the-coat-hanger/261413 (on file with the *Iowa Law Review*). For a history of abortion, see generally LESLIE J. REAGAN, WHEN ABORTION WAS A CRIME: WOMEN, MEDICINE, AND LAW IN THE UNITED STATES, 1867–1973 (1997) (discussing the interplay of the medical profession, state authority, and women during a period when abortion was illegal).

to abortion restrictions and clinic access problems before *Dobbs* and have skyrocketed in its wake.[229]

Notwithstanding the fact that most self-managed abortions are legal in this country, there have been cases in which people have been charged for using medication to induce their own abortions. In most cases, these charges are specious, such as the homicide charge against Lizelle Herrera in Texas, a state where the criminal code expressly states that a person cannot be charged for the death of her own "unborn child."[230] She spent two nights in jail after her bond was set at $500,000, only to have the charges immediately dismissed.[231] But there are many cases like hers, including some that resulted in convictions and lengthy prison sentences. A study by If/When/How found sixty-one cases between the years 2000 and 2020 where people were criminally investigated or charged for an SMA.[232] In some cases, the charges stem from related conduct, such as the Nebraska teenager and her mother who were charged and pled guilty to "concealing human remains" after the mother helped the teen procure abortion pills to end a pregnancy at twenty-eight weeks of gestation.[233] Although prosecutors began investigating the case under the state's abortion laws, none of them would have applied to an SMA. But her mother's conduct was not part of the "self-management"; she pled guilty to violating the state's abortion laws and was sentenced to two years in prison.[234]

In a world in which doctors could face criminal or civil penalties for performing abortions but patients do not, medication abortion plays a much larger role in the landscape. This has created a demand for new ways of accessing abortion pills, which would previously have come almost exclusively

229. On the use of SMMA before *Dobbs*, see, for example, R.J. Gomperts, K. Jelinska, K. Gemzell-Danielsson & G. Kleiverda, *Using Telemedicine for Termination of Pregnancy with Mifepristone and Misoprostol in Settings Where There Is No Access to Safe Services*, 115 BJOG 1171, 1172–74 (2008); Aiken et al., *supra* note 81, at 158–62; Sarah E. Baum et al., *"It's Not a Seven-Headed Beast": Abortion Experience Among Women that Received Support from Helplines for Medication Abortion in Restrictive Settings*, 41 HEALTH CARE FOR WOMEN INT'L 1128, 1140–43 (2020).

230. *See* Caroline Kitchener, Beth Reinhard & Alice Crites, *A Call, a Text, an Apology: How an Abortion Arrest Shook Up a Texas Town*, WASH. POST (Apr. 13, 2022, 10:35 AM), https://www.washingtonpost.com/nation/2022/04/13/texas-abortion-arrest (on file with the *Iowa Law Review*).

231. *Id.*; *see also* Jolie McCullough, *After Pursuing an Indictment, Starr County District Attorney Drops Murder Charge Over Self-Induced Abortion*, TEX. TRIB. (Apr. 10, 2022), https://www.texastribune.org/2022/04/10/starr-county-murder-charge [https://perma.cc/T3UU-W3Z6].

232. Laura Huss, *Self-Managed Abortion Is Not Illegal in Most of the Country, but Criminalization Happens Anyway*, IF/WHEN/HOW (Aug. 9, 2022), https://ifwhenhow.org/news/self-managed-abortion-is-not-illegal-in-most-of-the-country-but-criminalization-happens-anyway [https://perma.cc/8V26-TKQB].

233. *See* Michael Levenson, *Nebraska Teen Who Used Pills to End Pregnancy Gets 90 Days in Jail*, N.Y. TIMES (July 20, 2023), https://www.nytimes.com/2023/07/20/us/celeste-burgess-abortion-pill-nebraska.html (on file with the *Iowa Law Review*).

234. *See* Jesus Jiménez, *Mother Who Gave Abortion Pills to Teen Daughter Gets 2 Years in Prison*, N.Y. TIMES (Sept. 22, 2023), https://www.nytimes.com/2023/09/22/us/jessica-burgess-abortion-pill-nebraska.html (on file with the *Iowa Law Review*).

from providers at clinics.[235] Before *Dobbs*, states could not ban previability abortions, and mifepristone is only approved for use before the end of the tenth week of gestation; thus, barring other obstacles like cost, distance, or personal mobility, any patient who wanted to undergo a medication abortion during the first ten weeks of pregnancy could do so at a doctor's office or clinic. But with the complicated landscape of bans and restrictions in place, there are many people who have no access to legal abortion through a provider, no matter how early in the pregnancy. For many of them, it is legal to ingest abortion pills if they can get their hands on them. This makes the questions about who has the authority to regulate the medication even more pressing.

B. State Deviations from Federal Approval for Mifepristone/Misoprostol

Given the steady rise in self-managed abortions, antiabortion states attempted to regulate medication abortion in a variety of different ways.

The first type of state restriction on medication abortion is contained in general abortion laws, including bans. The statutory definition of abortion will always include both surgical procedures and medication used to induce an abortion. The Georgia Code provides,

> A person commits the offense of criminal abortion when, in violation of Code Section 16-12-141, he or she administers any medicine, drugs, or other substance whatever to any woman or when he or she uses any instrument or other means whatever upon any woman with intent to produce a miscarriage or abortion.[236]

Thus, if abortion is disallowed in general, or after a certain point in pregnancy, or without satisfaction of prerequisites like a waiting period of ultrasound, those limitations apply with equal force to medication abortion.

The second type of state restriction is one that specifically targets medication abortion. For example, in 2021, Texas enacted a law providing that a physician cannot give an abortion-inducing drug to a patient "whose pregnancy is more than [forty-nine] days of gestational age," even though mifepristone is approved by the FDA for use until the seventieth day of gestation and available for off-label use even later in pregnancy.[237] Moreover, at the time, Texas permitted abortion until the twentieth week of gestation. Indiana passed a law to criminalize the use of medication abortion after the tenth week of pregnancy, which prevents off-label use past the gestational age for which mifepristone is federally approved.[238]

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235. *See, e.g.*, Sarah McCammon, *Threats to Abortion Access Drive Demand for Abortion Pills, Analysis Suggests*, NPR (Jan. 2, 2024, 11:02 AM), https://www.npr.org/2024/01/02/1220733428/medication-abortion-advance-provision [https://perma.cc/68QZ-4YLG].

236. GA. CODE ANN. § 16-12-140(a) (2024).

237. TEX. HEALTH & SAFETY CODE ANN. § 171.063(c)(6) (West 2024).

238. IND. CODE ANN. § 16-34-2-1(a)(1) (LexisNexis 2024) ("[A]n abortion inducing drug may not be dispensed, prescribed, administered, or otherwise given to a pregnant woman after eight

The third type of state restriction tries to narrow usage of abortion medication by restricting off-label use. Although Oklahoma considered passing a law in 2000 to ban the prescription and use of mifepristone altogether, it later did pass a narrower law to prohibit off-label use of the drug. A 2010 version of the law required physicians to be familiar with the FDA labeling and to inform patients if they were deviating from it.[239] But a 2011 amended version was more restrictive, prohibiting a physician from providing "any abortion-inducing drug" without following "the protocol tested and authorized" by the FDA.[240] (The Oklahoma law required both mifepristone and misoprostol to be used only on-label, although misoprostol is not approved by the FDA for abortions.[241]) The intended effect was to effectively ban non-surgical abortions in Oklahoma.[242]

A law to force doctors to follow FDA labeling may seem innocuous, but it has significant consequences in the context of medication abortion. Within a very short time after mifepristone was originally granted FDA approval, the vast majority of providers were following an evidence-based protocol that deviated in three ways from the original approval. This protocol called for a much lower dose of mifepristone than the one originally described in the approval; it allowed misoprostol to be self-administered by the patient outside of the physician's office; and it allowed the two-drug regimen to be prescribed to induce abortion until the sixty-third day of gestation instead of until the forty-ninth day. The typical "off-label" but "evidence-based" protocol was recommended by ACOG and based on evidence related to safety (e.g., fewer side effects) and effectiveness.[243] Oklahoma's functional ban on medication abortion was struck down by the Oklahoma Supreme Court in 2012—in a three-paragraph, per curiam opinion—as violating the constitutional right under *Roe* and the subsequent 1992 *Planned Parenthood v. Casey* decision to access abortion.[244]

In a separate opinion the following year, the Oklahoma Supreme Court found that the law indeed prohibited *all* off-label uses of abortion-inducing

(8) weeks of postfertilization age."). Eight weeks "post-fertilization" is equivalent to ten weeks gestational age, given the way pregnancy is dated by the FDA and in the medical profession. A near-total ban on abortion took effect in Indiana on August 1, 2023, thus mooting the specific impact of this law. North Dakota also restricts use of abortion medication to the period approved by the FDA. N.D. CENT. CODE § 14-02.1-03.5(2) (2024) (noting that prohibiting the dispensing "of the abortion-inducing drug satisfies the protocol tested and authorized by the federal food and drug administration and as outlined in the label for the abortion-inducing drug").

239. S.B. 1902, 52d Gen. Assemb., Reg. Sess. (Okla. 2010).

240. H.B. 1970, 53d Gen. Assemb., Reg. Sess. (Okla. 2011).

241. *See supra* text accompanying note 29.

242. Zettler, *supra* note 87, at 449 n.123.

243. Heather D. Boonstra, *Medication Abortion Restrictions Burden Women and Providers—and Threaten U.S. Trend Toward Very Early Abortion*, GUTTMACHER INST. (Mar. 19, 2013), https://www.guttmacher.org/gpr/2013/03/medication-abortion-restrictions-burden-women-and-providers-and-threaten-us-trend-toward [https://perma.cc/WXR9-STZT].

244. Okla. Coal. for Reprod. Just. v. Cline, 292 P.3d 27, 27–28 (Okla. 2012); Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 873 (1992).

drugs, including misoprostol as part of the two-drug regimen and methotrexate used to treat ectopic pregnancies. The court noted that FDA-approved labeling is not supposed to restrict how providers practice medicine, nor to preclude reliance on new evidence about side effects, alternative doses, or new uses.[245] And in other contexts, "the Oklahoma legislature has recognized the importance of allowing physicians to prescribe medications based on science and their medical judgment rather than dogmatic adherence to FDA labeling."[246] Yet the court critiqued "the manner in which [the state legislature] restricts the long-respected medical discretion of physicians in the specific context of abortion,"[247] an exceptionalism that has shaped many of the battles both pre- and post-*Dobbs*.

The Oklahoma Legislature amended the statute again in 2014, in an attempt to save it. The prohibition on off-label usage of mifepristone was slightly reworded but substantively the same as the prior version. This version provides that:

> No physician who provides an abortion-inducing drug, including the Mifeprex regimen, shall knowingly or recklessly fail to provide or prescribe the drug according to the protocol authorized by the U.S. Food and Drug Administration and as outlined in the FDA-approved label. In the specific case of the Mifeprex regimen, the Mifeprex label includes the FDA-approved dosage and administration instructions for both mifepristone (brand name Mifeprex) and misoprostol . . . .[248]

But the 2014 law included for the first time a set of legislative findings about the FDA's approval process for mifepristone and about the (supposed) risks of medication abortion relative to surgical abortion and the risks associated with other deviations from the FDA-approved usage.[249] Among other findings, the statute asserts that the "'[o]ff-label' or so-called 'evidence-based' use of abortion-inducing drugs may be deadly."[250] This version of the statute was also invalidated, however.[251] The 2014 version of the law required

245. Cline v. Okla. Coal. for Reprod. Just., 313 P.3d 253, 260–62 (Okla. 2013).

246. *Id.* at 261.

247. *Id.* at 262.

248. OKLA. STAT. tit. 63, § 1-729a(D) (2024).

249. H.B. 2684, 54th Gen. Assemb., Reg. Sess. (Okla. 2014). The law also clarified that it does not mean that misoprostol cannot be used in conjunction with mifepristone, as called for by the mifepristone label, or that methotrexate cannot be used to treat ectopic pregnancies. *Id.* § A(16). One of the findings related to eight deaths from bacterial infection following the use of mifepristone with an off-label protocol. The FDA investigated those cases and found no causal relationship between the drug and the infection, and a study in 2013 of more than 700,000 medication abortions found no deaths from infection. *See* Planned Parenthood Ariz., Inc. v. Humble, 753 F.3d 905, 908 (9th Cir. 2014); *see also* James Trussell, Deborah Nucatola, Mary Fjerstad & E. Steve Lichtenberg, *Reduction in Infection-Related Mortality Since Modifications in the Regimen of Medical Abortion*, 89 CONTRACEPTION 193, 195 (2014) (noting that a study involving more than 930,000 medical abortions found only three deaths from infection).

250. H.B. 2684, 54th Gen. Assemb., Reg. Sess. (Okla. 2014).

251. *See* Okla. Coal. for Reprod. Just. v. Cline, 441 P.3d 1145, 1147–48 (Okla. 2019).

providers to adhere to the original FDA labeling, but the FDA approved new labeling in 2016 that was in line with the changes providers had made on their own. The question for the Oklahoma Supreme Court this time was whether a state could constitutionally require abortion providers to adhere to an outdated drug label. It noted that requiring providers to forego a "superior protocol" in favor an outdated one would "necessarily now fall below the acceptable standard of care" and result in an undue burden on the right of abortion.[252] Per our argument in Part IV below, the Oklahoma law prioritized ideology over evidence-based practice.

Arizona passed a similar law in 2012. The Arizona law called for the director of the state's Department of Health Services to adopt rules that "shall require" that "any medication, drug or other substance used to induce an abortion is administered in compliance with the protocol that is authorized by the [FDA] and that is outlined in the final printing labeling instructions for that medication, drug or substance."[253] The statute and its implementing regulation, which took effect in 2014, were invalidated by the Ninth Circuit because they imposed an undue burden on the constitutional right to seek an abortion.[254] The court noted that the "evidence-based regimen" in use by most providers had a "clear advantage" over the FDA-approved regimen and that "the FDA not only expects off-label use but encourages it as part of the effective practice of medicine."[255] The court found no justification in the record for curtailing that in the context of medication abortion. However, the pre-*Dobbs* cases were not uniform: Other federal circuit courts upheld similar laws in Ohio (2012) and Texas (2014) and took a different view of the undue burden analysis.[256] In the Texas case, the court reasoned that the law requiring providers to dispense mifepristone only through the seventh week of gestation, as permitted by the original approval, did not impose an undue burden under *Roe*/*Casey* because, while it shortened the window for using this method of abortion, it did not entirely ban it.[257] Moreover, the court did not think the challengers established that there was a subset of women for whom surgical abortion was not an alternative.[258]

The fourth type of state restriction requires that abortion drugs be dispensed only by physicians, even though the FDA now permits them to be dispensed by certified pharmacies, including ones that operate online. The Arkansas Code, for example, provides: "When mifepristone or another drug or chemical regimen is used to induce an abortion, the initial administration

252. *Id.* at 1160–61.

253. ARIZ. REV. STAT. ANN. § 36-449.03(E)(6) (2016); *see also* ARIZ. ADMIN. CODE § R9-10-1509(G) (2024).

254. *Humble*, 753 F.3d at 918.

255. *Id.* at 914–15.

256. Planned Parenthood Sw. Ohio Region v. DeWine, 696 F.3d 490, 509 (6th Cir. 2012); Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott, 748 F.3d 583, 605 (5th Cir. 2014).

257. *Planned Parenthood of Greater Tex.*, 748 F.3d at 604.

258. *Id.*

of the drug or chemical shall occur in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug or chemical to the patient."[259]

North Dakota law makes it a crime for anyone who isn't a physician to provide abortion medication to any person.[260] A related type of restriction prohibits the use of telehealth, even if otherwise permissible in the state. Kentucky law, for example, provides that "[t]he use of telehealth . . . shall not be allowed in the performance of an abortion."[261] Texas law allows only physicians to dispense abortion drugs also but separately provides that abortion drugs can never be provided by mail or other delivery service.[262]

The fifth type of state restriction imposes special conditions on medication abortion, such as a physician examination of the patient. In Alabama, for example, only a physician can dispense abortion medication, but they "must first examine the pregnant woman in person and document, in the woman's medical chart, the gestational age and intrauterine location of the pregnancy prior to giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug."[263] The Idaho Code requires a physician who dispenses abortion medication to "make reasonable efforts to ensure that the patient returns for a follow-up visit so that a physician can confirm that the pregnancy has been terminated and assess the patient's medical condition."[264] In Texas, the physician must document all the same information and must "determine the pregnant woman's blood type, and for a woman who is Rh negative, offer to administer Rh immunoglobulin (RhoGAM) at the time the abortion-inducing drug is administered or used or the abortion is performed or induced to prevent Rh incompatibility, complications, or miscarriage in future pregnancies."[265]

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259. ARK. CODE ANN. § 20-16-603(b)(1) (2023).

260. N.D. CENT. CODE § 14-02.1-03.5(2) (2023); *see also* NEB. REV. STAT. § 28-335 (2016) ("The performing of an abortion by any person other than a licensed physician is a Class IV felony."); TENN. CODE ANN. §§ 63-6-1103, 1105 (2023) ("An abortion-inducing drug may be provided only by a qualified physician . . . ."); N.C. GEN. STAT. § 90-21.82 (1)(a) (2023) (same).

261. KY. REV. STAT. ANN. § 311.728 (LexisNexis 2019); *see also* ARIZ. REV. STAT. ANN. § 36-3604 (2023) (prohibiting telehealth for abortion); IND. CODE ANN. § 16-34-1-11 (LexisNexis 2023) ("Telehealth may not be used to provide any abortion . . . ."); W. VA. CODE ANN. § 30-14-12d(g)(5) (LexisNexis 2023) ("A physician or health care provider may not prescribe any drug with the intent of causing an abortion.").

262. TEX. HEALTH & SAFETY CODE ANN. § 171.063(a)–(b-1) (2023) ("A manufacturer, supplier, physician, or any other person may not provide to a patient any abortion-inducing drug by courier, delivery, or mail service.").

263. ALA. CODE § 26-23E-7 (LexisNexis 2016); *see also* WIS. STAT. ANN. § 253.105(2)(a) (West 2022) (requiring physical exam of patient before abortion medication can be dispensed by physician).

264. IDAHO CODE § 18-617(3) (2016); *see also* MO. ANN. STAT. § 188.021 (West 2024) (listing requirements for the administration of mifepristone).

265. TEX. HEALTH & SAFETY CODE ANN. § 171.063(c)(4). This requirement is not based on any medical recommendation. Rh factor testing is only recommended for abortions past the eighth week of gestation, and Texas law doesn't permit the use of medication abortion past the seventh week of gestation. *See, e.g.*, Ellen R. Wiebe, Mackenzie Campbell, Abigail R.A. Aiken &

Wyoming has taken the most aggressive position against medication abortion. In March 2023, the governor signed into a law a bill banning the use of medication abortion even in some situations where abortion is allowed under the state's near-total abortion ban.[266] This provision has been blocked in a lawsuit pending a full trial on the merits.[267] Republicans in the Iowa State Legislature introduced a bill in 2023 that "would make it illegal to 'manufacture, distribute, prescribe, dispense, sell or transfer' generic or brand-name mifepristone in the state, punishable by up to ten years in prison."[268] Although the bill has not been enacted, it is largely mooted by the Iowa Supreme Court's decision to allow a six week ban on all abortions to take effect.[269]

A sixth and final type of state restriction is a total ban on medication abortion. Very soon after the FDA approved mifepristone in 2000, scholars began contemplating whether states could ever ban a drug approved by the agency.[270] Although several states considered outright prohibitions, they settled for various restrictions on its use, which tended to rise and fall in the courts based not on preemption grounds but on whether they posed an undue burden on the constitutional right to abortion.[271] But in the wake of *Dobbs*, the preemption questions now take center stage as the Fourteenth Amendment no longer provides a basis for invalidating (or maybe even analyzing) these targeted restrictions on medication abortion.

Table 2

State Approaches to Federal Conditions of Approval for Mifepristone[272]

Arianne Albert, *Can We Safely Stop Testing for Rh Status and Immunizing Rh-Negative Women Having Early Abortions? A Comparison of Rh Alloimmunization in Canada and the Netherlands*, CONTRACEPTION, 2019, no. 1, at 1, 4, https://doi.org/10.1016/j.conx.2018.100001 [https://perma.cc/2UYP-UCNX] (concluding based on the available evidence that doctors "should stop testing Rh status and administering anti-D IgG to women having medication-induced or spontaneous abortions at early gestations").

266. WYO. STAT. ANN. § 35-6-139(a) (2023) ("[I]t shall be unlawful to prescribe, dispense, distribute, sell or use any drug for the purpose of procuring or performing an abortion on any person.").

267. *See* Mead Gruver, *Judge Blocks Wyoming's 1st-in-the-Nation Abortion Pill Ban While Court Decides Lawsuit*, AP (June 22, 2023, 1:02 AM), https://apnews.com/article/wyoming-abortion-pill-ban-lawsuit-429266bcea6bf5ded1b9c9892ee5578b [https://perma.cc/U7KC-CZDJ].

268. Julia Shapero, *Iowa Republicans File Legislation Making It a Felony to Manufacture, Prescribe Abortion Drug*, HILL (Jan. 31, 2023, 4:10 PM), https://thehill.com/policy/healthcare/3838126-iowa-republicans-file-legislation-making-it-a-felony-to-manufacture-prescribe-abortion-drug [https://perma.cc/3UPU-3JLU].

269. *See* Planned Parenthood of the Heartland, Inc. v. Reynolds *ex rel.* Iowa, 9 N.W.3d 37, 51–52 (Iowa 2024) (lifting temporary injunction and holding that abortion is not protected as a fundamental right under the Iowa Constitution).

270. *See, e.g.*, Lars Noah, *A Miscarriage in the Drug Approval Process? Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 600 (2001).

271. Noah, *supra* note 188, at 18–19, 18 n.69 (citing cases).

272. Data from the Guttmacher Institute. *Medication Abortion*, GUTTMACHER INST. (Oct. 31, 2023), https://www.guttmacher.org/state-policy/explore/medication-abortion [https://perma.cc/82L5-MF85].

<table>
<tr><th>States that allow use of mifepristone consistent with FDA approval*</th><th>States that deviate from conditions of FDA approval</th><th>States with near-total abortion bans</th></tr>
<tr><td rowspan="4">(18) California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, Virginia, Washington</td><td>Medication abortion must be provided by a physician rather than a pharmacy:[273] (16) Alaska, Arizona, Florida, Georgia, Indiana, Iowa,‡ Kansas, Michigan, Minnesota,† Nebraska, Nevada, North Carolina, Ohio, Pennsylvania, South Carolina, Utah</td><td rowspan="4">(14) Alabama, Arkansas, Idaho, Kentucky, Louisiana, Mississippi, Missouri, North Dakota, Oklahoma, South Dakota, Tennessee, Texas, West Virginia, Wyoming†</td></tr>
<tr><td>Patient may only access mifepristone after an in-person physician appointment (no use of telehealth):[274] (9) Arizona, Indiana, Iowa, Kansas,† Montana,† Nebraska, North Carolina, Ohio,† South Carolina</td></tr>
<tr><td>Patient must take first dose in presence of a physician:[275] (2) Indiana, Ohio†</td></tr>
<tr><td>Ban on mailing abortion pills:[276] (2) Arizona, Montana†</td></tr>
<tr><td colspan="3">* Includes terms of the NDA for Mifeprex, the ANDA for mifepristone, and the REMS for both.
† Not in effect; temporarily enjoined by court order.
‡ Not in effect; permanently enjoined by court order.</td></tr>
</table>

These state deviations from federal conditions of approval, again, require judicial resolution. Can states ban or otherwise impose additional restrictions on the use of drugs approved by federal regulators as safe and effective under specific conditions of use?

C. Access to Abortion Medication After Dobbs

In states where abortion is legal, providers and clinics continue to be the primary source of abortion medication, although the increasing availability of mail-order pills means that some patients even in those states will opt for self-

273. FDA has approved mifepristone for dispensing "by or under the supervision of a certified prescriber or by certified pharmacies for prescriptions issued by certified prescribers." *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra* note 37.

274. FDA does not require an in-person physician visit to prescribe mifepristone. *See id.*

275. FDA does not require patients to take the drug in the presence of a physician. *See id.*

276. FDA allows mifepristone to "be dispensed in-person or by mail." *See id.*

managed abortion rather than a physician-assisted process. Even before *Dobbs*, studies showed that people in states with little abortion access were more likely to order abortion medication than those in states where abortion care was more available in person. For example, an online telemedicine abortion service called Women on Web ("WoW") received over six thousand requests from U.S. residents for abortion medication during a ten-month period in 2017 and 2018, several years before *Roe* and *Casey* were overturned by the Supreme Court.[277] The highest rate of requests came from Mississippi, a state that has famously had only one abortion clinic for years.[278] More than three-quarters of the total requests came from states that are classified as hostile to abortion, even though previability abortion remained legal in every state until *Dobbs*.[279] Many women faced barriers to clinic access either because there were no clinics nearby or because their own personal circumstances made it impossible to access services at a clinic.[280] Cost was the most common barrier cited by survey respondents.[281] But even those who had clinic access and could afford it sometimes preferred self-managed abortion for privacy or other reasons.[282] Evidence shows that the number of daily requests for abortion medication from another organization, Aid Access, rose dramatically after *Dobbs*—from 82.6 per day to 213.7 per day after the ruling.[283] The largest increases were found in states that banned abortion. And even the initial number reflected a prior increase from when Texas managed to severely curtail abortion access through Senate Bill 8, a law that did not criminalize abortion but which provided a civil cause of action that allowed any person to sue to collect ten thousand dollars from any person who provided or facilitated the provision of an abortion after the sixth week of gestation.[284] A study showed that the

277. *See* Abigail R. A. Aiken et al., *Demand for Self-Managed Medication Abortion Through an Online Telemedicine Service in the United States*, 110 AM. J. PUB. HEALTH 90, 92 (2020); Roe v. Wade, 410 U.S. 113 (1972); Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833 (1992).

278. *Frontline: The Last Abortion Clinic* (PBS television broadcast Nov. 8, 2005) (exploring how antiabortion activists managed to drive all but one abortion clinic out of Mississippi even though abortion remained constitutionally protected).

279. Aiken et al., *supra* note 277, at 92.

280. *Id.* at 93 (finding that sixty percent of those who opted for self-managed abortion were influenced by a combination of barriers to clinic access and preferences for self-management).

281. *Id.* at 93, 95 (finding that seventy-one percent of respondents in hostile states were deterred by the cost of in-person care).

282. *Id.* (finding that forty-nine percent of people who opted for self-managed abortion cited privacy as the reason).

283. *See* 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 (2022).

284. S.B. 8, 87th Leg., Reg. Sess. (Tex. 2021) (codified at TEX. HEALTH & SAFETY CODE ANN. §§ 171.203(b), 171.204(a) (2024)). The Supreme Court permitted this law to take effect on September 1, 2021, nine months before its ruling in *Dobbs*. *See* Whole Woman's Health v. Jackson, 595 U.S. 30, 50–51 (2021).

demand for self-managed abortion through Aid Access rose dramatically in Texas after this law took effect on September 1, 2021.[285]

In abortion-hostile states, patients are resorting to new mechanisms for obtaining abortion pills. In the wake of *Dobbs*, abortion pills are more likely to come from distributors outside of the United States. A few states, including Texas and Arizona, have enacted bans on shipping abortion medication.[286] And in other states, the abortion bans may leave distributors open to civil or criminal liability depending on how broadly the law sweeps. But providers from other countries are less likely to be vulnerable to enforcement as long as they don't set foot in the relevant state or maintain any kind of corporate presence there.

This has put the spotlight on Aid Access, an online-only organization founded by Rebecca Gomperts, a Dutch physician. People in all states can order abortion medication from Aid Access, an online service that provides telemedicine appointments with physicians followed by the shipment of abortion medication. It is organized as a nonprofit and provides services on a sliding fee scale. It began in 2018 and received 57,506 requests during the first two years it operated.[287] Depending on the patient's home state, Aid Access can ship the pills directly to the patient or to a P.O. Box in an abortion-friendly state and rely on a mail-forwarding order to get the pills to the patient. Even though Aid Access operates as a telemedicine service and is a physician-led organization, its services are considered to be in the SMMA sphere because it operates from outside the United States and did not comply with the mifepristone REMS even when they required dispensation in person only from physicians.[288] As noted above, the FDA suspended the in-person provision of the REMS during COVID-19 and has since eliminated it, a change that will only increase the demand for services like Aid Access even further.

Although Aid Access is the predominant online provider of abortion medication, patients have other sources for learning about and procuring abortion medication. Plan C Pills is a website that provides information about the ways to access abortion pills from every state, along with a rating system of the legal risk involved with various options.[289] If a user indicates they live in Texas, for example, the website provides information on different options: telehealth services; community support networks where volunteers mail free

285. *See* 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*, JAMA NETWORK OPEN 1 (Feb. 25, 2022), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2789428 [https://perma.cc/G5QS-UU8S].

286. *See* TEX. HEALTH & SAFETY CODE ANN. § 171.063(b-1) ("A manufacturer, supplier, physician, or any other person may not provide to a patient any abortion-inducing drug by courier, delivery, or mail service."); ARIZ. REV. STAT. ANN. § 36-2160(B) (2023) ("A manufacturer, supplier or physician or any other person is prohibited from providing an abortion-inducing drug via courier, delivery or mail service.").

287. *See* Madera et al., *supra* note 225, at 2.

288. *Id.*

289. *See* PLAN C, https://www.plancpills.org [https://perma.cc/3PMJ-5DGE].

generic pills; and websites that sell pills.[290] An older version of the webpage also suggested traveling to another state or country to obtain abortion pills. Another website, ineedana.com (short for "I need an abortion"), is a comprehensive resource that provides users with information about how to order pills online but also how to find in-person appointments at the closest clinics in another state (if abortion is banned in the user's state).[291] This site launched in 2016 and has been called the "Quintessential Post-Roe Resource."[292] To take that same hypothetical user in Dallas, Texas, this website would state that the closest clinic providing abortions is in Wichita, Kansas, 334 miles away, and that pills can be ordered from Aid Access and sent through a provider in a state with a "shield law" that protects the provider from criminal prosecution in a ban state.[293]

In order to further facilitate access to abortion medication and to prevent delays in obtaining it when needed, Aid Access fulfills "advance provision" orders, where a customer who is not currently pregnant orders abortion pills to have on hand in case they are needed in the future.[294] Like SMMA generally, advance provision is likely to play an increasingly significant role in abortion accessibility.

Thus, as the center of gravity shifted from surgical to medication abortion, and as antiabortion states consequently targeted medication abortion, abortion advocates naturally responded state restrictions. But abortion opponents did not stop at the states.

D. OTHER CHALLENGES TO MIFEPRISTONE ACCESS

In addition to the state laws discussed above, access to mifepristone was threatened by a legal challenge to the FDA's oversight of the drug. In *Alliance for Hippocratic Medicine v. U.S. Food and Drug Administration*, plaintiffs argued that the FDA should never have approved mifepristone in 2000 nor relaxed the REMS beginning in 2016.[295] The case was filed in federal district court in Amarillo, Texas, where only one judge sits. That judge, Matthew Kacsmaryk, is vehemently antiabortion and has issued other provocative

290. *See Where People Get Abortion Pills Online in Texas*, PLAN C, https://www.plancpills.org/abortion-pill/texas [https://perma.cc/MF2H-CUB5].

291. *See* INEEDANA.COM, https://www.ineedana.com [https://perma.cc/T8R7-M9H3].

292. *Id.*; *see also* Amy Littlefield, *The Anti-Abortion Movement Gets a Dose of Post-*Roe *Reality*, NATION (June 28, 2023), https://www.thenation.com/article/politics/anti-abortion-activists-dobbs (on file with the *Iowa Law Review*) (discussing how the number of abortions has not decreased significantly post-*Dobbs* and noting the continuing efforts by abortion rights groups).

293. *See* INEEDANA.COM, *supra* note 291.

294. *See* Abigail R. A. Aiken et al., *Advance Provision of Mifepristone and Misoprostol via Online Telemedicine in the U.S.*, 184 JAMA: INTERNAL MED. 220, 221 (2024); Katherine Ehrenreich, M. Antonia Biggs & Daniel Grossman, *Making the Case for Advance Provision of Mifepristone and Misoprostol for Abortion in the United States*, 48 BMJ SEXUAL & REPROD. HEALTH 238, 238 (2022); Anna E. Fiastro et al., *Advance Provision of Medication for Induced Abortion: A Qualitative Study of Patient Perspectives*, 123 CONTRACEPTION, July 2023, at 1, 2.

295. All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507, 521–22 (N.D. Tex. 2023).

rulings.[296] Judge Kacsmaryk, for example, invalidated the age nondiscrimination provision of Title X, a federal family planning law that first took effect in 1970.[297] As a result, minors in Texas lost their only access to birth control without parental consent, as Texas is one of just four states that does not permit minors under any circumstances to consent to medical care on their own, including to obtain access to prescription contraceptive drugs or devices.[298]

Had this challenge to the FDA's approval of mifepristone landed before almost any other judge, it would likely have gone nowhere. But Judge Kacsmaryk issued a preliminary injunction to "delay" the FDA's approval of the drug, which had been on the market at that point for twenty-three years. He issued a sixty-seven-page opinion that reads more like an antiabortion manifesto than a judicial opinion.[299] For example, he describes the FDA approval of Mifepristone like this:

> Mifepristone . . . is a synthetic steroid that blocks the hormone progesterone, halts nutrition, and ultimately starves the unborn human until death. Because mifepristone alone will not always complete the abortion, [the] FDA mandates a two-step drug regimen: mifepristone to kill the unborn human, followed by misoprostol to induce cramping and contractions to expel the unborn human from the mother's womb.[300]

The inflammatory rhetoric highlighted one judge's effort to undermine the availability of mifepristone across the country. Moreover, the holding required numerous overreaches of precedent and logic.

Judge Kacsmaryk first concluded that the plaintiffs had organizational standing to bring suit on behalf of its physician members who "allege adverse events from chemical abortion drugs can overwhelm the medical system and place 'enormous pressure and stress' on doctors during emergencies and

296. The media coverage of Judge Kacsmaryk's ruling is telling. *See, e.g.*, Lindsay Whitehurst & Alanna Durkin Richer, *Abortion Pill Order Latest Contentious Ruling by Texas Judge*, AP (Apr. 8, 2023, 9:07 AM), https://apnews.com/article/texas-judge-matthew-kacsmaryk-abortion-pill-fda-75964b777ef09593a1ad948c6cfc0237 [https://perma.cc/CA32-4ZUD]; *'Unborn Human': The Anti-Abortion Rhetoric of Texas Judge's Ruling*, GUARDIAN (Apr. 8, 2023, 10:42 AM), https://www.theguardian.com/world/2023/apr/08/texas-judge-kacsmaryk-abortion-pills-ruling-anti-abortion-rhetoric [https://perma.cc/RVV4-7SVQ]. It was also discovered that during his judicial confirmation process, he had removed his name from a co-authored law review article that criticized laws protecting transgender people and abortion seekers. *See* Caroline Kitchener, Robert Barnes & Ann E. Marimow, *The Controversial Article Matthew Kacsmaryk Did Not Disclose to the Senate*, WASH. POST (Apr. 15, 2023, 6:45 PM), https://www.washingtonpost.com/politics/2023/04/15/matthew-kacsmaryk-law-review (on file with the *Iowa Law Review*).

297. Deanda v. Becerra, 645 F. Supp. 3d 600, 628–29 (N.D. Tex. 2022).

298. *See* Eleanor Klibanoff, *Federal Court Ruling May Prevent Texas Teens from Getting Birth Control Without Parental Permission*, TEX. TRIB. (Dec. 22, 2022), https://www.texastribune.org/2022/12/21/texas-title-x-teens-birth-control [https://perma.cc/85DU-ZA9Y].

299. At one point, he cites *Sesame Street* to assert without support that pregnancy is not an "illness." *All. for Hippocratic Med.*, 668 F. Supp. 3d at 545.

300. *Id.* at 520–21 (citations omitted).

complications"[301] and who object to the possibility that they would be "forced to end the life of a human being in the womb for no medical reason, including by having to complete an incomplete elective chemical abortion."[302] Second, he concluded that plaintiffs' challenge to the FDA's actions were reviewable, despite the passage of twenty-three years since the initial approval and as many as seven years since the first modification to the REMS. According to the opinion, the FDA "reopened" its approval when it modified the REMS in 2016 and 2021, which triggered the beginning of a new six-year statute of limitations.[303] Alternatively, Judge Kacsmaryk concluded that plaintiffs' claims were not time-barred because of equitable tolling, which it deemed applicable "because of FDA's unreasonable delay in responding to" earlier administrative challenges to the drug's approval.[304] Third, Judge Kacsmaryk concluded that the plaintiffs were entitled to have their claims reviewed, despite their failure to exhaust administrative remedies.[305]

These various overreaches were necessary just to reach the question whether plaintiffs were entitled to a preliminary injunction based on the merits of the underlying claim. Judge Kacsmaryk concluded that the plaintiffs had a strong likelihood of success on the merits. With respect to the FDA's decision in 2021 to eliminate the in-person dispensing requirement (initially done due to the Covid-19 pandemic and made permanent two years later), Judge Kacsmaryk found a likelihood that plaintiffs would succeed in proving that it violates the federal Comstock Act to dispense abortion medication through the U.S. mail.[306] The Comstock Act is an obscenity law passed in 1873 that included a prohibition on sending "any article or thing designed or intended for the prevention of conception or producing of abortion" through the mail.[307] The language related to contraception was repealed in 1971, but the abortion provision remains on the books.[308] Between 1973 and 2022, this provision was a dead letter since the constitutional right of abortion recognized in *Roe v. Wade* clearly trumped any purported statutory prohibition on abortion. But after *Dobbs*, antiabortion advocates have sought opportunities to assert that it has sprung

301. *Id.* at 523–24.

302. *Id.* at 524.

303. *Id.* at 533.

304. *Id.* at 534.

305. *Id.* at 536.

306. *Id.* at 539–43.

307. Act of Mar. 3, 1873, ch. 258, sec. 2, § 148, 17 Stat. 598 (codified as amended at 18 U.S.C. §§ 1461–62). *See generally* AMY WERBEL, LUST ON TRIAL: CENSORSHIP AND THE RISE OF AMERICAN OBSCENITY IN THE AGE OF ANTHONY COMSTOCK (2018) (discussing the history and effects of the Comstock censorship campaign).

308. The Comstock Act as amended is codified at 18 U.S.C. §§ 1461–1462; *see also* Act of Jan. 8, 1971, Pub. L. No. 91-662, 84 Stat. 1973 (amending 18 U.S.C §§ 1461–1462 to exclude contraceptive articles).

back to life and, indeed, should operate as a de facto national ban on abortion.[309] Judge Kacsmaryk was a receptive audience for this argument.

The court also found that they were likely to succeed in proving that the FDA's original approval violated Subpart H of federal regulations that allow accelerated approval of new drugs that treat "serious or life-threatening illnesses" and that "provide a meaningful therapeutic benefit to patients over existing treatments."[310] In Judge Kacsmaryk's view, the FDA was wrong on both prongs because "[p]regnancy is not an 'illness'" and abortion medications do not provide a benefit over surgical abortion.[311] The court also concluded that the plaintiffs were likely to succeed in proving that both the original approval and the 2016 REMS modifications were arbitrary and capricious.[312]

Likelihood of success on the merits is only one prong of the test for a preliminary injunction, but the court concluded that the other three were met as well. The court found there to be a substantial threat of irreparable harm, citing the death of two women in the United States as a result of their use of mifepristone, the "physical and emotional trauma" inflicted by medication abortion on patients, and the "energy and resources" expended by doctors who have to treat patients who seek emergency care after undergoing a medication abortion. A preliminary injunction would serve the public interest, according to the court, because there is a public interest in preventing unsafe drugs from entering the market, ensuring public officials follow the law, and allowing states to regulate medication abortion in order to protect "life, health, and liberty."[313]

This ruling went to the U.S. Supreme Court the first time when the FDA sought emergency relief from the lower court rulings (and the Fifth Circuit's refusal to stay the district court's order pending a final determination on the merits). In that round of review, the Supreme Court declined to reach any questions on the merits but did issue an administrative stay of the ruling pending final resolution of the case.[314] On remand from that trip to the Supreme Court, the Fifth Circuit upheld the district court's injunction in part and vacated it in part.[315] The court of appeals held that the challengers were likely barred by the statute of limitations with respect to the original approval in 2000 and that they do not have standing to challenge the approval of the generic version of the drug because they made no showing that it contributes to the risk of harm.[316] Those portions of the injunction were thus

309. For more on the advocacy efforts and the underlying legal issues, see Mary Ziegler, *Harsh Anti-Abortion Laws Are Not Empty Threats*, ATLANTIC (Nov. 10, 2023), https://www.theatlantic.com/ideas/archive/2023/11/harsh-anti-abortion-laws-are-not-empty-threats/675928 (on file with the *Iowa Law Review*); Siegel & Ziegler, *supra* note 227, at 1140.

310. *All. for Hippocratic Med.*, 668 F. Supp. 3d at 543 (quoting 21 C.F.R. § 314.500 (1999)).

311. *Id.* at 544, 546–47.

312. *Id.* at 549–56.

313. *Id.* at 557–58.

314. Danco Lab'ys, LLC v. All. for Hippocratic Med., 143 S. Ct. 1075, 1075 (2023).

315. All. for Hippocratic Med. v. FDA, 78 F.4th 210, 222 (5th Cir. 2023), *rev'd*, 602 U.S. 367 (2024).

316. *Id.* at 241, 245.

vacated. But the court concluded that the plaintiffs were likely to prevail in showing that the modifications of the REMS from 2016 and on were arbitrary and capricious.[317] It thus upheld the injunction as to those changes.

The Supreme Court agreed to review the case but only to consider the FDA's actions beginning in 2016, leaving the original approval in place. For a unanimous Court, Justice Kavanaugh wrote the opinion, which rejected the challenge to Mifepristone regulation on standing grounds.[318] Article III of the Constitution grants jurisdiction to federal courts to consider "cases" and "controversies"; from this language, the Court has developed its standing doctrine.[319] The Court reiterated and applied the three-part test for standing: "[A] plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief."[320] The Court also elaborated on aspects of this test in ways that exposed how much of a stretch it was for the lower courts to conclude the standing requirement had been met. For example, it explained that the injury in fact must be "concrete," "real and not abstract," and more than "a general legal, moral, ideological, or policy objection to a particular government action."[321] Federal courts, moreover, are not a "vehicle for the vindication of the value interests of concerned bystanders."[322] The causation requirement is also an obstacle in a case like this, as "it is ordinarily substantially more difficult to establish" standing in a challenge to "the government's 'unlawful regulation (or lack of regulation) of *someone else*.'"[323] The challengers cannot speculate about a chain of events that might lead to an impact on them personally; rather, "the plaintiff must show that the 'third parties will likely react in predictable ways' that in turn will likely injure the plaintiffs."[324]

The Court ultimately concluded that the plaintiff doctors and medical associations did not make out the required showings to establish standing. They "are unregulated parties who seek to challenge FDA's regulation of *others*," as none of them "prescribe or use mifepristone."[325] The "FDA has not required the plaintiffs to do anything or to refrain from doing anything," and the plaintiffs had alleged no monetary, property, or physical injuries from the FDA's action.[326] In the Court's words, the challengers "are pro-life, oppose

317. *Id.* at 253.

318. FDA v. All. for Hippocratic Med., 602 U.S. 367, 374 (2024). Justice Thomas wrote separately to argue that in a case where the issue is squarely presented, the Court should overrule its associational-standing doctrine entirely. *Id.* at 405 (Thomas, J., concurring).

319. *Id.* at 378–79 (majority opinion).

320. *Id.* at 380.

321. *Id.* at 381.

322. *Id.* at 382 (quoting Allen v. Wright, 468 U.S. 737, 756 (1984)).

323. *Id.* (quoting Lujan v. Defs. of Wildlife, 504 U.S. 555, 562 (1992)).

324. *Id.* at 383 (quoting California v. Texas, 593 U.S. 659, 675 (2021)).

325. *Id.* at 385.

326. *Id.* at 385–86.

elective abortion, and ha[d] sincere legal, moral, ideological, and policy objections to mifepristone being prescribed and used *by others*."[327] In order to establish standing to vindicate their objections, they would have to establish some connection between the FDA's actions and their alleged injuries in fact.

The Court rejected all the purported theories. First, it concluded that there was insufficient proof that the FDA's changes to the REMS causes conscience injuries to doctors. They had argued that the relaxation of the REMS would lead more patients to suffer complications of mifepristone and to seek emergency intervention from doctors, which would increase the chance that an antiabortion challenger would be forced "to render emergency treatment completing the abortions or providing other abortion-related treatment."[328] While a conscience injury can qualify as a concrete injury in fact, the plaintiff doctors failed to show "that they could be forced to participate in an abortion or provide abortion-related medical treatment over their conscience objections."[329] Federal law protects the right of health care providers to refuse to participate in abortion care without penalty from their employers; many states provide similar protections.[330] The plaintiff doctors provided no examples of a situation in which the FDA's regulation of mifepristone could lead to the alleged conscience injury.

Second, the challengers claimed to have standing based on monetary and other resource-based injuries they will suffer because of the FDA's modification of the REMS, namely "diverting resources and time from other patients to treat patients with mifepristone complications; increasing risk of liability suits from treating those patients; and potentially increasing insurance costs."[331] The Court rejected this claim as well for a lack of causation. It was "highly speculative" to suggest that the modification of REMS would have a meaningful impact on the number of patients seeking emergency care and that the increase would force the diversion of time and resources from other patients.[332] The plaintiffs offered no concrete evidence that this had happened in the past nor gave any "reason to believe that the future w[ould] be different."[333] The Court also pointed out the limitlessness of the plaintiffs' argument—all medical care diverts resources from other patients. Could, the Court hypothesized, a pediatrician have standing to challenge a school district's decision to start a middle school football team given that she might have to divert resources toward concussion care? Obviously, the answer is no. If the plaintiffs had standing in this case and on this theory, "there would be no principled way to cabin such a sweeping doctrinal change to doctors or other healthcare providers."[334]

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327. *Id.* at 386.
328. *Id.* at 386–87.
329. *Id.* at 387.
330. *Id.* (citing and describing the so-called Church Amendments, 42 U.S.C. § 300a-7).
331. *Id.* at 390.
332. *Id.* at 390–91.
333. *Id.* at 391.
334. *Id.* at 392.

Third, the Court rejected the only remaining theory of standing—that the plaintiff organizations are stymied in trying to achieve their antiabortion mission by the FDA's action. The medical associations argued that the FDA's actions have forced them to spend time and money opposing them, which detracts from their mission-driven activities. The Court did not buy this theory, explaining that "an organization that has not suffered a concrete injury caused by a defendant's action cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action. An organization cannot manufacture its own standing in that way."[335] The Court also rejected the argument that the plaintiffs must be granted standing because otherwise it might be the case that no one has standing to challenge the FDA's actions.[336]

The Court in this case was clear in its rejection of standing for these plaintiffs. It acknowledged that they "have sincere legal, moral, ideological, and policy objections to elective abortion and to FDA's relaxed regulation of mifepristone," but denied them the opportunity to assert them in federal court.[337] It is the "wrong forum"; they should direct their objections instead "to the President and FDA in the regulatory process, or to Congress and the President in the legislative process. And they may also express their views about abortion and mifepristone to fellow citizens, including in the political and electoral processes."[338]

Despite the rejection of this particular lawsuit, the opinion in this case provides a blueprint for future plaintiffs who might be able to make the kind of showing of injury in fact that the Court requires. It is unlikely that this is the last we will see of challenges to the FDA's approval of mifepristone. Moreover, this case highlights the indirect challenges to evidence-based medicine and scientific expertise that underlie the antiabortion positions urged (and accepted) in this and similar cases. Both the district court and Fifth Circuit rulings, for example, accept without question the allegation by the plaintiffs that medication abortions are unsafe, which is what ostensibly leads to doctors who are not abortion providers being put in the position of tending in emergency rooms to the complications experienced by abortion patients.[339]

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335. *Id.* at 394.

336. *Id.* at 396.

337. *Id.* at 396–97.

338. *Id.*

339. All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507, 523–24 (N.D. Tex. 2023) (concluding that the plaintiffs have standing "because they allege adverse events from chemical abortion drugs can overwhelm the medical system and place 'enormous pressure and stress' on doctors during emergencies and complications"); All. for Hippocratic Med. v. FDA, 78 F.4th 210, 229–32 (5th Cir. 2023) (concluding based on anecdotal evidence that plaintiff-physicians are likely to encounter patient with complications from medication abortion). For a detailed analysis of how "facts" were used and misused in these two lower court opinions, see Rachel Rebouché, *Facts on Trial:* Alliance for Hippocratic Medicine v. FDA *and the Battle over Mailed Medication Abortion*, 95 U. COLO. L. REV. 413, 421–42 (2024); and see also Michelle S. Simon, *The Federal Future of Medication Abortion*, 57 IND. L. REV. 613, 638–47 (2024) (evaluating the arguments raised in the lower courts).

Yet, as discussed in more detail above, medication abortion has been proven safe by "[m]ore than [one hundred] scientific studies, spanning continents and decades."[340] Abortion medication cause fewer complications than Tylenol or Viagra, yet there have been no challenges to the FDA approval of those drugs.[341] While some patients who take abortion medications seek emergency care for complications, it is a small percentage of patients, and most of the complications are minor.[342] The risk of death from abortion, including medication abortion, is vanishingly small (.001%),[343] while death from pregnancy- and childbirth-related causes is high and increasing in some states (.03%).[344] And nowhere do any of the opinions in this case acknowledge that safety is a relative concept. Judge Kacsmaryk mentions one patient who allegedly died from a medication abortion but of course not the twelve hundred or more who die every year in the United States from pregnancy-related causes, nor the five hundred who die each year from Tylenol overdoses.[345] Nor does he compare the safety profile of medication abortion to surgical abortion, which is obviously relevant given that the inaccessibility of one method will increase the use of the other.

The district court ruling also assumes that patients who undergo abortions routinely suffer adverse mental health consequences;[346] the evidence, however,

340. Amy Schoenfeld Walker, Jonathan Corum, Malika Khurana & Ashley Wu, *Are Abortion Pills Safe? Here's the Evidence.*, N.Y. TIMES (Mar. 25, 2024), https://www.nytimes.com/interactive/2023/04/01/health/abortion-pill-safety.html (on file with the *Iowa Law Review*).

341. *Id.*

342. *See, e.g.*, Ushma D. Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 OBSTETRICS & GYNECOLOGY 175, 181–82 (2015) (reviewing 2009 to 2010 Medicaid data in California and finding major complications in only .23% of medication abortions and "minor and expected" complications in about 5%).

343. *See, e.g.*, Creinin et al., *supra* note 58; Raymond et al., *supra* note 39, at 28.

344. *See* Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, NAT'L CTR. FOR HEALTH STAT., CDC (Mar. 16, 2023), https://www.cdc.gov/nchs/data/hestat/maternal-mortality/2021/maternal-mortality-rates-2021.htm [https://perma.cc/6HXH-72VD]; *see also* Laura G. Fleszar et al., *Trends in State-Level Maternal Mortality by Racial and Ethnic Group in the United States*, 330 JAMA 52, 53 (2023) (finding that the U.S. has a higher maternal mortality rate than other high-income countries and that it is increasing).

345. All. for Hippocratic Med. v. FDA, 668 F. Supp. 3d 507, 553–56 (N.D. Tex. 2023), *vacated and remanded*, 117 F.4th 336 (5th Cir. 2024) (per curiam); *see also* Suneil Agrawal, *Acetaminophen Toxicity*, STATPEARLS, https://www.statpearls.com/nursepractitioner/ce/activity/93286/?specialty=APRN-Advanced%20Pharmacology [https://perma.cc/TF8Z-WCD3]. More than half of the Tylenol overdoses appear to be accidental. *See* Jeff Gerth & T. Christian Miller, *Use Only as Directed*, PROPUBLICA (Sept. 20, 2013, 10:00 AM), https://www.propublica.org/article/tylenol-mcneil-fda-use-only-as-directed [https://perma.cc/Z5E8-HVFM].

346. *All. for Hippocratic Med.*, 668 F. Supp. 3d at 526 ("Women who have aborted a child — especially through chemical abortion drugs that necessitate the woman seeing her aborted child once it passes — often experience shame, regret, anxiety, depression, drug abuse, and suicidal thoughts because of the abortion."); *id.* at 537 ("Many women also experience intense psychological trauma and post-traumatic stress from excessive bleeding and from seeing the remains of their aborted children.").

is to the contrary.[347] The largest longitudinal study of women's experiences with abortion and unwanted pregnancy found that women who have abortions are *not* more likely than those denied to have depression, anxiety, or suicidal ideation, and that ninety-five percent of women report five years later that having an abortion was the right decision.[348] On the other hand, women who are denied abortions are more likely to suffer anxiety and loss of self-esteem in the short term.[349] But rather than cite this study, Judge Kacsmaryk relies on scientifically false and pseudoscientific "studies" such as one that is based solely on anonymous posts on an antiabortion website called "Abortion Changes You."[350] And the studies he cites that were published in peer-reviewed journals were recently all retracted because they were deemed scientifically unsound.[351] He also eschews medically or legally accepted terminology throughout the entire opinion, substituting "abortionist" for "doctor" or "healthcare provider"; "chemical abortion" for "medication abortion"; "unborn human" or "unborn children" for "embryo" or "fetus"; and "kill" for "abort" or "terminate."[352] Even his description of the drug at the center of the case is described in ideological rather than medical terms: "Mifepristone . . . is a synthetic steroid that blocks the hormone progesterone, halts nutrition, and ultimately starves the unborn human until death."[353]

The opinion and its linguistic choices only reinforce the notion that the allocation of authority over medicine has potentially grave implications for the way health care is delivered and whether it is evidence-based. As a group of amici, including ACOG, wrote in a brief submitted to the district court that those challenging the FDA approval of mifepristone "have taken a position that is fundamentally ideological, not scientific" while leading medical societies "seek to center this dispute where it belongs—on the scientific evidence developed over more than two decades of study."[354]

This case reveals important aspects of the battle for control over medication abortion, bringing the conflict between politics and science into sharper relief. Although the Supreme Court did not reach the merits of the case, many

347. *See, e.g.*, M.A. Biggs, Ushma D. Upadhyay, Julia R. Steinberg & Diana G. Foster, *Does Abortion Reduce Self-Esteem and Life Satisfaction?*, 23 QUALITY LIFE RSCH. 2505, 2505–06 (2014); Corinne H. Rocca, Katrina Kimport, Heather Gould & Diana G. Foster, *Women's Emotions One Week After Receiving or Being Denied an Abortion in the United States*, 45 PERSPS. ON SEXUAL & REPROD. HEALTH 122, 122–23 (2013).

348. *See* DIANA GREENE FOSTER, THE TURNAWAY STUDY: TEN YEARS, A THOUSAND WOMEN, AND THE CONSEQUENCES OF HAVING—OR BEING DENIED—AN ABORTION 107–24 (2020).

349. *Id.*

350. *All. for Hippocratic Med.*, 668 F. Supp. 3d at 547 n.40.

351. *See* Brendan Pierson, *U.S. Publisher Retracts Studies Cited by Texas Judge in Suspending Abortion Pill's Approval*, REUTERS (Feb. 6, 2024, 4:54 PM), https://www.reuters.com/world/us/us-publisher-retracts-studies-cited-by-texas-judge-suspending-abortion-pills-2024-02-06 [https://perma.cc/89DV-2DW2].

352. *See generally All. for Hippocratic Med.*, 668 F. Supp. 3d 507.

353. *Id.* at 520.

354. Brief of Amici Curiae Med. & Pub. Health Soc'ys in Opposition to Plaintiffs' Motion for a Preliminary Injunction at 3, *All. for Hippocratic Med.*, 668 F. Supp. 3d 507 (No. 22-cv-00223).

read the majority opinion as signaling to potential plaintiffs how they might reframe a future challenge. Thus, the questions about who should regulate abortion—and medicine more generally—could not be more pressing.

E. PREEMPTION LITIGATION

The most obvious place where the gravity between federal and state oversight can shift is in preemption litigation. There, courts are prompted to consider areas of concurrent jurisdiction like abortion, where both federal and state authorities have plausible claims to oversight. Thus, for example, when West Virginia prohibited mifepristone from being prescribed via telemedicine,[355] it came into conflict with the FDA's 2023 REMS update allowing such access. A federal district court found the state law preempted because it was impossible to comply with both the federal REMS and the West Virginia law, and because "Congress ha[d] allocated to the FDA" the "manner in which mifepristone may be prescribed."[356] The court found that West Virginia had encroached on the domain of decisions given to FDA by Congress.[357] Likewise, North Carolina law allows only physicians to prescribe abortion medications after an in-person examination, with in-person dispensing and a mandatory follow-up visit seven to fourteen days after administering the drug.[358] But a federal district court found most of these requirements preempted because "the FDA explicitly considered and rejected [those] restriction[s] as unnecessary for safe use."[359] Other requirements, such as an advanced in-person consultation and an ultrasound, were not preempted, according to the court, because they remained the province of states as dual sovereigns.[360] As Professor Catherine M. Sharkey and Daniel Kenny note, determining which prescribing restrictions sit in the FDA's domain or states' domains can be thorny.[361]

In many cases, the argument for preemption is strong not only because the FDA's new drug approval ("NDA") process subjects drugs like mifepristone to an individualized and comprehensive risk-benefit assessment, but also because of the sustained attention mifepristone has received for the last two decades.[362]

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355. W. VA. CODE ANN. §§ 30-3-13a(g)(5), 30-1-26(b)(9) (LexisNexis 2023).

356. GenBioPro, Inc. v. Sorsaia, No. 23-0058, 2023 WL 5490179, at *11 (S.D.W. Va. Aug. 24, 2023).

357. *Id.*

358. N.C. GEN. STAT. § 90-21.83B (2024).

359. Bryant v. Stein, No. 23-cv-77, 2024 WL 1886907, at *15 (M.D.N.C. Apr. 30, 2024).

360. *See id.* at *14.

361. Catherine M. Sharkey & Daniel J. Kenny, *FDA Leads, States Must Follow*, 102 WASH. U. L. REV. 155, 213–14 (2024). They offer an "agency reference model" by which courts can evaluate whether and how closely the FDA has examined an issue to determine whether any given state approach conflicts with, interferes with, or complements the federal approach. *Id.* at 197.

362. On the preemption argument, see generally Patricia J. Zettler & Ameet Sarpatwari, *State Restrictions on Mifepristone Access — The Case for Federal Preemption*, 386 NEW ENG. J. MED. 705 (2022) ("A strong argument exists that state laws restricting mifepristone access — an important weapon in this fight — are preempted and should be challenged in court."); Patricia J. Zettler, Annamarie Beckmeyer, Beatrice L. Brown & Ameet Sarpatwari, *Mifepristone, Preemption, and*

As others have noted, mifepristone is one of the most heavily scrutinized drugs on the U.S. market today.[363] It has been subject to supplemental NDAs,[364] citizens petitions, congressional hearings, and GAO reports.[365] Moreover, as noted above, it is subject to a REMS, which applies to less than five percent of drugs on the U.S. market.[366] For most drugs, the FDA addresses its concerns by ensuring that the labeling for the drug discloses its risks and other warnings.[367] But the REMS statute allows FDA to go beyond typical requirements and mandates, for example, through special patient labeling or targeted communications to health care providers to help ensure the drug is used safely.[368] Additionally, the FDA can go even beyond the standard REMS requirements and impose additional elements to assure safe use ("ETASU") if there are known serious risks, which may include special prescriber or dispenser training and certifications, and special dispensing and monitoring requirements.[369] Mifepristone has been subject to all of these additional requirements,[370] even though medical societies (and many legal scholars)[371] now consider them unnecessary.[372]

Public Health Federalism, 9 J.L. & BIOSCIS., no. 2, 2022, at 1 (exploring challenges to state restrictions on FDA-approved pregnancy termination drugs on preemption grounds); *see also* James M. Beck, Philip W. Danziger, Sarah B. Johansen & Andrew R. Hayes, *Federal Preemption and the Post-*Dobbs *Reproductive Freedom Frontier*, 78 FOOD & DRUG L.J. 109, 112 (2023) (arguing that state bans on abortion drugs are preempted by the FDA's approval, at least to the extent they purport to regulate on-label use).

363. Zettler et al., *Mifepristone, Preemption, and Public Health Federalism*, *supra* note 362, at 5; Grossman, *supra* note 51, at 1043–44.

364. *See, e.g.*, CTR. FOR DRUG EVALUATION & RSCH., FDA, APPLICATION NUMBER: 020687ORIG1S020, MEDICAL REVIEW(S) (2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf [https://perma.cc/E4BU-ZFZF].

365. U.S. GOV'T ACCOUNTABILITY OFF., GAO-18-292, FOOD AND DRUG ADMINISTRATION: INFORMATION ON MIFEPREX LABELING CHANGES AND ONGOING MONITORING EFFORTS (2018), https://www.gao.gov/assets/gao-18-292.pdf [https://perma.cc/98RH-K4HG]; *Chaos and Control: How Trump Criminalized Women's Health Care: Hearing Before the S. Comm. on Fin.*, 118th Cong. (2024); Citizen Petition from Am. Coll. Of Obstetricians and Gynecologists, et al., to Lauren Roth, Assoc. Comm'r for Pol'y, FDA (Oct. 4, 2022) (on file with the *Iowa Law Review*).

366. Elizabeth G. Raymond et al., *Sixteen Years of Overregulation: Time to Unburden Mifeprex*, 376 NEW ENG. J. MED. 790, 790 (2017).

367. 21 U.S.C. § 355(o)(4).

368. 21 U.S.C. § 355-1(e).

369. *Id.* § 355-1(f). Donley notes that ninety percent of drugs with a REMS "also include ETASU." Donley, *supra* note 24, at 640.

370. *Information About Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, *supra* note 37.

371. Donley, *supra* note 24, at 630, 651–67; Brief of Amici Curiae Med. & Pub. Health Soc'ys in Opposition to Plaintiffs' Motion for a Preliminary Injunction, *supra* note 354, at 5–17.

372. *Improving Access to Mifepristone for Reproductive Health Indications*, ACOG (Mar. 2021), https://www.acog.org/clinical-information/policy-and-position-statements/position-statements/2018/improving-access-to-mifepristone-for-reproductive-health-indications [https://perma.cc/MG9Y-2TSF]; Letter from John S. Cullen, Bd. Chair, Am. Acad. of Fam. Physicians, to Stephen M. Hahn, Comm'r, FDA (Mar. 25, 2020), https://www.aclu.org/wp-content/plugins/pdfjs-viewer-shortcode/pdfjs/web/viewer.php?file=https://www.aclu.org/wp-content/uploads/document/Doc

By statute, the agency can impose a REMS only if it "is necessary to ensure that the benefits of the drug outweigh the risks of the drug."[373] Importantly, when Congress codified the REMS system, it specifically instructed the FDA not to impose any REMS requirements that would "be unduly burdensome on patient access to the drug."[374] It also requires that certain REMS requirements be "commensurate with [a] specific serious risk"[375] identified in the approved labeling for the drug, and "to the extent practicable, . . . minimize the burden on the health care delivery system."[376] In these ways, REMS requirements serve as both a floor and a ceiling, representing a complex balancing act that weighs not only the benefits and risks of the drug, but also the burdens on patients and the health care system.[377] Given these complex considerations, it is not a stretch to deem any state deviations as frustrating federal policy and serving as an obstacle to federal objectives.[378] These issues are being raised in three separate cases currently pending around the country.[379]

F. THE TELEHEALTH PROBLEM

Finally, the conflict between federal laws that deem mifepristone to be safe and effective and state laws limiting its use comes into sharp relief in the context of telehealth. Although the FDA's own policy had limited the use of telehealth (by requiring mifepristone to be dispensed in person by certified clinicians in certain health care settings),[380] the agency revised its policy in response to the Covid-19 pandemic[381] and a legal challenge.[382] Thus, the

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._1-5_Complaint_Ex._3,_AAFP_Letter.pdf&attachment_id=0&dButton=true&pButton=true&oButton=false&sButton=true#zoom=page-width&pagemode=none&_wpnonce=b0019cdffd (on file with the *Iowa Law Review*); *Supporting Access to Mifepristone (Mifeprex) H-100.948*, AMA (2023), https://policysearch.ama-assn.org/policyfinder/detail/mifepristone?uri=%2FAMADoc%2FHOD.xml-H-100.948.xml [https://perma.cc/YT8Z-6A6C].

373. 21 U.S.C. § 355-1(a)(1).

374. *Id.* § 355-1(f)(2)(C).

375. *Id.* § 355-1(f)(2)(A).

376. *Id.* § 355-1(f)(2)(D).

377. *See* Zettler, *supra* note 88, at 875.

378. English v. Gen. Elec. Co., 496 U.S. 72, 79 (1990); Cohen et al., *supra* note 6, at 57–59.

379. *See generally* Washington v. FDA, 108 F.4th 1163 (9th Cir. 2024) (finding a lack of standing for Idaho to intervene); Bryant v. Stein, No. 23-cv-77, 2024 WL 1886907 (M.D.N.C. Apr. 30, 2024) (finding that some of North Carolina's mifepristone laws were preempted while others were not and were unconstitutional for violating the Supremacy Clause); GenBioPro, Inc. v. Sorsaia, No. 23-cv-0058, 2023 WL 5490179 (S.D.W. Va. Aug. 24, 2023) (denying in part and granting in part the defendant's motion to dismiss).

380. FDA, MIFEPREX RISK EVALUATION AND MITIGATION STRATEGY (REMS) 1 (2016), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifeprex_2016-03-29_REMS_full.pdf [https://perma.cc/5JUL-PZ9L].

381. The temporary change adopted during the pandemic was made permanent in December 2021. *See Questions and Answers on Mifepristone for Medical Termination of Pregnancy Through Ten Weeks Gestation*, FDA (Sept. 1, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation [https://perma.cc/XU5Q-LLLL].

382. Am. Coll. of Obstetricians & Gynecologists v. FDA, 506 F. Supp. 3d 328, 349 (D. Md. 2020); Complaint at 62–63, Chelius v. Wright, No. 17-cv-00493 (D. Haw. Oct. 3, 2017).

agency's permanent policy as of December 16, 2021, has been to allow access to medication abortion via telehealth, if only through certified providers and pharmacies. However, as of May 2022, seven states expressly banned the use of telehealth for prescribing medication abortion (Arizona, Arkansas, Louisiana, Missouri, Tennessee, Texas, and West Virginia), while others require one or more in-person visits with a prescriber, creating a clinically unnecessary barrier to accessing medication abortion via telehealth.[383] These state laws clearly clash with federal policy.

Even before *Dobbs*, telehealth had become a major pathway for expanding access to abortion and thus a target for antiabortion states.[384] For example, the Kaiser Family Foundation found that as of May 2022, right before the Supreme Court published *Dobbs*, twenty-eight states required at least one in-person visit to access medication abortion, in contravention of federal policy.[385] Thus, even before *Dobbs*, telehealth generated a degree of overlap—and potential for conflict—between federal and state jurisdiction. After *Dobbs*, resolving these conflicts has become even more urgent. And the resolution, we argue, should be informed by broader priorities regarding the goals of government oversight of medicine.

IV. WHAT DO WE WANT OUT OF MEDICINE?

The turf wars over medication abortion raise deeper questions about who should be regulating medicine today, and to what ends. The answers depend on what we want out of medicine.[386] Most patients, we imagine, expect that the practitioners treating them and the products used on them will apply the best medical and scientific knowledge available at the time: so-called "evidence-

383. Laurie Sobel, Amrutha Ramaswamy & Alina Salganicoff, *The Intersection of State and Federal Policies on Access to Medication Abortion via Telehealth*, KAISER FAM. FOUND. (Feb. 7, 2022), https://www.kff.org/womens-health-policy/issue-brief/the-intersection-of-state-and-federal-policies-on-access-to-medication-abortion-via-telehealth [https://perma.cc/LDY6-P3QS].

384. *Id.* at app. 1.

385. *Id.*

386. We should be careful to distinguish our discussion over how to regulate medical products and practice from much broader policy debates regarding how to regulate *health care*, including health system organization, insurance, and financing. Moreover, the spirit of our inquiry is a thought experiment rather than an empirical survey of what patients value. In the spirit of a Rawlsian "veil of ignorance," if we were to conceive a legal and regulatory system for medicine from scratch, without considering our own embedded interests, what would this system prioritize? In John Rawls' famous work, *A Theory of Justice*, he contemplated an "original position," or a fair and impartial viewpoint from which we can derive fundamental principles of justice, without prior biases or inequalities. We are asked to adopt a "veil of ignorance" and imagine ourselves free and equal and committed to establishing a just political and social order. The "veil of ignorance" deprives us of all knowledge of our own personal, social, and historical circumstances and interests. From this baseline, Rawls posits, we can agree on basic principles of justice and liberty as part of a grand social contract. *See generally* JOHN RAWLS, A THEORY OF JUSTICE (1971). This is the spirit of our inquiry here.

based medicine."[387] Most patients, we surmise, also expect that medical products and practices will not cross clear ethical and moral boundaries, and that our laws and regulations reflect those boundaries. We also venture that patients expect medicine to be consistent and fair (similar care for similarly situated patients), and individualized (accounting for their own specific needs and circumstances).

But is this the medicine we have? To what extent do our laws and regulations encourage these priorities, or conversely, thwart them? In the case of medication abortion, the answer is complicated. Some approaches to medication abortion encourage care that meets these criteria—evidence-based, ethical, consistent, and individualized. Other approaches prioritize highly contested moral concerns, sacrificing medicine that is evidence-based, ethical, consistent, and individualized. When some values clash with others, how should we resolve these conflicts? In June 2024, the Supreme Court avoided these questions in *Alliance for Hippocratic Medicine*, where it found the plaintiffs lacked standing.[388] But the underlying merits arguments have implications far beyond mifepristone, touching on the larger questions we identify here. Below we explain how current struggles over medication abortion fail patients along these metrics, suggesting less intrusion by state legislatures and more assertive governance by evidence-based regulators.

A. EVIDENCE-BASED

Most patients, we surmise, expect that medical products and practices will reflect "evidence-based medicine," and that our laws will encourage or even require evidence-based medicine rather than thwart it.[389] In the early 1990s, medical researchers, practitioners, and policymakers began to coalesce around promoting "evidence-based medicine" ("EBM"),[390] which "de-emphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research."[391] This ideal prioritized "the conscientious, explicit, and judicious use of the current best evidence in making decisions about the care of individual patients."[392] Medical decision-making, it posits,

387. Gordon Guyatt et al., *Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine*, 268 JAMA 2420, 2420 (1992) (laying out the foundation of "evidence-based medicine" paradigm).

388. *See* FDA v. All. for Hippocratic Med., 602 U.S. 367, 374 (2024).

389. Both Arrow and Leffler discuss consumer demand for government regulation of medical professionals. *See* Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 967 (1963); Keith B. Leffler, *Physician Licensure: Competition and Monopoly in American Medicine*, 21 J.L. & ECON. 165, 172–76 (1978).

390. For a history of evidence-based medicine and the long question to better evaluate and measure health outcomes, see generally Daniel M. Fox & Lee Greenfield, *Helping Public Officials Use Research Evaluating Healthcare*, 14 J.L. & POL'Y 531 (2006); Ariel L. Zimerman, *Evidence-Based Medicine: A Short History of a Modern Medical Movement*, 15 VIRTUAL MENTOR 71 (2013).

391. Guyatt et al., *supra* note 387, at 2420.

392. David L. Sackett, *Editorial: Evidence-Based Medicine*, 23 SPINE 1085, 1085 (1998).

should be driven by randomized clinical trials and rigorous meta-analyses rather than the uncritical application of instincts, customs, or received wisdom.[393]

Do current laws on medication abortion reflect evidence-based medicine? First, consider federal policy toward mifepristone. As explained above, mifepristone is one of the most carefully scrutinized drugs on the U.S. market,[394] having been subject to numerous research studies that have informed numerous regulatory filings, government reports, and congressional hearings,[395] which support the conclusion that it is safe and effective for its intended use. Although federal policy toward medication abortion reflects this science, it also reflects other priorities. As explained above, mifepristone's approval was initially delayed, and once approved was subject to restrictions befitting much more dangerous drugs.[396] For decades, federal policy clung to mifepristone dispensing requirements that were not evidence-based and served neither to ensure the safety nor the efficacy of the drug.[397] Long ago, researchers dispelled the idea that in-person dispensing, on-label prescribing, and in-person follow-up care were necessary to ensure its safe use. In fact, some studies suggest it could be used safely and effectively without the involvement of a provider at all.[398] Since 2000, the agency has removed or altered the REMS for mifepristone after studies found some restrictions unnecessary for assuring its safety and efficacy, such as the requirement that patients consume the drug in-person, and the approval up to seven weeks even though research showed the drug would be safe and effective up through ten weeks.[399] And long before these changes, most providers had started following an off-label protocol.[400] Even today, of course, mifepristone is subject to unnecessary restrictions that do not reflect evidence-based medicine.[401] Overall, the federal approach is not perfectly calibrated to evidence-based medicine. But at least it is responsive.

Restrictive state approaches to mifepristone, on the other hand, often ignore or directly contradict evidence-based medicine. As a primary matter, as noted above in Section III.C, several states ban the use of a drug that is

393. David M. Eddy, *Designing a Practice Policy: Standards, Guidelines, and Options*, 263 JAMA 3077, 3081 (1990).

394. Zettler et al., *Mifepristone, Preemption, and Public Health Federalism*, *supra* note 362, at 7; Grossman, *supra* note 51, at 1115–17.

395. CTR. FOR DRUG EVALUATION & RSCH., FDA, *supra* note 364; U.S. GOV'T ACCOUNTABILITY OFF., *supra* note 365.

396. Raymond et al., *supra* note 366, at 790.

397. *See supra* text accompanying notes 239–44.

398. *See supra* text accompanying notes 39–44. The FDA approved the first over-the-counter birth control pill in 2023 based on proof that it can be used safely and effectively by consumers with nonprescription labeling and no involvement of a healthcare provider. *See* Press Release, FDA, FDA Approves First Nonprescription Daily Oral Contraceptive (July 13, 2023), https://www.fda.gov/news-events/press-announcements/fda-approves-first-nonprescription-daily-oral-contraceptive [https://perma.cc/K9UE-9GKC].

399. CTR. FOR DRUG EVALUATION & RSCH., FDA, *supra* note 364, at 5–9, 15, 17.

400. *See* Cline v. Okla. Coal. for Reprod. Just., 313 P.3d 253, 259–61 (Okla. 2013), *superseded by statute*, H.B. 2684, 54th Gen. Assemb., Reg. Sess. (Okla. 2014).

401. Raymond et al., *supra* note 366, at 792.

demonstrated to be safe and effective for medical uses. But beyond that, restrictive state approaches have a secondary effect of deterring non-controversial, non-abortion care. State laws enacted after *Dobbs* are having the unintended (or sometimes intended) consequence of deterring non-abortion care for lupus, arthritis, miscarriage management, and medically "necessary" abortions.[402]

For example, before *Dobbs*, physicians had few qualms about prescribing misoprostol for its other FDA-approved uses, such as ulcers[403] or miscarriage management.[404] After *Dobbs*, state laws that threaten felony charges or the loss of a medical license deter even non-abortive uses of these products.[405] Similarly, drugs like methotrexate are being denied to patients with lupus, psoriasis, and rheumatoid arthritis because it can also induce an abortion in ectopic pregnancies.[406] Because prescriptions typically do not state the patient's diagnosis or indicated use for the drug, patients are being asked to provide additional documentation or seek alternative treatments, even in alternative jurisdictions, which can delay necessary care.[407] Vaguely-worded abortion bans that might be construed broadly to include non-abortive care are in fact being construed to deter medically necessary care.[408] Physicians and pharmacists are reluctant to dispense drugs that might trigger felony charges or other penalties.

In these ways, federal law on mifepristone is more evidence-based than restrictive state laws. Moreover, on a broader level, FDA approval of any drug leaves room for physicians to prescribe the drug off-label, for unapproved uses, to individual patients if they see fit, based on their clinical judgment and consideration of the patient's specific circumstances.[409] Thus, federal policy leaves room for professional medical judgment; restrictive state laws do not.

This is quite contrary to the typical state approach toward medical judgment. Although the FDA ensures that drugs and devices are safe and effective for their intended uses, there is no comparable review by state medical boards for surgeries or other types of medical procedures.[410] Thus, clinical

402. Alice Miranda Ollstein & Daniel Payne, *Patients Face Barriers to Routine Care as Doctors Warn of Ripple Effects from Broad Abortion Bans*, POLITICO (Sept. 28, 2022, 12:00 PM), https://www.politico.com/news/2022/09/28/abortion-bans-medication-pharmacy-prescriptions-00059228 [https://perma.cc/62UE-DAYU].

403. Rebecca Allen & Barbara M. O'Brien, *Uses of Misoprostol in Obstetrics and Gynecology*, 2 REVS. OBSTETRICS & GYNECOLOGY 159, 159 (2009) (noting that misoprostol was originally approved to prevent stomach ulcers in patients that had taken certain anti-inflammatory drugs).

404. *Id.*

405. Ollstein & Payne, *supra* note 402.

406. *Id.*; Letter from Steven Newmark, Dir. of Pol'y, Glob. Healthy Living Found., to Gregory Abbott, Governor of Tex. (July 14, 2022), https://ghlf.org/wp-content/uploads/2022/07/State-22-7-14.pdf [https://perma.cc/EF59-GXLW].

407. Ollstein & Payne, *supra* note 402.

408. *Id.*; Donley, *supra* note 24, 655–56.

409. *See, e.g.*, WA Meadows & BD Hollowell, *'Off-Label' Drug Use: An FDA Regulatory Term, Not a Negative Implication of Its Medical Use*, 20 INT'L J. IMPOTENCE RSCH. 135, 136 (2008).

410. Noah, *supra* note 120, at 191.

"innovations" are unregulated by states,[411] and medical procedures may be used for decades without a solid evidence base or any rigorous scientific studies supporting them. Calls for greater government scrutiny of surgeries and procedures date back at least forty-five years.[412] Thus, states are more than capable of deferring to medical judgment when they see fit, and indeed generally do so in the vast majority of cases. But not with medication abortion.

B. ETHICAL

We also surmise that patients generally expect medical products and practices to be ethical and that our laws will police the outer boundaries of ethical practice. It is here where the distinction between medical practice and products is most salient. Medical practice is more clearly tethered to settled ethical standards than medical products are. Practitioners are governed by state medical practice acts and occupations codes that together prohibit specified practices and other "unprofessional conduct."[413] Medical practice is also governed by state medical board rules[414] which often include a mandatory ethics exam.[415] Finally, practitioners can look to extensive guidance from professional medical societies like the AMA, which publishes the *AMA Code of Medical Ethics*.[416] Although the AMA's *Principles of Medical Ethics* and the Opinions of the AMA's Council on Ethical and Judicial Affairs that together constitute the *AMA Code* are not legally binding,[417] they do reflect a very general national consensus on a variety of issues affecting medical practice. The AMA publishes policies, reports, and opinions that weigh in on "emerging dilemmas across a range of medical domains and specialties not imagined by its framers—genetics and reproductive medicine, managed care, organ transplantation, health information technologies, and others."[418]

On the question of abortion, the AMA's *Principles of Medical Ethics* state that:

411. Maxwell J. Mehlman, *Health Care Cost Containment and Medical Technology: A Critique of Waste Theory*, 36 CASE W. RSRV. L. REV. 778, 820–21 (1986); Frances H. Miller, *Health Care Information Technology and Informed Consent: Computers and the Doctor-Patient Relationship*, 31 IND. L. REV. 1019, 1039 (1998).

412. *See, e.g.*, J.P. Bunker, D. Hinkley & W.V. McDermott, *Surgical Innovation and Its Evaluation*, 200 SCIENCE 937, 941 (1978); Note, *The Open-Ended Investigation: A Method for Regulation of New Medical Services*, 91 YALE L.J. 550, 566–67 (1982); John E. Wennberg, *The Paradox of Appropriate Care*, 258 JAMA 2568, 2569 (1987).

413. *See, e.g.*, TEX. OCC. CODE ANN. § 105.002 (West 2024).

414. *See, e.g.*, 22 TEX. ADMIN. CODE §§ 163.1(8), 163.2 (2024).

415. *See, e.g.*, *id.* § 163.1(12); *Texas Medical Jurisprudence Exam*, TEX. MED. BD. (Oct. 21, 2024), https://www.tmb.state.tx.us/page/licensing-jp-exam [https://perma.cc/6VRL-JPEK].

416. AMA CODE OF MED. ETHICS, *supra* note 106.

417. *See FAQ*, AMA CODE OF MED. ETHICS, https://code-medical-ethics.ama-assn.org/faq [https://perma.cc/93YJ-WL5F] (directing grievances and complaints to be filed with state medical licensing boards).

418. *About*, AMA CODE OF MED. ETHICS, https://code-medical-ethics.ama-assn.org/about [https://perma.cc/JRL5-SS7W].

> Abortion is a safe and common medical procedure, about which thoughtful individuals hold diverging, yet equally deeply held and well-considered perspectives. Like all health care decisions, a decision to terminate a pregnancy should be made privately within the relationship of trust between patient and physician in keeping with the patient's unique values and needs and the physician's best professional judgment.
>
> The *Principles of Medical Ethics* of the AMA permit physicians to perform abortions in keeping with good medical practice.[419]

Other professional societies, like the Texas Medical Association ("TMA"), have also taken written positions on abortion and other controversial issues.[420] After the Supreme Court issued the *Dobbs* opinion, the TMA issued a statement:

> TMA remains committed to protecting the privacy and sanctity of the patient-physician relationship. TMA is unwavering in its stance against intrusions by government or other third parties that impede the patient-physician relationship, and any criminalization of acceptable and appropriate medical practices that may jeopardize that relationship or patients' safety.
>
> Especially in high-risk situations, patients need to know their physicians will be there to care for them, and TMA will continue to work with state lawmakers to ensure a safe practice environment for physicians and their patients.[421]

And, as noted above, the ACOG is a vocal supporter of access to abortion, featuring a page on its website titled, "Abortion Is Essential Health Care,"[422] that includes numerous resources, including a "Frequently Asked Questions"

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419. *Opinion 4.2.7: Abortion*, AMA CODE OF MED. ETHICS, https://code-medical-ethics.ama-assn.org/ethics-opinions/abortion [https://perma.cc/V9H6-ZX38].

420. *See, e.g.*, *Articles and Papers on Legal Issues*, TEX. MED. ASS'N (Aug. 28, 2023), https://www.texmed.org/Template.aspx?id=53&terms=abortion#Abortion [https://perma.cc/4TK7-FBU7].

421. *See* Press Release, Gary W. Floyd, President, Tex. Med. Ass'n, TMA Statement Regarding *Roe v. Wade* Opinion (June 24, 2022), https://www.texmed.org/Template.aspx?id=59894 [https://perma.cc/V5CG-WEH7]. Elsewhere, TMA has criticized controversial abortion bills proposed by the Texas legislature. *See* Kevin Reynolds, *Texas Doctors Association Condemns Abortion Ban, Says It Encourages "Vigilante Interference" in Doctor-Patient Relationship*, TEX. TRIB. (Sept. 3, 2021, 1:00 PM), https://www.texastribune.org/2021/09/03/texas-abortion-law-doctors [https://perma.cc/WPN6-ZM3L].

422. *Abortion Is Essential Health Care*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS, https://www.acog.org/advocacy/abortion-is-essential [https://perma.cc/WF5C-DEGX].

page on "Access to Mifepristone"[423] and resources for practitioners titled, "Practice Management."[424]

Thus, although professional medical societies are not uniform on the question of abortion, the vast majority publicly support it.[425] Shortly after the *Dobbs* opinion was published, seventy-five professional societies, including the AMA, ACOG, and the American College of Physicians, released a joint statement to "oppose all legislative interference in the patient clinician relationship."[426] The statement urged that "patients need to be able to access—and our clinicians need to be able to provide—the evidence-based care that is right for them, including abortion."[427] The letter continues that "[b]anning abortion care is a decision not founded in science or based on evidence. In all facets of medicine, clinicians train for years—some for decades—to learn how to provide the best evidence-based care possible to their patients."[428]

In fact, in the months after *Dobbs*, physicians openly contemplated civil disobedience—obeying an ethical duty to disregard ethically unacceptable laws.[429] When "the law mandates conduct that is ethically unacceptable," the *AMA Code of Medical Ethics* observes, physicians "should work to change the law."[430] But "[i]n exceptional circumstances of unjust laws, ethical responsibilities should supersede legal duties."[431] Thus, when law and ethics collide, there is a strong sense in the medical community that their first duty is to patients—that "medically nuanced decisions are best left in the hands of individual patients and their physicians — not state lawmakers."[432] Citing Henry David Thoreau, Mahatma Gandhi, and Martin Luther King, Jr., the article noted the threat to civil society from disregarding laws, potentially leading to anarchy

423. *Access to Mifepristone*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS (Apr. 2024), https://www.acog.org/clinical-information/physician-faqs/access-to-mifepristone [https://web.archive.org/web/20240722040524/https://www.acog.org/clinical-information/physician-faqs/access-to-mifepristone].

424. *Practice Management*, AM. COLL. OBSTETRICIANS & GYNECOLOGISTS, https://www.acog.org/advocacy/abortion-is-essential/practice-management [https://perma.cc/2RKH-ST34]. And, of course, ACOG denounced the *Dobbs* decision. *See* Press Release, Iffath Abbasi Hoskins, President, Am. Coll. of Obstetricians & Gynecologists, ACOG Statement on the Decision in *Dobbs v. Jackson* (June 24, 2022), https://www.acog.org/news/news-releases/2022/06/acog-statement-on-the-decision-in-dobbs-v-jackson [https://perma.cc/9CEQ-CX7M].

425. As one writer explained, "[m]edical organizations are rarely so united." Wynia, *supra* note 19, at 960.

426. Press Release, Am. Coll. of Obstetricians & Gynecologists et al., More than 75 Health Care Organizations Release Joint Statement in Opposition to Legislative Interference (July 7, 2022), https://www.acog.org/news/news-releases/2022/07/more-than-75-health-care-organizations-release-joint-statement-in-opposition-to-legislative-interference [https://perma.cc/LCR5-WSBM].

427. *Id.*

428. *Id.*

429. *See, e.g.*, Wynia, *supra* note 19, at 959–60.

430. *Id.* at 959; *Preface & Preamble*, AMA CODE OF MED. ETHICS (2016), https://code-medical-ethics.ama-assn.org/preface-preamble [https://perma.cc/WY6R-SAUY].

431. *Preface & Preamble*, *supra* note 430.

432. Wynia, *supra* note 19, at 960.

and chaos, is taken seriously.[433] But the profession must also account for past complicity with forced sterilization, experimentation, and other medical atrocities furthered under the color of state authority.[434]

If certain laws trigger these agonizing questions among serious professionals, perhaps the fault lies with those laws rather than the profession? If medical practitioners have to choose between their legal duties and their ethical duties, perhaps we should reexamine those legal duties and their foundations?

Of course, not all contests between law and medical ethics are easily answered. The outer bounds of medical practice can raise difficult questions on which there is no legal *or* ethical consensus. For example, euthanasia and physician-assisted suicide might be "evidence-based"—in that the methods used do in fact effectively end a life, with minimal to no suffering—but euthanasia remains widely prohibited, while physician-assisted suicide is allowed in only ten states and the District of Columbia.[435] There is no clear conflict between law and medical ethics because both remain in flux on these questions.

Of course, there have long been conflicts over who gets to define the scope of legitimate medical practice, whether it is the use of marijuana or other controlled substances for therapeutic purposes, or the use of certain procedures, such as abortion, physician-assisted suicide, or gender-affirming care.[436] As Professor Lars Noah asks, "[i]s the legitimate practice of medicine whatever physicians say it is, or is it instead in part a contested political and social question?"[437] "If [the practice] is contingent on something other than professional expertise, then it becomes less clear that the . . . government has no legitimate role in providing an answer."[438]

One area that demonstrates state overreach into a rapidly changing medical standard of care is gender-affirming care. Not too long ago, few physicians would have suggested gender-affirming care such as hormone therapy or gender-reassignment treatments for pediatric patients with gender dysphoria.[439] Today, with better understanding of gender dysphoria and related disorders, gender-affirming care is endorsed by numerous professional societies, including the American Psychiatric Association and the American

433. *Id.*

434. *Id.* at 960–61.

435. *World Map*, WORLD FED'N RIGHT TO DIE SOC'YS, https://wfrtds.org/worldmap [https://perma.cc/W5A8-H3QQ]; *Physician-Assisted Dying Legislation Around the World*, BRIT. MED. ASS'N, https://www.bma.org.uk/media/6706/bma-where-is-pad-permitted-internationally.pdf [https://perma.cc/9RS5-VJ2Q].

436. *See, e.g.*, Noah, *supra* note 120, at 154.

437. *Id.* at 185.

438. *Id.* Note that the quote omits the term "federal" before government, as Noah is focused on the federalism question. But the logic nonetheless applies.

439. Saver, *supra* note 114, at 979; Emily Bazelon, *The Battle Over Gender Therapy*, N.Y. TIMES MAG. (Mar. 17, 2023), https://www.nytimes.com/2022/06/15/magazine/gender-therapy.html (on file with the *Iowa Law Review*).

Academy of Pediatrics.[440] Yet, several states with conservative state legislatures, like Florida and Texas, passed laws outlawing such care,[441] drawing criticisms that the laws prioritize politics over science.[442] Indeed, before the FDA has had a chance to consider the safety and efficacy of any given therapeutic, states filled the void with laws banning gender-affirming care that relied on ad hoc safety evaluations and questionable secondary sources that were not scientifically reviewed.[443] But the medical field can quickly coalesce around a consensus, which suggests state legislatures should exercise patience, if not some measure of deference.

The "ethics" of medical products are much less structured and well-established and generally lean on principles from medical practice. On some occasions federal regulators must consider the ethics of a new medical technology. For example, when confronted with the possibility of human cloning in the late 1990s, the FDA sent a "Dear Colleague" letter to institutional review boards ("IRBs") clarifying that it would assert jurisdiction over any human trial involving cloning technology and "would not permit any such investigation to proceed" given "major unresolved safety questions."[444] Note that the FDA was careful to couch its objections in terms of safety, rather than in moral or ethical terms. In general, the White House has taken the federal lead on

440. *Position Statement on Treatment of Transgender (Trans) and Gender Diverse Youth*, AM. PSYCHIATRIC ASS'N (July 2020), https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-Transgender-Gender-Diverse-Youth.pdf [https://perma.cc/WQ53-BXRM]; Jason Rafferty et al., *Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents*, PEDIATRICS, Oct. 1, 2018, at 1, 4.

441. *See* FLA. ADMIN. CODE ANN. r. 64B8-9.019 (2023); S.B. 14, 2023 Leg., 88th Sess. (Tex. 2023) (amending Tex. Health & Safety Code §§ 62.151, 161, and other sections of the Human Resources Code and Occupations Code). A case challenging the validity of two such state laws is currently pending in the U.S. Supreme Court. *See* United States v. Skrmetti, 144 S. Ct. 2679 (June 24, 2024) (No. 23-477), *granting cert.* 83 F.4th 460 (6th Cir. 2023).

442. Saver, *supra* note 114, at 930; Alex Nguyen & William Melhado, *Gov. Greg Abbott Signs Legislation Barring Trans Youth from Accessing Transition-Related Care*, TEX. TRIB. (June 3, 2023), https://www.texastribune.org/2023/06/02/texas-gender-affirming-care-ban [https://perma.cc/RTD3-Q5NA].

443. *See* Sharkey & Kenny, *supra* note 361, at 219–20.

444. Stuart L. Nightingale, *Letter About Human Cloning*, FDA (Mar. 15, 2018), https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/letter-about-human-cloning [https://perma.cc/3TDV-5X47]; *Therapeutic Cloning and Genome Modification*, FDA (Mar. 16, 2018), https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/therapeutic-cloning-and-genome-modification [https://perma.cc/S4DC-ZYML]. As an interesting sidenote, several states banned human cloning. For an older list of states that responded to news that Dolly the sheep had been cloned, see John Kasprak, *OLR Research Report: Human Cloning*, CONN. GEN. ASSEMB. (Dec. 4, 2001), https://www.cga.ct.gov/2001/rpt/2001-R-0924.htm [https://perma.cc/FC93-RSY6]. And experts twenty years ago doubted that FDA could exercise jurisdiction over human cloning. *See, e.g.*, Rick Weiss, *Legal Barriers to Human Cloning May Not Hold Up*, WASH. POST (June 01, 2001), https://www.washingtonpost.com/archive/politics/2001/05/23/legal-barriers-to-human-cloning-may-not-hold-up/116dc527-4189-467a-926e-3cbd78137838 (on file with the *Iowa Law Review*).

bioethical issues since roughly the 1970s,[445] ranging from reports on genetic biobanks[446] to stem cell research[447] to cloning.[448] But these responses come in the form of careful, almost academic treatments of cutting-edge technologies rather than confident pronouncements that a technology is clearly ethical or unethical. Such a careful and preliminary stance, like professional ethical codes, leaves breathing room for debate and further consideration—unlike state laws that purport to speak definitively on an issue.

C. CONSISTENT

We also assume that patients expect medicine to be consistent and fair; that they will receive roughly the same care as similarly-situated patients and not be treated differently for non-medical reasons. Do our laws achieve this? The question is surprisingly difficult to answer. On one extreme, there is a long list of federal anti-discrimination laws that apply to health providers that participate in Medicare and other federal programs, including the Civil Rights Act, the Rehabilitation Act, the Age Discrimination Act, the Public Health Service Act, the Affordable Care Act, and of course the Americans with Disabilities Act.[449] But these laws affect clinical decision-making—the practice of medicine—only in glancing ways and mostly when doctors refuse to treat patients for impermissible reasons.[450] Physicians can refuse to provide certain types of services to *any* patient (rather than only *some* patients), and these refusals are sometimes protected by "conscientious objector" laws.[451] Thus, as Professor Holly Fernandez Lynch finds, "some types of discrimination against

445. In 1995, President Clinton created a National Bioethics Advisory Commission, Exec. Order No. 12975, which was replaced by the President's Council on Bioethics under the George W. Bush Administration, Exec. Order No. 13237, which itself was replaced by the Presidential Commission for the Study of Bioethical Issues under President Obama, Exec. Order No. 13521, 74 Fed. Reg. 62671 (Nov. 24, 2009). The first presidential commission was the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1974). *See History of Bioethics Commissions*, PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, https://bioethicsarchive.georgetown.edu/pcsbi/history.html [https://perma.cc/XV82-HVDH].

446. Susanne B. Haga & Laura M. Beskow, *Ethical, Legal, and Social Implications of Biobanks for Genetics Research*, 60 ADVANCES GENETICS 505, 508, 512 (2008).

447. *See, e.g.*, *Advancing Stem Cell Science Without Destroying Human Life*, WHITE HOUSE (Apr. 2007), https://georgewbush-whitehouse.archives.gov/dpc/stemcell/2007/index.html [https://perma.cc/UEQ4-YGH3].

448. Press Release, Off. of the Press Sec'y, The White House, President Clinton Announces Cloning Prohibition Act of 1997 (June 9, 1997), https://clintonwhitehouse5.archives.gov/New/Remarks/Mon/19970609-16602.html [https://perma.cc/3G3B-5HCZ].

449. For a list of such laws and citations to specific sections in each statute, see *Laws and Regulations Enforced by OCR*, U.S. DEP'T OF HEALTH & HUM. SERVS. (Aug. 27, 2024), https://www.hhs.gov/civil-rights/for-providers/laws-regulations-guidance/laws/index.html [https://perma.cc/5Z6P-87XF].

450. Holly Fernandez Lynch, *Discrimination in the Doctor-Patient Relationship*, BILL OF HEALTH (Sept. 7, 2012), https://blog.petrieflom.law.harvard.edu/2012/09/07/discrimination-in-the-doctor-patient-relationship [https://perma.cc/7ZV6-TX36].

451. *Id.*; HOLLY FERNANDEZ LYNCH, CONFLICTS OF CONSCIENCE IN HEALTH CARE: AN INSTITUTIONAL COMPROMISE 188 (2008).

patients are legally permitted and others aren't."[452] But federal and state laws largely defer to professional medical judgment so long as it does not cross well-established lines.

Federal and state laws do not always defer in matters of abortion or reproductive health. As explained above, reproductive care, and abortion care in particular, are areas where professional medical judgment is routinely superseded by the law. But why should reproductive health be exceptional this way? State laws focusing on reproduction tend to focus on females, suggesting likely gender bias at work.[453] Moreover, abortion restrictions have been proven to have a disproportionate impact on low-income women and people of color.[454] Consider the beginning of mifepristone's regulatory history in the United States, when the nomination of an FDA commissioner, Dr. Jane Henney, was held up for two years by Senate Republicans until they "receiv[ed] assurances that Dr. Henney would not actively facilitate final approval of mifepristone."[455] That exceptional treatment continued for decades. Even during the Covid-19 pandemic, when the FDA under the Trump Administration suspended in-person requirements for opioids and other drugs, it retained them for mifepristone.[456] And even when laws try to preserve some modicum of professional discretion in medical decision-making, they do so in clumsy ways that disrupt non-abortion care. For example, state laws prohibiting abortion sometimes leave narrow exemptions for abortions that are medically indicated or "necessary" as distinct from those deemed merely "elective."[457] The problem is that pregnancy is inherently risky,[458] and early evidence suggests women

452. Fernandez Lynch, *supra* note 450.

453. Donley, *supra* note 24, at 631. Allison Whelan argues that state control over abortion and contraception "disproportionately impacts vulnerable and historically marginalized communities and exacerbates health disparities and social inequities." Allison M. Whelan, *Aggravating Inequalities: State Regulation of Abortion and Contraception*, 46 HARV. J.L. & GENDER 131, 140 (2023).

454. *See, e.g.*, Liza Fuentes, *Inequity in US Abortion Rights and Access: The End of Roe is Deepening Existing Divides*, GUTTMACHER INST. (Jan. 17, 2023), https://www.guttmacher.org/2023/01/inequity-us-abortion-rights-and-access-end-roe-deepening-existing-divides [https://perma.cc/GYM4-X7FM].

455. Noah, *supra* note 270, at 583.

456. FDA, POLICY FOR CERTAIN REMS REQUIREMENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY: GUIDANCE FOR INDUSTRY AND HEALTH CARE PROFESSIONALS 7 (2020), https://www.supremecourt.gov/opinions/URLs_Cited/OT2020/20A34/20A34-5.pdf [https://perma.cc/X4ZR-5PG2].

457. The case of Dallas woman Kate Cox is illustrative. The Texas abortion ban does provide a very narrow exception for "a life-threatening physical condition," including a condition that "poses a serious risk of substantial impairment of a major bodily function unless the abortion is performed or induced," but the law is vague and confusing. *See* Greer Donley, Opinion, *What Happened to Kate Cox Is Tragic, and Completely Expected*, N.Y. TIMES (Dec. 17, 2023), https://www.nytimes.com/2023/12/17/opinion/kate-cox-abortion-texas-exceptions.html (on file with the *Iowa Law Review*).

458. Donley, *supra* note 24, at 634.

routinely are denied "necessary" care by providers worried about skirting the law.[459]

Thus, both federal and state laws exhibit reproductive exceptionalism or abortion exceptionalism to some degree. Again, this departs from the typical posture under both state and federal law. Professional medical judgment is protected from state interference. Unless it is not.

D. INDIVIDUALIZED

Finally, patients can reasonably expect that the care they receive reflects an individualized assessment of their specific medical needs and that the law will preserve necessary latitude for professionals to make those judgment calls. It is here where more granular state and federal laws governing abortion and reproductive care clearly intrude.

Practitioners argue "that they need the flexibility to judge what is best for a particular patient,"[460] thus preserving clinical judgment and minimizing state intrusions. Longstanding arguments against government control of the practice of medicine argue that it will decrease the quality of care, thus violating physicians' ethical duty to promote the patient's best interests and protect their individual autonomy.[461] Thus, government-mandated practice standards can violate the notion that the practice of medicine should be carried out "on an individual basis, with the best interests of the patient foremost in the practitioner's mind."[462] Indeed, federal regulation of controlled substances is criticized on these grounds, with restrictive Drug Enforcement Agency ("DEA") and FDA policies "making it difficult for practitioners to treat individual patients with legitimate needs for such drugs, in the name of addressing the prescription drug abuse problem."[463] In other words, standardized rules can subjugate an individual patient's best interests to a public health priority.[464] State medical practice laws have also long been criticized for being anticompetitive, adopted more to deter competition than protect patient safety.[465]

Thus, regulating medical decision-making can be tricky, particularly when regulation moves from general exhortations to use one's best medical judgment and exercise due care to more granular, bright-line rules. One reason is that the practice of medicine is dynamic, not static. Firmly drawn rules can

459. *See, e.g.*, J. David Goodman, *Abortion Ruling Keeps Texas Doctors Afraid of Prosecution*, N.Y. TIMES (Dec. 14, 2023), https://www.nytimes.com/2023/12/13/us/texas-abortion-doctor-prosecution.html (on file with the *Iowa Law Review*).

460. Zettler, *supra* note 87, at 436.

461. *Id.* at 437.

462. Jeffrey M. Drazen, *Government in Medicine*, 356 NEW ENG. J. MED. 2195, 2195 (2007).

463. Zettler, *supra* note 87, at 487; Jane C. Ballantyne, *Regulation of Opioid Prescribing: Over-Regulation Compromises Doctors' Ability to Treat Pain*, 334 BRIT. MED. J. 811, 812 (2007).

464. Zettler, *supra* note 87, at 487.

465. Roger D. Blair & Christine Piette Durrance, *Licensing Health Care Professionals, State Action and Antitrust Policy*, 100 IOWA L. REV. 1943, 1946 (2015); Teladoc, Inc. v. Tex. Med. Bd., No. 15-cv-343, 2016 WL 4362208, at *1 (W.D. Tex. Aug. 15, 2016) (involving an antitrust challenge by a telemedicine association against Texas requirements for in-person consultations).

generate a tension between orthodoxy and consensus practices, on one hand, and unorthodox, fringe, or even innovative practices on the other. State efforts to combat medical misinformation spread by providers during the Covid-19 pandemic had to confront this tension.[466] In some cases, it was the states themselves spreading the misinformation.[467] A California law that prohibited physicians and surgeons from spreading "misinformation" about Covid-19 defined it as "false information that is contradicted by contemporary scientific consensus contrary to the standard of care."[468] However, a federal district court found this to be unconstitutionally vague under the Due Process Clause of the Fourteenth Amendment, noting that the idea of "scientific consensus" is poorly defined and has no "established technical meaning" among those in the field.[469] The court also observed the "changing nature of scientific understanding, by which some 'experiments' will eventually become recognized as 'treatment.'"[470]

Moreover, as Professor Richard Saver notes, medical orthodoxy usually involves a sizable "epistemological grey area," as "there is no single customary standard of care in medicine. Rather, physicians routinely follow a spectrum of approaches."[471] Thus, "standards" of care really reflect a spectrum or range of reasonable approaches—recognizing that professional judgment needs breathing room to account for an almost infinite variety of circumstances that may be unique to each patient. Of course, tethering educational and practice standards to at least some standard of care has been the general approach for over a century, since the landmark Flexner Report in 1910 turned medicine away from the "unregulated, unskilled practitioners, including physicians who broadly peddled elixirs and promoted other false medical treatments to the public," toward more evidence-based training and practice.[472] Still, both state board regulation and medical malpractice law generally allow physicians to show that their actions comported with the opinions of a "respectable minority," even if it diverged from the majority's views.[473]

Again, many recent laws targeting abortion and reproductive care either reduce or completely eliminate any breathing room for professional medical

466. *See, e.g.*, Saver, *supra* note 114, at 917–18.

467. Michael J. Haller, Daniel A. Rubin & Matt D.T. Hitchings, *Confronting Health Misinformation Surrounding COVID-19 Vaccines in the States of Florida*, 39 J. GEN. INTERNAL MED. 1488, 1488 (2024).

468. CAL. BUS. & PROF. CODE § 2270(b)(4) (West 2023) (repealed 2024).

469. Høeg v. Newsom, 652 F. Supp. 3d 1172, 1186 (E.D. Cal. 2023).

470. *Id.* (citing Forbes v. Napolitano, 236 F.3d 1009, 1010–13 (9th Cir. 2000)).

471. Saver, *supra* note 114, at 920–21; CONG. BUDGET OFF., PUB. NO. 2975, RESEARCH ON THE COMPARATIVE EFFECTIVENESS OF MEDICAL TREATMENTS: ISSUES AND OPTIONS FOR AN EXPANDED FEDERAL ROLE 12 (2007).

472. Saver, *supra* note 114, at 927; Thomas P. Duffy, *The Flexner Report — 100 Years Later*, 84 YALE J. BIOLOGY & MED. 269, 269–70 (2011); *The Flexner Report and Medical Education*, NPR (Jan. 18, 2010, 3:00 PM), https://www.npr.org/templates/story/story.php?storyId=122702668 [https://perma.cc/E85W-6VXB].

473. Saver, *supra* note 114, at 976.

judgment, instead substituting the state's judgment. This, we argue, is not what patients expect out of medicine.

CONCLUSION

Regulating medicine is not a simple endeavor. Whether it is medical practice or medical products, policymakers must ensure that medicine is evidence-based, ethical, consistent, and responsive to individual patient needs and circumstances—all while preserving the necessary latitude for professionals to exercise their best medical judgment. State governments have always had a role in defining the outer bounds of legitimate medical practice, just as the federal government plays a longstanding role in reviewing new medical technologies.

But the arrival of one advancement over twenty years ago—medication abortion—is testing the limits of governance. Various state laws are sacrificing medicine that is evidence-based, ethical, consistent, and individualized to tackle the abortion controversy, an issue that has so far resisted any successful resolution through legislative intervention. These efforts, we show, are misguided, and might portend similarly misguided approaches to regulating gender-affirming care and other medical controversies not yet visible on the horizon. We advocate for a principled approach to regulation that keeps in mind core priorities, while accommodating both scientific advances and continued debate regarding the permissible scope of medicine. The battle over regulatory control of medication abortion both exposes the threat to medical care and presents an opportunity to rethink the allocation of power.