AGGRAVATING INEQUALITIES: STATE REGULATION OF ABORTION AND CONTRACEPTION

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ABSTRACT

Each year in the United States, pervasive inequities in health-care access and health outcomes contribute to tens of thousands of excess deaths among communities of color and other historically marginalized and vulnerable populations.[2] *Tragically, even that number may be a conservative estimate. These inequities transpire from structural barriers rooted deeply in racism, sexism, ableism, heterosexism, and other forms of discrimination. Health-care federalism in the United States—the division of power between the federal and state governments in the regulation of health care—although at times beneficial, too frequently exacerbates health disparities. This Article takes up one aspect of health-care federalism—state regulation of pharmaceutical products ("pharmaceutical federalism")—and exposes how state bans and restrictions on pharmaceuticals approved by the U.S. Food and Drug Administration (FDA) contribute to disparities in health-care access and outcomes. Specifically, this Article focuses on two pharmaceuticals currently in the crosshairs of health-care federalism and in need of urgent attention: medication abortion and contraceptives.*

Notwithstanding the states' long-standing role in regulating health care and the practice of medicine, the changing nature of the provision of health care—which increasingly crosses state or even international lines—raises serious and pressing questions about the logic of continuing to show strong deference to such state authority. This Article interrogates pharmaceutical federalism and considers whether federal law can, or should, preempt state bans and restrictions on FDA-approved pharmaceuticals. This question is now top of mind for lawyers, scholars, policymakers, and the public in the wake of the U.S. Supreme Court's ruling in Dobbs v. Jackson Women's Health Organization. *Its urgency cannot be understated. This Article exposes how current law, policy, and judicial precedent leave the answer to this*

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[2] Maureen R. Benjamins, *Comparison of All-Cause Mortality Rates and Inequities Between Black and White Populations Across the 30 Most Populous US Cities*, 4 JAMA OPEN NETWORK (2021); Meredith S. Shiels et al., *Racial and Ethnic Disparities in Excess Deaths During the COVID-19 Pandemic, March to December 2020*, 174 ANNALS OF INTERNAL MED. 1693, 1695–98 (2021).

question uncertain. Absent additional clarity, the significant harms of health-care federalism will continue unabated as states push back against federal authority and test the scope of their powers by restricting or banning certain FDA-approved pharmaceuticals. This Article proposes a legislative fix, along with other regulatory and policy changes, to combat the negative consequences of state pharmaceutical bans and restrictions.

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INTRODUCTION

"[H]ealth policy that allows for interstate variation might be a benefit of federalism, but it also leads to significant inequality when it comes to healthcare access across the country."[3]

On June 24, 2022, the U.S. Supreme Court issued *Dobbs v. Jackson Women's Health Organization*,[4] overruling *Roe v. Wade*[5] and *Planned Parenthood of Southeastern Pennsylvania v. Casey*,[6] gutting almost fifty years of precedent. The states now possess complete authority over the regulation of abortion. As of this writing, many states have banned or severely restricted access to abortion.[7] The implications of this ruling are dire, with more than just abortion at stake. As Justices Breyer, Sotomayor, and Kagan emphasized in their *Dobbs* dissent, "no one should be confident that the majority is done with its work. The right *Roe* and *Casey* recognized does not stand alone. To the contrary, the Court has linked it for decades to other

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[3] Abbe Gluck & Nicole Huberfeld, *What is Federalism in Healthcare For*?, 70 STAN. L. REV. 1689, 1698 (2018).

[4] No. 19-1392 (June 24, 2022).

[5] 410 U.S. 113 (1973), *overruled by Dobbs*, No. 19-1392.

[6] 505 U.S. 833 (1992), *overruled by Dobbs*, No. 19-1392.

[7] *See Interactive Map: US Abortion Policies and Access After Roe*, GUTTMACHER INST., https://states.guttmacher.org/policies/ [https://perma.cc/V28V-6GGT] (last updated Oct. 16, 2022) [hereinafter *Interactive Map*, GUTTMACHER INST.] (providing an interactive, periodically-updated map of state abortion laws and policies); *Tracking the States Where Abortion is Now Banned*, N.Y. TIMES, https://www.nytimes.com/interactive/2022/us/abortion-laws-roe-v-wade.html [https://perma.cc/A35N-XM7L] (last updated Oct. 13, 2022) (providing maps and a chart which are updated periodically and describe the current status of abortion laws in the states); *see also Abortion Ruling Prompts Variety of Reactions from States*, ASSOC. PRESS (July 21, 2022), https://apnews.com/article/supreme-court-abortion-ruling-states-a767801145ad01617100e57410a0a21d [https://perma.cc/4T94-ZD67] (noting how *Dobbs* "was expected to lead to abortion bans in roughly half the states"). On August 5, 2022, the Governor of Indiana signed into law the first abortion ban (with limited exceptions) enacted since *Dobbs*, making it the first state to approve *new* legislation since *Roe* was overturned. *See* Mitch Smith & Julie Bosman, *Indiana Governor Signs First Post-Roe Abortion Ban, With Limited Exceptions*, N.Y. TIMES (Aug. 5, 2022), https://www.nytimes.com/2022/08/05/us/indiana-abortion-vote.html [https://perma.cc/SK6V-BHWN]. This contrasts with "trigger laws" in other states, which were already on the books before *Dobbs* and took effect immediately or shortly after the *Dobbs* decision was issued. The Indiana law took effect on September 15, 2022, but was temporarily put on hold while the Indiana Supreme Court considers whether it violates the state's constitution. Meghan Messerly, *Indiana Supreme Court Allows Abortions to Continue Pending January Hearing*, POLITICO (Oct. 12, 2022), https://www.politico.com/news/2022/10/12/indiana-supreme-court-abortions-continue-00061569 [https://perma.cc/GH33-E4BL]. As of this writing, oral arguments have been scheduled for January 2023. *Id.* West Virginia followed Indiana's lead on September 16, 2022, becoming the second state to pass an abortion ban (with limited exceptions) after *Dobbs*. *See* Mary Kekatos & Nadine El-Bawab, *Near-Total Ban on Abortion Becomes Law in West Virginia*, ABC NEWS (Sept. 16, 2022), https://abcnews.go.com/Health/west-virginia-lawmakers-pass-total-ban-abortion/story?id=87744201 [https://perma.cc/5WX7-DXTH].

settled freedoms," including rights to contraceptives, same-sex intimacy, and same-sex marriage.[8]

Now more than ever since *Roe*, a person's access to abortion and other essential reproductive health care services depends on their state of residence and whether they have the means to travel to a state that protects access to abortion care. Importantly, *Dobbs* affects access to both surgical and medical abortions.[9] Fierce and ongoing battles over abortion, contraception, and myriad other health-care issues raise thorny questions that require new legal, regulatory, and policy frameworks. The conflicts demand serious consideration about whether health-care federalism—the division of power between the federal and state governments with respect to the regulation of health care—remains necessary or wise, particularly as health care and the practice of medicine increasingly cross state and even international lines. Importantly, state bans and restrictions involve more than just matters of federalism; they concern life and death.[10]

The negative externalities of health-care federalism exposed and brought to the fore in the lead-up to *Dobbs* require urgent attention. Yet the underlying issues are not new. Health-care federalism has long created barriers to necessary health care. Take "Carla," for example, a resident of Texas who sought an abortion in 2015 after learning she was pregnant at around five weeks gestation.[11] Given the early stage of her pregnancy, she believed that a medication abortion—which she preferred over a surgical abortion—would be an option.[12] She soon discovered, however, that a long drive to the nearest abortion clinic in Texas, a mandatory twenty-four-hour waiting period, and a long wait for the first available appointment meant she would be unable to obtain the medication in the time frame required by the Texas laws in place at the time.[13] Desperate, Carla found a clinic in New Mexico and made a "nightmare" 600-mile, 12-hour trip in dangerous winter conditions; she felt she had no other option and "every minute counted."[14] Tragically, Carla is not alone. For years, millions of women and pregnancy-capable persons[15] have faced similar and increasingly burdensome obstacles when seek-

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[8] *Dobbs*, slip op. at 4 (Breyer, Sotomayor, and Kagan, JJ., dissenting).

[9] There are also concerns that *Dobbs* could impact access to certain methods of contraception. *See infra* Part II.B.

[10] *See* Li Cohen, *"People Will Die": OB-GYNs Explain How Ectopic Pregnancy and Other Complications Threaten Lives Without Abortion Care*, CBS NEWS (July 1, 2022), https://www.cbsnews.com/news/abortion-doctors-ectopic-pregnancy-risk/ [https://perma.cc/QA9C-QL8Q].

[11] Jenna Jerman et al., *Barriers to Abortion Care and Their Consequences for Patients Traveling for Services: Qualitative Findings from Two States*, 49 PERSP. ON SEXUAL & REPROD. HEALTH 95, 99–100 (2017). As noted, Carla's experience occurred in 2015, prior to the decision in *Dobbs* and while *Roe* remained good law.

[12] *Id.* at 100.

[13] *Id.*

[14] *Id.*

[15] Abortion is often framed as a "woman's" issue, but transgender, nonbinary, and gender-nonconforming people may also become pregnant and need abortions. Whenever

ing both medication and surgical abortions.[16] With *Roe* and *Casey* overturned, this number will only continue to grow.[17]

With respect to medication abortion specifically, barriers arise from medically unnecessary federal and state restrictions imposed on mifepristone, a drug approved by the U.S. Food and Drug Administration (FDA) as safe and effective for the termination of intrauterine pregnancy through seventy days gestation.[18] Moreover, medication abortion is now also swept up in laws banning all abortions—medical and surgical—in certain states.[19] As described further in Part II.A., a recent decision by the FDA in December 2021 to relax some of the federal restrictions on mifepristone represents an important step toward removing barriers to medication abortion, particularly for low-income populations, people of color, rural communities, persons with disabilities, and others for whom travel may be logistically or financially difficult or impossible.[20] Yet the FDA's gradual easing of restrictions

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possible, this Article uses gender-neutral language. The term "woman" or "women" may be used, particularly where the literature/sources being discussed use that terminology.

[16] *See, e.g.*, Danielle Campoamor, *39 Abortion Stories Show Just How Important Abortion Access Is*, TEEN VOGUE (Jan. 9, 2020), https://www.teenvogue.com/story/abortion-stories [https://perma.cc/YF5F-72KJ]; Bianca Flowers, *As Supreme Court Signals Shift on Abortion, 3 Women Share the True Cost of Accessing One—Or Being Denied*, MARKETWATCH (Dec. 4, 2021), https://www.marketwatch.com/story/as-supreme-court-weighs-abortion-heres-the-true-cost-of-traveling-out-of-state-to-access-one-or-being-denied-altogether-11638393341 [https://perma.cc/9LY9-D3Z7] (reporting the experiences of three women, one of whom had to travel out-of-state to access medication abortion after Texas passed a law restricting access to medication abortion); Angela M. Hill & Karen Rodriguez, *Prescription Denied: Accessing the Abortion Pill*, NEWSY (July 9, 2020), https://www.newsy.com/stories/abortion-pill-access-restricted-by-fda/ [https://perma.cc/FLE5-CMRR] (recounting the experience of a woman who had to make multiple six-hour, round-trip drives to Mississippi's only abortion clinic to obtain a medication abortion).

[17] Benjamin Rader et al., *Estimated Travel Time and Spatial Access to Abortion Facilities in the US Before and After the* Dobbs v. Jackson Women's Health *Decision*, 328 JAMA 2041, 2045–46 (2022) (finding that the estimated travel time to abortion facilities in the United States was significantly increased in the post-*Dobbs* period).

[18] *MIFEPREX® (mifepristone) Prescribing Information*, U.S. FOOD & DRUG ADMIN. (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/020687s022lbl.pdf [https://perma.cc/HFJ7-EZ6F] [hereinafter *MIFEPREX® (mifepristone) Prescribing Information 2016*, U.S. FOOD & DRUG ADMIN.]; *see also infra* Part II.A.

[19] *See Tracking the States Where Abortion is Now Banned*, N.Y. TIMES, *supra* note 7; Spencer Kimball, *Women in States that Ban Abortion Will Still Be Able to Get Abortion Pills Online from Overseas*, CNBC (June 27, 2022), https://www.cnbc.com/2022/06/27/women-in-states-that-ban-abortion-will-still-be-able-to-get-abortion-pills-online-from-overseas.html [https://perma.cc/Q5JN-S5Y8] (noting that at least eight states banned all abortions immediately after *Dobbs*, including medication abortion). For example, a "trigger law" banning all abortions, with limited exceptions, took effect in Texas on August 25, 2022. TEX. HEALTH & SAFETY CODE § 170A.002. Texas law defines abortion to include, among other things, "using or prescribing . . . a medicine . . . with the intent to cause the death of an unborn child of a woman known to be pregnant." *Id.* §§ 170A.001, 245.002(1). Given this definition, medication abortion is now banned in Texas unless an exception applies.

[20] *See infra* notes 140–142 (describing the current mifepristone restrictions in effect after the December 2021 changes); *see also infra* Part III.B (discussing the negative consequences of pharmaceutical federalism).

on medication abortion has done little to combat the tidal wave of state restrictions.

Given the increasing use of medication abortion[21] and advocates' hope that it might provide a workaround for those living in states that severely restrict or ban abortion, it is no surprise that medication abortion became a target for anti-abortion legislators.[22] States with existing restrictions on medication abortion showed no signs of pulling back after the FDA's December 2021 decision and now, post-*Dobbs*, further restrictions and outright bans are in place or being contemplated.[23] And although some view medication abortion and the ability to access it through the mail as a potential workaround to abortion bans and severe restrictions,[24] there are risks involved if the person's state of residence bans the practice.[25] The future of medication abortion, and whether it represents the post-*Dobbs* panacea some hope, remains uncertain.

The *Dobbs* decision and the restrictive abortion legislation that followed suit make clear that issues of reproductive health raise some of the most politically contentious questions of our time. Unsurprisingly, medical and surgical abortions have been frequent targets for additional, burdensome, and medically unnecessary requirements long before the dismantling

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[21] Pregnant persons increasingly opt for medication abortion instead of surgical abortion, with 2020 marking the first year it comprised the majority (fifty-four percent) of U.S. abortions. Rachel K. Jones et al., *Medication Abortion Now Accounts for More than Half of All US Abortions*, GUTTMACHER INST. (Mar. 2, 2022), https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions [https://perma.cc/2WXF-2U7D].

[22] *See, e.g.*, Pam Belluck & Sheryl Gay Stolberg, *Abortion Pills Stand to Become the Next Battleground in a Post-Roe America*, N.Y. TIMES (May 5, 2022), https://www.nytimes.com/2022/05/05/health/abortion-pills-roe-v-wade.html [https://perma.cc/XRZ2-2FRC]; Dareh Gregorian & Ryan J. Reilly, *Garland Signals Brewing Battle with GOP-Led States Over Access to Abortion Pills*, NBC NEWS (June 24, 2022), https://www.nbcnews.com/politics/justice-department/garland-signals-brewing-battle-gop-led-states-access-abortion-pills-rcna35231 [https://perma.cc/59UC-BXEY]; Kate Zernicke, *Abortion Pills, Once a Workaround, Are Now a Target*, N.Y. TIMES (June 15, 2022), https://www.nytimes.com/2022/04/06/us/abortion-pills.html [https://perma.cc/KC7T-79CZ].

[23] Indeed, even before *Dobbs* overturned *Roe*, at least eight states had introduced legislation that would ban the drug completely. *See infra* notes 146–154 and accompanying text. And as noted, state laws that ban *all* abortions generally encompass a ban on medication abortion, as most states define abortion to include the prescription or use of medications with the intent of causing an abortion. *See* sources cited *supra* note 19.

[24] *See, e.g.*, Abigail Abrams, *Republican States Crack Down on Access to Abortion Pills as Supreme Court Decision Looms*, TIME (Apr. 12, 2022), https://time.com/6165848/abortion-pills-republican-states-roe-wade [https://perma.cc/8Z5W-Q95Q]; Shefali Luthra, *Is Medication Abortion an 'Existential Threat' to Abortion Restrictions?*, 19TH (Mar. 22, 2022), https://19thnews.org/2022/03/medication-abortion-state-restrictions/ [https://perma.cc/K7A3-GTRB]; Amy Weintraub & Fawn Bolak, *Medication Abortion is Key to the Future of Abortion Access*, REWIRE NEWS GRP. (Jan. 23, 2020), https://rewirenewsgroup.com/article/2020/01/23/medication-abortion-is-key-to-the-future-of-abortion-access/ [https://perma.cc/WX76-F3U3].

[25] *See infra* notes 299–327 and accompanying text.

of *Roe*.[26] That said, other pharmaceuticals[27] and medical procedures are not immune from state-level restrictions. Examples include states' attempts to restrict access to emergency contraception,[28] Massachusetts's attempted ban of an FDA-approved opioid,[29] and state classifications of controlled substances,[30] among others.[31] The regulation of future medical innovations, such as genomic and enhancement medicines, will likely foster similar frictions between federal and state authorities given their politically and ethically controversial nature.[32] Federalism tensions over pharmaceutical regulation thus transcend abortion, raising important and urgent questions about whether and to what extent states should have the authority to restrict access to pharmaceuticals that the FDA has determined to be safe and effective.

States typically impose restrictions on FDA-approved drugs pursuant to their "police powers," which have long been recognized to include the authority to make laws to protect public health and safety, including those that

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[26] *See* Allison M. Whelan & Michele Goodwin, *Abortion Rights and Disability Equality: A New Constitutional Battleground*, 79 WASH. & LEE L. REV. 965, 978 (2022) (noting that although "2021 marked the first time that states enacted more than one hundred abortion restrictions in a single year . . . the fierce push to curtail abortion rights began a decade prior, if not before"); Deepa Shivaram, *The Movement Against Abortion Rights is Nearing its Apex. But it Began Way Before Roe*, NAT'L PUB. RADIO (May 4, 2022), https://www.npr.org/2022/05/04/1096154028/the-movement-against-abortion-rights-is-nearing-its-apex-but-it-began-way-before [https://perma.cc/2GYD-X586].

[27] This Article uses the terms "pharmaceutical," "drug," or "medicine" to refer to drugs and biologics, including vaccines. *See* 21 U.S.C. § 321(g) (defining "drug"); 42 U.S.C. § 262(i)(1) (defining "biological product").

[28] *See infra* Part II.B.

[29] *See* Zogenix, Inc. v. Patrick, No. 14-11-689-RWZ, 2014 WL 1454696, at *1 (D. Mass. Apr. 15, 2014); *infra* notes 244–246 and accompanying text.

[30] For example, states can classify drugs as controlled substances under state law and/or move drugs to more restrictive Schedules under a state's controlled substances laws. *See, e.g.*, Lars Noah, *State Affronts to Federal Primacy in the Licensure of Pharmaceutical Products*, 2016 MICH. ST. L. REV. 1, 19–23 (2016) [hereinafter Noah, *State Affronts*]. Controlled substances may be subject to additional restrictions or requirements. Human chorionic gonadotropin (HCG) represents one drug that some states classify as a controlled substance that is not classified as such under federal law. *See, e.g.*, COLO. REV. STAT. § 18-18-205(e) (2022); *id.* § 18-18-102(3)(A)(X) (defining anabolic steroid to include HCG); N.Y. PUB. HEALTH LAW § 3306, Schedule III(g) (Consol. 2021).

[31] In recent years and with increasing fervor, states have sought to restrict gender-affirming health care for transgender youth, including prohibitions on the prescription of drugs used for gender transitioning. *See, e.g.*, *Legislative Tracker: Youth Healthcare Bans*, FREEDOM FOR ALL AM., https://freedomforallamericans.org/legislative-tracker/medical-care-bans/ [https://perma.cc/2WD9-J5EF] (tracking transgender medical care bans that have been filed). These laws, however, differ from state restrictions or bans on FDA-approved pharmaceuticals because currently there are no medications approved by the FDA for the purposes of gender affirmation or transition; all drugs for such uses are prescribed off-label. *See* Sophia Geffen et al., *Advocacy for Gender Affirming Care: Learning from the Injectable Estrogen Shortage*, 301 TRANSGENDER HEALTH 42, 43 (2018).

[32] These technologies may raise concerns about discrimination, eugenics, and the creation of "designer babies," for example. *See generally* Rachel Saady-Saxe, *An Analysis of State Interests in Regulating Germline CRISPR Use*, 12 ALA. C.R. & C.L. L. REV. 77 (2020) (exploring how increased parental access to evolving technology, like genome editing, may lead to eugenics and exacerbation of social inequity).

regulate the practice of medicine.[33] Scholars and courts assert that state police powers, and the doctrine of federalism generally,[34] promote numerous values, including (1) countering federal tyranny; (2) promoting democratic rule and accountability by providing citizens with more involvement in and influence over decision-making; (3) ensuring tailored approaches and responses to local problems; and (4) "allowing states to be laboratories for new ideas."[35]

This Article does not contest the important role that states play in regulating health care and protecting public health, nor does it suggest that states should have no role in regulating health care. That said, despite the potential benefits of federalism in certain circumstances, this Article questions whether the values of health-care federalism are, or even can be, achieved through state-level pharmaceutical regulation.[36] Today, the fragmentation caused by state restrictions on pharmaceuticals and health care harms, rather than protects and promotes, public and individual health.[37] Indeed, states may use their "laboratories" for ill rather than good.[38] This appears most glaringly in reproductive health, where state restrictions are often rooted in political, religious, or moral considerations of policymakers, absent any meaningful basis in science and medicine. In fact, state legislatures often go against current medical recommendations and standards of practice.[39] Troub-

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[33] The "practice of medicine" is difficult to define, and statutory definitions vary. Definitions often include treating diseases and conditions, which would include prescribing medication. *See* Lars Noah, *Ambivalent Commitments to Federalism in Controlling the Practice of Medicine*, 53 U. KAN. L. REV. 149, 162 & n.55 (2004) [hereinafter Noah, *Ambivalent Commitments*]; Patricia J. Zettler, *Toward Coherent Federal Oversight of Medicine*, 52 SAN DIEGO L. REV. 427, 435–37 (2015) [hereinafter Zettler, *Federal Oversight of Medicine*].

[34] "Federalism is a term that today is difficult to pin down." Gluck & Huberfeld, *supra* note 3, at 1696. For purposes of this Article, federalism, at the most basic level, refers to "the allocation of power between the federal and state governments." Erwin Chemerinsky, *The Values of Federalism*, 47 FLA. L. REV. 499, 504 (1995).

[35] *Id.* at 524–25; *see also* Gregory v. Ashcroft, 501 U.S. 452, 458–59 (1991) (discussing some of the values of federalism); Gluck & Huberfeld, *supra* note 3, at 1784–95 (discussing various values of federalism); Noah, *Ambivalent Commitments*, *supra* note 33, at 156 & n.29.

[36] *See supra* note 35 and accompanying text.

[37] *Cf.* Abigail R. Moncrieff & Joseph Lawless, *Healthcare Federalism*, *in* OXFORD HANDBOOK OF U.S. HEALTH LAW 96, 94 (I. Glenn Cohen et al. eds., 2017) ("[T]he presumed primacy of the American states in regulating health and medicine ha[s] been an important stumbling block for the growth of a rational healthcare system."); Zettler, *Federal Oversight of Medicine*, *supra* note 33, at 427 (discussing how state regulation of medical practice sometimes "drive[s] law and policy in directions that are problematic from a public health perspective").

[38] *See infra* Part III (examining the negative externalities of state pharmaceutical regulation).

[39] *See, e.g.*, *infra* note 361; Complaint at 7, Chelius v. Wright, No. 17-cv-00493-DKW (D. Haw. Oct. 3, 2017) (arguing that the mifepristone restrictions in effect at the time harmed patients by requiring a medically unnecessary trip, thereby potentially delaying or even precluding an abortion); Complaint at 4, Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., No. 20-cv-01320-TDC (D. Md. May 27, 2020) (arguing that the mifepristone restrictions in effect at the time subjected patients to an

lingly, the consequences of health-care federalism are most dire for vulnerable and historically marginalized populations, such as communities of color, the LGBTQ+ community,[40] persons with disabilities, and low-income populations—the very same communities historically ignored, exploited, or abused by the U.S. health-care system.[41] Consequently, health-care federalism can exacerbate and entrench health disparities and many forms of social inequity.[42] When states use their police powers for ill rather than good,

unnecessary risk of contracting COVID-19 by requiring patients to travel to pick up the medication in person); News Release, Am. Coll. Of Obstetricians & Gynecologists, ACOG Suit Petitions Court to Remove FDA's Burdensome Barriers to Reproductive Care During COVID-19 (May 27, 2020), https://www.acog.org/news/news-releases/2020/05/acog-suit-petitions-the-fda-to-remove-burdensome-barriers-to-reproductive-care-during-covid-19 [https://perma.cc/FV5E-7CJ3] (referring to the FDA's prior in-person dispensing requirement for mifepristone as "medically unnecessary").

[40] This Article's use of the acronym "LGBTQ+" should be read broadly. "LGBTQ+" includes but is not limited to lesbian, gay, bisexual, transgender, and queer people, including nonbinary, gender nonconforming, genderqueer, and questioning individuals.

[41] *See, e.g.*, Buck v. Bell, 274 U.S. 200, 205–07 (1927) (upholding a Virginia law authorizing the sterilization of "mental defectives"). *See generally* U.S. INST. OF MED. COMM. ON LESBIAN, GAY, BISEXUAL, AND TRANSGENDER HEALTH ISSUES AND RSCH. GAPS AND OPPORTUNITIES, THE HEALTH OF LESBIAN, GAY, BISEXUAL, AND TRANSGENDER PEOPLE: BUILDING A FOUNDATION FOR BETTER UNDERSTANDING 32 (2011) (describing how contemporary health disparities in the LGBTQ+ population "are rooted in and reflect the historical stigmatization of [LGBTQ+] people"); HARRIET WASHINGTON, MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT (2006) (providing a history of unethical and exploitative medical experimentation on Black Americans); Colleen C. Denny & Christine Grady, *Clinical Research with Economically Disadvantaged Populations*, 33 J. MED. ETHICS 382 (2007) (describing concerns about the exploitation of low-income populations in clinical research).

[42] Matters of equity matter within this space. While social justice concerns may not always be anticipated when thinking about the use of pharmaceuticals, one cannot separate an individual's need for medical care or particular medicines from their lived experiences and why they may need such care. To make this more concrete, consider the COVID-19 pandemic's disproportionate impact on Black Americans. Professor David Williams of Harvard University astutely notes how COVID-19, combined with the "pandemic of stress" experienced by Black Americans, "ma[de] everything that's already bad about a hundred times worse." David R. Williams, Opinion, *Stress Was Already Killing Black Americans. COVID-19 is Making it Worse.*, WASH. POST (May 13, 2020), https://www.washingtonpost.com/opinions/2020/05/13/stress-was-already-killing-black-americans-covid-19-is-making-it-worse/ [https://perma.cc/CTE6-FUY8]. Such chronic, persistent, daily stress impacts Black Americans' physical, mental, and emotional health in unique ways, coalescing to render them more susceptible to numerous health problems, including COVID-19. This chronic stress arises from multiple converging factors, including poverty, job insecurity, substandard housing, inaccessible or unaffordable health care, and systemic discrimination. And while "[s]tress is a normal part of life," these factors merge to expose Black Americans to higher rates of stress than white Americans. *Id.* Professor Williams urges that combatting the health problems—and the pandemic of stress—faced by Black Americans requires more than just targeting the disease itself. We must also target "the chronic stresses felt across black communities . . . We can't allow the added burden of stress to damage and shorten the lives" of these communities. *Id.; see also, e.g.*, ASTHMA & ALLERGY FOUND. OF AM., ASTHMA DISPARITIES IN AMERICA: A ROADMAP TO REDUCING BURDEN ON RACIAL AND ETHNIC MINORITIES 11, 14 (2020), https://www.aafa.org/media/2743/asthma-disparities-in-america-burden-on-racial-ethnic-minorities.pdf [https://perma.cc/6SXJ-Q7MC] (explaining how the burden of asthma in

there must be limits.[43]

This Article takes up these federalism concerns by examining as a case study state authority to restrict or ban the distribution, prescription, and use of FDA-approved pharmaceuticals. While this Article is informed by and draws upon state efforts to restrict or ban medication abortion and contraceptives given the current urgency of these issues, it illustrates a problem of greater magnitude. Increasing federal-state tensions and political polarization in the United States[44] render it likely, if not guaranteed, that states will continue to test how far they can go in regulating and restricting access to certain FDA-approved pharmaceuticals. Moreover, this examination of state-level pharmaceutical regulation—a concept described by Professor Patricia Zettler as "pharmaceutical federalism"[45]—exemplifies the far broader issue of health-care federalism generally.

This Article proceeds in four parts. Part I begins by providing a brief overview of the doctrine of preemption to inform the subsequent discussion and analyses. It then describes the division of labor between states and the federal government in the regulation of pharmaceuticals. Part II examines state bans and restrictions on FDA-approved pharmaceuticals, using medication abortion and contraceptives as case studies to expose the tensions that arise through health-care federalism. Part III then unpacks the negative externalities of state pharmaceutical regulation, illuminating how it disproportionately impacts vulnerable and historically marginalized communities and exacerbates health disparities and social inequities. Finally, Part IV first ex-

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the United States falls disproportionately on communities of color due, in part, to systemic racism, segregation, discriminatory policies, poverty, physical environment, employment, social support networks, and access to health care).

[43] Part IV.B of this Article proposes one such limit. *See infra* Part IV.B (recommending statutory and regulatory changes to clarify the preemptive force of FDA laws and regulations governing pharmaceuticals).

[44] Studies suggest polarization has increased in the United States. *See* Michael Dimock & Richard Wike, *America Is Exceptional in Its Political Divide*, PEW TR. MAG. (Mar. 29, 2021), https://www.pewtrusts.org/en/trust/archive/winter-2021/america-is-exceptional-in-its-political-divide [https://perma.cc/HG37-NSNB] (arguing that the COVID-19 pandemic has shown how deeply divided U.S. politics are compared to other nations); Levi Boxell et al., *Cross-Country Trends in Affective Polarization* 2 (Nat'l Bureau of Econ. Rsch., Working Paper No. 26669, 2021), https://www.nber.org/system/files/working_papers/w26669/w26669.pdf [https://perma.cc/DX79-G2R6] (finding that affective polarization has increased in the United States over the past four decades); *see also* Jacob M. Grumbach, *From Backwaters to Major Policymakers: Policy Polarization in the States, 1970–2014*, 16 PERSP. ON POL. 416, 417 (2018) (reporting that "[h]ealth and welfare [state] polic[ies] ha[ve] sharply polarized in recent years"); Jennifer Karas Montez et al., *US State Policies, Politics, and Life Expectancy*, 98 MILBANK Q. 668, 673–74 (2020) (discussing how an increase in policymaking authority among the states has led to increasing polarization of policies across the states); Jennifer Karas Montez, *US State Polarization, Policymaking Power, and Population Health*, 98 MILBANK Q. 1033, 1039–41 (2020) (describing how one consequence of policy polarization among the states is that where an individual lives can have a profound impact on an individual's health and well-being).

[45] *See* Patricia J. Zettler, *Pharmaceutical Federalism*, 92 IND. L.J. 845, 849 (2017) [hereinafter Zettler, *Pharmaceutical Federalism*].

amines the potential preemptive force of the Food, Drug, and Cosmetic Act (FDCA) with respect to state restrictions and bans on FDA-approved pharmaceuticals. Finding no clear answer to that question, Part IV continues by picking up where other scholars have left off, proposing potential solutions to address the ambiguities of preemption.

I. An Overview of Preemption & Health-care Federalism

The Supremacy Clause of the U.S. Constitution gives rise to frequent tensions between the federal and state governments in the regulation of health care. This Part first provides a general overview of the doctrine of preemption and then proceeds to briefly describe the history and current status of the division of authority between the states and federal government in the regulation of pharmaceuticals.

A. Preemption: A Brief Overview

The Supremacy Clause, found in Article VI, Clause 2, of the U.S. Constitution, provides that the "Constitution, and the Laws of the United States which shall be made in Pursuance thereof . . . shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."[46] This language provides the foundation for the doctrine of federal preemption, under which federal law supersedes conflicting state laws. Frequent claims by the U.S. Supreme Court might imply that general questions of preemption are settled. The Court succinctly suggests as much in *Hillsborough County v. Automatic Medical Laboratories*, where it states that "[i]t is a familiar and well-established principle that the Supremacy Clause . . . invalidates state laws that 'interfere with, or are contrary to,' federal law."[47]

The reality, however, is that questions of preemption remain far from resolved. The "presumption against preemption,"[48] for example, raises significant scholarly and judicial debate about when the presumption is appro-

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[46] U.S. Const. art. VI, cl. 2.

[47] Hillsborough Cnty, Fla. v. Automatic Med. Labs., 471 U.S. 707, 712–13 (1985) (quoting Gibbons v. Ogden, 9 Wheat 1, 211 (1824)); *see also, e.g.*, Morris v. Jones, 329 U.S. 545, 553 (1947) ("[W]here there is [a collision between state and federal law], the action of a State under its police power must give way by virtue of the Supremacy Clause."); Mayo v. United States, 319 U.S. 441, 445 (1943) ("Since the United States is a government of delegated powers, none of which may be exercised throughout the Nation by any one state, it is necessary for uniformity that the laws of the United States be dominant over those of any state. Such dominancy is required also to avoid a breakdown of administration through possible conflicts arising from inconsistent requirements. The supremacy clause of the Constitution states this essential principle.").

[48] *See, e.g.*, Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947) ("[W]e start with the assumption that the historic police powers of the States were not to be superseded by [a federal law] unless that was the clear and manifest purpose of Congress.").

priate versus when federal law should reign supreme.[49] Professor Viet D. Dinh and other scholars note the inconsistent and unpredictable nature of preemption and how the Court's application of the presumption has waxed and waned over time.[50] According to Professor Dinh, "[n]otwithstanding its repeated claims to the contrary, the Supreme Court's numerous preemption cases largely follow no predictable jurisprudential or analytical pattern."[51] This unpredictability proves problematic, because the presence or absence of preemption affects issues of national importance.[52]

Over time, Supreme Court jurisprudence has developed to recognize two general types of preemption: express and implied.[53] Congressional purpose represents the "ultimate touchstone" of the Court's preemption analysis.[54] Express preemption is relatively straightforward and more predictable: it occurs when a federal law or regulation contains explicit preemptive language.[55] Implied preemption, on the other hand, raises far more complicated

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[49] *See, e.g.*, S. Candice Hoke, *Preemption Pathologies and Civic Republican Values*, 71 B.U. L. Rev. 685, 687–88, 765–66 (1991) (cautioning against the continuation of a trend favoring federal preemption of state and local law); Marin R. Scordato, *Federal Preemption of State Tort Claims*, 35 U.C. Davis L. Rev. 1, 29–31 (2001) (criticizing the presumption against preemption). *See generally* Deborah J. Merritt, *Federalism as Empowerment*, 47 Fla. L. Rev. 541 (1995) (supporting federalism as a means of empowering different levels of government to deal with social problems).

[50] Viet D. Dinh, *Reassessing the Law of Preemption*, 88 Geo. L.J. 2085, 2085 (2000).

[51] *Id.*; *see also* Hope Babcock, *Can Vermont Put the Nuclear Genie Back in the Bottle?: A Test of Congressional Preemptive Power*, 39 Ecol. L.Q. 691, 730 (2012) (noting how the presumption against preemption and the focus on congressional intent "involves wide swathes of judicial discretion, making any particular outcome of a preemption case highly unpredictable"); Erwin Chemerinsky, *Empowering States When It Matters: A Different Approach to Preemption*, 69 Brook. L. Rev. 1313, 1314 (2004) (arguing that the Rehnquist Court shifted the presumption in favor of preemption); Gregory M. Dickinson, *Calibrating Chevron for Preemption*, 63 Admin. L. Rev. 667, 668 (2011) ("For years now, courts and commentators have struggled to reconcile the presumption against preemption . . . The Court's unpredictable approach sows uncertainty among regulated parties, the lower courts, and the agencies themselves."); Hoke, *supra* note 49, at 733 (calling the Supreme Court's adherence to the presumption against preemption "fickle"); Robert S. Peck, *A Separation-of-Powers Defense of the "Presumption Against Preemption"*, 84 Tul. L. Rev. 1185, 1186 (2010) (referring to the "ping-pong nature of the Court's treatment of" the presumption).

[52] *See* Chemerinsky, *supra* note 34, at 501.

[53] Gade v. Nat'l Solid Wastes Mgmt. Ass'n, 505 U.S. 88, 98 (1992).

[54] Wyeth v. Levine, 555 U.S. 555, 565 (2009) (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996)).

[55] One example of an express preemption provision found in the FDCA relates to medical devices, stating:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The provision includes a process by which states can apply for an exemption from preemption when "required by compelling local conditions." *Id.*

questions, producing much debate over whether and when federal law preempts state law. The doctrine of implied preemption makes it difficult to predict whether a court will find a state law preempted under one or more categories of implied preemption.

The Supreme Court breaks down implied preemption into "field preemption" and "conflict preemption."[56] Field preemption occurs "when the scope of a [federal] statute indicates that Congress intended federal law to occupy a field exclusively."[57] This intent can be reflected when the scheme of federal regulation is "so pervasive as to make reasonable the inference that Congress left no room for States to supplement it" or where federal law concerns "a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject."[58] Scholars note that field preemption is relatively rare in Supreme Court jurisprudence.[59]

Conflict preemption consists of two subcategories, occurring when (1) it is impossible to simultaneously comply with both federal and state law or regulation ("impossibility preemption")[60] or (2) the state law poses an obstacle to the accomplishment of Congress's purposes and objectives ("obstacle preemption").[61] According to the Court, impossibility preemption is a "demanding defense."[62] The case law is not well developed, but recent decisions about generic prescription drug labeling appear to expand the doctrine.[63] In analyzing obstacle preemption, "the Court has held that state law can interfere with federal goals by frustrating Congress's intent to adopt a uniform system of federal regulation, conflicting with Congress's goal of establishing a regulatory 'ceiling' for certain products or activities, or by impeding the vindication of a federal right."[64] Obstacle preemption does not,

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§ 360k(b)(2)(a); *see also infra* note 331 (listing other preemption provisions in the FDCA).

[56] *Gade*, 505 U.S. at 98.

[57] Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995).

[58] Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947).

[59] *See, e.g.*, THOMAS O. MCGARITY, THE PREEMPTION WAR 109, 264–65 (2008) ("The Supreme Court has applied field preemption sparingly to state common law claims, and the lower courts have followed suit."); *see also* PETER BARTON HUTT ET AL., FOOD AND DRUG LAW: CASES AND MATERIALS 435 (5th ed. 2022) (citing cases and reporting that courts have generally "resisted finding field preemption in areas covered by the [FDCA]"). For examples of where the Supreme Court has found field preemption, see Arizona v. United States, 567 U.S. 387, 401 (2012) (alien registration); Hines v. Davidowitz, 312 U.S. 52, 72–74 (1941) (alien registration); *Rice*, 331 U.S. at 218 (grain warehousing).

[60] Fla. Lime & Avocado Growers v. Paul, 373 U.S. 132, 142–43 (1963).

[61] *Hines*, 312 U.S. at 67.

[62] Wyeth v. Levine, 555 U.S. 555, 573 (2009).

[63] *See* Mutual Pharm. Co. v. Bartlett, 570 U.S. 472, 476 (2013); PLIVA, Inc. v. Mensing, 564 U.S. 604, 609 (2011); *infra* notes 371–382 and accompanying text.

[64] *See* JAY B. SYKES & NICOLE VANATKO, CONG. RSCH. SERV., FEDERAL PREEMPTION: A LEGAL PRIMER 25 (2019), https://sgp.fas.org/crs/misc/R45825.pdf [https://perma.cc/C97M-5GW7]. One example where the Supreme Court has found obstacle preemption relates to foreign sanctions. *See* Crosby v. Nat'l Foreign Trade Council, 530 U.S. 363, 366 (2000).

however, justify a "freewheeling judicial inquiry" into whether state laws are "in tension" with federal objectives, because Congress, not the judiciary, should be the body deciding whether to preempt state law.[65] Yet in practice, the courts possess "wide swathes of judicial discretion" when considering preemption.[66]

With that necessary background, the remaining sections in this Part explore the current and historical division of labor between federal and state governments in the regulation of health care, using the regulation of pharmaceuticals as a case study. Notwithstanding the state's traditional role in regulating health care and the practice of medicine,[67] the subsequent discussions in this Article explicate how the changing nature of medical practice raises serious questions about the logic of continuing to show strong deference to such state authority.[68] Increasingly, the provision of health care crosses state—and even international—lines.[69] The need for such travel may be compelled by state restrictions.[70] The claim that "[a]ll health care is lo-

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[65] Chamber of Com. v. Whiting, 563 U.S. 582, 607 (2011).

[66] Babcock, *supra* note 51, at 730.

[67] *See infra* Part I.C.

[68] Carl F. Ameringer, *State-Based Licensure of Telemedicine: The Need for Uniformity But Not a National Scheme*, 14 J. HEALTH CARE L. & POL'Y 55, 55 (2011) ("Over the last forty years, the practice of medicine in the United States has advanced from a predominantly isolated and local undertaking to a national and even international concern."); Nicole Huberfeld, *Federalizing Medicaid*, 14 U. PA. J. CONST. L. 431, 476 (2011) ("The practice of medicine is increasingly nationalized.").

[69] *See, e.g.*, Jacob D. Langley et al., *Empirical Analysis of Domestic Medical Travel for Elective Cardiovascular Procedures*, 19 AM. J. OF MANAGED CARE (Oct. 2013), https://www.ajmc.com/view/empirical-analysis-of-domestic-medical-travel-for-elective-cardiovascular-procedures [https://perma.cc/Y37S-ZSEM] (describing how patients travel to receive care from "high-volume providers," i.e., those with experience treating large numbers of patients with a particular condition); *Medical Tourism: Travel to Another Country for Medical Care*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 19, 2021), https://wwwnc.cdc.gov/travel/page/medical-tourism [https://perma.cc/C53V-UET5] (reporting that millions of Americans travel to another country for medical care each year); Katie Fairbanks, *To Save on Surgery, Out-of-State Patients Travel to Washington's Longview*, SEATTLE TIMES (Feb. 17, 2019), https://www.seattletimes.com/seattle-news/health/longview-surgery/ [https://perma.cc/V7XN-UHZ4] (describing a growing trend of "medical travel"); Harris Meyer, *Families With Sick Kids on Medicaid Seek Easier Access to Out-of-State Hospitals*, NAT'L PUB. RADIO (Apr. 5, 2021), https://www.npr.org/sections/health-shots/2021/04/05/984435809/families-with-sick-kids-on-medicaid-seek-easier-access-to-out-of-state-hospitals [https://perma.cc/K27L-4ABT] (reporting that children with complex medical needs often require care from out-of-state hospitals).

[70] *See generally* Katrina Kimport, *Reducing the Burdens of Forced Abortion Travel: Referrals, Financial and Emotional Support, and Opportunities for Positive Experiences in Traveling for Third-Trimester Abortion Care*, 293 SOC. SCI. & MED. 1 (2022) (describing how state abortion bans based on gestational duration reduce the availability of in-state abortion care and how that contributes to the need to travel out-of-state for abortion care); Mikaela H. Smith et al., *Abortion Travel Within the United States: An Observational Study of Cross-State Movement to Obtain Abortion Care in 2017*, 10 LANCET REG'L HEALTH—AMS. (June 2022) (describing how pregnant people often travel across state lines to access care if they live in a state with abortion restrictions and few abortion providers). For surrogacy, current law in Louisiana makes it illegal for same-sex couples to enter into surrogacy contracts because the law requires couples to use their own sperm

cal,"[71] while often true, can no longer withstand close scrutiny in many contexts.[72] Many individuals, by choice or necessity, now travel to other states or even other countries to obtain health care.[73] Or they may receive care at home via telemedicine from a provider in another state.[74] Indeed, the use of—and need for—telemedicine increased dramatically during the COVID-19 pandemic,[75] a trend that many hope will continue post-pandemic.[76]

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and egg, an impossibility for same-sex couples. *See* LA. STAT. ANN. § 9:2720.2(A)(1) (2021). Same-sex intended parents residing in Louisiana are advised to choose a surrogate from a more surrogacy-friendly state or country. *See What You Need to Know About Surrogacy in Louisiana*, AM. SURROGACY, https://www.americansurrogacy.com/surrogacy/lousiana-surrogacy-laws [https://perma.cc/5LXK-2Y9D]; *The Logistics of Completing a Surrogacy Across State Lines*, AM. SURROGACY BLOG (July 6, 2018), https://www.americansurrogacy.com/blog/the-logistics-of-completing-a-surrogacy-across-state-lines/ [https://perma.cc/5N87-BAFN] ("[I]f you live in a state that is not surrogacy-friendly, you can still become parents with a surrogate from another state. Indeed, this will likely be your best path of action.").

[71] Rene Bowser, *The Affordable Care Act and Beyond: Opportunities for Advancing Health Equity and Social Justice*, 10 HASTINGS RACE & POVERTY L.J. 69, 103 (2013); *see* Symposium, *Health Care Reform Symposium*, 26 AKRON L. REV. 137, 144 (1992).

[72] *See, e.g.*, John T. Finnell et al., *All Health Care is Not Local: An Evaluation of the Distribution of Emergency Department Care Delivered in Indiana*, AMIA ANN. SYMP. PROC. 409, 415 (2011).

[73] *See, e.g.*, sources cited *supra* notes 69–70 and accompanying text.

[74] A provider's ability to provide telemedicine services to an out-of-state patient depends on state law. *See Cross-State Licensing*, CTR. FOR CONNECTED HEALTH POL'Y, https://www.cchpca.org/topic/cross-state-licensing-professional-requirements/ [https://perma.cc/7XN3-VQHT]. In addition to state laws regulating telemedicine generally, additional restrictions may be imposed on the use of telemedicine for abortion care. *See* Pien Huang & Mara Gordan, *Telehealth Abortion Demand is Soaring. But Access May Come Down to Where You Live*, NAT'L PUB. RADIO (May 20, 2022), https://www.npr.org/sections/health-shots/2022/05/20/1099179361/telehealth-abortions-are-simple-and-private-but-restricted-in-many-states [https://perma.cc/6UE3-VSLR].

[75] *See U.S. States and Territories Modifying Requirements for Telehealth in Response to COVID-19*, FED'N OF STATE MED. BDS. (Nov. 15, 2022), https://www.fsmb.org/siteassets/advocacy/pdf/states-waiving-licensure-requirements-for-telehealth-in-response-to-covid-19.pdf [https://perma.cc/G9RB-PAPF]; Matt Volz, *The Boom in Out-of-State Telehealth Threatens In-State Providers*, KAISER HEALTH NEWS (Mar. 15, 2021), https://khn.org/news/article/the-boom-in-out-of-state-telehealth-threatens-in-state-providers/ [https://perma.cc/5V4W-E7NQ]. According to one report, overall utilization of telemedicine for office visits and outpatient care was seventy-eight times higher in April 2020 than in February 2020, and as of mid-2021, it remained thirty-eight times higher than pre-COVID-19 levels. Oleg Bestsennyy et al., *Telehealth: A Quarter-Trillion-Dollar Post-COVID-19 Reality?*, MCKINSEY & CO. (July 9, 2021), https://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/telehealth-a-quarter-trillion-dollar-post-covid-19-reality [https://perma.cc/S5RF-5NWM]; *see also* LOK WONG SAMSON ET AL., ASS'T SEC. FOR PLAN. & EVAL., OFF. OF HEALTH POL'Y, MEDICARE BENEFICIARIES' USE OF TELEHEALTH IN 2020: TRENDS BY BENEFICIARY CHARACTERISTICS AND LOCATION 1 (2021) https://aspe.hhs.gov/sites/default/files/documents/a1d5d810fe3433e18b192be42dbf2351/medicare-telehealth-report.pdf [https://perma.cc/2CZM-G8UW] (reporting a sixty-three-fold increase in telehealth visits among Medicare fee-for-service beneficiaries in 2020 compared to 2019).

[76] Results from the Telehealth Impact Study, for example, suggest that patients and physicians like telemedicine and want it to continue after the pandemic ends. *See* Tanya Albert Henry, *Patients, Doctors Like Telehealth. Here's What Should Come Next*, AM. MED. ASS'N (May 17, 2021), https://www.ama-assn.org/practice-management/digital/patients-doctors-telehealth-here-s-what-should-come-next [https://perma.cc/GNH6-YFP9]

Moreover, the federal government has long regulated areas that implicate the practice of medicine, both directly and indirectly.[77] Federal laws, regulations, and guidelines address issues such as (1) controlled substances;[78] (2) opioid prescribing practices;[79] (3) prescriber requirements for drugs approved with Risk Evaluation and Mitigation Strategies (REMS);[80] (4) requirements for prescription drug samples;[81] (5) prohibitions on physician self-referrals;[82] (6) prohibitions on off-label use of human growth hormone;[83] (7) exclusion of health-care professionals from participation in federal health-care programs for certain offenses;[84] and (8) prohibitions on the off-label use of COVID-19 vaccines authorized or approved by the FDA.[85]

(finding that seventy-nine percent of patients were very satisfied with care received in their last telehealth visit and sixty-eight percent of physicians were motivated to increase telehealth use in their practice). Detailed information about the study, including results and analyses, can be found here: COVID-19 Healthcare Coal. Telehealth Impact Study Work Grp., *COVID-19 Telehealth Impact Study*, COVID-19 HEALTHCARE COAL., https://c19hcc.org/telehealth/impact-home/ [https://perma.cc/4PHL-MLXZ]; *see also* Jintendra Singh et al., *Telemedicine During COVID-19 Crisis and in Post-Pandemic/Post-Vaccine World—Historical Overview, Current Utilization, and Innovative Practices to Increase Utilization*, 10 HEALTHCARE (2022) (arguing in favor of continued utilization of telemedicine technologies). Some of the changes to telemedicine laws and regulations that took effect during COVID-19 have been made permanent. *See, e.g.*, Health Res. & Servs. Admin., *Telehealth Policy Changes After the COVID-19 Public Health Emergency*, TELEHEALTH.HHS.GOV, https://telehealth.hhs.gov/providers/policy-changes-during-the-covid-19-public-health-emergency/policy-changes-after-the-covid-19-public-health-emergency/ [https://perma.cc/SST7-WUP9] (last updated Nov. 23, 2022) (describing a few permanent changes).

[77] For a brief overview of the "long history of national interventions into state health regulation," see Gluck & Huberfeld, *supra* note 3, at 1703, 1706–16. Gluck and Huberfeld do not, however, discuss federal and state regulation of pharmaceuticals. *Id.* at 1716.

[78] *See, e.g.*, United States v. Moore, 423 U.S. 122, 141–42 (1975) (stating that provisions in the Controlled Substances Act "reflect the intent of Congress to confine authorized medical practice within accepted limits").

[79] *See, e.g.*, Deborah Dowell et al., *CDC Clinical Practice Guideline for Prescribing Opioids for Pain—United States, 2022*, 71 MORBIDITY & MORTALITY WKLY. REP. (2022).

[80] *See, e.g.*, sources cited *infra* note 104–105 and accompanying text.

[81] *See, e.g.*, 21 U.S.C. § 353(d).

[82] *See, e.g.*, 42 U.S.C. § 1395nn.

[83] *See, e.g.*, 21 U.S.C. § 333(e).

[84] *See, e.g.*, 42 U.S.C. § 1320a-7.

[85] COVID-19 vaccine providers were required to sign and adhere to a Centers for Disease Control and Prevention (CDC) COVID-19 Vaccination Program Provider Agreement, which required that "[t]he age of the vaccine recipient must align with the [FDA] Emergency Use Authorization or Approval of the vaccine administered," thereby preventing providers from using the vaccines off-label to vaccinate children of ages for which the vaccine had not yet been authorized or approved. *Vaccines for Children Program vs. CDC COVID-19 Vaccination Program*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/vaccines/covid-19/vfc-vs-covid19-vax-programs.html [https://perma.cc/AHH7-CL46]; *see also* CDC COVID-19 VACCINATION PROGRAM PROVIDER AGREEMENT 2 (Sept. 14, 2020), https://scdhec.gov/sites/default/files/media/document/COVID19-Vaccination_Program_Provider_Agreement_and_Profile_Form.pdf [https://perma.cc/V2HP-J2FQ]; Jennifer E. deSante-Bertkau et al., *Off-Label Prescrip-*

The establishment of the FDA, the expansion of the Agency's power throughout the twentieth and twenty-first centuries, and recent federal actions and initiatives that affect medical practice and the provision of health care coalesce to create an environment ripe for conflict between federal and state authorities over these areas.[86]

B. The Expansive Authorities of the U.S. Food and Drug Administration

In his thorough account of the FDA's power and status, Professor Daniel Carpenter highlights the Agency's "battery of vast powers."[87] Indeed, the FDA's authorities now extend well beyond the Agency's early gatekeeping role of approving pharmaceuticals[88] through an extensive pre- and postapproval regulatory regime.[89] Through its powers, the Agency wields great influence over many facets of life, spanning the economy, politics, national security, the practice of medicine, scientific research, and public and individual health. The FDA touches the lives of Americans every day, in ways both seen and unseen.

The origins of the modern FDA date back to the nineteenth century, with its powers generally expanding ever since.[90] The FDA now represents the primary regulator of pharmaceuticals in the United States. As Professor Zettler and others note, however, state laws and regulations can act as a "complement [to] FDA regulation by" regulating the practice of medicine and compensating patients injured by pharmaceuticals through product liability schemes.[91] This federalist division of labor has long been a feature of

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tion of COVID-19 Vaccines in Children: Clinical, Ethical, and Legal Issues, 149 PEDIATRICS 1, 4, 5 (2022).

[86] *Cf.* Noah, *Ambivalent Commitments*, *supra* note 33, at 158–59 (noting that the regulation of public health and the professions "has seen increasing federal involvement in recent years").

[87] DANIEL CARPENTER, REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA 1 (2010).

[88] Pharmaceuticals must receive FDA approval prior to marketing in the United States. 21 U.S.C. § 355(a) (drugs); 42 U.S.C. § 262(a)(2)(C) (biologics).

[89] S. Rep. No. 105–43, at 6 (1997) ("Over the years, Congress has dramatically expanded the reach and responsibilities of the FDA."); *see also Postmarketing Requirements and Commitments: Introduction*, U.S. FOOD & DRUG ADMIN. (Jan. 12, 2016), https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments [https://perma.cc/QG9P-DR9A] (noting some of the FDA's postapproval authorities); *Postmarketing Surveillance Programs*, U.S. FOOD & DRUG ADMIN. (Apr. 2, 2020), https://www.fda.gov/drugs/surveillance/postmarketing-surveillance-programs [https://perma.cc/2GKP-GZGY] (same).

[90] S. Rep. No. 105-43, at 6; *When and Why Was the FDA Formed?*, U.S. FOOD & DRUG ADMIN. (Mar. 28, 2018), https://www.fda.gov/about-fda/fda-basics/when-and-why-was-fda-formed [https://perma.cc/FT38-ZQUZ].

[91] Zettler, *Pharmaceutical Federalism*, *supra* note 45, at 859–60; *see also* HUTT ET AL., *supra* note 59, at 424 (noting that state and local governments also play an important role in regulating drugs); Catherine M. Sharkey, *States Versus FDA*, 83 GEO. WASH. L. REV. 1609, 1610–11 (2015) (describing how federal and state law simultaneously regulate drug safety through an ex ante regulatory regime enforced by the FDA and an ex post system enforced primarily through state tort laws).

the U.S. health-care system. Nonetheless, the federal government has taken on a larger role over time, particularly in the context of pharmaceutical regulation. These complementary and sometimes conflicting roles frequently result in tension.

The FDA's statutory mandate includes two critical parts, the first of which is "protect[ing] the public health by ensuring that . . . [human] drugs are safe and effective."[92] One way the FDA achieves this mission is through its gatekeeping function, whereby new drugs cannot be marketed in the United States until the FDA approves the drug based on the Agency's determination that the drug is safe and effective for its proposed use.[93]

A second and critical part of the FDA's mission, added to the FDCA in 1997 by the Food and Drug Administration Modernization Act (FDAMA),[94] provides that the FDA "shall . . . *promote* the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner."[95] This addition, which extends the FDA's mission beyond merely determining whether a drug is safe and effective, suggests that Congress intended the Agency to play a role in ensuring the "prompt[ ]" availability of safe and effective drugs that promote public health.[96] Indeed, many of FDAMA's amendments focused on improving the speed of the FDA's review of—and thus patient access to—new pharmaceuticals and other medical products.[97]

Other provisions of the FDCA support the interpretation that the FDA plays an important role in ensuring that drugs are not just safe and effective, but also made available to patients in a timely, reasonable, and not unduly

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[92] 21 U.S.C. § 393(b)(2)(B) (2018).

[93] *Id.* § 355(b), (d) (2018); 42 U.S.C. § 262(a)(2)(C) (2018).

[94] Pub. L. No. 105-115, § 406, 111 Stat. 2296, 2369 (1997).

[95] 21 U.S.C. § 393(b)(1) (emphasis added).

[96] *Id. But see* Noah, *State Affronts*, *supra* note 30, at 9 (arguing that, generally, FDA rules are "designed to restrict rather than promote ready patient access").

[97] Among other things, FDAMA added provisions to the FDCA to explicitly address expanded access to investigational therapies, codifying in the statute much of the content in FDA regulations promulgated in the late 1980s and early 1990s. These regulations were largely in response to HIV/AIDS activists fighting for access to investigational drugs and thus sought to promote public health by providing a mechanism for certain patients to access needed treatments in a more prompt and efficient manner. *See* Pub. L. No. 105-115, § 402, 111 Stat. 2296, 2365–67 (1997) (codified at 21 U.S.C. § 360bbb); Michael D. Greenberg, *AIDS, Experimental Drug Approval, and the FDA New Drug Screening Process*, 3 N.Y.U. J. LEGIS. & PUB. POL'Y 295, 296–97 (2000) (describing how activism in the beginning of the HIV/AIDS epidemic spurred a "gradual liberalization of FDA drug development guidelines"). For other examples, see Pub. L. No. 105-115, § 205, 111 Stat. 2296, 2337 (requiring the Secretary to consider the "least burdensome means" in certain requirements for devices) (amending section 513(i) of the FDCA)); Pub. L. No. 105-115, § 406, 111 Stat. 2296, 2369 (requiring the FDA to collaborate with other countries to "reduce the burden of regulation") (amending section 903 of the FDCA)); Pub. L. No. 105-115, § 412, 111 Stat. 2296, 2374 (allowing states to enact additional requirements for nonprescription drugs only if the requirements will not "unduly burden interstate commerce") (adding section 751 to the FDCA)).

burdensome manner.[98] These include the REMS provisions, which state that REMS may "not be unduly burdensome on patient access to the drug."[99] It stands to reason, therefore, that the FDA may interpret other types of restrictions similarly, including those imposed by states. That is, the Agency may view state bans and restrictions, particularly those not justified by current evidence, as placing an undue and impermissible burden on patient access to FDA-approved drugs.

The FDA's powers continue after product approval. For example, the FDA can mitigate drug safety concerns by regulating drug labeling, advertising, and marketing, among other things.[100] A drug's labeling must include "warnings and precautions"[101] and "contraindications."[102] More serious side effects, such as serious injury or death, may be highlighted in a "boxed warning."[103] The FDA may also require a REMS for "medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks."[104] Imposing a REMS requires a "complex balancing of safety and burdens on the health care system."[105] The FDA can also address safety concerns through myriad other postapproval authorities, such as warning letters, product recalls and seizures, civil money penalties, and criminal penalties for violations of the FDCA.[106]

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[98] By using the term "available," this Article does not suggest that the FDA's mission includes making sure drugs are *affordable*, and therefore more broadly *accessible* to all populations. The FDA is not involved directly with drug pricing. *See Frequently Asked Questions About CDER*, U.S. Food & Drug Admin. (Oct. 28, 2019), https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/frequently-asked-questions-about-cder [https://perma.cc/TKQ2-APS2] ("[T]he FDA has no legal authority to investigate or control the prices set by manufacturers, distributors and retailers.").

[99] 21 U.S.C. § 355-1(f)(2)(C). FDA guidance reiterates this. U.S. Food & Drug Admin., REMS: FDA's Application of Statutory Factors in Determining When a REMS is Necessary: Guidance for Industry 5 (2019), https://www.fda.gov/media/100307/download [https://perma.cc/E83R-F5JZ] [hereinafter FDA, REMS Guidance] ("The REMS should be designed to meet the relevant goals, not unduly impede patient access to the drug, and minimize the burden on the health care delivery system to the extent practicable."); *id.* at 9–10.

[100] *See generally* 21 C.F.R. Part 201 (labeling regulations); *id.* Part 202 (advertising regulations); *id.* Part 203 (marketing regulations).

[101] *Id.* §§ 201.57(a)(10), (c)(6); *see also* U.S. Food & Drug Admin., Guidance for Industry: Warnings and Precautions, Contraindications, and Boxed Warning Sections of Labeling for Human Prescription Drug and Biological Products—Content and Format 3–8 (2011), https://www.fda.gov/media/71866/download [https://perma.cc/LDK7-RQGW] [hereinafter FDA, Warning Label Guidance].

[102] 21 C.F.R. §§ 201.57(a)(9), (c)(5); *see also* FDA, Warning Label Guidance, *supra* note 101, at 8–11.

[103] 21 C.F.R. §§ 201.57(a)(4), (c)(1); *see also* FDA, Warning Label Guidance, *supra* note 101, at 11–12.

[104] *Risk Evaluation and Mitigation Strategies*, U.S. Food & Drug Admin. (Dec. 17, 2021), https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems [https://perma.cc/7AFU-NGUW]; *see also* 21 U.S.C. § 355-1; FDA, REMS Guidance, *supra* note 99, at 3.

[105] Patricia J. Zettler & Ameet Sarpatwari, *State Restrictions on Mifepristone Access—The Case for Federal Preemption*, 386 New Eng. J. Med. 705, 706 (2022).

[106] Some of these enforcement authorities require cooperation with other government authorities, such as the Department of Justice or the courts. *See generally* Kathryn B.

Despite the breadth of the FDA's authorities, the Agency's powers are not unlimited. Provisions of the FDCA and statements by Congress, the courts, the FDA, and scholars all recognize boundaries on the Agency's powers.[107] For example, Congress and the FDA make clear that neither intends for the Agency to regulate or interfere with the practice of medicine.[108] When passing the Drug Amendments of 1962, which expanded the FDA's gatekeeping powers by requiring manufacturers to prove both safety and efficacy prior to drug approval, Congress stated that the Act "should not interfere with the professional function of the physician. FDA clearance would assure physicians that a drug effectively produces certain physiological actions, but the physician, not the FDA, would determine whether these specific physiological effects would be useful or beneficial with respect to particular patients."[109] Of relevance to the preemption questions considered by this Article, this statement focuses on protecting and deferring to the professional autonomy of health-care providers, as opposed to protecting state autonomy in the regulation of the practice of medicine.[110]

Despite recognized limits on the FDA's authority, FDA laws and regulations inescapably influence the practice of medicine. As one district court explained, the assumption that the FDA does not regulate the practice of medicine "does not imply an absence of federal jurisdiction over the same area, where the federal regulation constitutes a reasonable exercise of a

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ARMSTRONG & JENNIFER A. STAMAN, CONG. RSCH. SERV., ENFORCEMENT OF THE FOOD, DRUG, AND COSMETIC ACT: SELECT LEGAL ISSUES (2018) (noting that the FDA's lack of independent litigating authority requires the agency to coordinate with other federal entities), https://sgp.fas.org/crs/misc/R43609.pdf [https://perma.cc/3YUP-JXHS]; *Types of FDA Enforcement Actions*, U.S. FOOD & DRUG ADMIN. (July 14, 2022), https://www.fda.gov/animal-veterinary/resources-you/types-fda-enforcement-actions [https://perma.cc/B3L9-6RVG].

[107] *See, e.g.*, 21 U.S.C. § 396 ("Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship."); Margaret Crews, *Pharmacogenomics: Tailoring the Drug Approval Process for Designer Drugs*, 24 J. CONTEMP. HEALTH L. & POL'Y 363, 372–73 (2008) (referring to limits on the FDA's postapproval study requirements); Noah, *Ambivalent Commitments*, *supra* note 33, at 173 (describing some of the times when Congress has addressed concerns about the FDA interfering with the practice of medicine); Zettler, *Pharmaceutical Federalism*, *supra* note 45, at 849 ("[C]ourts, lawmakers, and the FDA itself have long opined that state jurisdiction is reserved for medical practice."); U.S. FOOD & DRUG ADMIN., "OFF-LABEL" AND INVESTIGATIONAL USE OF MARKETED DRUGS, BIOLOGICS, AND MEDICAL DEVICES: GUIDANCE FOR INSTITUTIONAL REVIEW BOARDS AND CLINICAL INVESTIGATORS (1998) (noting that the FDA does not oversee the off-label use of drugs when used pursuant to the practice of medicine) [hereinafter U.S. FOOD & DRUG ADMIN., OFF-LABEL USE GUIDANCE].

[108] *See* Noah, *Ambivalent Commitments*, *supra* note 33, at 173; U.S. FOOD & DRUG ADMIN., OFF-LABEL USE GUIDANCE, *supra* note 107.

[109] *Drug Industry Antitrust Act: Hearing on S. 1552 Before the Subcomm. on Antitrust & Monopoly of the S. Comm. on the Judiciary*, 87th Cong. 1998 (1962) (statement of Eugene N. Beesley, President, Eli Lilly & Co., & Chairman, Pharm. Mfrs. Ass'n).

[110] *Cf.* Noah, *Ambivalent Commitments*, *supra* note 33, at 167.

power vested in Congress under the Constitution."[111] The FDA's authority to impose a REMS illustrates how FDA laws and regulations impact the practice of medicine: Even though the states have long governed the prescription authorities of health-care providers, the FDA may require that health-care providers who prescribe a REMS drug have particular training, experience, or special certification.[112]

As the next Section illuminates further, the expansion of the FDA's powers pushes up against the state's traditional role in regulating public health and safety. Federal and state authorities in this area find themselves increasingly in tension, thus making the issue ripe for debate and further consideration.

C. State Regulation of Health and Safety

The Supreme Court has long recognized the breadth of the states' police powers, which provide states with broad authority "to establish and enforce standards of conduct within [their] borders relative to the health of everyone there."[113] Back in 1909, for example, in *District of Columbia v. Brooke*, the Court stated that the "exercise of the police power" represents "one of the least limitable powers of the powers of government."[114]

Nevertheless, because the Constitution does not provide the exact scope of the police powers, questions arise about the limits on those powers. In the years following *Brooke*, the Court acknowledged the uncertain and indefinite boundaries,[115] which scholars continue to debate.[116] On one side are those who argue that the state "may do all that is not expressly prohibited by the express provisions of the Constitution."[117] On the other side are those who "contend that, because governments with unlimited power are a form of

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[111] Pharma. Mfrs. Ass'n v. Food & Drug Admin., 484 F. Supp. 1179, 1187 (D. Del. 1980) (citations omitted); *see also* United States v. Evers, 643 F.2d 1043, 1048 (5th Cir. 1981) ("[W]hile the Act was not intended to regulate the practice of medicine, it was obviously intended to control the availability of drugs for prescribing by physicians." (emphasis omitted)).

[112] *See* 21 U.S.C. § 355-1(f)(3)(A).

[113] Barsky v. Bd. of Regents of Univ., 347 U.S. 442, 449 (1954); Zettler, *Federal Oversight of Medicine*, *supra* note 33, at 446–53.

[114] District of Columbia v. Brooke, 214 U.S. 138, 149 (1909); *see also* Whalen v. Roe, 429 U.S 589, 598, 603 n.30 (1977) (making numerous references throughout to the breadth of state police powers); Sligh v. Kirkwood, 237 U.S. 52, 59 (1915) (describing state police powers as "far-reaching" in scope).

[115] *See, e.g.*, *Sligh*, 237 U.S. at 58 ("The limitations upon the police power are hard to define."); Eubank v. City of Richmond, 226 U.S. 137, 142 (1912) (describing police powers as "not susceptible to circumstantial precision").

[116] *Cf.*, Randy E. Barnett, *The Proper Scope of the Police Power*, 79 NOTRE DAME L. REV. 429, 429 (2004) ("When it comes to the power of states over their people, the issue has always been shrouded in doubt . . . [The Constitution's silence on scope of the police powers] has invited a fundamental choice between two ways of construing the scope of state power.").

[117] *Id* at 430.

tyranny, some limits to the powers of the states must be identified."[118] The language used by the Supreme Court to describe these powers, however, makes their breadth clear, giving states the authority to impose myriad laws and regulations across a spectrum of issues. More than a century ago, the Court explained that "[t]he power of the state to impose restraints and burdens upon persons and property in conservation and promotion of the public health, good order, and prosperity is a power originally and always belonging to the states . . . and essentially exclusive."[119]

State police powers include the authority to regulate professional occupations, such as the practice of medicine and pharmacy.[120] With respect to pharmaceuticals specifically, states engage in various forms of direct and indirect regulation, including outright bans and other restrictions, such as which health-care providers possess the authority to prescribe drugs, to whom pharmaceuticals can be prescribed and under what conditions, and the purposes for which drugs may be prescribed. States may also impose prescription requirements or other access restrictions, such as requiring a nonprescription drug to be placed "behind-the-counter,"[121] even when the FDA classifies the drug as nonprescription (i.e., "over-the-counter" (OTC)).[122] Further, state tort law and product liability law provide additional mechanisms for postapproval regulation.[123]

States typically have departments of health or similar entities responsible for pharmaceutical regulation, but they generally do not act like mini-FDAs. Rather, these departments focus on matters such as licensure and registration of drug manufacturers and distributors. Importantly, they do not review products for safety and efficacy or issue product approvals. These latter powers and responsibilities fall to the FDA.

Professor Lars Noah observes that historically, when "[q]uestions about the appropriate role of the federal government in supervising medical practice have arisen . . . in most cases these were resolved with an expressed

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[118] *Id.*

[119] Wilkerson v. Rahrer, 140 U.S. 545, 554 (1891).

[120] *See* Noah, *Ambivalent Commitments*, *supra* note 33, at 159 n.39 (collecting Supreme Court cases recognizing that state police powers justify state regulation of the practice of medicine).

[121] Federal law also requires this for certain products, including cold medicines that contain pseudoephedrine. *See* U.S. Food & Drug Admin., Legal Requirements for the Sale and Purchase of Drug Products Containing Pseudoephedrine, Ephedrine, and Phenylpropanolamine (2017), https://www.fda.gov/drugs/information-drug-class/legal-requirements-sale-and-purchase-drug-products-containing-pseudoephedrine-ephedrine-and [https://perma.cc/G5YR-XYFC]; *see also* 21 U.S.C. § 830(e)(1)(A)(i) (requiring behind-the-counter placement of certain products, including pseudoephedrine).

[122] *See* Part II for examples of state restrictions on FDA-approved pharmaceuticals; *see also* Noah, *Ambivalent Commitments*, *supra* note 33, at 171–72 (discussing state primacy in controlling pharmaceuticals).

[123] *See* sources cited *supra* note 91 and accompanying text.

commitment to non-interference."[124] This was even true in the *Lochner* era, during which the Supreme Court tended to strike down state economic regulations, yet continued to "give[ ] the states unusually broad latitude to regulate health and medicine, even while prohibiting the states from regulating other aspects of economic life."[125] That said, the Pure Food and Drug Act of 1906,[126] a precursor to the FDA's current regulatory regime, represents an important exception to state powers over health and medicine during this era. This Act "could claim constitutionality by limiting its reach to drugs as they actually traveled between or among states."[127]

Today, there are many reasons to question the propriety of health-care federalism and whether state-level control of health care achieves the alleged benefits of federalism.[128] As Professor Noah suggests, federal involvement in the regulation of medical practice may now be more "plausible" because "[t]he increasing reliance on the use of advanced technologies has transformed some of its purely local character, and many healthcare professionals work within large managed care networks or nationwide chains of hospitals."[129] Undoubtedly, greater federal involvement in the regulation of health care and medical practice will face obstacles, particularly with the current makeup of the Supreme Court and the Court's revival of a form of federalism that tends to lean toward protecting states' rights.[130] And while it is be-

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[124] Noah, *Ambivalent Commitments*, *supra* note 33, at 150; *see also* Moncrieff & Lawless, *supra* note 37, at 101–03 (describing the regulation of health care from the mid-nineteenth to mid-twentieth century, which was dominated almost entirely by state regulation and professional self-regulation).

[125] Moncrieff & Lawless, *supra* note 37, at 94; *see also* Nat'l Inst. of Fam. & Life Advocates v. Becerra, 138 S. Ct. 2361, 2382 (2018) (Breyer, J., dissenting) ("Even during the *Lochner* era, when this Court struck down numerous economic regulations concerning industry, this Court was careful to defer to state legislative judgments concerning the medical profession.").

[126] Pub. L. No. 59-384, 34 Stat. 768 (1906) (repealed 1938).

[127] Moncrieff & Lawless, *supra* note 37, at 101. However, the Pure Food and Drug Act did not achieve true national uniformity. *See generally* HUTT ET AL., *supra* note 59, at 429–30 (discussing the limits of the Act).

[128] *See supra* note 34 and accompanying text (listing the alleged benefits of federalism).

[129] Noah, *Ambivalent Commitments*, *supra* note 33, at 169.

[130] Moncrieff & Lawless, *supra* note 37, at 93–94 (describing the recent "federalism revival"). In recent years, however, the judiciary's tendency to support states' rights often seems to take a partisan approach. That is, the current Supreme Court has exhibited a pattern of protecting state powers, but only for certain, largely conservative-led states and/or when conservative-leaning policies are at issue, such as upholding anti-abortion laws and voter restrictions (conservative policies), while striking down or prohibiting gun restrictions and vaccine mandates (more liberal policies). *See generally* Dobbs v. Jackson Women's Health Org., No. 19-1392 (June 24, 2022) (overruling *Roe v. Wade* and *Planned Parenthood of Southeastern Pennsylvania v. Casey*, thereby returning complete control over abortion regulation to the states); Whole Woman's Health v. Jackson, No. 21-463 (Dec. 10, 2021) (allowing Texas ban on abortions after detection of fetal heartbeat to remain in effect); Merrill v. Milligan, No. 21–1086 (Feb. 7, 2022) (allowing Alabama to implement a redistricting plan being challenged as illegal racial gerrymandering); N.Y. State Rifle & Pistol Ass'n v. Bruen, No. 20–843 (2022) (overturning New York's proper-cause requirement for obtaining an unrestricted license to carry a concealed firearm);

yond the scope of this current Article to address the many areas of health care and medical practice that may be better served through a national regulatory regime, this Article tackles one important part: federalism in the control and regulation of pharmaceuticals.

II. State Regulation of Medication Abortion and Contraceptives

As described in Part I, the FDA wields significant authority over the regulation of pharmaceuticals. Prior to the establishment of the FDA, however, states frequently engaged in drug regulation.[131] This Part explores how states continue to do so, highlighting the most salient and urgent examples: medication abortion and contraceptives.[132]

A. Medication Abortion

Abortion, and matters of reproductive justice more generally, raise some of the most politically and ethically contentious questions of our time, making them "particularly vulnerable to sacrifice for political expediency."[133] Many states have long engaged in "abortion exceptionalism," sin-

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Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., No. 21A244 (Jan. 13, 2022) (per curiam) (granting stay of federal COVID-19 vaccine mandate for employers with more than 100 employees). The Court did, however, hand Republican lawmakers at least a temporary defeat in two cases involving congressional maps drawn by the North Carolina and Pennsylvania Supreme Courts. *See* Moore v. Harper, No. 21-1271 (Mar. 7, 2022) (declining, without explanation, Republican legislator's request for the Supreme Court to intervene, thus allowing North Carolina Supreme Court's new map to remain in effect); Toth v. Chapman, No. 21A57 (Mar. 7, 2022) (allowing redrawn map to remain in effect instead of the Republican-led legislature's map). The Court will consider the merits of *Moore* in the October 2022 term. *See* Amy Howe, *Justices Will Hear Case that Tests Power of State Legislatures to Set Rules for Federal Elections*, Howe on the Court (June 30, 2022), https://amylhowe.com/2022/06/30/justices-will-hear-case-that-tests-power-of-state-legislatures-to-set-rules-for-federal-elections/ [https://perma.cc/ETH4-TF4D].

[131] Zettler, *Pharmaceutical Federalism*, *supra* note 45, at 852–59 (describing the "long history" of state drug regulation and the emergence of the FDA as a response to disparate state laws); *see also* William F. Reindollar, *The Association of Food and Drug Officials*, 6 Food Drug Cosmetic L.J. 52, 54 (1951) (describing the creation and purposes of the Association of Food and Drug Officials, which sought to "promote and enforce the enactment of uniform laws . . . for the protection of the public health . . . in the production, manufacture, distribution and sale of . . . drugs").

[132] Opioids represent another prime example in recent years. *See infra* notes 244–246 and accompanying text.

[133] Sarah Christopherson & Olivia Snavely, *The FDA's Convoluted Stance on Abortion Pills Doesn't Protect Patients—It Endangers Them*, Nat'l Women's Health Network (May 8, 2020), https://nwhn.org/the-fdas-convoluted-stance-on-abortion-pills-doesnt-protect-patients-it-endangers-them/ [https://perma.cc/2QKJ-829S]. Currently, there seems to be no shortage of contentious and controversial issues facing society. Others include rights for LGBTQ+ persons, gun rights, and education policies. *See, e.g.*, Allison M. Whelan, *An Inclusive Approach to LGBTQ+ Abortion Rights*, Harv. Soc. Impact Rev. (Apr. 25, 2022), https://www.sir.advancedleadership.harvard.edu/articles/an-inclusive-approach-to-lgbtq-abortion-rights [https://perma.cc/G56W-4KTK] (mentioning recent legislative actions that single out and target the LGBTQ+ population); Terry Gross, *From Slavery to Socialism, New Legislation Restricts What Teachers Can*

gling out abortion with "unique, and uniquely burdensome, rules."[134] Abortion exceptionalism affects both surgical and medical abortion, and state encroachment on the FDA's regulatory authority over mifepristone foreshadows preemption conflicts on the horizon. After *Dobbs*, U.S. Attorney General Merrick Garland made the position of the Department of Justice (DOJ) clear, stating: "[T]he FDA has approved the use of the medication Mifepristone. States may not ban Mifepristone based on disagreement with the FDA's expert judgment about its safety and efficacy."[135] Yet not all agree with this position, setting the stage for battles to come.[136]

The FDA first approved mifepristone in a regimen with misoprostol for the termination of intrauterine pregnancy in 2000.[137] Mifepristone is currently approved by the FDA for use through seventy days gestation[138] but is available only through a restricted program called a REMS.[139] The mifepristone REMS has been modified over time. As of December 21, 2021, the primary components of the mifepristone REMS require that (1) the prescriber be certified to prescribe mifepristone, (2) the prescriber review the "Patient Agreement Form" with the patient and fully explain the risks, (3) the patient sign the Patient Agreement Form, and (4) pharmacies be certified to dispense mifepristone.[140] As a result of the most recent changes in December 2021, the REMS no longer requires that mifepristone be dispensed in person only from certain health-care settings, specifically clinics,

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Discuss, NAT'L PUB. RADIO (Feb. 3, 2022), https://www.npr.org/2022/02/03/1077878538/legislation-restricts-what-teachers-can-discuss [https://perma.cc/J48E-FD6C] ("Across the U.S., educators are being censored for broaching controversial topics . . . [such as] race, American history, politics, sexual orientation and gender identity."); Libby Cathey, *Why the Second Amendment May Be Losing Relevance in Gun Debate*, ABC NEWS (Oct. 28, 2021), https://abcnews.go.com/US/amendment-losing-relevance-gun-debate/story?id=79474562 [https://perma.cc/Z8VX-VNEA] (referring to the "bitter debate over gun control").

[134] Caitlin E. Borgmann, *Abortion Exceptionalism and Undue Burden Preemption*, 71 WASH. & LEE L. REV. 1047, 1048, 1048 n.2 (2014).

[135] Press Release, 22-663, U.S. Dep't of Justice, Att'y Gen. Merrick B. Garland Statement on Sup. Ct. Ruling in Dobbs v. Jackson Women's Health Org. (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/G27M-XQ58] [hereinafter Garland Statement].

[136] *See* Rachel Roubein, *Can States Outright Ban Abortion Pills? It's Unclear*, WASH. POST (May 20, 2022), https://www.washingtonpost.com/politics/2022/05/20/can-states-outright-ban-abortion-pills-it-unclear/ [https://perma.cc/7DMR-SAUA].

[137] *MIFEPREX™ (mifepristone) Tablets, 200 mg*, U.S. FOOD & DRUG ADMIN. (Sept. 28, 2000), https://www.accessdata.fda.gov/drugsatfda_docs/label/2000/20687lbl.pdf [https://perma.cc/4VE2-EZHA].

[138] *MIFEPREX® (mifepristone) Prescribing Information 2016*, U.S. FOOD & DRUG ADMIN., *supra* note 18.

[139] *See id.*; 21 U.S.C. § 355-1 (codifying the REMS requirement); *Risk Evaluation and Mitigation Strategies*, U.S. FOOD & DRUG ADMIN., *supra* note 104 (defining REMS); *supra* notes 104–105 and accompanying text.

[140] *Questions and Answers on Mifeprex*, U.S. FOOD & DRUG ADMIN. (Dec. 16, 2021), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex [https://perma.cc/2C5X-PP5D].

medical offices, and hospitals.[141] Importantly, the removal of this restriction opened the door for dispensing mifepristone through mail and certified pharmacies after a telemedicine appointment.[142]

Since its approval over twenty years ago, the FDA has consistently reaffirmed that mifepristone is safe and effective for its indicated use, reflected by the Agency's gradual easing of the REMS requirements. In fact, mifepristone is safer than many medications not subject to similar restrictions, including Viagra and penicillin, and it is also safer than carrying a pregnancy to term.[143] The remaining restrictions imposed by the FDA represent the culmination of years of extensive deliberation and ongoing review of the drug's safety and efficacy. Although some of the remaining FDA restrictions are considered medically unnecessary by leading medical groups,[144] the recent changes nevertheless bring the restrictions much closer in alignment with current data and medical practice.

Many state regulations and restrictions imposed on mifepristone are in direct conflict with the FDA's determinations, as well as those of leading medical organizations.[145] Even before the *Dobbs* decision, at least eight states[146]—Alabama,[147] Arizona,[148] Illinois,[149] Iowa,[150] Missouri,[151] South Da-

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[141] *Id.*

[142] *Id.*; Letter from Patrizia A. Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch., to Graham Chelius, Soc'y of Fam. Plan., Cal. Acad. of Fam. Physicians (Dec. 16, 2021), https://www.aclu.org/sites/default/files/field_document/fda_letter_to_chelius.pdf [https://perma.cc/MF86-XUH4] [hereinafter Cavazzoni Letter].

[143] *Analysis of Medication Abortion Risk and the FDA Report "Mifepristone U.S. Post-Marketing Adverse Events Summary Through 12/31/2018"*, ANSIRH ISSUE BRIEF (Apr. 2019), https://www.ansirh.org/sites/default/files/publications/files/mifepristone_safety_4-23-2019.pdf [https://perma.cc/684A-3DMT].

[144] *See, e.g.*, *Public Health Experts Call for an End to Overregulation of Mifepristone*, ANSIRH (Feb. 23, 2017), https://www.ansirh.org/research/research/public-health-experts-call-end-overregulation-mifepristone [https://perma.cc/73KH-V74M] (referring to the prescriber certification requirement as "unnecessary"); Letter from Soc'y of Fam. Plan. Bd. of Dirs. to Catherine Sewell, U.S. Food & Drug Admin. (Aug. 11, 2021), https://societyfp.org/wp-content/uploads/2021/08/SFP-letter_FDA-mifepristone-REMS_final.pdf [https://perma.cc/3K8Z-38BZ] ("Requiring provider certification and registration to prescribe mifepristone is unnecessary because it does not increase patient safety and constrains abortion provision.").

[145] *See, e.g.*, Comm. on Prac. Bulls.—Gynecology & the Soc'y of Fam. Plan., *Medication Abortion Up to 70 Days Gestation*, 136 OBSTETRICS & GYNECOLOGY e31, e31–32 (2020); Letter from Twenty-One Medical Organizations to the Honorable Joseph R. Biden, President, and the Honorable Kamala D. Harris, Vice President (Mar. 1, 2021), https://searchlf.ama-assn.org/letter/documentDownload?uri=%2Funstructured%2Fbinary%2Fletter%2FLETTERS%2F2021-3-1-Sign-On-Lettter-to-Biden-and-Harris-Administration-re-Mifepristone.pdf [https://perma.cc/L47L-98JF].

[146] *See generally* Caroline Kitchener et al., *The Latest Action on Abortion Legislation Across the States*, WASH. POST, https://www.washingtonpost.com/nation/interactive/2022/abortion-rights-protections-restrictions-tracker/ [https://perma.cc/P6DE-SP7H] (last updated May 2, 2022) (tracking the status of abortion legislation in state legislators). Although these specific bills did not or have not yet passed, they made clear that states were taking increasing interest in targeting medication abortion.

[147] H.B. 261, 2022 Leg., Reg. Sess. (Ala. 2022).

[148] H.B. 2811, 55th Leg., 2d Reg. Sess. (Ariz. 2022).

[149] H.B. 5231, 102d Gen. Assemb. (Ill. 2022).

kota,[152] Washington,[153] and Wyoming[154]—had introduced legislation with provisions that explicitly singled out mifepristone to ban its use entirely.[155] Post-*Dobbs*, complete bans on both medical and surgical abortions are now a reality in many states.[156]

In states with or considering abortion bans after *Dobbs*, these bans capture both medical and surgical abortions.[157] On the same day *Dobbs* was issued, state abortion bans began to take effect.[158] The inclusion of medication abortion in these bans is made clear in some of the laws. As one example, South Dakota's trigger law makes it a felony to administer, prescribe, or procure "any medicine, drug, or substance" with the intent to cause an abortion.[159] As reproductive justice advocates develop new strategies to combat abortion bans and restrictions, a new wave of litigation challenging states'

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[150] H.F. 331, 89th Gen. Assemb. (Iowa 2021).

[151] H.B. 2810, 101st Gen. Assemb., 2d Reg. Sess. (Mo. 2022).

[152] H.B. 1208, 97th Leg. Sess. (S.D. 2022).

[153] H.B. 1679, 67th Leg., Reg. Sess. (Wash. 2022).

[154] S. File 83, 66th Leg., Reg. Sess. (Wyo. 2022).

[155] Earlier attempts to ban the drug in Montana and Oklahoma were permanently and temporarily enjoined by court order, respectively. *See Medication Abortion*, GUTTMACHER INST. (Nov. 1, 2022), https://www.guttmacher.org/state-policy/explore/medication-abortion [https://perma.cc/8ZAU-H67W] (noting the injunctions).

[156] *See supra* note 7 and accompanying text.

[157] *See supra* note 19 and accompanying text. Patients in such states, however, may continue to access medication abortion by going out of state or through various organizations willing to mail patients the drug. *See* Bob Christie, *Arizona Clinic Has Workaround for Abortion Pill Ban*, ASSOC. PRESS (Oct. 3, 2022), https://apnews.com/article/abortion-health-arizona-california-medication-2cc48f943f339d1959b6ca89883fd2f4 [https://perma.cc/58GT-YQ5P] (reporting how patients can get "an ultrasound in Arizona, get a prescription through a telehealth appointment with a California doctor and then have it mailed to a post office in a California border town for pickup"); *infra* notes 173–174 and accompanying text (providing information about some of the organizations). Obtaining the medication through these organizations, however, comes with legal risks. *See infra* notes 175, 299–327 and accompanying text.

[158] Sarah Knight et al., *Here's Where Abortions are Now Banned or Severely Restricted*, NAT'L PUB. RADIO, https://www.npr.org/sections/health-shots/2022/06/24/1107126432/abortion-bans-supreme-court-roe-v-wade [https://perma.cc/45RY-KEFA] (last updated Oct. 11, 2022); *see also Tracking the States Where Abortion is Now Banned*, N.Y. TIMES, *supra* note 7.

[159] S.D. CODIFIED LAWS § 22-17-5.1 (2022). South Dakota Governor Kristi Noem also reintroduced a bill that bans telemedicine appointments with abortion care providers who prescribe abortion pills to patients who receive them in the mail. Brad Dress, *South Dakota Governor Says She Will Ban Abortion Pills Prescribed Online*, HILL (Jun. 26, 2022), https://thehill.com/homenews/sunday-talk-shows/3537363-south-dakota-governor-says-she-will-ban-abortion-pills-prescribed-online/ [https://perma.cc/4AB6-68W4]. The definition of "abortion" in most states includes inducing abortion through drugs. For example, the definition of "abortion" in Missouri includes the prescription of medicines or drugs with the intent of causing an abortion. Missouri's trigger law, now in effect, thus bans all abortions, including medication abortion, at any time except in cases of medical emergency. *See* MO. ANN. STAT. §§ 188.015, 188.017 (West 2022) (listing definitions and codifying Missouri's trigger law, respectively); *see also* WYO. STAT. ANN. § 35-6-101(a)(i) (2011) (defining abortions to include a "prescription administered to or prescribed for a pregnant woman" with the intent of causing an abortion); H.B. 92, 66th Leg., Budget Sess. (Wyo. 2022) (to be codified at WYO. STAT. ANN. §§ 35-6-102, 35-6-117) (Wyoming's trigger law).

authority to ban FDA-approved mifepristone may be on the horizon, a battle almost guaranteed by Attorney General Garland's statement in the wake of *Dobbs*.[160]

In states that restrict but do not ban abortion entirely, the restrictions continue to impose significant and sometimes insurmountable barriers to abortion access, resulting in de facto bans for some patients. Unless repealed or replaced, restrictions on medication abortion enacted before *Dobbs* remain. Such restrictions often include limiting prescribing authority to physicians; requiring the provision of false or misleading risk information; mandating in-person examinations prior to prescription; prohibiting the use of telemedicine; requiring patients to pick up and/or take the drug in the presence of the prescriber; imposing a twenty-four hour (or longer) waiting period; limiting the gestational period under which the drug may be used (e.g., from the FDA-approved seventy days to forty-nine days gestation[161]); and requiring a follow-up visit at a specified time after the patient completes the medication abortion regimen.[162]

These state laws raise serious and urgent questions about whether states have, or should have, the authority to impose restrictions beyond those required by the FDA. Certain state restrictions are more troubling and burdensome than others, as they more clearly encroach on the authorities of the FDA. For example, before *Dobbs* and before the Texas trigger law took effect and banned all abortions in the state, Texas law essentially changed the approved indication for mifepristone in the state. The FDA has approved mifepristone for use up to seventy days gestation,[163] but Texas law reduced that to forty-nine days.[164] Thus, even absent a complete ban, prohibiting the prescription of the drug after forty-nine days gestation amounts to a de facto ban on mifepristone for the full period that the FDA has determined the drug can be used safely and effectively. Additionally, other state laws that do not

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[160] *See* Garland Statement, *supra* note 135, and accompanying text. At least one case raising a preemption argument was filed, but it has since been dismissed voluntarily by the plaintiff. *See* Complaint at 1, GenBioPro, Inc. v. Dobbs, No. 3:20-cv-00652-HTW-LRA (S.D. Miss. Oct. 9, 2020); Ian Lopez & Celine Castronuovo, *GenBioPro Gives Up Abortion Pill Suit Against Mississippi (2)*, Bloomberg Law (Aug. 19, 2022), https://news.bloomberglaw.com/health-law-and-business/genbiopro-gives-up-abortion-pill-suit-against-mississippi [https://perma.cc/P2U8-36F2]. The company is searching for a new court to revive its challenge. Ian Lopez, *Abortion Pill Maker Eyes Changed Judiciary as It Mulls New Suit*, Bloomberg Law (Sept. 14, 2022), https://news.bloomberglaw.com/us-law-week/abortion-pill-maker-eyes-changed-judiciary-as-it-mulls-new-suit [https://perma.cc/59NP-YSTY].

[161] *See, e.g.*, Tex. Health & Safety Code § 171.063(c)(6) (West 2021).

[162] *See, e.g.*, Miss. Code Ann. §§ 41-41-33, 41-41-34 (West 2022); Tex. Health & Safety Code § 171.063; *see also Medication Abortion*, Guttmacher Inst., *supra* note 155 (listing common types of restrictions at the state level).

[163] *MIFEPREX® (mifepristone) Prescribing Information 2016*, U.S. Food & Drug Admin., *supra* note 18.

[164] Tex. Health & Safety Code § 171.063(c)(1). This provision remains in place even though a separate provision in the Texas Health & Safety Code, which went into effect after the *Dobbs* decision, bans all abortions with limited exceptions, such as serious risks to the woman's physical health. *Id.* § 170A.002.

ban abortion completely and apply to all abortions—surgical and medical—in effect have the same result as the Texas law. In Georgia, for example, a 2019 law that took effect after *Dobbs* prohibited all forms of abortion after detection of a fetal heartbeat, which occurs around six weeks gestation.[165] As a result, the law limited the use of medication abortion to approximately six weeks, providing individuals less time to use mifepristone than allowed by the FDA-approved indication. In November 2022, Fulton County Superior Court Judge Robert McBurney ruled that Georgia's six-week abortion ban was invalid.[166] As a result, Georgia's prior abortion law, which allows abortions until around twenty weeks gestation, is back in place.[167] Nevertheless, the state is appealing the ruling, and the six-week abortion ban could go back into effect if a higher court disagrees with Judge McBurney, or if the legislature proposes and passes another restrictive law in the future.[168]

In practice, time restrictions like those imposed by Georgia's six-week abortion ban amount to de facto bans for the many individuals who may just discover they are pregnant around the time of the gestational limit, leaving them insufficient time, if any, to (1) make a decision; (2) obtain access to the drugs; and (3) meet any of the other requirements of state law, such as an in-person examination. For many pregnant persons residing in states with such laws, medication abortion will not be an option. According to one study, one in three people confirm they are pregnant *after* six weeks, and one in five

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[165] *See* H.B. 481, 2019–2020 Leg., Reg. Sess. (Ga. 2019).

[166] SisterSong Women of Color Reproductive Just. Collective v. Georgia, No. 2022-CV-367796, 2022 WL 16960560, at *3 (Ga. Super. Ct. Nov. 15, 2022). The Judge did not reach the merits of the constitutional claims as they exist *today*, post-*Dobbs*. Instead, he based his conclusion on Georgia's "void *ab initio*" doctrine. *Id.* at *3–4. Under that doctrine, legislation in violation of the state or federal Constitution, in effect *at the time* the law was passed, is void. Put plainly, a law that was unconstitutional at the time it was passed is forever void, even if subsequent changes in state or federal constitutional doctrine would now render that law constitutional. *Id.* at *3. Thus, because Georgia's six-week abortion ban was unconstitutional when it was passed in 2019, when *Roe v. Wade* was still good law, it was invalid, even after *Dobbs*. *Id.*

[167] GA. CODE ANN. § 16-12-141(c)(1) (2012).

[168] Because the court invalidated the law based on Georgia's void *ab initio* doctrine and not constitutional doctrine as it now stands post-*Dobbs*, the legislature could still come back and re-enact the same or similar restrictions. As noted by Judge McBurney:

> Under *Dobbs*, it may someday become the law of Georgia, but only after our Legislature determines in the sharp glare of public attention that will undoubtedly and properly attend such an important and consequential debate whether the rights of unborn children justify such a restriction on women's right to bodily autonomy and privacy.

SisterSong, 2022 WL 16960560, at *3; *see also* Grayson-Robinson Stores v. Oneida, Ltd., 75 S.E.2d 161, 164 (Ga. 1953) (holding that void statutes "can be made effective only by re-enactment" (quoting State v. Miller, 66 S.E. 522, 523 (W. Va. 1909)). The state has appealed the ruling and has asked the Supreme Court of Georgia to immediately reinstate the abortion ban while the appeal proceeds. Sudhin Thanawala, *Georgia Asks Court to Immediately Reinstate Abortion Ban*, ASSOC. PRESS (Nov. 18, 2022), https://www.msn.com/en-us/news/crime/georgia-asks-court-to-immediately-reinstate-abortion-ban/ar-AA14hcOi [https://perma.cc/TCQ7-NW2M].

past seven weeks.[169] Studies also suggest that later discovery of pregnancy may be higher among certain vulnerable populations, including young people, people of color, and low-income populations.[170] Other state-level restrictions—such as those requiring physicians who prescribe mifepristone to have admitting privileges at a hospital within thirty miles[171]—can also amount to de facto bans because some physicians, particularly those in rural areas, will be unable to comply with such requirements.

Pregnant persons facing barriers to medication abortion may seek potential ways around the restrictions. The website for the organization "Plan C," for example, provides information about how to order medication abortion from foreign suppliers such as AidAccess,[172] including to states where the practice is illegal.[173] People also seek out information via social media for creative ways around these laws, such as "how to change their VPNs, have pills illicitly mailed to a FedEx drop-off point in a neighboring state, or how to have pills sent to someone else who can deliver them."[174] As discussed further in Part III, self-managed abortions are not without medical and legal risks.[175] Troublingly, anti-abortion states have created a situation in

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[169] Lauren J. Ralph et al., *Home Pregnancy Test Use and Timing of Pregnancy Confirmation Among People Seeking Health Care*, 107 CONTRACEPTION 10, 10 (2022).

[170] *See* Amy M. Branum & Katherine A. Ahrens, *Trends in Timing of Pregnancy Awareness Among US Women*, 21 MATERNAL & CHILD HEALTH J. 715, 724 (2017); Ralph et al., *supra* note 169.

[171] *See, e.g.*, ARIZ. REV. STAT. ANN. § 36-449.03(C)(3)(a).

[172] *See infra* notes 311–313 and accompanying text.

[173] PLAN C, https://www.plancpills.org/ [https://perma.cc/6CDT-UGQW]. When you use Plan C's website to find access to abortion pills online and you are located in Texas, it provides a list of telehealth services and online pharmacies but also refers users to read more about potential legal risks of using these and other alternative suppliers. *See Texas: How to Get Abortion Pills*, PLAN C, https://www.plancpills.org/states/texas#results-anchor [https://perma.cc/8DFC-KBBB]. It also provides information about "creative options" for accessing pills, such as "mail-forwarding services, driving across state borders, or using General delivery addresses." *Id.*

[174] Adrienne Matei, *Mail-Order Abortion Pills Become Next US Reproductive Rights Battleground*, GUARDIAN (Apr. 7, 2022), https://www.theguardian.com/us-news/2022/apr/07/us-mail-order-abortions-oklahoma [https://perma.cc/3VSL-GW2X].

[175] Most states do not have laws criminalizing self-induced abortion explicitly, but this is a legal gray area, and one where conservative states could venture as they seek to clamp down on medication abortions. Although a recent attempt in Louisiana to criminalize those who receive abortions failed, it nevertheless illustrates that some politicians are entertaining that idea. *See infra* notes 322–323 and accompanying text. Further, even when *Roe* remained good law, there were instances of states seeking to prosecute people for self-managed abortions. According to Plan C, "from 2000 to 2020, at least 61 people who have self-managed an abortion or have helped someone else are known to have been arrested and prosecuted." *Frequently Asked Questions: Can I Get in Trouble for Using Abortion Pills*?, PLAN C, https://www.plancpills.org/guide-how-to-get-abortion-pills [https://perma.cc/A4ZX-Y8ST]. A Georgia woman, for example, was charged with murder for allegedly taking misoprostol, which she purchased online, to try to terminate her pregnancy. The murder charge was ultimately dismissed, but she still faced a charge of possession of a dangerous drug. Lauren Gambino, *Georgia Woman Who Took Abortion Pill Has Murder Charges Dismissed*, GUARDIAN (June 10, 2015), https://www.theguardian.com/us-news/2015/jun/10/georgia-woman-abortion-pill-murder-charge-dismissed [https://perma.cc/W2RX-EV32]. More recently, a Texas woman was

which pregnant persons are forced to choose between their health and potentially exposing themselves or others to legal liability and unnecessary medical risks.

States will likely argue that these restrictions fall under their police powers and authorities to regulate the practice of medicine.[176] For some restrictions, such as those restricting prescriptive authority to licensed physicians, this argument will prove harder to overcome in the absence of express preemption, given the states' long-standing role in determining the prescriptive authority of different health-care professionals.[177] For other restrictions, such as those that change the FDA-approved indication explicitly or in effect, the strength and breadth of the FDA's drug review and approval authorities, established and expanded upon over the last century, weaken such arguments. As noted by Professors Zettler and Sarpatwari, "[s]tate medication-abortion laws, particularly those that are grounded in drug-safety arguments, encroach on the FDA's purview over drug safety and effectiveness—including the agency's responsibility to promote public health by making safe and effective drugs available."[178] In fact, Texas did not even attempt to justify its law under the practice of medicine. Instead, it pointed to safety and efficacy, stating that "the use of Mifeprex or mifepristone presents significant medical complications" and "the failure rate and risk of complications increases with advancing gestational age."[179] The intent of Texas was

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charged with murder for allegedly inducing her abortion. The charges were subsequently dropped. 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/B2PQ-VAHD]. And in Nebraska, a woman was charged with helping her teenage daughter end her pregnancy after investigators obtained Facebook messages in which the two discussed using medication to induce an abortion. Assoc. Press, *A Nebraska Woman is Charged With Helping Her Daughter Have an Abortion*, Nat'l Pub. Radio (Aug. 10, 2022), https://www.npr.org/2022/08/10/1116716749/a-nebraska-woman-is-charged-with-helping-her-daughter-have-an-abortion [https://perma.cc/69MF-YFGV]; *see also infra* notes 299–327 and accompanying text (describing legal and other risks).

[176] For example, in the GenBioPro litigation challenging Mississippi's restrictions on mifepristone, *see infra* notes 389–392 and accompanying text, the defendant (the State Health Officer of the Mississippi Department of Health) supported his motion to dismiss by arguing, among other things, that it is

> unquestionable that Congress has never displaced the authority of the states to continue to play a significant role regarding distribution of medications, a task performed exclusively by the states prior to the creation of the FDA. The police power to protect the health and safety of its citizens has been traditionally recognized as one of the most fundamental aspects of State sovereignty under our federal system of government.

Memorandum of Authorities in Support of Motion to Dismiss Pursuant to Rules 12(b)(1) and 12(b)(6) at 5, GenBioPro, Inc. v. Dobbs, No. 3:20-CV-00652-HTW-LGI (S.D. Miss. Nov. 6, 2020).

[177] *Cf.* Phillip Zhang & Preeti Patel, Practitioners and Prescriptive Authority 1–3 (2022) (describing state approaches to practitioners and prescriptive authority).

[178] *Cf.* Zettler & Sarpatwari, *supra* note 105, at 706 (noting the potential vulnerability of state abortion restrictions ostensibly premised on drug safety grounds).

[179] S.B. 4, 87th Leg., 1st Spec. Sess. (Tex. 2021).

clear: to displace the FDA's determination of drug safety and efficacy with its own.

B. Contraceptives

The consequences of *Dobbs* may extend far beyond abortion, with potential ramifications for a host of other important rights, including the right to contraceptives. Despite attempts by the majority to assure that *Dobbs* does not "call[ ] into question"[180] cases like *Griswold v. Connecticut* and *Eisenstadt v. Baird*, which established the right to contraceptives,[181] the dissent written by Justices Breyer, Sotomayor, and Kagan questions that assertion. According to the dissenting Justices, "the majority could write just as long an opinion" using its reasoning and analysis in *Dobbs*—based largely on the conclusion that abortion is not "deeply rooted in this Nation's history and tradition"[182]—to conclude "that until the mid-20th century, 'there was no support in American law for a constitutional right to obtain' [contraceptives]."[183] Many scholars agree with the dissent's analysis on this point.[184]

Of even greater concern, at least one Justice appears ready and willing to reconsider the right to contraceptives, and more. In his concurring opin-

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[180] Dobbs v. Jackson Women's Health Org., No. 19-1392, slip op. at 71 (June 24, 2022).

[181] *See* Griswold v. Connecticut, 381 U.S. 479, 485–86 (1965) (establishing the right of married couples to buy and use contraceptives, based on a right to privacy inferred from the Constitution); Eisenstadt v. Baird, 405 U.S. 438, 454 (1972) (extending the holding in *Griswold* to unmarried persons).

[182] *Dobbs*, slip op. at 5 (Breyer, Sotomayor & Kagan, JJ., dissenting).

[183] *Id.* (quoting *Dobbs*, slip op. at 15).

[184] Rebecca Reingold, Associate Director of the O'Neill Institute at Georgetown University Law Center, for example, notes the risks to contraception, stating that "[a]dvocates of restrictions on access to contraception may argue that the right to contraception similarly 'destroys a potential life.'" Olivia Goldhill, *Supreme Court Decision Suggests the Legal Right to Contraception is Also Under Threat*, STAT (June 24, 2022), https://www.statnews.com/2022/06/24/supreme-court-decision-suggests-the-legal-right-to-contraception-is-also-under-threat/ [https://perma.cc/L6RA-VUM3]; *see also* Opinion, *'Abortion is Just the Beginning': Six Experts on the Decision Overturning Roe*, N.Y. TIMES (June 24, 2022), https://www.nytimes.com/interactive/2022/06/24/opinion/politics/dobbs-decision-perspectives.html [https://perma.cc/KSC3-3ZF2] (providing the opinions of experts from various disciplines about the potential implications of Dobbs); Erik Larson & Emma Kinery, *Same-Sex Marriage, Contraception at Risk After Roe Ruling*, BLOOMBERG LAW (June 24, 2022), https://news.bloomberglaw.com/us-law-week/supreme-court-justices-disagree-on-scope-of-dobbs-ruling [https://perma.cc/83PH-43KE] (citing Jenny Pizer, the Law and Policy Director for Lambda Legal, who agrees with the dissent's concerns); Becky Sullivan & Juliana Kim, *These 3 Supreme Court Decisions Could be at Risk After Roe v. Wade Was Overturned*, NAT'L PUB. RADIO (June 24, 2022), https://www.npr.org/2022/05/05/1096732347/roe-v-wade-implications-beyond-abortion [https://perma.cc/V5FC-9WD8] ("Some legal experts say that Alito's language may not be enough to keep such a ruling from being used to challenge other rights [including contraception] down the road."); Myah Ward, *Alito's Roe Draft, Beyond Abortion*, POLITICO NIGHTLY (May 3, 2022), https://www.politico.com/newsletters/politico-nightly/2022/05/03/alitos-roe-draft-beyond-abortion-00029725 [https://perma.cc/FY38-UA87] (similar).

ion, Justice Thomas writes: "in future cases, we should reconsider all of this Court's substantive due process precedents, including *Griswold*, *Lawrence*, and *Obergefell*" [185]—cases that established rights to contraceptives, same-sex intimacy, and same-sex marriage, respectively. Some claim that such concerns are "hyperbolic,"[186] but the *Dobbs* decision makes clear that no right is guaranteed and that the current Court is willing to revisit and overturn decades-old precedent. As Professor Melissa Murray astutely noted in response to the leaked draft of the *Dobbs* opinion[187]—which remained largely unchanged once final[188]:

> To quote Justice Antonin Scalia, "it takes real cheek" for Justice Alito to insist that the draft opinion's logic can be confined to abortion and does not implicate any other rights. The document, if finalized, will not simply lay waste to almost 50 years' worth of precedent—it will provide a blueprint for going even further.[189]

The threat remains real and urgent, and must not be minimized.

The FDA maintains primary authority over the approval and regulation of contraceptive drugs and devices.[190] With the exception of one emergency

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[185] *Dobbs*, slip op. at 3 (Thomas, J., concurring). *Lawrence* invalidated sodomy laws across the United States, thereby legalizing same-sex sexual activity in the United States. Lawrence v. Texas, 539 U.S. 558, 578 (2003). *Obergefell* ruled that the fundamental right to marry is guaranteed to same-sex couples by both the Due Process Clause and the Equal Protection Clause of the Fourteenth Amendment to the U.S. Constitution. Obergefell v. Hodges, 576 U.S. 644, 672 (2015).

[186] Melissa Murray, Opinion, *How the Right to Birth Control Could Be Undone*, N.Y. TIMES (May 23, 2022), https://www.nytimes.com/2022/05/23/opinion/birth-control-abortion-roe-v-wade.html [https://perma.cc/J9GN-77Q8] (citing commentators who claim that the risks to other rights like contraception are "little more than hyperbolic 'catastrophizing'"); *see also* Akhil Reed Amar, *The End of Roe v. Wade*, WALL ST. J. (May 14, 2022), https://www.wsj.com/articles/the-end-of-roe-v-wade-11652453609 [https://perma.cc/FAS3-F7N5] (describing concerns about threats to a range of basic rights as "dire assessments" that "don't stand up to scrutiny"); Editorial, *Alito Doesn't Want Your Contraceptives*, WASH. POST (May 15, 2022), https://www.wsj.com/articles/samuel-alito-doesnt-want-your-contraceptives-supreme-court-griswold-roe-v-wade-11652450423 [https://perma.cc/634A-TH5H] (referring to concerns about risks to same-sex marriage and contraception as an "implausible parade of horribles").

[187] On May 2, 2022, a draft opinion of Justice Alito's majority opinion in *Dobbs* overturning *Roe* and *Casey* was published by *Politico*. *See* Josh Gerstein & Alexander Ward, *Supreme Court has Voted to Overturn Abortion Rights, Draft Opinion Shows*, POLITICO (May 2, 2022), https://www.politico.com/news/2022/05/02/supreme-court-abortion-draft-opinion-00029473 [https://perma.cc/5WBM-HNAN] (last updated May 3, 2022).

[188] The bulk of the opinion remained largely unchanged, with the exception of some discussion of the concurring and dissenting opinions.

[189] Murray, *supra* note 186; *see also* Paul Waldman, Opinion, *Liberals are Right to Panic About What Will Follow Roe's Demise*, WASH. POST (May 5, 2022), https://www.washingtonpost.com/opinions/2022/05/05/liberals-not-overstating-roes-demise/ [https://perma.cc/E7PA-MT4M] ("[L]iberals are not being hyperbolic when they warn about the retrograde right-wing revolution that could follow the end of *Roe*.").

[190] There are various forms of birth control, including long-acting reversible contraceptives (LARCs), contraceptive injections, short-acting hormonal methods (such as oral contraceptives), barrier methods, permanent surgical sterilization, and emergency contra-

contraceptive pill, Plan B, and certain barrier methods of birth control, other contraceptive drugs and devices are available only by prescription.[191] The FDA's laws and regulations require that both prescription and nonprescription products are safe and effective for their intended use (here, the prevention of pregnancy).[192]

Like mifepristone, the Agency's regulation of contraceptives has invited controversy. The FDA's handling of Plan B's switch from prescription to nonprescription status represents one of the more troubling examples of how the FDA, like many state legislatures, allowed politics to trump science and medicine in decisions about the regulation of contraceptives.[193]

Plan B and Plan B One-Step are FDA-approved emergency contraceptives to reduce the chance of pregnancy when taken within seventy-two hours after unprotected sex.[194] The drug's potential side effects are generally mild and short-term, and it does not have any known serious or long-term side effects.[195] The FDA approved Plan B in 1999 as a prescription-only

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ceptives. *See Birth Control*, U.S. FOOD & DRUG ADMIN. (June 18, 2021), https://www.fda.gov/consumers/free-publications-women/birth-control [https://perma.cc/VT4X-F358].

[191] *Id.* At the time of this writing, the FDA is in the process of considering an application by the pharmaceutical company Perrigo to make its oral contraceptive available without a prescription (i.e., over the counter). Joseph Choi, *FDA Schedules Meeting on OTC Birth Control Pill Application*, HILL (Sept. 12, 2022), https://thehill.com/policy/healthcare/3639058-fda-schedules-meeting-on-otc-birth-control-pill-application/ [https://perma.cc/52BA-KZM2]. If approved, it would be the first daily birth control pill available in the United States without a prescription. *Id.* A decision is expected sometime in 2023. Oriana Gonzalez, *FDA Postpones Meeting to Review Over-the-Counter Birth Control Pills*, AXIOS (Oct. 26, 2022), https://www.axios.com/2022/10/26/fda-postpones-birth-control-over-the-counter-otc [https://perma.cc/V69P-YRBU].

[192] *See* 21 U.S.C. § 355(d) (requiring the FDA to deny approval of a drug if the evidence fails to establish that it is safe and effective for its intended use); § 360e(c)(1)(A) (requiring sponsors of certain devices to submit, as part of a premarket approval application, evidence that their device is safe and effective); § 360c (including various provisions indicating that devices must have reasonable assurance that they are safe and effective); Pat Clark, *How FDA Strives to Ensure the Safety of OTC Products*, U.S. FOOD & DRUG ADMIN. (Mar. 10, 2016), https://www.fda.gov/drugs/special-features/how-fda-strives-ensure-safety-otc-products# [https://perma.cc/49PT-6GXK] ("FDA regulations ensure that OTC drugs are safe and that the labels are easy to understand. OTC drugs can be bought and used safely without the need for a prescription. All OTC drug products have to meet FDA quality, effectiveness, and safety standards.").

[193] For a detailed discussion of Plan B's switch to nonprescription status, see Allison M. Whelan, *Executive Capture of Agency Decisionmaking*, 75 VANDERBILT L. REV. 1787, 1818–25 (2022).

[194] Plan B, now discontinued, consisted of two 0.75 mg pills taken twelve hours apart. *FDA-Approved Drugs, Plan B–NDA No. 021045*, U.S. FOOD & DRUG ADMIN., https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=021045 [https://perma.cc/MJM8-V7SE]. Plan B One-Step, which remains available, consists of one 1.5mg pill. U.S. FOOD & DRUG ADMIN., PLAN B ONE-STEP LABEL (Jan. 4, 2019), https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/021998Orig1s006lbl.pdf [https://perma.cc/9QYJ-EQBF] [hereinafter PLAN B ONE-STEP LABEL].

[195] *See* PLAN B ONE-STEP LABEL, *supra* note 194; Tummino v. Torti, 603 F. Supp. 2d 519, 522 (E.D.N.Y. 2009).

drug.[196] In 2001, medical and public health groups filed a citizen petition requesting that the FDA make Plan B available without a prescription (i.e., OTC).[197] In 2003, Plan B's sponsor submitted a supplemental new drug application, also requesting a switch to nonprescription status.[198] After over a decade of delay and multiple trips to court—which unearthed evidence of political meddling in the FDA's decisions by the second Bush Administration and the Obama Administration—the Agency finally approved Plan B for nonprescription use for all ages, but only after it was ordered to do so by a district court in 2013.[199]

Unsurprisingly, the FDA's decision to make Plan B available without a prescription was not the end of the matter, and *Dobbs* now brings contraceptives back into the crosshairs in a very clear and acute way. That said, contraceptives have long been a target for state regulation, with emergency contraceptives like Plan B bearing the brunt of the attacks. During and after the decade-long battle to make Plan B available without a prescription under federal law, some states sought to impose their own prescription requirements. Michigan,[200] Missouri,[201] and Oklahoma[202] all attempted to require a prescription for emergency contraceptives, even after the FDA first made Plan B available without a prescription for individuals over eighteen in 2006.[203] The Michigan and Missouri bills did not pass, and a state district court permanently enjoined the Oklahoma law in 2014.[204] Oklahoma legislators, however, continued to propose restrictions on emergency contraceptives, claiming, for example, that the restrictions addressed a "public health issue, not a pro-life issue" and were necessary because "the emergency con-

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[196] *See Torti*, 603 F. Supp. 2d at 522.

[197] *Id.* at 526; GRETCHEN GOLDMAN ET AL., PRESERVING SCIENTIFIC INTEGRITY IN FEDERAL POLICYMAKING 15 (2017), https://www.ucsusa.org/sites/default/files/attach/2017/01/preserving-scientific-integrity-in-federal-policymaking-ucs-2017.pdf [https://perma.cc/TF7M-G3KN].

[198] *Torti*, 603 F. Supp. 2d at 527; GOLDMAN ET AL., *supra* note 197, at 15.

[199] Tummino v. Hamburg, 936 F. Supp. 2d 162, 197 (E.D.N.Y. 2013).

[200] H.B. 5311, 93d Leg., Reg. Sess. (Mich. 2005).

[201] S.B. 608, 93rd Gen. Assemb., 2d Reg. Sess. (Mo. 2006).

[202] H.B. 2226, Reg. Sess. (Okla. 2013).

[203] *Torti*, 603 F. Supp. 2d at 535–36. In 2013, the FDA approved Plan B for nonprescription use for all ages. U.S. FOOD & DRUG ADMIN., PLAN B ONE-STEP LABEL (June 20, 2013), https://www.accessdata.fda.gov/drugsatfda_docs/label/2013/021998Orig1s003lbl.pdf [https://perma.cc/5C8K-744A].

[204] Okla. Coal. for Reprod. Just. v. Okla. State Bd. Of Pharmacy, No. CV-2013-1640, 2014 WL 585353, at *1 (Dist. Ct. Okla. Jan. 29, 2014). The court did not, however, rely on preemption. Instead, it concluded that the bill, which focused primarily on regulating health insurance benefit forms, violated the "single subject rule" of the Oklahoma Constitution prohibiting "politicians from addressing unrelated issues in a single law." *Oklahoma Judge: Restrictions on Emergency Contraception Violate State Constitution*, CTR. FOR REPROD. RIGHTS (Jan. 24, 2014), https://reproductiverights.org/oklahoma-judge-restrictions-on-emergency-contraception-violate-state-constitution/ [https://perma.cc/PB9V-D7MQ].

traceptive is a powerful drug."[205] As with mifepristone, policymakers grounded their proposals in drug safety arguments—largely unsupported by the evidence and leading medical experts—thereby "encroach[ing] on the FDA's purview over drug safety and effectiveness."[206]

In the leadup to the release of the *Dobbs* decision, after a period of relative quiet among the states, some policymakers suggested they would consider banning or restricting contraceptives, particularly emergency contraceptives like Plan B and intrauterine devices (IUDs).[207] In Idaho, for instance, House State Affairs Committee Chairman Brent Crane (R-Nampa) indicated that he would be willing to hold hearings on legislation banning emergency contraceptives.[208] Although he stated that he supports contraception, he also stated that he is "not for certain yet where I would be on [IUDs]."[209]

Chairman Crane's statements represent the tip of the iceberg. The troubling Louisiana bill discussed below,[210] which defined a "person" as "a human being from the moment of *fertilization*,"[211] initially raised concerns that the law could "technically criminalize some forms of birth control."[212] A later amendment eased those concerns by carving out an exception for contraception.[213] Missouri's "trigger law," which bans abortion and is now in effect,[214] raised similar concerns because it bans abortions "from the moment of conception," i.e., fertilization.[215] Historically, information from the

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[205] *Morning After Pill Restrictions in Oklahoma*, NEWS CHANNEL 10 (July 11, 2018), https://www.newschannel10.com/story/24902289/morning-after-pill-restrictions-in-oklahoma/ [https://perma.cc/WD7Q-MJBZ].

[206] *Cf.* Zettler & Sarpatwari, *supra* note 105, at 706.

[207] Certain types of IUDs can also be used as a method of emergency contraception, although they are not approved by the FDA for that purpose. *See Practice Bulletin Number 152: Emergency Contraception*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (Sept. 2015), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2015/09/emergency-contraception [https://perma.cc/Z9W3-9889] (reaffirmed 2022).

[208] Ian Max Stevenson, *After Roe Decision, Idaho Lawmakers May Consider Restricting Some Contraception*, IDAHO STATESMAN, https://www.idahostatesman.com/news/politics-government/state-politics/article261207007.html [https://perma.cc/LC6W-M3DH] (updated May 10, 2022).

[209] *Id.*

[210] *See infra* notes 322–323 and accompanying text.

[211] H.B. 813, 2022 Reg. Sess. (La. 2022) (emphasis added).

[212] Dani Blum & Nicole Stock, *A Comprehensive Guide to Birth Control*, N.Y. TIMES (May 9, 2022), https://www.nytimes.com/article/birth-control-options.html [https://perma.cc/6A3T-FQFA].

[213] H. Floor Amendments, 2022 Reg. Sess. (La. 2022) (adding exception for contraceptives).

[214] MO. ANN. STAT. § 188.017 (West 2022).

[215] *See id.* §§ 188.015(10), 188.017(2) (defining "unborn child" as "the offspring of human beings from the moment of conception" and prohibiting the "abortion of an unborn child," respectively); *see also* Kayla Drake, *Missouri's 'Trigger Law' Is Ready for Roe's Demise. What Happens Then?*, ST. LOUIS PUB. RADIO (May 6, 2022), https://news.stlpublicradio.org/show/st-louis-on-the-air/2022-05-06/missouris-trigger-law-is-ready-for-roes-demise-what-happens-then [https://perma.cc/ML9Q-KLWD] (quoting a law professor and stating that the language of the law "is ambiguous and leaves room for many interpretations when it comes to other areas related to conception, such as emer-

FDA provided that Plan B works primarily by stopping ovulation and preventing fertilization, but if fertilization does occur, it may prevent implantation.[216] It does not, however, have any effect on a fertilized egg once implanted in the uterine wall.[217] Notwithstanding the FDA's description of the drug's mechanism of action, which suggests Plan B could prevent the implantation of a fertilized egg, numerous studies show that emergency contraceptives are unlikely to prevent implantation of a fertilized egg.[218] Moreover, the American College of Obstetricians and Gynecologists (ACOG) defines pregnancy as beginning with implantation, not fertilization.[219] Under that definition, a drug or device that prevents implantation would *not* be considered an abortifacient.

Nevertheless, misinformation continues to swirl about emergency contraceptives and abortion. For example, a bill introduced in Alabama that focused on the use of public funds for abortion appeared to lump emergency contraceptives with abortion, prohibiting certain state entities from using state funds to procure or distribute emergency contraceptives.[220] Mississippi's governor would not rule out banning certain contraceptives.[221] And

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gency contraception"); Ryan Krull, *IUDs, Plan B Likely Illegal in Missouri Post-Roe*, RIVERFRONT TIMES (May 5, 2022) https://www.riverfronttimes.com/news/iuds-plan-b-likely-illegal-in-missouri-post-roe-37654014 [https://perma.cc/QK8W-N96E] (explaining that the law defines an unborn child as a human being from the moment of conception and in every stage of its biological development).

[216] *See FDA's Decision Regarding Plan B: Questions and Answers*, U.S. FOOD & DRUG. ADMIN. (Dec. 7, 2015), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-decision-regarding-plan-b-questions-and-answers# [https://perma.cc/7QYH-Y749] [hereinafter *FDA's Decision Regarding Plan B*, U.S. FOOD & DRUG. ADMIN.]; *see also* PLAN B ONE-STEP LABEL, *supra* note 194.

[217] *See FDA's Decision Regarding Plan B*, U.S. FOOD & DRUG. ADMIN., *supra* note 216.

[218] *See Practice Bulletin Number 152: Emergency Contraception*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 207 (citing studies and explaining the difference between emergency contraceptives and medication abortion). Shortly before this Article's publication, the FDA announced that it will update the labeling for Plan B to clarify that the drug does not cause an abortion. *See Plan B One-Step (1.5 mg levonorgestrel) Information*, U.S. FOOD & DRUG ADMIN. (Dec. 23, 2022), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/plan-b-one-step-15-mg-levonorgestrel-information [https://perma.cc/M2F5-4ES7] ("Evidence does not support that the drug affects implantation or maintenance of a pregnancy after implantation, therefore it does not terminate a pregnancy."); Assoc. Press, *FDA Changes Plan B Label to Clarify 'Morning-After' Pill Doesn't Cause Abortion*, NAT'L PUB. RADIO (Dec. 23, 2022), https://www.npr.org/2022/12/23/1145405404/fda-changes-plan-b-label-to-clarify-morning-after-pill-doesnt-cause-abortion [https://perma.cc/H98V-XL5G].

[219] *See* Rachel Benson Gold, *The Implications of Defining When a Woman is Pregnant*, GUTTMACHER POL'Y REV. (May 9, 2005), https://www.guttmacher.org/gpr/2005/05/implications-defining-when-woman-pregnant [https://perma.cc/UXB3-6WKD] (citing ACOG's definition of pregnancy, which states that "[a] pregnancy is considered to be established only after implantation is complete").

[220] H.B. 118, 2022 Leg., Reg Sess. (Ala. 2022).

[221] Amy B. Wang & Silvia Foster-Frau, *Miss. Governor Doesn't Rule Out Banning Contraception if Roe Falls*, WASH. POST (May 8, 2022), https://www.washingtonpost.com/politics/2022/05/08/abortion-tate-reeves-mississippi-contraception/ [https://perma.cc/PAB6-UUHK].

Jacky Eubanks, a Republican candidate for the Michigan State Senate, said she would vote to outlaw contraceptives if elected, stating that they "should not be legal" and that prohibiting them would make people "more careful about their actions" and more likely to "practice chastity."[222] Similarly, Republican Senator Marsha Blackburn from Tennessee announced that she believes *Griswold* is "constitutionally unsound."[223] Such a statement suggests that she supports the views of Justice Thomas and is willing to revisit the right to contraceptives.

The potential consequences of misunderstanding how emergency contraceptives work were aptly illustrated by the decision of a health system in Kansas City, Missouri, to stop providing Plan B in the week following *Dobbs*.[224] The health system cited the lack of clarity in Missouri's abortion ban, stating, "the Missouri law is ambiguous but may be interpreted as criminalizing emergency contraception. As a system that deeply cares about its team, we simply cannot put our clinicians in a position that might result in criminal prosecution."[225] The health system quickly reversed course, however, following comments from the Missouri Attorney General's Office and Governor Mike Parson clarifying that the abortion ban does not affect Plan B or similar products.[226] While this case provides temporary comfort, different officials in the future could reach different interpretive conclusions about the ban.

Similarly, some public universities in Idaho issued statements to their employees warning them not to refer students to abortion providers or inform them how to get emergency contraceptives.[227] These warnings arise from the universities' interpretations of Idaho's No Public Funds for Abor-

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[222] Nicole Gaudino, *A Trump-Backed Michigan State House Candidate Says Birth Control 'Should Not Be Legal'*, BUS. INSIDER (May 20, 2022), https://www.businessinsider.com/trump-backed-candidate-says-birth-control-should-not-be-legal-2022-5 [https://perma.cc/HVL7-87JN].

[223] Justice Allen Rose, Opinion, *Blackburn Warning Us of Plans of Some in GOP to Outlaw Abortion, Birth Control*, TENNESSEAN (Apr. 7, 2022), https://www.tennessean.com/story/opinion/2022/04/07/blackburn-warning-us-plans-gop-outlaw-abortion-birth-control/7222285001/ [https://perma.cc/MC58-9FU8].

[224] Savannah Hawley, *Major Health System Stops, then Resumes Plan B Amid Missouri's Abortion Ban Ambiguity*, NAT'L PUB. RADIO (June 29, 2022), https://www.npr.org/sections/health-shots/2022/06/29/1108682251/kansas-city-plan-b [https://perma.cc/3Q3A-K4V6].

[225] *Id.*

[226] *Id.*

[227] Rebecca Boone, *All Three Idaho Universities Disallow Abortion Referral; ISU Differs on Contraception Direction*, IDAHO ST. J. (Oct. 4, 2022), https://www.idahostatejournal.com/freeaccess/all-three-idaho-universities-disallow-abortion-referral-isu-differs-on-contraception-direction/article_35a913e1-716d-55da-ba4a-7a3fe6c4690e.html [https://perma.cc/VZT4-79VW]. At the time of this writing, University of Idaho and Boise State prohibit referrals for both abortion and emergency contraceptives. Idaho State University, however, has not yet issued any guidance, stating that it does not interpret the law to prohibit "employees from engaging in discussions on topics related to abortion and does not interpret the law to prevent our on-campus health center from providing birth control to patients in addition to other family planning services." *Id.*

tion Act, enacted in 2021.[228] The law prohibits "promoting" abortion or referring students for abortions and prohibits dispensing emergency contraceptives except in the case of rape.[229] The University of Idaho went even further, stating that it will no longer be dispensing any form of birth control.[230] Even condoms may be "distributed for the purposes of preventing disease transmission only, not for birth control."[231]

No matter how the Supreme Court might ultimately rule if asked to consider state laws banning or severely restricting access to contraceptives, comments and actions by anti-abortion legislators and advocates signal that some view *Dobbs* as an opening to attack the right to contraceptives.[232] If enacted, such laws will be challenged. Thus, unless a lower court enjoins the law while litigation proceeds,[233] state residents may find themselves without access to contraceptives and scrambling to find alternative, potentially back-channel methods to obtain them. Indeed, students at the University of Idaho already face this reality.[234]

Ongoing and forthcoming battles over state restrictions and bans on medication abortion and contraceptives require urgent attention given the grave implications for the rights and health of women, girls, and other persons capable of pregnancy. Their bodily autonomy and integrity hang in the balance. Undeniably, medication abortion receives distinct and outsized attention from state policymakers. But states have also attempted, successfully and unsuccessfully, to restrict or ban other drugs, potentially encroaching on the FDA's authority to regulate drug safety and efficacy and to promote pub-

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[228] IDAHO CODE. §§ 18-8701–18-8711 (2022).

[229] *Id*.

[230] Boone, *supra* note 227.

[231] Moira Donegan, Opinion, *In Idaho, We're Seeing How Freedom of Speech is Being Curtailed Around Abortion*, GUARDIAN (Oct. 3, 2022), https://www.theguardian.com/commentisfree/2022/oct/03/university-of-idaho-abortion-emergency-contraception [https://perma.cc/3Q23-32LM].

[232] *See* Melody Schreiber, *Contraception Could Come Under Fire Next if Roe v. Wade is Overturned*, GUARDIAN (May 4, 2022), https://www.theguardian.com/us-news/2022/may/03/roe-v-wade-birth-control [https://perma.cc/6HD6-847J].

[233] To potentially avoid an injunction, states could craft their laws like Texas's Senate Bill (SB) 8, which is enforced solely by private citizens. S.B. 8, 87th Leg., Reg. Sess. (Tex. 2021). As illustrated by SB 8, the private enforcement mechanism makes such laws difficult to challenge in court. After refusing to intervene and allowing the law to remain in effect, the Supreme Court returned the case to the Fifth Circuit Court of Appeals, ruling that of all the claims, only those brought by abortion providers could proceed against a group of state medical licensing officials. Whole Woman's Health v. Jackson, No. 21-463, slip op. at 17–18 (Dec. 10, 2021); Order, Whole Woman's Health v. Jackson, No. 21-463 (Dec. 16, 2021). The Fifth Circuit then sent the case to the Texas Supreme Court for further interpretation. Whole Woman's Health v. Jackson, No. 21-50792, slip op. at 9–10 (5th Cir. Jan. 17, 2022). Finally, on March 11, 2022, the Texas Supreme Court dealt the final blow to the legal challenges, ruling that medical licensing officials did not have any power to enforce the law and thus could not be sued. Kate Zernike & Adam Liptak, *Texas Supreme Court Shuts Down Final Challenge to Abortion Law*, N.Y. TIMES (Mar. 11, 2022), https://www.nytimes.com/2022/03/11/us/texas-abortion-law.html [https://perma.cc/A7FF-E2UD].

[234] *See supra* notes 227–231 and accompanying text.

lic health by ensuring that safe and effective drugs are available to the public. Moreover, the current political climate in the United States and long-running tensions and controversies over health-care federalism foster an environment in which states are emboldened to test how far they can go to regulate and restrict access to myriad FDA-approved pharmaceuticals.

Apart from medication abortion and contraceptives, future state encroachment is likely to occur most frequently for pharmaceuticals that raise contentious political, social, and ethical questions. For example, despite strong evidence supporting their overall safety, effectiveness, and importance to public health, debates over vaccines continue to rage.[235] Might a state led by politicians opposed to vaccines attempt to ban or significantly restrict the use of an FDA-licensed vaccine? Even if a legislator does not personally oppose vaccines, might he be willing to do so to appease his anti-vaccine supporters? Florida, for example, while not banning the COVID-19 vaccines, became the first state to recommend against their use in healthy children.[236] And what about new innovations, such as nontherapeutic enhancement products? New and future innovations in reproductive and genomic medicine may add new options for people deciding whether, when, and how to have a child. These and other developments will give rise to thorny questions ripe for state divergence and federal-state friction.

The current trend of more aggressive state regulation of pharmaceuticals, even while still limited to a select number of drugs, make it imperative to consider the potential negative consequences of state bans and restrictions, as well as the preemptive effect of federal law. The remainder of this Article takes up those issues in turn.

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[235] *See, e.g.*, *Safety of COVID-19 Vaccines*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html [https://perma.cc/5WLZ-6U2P] (last updated Nov. 21, 2022) ("COVID-19 vaccines are safe and effective."); Alana Wise, *The Political Fight Over Vaccine Mandates Deepens Despite Their Effectiveness*, NAT'L PUB. RADIO (Oct. 17, 2021), https://www.npr.org/2021/10/17/1046598351/the-political-fight-over-vaccine-mandates-deepens-despite-their-effectiveness [https://perma.cc/GW6H-LU8M] ("The science is clear: Vaccines are a safe and effective way to prevent serious illness, hospitalization and death from the coronavirus . . . Still, the battle to inoculate the nation against the coronavirus has reached a fever pitch in recent months.").

[236] Owen Dyer, *COVID-19: Florida Surgeon General Says State Will Be First Not to Recommend Vaccination for Children*, BRIT. MED. J. (Mar. 9, 2022), https://www.bmj.com/content/376/bmj.o622 [https://www.bmj.com/content/376/bmj.o622]; Bruce Y. Lee, *Florida Surgeon General Ladapo Will Recommend Against COVID-19 Vaccines for Healthy Children*, FORBES (Mar. 8, 2022), https://www.forbes.com/sites/brucelee/2022/03/08/florida-surgeon-general-ladapo-will-recommend-against-covid-19-vaccines-for-healthy-children/?sh=3eac8d0d3e4e [https://perma.cc/2FPZ-8CUX].

III. Negative Externalities of State Pharmaceutical Regulation

Compared to the vast number of FDA-approved drugs available in the United States,[237] state bans and restrictions on FDA-approved pharmaceuticals remain relatively infrequent and limited to a select number of drugs at this time. This may raise questions about whether state pharmaceutical regulation truly represents a pressing issue. This Article asserts that it does. Even if relatively infrequent, severe and widespread harms result from state pharmaceutical bans and restrictions, which are likely to continue during this period of increasing polarization.[238] Court battles and other fights loom, including potential action by the federal government, as foreshadowed by Attorney General Garland's statement about states' inability to ban medication abortion.[239] Congress, the FDA, and other stakeholders must prepare for these upcoming battles and consider the issue sooner rather than later. This Part illustrates the import of these issues by first acknowledging the potential benefits of health-care federalism and then examining the negative externalities of state pharmaceutical regulation, exposing how it disproportionately impacts historically marginalized and vulnerable communities and exacerbates health disparities and social inequities.

A. The Values of Health-Care Federalism

It must first be acknowledged that state health-care regulations produce both positive and negative externalities. On the positive side, states can sometimes expand beyond federal requirements in ways that enhance health and well-being.[240] Insurance coverage of contraceptives provides one example. The contraceptive coverage guarantee under the federal Patient Protection and Affordable Care Act applies to most private health plans nationwide and requires coverage of FDA-approved contraceptives, along with related counseling and services. Subject to certain exceptions, plans must cover these services without cost-sharing requirements such as deductibles or

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[237] As of November 2021, there were over 20,000 FDA-approved prescription drug products and 621 FDA-approved biologics. *Fact Sheet: FDA at a Glance*, U.S. Food & Drug Admin. (Nov. 2021), https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance [https://perma.cc/SZ26-BCLF].

[238] *See supra* note 42 and accompanying text.

[239] *See* Garland Statement, *supra* note 135 and accompanying text.

[240] States are limited, however, in how far they can go to *increase* access to pharmaceuticals. States generally cannot "approve" a drug for use in their state if that drug has not been approved by the FDA. The only possible way to do this without running afoul of the FDCA is if the manufacture, distribution, and use of that drug remain wholly within the state and no drug or component of that drug enters interstate commerce. *See* 21 U.S.C. § 355(a). In today's marketplace, that seems highly unlikely, and drug manufacturers would likely be wary to risk violating the FDCA.

copays.[241] Some states go further, such as by requiring coverage for OTC contraceptives, allowing patients to receive an extended supply of contraceptives at one time, or requiring coverage of male sterilization without out-of-pocket costs.[242]

State restrictions on FDA-approved drugs may also prove beneficial in certain circumstances, a reality this Article does not contest and recognizes through the solutions proposed below.[243] There is a strong argument, for example, that Massachusetts's ban, and then restrictions, on Zohydro, an FDA-approved extended-release hydrocodone product, represents such a case. In 2014, to confront the opioid epidemic, Massachusetts Governor Deval Patrick declared a public health emergency and authorized a prohibition on prescribing and dispensing Zohydro.[244] Throughout the opioid epidemic, Massachusetts has frequently been among the states with the highest rate of opioid-involved overdose deaths,[245] giving the Commonwealth good reason to be concerned about the potential consequences of an opioid like Zohydro, which lacked abuse-deterrent properties.[246]

When making decisions about pharmaceutical safety and efficacy, the FDA adopts a national rather than local perspective and thus may overlook local circumstances like those in Massachusetts that might render a drug less safe or effective in a particular region. If a locality's current situation makes a drug less safe for the local population compared to the broader U.S. population and evidence exists to support that increased risk, states have a stronger justification for restricting access under their police powers to ensure the safety of their citizens. Indeed, this achieves an important goal of federalism because local governments may "be more sensitive to the diverse needs of a heterogenous society."[247] It is thus imperative to strike a delicate

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[241] *Birth Control Benefits*, HEALTHCARE.GOV, https://www.healthcare.gov/coverage/birth-control-benefits/ [https://perma.cc/AF3H-T7A5]. Certain religious employers and nonprofit religious organizations are exempt from this requirement. *See id.*

[242] *Insurance Coverage of Contraceptives*, GUTTMACHER INST., https://www.guttmacher.org/state-policy/explore/insurance-coverage-contraceptives [https://perma.cc/2QKK-9XC9] (last updated Oct. 1, 2022).

[243] *See infra* Part IV.B.

[244] Zogenix Inc. v. Patrick, No. 14-11-689-RWZ, 2014 WL 1454696, at *1 (D. Mass. Apr. 15, 2014). The ban was ultimately struck down by a district court, based in part on preemption. Litigation continued, with Massachusetts amending its policies to set restrictions and requirements for the prescription and use of Zohydro, rather than an outright ban. For a more detailed discussion of the Zohydro controversy, see Noah, *State Affronts*, *supra* note 30, at 3–16.

[245] *See, e.g.*, Peter Ciurczak, *Opioid-Related Deaths in Massachusetts Remain Elevated Four Years After Peak*, BOS. INDICATORS (Sept. 17, 2021), https://www.bostonindicators.org/article-pages/2021/september/opioid-deaths-2021 [https://perma.cc/C3UV-YLH3]; Anise Vance & Luc Schuster, *Opioid Addiction is a National Crisis. And It's Twice as Bad in Massachusetts*, BOS. INDICATORS (2018), https://www.bostonindicators.org/reports/report-website-pages/opioids-2018 [https://perma.cc/28Q9-JVVT].

[246] *Zogenix*, 2014 WL 1454696, at *1.

[247] Gregory v. Ashcroft, 501 U.S. 452, 458 (1991).

balance between federal and state interests. Health-care regulation can "no longer be understood . . . [as] an either-or separate spheres model."[248]

Additionally, states can help guard against internal capture of the FDA by the federal government.[249] There are times when the executive has captured the FDA in ways that rendered the Agency unreliable to vulnerable groups.[250] Concerns remain about capture of the FDA and how the executive or others within the federal government may use the Agency as a political tool to create obstacles to important pharmaceuticals, as was seen during the height of the COVID-19 pandemic when the Trump Administration refused to waive the in-person dispensing requirements then required by the mifepristone REMS.[251] That decision represented a stark contrast to other related decisions during the pandemic, when the Department of Health and Human Services and the FDA waived certain in-person requirements for other drugs, including powerful opioids, and the Centers for Disease Control and Prevention "advised medical providers to use telemedicine 'whenever possible' because it is 'the best way to protect patients and staff from COVID-19.'"[252] Even while recognizing the risks associated with in-person medical care during the pandemic, the Trump Administration nevertheless "refused to extend that same grace to women seeking medication abortions."[253]

These are not all the potential benefits of health-care federalism, but their existence highlights the importance of striking a delicate balance between federal and state rights when considering potential solutions.

B. The Pernicious Consequences of Health-Care Federalism

Notwithstanding the potential benefits of state health-care regulation, serious equity concerns arise because state bans and restrictions do not affect a state's population in a uniform manner. Rather, they exacerbate and entrench existing health disparities within and between states by disproportion-

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[248] Gluck & Huberfeld, *supra* note 3, at 1719.

[249] For a more detailed discussion of internal capture of the FDA, see Whelan, *supra* note 193. The term "executive" is used here to refer to the President and other White House offices and officials, such as the Chief of Staff, White House Counsel, presidential advisors, and others. "Executive" or "internal" capture thus includes influence and control of agencies by the President directly as well as by those who engage with agencies on the President's behalf and at his direction. *Id.* at 1791 & n.10.

[250] *See generally id.* at 1818–36 (describing the internal capture of the FDA relating to its regulation of mifepristone and emergency contraceptives, which disproportionately impacted myriad vulnerable populations).

[251] *See* Press Release, Am. Civ. Lib. Union, In Its First Abortion Decision Since Justice Barrett's Confirmation, the Court Allowed the Trump Administration to Subject Abortion Patients to Needless COVID-19 Risk (Jan. 12, 2021), https://www.aclu.org/press-releases/supreme-court-grants-trump-administration-request-endanger-abortion-patients-during [https://perma.cc/7ZVL-MP8S].

[252] FDA v. Am. Coll. of Obstetricians & Gynecologists, 141 S. Ct. 578, 580 (2021) (Sotomayor, J., dissenting).

[253] *Id.*

ately impacting vulnerable and historically marginalized populations, including low-income populations, communities of color, the LGBTQ+ population, and persons with disabilities—the very populations racked by a long history of discrimination in the health-care system and society more generally. As a result of state bans and restrictions, millions of patients may find themselves trapped, forced to drive hours—if they can even do so—to obtain time-sensitive or even life-preserving medical care.

In passing FDAMA, which included a preemption provision relating to nonprescription pharmaceuticals,[254] Congress acknowledged the consequences of disparate state laws in this space, stating:

> Under our Federal system, it is important that State and local officials enforce the same regulatory requirements for products as do our Federal officials. Different or additional requirements a[t] the State or local level can work against our national marketplace, confuse consumers, raise prices, undermine public confidence in our regulatory system and in products important to public health, and *result in divergent public health protection throughout the country*.[255]

Despite this recognition, Professors Gluck and Huberfeld observe how "[u]niformity and equality of access to health care are still wanting" in the United States and how this "fragmented structure leads different populations in our system to access health care in different ways," which "fosters disparities and inefficiencies."[256]

Consider the following hypothetical. Jamie is a Black transgender man with a mobility-limiting disability and Taylor is a white, cisgender, heterosexual, nondisabled man. Both live in a state that bans the prescription and use of "Drug X," which both need to treat a life-threatening condition. The law also bans in-state and out-of-state providers from using telemedicine to prescribe Drug X to patients located in the state. Jamie makes minimum wage, living paycheck-to-paycheck; Taylor makes over $200,000 per year. The state ban will impact Jamie in far more significant ways. Taylor would likely face little difficulty and few economic constraints traveling to another state to obtain access to Drug X. The same most certainly cannot be said for Jamie.

That hypothetical is not unrealistic. To make this more concrete: in 2020, the median income for white, non-Hispanic households was $74,912, compared to $45,870 for Blacks and $55,321 for Hispanics.[257] In 2020, the poverty rate for persons with disabilities ages eighteen to sixty-four was

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[254] *See* 21 U.S.C. § 379r.

[255] S. Rep. No. 105-43, at 64 (1997) (emphasis added).

[256] Gluck & Huberfeld, *supra* note 3, at 1705, 1719.

[257] EMILY A. SHRIDER ET AL., U.S. CENSUS BUR., INCOME AND POVERTY IN THE UNITED STATES: 2020 3 (2021), https://www.census.gov/content/dam/Census/library/publications/2021/demo/p60-273.pdf [https://perma.cc/ES3V-KQEN].

25.0%, compared to 9.3% for persons without disabilities.[258] Further, LGBTQ+ persons experience higher rates of poverty compared to cisgender heterosexuals (21.6% vs. 15.7%), with significant variation depending on sexual orientation, gender identity, and other factors such as race, age, and disability.[259] Transgender men, for example, experience the highest poverty rate, 33.7%.[260] Importantly, historic and ongoing racism, discrimination, and other structural barriers[261] mean that members of historically marginalized and vulnerable populations begin at a disadvantage, as they are more likely to suffer from poor health than their white, more affluent, counterparts are.[262]

Individuals with limited incomes and other barriers to travel may be unable to access necessary care and medicines by traveling out of state. Post-*Dobbs*, the feasibility of travel for persons needing abortion care is hampered further for those living in certain regions of the United States, who are now locked in a state surrounded by other abortion-hostile states, thus requiring them to travel even further for care.[263] The costs compound for those without health insurance or with health insurance that imposes strict "in-network" requirements.[264] And although travel constraints appear most relevant to surgical abortions, they can also affect access to medication abortion. For example, in states that ban all abortions and/or prohibit the use of telemedicine to provide abortion care and prescribe medication abortion, residents may face significant difficulty obtaining access to medication abortion while remaining in state.[265] To get around these restrictions, some

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[258] *Id.* at 53.

[259] Cisgender gay men, for example, tend to have much lower rates of poverty (12.1%) than bisexual cisgender women and transgender persons (29.4% for both). M. V. Lee Badgett et al., Williams Inst., LGBT Poverty in the United States 2–3 (2019), https://williamsinstitute.law.ucla.edu/wp-content/uploads/National-LGBT-Poverty-Oct-2019.pdf [https://perma.cc/FM8L-MVK4].

[260] *Id.* at 8. Cisgender straight men have a poverty rate of 13.4%. *Id.* at 3.

[261] *See generally* Ruqaiijah Yearby et al., *Structural Racism in Historical and Modern US Health Care Policy*, 41 Health Affairs 187 (2022) (providing an account of structural racism in health-care policy and its consequences).

[262] *See* Sofia Carratala & Connor Maxwell, *Health Disparities by Race and Ethnicity*, Ctr. for Am. Progress (May 7, 2020), https://www.americanprogress.org/article/health-disparities-race-ethnicity/ [https://perma.cc/ZJP7-RV5Y]; Latoya Hill et al., *Key Facts on Health and Health Care by Race and Ethnicity*, Kaiser Fam. Found. (Jan. 26, 2022), https://www.kff.org/racial-equity-and-health-policy/report/key-facts-on-health-and-health-care-by-race-and-ethnicity/ [https://perma.cc/23EM-XQJK].

[263] For periodically updated maps and charts that describe the current status of abortion laws in the states, *see Interactive Map*, Guttmacher Inst., *supra* note 7, and *Tracking the States Where Abortion is Now Banned*, N.Y. Times, *supra* note 7.

[264] *See* Megan Messerly, *Will Health Insurers Continue to Cover Abortion Now that Roe Has Been Overturned?*, Politico (June 27, 2022), https://www.politico.com/news/2022/06/27/will-health-insurers-continue-to-cover-abortion-now-that-roe-has-been-overturned-00041117 [https://perma.cc/KCX4-A5LA] (noting that out-of-state abortion clinics may be out-of-network, resulting in "high deductibles and out-of-network costs that make their coverage unaffordable").

[265] *See* Kimball, *supra* note 19 ("U.S. telehealth providers will be banned from prescribing and sending abortion pills to women in states that outlaw the procedure.").

individuals may have to travel out of state for a telemedicine appointment or to pick up their pills that they have shipped to an out-of-state address.[266]

Out-of-state care proves particularly problematic for persons with disabilities, for whom travel may be "physically or logistically difficult."[267] Finding an accessible and affordable out-of-state provider and "coordinating transportation" requires time and resources.[268] This proves problematic if the medical needs are time-sensitive, as is often the case with abortion, particularly medication abortion. Moreover, both persons with and without disabilities may be unable to travel long distances due to the medical risks of doing so.[269]

A recent report of an American woman in Malta, where abortion is illegal without exception, paints an ominous picture of what could occur in the United States, if it has not already.[270] While traveling in Malta at sixteen weeks pregnant, Andrea Prudente suffered an incomplete miscarriage and required a procedure to remove the remaining fetal tissue to prevent a life-threatening infection.[271] Malta law prohibited her from doing so and she was unable to fly back to the United States given the risks of a long flight, leaving her trapped and fighting for her life.[272] Fortunately, Prudente has a generous insurance plan and was able to organize an emergency flight accompanied by a doctor to a nearby country where she could receive the lifesaving procedure.[273]

Realistically, many will not have Prudente's options and her fortunate outcome. And while abortion bans and restrictions typically contain exceptions for "medical emergencies" or when the mother's life or health is in danger, even those exceptions are at risk.[274] Anti-abortion activists have

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[266] Christopher Rowland, *To Get Banned Abortion Pills, Patients Turn to Legally Risky Tactics*, WASH. POST (July 6, 2022), https://www.washingtonpost.com/business/2022/07/06/abortion-pills-mail-telehealth/ [https://perma.cc/867W-WZFE] (reporting how Carafem, a telehealth abortion provider, "encourages women from states with abortion bans and bans on medication abortions to travel to the border of the closest state where the pills are legal and pull into a parking lot for their telehealth visit"); *see also* Christie, *supra* note 157 (describing how patients in Arizona can mail medication abortion to a California address and then go pick it up).

[267] Whelan & Goodwin, *supra* note 26, at 996.

[268] *Id.* at 996–97.

[269] *See id.* at 992–1000 (describing the impact of restrictive abortion laws on persons with physical disabilities).

[270] *See* Maggie Rulli et al., *US Woman on Vacation in Malta Denied Lifesaving Abortion*, ABC NEWS (June 23, 2022), https://abcnews.go.com/International/us-woman-vacation-malta-denied-lifesaving-abortion/story?id=85594901 [https://perma.cc/AEZ7-2KGE].

[271] *Id.*

[272] *Id.*

[273] *Id.*

[274] *See* Ariana Eunjung Cha & Emily Wax-Thibodeaux, *Abortion Foes Push to Narrow 'Life of Mother Exceptions'*, WASH. POST (May 13, 2022), https://www.washingtonpost.com/health/2022/05/13/abortion-ban-exceptions-mothers-life/ [https://perma.cc/NRP3-W8KX] (highlighting efforts to narrow, or even remove, many exceptions).

made their position clear. According to Matt Sande, legislative director of Pro-Life Wisconsin, they want "'a total ban, no exceptions . . . We don't think abortion is ever necessary to save the life of the mother.'"[275] And even where exceptions remain, many medical experts and legal scholars acknowledge that defining "life-threatening" or what qualifies as a medical "emergency" can be difficult and confusing for providers.[276] According to Professor Lawrence Gostin, these laws "place physicians in an untenable position not knowing that if they serve the medical interests of their patients, whether they'll be subject to criminal liability . . . At best, it will make physicians hesitate to save the life of a woman; at worst, outright refuse to."[277]

The dangers associated with traveling for out-of-state care magnify for victims of domestic violence, whose whereabouts, "daily tasks, bank accounts, and access to friends and family may be controlled by an abusive partner."[278] The overturn of *Casey* heightens these risks. One of *Casey's* core yet underdiscussed holdings was the invalidation of a spousal notification law, which the Court held placed an undue burden on the right to an abortion.[279] In reaching this conclusion, the Court discussed at length the risks of violence posed by such requirements.[280] With the evisceration of *Casey*, states are free to again enact spousal/partner consent laws, which will disproportionately harm historically marginalized populations who experience higher rates of intimate partner violence.[281]

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[275] *Id.*; *see also* Lexi Lonas, *Herschel Walker Says He Wants Total Ban on Abortion: 'There's No Exception in My Mind'*, HILL (May 20, 2022), https://thehill.com/news/campaign/3495657-herschel-walker-says-he-wants-total-ban-on-abortion-theres-no-exception-in-my-mind/ [https://perma.cc/KQ7Q-2ZLR] (reporting Georgia Republican Senate candidate Herschel Walker's support for an abortion ban without exceptions for rape, incest, or health of the mother).

[276] Tina Reed, *Defining "Life-Threatening" Can be Tricky in Abortion Law Exceptions*, AXIOS (June 28, 2022), https://www.axios.com/2022/06/28/abortion-ban-exceptions-women-medical-emergencies [https://perma.cc/J9R4-3T7Z].

[277] *Id.*; *see also* Eunjung Cha & Wax-Thibodeaux, *supra* note 274 (citing other experts on the murkiness of these terms); Mary Kekatos, *Why Doctors Say the 'Save the Mother's Life' Exception of Abortion Bans is Medically Risky*, ABC NEWS (June 13, 2022), https://abcnews.go.com/Health/doctors-save-mothers-life-exception-abortion-bans-medically/story?id=84668658 [https://perma.cc/GMH6-HJ4T] (discussing how the exceptions to relevant laws are "vague").

[278] *See* Lysaundra Campbell, *The Hidden Link Between Domestic Violence and Abortion*, REWIRE NEWS GRP. (Oct. 24, 2019), https://rewirenewsgroup.com/article/2019/10/24/the-hidden-link-between-domestic-violence-and-abortion/ [https://perma.cc/5DM5-ESN2].

[279] Planned Parenthood of Se. Pennsylvania v. Casey, 505 U.S. 833, 887–98 (1992), *overruled by* Dobbs v. Jackson Women's Health Org., No. 19-1392 (June 24, 2022).

[280] *Id.* at 889–94.

[281] These include persons with disabilities; Black, multiracial, and American Indian/Alaska Native women; and the LQBTQ+ community. *See* TAYLOR N.T. BROWN & JODY L. HERMAN, WILLIAMS INST., INTIMATE PARTNER VIOLENCE AND SEXUAL ABUSE AMONG LGBT PEOPLE 1–4 (2015), https://williamsinstitute.law.ucla.edu/wp-content/uploads/IPV-Sexual-Abuse-Among-LGBT-Nov-2015.pdf [https://perma.cc/9CAR-JSQC]; OFF. FOR VICTIMS OF CRIME ET AL., INTIMATE PARTNER VIOLENCE FACT SHEET (2018), https://ovc.ojp.gov/sites/g/files/xyckuh226/files/ncvrw2018/info_flyers/fact_sheets/

The chilling effects on health-care providers and patients represent another consequence of state bans and restrictions. These are particularly troublesome because they often result from medically unnecessary restrictions, which are instead based largely on policymakers' moral and ethical views or their concerns about political backlash from their supporters and large financial donors.[282] Too often, policymakers do not understand the ramifications of their actions on health-care policy. Or, even more troubling, they understand but act in blatant disregard of the consequences.[283]

Providers in states with bans or restrictions encounter real or perceived constraints on their ability to act in the best interests of their patients, fearing criminal and civil liability as well as loss of their licenses to practice.[284] For

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2018NCVRW_IPV_508_QC.pdf [https://perma.cc/E8TV-2Q4X]; ERIKA HARRELL, U.S. DEP'T OF JUSTICE, CRIME AGAINST PERSONS WITH DISABILITIES, 2009–2019—STATISTICAL TABLES 6 (2021), https://bjs.ojp.gov/content/pub/pdf/capd0919st.pdf [https://perma.cc/RR7X-4CMV]; *Sexual Violence and Intimate Partner Violence Among People with Disabilities*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 1, 2020), https://www.cdc.gov/violenceprevention/sexualviolence/svandipv.html [https://perma.cc/EXA2-FV73].

[282] In presidential elections, for example, the American electoral system tends to encourage candidates to focus on a handful of "swing states," and candidates often focus on "financially generous constituents" at the expense of the public interest, both prior to and after taking office. *See* John D. Graham & Paul R. Noe, *Beyond Process Excellence: Enhancing Societal Well-Being*, *in* ACHIEVING REGULATORY EXCELLENCE 72, 84–85 (Cary Coglianese ed., 2017) (describing the noncompetitive nature of U.S. elections except in a few "battleground states"); Kathryn Harrison, *Regulatory Excellence and Democratic Accountability*, *in* ACHIEVING REGULATORY EXCELLENCE 56, 58 (Cary Coglianese ed., 2017) (describing how elected regulators are more likely to "eschew publicly beneficial regulations" compared to independent bureaucrats); *see also* Wendy Wagner, *Regulating by the Stars*, *in* ACHIEVING REGULATORY EXCELLENCE 36, 38 (Cary Coglianese ed., 2017); *cf. also* Michele McKeegan, *The Politics of Abortion: A Historical Perspective*, 3 WOMEN'S HEALTH ISSUES 127, 127–29 (1993) (providing a historical perspective on the power and influence of religious and anti-abortion conservatives); *Top Contributors—Abortion Policy/Anti-Abortion: Top Contributors to Federal Candidates, Parties, and Outside Groups*, OPEN SECRETS, https://www.opensecrets.org/industries/contrib.php?ind=Q14&Bkdn=DemRep&cycle=2020 [https://perma.cc/NL9L-KA4E] (showing contributions by certain pro-life organizations to federal candidates, parties, and outside groups during the 2020 election cycle). Studies also show that elected officials are more responsive to donor interests than constituent interests and that the largest donors tend to be white men. SEAN MCELWEE ET AL., DEMOS, WHOSE VOICE, WHOSE CHOICE? 9, 15 (2016) https://www.demos.org/sites/default/files/publications/Whose%20Voice%20Whose%20Choice_2.pdf [https://perma.cc/WZ55-P34U] (showing that elected officials are more responsive to donor interests than constituent interests and that the largest donors tend to be white men); Martin Gilens & Benjamin I. Page, *Testing Theories of American Politics: Elites, Interest Groups, and Average Citizens*, 12 PERSP. ON POL. 564, 565 (2014).

[283] *Cf.* Lindsay Whitehurst & Lindsey Tanner, *If Roe Falls, Some Fear Repercussions for Reproductive Care*, ASSOC. PRESS (May 23, 2022), https://apnews.com/article/abortion-us-supreme-court-politics-health-d8821fc3293e490db54441e6c838da59 [https://perma.cc/V2CP-Z9BQ] ("I truly think the people writing these [abortion] laws either have no concept of the broad implications or do not care about how this impacts so many aspects of women's health care," quoting Dr. Kristyn Brandi, a New Jersey obstetrician/gynecologist.).

[284] *See, e.g.*, Selena Simmons-Duffin, *For Doctors, Abortion Restrictions Create an 'Impossible Choice' When Providing Care*, NAT'L PUB. RADIO (June 24, 2022), https://www.npr.org/sections/health-shots/2022/06/24/1107316711/doctors-ethical-bind-abor-

example, after Senate Bill (SB) 8 went into effect in Texas, which banned abortion starting around six weeks gestation, "nearly half the doctors at one of the state's biggest providers stopped working."[285] And even when states provide exceptions, such as for "medical emergencies," vaguely defined terms create uncertainty about what qualifies as a "medical emergency," as noted above.[286] In Texas, providers also recognize that even if they comply with the law, that "doesn't stop extremists" from claiming they violated the law, leading to costly, time-consuming legal proceedings that interfere with a provider's ability to care for their patients.[287]

Other unintended collateral consequences arise, such as effects on the treatment of other conditions not intended to be covered by the ban or restriction.[288] Mifepristone, for example, is used not only to induce abortion, but also in the management of early pregnancy loss.[289] Patients and providers have also reported difficulties accessing certain drugs for autoimmune diseases and cancer because the drugs are considered "abortion inducing."[290]

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tion [https://perma.cc/5BSW-VKZL] (noting that violations of certain anti-abortion laws can result in "loss of license, money loss, potentially even criminal sanctions"); *see also* Reed, *supra* note 276 (citing Professor Gostin).

[285] Jennifer Gerson, *'No One Wants to Get Sued': Some Abortion Providers Have Stopped Working in Texas*, 19TH (Sept. 15, 2021), https://19thnews.org/2021/09/abortion-providers-texas-stopped-working-under-threat-sued/ [https://perma.cc/6FRW-TQSH].

[286] *See* Reed, *supra* note 276 and accompanying text; *see also* Caroline Kitchener, *The Texas Abortion Ban Has a Medical Exception. But Some Doctors Worry It's Too Narrow To Use*, LILY (Oct. 22, 2021), https://www.thelily.com/the-texas-abortion-ban-has-a-medical-exception-but-some-doctors-worry-its-too-narrow-to-use/ [https://perma.cc/ES6S-MRRA]; Sean Murphy & John Hanna, *Days Before Oklahoma Bans Abortion, Details Still Uncertain*, U.S. NEWS (May 20, 2022), https://www.usnews.com/news/politics/articles/2022-05-20/days-before-oklahoma-bans-abortion-details-still-uncertain [https://perma.cc/M4ZT-VUP4] (reporting uncertainty about the law's exceptions and providers' concerns about liability).

[287] Gerson, *supra* note 285.

[288] *See, e.g.*, Amanda D'Embrosio, *Restrictions on Mifepristone a Barrier to Miscarriage Care, Surveys Show*, MEDPAGE TODAY (May 10, 2022), https://www.medpagetoday.com/meetingcoverage/acog/98635 [https://perma.cc/8M45-MJ5V] (reporting that many clinicians believe that restrictions on mifepristone create barriers to providing miscarriage care); Julie Strasser et al., *Penalizing Abortion Providers Will Have Ripple Effects Across Pregnancy Care*, HEALTH AFFAIRS (May 3, 2022), https://www.healthaffairs.org/do/10.1377/forefront.20220503.129912/ [https://perma.cc/LDN7-UP3E] (describing effects on pregnancy care if *Roe* is overturned and abortions, including medication abortions, are banned).

[289] D'Embrosio, *supra* note 288.

[290] Elisabeth Mahase, *US Anti-Abortion Laws May Restrict Access to Vital Drug for Autoimmune Diseases, Patient Group Warns*, BRIT. MED. J. (July 6, 2022), https://www.bmj.com/content/378/bmj.o1677 [https://perma.cc/H3NH-EMBX]. Methotrexate represents one example. The drug can be used off-label to terminate a pregnancy, but it is approved by the FDA for the treatment of rheumatoid arthritis, lupus, and cancer. *Id.* It is also used to treat patients after early pregnancy loss, including ectopic pregnancies and miscarriages. *Id.* There have been reports that pharmacists in states with abortion bans are refusing to fill prescriptions for these drugs. *Id.*; María Luisa Paúl, *14-Year-Old's Arthritis Meds Denied After Ariz. Abortion Ban, Doctor Says*, WASH. POST (Oct. 5, 2022), https://www.washingtonpost.com/nation/2022/10/05/abortion-arizona-arthritis-prescription-refill/ [https://perma.cc/TA7H-WGJJ] (reporting a pharmacy's refusal to refill a fourteen-year-old patient's prescription for methotrexate to treat her rheumatoid arthritis).

Troublingly, patient morbidity and mortality may increase,[291] particularly among communities of color.[292] The consequences may spread even further, such as by affecting provider education in states with bans and restrictions[293] or discouraging new providers from pursuing a practice area likely to be subject to extra scrutiny by the state.[294]

The chilling effects extend to patients, who may hesitate to seek care due to concerns about liability[295] or distrust of providers and institutions who they fear could report them.[296] Because state bans and restrictions can imply, erroneously, that a drug is unsafe, unethical, or immoral, they may also fuel stigmatization of those who need these medications. Patients who experience

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[291] *See, e.g.*, Olga Khazan, *When Abortion is Illegal, Women Rarely Die. But They Still Suffer*, ATLANTIC (Oct. 11, 2018), https://www.theatlantic.com/health/archive/2018/10/how-many-women-die-illegal-abortions/572638/and [https://perma.cc/3EGE-EBR2] (reporting the story of a woman in Argentina, where abortion was criminalized at the time, who died from septic shock after attempting to terminate her pregnancy using parsley); Amanda Jean Stevenston, *Study Shows an Abortion Ban May Lead to a 21% Increase in Pregnancy-Related Deaths*, OHIO CAPITAL J. (May 4, 2022), https://ohiocapitaljournal.com/2022/05/04/study-shows-an-abortion-ban-may-lead-to-a-21-increase-in-pregnancy-related-deaths/ [https://perma.cc/26DU-GFGM].

[292] *See* Aria Bendix & Dana Varinsky, *The Biggest Health Risks Women Would Face if Roe v. Wade is Overturned*, NBC NEWS (May 4, 2022), https://www.nbcnews.com/health/health-news/health-risks-overturning-roe-v-wade-abortion-rcna27109 [https://perma.cc/37GK-2BQ6]; Elizabeth Weise, *Pregnancy-Related Deaths Could Rise 20% or More in States that Outlaw Abortion, Experts Say*, USA TODAY (May 4, 2022), https://www.usatoday.com/story/news/health/2022/05/04/roe-abortion-ban-pregnancy-deaths/9630025002/ [https://perma.cc/ZF48-5B3Y].

[293] *See* Michael DePeau-Wilson, *Ending Roe Could Lead to Decline in Residency Abortion Training*, MEDPAGE TODAY (May 4, 2022), https://www.medpagetoday.com/special-reports/features/98548 [https://perma.cc/22VF-H5S4]; Marisa E. Giglio et al., *Abortion Training in Medical Education—Implications of the Supreme Court's Upcoming Decision*, 386 N. ENG. J. MED. 707, 708 (2022).

[294] *See* Shannon Firth, *Experts Warn of Roe Reversal's Impact on Patients, Ob/Gyns*, MEDPAGE TODAY (June 29, 2022), https://www.medpagetoday.com/obgyn/pregnancy/99511 [https://perma.cc/Q975-HXSE] (citing concerns that legal restrictions and uncertainties "will have a chilling effect on the number of students entering the field of obstetrics and gynecology").

[295] *Cf.* Jessica Glenza, *'A Severe Chilling Effect': Abortion Bans Will Inhibit Doctors' Advice to Patients, Experts Fear*, GUARDIAN (May 6, 2022), https://www.theguardian.com/world/2022/may/06/abortion-bans-patient-doctor-medical-advice [https://perma.cc/A5TE-Z5HW] (stating that if the Supreme Court overturns *Roe* and *Casey*, there will be "profound and detrimental impacts on . . . patients' ability to seek medical advice without fear of prosecution").

[296] *See id.*; Ella Ceron, *What Happens When Women Get Illegal Abortions in Post-Roe America*, BLOOMBERG (June 24, 2022), https://www.bloomberg.com/news/articles/2022-06-24/is-abortion-illegal-overturning-roe-v-wade-means-penalties-for-some [https://perma.cc/NWB5-56LA] ("Experts and healthcare providers worry that the current environment will scare people out of seeking reproductive care overall, as well as create distrust between patients and the institutions and groups that want to help them.").

stigma and discrimination are more likely to avoid seeking health care,[297] which can have profound consequences.[298]

If states with abortion bans attempt to prosecute patients, the patients most likely to be subject to prosecution are the populations already most susceptible to discriminatory oversurveillance, such as communities of color.[299] States have not historically prosecuted pregnant persons who have abortions in violation of a state law and typically target providers instead. But as conservative states seek to end abortion entirely, this could be their next step.[300]

Relatedly, some abortion-rights advocates express concern that liability risks increase if patients obtain medication abortion without the involvement of a health-care provider.[301] Prosecuting pregnant persons would not be without precedent. There are many examples of states prosecuting women for

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[297] *Cf.* Shabab Ahmed Mirza & Caitlin Rooney, *Discrimination Prevents LGBTQ People from Accessing Health Care*, CTR. FOR AM. PROGRESS (Jan. 18, 2018), https://www.americanprogress.org/article/discrimination-prevents-lgbtq-people-accessing-health-care/ [https://perma.cc/49MJ-ZHHE] (explaining that discrimination in health-care settings discourages LGBTQ people from seeking care).

[298] *See* Sharon K. Byrne, *Healthcare Avoidance: A Critical Review*, 22 HOLISTIC NURSING PRAC. 280, 289–90 (2008) (describing some of the potential costs of health-care avoidance).

[299] *See generally* MICHELE GOODWIN, POLICING THE WOMB 21–22 (2020) (describing how women of color are disproportionately targeted for drug use during pregnancy); Anita L. Allen, *Dismantling the "Black Opticon": Privacy, Race, Equity, and Online Data-Protection Reform*, 131 YALE L.J. F. 907 (2022) (describing African Americans' susceptibility to discriminatory oversurveillance, exclusion, and fraud); Barton Gellman & Sam Adler Bell, *The Disparate Impact of Surveillance*, CENTURY FOUND. (Dec. 21, 2017), https://tcf.org/content/report/disparate-impact-surveillance/ [https://perma.cc/3ALX-S7AF] (explaining that mass surveillance is "heaviest in communities already disadvantaged by their poverty, race, religion, ethnicity, and immigration status"); Kylie Cheung, *Abortion in the Surveillance State*, JEZEBEL (Nov. 22, 2021) https://jezebel.com/abortion-in-the-surveillance-state-1848076906 [https://perma.cc/UQX8-5EPP] (last updated Nov. 24, 2021) ("Those who are most vulnerable to surveillance and criminalization for pregnancy loss are notably people of color.").

[300] According to one report, around two dozen people have been prosecuted for self-managed abortions since 2000. *See* Nicole Fallert, *Self-Managed Abortions Could be Legally Riskier After Texas's Six-Week Law, Advocates Say*, BUZZFEED NEWS (Sept. 16, 2021), https://www.buzzfeednews.com/article/nicolefallert/self-managed-abortion-defense-fund [https://perma.cc/CN48-W82L]; *see also* Andrea Rowan, *Prosecuting Women for Self-Inducing Abortion: Counterproductive and Lacking Compassion*, 18 GUTTMACHER POL'Y REV. 70, 71 (2015) ("There have been at least half a dozen U.S. cases where women have been arrested and charged after attempting to self-induce an abortion using illicitly obtained abortifacients."). At least a few states currently have laws on the books that explicitly prohibit self-induced abortions. *See, e.g.*, NEV. REV. STAT. § 200.220 (2022); OKLA. STAT. TIT. 63 § 1-733 (2022); S.C. CODE ANN. § 44-41-80(b) (2022).

[301] Rowan, *supra* note 300, at 71 ("The advent of medication abortion has further allowed some women to take matters into their own hands; however, doing so has exposed them to the risk of criminal prosecution."); Michelle Oberman, Opinion, *What Happens When Abortion is Banned?*, N.Y. TIMES (May 31, 2018), https://www.nytimes.com/2018/05/31/opinion/sunday/abortion-banned-latin-america.html [https://perma.cc/L32E-ZYLB] ("When no doctor is involved, the woman who uses abortion drugs might seem less like a 'second victim' and more like a criminal.").

their behaviors during pregnancy, alleging that such behaviors contributed to a miscarriage or stillbirth.[302] Moreover, in some states, surveillance will now come not just from state prosecutors, but also from private citizens incentivized by laws allowing them to take civil action against persons who violate state abortion laws, providing them significant monetary rewards for each successful suit.[303] With SB 8, Texas became the first state to enact such a law, inspiring numerous copycat bills after the courts—including the Supreme Court—allowed the Texas law to remain in effect.[304]

Troublingly, the information needed to pursue criminal enforcement is often readily available. As Professor Danielle Citron presciently warns:

> Our fertility, dating, and health apps, digital assistants, and cellphones track our every move, doctor visit, health condition, prescription, and search; the details of our intimate lives are sold to advertisers, marketers, and data brokers. Law enforcers can purchase or subpoena data about women's missed periods, health clinic visits, and resumed menstruation.[305]

Current federal law does not shield individuals' reproductive health data from state law enforcement or other legal action.[306] Absent additional protections,[307] "[e]veryone's life opportunities are on the line in a world without intimate privacy," warns Professor Citron.[308] The privacy threats are real: in August of 2022, a Nebraska woman was charged with helping her daughter end her pregnancy after law enforcement authorities obtained Facebook

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[302] Regina McKnight, for example, was charged with and convicted of "homicide by child abuse" after she gave birth to a stillborn baby and it was discovered she had cocaine in her system. Her conviction was ultimately overturned. *See* McKnight v. State, 661 S.E.2d 354, 356–357, 366 (S.C. 2008); *see also* sources cited *supra* note 175 and accompanying text. *See generally* GOODWIN, *supra* note 299 (describing how state legislators have sought to criminalize women for miscarriages, stillbirths, and other behaviors that may threaten the health of their pregnancies).

[303] *See Copycat Bans Follow After Texas SB 8*, AUSTIN WOMEN'S HEALTH CTR. BLOG (May 20, 2022), https://www.austinwomenshealth.com/copycat-bans-follow-after-texas-sb-8/ [https://perma.cc/YAT9-9CEE] (citing some of the states that copied Texas SB 8).

[304] *See id.*

[305] Danielle Keats Citron, *The End of* Roe *Means We Need a New Civil Right to Privacy*, SLATE (June 27, 2022), https://slate.com/technology/2022/06/end-roe-civil-right-intimate-privacy-data.html [https://perma.cc/X7RZ-L8P8].

[306] Eric Boodman et al., *HIPAA Won't Protect You if Prosecutors Want Your Reproductive Health Records*, STAT (June 24, 2022), https://www.statnews.com/2022/06/24/hipaa-wont-protect-you-if-prosecutors-want-your-reproductive-health-records/ [https://perma.cc/XK83-SJDV].

[307] On June 27, 2022, Nancy Pelosi, Speaker of the House, sent a "Dear Colleague" letter to House Democrats describing a series of possible bills that would, among other things, protect "intimate and personal data stored in reproductive health apps." Letter from Nancy Pelosi, Speaker of the House, to Democratic Colleagues (June 27, 2022), https://www.speaker.gov/newsroom/62722-0 [https://perma.cc/YRW4-T6D7].

[308] Citron, *supra* note 305.

messages between the two discussing the use of medication abortion to end the daughter's pregnancy.[309]

Importantly, even while patients may hesitate to seek care through traditional means, banning or restricting access to medications and health-care services does not eliminate the need for those services or their use. Those with means and the ability to do so will travel to obtain medications or services where they continue to be available,[310] while those unable to do the same may seek out alternatives, some of which may be illegal or unsafe. Bans on medication abortion merely drive it underground, as illustrated by the emergence and growing use of organizations providing access to or information about medication abortion through the mail, sometimes without a prescription and even in states where the practice is illegal.[311] For example, the week after SB 8 went into effect, requests made by Texans to "AidAccess," an international organization that provides medication abortion through the mail, increased by an astonishing 1,180%.[312] According to its website, AidAccess utilizes European doctors to prescribe medication abortion for patients in states with abortion bans or restrictions on the use of telemedicine.[313]

Conservative states will likely increase enforcement of their medication abortion bans and restrictions to clamp down on the "existential threat" medication abortion poses to their anti-abortion platforms.[314] Enforcing bans

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[309] Assoc. Press, *supra* note 175.

[310] Yet even interstate travel to obtain abortion care may not be safe in a post-*Dobbs* world. Some state legislators have proposed prohibiting travel to other states for abortions. *See, e.g.*, Aaron Blake, *How Far the GOP Might Go Post-Roe on Abortion, Contraception, and Travel*, WASH. POST (May 9, 2022), https://www.washingtonpost.com/politics/2022/05/09/gop-beyond-roe-restrictions/ [https://perma.cc/Q76Z-87P3]. States have also pursued similar legislation to ban families from traveling out-of-state to obtain gender-affirming care for their children. *See, e.g.*, H.B. 675, 66th Leg., 2nd Reg. Sess. (Idaho 2022), https://legislature.idaho.gov/wp-content/uploads/sessioninfo/2022/legislation/H0675.pdf [https://perma.cc/XEK7-F5SE] (criminalizing anyone who "removes or causes, permits, or facilitates the removal of a child from this state for the purpose of facilitating" gender-affirming care). There are strong arguments such laws would not withstand judicial scrutiny, but that will not stop states from trying. *See, e.g.*, Anthony Michael Kreis, *Prison Gates at the State Line*, HARV. L. REV. BLOG (Mar. 28, 2022), https://blog.harvardlawreview.org/prison-gates-at-the-state-line/ [https://perma.cc/9E7E-2G8L] ("These proposals are incongruous to a fundamental, associative right to travel that is embedded in the American constitutional tradition.").

[311] *See* Olga Khazan, *The Abortion Backup Plan No One Is Talking About*, ATLANTIC (Oct. 12, 2021), https://www.theatlantic.com/politics/archive/2021/10/plan-c-secret-option-mail-order-abortion/620324/ [https://perma.cc/3U5W-8QBA]; *see also* ABORTION ON DEMAND, https://abortionondemand.org/ [https://perma.cc/BT8R-U2HC]; AIDACCESS, https://aidaccess.org/en/ [https://perma.cc/NK52-VPMQ]; CARAFEM, https://carafem.org/ [https://perma.cc/GCN6-V4PZ]; PLAN C, *supra* note 173 (providing medication abortion kits online).

[312] Abigail R. A. Aiken et al., *Association of Texas Senate Bill 8 With Requests for Self-Managed Medication Abortion*, 5 JAMA OPEN NETWORK (2022).

[313] *See Consultation*, AIDACCESS, https://aidaccess.org/en/i-need-an-abortion [https://perma.cc/7UXU-X36W].

[314] *See* Luthra, *supra* note 24.

will be difficult[315] but not impossible, particularly given the wealth of data available to prosecutors noted by Professor Citron and illuminated by the recent case in Nebraska.[316] Enforcing a ban would not necessarily require a state to access people's mail. Instead, states could target digital data, including internet search histories, period tracking apps, and online payments for medication abortion and related services.[317] Moreover, regardless of the likely success of enforcement, the mere possibility of being penalized could create a chilling effect among both patients and providers.

Most Americans, including many abortion opponents, agree that patients who seek or obtain illegal abortions should not be prosecuted.[318] The risk, however, is more than hypothetical. Pregnancy Justice (formerly National Advocates for Pregnant Women) has compiled at least 1,700 cases between 1973 and 2020 that targeted pregnant people for pregnancy outcomes.[319] And in April 2022, a Texas woman was arrested and charged with murder for allegedly self-inducing an abortion.[320] Fortunately, the charges were ultimately dropped.[321] Also revealing was Louisiana's recent attempt to pass legislation that would classify abortions as homicides and allow individuals to be criminally charged for terminating their pregnancies.[322] That language was removed in later amendments,[323] but patients and providers

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[315] *See, e.g.*, Howard Fischer Capitol Media Serv., *AZ Law Banning Abortion Pills by Mail Difficult to Enforce*, Herald Rev. (May 10, 2022), https://www.myheraldreview.com/news/state/az-law-banning-abortion-pills-by-mail-difficult-to-enforce/article_25819986-cfad-11ec-9c56-0f11c335a0f9.html [https://perma.cc/DW9E-VTX2], Bonnie Petrie, *If Roe Falls, How Would States Regulate Mail-Order Abortion Pills? Look to Texas*, Tex. Pub. Radio (May 5, 2022), https://www.kut.org/politics/2022-05-05/if-roe-falls-how-would-states-regulate-mail-order-abortion-pills-look-to-texas [https://perma.cc/TS46-G5LZ]; Dianna Wray, *Texas Aimed to Ban Abortion Pills—But the Law Has Had Little Effect*, Tex. Monthly (Mar. 8, 2022), https://www.texasmonthly.com/news-politics/texas-medication-abortion-pill-ban-ineffective/ [https://perma.cc/2ZX7-VESR].

[316] *See* Citron, *supra* note 305; Assoc. Press, *supra* note 175.

[317] *See* Sadia Samee Ali, *Prosecutors in States where Abortion is Now Illegal Could Begin Building Criminal Cases Against Providers*, NBC News (June 24, 2022), https://www.nbcnews.com/news/us-news/prosecutors-states-abortion-now-illegal-begin-prosecute-abortion-provi-rcna35268 [https://perma.cc/KNH6-D4CW]; *cf. also* Boodman et al., *supra* note 306 (citing Carmel Shachar, Executive Director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics at Harvard Law School, who would advise against using online payment apps to buy abortion-related services).

[318] Veronica Stracqualursi, *Leading Anti-Abortion Groups Urge State Lawmakers Not to Pass Bills Criminalizing Women for Abortions*, CNN (May 12, 2022), https://www.cnn.com/2022/05/12/politics/anti-abortion-groups-letter-criminalizing-women/index.html [https://perma.cc/JUS9-2CYK].

[319] *See Confronting Pregnancy Criminalization: A Practical Guide for Healthcare Providers, Lawyers, Medical Examiners, Child Welfare Workers, and Policymakers*, Pregnancy Just. (June 23, 2022), https://www.pregnancyjusticeus.org/confronting-pregnancy-criminalization/ [https://perma.cc/V2BZ-H3TV].

[320] Ceron, *supra* note 296.

[321] *Id.*; *see also* Assoc. Press, *supra* note 175 and accompanying text.

[322] H.B. 813, 2022 Reg. Sess. (La. 2022) (original).

[323] H. Floor Amendments, 2022 Reg. Sess. (La. 2022) (adding a provision to explicitly exclude from criminal consequences any pregnant females who receive an abortion in violation of the law); Kevin McGill, *No More Murder Charges for Women in Louisiana*

remain justifiably fearful. The difficulties that states will face enforcing medication abortion bans may also cause states to reconsider prosecuting pregnant persons.[324]

Given the legal risks and uncertainties, patients who access medications through informal or illegal channels may hesitate to seek medical care if they have questions, concerns, or experience an adverse event from a medication, fearing they will be reported by a health-care provider or institution. Even if rare, all drugs have risks, and medications subject to prescription requirements by the FDA are safest when used under the care of a health-care provider.[325] And although studies show that people can safely and effectively end their own pregnancies with medication abortion, the fear of engaging with a health-care provider raises serious concerns in the event a rare side effect does occur.[326] Moreover, some of the abortion pills accessible without a prescription may not be the FDA-approved versions, raising concerns about drug quality.[327] Patients should have access to a health-care provider and feel comfortable seeking care without fearing liability for themselves or their providers. Creating a system that essentially encourages health-care avoidance and in which patients feel no choice but to take matters into their own hands harms rather than protects patient health and safety.

Lastly, a state's bans or restrictions not only affect that state's residents. Neta Meltzer of Planned Parenthood notes that a "ban in one state doesn't just stay in that state . . . . It absolutely has ripple effects in neighboring states and across the country."[328] Bans and restrictions burden health-care providers and systems in other states where patients travel to receive care, as illustrated by the influx of patients from Texas to neighboring states after SB 8 went into effect. Some clinics in nearby states saw their patient numbers more than double after SB 8 took effect in Texas.[329] States without bans or

Abortion Bill, ASSOC. PRESS (May 13, 2022), https://apnews.com/article/abortion-us-supreme-court-health-religion-louisiana-b73a7cfb0afc29c30d106a85c80c7c50 [https://perma.cc/H9JR-RGSD].

[324] Petrie, *supra* note 315.

[325] *Cf.* 21 U.S.C. § 353(b)(1)(A) (requiring prescriptions for certain drugs that are "not safe for use except under the supervision of a practitioner licensed by law to administer such drugs" because of their "toxicity or other potentiality for harmful effect").

[326] Greer Donley, *Medication Abortion Exceptionalism*, 107 CORNELL L. REV. 627, 659 (2022) (describing abortion care through a health-care provider as "the gold standard").

[327] *See* Dominique Mosbergen & Vibhuti Agarwal, *Websites Selling Unapproved Abortion Pills Are Booming*, WALL ST. J. (Aug. 21, 2022), https://www.wsj.com/articles/websites-selling-unapproved-abortion-pills-are-booming-11661079601 [https://perma.cc/DH3D-4P8R] (quoting an FDA spokesperson, who stated: "Drugs that have circumvented regulatory safeguards may be contaminated, counterfeit, contain varying amounts of active ingredients, or contain different ingredients altogether"); Laurel Wamsley, *How Medication Abortion Works and What the End of Roe v. Wade Could Mean for It*, NAT'L PUB. RADIO (May 13, 2022), https://www.npr.org/2022/05/13/1098000879/abortion-pills-medication-abortion-roe-v-wade [https://perma.cc/FW63-JGDK].

[328] Murphy & Hanna, *supra* note 286 (quoting Neta Meltzer).

[329] *See* Shefali Luthra, *Texas' Six-Week Abortion Ban is Still Causing More Than Twice as Many Patients at Clinics in Nearby States*, 19TH (Feb. 11, 2022), https://

restrictions will face significant costs as they try to ensure all patients, both residents and nonresidents, can access the care they need.[330] Realistically, "haven" states may be unable to keep up with the influx of out-of-state patients.[331]

The examination in this Part makes abundantly clear the breadth of state pharmaceutical bans and restrictions and the severe consequences that result. Further, it illuminates how the populations most affected are those already suffering from persistent health disparities caused by centuries of inequality, discrimination, exploitation, and abuse.[332] State bans and restrictions, frequently driven by politics rather than public health and science, allow the gaps to continue to widen. Can preemption provide the prescription to these societal ills?

19thnews.org/2022/02/texas-abortion-ban-patients-clinics-surrounding-states/ [https://perma.cc/482G-7GS7]; *see also* Rachel K. Jones et al., *New Evidence: Texas Residents Have Obtained Abortions in at Least 12 States That Do Not Border Texas*, GUTTMACHER INST. (Nov. 2021), https://www.guttmacher.org/article/2021/11/new-evidence-texas-residents-have-obtained-abortions-least-12-states-do-not-border [https://perma.cc/57DQ-7RCV].

[330] *See* Lisa Kashinsky et al., *Blue States Want to Become Abortion Safe Havens. It Will Cost Them*, POLITICO (May 11, 2022), https://www.politico.com/news/2022/05/11/blue-states-abortion-safe-havens-00031526 [https://perma.cc/MM32-GALJ].

[331] *See, e.g.*, Heather Hollingsworth, *Abortion Clinic that Opened Days After Roe Fell is Inundated*, ASSOC. PRESS (Nov. 4, 2022), https://apnews.com/article/abortion-us-supreme-court-health-missouri-birth-control-8172dc0f46feaa8dd48e73b8aad3ada [https://perma.cc/D83Y-D79H]; Spencer Kimball, *Four Abortion Clinics in Kansas Brace for a Deluge of Patients from States Banning the Procedure*, CNBC (June 24, 2022), https://www.cnbc.com/2022/06/24/roe-vs-wade-four-abortion-clinics-in-kansas-brace-for-a-deluge-of-patients-from-states-banning-the-procedure.html [https://perma.cc/JE77-ZYFR]; Rachana Pradhan & Christina Saint Louis, *'It's Not a Haven': With Limited Capacity for Abortion Care, Minnesota Clinics Brace for Influx*, MINNPOST (June 27, 2022), https://www.minnpost.com/health/2022/06/its-not-a-haven-with-limited-capacity-for-abortion-care-minnesota-clinics-brace-for-influx/ [https://perma.cc/ENC4-BTCQ].

[332] *See, e.g.*, Mark L. Hatzenbuehler & John E. Pachankis, *Sexual and Gender Minority Health Disparities*, *in* THE SCIENCE OF HEALTH DISPARITIES RESEARCH 429–30 (Irene Dankwa-Mullan et al. eds., 2021) (noting that sexual and gender minorities are at heightened risk for numerous adverse mental and physical health outcomes compared to the cisgender heterosexual population); Hill et al., *supra* note 262 (reporting that Black, Hispanic, and American Indian and Alaska Native people fare worse than white people across a majority of measures of health coverage, access, and use; health status, outcomes, and behaviors; and social determinants of health); Off. of Disease Prevention & Health Promotion, *Disability and Health*, HEALTHYPEOPLE.GOV, https://wayback.archive-it.org/5774/20220413202458/https://www.healthypeople.gov/2020/topics-objectives/topic/disability-and-health [https://perma.cc/J6BK-XWHD] ("[I]ndividuals with disabilities, as a group, experience health disparities in routine public health arenas such as health behaviors, clinical preventive services, and chronic conditions."). Disparities increase for individuals at the intersection of multiple disadvantaged identities. *See* Ayden I. Scheim et al., *Advancing Intersectional Discrimination Measures for Disparities Research: Protocol for a Bilingual Mixed Methods Measurement Study*, 10 JMIR RSCH. PROTOCOLS (2021).

IV. Preemption: A Prescription for the Harms of State Pharmaceutical Regulation

As demonstrated in Part III, state bans and restrictions on FDA-approved pharmaceuticals exacerbate deeply entrenched disparities and result in distressful harms to health and even death. This Part now turns to potential solutions. Section A first examines the potential preemptive force of the FDCA with respect to such state laws and regulations based on current law, policy, and judicial precedent. Upon evaluation, Section A concludes that those sources do not provide clarity on this issue. Part B thus turns to potential new pathways, proposing a possible legislative fix and other steps that can be taken to clarify whether, and under what circumstances, a state may ban or restrict access to an FDA-approved pharmaceutical.

A. Preemption Under Current Law and Policy

Whether state bans on FDA-approved pharmaceuticals unconstitutionally preempt federal law is top of mind for legal scholars, policymakers, and the public. Preemption is receiving media and public attention like never before, as reproductive justice advocates, patients, and providers grapple with the consequences and uncertainties of state bans and restrictions on medication abortion. Many scholars, including Professors Greer Donley, Rachel Rebouché, and David Cohen, believe that preemption "provides the building blocks for one of the most promising strategies to invalidate" certain abortion bans.[333] At the same time, others like Professor Noah have highlighted the uncertainties, recognizing that this question "does not admit of an easy answer."[334]

This Section examines the potential preemptive force of current FDA laws and regulations with respect to state bans and restrictions. In so doing, it does not intend to provide an exhaustive recitation or analysis of these decisions or statements, but instead aims to illustrate the uncertainty about whether, under current law and judicial precedent, states are preempted from banning or enacting certain restrictions on FDA-approved pharmaceuticals. This uncertainty demonstrates a clear need to consider pathways forward to improve clarity and mitigate the harmful consequences of state pharmaceutical regulation.

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[333] Greer Donley et al., *Existing Federal Laws Could Protect Abortion Rights When Roe is Overturned*, Time (Jan. 22, 2022), https://time.com/6141517/abortion-federal-law-preemption-roe-v-wade/ [https://perma.cc/7TYM-GNXC]; Zettler & Sarpatwari, *supra* note 105, at 706–07; *see also* Greer Donley (@GreerDonley), Twitter (Dec. 16, 2021, 8:28 PM), https://twitter.com/GreerDonley/status/1471653570214776834?s=20&t=CrhuHrlomJVxJpi89W65OA [https://perma.cc/9AHT-XFF5] ("Though not a slam dunk, the preemption argument has merit and should be pursued.").

[334] Noah, *State Affronts*, *supra* note 30, at 53; *see also* Zettler, *Pharmaceutical Federalism*, *supra* note 45, at 885.

1. *The FDCA and Congressional Statements*

The statutory text provides the starting point when considering the preemptive effect of federal law. The FDCA and FDA regulations both include provisions that expressly preempt state laws in certain areas, including nutrition labeling, devices, electronic products, nonprescription drugs, cosmetic labeling, and tobacco products.[335] Many of these provisions allow states to seek an exemption from federal preemption if certain criteria are met. For example, under a provision preempting state and local requirements for nonprescription drugs, states can enact regulations that "protect[ ] an important public interest that would otherwise be unprotected, including the health and safety of children," provided such regulations do not "unduly burden interstate commerce."[336] The inclusion of express preemption provisions in some areas, but not for bans or restrictions on FDA-approved pharmaceuticals, adds strength to an argument that states can be expected to put forth: Congress did not intend the FDCA to preempt state laws in the absence of an express preemption provision.[337]

Aside from these provisions, the preemptive force of the FDCA "ha[s] never been powerful enough to entirely squelch the continued enactment and enforcement of state and local food and drug laws."[338] Absent express preemption, preemption must arise from one or more forms of implied preemp-

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[335] A search of the FDCA at https://uscode.house.gov/ [https://perma.cc/FGW3-2G6E], and Title 21 of the Code of Federal Regulations at https://www.ecfr.gov/ [https://perma.cc/RT44-NYWH] for the terms/phrases "preempt," preemption," "no state or local governing entity," "no state or political subdivision," and "different from or in addition to" (phrases commonly used in explicit preemption clauses) provided the following express preemption provisions:

- 21 U.S.C. § 343-1 – Nutrition labeling
- 21 U.S.C. § 346a – Tolerances and exemptions for pesticide chemical residues
- 21 U.S.C. § 350e – Sanitary transportation practices
- 21 U.S.C. § 360k – Devices
- 21 U.S.C. § 360ss – Electronic products
- 21 U.S.C. § 360eee-4 – Pharmaceutical supply chain and track and trace requirements
- 21 U.S.C. § 379r – Nonprescription drugs
- 21 U.S.C. § 379aa – Serious adverse event reporting for nonprescription drugs
- 21 U.S.C. § 379aa-1 – Serious adverse event reporting for dietary supplements
- 21 U.S.C. § 379s – Cosmetic labeling
- 21 U.S.C. § 387p – Tobacco products
- 21 U.S.C. § 1603 – Recovery for harm caused by a medical device implant

Some of these statutory provisions are reiterated in FDA regulations and not repeated here. *See also* 21 C.F.R. § 20.63 (disclosure of identity of reporters of adverse events); *id.* § 50.23 (informed consent for investigational in vitro diagnostic device during suspected terrorism event or other public health emergency); *id.* § 101.91(d) (gluten claims); *id.* §§ 101.17(h)(9), 115.5, 118.12(g) (shell eggs); *id.* Part 808 (prescribing procedures for seeking an exemption); Nathan A. Brown & Eli Tomar, *Could State Regulations be the Next Frontier for Preemption Jurisprudence?*, 71 Food & Drug L.J. 271, 279–80 (2016) (listing examples of express preemption in the FDCA).

[336] 21 U.S.C. § 379r(b)(1).

[337] *See, e.g.*, *supra* note 176.

[338] Hutt et al., *supra* note 59, at 430.

tion.[339] A significant and important consequence of relying on implied preemption is that it "involves wide swathes of judicial discretion, making any particular outcome of a preemption case highly unpredictable."[340] Such discretion proves particularly problematic for medication abortion, given the current Supreme Court's hostility toward abortion.

Implied preemption is difficult, though not impossible, to show. In all areas, field preemption is rare and case law shows that courts regularly decline to find field preemption in areas covered by the FDCA.[341] One could, however, argue that when Congress created the FDA and gave it the authority to approve drugs for marketing based on safety and efficacy, it intended to grant the Agency exclusive control over the field of drug approval. By restricting or banning FDA-approved pharmaceuticals, states essentially substitute their own drug approval process for that of the FDA.[342] Such an argument would likely not fare well based on current statutory language and judicial precedent.[343]

When Congress passed the Drug Amendments of 1962, which established the requirement that a drug be deemed both safe and effective prior to approval, it included language suggesting that Congress intended to preserve state authority absent impossibility of dual compliance. Specifically, Congress stated that nothing in the Amendments "shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."[344]

Courts have cited this statement when considering whether state law failure-to-warn claims are preempted by federal law.[345] According to Professor Noah, the statement expresses Congress's intent to foreclose all forms of implied preemption except impossibility preemption.[346] As discussed further below, some support exists for an impossibility preemption argument when a state law effectively requires a manufacturer to stop selling their product to comply with both state and federal law[347]—a consequence that results from state bans and certain restrictions that amount to de facto bans. Nevertheless, the statutory text of the FDCA alone does not resolve the issue.

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[339] *See* sources cited *supra* notes 53–66 and accompanying text.

[340] Babcock, *supra* note 51, at 730.

[341] HUTT ET AL., *supra* note 59, at 435; Zettler, *Pharmaceutical Federalism*, *supra* note 45, at 862.

[342] *Cf.* Zettler, *Pharmaceutical Federalism*, *supra* note 45, at 880 n.245.

[343] *See id.*

[344] Drug Amendments of 1962, Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (Oct. 10, 1962).

[345] *See, e.g.*, PLIVA, Inc. v. Mensing, 564 U.S. 604, 609, 612 (2011); Wyeth v. Levine, 555 U.S. 555, 567 (2009); Jackson v. Pfizer, Inc., 432 F. Supp. 2d 964, 966 (D. Neb. 2006).

[346] Noah, *State Affronts*, *supra* note 30, at 8–9.

[347] *See infra* notes 370, 386–387, and accompanying text.

2. *FDA Statements*

The Agency itself has addressed preemption in certain contexts but has not promulgated any regulations or policies establishing a formal position on whether federal law preempts state pharmaceutical bans or restrictions. In 2006, however, when the Agency enacted regulations changing certain labeling requirements for prescription drugs, the rule's preamble contained broad statements regarding the preemption of state common law failure-to-warn claims. The FDA asserted that its position "represents the government's long-standing views on preemption" and made a few critical points.[348] First, FDA approval "preempts conflicting or contrary State law" because the "FDA is the expert Federal public health agency charged by Congress" to ensure that drugs are safe and effective.[349] Second, state laws that conflict with the Agency's interpretations "frustrate the agency's implementation of its statutory mandate."[350] Third, state requirements mandating the disclosure of risk information that is not required by the FDA "are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of" a drug's benefits and risks.[351] Relatedly, exaggerating risks may "discourage appropriate use of a beneficial drug."[352] Fourth, state actions are generally "not characterized by centralized expert evaluation of drug regulatory issues" but rather encourage or even require "*lay judges and juries to second-guess* the assessment of benefits versus risks of a specific drug to the general public."[353] And finally, the FDA also stated that "[p]reemption would include not only claims against manufacturers . . . but also against health care practitioners for claims related to dissemination of risk information to patients beyond what is included in the labeling."[354]

Even though the statements in the preamble were largely directed toward state tort claims, the reasoning used by the FDA in these statements supports the argument that certain state bans and restrictions should be preempted. Undeniably, state bans on an FDA-approved pharmaceutical not only "*discourage* appropriate use of a beneficial drug," they also prevent its

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[348] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (codified June 30, 2006, at 21 C.F.R. §§ 201.56(d), 201.57).

[349] *Id.*

[350] *Id.*

[351] *Id.* at 3935.

[352] *Id.*

[353] *Id.* (emphasis added).

[354] *Id.* at 3936. Under the reasoning in this statement, states could be preempted from requiring physicians to provide patients with information beyond the information required by the FDA-approved labeling, such as misleading information about the risks of abortion and other health issues such as breast cancer. *See infra* note 351 and accompanying text.

use in that state entirely.[355] Importantly, states do not engage in the same type of rigorous premarket safety and efficacy review as the FDA. As a result, such bans may be based on "lay" politicians "second-guess[ing] the assessment of benefits versus risks of a specific drug . . . the central role of FDA."[356] Under this reasoning, state laws that make a drug less accessible than envisioned by the FDA frustrate Congress's purpose to make safe and effective drugs available.[357] Indeed, "to the extent that Congress intended for the FDA to make definitive and nationally uniform judgments about the safety and effectiveness of pharmaceutical products, state efforts to second-guess the Agency's determinations certainly would threaten to frustrate" that purpose.[358]

In addition to bans, the arguments in the preamble could also support preemption of certain state restrictions, particularly those that essentially change the FDA-approved indication and/or require the provision of warnings and risk-related information considered and rejected by the Agency. Similar to bans, state restrictions on who can use the drug and when it can be used, such as the Texas law limiting the use of mifepristone to forty-nine days gestation instead of the FDA-approved seventy days, "discourage appropriate use of a beneficial drug."[359] Importantly, the FDA updated mifepristone's approved indication from forty-nine to seventy days gestation after thorough review of the drug's safety and efficacy through seventy days.[360]

Other restrictions that could be preempted using the FDA's reasoning are those that require the provision of irrelevant, misleading, or scientifically unsupported information before a patient may be prescribed a drug, as is often the case with mifepristone.[361] Such requirements "can erode and dis-

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[355] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935 (emphasis added).

[356] *Id.*

[357] Some scholars, however, question whether one of Congress's purposes in creating a national drug review system was to make approved drugs *accessible*, instead of just ensuring safety and effectiveness. *See* Noah, *State Affronts*, *supra* note 30, at 9 (arguing that the FDA's rules are generally "designed to restrict rather than promote ready patient access").

[358] *Id.* at 12.

[359] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935.

[360] *Compare MIFEPREX® (mifepristone) Prescribing Information*, U.S. FOOD & DRUG ADMIN. (Apr. 22, 2009), https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020687s015lbl.pdf [https://perma.cc/G5NW-3NMD] (approving mifepristone through forty-nine days gestation and reviewing clinical data for use through forty-nine days), *with MIFEPREX® (mifepristone) Prescribing Information 2016*, U.S. FOOD & DRUG ADMIN., *supra* note 18 (approving mifepristone through seventy days gestation and reviewing clinical data for use through seventy days).

[361] *See, e.g.*, KAN. STAT. ANN. § 65-6709(a)(3) (West 2022) (requiring patients to be informed about potential links between abortion and "risk of premature birth in future pregnancies, breast cancer, and woman's reproductive health"); MISS. CODE ANN. § 41-41-33(1)(a)(ii) (2022) (same); TEX. HEALTH & SAFETY CODE ANN. § 171.012(1)(a)(B)(ii)–(iii) (West 2022) (similar); *see also* OKLA. STAT. tit. 63, § 1-756 (2022) (requiring of-

rupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use" and may "discourage appropriate use of a beneficial drug."[362] Similar to state bans and restrictions, many of these disclosure laws are not based on a "centralized expert evaluation of drug regulatory issues," but rather on the nonexpert determinations or personal opinions of lay politicians about the safety, efficacy, or morality of certain drugs. Enacting laws based on those views "threatens[s] FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs."[363] The consequences of requiring the provision of misleading and unsupported information raise serious questions about the validity of state laws that require such disclosures.

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fices that provide medication abortion to post a sign stating that "[i]t may be possible to reverse" the effects of medication abortion if the second pill in the regimen has not been taken). ACOG, the American Cancer Society, and other leading medical associations have all stated that the best available evidence shows no causal link between abortion and breast cancer, and no negative impact on future fertility or pregnancy outcomes. *See, e.g.*, Comm. on Prac. Bull., Gynecology & the Soc'y of Fam. Planning, *Medication Abortion Up To 70 Days of Gestation*, 136 OBSTETRICS & GYNECOLOGY e31, e39 (2020); Comm. on Gynecologic Practice, *ACOG Comm. Opinion No. 434: Induced Abortion and Breast Cancer Risk*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (June 2009), https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2009/06/induced-abortion-and-breast-cancer-risk.pdf [https://perma.cc/CV9T-4NJ6] (reaffirmed 2019); *Abortion Care: Overview*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS (July 2021), https://www.acog.org/womens-health/faqs/induced-abortion?utm_source=redirect&utm_medium=web&utm_campaign=otn [https://perma.cc/L9U3-FCA8] (last updated August 2022); *Reproductive History and Cancer Risk*, NAT'L CANCER INST., https://www.cancer.gov/about-cancer/causes-prevention/risk/hormones/reproductive-history-fact-sheet#is-abortion-linked-to-breast-cancer-risk [https://perma.cc/D4FD-L4N2]; *Abortion and Breast Cancer*, AM. CANCER SOC'Y, https://www.cancer.org/cancer/cancer-causes/medical-treatments/abortion-and-breast-cancer-risk.html [https://perma.cc/ZVF6-6M9F] (last updated June 19, 2014); Jen Gunter, *Can an Abortion Affect Your Fertility?*, N.Y. TIMES (May 30, 2019), https://www.nytimes.com/2019/05/30/well/can-an-abortion-affect-your-fertility.html [https://perma.cc/42WQ-JCJM] (noting that only abortions associated with complications, such as uterine injury from the procedure, infection, or serious bleeding that requires surgery may potentially impact future fertility). And medical experts consider abortion "reversal" procedures to be experimental, unethical, and unproven. Daniel Grossman & Kari White, *Abortion "Reversal"—Legislating Without Evidence*, 379 N. ENG. J. MED. 1491, 1493 (2018); *Facts are Important: Medication Abortion "Reversal" Is Not Supported by Science*, AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, https://www.acog.org/advocacy/facts-are-important/medication-abortion-reversal-is-not-supported-by-science [https://perma.cc/EC8T-B2BQ]; *Abortion Pill "Reversal": Where's the Evidence*?, ANSIRH (July 2020), https://www.ansirh.org/sites/default/files/publications/files/so-called_medication_abortion_reversal_7-14-2020_1.pdf [https://perma.cc/AUK2-ZSTL]. *But see* George Delgado et al., *A Case Series Detailing the Successful Reversal of the Effects of Mifepristone Using Progesterone*, 33 ISSUES IN L. & MED. 21, 29 (2018).

[362] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935; *cf.* Seufert v. Merck Sharp & Dohme Corp., 187 F. Supp. 3d 1163, 1175 (S.D. Cal. 2016) (arguing that a rule requiring manufacturers to make labeling changes to include information about risks not "readily apparent from available data . . . could lead to overwarning consumers and deterring potentially beneficial use of a prescription drug").

[363] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. at 3935.

All that said, while statements in a preamble help indicate the position held by the FDA on these issues, courts are unlikely to rely on them alone to find preemption. There is some controversy over "preemption by preamble," and after a period of increasing deference to agency preemption determinations—including those contained in clear statements in preambles[364]—President Obama issued a "Memorandum for the Heads of Executive Departments and Agencies" on Preemption, which directed executive agencies not to include preemption statements in regulatory preambles unless preemption provisions are also codified in the regulation's text.[365]

Conflict preemption may be more likely for state restrictions that the FDA has considered and rejected, a factor considered by some courts in preemption cases.[366] Importantly, for medication abortion, the FDA has now considered, and removed or rejected, various restrictions on mifepristone that remain imposed by many states, such as those limiting prescriptive authority to physicians or requiring mifepristone to be dispensed in person.[367]

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[364] *See* Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227, 228 (2007) [hereinafter Sharkey, *Preemption by Preamble*]; *see also* Cristina Rodríguez, *The FDA Preamble: A Backdoor to Federalization of Prescription Warning Labels*, 41 JOHN MARSHALL L. REV. 161, 172–79 (2007).

[365] Presidential Memorandum Regarding Preemption, 2009 DAILY COMP. PRES. DOC. 200900384 (May 20, 2009).

[366] As stated by one court:

> [A] drug manufacturer, upon having "reasonable evidence of an association of a serious hazard with a drug," *which has not been considered and rejected by the FDA*, may unilaterally add that warning to a drug's labeling and then submit [ ] the change to the FDA for approval without facing any risk of noncompliance with federal law. By the same token, however, a drug manufacturer cannot, without violation of federal law, change the labeling of a drug to include the warning of a potential association between a hazard and the drug in the face of an express FDA rejection of that warning or absent "reasonable evidence" of such an association.

Knipe v. SmithKline Beecham, 583 F. Supp. 2d 553, 569 (E.D. Pa. 2008) (emphasis added); *see also, e.g.*, Dusek v. Pfizer Inc., Case No. Civ.A. H-02-3559, 2004 WL 2191804, at *6–8 (S.D. Tex. Feb. 20, 2004) (addressing the FDA's rejection of changes in labeling regarding certain risks of a drug); Kellogg v. Wyeth, 612 F. Supp. 2d 421, 434 (D. Vt. 2008); *Seufert*, 187 F. Supp. 2d at 1177 (finding "clear evidence that the FDA would have rejected" a labeling change based on the FDA's review, independent investigation, and public comment on that specific issue); *In re* Zofran (Ondansetron) Prods. Liability Lit., 541 F. Supp. 3d 164, 203 (D. Mass. 2021) (similar); Mary J. Davis, *The Battle Over Implied Preemption: Products Liability and the FDA*, 48 BOS. COLL. L. REV. 1089, 1148 (2007) ("The best argument for preemption in the prescription drug labeling context will be based on the FDA's specific consideration, and subsequent rejection of particular labeling proposed by a manufacturer that the FDA finds to be unsubstantiated based on the available data."); Zettler, *Pharmaceutical Federalism*, *supra* note 45, at 881 (concluding that preemption is more likely "where there is evidence that the FDA carefully considered the safety and effectiveness" of a drug, compared to when "there is no publicly available documentation that the FDA has considered" such issues).

[367] In 2016, the FDA revised the mifepristone REMS to allow providers who are not physicians to become certified to prescribe mifepristone. *See* U.S GOV'T ACCOUNTABILITY OFF., GAO-18-292, U.S. FOOD AND DRUG ADMINISTRATION: INFORMATION ON MIFEPREX LABELING CHANGES AND ONGOING MONITORING EFFORTS 7 (2018), https://

Impossibility preemption, which occurs when it is impossible to simultaneously comply with both federal and state law or regulation,[368] seems less likely to succeed under current law, although some Supreme Court precedent suggests it might apply under specific circumstances.[369] It would apply most strongly to state bans, but could apply to state restrictions that make the sale, distribution, and/or prescription of a drug far more onerous than what federal law requires, potentially amounting to a de facto ban. Here, the argument would be that the only "possible" way to comply with both federal and state law would be for the manufacturer to stop selling, and for health-care providers to stop prescribing, the FDA-approved drug within that state. As discussed below, the Supreme Court has rejected a plaintiff's "stop-selling" argument in at least one case.[370]

More informally, the FDA addressed preemption during the Zohydro litigation mentioned in Part III.[371] The FDA expressed concern about state efforts to ban FDA-approved drugs, calling the Zohydro ban "extremely troubling."[372] The Agency stated that although the prevention of opioid abuse is a "top public health priority" for the FDA, concerns about opioid abuse must "be balanced with the needs of patients to access adequate and necessary therapies."[373] These statements from the FDA over the past two decades illustrate the Agency's unease and disagreement with state bans and restrictions on FDA-approved pharmaceuticals. As for medication abortion, although Attorney General Garland has set forth the DOJ's position on preemption with respect to mifepristone,[374] the FDA has thus far remained silent.

3. *Judicial Precedent*

Supreme Court cases addressing preemption of state pharmaceutical regulations have revolved primarily around whether the FDCA preempts state tort law claims, such as failure-to-warn claims for labeling deficiencies and design defect claims for unreasonably dangerous products. The Court

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www.gao.gov/assets/gao-18-292.pdf [https://perma.cc/RU8F-CDXU] (comparing language in original regimen to the 2016 revised regimen). Then, in December 2021, the FDA permanently removed the requirement that mifepristone be dispensed in-person only from certain health-care facilities (clinics, medical offices, and hospitals). Cavazzoni Letter, *supra* note 142; *Questions and Answers on Mifeprex*, U.S. Food & Drug Admin., *supra* note 140.

[368] *See supra* notes 60–63 and accompanying text.

[369] *See infra* notes 386–387 and accompanying text.

[370] Mutual Pharm. Co., Inc. v. Bartlett, 570 U.S. 472, 488–90 (2013); *infra* note 383 and accompanying text.

[371] *See supra* notes 244–246 and accompanying text.

[372] Alexander Gaffney, *FDA: Federal Efforts to Reduce Access to Zohydro 'Extremely Troubling'*, RAPS (Mar. 31, 2014), https://www.raps.org/regulatory-focus%E2%84%A2/news-articles/2014/3/fda-state,-federal-efforts-to-reduce-access-to-zohydro-extremely-troubling (last visited Dec. 26, 2022).

[373] *Id.*

[374] *See* Garland Statement, *supra* note 135.

has not squarely addressed whether the FDCA preempts states from banning FDA-approved drugs or imposing restrictions beyond those required by the FDA.

In 2009, the Court held in *Wyeth v. Levine* that state law failure-to-warn claims against a brand name manufacturer were not preempted.[375] The Court rejected the defendant's impossibility preemption argument because under FDA regulations, it is not impossible to comply with both state and federal law because FDA regulations permit manufacturers to unilaterally change their drug labels to be more (but not less) protective than the FDA-approved labeling.[376] Additionally, the Court discarded the defendant's obstacle preemption argument, citing Congress's "silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation," as "powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness."[377]

The Court also rejected the defendant's reliance on the FDA's statements in the 2006 preamble discussed above,[378] refusing to defer to the Agency's conclusions and views therein because they were at odds with available evidence of congressional purpose, "reverse[d] the FDA's own longstanding position without providing a reasoned explanation," and were finalized "without offering States or other interested parties notice or opportunity to comment."[379] The reasoning used and conclusions reached in *Wyeth* may be difficult to overcome, particularly with respect to brand name manufacturers and state restrictions that explicitly or implicitly change the labeling in ways that a state claims is more protective than the FDA-approved labeling.

Two years later, in *PLIVA, Inc. v. Mensing*,[380] the Court held that generic drug manufacturers, unlike the brand name manufacturers in *Wyeth*, cannot be sued for failing to warn about potentially dangerous side effects on their drug labels when they follow federal rules. The Court relied on impossibility preemption, noting that under federal rules and FDA interpre-

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[375] 555 U.S. 555, 581 (2009).

[376] *Id.* at 568–73. Under FDA's "changes being effected" (CBE) regulations, manufacturers can add or strengthen a contraindication, warning, precaution, or adverse reaction. The manufacturer may distribute labeling with such changes upon the Agency's receipt of a supplemental application with the change (i.e., FDA "approval" is not necessary prior to distributing the labeling change). *See* 21 C.F.R. § 314.70(c)(6)(iii)(A); U.S. Food & Drug Admin., Guidance for Industry: Changes to an Approved NDA or ANDA 25–26 (2004), https://www.fda.gov/files/drugs/published/Changes-to-an-Approved-NDA-or-ANDA.pdf [https://perma.cc/QE2N-YFHB]. The FDA has the authority to disapprove of the change and order the manufacturer to cease distribution of the drug made with the change. 21 C.F.R. § 314.70(c)(7).

[377] *Wyeth*, 555 U.S. at 575.

[378] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (codified June 30, 2006, at 21 C.F.R. §§ 201.56(d), 201.57). *See also supra* notes 348–354 and accompanying text.

[379] *Wyeth*, 555 U.S. at 577.

[380] PLIVA, Inc. v. Mensing, 564 U.S. 604, 614–15, 618 (2011).

tation, generic manufacturers may not strengthen or change their warning labels unless the brand name equivalent has done so.[381] The Court therefore distinguished *Wyeth*, which involved claims against a brand name manufacturer.[382]

The Court revisited the issue in 2013 in *Mutual Pharmaceutical Co. v. Bartlett*.[383] In *Mutual Pharmaceutical*, the plaintiff alleged both failure-to-warn and design defect claims relating to a generic drug. The district court granted summary judgment to the defendant on the failure-to-warn claim because the plaintiff's physician admitted he did not consult the product's labeling.[384] The jury found in the plaintiff's favor on the design defect claim, but the Supreme Court ultimately held that design defect claims that turn on the adequacy of a drug's warnings are preempted by federal law under *PLIVA*.[385]

Important to the considerations of this Article, the majority in *Mutual Pharmaceutical* rejected the plaintiff's "stop-selling" argument, which asserted that it was not impossible for the manufacturer to comply with both state and federal requirements because it could simply choose not to sell the drug in states with laws that conflicted with federal law.[386] The majority's rejection of this argument suggests that the Court could find certain state pharmaceutical regulations, particularly outright bans that require a manufacturer to stop selling the drug within a state, to be preempted by federal law.[387]

There is limited lower court case law addressing this preemption question. The litigation over the Zohydro ban in Massachusetts, discussed above, provides one important example.[388] Courts may soon be confronted with thorny preemption questions as cases are filed to challenge medication abortion bans. At least one challenge was already attempted, but has since been dismissed voluntarily by the plaintiffs.[389] GenBioPro, Inc., a company that

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[381] *Id.* at 618–19.
[382] *Id.* at 624–26.
[383] 570 U.S. 472, 475 (2013).
[384] *Id.* at 479.
[385] *Id.* at 493.
[386] *Id.* at 487–90 & n.3. Justice Breyer disagreed, stating it was "not 'literally impossible'" for the manufacturer to comply with conflicting state and federal law, because it could "comply with both either by not doing business in the relevant State or by paying the state penalty, say damages, for failing to comply with" the state law. *Id.* at 493 (Breyer, J., dissenting); *cf. also id.* at 513–15 (Sotomayor, J., dissenting) (rejecting the majority's stop-selling analysis). Justice Breyer did suggest that obstacle preemption might be possible, stating that "one might infer that, the more medically valuable the drug, the less likely Congress intended to permit a State to drive it from the marketplace." *Id.* at 494 (Breyer, J., dissenting).
[387] Noah, *State Affronts*, *supra* note 30, at 35 ("[I]f the relatively more attenuated command of design defect scrutiny in tort law created an actual conflict with federal law governing FDA-approved drugs, then surely an outright sales prohibition imposed by state officials would do so.").
[388] *See supra* notes 244–246 and accompanying text.
[389] *See* Complaint at 1, GenBioPro, Inc. v. Dobbs, No. 3:20-cv-00652-HTW-LRA (S.D. Miss. Oct. 9, 2020); Lopez & Castronuovo, *supra* note 160.

markets and sells generic mifepristone, filed a lawsuit against Mississippi on October 9, 2020, claiming that "Mississippi's laws restricting the use of the [FDA] approved drug mifepristone conflict with federal law and are therefore preempted."[390] In August 2022, GenBioPro dismissed its claims and abandoned its challenge to Mississippi's restrictions on medication abortion.[391] The GenBioPro litigation represents a missed opportunity for a court to provide some clarity on the preemptive effect of current FDA law and regulation.[392] There exists little doubt that legal challenges will continue as anti-abortion advocates and legislators attack medication abortion directly and with more force than in the past, as they realize that medication abortion could represent an "existential threat [to] the anti-abortion movement."[393]

As litigation arises, plaintiffs challenging the laws have reasonable arguments in favor of federal preemption, particularly for complete bans, but much uncertainty remains. The absence of express preemption, the presumption against preemption, and an overall lack of clarity and consistency in preemption jurisprudence will enable courts to wield their discretion and refuse to find state bans and restrictions preempted. If a case raising the question of whether federal law preempts state bans and restrictions on FDA-approved pharmaceuticals reaches the Supreme Court, the first case will most likely involve medication abortion. Given the current majority's hostility toward abortion rights, the Court will likely conclude that federal law does *not* preempt such state bans or restrictions. Depending on the Court's analysis and reasoning used to reach that conclusion, such a case could have implications well beyond medication abortion. The current political and judicial landscape create great risk to patient access to medication abortion, contraceptives, and other FDA-approved medications.

B. Pathways Forward: The Need for Clarity

Section A reveals that the question of whether a state may ban or impose significant restrictions on FDA-approved pharmaceuticals lacks a clear or easy answer. The absence of clarity leaves access to FDA-approved medications vulnerable in all states, particularly those with politicians eager to

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[390] Complaint, *supra* note 389, at 1.

[391] Lopez & Castronuovo, *supra* note 160.

[392] Litigation remains possible. Counsel for GenBioPro has stated that the company is searching for a new court to revive its challenge. Lopez, *supra* note 160.

[393] Luthra, *supra* note 24 (quoting Greer Donley, Professor at University of Pittsburgh Law School). Indeed, on November 18, 2022, the abortion opponents who helped challenge *Roe* filed a federal lawsuit, arguing that the FDA should not have approved medication abortion and overstepped its authority in doing so. Complaint at 3, Alliance for Hippocratic Med. v. U.S. Food & Drug Admin., No. 2:22-cv-00223-Z (D. Tex. Nov. 18, 2022). The plaintiffs are asking for a preliminary and permanent injunction that orders the FDA to withdraw the approval of medication abortion. *Id.* at 110; *see also* Paul J. Webber, *Opponents File Lawsuit Targeting Medication Abortions*, Assoc. Press (Nov. 18, 2022), https://apnews.com/article/abortion-health-business-texas-lawsuits-71b8e54b97b016bf2cc0d9380d478991 [https://perma.cc/TJQ7-BCZA].

push back against the federal government. The import and urgency of the issue must not be dismissed merely because it affects a relatively limited number of drugs at this time. Part III exposed the pernicious consequences of state pharmaceutical regulations, illustrating how they exacerbate existing health disparities and disproportionately impact communities already burdened by myriad social inequities.[394] State bans and restrictions involve more than just matters of federalism; they concern life and death. Absent further clarity, the legality of state pharmaceutical bans and restrictions will be left to the discretion of the courts, an institution that increasingly proves to be unreliable in the protection of individual rights and the promotion of equality.[395] To address these issues and chart pathways forward, this Article picks up where other scholars have left off by proposing a possible legislative fix and other steps that can be pursued to clarify whether, and under what circumstances, a state may ban or restrict access to an FDA-approved pharmaceutical.

1. *Adding an Express Preemption Provision to the FDCA*

To promote the best interests of patients and the public health, reduce health disparities, and provide clarity to patients, providers, industry, the judiciary, and other stakeholders, this Article recommends amending the FDCA to include an express preemption provision specific to pharmaceutical bans and restrictions. The amendment would prohibit states from (1) banning FDA-approved pharmaceuticals; (2) changing the FDA-approved indication; (3) requiring the provision of risk information that is false, misleading, or unsupported by current evidence and medical consensus; or (4) otherwise restricting FDA-approved pharmaceuticals in ways that go beyond the requirements of a drug's federally approved labeling, including those found in a REMS.[396]

Importantly, preemption would not be absolute. Recognizing the need to strike a delicate balance between federal and state interests, and to allow states to continue "to fulfill their role as policy 'laboratories' "[397] in appropri-

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[394] This Article does not suggest that prohibiting state bans and restrictions on FDA-approved pharmaceuticals will solve the many issues that exacerbate health disparities. Rather, it focuses on reducing the effects of one factor contributing to health disparities.

[395] *Cf. generally* Aziz Z. Huq, The Collapse of Constitutional Remedies (Geoffrey R. Stone ed., 2021) (exploring how and why the courts have failed to protect individuals' constitutional rights).

[396] The case for preemption is arguably stronger when a drug has a REMS because it illustrates an extensive consideration of the drug's risks, benefits, and related safety measures. Imposing a REMS essentially requires the FDA to take additional steps when reviewing and approving drugs. *Cf.* Zettler, *Pharmaceutical Federalism*, *supra* note 45, at 875 ("[A] court might reasonably conclude that state requirements additional to those in an FDA-required REMS pose an obstacle to the FDA's responsibility to satisfy these Congressional objectives, particularly if courts increasingly view federal regulatory choices as an effort to find the optimal balance between competing policy goals.").

[397] Gluck & Huberfeld, *supra* note 3, at 1782.

ate circumstances, the amendment would include a process whereby states could seek an exemption, which would allow them to issue temporary or permanent state laws or regulations that ban or restrict access to a particular drug in their state.[398] States would be required to justify the need for an exemption by demonstrating a state-specific public health need.[399] In the case of Zohydro, for example, Massachusetts would request an exemption while the Commonwealth's public health emergency remained in effect, using the spike in opioid-related deaths and injuries in the Commonwealth—which fell above national averages—as justification.

Along with balancing state and federal interests, the interests of individuals and the public must also be balanced. Thus, to ensure banned or restricted drugs remain available to patients in appropriate circumstances, the law could also require states that receive exemptions to allow health-care providers to request access to the banned or restricted drugs for individual patients. In practice, such requests could draw on the procedures used for individual expanded access investigational new drug applications (INDs) (often referred to as "compassionate use"), which allow an investigational drug to be provided to a single patient for treatment by a licensed physician if the FDA determines that, among other things, the benefit justifies the potential risks and that the patient cannot obtain the drug through other means.[400]

The exemption process could work in a few different ways:

- *Approval Process*: A state's public health department (or equivalent entity) would submit an exemption request to the FDA, which the Agency would review and either approve or deny in writing. The state would be required to submit evidence to justify why an exemption is necessary to protect the public health and safety of its citizens and to indicate how long it intends the exemption to last.
- *Notification Process*: A state's public health department (or equivalent entity) could notify the FDA that it intends to enact a ban or impose additional restrictions on an FDA-approved pharmaceutical, again with information to justify the need for the exemption and how long the state intends the exemption to remain in effect. Absent the FDA's objection within a specific timeframe (e.g., thirty days), the ban or restrictions could take effect.
- *Emergency Process*: If a state emergency requires an immediate ban or restriction, the FDA could authorize the ban or restriction without a written submission, such as via telephone or electronic communica-

[398] 21 U.S.C § 360k(b); *id.* § 379r(b); *see* H.R. Rep. No. 94-853, at 45 (1975) ("Because there are some situations in which regulation of devices by States and localities would constitute a useful supplement to Federal regulation, the reported bill authorizes a State or political subdivision thereof to petition the Secretary for exemptions from the bill's general prohibition of non-Federal regulation.").

[399] *See* H.R. Rep. No. 94-853, at 45–46.

[400] *See* 21 C.F.R. §§ 312.305(a), 312.310.

tions. The state would be required to submit a written application (or notification) within a certain number of days of the FDA's authorization (e.g., fourteen business days).[401]

For those concerned about the evisceration of state tort or product liability claims, amending the FDCA to include an express preemption provision need not eliminate a person's private right of action or otherwise enable companies "to sell a federally approved drug free from common-law liability."[402] Although failure-to-warn claims against generic manufacturers remain less likely to be successful because of the Supreme Court's holdings in *PLIVA* and *Mutual Pharmaceutical*, claims against brand name manufacturers might continue under the Court's decision in *Wyeth*. In *Wyeth*, the Court concluded that because manufacturers can change certain aspects of their labeling, including warnings and precautions, with notice but not prior approval of the FDA, no conflict arises between the FDA's regulatory scheme and a tort claim demanding a labeling change without prior FDA approval.[403] Allowing state common law liability to remain available does not, however, mean that plaintiffs should necessarily prevail on their claims that a manufacturer should have updated its labeling to add a new warning or contraindication. As required by FDA regulation, such changes may only be made when there is "evidence of a causal association" between the drug and the contraindication, warning, precaution, or adverse reaction.[404] To prevail, plaintiffs must be required to show this causal connection.

To further protect state tort and liability claims, when amending the FDCA to include an express preemption provision Congress should be clear that state common law liability claims remain available, such as by including a "savings clause." This would be modeled on a provision in the nonprescription drug preemption provision, which states: "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."[405] Further, states concerned about whether the preemption provision will eliminate certain remedies could enact state requirements equivalent to federal requirements that provide injured plaintiffs with different and additional remedies.[406]

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[401] This provision would draw upon FDA regulations governing emergency INDs. *See id.* § 312.310.

[402] Mutual Pharm. Co. v. Bartlett, 570 U.S. 472, 497 (2013) (Sotomayor, J., dissenting).

[403] *See* Wyeth v. Levine, 555 U.S. 555, 568–72 (2009).

[404] 21 C.F.R. § 314.70(c)(6)(iii)(A). For example, this would preclude plaintiffs from claiming that manufacturers of mifepristone must include warnings on their labels about a risk of breast cancer or infertility. *See supra* note 361 and accompanying text.

[405] *See* 21 U.S.C. § 379r(e).

[406] *See* SYKES & VANATKO, *supra* note 64, at 12.

2. *Non-Legislative Alternatives*

An express preemption provision codified in the FDCA represents the ideal solution because it provides the greatest clarity, certainty, and consistency.[407] That said, absent or prior to a statutory amendment, there are other ways the FDA could clarify the preemptive effect of FDA approval. All statutory amendments take time, face obstacles, and may not succeed, so the FDA should take important steps in advance to clarify its position on the issue. Such steps could include new FDA regulations,[408] guidance documents, and policy statements in which the Agency sets forth its position on whether states may ban or restrict access to FDA-approved drugs.[409] At a minimum, the FDA could issue public statements, as it did about the Zohydro ban.[410]

The promulgation of FDA regulations provides the second-best option to a statutory amendment, as the Supreme Court "has recognized that an agency regulation with the force of law can pre-empt conflicting state requirements."[411] The preemption statement should be placed in the codified regulatory text, as opposed to the preamble alone.[412] Statements in preambles, as well as other, less formal policy or media statements would help establish a record of the Agency's views on preemption but likely would hold little weight in court.

The nonlegislative options all suffer from limitations. First, they are easier to challenge because except for certain codified regulations, most would be reviewed under doctrines of implied rather than express preemption. Moreover, courts may give little weight or deference to these informal statements. In *Wyeth*, for example, the Court refused to defer to the Agency's position in the 2006 preamble[413] that federal labeling regulations preempted

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[407] *Cf.* Catherine M. Sharkey, *Inside Agency Preemption*, 110 MICH. L. REV. 521, 523 (2012) ("Congress, with the stroke of a pen, [can] definitively resolve preemption questions by specifying the impact of its legislation on state law . . .").

[408] For the FDA to preempt by regulation, rather than legislation, the Agency must first consult with the states. *See* Exec. Order No. 13132, 64 Fed. Reg., 153, § 4 (Aug. 4, 1999), https://www.govinfo.gov/content/pkg/FR-1999-08-10/pdf/99-20729.pdf [https://perma.cc/A9WH-M6Y9]; Sharkey, *Preemption by Preamble*, *supra* note 364, at 1611.

[409] In *Hillsborough County v. Automated Medical Laboratories, Inc.*, the Supreme Court gave weight to the FDA's statements when considering implied preemption, and also noted that the weight of prior statements can change if "subsequent developments reveal a change in that position." 471 U.S. 707, 714–15 (1985). Thus, a statement made at the time of a law's initial passage may not be dispositive if the FDA later changes its position.

[410] *See supra* notes 372–373 and accompanying text.

[411] Wyeth v. Levine, 555 U.S. 555, 576 (2009); *see also Hillsborough Cnty.*, 471 U.S. at 713 ("[T]he FDA possesses the authority to promulgate regulations pre-empting local legislation.").

[412] *See supra* notes 364–365 and accompanying text.

[413] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3934 (Jan. 24, 2006) (codified June 30, 2006 at 21 C.F.R. §§ 201.56(d), 201.57) (requiring that the labeling of new and recently ap-

state tort laws.[414] Realistically, many courts will have their first opportunity to consider the preemption of state pharmaceutical bans and restrictions in cases involving medication abortion. The hostility of certain courts to abortion rights, most importantly the Supreme Court, makes it unlikely they will find in favor of preemption. A second and important limitation is that informal positions and agency regulations are easier to change, allowing future administrations to easily "flip-flop" between different interpretations of preemption.[415] This would "undermine long-term administrative stability" and only further exacerbate ambiguities and uncertainties for patients, providers, and drug manufacturers.[416]

Along with steps that should be taken by Congress and the FDA, individuals and groups concerned about state bans and restrictions can push for action by Congress and the FDA, such as advocating for legislative and regulatory changes to clarify the preemptive force of FDA approval. Any person can submit a citizen petition to the FDA requesting the Agency to issue, amend, or revoke a regulation or order; or to take or refrain from taking any other form of administrative action.[417] Advocates could thus petition the FDA to issue regulations or guidance documents pertaining to preemption. Importantly, the voices of health-care providers concerned about the impact of state bans and restrictions on their ability to provide comprehensive care in their patients' best interests must be heard. Providers should welcome a regulatory state in which states cannot restrict or ban FDA-approved pharmaceuticals. Providing the FDA with clearer authority to set both the floor and ceiling for drug regulation will enhance, rather than curtail, the autonomy of health-care providers and their ability to practice their profession in the best interests of their patients.[418] Congress has recognized the

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proved products include highlights of prescribing information and a table of contents); *see also supra* notes 348–354 and accompanying text.

[414] *See Wyeth*, 555 U.S. at 576–79.

[415] For example, the Biden Administration has indicated its commitment to reproductive justice and the right to an abortion, but future administrations with anti-abortion views may roll back policies or interpretive guidance intended to limit states' ability to restrict access to medication abortion or other forms of reproductive health care. This was seen during the Trump Administration, when it refused to relax the in-person dispensing requirements for medication abortion during the COVID-19 pandemic, as well as through the Administration's regulatory agenda more generally, such as its expansion of religious and moral exemptions to the Affordable Care Act's birth control coverage mandate. *See* Osub Ahmed et al., *Women Have Paid the Price for Trump's Regulatory Agenda*, CTR. FOR AM. PROGRESS (Sept. 10, 2020), https://www.americanprogress.org/article/women-paid-price-trumps-regulatory-agenda/ [https://perma.cc/96LH-EET7].

[416] Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 NW. U. L. REV. COLLOQUY 54, 63 (2008).

[417] *See* 21 C.F.R. § 10.30.

[418] Arguably, the proposal should also appeal to those who oppose government intrusion and over-regulation, as it would reduce the breadth and scope of regulations that health-care providers would be subject to. That said, politicians often hold hypocritical views about government regulation. Debates about abortion and vaccines illustrate this clearly. *See, e.g.*, Michael A. Cohen, *Anti-Covid Vaccine Arguments are Being Weaponized by Republican Men*, MSNBC (Aug. 18, 2021), https://www.msnbc.com/opinion/how-republican-men-are-weaponizing-anti-covid-vaccine-arguments-n1276967

importance of such autonomy in past statements,[419] and liberals and conservatives alike express support for physician autonomy.[420]

Ultimately, amending the FDCA represents the best approach to combat the negative consequences and inequities created by state bans and restrictions on FDA-approved pharmaceuticals. By clarifying the preemptive effect of FDA approval, the statutory amendment proposed by this Article represents one important step toward reducing unequal access to FDA-approved drugs based on one's geographic location, income, other demographic characteristics, and state politics. At a time when health disparities continue to grow, all strategies to combat that trend must be considered. Policy goals such as reducing health disparities should be considered when thinking about federalism and whether and when it is beneficial. As Professors Gluck and Huberfeld observe, using federalism to promote policy goals has historic roots: "[t]he Federalist papers themselves contain a well-known-statement" that "put[s] 'the public good' above 'the sovereignty of the States' in the event the two . . . conflict."[421] This Article addressed one important area where the consequences of federalism must be considered and where the federal government and administrative state can, and should, play a role in mitigating barriers to patient access to safe and effective medical care.

CONCLUSION

The reforms proposed by this Article will all face challenges. States may argue, for example, that the reforms curtail states' long-held authority to regulate the practice of medicine. But what has been need not always be. There are reasons to respect past practices, but evolutions in medical practice; the increasingly national, and even international, scope of the practice

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[https://perma.cc/62SF-8BVV] (noting that conservatives' "opposition to health care mandates exposes a glaring hypocrisy. After all, a party that believes so strongly in individual freedom and stopping the heavy hand of government should, at least theoretically, be opposed to health restrictions that take decision-making away from a woman and give it to the state").

[419] *See supra* notes 109–110 and accompanying text.

[420] Robert E. Moffit, senior fellow at the Heritage Foundation, a well-known conservative organization, states: "The right policy goal should be to restore, to the maximum extent feasible, the traditional doctor-patient relationship. That goal would be realized when . . . the physician enjoys greater professional independence in the delivery of medical care." Robert E. Moffit, *How to End the Overregulation of Medical Care*, NAT'L INTEREST (Aug. 2, 2020), https://nationalinterest.org/feature/how-end-overregulation-medical-care-165991 [https://perma.cc/T3TP-FXRR]. The Center for American Progress, a liberal-leaning organization, has also expressed concerns about political interference in the practice of medicine that affects the patient-provider relationship. *See, e.g.*, Donna Barry et al., *Changing the Conversation on Abortion Restrictions: A Proactive Response to Political Interference in Health Care*, CTR. FOR AM. PROGRESS 1, 1–3 (Sept. 30, 2015), https://americanprogress.org/wp-content/uploads/2015/09/barry-Abortion-Care-brief.pdf [https://perma.cc/KRH2-S6CW].

[421] Gluck & Huberfeld, *supra* note 3, at 1787 (quoting THE FEDERALIST No. 45, at 289 (James Madison) (Clinton Rossiter ed., 1962)).

of medicine; and the undeniable negative consequences caused by certain state pharmaceutical regulations make blind adherence to health-care federalism nonsensical, unworkable, and even dangerous or life-threatening.

The exacerbation of health disparities and social inequities that result from state pharmaceutical regulation must be addressed. This Article focused on medication abortion and contraceptives, but the issues reverberate across the U.S. health-care system. Moreover, the future of medicine will give rise to new and controversial medicines likely to engender political and ethical debates and federal-state tensions. To mitigate the impact of a fractured state-by-state drug regulatory regime, this Article proposed a compromise solution: amending the FDCA to expressly preempt state bans or restrictions on FDA-approved pharmaceuticals while also providing a process for states to seek exemptions when necessary to protect the health, safety, and well-being of their citizens. Combatting deeply entrenched health disparities requires creative thinking and this proposal provides an important tool in the fight to close these tragic gaps.