ABORTION EXCEPTIONALISM IN THE REGULATION OF TELEMEDICINE MEDICATION ABORTION CARE

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Abortion exceptionalism is the trend of singling out abortion care for special treatment through government policy.[1] One example of this phenomenon is the Food and Drug Administration's (FDA) excessive regulation of access to mifepristone, a prescription drug used for medication abortion care during the first ten weeks of pregnancy. Historically, the FDA has required that mifepristone is "only available to be dispensed in healthcare settings . . . by or under the supervision of a certified prescriber."[2] Although the FDA recently paused this restriction due to COVID-19 pandemic related health risks,[3] the policy remains an example of blatant abortion exceptionalism: "Of the over 20,000 FDA-approved drugs, mifepristone is the only one that the FDA requires to be picked up in person for patients to take at home."[4]

Months before the FDA lifted the mifepristone restrictions, a Maryland district court attempted to ameliorate public health concerns about access to abortion care for the duration of the pandemic by issuing a nationwide preliminary injunction, enjoining the FDA's in-person dispensing and signature requirements that force patients to go to a hospital, clinic, or medical office to pick up mifepristone.[5] Unfortunately, this evidence-based intervention was short-lived. In January 2021, the Supreme Court stayed the district court's injunction in *Food and Drug Administration, et al. v. American College of Obstetricians and Gynecologists, et al.*[6] As this piece will show, permanently eliminating these burdensome regulations is not only necessary in the short-term to bolster public health during a pandemic,

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1 *See generally* Caitlin Borgmann, *Abortion Exceptionalism and Undue Burden Preemption*, 71 WASH. & LEE L. REV. 1047 (2014); Caroline Mala Corbin, *Abortion Distortion*, 71 WASH. & LEE L. REV. 1175, 1177 (2014); Ian Vandelwalker, *Abortion and Informed Consent*, 19 MICH. J. GENDER & L. 1, 3 (2012).

2 U.S. Food & Drug Admin., *Questions and Answers on Mifeprex* (Apr. 12, 2019), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-mifeprex.

3 Alice Miranda Ollstein & Darius Tahir, *FDA Lifts Curbs on Dispensing Abortion Pills During Pandemic*, POLITICO (Apr. 12, 2021, 11:06 PM), https://www.politico.com/news/2021/04/12/abortion-pills-481092. "Acting FDA Commissioner Janet Woodcock informed the American College of Obstetrics and Gynecologists in a letter . . . that her agency concluded that allowing patients to receive the pills via telemedicine and through the mail will not increase risks and will keep people safe from contracting the virus.". *Id*.

4 U.S. Food & Drug Admin. v. Am. Coll. of Obstetrics & Gynecologists, 141 S. Ct. 578, 579 (2021) (Sotomayor, J., dissenting). Notably, Viagra—a drug that treats erectile dysfunction—is not subject to any distribution restrictions, despite the fact that its fatality rate is six times higher than mifepristone's. Greer Donley, *Biden Could Expand Abortion Access, Even Without the Senate*, ATLANTIC (Nov. 28, 2020), https://www.theatlantic.com/ideas/archive/2020/11/biden-abortion-access/616913/.

5 Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., 472 F. Supp. 3d 183, 189 (D. Md. 2020), order clarified sub nom. Am. Coll. of Obstetricians & Gynecologists on behalf of Council of Univ. Chairs of Obstetrics & Gynecology v. U.S. Food & Drug Admin., No. CV TDC-20-1320, 2020 WL 8167535 (D. Md. Aug. 19, 2020).

6 141 S. Ct. 578, 578 (2021).

but also to protect the long-term health and safety of individuals seeking abortion care by beginning the reversal of policies that perpetuate abortion exceptionalism.

I. Telemedicine Abortion Care as a Public Health Intervention

Telemedicine medication abortion care was absolutely necessary to address gaps in access prior to the pandemic, but it has become a lifeline during a historic, public-health crisis. Abortion care in the United States has historically been a "clinic-based service," which has resulted in large gaps in access, particularly in "medical deserts," where health centers providing abortion care are unreasonably far away from potential patients.[7] An estimated 11.3 million women of reproductive age currently live more than a one-hour driving distance away from the nearest abortion facility.[8] As burdensome state laws continue to force more abortion clinics to close and healthcare facilities to discontinue abortion-care services, the threat to safe, accessible abortion care during early pregnancy is increasingly dire.[9] Medication abortion care is even more important during a deadly pandemic. COVID-19 has increased the risk of in-person visits to hospitals and other medical facilities—a fact that motivated the FDA to relax similar restrictions for the distribution of other drugs and laboratory testing, [10] and eventually led to the FDA's use of enforcement discretion to temporarily make mifepristone available through telemedicine and mail.[11] In the middle of these public-health crises, the Supreme Court's continued politicization of abortion care over the wellbeing of patients and population health was disappointing and dangerous.

As a telemedicine alternative to in-clinic abortion services, mifepristone offers the dual benefit of low-risk care and increased access to populations residing in medical deserts. Medical research has proven that mifepristone is safe and effective for patients who choose to receive medication abortion care.[12] In fact, medication abortion care has a lower risk of health complications during the first trimester than in-clinic surgical abortion care, which is already known to be a safe procedure.[13] In comparison to carrying pregnancies to term, patients who cannot access timely abortion care are fourteen times more likely to die from childbirth than from medication abortion.[14] Telemedicine also increases access to medication abortion, particularly for patients who may live more than fifty miles from the nearest surgical-abortion site.[15] Telemedicine medication abortion care has proven to be just as safe and effective as an in-person physician consultation.[16] As a testament

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[7] Megan K. Donovan, *Improving Access to Abortion via Telehealth*, GUTTMACHER INST. (May 16, 2019), https://www.guttmacher.org/gpr/2019/05/improving-access-abortion-telehealth.
[8] *Id.*
[9] *Id*.
[10] Beatrice L. Brown, Susan F. Wood & Ameet Sarpatwari, *Ensuring Safe Access to Mifepristone During the Pandemic and Beyond*, 174 ANNALS INTERNAL MED. 1 (2021).
[11] *See* Ollstein & Tahir, *supra* note 3.
[12] Brown, et. al, *supra* note 10.
[13] *Id*.
[14] Elizabeth G. Raymond & David A. Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 OBSTETRICS & GYNECOLOGY 215, 216 (2012).
[15] Liza Fuentes & Jenna Jerman, *Distance Traveled to Obtain Clinical Abortion Care in the United States and Reasons for Clinic Choice*, 28 J. WOMEN'S HEALTH 1623, 1625 (2014).
[16] *Id.* at 1630.

to the safety (and convenience) of the procedure, telemedicine medication abortion care is widely used by the United States military, where circumstances may necessitate increased flexibility and access, with widespread satisfaction.[17] Given these evidence-based benefits, federal policymakers should increase access to medication abortion care, not continue to uphold a burdensome and medically-unnecessary regulatory scheme that preferences in-person dispensing requirements.

II. An Unduly Burdensome Regulatory Scheme

Although dispensing restrictions have been temporarily lifted during the COVID-19 pandemic, mifepristone continues to be overregulated by FDA, which makes it unnecessarily difficult to access a safe and effective product for abortion care. Mifepristone is subject to a Risk Evaluation and Mitigation Strategy (REMS), which limits the drug's availability in commercial pharmacies and requires signature upon dispensation.[18] Proponents of the REMS classification would argue that the additional measures guard against poor health outcomes and provide patients with "an appropriate pause" to consider their decision.[19] However, medical research and the consensus among physicians, *see supra* Part I, suggest medication abortion care is safe and effective, and that the time-sensitive provision of care requested by a patient should not be subject to additional barriers and waiting periods based on the government's exceptional treatment of an abortion-inducing drug.

The Maryland district court correctly applied the embattled undue burden test—itself a manifestation of abortion exceptionalism—to find that the REMS regulatory scheme of mifepristone posed an undue burden to abortion access during the pandemic.[20] The Supreme Court granted a stay of the lower court's injunction, pending disposition of the appeal filed in the Fourth Circuit.[21] The stay of the district court's injunction, however, amounts to "extraordinary relief," which

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[17] TELEHEALTH FOR MEDICATION ABORTION DELIVERY MODELS, IBIS REPROD. HEALTH 4 (Oct. 2019), https://www.ibisreproductivehealth.org/sites/default/files/files/publications/Telehealth%20for%20medication%20abortion%20delivery%20models.pdf.

[18] U.S. Food & Drug Admin., *Mifeprex (mifepristone) Information* (Feb. 5, 2018), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/mifeprex-mifepristone-information.

[19] *See* Mara Gordon & Sarah McCammon, *A Drug That Eases Miscarriages Is Difficult For Women To Get*, NPR (Jan. 10, 2019), https://www.npr.org/sections/health-shots/2019/01/10/666957368/a-drug-that-eases-miscarriages-is-difficult-for-women-to-get.

[20] Am. Coll. of Obstetricians & Gynecologists v. U.S. Food & Drug Admin., 472 F. Supp. 3d 183, 189, 223−24 (D. Md. 2020), order clarified sub nom. Am. Coll. of Obstetricians & Gynecologists on behalf of Council of Univ. Chairs of Obstetrics & Gynecology v. U.S. Food & Drug Admin., No. CV TDC-20-1320, 2020 WL 8167535 (D. Md. Aug. 19, 2020). ("[T]he burdens of the In-Person Requirements in light of the COVID-19 pandemic are significant and likely place 'a substantial obstacle in the path of a woman's choice.' . . . [D]uring the pandemic, medical offices that dispense mifepristone may be closed or operating with limited capacity, a disproportionate number of abortion patients are from demographic groups with heightened risk for serious illness from COVID-19, and such patients face particularized barriers posed by transportation, childcare, and the economic downturn during the pandemic, the burdens are properly characterized as creating such a substantial obstacle, particularly where any delay in obtaining mifepristone that extends past the tenth week of pregnancy can force a woman to consider more complicated, invasive surgical abortions." (internal citations omitted)).

[21] U.S. Food & Drug Admin. v. Am. Coll. of Obstetrics & Gynecologists, 141 S. Ct. 578, 578 (2021)

cannot be granted unless the stay applicant demonstrates both an erroneous judgement on the merits and irreparable injury if the judgment is not stayed pending appeal.[22] Chief Justice Roberts issued a concurring opinion, arguing for judicial deference to politically accountable bodies with the "expertise to assess public health,"[23] with no mention of undue burden test and the courts' duty to apply it to determine whether abortion restrictions violate the Constitution.[24] In other instances where governing bodies have issued public health restrictions related to the pandemic, however, the Supreme Court has not deferred to executive and legislative authorities with "expertise to assess public health," particularly when safeguarding against violations of the Constitution, such as the free exercise of religion.[25] In these cases, Chief Justice Roberts similarly opined on the importance of judicial deference to politically accountable officials, but he also stated that the Constitution "entrusts the protection of the people's rights to the Judiciary—not despite judges being shielded by life tenure . . . but because they are. Deference, though broad, has its limits."[26] It appears the limits of deference extend only to some constitutionally-protected rights, like free exercise of religion, but not to others, such as access to abortion care without undue burden.

The Supreme Court's erroneous decision is even more disconcerting given the scant record it relied upon for its reasoning. Not only did the FDA fail to provide any specific explanation of irreparable harm in this case, but it also failed to submit "a single declaration . . . explaining why the Government believes women must continue to pick up mifepristone in person, even though it has exempted many other drugs from such a requirement given the health risks of COVID-19."[27] In a blatant display of abortion exceptionalism, the Supreme Court added to the long legacy of government agencies and judicial bodies examining access to abortion care as a political and moral issue rather than a medical and public health one.

III. Deregulation in the Abortion Care Context

The combination of public-health crises and evidence-based recommendations point to one obvious solution: deregulation. The FDA should immediately and permanently rescind restrictions on mifepristone and allow for telemedicine counseling and mail dispensation of medication abortion care well-beyond the pandemic. As a first step towards making these public health and safety measures a reality, Acting FDA Commissioner Janet Woodcock, who has already prioritized

[22] *Id.* at 579 (Sotomayor, J., dissenting).
[23] *Id.* (Roberts, C. J., concurring).
[24] *See* Planned Parenthood of Southeastern Pennsylvania v. Casey, 505 U.S. 833, 877−78 (1992) (articulating the "undue burden" standard for regulations with "the purpose or effect of placing a substantial obstacle in the path of a woman seeking an abortion" as an unconstitutional infringement on the fundamental right of privacy).
[25] *See* Roman Catholic Diocese of Brooklyn, N.Y. v. Andrew M. Cuomo, Governor of N.Y., 141 S. Ct. 63, 67−68 (finding that pandemic restrictions on religious services in New York violated the First Amendment's protection of the free exercise of religions); South Bay United Pentecostal Church et al., v. Gavin Newsom, Governor of California, et al., 141 S. Ct. 716, 716 (2021) (granting injunctive relief for challengers to California's prohibition on indoor worship services).
[26] South Bay United Pentecostal Church et al., 141 S. Ct. at 717 (Roberts, C.J., concurring).
[27] Am. Coll. of Obstetrics & Gynecologists, 141 S. Ct. at 584 (Sotomayor, J., dissenting).

the deconstruction of abortion exceptionalism through mifepristone's temporary deregulation, should make these dispensing changes permanent.[28] Mifepristone's REMS classification outside of this public health emergency remains intact as a harmful and unnecessary regulation. Although regulations can be an important tool for policy implementation, they can also be dangerous in the healthcare context if not grounded in medical research, evidence-based recommendations, and public-health objectives. In the case of telemedicine abortion care, abortion exceptionalism has unmoored the regulatory scheme from any semblance of patient-centered, evidence-based policy.

From the unsubstantiated REMS classification to the undue burden standard's application to routine public-health measures, abortion exceptionalism has resulted in unwieldy and overreaching regulations at the expense of patient care. The hypocrisy of conservative legal theorists and political actors is that they are unequivocally in favor of deregulation and limiting the size of government, except when it comes to interfering with reproductive health care. The Biden-Harris administration has an opportunity to reform abortion-care regulation by using medical research and public-health reasoning to lift restrictions permanently and to create the long-term impact of increased access to care. This opportunity must not be wasted.

[28] *See* Ollstein & Tahir, *supra* note 3.