Nos. 21-2480 & 21-2573

United States Court of Appeals
for the Seventh Circuit

WHOLE WOMAN'S HEALTH ALLIANCE, *et al.*,
Plaintiffs-Appellees,

v.

THEODORE E. ROKITA, *et al.*,
Defendants-Appellants.

On Appeal from the United States District Court
for the Southern District of Indiana
Case No. 1:18-cv-01904-SEB-MJD

BRIEF FOR THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS, THE AMERICAN COLLEGE OF NURSE-MIDWIVES, THE AMERICAN COLLEGE OF PHYSICIANS, THE AMERICAN MEDICAL WOMEN'S ASSOCIATION, THE AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, THE NATIONAL ASSOCIATION OF NURSE PRACTITIONERS IN WOMEN'S HEALTH, THE SOCIETY FOR ACADEMIC SPECIALISTS IN GENERAL OBSTETRICS AND GYNECOLOGY, THE SOCIETY FOR MATERNAL-FETAL MEDICINE, AND THE SOCIETY FOR REPRODUCTIVE ENDOCRINOLOGY AND INFERTILITY AS AMICI CURIAE IN SUPPORT OF PLAINTIFFS-APPELLEES AND AFFIRMANCE

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APPEARANCE & CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 21-2480 & 21-2573

Short Caption: Whole Woman's Health Alliance, et al. v. Theodore E. Rokita, et al.

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(5) Provide Debtor information required by FRAP 26.1 (c) 1 & 2:

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Attorney's Signature: /s/ Benjamin H.C. Lazarus Date: 11/08/2021

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INTEREST OF AMICI CURIAE[1]

The American College of Obstetricians and Gynecologists ("ACOG") is the nation's leading group of physicians providing health care for women. With more than 60,000 members, ACOG advocates for quality health care for women, maintains the highest standards of clinical practice and continuing education of its members, promotes patient education, and increases awareness among its members and the public of the changing issues facing women's health care.

ACOG is committed to ensuring access to the full spectrum of evidence-based quality reproductive health care, including abortion care. ACOG has appeared as amicus curiae in courts throughout the country. ACOG's briefs and medical practice guidelines have been cited by numerous authorities, including the U.S. Supreme Court and this Court, as a leading provider of authoritative scientific data regarding childbirth and abortion.[2]

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[1] All parties have consented to the filing of this amicus brief. No counsel for a party authored any part of this brief and no person other than amici curiae, their members, and their counsel made a monetary contribution to the preparation or submission of the brief.

[2] *See, e.g.*, *June Med. Servs. LLC v. Russo*, 140 S. Ct. 2103, 2131-2132 (2020) (citing ACOG brief in assessing and rejecting disputed hospital admitting privileges requirements); *Whole Woman's Health v. Hellerstedt*, 136 S. Ct. 2292, 2312, 2315 (2016) (citing ACOG brief in assessing and rejecting disputed hospital admitting privileges and ambulatory surgical center requirements); *Stenberg v. Carhart*, 530 U.S. 914, 932-936 (2000) (quoting ACOG

The American College of Nurse-Midwives ("ACNM") is the professional association representing certified nurse-midwives and certified midwives in the United States. ACNM's members are primary health care clinicians who provide evidence-based midwifery care for people throughout the lifespan, with an emphasis on pregnancy, childbirth, gynecologic, and reproductive health care.

The American College of Physicians ("ACP") is the largest medical specialty organization in the U.S. Its membership includes 161,000 internal medicine physicians, related subspecialists, and medical students.

The American Medical Women's Association ("AMWA") is the oldest multispecialty organization dedicated to advancing women in medicine, advocating for equity, and ensuring excellence in healthcare.

The American Society for Reproductive Medicine ("ASRM") is dedicated to the advancement of the science and practice of

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brief extensively and referring to ACOG as among the "significant medical authority" supporting the comparative safety of the abortion procedure at issue); *Planned Parenthood of Wis., Inc. v. Schimel*, 806 F.3d 908, 912-913 (7th Cir. 2015) (citing ACOG's brief in rejecting hospital admitting privileges requirement for abortion providers because "complications from an abortion are both rare and rarely dangerous").

reproductive medicine. Its members include approximately 8,000 professionals.

The National Association of Nurse Practitioners in Women's Health ("NPWH") is the nonprofit organization that represents Women's Health Nurse Practitioners and other advanced practice registered nurses who provide women's and gender-related healthcare.

The Society for Academic Specialists in General Obstetrics and Gynecology ("SASGOG") seeks to enhance women's health by supporting academic generalist physicians in all phases of their careers.

The Society for Maternal-Fetal Medicine ("SMFM") is the medical professional society for obstetricians with additional training in high-risk, complicated pregnancies. Representing over 5,000 members, SMFM supports the clinical practice of maternal-fetal medicine by providing education, promoting research, and engaging in advocacy to reduce disparities and optimize the health of high-risk pregnant people.

The Society for Reproductive Endocrinology and Infertility ("SREI") is a professional group of Reproductive Endocrinologists within the American Society for Reproductive Medicine. SREI's mission is to serve a leadership role in reproductive endocrinology and infertility by

promoting excellence in patient care, fostering training and career development, developing new research, and supporting ethical practice and advocacy.

SUMMARY OF ARGUMENT

Reproductive health care is essential to women's overall health, and access to abortion is an important component of reproductive health care. ACOG represents physicians who serve patients in Indiana and nationwide, and whose policies represent the education, training, and experience of physicians in this country. ACOG's position is that laws regulating abortion should be evidence-based, supported by a valid medical or scientific justification, and designed to improve—not harm—patients' health.

At issue in this case are numerous Indiana statutes and regulations that place various restrictions on patients' access to abortion and physicians' and clinicians' ability to provide abortion services. This brief specifically addresses three categories of

restrictions in Indiana law that provide no medical benefit and are not supported by accepted medical practice or scientific evidence[3]:

- The ban on telemedicine in abortion care, which requires that all patients seeking abortions attend an in-person pre-abortion counseling session, requires that all patients seeking medication abortions[4] receive an in-person physical examination from a physician, and forbids clinicians from prescribing "an abortion inducing drug" via telemedicine.[5]
- The physician-only law, which allows only physicians to perform first-trimester abortions and excludes other qualified clinicians like Advanced Practice Clinicians ("APCs") from providing these abortions.[6]

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[3] ACOG opposes legislation and regulations that create barriers to abortion access and interfere with the patient-clinician relationship and the practice of medicine. ACOG, *Committee Opinion No. 815: Increasing Access to Abortion*, 136 Obstet. Gynecol. e107, e108-e109 (Dec. 2020). For purposes of this brief, amici address only three of the disputed restrictions.

[4] In a medication abortion, pregnancy is terminated through the use of medicines instead of through interventions like uterine aspiration. The medication abortion regimen supported by major organizations nationally and internationally includes the oral administration of two medications, mifepristone and misoprostol. *See* ACOG, *Practice Bulletin No. 225: Medication Abortion Up to 70 Days of Gestation,* 136 Obstet. Gynecol. e31 (Oct. 2014) ("ACOG Practice Bulletin 225"). Sixty percent of abortions performed up to 10 weeks of pregnancy are medication abortions. *See* Jones et al., Guttmacher Inst., *Abortion Incidence and Service Availability in the United States, 2017*, at 8 (Sept. 2019).

[5] *See* Ind. Code §§ 16-34-2-1.1(a)(1), 16-34-2-1(a)(1), 25-1-9.5-8(a)(4).

[6] *Id.* § 16-34-2-1.1(a)(1); Short Appendix of Appellants ("SA") 57-58.

- The second-trimester hospitalization/ambulatory surgical center requirement, which requires that "after the first trimester of pregnancy" an abortion be "performed in a hospital or ambulatory outpatient surgical center" ("ASC").[7] Under Indiana law, hospitals and ASCs are subject to heightened construction and staffing requirements, including the requirement to maintain a sterile operating environment, which are typically required only for complex procedures and are not medically necessary for abortions.[8]

None of these provisions are necessary to protect patient safety. Telemedicine is a safe and effective way to provide counseling to abortion patients and to prescribe and administer medication abortion drugs. Additionally, both physicians and APCs are qualified to provide medication abortions, and allowing APCs to provide this care will increase access to abortions in Indiana. Finally, the medical evidence shows that second-trimester abortions can be and are safely performed in outpatient, office-based settings. Complications from abortions in

[7] Ind. Code § 16-34-2-1(a)(2).

[8] SA67, 112.

these settings are rare, rarely serious, and can be safely treated through transfer to a hospital or, more commonly, by patients following up on their own at a later time.

The ban on telemedicine in abortion care, the physician-only law, and the second-trimester hospitalization/ASC requirement all delay or prevent patients from accessing safe, legal abortion care. These barriers to access have serious, negative health consequences that are experienced most acutely by individuals with fewer economic resources, individuals of color, and young people.

States should not be permitted to enforce laws that restrict access to abortion when those laws are not medically necessary to protect patient safety. Because Indiana's telemedicine ban, physician-only law, and second-trimester hospitalization/ASC requirement restrict access to abortion care but offer no medical benefit to patients, amici urge this Court to affirm the district court's decision holding these provisions unconstitutional.

ARGUMENT

I. ABORTION IS A SAFE, COMMON, AND ESSENTIAL COMPONENT OF HEALTH CARE

Abortion is a common medical procedure. In 2017, over 860,000 abortions were performed nationwide.[9] Approximately one quarter of American women have an abortion before the age of 45.[10]

The overwhelming weight of medical evidence conclusively demonstrates that abortion is a very safe medical procedure, including medication abortion, aspiration abortion, and abortion through dilation and evacuation ("D&E").[11] Indeed, the vast majority of abortions are performed—safely—in a clinic or office-based setting,[12] without any need for hospitalization. Complication rates from abortion are extremely low, averaging around 2%, and most complications are minor and easily treatable without going to a hospital in an outpatient

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[9] Jones et al., Guttmacher Inst., at 7.

[10] Jones & Jerman, *Population Group Abortion Rates and Lifetime Incidence of Abortion: United States*, *2008-2014*, 107 Am. J. Pub. Health 1904, 1908 (2017).

[11] *See, e.g.*, Nat'l Acads. of Sci., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States* 10 (2018) ("NASEM Report") ("The clinical evidence clearly shows that legal abortions in the United States—whether by medication, aspiration, D&E, or induction—are safe and effective. Serious complications are rare.").

[12] Roberts et al., *Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions*, 319 J. Am. Med. Ass'n 2497, 2502 & tbl. 1 (2018); NASEM Report at 31.

setting.[13] Major complications from abortions are exceptionally rare, occurring in just 0.1 to 0.5% of instances across gestational ages and types of abortion methods.[14] The risk of death from an abortion is even lower: nationally, fewer than one in 100,000 patients die from an abortion-related complication.[15] In contrast, the "risk of death associated with childbirth [is] approximately 14 times higher."[16] In fact, abortion is so safe that there is a greater risk of complications or mortality for procedures like wisdom-tooth removal, cancer-screening colonoscopy, and cosmetic surgery.[17]

Moreover, access to abortions remains vital for pregnant patients' overall health and well-being. Unnecessary regulations that delay or

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[13] *See*, *e.g.*, Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstet. Gynecol. 175, 181 (2015); NASEM Report at 55, 60, 116; ACOG, *Abortion Care: Possible Risks and Side Effects* (July 2021).

[14] White et al., *Complications from First-Trimester Aspiration Abortion: A Systematic Review of the Literature*, 92 Contraception 422, 434 (2015).

[15] *See* Jatlaoui et al., *Abortion Surveillance—United States, 2015*, 67 Morbidity & Mortality Weekly Rep. 1, 45 tbl. 23 (2018) (finding mortality rate from 0.00052 to 0.00078% for approximately five-year periods from 1978 to 2014); Zane et al., *Abortion-Related Mortality in the United States, 1998-2010*, 126 Obstet. Gynecol. 258, 261-262 (2015) (noting an approximate 0.0007% mortality rate for abortion).

[16] Raymond & Grimes, *The Comparative Safety of Legal Induced Abortion and Childbirth in the United States*, 119 Obstet. Gynecol. 215, 216 (2012).

[17] ANSIRH, Issue Brief No. 6, *Safety of Abortion in the United States*, at 2 (Dec. 2014); Am. Soc'y for Gastrointestinal Endoscopy, *Complications of Colonoscopy*, 74 Gastrointestinal Endoscopy 745, 747 (Oct. 1, 2011); Grazer & de Jong, *Fatal Outcomes from Liposuction: Census Survey of Cosmetic Surgeons*, 105 Plastic & Reconstructive Surgery 436, 441 (2000).

prevent access to safe abortion care can seriously harm individuals' physical and mental health. Pregnant patients who are forced to continue an unwanted pregnancy to term face much greater risks of death than those who receive an abortion,[18] and continued pregnancy and childbirth entail other substantial health risks and potential complications that patients who can access abortions early in pregnancy can avoid.[19] Delaying or preventing access to abortion also increases the possibility that pregnant individuals may attempt self-managed abortions through harmful or unsafe methods,[20] such as through herbal or homeopathic remedies, intentional trauma to the abdomen, abusing

[18] *See* Raymond & Grimes, 119 Obstet. Gynecol. at 216; MacDorman et al., *Recent Increases in the U.S. Maternal Mortality Rate: Disentangling Trends from Measurement Issues*, 128 Obstet. Gynecol. 447 (2016) (finding a 26.6% increase in maternal mortality rates between 2000 and 2014).

[19] *See, e.g.*, ACOG, *Practice Bulletin No. 190: Gestational Diabetes Mellitus*, 131 Obstet. Gynecol. e49 (Feb. 2018); ACOG, *Practice Bulletin No. 222: Gestational Hypertension and Preeclampsia*, 135 Obstet. Gynecol. e237 (Dec. 2018). Labor and delivery also have significant risks, including hemorrhage, placenta accreta spectrum, hysterectomy, cervical laceration, and debilitating postpartum pain, among others. *See* ACOG, *Practice Bulletin No. 183: Postpartum Hemorrhage*, 130 Obstet. Gynecol. e168 (Oct. 2017); ACOG, *Obstetric Care Consensus: Placenta Accreta Spectrum*, 132 Obstet. Gynecol. e259 (July 2012, reaff'd 2021); ACOG, *Practice Bulletin No. 198: Prevention and Management of Obstetric Lacerations at Vaginal Delivery*, 132 Obstet. Gynecol. e87 (Sept. 2018); ACOG, *Clinical Consensus No. 1: Pharmacologic Stepwise Multimodal Approach for Postpartum Pain Management*, 138 Obstet. Gynecol. 507 (Sept. 2021).

[20] *See, e.g.,* Jones et al., Guttmacher Inst., at 3, 8. (noting a rise in patients who had attempted to self-manage an abortion, with highest proportions in the South and Midwest).

alcohol or illicit drugs, or misusing dangerous hormonal pills.[21] Finally, evidence shows that denying individuals a wanted abortion can have a detrimental impact on their mental health, including an increased likelihood of experiencing depression, anxiety, lower self-esteem, and lower life satisfaction.[22] Conversely, one recent study found that 95% of participants believed an abortion was the "right decision for them" three years after the procedure.[23] The medical community recognizes abortion as a safe and essential component of women's health care.[24]

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[21] Grossman et al., Tex. Pol'y Eval. Proj. Res., *Knowledge, Opinion and Experience Related to Abortion Self-Induction in Texas* 3 (Nov. 17, 2015).

[22] Biggs et al., *Women's Mental Health and Well-Being 5 Years After Receiving or Being Denied an Abortion: A Prospective, Longitudinal Cohort Study*, 74 JAMA Psychiatry 169, 172, 177 (2017); Biggs et al., *Does Abortion Reduce Self-Esteem and Life Satisfaction?*, 23 Quality of Life Research 2505 (2014).

[23] Rocca et al., *Decision Rightness and Emotional Responses to Abortion in the United States: A Longitudinal Study*, 10 PLoS ONE 1, 7 (2015).

[24] *See*, *e.g.*, Eds. of the *New Eng. J. of Med.* et al., *The Dangerous Threat to* Roe v. Wade, 381 New Eng. J. Med. 979, 979 (2019) (stating the position of the Editors of the New England Journal of Medicine, the American Board of Obstetrics and Gynecology, and several other key organizations in obstetrics, gynecology, and maternal-fetal medicine); ACOG, *Abortion Policy* (Nov. 2014, reaff'd Nov. 2020); Soc'y for Maternal-Fetal Med., *Access to Pregnancy Termination Services* (2017).

II. MEDICATION ABORTION CAN BE PERFORMED SAFELY THROUGH TELEMEDICINE AND INDIANA'S MEDICALLY UNNECESSARY BAN ON TELEMEDICINE IN ABORTION CARE HURTS PATIENTS

With three related statutes, Indiana has effectively banned the use of telemedicine in abortion care.[25] First, a patient seeking an abortion in Indiana must attend a pre-abortion counseling session "in the presence" of a medical provider, at least 18 hours in advance of the abortion procedure.[26] Second, if the patient is eligible and elects for a medication abortion, Indiana requires that prior to dispensing the medication, a physician examine the patient "in person," which expressly excludes "the use of telehealth or telemedicine services."[27] Finally, Indiana forbids clinicians from prescribing "an abortion inducing drug" via telemedicine.[28] None of those provisions are supported by the medical evidence on the safety and efficacy of telemedicine generally or specifically telemedicine in abortion services. The current Indiana scheme restricts access to safe abortion services,

[25] When this suit was filed, Indiana defined telemedicine as "the delivery of health care services using electronic communications and information technology, … including: (1) secure videoconferencing; (2) [interactive audio-using] store and forward technology; or (3) remote patient monitoring technology; between a provider in one (1) location and a patient in another location." Ind. Code § 25-1-9.5-6(a).

[26] *Id.* § 16-34-2-1.1(a)(4).

[27] *Id.* § 16-34-2-1(a)(1).

[28] *Id.* § 25-1-9.5-8(a)(4).

particularly to patients in vulnerable communities, with no corresponding medical benefit.

In the past decade, the use of telemedicine increased substantially. The American Medical Association ("AMA") called telemedicine "a key innovation in support of health care delivery reform [that] is being used in initiatives to improve access to care, care coordination and quality, as well as reduce the rate of growth in health care spending."[29] One study that analyzed over 29 billion private health care claim records found that the use of provider-to-patient telemedicine grew 1,393% from 2014 to 2018.[30]

In the past two years, the COVID-19 pandemic demonstrated the importance and potential of telemedicine for patient care. According to the AMA, telemedicine is "critical to the management of the COVID-19 pandemic" because it "ensures uninterrupted care for patients, including those with chronic conditions."[31] During the pandemic, the U.S. Department of Health and Human Services and the Drug

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[29] Am. Med. Ass'n, *Report 7 of the Council on Medical Service (A-14), Coverage of and Payment for Telemedicine* at 1 (2014).

[30] Fair Health, *A Multilayered Analysis of Telehealth,* FAIR Health White Paper 7 (July 2019).

[31] Am. Med. Ass'n, *AMA Telehealth Quick Guide* (Nov. 2, 2021).

Enforcement Administration revised their policies to allow clinicians more flexibility to serve patients, and even to prescribe controlled substances, through common communications technologies.[32] The AMA reported that "[m]ore than 90% of physicians connected remotely with at least some patients in 2020."[33] In the fields of obstetrics and gynecology, telemedicine "emerged as a primary method to reduce patient and physician exposure [to COVID-19], while ensuring delivery of needed health care."[34]

Despite the prevalence and safety of telemedicine, all abortion patients in Indiana are required to attend a pre-abortion counseling session in person, and patients seeking a medication abortion must first be physically examined by a physician. Additionally, there is an outright ban on prescribing "abortion-inducing drugs" via

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[32] ACOG, *COVID-19 FAQs for Obstetrician-Gynecologists, Telehealth*, https://www.acog.org/clinical-information/physician-faqs/covid-19-faqs-for-ob-gyns-telehealth (last visited Nov. 7, 2021); *see also* U.S. Dep't of Health & Hum. Servs., Off. for C.R., Press Release (Mar. 20, 2020).

[33] Robeznieks, *Dr. Madera: Pandemic Demands Nimble Response and AMA is Delivering* (Nov. 13, 2020).

[34] ACOG, *COVID-19 FAQs for Obstetrician-Gynecologists, Telehealth*, https://www.acog.org/clinical-information/physician-faqs/covid-19-faqs-for-ob-gyns-telehealth (last visited Nov. 7, 2021).

telemedicine.[35] Those restrictions are not supported by medical evidence.

First, abortion counseling can be provided effectively via telemedicine. A peer reviewed 2019 study from Utah found that patients who used telemedicine to attend a state mandated pre-abortion information session were "highly satisfied" and that "telemedicine aided in decreasing anticipated burdens associated with the cost, travel, and social consequences [of seeking an abortion]."[36] Clinicians can also screen for risk factors, such as intimate-partner violence, effectively through telemedicine, as two experts testified at trial.[37] Second, research shows that telemedicine is a safe method for administering medication abortions and that an in-person physical examination is unnecessary in this context. ACOG's most recent practice bulletin addressing medication abortion recommends that "[m]edication abortion can be provided safely and effectively by telemedicine with a

[35] Aspiration or "dilation and curettage" abortion procedures must be performed in person.

[36] Ehrenreich et al., *Women's Experiences Using Telemedicine to Attend Abortion Information Visits in Utah: A Qualitative Study*, 29 Women's Health Issues 407, 412 (April 2019).

[37] *See* SA47-48.

high level of patient satisfaction."[38] That recommendation is based on studies that found medication abortion through telemedicine is as effective as medication abortion administered through an in-person visit.[39] An analysis of nearly 20,000 medication abortions showed that "adverse events were rare (0.3% overall) and did not differ between those who chose telemedicine or in-person services."[40] In 2018, an expert panel convened by the National Academies of Science, Engineering and Medicine concluded that the "risks of medication abortion are similar in magnitude" to those of commonly prescribed antibiotics and over-the-counter medications such as aspirin and ibuprofen.[41] That report found further that "telemedicine provision of medication abortion was not associated with a significantly higher prevalence of adverse events" than in-person provision.[42] This research shows that Indiana's telemedicine ban for abortion care does not enhance patient safety.

[38] ACOG Practice Bulletin 225 at e40.

[39] *Id.* at e35.

[40] *Id.*

[41] NASEM Report at 79.

[42] *Id.* at 57-58.

Moreover, the ban on telemedicine imposes significant burdens on patients and decreases access to abortion care. Because of the in-person counseling requirement, individuals seeking abortions must make two separate trips, at least 18 hours apart, first to obtain pre-abortion counseling and then for the abortion procedure—the administration of a pill, in the case of patients seeking a medication abortion.[43] The two-trip requirement's cost in time and money is exacerbated by the fact that only seven abortion clinics operate in the state, each with irregular hours.[44] No abortion clinics operate east of Indianapolis or south of Bloomington, meaning that patients in Indiana's second and third largest cities must travel 250 miles round trip to obtain abortion care in the state.[45] Those burdens fall more heavily on patients with limited financial resources, who are less likely to have flexible work

[43] As of November 2021, the U.S. Food and Drug Administration ("FDA"), via a "risk evaluation and mitigation strategy" ("REMS"), requires mifepristone "only be dispensed in clinics, medical offices, and hospitals by or under the supervision of a certified healthcare provider." *See* FDA, *Mifeprex (mifepristone) Information* (Apr. 13, 2021). However, given the weight of the scientific evidence against the REMS, the FDA announced that it intended "to exercise enforcement discretion … with respect to the in-person dispensing requirement" during the COVID-19 pandemic. Letter from Janet Woodcock, Acting Comm'r of Food & Drugs, FDA, to Drs. Maureen Phipps & William Grobman (Apr. 12, 2021). ACOG continues to advocate for permanently removing the in-person dispensing requirement from the REMS. *See* ACOG, *Improving Access to Mifepristone for Reproductive Health Indications* (June 2018).

[44] *See* SA50-51.

[45] *See* SA23, 65, 118.

schedules[46]; on Black and Hispanic patients, who missed or delayed sexual or reproductive health care at a rate higher than white patients during the COVID-19 pandemic[47]; and on rural patients, who face more significant travel barriers. Telemedicine provides greater access to abortion services for all patients, but especially those in vulnerable communities. For example, after the introduction of telemedicine in Iowa, "a significant reduction in second-trimester abortion was reported, and patients in remote parts of the state were more likely to obtain a medication abortion."[48] Moreover, the lack of abortion services in Indiana is largely attributed to the unavailability of physicians, which would be addressed squarely by allowing physicians and other abortion clinicians to use technology to provide services throughout the state.[49]

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[46] *See* Schneider & Harknett, *Hard Times: Routine Schedule Unpredictability and Material Hardship Among Service Sector Workers* (Washington Center for Equitable Grown, Working Paper, Oct. 2019).

[47] CDC, Morbidity and Mortality Weekly Report, *Delay or Avoidance of Medical Care Because of COVID-19-Related Concerns-United States, June 2020* (Sept. 11, 2020).

[48] ACOG Practice Bulletin 225 at e35; *see also* Grossman et al., *Changes in Service Delivery Patterns After Introduction of Telemedicine Provision of Medical Abortion in Iowa*, 103 Am. J. Public Health 73 (Jan. 2013).

[49] *See* SA29, 105.

Indiana's requirements that patients seeking abortions attend a counseling session in person, that patients seeking medication abortions receive a physical examination by a physician in person, as well as its outright ban on telemedicine for prescribing "abortion-inducing drugs," are medically unnecessary and impose significant burdens on patients, particularly those from vulnerable communities.

III. APCs Are Qualified to Provide Medication Abortions and the Physician-Only Law Limits Access to Abortions

Indiana's physician-only law, which restricts APCs from providing medication abortions in the first trimester, is also medically unnecessary. The law limits access to abortions in the state and in particular harms patients without ample financial resources, who have a harder time scheduling an appointment due to difficulty finding transportation, childcare, and time off of work. Ensuring access to medication abortion is an important part of providing quality and safe health care.

There is consensus among health care clinicians that to provide medication abortion, the clinician must have the skills necessary to screen patients for medication eligibility, be able to provide appropriate follow-up care after the patient takes the medication, and be trained to

perform uterine evacuation procedures or be able to refer to a clinician who has this training.[50] The district court correctly found that APCs, like certified nurse-midwives, physician assistants, and nurse practitioners, are qualified to meet these requirements.[51] In addition to ACOG, the World Health Organization and the American Public Health Association also support APCs providing abortion care.[52] The NASEM report, which the district court noted is the "authoritative source on abortion care standards/procedures in the United States," also concludes that APCs can safely provide medication abortions.[53] The district court also found that the published medical literature and expert testimony of an ACOG member, Dr. Grossman, a clinical and social science researcher whose research focuses on access to contraception and safe abortion and who works with APCs, confirmed that APCs are qualified to and do in fact provide medical abortions "as safely and effectively as physicians."[54] Numerous medical studies

[50] ACOG Practice Bulletin 225 at e34.

[51] SA107-108; *see also* ACOG Practice Bulletin 225 at e34.

[52] World Health Org., *Health Worker Roles in Providing Safe Abortion Care and Post-Abortion Contraception* 37 (2015); Am. Pub. Health Ass'n, *Provision of Abortion Care by Advanced Practice Nurses and Physician Assistants* (Nov. 1, 2011).

[53] NASEM Report at 119; SA59.

[54] SA58-59 (discussing several studies).

support that conclusion. For example, randomized trials in Mexico, Nepal, and Sweden have found that patients randomized to have a nurse or nurse-midwife provide medication abortion had a statistically equivalent risk of complete abortion versus those who received the medication from a physician, and without any increased risk for adverse events.[55]

The FDA's actions further support the ability of APCs to provide medication abortion. As the district court discussed, in 2016 the FDA amended the Mifeprex (the brand name for mifepristone) label to remove the requirement that the drug be administered by physicians, replacing it with the more general term, "healthcare provider."[56] To dispense Mifeprex, clinicians must be able to date pregnancies accurately, diagnose ectopic pregnancies, provide necessary surgical intervention or make arrangements with others to provide that care, ensure patients have access to medical facilities for emergency care, and perform other responsibilities like signing the patient agreement form—all tasks APCs can perform.[57]

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[55] *See* ACOG Practice Bulletin 225 at e34.

[56] SA57-58; NASEM Report at 101.

[57] FDA, *Questions and Answers on Mifeprex* (Apr. 13, 2021).

Indiana's limitation on who can prescribe medication abortion also singles it out from other similar medical procedures that APCs currently conduct. For example, as the district court found, Indiana University Health allows APCs to provide miscarriage management care through the use of the same drugs required for medication abortion—mifepristone and misoprostol.[58] The use of these drugs in the miscarriage context has comparable risks to their use in the abortion context, as Dr. Grossman testified at trial.[59] And as the district court pointed out, the State's own experts did not dispute that APCs can prescribe medications involving comparable or greater risks than abortion-inducing drugs, like birth control and opioids.[60] In addition, APCs can conduct other gynecological procedures that are comparable, and sometimes riskier, than abortions in the first trimester.[61]

The district court correctly found that preventing APCs from providing medication abortion will also restrict access to abortion in

[58] SA60-61, 100-101.

[59] SA60.

[60] SA60, 101-102.

[61] SA60-61.

Indiana.[62] There is currently a shortage of abortion clinicians, which in Indiana has resulted in clinics only being able to schedule abortion appointments for one to two days per week, leaving many patients to wait weeks for an appointment.[63] This delay can make it harder to obtain an abortion in the first trimester, thus restricting patients' access to medication abortions.[64] This is especially true for low-income women, who have less flexibility in work schedules and childcare and who, as the district court noted, are the primary group seeking abortions in Indiana.[65] And restricting access to first-trimester abortions forces more patients to seek abortions in their second trimester, procedures which are more invasive, more costly, and even more difficult to obtain due to Indiana's hospitalization/ASC requirement, as discussed below. Many facilities that provide abortions already employ APCs who could perform medication abortions if they were allowed to do so.[66] As the district court found, the physician-only

[62] SA105-107.

[63] SA105.

[64] Grossman et al., 103 Am. J. Public Health at 73-78.

[65] SA105.

[66] SA65-66.

law "places concrete and significant burdens" on those seeking medication abortions in Indiana because there are abortion clinics in the state that would expand their abortion services to five days a week if this law were not in place.[67] Moreover, APCs are less expensive than physicians and thus the physician-only law prevents patients from obtaining more affordable care, which further limits access particularly for those who have limited financial resources.[68]

IV. A HOSPITALIZATION/ASC REQUIREMENT IS MEDICALLY UNNECESSARY BECAUSE SECOND-TRIMESTER ABORTIONS PERFORMED IN OUTPATIENT, OFFICE-BASED SETTINGS ARE EXCEEDINGLY SAFE

Indiana's hospitalization/ASC requirement for second-trimester abortions reduces access to and increases the costs of obtaining those abortions without any medical benefit to the patient. The vast majority of second-trimester abortions are performed by D&E,[69] which is an extremely safe and effective procedure. This technique usually requires cervical dilation before the procedure and a combination of suction and

[67] SA106.

[68] SA107.

[69] ACOG, *Practice Bulletin No. 135: Second Trimester Abortion* 1 (June 2013, reaff'd 2017) ("ACOG Practice Bulletin 135"); *see also* SA67.

forceps to remove the fetus.[70] Complications arising from this procedure are rare and rarely serious.[71] Very few abortions are followed by an emergency department visit because, in the rare cases where complications do arise, patients can typically be treated by follow-up procedures at a clinic and/or with antibiotics.[72] Moreover, the very low mortality rates for second-trimester abortions, 6.7 per 100,000 procedures after 17 weeks' gestation,[73] and 8.9 per 100,000 procedures at 21 weeks' gestation or later,[74] further evidences the lack of medical benefit of Indiana's hospitalization/ASC requirement.

Because of the general safety of abortions and the rare need for hospitalization, the vast majority of abortions, including second-trimester abortions, are performed in a clinic or office-based setting.[75] Indeed, the district court here found that "the uncontroverted evidence

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[70] ACOG Practice Bulletin 135 at 2.

[71] *Id.* at 4-5 (finding that hemorrhage requiring blood transfusion occured in only 0.1-0.6% of D&E procedures, retained tissue or incomplete abortion reported in less than 1% of D&E procedures, uterine atony occurred in 2.6% of D&E procedures, cervical lacerations occurred in up to 3.3% of second-trimester abortions, and uterine perforation reported in 0.2-0.5% of second trimester surgical abortions).

[72] Upadhyay et al., 125 Obstet. Gynecol. at 180 tbl. 4; ACOG, *Abortion Care: Possible Risks and Side Effects* (June 2021); NASEM Report at 116.

[73] NASEM Report at 75.

[74] ACOG Practice Bulletin 135 at 4.

[75] Roberts et al., 319 J. Am. Med. Ass'n at 2502 & tbl. 1; *see also* NASEM Report at 31.

… leads easily to the conclusion that there are no benefits which flow to the State from mandating that second-trimester abortions be performed in spaces that satisfy the[] heightened structural requirements" of hospitals and ASCs because D&Es "do not necessitate a sterile operating room, given that th[ey] do not require making of incisions into sterile tissue," "[n]or do [they] require the use of general anesthesia."[76] Moreover, the district court found that "[t]he State also has not refuted Plaintiffs' evidence … that complications associated with D&E abortions are extremely rare, and that this procedure can be and is elsewhere (outside of Indiana) safely performed in out-patient, office-based settings, including in Ohio … , in California … , in Illinois … , and numerous other states where Planned Parenthoods and [Whole Woman's Health Alliance] operate."[77] The district court also found that "[t]he State does not contest that the conclusions advanced in th[e] [medical] literature hold that there is no evidence showing that second-trimester abortions are any safer when they are performed in an ASC as compared to an outpatient, office-based setting."[78] These factual

[76] SA112; *see also Whole Woman's Health*, 136 S. Ct. at 2315-2316.

[77] SA113.

[78] *Id.*

findings are well-supported by the medical evidence in the record[79] and this Court should defer to them.

Furthermore, Indiana allows other types of procedures of similar complexity and with similar or greater risk to be performed in non-hospital settings. For example, D&Es in the context of miscarriage management and operative hysteroscopies are provided in office-based settings, both of which involve dilation of the cervix and insertion of instruments to remove material or growths from the uterus.[80] The mortality rates for colonoscopies and liposuction, both often done in an outpatient setting, are higher than the national mortality rate for abortion.[81] Moreover, the complication rates for abortion and colonoscopy are similar, and having one's wisdom teeth removed carries

[79] *See, e.g.*, Levy et al., *Consensus Guidelines for Facilities Performing Outpatient Procedures: Evidence Over Ideology*, 133 Obstet. Gynecol. 255, 260 (2019) ("Requiring facilities that perform office-based procedures, including abortion, to meet standards beyond those currently in effect for all general medical offices and clinics is unjustified based on this thorough review and analysis of available evidence; safety concerns were not identified in any area of study."); Roberts et al., 319 J. Am. Med. Ass'n at 2502-2503, 2503 tbl. 2 (finding no significant difference between ASCs and office-based settings in abortion-related adverse events for second-trimester abortions).

[80] SA70.

[81] Am. Soc'y for Gastrointestinal Endoscopy, 74 Gastrointestinal Endoscopy at 747; Grazer & de Jong, 105 Plastic & Reconstructive Surgery at 441; *see also* NASEM Report at 31; *Whole Woman's Health*, 136 S. Ct. at 2315.

a higher risk of complications than having an abortion.[82] That these other types of procedures can be safely performed in outpatient, office-based settings further undermines Indiana's purported medical justification for the hospitalization/ASC requirement for abortion procedures.

Even where complications arise after a second-trimester abortion, a hospitalization/ASC requirement is unlikely to make a difference with respect to a patient's safety. That is because of the small number of patients who experience complications and seek hospital care following an abortion, most do so the day after the procedure or later—not at the time the abortion is performed.[83] When emergency department visits after an abortion do occur, they are rarely for a major incident.[84]

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[82] ANSIRH, Issue Brief No. 6, *Safety of Abortion in the United States*, at 2 (Dec. 2014).

[83] Upadhyay et al., *Distance Traveled for an Abortion and Source of Care After Abortion*, 130 Obstet. Gynecol. 616, 619 (2017) (finding that of participants who sought care at an emergency department following an abortion, 88% sought care the day after the abortion or later); *see also* Upadhyay et al., 125 Obstet. Gynecol. at 180-181 (finding that only 1 in 5,491 (0.03%) abortions led to transfer by ambulance to an emergency department for immediate care, while about 343 in 5,491 abortions were followed by an emergency department visit in the six weeks following an abortion); Upadhyay et al., *Admitting Privileges and Hospital-Based Care After Presenting for Abortion: A Retrospective Case Series*, 54 Health Servs. Research 425, 434 (2019); *Whole Woman's Health*, 136 S. Ct. at 2311.

[84] Upadhyay et al., *Abortion-Related Emergency Department Visits in the United States: An Analysis of a National Emergency Department Sample*, 16 BMC Med. 1, 5-7 (2018) (finding that only 0.11% of abortions were followed by an emergency department visit for a major incident, defined as an incident requiring blood transfusion, surgery, or overnight inpatient

As for ASCs, their response to a complication from a second-trimester abortion is exactly the same as that for a clinic, which is to transfer the patient immediately to a hospital for further care.[85] The district court found there was "no dispute that a patient could be transported and referred for such hospital-based care just as safely from an out-patient clinic as she could from an ASC."[86] Federal law requires that hospital emergency departments must treat and stabilize all emergency patients.[87] Accepted medical practice requires a clinic to have a plan to provide access to prompt emergency services and (if needed) to transfer a patient to a nearby emergency facility if complications occur.[88] This practice ensures that the rare patient who experiences an abortion-related complication requiring hospital care can be treated appropriately by a trained emergency-room clinician or

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stay, and that about half of abortion-related emergency department visits resulted in only observational care and no other treatment); *see also* Upadhyay et al., 125 Obstet. Gynecol. at 180-181 (finding that only about 40% of emergency department visits following an abortion were abortion-related, and that of that 40%, two-thirds did not require a diagnosis or treatment).

[85] SA69, 114; *see also Whole Woman's Health*, 136 S. Ct. at 2316.

[86] SA114.

[87] 42 U.S.C. § 1395dd.

[88] ACOG, *Guidelines for Women's Health Care: A Resource Manual* 720 (4th ed. 2014); ACOG, Comm. on Patient Safety & Quality Improvement, *Committee Opinion Number 590: Preparing for Clinical Emergencies in Obstetrics and Gynecology*, 123 Obstet. Gynecol. 722, 722 (Mar. 2014, reaff'd 2018); NASEM Report at 14, 71-72.

the hospital's on-call specialist.[89] There is simply no evidence-based medical justification for a second-trimester hospitalization/ASC requirement.

That requirement also imposes substantial barriers to access for patients seeking second-trimester abortions. Because no ASCs currently perform such abortions and only five hospitals in or near Indianapolis perform such abortions—and even then only where there is a fetal or maternal indication—most patients are effectively foreclosed from getting a second-trimester abortion in Indiana and are forced to travel outside the state for that care.[90] This requires individuals—many of whom are low-income and already have children[91]—to find transportation and overnight lodging, to travel longer distances for care,[92] to take substantial time off from work, and/or to secure adequate

[89] *See* White et al., 92 Contraception at 435.

[90] SA74-75, 115-116.

[91] Jerman et al., Guttmacher Inst., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008,* at 7 (May 2016).

[92] Increased travel costs are among the burdens the Supreme Court concluded imposed substantial obstacles to patients seeking abortions in *June Medical Services* and *Whole Woman's Health*. *See June Med. Servs.*, 140 S. Ct. at 2130; *Whole Woman's Health*, 136 S. Ct. at 2313, 2318.

child care for multiple days.[93] These additional costs and delayed access can be prohibitive. Even for patients who can access a second-trimester abortion within Indiana, the cost of a hospital-provided abortion is significant—up to $20,000—and significantly greater than the cost for the same type of abortion provided by a clinic—between $800 and $2,400.[94] Moreover, patients with access to second-trimester abortion care cannot typically rely on health insurance to offset any of these costs as health insurance usually does not cover the costs of abortion care.[95]

These numerous burdens fall disproportionately on individuals with limited financial resources, individuals of color, and young patients, who are more likely than others to experience unintended pregnancies[96] and to seek abortion care.[97] Individuals of color and

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[93] SA75, 115; *see also* Barr-Walker et al., *Experiences of Women who Travel for Abortion: A Mixed Methods Systematic Review* 18 (Apr. 9, 2019); Upadhyay et al., *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, 104 Am. J. Pub. Health 1687, 1689, 1692 (2014); NASEM Report at 165.

[94] SA75, 115.

[95] *Id.*

[96] Parks & Peipert, *Eliminating Health Disparities in Unintended Pregnancy with Long-Acting Reversible Contraception (LARC)*, 214 Am. J. Obstet. Gynecol. 681, 681-682 & n.2 (2016) (citing Finer & Zolna, *Unintended Pregnancy in the United States: Incidence and Disparities, 2006*, 84 Contraception 478 (Aug. 25, 2011)); *see also* Morse et al., *Reassessing Unintended Pregnancy: Toward a Patient-Centered Approach to Family Planning*, 44 Obstet. Gynecol. Clinics 27, 27 (2017).

[97] NASEM Report at 29-31.

individuals living at or below the poverty line are also more likely to experience complications or deaths in attempting to carry a pregnancy to term.[98]

It is prohibitively expensive for clinics providing abortions in Indiana to retrofit existing facilities to comply with ASC regulations—which can cost more than $2 million for clinics that primarily serve individuals with limited financial resources—and several of these clinics would provide second-trimester abortions if they were legally allowed to do so.[99] Indiana's medically unnecessary hospitalization/ASC restriction should be removed to increase Indiana patients' access to safe and timely abortion care.

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[98] Petersen et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths — United States, 2007–2016*, 68 Morbidity & Mortality Weekly Rep. 762, 762 (2019); CDC, *Pregnancy Mortality Surveillance System*, https://bit.ly/2K7Ans3 (last visited Nov. 2, 2021); Singh, U.S. Dep't of Health & Hum. Servs., *Maternal Mortality in the United States, 1935-2007: Substantial Racial/Ethnic, Socioeconomic, and Geographic Disparities Persist* 1-2 & fig. 2 (2010); ACOG, Comm. on Health Care for Underserved Women, *Committee Opinion No. 649: Racial and Ethnic Disparities in Obstetrics and Gynecology*, 126 Obstet. Gynecol. e130, e131 & tbl. 1 (Dec. 2015).

[99] SA72, 116.

CONCLUSION

For the foregoing reasons, the judgment of the district court with respect to the telemedicine ban, physician-only law, and second-trimester hospitalization/ASC requirement should be affirmed.

Dated: November 8, 2021

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CERTIFICATE OF COMPLIANCE

Pursuant to Fed. R. App. P. 29 and 32, the undersigned hereby certifies that this brief complies with the type-volume limitation of Fed. R. App. P. 29(b)(4) and Cir. R. 29.

1. Exclusive of the exempted portions of the brief, as provided in Fed. R. App. P. 29(b)(4) and 32(f), the brief contains 6641 words.

2. The brief has been prepared in proportionally spaced typeface using Microsoft Word 2016 in 14 point Century Schoolbook font. As permitted by Fed. R. App. P. 32(g)(1), the undersigned has relied upon the word count feature of this word processing system in preparing this certificate.

/s/ Kimberly A. Parker
KIMBERLY A. PARKER

November 8, 2021

CERTIFICATE OF SERVICE

I hereby certify that on November 8, 2021, I caused the foregoing to be filed through the Court's CM/ECF system, which caused it to be served on all counsel of record.

/s/ Kimberly A. Parker
KIMBERLY A. PARKER