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**MONTANA THIRTEENTH JUDICIAL DISTRICT COURT,
YELLOWSTONE COUNTY**

PLANNED PARENTHOOD OF MONTANA, and JOEY BANKS, M.D., on behalf of themselves and their patients, Plaintiffs, vs. STATE OF MONTANA, by and through Austin Knudsen, in his official capacity as Attorney General, Defendant.	Cause No. DV21-00999 Judge: Jessica T. Fehr **AFFIDAVIT OF COLLEEN P. McNICHOLAS, DO, MSCI, FACOG**

STATE OF MISSOURI)
: ss.
County of St. Louis)

I, Colleen P. McNicholas, DO, MSCI, FACOG, being first duly sworn upon her oath, state as follows:

1. I submit this affidavit at the request of counsel for Plaintiffs Planned Parenthood of Montana ("PPMT") and Dr. Joey Banks, M.D. to provide my expert opinions relating to Montana House Bills 136 ("HB 136"), 140 ("HB 140"), and 171 ("HB 171").

Professional Qualifications and Experience

2. I am a board-certified obstetrician-gynecologist ("OB/GYN") licensed to practice medicine in Missouri (as well as Illinois and Oklahoma). On July 1, 2019, I became the Chief Medical Officer of Planned Parenthood of the St. Louis Region and Southwest Missouri ("PPSLR") and Reproductive Health Services of Planned Parenthood of the St. Louis Region ("RHS"). In this capacity, I oversee clinical operations, including the provision of care, implementation of policy, and quality improvement. I am also an Attending Physician at Barnes-Jewish Hospital in St. Louis, Missouri, and Memorial Hospital in Bellevue, Illinois, and I am Volunteer Clinical Faculty at Washington University School of Medicine, Department of Obstetrics and Gynecology.

3. Before I became Chief Medical Officer, I was an Associate Professor in the Department of Obstetrics and Gynecology, Division of Family Planning and the Director of the Ryan Residency Training Program at the Washington University School of Medicine. I was also Co-Director of the Fellowship in Family Planning and a member of the Obstetrics and Gynecology Performance Evaluation Committee at Washington University School of Medicine. In my role as Associate Professor, I provided family planning services, including abortion care, at Washington University; its affiliated teaching hospital, Barnes-Jewish Hospital; and RHS. In my current role, I continue to provide comprehensive sexual and reproductive health care, including abortion care.

4. I earned a B.S. in forensic chemistry from Benedictine University in 2003 and a doctorate in osteopathic medicine from Kirksville College of Osteopathic Medicine in 2007. I completed a residency in obstetrics and gynecology at Washington University School of Medicine in 2011, and a two-year fellowship in family planning and a Masters of Science in clinical

investigation from Washington University in 2013. I became board-certified in obstetrics and gynecology in 2014.

5. I am a Fellow of the American College of Obstetricians and Gynecologists ("ACOG"), where I have served on the Committee on Health Care for Underserved Women. I am also the current secretary/treasurer of the Missouri Section of ACOG. I am a Fellow of the Society of Family Planning ("SFP").

6. I have published nearly 30 articles in peer-reviewed journals, as well as several book chapters. I am a reviewer for the following peer-reviewed journals: *Contraception*, *Journal of Family Planning and Reproductive Health Care*, *American Journal of Obstetrics and Gynecology*, *European Journal of Obstetrics and Gynecology and Reproductive Biology*, and *Obstetrics and Gynecology*.

7. I attach a current version of my curriculum vitae to this report as Exhibit A.

8. The opinions in this report are based on my education, clinical training, experience as a practicing physician, regular review of other medical research in my field, and regular attendance and presentation at professional conferences, including conferences for abortion providers. The literature considered in forming my opinions includes, but is not limited to, the sources cited in this report.

The Challenged Laws

9. I have reviewed HB 136, HB 140, and HB 171. I understand that HB 136 bans abortion beginning at 20 weeks measured from the first day of a patient's last menstrual period ("LMP"), with very narrow exceptions. I understand that HB 140 requires abortion providers to offer patients the opportunity to view "an ultrasound image" and "active ultrasound," and to "listen to the fetal heart tone of the unborn child, if audible," except where the abortion is performed with the intent to save the patient's life, ameliorate a serious risk of bodily harm, or remove an ectopic pregnancy. And I understand that HB 171 imposes numerous restrictions on medication abortion, including: a 24-hour mandatory delay; a multi-trip requirement; a ban on providing medication abortion through telemedicine; an effective ban on very early abortions; "informed consent" requirements that mandate the provision of inaccurate information regarding complications and so-called medication abortion "reversal"; a requirement that providers have contracts with back-

up physicians; and reporting requirements that make public the names of providers and threaten to reveal patient identities.

10. As I explain in more detail below, it is my opinion that none of these bills will serve the public health, and that they serve only to harm patient health by making abortion more difficult to access and in some cases putting it entirely out of reach.

Abortion Reasons, Methods & Safety

11. A patient's reasons for terminating a pregnancy depend on their own complex personal, medical, financial, and/or family circumstances. These are closely tied to each patient's values, culture and religion, health and reproductive history, family situation and support system, educational or career goals, and resources and financial stability.

12. Many patients seeking abortion are already parenting and after careful consideration of their lived reality, decide that expanding their family at that time is not in their or their family's best interest. Indeed, a majority of patients having abortions in the United States have already had at least one birth.[1] The strain of trying to adequately provide for their existing children—both materially and emotionally—is all the more apparent if one considers that approximately 75% of abortion patients nationwide are poor or low-income.[2]

13. Some people seeking abortion care are young and feel they are not ready to become a parent, and others are pursuing school or work opportunities. Some patients have health conditions that are complicated by pregnancy or have been diagnosed with health conditions that cannot be safely treated during pregnancy. Some patients are struggling with addiction and do not wish to carry a pregnancy under those circumstances. Some patients lack the necessary financial resources or partner or familial support or stability to become a parent. Others are in abusive relationships or are pregnant as a result of rape or sexual assault, and are concerned that carrying to term will tether them to their abuser. Each decision is valid in its own right.

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[1] *See* Jenna Jerman, Rachel K. Jones & Tsuyoshi Onda, Guttmacher Inst., *Characteristics of U.S. Abortion Patients in 2014 and Changes Since 2008*, at 6–7 (2016), https://www.guttmacher.org/sites/default/files/report_pdf/characteristics-us-abortion-patients-2014.pdf; *see also* Guttmacher Inst., *Induced Abortion in the United States* 1 (2019), https://www.guttmacher.org/sites/default/files/factsheet/fb_induced_abortion.pdf.

[2] Guttmacher Inst., *supra* note 1, at 1.

14. There are two main methods of abortion: medication abortion and procedural abortion. Medication abortions, which are provided in the first trimester, most commonly involve the administration of two types of medications (mifepristone and misoprostol) to cause passage of the pregnancy tissue in a manner similar to a miscarriage. Medication abortion requires no anesthesia or sedation; the patient simply takes the pills. Medication abortion is extremely safe.[3]

15. Procedural abortions, which are provided in both the first and second trimesters, are performed by dilating (opening) the uterine cervix and then using gentle suction and/or instruments to empty the contents of the uterus. Despite sometimes being referred to as "surgical abortions," these procedures are not surgical in the usual sense: they do not involve any incision into the patient's skin and in many cases can be performed with only local anesthesia.

16. A full-term pregnancy lasts approximately 40 weeks. I understand that PPMT provides medication abortion to 77 days (11 weeks) LMP, and procedural abortion to 21 weeks and 6 days LMP. While the FDA label for mifepristone describes use of medication abortion to 70 days LMP,[4] it is evidence-based and standard-of-care practice to use medication abortion through 77 days LMP.[5]

17. For some patients, medication abortion offers important advantages over procedural abortion. Many patients prefer medication abortion because they can complete the process in the privacy of their homes and at a time of their choosing. Some patients choose medication abortion because they fear a procedure involving instrumentation. Patients with a trauma history and survivors of rape or abuse may choose medication abortion to feel more in control of the experience and to avoid further trauma from having instruments placed in their

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[3] Nat'l Acads. of Scis., Eng'g, & Med., *The Safety and Quality of Abortion Care in the United States* 79 (2018) [hereinafter "Nat'l Acads."] (finding that "[t]he risks of medication abortion are similar in magnitude to the risks of taking commonly prescribed and over-the-counter medications such as antibiotics and NSAIDs [nonsteroidal anti-inflammatory drugs]," such as ibuprofen).

[4] MIFEPREX (Mifepristone) Tablets Label, FDA, https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf (2016).

[5] Ilana G. Dzuba et al., *A Repeat Dose of Misoprostol 800 mcg Following Mifepristone for Outpatient Medical Abortion at 64–70 and 71–77 Days of Gestation: A Retrospective Chart Review*, 102 Contraception 104 (2020); Ilana G. Dzuba et al., *A Non-Inferiority Study of Outpatient Mifepristone-Misoprostol Medical Abortion at 64–70 days and 71–77 Days of Gestation*, 101 Contraception 302 (2020).

vagina. Other patients have medical conditions that make medication abortion a safer option. In my experience, also documented in research studies, most people who choose a medication abortion have a strong preference for this method.[6]

18. Regardless of the method of abortion used, abortion is safe and effective, and is safer than continuing a pregnancy through to childbirth. Recently, the National Academies of Sciences, Engineering, and Medicine—a body of esteemed experts that was established by Congress to provide independent, objective expert analysis and advice to the nation to inform public policy and "focused on finding reliable, scientific information"—conducted an analysis of the full range of abortion care in the United States and concluded that abortion continues to be one of safest, most common medical procedures performed in the nation.[7] As the National Academies summarizes: "Today, the available scientific evidence on abortion's health effects is quite robust,"[8] and "[t]he extensive body of research documenting the safety of abortion care in the United States reflects the outcomes of abortions provided by thousands of individual clinicians."[9]

19. The National Academies also concluded that regulations like those at issue here—including mandatory delays, mandates for clinically unnecessary services, prohibitions on qualified clinicians providing abortion, and requirements that informed consent include inaccurate information—all "may limit the number of available providers, misinform women of the risks of the procedures they are considering, overrule women's and clinician's medical decision making, or require medically unnecessary services and delays in care," thus increasing the risks of abortion without any medical benefit.[10]

20. Both medication and procedural abortion carry a low risk of complications and a very low risk that hospitalization is necessary to treat a complication.[11] As the National Academies explain, "[s]erious complications are rare; in the vast majority of studies, they occur in fewer than

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[6] Daniel Grossman et al., *Effectiveness and Acceptability of Medical Abortion Provided Through Telemedicine*, 118 Obstetrics & Gynecology 296, 300 (2011).

[7] Nat'l Acads. 37 & 77–78; *see also id.* at 162–63.

[8] *Id.* at 17.

[9] *Id.* at 14.

[10] *Id.* at 11.

[11] Ushma Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 175 (2015).

1 percent of abortions."[12] Studies have estimated that the risk of death associated with childbirth nationwide is approximately 14 times higher than that associated with abortion,[13] and every pregnancy-related complication is more common among people giving birth than among those having abortions.

21. In addition to being extremely safe, abortion is also extremely common: nearly one in four women in the United States will have an abortion by age 45.[14]

Abortion Access & Harms of Delay

22. Abortion is a time-sensitive, essential health service. ACOG and other leading medical organizations recently stressed in a joint statement that abortion "is an essential component of comprehensive health care" and "a time-sensitive service for which a delay of several weeks, or in some cases days, may increase the risks [to patients] or potentially make it completely inaccessible."[15]

23. Patients generally seek abortion as early in their pregnancy as they are able to. Nevertheless, in practice, there are many daunting economic and logistical challenges that can cause delay.

24. Some patients cannot afford to take multiple days off work in close proximity, as doing so will risk jeopardizing their jobs. Some patients cannot afford to arrange childcare for multiple days in close proximity without revealing to family or caregivers the reason for their need, thus compromising the confidentiality of their decision to obtain an abortion. Patients who seek abortion care after surviving rape, incest, or other violent abuse may be delayed in seeking care while they deal with associated trauma.

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[12] Nat'l Acads. 77–78.

[13] 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).

[14] *See* Rachel K. Jones & Jenna Jerman, *Population Group Abortion Rates and Lifetime Incidence of Abortion: United States, 2008–2014*, 107 Am. J. Pub. Health 1904, 1907 (2017).

[15] ACOG, Joint Statement on Abortion Access During the COVID-19 Outbreak (Mar. 18, 2020), https://www.acog.org/news/news-releases/2020/03/joint-statement-on-abortion-access-during-the-covid-19-outbreak.

25. Finding the money to pay for the procedure, arranging and paying for childcare, arranging and paying for travel, and securing time off work to travel to and attend appointments often cause additional delay. These barriers are especially problematic for patients living in or near poverty, who often need time to figure out how to pay for abortion care, as well as to cover the cost of traveling to obtain that care. They need to figure out arrangements for transportation, arrangements for time off work, and possibly arrangements for childcare during appointments.

26. As of 2017, 89% of U.S. counties lacked an abortion clinic with 38% of women of reproductive age living in said counties.[16] I understand from Plaintiffs' counsel that these figures are even starker in Montana. In these medically isolated communities, if telemedicine is unavailable, patients must go without care or else travel hundreds of miles for high-quality care, resulting in significant gaps in care and poor health outcomes, including higher rates of unintended pregnancy.

27. Indeed, a study of abortion in Washington state found that rural women who had to travel more than 75 miles to obtain an abortion were two to three times more likely than women travelling less than 75 miles to terminate after 12 weeks, and that after abortion became less available in Washington, "the proportion of rural women having their abortions at later than 18 weeks more than doubled . . . growing from 2% to 5%," and the proportion of rural women having abortions after 18 weeks was "significantly higher than that among their urban counterparts."[17]

28. Another study, in which researchers interviewed women who sought an abortion at a "last stop" abortion provider but were turned away because their pregnancy was too far along, found that 58.3% were delayed by travel or procedure costs, 33.5% were delayed because they

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[16] Rachel K. Jones et al., *Abortion Incidence and Service Availability in the United States, 2017*, Guttmacher Inst. (Sept. 2019).

[17] Sharon A. Dobie et al., *Abortion Services in Rural Washington State, 1983–1984 to 1993–1994: Availability and Outcomes*, 31 Fam. Plan. Persp. 241, 243 (1999); *see also* Rachel K. Jones & Jenna Jerman, *How Far Did US Women Travel for Abortion Services in 2008?* 22(8) J. Women's Health 706, 706–10 (2013) (explaining that "rural women were more likely to travel greater distances relative to their counterparts" and "women at 16 + weeks gestation were twice as likely to have [traveled farther] compared with women seeking abortions at less than 12 weeks gestation"); Ushma D. Upadhyay et al., *Denial of Abortion Because of Provider Gestational Age Limits in the United States*, 104(9) Am. J. Pub. Health 1687 (2014).

could not find a provider, and 29.8% were delayed because they did not know how to get to a provider.[18]

29. Delay causes harm to patients. Though abortion is extremely safe, the risk of serious complication associated with abortion increases as a patient's pregnancy advances.[19]

30. Moreover, pregnancy carries risk, and delaying abortion forces a pregnant person to remain pregnant longer, experiencing the symptoms, risks, and potential complications of pregnancy. Even an uncomplicated pregnancy stresses a pregnant person's body, affects every organ system, and increasingly compresses abdominal organs as pregnancy progresses. Delay is also problematic for people for whom pregnancy worsens underlying health conditions, such as hypertension, heart failure, lung disease, or sickle cell crisis.

31. For other patients, being forced to remain pregnant against their will causes psychological harm. Some patients may need to conceal the pregnancy from an abusive or controlling partner or others who would disapprove or shame them. Delay can be very upsetting to patients terminating wanted pregnancies due to lethal or severe fetal anomalies.

32. When legal abortion is unavailable or difficult to access, some people will be prevented from obtaining abortion care entirely, and be forced to carry their pregnancies to term against their will (resulting in risks to their physical, mental, and emotional health); others will attempt to seek abortions outside the medical system (with the risks that may entail); others will be forced to delay their access to abortion (increasing risk to their health and well-being); and some will have to travel hundreds of miles to obtain care in other states (and incur all the associated economic and logistical burdens).

HB 136 (20-Week Ban)

33. HB 136 prohibits abortion before viability. I understand that in Montana abortion is currently legal until viability, but that HB 136 would ban abortion beginning at 20 weeks LMP.

34. It is commonly accepted in the field of OB/GYN that a normally developing fetus will not attain viability—i.e., will not have a reasonable chance of survival outside the womb with or without artificial assistance—until approximately 24 weeks LMP. But viability is not the same

[18] Upadhyay, et al. (2014), *supra* note 17, at 1689.

[19] Nat'l Acads. 10–11, 65.

for every pregnancy. Some fetuses are not viable even after that time, and some fetuses (including those with anencephaly or other fatal conditions) are never viable. It is a determination that must be made by a trained medical professional on a case-by-case basis.

35. No fetus is viable at 20 weeks LMP or at any earlier gestational age.

36. As I explain above, while people seeking abortion care generally do so as soon as they are able, the availability of abortions at or after 20 weeks is critical to those who need them. That is because many patients face logistical delays in obtaining abortions—including raising the necessary funds, arranging for travel and time off work, and dealing with unsupportive or abusive partners. Other patients seek abortions later in their pregnancies because they discover a fetal medical condition or diagnosis. Many fetal diagnoses are discovered through testing that occurs generally around 20 weeks LMP. Sometimes the results of those tests are inconclusive, which necessitates referrals to other medical professionals and additional testing, further delaying the point at which patients decide to have an abortion. If abortions are banned beginning at 20 weeks, these patients may run out of time and be forced to travel out of state or carry to term against their will, or may decide to have an abortion without complete information about the fetal diagnosis.

37. I understand that HB 136 is premised on the theory that "there is substantial medical evidence that an unborn child is capable of experiencing pain by 20 weeks [LMP]," and asserts a "compelling state interest in protecting the lives of" fetuses from "the stage at which substantial medical evidence indicates that they are capable of feeling pain."

38. But there is a consensus in the medical community, based on reliable evidence and research, that it is not possible for a fetus to feel pain before at least 24 weeks LMP. Key connections to the brain do not develop before that time. This consensus is based on input from physicians and scientists from a variety of fields and areas of expertise.[20]

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[20] Royal College of Obstetricians & Gynaecologists, *Fetal Awareness: Review of Research and Recommendations for Practice* (Mar. 2010) (concluding that fetal pain is not possible before 24 weeks gestation, based on a review of available medical and scientific literature by a panel of experts from fields such as neuroscience, neonatology, obstetrics, and psychology); Susan J. Lee et al., *Fetal Pain: A Systematic Multidisciplinary Review of the Evidence*, 294 J. Am. Med. Ass'n 947 (2005) (review of scientific and medical literature by physicians from multiple specialties, including obstetric anesthesiology); *see also* American College of Obstetricians & Gynecologists, *Facts Are Important: Fetal Pain*, https://www.acog.org/advocacy/facts-are-important/fetal-pain.

39. I also understand that HB 136 has a very narrow health exception, which allows abortions to be performed at and after 20 weeks LMP only if they are necessary "to avert the mother's death or to avert serious risk of substantial and irreversible physical impairment of a major bodily function." This exception would exclude patients seeking abortion because of a fetal anomaly diagnosis, as well as patients with serious but not immediately life-threatening health conditions (like pre-existing medical conditions that become exacerbated during pregnancy, or health risks as a result of a condition related to or brought on by the pregnancy itself). If HB 136 is permitted to go into effect, providers will be unable to provide such patients with appropriate care unless and until they have deteriorated to the point of emergency. Even then, the physician that performs the abortion would still be subject to prosecution and could only advance the fact of the emergency as an affirmative defense that may or may not be accepted. As a result of HB 136's language, a physician's decision to initiate a medically-indicated pregnancy termination may be inappropriately delayed, putting the patient's long-term health in serious jeopardy.

HB 171 (MAB Restrictions)

40. I understand that HB 171 would impose on medication abortion a 24-hour mandatory delay; a multi-trip requirement (once 24 hours before the abortion for an in-person exam and to obtain "informed consent," another for the abortion, and yet another for a patient who returns for a follow up that providers are required to schedule); a ban on medication abortion via telemedicine; an effective ban on very early abortions; "informed consent" requirements that mandate the provision of inaccurate information regarding complications and so-called medication abortion "reversal"; a requirement that providers have contracts with back-up physicians; and reporting requirements that make public the names of providers and threaten to reveal patient identities. As I explain below, none of these restrictions are medically necessary, and instead each serves only to harm patient health.

41. First, the 24-hour mandatory delay and multi-trip requirement would serve only to put abortion further out of reach for patients, who already struggle to make time and gather funds for one trip. These requirements would do nothing to improve a patient's decision-making with respect to their decision to have an abortion. In my experience, by the time a patient decides to make an appointment for abortion care, they have invested the time, research, introspection, and self-care required to make an informed and confident decision to terminate the pregnancy. Indeed,

research has shown that delay periods do not increase decisional certainty.[21] To the contrary, as explained above, *see supra* ¶¶ 29–32, delaying access to abortion care harms patient health.

42. Moreover, the follow-up visit requirement is also medically unnecessary. While it is important to follow up with a patient following a medication abortion to confirm termination of pregnancy, this need not be accomplished by the patient returning to the health center. Patients may instead confirm termination of pregnancy with an at-home pregnancy test or by visiting a more convenient provider for blood work, which is consistent with the current FDA label for mifepristone.[22] It is also consistent with my own practice at RHS.

43. Second, the telemedicine ban also harms patients without providing any medical benefit. I understand from Plaintiffs' counsel that PPMT provides medication abortion via telehealth in two ways: site-to-site, which involves the same procedures as in-person medication abortion, with the sole exception being that the provider meets with the patient via face-to-face secure, interactive videoconference rather than in person; and direct-to-patient, which involves a videoconference with a provider, who then mails the eligible patient the MAB medications.

44. Telemedicine abortion provides patients with many benefits, including by improving access to early medication abortion in underserved areas (including rural areas), and by increasing access to abortion for patients with low incomes or who otherwise find it difficult to travel. Indeed, a 2011 study demonstrated that patients generally reported greater satisfaction rates with the telemedicine abortion service (particularly with their wait time).[23] Telemedicine also allows patients to obtain abortions earlier in pregnancy, when the risks of complications are lower and procedures are less costly, and in the privacy of their own home, where they do not have to confront anti-abortion protestors.

45. I understand that HB 171 would ban telemedicine abortions in multiple ways, including by (a) prohibiting the mailing of "an abortion-inducing drug" (banning direct-to-patient telehealth), and (b) requiring that the same physician who provides the medication abortion

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[21] *See* Iris Jovel et. al., *Abortion Waiting Periods and Decision Certainty Among People Searching Online for Abortion Care*, 137 Obstetrics & Gynecology 597 (2021).

[22] MIFEPREX (Mifepristone) Tablets Label, *supra* note 4, at 4 ("Termination can be confirmed by medical history, clinical examination, human Chorionic Gonadotropin (hCG) testing, or ultrasonographic scan.").

[23] Grossman et al. (2011), *supra* note 6, at 300.

conduct an in-person exam of the patient that consists of an ultrasound and Rh testing (banning both site-to-site and direct-to-patient telehealth).

46. There is no health- or safety-based reason for any of these requirements, as multiple studies have demonstrated that medication abortion by both site-to-site and direct-to-patient telehealth are just as safe and effective as in person.

47. Multiple systematic reviews and studies have found that providing medication abortion via site-to-site telemedicine is safe, effective, and well-liked by both patients and providers.[24] Consistent with this research, ACOG—the leading U.S. professional association of OBGYNs—updated its guidance on medication abortion in 2020 to recognize that medication abortion provided through telemedicine is not only as safe, effective, and well-liked as in-person care, it may also help reduce delays to care.[25]

48. For example, a 2011 study found that regardless of whether it is provided in person or by site-to-site telemedicine, medication abortion is both safe and effective.[26] There was no significant difference in the occurrence of adverse events between the two study groups, and indeed the abortion success rate was higher for telemedicine patients (98.7% for site-to-site telemedicine patients and 96.9% for in-person patients).[27] None of the study subjects, in either group, required hospitalization.[28] Likewise, a 2017 study that spanned 7 years and nearly 20,000 patients (8,765 site-to-site telemedicine medication abortions and 10,405 in-person medication abortions) came to very similar conclusions: there were no significant differences in the occurrence of adverse events between the two groups (0.18% of telemedicine patients, 0.26% of

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[24] *See, e.g.*, Margit Endler et al., *Telemedicine for Medical Abortion: A Systematic Review*, 126 BJOG 1094, 1097 & table 1, 1100 (2019); Grossman et al. (2011), *supra* note 6; *see also* Daniel Grossman, Commentary, *Telemedicine for Medical Abortion – Time to Move Towards Broad Implementation*, 126 BJOG 1103 (2019).

[25] ACOG, Practice Bulletin No. 225, *Medication Abortion Up to 70 Days of Gestation*, https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2020/10/medication-abortion-up-to-70-days-of-gestation.

[26] *See* Grossman et al. (2011), *supra* note 6.

[27] Grossman et al. (2011), *supra* note 6, at 299.

[28] *Id.*

all patients), no patients required surgery, and there were no reports of protocol-associated mortality.[29]

49. The direct-to-patient model has also been found to be both safe and effective, with 95% of abortions resulting in a complete abortion without a procedure; only 1.8% of attempted abortions resulting in an ongoing pregnancy; and only 10 out of 1,390 abortions resulting in a serious adverse event, none of which were due to the fact that the care was administered via telemedicine (i.e., the adverse events would have occurred regardless of the setting).[30] Providers were able to confirm that the patients' abortions were complete via telemedicine without an in-person visit to a facility in the majority of cases.[31] All in all, participants in the study who had medication abortions via the direct-to-patient telemedicine model "were overwhelmingly satisfied with the service, and with speaking to their providers remotely."[32] Similarly, over the past 15 years, international health organizations have provided mifepristone and misoprostol—the second pill in a medication abortion—by mail to tens of thousands of patients, and reported rare adverse outcomes.[33]

50. In the extremely rare event that serious adverse events do occur as a result of ingesting mifepristone, they do not occur until after the patient has already left the health center, meaning that in-person dispensing requirements play no role in protecting patients from those rare outcomes.

51. Furthermore, it is often medically unnecessary to assess gestational age by ultrasound.[34] Research has shown that patients can generally estimate their gestational age based

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[29] Daniel Grossman & Kate Grindlay, *Safety of Medical Abortion Provided Through Telemedicine Compared With In Person*, 130 Obstetrics & Gynecology 778, 780 (2017).

[30] Erica Chong et al., *Expansion of a Direct-to-Patient Telemedicine Abortion Service in the United States and Experience During the COVID-19 Pandemic*, 104 Contraception 43, 46 (2021).

[31] *Id.*

[32] *Id.*

[33] *See* Elizabeth G. Raymond et al., Commentary: *No-Test Medication Abortion: A Sample Protocol for Increasing Access During a Pandemic and Beyond*, 101 J. Contraception 361, 361 (2020) (citing studies).

[34] *See, e.g.*, Nat'l Abortion Fed'n, *2020 Clinical Policy Guidelines for Abortion Care*, at 12 (2020), https://prochoice.org/wp-content/uploads/2020_cpgs_final.pdf ("The use of ultrasound is not a requirement for the provision of first-trimester abortion care."); *see also id.* at 15 (requiring confirmation of pregnancy and verification of gestational age but not specifically

on their LMP,[35] and additional studies have confirmed that medication abortions performed without routine ultrasounds for eligible patients are safe and effective.[36]

52. Nor is an ultrasound necessary to screen for ectopic pregnancy. While ultrasounds can be helpful in detecting ectopic pregnancies, clinicians do not rely exclusively on ultrasound to screen for ectopic pregnancy, but rather routinely consider known risk factors, including symptoms and history, which can be assessed by telemedicine.[37] Ultimately, the decision whether or not to perform an ultrasound should be at a clinician's discretion in consultation with the patient, and based on knowledge of an individual patient's history, presenting symptoms, and other risk factors. Recent research studying patients screened for ectopic pregnancy via phone or video call who went on to have medication abortions without prior ultrasound found no statistically significant difference in the rate of ectopic pregnancy between the no-ultrasound and ultrasound groups, demonstrating the safety and efficacy of using telemedicine screenings for medication abortion.[38]

53. HB 171's Rh requirement is also medically unnecessary. Research has also shown that the risk of Rh sensitization after an early abortion is negligible.[39] Furthermore, testing is

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by ultrasound); Chong et al., *supra* note 30, at 46 ("Preabortion ultrasounds are usually unnecessary for safe and effective medication abortion . . .").

[35] *See* Elizabeth Raymond & Hillary Bracken, *Early Medical Abortion Without Prior Ultrasound*, 92 Contraception 212, 214 (2015) (finding that gestational dating using LMP rather than ultrasound may be reasonable for selected patients before medication abortion).

[36] Elizabeth Raymond et al., *Simplified Medical Abortion Screening: A Demonstration Project*, 97 Contraception 292 (2018); *see also* Abigail R. Aiken et al., *Effectiveness, Safety and Acceptability of No-Test Medical Abortion (Termination of Pregnancy) Provided Via Telemedicine: A National Cohort Study*, 128 BJOG 1464, 1469 (2021).

[37] *See, e.g.*, Aiken et al., *supra* note 36, at 1466 (explaining that patients "were offered a consultation via phone or video call, during which an assessment of eligibility for treatment via telemedicine was made," which included assessing whether "they had a low risk of ectopic pregnancy").

[38] *Id.* at 1469 (finding that "[t]he overall incidence of ectopic pregnancy was equivalent in both cohorts—39 (0.2%) in the traditional cohort and 49 (0.2%) in the telemedicine-hybrid cohort").

[39] Raymond et al., Commentary: *No-Test Medication Abortion*, *supra* note 33, at 363 (citing Nat'l Abortion Fed'n, *Clinical Policy Guidelines*, *supra* note 34; Alice Mark et al., *Commentary: Foregoing Rh Testing and Anti-D Immunoglobulin for Women Presenting for Early Abortion: A Recommendation from the National Abortion Federation's Clinical Policies Committee*, 99 Contraception 265 (2019)).

unnecessary for patients who can report an Rh-positive blood type.[40] A recent statement by ACOG notes that if Rh testing and RhD immunoglobulin administration are unavailable or would significantly delay the abortion, they should not be a barrier to a patient accessing medication abortion.[41]

54. Thus, it is my expert opinion that HB 171's telemedicine abortion ban—effected by its mailing ban, same-doctor in person exam requirement, and ultrasound and Rh testing mandate—will serve only to harm people seeking abortion, as it will increase travel burdens and delay access to abortion care, which may force some patients to carry an unwanted pregnancy to term (especially given that HB 136 would ban abortion beginning at 20 weeks LMP). These burdens would disproportionately affect people with low incomes, who would find it difficult if not impossible to overcome the cost and logistical barriers imposed by not one, not two, but potentially *three* trips to the health center, when now they can make either one trip to a health center that is convenient for them or zero trips at all.

55. Third, I understand that HB 171 requires the abortion provider to "document in the woman's medical chart the . . . intrauterine location of the pregnancy" before providing a medication abortion. Not only does this prohibit direct-to-patient telemedicine for patients for whom a procedure can safely be provided without an ultrasound, *see supra* ¶¶ 51–52, but it also effectively bans very early medication abortions, which can safely be provided without a documented intrauterine pregnancy as long as the provider also screens for extrauterine pregnancy. HB 171, however, would ban these very early medication abortions by requiring that the intrauterine location be documented.

56. I understand that the State suggests that documentation of intrauterine location is necessary to rule out spontaneous abortion (miscarriage) "because the routine administration of an abortion-inducing drug following spontaneous miscarriage is unnecessary and exposes the woman to unnecessary risks associated with the abortion-inducing drug." This is absolutely incorrect: the mifepristone and misoprostol regimen used for medication abortion is routinely used to treat

[40] *Id.*

[41] ACOG, Practice Bulletin No. 225, *supra* note 25.

miscarriage, and has been shown to be the most effective medical regimen.[42] The documentation requirement, therefore, serves no medical purpose and instead only delays patients' access to safe care.

57. Fourth, I understand that HB 171 requires that abortion providers provide patients with "information about the possibility of reversing the effects of the chemical abortion" including by directing them to www.abortionpillreversal.com. I am aware of no evidence that supports the theory underlying so-called medication abortion "reversal": that because mifepristone is a progesterone antagonist, large doses of a progestin medication taken after mifepristone but before misoprostol may "reverse" mifepristone's effects. Indeed, ACOG has concluded that "[t]here is no evidence that treatment with progesterone after taking mifepristone increases the likelihood of the pregnancy continuing."[43]

58. I am aware of only one randomized controlled study of "reversal," which was halted due to safety concerns raised when three participants experienced severe hemorrhage requiring hospital transport.[44] Reviewing this study, ACOG advised that "limited available evidence suggests that use of mifepristone alone without subsequent administration of misoprostol may be associated with an increased risk of hemorrhage."[45] This requirement, therefore, will result in patients receiving misleading and inaccurate information about the consequences of their decision to proceed with taking mifepristone. This may lead some patients to terminate their pregnancies without having come to a final decision on the mistaken belief that their actions were "reversible" and may lead others to seek an experimental treatment, the safety and efficacy of which has never been demonstrated.

59. Fifth, the list of complications in HB 171 is far too broad and will only mislead and frighten patients. As I explained above, potential serious complications from medication abortions are extremely rare; they generally are limited to infection and significant bleeding (beyond what

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[42] Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss,* 378 New Eng. J. Med. 2161 (2018).

[43] ACOG, Practice Bulletin No. 225, *supra* note 25.

[44] Mitchell D. Creinin et al., *Mifepristone Antagonization with Progesterone to Prevent Medication Abortion: A Randomized Controlled Trial*, 135 Obstetrics & Gynecology 158 (Jan. 2020).

[45] ACOG, Practice Bulletin No. 225, *supra* note 25.

is expected and normal). These complications, in the event they occur, are generally appropriately and safely managed and resolved by the medical provider in an outpatient clinic and do not result in any significant or longstanding damage to the health of the patient.

60. I understand that HB 171 requires that providers give patients seeking medication abortion "a description of the risks of complications from a chemical abortion," which it defines elsewhere as:

> an adverse physical or psychological condition arising from the performance of an abortion, including but not limited to uterine perforation, cervical perforation, infection, heavy or uncontrolled bleeding, hemorrhage, blood clots resulting in pulmonary embolism or deep vein thrombosis, failure to actually terminate the pregnancy, incomplete abortion, pelvic inflammatory disease, endometritis, missed ectopic pregnancy, cardiac arrest, respiratory arrest, renal failure, metabolic disorder, shock, embolism, coma, placenta previa in subsequent pregnancies, preterm delivery in subsequent pregnancies, free fluid in the abdomen, hemolytic reaction due to the administration of ABO-incompatible blood or blood products, adverse reactions to anesthesia and other drugs, subsequent development of breast cancer, death, psychological complications such as depression, suicidal ideation, anxiety, and sleeping disorders, and any other adverse event.

61. This list is overbroad and inaccurate. To begin, the alleged link between abortion and breast cancer has been thoroughly disproven,[46] and abortion has repeatedly been shown not to have a deleterious effect on mental health.[47] Placenta previa, a condition in which the placenta partially or totally covers the cervix, is not associated with abortion. Nor are pelvic inflammatory

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[46] *See, e.g.*, Mads Melbye et al., *Induced Abortion and the Risk of Breast Cancer*, 336 New Eng. J. Med. 81, 84 (1997) (study of 1.5 million women found that "induced abortion had no overall effect on the risk of breast cancer"); Collaborative Group on Hormonal Factors in Breast Cancer, *Breast Cancer and Abortion: Collaborative Reanalysis of Data from 53 Epidemiological Studies, Including 83,000 Women with Breast Cancer from 16 Countries*, 363 Lancet 1007 (2004) (analysis of 53 studies conducted in 16 countries found that "[p]regnancies that end as a spontaneous or induced abortion do not increase a woman's risk of developing breast cancer").

[47] *See, e.g.*, Academy of Medical Royal Colleges & National Collaborating Centre for Mental Health, *Induced Abortion and Mental Health: A Systematic Review of the Mental Health Outcomes of Induced Abortion, Including Their Prevalence and Associated Factors* 8 (Dec. 2011), https://www.aomrc.org.uk/wp-content/uploads/2016/05/Induced_Abortion_Mental_Health_1211.pdf; American Psychological Association, Position Statement on Abortion (July 2018), https://www.psychiatry.org/File%20Library/About-APA/Organization-Documents-Policies/Policies/Position-2018-Abortion.pdf; Nat'l Acads. 149–52.

disease, endometritis, or pre-term delivery in a subsequent pregnancy recognized complications of abortion care.

62. Other items in the law's list are entirely inscrutable; I do not know what a metabolic disorder is in this context.

63. HB 171 also lists as "complications" many things that almost never occur as a result of an abortion procedure, like cardiac arrest, respiratory arrest, renal failure, metabolic disorder, shock, embolism, coma, hemolytic reaction due to the administration of ABO. In my many years providing abortion care, I have never had a patient experience any of these conditions as a result of their abortion. Instead, these complications—which are in fact general risks of almost any medical procedure—occur much more frequently following plastic surgery, orthopedic surgery, hysterectomy, cesarean section, vaginal birth, and a host of other indications, which, as I understand it, are not subject to similar reporting requirements.

64. Further, uterine perforation and cervical laceration are potential (but very rare) complications of procedural abortion, not medication abortion. "Free fluid in the abdomen," another item listed in HB 171's definition, is not considered to be a direct complication of an abortion procedure, but may be due to bleeding into the abdomen caused by a uterine perforation (which is, again, extremely rare, and would occur in a procedural, not medication abortion), or non-abortion-related issues, like rupture of a non-ectopic ovarian cyst.

65. Moreover, it is expected that following a medication abortion, a patient will experience some combination of significant cramping, bleeding, diarrhea, vomiting, fatigue, and/or soreness. These are all considered to be normal side-effects and are generally not cause for any concern and do not require any additional medical interventions, beyond routine follow-up and responding to patient questions as they arise. HB 171, however, may cause providers to overreport this normal bleeding as "hemorrhage," "heavy or excessive bleeding," or "blood clots," as there may be ambiguity as to when expected bleeding becomes reportable "heavy" bleeding.

66. Similarly, several items listed "complications" are not actually complications at all but known occurrences for patients who choose medication abortion (like "failure to actually terminate the pregnancy" and "incomplete abortion or retained tissue"). In any event, these occur very rarely. And to the extent any of these conditions do arise following an abortion, they are most often non-emergencies that are safely and effectively treated by an outpatient medical provider,

such that the patient does not suffer any sustained or long-term health consequences. As such, I do not see how reporting these complications would assist in improving patient safety or the public health in general.

67. Overall, the over-reporting that HB 171 will promote may lead to the erroneous public perception that abortions are dangerous.

68. Sixth, I understand that HB 171 requires providers to "be credentialed and competent to handle" the broad swath of "complications," listed *supra* ¶ 60, or else "must have a signed contract with an associated medical practitioner who is credentialed to handle complications." There is no single person who could be "credentialed" in handling all of the "complications" HB 171 identifies; arguably, not even an emergency department could "handle" every one of those complications.

69. But even if there were a provider or emergency department equipped to handle everything from breast cancer to anxiety to endometriosis, the contractual requirement would be medically unnecessary, as the very rare complications from medication abortion occur long after the patient has left the health center. In such a situation, if the patient required care that the provider could not provide, the patient would be advised to go to a health care provider near them or the nearest emergency room. The rare complications from medication abortion are familiar to emergency physicians because they generally are very similar to the symptoms of a miscarriage, which is a condition very commonly seen in emergency departments. Further, a contractual requirement is unnecessary and irrelevant to providing optimal care because of the distances some people travel to obtain a medication abortion. A patient who needs hospital care following a medication abortion should go to a hospital close to them; they should not travel farther than necessary to be treated at a specific hospital just because their abortion provider has a contract with a physician there.

70. Finally, I understand that HB 171's reporting requirements would make public the names of all providers of medication abortion in the state. I know many clinicians who keep the fact that they provide abortions secret, for fear of violence, harassment, or retribution. Some even wear bulletproof vests. I personally regularly deal with anti-abortion protesters who shout my name as I enter my workplace; I have even had protestors stand outside my home and terrify my family. Especially during times of heightened political rhetoric, providers and clinics face

increased harassment. In 2019, for example, an anti-abortion extremist threw a Molotov cocktail into Planned Parenthood health center in Missouri.[48] Thus, I believe the requirement that provider names be made public is an inappropriate form of harassment of medical professionals that may prevent some providers from providing medication abortion altogether.

HB 140 (Ultrasound Offer)

71. I understand that HB 140 requires abortion providers to offer patients the opportunity to view "an ultrasound image" and "active ultrasound," and to "listen to the fetal heart tone of the unborn child, if audible," except where the abortion is performed with the intent to save the patient's life, ameliorate a serious risk of bodily harm, or remove an ectopic pregnancy. As explained above, this requirement is medically unnecessary because an ultrasound is not required before all procedures. Instead, it seems designed only to shame the patient for their decision to seek abortion care.

* * *

72. In sum, these requirements have no basis in medicine. They single out abortion—an extremely safe and common procedure—for more burdensome treatment and rather than helping patients, impede their access to care. My opinion is supported not only by all of the medical literature cited above, but also by my many years of experience providing care both in environments where politicians have restricted access to abortion care (like Missouri) and in environments where patients are safely able to effectuate their choice to terminate a pregnancy without additional abortion, specific regulation (like Illinois). I have treated thousands of patients over my career, and I am certain that laws like the ones at issue here not only do not improve care, but instead they burden, shame, and block access to care that for many patients is nothing short of life-saving.

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[48] Phil Helsel, *Missouri Man Sentenced to 5 Years for Arson at Planned Parenthood Clinic,* NBC News (Sept. 2, 2020), https://www.nbcnews.com/news/us-news/missouri-man-sentenced-5-years-arson-planned-parenthood-clinic-n1239152.

I declare under penalty of perjury the foregoing is true and correct.

Colleen P. McNicholas, DO, MSCI, FACOG

Subscribed and sworn to before me this 13th day of August, 2021.

(NOTARIAL SEAL)

Printed Name: Kayla D. Gaskill

KAYLA D.GASKILL
Notary Public - Notary Seal
State of Missouri
St. Louis County
My Commission Expires: Oct. 19 2024
Commission # 20623844