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Angie Sparks

Lewis & Clark County District Court
STATE OF MONTANA

By: <u>Helen Coleman</u>
DV-25-2023-0000592-CR
Abbott, Christopher David
10.00

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MONTANA FIRST JUDICIAL DISTRICT COURT, COUNTY OF LEWIS & CLARK

)
S)
) Cause No
) Judge:
)
)
AFFIDAVIT OF JOEY BANKS, MD, IN SUPPORT OF PLAINTIFFS' APPLICATION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION 1)
)))

I, Joey Banks, MD, being duly sworn, affirm as follows:

1. I submit this affidavit in support of Plaintiffs' Application for a Temporary Restraining Order and Preliminary Injunction against enforcement of HB 937 related to the licensure of clinics that provide abortion care.

Background and Experience

- 1. I am a board-certified family medicine physician licensed to practice in Montana, where I have practiced for over a decade. I have more than 23 years' experience providing primary care and reproductive health care and have been performing and supervising abortion care for more than 17 years.
- 2. I received my medical degree from Indiana University School of Medicine and am board-certified as a family physician by the American Board of Family Medicine. I completed my residency in family medicine at the Alaska Family Medicine Residency in Anchorage, Alaska, where I also served as chief resident. I have previously been a faculty member at the Alaska Family Medicine Residency and the Central Maine Medical Center Family Medicine Residency, as well as a community preceptor for Family Medicine Residency Western Montana. In addition to Montana, I am currently licensed to practice medicine in Illinois, New Mexico, Oklahoma, and Wyoming.
- 3. I worked as a family practice physician for nine years at Blue Mountain Clinic, providing full primary care, and sexual and reproductive health care, including abortion care. I then provided abortion care at Planned Parenthood Montana and served as its chief medical officer. I have also worked and provided abortion care at Planned Parenthood of Northern New England, Planned Parenthood of Alaska, and Central Maine Family Medicine Residency Family Practice Clinic. I have been the lead and assistant-lead on two reproductive health education in family

medicine ("RHEDI") grants for educating family medicine residents in abortion care. I currently provide abortion care on a contract basis at Blue Mountain Clinic and clinics in other states.

- 4. A current version of my curriculum vitae, which sets out my experience and credentials more fully, is attached to this affidavit as Exhibit A.
- 5. The opinions in this affidavit are my expert medical opinions, based on my education, training, clinical experience, ongoing review of relevant, peer-reviewed professional literature on reproductive health, discussions with colleagues, and my attendance at professional conferences.
- 6. I am familiar with HB 937, which relates to licensure for abortion clinics in Montana. I am also aware that the Montana Department of Public Health and Human Services ("DPHHS") has not proposed regulations or a process by which clinics that provide abortion care may become licensed. It is my opinion that to the extent HB 937 requires clinics that provide abortion to obtain facility licensure in order to continue offering abortion care, it is unnecessary to protect patient health and safety. Abortion is one of the safest types of medical care available in the United States, and there is no medical reason to single it out for additional regulation. In particular, there is no medical reason to single out abortion for unique and additional regulation when those requirements do not apply to nearly identical care, such as miscarriage care; other comparable gynecological and non-gynecological procedures; or even care that can entail more risk than abortion care, such as colonoscopy or labor and delivery.

Abortion in the United States

7. Abortion is common and safe medical care. The vast majority of legal abortions in the United States are provided during the first trimester of pregnancy. In Montana in 2020, more

than 95% of the 1,675 abortions were performed at 13 weeks or earlier.¹

- 8. Abortion care provided in the United States is either through the use of medication (medication abortion) or via an outpatient procedure (procedural abortion). Both methods are safe and effective.
- 9. Medication abortions are typically indicated up to 11 weeks of pregnancy, as measured from the first day of the patient's last menstrual period ("LMP") and involve the ingestion of medication to terminate the pregnancy, expelling the pregnancy via vaginal bleeding, akin to a heavy period or spontaneous miscarriage. The medications used in a medication abortion are the same medications that providers use to manage a patient's spontaneous miscarriage.
- 10. The most common regimen of medication abortion in the U.S. is a combination of two prescription drugs, mifepristone and misoprostol. Mifepristone was first approved by the U.S. Food and Drug Administration in 2000 for use, in conjunction with misoprostol, to terminate an early pregnancy. Typically, in a medication abortion, a patient takes the first medication, mifepristone, then the second medication, misoprostol, up to 72 hours later, and passes the pregnancy in a process similar to a miscarriage. Medication abortion can also safely and effectively be provided with misoprostol-only.
- 11. Medication abortion is safely and effectively provided in-clinic or via telehealth.² When it is accessed via telehealth, a patient with internet access connects with a health care provider from their home, health center, or other location. After screening the patient for their eligibility for medication abortion, and obtaining informed consent, medication abortion pills are mailed to the patient. Access to abortion via telehealth improves abortion access, in particular for

¹ Mont. Dep't of Pub. Health and Hum. Servs., *2020 Montana Vital Statistics*, Tbl. A2 (Feb. 2022) https://dphhs.mt.gov/assets/publichealth/Epidemiology/VSU/VSU2020AnnualREport.pdf.

² See Nat'l Acads. of Scis., Eng'g, & Med., The Safety and Quality of Abortion Care in the United States, 57-58 (2018), https://nap.nationalacademies.org/read/24950 / [hereinafter "Nat'l Acads."].

underserved communities, including patients living in rural, and patients who face challenges accessing transportation and arranging the logistics associated with in-clinic abortion care.

- 12. Under these regimens, the patient completes the abortion process outside a clinical setting in a location of their choice, usually at home. Medication abortion requires no anesthesia or sedation; the patient simply takes the pills.
- 13. As the FDA and dozens of studies have found, medication abortion is exceedingly safe, with complications occurring in a fraction of a percent of cases.³ The risks of medication abortion are low and similar in magnitude to the risks of taking commonly prescribed and overthe-counter medications, such as antibiotics and non-steroidal anti-inflammatory drugs ("NSAIDS").⁴ Mifepristone and misoprostol are substantially safer than aspirin, Tylenol, and Viagra. Because of mifepristone's track record of safety and efficacy, in January 2023, the FDA took the long overdue action of removing medically unnecessary restrictions that required it to be dispensed in-person by a certified health care provider instead of direct to patient telehealth.⁵
- 14. Procedural abortion can be provided to patients in the first and second trimesters. It involves dilating (opening) the uterine cervix and then evacuating the uterus using suction aspiration, instruments, or some combination. Dilation is done either the same day or the day before and the procedural abortion typically takes around ten minutes in the first trimester of pregnancy and twenty minutes in the second trimester. Despite sometimes being referred to as "surgical abortions," these procedures are not surgical: they do not involve any incision, are

³ *Id.* at 55.

⁴ Id. at 58, 79.

⁵ See U.S. Food & Drug Admin., *Information About Mifepristone for Medical Termination of Pregnancy Through 10 Weeks Gestation* (Aug. 9, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

routinely performed in office-based settings, and involve minimal recovery.

15. Procedural abortion commonly involves administration of a local anesthetic to numb the cervix. Patients may also be offered mild to moderate sedation, where they are relaxed, but awake.

16. Regardless of the method of abortion used, abortion is extremely safe. Indeed, the National Academies of Sciences, Engineering, and Medicine ("National Academies")—a body of experts established by Congress to provide independent, objective expert analysis and advice to inform public policy that is "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 the safest, most common forms of medical care provided in the nation.⁶

Abortion is far safer than continuing a pregnancy through to childbirth, which carries a risk of death that is approximately 13 times higher than that associated with abortion.⁷ Abortion-related mortality (0.7 per 100,000) is also significantly lower than that for other common outpatient medical procedures, including colonoscopy (2.9 per 100,000) and adult tonsillectomy (2.9 to 6.3 per 100,000).⁸

18. Complications associated with abortion are also not common. Major complications are exceptionally rate—less than a fraction of one percent a fraction of one percent. The overall rate of abortion-related complications is approximately 2%, with most complications minor and easily treatable. This is far lower than the overall rate of complications for such common

⁶ *Id.* at 77–78; see also id. at 162–63.

⁷ *Id*. at 74.

⁸ *Id.* at 75.

⁹ See, e.g., Ushma Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 181 (2015); see also Nat'l Acads. at 60.

¹⁰ See, e.g., Ushma Upadhyay et al., *Incidence of Emergency Department Visits and Complications After Abortion*, 125 Obstetrics & Gynecology 175, 181 (2015); *see also* Nat'l Acads. at 55, 60, 63.

procedures as wisdom tooth removal (7%) and tonsillectomy (between 8–9%).¹¹ It is similar to or lower than the overall rate of complications associated with vasectomy, a surgical procedure that is associated with an overall low risk of complications.¹²

19. Abortion is also time-sensitive care. Delayed access to abortion care means patients must endure the symptoms and risks associated with continued pregnancy. Delays can also push patients past the point in pregnancy during which they are eligible for a medication abortion. For others, delay may make patients ineligible for a one-day procedure and instead mean they have a two-day procedure involving overnight dilation. Additionally, delays can push a patient past the point in pregnancy where abortion is available in Montana, which would force patients to have to travel to providers in Oregon, Washington, or Colorado. The cost and logistics of accessing abortion out of state may be insurmountable for some patients.

Abortion Is Comparable to Other Outpatient Care

- 20. Abortion by medication or procedure abortion is essentially identical to the care provided to manage a patient's spontaneous miscarriage or following fetal demise. In fact, gynecology or family practice providers routinely refer to abortion clinics for treatment following a fetal demise, to provide safe care that is also cost-efficient and timely.
- 21. Managing miscarriage by medication involves the *same* medications as an induced abortion: mifepristone and misoprostol, or misoprostol alone. The same procedures are used to manage a patient's miscarriage as to induce an abortion.
- 22. Procedural abortion is also comparable to other gynecological procedures, including insertion and removal of intrauterine devices (a long-acting, reversible method of birth

¹¹ See Advancing New Standards in Reprod. Health, *Issue Brief #6: Safety of Abortion in the United States* 1, 2 (Dec. 2014), https://www.ansirh.org/sites/default/files/publications/files/safetybrief12-14.pdf (citing studies).

¹² See, e.g., Christopher E. Adams & Moshe Wald, *Risks and Complications of Vasectomy*, 36(3) Urol Clin North Am. 331 (2009).

control), endometrial biopsy, LEEP (a procedure in which abnormal cells from the cervix are removed to prevent cancer), and dilation and curettage for abnormal uterine bleeding. It is also comparable in some respects to vasectomy (although that is a minor surgical procedure that involves an incision, unlike an abortion procedure). Each of these procedures may involve in-office administration of local anesthesia and/or moderate sedation. Like abortion care and miscarriage care, these other procedures can and are safely and effectively provided in clinicians' offices, including in Montana.

Because of the safety of legal abortion, mainstream medical authorities including the American College of Obstetricians and Gynecologists ("ACOG") recognizes that abortion may appropriately be provided in clinicians' offices and clinics and opposes unnecessary regulations that limit or delay access to care. ¹³ The National Academies agree, concluding that most abortions can be provided safely in office-based settings, ¹⁴ and that the "clinical evidence . . . on the provisions of safe and high-quality abortion care stands in contrast to the extensive regulatory requirements that state laws impose on the provision of abortion services," including the requirement that "care take place in costlier and more sophisticated settings than are clinically necessary." ¹⁵ As the National Academies made clear, these requirements "go beyond the accepted standards of care in the absence of evidence they improve safety." ¹⁶

24. As to medication abortion in particular, the National Academies found "no evidence that the dispensing or taking of mifepristone tablets requires the physical presence of a clinician or a facility with the attributes of an [Ambulatory Surgical Center] or hospital to ensure

¹³ Am. C. Obstet. Gynecol., *Committee Opinion 815: Increasing Access to Abortion* (Dec. 2020), https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2020/12/increasing-access-to-abortion.

¹⁴ Nat'l Acads. at 162.

¹⁵ *Id*. at 77.

¹⁶ *Id*.

safety or quality."¹⁷ Medication abortion may occur wholly outside the clinic setting, and extensive research shows that complications are exceedingly rare, similar to those of common over-the-counter medications (which can be taken at home).¹⁸

- 25. Procedural abortions likewise can be and are provided safely and effectively in clinicians' office settings.¹⁹
- A recent study investigated the safety of abortions performed in ambulatory surgical centers ("ASCs") compared to office-based settings.²⁰ It analyzed data from 50,311 abortions performed between 2011 and 2014 in ASCs or office-based settings.²¹ There was no statistically significant difference in complication rates or major complication rates between abortions performed in ASCs and abortions performed in office-based settings.²² There was also no significant difference in complication rates for first trimester aspiration abortions between ASCs and office-based settings (2.2% vs. 2.6%) or in complication rates for second trimester or later abortions between ASCs and office-based settings (2.6% in both settings).²³ This confirms that the safety of abortion does not differ depending on the type of facility in which the abortion is performed and corroborates previous studies indicating that there is no difference in patient safety for outpatient procedures performed in ASCs rather than office-based settings.²⁴
 - 27. Moreover, in the rare event of a complication, nearly every complication associated

¹⁷ *Id*. at 79.

¹⁸ *Id*.

¹⁹ Id.

²⁰ See Sarah C.M. Roberts, et al., Association of Facility Type with Procedural-Related Morbidities and Adverse Events Among Patients Undergoing Induced Abortions, 319 J. Am. Med. Assoc. 2497 (2018).

²¹ *Id*.

²² *Id*.

 $^{^{23}}$ Id

²⁴ See e.g., Nancy F. Berglas, et al., The effect of facility characteristics on patient safety, patient experience, and severe availability for procedures in non-hospital-affiliated outpatient settings: a systematic review, 13 PloS ONE 1 (2018) (citing studies).

with abortion can be safely managed in an outpatient setting.²⁵ For example, in the rare event of a hemorrhage, most are managed in the clinic with medications that increase uterine contractions and reduce bleeding, or by repeat aspiration. Incomplete abortion can also generally be managed in an outpatient setting with medication or repeat aspiration. Infection can be managed with outpatient antibiotic treatment.

- In my opinion, there is no medical justification for arbitrarily singling out clinics that provide abortion care for facility licensure, as HB 937 does. Abortion is exceedingly safe, including when provided in clinicians' offices—as it has been in Montana for decades. Abortion is also nearly identical to miscarriage care, and comparable to other gynecological care and to vasectomy—none of which is subject to unique regulation in Montana. Abortion also carries far less risk than labor and delivery of a child—but a pregnant person can decide to deliver at home or in a birth center not subject to mandatory facility-licensure requirements in Montana. Many other clinicians, such as dentists and dermatologists, also provide care in their offices or clinics without facility licensure.
- 29. There is no reason to subject to abortion to mandatory facility-licensure requirements, in particular when those requirements do not apply to identical or similar care, or care that carries more risk is not.

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²⁵ See Nat'l Acads. at 56, 59–62, 166.

I declare under penalty of perjury that the foregoing is true and correct.				
Dated: 8/30/23	Joey Banks, MD			
State of Montana				
County of Missoula	SUNDI JO HAMILTON NOTARY PUBLIC for the State of Montana Residing at Missoula, MT My Commission Expires November 08, 2024.			
Signed and affirmed to me this $\frac{30}{20}$ day of $\frac{8}{20}$	2023.			
Sundo 2 Hamilton Notary Public	Tax:			

Exhibit A

Joey Banks, MD ABFM (she/her)

Employment

Oct 2022 to May 2023 Staff family physician Missoula MT **Western Montana Clinic**

• Full family medicine practice with procedures

Oct 2021 to June 1,2021 University of Montana Genomics Core Lab Laboratory Director- High Complexity Lab Emergent Covid- 19 testing site for Montana

Provided QA and QI for lab and supervised testing and staff

Jan 23, 2019, to July 2021 Planned Parenthood of Montana

Chief Medical Officer

Missoula Montana

April 2021 became interim medical director only

July 2021 became contract doctor for abortion care only, Principal Investigator for Gynuity research, Moderate Complex Lab director, physician consult for US cases and as needed for other cases. Jan 2022 Contract doctor only

- Staff physician- primary care and abortion medical and procedural to 21.6 EGA
- Supervise medical staff at all statewide sites (MD, ANP, PA, RN, LPN, CA)
- Lab director Moderate Complex Lab for 5 sites. Trains and hires personnel. Provides quality assurance. Develops policy and protocol for new tests PPMT uses.
- Ensure guidelines and standard protocols are fulfilled per PP Medical Standard and Guidelines.
- Staff Clinician
- New project supervision
- PI Gynuity Research project
- PA staff supervisor
- Train residents and students
- Hire and train contract physicians
- Serve as senior leadership for PPMT and work with team to help with state-wide initiatives

July 2012—Jan 2019 Blue Mountain Clinic Reproductive Health Medical Director Missoula Montana Jan 2019 became contract doctor only

- Staff physician- primary care
- Community preceptor for Family Medicine Residency Western Montana
- Gender affirming care hormone therapy including youth care and blockers.
- Youth gender affirming care community organizer/lecturer.
- Western Montana Family Medicine Resident Community Attending- award for best community attending in 2014/2020
- Awarded RHAP Miscarriage Care Initiative Grant for WMFMR and our clinic.
- Assisted in RHEDI grant application and implementation.
- Partnered with OAA as medical supervisor for GC/CT program testing and treatment.
- LEEP, vasectomy, cryo-therapy, skin lesions, primary care, reproductive care, procedural abortion to 21.6 weeks EGA, medical abortion, Accutane
- Assisted in Lab Management with lab director to hire and train personnel and to provide quality assurance and training for moderate complex lab.

February 2010- July 2012 Arusha Lutheran Medical Center Arusha Tanzania Family Physician

- Outpatient clinic volunteer and school-based clinic/educator
- Grounds for Health volunteer for VIA training Prenatal, gynecology, pediatrics, family medicine

- Sexual Abuse and Rape Care Committee chair
 - ✓ Wrote medical policy, training program, and curriculum.
- ALSO- Advanced Life Saving Obstetrics instructor.

2007-December 2009 Central Maine Medical Center Family Medicine Residency Lewiston ME

Family Physician Faculty-Inpatient/Outpatient/Obstetrics

- Faculty
- Curriculum Committee Chair
- Gynecology Curriculum Coordinator
- **RHEDI grant coordinator** IPAS MVA abortion, miscarriage, and ultrasound training director (200,000\$ grant)- wrote curriculum, policy and initiated.

2005-2007

Planned Parenthood of Alaska

Anchorage AK

Medical Director for State of AK (2 clinics)

- Supervised medical staff at 4 clinics (MD, ANP, RN, LPN, RHS)
- Colposcopy, LEEP, vasectomy, Implanon master trainer, family practice, abortion, and gynecology health service clinician
- Assisted in writing Men's Reproductive Health Protocol for medical care for National Planned Parenthood of America
- Worked with Patient Service Director on drug formularies, lab manuals, education issues for staff, coding and billing.
- Helped with statewide education, public policy, and fundraising issues
- Lab Director for 2 sties. Moderate Complexity. Helped to establish moderate complex lab and develop policy and protocols for the lab. Hired personnel and trained staff on testing. Maintained quality assurance for the lab.

2005-2007

Providence Family Medicine Residency

Anchorage AK

Faculty and Gynecology/Elective/Evaluation Coordinator

- Supervised residents in clinic and inpatient care for pediatric, obstetrical, and medical admissions.
- Developed curriculum for gynecology rotations for the residents
- "Faculty of the Year Award"- for 2006 (voted by residents)
- Managed panel of patients and did clinic outpatient visits
- Faculty for 2005-2006, then volunteer faculty 2006-2007

2001-2005

ANMC-Primary Care Center

Anchorage AK

Family Practice Clinician

- Medical Student Supervisor through University of Washington
- Secretary Medical Staff ANMC 2002-2003
- PCC liaison for women's health and obstetrical care
- Village MD for Sandpoint AK (pop 3000)
- Team physician for panel of approximately 1400 patients
- Family practice care including prenatal and obstetrics
- Member of Quality Assurance PCC committee

1998-2001

Alaska Family Practice Residency

Anchorage AK

Providence Family Practice Resident

- Chief Resident
- Third Year Resident Teacher of Year (2001) and Intern of the Year (1998)
- AAFP National Resident Rural Committee representative 2000

Contract Doctor Employment Positions:

Jan 2022 to current Alamo Clinic

Carbondale IL and Albuquerque NM

 Medical abortion procedural abortion first and second trimester, IV sedation provider, Ultrasound provider

July 2022 to current Whole Woman's Health Contract doctor NM, IL

Medical abortion and procedural abortion

February 2021 to June 2022 Tulsa Women's Clinic Tulsa, Oklahoma

 Medical abortion, procedural abortion first and second trimester, IV sedation provider, Ultrasound provider

April 2021 to current Planned Parenthood of Montana

Billings, Missoula, Helena Montana

 Medical abortion, procedural abortion first and second trimester, IV sedation provider, Ultrasound provider, abortion trainer for other physicians and residents

March 2019 to current Blue Mountain Clinic Family Medicine

Missoula Montana

 Medical abortion, procedural abortion first and second trimester, IV sedation provider, Ultrasound provider, abortion trainer for other physicians or residents

Dec 2019 to March 2020 Trust Women

Oklahoma City, Oklahoma

 Medical abortion, procedural abortion first and second trimester, IV sedation provider, Ultrasound provider

2008-December 2009 Planned Parenthood NNE Portland ME

Colposcopy, Cryo, for cervix, miscarriage care, LEEP, fetal demise and abortion care, family planning

2001-2003 Providence Seward ER

Seward K

ED Locum Physician

Education

1998-2001 Alaska Family Medicine Residency
 1994-1998 Indiana University School of Medicine
 1986-1989 Baylor University- BA Sociology

Certifications

- Board Certification Family Medicine current exp 1/1/2028
- State of Alaska, Maine, Idaho previous MD license
- DEA current
- COLA Lab Director Certification- Lab Director course completion
- ACLS current

Licenses

Montana	Physician License	12588	03/31/2025
Wyoming	Active License	15373C	06/30/2024
New Mexico	Medical Doctor License	MD2022-0903	07/01/2026

Illinois	Physician	036161340	07/31/2026
Oklahoma	Full Physician License	34204	10/01/2023

Previous Maine 017531, Idaho 15247, Alaska 4340- all inactive currently

Other/Lectures and Associations

- •Contraception Update Lecturer for AAFP AK and AK PA association multiple times
- Speaker for MT AFFP meetings/statewide hospital CME (contraception update, miscarriage care, care, gender dysphoria)
- Co- Author Gynuity Research articles 2021
- •Community Preceptor for WMFMR
- •Ultrasound training for basic gynecology and prenatal care Lecturer STFM
- •Member of AAFP, RHAP, SFP, ACOG, MT AAFP
- •Peace Corps Volunteer Ghana West Africa- teacher (1990-1993)
- •Merck Nexplanon master trainer 2006- current Contract MD
- •Residency International Experience Cameroon
- •Medical School International Experience Kenya

CERTIFICATE OF SERVICE

I, Alexander H. Rate, hereby certify that I have served true and accurate copies of the foregoing Affidavit - Affidavit in Support to the following on 09-01-2023:

Austin Miles Knudsen (Govt Attorney) 215 N. Sanders Helena MT 59620

Representing: Charlie Brereton, State of Montana, Department of Public Health and Human Services

Service Method: eService

Electronically signed by Krystel Pickens on behalf of Alexander H. Rate Dated: 09-01-2023